K R U S E | L A W
MLaw Philipp Kruse, Rechtsanwalt, LL.M.

Juristischer Mitarbeiter
Dr. iur. Markus Zollinger, Rechtsanwalt*

DEEPL Translation

REGISTERED MAIL

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Only the German version is authoritative.

Zurich, February 7, 2024
PK / MZ

Criminal complaint - Version 2.0

Dear Ms. Prosecutor, Dear Mr. Prosecutor,

in matters of

Indicators 1-37, according to separate list,

hereinafter: the **complainants**,

all represented by
Philipp Kruse, Attorney at Law, LL.M., Talstrasse 20, 8001 Zurich,

and

Private Claimants 1-6, according to separate list,

hereinafter: the **private claimants**,

all represented by
Philipp Kruse, Attorney at Law, LL.M., Talstrasse 20, 8001 Zurich,

* Resigned from Kruse | Law as of June 15, 2023; since then independent attorney at *Zollinger.Legal*.

vs.

1. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,
2. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,
3. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,
9. **[...]** Swissmedic,
   Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,
10. **[...]** Swissmedic,
    Swiss Agency for Therapeutic Products, Hallerstrasse 7, 3012 Bern,

and against

4. **[...]** Insel Group,
   Inselspital, Bern University Hospital, Freiburgstrasse 18, 3010 Bern,
5. **[...]** Insel Group,
   Inselspital, Bern University Hospital, Freiburgstrasse 18, 3010 Bern,
6. **[...]** Insel Group,
   Inselspital, Bern University Hospital, Freiburgstrasse 18, 3010 Bern,
7. **[...]** Insel Group,
   Inselspital, Bern University Hospital, Freiburgstrasse 18, 3010 Bern,
8. **[...]** Insel Group,
   Inselspital, Bern University Hospital, Freiburgstrasse 18, 3010 Bern,

and against

Unknown

in the following: the **notified parties**

concerning
the urgent suspicion

multiple (possibly) intentional, possibly negligent,
breach of the duty of care under therapeutic products law
(Art. 86 para. 1 lit. a and para. 2 lit. a TPA; possibly para. 4),

multiple (possibly) intentional, possibly negligent,
violation of the reporting obligations under therapeutic products legislation
(Art. 87 para. 1 lit. c TPA; possibly para. 3),

multiple (possibly) intentional, possibly negligent,
violation of the prohibition of advertising under therapeutic products law
(Art. 87 para. 1 lit. b TPA; possibly para. 3),

multiple (possibly) intentional, possibly negligent, homicide (Art. 111 StGB; possibly Art. 117 StGB),

multiple punishable (possible) intentional termination of pregnancy (Art. 118 para. 2 SCC),

multiple serious (possibly) intentional, possibly negligent, bodily injury (Art. 122 StGB; possibly Art. 125 para. 1 and para. 2 StGB),

multiple endangerment of life (Art. 129 StGB),

multiple (possibly) intentional, possibly negligent, endangerment by genetically modified or pathogenic organisms (Art. 230bis para. 1, possibly para. 2, Swiss Criminal Code),

the punishable preparatory acts under Art. 260bis para. 1 lit. a-c SCC,

multiple (possibly) intentional, possibly negligent, falsification of documents in office (Art. 317 para. 1, possibly para. 2, Swiss Criminal Code),

we present you the following

(Updated) criminal complaint

with the following

Applications

1. A criminal investigation should be opened against the defendants. If necessary, the authorization procedure should be initiated in advance with regard to the defendants, whereby urgent protective measures should be taken immediately.

2. The criminal investigation should be extended to include any other parties involved.

3. The coercive measures required to establish the facts of the case should be ordered and the documents, dossiers, e-mails, internal notes, minutes of conversations, etc. used to establish the facts of the case should be confiscated.

4. In order to establish the facts of the case, all marketing authorization documents (modules 1-5) of Spikevax (Moderna) and Comirnaty (Pfizer/BioNTech) should be confiscated.

5. All mRNA "vaccines" and batch samples located in Switzerland, and possibly all those located at the manufacturers and in the cantonal vaccination centers, are to be seized, confiscated and randomly tested by batch by at least two independent experts in accordance with Art. 182 ff. StPO in accordance with a standardized test protocol for their ingredients.

6. New preliminary proceedings should be opened in respect of all cases of unusual deaths in Switzerland that have been discontinued since December 2020 (if necessary, these should be reopened in accordance with Art. 323 of the Code of Criminal Procedure), insofar as no sufficient investigations and examinations were carried out into mRNA therapies as a possible cause of death despite the cause of death being unknown or recorded as an internal event of any kind.
   In particular, the evidence of all unusual deaths in Switzerland since December 2020, in which corresponding tissue samples were seized by the Institutes of Forensic Medicine following a post-mortem examination, should be confiscated and examined in accordance with a standardized test protocol.

7. In view of the health problems of the victims, any hearings of victims should be carried out by means of a one-off video conference while safeguarding the rights of the accused to participate.

8. The private plaintiff's right to participate in all investigative proceedings must be respected.

9. The accused should be punished appropriately.

10. All with costs and compensation to be borne by the accused.

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Professional translation of the "Executive Summary" available at *corona-complaint.ch*

"Executive Summary" (2.0)

"All things are poison, and nothing is without poison; it is only the dose that makes a thing not poison." (Paracelsus [1493-1541], Swiss physician, alchemist and philosopher)

"Anyone handling therapeutic products must take all measures required by the state of the art in science and technology to ensure that human and animal health is not endangered." (Art. 3, Federal Act on Medicinal Products and Medical Devices, Therapeutic Products Act, TPA).

1. Initial situation

1 37 complainants and 6 private plaintiffs directly harmed by mRNA "vaccinations" (all according to the rubric) filed criminal charges against certain persons acting on behalf of Swissmedic (according to the rubric) and against persons unknown on July 14, 2022. They filed this criminal complaint to protect their own health and out of legitimate concern for the health of their fellow human beings. They did so because their health had either already been seriously harmed (private claimants) or at least permanently threatened (private claimants and complainants) due to **[i.] the** unlawful authorization of mRNA-based "COVID-19 vaccines" by Swissmedic, **[ii.]** the permanent lack of product monitoring by Swissmedic and, last but not least, **[iii.)** the sustained misleading product information provided by Swissmedic, and because this threat is still ongoing (private claimants and persons making a complaint).

2 Since the submission of the criminal complaint of 14 July 2022, the facts have been continuously and Since the facts have been confirmed continuously and without exception since the criminal complaint was filed on July 14, 2022 and have even worsened in the sense of the criminal complaint, because Swissmedic has continued its factually and illegally unlawful approval practice to this day, because it has still not taken adequate account of the risks it has created, and because the competent public prosecutor's office has not yet seen fit to open criminal proceedings against those responsible - i.e. because the original risk situation continues to exist - the 37 complainants and the 6 private plaintiffs hereby submit a comprehensively updated version of the criminal complaint.

3 This updated Criminal Complaint 2.**0 (including the separate Evidence Report 2.0)** takes into account the legally relevant evidence that has become known since the end of June 2022 up to 31 March 2023 and, where possible or particularly relevant, the legally relevant evidence up to August 2023. In addition, this Criminal Complaint 2.0 also contains significant clarifications and additions in the legal section, in particular regarding the allegation of

falsification of documents in office (Art. 317 SCC), committed by responsible persons at Swissmedic. This Criminal Complaint 2.0, together with the Evidence Report 2.0, which has also been thoroughly updated and clarified, replaces the original Criminal Complaint and Evidence Report of July 14, 2022 in their entirety.

2. Suspicion of a crime

4 In the present case, we are dealing with the **greatest threat to and violation of human health caused by pharmaceuticals themselves and by official misinformation in this regard that has ever occurred in the history of Switzerland.** The mRNA "vaccines", which are largely ineffective against SARS-CoV-2 infections and pose an above-average risk, have been proven to pose a far greater threat to the healthy population than the SARS-CoV-2 pathogen itself, against which these "vaccines" were supposed to protect.

5 Swissmedic, or the persons acting on its behalf, are primarily responsible for the harm to human health already caused by mRNA-based substances and for the further resulting risk. By law, Swissmedic has the task of protecting the health of the Swiss population from ineffective or harmful medicinal products. According to the Swiss Therapeutic Products Act (TPA), it is obliged to ensure that only high-quality, safe and effective therapeutic products are placed on the market. It must also protect consumers of therapeutic products from being deceived in this context (Art. 1 TPA). Those acting on behalf of Swissmedic repeatedly and to a considerable extent failed to comply with these and other clear legal obligations to the detriment of the injured complainants, which is why they have been under urgent suspicion since December 2020 until today,

- within the scope of approval, manufacture or batch testing (N 1257 ff.) and import (N 1267 ff.), the **duties of care under therapeutic products law** (Art. 86 para. 1 lit. a TPA in conjunction with Art. 3 TPA [general duty of care] and Art. 7 TPA [duty of care]) apply on several occasions. Art. 3 TPA [general duty of care] and Art. 7 TPA [manufacturers' duty of care]) (N 1251 ff.),
    - by granting a "temporary" marketing authorization for various mRNA-based preparations reserved only for special emergency situations in accordance with Art. 9a TPA for various mRNA-based preparations, maintaining this permanently and extending its scope of application to all age groups, although it was already sufficiently proven at the time of the initial authorization that a COVID-19 disease was neither "life-threatening" nor "disabling" for the healthy population under 65 years of age within the meaning of the Therapeutic Products Act (and that even for those over 65 years of age, a conspicuous mortality rate could only be determined during short

phases in 2020, if at all - albeit without any evidence of a causal link with SARS-CoV-2 (ER N 1540 et seq., 1576 ff., 1597 ff.),

- by granting this de facto emergency authorization under Art. 9a TPA without actual need, maintaining this de facto emergency authorization permanently and extending its scope of application to all age groups, although suitable alternative treatment protocols were already available in the course of 2020 (N 1104 ff.) ,
- by promoting the mRNA "vaccines" despite the lack of sufficient evidence of efficacy (N 296 ff, 376 ff., 498 ff, 688 ff.), despite massive risk signals (N 186 et seq, 319 et seq, 388 ff., 526 ff.) and despite the absence of a life-threatening or disabling disease for the population as a whole (N 744 ff.) granted an authorization within the meaning of the TPA - as "temporary authorizations" according to Art. 9a TPA,
- by - instead of respecting the mandatory and otherwise customary requirements of the ordinary approval procedure - issuing "pandemic approvals" under the guise of "pandemic approvals" (N 857 ff., in particular N 992 ff.), they themselves **massively undercut the** already very low **safety requirements** applicable to the procedure under Art. 9a TPA**,** thereby creating additional risks to public health that had never before been posed by a medicinal product,
- by - instead of conducting a comprehensive risk-benefit analysis (N 807 ff.) and immediately revoking or at least allowing the granted approvals to expire - by renewing their decision to act at the end of 2022 (i.e. long since against their better judgment) and perpetuating the novel, still experimental mRNA therapy/prophylaxis from 2023 in the sole interest of the manufacturers as a new platform for widespread use by means of allegedly "proper" approvals (N 1131 ff.),
- by not only permanently withholding elementary information from the population and the medical profession on the minimal to non-existent protective effect of the mRNA "vaccines" and on the actual risks of side effects, but also by permanently and systematically disseminating misleading information on these issues (N 1187 ff.),

- the obligation to monitor products after marketing authorization (so-called "pharmacovigilance") is not even remotely risk-adequate (N 1151 et seq.), but rather to have seriously and permanently violated the **obligation to report side effects under therapeutic product law** (Art. 87 para. 1 lit. c TPA) (N 1364 ff.),
- to have seriously violated the **prohibition on advertising medicinal products under therapeutic products law** (Art. 87 para. 1 lit. b TPA) (N 1385 ff.),
- to have fulfilled the relevant **elements of the Criminal Code in** the case of the undesirable side effects (death, damage to health) that were foreseeable from the approval studies and then occurred after approval (N 1457 ff.),

- knowingly and persistently **misleading** both the public and healthcare professionals in a criminally relevant manner **about facts that are essential for the benefit/risk assessment when making a vaccination decision** (in particular: **Falsification of documents in office, Art. 317 StGB,** N 1198 et seq, 1427 ff.; see also ER N 1964 ff., in particular N 2111 ff.).

3. Acts of Swissmedic

3.1. Initial registration contrary to law and duty

6 The breaches of the law and duty of care complained of here essentially consist of the fact that the notified persons acting on behalf of **Swissmedic** approved mRNA medicinal products for preventive purposes "for a limited period" within the meaning of Art. 9a TPA for the first time, although Swissmedic must have been aware of countless risk factors as early as **December 2020**, each of which in itself would have stood in the way of granting a "temporary" authorization until the corresponding risk factors had been thoroughly clarified and eliminated under normal circumstances. The following should be highlighted here (in addition to **many** other risk factors N 1291 ff.):

- The mRNA COVID-19 vaccines are based on the same mode of action as **gene therapies** and have therefore been classified as an "**Advance Therapy Medicinal Product" (ATMP)** by regulators such as Swissmedic and the European Medicine Agency (EMA) as well as by the manufacturers themselves (N 529 ff., N 1422; ER N 19 ff., N 28 ff.), which poses a particular risk for the following reasons:
  - Until the end of 2020, mRNA technology had only been used in cancer patients at the pre-mortem stage, i.e. only to combat an existing life-threatening disease, but had never before been used purely prophylactically **to immunize a healthy population as a whole** (N 186 ff.; ER N 62, N 67 ff.). Compared to all other drugs that have been approved to *date*, either on a regular or "temporary" basis, the approval of this mRNA technology as an alleged "vaccine" for healthy people represents an **absolute novelty and therefore a considerable risk**.
  - The mRNA technology used here is characterized by the fact that the **production process of the actual immunizing active** ingredient (Active Pharmaceutical Ingredient: = the spike protein) **is transferred to the human body.** The end product of this internal "vaccine production" is completely unknown in terms of dosage and quality. To date, there are still no sufficient empirical data available that would make this endogenous production of the spike protein appear controllable with regard to: **(1) quantity** of endogenous production (ER N 51 ff.), **(2) duration** of spike

production (ER N 77 ff.); **(3) location** of production in the body (affected organs; ER N 45 ff.); **(4) quality** of the proteins produced (ER N 54 ff.); and with regard to **(5) efficacy and safety** of the active substance produced for a healthy population treated purely prophylactically (N 191 ff.; N 195 ff.; ER N 32 ff.; 51 ff. 62 ff.). The administration of a substance that proves to be uncontrollable with regard to all pharmaceutically relevant parameters must necessarily be qualified as an **experiment on humans** (N 843 ff.).

  - Both the Federal Office for the Environment (FOEN; N 528) and Swissmedic (N 529 f.) were aware of the particular problems associated with mRNA substances and recognized that these mRNA active substances are **gene-modified [gene-modified] organisms** (GMO / GMMO) and **Advanced Therapy Medicinal Products** (ATMP). In doing so, they implicitly recognized that both the Gene Technology Act (GTG, SR 814.91; see Art. 5 para. 2) and Art. 260bis StGB (N 1407 ff.) must be observed and that, above all, an authorization of these products **in the simplified authorization procedure** (Art. 9a TPA) would have been **excluded** (N 200 ff.; ER N 73 ff., N 872 ff.).

- In addition, Swissmedic abandoned the requirements for a **uniform dosage** of the (mRNA) preparations authorized for injection, which are otherwise mandatory for every other medicinal product: Thus, Swissmedic accepted an **mRNA content per dose in an arbitrarily wide range of 37% - 126% of the amount of active substance formally declared by the manufacturer** (N 225 ff.; ER N 174 ff.). Swissmedic thus accepted the corresponding risks of a high proportion of **non-intact mRNA** and a considerable risk of **genotoxicity and carcinogenicity**. The same applies to other **toxic impurities** such as nitrosamine and benzene (N 231 ff.).
- As the public only learned at the end of 2023 (but Swissmedic already knew from the end of 2020), the manufacturing process for the mRNA products actually administered ("manufacturing **process 2**" with plasmid DNA) differed fundamentally from the manufacturing process for the products approved by Swissmedic ("**manufacturing process 1**"). The administered products of manufacturing process 2 contain a **scandalously high level of bacterial autonomously replicating DNA impurities** (so-called "plasmids"), so that consequently all products according to manufacturing process 2 would have to be regarded as "never approved". However, Swissmedic tolerated this further massive risk factor without informing the public and without suspending the mRNA authorizations (N 828; ER N 190, N 207 ff.).
- **Initial animal studies** - a mandatory prerequisite for clinical phase 2 and 3 trials and a central safety element - had not been carried out by the producers at all or not

sufficiently, but already showed worrying results - for example regarding the **accumulation of toxic lipid nanoparticles** (N 212 ff., N 251 ff., N 258 et seq.).

- The subsequent **studies in humans, on the basis of which the "temporary" approvals were granted at the end of 2020,** had run for just **two months** (instead of the usual 12-24 months) and were then **de facto discontinued** by the **manufacturers** by **dissolving the control groups and largely deprived of their medium and long-term significance** (N 247 ff., N 275 ff.).

7 Despite this downright alarming initial situation from a safety perspective within the meaning of Art. 1 and Art. 3 of the Therapeutic Products Act and numerous other risk-increasing circumstances, the first authorization of the mRNA "vaccines" was literally rushed through by Swissmedic: the authorization applications were "reviewed" and approved in just 63 calendar days (an ordinary procedure would take 330 days, a procedure for "temporary" authorization usually takes 140 days), whereby important - mandatory - milestones were simply omitted (N 1024 ff.; see also N 916 et seq; 963 et seq; 992 ff; 1021 ff.).

8 **As a result, these "temporary" authorizations within the meaning of Art. 9a TPA mean nothing other than that the entire Swiss population participated without their knowledge in the riskiest and largest clinical experiment ever conducted** in Switzerland (and at the same time worldwide)**. And this experiment has not been discontinued to this day** (regarding the experimental character N 843 ff.).

3.2. Perpetuation of illegal authorizations in breach of the law and obligations

3.2.1. Fade out all additional risk signals

9 Without adequately addressing this immense risk created by **Swissmedic** itself (through the "temporary" authorization) and without at least informing the public about all the risks, Swissmedic proceeded unperturbed in **June 2021** to extend its authorizations to adolescents aged 12 and over. And this despite the fact that, in addition to all previous risk-increasing and therefore legally relevant facts, by mid-June 2021 (among **many** other risk factors N 1298) were known,

- that regulatory authorities such as Swissmedic were **flying completely blind due to a lack of strict batch testing** and thus a lack of adequate quality controls (N 321 f.),
- that the dose approved for adolescents was **half** (Comirnaty) or **five times** (Spikevax) **higher than the recommended dose**, which means that Swissmedic accepted an additional and again completely unnecessary risk for adolescents (N 323 f.), for an age

group that was never at serious risk in the pandemic year 2020 - i.e. from COVID-19 alone without "vaccination",

- that according to ***Pfizer****'s Post Marketing Pharmacovigilance Report,* as many as **42,086 side effects and over 1,200 deaths** had been reported **for Comirnaty** alone by February 2021 - i.e. within 2.5 months (N 325 ff.; ER N 469), which should have led to the **immediate discontinuation of the trial** (N 354 ff.),
- that according to this devastating Pfizer report, as many as 13% of breastfed infants were affected by side effects (N 328; ER N 474) and even Pfizer had identified a **negative impact on male fertility** as a potential risk (N 333 f.; ER N 477 ff.),
- that, according to global adverse event reports, the **alert value of 50 deaths had already** been **exceeded by a factor of 150** by June 2021 (N 341 f.),
- that the **COVID-19 "vaccines"** had already proven to **be significantly more dangerous than the previously common flu, swine flu and measles vaccines** in view of these massive side effect reports in May 2021 (N 364 ff.).

10 **Even these scandalous alarm signals did** not **prompt Swissmedic to seriously question the wrong path it had taken:** Swissmedic neither restricted the authorizations nor informed the public about the risks identified. Swissmedic did not even feel compelled to improve its own purely passive pharmacovigilance to record the side effects identified in Switzerland. Instead, **at the end of 2021,** Swissmedic took the step of extending the authorizations to a third dose ("booster") and to **children aged five and over**, even though this youngest age group was at no time seriously at risk in the pandemic year 2020 - i.e. from COVID-19 alone without "vaccination" - and even though, among other things (in addition to **many** other risk factors N 1305) were also known,

- that even representatives of the pharmaceutical industry openly described mRNA injections as what they are - namely a form of gene therapy (N 389 f.),
- that the **toxic spike protein** produced in the body of vaccinated persons is present in the body for much longer and in a much higher concentration (ER N 51 ff., N 77 ff., N 1168) than originally stated by Swissmedic and the manufacturers, which can lead to a variety of serious side effects (including death) (N 391 ff.),
- that **data** had been **falsified** and risk signals concealed in the context of the **Comirnaty approval study (Pfizer/BioNTech)** (N 397 ff.), which should have led to the immediate withdrawal of the study,
- that **Pfizer/BioNTech** had presented an alarming interim report (*PSUR*) at the end of August 2021, according to which **46 cases** had ended **fatally in the clinical trials** and **5,069 cases (1.6%)** had already ended **fatally** in the so-called **"postmarketing phase"**

(N 406), which under normal circumstances should have led to an immediate revocation of the approvals,

- that Pfizer had **delivered 7 batches with a massively increased number of adverse reaction reports to Switzerland** - an alarm signal that should have led Swissmedic to issue an immediate **warning to the population, including a batch recall** (N 413), but this has not happened to date,
- that **at least 60 deaths** were recorded in children in Switzerland, the EU and the USA for Comirnaty and Spikevax alone (N 438 f.), which means that the absolute **alarm value of 50 deaths was clearly exceeded** in this target group alone - which is in no way endangered by SARS-CoV-2 - which **should have led to the immediate stop of at least this extension of approval - if not to the suspension of all mRNA approvals,**
- that only in the USA and the EU **more than 2,000 premature births and stillbirths** had been reported after mRNA injections (N 473 ff., esp. N 478),
- that a worrying trend was already evident in Switzerland in 2021, namely a **conspicuous and persistent mortality rate in younger age groups in close temporal relation to "vaccination activity"** (N 494, N 765 and N 774),
- that the mRNA "vaccines" (Comirnaty and Spikevax) had received **60 times the number of reports of serious side effects** and **20 times the number of death reports per million doses administered as** of the end of 2021 compared to the influenza vaccines (N 427 ff., in particular N 429 f.).

11 Instead of finally suspending the mRNA authorizations, carrying out an in-depth analysis of the decisions taken, informing the public truthfully about the risks that can actually be identified and improving the reporting system for recording vaccination side effects in line with these risks, Swissmedic continued to maintain all "temporary" authorizations in 2022. This was despite the fact that, in addition to all the already prevailing risk and legally relevant facts, **many** other risk factors N 1311),

- **that mRNA products belong to the group of ATMP high-risk products because "they contain nucleic acid, regulate gene expression and, as 'biologically active material' (namely RNA), are equivalent to genetically modified organisms (GMOs)",** which even Swissmedic acknowledged (N 529 ff.),
- that for this reason alone and also in accordance with Art. 12 para. 5 lit. c and lit. e of the Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Authorization of Medicinal Products and the Authorization of Medicinal Products by the Notification Procedure (VAZV, SR 812.212.23), a **temporary authorization in accordance**

with Art. 9a TPA was inadmissible from the outset (see N 530, N 916 ff., N 992 et seq.),

- that almost four million adverse reactions to all COVID "vaccines" had already been reported worldwide (Switzerland, EU, USA) by May 2022 (N 538 ff.), with Comirnaty and Spikevax alone accounting for **over 1.7 million reports** - including **464,971 serious** adverse reactions and **20,886 deaths** (N 548 ff.) - which meant that the **alarm value of 50 deaths was exceeded by a factor of over 400** worldwide at the time, and that these figures continued to rise (N 562 ff.),
- that an alarming interim report on Comirnaty had once again been published by Pfitzer/BioNTech ("PSUR No. 3") (N 595 ff.), from which it emerged that,
  - that **the under-50 age group** was **excessively affected by side effects**, i.e. a population group only minimally affected by COVID-19 (N 597 ff.),
  - that **information** on the safe use of Comirnaty in **pregnant women**, breastfeeding women and other patient groups **was still lacking** (N 605 ff.),
  - that there had been **massive differences in quality** between the individual batches and that once again **many dangerous batches** had been delivered **to Switzerland** (N 608 ff.),
- that despite Swissmedic's statements that the mRNA "vaccines" had no effect on pregnancy, **2,135 stillbirths after injection of Comirnaty** and **798 stillbirths after injection of Spikevax as** well as **5,055 miscarriages for all COVID-19 "vaccines**" - not including underreporting - had already been reported by May 2022 in the EU and the USA alone (N 636 f.), with the manufacturers still openly admitting in 2022 that **- in the absence of corresponding studies - "the safety profile of the vaccine in pregnant or breastfeeding women** is **not known"** (N 631 ff.),
- that in 2022 worldwide (N 639 ff.) and also in **Switzerland in 2022, there was a historic decline in live births of 8.5%**, for which, after excluding all other hypotheses, **the only plausible reason** remaining is **mRNA injections** (N 644 f.),
- that according to a study on male fertility published in June 2022, the **sperm concentration 150 days after the 2nd "vaccination" was still 15.9% below the initial value** (N 649 ff.), which means that not only female but also male fertility is potentially significantly impaired by the "vaccination",
- that an in-depth analysis of the BfS *data* by Prof. Konstantin Beck revealed a **conspicuous and persistent mortality rate in all age groups in close temporal relation to "vaccination activity"** (N 663 ff.),
- that based on the *BfS data* in Switzerland - especially in age groups not threatened by COVID-19 in any way - a massive increase in various disease diagnoses **(damage to the nervous system: +29%; cancers: +48%; pregnancy complications: +25%;**

pulmonary embolism, cardiac arrest, stroke and cerebral infarction in 0- to 14-year-olds: +125%) can be identified since the start of the "vaccination campaign" (N 664 ff.),

- that, according to several autopsy results, the **"vaccine" spike protein** has been proven to be **the cause of death** and that - contrary to the official statements of Swissmedic - it is by no means only detectable **in the human body** for a short time, but for **up to nine months** (N 669 ff.),
- that the occurrence of **myocarditis,** which can be fatal in the worst case, in connection with a COVID-19 mRNA injection is much **more frequent** - according to a (now peer-reviewed) Basel study **up to 800 times more frequent -** than officially reported by the regulatory authorities (N 674 ff.),
- that with **V-AIDS**, a serious side effect long suspected and now increasingly detected since 2022 has made itself felt, which is **damage to the immune system**, **which** can lead **not only to the increased incidence of autoimmune diseases and cancer, but above all to the increased incidence of infectious diseases** - **and in particular also to a greater susceptibility to COVID-19 diseases ("Long COVID")** (N 677 ff.),
- that by March 1, 2022, at least **128 peer-reviewed publications on heart problems, 216 peer-reviewed publications on life-threatening coagulation disorders (thrombosis, etc.) and six peer-reviewed publications on possible deaths as a result of COVID vaccinations** had appeared (N 685 f.; ER N 1245 ff.).

12 With the "temporary" approval of the mRNA "vaccines", Swissmedic therefore accepted an **unprecedented and ever-increasing risk to** public health. At best, this could only have been justified by the fact that it could have averted an unprecedented threat (from SARS-CoV-2) that could have outweighed the exceptionally high risk associated with the mRNA "vaccines". This is clearly not the case:

3.2.2. Absence of a "life-threatening or disabling" illness

13 There is and never was a "life-threatening or disabling" disease with "COVID-19" - *the* main prerequisite for "temporary" approval - that would have threatened the entire population (see also N 1292, N 1300, 1307, 1313; in detail: ER 1576 ff., N 1583 ff.):

- With an IFR of 0.15%-0.20%, COVID-19 was already recognizably **no more dangerous than moderate influenza** at the end of 2020**, there was no historically conspicuous excess mortality in** relation to the total population and **hospitals were never overcrowded** (N 752 ff., N 767).
- Even in 2021 - when the vaccination was introduced on a large scale - there was **no historical excess mortality** according to the official BfS methodology (N 774),

hospitals were **never operating at over 80% capacity** (N 776) and "Delta" was a variant that corresponded to a normal **mild flu in terms of** danger (N 771 ff.).

- In 2022, it was clear that COVID-19 was **not a "pandemic of the century"** (N 782 and N 784 f.), despite the publicized **massive manipulation of COVID "case numbers" in hospitals,** the hospital system had never been overloaded (N 786 ff.), and that the IFR for "Omikron" was only **0.001-0.002%, i.e. a factor of at least 50 below the IFR of a normal flu** (N 780 f.).

3.2.3. Lack of benefit: Ineffective to harmful mRNA injections

14 In view of the above, Swissmedic has authorized a highly experimental and dangerous medicinal product against a disease that poses no greater threat to the population as a whole than influenza. The only last "lifeline" left to Swissmedic would be to prove that the target population of older and previously ill people, who were at somewhat higher risk to begin with, would have been at least reasonably effectively protected against SARS-CoV-2. But this is not the case in any way either. The "vaccination" clearly failed to achieve the necessary "high" effectiveness by the end of 2020 (N 1293):

- The "vaccinations" should protect against serious (fatal or disabling) diseases. In the (still ongoing, but deprived of the control group; N 275 f.) approval studies primarily investigated whether the "vaccinations" protect against headaches, coughs, fever and other trivial events in combination with a positive PCR test result (N 297 f.).
- The reported effectiveness figures of up to 100% relate only to such **minor events** and are based on calculations that in no way reflect reality: Rather, an **effectiveness in the low single-digit percentage range** - if at all - can be assumed (N 299 ff.).
- **No single study has even come close to providing evidence of protection against serious illness:** the few cases investigated are within the range of statistical chance (N 305 ff).
- However, "vaccinations" should have "immunized" in the long term (N 1097), which was not possible in view of the "booster vaccinations" planned from the outset (N 508) was an impossible goal to achieve.
- Without any doubt, the "vaccinations" did not offer any protection against the transmission of SARS-CoV-2 (N 309 f.) - they were therefore simply unsuitable for "pandemic control".

15 In 2021 and 2022, this lack of effectiveness manifested itself in an obvious way (N 1299, N 1306, N 1312):

- In February 2021, there were already **indications** that **the mRNA injections** were largely **ineffective,** as the most common side effects included the lack of effectiveness of the "vaccination" and COVID disease (N 317).
- To date, **no effective proof of efficacy** for immunization has been provided by the manufacturers, nor **has protection against transmission been proven in any way** (N 498 ff., N 688 ff., N 723 et seq.).
- With regard to **"boosters", a negative effect was observed early on,** as the transmission time was not shortened but extended (N 696 f.).
- There is also **an increased incidence of illness and death worldwide,** which correlates **with the start of the "vaccination campaign"** in 2021 (and not with the start of the "pandemic" in 2020), which clearly indicates a **negative effectiveness of the mRNA injections** (N 708 ff., N 782 f.).

3.2.4. Omission of the most elementary safety and effectiveness tests

16 To make matters worse, Swissmedic had not based its decision on the strictest legal requirements for ordinary marketing authorizations for therapeutic products, but had allegedly issued "temporary authorizations" in accordance with Art. 9a TPA. However, under the guise of an alleged "pandemic", Swissmedic had circumvented even the minimum requirements of Art. 9a TPA. The "pandemic authorization" of the mRNA "vaccines" granted in the present case deviates from the ordinary authorization in all essential safety aspects in a way that increases the risk, and even falls below the authorization hurdles of the simplified and temporary authorization. The authorization of the mRNA "vaccines" was therefore **accompanied by** a **blatant omission of the most elementary safety and efficacy tests, thereby taking the greatest possible risk of all** to the **health of the Swiss population** (for the whole N 857 ff., in particular N 992 ff.).

3.2.5. Swissmedic prevented effective alternative treatments

17 Another complicating factor is that Swissmedic has long been aware of more effective and less harmful interventions such as treatment with ivermectin or other suitable approaches (N 1110 ff; 1115 ff.) have not yet been approved for the treatment of COVID-19 diseases. In **this way, Swissmedic has deliberately sidelined the authorization requirement of the absence of alternative treatment methods (see Art. 9a para. 1 lit. c TPA) and thus actively prevented demonstrably more effective protection against COVID-19 diseases (than the mRNA "vaccinations").**

3.2.6. Benefit/risk analysis: clearly negative profile

18 Any serious analysis carried out in accordance with the law and practice to determine the net benefit of the mRNA-based COVID-19 vaccines for the entire population would have had to include the above (N 6 ff., N 9 ff.) summarized above and presented in detail in the evidence report. Such an analysis would have clearly shown that Swissmedic had authorized a medicinal product on the Swiss market with a **devastatingly negative benefit/risk profile** (see also benefit/risk analysis: N 807 ff.; ER N 1835 ff.):

19 Swissmedic's plan to authorize the mRNA "vaccines" for all adults in Switzerland from December 2020 must be qualified as a **project with maximum, unprecedented risk and experimental character.** At the same time, the **lack of efficacy** of the mRNA "vaccines" was apparent from the outset - and has become increasingly obvious as time has gone on. A risk that had never been taken before, which has meanwhile already been impressively realized in a multitude of serious side effects, was and is therefore not offset by any proven benefit. This consideration alone should have long since led to the compelling conclusion that the mRNA "vaccines" should never have been authorized and that the authorizations that were nevertheless granted represent a **massive violation of the law and of Swissmedic's duty of care.**

3.2.6.1 New risks created by Swissmedic: maximum

20 The residual risk from "COVID-19" that may still exist at the end of 2020 was perfectly manageable by conventional means for the general population up to the age of 65 (N 1110 ff; 1115 ff.) and could have been safely managed without mRNA-based novel active substances. In view of this low initial risk, Swissmedic should have applied a very restrictive risk tolerance to novel medicinal products in order to ensure compliance with the legal requirements of Art. 1, Art. 3 and Art. 7 TPA. **Swissmedic should have rejected medicinal products with an increased risk potential from the outset in order to avoid jeopardizing public health with new risks.**

21 **However, by authorizing mRNA-based COVID-19 vaccines, Swissmedic actually created new risks that were many times greater and more uncontrollable than the COVID-19 disease itself** (benefit/risk analysis: N 807 ff.; ER N 1835 ff.).

3.2.6.2 Corrupted modeling study: "14.4 million deaths prevented"

22 The above statements on the fatally negative benefit/risk ratio of COVID-19 "vaccinations" are countered by official bodies and many media outlets with a "modeling study" published

in September 2022. This caused a worldwide stir because it allegedly proved that the COVID "vaccines" had prevented 14.4 million deaths during the pandemic.

23 The evidence report examined this study in detail and demonstrated that it is based on false and manipulated data and was written by authors with obvious conflicts of interest. This study, which is based on model calculations that can be manipulated almost at will, is not suitable as court-proof evidence to prove an alleged positive benefit of COVID-19 vaccinations (N 851 ff.; ER N 1370 ff.). Rather, it stands in stark contradiction to all the risks that had long since manifested themselves - based on real indicators - by the end of 2022 and the continuing lack of effective proof of efficacy.

3.2.7. Perpetuation despite an obviously negative benefit/risk ratio

24 However, instead of finally carrying out a comprehensive risk-benefit analysis after two years of illegal "temporary" "pandemic approvals" (see N 807 ff.) and to immediately revoke the granted authorizations or at least allow them to expire, those responsible at Swissmedic took the completely opposite decision at the end of 2022: first, **they *de facto* tacitly extended the illegal authorizations** and, from 2023, perpetuated the novel, still experimental **mRNA therapy/prophylaxis in the sole interest of the manufacturers as a new platform for** broad-based use by means of supposedly "regular" authorizations (N 1131 ff.). However, the requirements for extensions of these "temporary" authorizations, and indeed for the granting of supposedly "ordinary" (Art. 9 / 11 TPA) authorizations, were not even remotely met, meaning that those acting on behalf of Swissmedic violated their duty of care under Art. 3 TPA and Art. 7 TPA much more clearly than before in a manner relevant under criminal law.

25 **All approval orders or breaches of duty from the end of 2022 onwards are to be qualified as independent, new criminal acts with independent new intent to commit an offense**. In terms of criminal law, these new offences are particularly relevant because all the facts relevant to the assessment of efficacy and safety, both qualitatively and quantitatively, were much clearer at the end of 2022 than at the end of 2020. By the end of 2022 at the latest, Swissmedic should have recognized that the manufacturers of these mRNA-based substances would never be able to provide the legally required evidence regarding controllability of production and efficacy and safety (**objective impossibility**; see also N 1122 ff.; in detail: ER N 1835 ff., in particular N 1930 ff.; 1935 ff.).

3.3. No risk-adequate product monitoring

26 From the beginning until today, **Swissmedic has** also **failed to take any adequate risk-reducing measures** to minimize the risk to the population as a whole posed by these mRNA "vaccines", which were approved in contravention of the law and recognized rules of good manufacturing practice. **In particular, Swissmedic failed to ensure rigorous product monitoring** (N 1151 ff. with further omissions; see also N 1296, N 1302, N 1308 and N 1314):

- Despite the negative experience with Pandemrix in 2009/2010, Swissmedic was content with a purely passive reporting system for market surveillance (N 1154 ff.), which can in no way be considered risk-adequate and is obviously insufficient for such a **novel and risky medicinal product that is** still in the human trial stage (clinical phase III). **Instead, the mRNA "vaccines" should have been subjected to active monitoring (pharmacovigilance) from the outset - as under trial conditions. This would have been reasonable.**
- However, Swissmedic did not even enforce the passive reporting system to a legally adequate extent: In Switzerland, **only about 10% of all adverse drug reactions** are **reported at all.** This **massive underreporting** makes it impossible for Swissmedic and the public to recognize the full extent of the devastating consequences (N 1159 ff.).
- At the end of 2020 and the beginning of 2021, Swissmedic approved the almost complete discontinuation of the approval studies, thereby relinquishing the central control instrument for checking efficacy and safety without need (N 1174 ff.; see also N 275 ff.).
- Swissmedic probably also failed to ensure rigorous batch testing from the outset (N 1184 with reference to N 321 f.), which in no way ensured that the quality of the experimental mRNA medicinal products was checked independently of the manufacturers.

3.4. Misleading instead of risk-adequate information

27 As a reasonable and absolutely necessary risk-reducing measure, **Swissmedic failed** in particular to **provide the public with effective information and instead disseminated misleading or completely false information in prominent places** (N 1187 ff. with **many** further examples; see also N 1296, N 1302, N 1308 and N 1314):

- Swissmedic informed the Swiss population about each authorization by means of **media releases,** which contained a **whole range of misleading information** (N 1191; in detail ER N 1964 ff.). For example, at the end of 2020, Swissmedic announced that the authorization of Comirnaty had been granted in an "ordinary" procedure, which is a **blatant lie** that many people still believe today. Swissmedic also propagated a high level of

efficacy that had never been proven and concealed the fact that dozens of questions regarding quality, efficacy and safety were still completely unresolved. Particularly reprehensible is the claim made at the end of 2021 that Comirnaty had shown "high clinical efficacy in younger children", although the clinical trials had only shown minimal therapeutic benefit for minor conditions (such as sore throats/headaches). **Swissmedic thus exposed the least threatened population group to the risk of serious side effects and deaths without need and in an absolutely misleading manner.**

- To date, Swissmedic has failed to explicitly draw the public's attention to the fact that the "mRNA technology" in question is to be regarded as a procedure with special risks (gene therapy; GMO; ATMP; pre N 6), and that not only the dosage of the injected mRNA ("pro-drug"; N 225 ff.; ER N 174 ff.) but also the dosage, quality, production time and location of the spike proteins produced in the body ("active pharmaceutical ingredients") are in no way known or controllable, which is why these highly experimental substances should **only** have been tested **under the highest safety standards** as part of a proper authorization procedure (N 200 ff., N 526 ff., N 916 ff., N 1407 ff.; ER N 32 ff., N 45 ff., N 51 ff., N 62 ff.).
- In the **information for healthcare professionals,** Swissmedic provided doctors and patients with all kinds of information that was obviously incorrect (N 1199; in detail ER N 2111 ff.): For example, the information that "no vaccine-related effects on female fertility, pregnancy, embryo-fetal development or the development of offspring have been identified", which is in stark **contradiction to study results** and warnings from manufacturers and expert committees that were already available to Swissmedic at the end of 2020.
- Also **missing - despite the thousands of reports received - are any references to serious side effects** such as "thromboembolic side effects", "herpes zoster", "hearing loss/tinnitus" or "COVID-19 disease" ("vaccination failure"). This ongoing deception by means of **untrue documents within the meaning of Art. 317 SCC (see** in detail N 1427 ff.) - not least supported by the other systematic acts of deception listed here - presumably led to incorrect vaccination decisions in millions of cases.
- Swissmedic also published a **"FAQ" on** its own website for a long time, which was aimed at the general public and **contained countless misleading information on mRNA preparations,** although Swissmedic already had internal data at the end of 2020 that showed its own "FAQ" to be clearly misleading (N 1204 ff.; ER N 2240 ff.). For example, in March 2023, Swissmedic still claimed in its answer to the first question in this prominent FAQ that the **vaccines were "*demonstrably safe, effective and of high quality*"**. Swissmedic even explicitly negated the fact of serious side effects: "***So far, there is no evidence of lasting negative health consequences***." This answer,

like the entire official "FAQ", is symptomatic of an actual policy of permanent disinformation by the highest supervisory authority for drug safety in Switzerland.

28 Swissmedic did not stop at misleading media releases, technical information and statements on its own website such as the "FAQ". **Swissmedic** also **continuously spread misinformation** about mRNA injections through numerous other channels (magazines, television, e-mail correspondence) - quite obviously with the aim of reassuring the Swiss population and maintaining "willingness to vaccinate" (see N 1208 ff.).

29 In addition to all of the above, the mere designation of **the mRNA-based preparations** as **COVID-19 "vaccines"** per se constitutes an independent act of deception of unique proportions. According to Art. 2 lit. b of the Medicinal Products Licensing Ordinance (MPLO), medicinal products may only be authorized as **vaccines within the meaning of this ordinance if** they actually produce "**active or passive immunity**". With regard to COVID-19 vaccines, however, the opposite has proven to be true: **Empirical data from numerous countries show a correlation between frequency of COVID-19 vaccination and susceptibility to COVID-19-related illnesses, hospitalizations and deaths, i.e.: The more COVID-19 vaccinations, the greater the susceptibility to COVID-19 - and the weaker the natural immune system** (see N 1095 f.; see also ER N 588 f., N 819, N 867, N 1291 ff., N 2248).

30 **Swissmedic has therefore not only created enormous risks and dangers for the entire population. It has also left the population permanently in the dark with regard to these risks and dangers and created an impression of false safety. To this end, Swissmedic has also made use of official documents** (authorization decrees; specialist and patient information) **and its own official website.**

4. Medical malpractice: lack of information, lack of reporting

31 The effect of this consistent disinformation by Swissmedic essentially continues to this day and affects all the decision-relevant topics listed above:

1) **Dangerousness of SARS-CoV-2** (reality: less dangerous than proclaimed);
2) **Alternative treatment methods** (reality: were available);
3) **mRNA technology** (reality: pharmacologically uncontrollable preparation; high-risk technology GMO; ATMP);
4) **Manufacturing and auditing standards** (reality: blatantly violated);
5) **Protective effect of the mRNA preparations** (reality: negative; no "vaccination");
6) **Risk profile** (reality: historically high).

32 A large proportion of the population, who had only believed the official information, obviously only consented to this mRNA injection on the basis of inadequate information regarding the above 6 issues relevant to the decision. However, consent can never become legally effective without proper information on all facts relevant to the decision, which is why every mRNA injection carried out on this basis of inadequate information must be qualified as bodily harm (for the requirements for valid consent, see N 1589 et seq.).

33 However, even the "vaccinating" doctors are by no means able to evade their own responsibility by referring to Swissmedic's misconduct. Rather, criminal liability of the **managing and vaccinating physicians** (in the present case: the defendants of the Insel Group) must also be examined, in particular if they did not provide any or completely insufficient information to patients prior to the use **(Art. 86 para. 1 lit. a TPA in conjunction with Art. 26 TPA)** of the mRNA "vaccines" (N 1226 ff.; N 1320 ff.).

34 Based on the documents available to date, it can be stated that in the cases reported here, either **no information was provided at all,** or at best a five-minute explanation was documented, which is simply not sufficient in view of the complexity of the mRNA "vaccines". Without informed *consent,* the "vaccination" was therefore hastily administered in a way that was physically harmful or even fatal (N 1589 ff.; cf. also N 1358 et seq.), which means that **elements of the Criminal Code** must also be examined.

35 In addition, a **violation of the prohibition on advertising medicinal products under the Therapeutic Products Act** (Art. 87 para. 1 lit. b TPA) must also be examined in the case of the medical profession if misleading information (such as on the Insel Gruppe website) has been and is being disseminated (N 1398). In view of the massive underreporting, there is also an urgent suspicion that a large number of physicians have breached their duty of care in the area of **reporting obligations under therapeutic products law** (Art. 87 para. 1 lit. c TPA; N 1364 ff.).

5. Unleashed Swissmedic acts to the detriment of the state and the population

36 By the end of 2022, the persons acting on behalf of Swissmedic - as well as the medical profession involved - have had more than sufficient time and cause to recognize the overwhelming risks and dangers of mRNA technology described in this criminal complaint and to respond adequately. They all had a duty, and still have, to put an immediate end to this disastrous experiment and to do everything possible to inform the public immediately and protect them from further danger. However, against their better judgment, they did not do so and continue to fail to do so, even though all the information disseminated by Swissmedic

(as the highest authority for drug safety in Switzerland) to the public is given maximum credibility by law and even though the layperson cannot recognize Swissmedic's misconduct without special effort and supporting expertise.

37 With the repeated, repeated and serious violations of the most fundamental duties of care under therapeutic products law and standards for the protection of public health (illegal "pandemic approvals" [N 857 ff.] and their perpetuation [N 1131 ff.], inadequate risk monitoring [N 1151 ff.] and by misleading the public [N 1187 ff.]), Swissmedic is not only violating Swiss law. In the absence of information about the particular experimental nature of the substances at issue here and the risky mRNA technology per se, Swissmedic's actions and the administration of the mRNA injections are in conflict with provisions of mandatory international law (N 1211 ff.). Art. 7 of the UN Covenant on Civil and Political Rights (UN Covenant II; SR 0.103.2) stipulates that **no one may be subjected to medical or scientific experiments without their voluntary consent - not even "in the event of a public emergency threatening the life of the nation and which has been officially proclaimed"** (Art. 4 para. 1 of the UN Covenant). Without the necessary information about all risks and side effects relevant to the decision - in particular about the experimental nature of the mRNA substances themselves - any injection of mRNA-based COVID-19 preparations based on Swissmedic's approvals and its misinformation constitutes an act of "cruel, inhuman or degrading treatment or punishment" within the meaning of the UN Covenant and also within the meaning of Art. 10 para. 3 of the Federal Constitution (FC). There can never be any justification for violating this principle, which is mandatory under international and constitutional law - particularly to the detriment of a large proportion of the population - as it is the very core of the human right to life (N 1214 ff.).

38 All in all, the mRNA-based COVID-19 vaccines are proving to be a **real NONVALEUR** for Switzerland, both in epidemiological and medical terms and in economic terms **- with an unacceptably high risk and potential for harm. What** is particularly reprehensible is the fact that Swissmedic and the persons involved still **do not want to correct** their misconduct **even after more than 3 years, i.e.** [i.] that they have converted the authorizations originally granted for a limited period of two years - illegally granted - into permanent or ordinary authorizations, [ii.] that they have not revoked any of the authorizations granted, and [iii.] that they have still not adequately informed the population about the danger created by this.

39 **In essence, this is a total failure of the "Swissmedic safety system" - the highest authority responsible for drug safety, which has virtually taken on a life of its own and is acting outside its legal mandate. The actual purpose of the Therapeutic Products Act - to protect the population from ineffective and harmful medicinal products - has been completely disregarded by Swissmedic to this day and has almost been**

turned into its opposite. This special authority is unscrupulously deceiving the entire political community, all the media and the general public about the real known risk factors of mRNA technology, even though Swissmedic knows full well that the whole of Switzerland has blind faith in it and uncritically accepts Swissmedic's statements as the primary basis for any risk/benefit assessment in connection with the so-called COVID-19 "vaccinations".

40 Without effective intervention at all relevant levels - including through parliamentary oversight by the Swiss Confederation (Art. 169 ff. BV) - **the suffering of the Swiss population,** which is already immeasurable in too many individual cases, will be unnecessarily increased. There is also the threat of massive additional economic damage for the people affected, for the economy, for health insurance companies and for public budgets. Furthermore, there is also the threat of lasting and massive credibility damage for all the authorities involved and for the entire Swiss Confederation.

41 Finally, in the event of a renewed declaration of an international health emergency (WHO: "Public Health Emergency of International Concern", Art. 12 International Health Regulations; Federal Council: "Special Situation", Art. 6 EpG), there is a risk that the dangerous mRNA preparations with negative efficacy will once again be purchased and administered millions of times despite the more than clearly proven unsuitability and despite the established predominant risk elements of this experimental technology against new pathogens - and once again without conducting the randomized, controlled and non-manipulated long-term studies that are absolutely necessary for this.

42 For all these reasons, urgent coercive measures (house search at Swissmedic; seizure of the mRNA "vaccines") must be taken immediately to protect against these illegal and high-risk mRNA injections. In addition, it must finally be effectively ensured that the population, which continues to be misled, is fully and transparently informed about this complex of problems.

43 In addition, the 37 complainants and the 6 private plaintiffs reserve the right to **publish** this **updated version 2.0 of the criminal complaint, including the enclosures, in order to protect the public.**

Preliminary remarks on the file regulations

44 All **publicly accessible sources are** listed in footnotes. In order to preserve evidence, all sources that do not originate from legal literature (e.g. Basel Commentary), Swiss case law (e.g. Federal Supreme Court) and legislation (e.g. dispatches, ordinances) have been saved digitally and are listed in a separate **list of sources** (e.g. scientific literature, Swissmedic publications), which in turn is offered as evidence.

BO: Enclosure **1:** "List of sources for the criminal complaint", 14.07.2022

BO: Supplement **12:** "List of sources for criminal charges" 2.0, 14.12.2023

45 **Evidence that is not publicly accessible** (e.g. correspondence, additional modules of the criminal complaint, named source lists) is offered as evidence in the body text ("offers of evidence", "BO") and listed in the list of evidence. In contrast to version 1.0, all offers of evidence (with the exception of Exhibit **13) are** submitted exclusively in digital form in this version 2.0 due to the massive volume.

46 The additional modules of the criminal complaint include:

BO: Enclosure **2:** List of notifying parties, 14.07.2022

BO: Enclosure **3:** List and documentation of private plaintiffs, 14.07.2022

BO: Enclosure **4:** Evidence report, 14.07.2022

BO: Enclosure **5:** Analysis of 15 deaths, 14.07.2022

BO: Enclosure **13:** Evidence report 2.0, 07.02.2024

BO: Enclosure **14**: Analysis of deaths in the Canton of Bern, 24.08.2022

47 The aforementioned enclosures (modules) in turn contain separate lists of sources and evidence according to the same model (public / non-public). **All six modules are an integral part of this criminal complaint.**

48 All documents of the present criminal complaint (including the sources and offers of evidence that have only been digitally secured) are offered on data DVDs or USB sticks as additional evidence:

BO: Enclosure **6:** Data DVD Sources, 14.07.2022

BO: Enclosure **15**: USB stick, complete digital dossier, 07.02.2024

Reason

A. FORMAL / PROCEDURAL

I. Legitimization

49 The legal representative of the private claimants and complainants is duly authorized: The legitimation is based on the attached lists and documentation **(enclosures 2 and 3)** with further documentary evidence in each case.

II. Local responsibility

50 An offense is deemed to have been committed where the perpetrator carries it out or fails to act in breach of duty and where the result has occurred (Art. 8 para. 1 SCC; in some cases in conjunction with Art. 104 SCC). The authorities of that place are responsible for prosecution and judgment (Art. 31 para. 1 CCP).

1. Concerning Swissmedic

51 The Swiss Agency for Therapeutic Products Swissmedic has its registered office at Hallerstrasse 7, 3012 Bern, according to the extract from the commercial register.[1]

52 [...].

53 [...].

54 [...].

55 [...].

56 [...].

57 If Swissmedic has granted "temporary authorization" for COVID "vaccines" in violation of its duties of care under therapeutic products law and if Swissmedic maintains an inadequate reporting system that endangers or has already endangered the health of a large number

[1] Commercial Register Office of the Canton of Bern, "Internetauszug Swissmedic", 09.06.2022, https://be.chregister.ch/cr-portal/auszug/auszug.xhtml?uid=CHE-108.952.985.

of people, the acts alleged in this regard by defendants 1-3 and 9-10 are deemed to have been committed in 3012 Bern.

2. Concerning "Island Group"

58 According to the extract from the commercial register, "Insel Gruppe AG" has its registered office at Freiburgstrasse 18, 3010 Berne.[2]

59 [...].

60 [...].

61 [...].

62 [...].[3]

[...].[4]

[...].[5]

[...].

63 If the "Insel Gruppe" has used COVID "vaccines" on humans in breach of its duties of care under therapeutic products law, has inadequately reported side effects to Swissmedic and has endangered or already injured the health of a large number of people through the careless use of the mRNA "vaccines", the acts alleged in this regard by defendants 4-8 are deemed to have been committed in 3010 Bern and/or at Friedbühlstrasse 15 in 3008 Bern (Inselspital vaccination center site).

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2 Commercial Register Office of the Canton of Berne, "Internetauszug Insel Gruppe AG", 09.06.2022, https://be.chregister.ch/cr-portal/auszug/auszug.xhtml?uid=CHE-433.951.246.

3 [...].

4 [...].

5 [...].

III. Material responsibility

64 If criminal provisions of the Therapeutic Products Act are to be examined, it must be determined whether the federal or cantonal prosecution authorities have jurisdiction in accordance with the "split" jurisdiction provided for in Art. 90 TPA.

65 In the present case, the reported violation of the reporting obligations constitutes an offense under Art. 87 para. 1 lit. c TPA. However, there is also a strong suspicion of other - more serious - offenses under the Therapeutic Products Act within the meaning of Art. 86 TPA. Swissmedic is primarily responsible for the testing and authorization of new medicinal products (medicines) and for granting licenses to companies that manufacture or wish to trade in medicinal products (Art. 5, 9 ff., 18 f. and 28 f. TPA). Swissmedic therefore controls the production of medicinal products as bulk goods.[6] According to Art. 58 para. 3 TPA (TPA; SR 821.21), the Agency (Swissmedic) is also responsible for monitoring the safety of therapeutic products, which would in principle give the federal government jurisdiction for prosecution in accordance with Art. 90 TPA.

66 However, the cantonal prosecution authority is responsible in the case of more serious penalties under the SCC. If only an offense under Art. 87 para. 1 lit. c TPA were assumed, the criminal offences also charged under the SCC would clearly take precedence and the cantonal prosecution authorities would have jurisdiction. However, the same would also apply if an offense under Art. 86 para. 1-3 TPA were relevant: The TPA offenses are only consumed by Art. 230bis para. 1 SCC, which is also invoked here, due to the higher minimum penalty of one year imprisonment and due to the same protected legal interests.[7] In addition, there are the homicide and bodily injury offenses under the Swiss Criminal Code, which are in genuine competition with the HMG offenses.[8] The cantonal criminal authorities therefore have jurisdiction.

67

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6 BURRI, in: Eicker (ed.), Swissmedic, Heilmittelgesetz und Strafverfahren - Gesetzeskonkurrenzen, Zuständigkeitskonflikte und Information der Öffentlichkeit, Bern 2017, p. 147.

7 BURRI, in: Eicker (ed.), Swissmedic, Heilmittelgesetz und Strafverfahren - Gesetzeskonkurrenzen, Zuständigkeitskonflikte und Information der Öffentlichkeit, Bern 2017, p. 150 FN 24.

8 BURRI, in: Eicker (ed.), Swissmedic, Heilmittelgesetz und Strafverfahren - Gesetzeskonkurrenzen, Zuständigkeitskonflikte und Information der Öffentlichkeit, Bern 2017, p. 150 FN 24; SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 8 f., N 116. Cf. also Dispatch on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3562.

[...].[9]

IV. Sufficient and urgent suspicion

68 According to Art. 309 para. 1 lit. a StPO, "reasonable suspicion", which may arise from a criminal complaint, is sufficient to open an investigation. **The principles of fair proceedings and the principle of legality require an investigation to be opened in cases of doubt.** If the requirements of Art. 309 para. 1 of the Code of Criminal Procedure are met, an investigation must be opened **immediately.**[10]

69 The **opening of a criminal investigation** requires the existence of a concrete or **sufficient suspicion, i**.e. the necessary factual indications of a criminal offense must be of a concrete nature. The suspicion is concrete if there is a **certain probability that the perpetrator will be convicted under criminal law**. The totality of the factual indications must allow a plausible prognosis that the accused will be convicted with a certain degree of probability.[11] According to the case law of the Federal Supreme Court, suspicion is considered sufficient in particular if **detailed allegations in the criminal complaint do not appear to be completely implausible or without any doubt unfounded** - especially if the criminal complaint is filed by a lawyer who is aware of the implications of such a step and does not take it lightly and without reason.[12]

70 If there is a **substantial probability of a subsequent conviction** because there are substantial factual indications that a criminal offense has been committed, then there is an **urgent suspicion of a crime,** which is a prerequisite for the **ordering of coercive measures** within the meaning of Art. 196 of the Code of Criminal Procedure.[13]

71 In the following material part, an overwhelming number of factual indications are presented, each of which is sufficient to open a criminal investigation (sufficient suspicion). Since the evidence and circumstantial evidence is already so concentrated, there is a considerable likelihood of a subsequent conviction (**strong suspicion**), **at least with regard to the**

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9 [...].

10 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 309 N 10a.

11 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 309 N 25.

12 Thus BGE 106 IV 413 E. 4a p. 418 f.

13 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 309 N 27.

reported HMG offenses and the negligence offenses of the StGB, which is why coercive measures must be ordered immediately.

V. Authorization procedure (Swissmedic)

72 Swissmedic is an institution under public law that fulfills the tasks assigned to it by law and assigned to it by the Federal Council as part of its service mandate in accordance with its purpose. [14]

73 According to Art. 1 para. 1 VG (SR 170.32), all persons who are entrusted with the exercise of a public office of the Confederation, namely members and substitutes of federal authorities (and commissions) that are outside (the federal courts and) the federal administration (lit. d) as well as all other persons insofar as they are directly entrusted with public-law tasks of the Confederation (lit. f), are subject to the Liability Act. The appellants 1-3 and 9-10 (Swissmedic) are therefore likely to be subject to the protection of the Responsibility Act.

74 Art. 15 para. 1 VG stipulates that the prosecution of civil servants for criminal offences relating to their official activities or position, with the exception of road traffic offences, requires the authorization of the FDJP. The authorization must be obtained by the cantonal prosecution authorities "without delay" at the start of criminal proceedings, with **urgent protective measures being taken in parallel** (Art. 15 para. 2 VG). However, a delayed authorization does not result in the nullity of the criminal judgement if it is obtained at the beginning of the proceedings before the higher cantonal instance and the latter has full legal and factual cognizance (BGE 139 IV 161 E. 2.5 p. 166 f.).

75 If an offence and the legal requirements for prosecution appear to be fulfilled, authorization may only be refused in minor cases and if the offence appears to be sufficiently punishable by disciplinary measures against the offender (Art. 15 para. 3 VG). A "minor case" was assumed for an offense of up to approx. CHF 500 (BGE 139 IV 161 E. 2.3 f. p. 165). The present allegations are far more serious and clearly do not constitute a minor case. Since - as shown below - various elements of the offence appear to be fulfilled and the other requirements for prosecution are met, the authorization must be granted by the FDJP. An appeal must be lodged against any refusal to grant authorization (Art. 15 para. 5 and para. 5bis VG). **In addition, urgent measures - in particular house searches to be carried out (N 101 ff.) - must be carried out in parallel and therefore without delay.**

14 Commercial Register Office of the Canton of Berne, FN 1.

VI. Victim interrogations

76 Only those who have the capacity to act (Art. 106 para. 1 of the Code of Criminal Procedure), i.e. who are physically and mentally able to follow the proceedings, are competent to stand trial. As a rule, serious illnesses are likely to negate the capacity to stand trial and be questioned.[15] If the prosecuting authority deems it necessary to question victims in addition to the factual evidence (such as patient files) in order to establish the facts of the case, any questioning of victims due to health problems must be conducted by video conference (Art. 144 StPO; Art. 78 para. 6 StPO).[16] The public prosecutor's office must ensure that the person to be questioned is not subject to any influence by third parties during the video conference.[17] Such a situation-specific modified right to participate is permissible: The requirements of Art. 144 StPO form the basis for the partial restriction of the physical right to participate in audiovisual hearings. The parties' rights to participate are sufficiently safeguarded if they are able to attend the audiovisual hearing and have the opportunity to ask supplementary questions (via video conference).[18]

77 Taking into account the respective state of health of the victims, it must also be ensured that they do not have to testify more than once if possible, but that a single video conference is held for each victim while safeguarding the rights of the accused to participate (analogous to Art. 155 para. 1 and Art. 154 para. 4 lit. b and c of the Code of Criminal Procedure). Cases of urgent preservation of evidence (such as imminent complete incapacity to stand trial) are reserved, whereby the participation rights of the accused may still be granted retrospectively depending on the state of health of the victims. If the facts of the case are based on statements by informants or witnesses, the accused person's right to participate must be safeguarded (Art. 147 ff. StPO). An incriminating (witness) statement can be used if the accused has had at least one reasonable and sufficient opportunity during the proceedings to cast doubt on the statements and ask questions of the person incriminating him (BGE 133 I 33 E. 3.1; judgment 6B_492/2015 of the Federal Supreme Court of December 2, 2015 E. 1.2.1.; judgment 6B_183/2013 of the FSC of June 10, 2013 E. 1.3). It should also be noted that evidence collected by criminal authorities in breach of validity provisions (e.g. Art. 147 para. 4 of the Code of Criminal Procedure) may nevertheless be used if its use is essential for the investigation of serious criminal offenses (generally crimes, such as Art. 111 of the Swiss Criminal Code) (Art. 141 para. 2 of the Code of Criminal Procedure).[19]

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15 WEHRENBERG, in: BSK StGB, 4th edition, Basel 2019, Art. 114 StPO N 7.
16 See HÄRING, in: BSK StGB, 4th edition, Basel 2019, Art. 144 StPO N 6.
17 GODENZI, in: Donatsch et al [eds.], Commentary on the Code of Criminal Procedure, Art. 144 N 4.
18 On the whole HÄRING, in: BSK StGB, 4th edition, Basel 2019, Art. 144 StPO N 10a
19 GLESS, in: BSK StPO, 2nd edition, Basel 2014, Art. 141 StPO N 67, N 72.

VII. Private plaintiff

1. Constitution

78 The aggrieved persons 1-6 listed in the rubric constitute themselves as private claimants within the meaning of Art. 118 StPO .

79 Any necessary criminal applications are treated in the same way as this constitutive declaration (Art. 118 para. 2 StPO).

1.1. Constitution as a criminal claimant

80 The private prosecutor expressly demands the prosecution and punishment of the persons responsible for the offenses (Art. 119 para. 2 lit. a StPO).

81 As a criminal claimant, the private claimant has full party status (Art. 104 para. 1 lit. b StPO).

1.2. Constitution as a civil claimant

82 In addition, the private plaintiff also constitutes itself as a civil plaintiff and examines the assertion of claims under private law by way of adhesion (Art. 119 para. 2 lit. b StPO).

83 The right to quantify the civil claim is expressly reserved (Art. 123 StPO).

2. Brief justification of injured party status

84 The detailed justification of the aggrieved party status, including supporting documents (offers of evidence), is provided at in the separate document "List and documentation of private claimants" (Annex **3**).

85 For the sake of form, it should be noted at this point that the rights of the named private plaintiffs were directly violated by the offenses reported (Art. 115 para. 1 StPO); in detail:

2.1. Private plaintiff 1

86 Private plaintiff 1, who was around 45 years old during the relevant period, received an mRNA injection from Moderna in April 2021.

87 Within 5-15 minutes of this injection, private plaintiff 1 suffered a grade III anaphylactic shock and only survived thanks to immediate emergency hospitalization and intensive medical care. Her "vaccinating" family doctor was aware that private claimant 1 had already suffered grade III anaphylactic shock twice after ingesting peanuts. To this day, the private

plaintiff continues to suffer from various physical ailments. She was released from further mRNA injections as these are life-threatening for her.

2.2. Private plaintiff 2

88 Private plaintiff 2, who was 43 and 44 years old in the relevant period, received two injections of "Moderna" in May and June 2021 and the "Booster" from "Moderna" in December 2021.

89 After the second mRNA injection, strong reactions (pain) occurred for the first time, but these were not yet linked to the injection. Shortly after receiving the "booster", the pain worsened considerably (back and legs). The joints were swollen and private claimant 2 could no longer move, which led to an emergency hospitalization by the family doctor on December 19, 2021.

90 In February 2022, a blood test revealed a reactivation of viruses (adenoviruses, Epstein-Barr virus **[EBV],** herpes simplex virus). Her state of health then continued to deteriorate until her skin turned blue/purple in March 2022 and the private claimant had to be admitted to hospital as an emergency case. Various examinations and treatments were carried out on site; she was discharged on April 1, 2022.

2.3. Private plaintiff 3

91 Private plaintiff 3, who was 47 years old during the relevant period, received an injection of Moderna in August 2021. From the second day after the mRNA injection, migraine-like headaches and increased pressure in the head occurred, which was accompanied by latent fatigue.

92 About a week after the mRNA injection, tachycardia (palpitations) occurred for the first time (which had been successfully treated a few years previously). About 10 days later, atheromas appeared in the armpit area (sebaceous cyst) and about a month after the "vaccination", circular hair loss occurred. In addition, there was an unexplained weight gain and a complete derailment of the menstrual cycle (cramp-like pain in the middle of the cycle, previously unknown heavy menstrual bleeding).

2.4. Private plaintiff 4

93 Private plaintiff 4, who was 27 years old during the relevant period, received mRNA injections from Pfizer/BioNTech in June and July 2021.

94 Approximately 1-1½ hours after the second "vaccination", private plaintiff 4 became increasingly unwell (dizziness, feeling of weakness, fever > 40 degrees, chest pain, shortness of breath, fainting several times). Despite multiple examinations and a stay in rehab, private claimant 4's state of health continued to deteriorate. In December 2021, a possible reactivation of the Epstein-Barr virus **(EBV)** was diagnosed, among other things. In March 2022, an allergy to polysorbate 80 was diagnosed and, based on this, a "booster vaccination" was expressly not recommended.

2.5. Private plaintiff 5

95 The 20-year-old daughter of private plaintiff 5 received two mRNA injections from "Moderna" in 2021 and one from "Pfizer" ("off-label") in 2022.

96 Subsequently, the "vaccination" presumably led to an activation of the Epstein-Barr virus **(EBV;** possibly also to an activation of blood clotting) in the previously healthy young woman, whereupon the 20-year-old died of a ruptured spleen (possibly also from a pulmonary embolism) on April 1, 2022 after a rapid deterioration and very brief treatment in hospital. After the Institute of Forensic Medicine determined a natural cause of death following a superficial autopsy, flatly denied any connection with the "vaccinations" and accordingly did not investigate this in any way, **the public prosecutor's office ordered a supplement and improvement of the forensic medical report at the end of June 2022 at the request of the private plaintiff.**

2.6. Private plaintiff 6

97 Private plaintiff 6, who was 17 years old during the relevant period, received mRNA injections from Pfizer / BioNTech in January and March 2021,

98 Immediately after the first injection, very severe headaches, aching limbs and high fever began; private claimant 6 had reported the severe headaches before the second injection. In July 2021, private claimant 6 experienced acute severe spasms in the form of twitching, uncontrolled movements and uncontrolled rolling of the eyes. The twisting of the eyes has not subsided to this day. Her blood values are very much outside the normal range.

VIII. Access to files of private plaintiffs

99 The injured complainants constituted as private plaintiffs must be granted access to the files in accordance with Art. 101 para. 1 CPC (Art. 104 para. 1 lit. b CPC) at the latest.

100 If experts are to be appointed, the private prosecutor shall request prior access to the files and the opportunity to comment within the meaning of Art. 184 para. 3 of the Code of

Criminal Procedure. In any case, however, access to the files must be granted in accordance with Art. 188 and Art. 189 SCC, including all files and documents on which any expert opinion commissioned is based.[20]

IX. Seizures (and confiscations)

101 Pursuant to Art. 263 para. 1 of the Code of Criminal Procedure, objects belonging to an accused person or a third party may be seized if the objects and assets are likely to be used as evidence (lit. a) or are to be confiscated (lit. d; in particular forfeiture as security pursuant to Art. 69 SCC). **Urgent protective measures must be taken in parallel with any proceedings for authorization** (Art. 15 para. 2 VG; see N 74). Coercive security measures are permissible, for example, if the mere request for disclosure would frustrate the purpose of the measure (Art. 265 para. 4 CCP).[21] Since there is a risk in the present case that the mere request to hand over the evidence listed below will lead to the defendants' actions being thwarted, and because there is considerable imminent danger to public health on the basis of the explanations given here, the evidence to be secured as described below must be obtained primarily in the context of **house searches** (Art. 244 para. 2 lit. b and c CCP).

1. Securing authorization documents (application 4)

102 As with the rear (N 388 ff.), there is practically no publicly available approval documentation concerning the approval of the mRNA "vaccine" from Spikevax (Moderna). This is in stark contrast to Comirnaty - but only because Pfizer (or the US regulatory authority *FDA*) was forced by US lawyers to hand over the documents.[22] Since the corresponding court order, thousands of pages (Comirnaty for over 15-year-olds) have gradually been released to the public since around the beginning of 2022, whereby the *FDA* (or Pfizer) had originally wanted to keep this data (approx. 451,000 pages) under lock and key until 2076 (!) and is now continuing to try by all means to delay its release despite the court order.[23] In May 2023, the US lawyers also pushed through with a further demand: the *FDA*, which had wanted to withhold additional data packages from Pfizer (relating to adolescents aged 12-

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20 DONATSCH, in: Donatsch/Lieber/Summers/Wohlers [eds.], Commentary on the Swiss Code of Criminal Procedure, 3rd edition, Zurich/Basel/Geneva 2020, Art. 189 N 3.

21 BGE 143 IV 270 E. 7.5 S. 283

22 Civil Action No. 4:21-cv-01058-P, Public health and medical professionals for transparency against food and drug administration, Nov. 15, 2021, https://www.sirillp.com/wp-content/uploads/2021/11/020-Second-Joint-Status-Report-8989f1fed17e2d919391d8df1978006e.pdf.

23 On the whole: SIRI, "FDA Doubles Down: Asks Federal Judge to Grant it Until at Least the Year 2096 to Fully Release Pfizer's COVID-19 Vaccine Data", 08.12.2021, https://aaronsiri.substack.com/p/fda-doubles-down-asks-federal-judge?s=r; SIRI, "FDA Asks the Court to Delay First 55,000 Page Production Until May and Pfizer Moves to Intervene in the Lawsuit", 26.01.2022, https://aaronsiri.substack.com/p/fda-asks-the-court-to-delay-first?s=r.

15) and Moderna (adults) for over 20 years, must now release all 4.8 million pages by the end of June 2025 as a result of the court ruling.[24] Even if this data had all been released by mid-June 2025, all the data on the children and all the data on the "Omikron boosters" would still be missing.

103 The same picture can be seen in Germany, but there previous legal requests from the responsible authorities (in particular the Paul Ehrlich Institute [*PEI*]) have remained completely or at least materially unanswered without even the slightest comprehensible justification. Although the requested authorities have even admitted that they have the requested documents, their release has so far been refused and delayed with ever new excuses.

BO:	Enclosure **7:**	Request from the University of L. to the Paul Ehrlich Institute, "Subject: Our request pursuant to Section 1 IFG of 3.3.2022 [...]", 13.04.2022
BO:	Enclosure **8:**	Law firm R.: "Inquiry by Professors Prof. Dr. M. et al. [...]", 14.04.2022
BO:	Enclosure **9:**	Law firm R.: "Inquiry from Professors Prof. Dr. M. et al. [...] - My letter dated April 13, 2022", 29.04.2022

104 No data from the approval documents have been published in Switzerland either. As in the back (N 321 f.), Swissmedic has not even published the **batch release protocols** since September 2021 for unknown reasons**.**

105 This **complete lack of transparency** is incomprehensible and downright unacceptable in view of the mRNA "vaccines" that are still in the experimental phase. In addition, the relevant authorization documents (including batch release protocols) are indispensable for assessing the criminal liability of the persons acting on behalf of Swissmedic and other perpetrators. The few available Comirnaty documents already reveal **serious irregularities and indications that Swissmedic suppressed information from the public. There is** not a single rational or legal reason not to publish this elementary data - unless there is something to hide, which the first leaks and the forced - not even remotely complete - release of the Pfizer documents unfortunately clearly indicate (for more details on these, see N 235, N 258 f., N 275 ff., N 397 ff., N 400 ff., N 405 ff., N 473 f., N 475).

106 In approval of **application 4,** all Spikevax approval documents, including batch release protocols, should therefore primarily be seized and confiscated as part of the evidence gathering to be carried out. Since competent foreign authorities such as the *FDA* (USA) and also the *PEI* (Germany) are resisting the rapid release of the Comirnaty documents, these must also be seized from Swissmedic for the purpose of confiscation in accordance with Art. 263

24 Siri, "FDA ordered to produce Moderna C-19 Vaccine and Pfizer adolescent C-19 Vaccine data at average rate of 180'000 pages per month", 13.05.2023, https://aaronsiri.substack.com/p/fda-ordered-to-produce-moderna-c.

para. 1 lit. a StPO. With regard to application 5 concerning Module 3 (quality), the following in particular must be secured:

a. Analysis and control methods of all ingredients, including the active ingredient, lipid nanoparticles and the finished product.

b. Manufacturing and test protocols for the individual manufacturing steps of the active ingredient, the lipid nanoparticles and the finished product.

c. Release specifications of the finished product.

d. Batch release protocols for all batches released by Swissmedic.

e. Certificates of analysis from the manufacturers of the active substance, the excipients and the finished medicinal product.

f. Excipient Master Files for excipients not listed in the European Pharmacopoeia

g. Control methods for analyzing mRNA for purity and identity.

h. Control methods for analyzing the amount of mRNA contained in the finished medicinal product.

i. Control methods for the analysis of mRNA concentration determination and distribution when using multi-dose containers.

j. Control methods to ensure that no proteins other than the spike protein are produced in the body.

k. Studies on the pharmacokinetics of the ingredients and their biological degradation products.

l. Studies on toxicity, genotoxicity and carcinogenicity of all components.

2. Securing "vaccines" and batch samples (application 5)

107 In approval of **motion 5**, all mRNA "vaccines" (Comirnaty; Spikevax) including batch samples - at least those stored at the official "vaccination centers", the Swiss army and the manufacturer Moderna - are to be seized throughout Switzerland and confiscated with the following (alternative) justifications:

BO: Enclosure **10:** "List of addresses of vaccination centers CH", 01.04.2022

2.1. Seizure as evidence

108 The mRNA "vaccines" must be confiscated as evidence so that they can finally and for the first time be subjected to a high-quality independent official examination with regard to the ingredients. In particular, the mRNA "vaccines" on the market must be compared with the batch samples[25] that must be provided and retained on the occasion of batch release (see N 1257 ff.).

2.2. Seizure for the purpose of confiscation

109 According to Art. 69 SCC, objects that have served or were intended to serve the commission of a criminal offense or that have been produced by a criminal offense are to be confiscated regardless *of the criminal liability of a specific person* if these objects endanger the safety of people, morality or public order.

110 Confiscation by way of security first requires an offense that is objectively and subjectively criminal and unlawful. However, the decision on confiscation is independent of the decision concluding the criminal proceedings, even if it is not a conviction; this is because **confiscation is possible regardless of the criminal liability of a specific person** and therefore does not require criminal proceedings to be conducted against a specific person. Nor does the presumption of innocence preclude confiscation.[26]

111 The risk of (further) criminal use of the object can arise both from its nature and only from the expected use by its owner. The prosecution authorities must therefore make a prognosis as to whether it is sufficiently likely that the object in the hands of the offender will endanger the safety of people, morality or public order in the future.[27] The requirements for endangerment are not too high: public order can already be endangered by counterfeit objects.[28]

112 Already in the introduction (front N 0 ff.) and in detail at the back (e.g. N 212 ff., N 231 ff.), it is explained that the mRNA "vaccines" are toxic, potentially carcinogenic and possibly even mutagenic, while they are in no way effective in protecting against SARS-CoV-2. The mRNA "vaccines" therefore pose an unjustifiable major risk to human health safety, which is why they must be withdrawn from circulation immediately in order to protect public health.

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25 On this retention obligation, see DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 11.

26 BGE 117 IV 233 E. 3 p. 237; HUG, in: Donatsch [ed.], loc. cit., Art. 69 N 5.

27 BGE 116 IV 117 E. 2a p. 119 f.; HUG, in: Donatsch [ed.], loc. cit., Art. 69 N 7.

28 BGE 101 IV 36 E. III.7. p. 41; BGE 89 IV 62 E. 2d p. 70.

X. New preliminary proceedings / retrials (application 6)

113 Analyses of **exceptional deaths are** available for the cantons of Zurich and Bern (see N 449 ff. [**Supplement 5**] and N 456 ff. [Supplement **12**]). The analysis of these cases has shown that there is no systematic police investigation of the "vaccination status", that no autopsies are ordered by the public prosecutor's offices despite "unclear internal events" and that in the few autopsies that have been carried out, forensic medicine has only investigated superficial causes of death.

114 These omitted investigations not only contribute to the massive underreporting of deaths suspected to be directly related to the mRNA "vaccines" (see N 447 ff.). They also make it considerably more difficult to prove a direct causal link between "vaccination" and "death", which is why Swissmedic still freely claims that there have been no deaths in connection with mRNA injections in Switzerland (see for example N 624 and N 1199).

115 From a criminal law perspective, however, it is important to note that all of these criminal proceedings were presumably incomplete. The opening of new preliminary proceedings should therefore be examined, or possibly (if the perpetrators and offenders are identical) the reopening (Art. 323 of the Code of Criminal Procedure) of the AgT proceedings, many of which have presumably already been discontinued:

1. New preliminary proceedings: No identity of perpetrator and crime

116 According to Art. 11 para. 1 of the Swiss Code of Criminal Procedure, anyone who has been finally convicted or acquitted in Switzerland may not be prosecuted again for the same offense *("ne bis in idem"). The* prerequisite for the "ne *bis in idem"* barring effect to apply is that the proceedings in question concern the same offender and the same offense. The *identity of the perpetrator and the act* is required.[29] While the identity of the perpetrator generally poses no problems, there are different opinions regarding the identity of the act (single vs. double identity). Simple identity exists if the same life event ("the same factual situation") has already been adjudicated. [30]

117 If the identity of the perpetrator and/or the offense is missing, *new preliminary proceedings* can be opened at any time. Likewise, no reopening under Art. 323 of the Code of Criminal Procedure, but new preliminary proceedings must be initiated if new facts relevant to the offense become known that only *arose after the case was discontinued*. The same applies

29 WOHLERS, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 11 N 13.
30 WOHLERS, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 11 N 14 et seq.

to new facts that point to *actions relevant to criminal law* but which were *not the subject of the discontinued investigation and the discontinuation order.*[31]

118 On the basis of the exceptional deaths submitted so far in the cantons of Zurich (15 cases) and Bern (10 cases), it is obvious that in none of these cases was Swissmedic and/or the "vaccinating" medical profession even considered as perpetrators. In each of these 25 cases, **the identity of the perpetrator** is therefore already **lacking,** which means that the *"ne bis in idem"* blocking effect does not apply and new preliminary proceedings must be opened.

119 As also shown above (N 102 ff.), **essential information on the efficacy and safety of mRNA therapies** has been and continues to be **withheld from the** public (and thus also from the prosecution authorities) by the manufacturers and the regulatory authorities: Although some have since been partially cleared (Pfizer's approval documents, which are, however, only released with great delay), others still remain almost completely hidden from the public (Moderna). The emergence of these facts (at least with regard to Moderna, and to a large extent also with regard to Pfizer) therefore falls at a time after the presumed discontinuations in many cases - the facts are therefore obviously not the same. In addition, **criminal acts committed by means of mRNA gene therapies** are unlikely **to have been the subject of the discontinued investigations** (and the corresponding discontinuation orders): Where police journals or reports already lack any evidence of "vaccinations" having taken place and no autopsies have been ordered, there was definitely no police investigation in this direction and no investigation by the public prosecutor's office. There is therefore also a lack of **identity.**

120 **New preliminary proceedings** must therefore **be opened** in respect of the exceptional deaths referred to in proposal 6.

2. Contingency: resumption

121 Borderline cases - at least with regard to identity of the offense (but hardly with regard to the cumulatively required identity of the perpetrator) - would at best be those exceptional deaths,

- in which the "vaccination status" is determined,
- also examined in this direction as part of an ordered autopsy and
- a corresponding connection would have been excluded in a discontinuation order.[32]

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31 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 323 N 10 f.

32 Cf. above N 117.

122 If the offense *and the perpetrator are identical*, Art. 11 para. 2 of the Code of Criminal Procedure reserves the right to reopen proceedings that have been discontinued or not taken (Art. 323 of the Code of Criminal Procedure) and to appeal (Art. 410 et seq. of the Code of Criminal Procedure). Pursuant to Art. 323 para. 1 of the Code of Criminal Procedure, the public prosecutor's office shall order the reopening of proceedings that have been legally terminated by a discontinuation order if it becomes aware of new evidence or facts that (a.) indicate that the accused person is criminally responsible and (b.) are not apparent from the previous files.

2.1. Current state of knowledge: No investigation of "vaccine damage"

123 At least in the **Canton of Zurich, there are** 7-8 cases in which information on the "vaccination status" can be found and an autopsy was ordered. However, in only one of these cases (in the present case: private claimant 5) is the result of the autopsy, which was only superficially carried out (and in no way in the direction of investigating "vaccine damage"), known; without the intervention of the undersigned lawyers, no further investigations would have been carried out there either.[33] It must therefore be assumed, until proven otherwise, that the "vaccinations" were not investigated as possible causes of death. In none of the cases can it be assumed (according to the current state of knowledge) that the perpetrators are the same.

124 In the **canton of Bern,** only three cases can be identified in which the "vaccination status" was at least discussed and then, if necessary (the journal references are unclear), an autopsy was ordered. However, the journals do not indicate that the relevant "vaccination documentation" or similar clarifications were immediately consulted. The fact that **none of the cases were actually investigated for "vaccine damage" is** also strikingly evident in case 9: Despite a quick autopsy and the discovery of abnormalities in the heart area (!), the body was released immediately (for more details, **see Appendix 12**).

125 Based on the current state of knowledge, it can therefore be assumed, until proven otherwise, that in none of the 25 deaths is there likely to be a discontinuation order that excludes or even discusses the cause of death as mRNA gene therapy. Based on the current state of knowledge, a retrial is therefore ruled out - instead, **new preliminary proceedings should be opened** (see N 116 ff.).

33 See on the case of the private plaintiff 5 **Exhibit 3,** N 95 et seq. and **Exhibit 5,** N 23 et seq.

2.2. Reopening only if the offender and the offense are identical

126 However, if the discontinuation orders and/or case files still reveal corresponding investigative and investigative actions in the direction of "vaccination damage" (with regard to the offense *and perpetrator),* the requirements for a retrial under Art. 323 of the Code of Criminal Procedure would have to be examined:

127 In this case, "**new evidence or facts** must become known" that "**do not** result **from the previous files**".[34] The basic prerequisite for a retrial is therefore that the factual or evidentiary situation has changed since the time of the discontinuation.[35] Evidence that was already mentioned in the discontinued proceedings (but was not pursued further, for example, contrary to corresponding applications by the parties to the proceedings) or was even removed is not considered new - i.e. it is effectively derived from the previous files.[36] Evidence that existed at the time (e.g. was publicly available) but was not introduced into the criminal proceedings is therefore also considered new. This is stated in the dispatch:[37]

> "Conversely, it cannot be demanded that a fact or a piece of evidence only be regarded as new if it could not have been known to the public prosecutor's office in the first proceedings even if the necessary care had been exercised. This approach would be too strict, as in view of the volume of criminal proceedings to be completed, there is a natural tendency on the part of the investigating authorities to discontinue proceedings and the duty of care should not be too demanding."

128 **A reopening is therefore also possible if the public prosecutor's office could have easily recognized the evidence that was not taken.**[38] Any existing file references (e.g. in the police report) to "vaccinations" carried out therefore do not prevent the corresponding proceedings from being reopened, as these do not yet reach the necessary extent of the investigative actions to be carried out. At the very least, it would be necessary to include corresponding "proof of vaccination" (certificates etc.) and post-mortem examinations that have been carried out to provide possible evidence of third-party involvement through "vaccination". However, the documents available to date suggest that no such investigations were carried out in any of the cases. Accordingly, all the evidence and facts presented in the present criminal complaint are to be regarded as new, which means that from this point

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34 Front N 121.

35 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 323 N 15.

36 Message on the unification of criminal procedure law of December 21, 2005, p. 1274 f.

37 Message on the unification of criminal procedure law of December 21, 2005, p. 1275.

38 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 323 N 22.

of view, too, **there is nothing to prevent the exceptional deaths referred to in application 6 from being reopened.**

129 It should also be mentioned that the probability is also required that the new evidence or facts will lead to a different assessment of the decisive circumstances than was assumed in the discontinuation order. This assessment of probability does not have to meet high standards - especially if the charges are serious.[39] Likewise, no high demands are to be placed on the proof of whether the new facts can be established in the new proceedings to be initiated.[40] The new facts listed in the criminal complaint are obviously suitable for bringing about a criminal conviction of the persons reported. The fact that important evidence has been destroyed with regard to individual deaths, for example due to the lack of a post-mortem examination and the release of the body, does not exempt a retrial. Although this makes it more difficult to prove a connection between mRNA therapy and death, it does not make it impossible: the establishment of these facts can also be provided on the basis of other documents (such as patient files, interviews with treating physicians, etc.).

3. Urgent: Seizure of evidence from autopsies performed

130 Post-mortems were carried out in some of the exceptional deaths analyzed: In the **canton of Zurich,** these are the deaths on 02.01.2022, 03.01.2022 and 16.01.2022 and also on 12.02.2021, 13.02.2021, 13.02.2021, 15.02.2021 and 09.06.2021 (**Enclosure 5**). In the Canton of Bern, this is only the death on 06.01.2022, possibly also the deaths on 28.12.2021, 29.12.2021, 03.01.2022 and (a second case on) 06.01.2022 (**Enclosure 12**). As already explained in the submission of 14 July 2022 (**enclosure 5,** N 29), the evidence from a post-mortem examination case is generally (only) retained by the forensic institutions for at least six months after the date on which the expert opinion is prepared. [41]

131 It should therefore be reiterated that in all discontinued proceedings concerning unusual deaths, **there is a risk of loss of evidence once the** autopsy has been carried out. Accordingly, any evidence from the autopsy (see N 130) must be confiscated immediately. Furthermore, the competent public prosecutor's office is requested to immediately order the competent police to investigate further deaths of a similar nature and to seize the corresponding evidence.

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39 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 323 N 17.

40 BOSSHARD / LANDSHUT, in: Donatsch et. al [eds.], Kommentar StPO, 3rd ed., Zurich 2020, Art. 323 N 17a.

41 ZOLLINGER, in: BSK StPO, Art. 253 N 66.

XI. Appointment of experts

132 In accordance with Art. 182 ff. StPO, the following expert investigations must be carried out and corresponding experts appointed:

1. "Vaccines": Investigation by means of test protocol (application 5)

133 In approval of **application 5**, the seized mRNA "vaccines" are to be subjected to an independent and thorough review.

134 Primarily, all quality controls (allegedly) carried out by the manufacturers must be checked on the basis of the manufacturers' own manufacturing and test protocols. Accordingly, the securing of the corresponding protocols for Module 3, as requested in Application 4, is of central importance. In addition, the mRNA "vaccines" must be checked for declared and undeclared ingredients in order to be able to identify all the ingredients contained in each "vaccine" and batch. Without precise knowledge of all the ingredients, it will not be possible to provide the right medical assistance to the many people in Switzerland who have already suffered adverse reactions to vaccines.

2. Post-mortem examinations: Secondary examination based on test protocols (application 6)

135 In approval of **application 6,** the following investigations in particular are to be carried out:

2.1. Standardized protocol Prof. Burkhardt

136 A second examination must be carried out on the basis of the recovered evidence. The re-examination must be based on a protocol that not only superficially searches for the obvious final causes of death (such as organ damage and bleeding), but also investigates the causal pathogenesis of these final causes of death - such as vascular damage caused by toxic ingredients of the vaccine or components produced by it (in particular spike protein).

BO: Enclosure **11:** Autopsy protocol Prof. Dr. A. Burkhardt, "Notes and recommendations for conducting post-mortem examination (autopsy) of persons deceased in connection with COVID vaccination", March 17, 2022

137 If the forensic medicine institutes are not able to do this for technical or other reasons, the institutes must report this immediately and give reasons. **The private prosecution offers to call in and provide appropriate experts (in particular pathologists) at its own expense, who will carry out the examination at the institute under the supervision of the responsible institute.**

2.2. Addition to the protocol: qPCR and DNA sequencing

138 The main characteristic of all corona "vaccines" was that the mRNA components remain at the injection site and that they do not spread in the body and organs. However, this has proven to be clearly false information in recent months (see N 258 ff., cf. also N 391 ff.). If parts of the "vaccine" mRNA are found in the tissue of various organs of the deceased, this indicates an unintended mode of action of the mRNA therapy and the existence of a corresponding causal link with the death of the deceased. RNA viruses and mRNA also have the - in itself "undesirable" - potential to integrate into human DNA (see N 200 ff.), which also needs to be investigated.

139 In addition to the "Burkhardt autopsy protocol", the following (cumulative or alternative) examinations must therefore be carried out to provide strict proof of a causal relationship between mRNA therapy and the cause of death.

140 If the forensic institutes are unable to carry out subsequent examinations for technical or other reasons, the institutes must be notified immediately and the reasons given. **The private claimant offers to bring in appropriate experts (including biomedical experts and bioinformaticians) at their own expense to carry out the examination under the supervision of the responsible institute.**

2.2.1. Test using qPCR

141 For a (rapid and cost-effective) analysis of the tissue samples using the PCR method, proceed as follows:[42]

- Extract DNA using standard protocol measures (order e.g. here*:* https://www.qiagen.com).
- Use state of the art primers to detect spike mRNA sequence in tissue DNA (order e.g. here: *https:*//www.sigmaaldrich.com/).
- Design primers based on WHO Pfizer mRNA sequence to produce 100 bp amplicon to amplify Spike mRNA specific DNA using qPCR.
- Negative control: tissue from non-infected, non-vaccinated individual.
- Positive control: RNA vaccine vial, reverse transcribed to cDNA.

2.2.2. DNA sequencing

142 For a (more complex and, due to the necessary evaluation, more cost-intensive) analysis of the tissue samples by means of DNA sequencing, proceed as follows:[43]

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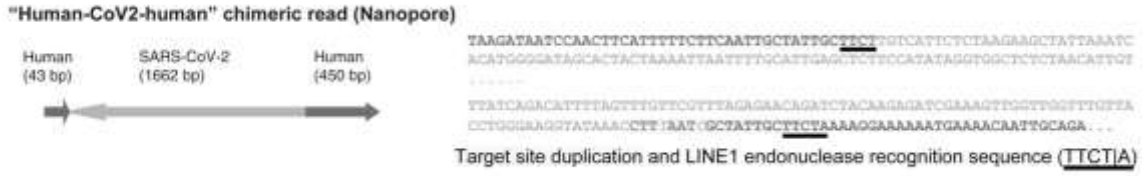
42 The information is given in English in the same way as the "Burkhardt autopsy protocol".
43 The information is given in English in the same way as the "Burkhardt autopsy protocol".

- Extract DNA using standard protocol measures (order e.g. here*:* https://www.qiagen.com).
- The PNAS publication addresses integration with long read sequencing methods using Nanopore (send e.g. here: *https:*//www.baseclear.com/).
- This process is non targeted and sequenced reads can be aligned to the human genome to check for integration using target site duplication evidence of LINE1 recognition site:



B. FACTS OF THE CASE

I. Protection of health as the primary goal: Therapeutic Products Act

1. Relevant legal norms; protected legal interest

143 The actions reported in this case concern the protection of public health and consumer confidence in authorized medicinal products. Public health (including life) is one of the most important police assets in Switzerland. Its protection is ensured by numerous standards in the constitution and in various federal laws. The protection of public health against *risks in connection with medicinal products falls within the* competence of the Confederation in accordance with Art. 118 para. 2 lit. a of the Federal Constitution and has been specified as follows in the Therapeutic Products Act, including penal sanctions that directly serve its implementation or the protection of health as a whole:

1.1. Therapeutic Products Act

144 With the Therapeutic Products Act (SR 812.21; Federal Act on Medicinal Products and Medical Devices), the Confederation specifies its competence in accordance with Art. 118 para. 2 of the Federal Constitution and clearly defines the purpose and the associated areas of responsibility of the competent authorities at the beginning of the Act:

> "This law is intended to protect human and animal health by ensuring that only high-quality, safe and effective therapeutic products are placed on the market."

145 Art. 1 para. 2 HMG also states the purpose:

"[This law] is also intended to:

a. protect consumers of therapeutic products from being misled;
b. help to ensure that therapeutic products placed on the market are used appropriately and moderately for their intended purpose;
c. contribute to the provision of a safe and orderly supply of therapeutic products, including the necessary professional information and advice, throughout the country."

146 Particular attention must also be paid to *the efficiency and independence of the Swiss Therapeutic Products Control Authority* (Art. 1 para. 3 lit. a TPA) when enforcing this Act, in particular when issuing ordinances and in individual cases.

147 The purpose article of the TPA already makes it clear that the legislator wanted to protect public health from poor-quality, ineffective and, above all, unsafe therapeutic products as well as from misleading information. The authorization of unsafe, ineffective or risky therapeutic products was to be excluded, as were misleading information on the therapeutic products and inadequate specialist information.

148 The above basic features of the Federal Therapeutic Products Act are not the only, but an important basis for the criminal assessment of the reported conduct. The following summary of the legally relevant facts shows that, in addition to the special offenses reported here, the persons reported have clearly, repeatedly and permanently disregarded all the essential fundamental objectives of the Therapeutic Products Act cited above in a criminally relevant manner.

1.2. Penal provisions on health protection

1.2.1. Penal sanctions under the HMG

149 The Therapeutic Products Act itself already contains criminal law norms that serve to realize and ultimately enforce the objectives of therapeutic products law: The provisions of Art. 86 et seq. TPA are intended in particular to ensure that only high-quality, safe and effective therapeutic products are placed on the market (Art. 1 para. 1 TPA).[44]

44 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Vor 8. Kapitel N 17; see also Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., 3456 f.

1.2.1.1 Basic standard: Abstract endangering offense

150 The basic provision of Art. 86 para. 1 TPA is even designed as an **abstract endangering offense**: A mere abstract endangerment of human health is therefore sufficient for criminal liability.[45]

151 The protection of legal interests has therefore been brought forward by the legislator to the maximum: There is no need for an actual violation of the legal interest of health, or even a concrete threat to it. **Even the mere performance of certain acts that are considered dangerous is declared punishable.**[46] Abstract endangerment is presumed in the case of criminal acts and does not have to be proven as an additional element of the objective offense in individual cases.[47] According to the Federal Supreme Court, any violation of the TPA implies an abstract danger to human health.[48]

152 In view of the high goal of protecting human health, the legislator has therefore resorted to the most severe of all available offense types by structuring Art. 86 para. 1 TPA as an abstract endangering offense.

1.2.1.2 Qualification: Concrete endangering offense

153 If the health of people is not only endangered in the abstract, but already in concrete terms, Art. 86 para. 2 lit. a TPA provides for a massive increase in the threatened penalty to ten years' imprisonment.

154 Such a specific risk exists if **the probability or remote possibility of injury to people's health is created or increased**.[49] Concrete endangerment of people as a qualifying criterion means that **"proof** must **be provided that the health of at least one person has actually been endangered"**; the mere possibility or presumption of endangerment is not sufficient. In contrast to the offense of injury, however, endangering the protected legal interest is sufficient - an injury is not required.[50]

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45 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 4, N 10; see also JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 20 ff.

46 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 106 f.

47 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 4, N 19.

48 Judgment 6B_1354/2017 of the Federal Supreme Court of June 14, 2018, E 1.3: "The provisions of the Therapeutic Products Act serve to protect human and animal health (see Art. 1 para. 1 TPA). If such a provision is violated, an abstract risk to human and animal health must be assumed. No further examination of possible health hazards is required".

49 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 100; JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 21; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 106.

50 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 4, cf. also N 100; BGE 135 IV 37 E. 2.4.1 p. 40.

155 Accordingly, if a violation of a relevant provision of drug law (para. 1) is accompanied by a specific risk to the health of a single person (para. 2), the offender is already threatened with long-term imprisonment as the most severe of all possible sanctions.

1.2.2. Further punitive sanctions to protect health

156 Art. 230bis SCC - endangerment by genetically modified or pathogenic organisms - also protects the legal interests of human life and limb.[51] As with Art. 86 para. 2 TPA, the mere **concrete endangerment** of an individual is sufficient.[52] If there is no concrete danger, the **abstract endangerment offenses** of the Gene Technology Act (GTG; SR 814.91) and the Environmental Protection Act (USG; SR 814.01) are relevant, which also serve to protect human health.[53] For example, anyone who handles genetically modified organisms (as intended) in such a way that people are endangered in the abstract (Art. 35 para. 1 lit. a **GTG** in conjunction with Art. 6 para. 3 lit. f and para. 1 lit. a GTG) is liable to a custodial sentence. The same applies to anyone who places pathogenic organisms on the market (as intended) and thereby endangers people in the abstract (Art. 60 para. 1 lit. i **EPA** in conjunction with Art. 29d para. 1 and Art. 29d para. 3 lit. a EPA). Art. 29d para. 1 and Art. 29a para. 1. lit. a USG). Furthermore, anyone who places genetically modified organisms on the market without labeling them as such for the recipient is also liable to prosecution (Art. 35 para. 1 lit. g GTG).

157 Like the criminal provisions of the TPA, the **offences of injury under the SCC** also protect human health - in the form of the protection of life itself (Art. 111 et seq. SCC)[54] and the protection of physical and health integrity (Art. 122 et seq. SCC).[55] For these, the actual injury to human health is required to constitute the offence.

1.3. Other national and international standards for the protection of public health

158 In addition to the standards of the Therapeutic Products Act and its implementing provisions as well as penal sanctions for health protection, a large number of standards exist at both national and international level for the purpose of protecting human health. It would go beyond the scope of this report to provide even a remotely comprehensive description. Where

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51 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 3.
52 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 4 f.
53 See ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 50; Wohlers / Godenzi / Schlegel, Handkommentar StGB, 4th ed., Bern 2020, Art. 230bis StGB N 4.
54 SCHWARZENEGGER / STÖSSEL, in: BSK StGB, 4th ed., Basel 2019, before Art. 111 StGB N 1.
55 ROTH / BERKEMEIER, in: BSK StGB, 4th ed., Basel 2019, before Art. 122 StGB N 6.

necessary, the relevant standards are used below to interpret the relevant criminal provisions.

2. Principles and maxims for the protection of public health

159 The benchmark for health protection is always whether government action - whether in the form of implementing ordinances or direct application of the law - ensures that therapeutic products are of high quality, **safe** and effective. [56]

2.1. Precautionary principle

160 The top priority and **decisive factor** in all ordinary and special ("temporary" or "simplified") approval procedures **is always "that safety is guaranteed".**[57]

161 Both ordinary authorization (Art. 9, Art. 10 ff. TPA) and temporary authorization (Art. 9a TPA) are only possible from the outset if **the protection of health and life is guaranteed.**[58] This means that a refusal of authorization is not only possible if there is a concrete risk to the health of users. Rather, it is sufficient if a preparation poses a "not insignificant potential risk to public health" in the sense of an abstract risk, which must be eliminated as far as possible in accordance with the precautionary **principle under therapeutic products law.**[59] This precautionary principle under therapeutic products law is specified in Art. 3 para. 1 TPA:[60] According to this, anyone who handles therapeutic products must take all measures that are necessary according to the state of the art in science and technology to ensure that human and animal health is not endangered (for more details on the **duty of care under therapeutic products law,** see N 1274 ff.).

2.2. Effectiveness of government action

162 If the standard of review for all actions under therapeutic products law is to be based on the purpose of Art. 1 TPA, it necessarily follows that the protective purpose of the law - protection of public health - requires the entire situation to be considered in terms of its effect. Compliance with formal regulations does not in itself provide sufficient security to ensure the protection of public health. All circumstances must be considered in their entirety with regard **to their impact on health protection** in accordance with the current state of scientific knowledge and general life experience. Government action must therefore be effective with regard to the highest legal interest - human health **(principle of effectiveness)** and

56 RICHLI, BSK HMG, 2nd ed., Basel 2022, Art. 81 N 17.
57 Message HMG, 3501; cf. RICHLI, BSK HMG, 2nd ed., Basel 2022, Art. 81 N 17.
58 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 5.
59 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 8.
60 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 3.

must not be limited to a formalistic approach. There can and must therefore be no "service by the book" in the area of health protection, especially as government actions have a direct impact on people's health.[61]

2.3. Risk-based handling of special risk factors

163 "Anyone handling therapeutic products must take all measures required by the state of the art in science and technology to ensure that human and animal health is not endangered". Art. 3 para. 1 TPA explicitly describes the principle and the standard of care for the handling of therapeutic products, which follows inevitably from the principles and maxims for the protection of public health set out above: It is the central task of the highest licensing authority to focus its attention from the outset on the type and number of risk factors of which it becomes aware in connection with the licensing of medicinal products and to take effective measures to exclude these risks. [62]

164 Classic risk factors in connection with drug approvals include

1) Novelty of the ingredients,
2) Novelty of the manufacturing process,
3) Novelty of the disease to be combated,
4) Lack of experience of the manufacturing companies in the production of similar medicinal products,
5) Approvals without the usual clinical trials,
6) particular time pressure, for example in the form of political and media pressure.

165 The less certainty and certainty can be gained in the approval process, the higher the hurdles for approval must be, or - in the case of approval despite risk factors - the more effective and closely meshed the approval must be.

1) informing the consumer in advance about these risks and
2) be designed for the timely detection of side effects.

166 Major uncertainties of a substance at the time of authorization therefore necessarily and without exception mean: maximum care with regard to risk/benefit information for consumers and maximum care with regard to effective recording and publication of side effects ("best effort standard"). Otherwise, public health cannot be protected from risks that were

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61 Cf. on the effectiveness of state measures HÄFELIN / MÜLLER / UHLMANN, Allgemeines Verwaltungsrecht, 8th edition, Zurich / St. Gallen 2020, N 1579.

62 For further details on the duties of care under therapeutic products law pursuant to Art. 3 TPA, see N 1275 ff.

underestimated at the time of authorization, that were still unknown at that time or that only materialize after authorization of the substances in question.

II. Perpetrators

167 In principle, anyone can be considered an offender under the above-mentioned penal provisions on health protection - but certainly those persons who appear to have breached their duty of care.[63] In particular, anyone who **manufactures** medicinal products in breach of Art. 3 TPA (general duty of care) (Swissmedic is deemed to be the manufacturer, particularly in the context of batch testing)[64] or **uses them** (use of the medicinal product on patients by doctors) is liable to prosecution under Art. 86 para. 1 lit. a TPA.

168 Both the reported natural persons of Swissmedic and the "Insel Gruppe" are therefore potential perpetrators. Accordingly, the legal status and the associated framework conditions of the aforementioned organizations will be briefly discussed:

1. Manufacturer - Swissmedic

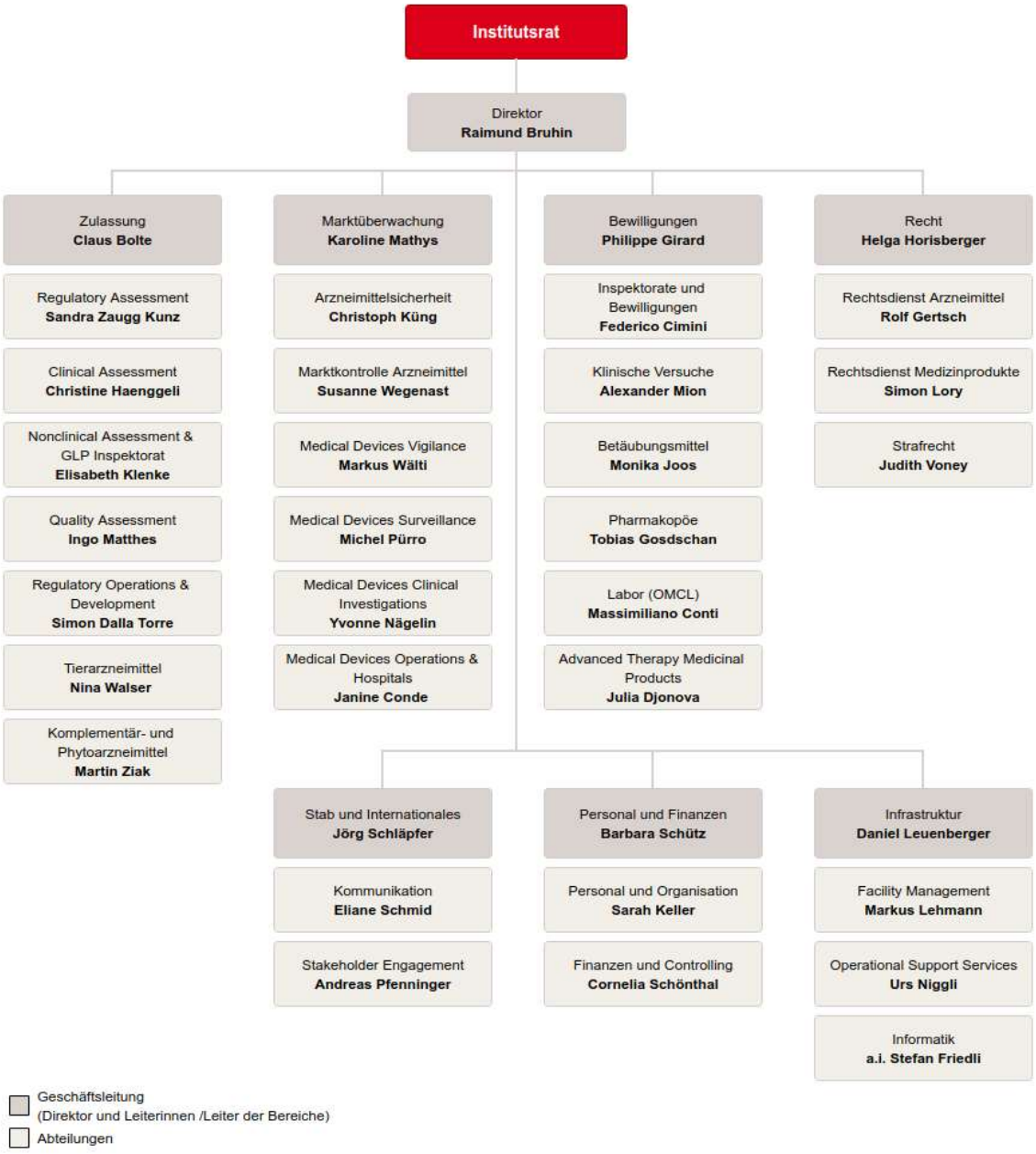
169 As behind (N 1257 ff.), Swissmedic is considered a manufacturer within the meaning of the Therapeutic Products Act due to its obligation to carry out batch testing, which means that it is the addressee of the sanction standards formulated in Art. 86 TPA and the corresponding due diligence obligations in Art. 3 TPA and Art. 7 TPA.

1.1. Organization of the licensing authority

170 Swissmedic, the Swiss regulatory and supervisory authority for medicinal products and medical devices (therapeutic products), is a federal institution under public law with its own legal personality. It is independent in its organization and management and keeps its own accounts.[65]

171 Swissmedic was founded in 2002[66] and is currently organized as follows:[67]

63 See SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 86.
64 For more details see N 1257 ff.
65 Swissmedic, "Strategic objectives 2019 to 2022", 24.10.2018, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/direktion/strategischeziele2019-2022.pdf.download.pdf/strategischeziele2019-2022.pdf, p. 1.
66 General Secretariat FDHA, "Bundesrat genehmigt den neuen Leistungsauftrag an Swissmedic", 24.11.2010, https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-36375.html.
67 Swissmedic, "Organigram as of May 2022", https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/organisation.html.



172 Swissmedic states that it is in regular contact with international partner authorities regarding the safety of medicinal products and considers this exchange to be particularly important when new safety risks are suspected.[68]

68 Swissmedic, "On the trail of pharmacovigilance", 03/2021, https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/publikationen/visible/swissmedic-visible-april-2021.spa.v3.app/de/arzneimittelsicherheit.html.

1.2. Performance mandate or "strategic objectives" of Swissmedic

173 According to Art. 69 TPA, Swissmedic must fulfil the tasks assigned to it under the Therapeutic Products Act and other federal legislation. To fulfill these tasks, the Federal Council approves **the** Agency's **strategic objectives** for a period of four years at the **proposal of the Agency Council** (Art. 70 para. 1 TPA). This standard is new and has only been in force since January 1, 2019. Previously, the Federal Council had issued a performance mandate (with performance agreement) to Swissmedic.[69] The Federal Council did not provide any further justification for this change of instrument in its dispatch on the revision of the TPA.[70] **However, the change to these "strategic objectives" clearly shifted the balance of power between Swissmedic and the Federal Council:** whereas the Federal Council had previously controlled the Agency by means of a unilateral, sovereignly issued performance mandate, it now only has approval powers.[71] Swissmedic has set itself the following "strategic priorities" for the period 2019-2022:[72]

174 In its introductory "programmatic priorities", Swissmedic states that it operates in a "field of tension between potentially conflicting interests": on the one hand, it is concerned with **protecting against risks that may emanate from therapeutic products. On the** other hand, consumers and patients expect **rapid access to safe and effective therapeutic products.** In addition, the **therapeutic products industry** also has **"a legitimate interest in competitive framework conditions".** Against this backdrop, **"competent and independent control of therapeutic products" is** indispensable both for the safety of patients and for Switzerland as a location for pharmaceutical and medical technology.

175 Swissmedic then formulates a total of seven "task- and company-related objectives". Of these, three are aimed at **international harmonization in order to reduce costs (objective 1), support for authorisation decisions by foreign authorities (objective 2)** and **acceleration of authorisation procedures based on the fastest authorities (objective 6).** Swissmedic states the following in this regard:

> "Harmonized international standards are an important basis for reducing the workload of authorities [...]" (Goal 1)

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69 RICHLI / MEYER, BSK HMG, 2nd edition, Basel 2022, Art. 70 N 3. See also Swissmedic, "Strategic objectives", 30.09.2019, *https://www.swissmedic.ch/swissmedic/de/home/ueber-uns/swissmedic--schweizerisches-heilmittelinstitut/strategy.html.*

70 RICHLI / MEYER, BSK HMG, 2nd ed., Basel 2022, Art. 70 N 4.

71 RICHLI / MEYER, BSK HMG, 2nd ed., Basel 2022, Art. 70 N 5 f.

72 Swissmedic, FN 65.

> "[...] Swissmedic intends [...] to rely on the assessment results of other recognized authorities wherever the minimum material requirements are met" ('reliance')" (Objective 2)
>
> "Swissmedic will shorten the duration of the relevant procedures by an average of 10 percent while maintaining quality by speeding up time-critical processes. In the area of authorization procedures, it will align itself with the fastest authorities." (Goal 6)

176 None of these three objectives - nor any of the four[73] not mentioned in detail here - is designed to ensure the most careful and thorough review possible in Switzerland to ensure the best possible handling of the risks associated with the authorization of medicinal products. **Everything is aimed at speeding up the procedure and adopting foreign (authorization) decisions with as little scrutiny as possible** - entirely in the interests of the pharmaceutical industry. In contrast, protection against risks and thus the main purpose of therapeutic products legislation - the protection of human health - is only addressed once under the heading of "programmatic priorities". Even there, however, this elementary point is not particularly emphasized, but is immediately blurred with the (alleged) interests of consumers and the (inherent) interests of the pharmaceutical industry in quick and uncomplicated approvals.

177 Whether Swissmedic can achieve the main purpose of therapeutic products legislation with this weak guiding principle - the protection of human health in the sense of the explicit legal bases and legal principles set out above (see above N 143 ff.) - can be fulfilled at all appears extremely questionable. However, this question does not need to be conclusively assessed here, as Swissmedic must be measured against the (authorization) decisions that are actually made: These must satisfy the legal requirements at all times - an autonomous "discharge" of the legal obligations by way of conflicting or at least weakening formulations of objectives is not possible according to the principle of legality, as this would violate the principles of delegation according to the practice of the Federal Supreme Court: a delegation of the law regarding important or fundamental provisions by the Federal Council is not possible.[74] Increasing the autonomy of an administrative unit can and must never lead to a circumvention of the principle of legality (Art. 5 para. 1; 164 para. 1 Federal Constitution). [75]

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73 The other objectives relate to communication with the public (Objective 3), exchange with national decision-makers in the healthcare sector (Objective 4), digitalization (Objective 5) and strengthening regulatory systems in other countries (Objective 7).

74 BGE 141 II 169 E. 3.2.

75 See HÄFELIN / MÜLLER / UHLMANN, Allgemeines Verwaltungsrecht, 8th edition, Zurich / St. Gallen 2020, N 1584 and N 1586 f. on the principle of legality and impact-oriented administrative management.

2. Users - the example of the Inselspital in Bern

178 Anyone who uses medicinal products is also subject to the sanction standards formulated in Art. 86 TPA. In this case, the duties of care under Art. 26 TPA, i.e. the duties of care when prescribing, dispensing and using medicinal products, are particularly relevant. The central obligation here is to fully inform the patient before the procedure (for more details, see N 1320 ff.).

179 The "Insel Gruppe" operates a "COVID vaccination center" on the grounds of the Inselspital Bern.[76] Under the title "Every vaccination counts", "initial vaccinations", "booster vaccinations", "childhood vaccinations from 5 to 11 years" and other "COVID vaccinations" have been offered there since 2021.[77] Accordingly, the authorized persons acting on behalf of the "Insel Gruppe" are responsible for ensuring that the vaccinated persons are informed in accordance with therapeutic products legislation.

180 In the present case, at least the private plaintiff 2 received two mRNA injections at the "Insel vaccination center" - and this without sufficient clarification, given the current state of knowledge, which means that the defendants acting on behalf of the "Insel Group" belong to the potential group of perpetrators.

III. Crime - mRNA "vaccines" : Risks and efficacy [ER N 18]

181 All statements made in this section are based entirely on the **evidence report** enclosed with this criminal complaint **(Annex 4),** which contains further discussions and lists the relevant supporting documents. The title structure in this section of the criminal complaint and the enclosed evidence report (section "mRNA 'vaccines': risks and efficacy") are identical in content, but are shifted by one level (e.g: Title level "**1st** state of knowledge at the end of 2020" of the criminal complaint corresponds to title level "**I.** State of knowledge at the end of 2020" of the evidence report). **Accordingly, full reference is made to the detailed evidence report for proof and in-depth explanations below.**

182 All the above-mentioned penal provisions with the purpose of protecting public health have mRNA "vaccines" in common. In this respect, the authorization authority Swissmedic had different levels of information on the substances to be authorized at different times. In view of the legal bases and legal principles set out above (see above N 143 et seq.), the information of particular interest for the present criminal proceedings is that which contains

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76 INSEL GRUPPE, "Situationsplan Inselspital", 03.2022, https://www.insel.ch/fileadmin/Inselspital/Bilder/Patienten_und_Besucher/Corona/Situationsplan-Impfzentrum-Inselcampus.pdf.

77 INSEL GRUPPE, "Every vaccination counts", 20.06.2022, https://www.insel.ch/de/patienten-und-besucher/coronavirus/covid-impfzentrum-auf-dem-inselcampus.

indications of risks to public health, i.e. indications of (as already mentioned in part above N 164 listed above):

1) Novelty of the ingredients,
2) Novelty of the manufacturing process,
3) Novelty of the disease to be combated,
4) Lack of experience of the manufacturing companies in the production of similar medicinal products,
5) Approvals without the usual clinical trials,
6) Results from empirical studies available worldwide,
7) Results from adverse event reports available worldwide,
8) All other information submitted to the Institute.

183 Furthermore, all actions by Swissmedic and the persons involved that have led to an increase or reduction in these risks to public health are of interest.

184 Against this background, the following facts are to be classified as legally relevant for the present criminal proceedings (in each case according to their temporal availability at the time of the respective admission) and are to be assessed accordingly:

1. Swissmedic's state of knowledge at the end of 2020 (first authorizations for adults)

185 Swissmedic was already aware of the following circumstances with regard to the risk-benefit profile when the mRNA "vaccines" were first authorized in December 2020 (and January 2021):

1.1. Risks

1.1.1. New, as yet untested mode of action: "gene therapy"

1.1.1.1 Initial situation at the end of 2020 [ER N 19 ff.]

186 From the outset, Swissmedic classified the mRNA preparations as "vaccinations" or "vaccines" intended to induce "active immunization to prevent COVID-19 disease caused by the SARS-CoV-2 virus".

187 It was already clear at the end of 2020 that the mRNA preparations could not be conventional vaccines. This was because both the manufacturers and the regulatory authorities in the USA (*FDA*) and the EU (*EMA*) **potentially classified** the mRNA preparations **as gene**

therapies. This meant that these substances fell into special regulatory categories that would have been subject to stricter requirements for approval.

188 This confusion of terms is cleared up below, and the risks that existed simply because of the way the mRNA injections worked are explained:

1.1.1.2 Modes of action: Vaccine versus gene therapy [ER N 24 ff].

189 In established vaccinations used to date, a harmless amount of a killed or weakened pathogen or antibodies were introduced directly into the body to trigger an immune response. The immune system was thus prophylactically "trained" by recognizing and reacting to **foreign recognition characteristics of a foreign pathogen** and quickly destroying the pathogen in a subsequent encounter.

190 In conventional gene therapies (for example against cancer), on the other hand, the aim is to eliminate a gene-related malfunction in order to cure a pre-existing disease. For this purpose, genetic material (such as RNA) with the "correct genetic information" is introduced into the body so that the targeted **endogenous cells** ultimately produce the predefined proteins themselves in order to cure the disease.

1.1.1.3 mRNA injections: Manufacturing process and intended mode of action [ER N 28 ff].

191 In the production of the mRNA "vaccines", the spike protein gene is produced synthetically, inserted into a circular piece of DNA "plasmid", then introduced into E. coli bacteria and multiplied on a massive scale. After this multiplication, the DNA templates are broken up and transcribed into mRNA strands. This does not produce natural RNA, but a deliberately more stable "modified" version (mRNA) in order to delay degradation in the human body. In addition, this mRNA is coated with several layers of lipids ("lipid nanoparticles"), which protect the mRNA and facilitate its entry into human cells.

192 This mRNA-lipid nanoparticle mixture is then injected into people to induce **their own healthy body cells to produce the foreign recognition marker (spike protein) and attach it to their cell surface**. This causes our own healthy body cells to "disguise" themselves and appear "foreign" to our immune system. The blueprint for this foreign feature (the spike protein) is injected into the body via a genetically artificially stabilized mRNA. The mRNA then forces the body's own cells to produce this foreign recognition feature, the "spike protein". This is then transported to the surface of the cell and recognized by the immune cells. The mechanism of action of **mRNA injections** thus differs **fundamentally from the principle of conventional vaccines.**

193 On the other hand, the **mechanism of action of mRNA injections is** indistinguishable from **that of conventional gene therapy: In both cases, the human body is forced to produce proteins via the administered mRNA sequence, thus becoming the actual active ingredient factory.** Unlike conventional gene therapies, however, COVID injections do not "correct" a genetic defect, i.e. a pre-existing disease. Rather, an **mRNA sequence is administered for the prophylactic manipulation of a healthy human body with** the intention of forcing the body's own spike production and thereby triggering a preventive immune response to a disease that has not yet broken out.

194 In terms of their mode of action, COVID injections can therefore clearly be classified as conventional gene therapeutics - except that nothing is "treated", but something is administered "in advance" (prophylactically). Accordingly, instead of the term "gene therapy", the term "gene prophylaxis" should rather be used.

1.1.1.4 Recognizable risk signals based solely on the mode of operation [ER N 37 ff.].

195 Various risk signals could be identified at the end of 2020 simply due to the way mRNA injections work:

- Until 2020, the special mode of operation of gene therapy was only tried **in individual cases** with seriously ill **(cancer) patients**, but **without success:** neither an effect was proven nor could safety be guaranteed.
- One aim of gene therapy is to mark the body's own (cancer) cells as "foreign" in order to eliminate them using immune mechanisms - it was therefore already apparent at the end of 2020 that the same mode of action of mRNA injections can lead to previously **healthy cells** being **attacked by the body's own immune system** (**autoimmune diseases** as possible long-term consequences).
- In view of the way the human immune system works, it was feared that the intended mode of action of the **mRNA injection to prevent a respiratory infection** was **unsuitable from the outset,** because the immune response is not generated in the mucous membranes (upper respiratory tract: nose; oral cavity), as is the case with natural infections, but in the systemic immune system (blood, spleen, lymph nodes).
- Since the actual active ingredient (spike protein) is only produced in the human body, **the amount of toxic spike protein** produced **in the human body** was **completely unknown** from the outset (and still is today).
- In addition, the manufacturers were unable to prove that only the intended spike protein was actually produced in the body, as other **- unknown and undesirable - proteins** could be found in the approval studies, which represents a **massive quality problem.**

- In addition to all these risk signals, no comparable pharmaceutical product had ever received market approval for **prophylactic use** in healthy - not previously ill - population groups by the end of 2020. In fact, mRNA "vaccines" for flu prevention, for example, were still in animal studies (preclinical phase) at the end of 2019 - a long way from being properly approved.

1.1.1.5 Conclusion: Authorization of an untested, uncontrollable substance [ER N 67 ff].

196 At the end of 2020, Swissmedic therefore approved a substance that fulfilled all the definitional characteristics of a gene therapy (and therefore would have had to comply with special testing and approval hurdles) and which was still completely unexplored at the end of 2020:

- which body cells are ultimately involved in the production of the spike protein;
- how long production will last and in what quality and quantity, and
- how large the proportion of the population is that does not tolerate the large-scale administration of mRNA injections or the body's own production of new substances in the intended manner without side effects.

197 In addition, it was already a major alarm signal at the time that gene therapies that had previously been tried on cancer patients had been unsuccessful or even fatal. It was also obvious that the mRNA injections were not suitable for preventing the transmission of a respiratory virus, as the required immune response is simply triggered in the wrong place.

198 A drug that is based on a **method that has never before been used on a healthy population as a whole**, that has **all the characteristics of a gene therapy drug,** and for which **all the parameters that are relevant for drugs and must be controlled** (quality of the spike proteins produced by the body?; location of production in the body?, duration and quantity of the immunizing substances produced?) are **still largely unexplored**, must inevitably be regarded as a high-risk drug. A purely prophylactic distribution of this high-risk preparation to the healthy population should never have taken place.

199 **In view of the high standard of care pursuant to Art. 3 para. 1 TPA, the complete novelty and considerable uncertainties of the mRNA mode of action in the body of healthy humans would have made it imperative to carry out all necessary preclinical and clinical studies until all risks and uncertainties had been reliably eliminated. The fact that this was not possible within the framework of the approval procedure (described below) of the so-called "temporary" approval, or that this was deliberately dispensed with, must be assessed as a significant and self-inflicted risk factor, which was known to the competent authority**.

1.1.2. Prohibited use of *GMOs* on humans? [ER N 70 ff.]

200 Moreover, there are clear indications that the mRNA "vaccines" are not "only" a "gene therapy" (or "gene prophylaxis"; see N 194), but even genetically modified organisms (*GMOs*). If this is the case, a "temporary authorization" should never have been granted:

201 *GMOs* are entities (including mixtures etc.) that are capable of reproducing or transferring **genetic material** and have been produced or modified "in a way that **does not occur naturally** by crossing or natural recombination**".** If such a *GMO is* present, massively increased requirements are placed on authorization, which are referred to at the back (N 926 ff., N 944, N 948, N 1003 f., N 1199 *in fine)* and which cannot be fulfilled in any way with a temporary authorization: In particular, according to Art. 12 para. 5 lit. c and lit. e of the Ordinance of the Swiss Agency for Therapeutic Products on the simplified authorization of medicinal products and the authorization of medicinal products by the notification procedure (VAZV, SR 812.212.23), "medicinal products containing **genetically modified organisms**" and **"medicinal products for advanced therapies** based on gene transfer methods (gene therapy medicinal products**)"** are **explicitly excluded from the simplified authorization procedure.**

202 If the genetic material were to be transferred into human **germ cells,** this would violate the integrity of the human genome, which **is absolutely protected** under **Art. 119 para. 2 lit. a BV: "all [...] interventions in the genetic material of human germ cells and embryos are inadmissible".** It is sufficient for individual gene sequences to be directly modified, as is the case with CRISPR/Cas9 **technology, for** example, in which DNA sequences are "cut out" and replaced with genetically modified DNA sequences with pinpoint accuracy.

203 The intended mode of action of the mRNA "vaccines" does not, on the face of it, involve any direct intervention in DNA. However, **various studies were** already available at the end of 2020 that **showed a so-called "reverse transcription" of mRNA into DNA in human cells.** The mRNA in the "vaccines" was modified in this way (in particular Replacement of uridine by pseudouridine, modified capping of the 5'-end) so that it "survives" longer in the body and is protected from degradation by enzymes ("ribonucleases") and from the immune system. The aim of this artificial adaptation of the mRNA is to bring it safely into the cells so that as much spike protein as possible can be synthesized. The risk posed by the "spike protein" was assessed by Swissmedic as "low" because "minimal systemic exposure after intramuscular application" was to be expected. It was already known at the end of 2020 that **prolonged expression of the toxic spike protein increases** the **potential for possible side effects (such as cancer)** (for more information on the toxicity of the spike protein and the corresponding consequences, see N 235, N 258 ff., N 391 ff.). On the

other hand, the artificial modification means that the mRNA remains in the body for longer than under natural circumstances - and possibly reaches places where it should not go, such as the genitals, as has been observed in animal experiments. The enclosed evidence report explains in detail that in this way an **- unintended - effect of the mRNA on the human DNA in the germ cells could take place.**

204 Swissmedic was already aware of this problem in principle at the end of 2020. In a letter to Moderna, it took the precaution of stating that the **risk of integration into the genome** was **considered to be "very low".** However, Swissmedic, quite incomprehensibly, did not insist that studies be carried out to rule out this risk. Swissmedic did not even draw the public's attention to the - albeit "very low" - risk, but rather blurred this fact. Contrary to the data available at the time, Swissmedic stated in the first version of Comirnaty's Information for healthcare professionals ("Genotoxicity/caricinogenicity" section): **"In particular, it can be assumed that the mRNA does not enter the cell nucleus or interact with the genome."** This passage was **deleted** in subsequent versions - the reasons for this are not officially known.

205 **Whether the mRNA substances have the potential to permanently (hereditarily) modify human DNA can therefore not be ruled out.** If this were the case, the use of mRNA would violate mandatory constitutional provisions. In addition, the potential to modify the DNA of a single person is sufficient to ensure that the strict approval requirements applicable to *GMOs* (including CRISPR/Cas9) would have had to be met. The modification of the DNA of a single person - and even more so the potential for permanent, heritable modification of the human genome - would probably mean the immediate end of mRNA research, as it would no longer have any regulatory advantages over CRISPR/Cas9.

206 To make matters worse, according to the *FOEN,* even Swissmedic admitted in 2022 that **mRNA injections are treated in the same way as genetically modified organisms (*GMOs*)** (see N 526 ff.).

207 In view of these serious uncertainties, an authorization that is nevertheless granted constitutes a violation of the **precautionary principle** under therapeutic products law: The **potentially gene-modifying mode of action of the mRNA substances** - the **potentially permanent, irreversible modification of the human genome** - is not merely a "risk factor" that can hardly or not at all be calculated, but an **absolute exclusion criterion for any authorization. This fact was also known to the approval authority at the time of the first approval in December 2020.**

1.1.3. Spikevax: mRNA dose far too high [ER N 99 ff.].

208 The "vaccines" Comirnaty and Spikevax basically contain the same active ingredient: mRNA. It would therefore be expected that this active ingredient would be administered in a uniform dosage. However, the opposite is obviously the case: adults and adolescents aged 12 and over receive **30 µg of mRNA** (0.3 ml dose) per administration of Comirnaty. With **Spikevax**, on the other hand, **100 µg mRNA** (0.5 ml dose) is injected - i.e. **over three times more active ingredient.**

209 The reason for this deviation is presumably due to purely factual circumstances, which can be attributed to **poorly conducted dose-finding studies:** Whereas with Comirnaty the doses were tested in small increments (10 µg, 20 µg, **30 µg** and 100 µg) in humans, with Spikevax not only were fewer doses tested, but these were also set much higher (25 µg, **100 µg** and 250 µg). This is precisely what four representatives of the University Hospital of London criticized in an in-depth analysis from September 2022: Not only had too few doses been studied, but the intervals had also been chosen too large. With Spikevax, it was therefore not even investigated whether a dose between 25 µg and 100 µg - e.g. 30 µg as with Comirnaty - would have been sufficient. Instead, the next highest value of 100 µg was simply selected.

210 In addition, the doses mentioned for Comirnaty were **tested** on 195 test subjects, but for Spikevax **on just 45 study participants.** This is far too low a number even for a "Phase I" study (see N 880). Especially in view of the fact that this dosage of **100 µg** was subsequently administered billions of times to basically healthy people.

211 By authorizing this high, barely tested **dosage of 100 µg mRNA for Spikevax**, Swissmedic therefore **took a completely unnecessary risk from the outset.**

1.1.4. New, as yet untested ingredients: Toxic lipid nanoparticles

1.1.4.1 Functionality and toxicity of lipid nanoparticles (LNP) [ER N 118 ff].

212 In order to protect the mRNA in the COVID "vaccines" from degradation and to facilitate its uptake into the body's cells, it is "packaged" in a coating of fats (lipid nanoparticles, LNP). The use of **LNPs** - i.e. so-called "nanotechnology" - in humans has been **classified as critical for years** due to their **toxicity** and associated dangerous side effects**.** As early as 2016, warnings were issued that nanoparticles could overcome important protective barriers such as the blood-brain and placenta barrier and thus potentially harm unborn babies.

213 Nevertheless, LNP and in particular the problematic components ALC-0159 and ALC-0315 (Comirnaty) and SM-102 (Spikevax) were used in the COVID "vaccines" :

1.1.4.2 ALC-0159 and ALC-0315 (Comirnaty) [ER N 126 ff].

214 The approval documents already showed that ALC-0315 in particular appeared in the blood plasma of animals (rats and mice) after a very short time and **accumulated in high concentrations in the liver, spleen and ovaries, where it only degraded slowly. There** were also worrying data on ALC-0159, which is why the *EMA* classified the component as **potentially carcinogenic** to humans.

215 These results are hardly surprising: the manufacturer of the two lipids clearly stated that they were only designed for research purposes and not for human use ("This product is for research use only and not for human use."). Without any scientifically indicated reason, this warning was replaced by "for research use only" at the end of 2021. Of course, this means exactly the same thing: **Not intended for human use.**

216 The approval letter from Swissmedic to Pfizer also shows that **relevant documentation regarding quality and safety,** particularly with regard to the LNP components ALC-0159 and ALC-0315, had **not been submitted.**

1.1.4.3 SM-102 (Spikevax) [ER N 146 ff].

217 According to the current state of knowledge, **a toxicity study** was carried out on **SM-102** in rats (but without investigating genotoxicity and carcinogenicity). However, this study did not show that SM-102 is harmless, but rather that it has a **considerable potential to cause damage:** The rats showed various worrying changes in the body such as increased inflammation levels in the blood or enlargement of various organs (spleen, liver, adrenal glands, lymph nodes), which can be signs of various diseases (including **cancer)**.

218 However, it was not only the data on the safety of the LNP that was clearly completely inadequate - the data on quality was also incomplete: For example, Swissmedic explicitly requested Moderna in the approval letter to provide "further data" on the purity of SM-102 ("More data on the tests purity and assay of SM-102"). Swissmedic was therefore well aware of the problem of the demonstrably **inadequate documentation on the quality** of the lipid nanoparticles used in the "vaccines" and the components they contain.

219 Just how toxic these LNP components actually are can also be seen from the "Safety Data Sheet" of a manufacturer of SM-102 , which is used in Spikevax and is of course no longer publicly available. As of April 11, 2021, it still explicitly stated:

- H310 **Risk of death** by skin contact
- H351 Suspected of causing **cancer**
- H361 Suspected of **damaging fertility** or the **unborn child**

- H372 **Causes damage to the central nervous system, kidneys, liver and respiratory system through prolonged or repeated exposure**

GHS06 Skull and crossbones

Acute Tox. 2	H310 Fatal in contact with skin.

GHS08 Health hazard

Carc. 2	H351 Suspected of causing cancer.
Repr. 2	H361 Suspected of damaging fertility or the unborn child.
STOT RE 1	H372 Causes damage to the central nervous system, the kidneys, the liver and the respiratory system through prolonged or repeated exposure.

220 All these hazard warnings were then successively downgraded by the manufacturer from 2021: "**Danger to life in** contact with skin" first became "**Toxic** if swallowed or inhaled" and finally "**Harmful** if swallowed". From the second-highest toxicity level (Acute Tox. 2), it was first downgraded to level 3 (Acute Tox. 3) and finally to level 4 (Acute Tox. 4).

221 In addition, the suspected carcinogenicity and proven damage to vital organs, the suspected impairment of fertility, including damage to the child in the womb, was initially simply changed to "may cause cancer" before this information was completely removed in June 2022. Here, too, it remains completely unclear where this sudden re-declaration comes from. Unless one considers that these same ingredients were approved for a "limited period" as part of the vaccine approvals and that corresponding warnings for these isolated ingredients could be critical for a longer-term approval after arousing public interest or reduce the willingness to vaccinate.

222 For the sake of good order, it should be noted that these warnings "only" apply to the isolated concentrate of SM-102 - and not to the admixture in the mRNA "vaccines". "The dose makes the poison". But one would at least expect that, in view of the officially declared toxicity of LNP, the "vaccine" manufacturers would have carried out appropriate studies. Such studies were - as just explained (front N 217; cf. also 214) - were actually carried out to a very limited extent, but they confirmed the **massive toxic hazard potential.** In addition, according to the current state of knowledge, **no studies on the genotoxicity and carcinogenicity of the novel "vaccine" substances had been carried out** by the time the mRNA "vaccines" were first approved**.**

1.1.4.4 Conclusion: Novel lipid nanoparticles recognizably toxic [ER N 165 ff].

223 Swissmedic already knew at the time of approval that the lipid nanoparticles were toxic. The few animal studies carried out showed massive risk signals - which is why the *EMA*

classified the novel components as potentially carcinogenic for humans. Despite this, no studies on genotoxicity and carcinogenicity were carried out. Under normal circumstances, the first-time use of ingredients already known for their toxic effects would have required all necessary studies to be carried out. The fact that this was waived as part of the so-called "temporary" authorization must be seen as a significant risk factor.

1.1.5. Pharmaceutical production was not GMP-compliant [ER N 169 ff.].

224 According to Art. 1 TPA (intended purpose), only high-quality, safe and effective medicinal products may be placed on the market in Switzerland. Medicinal products that are produced in accordance with the rules of Good Manufacturing Practice (GMP) are considered to be of "high quality" (see also N 1285 ff.).

1.1.5.1 Release specifications deviate significantly from applicable standards [ER N 174 ff].

225 The specification for the content of the active pharmaceutical ingredient of a medicinal product for the purpose of batch release is usually set at **95 to 105 percent** of the declared quantity. There must be sufficient justification for exceeding or falling below this range. At the **end of the term,** the active pharmaceutical ingredient content of a medicinal product must **not fall below 90 percent** of the declared value, which the manufacturer must prove when applying for authorization.

226 With regard to Comirnaty, the release specification was **74% to 126%** of the declared total RNA. If, in extreme cases - i.e. when the specification limits were exhausted - only 50% of intact mRNA was contained, the total **active substance content (mRNA per dose) was** reduced to **just 37%.** These release specifications deviate **drastically from all previously established rules** and would never have been accepted by the authorities for established drugs that had long since proven their efficacy and safety in the medium and long term.

227 To make matters worse, these release specifications apply to Comirnaty's non-ready-to-use solution (multi-dose container). Before administration, these solutions must first be diluted, which is absolutely unusual for vaccines (normally: marketing in single doses). The manual dilution by vaccination centers, doctors' surgeries and pharmacies has therefore created an additional risk. It therefore seems simply **inconceivable** that a **uniform active ingredient content could have been** guaranteed for the single dose that was ultimately injected.

228 Although the *EMA* criticized the high proportion of non-intact mRNA ("truncated RNA"), the **manufacturers were apparently not prepared to answer questions about the lack of quality assurance, according to leaked e-mails.**

229 **This is simply an unacceptable risk: non-intact mRNA (especially so-called micro-RNA) is considered a genetic contaminant that** carries the risk of **genotoxicity and carcinogenicity.** It must therefore be eliminated (or at least minimized as far as possible) so that the same amount of intact pure mRNA is present in each batch.

230 Due to the internationally standardized production process and the internationally identical authorisation documents, it can be assumed that Swissmedic was already aware of this risk signal of the **lack of GMP *conformity*** at the time of authorisation. On the basis of these **massive fluctuations in the active substance content** alone, the product could not be a "high-quality medicinal product" within the meaning of Art. 1 TPA - Swissmedic nevertheless granted the authorization.

1.1.5.2 COVID-19 "vaccines" contain potentially toxic, mutagenic and carcinogenic impurities [ER N 198 ff].

231 The approval documents also show that the COVID-19 "vaccines" were **contaminated** with **highly problematic substances (nitrosamine and benzene) and with bacterial DNA from the manufacturing process at the** time the temporary approval was granted.

232 **Nitrosamines are highly toxic even in the smallest concentrations, are among the most carcinogenic substances of all and are mutagenic. Benzene (=benzene) is proven to be toxic, carcinogenic and mutagenic.**

233 The bacterial DNA contaminations (especially non-linear DNA, so-called plasmids) are also a strong indication that the production process of the mRNA is not under control and that the production of the "vaccine" was therefore not *GMP-compliant* overall. The DNA contained in the "vaccine" as an impurity can be **integrated into the genome of the host cells** and thus cause potentially harmful mutations. Bacterial DNA also promotes non-specific inflammation.

234 **The production of COVID-19 "vaccines"** thus **took place**, at least at the time of market entry, but probably also for a long time afterwards (N 417 ff.) and N 532 ff.) were **not GMP-compliant**. The **COVID-19 "vaccines" therefore** demonstrably **did not meet the criteria for "high-quality" medicinal products.**

1.1.6. Increased risk for pregnant women

1.1.6.1 Animal study: Double the number of preimplantation losses and malformations at Comirnaty [ER N 216 ff.].

235 Pregnant women were excluded from participation in the Phase III trials for both Comirnaty and Spikevax. The *Human Medicines Experts Committee (HMEC)* commissioned by Swissmedic stated unequivocally at the end of 2020: "Pregnancy should be listed under **'Precautions'. There is** currently little data in pregnant women, and preclinical studies have identified a **possible risk in pregnancy** ." From the only study conducted in this regard - as far as can be seen - (a study conducted by Pfizer in female rats), there was a **twofold increase in pre-implantation losses** (9.77%, compared to 4.09% in the control group), and **malformations were** found in the fetuses. Both indicate a toxic effect of the "vaccines" - presumably caused by the toxic LNP they contain and the equally toxic spike protein (see N 391 ff.) - on the embryo or the developing placenta. However, such striking negative results did not lead to further investigations by either the manufacturer or Swissmedic that could have ruled out the risk identified in animals in the case of human pregnancies; on the contrary: Pfizer itself pointed out that **"no data on the placental transfer of BNT162b2 [Comirnaty]** are **available". In** addition, the study was extremely sparse: only 21 litters of rats were examined.

1.1.6.2 Animal study: Increased rate of malformations with Spikevax [ER N 228 ff].

236 The "*Nonclinical Overview" ("Nonclinical Results Spikevax")* then shows that the administration of Spikevax (mRNA-1273) in pregnant rats was associated with a significantly **increased rate of malformations in** the offspring (in 4% of the fetuses and in 18% of all litters). It is in no way comprehensible why Swissmedic did not request further animal studies after becoming aware of these indications. The fact that **Swissmedic allowed claims to be made in the Spikevax Information for healthcare professionals that there were "no vaccine-related adverse effects on embryo development"** and that it was even claimed that animal studies had shown "no direct or indirect adverse effects" on embryonic/fetal development is downright unbelievable.

1.1.6.3 Consequences of misleading information for healthcare professionals: "Vaccination recommendation" for pregnant women [ER N 232 ff.]

237 The direct consequence of the misleading Swiss expert information was that the responsible authorities in Switzerland (*Federal Office of Public Health [BAG] / Federal Commission for*

Vaccination Issues [EKIF] / Swiss Society for Gynecology and Obstetrics [SGGG]) all issued "vaccination recommendations" for pregnant women.

1.1.6.4 British Health Authority and WHO: No recommendation for pregnant women [ER N 239 ff].

238 However, a conclusive assessment of the risks to pregnancy in animals - let alone in humans - was in no way possible on the basis of the approval documents at the end of 2020. Even the *WHO* therefore did not generally recommend the "vaccination" of pregnant women in February 2021. And the British health authority had already correctly stated this in the British drug information as of December 8, 2020,

- that the **influence on fertility** is **not known,**
- that the **Pfizer vaccine cannot** be **recommended for use during pregnancy,**
- that pregnancy must be ruled out before the "vaccination" and
- Women of childbearing age should avoid pregnancy for at least two months after the second dose.

1.1.6.5 Australian health authority also ignores warnings [ER N 243 ff.].

239 Similar to Switzerland, the preclinical data reviewer in Australia recommended that Comirnaty should only be approved for pregnant women with a risk warning that animal studies were inadequate or lacking. As in Switzerland, the Australian regulatory authority ignored this warning and stated that animal studies did not indicate any direct or indirect adverse effects on pregnancy, embryonic/fetal development, birth or postnatal development.

1.1.6.6 Interim conclusion: mRNA substance poses considerable risks for pregnant women [ER N 247 f.].

240 Swissmedic therefore already knew in December 2020 that **a possible risk in pregnancies** - in particular the risk of malformations - had been identified in **preclinical studies** . Swissmedic did not adequately address this risk either - indeed, it even **concealed it** in the information for healthcare professionals (for more details on the numerous acts of deception, see N 1198 ff.).

241 It was subsequently shown that COVID-19 "vaccinations" in Switzerland and internationally were associated with a drastic decline in live births, which correlated in time with the "vaccination campaigns" (N 639 ff.). A causal relationship with the mRNA injection must be classified as probable (especially in Switzerland) (N 644).

1.1.7. Exacerbation of disease progression through mRNA injection (ADE)

1.1.7.1 ADE has long been known as a risk factor [ER N 249 ff].

242 COVID vaccines against SARS and MERS had never made it to market approval in the past because, among other things, **extremely severe courses and deaths** occurred in "vaccinated" people - via antibody-dependent enhancement (ADE) - **as soon as** they were **exposed to the virus.** With regard to coronavirus in particular, the risk of ADE was identified by a research group in 2020 and the manufacturers of the COVID-19 "vaccines" were also aware of this problem from the outset (Pfizer/BioNTech addressed this in the protocol of the approval study).

243 In April 2020, a study also explicitly pointed out that the risk of ADE must be taken into account in the development and safety assessment of COVID-19 "vaccines" and that **elevated levels of certain antibodies** have **been associated with an exacerbation rather than an improvement in disease progression in the past.**

1.1.7.2 Comirnaty: Animal study completely unsuitable for investigating ADE [ER N 253 ff].

244 Pfizer had investigated the problem of exacerbation of disease progression through mRNA injection, but with a completely unsuitable animal model and with fewer than 10 test animals: 6 rhesus monkeys were given two mRNA "vaccinations" and 3 animals received a saline solution. All animals were then exposed to SARS-CoV-2 (via the nose and trachea). **Neither the "vaccinated" monkeys nor the monkeys in the control group developed any symptoms of illness.** Accordingly, the risk of ADE after mRNA injection could not be ruled out in this animal study.

1.1.7.3 ADE: Swissmedic is aware of the problem, but does not take any measures to monitor the risk signal [ER N 258 ff.].

245 Swissmedic was fully aware of the potential risk of disease exacerbation following mRNA injection at the time of authorization. It therefore addressed this aspect in the approval letter to Pfizer and classified the pharmacovigilance measures taken to "characterize" the risk as "sufficient". It is not known what these measures are.

246 Subsequently, Swissmedic made no effort to systematically record the "vaccination status" of COVID-19 hospitalizations, which would have been necessary to clarify the question of whether "vaccinated" people are more likely to contract SARS-CoV-2 in the sense of an ADE (N 703 ff.). It was later shown that "vaccinated" people actually fall more seriously ill

with COVID-19 and die than "unvaccinated" people (N 709 ff.), which supports the thesis of ADE due to mRNA injection.

1.1.8. Unprecedentedly short "development time" [ER N 262 ff].

247 As before (N 195), mRNA therapies were still in the preclinical phase (animal trials) at the end of 2019. Only when these have been successfully completed will it be possible to proceed to in-depth trials on humans (clinical phase), which will take well over a year in total. And only if these trials are all positive can the one-year ordinary approval procedure be initiated.[78] Under normal circumstances, the **development and approval of an unprecedented mRNA "vaccine" for the prevention of influenza** would therefore still have **taken at least two years in the very best case scenario** - and probably many more years in view of the many unknown parameters. The Pfizer/BioNTech "Phase III" study, for which 12-month results must normally be available for proper approval and 24-month results are available at the time of approval, will therefore continue until at least February 8, 2024.[79]

248 In this case, the mRNA "vaccines" were "developed" in just under a year - and approved in the same year. The temporary approvals of the COVID "vaccines" were initially granted based on **"Phase I/II/III" studies**, in which the study participants were observed for a median of **just two months** .

249 The fact that such a completely new drug with a novel mode of action and novel substances was launched on the market in such a short time is a serious risk factor, if not an actual alarm signal. Even then it was clear that after this short study phase, neither relevant efficacy had been demonstrated nor could safety be adequately guaranteed.

1.1.9. Animal studies: alarming and missing results

250 Even in the case of an emergency authorization - as the so-called "temporary" authorization within the meaning of Art. 9a TPA *de facto* represents (see below N 963 ff.) - **the most basic information on safety** must be available, which can only be provided on the basis of (fully) conducted **animal studies** and at least **the first meaningful tests on humans** in the context of dose finding (Phase I studies). Even these minimal requirements - which are far below those of a "regular authorization" - were not met in the present case:

78 Incoming rear N 862 ff., in particular N 887 ff.
79 Plus rear N 884.

1.1.9.1 Animal studies must be carried out in accordance with GLP [ER N 265 ff].

251 The requirements for the organization, conduct and recording of **pharmacological and toxicological tests** in accordance with Art. 11 para. 2 lit. a no. 2 TPA are contained in the Ordinance on Good Laboratory Practice (GLPV; SR 813.112.1).[80] Such tests are performed on the basis of animal studies, which are carried out according to an internationally standardized procedure (guidelines on **"Good Laboratory Practice"**) in order to ensure high scientific quality and reproducibility of the results.

252 Conversely, **if animal studies are not carried out "*GLP-compliant*", it can be assumed** that their **results** are **not sound and reproducible**, must therefore be classified as **unreliable and may not serve as a data basis for drug approval**.

1.1.9.2 Missing and incomplete animal studies on toxicity [ER N 272 ff].

253 As far as can be seen from the publicly available information, only three toxicity studies were available at the time of the first authorization of Comirnaty:

254 One of these is the previously (N 235) on developmental and reproductive toxicity, in which only female rats were examined. In the other two studies, male rats were also examined - but not with regard to reproductive capacity. The indispensable **data that could have proven the safety of using mRNA "vaccines" in young men of reproductive age was therefore completely lacking at the end of 2020.**

255 A waiver of absolutely necessary further studies was justified with a reference to a *WHO recommendation* from 2005, which is in no way permissible: this "recommendation" dates from a time when only conventional vaccines were used and the use of experimental mRNA gene therapies in humans was at best a distant prospect. The application of this guideline is therefore not objectively justifiable. However, even if reference to this outdated guideline were to be deemed permissible, the *WHO* itself expressly states the following:

> "For a product for which there is **no previous non-clinical and clinical experience, for example,** the **non-clinical tests** are likely to be **more extensive** than for vaccines that are already approved and used in humans."

256 The *WHO* guideline thus does not give a "free pass" to omit elementary studies to ensure the most basic safety of mRNA "vaccines" that have been approved for the first time and tested on humans for the first time - on the contrary, it requires that non-clinical tests should tend to be even more extensive than under normal circumstances. **The omission of the**

80 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 71.

most elementary animal studies thus represents a massive and obvious increase in risk.

1.1.9.3 Lack of data on the degradation of the modified mRNA [ER N 280 ff.].

257 Only because of the previously (N 203) mentioned above (in particular: replacement of uridine by pseudouridine, modified capping of the 5'-end), studies on the degradation of the modified mRNA were urgently required. Swissmedic had even recognized this and complained to Pfizer in the approval letter of 19 December 2020: **"Swissmedic strongly recommends that the kinetics of the modified mRNA be analysed in detail in vitro and in vivo."** It is not known whether Swissmedic has ever requested these studies in a legally sufficient manner. However, in view of the lack of references in the Information for healthcare professionals, it must be assumed that **no adequate measures** were **taken to ensure the safety of the medicinal product.**

1.1.9.4 Comirnaty: Accumulation of "vaccine" components in organs [ER N 291 ff].

258 In one of the few animal studies conducted with rats, rapid uptake into the bloodstream and distribution of lipid nanoparticles (LNP) throughout the body was observed within the first 48 hours after application to the muscle. **The reported measurements were stopped after 48 hours, although the concentrations were still increasing in various organs** (adrenal gland, bone marrow, liver, lymph nodes, ovaries) **at this time.**

259 Even after these study results were available, it **was clear that the COVID-19 "vaccines" did not remain at the injection site, but were distributed throughout the body and accumulated in various organs.**

260 Although there was therefore a risk of distribution and even accumulation of the mRNA "vaccines" throughout the human body, Swissmedic completely ignored this fact in the information for healthcare professionals on Comirnaty (see N 1198 ff.).

1.1.9.5 Spikevax: Swissmedic accepts non-GLP-compliant pharmacokinetic study in animals [ER N 297 ff.].

261 As with Comirnaty, according to the current state of knowledge, it can be assumed that **only a single preclinical pharmacokinetic study** was **conducted** on Spikevax **in rats.** And although this had only been conducted with a "model vaccine" ("CMV vaccine **mRNA-1647**") - i.e. not with the ultimately marketed Spikevax - and although **Moderna itself**

declared that this study had <u>not been</u> conducted *<u>in accordance with</u>* <u>GLP</u>, Swissmedic obviously accepted this study.

262 Swissmedic referred to the study in its own *SwissPAR* and admitted that **mRNA-1647 did not remain at the injection site but reached various organs such as the <u>brain or liver.</u>** However, Swissmedic was completely untruthful in stating that mRNA-1647 had been detectable in the tissues of these organs for **"no longer than 1-3 days".**

263 This is blatant misinformation: according to an *FDA* data package that was not released until 2022, it was made public that the **measurements of the concentration of mRNA-1647** in certain organs such as the **<u>brain or liver</u>** had only been carried out incompletely and had **simply** been **aborted after 20 hours.** In addition, it was noted that **mRNA-1647 was still detectable** in **lymph nodes and spleen** after 120 hours (= 5 days). As the test facility was limited to 120 hours, there is also no information about an even longer retention time in the body. This must also be regarded as a deliberate, intentional error: a pharmacokinetic study is only considered to be completed when the active substance can no longer be detected over a longer period of time.

264 Swissmedic therefore accepted the pharmacokinetic study for Spikevax (study no. 5002121; "model vaccine" mRNA-1647) even though the applicable standards were clearly not met. Swissmedic thus disregarded all regulations that guarantee the quality and reproducibility of animal studies. It did so in the full knowledge that *non-GLP-compliant* animal studies should never be accepted as evidence of the safety of a medicinal product, as their correct conduct and thus the reproducibility of the results cannot be guaranteed.

265 Swissmedic published the obviously erroneous conclusion of the study, according to which the mRNA remains in the tissue for "no longer than 1-3 days", in the *SwissPAR*. In addition, it made misleading statements in the Information for healthcare professionals, according to which only "minimal systemic exposure after intramuscular application" should be assumed for Spikevax (see N 1198 ff.). **Swissmedic** thus covered up the true **facts in an irresponsible manner.**

266 Swissmedic's misinformation and embellishments are all the more serious in view of the fact that the spike protein produced by the mRNA injection **was detectable in the human body for up to nine months** (back N 669 ff., in particular N 672).

1.1.9.6 Conclusion: Alarming animal studies, results glossed over and concealed [ER N 337 f.].

267 Contrary to the declaration in the corresponding technical information (see below N 1198), pharmacokinetic studies in animals were indeed carried out for the COVID-19 "vaccines". It

can be assumed that this information was available to Swissmedic before authorization was granted - at least with regard to Spikevax, Swissmedic had mentioned the animal study in the *SwissPAR that* was not carried out *in accordance with GLP* and was therefore obviously in possession of it.

268 The animal studies show that **components of the "vaccines" were measurable or even accumulated in various organs.** By supporting the concealment of the explosive data on pharmacokinetics and not making it available to the medical profession in the information for healthcare professionals, Swissmedic actively contributed - once again - to the trivialization of COVID-19 "vaccines" and failed to protect the population from the emerging risks.

1.1.10. Clinical studies: missing and sabotaged

1.1.10.1 Studies on humans must be conducted in accordance with GCP [ER N 339 ff].

269 Studies on humans must be conducted in accordance with the recognized rules of *Good Clinical Practice (GCP).* For example, data on **clinical pharmacology** (human pharmacology) and **pharmacokinetic and pharmacodynamic interactions** must be submitted (Art. 5 para. 2 AMZV).

270 However, the basic prerequisite for studies with humans (clinical studies) are always completed animal studies. Although the latter were not available, "clinical trials" of so-called "Phase I", "Phase II" and "Phase III" were started simultaneously for the COVID "vaccines". Normally, each of these phases lasts several months (phase I) to several years (especially phase III), with the next phase only being started once one phase has been successfully completed (see N 876 et seq.). In December 2020, however, data was only available on a **two-month investigation phase** of a "Phase I/II/III" study referred to as "telescoped". This alone represents another massive increase in risk: This so-called "telescoping" carries the risk that time-delayed side effects will only be recognized after the vaccine has already been widely used. **Without long-term studies in humans, any kind of approval is a real blind flight.**

271 At best, such a blind flight could be dared if initial clinical data did not indicate any problems with the application in humans. However, the opposite was the case:

1.1.10.2 No pharmacokinetic studies in humans despite requirement [ER N 341 ff].

272 While a few pharmacokinetic studies have been carried out in animals, **there is a lack of pharmacokinetic studies in humans** - for example on the behavior of the spike protein in the human body.

273 Swissmedic's advisory body, *HMEC,* had already expressed the view at the end of 2020 that further investigations were urgently required. **As a condition for granting temporary authorization, HMEC explicitly demanded** that the **expression of the spike protein in the tissues "*should be further investigated*".**

274 However, no such official studies appear to have been carried out to date, which is simply unacceptable. Private studies have revealed that the spike protein remains in the tissue of "vaccinated" people for up to nine months after the mRNA injection (see N 672).

1.1.10.3 Approval studies: sabotage by removing the control group [ER N 349 ff.].

275 The aforementioned approval studies by Pfizer and Moderna ("Phase I/II/III") were planned, set up and initiated as "placebo-controlled, randomized and observer-blinded" studies (so-called "double-blind studies") in line with standard practice. However, as early as December 2020 - i.e. at the time of the limited initial approvals - all study participants were offered the opportunity to switch from the placebo group to the vaccine group "for ethical reasons". Citing "ethical reasons" for such a ***de facto discontinuation*** **of the approval studies** was and is unacceptable in view of the massive risk potential identified, the proven lack of effect of the mRNA "vaccines" (see N 296 ff.) and the overall absolutely negligible danger of SARS-CoV-2 (see N 750 et seq.) are obviously not justified in any way.

276 Approx. 93.5% - 98% of study participants made use of the "offer" (by June 2021 at the latest). The control groups thus "shrank" to a size of approx. 2-6.5% of all study participants, which meant that the **studies were largely "unblinded"** and thus degraded from so-called "double-arm" approval studies to mere observational studies. This means that **the only two human trials that should (and could) have mandatorily demonstrated the safety and efficacy of the mRNA "vaccines" according to the recognized rules for clinical trials were downright sabotaged by both manufacturers themselves without any corresponding intervention on the part of the regulatory authorities.**

277 Irritatingly, Swissmedic was already aware at the time of the first authorizations in December 2020 and January 2021 that the manufacturers had "unblinded" the studies - but more on this later (N 1174 ff.) under "Acts of commission".

1.1.10.4 Authorization studies: worrying two-month data [ER N 359 ff].

278 Although the approval studies were downgraded to mere observational studies due to the removal of the control groups, some conclusions can still be drawn from the available data - and these were already at least worrying at the time of approval at the end of 2020:

279 The approval studies of Comirnaty and Spikevax provided **evidence of increased morbidity in the "vaccine group".** For example, **3042 more serious events occurred** with Spikevax **in the vaccine group than in the placebo group (3985 cases versus 913 cases).** With Comirnaty, there were - unfortunately with incomplete data - approx. 90-100 more serious events in the vaccine group than in the placebo group (approx. 240 cases versus approx. 139 cases). There was therefore also a **risk signal** here that the "vaccines" could do more harm than good to people's health.

280 In August 2022, a **follow-up analysis** of the **phase 3 trial data** of the COVID-19 "vaccines" from Moderna and Pfizer available until the end of 2020 was published. The post-analysis came to the devastating conclusion for both "vaccines" that the **"vaccine"-related risk** far exceeded the risk reduction for COVID-19 hospitalizations compared to the placebo group. It also showed an **increased risk of serious side effects** from the "vaccines", in particular a high risk of **coagulation disorders and heart damage,** which was later made abundantly clear in the real-world data (N 341 ff.). However, neither the marketing authorization holders nor Swissmedic took any steps to include these side effects in the medicinal product texts.

281 The follow-up analysis refers to the identical data that led Swissmedic to the verdict "effective and safe" and was confirmed by a later analysis of the 6-month data (N 400 ff.). Given this initial situation, the **removal of the control group** in the approval studies (N 275 ff.) must be classified as a **malicious cover-up attempt**, which **Swissmedic** indirectly supported by **not** taking **any countermeasures** (detailed N 1174 ff.).

1.1.10.5 Conclusion: Completely inadequate clinical study situation [ER N 385 f.].

282 The clinical study situation at the time of approval was inadequate in every respect:

- elementary pharmacokinetic studies in humans were omitted without any comprehensible reasons;
- the 2-month data showed an apparent negative benefit-risk ratio of the COVID-19 "vaccines"; and
- by the indiscriminate destruction of the control group and went into a largely "blind flight".

283 The risk was therefore maximally increased - but Swissmedic nevertheless granted authorization.

1.1.11. Moderna: Pharmacovigilance system (PVS) unsuitable for monitoring drug safety [ER N 387 ff].

284 According to Art. 59 TPA, anyone who manufactures or distributes medicinal products must ensure that a suitable (PV) reporting system is in place for the purpose of recording and forwarding adverse reactions. Therefore, according to the corresponding Swissmedic guidelines, documents on "Pharmacovigilance Planning", which describe the **pharmacovigilance system (PVS)** in detail, must be submitted when applying for a medicinal product authorization.

285 A manufacturer of medicinal products must therefore **prove,** even **before** marketing **authorization is granted,** that it has a **suitable PVS in place at the** time the medicinal product enters the market that meets all applicable quality standards for the purpose of monitoring risk signals in order to protect the population.

286 The inspection of PVS at the manufacturers is the responsibility of the regulatory authority. Swissmedic carried out such an inspection - **prior to the approval of Spikevax -** at Moderna in Switzerland on December 21/22, 2020. **One critical, three serious and one minor deficiency** were identified.

287 Critical defects lead to the failure of a system if they are not rectified immediately. As a result, a system cannot be certified. Serious deficiencies, if not corrected immediately, lead to errors in a system and relevant problems with certification.

288 The deficiencies in Moderna's PVS were subsequently not adequately remedied, as a re-inspection on March 8/9, 2021 **still** revealed **4 serious and 2 minor deficiencies. Internationally,** various approval authorities **also found critical and serious deficiencies in Moderna's PVS**.

289 **A functioning PVS is an elementary prerequisite for the correct processing of adverse drug reactions and thus for the monitoring of a drug.** Due to the serious deficiencies in the PVS, the data generated by Moderna must be classified as incomplete and erroneous from the outset and it is **not possible to make a benefit-risk assessment** based on such poor data. Nevertheless, Swissmedic granted the temporary authorization and made no effort whatsoever to establish a suitable PVS. In doing so, Swissmedic exposed the public to a potentially dangerous medicinal product whose risks are not adequately monitored.

1.1.12. First indications of possible long-term consequences [ER N 409 ff.]

290 At the time of the first approvals in December 2020, it was only possible to speculate about potential (further) late effects due to a lack of relevant data (no long-term studies on humans). Nevertheless, **blood disorders, neurodegenerative diseases and autoimmune diseases** (especially ADE) had already been discussed in detail beforehand. In this initial situation, manufacturers such as Pfizer had apparently exempted themselves from any liability and stated in the leaked "vaccine" contracts with Brazil, for example, that "the efficacy and long-term effects of the vaccine are not yet known and that there **may be adverse effects of the vaccine that are not yet known"**.

291 This is another clear alarm signal which, under normal circumstances, would at least have required all necessary animal studies to be carried out. The failure to do so must once again be seen as a significant risk factor.

1.1.13. Epidemiologically motivated measure for the entire population

292 In contrast to all previous medicines that have been approved under the so-called temporary authorization procedure, the mRNA "vaccines" are medicines that should potentially be given to all residents of the whole of Switzerland (from a certain age). This circumstance also leads to a massive **increase in the risk profile** - after all, if the "vaccination strategy" fails, it is not only people who are already ill and close to death who are **affected**, but the **entire - basically healthy - population, including children,** who - as shown below (N 744 ff.) - would not have had to expect any significant disadvantages even without this active substance. This means that any risk of "vaccination" side effects, however small, results in a negative net benefit for this population group, which Swissmedic was aware of. The licensing authority should therefore have taken special care to exclude all vaccine-related risks for this large population group (Art. 3 para. 1 TPA).

1.1.14. Ongoing phase III study, human trial in the general population

293 As before (N 247 ff.), the temporary approvals were granted in December 2020 based on provisional 2-month data from the approval studies. The studies have not yet been completed and are expected to run until at least 2024.[81] The otherwise usual test procedures with animals were - as far as can be seen from the Pfizer documents that have been released - carried out to a symbolic extent at best.

294 In the present case, it was shown that no meaningful clinical studies were available for the new "vaccines", in particular no studies on a larger and representative group of people that

81 Plus rear N 884.

would have gone beyond an observation period of a few months. The protection of public health within the meaning of Art. 1 and Art. 3 para. 1 TPA is not based on formal criteria, but must be assessed according to the respective actual effects of certain facts (efficacy principle; see N 162). It should therefore be noted that all mRNA "vaccines" **are de facto still in the clinical trial phase since the date of the first approval in December 2020.** This legally relevant fact will have to be referred to again and again in the present criminal complaint.

295 Every person who is administered the mRNA "vaccines" is thus *de facto a* participant in the **largest clinical experiment ever conducted by mankind.** However, only those who have explicitly consented to participate in a clinical trial after having been adequately informed of the foreseeable risks and burdens (*"informed consent"*; Art. 16 HRA [SR 810.30]; Art. 7 ff. ClinO [SR 810.305]) can do so. In particular, this includes all facts relevant to the decision, such as the lack of studies and the corresponding unknown potential side effects (for information requirements, see N 1322 ff.). In the absence of appropriate communication in the sense of complete and transparent information, very few "vaccinated persons" are likely to have been aware of these facts relevant to the decision (on Swissmedic's misleading communication, see N 1187 et seq.).

1.2. Effectiveness

296 In December 2020, the mRNA "vaccines" therefore presented themselves as medicinal products with a risk profile that is unparalleled in the history of Swiss therapeutic products legislation. This massive risk could only be offset by an almost miraculous efficacy that is also unparalleled. At the very least, according to Art. 9a para. 1 lit. b TPA, a **"major"** therapeutic benefit should be expected. This was and is by no means the case:

1.2.1. Minimal therapeutic benefit for merely trivial events [ER N 412 ff].

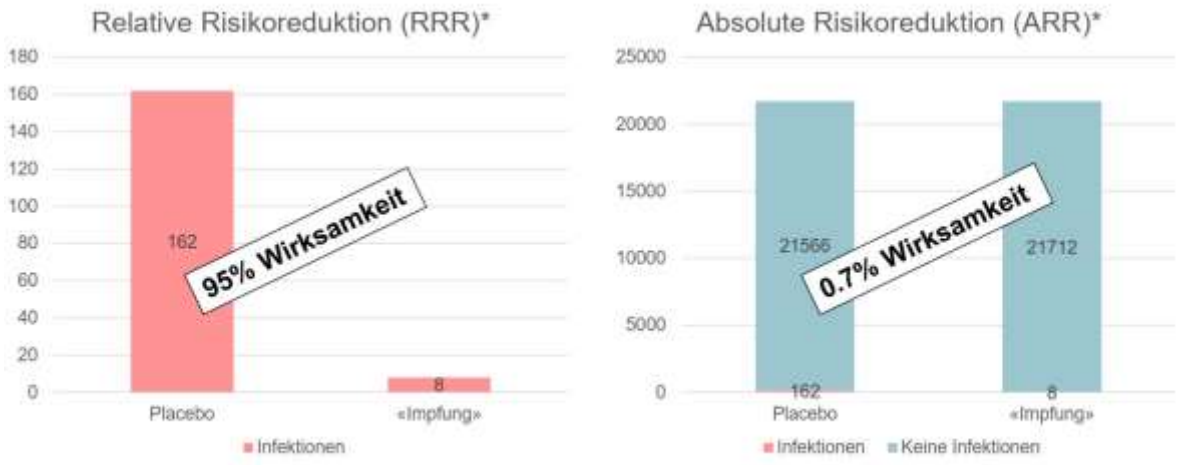
297 According to Art. 9a para. 1 TPA, a medicinal product can only be authorized "for a limited period" if it can be used to treat a life-threatening or debilitating disease. It must be possible to prove this in (clinical) authorization studies.

298 This was clearly not the case: the so-called "**primary efficacy endpoint"** chosen in the approval studies by Pfizer and Moderna was selected in such a way that primarily mild "COVID illnesses" were recorded - defined on the basis of a positive PCR test plus one or two symptoms such as fever, cough, shortness of breath, cold, sore throat, headache, aching limbs, loss of smell/taste, nausea, vomiting or diarrhoea. **This type of study design**

therefore only records minor events - and not the fatal or disabling events required by law.

299 Officially, Pfizer and Moderna reported a high efficacy of 95% and 94.1% respectively for these criteria. Once again, this allegedly high "efficacy" refers to primarily mild symptoms that are in no way life-threatening or disabling. **The "efficacy" calculated in relation to the above-mentioned minor events is therefore not a sufficient basis from the outset for authorization in accordance with Art. 9a TPA.**

300 In addition, this unrealistically high efficacy of almost 100% was communicated using a non-transparent, scientifically questionable methodology based on the calculation of the relative risk reduction (RRR), which will be shown using the example of Comirnaty ("efficacy 95%"): In the Pfizer study, "confirmed COVID disease" occurred in only **8** (=0.04%) of 21,720 subjects in the vaccine group and in only **162** (=0.74%) of 21,728 subjects in the placebo group. Therefore, if a total of 170 cases (8 plus 162) occurred, a total of 162 cases were formally "prevented" in the vaccine group. Pfizer then deduced from this ratio (162 "prevented" cases out of a total of 170 cases) that there was an **efficacy of 95%** (162 ./. 170), which is referred to in science as a relative risk reduction (RRR). Of course, this does not mean that 95% of the more than 40,000 study participants were "successfully" protected against disease: In absolute numbers, **just 162 people out of the more than 40,000 study participants had been "protected" from disease.** Presenting efficacy solely on the basis of the RRR - without placing it in the context of the overall figures (which are presented on the basis of the ARR; more on this below) - therefore leads to a **complete distortion of reality, as the** following graph illustrates:



* Datenbasis: Pfizer-Zulassungsstudie Phase I/II/III (Comirnaty®); Placebogruppe 21'728 Teilnehmer; «Impfgruppe» 21'720 Teilnehmer

301 It is unscientific and dubious for manufacturers to operate on this factual basis solely with information on the RRR - but at the same time provide no information on the ARR: it has been **known for over 20 years that the presentation of the RRR without simultaneous**

disclosure of the ARR and the underlying figures distorts the efficacy data. Announcements and publications presented in a correspondingly distorted manner - in other words: massively embellished - serve the sole purpose of promoting sales, which even qualifies them as advertising.

302 It would therefore have been correct to calculate the efficacy from the outset using the **absolute risk reduction (ARR)** and to disclose this in relevant documents such as the drug texts: If 162 out of 21,728 people **(= 0.74%)** fell ill with COVID-19 in the Pfizer study with placebo and only 8 out of 21,720 people **(= 0.04%)** with the "vaccine", **the absolute risk reduction (ARR) with Comirnaty is just 0.70%** (0.74% minus 0.04%). The same applies to Moderna: the ARR of **Spikevax is just 1.2%.** Such values are definitely far from a "major" therapeutic benefit.

303 The RRR is not an impermissible calculation method per se. What is relevant, however - as just explained - is the context. If several thousand or only several hundred people out of over 40,000 study participants had been identified as suffering from the disease instead of just 170 people, representative efficacy values could certainly be calculated using the RRR. And this is where a **further deception on the part of the manufacturers** comes into play:

304 The allegedly high efficacy of **95%** at Pfizer was calculated on the basis of data that had been **falsified by "adjustments".** For example, in the Pfizer vaccine group there were not just 8 - as officially declared - but 1,594 "symptomatic COVID cases" and in the placebo group not just 162 - as officially declared - but 1,816. For inexplicable and undisclosed reasons, however, no PCR test was carried out on these 3,410 cases despite their symptoms and the corresponding cases were "sorted out" without further ado. To make it perfectly clear: **Any conceivable and "desired" result can be manipulated in this way.** However, if these "sorted out" cases are included in the calculation, even after the **"relative risk reduction" (RRR) the "effectiveness" is** still **just 12-19%.** This is also a far cry from a "major" therapeutic benefit, which is a mandatory requirement for the applicability of Art. 9a TPA.

1.2.2. No proven therapeutic benefit for "serious" diseases [ER N 430 ff].

305 "Severe" COVID diseases - i.e. those that could meet the requirements of a life-threatening or disabling disease - were incomprehensibly only examined in a secondary manner. For these, Pfizer still reported an efficacy rate of 66.4%. Moderna claimed that only 30 to 185 severe cases occurred in the placebo group, but not a single one in the vaccine group - but

refrained from stating an efficacy percentage (which would be an incredible 100% according to the RRR calculation method) for severe cases.

306 Pfizer again calculated the 66.4% using the "relative risk reduction" (RRR). In the vaccine group, only **1** (=0.005%; rounded) of 21,720 subjects and in the placebo group only **3** (=0.01%; rounded) of 21,728 subjects developed a "severe" COVID disease. **With a total of 4 cases out of over 40,000 study participants, one is obviously in the realm of statistical chance. To conclude an effectiveness of 66.4% from these 4 cases is simply dubious, unscientific and misleading.** The same would also apply to the 100% efficacy of Moderna determined using the RRR method.

307 Here too, the efficacy should have been calculated correctly from the outset on the basis of the **absolute risk reduction (ARR):** For Comirnaty, this would be just **0.0092%** (0.0138% minus 0.0046%), for Spikevax it would be **0.2%**.

308 Such values, which are not even in the percentage range, are far from a **"major"** therapeutic benefit, which should be given for life-threatening or disabling diseases according to Art. 9a TPA.

1.2.3. No protection against transfer [ER N 438 ff].

309 Given this initial situation, even the manufacturers never claimed that the mRNA "vaccines" could prevent transmission of SARS-CoV-2 Even Swissmedic stated in its letter of approval to Pfizer dated December 19, 2020: **"the question of preventing virus transmission remains unanswered".** The fact that the chain of infection could not be interrupted in any way by the mRNA injections was therefore already known at the time of approval and was subsequently confirmed several times (see, for example, N 504 f. and N 693 ff.).

310 Nevertheless, Swissmedic misleadingly provided the public with information to the contrary, stating that "current data" showed that "the possibility of transmission of the coronavirus to other people after full vaccination is low" (see the relevant FAQ at N 1204 ff.).

1.2.4. *FDA* requirement: 50% efficacy should be sufficient [ER N 442 f.].

311 The *FDA* also announced to manufacturers back in June 2020 that it would accept an efficacy of just 50%.

312 Apart from the fact that such a low level of efficacy can in no way be described as a "major therapeutic benefit" (Art. 9a TPA) - even this low value was not even remotely achieved by the manufacturers when viewed correctly (absolute risk reduction, ARR).

1.3. Interim result at the end of 2020: maximum risk, minimum effectiveness [ER N 444 ff.].

313 In December 2020, for the first time, the regulatory authority was presented with a medicinal product for approval that exhibited **significant to maximum risk factors in all key aspects of the approval process** - possibly even one or more absolute exclusion criteria - the likes of which have probably never been seen before in the history of the Institute. First and foremost, the completely new basic principle of "gene therapy" for preventive purposes, i.e. the manipulation of the body's own functions in a healthy population with the aim of shifting the production of the spike protein into the human body. At the end of 2020, Swissmedic had no reliable empirical data on the mode of action and effects of this new technology in a healthy population. In particular, Swissmedic had no reliable empirical data on the question of which organs would ultimately carry out this production process and, above all, in what quality, in what quantity and over how long a period of time, although the right quality and individually correct dosage of medicinal products are essential prerequisites for any successful treatment.

314 At the same time, the **efficacy of the mRNA preparations was in no way proven - there could be no question of a "major therapeutic benefit" for the treatment of a fatal or debilitating disease.** The basic requirements for an emergency authorization according to Art. 9a TPA ("temporary authorization") were therefore clearly not fulfilled even at that time.

315 Accordingly, Swissmedic would have been obliged to **choose** an **authorization procedure that took maximum account of these risks and uncertainties.** Nevertheless, Swissmedic granted the "temporary" authorization - without having previously requested the relevant documentation on the identified risks as a mandatory condition for authorization. The licensing authority therefore authorized completely new medicinal products with an exceptionally unfavourable risk profile without having thoroughly convinced itself of the required quality, safety and efficacy of the "vaccine" (including the new endogenous production technology).

316 With this decision**, Swissmedic took the path of maximum risk - in violation of Art. 9a and Art. 3 para. 1 TPA.** However, if this path of inadmissible risk was chosen, the Agency was at least obliged to **exercise all possible care to contain and minimize the inadmissible risk it had created.** Risks that are not yet fully known at the time the license is granted and therefore cannot be controlled must be offset with effective countermeasures: Anyone who authorizes a high-risk product must subsequently exercise the utmost care and transparency when informing the public, users and patients. This means: **comprehensive information about all conceivable risks and side effects - with a clear indication that the**

product is a high-risk product in the trial stage. In addition, the use of the high-risk product must be closely monitored - with **active nationwide monitoring of unintended side effects, which could only have been achieved by clearly instructing and monitoring users to report side effects across the board.** The necessary personnel would have had to be made available for this purpose, for example as part of a special safety task force - if necessary, with the deduction of personnel in other departments.

317 As will unfortunately become clear from the following explanations, Swissmedic did not fulfill its mandatory duty to contain the risks in any way, but instead made the desolate situation worse and worse with each new extension of the authorization, with each misleading orientation of the public and with the abandonment of effective monitoring of side effects:

2. Knowledge status Swissmedic mid-2021 (approval for adolescents)

318 Six months later, in June 2021, Swissmedic extended the authorization of the mRNA "vaccines" to adolescents aged 12 and over, although further facts were added in the meantime that further worsened the risk-benefit profile of the experimental substances:

2.1. Risks

2.1.1. Lack of quality controls: Batch testing waived?

2.1.1.1 Germany: The Paul Ehrlich Institute (PEI) remains silent on batch testing [ER N 456 f.].

319 Since the approval of the mRNA "vaccines", a team of physicists from Germany has still not received an answer to the *PEI,* despite several inquiries about the standards according to which the individual "vaccine" batches were tested by the approval authorities.

320 There is therefore a serious suspicion, at least with regard to Germany, that ultimately only the manufacturers had checked themselves and the regulatory authorities had not carried out sufficient batch testing in any respect. However, this circumstance also affects Swissmedic, insofar as the corresponding batches were imported.

2.1.1.2 Switzerland: Batch testing only on a random basis? [ER N 458 ff.]

321 Swissmedic is responsible for batches of the mRNA active substance Spikevax manufactured in Switzerland (in Valais). Swissmedic had apparently published the batch tests carried out until September 2021 - but then suddenly ceased publication and removed all previously published documents from its website.

322 In response to a private inquiry in October 2021, Swissmedic admitted **that it does not review every "delivery" - i.e. not every batch.** This is not only in view of the novelty and widespread use of these mRNA injections, but also in view of the much too loose release specifications (in front N 225 ff.), this is an **irresponsible blind flight in** every respect.

2.1.2. High-risk unit dose, especially for adolescents [ER N 462 ff].

323 For all adults and adolescents aged 12 and over, a single dose was approved for basic immunization with both "vaccines", which meant that an absolutely **unnecessary and long-established risk** had been taken.

324 It was already clear from a dose-finding study - which had to form part of the approval dossier - by Pfizer/BioNTech that younger study participants (18-55-year-olds) generated side effects more frequently and to a greater extent than older study participants (65-85-year-olds) at all doses investigated (10µg, 20µg, 30µg). According to the study, a dosage of **20 micrograms (µg)** for Comirnaty would therefore have been **"appropriate"** for 18- to 55-year-olds - despite this, **30 µg mRNA** was approved for **Comirnaty** and **even 100 µg mRNA** for **Spikevax**, i.e. a **fivefold increase**.

2.1.3. Comirnaty: 42,086 adverse events and 1,223 reported deaths by February 2021 [ER N 469]

2.1.3.1 Massive side effects, considerable risk of underreporting [ER N 470 ff.].

325 Pfizer/BioNTech presumably submitted a "*Post Marketing Pharmacovigilance Report*" to the regulatory authorities in April/May 2021. The report, which summarized the data from the time of market approval until February 28, 2021 - i.e. just 2 ½ months - already contained the sheer number of **suspected reports of 42,086 adverse reactions and 1,223 deaths** in connection with the "vaccination". These figures alone were already highly alarming and - as far back as N 357 ff. and N 354 f. - would have led to an **immediate ban on licensing** in earlier times.

326 The most common side effects included a **lack of effectiveness of the "vaccination"** (5.2%) and **COVID disease** (4.6%) - i.e. so-called "vaccine breakthroughs". Even then, the serious side effects included 946 cardiovascular side effects (including 130 heart attacks and 91 cases of **heart failure)**, 449 cases of **facial paralysis**, 275 strokes, 298 cases of **herpes zoster** and 151 cases of **thromboembolic events.**

327 Pfizer itself assumed a considerable risk of underreporting and noted that these **case numbers only cover a fraction of the true adverse events.**

2.1.3.2 Side effects in infants [ER N 474]

328 Particularly striking: For 133 **infants who had been breastfed** by a **"vaccinated" mother, 17 suspected cases of adverse reactions** were reported, **3** of which were **serious.** This means that around 13% of breastfed infants were affected by adverse reactions.

2.1.3.3 ADE again recognized as a risk signal [ER N 475 f.].

329 Under the heading "*Safety concerns*", the report again referred to the occurrence of severe allergic reactions and disease exacerbations due to the "vaccination" (*vaccine associated enhanced disease*, "*VAED"*), including exacerbations of respiratory infections (*vaccine associated enhanced respiratory disease*, "*VAERD"*). This is a problem that was already known prior to approval (see N 242 ff.).

330 By the end of 2021 at the latest, a trend towards negative effectiveness was already apparent (rear N 502 et seq.).

331 In addition, it became increasingly clear from 2022 onwards that it was predominantly "vaccinated" people with severe COVID-19 disease who had to be hospitalized (N 706 ff.), which strongly suggests that the mRNA injections actually led to an exacerbation of the disease.

2.1.3.4 Conclusion

332 In view of this devastating data, Swissmedic had compelling reason to discontinue the ongoing experiment immediately by spring 2021 at the latest. Instead, Swissmedic accepted a risk that reversed the actual objective, namely to ensure protection against severe infection by SARS-CoV-2: The substances carried the risk of worsening the course of the disease compared to people without injections. It is not apparent that at least an attempt was made to somehow counter this massive risk - if possible at all - and this is discussed below (see N 1151 ff. and 1198 et seq, 1208 ff.).

2.1.4. Pfizer identifies negative impact on male fertility as a potential risk [ER N 477 ff].

333 Pfizer mentioned an alarming event of particular interest triggered by the mRNA substance in an approval document that was available to international approval authorities - and therefore probably also to Swissmedic - at the end of April 2021. Among 1,290 such events, **"anti-sperm antibody positive"** was listed, which according to fertility experts is an **immunological cause of male infertility.**

334 The potential reduction in male fertility was therefore already known to the regulatory authorities and Swissmedic in spring 2021. This initial suspicion was subsequently confirmed:

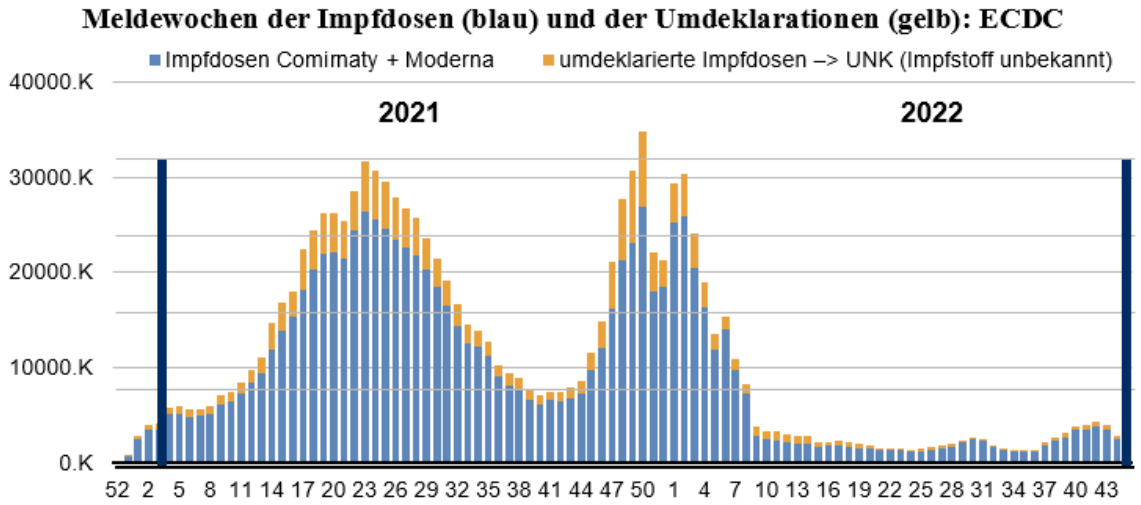
In June 2022, a study was published showing that sperm production is permanently impaired by Comirnaty (N 649 f.).

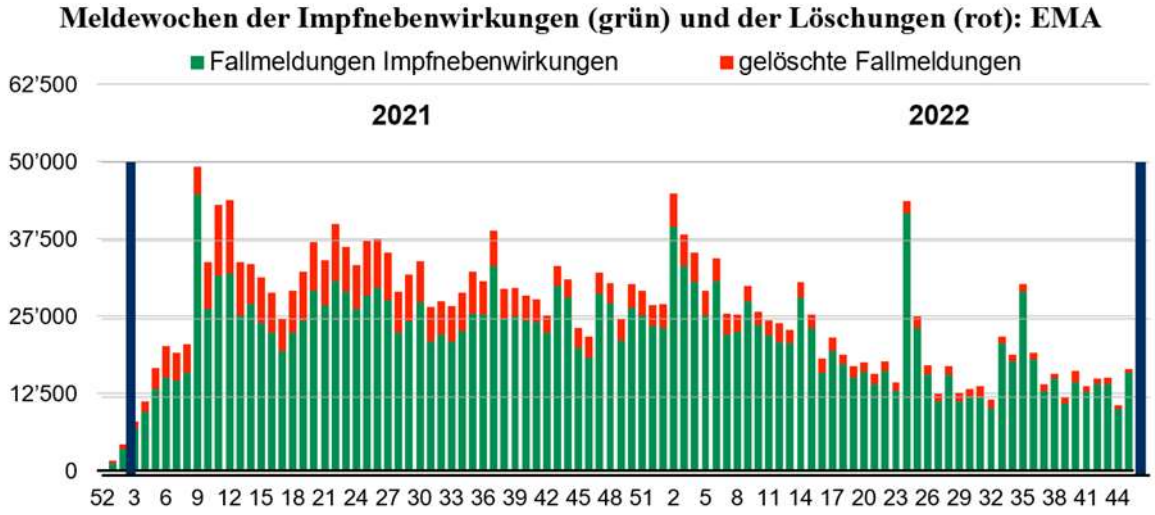
2.1.5. Worldwide adverse event reports until June 2021

2.1.5.1 Preliminary remarks: Sources used, methods of presentation, anomalies [ER N 481 ff].

335 The evidence report details the data basis for the adverse event reports shown in the following graphic.

336 In particular, it should be mentioned at this point that there has been a massive deletion of adverse reaction reports, especially in the EU, since the first version of this criminal complaint was submitted (July 14, 2022): **In *EudraVigilance,* approximately 16% of all adverse reaction reports were deleted retroactively.** At the same time, **vaccine doses** previously **reported as Comirnaty and Spikevax were reclassified as "unknown vaccines"** in the "vaccines" administered. It is not immediately clear what this is intended to achieve - but there is a **striking correlation between the re-declarations and the deletion of the adverse reaction reports**:





337 The re-declarations (yellow) and deletions (red) were particularly high in 2021 and decreased for 2022.

338 Accordingly, the adverse reaction reports submitted in the first version of this criminal complaint concerning the EU were "corrected" downwards massively (on average approx. 16%). The adverse reaction reports in the USA, on the other hand, are roughly stable (decrease of approx. 2%), while no subsequent deletions were published in Switzerland.

2.1.5.2 Data situation for June 2021 (CH, EU, USA) [ER N 492 ff.].

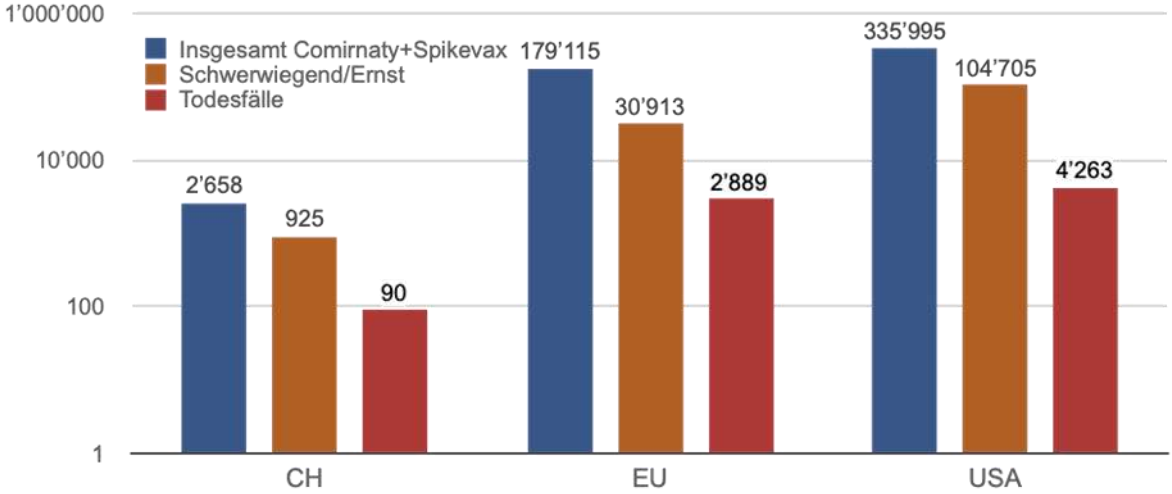
339 Due to deletions/redeclarations (especially in the EU, but also in the USA) as well as reference and calculation errors (see notes in the evidence report) in the previous version, the following corrections had to be made for June 2021:

	CH	Kinder (CH)	EU	Kinder (EU)	USA	Kinder (USA)
Comirnaty	nachträgliche Korrekturen sind nicht veröffentlicht		-4.2%	-20.5%	-0.2%	-0.3%
Ernst Comirnaty			-11.1%	-29.2%	-1.5%	-0.7%
Todesfälle Comirnaty			-17.2%	-100.0%	0.5%	0.0%
Spikevax			-6.0%	-30.0%	1.1%	-0.2%
Ernst Spikevax			-13.0%	-62.5%	0.5%	0.0%
Todesfälle Spikevax			-24.9%	0.0%	0.2%	0.0%
Insgesamt Comirnaty+ Spikevax			-4.4%	-21.5%	0.5%	-0.2%
Schwerwiegend/ Ernst			-11.3%	-32.9%	-0.5%	-0.6%
Todesfälle			-17.8%	-100.0%	0.3%	0.0%

340 The massive decreases in the EU are particularly striking - especially in the number of serious adverse reaction reports and even more extreme in the number of reported deaths. The EU had obviously made **a disproportionate reduction in the number of deaths reported (-17.2% and -24.9% respectively).** The reasons for this approach are *still* unknown.

2.1.5.3 Side effects with Comirnaty and Spikevax (absolute numbers) [ER N 502]

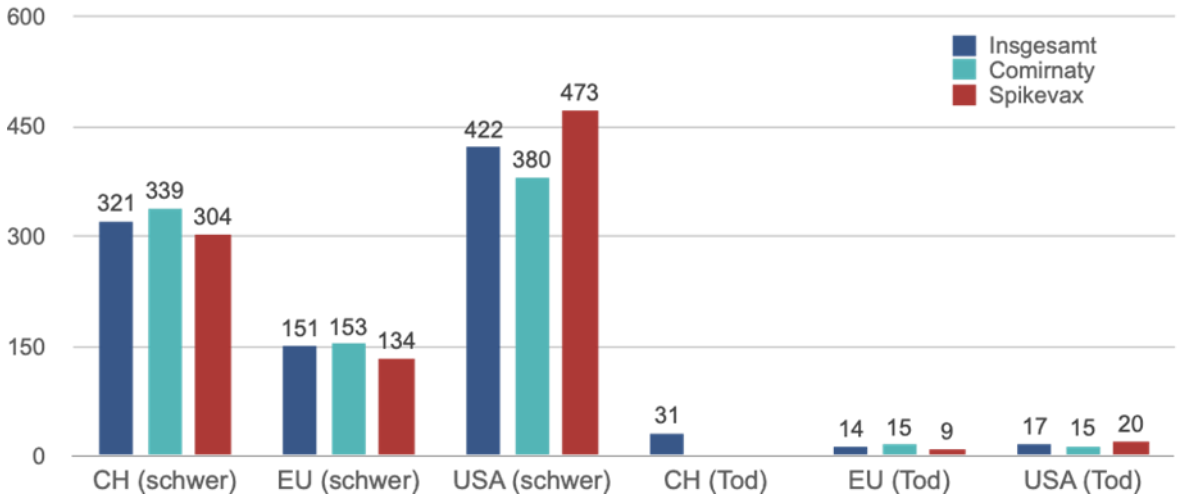
341 As of June 4, 2021 in Switzerland and June 5, 2021 in the EU and the USA, a total of **517,768 adverse reactions** have been reported **to for Comirnaty and Spikevax** - including **136,543 serious adverse reactions** and **7,242 deaths**:



342 As shown below (N 354 f.), studies used to be discontinued or approvals withdrawn immediately if only around 50 deaths (suspected cases) occurred worldwide. **In June 2021,** this **alarm value had already been almost doubled in Switzerland alone - worldwide by around 150 times.**

2.1.5.4 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses") [ER N 503]

343 **Per 1 million doses administered,** the adverse reaction reports for Comirnaty and Spikevax as of **June 2021** were as follows



344 As shown below (N 366 ff.), the risk profile of all COVID "vaccines" is downright devastating compared to influenza vaccines, for example:

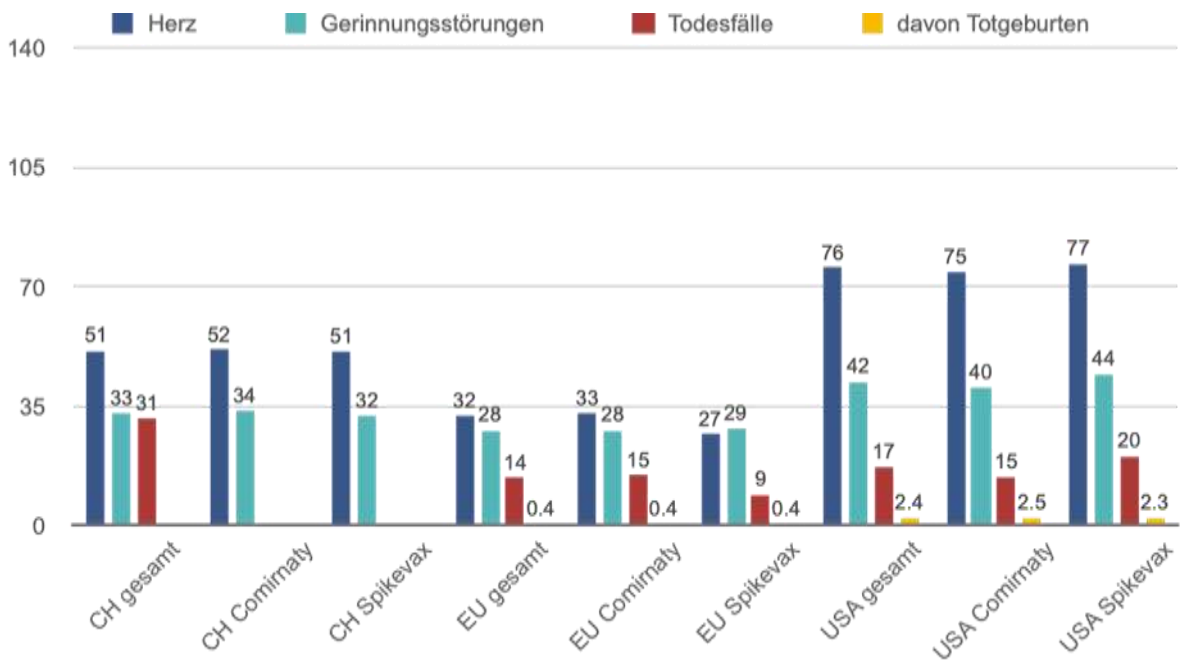
345 Unfortunately, it is admittedly difficult to compare the serious side **effects** due to different counting methods (in particular the different recording of all serious side effects or only those with permanent damage or hospitalization). However, the picture is very clear: while **0.28 to 3.3** serious side effects per 1 million doses are reported for influenza vaccinations (N 366), the figure for **Comirnaty / Spikevax** as of June 2021 is **151 (EU) to 422 (USA) - that is at least 50 times the number of serious side effects.**

346 The comparison is simpler due to the same method of counting deaths: While **0.38 to 0.63** deaths per 1 million doses are reported for influenza vaccines (N 366), the figure for **Comirnaty / Spikevax** is **14 (EU) to 31 (CH) - that is at least 20 times the number of reported deaths.**

347 None of these are marginal, tolerable deviations in the low percentage range, but deviations that are alarming in every respect. It was therefore already clear in June 2021 that the **"temporary" approvals** were **devastatingly wrong decisions.**

2.1.5.5 Selected side effects: Heart problems, thromboses, deaths, stillbirths [ER N 504 ff].

348 A more detailed analysis of all adverse reaction reports for Comirnaty and Spikevax - broken down by symptoms such as cardiac disorders (myocarditis etc.), coagulation disorders (thrombosis etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **June 2021:**



349 At that time, the number of adverse reaction reports concerning **cardiac disorders (myocarditis/pericarditis** etc.) worldwide was 27-77 per 1 million doses, which according to the definition (MedDRA system organ classes) were **"very rare" adverse reactions**, as less than 1 case per 10,000 doses occurred - and this was already without taking into account the massive underreporting. Swissmedic's information for healthcare professionals at the time made completely inadequate reference to this risk, which was already known at the time (see N 1199).

350 Even then, the reports of coagulation disorders, which ranged from 28 to 44 cases per 1 million doses worldwide, were worrying. The official data worldwide was therefore already in a range that could clearly be compared, measured and estimated. There were 0.28 to 0.44 cases per 10,000, meaning that **coagulation disorders** were **already** classified **as "very rare" side effects (<1/10,000) in June 2021**. Swissmedic's information for healthcare professionals at the time did not adequately address this significant risk in any way (see N 1199).

351 The **high number of deaths reported in Switzerland** of 31 per 1 million doses is very striking: such high values were never reached again in Switzerland - in stark contrast to the USA from May 14, 2022 (see N 550).

352 Even then, data from the USA showed that there was **an increase in stillbirths.** The increased risk potential for pregnant women (see N 235 ff.) had already materialized.

2.1.6. Alarm signal Deaths and serious side effects [ER N 513]

353 As before (N 341 ff.), the reports of side effects - in particular serious side effects and deaths - concerning Comirnaty and Spikevax alone had already reached absolutely alarming levels in June 2021. It is explained below that such alarm signals would have long since led to an immediate "termination of the exercise" in earlier times:

2.1.6.1 Withdrawal of medicinal products in the event of 50 deaths / serious side effects [ER N 514 ff].

354 In 1976, just **three deaths** in the USA at the same time as the swine flu vaccination were enough for the **vaccination program to be suspended in nine states** due to safety concerns.

355 In 2001, Bayer withdrew the cholesterol-lowering drug Lipobay. This was after **52 deaths that** had occurred in connection with the use of Lipobay and muscle weakness. Something similar happened in 2004, when Merck withdrew the anti-inflammatory Vioxx , which was **suspected** of having caused **41 heart attacks** worldwide. Furthermore, in a 2008 ruling, the Federal Supreme Court stated that "discontinuation criteria" had been defined in a clinical trial, according to which the trial would have been "discontinued after the first **50 patients"** if there had been any findings about the "harmfulness of the therapeutic procedure".

356 In the past, the occurrence of around 50 fatal or life-threatening incidents worldwide - including merely suspected cases - had already led to a suspension of approval or discontinuation of studies. This alarming figure had already been **exceeded more than 100 times** in June 2021. In addition, the drugs mentioned were only used to treat people who were already ill - mRNA "vaccines", on the other hand, are used prophylactically in a healthy population, which makes a fatal risk from the drug even more serious.

2.1.6.2 Pandemrix: 5000 serious side effects worldwide [ER N 518 ff].

357 After the *WHO* declared a "swine flu pandemic" for the H1N1 virus (which is largely harmless because it causes mostly harmless cases) in June 2009, the *Pandemrix* vaccine from Glaxo Smith Kline (GSK), among others, was approved in Switzerland as early as October 2009, probably under a "temporary authorization" (the precursor standard to "temporary authorization"). Swissmedic needed one month longer than the *EMA* to do this. But for good reason: Swissmedic **(unlike the *EMA*) decided against authorization for pregnant women, children/adolescents under the age of 18 and adults over the age of 60 - because it had simply received too little information from GSK for full approval.**

Although Swissmedic was criticized for this, this **caution - in line with Art. 1 and Art. 3 para. 1 TPA -** *should pay off for the Swiss population.*

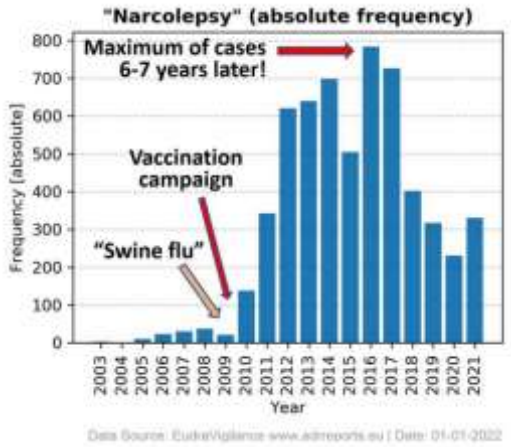
358 *The subsequent vaccination campaign turned into a real disaster worldwide: in just a few months* up to March 31, 2010, a total of 5,069 serious adverse events were reported for ***Pandemrix*** **(72 cases per million doses administered).** Although politicians and regulatory authorities were aware of the lack of threat posed by the H1N1 virus and the serious side effects associated with *Pandemrix*, the population was not informed and the vaccination campaign continued undeterred. Of *the approximately 30 million people vaccinated in Europe, over 1,300 people (mainly children) ultimately* suffered **narcolepsy in** *connection with Pandemrix* **(43 cases per million doses administered).** Thanks to Swissmedic's rightful refusal to approve the vaccine for children, **Switzerland** was **largely spared these consequences.**

359 The supposed "pandemic" was declared over by the *WHO* around August 12, 2010, which also rendered the failed vaccination campaign obsolete and discontinued. The legal proceedings against GSK regarding vaccination damage are apparently still pending.

360 As a result, **the swine flu vaccination campaign was stopped after a few thousand serious side effects were reported worldwide. In** June 2021, this value had long since been exceeded **several times** with regard to COVID "vaccines" - once again a serious alarm signal.

361 Following this supposed "pandemic", Swissmedic reviewed the **pharmacovigilance database** it had created called PaniFlow. This was a purely passive reporting system and Swissmedic stated at the time - quite self-critically - that "only some of the reactions that occurred were actually reported". **Swissmedic thus recognized as early as 2010 that a passive reporting system for the purpose of monitoring drug safety had to be classified as inadequate, as risk signals were only incompletely recorded.**

362 It is particularly worrying that in 2010, the full extent of the unrecognized side effects was not even remotely recognizable: the cases of narcolepsy only reached their sad peak much later - in 2017. **The hasty approval of drugs that have not been adequately tested is therefore obviously associated with risks that are difficult to assess.**



363 Despite these experiences in the context of the "swine flu", Swissmedic quite obviously did not take any measures to eliminate the risk of inadequate recording of side effects, but also relied on a purely passive - and completely inadequate - reporting system for monitoring mRNA injections (see N 1154 ff.).

2.1.7. COVID-19 "vaccine" significantly more dangerous than flu, swine flu and measles vaccine [ER N 539 f.].

364 As of May 2021, Swissmedic reported 1,953 suspected cases of adverse reactions from 2.8 million doses of COVID "vaccines" administered, of which 701 cases were classified as serious. This resulted in a rate of **250 serious adverse reactions per 1 million doses administered.**

365 In spring 2021, this rate already clearly exceeded anything that had previously been observed in comparison with other vaccines:

2.1.7.1 Comparison with influenza and swine flu vaccines [ER N 541 ff].

366 In Switzerland, only very insufficient data is available on the side effects of influenza vaccines, which is why a direct comparison with the mRNA "vaccines" is difficult. Accordingly, data from the EU and the USA must be used. The relevant sources are presented in detail in the evidence report. A comparison of **serious side effects** (side effects that are fatal or life-threatening, require hospitalization or lead to significant or permanent damage) **and deaths** is shown in the following overview (figures in cases per million "vaccine doses" administered):

Table 1: Serious side effects (per million "vaccine doses")

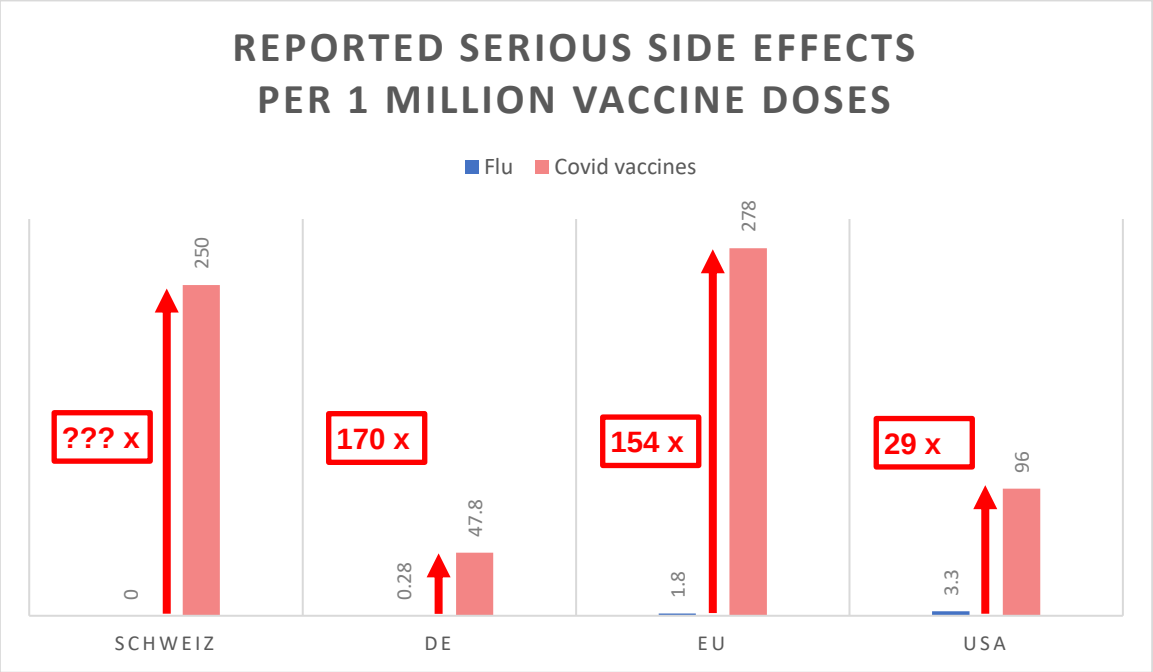
	Flu	Pandemrix	COVID "vaccines"
Switzerland	--	--	**250**

EN	0.28	--	**47.8**[82]
EU	1.8	72	**278**
USA	3.3	--	**96**[83]

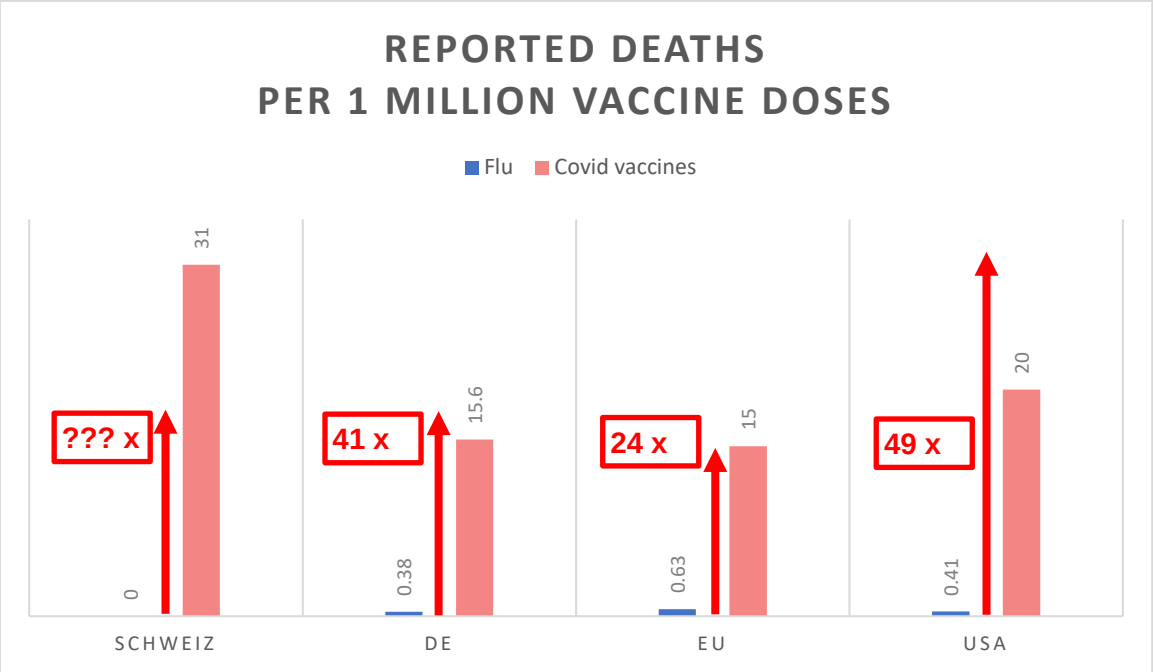
Table 2: Deaths (per million "vaccine doses")

	Flu	Pandemrix	COVID "vaccines"
Switzer-land	--	--	**31**
EN	0.38	--	**15.6**
EU	0.63	--	**9-15**
USA	0.41	--	**15-20**

367 Graphically, this results in the following picture:



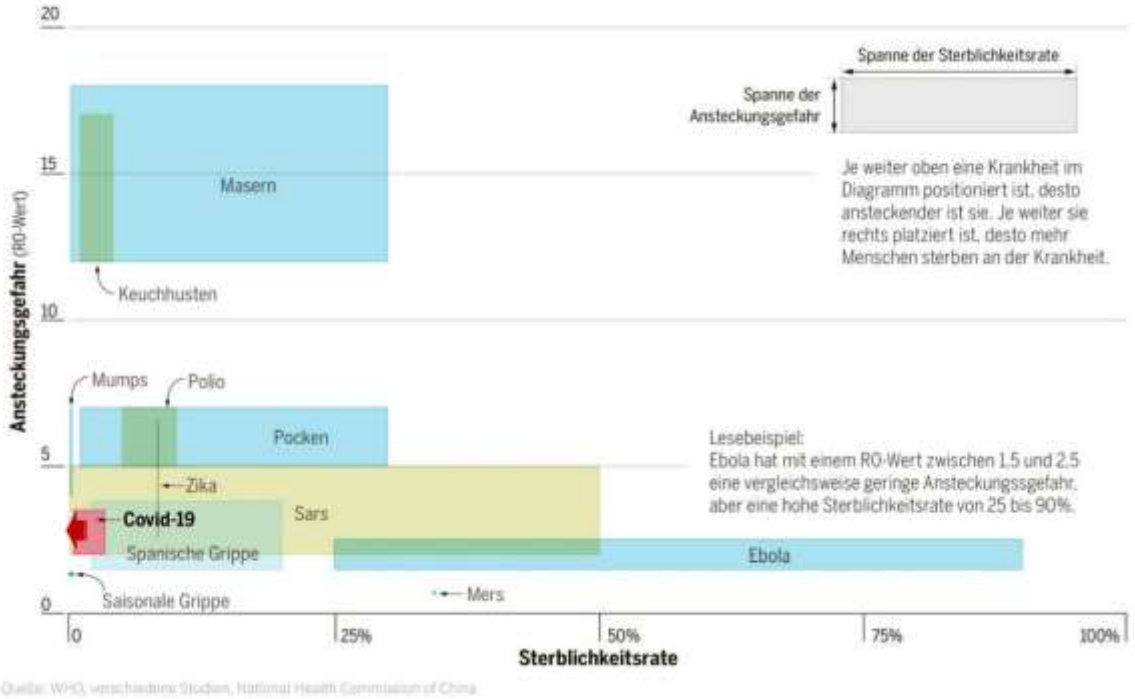
82 Side effects with *permanent* damage.
83 Side effects associated with *hospitalization*.



368 Even if the figures collected are subject to greater fluctuation depending on their origin and due to the lack of a uniform definition of "serious side effects", the findings are clear: the COVID "vaccines" showed an absolutely devastating result after just a few months of use. **For every million doses vaccinated, the reported serious side effects were at least 30 times higher and the reported number of deaths at least 20 times higher than with the flu vaccines.** Any (medium- and) long-term side effects of the COVID "vaccines" are not even included here, depending on the circumstances - in contrast to the other vaccines presented.

2.1.7.2 Comparison with measles vaccines [ER N 553 ff].

369 A comparison of the COVID "vaccines" designed for Sars-Cov-2 with the measles vaccines is not expedient solely in terms of the lethality of the two diseases to be "combated": **measles has a high lethality rate of up to 30%,** while COVID-19 has a lethality rate of just 0.15% (alpha variant), even as low as 0.002% (Omikron variant) (back N 752 ff. and N 779 f.). However, measles is not only many times more deadly, it is also **many times more contagious:**



370 A comparison of adverse reaction reports in *VAERS* and *EudraVigilance* also reveals that the **risk of an adverse reaction after COVID "vaccination"** is **13 times higher in the USA and 72 times higher in the EU than with the measles vaccination.**

371 **The comparison with the measles vaccines is also absolutely devastating for the COVID "vaccines": They are supposed to "combat" a far <u>less</u> dangerous disease - while at the same time generating <u>massively more</u> side effects.** The "signs" should be the other way around: More side effects than with the measles vaccine would only be tolerable if they were used to "combat" a much more dangerous disease than measles.

2.1.7.3 Conclusion: Unprecedented number of side effects per 1 million doses [ER N 565]

372 In May 2021, Swissmedic published a rate of **250 serious adverse reactions per 1 million doses administered** without drawing the necessary conclusions. It was already clear at the time that **this rate clearly exceeded anything that had previously been observed in comparison with other vaccines.** Swissmedic therefore had every reason to immediately take all measures to protect the Swiss population.

2.1.8. First studies on heart problems, coagulation disorders and one death [ER N 566 ff].

373 All these reported side effects were not in a "vacuum": there was already a strong suspicion at the time that they were **directly causally linked to the COVID "vaccines"**:

374 As of June 4, 2021, at least **5 peer-reviewed publications on heart problems, 44 peer-reviewed publications on life-threatening coagulation disorders (thrombosis, etc.) and one peer-reviewed publication on possible deaths as a result of COVID "vaccinations" had** already appeared. Narrowed down to the mRNA "vaccines" Comirnaty and Spikevax , there were 4 publications on heart problems and 15 publications on life-threatening coagulation disorders (thromboses, etc.). Even at that time, the available studies alone were therefore a considerable cause for alarm. The authors of the study relating to the identified death (Astrazeneca) already strongly recommended at that time that **an autopsy should be performed for all deaths** that occur in a temporal connection with a COVID-19 "vaccination" - **regardless of the mechanism of action.**

375 **All these studies showed an alarmingly high number of side effects for the first few months of the COVID "vaccination". All these studies were peer-reviewed and publicly available - i.e. also available to Swissmedic - and highly relevant in terms of the protection of public health within the meaning of Art. 3 para. 1 TPA.**

2.2. Effectiveness

2.2.1. Efficacy data in adults [ER N 580]

376 As far as can be seen, nothing had changed in the official effectiveness data for adults up to this point compared to the time of initial approval in December 2020 (see above N 296 et seq.).

2.2.2. Efficacy data for adolescents

2.2.2.1 Minimal therapeutic benefit for merely trivial events [ER N 581 ff].

377 As with adults, primarily **minor events** were investigated in adolescents, which - as already mentioned - **do not** constitute a **"life-threatening or disabling disease" within the meaning of Art. 9a TPA**. Here too, therefore, no evidence of a "major" therapeutic benefit could be provided from the outset.

378 Once again, the distorting calculation method of the RRR was used to "calculate" an almost implausible efficacy: For Comirnaty, **100% efficacy** was proclaimed in adolescents aged 12-15 years because **16** out of 1129 subjects (prevalence 1.4%) in the placebo group vs. **0** out of 1131 subjects in the "vaccination group" had experienced a "confirmed COVID disease" (i.e. a minor event). A similar picture emerged for Spikevax: An efficacy of **93.**3% (-

100%) was published in the information for healthcare professionals, whereby, depending on one of the two case definitions used, **7 versus 1** (or 4 versus 0) "confirmed COVID cases" (minor events) were reported in the placebo versus vaccine group among the 3,732 study participants. Again, these figures do not mean that up to 100% of the 2,260 or 3,732 study participants were "successfully" protected from disease. In addition, 16 or 8 cases out of several thousand study participants are obviously in the realm of statistical chance). **To infer an effectiveness of up to 100% from these few cases is dubious, unscientific and misleading.**

2.2.2.2 No data for "serious" illnesses [ER N 585 ff.].

379 "Severe" COVID diseases - i.e. those that could meet the requirements of a life-threatening or disabling disease within the meaning of Art. 9a TPA - could not be investigated at all. This is for a very simple reason: **neither the approval study of Comirnaty nor Spikevax reported "severe COVID diseases" for adolescents aged 12 and over.**

380 Although not a single adolescent was seriously ill with corona in the approval studies, a **"temporary" approval** was granted **for "protection" against corona, which adolescents obviously do not need.** In the absence of corresponding data, there is no evidence that the "vaccination" even has the potential to effectively protect adolescents from a serious (life-threatening or disabling) disease.

2.2.3. Infection with SARS-CoV-2 reliably protects against re-infection [ER N 588]

381 Even at the time of the approval of COVID "vaccinations" for children and adolescents aged 12 and over, it was already apparent that having had the disease reliably protects against re-infection: In a large-scale American study from March 15, 2021 with over 150,000 patients, it was shown that having had the disease protected against a recurrence of symptomatic disease with an "efficacy" of 84.5%. This early study joins a total of **at least 37 publications and pre-print publications** that have also come to the conclusion up to this point that having had the disease generates a broad and long-lasting immune response or protects against COVID disease at least as well or even better than the "vaccination".

382 Exposing young people to the risk of an experimental "vaccination", even though they were in no way at risk from the disease to be "combated" and, moreover, were even more reliably protected after infection than after "vaccination", was already recognized as a clear mistake in June 2021.

2.3. Interim result (mid-2021): High risk already realized [ER N 589 ff.]

383 The high risk potential of the "vaccines", which had already been identified when they were first approved in December 2020, had materialized in the most impressive way by June 2021: thousands of people died in close connection with the administration of the mRNA "vaccines", tens of thousands suffered severe side effects.

384 At the same time, the approval studies had not proven any relevant efficacy for adolescents up to this point. The mRNA injections were and are not associated with any relevant benefit for this age group, which means that even a single significant complication leads to a negative risk-benefit ratio.

385 However, instead of reacting immediately and finally withdrawing the toxic, suspected carcinogenic and potentially mutagenic medicinal products from the market, their authorization was extended in a further risk-increasing manner - by now also allowing adolescents to be "vaccinated" with the same demonstrably dangerous substances in the same high - potentially fatal - dose, even though the basic requirement for a temporary authorization within the meaning of Art. 9a TPA - a life-threatening or disabling disease - was not proven by the manufacturers in a single case for the placebo group of adolescents aged 12 and over.

386 The requirements for a temporary authorization of the "COVID" vaccines in the privileged examination procedure according to Art. 9a TPA were therefore obviously not met for this age group.

3. Status of knowledge at Swissmedic at the end of 2021 (approvals for "boosters" / children)

387 On October 26, 2021, Swissmedic approved a third dose of the mRNA "vaccines" ("booster") and extended the scope of application to children aged 5 years and older on December 10, 2021. Again, this was done in the knowledge of other facts that further worsened the risk-benefit profile of the experimental medicinal products:

3.1. Risks

388 For the sake of clarification, it should be noted that the violations at Comirnaty are only shown below because **no such information** is **publicly available for Spikevax due to the lack of publication of the corresponding reports.** This circumstance must be corrected, which is why corresponding requests for evidence are made at the beginning.

3.1.1. COVID-19 "vaccines" are publicly referred to as gene therapy [ER N 592 f.].

389 As before (N 200 ff.), there was already more than just a suspicion at the time of approval at the end of 2020 that the mRNA injections were not vaccinations, but actual "gene therapies" (gene prophylaxis; see N 194). The reason why both the regulatory authorities and the manufacturers repeatedly referred to "vaccination" and not "gene therapy" was revealed by a representative of the pharmaceutical industry just under a year after initial approval - and thus after billions of mRNA injections had already been carried out. Stefan OELRICH, member of the Board of Management of Bayer AG and head of the chemical and pharmaceutical company's drug division, explained this at the World Health Summit in October 2021:

> "The mRNA vaccinations are an **example of cell and gene therapy.** If we had done a public survey two years ago and asked who would be willing to take up gene or cell therapy and have it injected into their body, probably 95% of people would have refused. This pandemic has opened many people's eyes to innovation in a way that wasn't possible before."

390 This open declaration of mRNA injections as "gene therapies" was also deliberately concealed by the media and also by Swissmedic - Swissmedic continued to use the misleading term "vaccinations" (see, for example, the media releases at the end of N 1190 ff.).

3.1.2. Toxic effect of the spike protein [ER N 594 ff].

391 Previously (N 212 ff.) it was shown that the lipid nanoparticles (LNP) contained in the mRNA "vaccines" - contrary to official statements - did not remain at the injection site, but spread throughout the body and accumulated in various organs. However, it was not only the LNPs that were insufficiently tested for toxicity. The same applies to the effect of the spike protein on the human body:

392 The amount of spike protein effectively produced in the body of individual "vaccinees" is - as far as can be seen - completely unknown: Data on this is still completely lacking, as no pharmacokinetic studies have been carried out on humans in this regard. This fact is completely untenable in view of the proven toxic effect of the spike protein:

393 Several studies from 2021 (and 2022) still detected the **spike protein in the entire human body two to four months after the "vaccination". There** was and is no question of a "short-term" application. This prolonged presence in the body has numerous devastating consequences:

394 **Every cell in the body that expresses the spike protein becomes a target for the immune system over a longer period of time.** As early as April 2021, animal studies showed that the spike **protein causes vascular damage,** which in turn can lead to cardiovascular events such as heart attacks, strokes, etc. However, due to its mode of action, the spike protein not only causes vascular damage in all kinds of organs (the immune system attacks the cells that form the spike protein) - it is also able to directly activate blood platelets. Both lead to increased blood clotting and thus to **blood clots.** This explains the thousands of reported side effects such as **heart attacks, strokes, pulmonary embolisms, thromboses** etc. since the start of the "vaccination campaign".

395 The **prolonged presence of the toxic spike protein, which was not intended in any way, therefore presumably leads to a large number of serious side effects (including death).** It is not apparent that Swissmedic has in any way effectively countered this obvious and, in the absence of detailed studies, hardly controllable risk.

396 It cannot be explained why the manufacturers chose the spike protein of all proteins for "vaccine production": In addition to the spike protein, there would have been various other suitable **- safer - surface proteins that could have been used for** this purpose in terms of less aggressive alternatives.

3.1.3. Comirnaty: Approval study not *GCP-compliant*, falsified data [ER N 605 ff.].

397 It has already been explained in detail that the approval studies were sabotaged by "unblinding" on the part of the manufacturers. However, this serious violation of the *GCP rules was* not the only one; other violations also occurred:

398 According to a publication dated November 2, 2021 in the renowned *British Medical Journal,* the Pfizer/BioNTech phase 3 trial was not conducted in accordance with the rules of *"Good Clinical Practice (GCP)"* (Art. 5 para. 1 lit. a AMZV) at various study centers: Reports concerning the contract research organization *Ventavia* include **protocol deviations, falsification of data, poor laboratory management, incorrect storage of vaccine vials and untrained study personnel.**

399 In view of these serious violations of the GCP, **the data integrity of the Pfizer/BioNTech approval study can hardly be guaranteed.** Normally, such findings would compel marketing authorization holders and regulatory authorities to conduct extensive investigations and recall the medicinal product concerned until the results of the investigation are available. The fact that this has not happened to date must once again be seen as a massive increase in risk, of which Swissmedic must have been aware.

3.1.4. Comirnaty: Falsified death reports, more deaths in "vaccination group" [ER N 610 ff].

400 In July 2021, Pfizer reported 15 deaths in the vaccine group versus 14 deaths in the placebo group in the 6-month report. The deaths were not "COVID deaths", but "deaths from any cause" ("all cause mortality"). All-cause mortality figures have always been considered a sensitive marker for the safety of a drug, which is why even small numbers are relevant.

401 What is most alarming is that the reported death figures were apparently incorrect, which even the *FDA* noted: Instead of 14 deaths, **17 deaths** were recorded in the **placebo group** and instead of 15, **21 deaths** were recorded **in the vaccine group.** In a further analysis of the same report figures, the *Canadian COVID Care Alliance* ("CCCA") came to a similar conclusion: there were actually **14 deaths in the placebo group,** but a full **20 deaths in the vaccine group**.

402 This obviously self-inflicted, inadmissibly **embellished deviation "in favor" of the vaccine group** should once again have raised serious doubts among the competent authorities about the trustworthiness of the company, the data it provided and ultimately the safety of the mRNA vaccine.

3.1.5. Comirnaty: More (serious) events in "vaccination group" [ER N 614 ff].

403 In the aforementioned analysis, the *Canadian COVID Care Alliance* ("CCCA") uncovered another explosive fact: A full 5,241 *adverse events* occurred in the vaccine group, compared to only 1,311 in the placebo group, for which a link to the study medication was established. For ***serious*** *adverse events,* the number of cases was 262 (vaccine group) vs. 150 (placebo group).

404 In the **vaccine group, four times more *adverse events* and almost two times more *serious adverse events*** occurred as a result of the medication. This, too, is an actual exclusion signal as far as the safety of the mRNA "vaccines" is concerned.

3.1.6. Comirnaty: Alarming interim report (*PSUR*)

3.1.6.1 PSUR: Content, purpose and requirements on the part of licensing authorities [ER N 617 ff].

405 The manufacturers were obliged by the regulatory authorities to submit interim reports, so-called *Periodic Safety Update Reports* (*PSUR*). Pfizer's first *PSUR* was made public; Moderna also lacks corresponding publicly available information. The aforementioned Pfizer *PSUR covers* the observation period from December 19, 2020 to June 18, 2021. It

was finalized on August 19, 2021 and had to be submitted to the regulatory authorities from this date. This interim report once again contains a **large number of additional risk-increasing facts:**

3.1.6.2 Excessive number of deaths [ER N 623 ff].

406 Of 702 serious events that occurred in the **clinical trials, 46 cases (6.6%) were fatal**. The study also examined 327,827 cases from the so-called **"postmarketing phase"**: of these, 100,808 (30.8%) were classified as serious, with **5,069 cases (1.6%)** ending **fatally**.

407 As before (N 354 f.), in earlier times 50 deaths were already sufficient for an immediate ban on approval. Why this is now handled differently for the mRNA "vaccines" is in no way comprehensible.

3.1.6.3 Deaths: Older people with previous illnesses particularly at risk - missing data [ER N 626 ff.].

408 Due to 23 deaths - which only occurred in the first weeks after approval (until January 14, 2021) in Norwegian nursing homes - the Norwegian regulatory authority adjusted its vaccination recommendations: **Caution should be exercised when vaccinating frail elderly people** and decisions should be made on a case-by-case basis.

409 Once again, the completely inadequate data situation is evident here: in Comirnaty's approval study, only 804 (4.4%) of the study participants in the vaccine group were aged ≥ 75 years. In addition, only 21% of the study participants had a concomitant disease. Comirnaty was therefore studied in a predominantly younger and healthy population. The studies regarding the safety of the older and previously diseased population are therefore completely inadequate, which even the manufacturers openly admit: **Pfizer itself classified the use of Comirnaty in frail patients with concomitant diseases (cardiovascular or neurological diseases, diabetes, chronic obstructive pulmonary disease [COPD]) as "missing information".**

410 Despite this, the "booster" was approved as a priority for the elderly population without any warning (see N 1199).

3.1.6.4 Side effects: Under 50s excessively affected [ER N 632 f.].

411 *PSUR* No. 1 also showed that the **age group of 13 to 50-year-olds** was **most affected by the side effects.** Tragically, this is precisely the age group for which COVID-19 is not associated with any relevant risk (N 752 ff.).

3.1.6.5 Number of side effects: Massive differences between the batches [ER N 634 f.].

412 It is also striking that **19 batches** led to **an above-average number of cases of adverse reactions** (≥ 2000). 3 batches also stand out clearly with > 10,000 cases each. Contrary to the claims of the marketing authorization holders, this uneven distribution strongly suggests that there are **relevant quality problems during production** (see also N 417 ff.).

3.1.6.6 Many dangerous batches in Switzerland? [ER N 636 f.]

413 Of the 19 batches mentioned with an above-average number of cases of adverse reactions, **7 batches** were **supplied to Switzerland. It** is not yet known how many mRNA injections from these 7 batches actually reached Switzerland, as these batches were always also supplied to other countries. Either way, the fact that 7 obviously particularly dangerous batches were delivered to Switzerland is an **alarm signal** and should have led to the necessary actions by the regulatory authority Swissmedic - **warning the population, batch recall, etc.** - without fail.

3.1.6.7 Side effects prematurely classified as "signals that pose no risks" [ER N 638 ff.].

414 What is also striking about *PSUR* No. 1 is that Pfizer had classified various side effects that had occurred, such as **thrombosis** or **herpes zoster,** as **"signals that do not pose any risks".** As early as mid-2021, this was in obvious contradiction to the side effects actually reported: **According to the *EMA,* thromboses** were **among the most frequently reported serious suspected cases.** Swissmedic itself had also recognized herpes zoster as a potential safety signal, according to 92 reported cases. Swissmedic had therefore recognized that, **contrary to the manufacturers' assessments, thromboses or herpes zoster could certainly be classified as "signals that pose risks".**

3.1.6.8 Conclusion: PSUR No. 1 should have led to the immediate "termination of the exercise" [ER N 644 ff.].

415 All of these alarm signals should have led to a far-reaching investigation and a "discontinuation of the practice" in view of the central protected good according to Art. 1 and Art. 3 para. 1 TPA - public health. At the very least, however, the licensing authority should have imposed mandatory conditions and corrective measures on the manufacturers. Above all, however, there was a compelling need to finally take effective measures for the effective

detection of risk signals - particularly in the form of rigorous market surveillance - in order to protect public health.

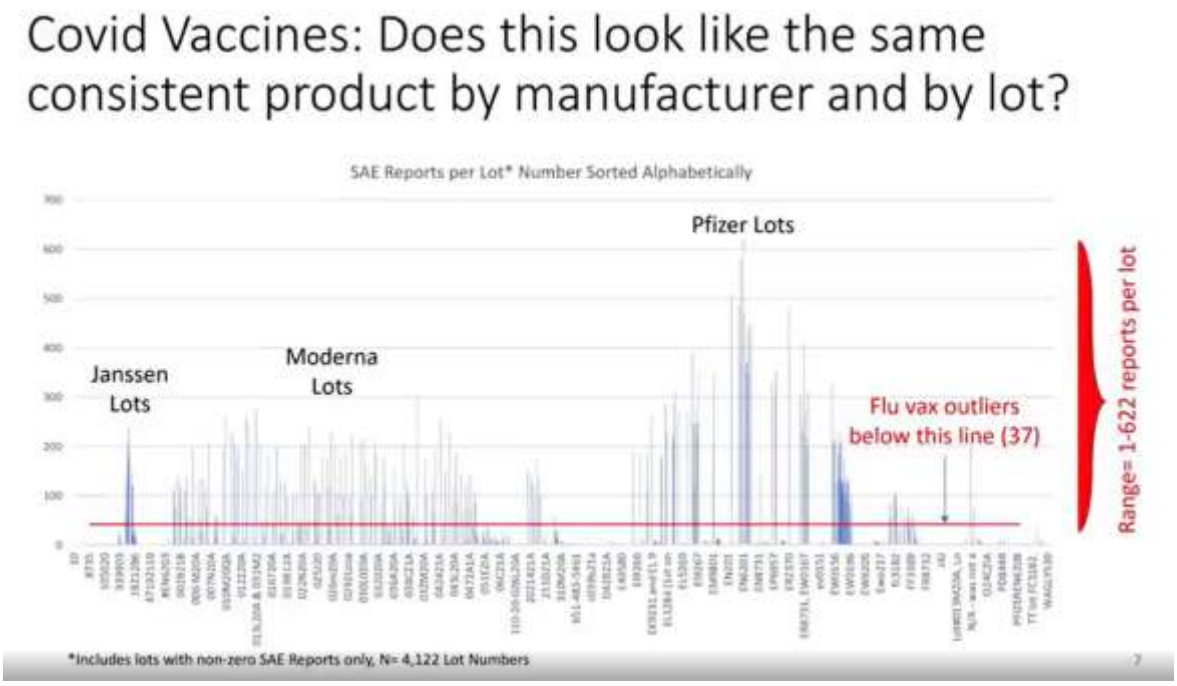
3.1.7. Spikevax: 2 of 149 (1.3%) of the study participants suffered pericarditis [ER N 649 f.].

416 According to Swissmedic's information for healthcare professionals, "only limited data are available on booster vaccination with Spikevax". One figure, however, is striking: **In 2 out of 149 (1.3%) participants, pericarditis was observed in temporal connection with the administration of the booster vaccination,** which would have to be classified as a **"frequent" side effect.** However, the study is so poorly designed that no clear conclusions can be drawn from it, as these cases are in the realm of statistical chance.

3.1.8. Significant variability in side effects per "vaccination batch" indicates serious production problems and lack of *GMP compliance* [ER N 651 ff.].

417 With regard to the following statements, it should be expressly noted that these are not results from peer-reviewed or even properly published studies. However, the apparently obtained findings appear to be so important that they should at least be taken as an *initial indication* of possible irregularities and must give rise to further investigations.

418 In December 2021, US researchers published results showing that the **individual vaccine batches were responsible for the occurrence of severe side effects to very different degrees.**



419 They came to this conclusion based on an evaluation of the adverse drug reactions registered in the US *VAERS* database. Even if, in principle, factors such as different reporting behavior at different sites, incorrect transport or incorrect storage could have contributed to these differences, the overall differences are so serious that they indicate **non-uniform production** of the COVID "vaccines" and thus a **serious quality problem** and a **serious violation of GMP *rules***.

420 After this evaluation at the latest, the responsible approval authorities had the most urgent reason to **immediately and consistently detect** the corresponding **signals of non-uniform production - by means of rigorous batch testing.** Apparently, however, this was (still) not done (see above N 319 ff.).

3.1.9. Further massive increase in adverse event reports worldwide [ER N 658]

421 For the sake of completeness, two complete data sets (October/November 2021 and December 2021) are presented in the evidence report. The following presentation is limited to the data situation as of October/November 2021 (for the "booster" approvals), supplemented by the data situation as of December 2021 (for the approval extension for children).

3.1.9.1 Data situation for November 2021 (CH, EU, USA) [ER N 659 ff.].

422 For information on the subsequent deletion of adverse reaction reports and re-declarations of "vaccine doses", see above (N 335 ff.) .

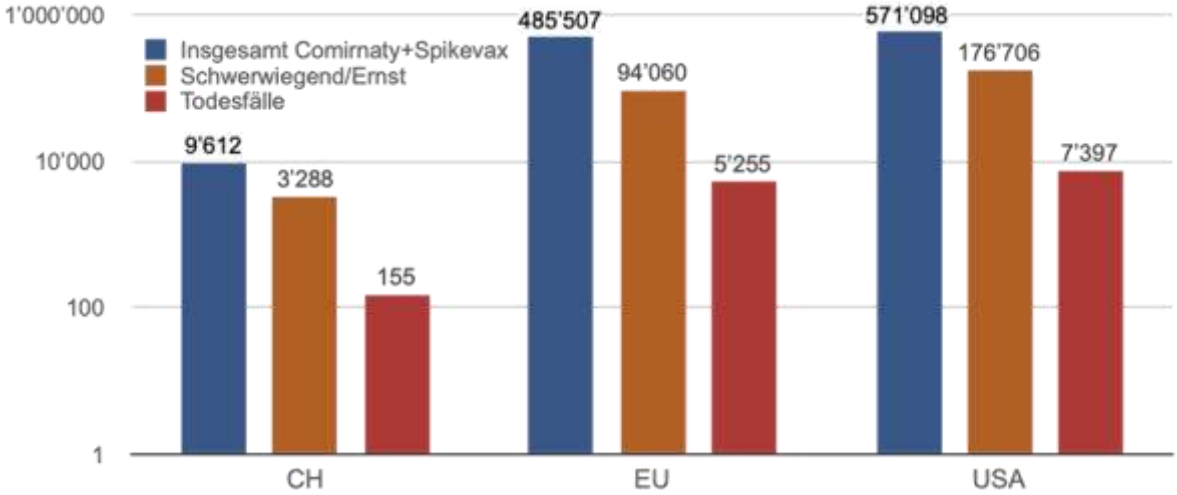
423 Due to deletions/redeclarations (especially in the EU, but also in the USA) as well as reference and calculation errors (see notes in the evidence report) in the previous version, the following corrections had to be made for November 2021:

	CH	Kinder (CH)	EU	Kinder (EU)	USA	Kinder (USA)
Comirnaty	nachträgliche Korrekturen sind nicht veröffentlicht		-5.7%	-8.4%	-1.0%	-0.7%
Ernst Comirnaty			-11.5%	-17.8%	-1.9%	-1.3%
Todesfälle Comirnaty			-13.7%	-37.5%	0.3%	-3.4%
Spikevax			-4.4%	-7.4%	0.5%	-0.4%
Ernst Spikevax			-9.7%	-19.9%	0.1%	0.0%
Todesfälle Spikevax			-14.0%	0.0%	0.0%	0.0%
Insgesamt Comirnaty+ Spikevax			-5.5%	-8.3%	-0.2%	-0.7%
Schwerwiegend/ Ernst			-11.3%	-18.0%	-1.0%	-1.2%
Todesfälle			-13.7%	-36.0%	0.1%	-3.0%

424 Once again, the massive reductions in the EU are striking - particularly in the number of serious adverse reaction reports and even more extreme in the number of reported deaths. The EU had obviously made **a disproportionate reduction in the number of deaths reported (-13.7% and -14.0% respectively).** The reasons for this approach are *still* unknown.

3.1.9.2 Side effects with Comirnaty and Spikevax (absolute figures) [ER N 669]

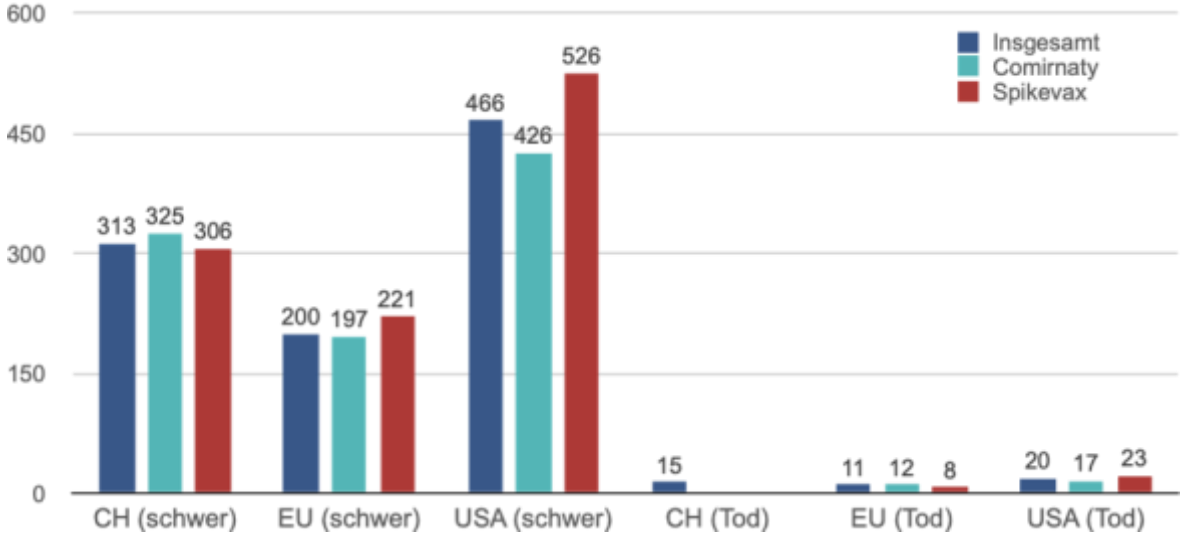
425 By November 4, 2021 in Switzerland and by October 30, 2021 in the EU and the USA, a total of **1,066,217 adverse reactions** had been reported to for Comirnaty and Spikevax - including **274,054 serious adverse reactions** and **12,807 deaths:**



426 The **alarm value of 50 deaths was therefore massively exceeded with 12,807 deaths - more than 250 times as many.**

3.1.9.3 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses") [ER N 670]

427 **Per 1 million doses administered,** the adverse reaction reports for Comirnaty and Spikevax as of **November 2021 were** as follows



428 As previously (N 366), the risk profile of all COVID "vaccines" is downright devastating compared to the flu vaccines, for example:

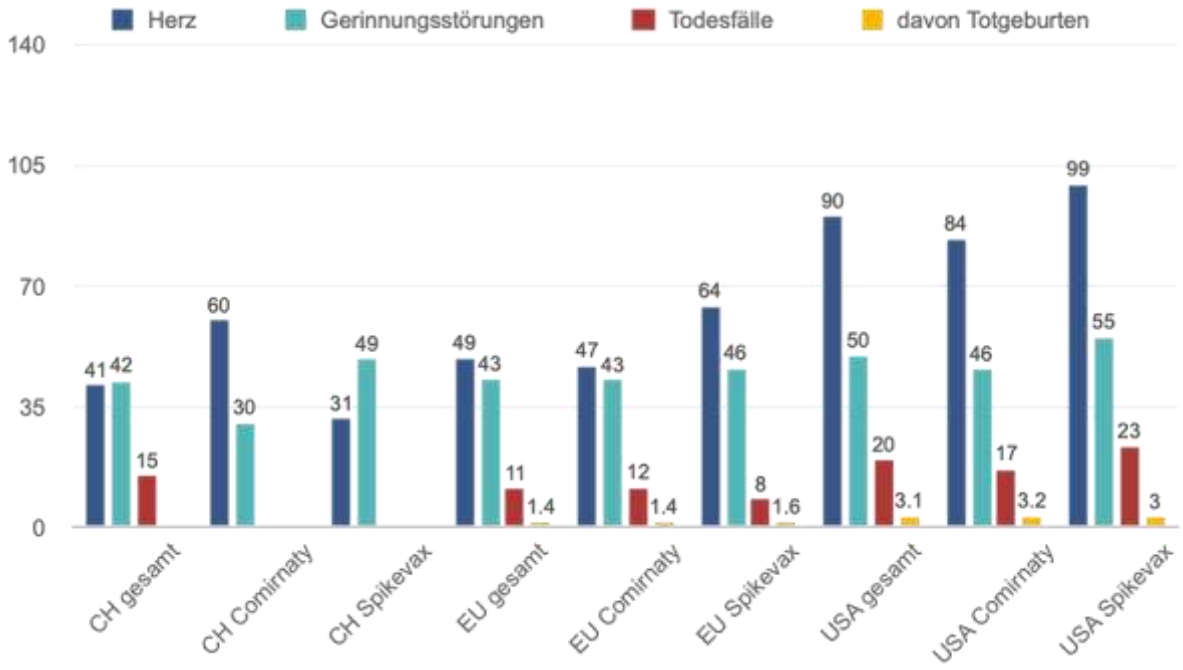
429 The comparison with the influenza vaccinations is similar to the previous comparison for **severe side effects** (N 345), whereby a slight "increase" is even recognizable: **Comirnaty / Spikevax show at least (197 [EU]) 60 times the number of severe side effects compared with the influenza vaccination.**

430 Compared to the influenza vaccines, **Comirnaty / Spikevax continue to** record **around 20 times the number of reported deaths** (EU: 11 vs. 0.63 = 17-fold increase; CH: 15 vs. 0.63 = 23-fold increase; USA: 20 vs. 0.63 = 31-fold increase).

431 None of these are marginal, tolerable deviations in the low percentage range, but deviations that are alarming in every respect. In November 2021, it once again became clear to everyone that the **"temporary" approvals** were **devastatingly wrong decisions**.

3.1.9.4 Selected side effects: Heart problems, thromboses, deaths, stillbirths [ER N 671 ff].

432 A more detailed analysis of all adverse reaction reports for Comirnaty and Spikevax - broken down by symptoms such as cardiac disorders (myocarditis etc.), coagulation disorders (thrombosis etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **November 2021:**



433 The tendency towards **comparatively higher reporting rates** regarding "heart" and the double to triple higher reporting rates regarding deaths **in the USA** are already striking here. Whether these differences are population- or reporting-related would need to be investigated more closely. Under no circumstances, however, should a Swiss regulatory authority ignore conspicuously higher reporting rates in the USA and also in individual EU countries - on the contrary: with regard to its mandate to protect public health, these figures are just as important as the figures in Switzerland, as the same "vaccine" substances are involved in all countries.

434 As early as November 2021, adverse event reports in the USA regarding **cardiac disorders (myocarditis/pericarditis** etc.) were 84 (Comirnaty) to 99 (Spikevax) per 1 million "vaccine doses". The USA had therefore made massive "corrections" in this area in particular, as **originally** (see first version of the present criminal complaint, N 298) there were **109.2 reports per 1 million doses of Spikevax**, which meant that these were **"rare" side effects**. Due to the "correction" to (very) just under 100 reports, these are now officially only **"very rare" side effects.** However, Swissmedic's information for healthcare professionals does not reflect this considerable risk (see N 1199).

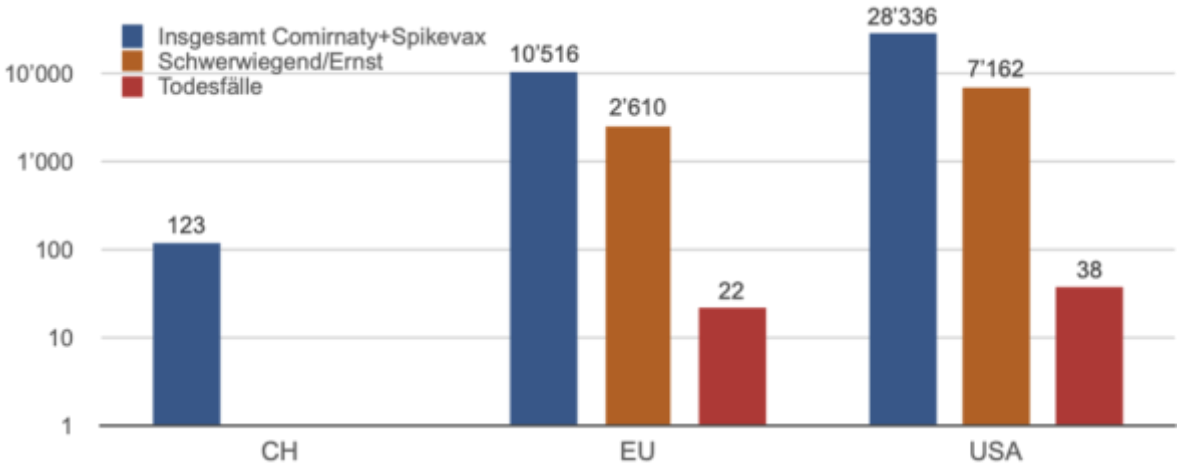
435 Even then, the reports of coagulation disorders, which ranged from 30 to 55 cases per 1 million doses worldwide, were worrying. The official data worldwide was therefore in a range that could clearly be compared, measured and estimated. There were 0.3 to 0.55 cases per 10,000, which means that the **coagulation disorders** were classified **as "very rare" side effects (<1/10,000).** However, Swissmedic's information for healthcare professionals does not reflect this considerable risk (see N 1199).

436 It is very striking that the number of **deaths reported in Switzerland has** suddenly halved to 15 (previously: 31) per 1 million doses. In addition to effectively fewer deaths, possible reasons for this could be the increased number of "preliminary tests" carried out by Swissmedic (see N 446) or a change in reporting behavior (see also N 447 et seq.).

437 In contrast, there has been an increase in **stillbirths in** the USA over the same period and stillbirths are now also listed in the EU. As far as our work is concerned, there is no corresponding information in Switzerland. Based on the international data, it is now clear that the presumed increased risk potential for pregnant women (see N 235 ff.) had already been impressively realized.

3.1.9.5 In particular: Side effects in children [ER N 701 ff].

438 By December 17, 2021 in Switzerland and by December 11, 2021 in the EU and the USA, a total of **38,975 adverse reactions** were reported in **children** (including adolescents) - including **9,772 serious** adverse reactions and **60 deaths:**



439 This means that the **alarm value of 50 deaths** was already **clearly exceeded** in children alone at the time of the extension of approval from the age of 5 in December 2021**.** If you consider that not a single child in Switzerland was proven to have died from COVID-19, there was no justification for the extension of the authorization.

3.1.9.6 Interim conclusion

440 As an interim conclusion, it can therefore be stated that nationally and internationally, **the reported side** effects at **the end of 2021 had reached an unprecedented level** - even though massive underreporting can be assumed in all countries due to the purely passive reporting system:

3.1.10. Massive underreporting in general [ER N 704]

441 The worldwide passive reporting systems have one thing in common: the reports are not automated or systematic in any way. Rather, the reports depend on the knowledge and awareness that an observation could be an adverse reaction and on the willingness of those involved to go to the effort of reporting in the first place. This leads to massive underreporting:

3.1.10.1 Studies on (worldwide) underreporting: only 6% reporting rate [ER N 705]

442 As early as 1991, it was estimated that with passive reporting systems, only around 5% of all side effects are reported at all. A peer-reviewed study from 2012 confirmed this estimate: 37 studies on the underreporting of side effects from 12 countries were analyzed. The study found that **only 6% of all actual adverse drug reactions were reported.**

443 **The problem of global underreporting in passive reporting systems has therefore long been a general problem.**

3.1.10.2 USA: Under 3% of all side effects reported [ER N 706 f.].

444 This is also confirmed by analyses from individual countries: In the USA, for example, according to a Harvard study from 2010, just 1% of all adverse reactions are reported to the *VAERS* vaccination adverse reaction database. More recent studies have come to a similar conclusion for mRNA "vaccines": due to underreporting, **all registered serious adverse reaction reports** would have to **be multiplied by a factor of at least 41 to reflect reality** (which corresponds to an effective coverage of 2.43%).

3.1.10.3 Switzerland: Reporting rate is 50% of the reporting rate in Germany [ER N 708 ff.].

445 A comparison of Switzerland with Germany also leads to the conclusion that the reporting rate here is likely to be even worse than in Germany: While a reporting rate of 1.7/1000 "vaccine doses" can be seen in Germany, this **reporting rate in Switzerland is just 0.8/1000 doses, i.e. half as much.**

446 One possible reason for this massive underreporting in Switzerland could be that Swissmedic claims to carry out a "preliminary check". Other countries also check the meaningfulness of the reports - but nevertheless publish the total number of reports. **Swissmedic only publishes suspected cases of adverse reactions that it has approved following the preliminary review.** In the interests of transparent communication, it is in no way

comprehensible why Swissmedic does not also publish the total number of suspected adverse drug reactions.

3.1.11. Underreporting of deaths: No "vaccine" deaths without autopsies

3.1.11.1 International warnings and calls to carry out more autopsies [ER N 715 ff].

447 Another serious problem of underreporting is the widespread **lack of autopsies:** From May to August 2021, professors across Europe had already warned that there was a large number of unreported cases regarding a causal link between the COVID "vaccination" and deaths that had occurred in a temporal context. Accordingly, they called for an autopsy to be mandatory for deaths in a temporal connection with the "vaccination".

448 The demand was not heard: for example, **by the end of September 2021, fewer than ten people who** died in connection with the "vaccination" had **undergone autopsies** at **Zurich University Hospital.**

3.1.11.2 Own investigation: Too few and unsuitable autopsies (Canton of Zurich) [ER N 720 f.].

449 A specially conducted "Analysis of 15 deaths" **(Appendix 5)** in the periods from February 2021 to June 2021 and December 2021 to mid-January 2022 (plus two further deaths outside these periods) confirms this misguided approach:

450 In a total of five deaths during the two periods mentioned, in which **explicit references** were made by the police to "vaccinations" (e.g. "vaccinated the day before", "vaccinated 10 days ago"), no autopsy was ordered by the responsible public prosecutor's office. Moreover, it is particularly disturbing that in two cases it was even stated that the **"cause of death** was **unclear"** and **in one case a post-mortem was not ordered by the public prosecutor, contrary to the assessment of the cantonal doctor**.

451 It is also incomprehensible why, outside of the above-mentioned periods, the police have not provided any information about COVID "vaccinations", although in at least two cases (September 2021 and April 2022) it is known from their own investigations that the deceased were "vaccinated". **The police investigation of the "vaccination status" is an indispensable prerequisite for the decision to carry out a post-mortem examination.** This clarification must be carried out systematically. On the contrary, however, it can unfortunately be observed that this clarification is omitted - there is hardly any other explanation for the

abrupt refusal to report "vaccination" information by the police from June 9, 2021 and from January 16, 2022 despite two deaths with "vaccinated persons" according to these dates.

452 Of the 15 unusual deaths, an autopsy was ordered in eight to nine cases. Only one autopsy result of a 20-year-old woman is known in more detail: The result of the autopsy performed was recorded as "bleeding to the inside with rupture of the spleen" following infection with Epstein-Barr virus (EBV). Over 90 percent of people become infected with EBV in the course of their lives, usually without symptoms and mostly without consequences. Life-threatening complications such as respiratory distress or rupture of the spleen are rare. If such a rare event occurs, the chance of survival is 85-95%. In the case of the very young patient, an accumulation of unfortunate circumstances must have contributed to her effective death from this diagnosis. The link between a higher incidence of EBV infections and the COVID "vaccinations" has now been documented in several publications.

453 It is explosive that the young woman had **already** received **two injections of Spikevax** in 2021 **and a "booster" with Comirnaty in spring 2022**. **This fact was neither clarified in detail by the police or the public prosecutor's office, nor was it examined in detail by forensic medicine.** Rather, the expert opinion of the Institute of Forensic Medicine stated in a brief note that there was "no connection" from a forensic medical point of view. It was also added: "Furthermore, it should be noted that, given the high COVID-19 vaccination rate in the [institute's] catchment area, if there were a causal link between COVID-19 vaccinations and spleen ruptures, an increase in such spleen ruptures would have to be observed, but this is not the case."

454 To summarize: There is a strong suspicion that **the police and public prosecutor's office omit relevant evidence of "vaccinations" and thus of a possible link between "vaccinations" and deaths, which means that in many cases forensic investigations are not even carried out. And in the few forensic examinations that are nevertheless carried out, a causal link is not even clarified because it is not considered plausible from the outset due to the small number of cases admitted.** The cat is obviously biting its own tail. There could not be a more obvious demonstration of how research and evidence of possible connections are - intentionally or unintentionally - being prevented.

455 The responsible law enforcement authorities would have every reason to carry out post-mortems: **Various causes of death (namely poisoning etc.) cannot be uncovered without an autopsy.** Accordingly, if a demonstrably toxic, experimental and in no way properly authorized substance has been injected into the body of a deceased person, **this must necessarily result in a post-mortem examination to clarify the exact cause of death.**

In the case just described (front N 452 f.), **a supplement and improvement of the forensic medical report** was **ordered at the request of the private plaintiff** (see N 96).

3.1.11.3 Own investigation: Too few and unsuitable autopsies (Canton of Berne) [ER N 722 f.].

456 The same picture emerges from a further analysis of unusual deaths in the canton of Berne (**Appendix 12**):

457 In the 10 cases investigated, there were only four cases in which any evidence of coronavirus "vaccinations" was recorded. In one case, a post-mortem was **not carried** out, although the **cause of death was** openly stated as **"unclear"** after legal inspection and it was known that the **deceased had received the "booster" just 10 days before his death.** In another case, a post-mortem was carried out and it was even found that there were **"various discolorations/calcifications in the heart".** Nevertheless, the body was released immediately, although at that time the **problem of myocarditis/periocarditis as a result of mRNA gene therapies** had long been generally known and investigations in this direction should have been carried out. Other cases have in common that in each case the **cause of death was** recorded as **"unknown",** "an unknown natural internal event" or similar. Even possible - but obviously not further investigated - causes such as **"cardiovascular arrest"** or **"heart attack"** were noted. Although these causes of death in particular can be attributed to mRNA gene therapies, no clarification of the "vaccination status" can be found in any of the cases and in each case the body was released immediately without a post-mortem examination.

458 This approach by the public prosecutor's office is in no way comprehensible, coincides with the behavior of the public prosecutor's office in Zurich and proves to be inadequate in several respects:

- There is **no systematic police investigation of the "vaccination status".**
- "Unclear" or "sudden and unexpected" deaths are not investigated in any detail, and a possible connection with the "vaccinations" is not even raised.
- **Despite the discovery of a "vaccination", the public prosecutor's office does not systematically order an autopsy,** although this should be mandatory due to the "unusual substance" administered as part of medical treatment, which can lead to internal damage to the body.
- **Forensic medicine only investigates superficial causes of death.**

3.1.12. Children and adolescents: No risk of disease, massive "vaccination" risk

459 **Children and adolescents are demonstrably not at risk from SARS-CoV-2** (see N 750 ff., in particular N 762 and N 772 f.), a "life-threatening or disabling disease" for the entire target population of minors clearly does not exist. Nevertheless, the "vaccines" were approved worldwide - with absolutely unacceptable consequences for the youngest and weakest members of our society:

3.1.12.1 Deaths of children and adolescents [ER N 724 ff.]

460 Previously (N 438 f.) it was explained that the **alarm value of 50 deaths was clearly exceeded** at the time of the extension of the approval from 5 years.

461 According to a report by the German *Paul Ehrlich Institute* (*PEI),* **8 children and adolescents** died in Germany **between 2 days and 5 months apart in connection with the COVID "vaccination"** as of December 31, 2021. **In 6 of these 8 cases, a causal link with the "vaccination" has not yet been disproved.** This means that children who were demonstrably in no way at risk from SARS-CoV-2 died and are therefore presumably dying as a **result of mRNA therapy.**

3.1.12.2 Appropriate response to an alarm signal: Stop approval for as few as 15 cases with side effects [ER N 727 ff].

462 **The fact that these deaths - given the lack of danger of SARS-CoV-2 for minors - did not lead to the immediate withdrawal of worldwide approvals is in no way comprehensible.**

463 A comparison: In July 1999, on the recommendation of the American *Centers for Disease Control and Prevention* (*CDC*), the rotavirus vaccine for infants was suspended. This was preceded by just **15 reports** to *VAERS* of intestinal obstructions (which can in principle be life-threatening, but usually heal without complications if treated early) in vaccinated infants. At the same time, rotavirus, which causes vomiting and severe watery diarrhea, is responsible for 20-40 deaths and more than 50,000 hospitalizations annually in the US alone.

464 **15 Reports of mostly reversible side effects therefore led to the immediate suspension of approval,** even though the disease to be treated (rotavirus) is potentially serious for the target population and may be associated with hospitalization. With the mRNA "vaccinations", the opposite is true: even deaths in the target population as a result of "vaccination" did not lead to an immediate suspension of approval, even though the target population is not threatened by a life-threatening or disabling disease and the efficacy of the "vaccinations" has not been proven in any way.

3.1.12.3 Interim conclusion: alarm values long exceeded

465 Although **children and adolescents** are **demonstrably not at risk from SARS-CoV-2** and although **the number of vaccine-related deaths (and side effects) worldwide had long since reached critical levels in this age group alone** and had probably far exceeded them, Swissmedic granted approval for the childhood "vaccinations" and downplayed the consequences of myocarditis/pericarditis (see N 1199; see also N 1191 and N 1192). An immediate revocation of the temporary authorization - at least for children - would have been the only correct consequence in order to meet the strict requirements of the Swiss Therapeutic Products Act (in particular Art. 1; 3 para. 1 and 9a TPA) for the protection of public health.

466 The consequences of myocarditis/pericarditis are discussed in more detail below:

3.1.13. Alarm signal: myocarditis [ER N 730 ff].

467 As before (N 432 ff.), myocarditis is generally one of the most frequently reported suspected adverse drug reactions. However, the frequency in children and adolescents is particularly striking: By September 2021, so many cases of **myocarditis/pericarditis had** already been officially reported in the EU that it **ranked second among serious adverse reactions** and **seventh among adverse reactions with a fatal outcome.** As of August 30, 2021, the US *CDC* reported a risk of myocarditis **of 71.5** for males aged 16-17 years after the 2nd dose of **Comirnaty and 31.2 for Spikevax per million doses administered.** According to official *FDA* data, the risk of myocarditis after the 2nd "vaccination dose" was thus increased by a factor of 2.3 with Comirnaty compared to Spikevax.

468 But even these figures were far too low: the *CDC* corrected its own figures massively upwards in August 2022: according to **Comirnaty**, the incidence of **myocarditis/pericarditis in the** same age group was **137.1 cases per 1 million "vaccine doses" administered - twice as high as previously stated.**

469 In severe cases, the fatal outcome is a matter of time: the **damage to the heart muscle is permanent** and leads to a massively increased mortality rate for those affected in the years that follow. **Based on earlier studies, it must therefore be assumed that between 7% and 55% of young people affected could die before the age of 30.** These possible deaths are therefore not yet reflected in the statistics. However, it should be noted that there is currently no clear picture of whether and, if so, to what extent "vaccine" myocarditis differs from "classic" myocarditis, such as that caused by viruses. This would also have to be investigated in detail - until a difference is proven, it must therefore be assumed that the (fatal) consequences of "vaccine" myocarditis are the same as those of "classic" myocarditis.

470 This massive danger from the "vaccination" is disproportionate to the "danger" posed to young people by SARS-CoV-2 (see N 764). Accordingly, a study from August 2021 concluded that **teenagers are six times more likely to suffer from heart problems caused by the COVID "vaccine" than the likelihood of a severe course of COVID disease. In particular, it should be noted that there is still no evidence that myocarditis/pericarditis poses an equally relevant risk for unvaccinated adolescents. Such proof would have had to be provided by the manufacturers.**

471 In view of this devastating risk-benefit balance, Swissmedic announced in August 2021 that **"there could at least possibly be a causal link between COVID-19 mRNA vaccines and myocarditis or pericarditis."** In October 2021, various countries (such as Denmark, Sweden, Norway, Finland and Iceland) at least suspended the use of Spikevax for young adults - but instead recommended Comirnaty as a second dose in under-30s. In November 2021, the "vaccination" of under-30s with Spikevax was also suspended in Germany and France.

472 Despite the obvious - and in the worst case fatal - danger of myocarditis/pericarditis, Swissmedic continued to reassure the public in November 2021, stating, for example, that **the clinical course after drug treatment was usually "mild".** In addition, the cases registered in Switzerland indicate massive **underreporting** compared to other countries. Swissmedic's communication on the subject of myocarditis/pericarditis remained trivializing, with Swissmedic concealing the true risks and long-term damage in particular.

3.1.14. Pregnant women: Inadequate risk management and realized risk

3.1.14.1 Data still missing [ER N 759]

473 As before (N 235 ff.), the sparsely conducted animal studies indicated possible malformations, which made the blind approval for pregnant women a high-risk project. One would expect that this major risk would be adequately addressed. But the opposite was the case:

474 At the end of 2021, Pfizer submitted a consent form dated December 15, 2021 to the participants of a Comirnaty study with the following passage: **"The effects of the COVID-19 vaccine on sperm, pregnancy, a fetus or a nursing child are not known."**

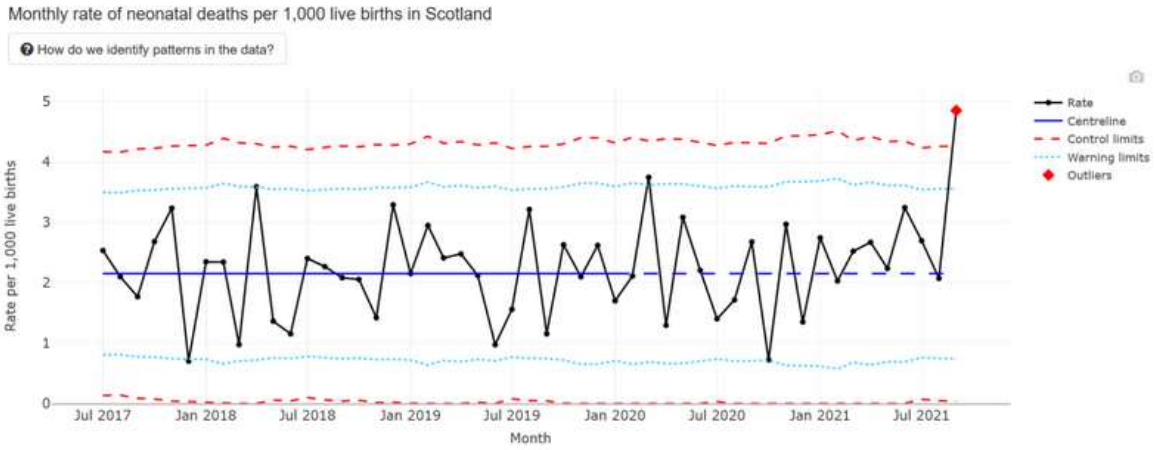
3.1.14.2 Manufacturer data: Multiple stillbirths in pregnant women [ER N 760 f.].

475 However, there was no complete lack of data: Pfizer disclosed in the "*Post Marketing Pharmacovigilance Report*" that in the first 2.5 months after market approval alone, 270 pregnant women reported side effects in connection with Comirnaty: **23 cases involved abortion,** two cases involved premature birth with subsequent death of the child, two cases involved

intrauterine death (death of the child in utero), in five cases the outcome of the case was pending, and in 238 cases "no information" was available.

3.1.14.3 Scotland: Massive increase in neonatal mortality [ER N 762 ff].

476 In Scotland, there was a sudden increase in neonatal mortality in September 2021. There were 4.9 stillbirths per 1,000 births - an enormously high figure not seen since the late 1980s.

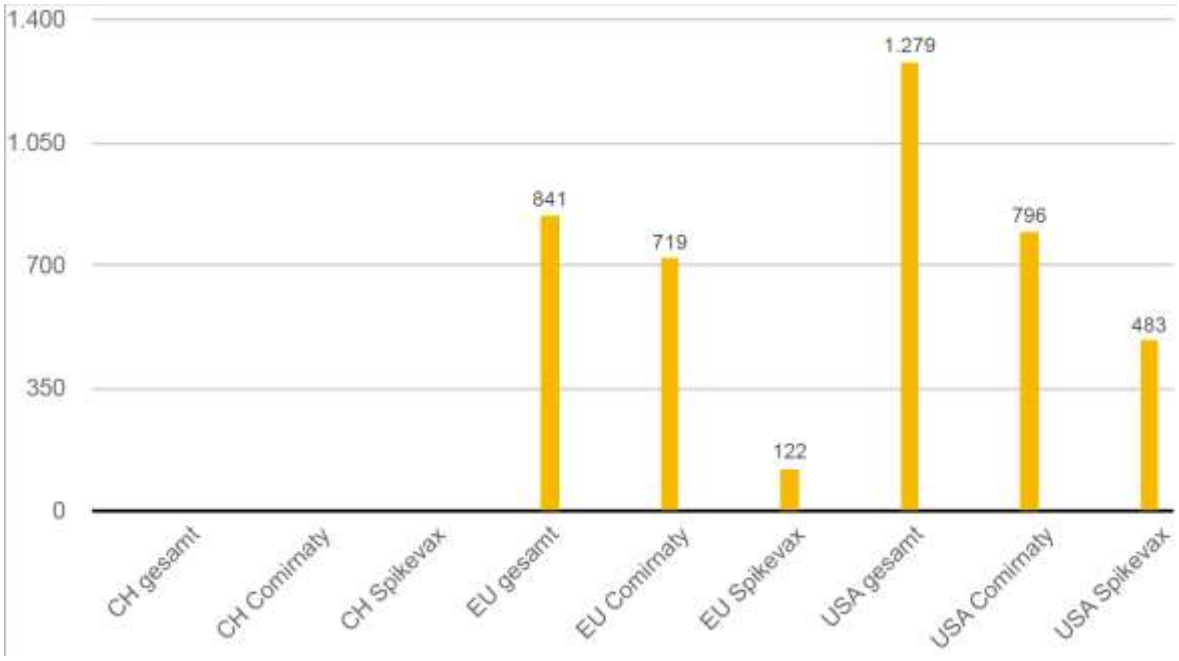


3.1.14.4 Utah: Miscarriages up 12 percent after fertility treatment [ER N 765]

477 A report by the *Health Independence Alliance showed* that the miscarriage rate at a large fertility clinic in Utah rose from 28 to 40 percent since the introduction of the COVID "vaccination", which corresponds to an absolute increase of 12 percent.

3.1.14.5 Thousands of stillbirths worldwide [ER N 766 f.].

478 As of December 11, 2021, **over 2,000 stillbirths** have already been reported in the EU and the USA in connection with the mRNA "vaccines" Spikevax and Comirnaty:



479 As far as can be seen, no figures are available for Switzerland. Even when this data was published, it must have been clear to the licensing authority that these figures only represented the "tip of the iceberg". On the one hand, due to the massive underreporting (see N 612 ff.), on the other hand due to the fact that pregnancies generally last nine months, which inevitably goes hand in hand with a delayed reporting rate.

3.1.14.6 Breastfeeding mothers: Spike protein and LNP with mRNA in breast milk? [ER N 768 ff.]

480 In addition, there is another problem: components of the mRNA "vaccines" are probably not only passed on to unborn babies in the womb, but presumably also to infants via breast milk. There is a strong suspicion that the toxic spike protein and toxic lipid nanoparticles (LNP) pose a risk to newborns who are breastfed by vaccinated mothers. A study involving just eight mothers, which was intended to disprove such transmission via breast milk, is not very valid due to the small number of participants and the improper storage of breast milk. This risk is also real and legally relevant, which is why it should have been addressed appropriately long ago.

481 In September 2022, a further study was published in which mRNA was detected in the breast milk of 5 out of 11 "vaccinated" breastfeeding mothers (Comirnaty n=6, Spikevax n=5), once again clearly confirming the existing risk.

3.1.15. Correlation of "suspected cases" of side effects with COVID-19 mRNA injection

3.1.15.1 Disproportionate increase in side effects [ER N 772 ff.].

482 At the end of 2021, there were already a large number of indications that the many suspected cases reported were actually deaths and serious injuries caused by the mRNA "vaccines". In advance, of course, purely due to the unprecedented number of cases - which in reality are likely to be many times higher due to the massive underreporting.

3.1.15.2 Close temporal connection between "vaccinations" and adverse event reports [ER N 775 ff.].

483 New Zealand has reported that **overall mortality in the over-60s correlates with the administration of the COVID "vaccine" in this age group.**

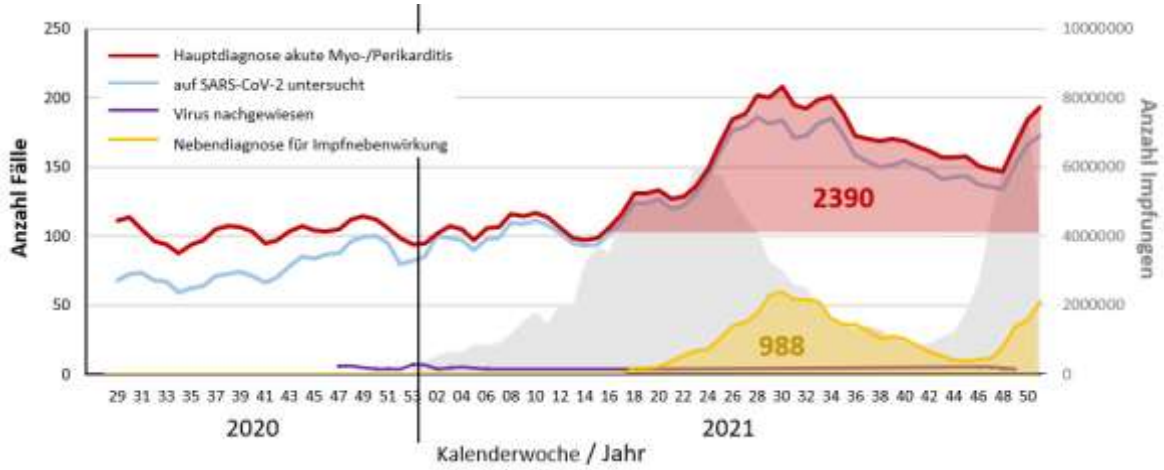
484 In the EU, comprehensive studies have shown that there is effectively a **close temporal relationship** between the administration of the mRNA "vaccines" and the side effects that have occurred. An analysis of more than 7.8 million adverse reaction reports (from 1.6 million people affected) from the *EudraVigilance* and *VAERS database* from October 2020-October 2021 showed **that in 77.6-89.1% of cases, serious adverse reactions occurred within seven days of 'vaccination' .**

485 Another study, which took into account *EudraVigilance data* up to August 29, 2021, came to a similar conclusion: **of 13,801 reported deaths, 61% occurred in the first two days after the "vaccination".** Most of the serious side effects (such as cardiac arrest and thrombotic events) also occurred early - usually in the first four to five days after the "vaccination".

486 The fact that there is a fundamentally close temporal connection is also confirmed by a study from Israel published in 2022, according to which there was a **25% increase in emergency calls for cardiac arrests among the 16 to 39-year-old population** (back N 683).

3.1.15.3 Delayed connection between "vaccination" and hospitalizations [ER N 786 f.].

487 An analysis carried out in Germany also revealed that there is also a temporal, albeit slightly delayed, correlation between administered mRNA "vaccines" and hospitalizations due to myo-/pericarditis:



488 The increases in myo-/pericarditis cases fall in those calendar weeks in which the most "vaccine doses" against COVID-19 (gray shaded area) were administered: On the one hand in summer 2021 for the (first and) second "vaccinations" and then in fall 2021 for the "booster". However, it should be noted that the number of cases remains high even weeks after the number of "vaccinations" fell in late summer. This **long-lasting increase in the number of myo-/pericarditis cases reinforces the suspicion that the side effects can also occur weeks after the "vaccination"**.

3.1.15.4 Further indications of a temporal connection between mortality and hospitalizations

[ER N 788 ff.].

489 Worldwide, there was also increasing evidence in 2021 of a temporal link between "vaccination" and side effects:

490 In the US, a large-scale study of data from 145 countries concluded that the COVID-19 "vaccines" must be linked to higher rates of COVID-19 infections and COVID-19-related deaths. **In the US, the "vaccines" were specifically linked to a 38% increase in COVID-19 cases and a 31% increase in COVID-19-related deaths.**

491 US life insurers also reported that the **mortality rate for non-COVID-related deaths among working-age people aged 18 to 64** had **increased by 40% compared to the pre-pandemic period**.

492 The situation was similar in Germany with regard to children and adolescents: According to the *RKI*'s "Emergency Department Situation Report", **emergency admissions to hospitals in the 0 to 19 age group** had **more than doubled by** December 1, 2021 compared to January 2021**:**

3.1.15.5 Australia: Compensation for myocarditis and other side effects [ER N 791 f.].

493 In December 2021, the Australian government recognized in principle the existence of a causal link between the mRNA "vaccines" and side effects such as severe allergic reactions, **myocarditis/pericarditis** or Guillain-Barré syndrome: it launched a **program to compensate those affected.**

3.1.16. Switzerland: Conspicuous mortality in younger age groups [ER N 793]

494 A worrying trend was already evident for 2021, which will continue in 2022 (see N 663): Prof. Beck's in-depth analysis of the *BfS data using* a robust methodology revealed a **conspicuous and persistent death rate in younger age groups in close temporal relation to "vaccination activity"** (back N 765 and N 774).

3.1.17. Studies on heart problems, coagulation disorders and deaths [ER N 794 ff].

495 By October 26, 2021, the previously (N 374), which indicate a connection between the COVID "vaccines" and the side effects, many more studies were added: A total of at least **84 peer-reviewed publications on heart problems, 129 peer-reviewed publications on life-threatening coagulation disorders (thrombosis, etc.) and 3 peer-reviewed publications on possible deaths as a result of COVID "vaccinations" have** already appeared. Narrowed down to the **Comirnaty and Spikevax** mRNA "vaccines", there were 80 publications on heart problems, 38 publications on life-threatening coagulation disorders

(thromboses, etc.) and **3 publications on possible fatalities.** Even at that time, the available studies alone were a considerable cause for alarm.

496 In view of this flood of scientific studies, no one could seriously claim from this point onwards that the mRNA "vaccines" were not at least strongly suspected of causing serious side effects, including death.

497 All this information was available to the Swiss therapeutic products regulatory authority Swissmedic. They were and are of particular legal significance for the fulfillment of its basic legal mandate - the protection of public health from harmful medicinal products - which is why these facts must also be assumed to be known by Swissmedic.

3.2. Effectiveness

3.2.1. First and second "vaccinations": Updated and missing data [ER N 807]

3.2.1.1 Minimal therapeutic benefit for merely trivial events [ER N 808 ff].

498 Based on extremely reduced 6-month data (data from only 7% of the study participants were actually available over a period of 6 months), it was stated in the *NEJM (New England Journal of Medicine)* on November 4, 2021 regarding **Comirnaty that** although the **efficacy** was not 95% as originally stated, it was still a high **91.3%.** This calculation was again based on the RRR method, which - as before (N 300 ff.) - is in no way able to accurately represent the effective efficacy.

499 By the end of 2021, there were apparently still no new efficacy data available for Spikevax, which is very surprising after one year of "authorization": These must always be kept up to date with the latest scientific findings (Art. 28 TPO) and data on efficacy (and risks) must be submitted continuously by the authorization holders and reviewed by Swissmedic, particularly in the "rolling authorization procedure".

3.2.1.2 No proven therapeutic benefit for "serious" diseases [ER N 813 ff].

500 While, according to official data, the efficacy of Comirnaty is said to have decreased for minor events, a new efficacy of 96.7% was published for "severe" illnesses instead of the originally stated efficacy of 66.4%. This seems paradoxical even without consulting the underlying data: it is not rationally explainable why the efficacy of Comirnaty should have deteriorated in "confirmed COVID diseases" but improved significantly in "severe COVID

diseases". The efficacy claim of 96.7% also lacks any scientific basis: According to "6-month data", **1** "severe COVID cases" were reported for the vaccine group and **30** "severe COVID cases" for the placebo group, resulting in **96.7%** according to RRR. As already explained above: **With a total of 31 cases out of originally over 40,000 study participants, one is obviously in the realm of statistical chance. It is dubious, unscientific and misleading to infer an efficacy of 96.7% from these 31 cases.** The relevant absolute risk reduction (**ARR) is** just **0.1%.**

501 No new data was available for Spikevax under this title until the end of 2021.

3.2.1.3 International data: Effectiveness falls into the negative range [ER N 818 ff].

502 The fact that the manufacturers' claims have little in common with reality was impressively demonstrated over the course of 2021: mRNA therapy did not protect against infection with SARS-CoV-2, nor did it protect people from severe cases. It was even shown that the **"vaccination rate**" - despite the decreasing danger of SARS-CoV-2 - **correlated positively with COVID-19 infections and associated illnesses and deaths.** For example, 72.5% of patients hospitalized for COVID-19 in England and Scotland were "vaccinated" in December 2021. If the mRNA injections actually protected against severe cases, a different ratio would of course be expected.

503 Accordingly, several studies, even using the RRR, came to the conclusion that the supposedly almost 100% **effectiveness** fell to 64% or 37%-55% after a short time and was ultimately still **a meagre 23%.** The originally propagated "years-long" or even "decades-long" protection also quickly proved to be completely misleading information, which became obvious only because of the alleged "necessity" of "booster vaccinations".

3.2.1.4 No protection against transfer [ER N 832 ff].

504 What Swissmedic already knew at the time of authorization (see N 309 f.), the *EMA* confirmed in 2021 in corresponding "Assessment reports" on Spikevax and Comirnaty: the **effect of the mRNA injection on the spread of the SARS-CoV-2 virus in the population is simply not known.**

505 In Switzerland, Ms. Virginie Masserey, head of the Infection Control Section of the *FOPH,* confirmed on 3 August 2021 in response to a corresponding question that "vaccinated" people are just as infectious as "unvaccinated" people ("that a vaccinated person who becomes infected is just as infectious as an unvaccinated person who becomes infected").

The mRNA injections were therefore simply unsuitable for breaking the chain of infection.

3.2.1.5 Interim conclusion: Pure fantasy figures of the manufacturers [ER N 837 f.].

506 The allegedly high effectiveness of COVID "vaccinations" is not supported by the approval studies and the observations based on them. **No proof of protection against transmission has ever been provided.**

507 According to international data, the effectiveness of COVID "vaccinations" also tended towards zero after a short time. Analogous to conventional vaccines, it would be expected that a long-lasting immunization would be achieved after one or two vaccinations - however, the alleged need for "boosters" clearly shows that COVID "vaccinations" will never be able to achieve a lasting immunizing effect, which fundamentally calls their effectiveness into question.

3.2.2. " Booster": Lack of or insufficiently proven efficacy

3.2.2.1 "Booster" planned from the outset [ER N 839]

508 It was originally publicly communicated to the public that "two shots" would be sufficient to immunize against SARS-CoV-2 (and that this would restore freedom). In reality, the "booster" was already planned covertly at the time of the initial approvals. This is what Swissmedic wrote to Moderna in the **approval decision of January 21, 2021**:

> **"Moderna is considering additional booster doses** of mRNA-1273 with ongoing clinical trials to investigate safety and immunogenicity endpoints. As the **duration of protection and the potential need for booster doses** are **unknown at** this time, Swissmedic requests Moderna to keep Swissmedic informed by submitting amended protocols."

509 How a high and implicitly sustainable efficacy could ever have been communicated to the public in good conscience under these circumstances is in no way comprehensible: **Communicating an efficacy of almost 100% to the medical profession and population (which the average addressee equates in layman's terms with a reliable and long-lasting protective effect as with conventional vaccines), while secretly knowing about the lack of protection duration, is simply irresponsible and incompatible with the legal protection mandate of a regulatory authority.**

3.2.2.2 Booster" data situation: Insufficient studies and misleading calculations [ER N 840 ff].

510 In the case of **Comirnaty,** the efficacy of the "booster vaccination" was investigated in three studies. Studies 1 and 2 were in no way able to meet the requirements normally placed on efficacy studies: The first study included just 23 study participants, the second was conducted retrospectively using database analyses. That leaves study 3: In this placebo-controlled study, the incidence of confirmed COVID-19 cases in around 10,000 participants aged 16 and over was investigated in the period from at least 7 days after the "booster vaccination" to the data cut-off date of October 5, 2021, which corresponds to a **very short follow-up period of 2.5 months.** The number of "confirmed COVID cases" was - as in the pivotal studies - in the low percentage range: **6** out of 4,695 **(0.1%)** study participants in the vaccine group and **123** out of 4,671 **(2.6%)** in the placebo group experienced symptoms. Again, a relative effectiveness (RRR) of 95% was proclaimed on the basis of these low figures, **but the absolute risk reduction (ARR) was only 2.5%.** Furthermore, this study lacked any significance with regard to "vaccination" protection for the period after the observation period of 2.5 months.

511 The data situation for **Spikevax** is even poorer: according to the information for healthcare professionals, "only limited data are available on booster vaccination with Spikevax". For example, proof of efficacy was apparently to be provided on the basis of a study with **just 198 study participants. Due to the very small number of participants, none of the studies submitted even remotely meet the most basic requirements for approval under the Swiss TPA.**

3.2.2.3 "Third dose" for immunocompromised patients: No relevant proof of efficacy [ER N 848 ff.].

512 For both COVID "vaccines", a third dose in two small studies (101 and 120 participants respectively) did not lead to increased antibody levels in a not insignificant proportion (32% Comirnaty; 45% Spikevax) of those immunosuppressed as a result of organ transplantation. For both "vaccines", it is not known whether and to what extent an increase in antibodies to SARS-CoV-2 is associated with the prevention of (severe) COVID disease.

513 The data situation for immunocompromised patients is so unclear that this is even expressed in the Spikevax information for healthcare professionals: "The additional dose **could** increase protection in at least **some** patients". For both COVID "vaccines", Swissmedic's information for healthcare professionals also states: "The **efficacy, safety** and immunogenicity of the vaccine have **not been studied** in immunocompromised individuals,

including those undergoing immunosuppressive treatment**."** This is also an obvious **warning signal: instead of simply approving the "vaccination" in the complete absence of data, Swissmedic should have demanded mandatory studies.**

514 It is also irritating that Spikevax only recommends half the dosage (0.25ml corresponding to 50µg mRNA) for the "booster" compared to the first and second "vaccinations" for the general population, but the full dosage (0.5ml corresponding to 100µg mRNA) for immunosuppressed patients, while Comirnaty uses one and the same dose for the basic immunization, "booster" and the third dose for immunosuppressed patients. These differing dosing concepts are inconsistent and incomprehensible from a scientific and medical point of view.

515 In view of all these inconsistencies and information gaps, the approval of the third "vaccination" for immunosuppressed patients is without foundation (see N 1199).

3.2.3. Children aged 5 and over: lack of effectiveness of COVID-19 "vaccination"

3.2.3.1 Minimal therapeutic benefit for minor events [ER N 861]

516 In Comirnaty's pivotal study, "confirmed COVID disease" occurred in **3** out of 1517 (0.2%) 5-11-year-olds in the vaccine group and **16** out of 751 (2.1%) in the placebo group. The absolute risk reduction (ARR) is therefore just 1.9%. In order to prove a "major therapeutic benefit", it would be imperative to expect clearer figures.

3.2.3.2 No data for "serious" illnesses [ER N 862 f.].

517 "Severe" COVID diseases - i.e. those that could meet the requirements for a life-threatening or disabling disease - could not be investigated at all. There was a very simple reason for this: **as with adolescents aged 12 and over, there were no "severe COVID diseases"** among **5-11-year-olds in the approval studies.**

518 Although not a single child was seriously ill with corona in the approval studies, a **"temporary" approval** was granted **for "protection" against corona, which children obviously do not need.** In the absence of corresponding data, it is not even possible to provide any evidence that the "vaccination" has the potential to effectively protect children from a serious (life-threatening or disabling) disease. Evidence of a major therapeutic benefit for the prevention of a serious or disabling disease within the meaning of Art. 9a para. 1 TPA has therefore not been provided even for the age group of children between 5 and 12 years.

3.2.3.3 Conclusion: Negative risk-benefit ratio for children aged 5 to 11 years [ER N 864 ff].

519 The approval studies of Comirnaty show no relevant efficacy in children aged 5 to 11 years. Data from 2020 already showed that children do not become severely ill with COVID-19, generate long-lasting immunity in the event of illness and that they do not expose adults to an increased risk of illness or hospitalization in the event of infection. On this basis, it was therefore already obvious before the temporary approval was granted that COVID-19 mRNA injection could not be associated with any benefit for children.

520 **Since serious risks with serious events and deaths were already apparent in adolescents aged 12 years and older in connection with the use of COVID-19 "vaccines" before authorization was granted for children aged 5 to 11 years in the suspected cases of adverse reactions recorded worldwide, Swissmedic exposed children aged 5 years and older to a high risk by authorizing Comirnaty, since it has been proven that the mRNA injection can only do harm, not good.**

3.2.4. Infection with SARS-CoV-2 protects against re-infection (continued) [ER N 867]

521 In addition to the previously (N 381), **at least another 24 publications and pre-print publications** came to the conclusion by around the end of 2021 that **having undergone the disease generates a broad and long-lasting immune response** or protects against COVID disease at least as well or even better than the "vaccination".

3.3. Interim result (end of 2021): High risk, no effectiveness [ER N 868 ff.]

522 The devastating development, which had already become apparent in mid-June 2021, continued until the end of 2021: tens of thousands of people died in close connection with the administration of the mRNA "vaccines", hundreds of thousands - indeed several million - suffered severe side effects.

523 At the same time, the manufacturers - as shown above - were in no way able to finally provide the necessary evidence for the effectiveness of their "vaccines". On the contrary: they continued to use calculation methods that have nothing whatsoever in common with reality and must even be described as deception. In the absence of suitable proof of efficacy, they manipulated data or had it manipulated by commissioned research institutions. And they also commissioned these same research institutions for future studies. The globally networked regulatory authorities were aware of all this.

524 However, instead of reacting and finally withdrawing the proven ineffective drugs, which are now associated with a long list of serious side effects and deaths and are potentially harmful to genetic material, their approval has been extended in a way that further increases the risk - by now also "vaccinating" children and the entire population for a third time at the end of 2021.

4. Knowledge status Swissmedic from 2022 ("Omikron variant")

525 Even in 2022, all temporary authorizations of mRNA "vaccines" were maintained unchanged, although various other incriminating facts should have long since led to the immediate revocation of the authorization (Art. 16c TPA):

4.1. Risks

4.1.1. Swiss authorities: mRNA injections are gene therapies / *GMOs* [ER N 871 ff.]

526 In 2022, Swiss authorities such as Swissmedic and the FOEN performed a quite surprising U-turn with regard to the classification of mRNA injections - without, however, communicating this sufficiently to the public:

527 In January 2022, Swissmedic established a new department for "Advanced Therapy Medicinal Products" (ATMP), stating that it was "responsible for products and procedures with properties **comparable to gene therapy products**", including **"preparations [...] such as [...] mRNA"**. Swissmedic thus at least recognized the similarity of mRNA injections to gene therapies.

528 The *FOEN* went even further in January 2022, stating that the **combination of mRNA with lipid nanoparticles** led to the assumption of a genetically modified organism **(*GMO*):**

> "However, the mRNA achieves this ability [of cell permeability] through its packaging in a lipid envelope of specific components. The resulting nanoparticle has the necessary cell permeability to carry out the biological activities described.
>
> ***Therefore, mRNA vaccines are biologically active genetic material and are therefore legally equivalent to an organism.*"**

529 In response to a private request, Swissmedic even announced in November 2022, , that it equated mRNA products with *GMOs:*

> "However, **mRNA products are** ATMPs because they contain nucleic acid, regulate gene expression and **are considered 'biologically active material' (i.e. RNA) equivalent to genetically modified organisms (GMOs).** Thus, the vaccines are not defined as therapy, but due to their **classification as GMOs** in the category **Advanced Therapy Medicinal Products** [ATMP]."

530 The classification of mRNA active substances as **genetically modified organisms (GMOs)** or as ATMPs means that, in the present context, both the Genetic Engineering Act and the Release Ordinance (see N 916 ff.) and, moreover, Art. 230bis StGB (see N 1407 ff.) must be observed. In particular, the **classification as a GMO** means that additional (and massively) stricter regulatory requirements would have had to be observed for its authorization in Switzerland (see also ER N 74): According to Art. 12 para. 5 lit. c and lit. e of the **Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Authorization of Medicinal Products and the Authorization of Medicinal Products under the Notification Procedure** (VAZV, SR 812.212.23), "medicinal products containing genetically modified organisms" and "medicinal products for advanced therapies based on gene transfer methods (gene therapy medicinal products)" are **excluded from the simplified authorization procedure** (back N 916 ff.). And according to Art. 6 of the Therapeutic Products Ordinance (TPO, SR 812.212.21), "medicinal products containing GMOs" must meet the requirements of Art. 28 TPO (Release Ordinance; SR 814.911) in addition to those of the Therapeutic Products Act (TPA). An application for authorization in accordance with Art. 28 lit. a-i FrSV must contain, among other things, a comprehensive technical dossier , results of previous closed-system studies with the same organisms regarding hazards or adverse effects on humans, authorisations for release trials and placing on the market, a monitoring plan, a proposal for labelling (Art. 10 FrSV), information for recipients (Art. 5 FrSV) and proof that the safety obligations have been fulfilled (see N 926 f.).

531 If the mRNA injections qualify as *GMOs* according to the concurring statements of the *FOEN* and Swissmedic, a "temporary authorization" should not have been granted at any time for this reason alone (see in detail N 200 ff.). In addition, Swissmedic would have been obliged to inform the public about the qualification as a *GMO* in the technical information, which it failed to do in a misleading manner (see below N 1198 et seq.).

4.1.2. *GMP compliance* still lacking: German chemistry professors concerned about the quality of Comirnaty [ER N 882 ff.].

532 *Good Manufacturing Practice (GMP)* regulations are intended to guarantee that medicinal products are manufactured and controlled uniformly in accordance with internationally

applicable quality standards. In particular, this concerns processes relating to production, quality assurance and batch release. Corresponding standards also apply in Switzerland (N 224; N 1285 ff.).

533 In January 2022, four German chemistry professors were concerned about possible quality defects in Comirnaty - in particular about the color deviation of the mRNA substance from the color specified in the drug text (gray as "diluted black" cannot be explained by any of the specified manufacturing steps). They therefore asked BioNTech by means of a detailed questionnaire how the color difference could be explained and how uniform product quality could be ensured (since quality assurance is difficult in principle with mRNA technology and such a large product volume). The chemistry professors also requested data on the safety of ALC-0315 and ALC-0159 (N 212 ff.) and planned or ongoing studies on them. Finally, they also wanted information on which batches in Germany were associated with which side effects (N 417 ff.).

534 BioNTech's response was superficial and unspecific - it raised even more questions than it clarified. For this reason, the four chemistry professors - now joined by a Swiss colleague - approached the German *Paul Ehrlich Institute (PEI)* on February 11, 2022 with an application for access to documents relevant to the approval process. A comprehensive list of questions was submitted, particularly with regard to Comirnaty's quality assurance.

535 However, both the *PEI and* BioNTech refused access to the requested documents. Only the test methods for the integrity and identity of the mRNA and the information for characterizing the colour and scattering strength of the dispersion were released by the *PEI.*

536 The refusal to release this central data is a **strong indication of the lack of *GMP compliance* of the mRNA injections**. This circumstance reinforces - once again - the serious suspicion that **the production and release of Comirnaty never took place in accordance with valid standards and still does not.**

4.1.3. Side effects at all-time highs worldwide - concealment tactics

537 With all the following figures, it should - once again - be remembered that these are the officially reported side effects. These figures are subject to massive **underreporting** due to the passive reporting systems, which is why the **actual figures** are likely to be **at least five to ten times higher** (front N 441 ff.; back N 612 ff.; at best even 28 times [N 613] up to 41 times [N 444] higher). But even without this correction, the officially reported figures are highly alarming - **and above all, they are generally alarming:**

4.1.3.1 Side effects of all "COVID vaccines" [ER N 896 ff].

538 With regard to all "COVID vaccines" (i.e. including "COVID-19 Vaccine Janssen" or "COVID-19 Vaccine AstraZeneca"), **1.8 million suspected cases of adverse reactions** were reported **across Europe** as of May 6, 2022, 586,363 of which were classified as serious and **24,619 deaths** were registered in connection with a COVID "vaccination".

539 In the **USA, 2.1 million suspected cases** of adverse reactions, 155,633 hospitalizations and **27,968 deaths** associated with a COVID "vaccination" were reported for all COVID vaccines as of May 6, 2022.

540 In Switzerland, Swissmedic reported **15,228 cases of evaluated adverse reactions** as of May 2022. Around **38% of** these cases were classified as **serious.** In **210** cases, **death was reported "at varying intervals after vaccination"**, but other more probable causes were given as explanations. In November 2022, there were already 227 reported deaths, and by February 2023 this figure had risen further to **236 deaths.**

541 Worldwide, adverse drug reaction reports have thus reached an unprecedented - and absolutely alarming - high. As a reminder: in earlier times, drug approvals were withdrawn or corresponding studies discontinued if only around **50 deaths** (suspected cases) were identified (front N 354 f.). **This alarm value has been exceeded <u>thousands of times.</u>**

4.1.3.2 Concealment tactics of the competent authorities [ER N 904 ff].

542 In order to cover up this unprecedented number of (serious to fatal) side effects, the responsible authorities around the world not only refuse to allow access to basic quality and safety documentation, but also continue to do everything they can to keep the number of side effects as low as possible with all kinds of smokescreens. For example, **post-vac cases** are **quickly reclassified as "long COVID",** although according to the German treatment center "Post-COVID-19 Kids Bavaria", 75% of "long COVID" patients are "vaccinated". The **regular reports on side effects** are also repeatedly changed or ultimately - as with Swissmedic in February 2023 - **stopped altogether**, although the number of reports has continued to rise steadily in recent months. **Deaths continue to be denied** and every effort is made to ensure that no autopsies are carried out or that the corresponding **results** remain **under lock and key.**

543 In addition, the above (N 102) that the *FDA is* trying by all means to delay the release of the manufacturer data from Pfizer and Moderna.

4.1.4. Worldwide adverse event reports for Comirnaty and Spikevax: May 2022

544 Compared to the previous year 2021, the number of worldwide reports of adverse reactions to Comirnaty and Spikevax has increased further:

4.1.4.1 Data situation for May 2022 (CH, EU, USA) [ER N 912 ff.].

545 For information on the subsequent deletion of adverse reaction reports and re-declarations of "vaccine doses", see above (N 335 ff.).

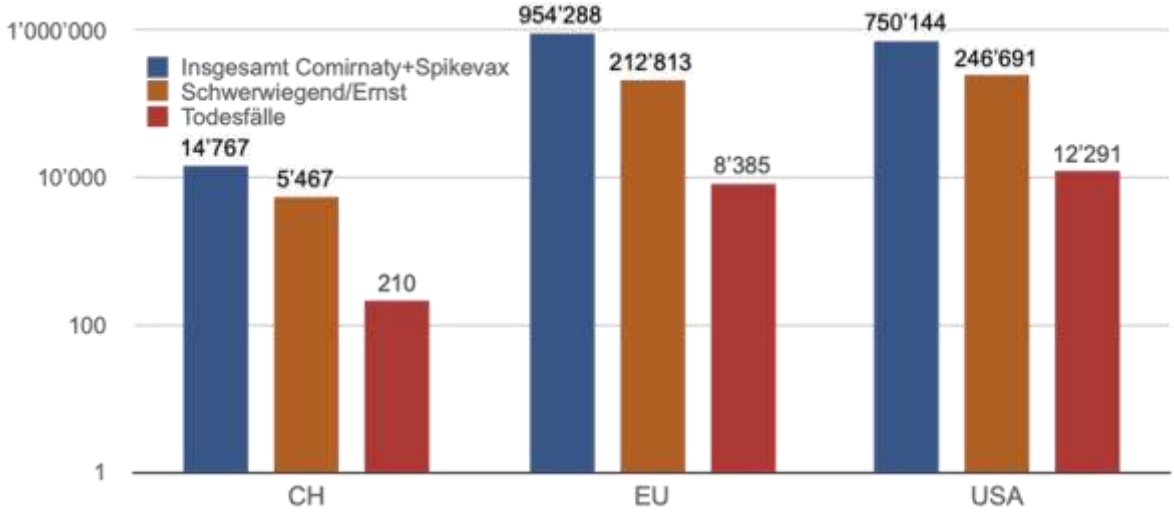
546 Due to deletions/redeclarations (especially in the EU) as well as reference and calculation errors (see notes in the evidence report) in the previous version, the following corrections had to be made for May 2022:

	CH	Kinder (CH)	EU	Kinder (EU)	USA	Kinder (USA)
Comirnaty	nachträgliche Korrekturen sind nicht veröffentlicht		-2.8%	-3.4%	0.1%	0.2%
Ernst Comirnaty			-4.4%	-4.6%	-0.3%	-0.8%
Todesfälle Comirnaty			-5.3%	-10.0%	5.9%	-2.1%
Spikevax			-1.9%	-1.5%	1.5%	0.1%
Ernst Spikevax			-3.6%	-3.7%	1.9%	0.9%
Todesfälle Spikevax			-9.4%	0.0%	12.4%	0.0%
Insgesamt Comirnaty+ Spikevax			-2.6%	-3.2%	0.8%	0.2%
Schwerwiegend/ Ernst			-4.3%	-4.5%	0.7%	-0.8%
Todesfälle			-5.8%	-9.3%	9.0%	-1.8%

547 What is striking is the continuing decline in the EU, particularly in the number of deaths (reduction of 5.3% and 9.4% respectively), while reported deaths in the USA actually increased (increase of 5.9% and 12.4% respectively). The reasons for this **opposing trend** are *still* unknown.

4.1.4.2 Side effects with Comirnaty and Spikevax (absolute numbers) [ER N 922]

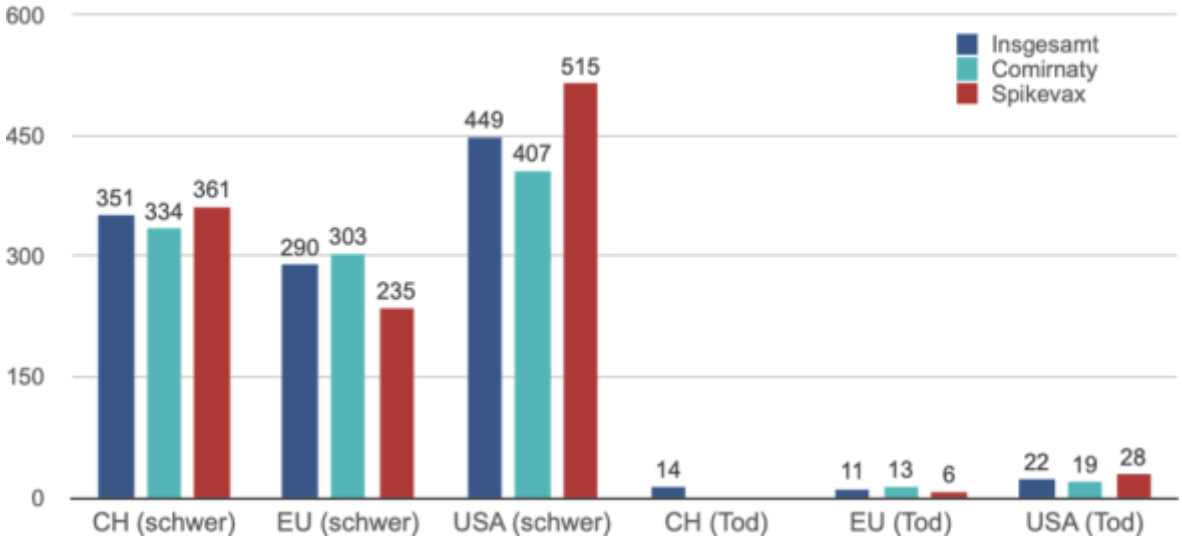
548 The two "vaccines" examined here, Comirnaty and Spikevax, make a significant contribution to the aforementioned catastrophic results. By May 6, 2022 in Switzerland and by May 14, 2022 in the EU and the USA, a total of **1,719,199 adverse reactions** had been reported for Comirnaty and Spikevax - including **464,971 serious adverse reactions** and **20,886 deaths:**



549 Here, too, the **alarm value of 50 deaths has been massively exceeded - by more than <u>400 times</u>.**

4.1.4.3 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses") [ER N 923]

550 **Per 1 million doses administered,** the adverse reaction reports for Comirnaty and Spikevax as of **May 2022 were** as follows:



551 As previously (N 366 ff.), the risk profile of all COVID "vaccines" is downright devastating compared to influenza vaccines, for example:

552 Unfortunately, a comparison of **serious side effects** is admittedly difficult due to different counting methods (in particular the different recording of all serious side effects or only those with permanent damage or hospitalization). However, the picture is very clear: while **0.28 to 3.3** cases of serious side effects are reported per 1 million doses for flu vaccinations,

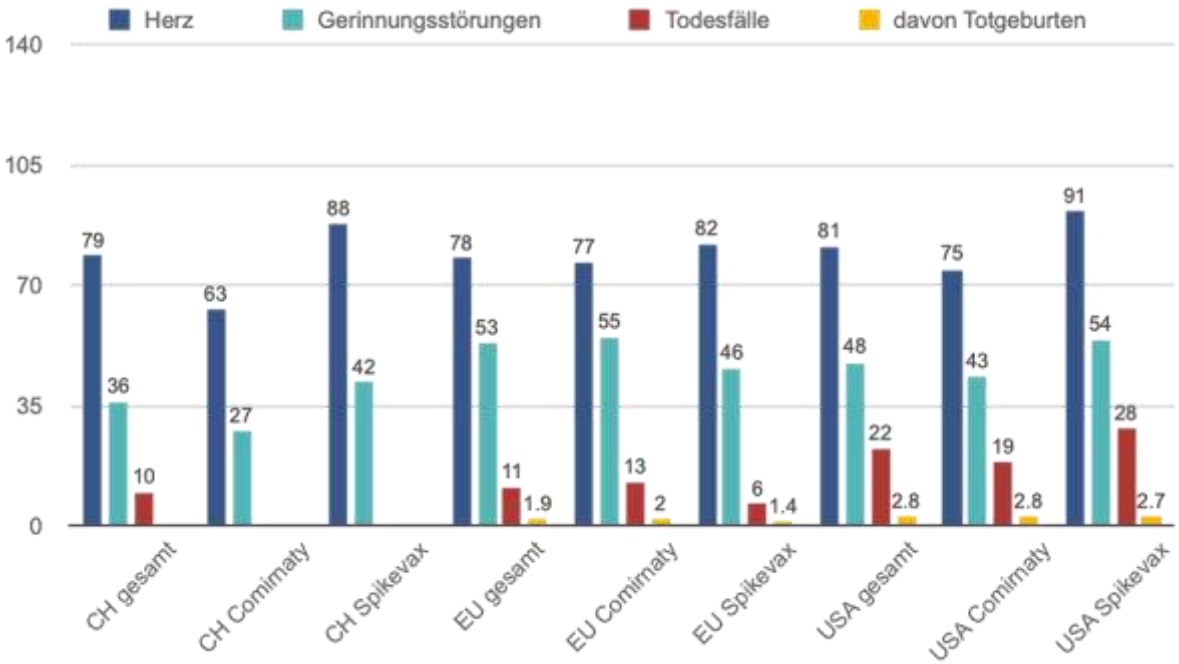
the figure for **Comirnaty / Spikevax as of May 2022** is **290 (EU) to 449 (USA) cases - roughly 100 times the number of serious side effects**.

553 The comparison is simpler due to the same method of counting deaths: While **0.38 to 0.63** deaths per 1 million doses are reported for the flu vaccines, the figure for **Comirnaty / Spikevax as of May 2022** is **11 to 22 cases - at least 20 times the number of reported deaths.**

554 None of these are marginal, tolerable deviations in the lower percentage range, but deviations that are alarming in every respect. **With this devastating result, no - really not a single - drug should be on the market for even one more day.**

4.1.4.4 Selected side effects: Heart problems, thromboses, deaths, stillbirths [ER N 924 ff].

555 A more detailed analysis of all adverse reaction reports for Comirnaty and Spikevax - broken down by symptoms such as cardiac disorders (myocarditis etc.), coagulation disorders (thrombosis etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **May 2022:**



556 Once again, the **reporting rates for deaths in the USA were up to four times higher.** Whether this difference was due to the population or to reporting would need to be investigated in more detail.

557 Striking in comparison to the previous data at the end of 2021 (front N 434), the worldwide harmonization of adverse reaction reports in the area of **cardiac disorders**

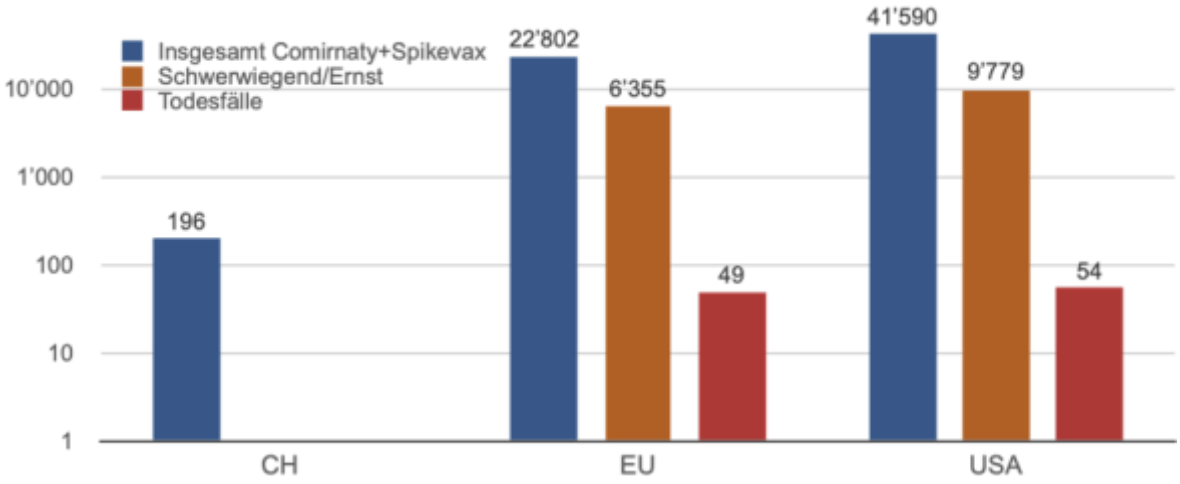
(myocarditis/pericarditis) is also striking**:** It is evident that the reports worldwide are kept in a range of less than 100 reports per 1 million doses, which according to the definition (MedDRA system organ classes) would "only" be **"very rare" adverse reactions** (not: "rare"). However, taking into account the massive underreporting and international studies alone, a far more frequent occurrence can be assumed. A circumstance that is not taken into account in any way by Swissmedic's information for healthcare professionals (see N 1199).

558 The reports of coagulation disorders, which range from 27 to 55 cases per 1 million doses worldwide, were also worrying. The official data worldwide is therefore in a range that can clearly be compared, measured and estimated. There are 0.27 to 0.55 cases per 10,000, which means that **coagulation disorders are** classified **as "very rare" side effects (<1/10,000).** However, the information for healthcare professionals from Swissmedic does not adequately reflect this risk (see N 1199).

559 For more details on the reported stillbirths, see N 636.

4.1.4.5 In particular: Side effects in children [ER N 932 ff].

560 Up to May 6, 2022 in Switzerland and up to May 14, 2022 in the EU and the USA, a total of **64,588 adverse reactions** were reported for Comirnaty and Spikevax in **children** (including adolescents) - including **16,134 serious** adverse reactions and **103 deaths:**



561 This means that the **alarm value of 50 deaths has** already been **doubled** in children alone**.** If you consider that not a single previously healthy child in Switzerland has demonstrably died as a result of COVID-19, the risk of death from vaccination bears no relation to the risk of death from infection with SARS-CoV-2.

4.1.5. Worldwide adverse event reports for Comirnaty and Spikevax: August 2022

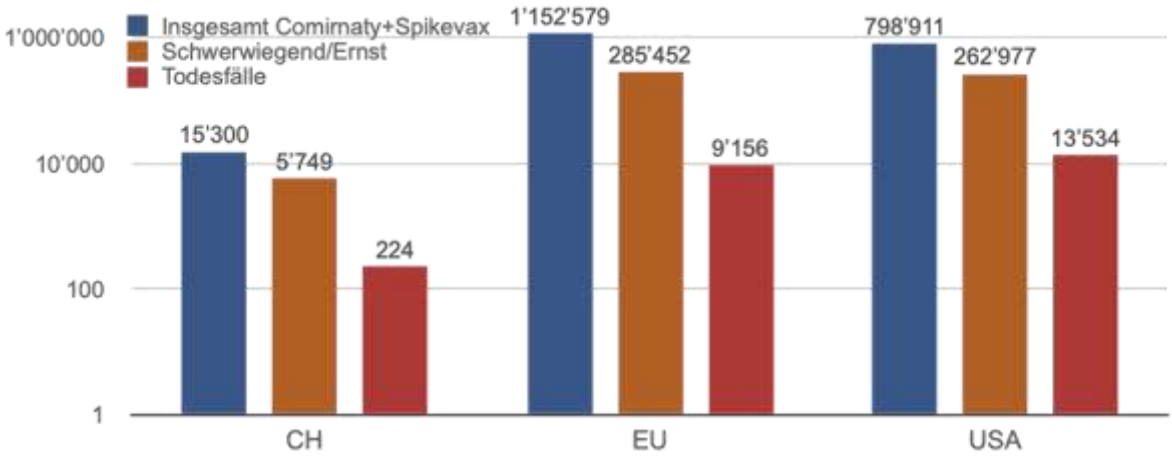
4.1.5.1 Data situation for August 2022 (CH, EU, USA) [ER N 935 ff.].

562 For information on the subsequent deletion of adverse reaction reports and re-declarations of "vaccine doses", see above (N 335 ff.).

563 Compared to May 2022, worldwide reports of adverse reactions to Comirnaty and Spikevax have increased further up to August 2022:

4.1.5.2 Side effects with Comirnaty and Spikevax (absolute figures) [ER N 941]

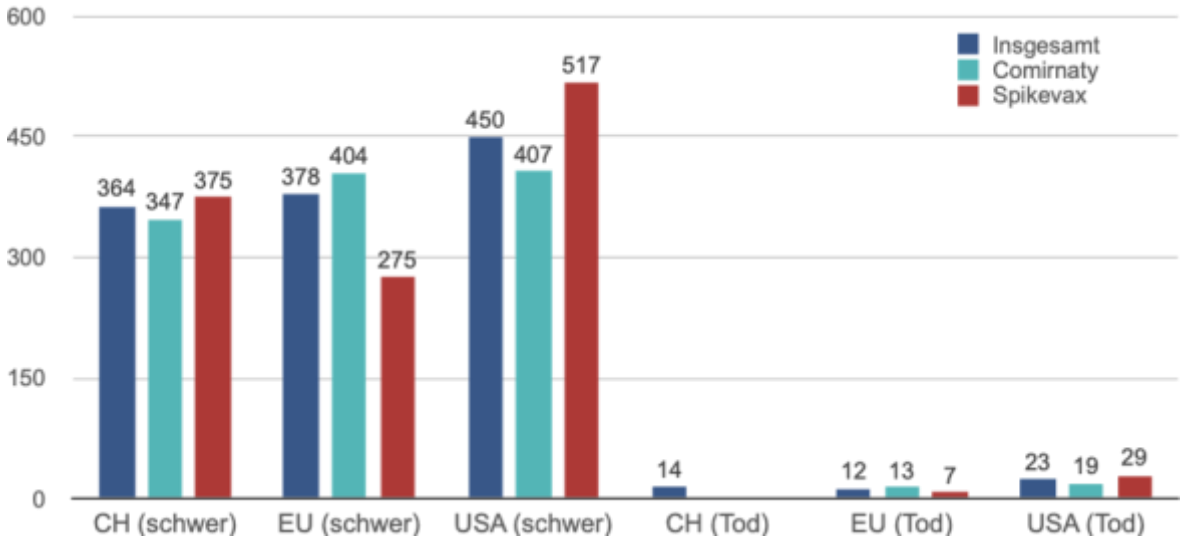
564 By August 26, 2022 in Switzerland and by September 5, 2022 in the EU and the USA, a total of **1,966,790 side effects** were reported - of which **554,178 were serious side effects** and **22,914 deaths:**



565 Here, too, the **alarm value of 50 deaths has been massively exceeded - by more than 450 times.**

4.1.5.3 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses") [ER N 942]

566 **Per 1 million doses administered,** the adverse reaction reports for Comirnaty and Spikevax as of **August 2022 were** as follows



567 As previously (N 366 ff.), the risk profile of all COVID "vaccines" is downright devastating compared to influenza vaccines, for example:

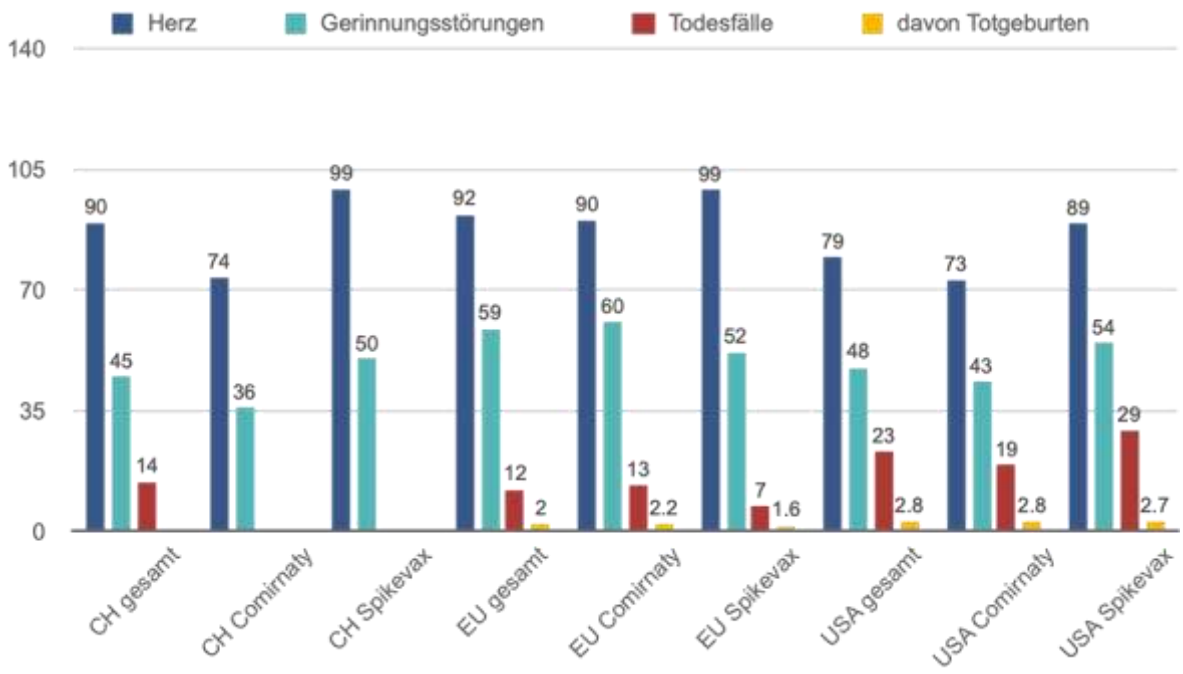
568 Unfortunately, a comparison of **serious side effects** is admittedly difficult due to different counting methods (in particular the different recording of all serious side effects or only those with permanent damage or hospitalization). However, the picture is very clear: while **0.28 to 3.3** serious side effects are reported per 1 million doses of flu vaccinations, the figure for **Comirnaty / Spikevax as of August 2022** is **364 (CH) to 450 (USA) cases - at least 100 times as many serious side effects**.

569 The comparison is simpler due to the same method of counting deaths: While **0.38 to 0.63** deaths per 1 million doses are reported for the flu vaccines, the figure for **Comirnaty / Spikevax as of August 2022** is **12 to 23 cases - at least 20 times the number of reported deaths.**

570 None of these are marginal, tolerable deviations in the low percentage range, but deviations that are alarming in every respect. **With this devastating result, no - really not a single - drug should be on the market for even one more day.**

4.1.5.4 Selected side effects: Heart problems, thromboses, deaths, stillbirths [ER N 943 ff].

571 A more detailed analysis of all adverse reaction reports for Comirnaty and Spikevax - broken down by symptoms such as cardiac disorders (myocarditis etc.), coagulation disorders (thrombosis etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **May 2022:**



572 Once again, the **reporting rates for deaths in the USA were up to four times higher.** Whether this difference was due to the population or to reporting would need to be investigated in more detail.

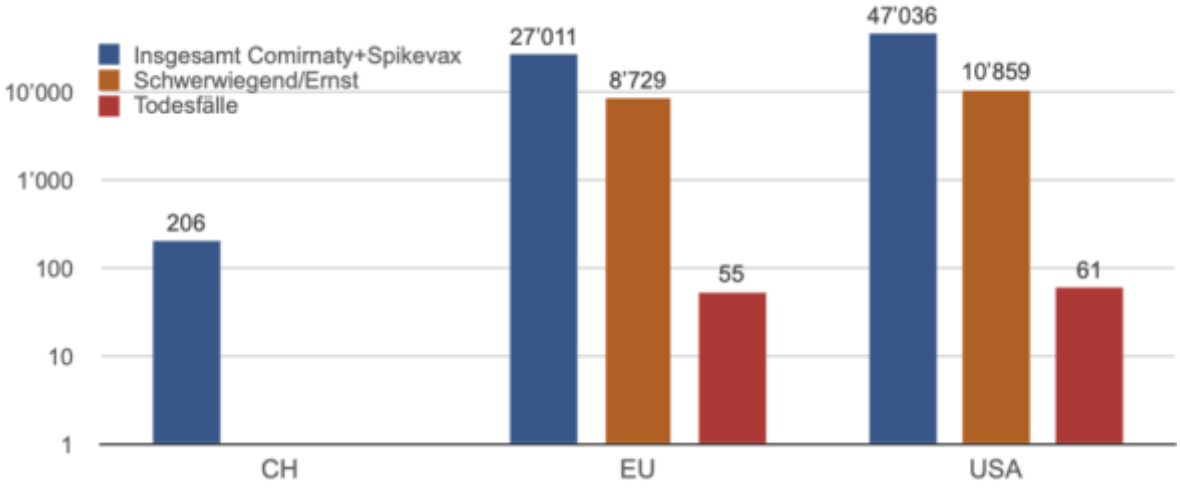
573 Once again, this is striking in comparison to the previous data (see in particular with regard to the USA above N 434 and N 557), the worldwide harmonization of adverse reaction reports in the area of **cardiac disorders (myocarditis/pericarditis)** is striking**:** Obviously, the reports worldwide are kept in a range of less than 100 reports per 1 million doses, which would mean that they are "only" **"very rare" adverse** reactions (not: "rare"). In Switzerland, however, this threshold value of 99 reports was only just not reached. However, taking into account the massive underreporting and international studies alone, a far more frequent occurrence can be assumed. A circumstance that is not taken into account in any way by Swissmedic's information for healthcare professionals (see N 1199).

574 The reports of coagulation disorders, which ranged from 36 to 60 cases per 1 million doses worldwide, were also worrying. The official data worldwide was therefore in a range that can clearly be compared, measured and estimated. There were 0.36 to 0.60 cases per 10,000, which means that the **coagulation disorders** can be classified **as "very rare" side effects (<1/10,000).**

575 For more details on the reported stillbirths, see N 636.

4.1.5.5 In particular: Side effects in children [ER N 951 ff].

576 By August 26, 2022 in Switzerland and by September 5, 2022 in the EU and the USA, a total of **74,253 adverse reactions** were reported in **children** (including adolescents) - including **19,588 serious** adverse reactions and **116 deaths:**



577 This means that the **alarm value of 50 deaths has** already been **doubled** for children alone**.** If you consider that not a single previously healthy child in Switzerland has demonstrably died as a result of COVID-19, the risk of death from vaccination bears no relation to the risk of death from infection with SARS-CoV-2.

4.1.6. Worldwide adverse event reports for Comirnaty and Spikevax: February 2023

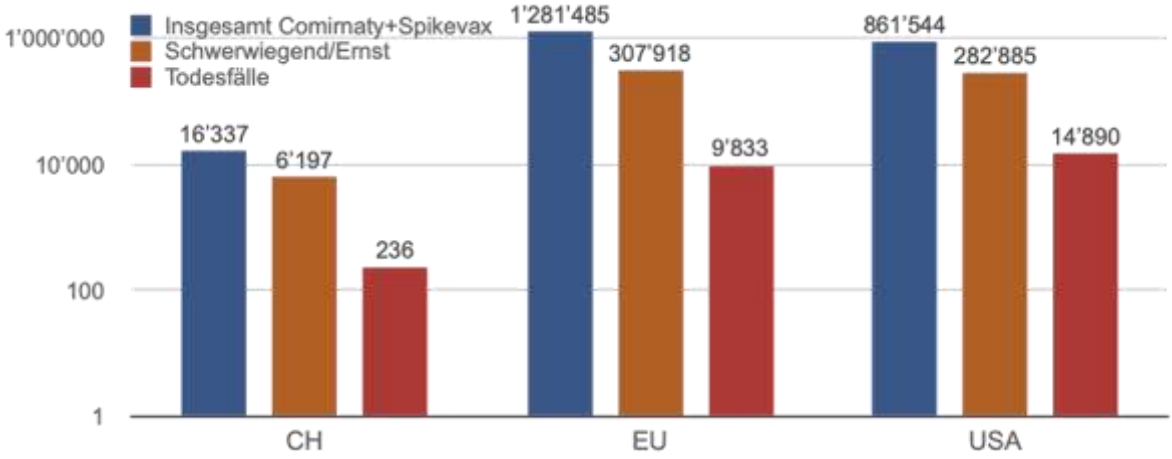
4.1.6.1 Data situation for February 2023 (CH, EU, USA) [ER N 954 ff.].

578 For information on the subsequent deletion of adverse reaction reports and re-declarations of "vaccine doses", see above (N 335 ff.).

579 Compared to August 2022, worldwide reports of adverse reactions to Comirnaty and Spikevax have increased further up to February 2023:

4.1.6.2 Side effects with Comirnaty and Spikevax (absolute figures) [ER N 957]

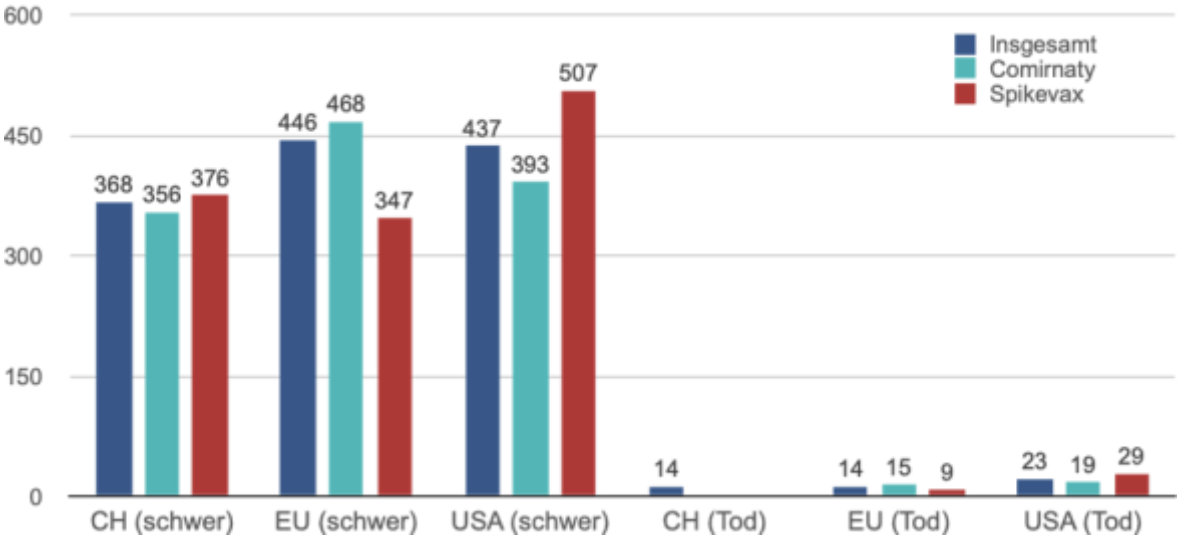
580 By February 24, 2023 in Switzerland and by February 18, 2023 in the EU and the USA, a total of **2,159,366 side effects** had been reported - **597,000** of which were **serious side effects** and **24,959 deaths:**



581 Here, too, the **alarm value of 50 deaths has been massively exceeded - by a factor of 500.**

4.1.6.3 Side effects with Comirnaty and Spikevax (per 1 million "vaccine doses") [ER N 958]

582 **Per 1 million doses administered,** the adverse reaction reports for Comirnaty and Spikevax as of **February 2023 were** as follows:



583 As previously (N 366 ff.), the risk profile of all COVID "vaccines" is downright devastating compared to influenza vaccines, for example:

584 Unfortunately, a comparison of **serious side effects** is admittedly difficult due to different counting methods (in particular the different recording of all serious side effects or only those with permanent damage or hospitalization). However, the picture is very clear: while **0.28 to 3.3** serious side effects per 1 million doses are reported for flu vaccinations, the

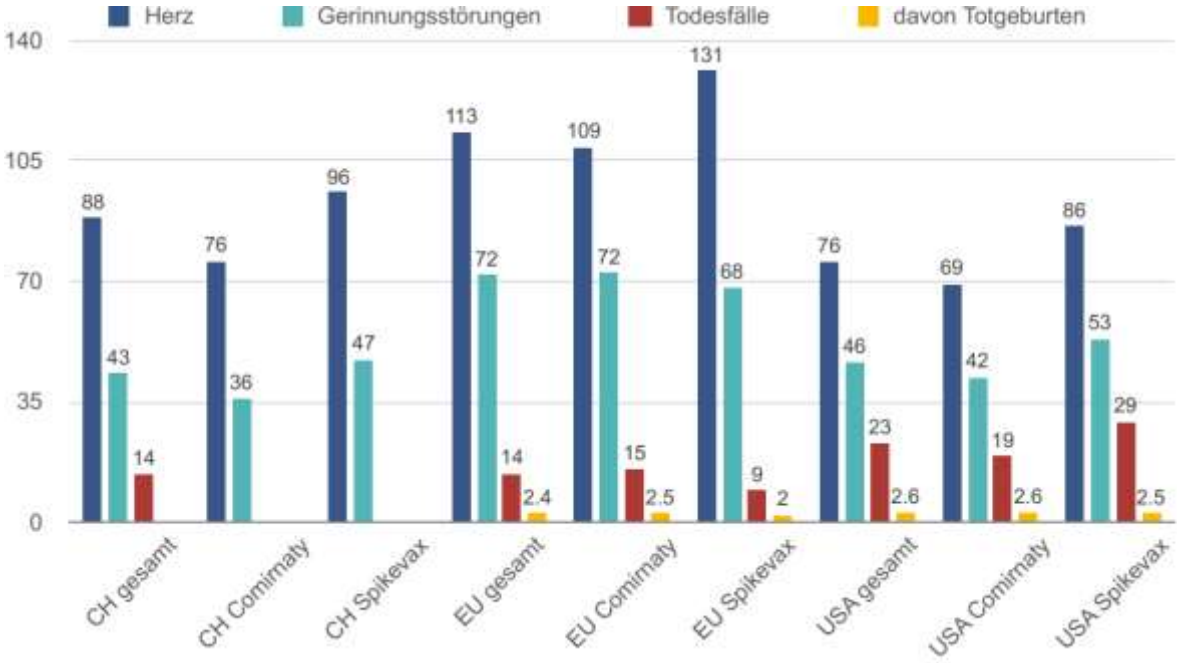
figure for **Comirnaty / Spikevax as at February 2023** is **368 (CH) to 446 (EU) cases - that is at least 100 times the number of serious side effects**.

585 The comparison is simpler due to the same method of counting deaths: While **0.38 to 0.63** deaths per 1 million doses are reported for the flu vaccines, the figure for **Comirnaty / Spikevax as of February 2023** is **14 to 23 cases - at least 20 times the number of reported deaths.**

586 None of these are marginal, tolerable deviations in the lower percentage range, but deviations that are alarming in every respect. **With this devastating result, no - really not a single - drug should be on the market for even one more day.**

4.1.6.4 Selected side effects: Heart problems, thromboses, deaths, stillbirths [ER N 959 ff].

587 A more detailed analysis of all adverse reaction reports for Comirnaty and Spikevax - broken down by symptoms such as cardiac disorders (myocarditis etc.), coagulation disorders (thrombosis etc.) as well as deaths and stillbirths - gives the following picture **per 1 million "vaccine doses"** as of **February 2023:**



588 Once again, the more than **threefold higher reporting rates of deaths in the USA** were striking. Whether this difference was due to the population or to reporting would need to be investigated in more detail.

589 The 109-131 cases of adverse reactions reported in the **EU** in the area of **cardiac disorders (myocarditis/pericarditis)** are alarming**:** for the first time - with the exception of the

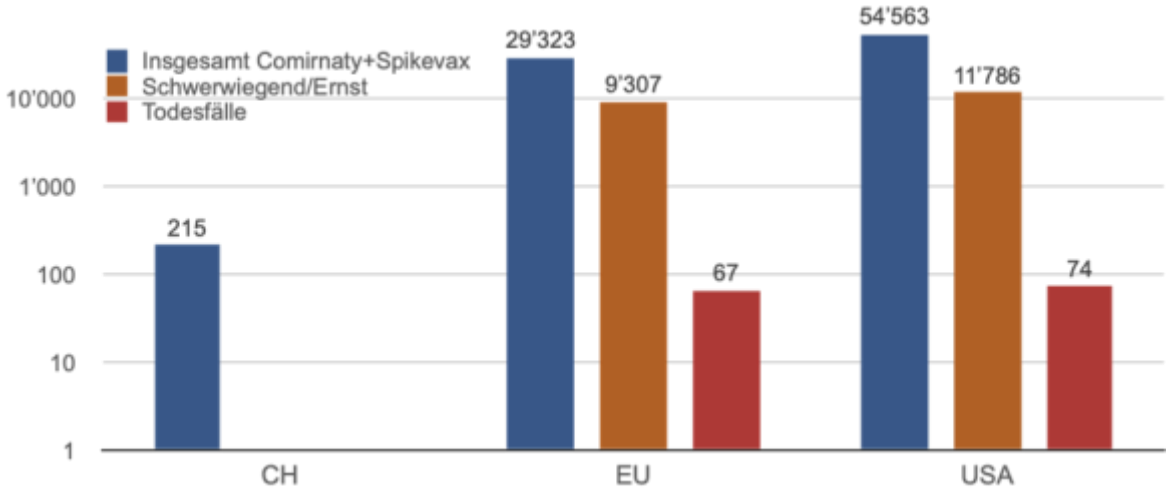
original data in the USA (front N 434) - the threshold of 100 reports per 1 million doses was clearly exceeded, making it a **"rare" adverse reaction** according to the definition (MedDRA system organ classes)[84] . The reason for the massive increase can only be speculated upon: It cannot be ruled out that the European authorities failed to make further downward "corrections" in spring 2023 (for the conspicuous data adjustments in the EU, see N 335 ff.).

590 The reports of coagulation disorders, which ranged from 36 to 72 cases per 1 million doses worldwide, were also worrying. The official data worldwide was therefore in a range that can clearly be compared, measured and estimated. There were 0.36 to 0.72 cases per 10,000, which means that **coagulation disorders** can be classified **as "very rare" side effects (<1/10,000).**

591 For more details on the reported stillbirths, see N 636.

4.1.6.5 In particular: Side effects in children [ER N 965 ff].

592 By **February 24, 2023** in Switzerland and by February 18, 2023 in the EU and the USA, a total of **84,316 adverse reactions** were reported in **children** (including adolescents) - including **21,093 serious** adverse reactions and **141 deaths:**



593 In children alone, the **alarm value of 50 deaths** has therefore **been exceeded almost threefold.** If you consider that not a single previously healthy child in Switzerland has demonstrably died due to COVID-19, the risk of death from vaccination bears no relation to the risk of death from infection with SARS-CoV-2.

594 A total of 57,760 "vaccine doses" were administered in the **0-9 age group** as follows: **32,736 children were "vaccinated"** by **February 24, 2023,** of which 335 received the first and 69

84 Pharmawiki, Undesirable effects, 08.06.2021, *https://www.pharmawiki.ch/wiki/index.php?wiki=Unew%C3%BCnschte%20Wirkungen* .

also the second "booster". From 0-4 years, 309 children were "vaccinated", with 222 administered first and 62 second "booster vaccinations". **So although hardly at risk from SARS-CoV-2, over 30,000 children up to the age of 10 were exposed to the high risk of mRNA injections in Switzerland.**

4.1.7. Comirnaty: Another alarming interim report (*PSUR* No. 3) [ER N 970 ff.].

595 The alarming *PSUR* No. 1, which should have led to an immediate "termination of the exercise", has already been discussed (N 405 ff.).

596 *PSUR* No. 2 is not yet publicly available; ***PSUR* No. 3** is. This covers the observation period from **19.12.2021 to 18.06.2022.** The report was finalized by the marketing authorisation holder on 19.08.2021. It can be assumed that the document was also submitted to Swissmedic for review immediately afterwards.

4.1.7.1 60% of adverse events affect people under the age of 50, severe COVID illnesses are common [ER N 975 ff].

597 **A total of 508,351 cases of adverse events** are reported in *PSUR* No. 3 for the observation period. **668 cases from the clinical trials** are classified as **serious, 35** of these **cases were fatal.**

598 As with *PSUR* No. 1, *PSUR* No. 3 also shows that the majority of adverse events (60.5%) occurred in the ≤ 50 age group. This is precisely the age group for which COVID-19 is not associated with any relevant risk (see for example N 752 ff.).

599 In **92.4%** of all cases there were **no pre-existing conditions**, **29.9% were considered serious** and 0.6% were **fatal** (which is **3,280 cases**).

600 In addition, **since market launch until June 2022, the** serious events included **9.8%** cases of **no effect**, **8.9%** cases of **vaccine failure** and **17.1% cases** of **severe COVID-19 disease**. In other words, the mRNA injection was useless or even led to severe COVID-19 disease in a larger number of "vaccinated" people. This is in line with international observations: According to data from the European adverse event database *EudraVigilance,* **COVID-19** disease was the **most common clinical picture reported as a serious adverse event** in connection with COVID-19 "vaccinations" **as at 04.03.2022** (N 709 ff.).

601 To date, Swissmedic has not taken sufficient measures with regard to this clear safety signal (see N 1198 ff.).

4.1.7.2 Hearing loss/tinnitus as a safety signal [ER N 982 ff].

602 **Hearing loss/tinnitus** is classified as a persistent **safety signal**, which is why a special committee of the *EMA* (the "*PRAC*") and *Health Canada* asked the marketing authorization holder to comment on it.

603 In **Switzerland, there were 165 cases of** adverse events affecting the ear up to 24.02.2023. Accordingly, this event is listed among the 15 most frequently affected organ systems, which can also be observed in the EU.

604 Despite the emphasis on hearing loss/tinnitus as a safety signal in *PSUR* No. 3, and even more so because this safety signal is supported by national and international figures and the inquiries of two international regulatory authorities, it is incomprehensible that Swissmedic has not yet taken any measures to ensure that this side effect is referred to in Comirnaty's information for healthcare professionals (cf. on the misleading information for healthcare professionals below N 1198 ff.).

4.1.7.3 Information on the safe use of Comirnaty in pregnant women, breastfeeding women and other patient groups is still lacking [ER N 988 ff].

605 The **use of Comirnaty in pregnant and breastfeeding women** is still classified as **"missing information"** (as in *PSUR* No. 1). This also applies **to frail elderly patients with concomitant diseases**, **patients with autoimmune** or **inflammatory diseases** and for **"long-term safety data"**.

606 Despite this initial situation, however, adequate information regarding pregnant women in the **medicinal product texts** of Comirnaty and Spikevax is completely **insufficient** and even **misleading** (cf. on the misleading specialist information below N 1198 ff.).

607 The current summary of product characteristics for Comirnaty (as of January 2023) at least points out that the data available for use in immunocompromised individuals is limited, but there is a lack of analogous information for older patients with concomitant diseases and for patients with autoimmune or inflammatory diseases.

4.1.7.4 Number of side effects: Massive differences between batches [ER N 993 ff].

608 As in *PSUR No*. 1, *PSUR* No. 3 also lists the 16 batches that led to the most adverse reactions. All of these **high-risk batches originate from a single production site in Belgium,** which is extremely striking and indicates a serious quality problem. The once again

uneven distribution of side effects is another strong indication that there were **still relevant quality problems during production** (see also N 417 ff.).

609 It is not known whether an inspection was carried out by an approval authority at the relevant production facility in Belgium after viewing this data.

4.1.7.5 Many dangerous batches in Switzerland [ER N 996 f.].

610 The 16 high-risk batches with an above-average number of cases of adverse reactions include **4 batches** that were **supplied to Switzerland.** It is not yet known how many mRNA injections from these 4 batches actually reached Switzerland, as these batches were always also supplied to other countries. Either way, the fact that 4 obviously particularly dangerous batches were delivered to Switzerland is an **alarm signal** and should have led to the necessary actions by the regulatory authority Swissmedic - **warning the population, batch recall, etc.** - without fail.

4.1.7.6 Conclusion: Insufficient consideration of the data from PSUR No. 3 by Swissmedic [ER N 998 ff.].

611 Even after receiving this alarming *PSUR* No. 3, Swissmedic clearly did not adequately consider the data and findings for its benefit-risk assessment of Comirnaty, did not initiate an update of the SmPC with regard to important findings and has (to date) withheld this important information from the medical profession and the public. But even such improvements would clearly have been sufficient: In view of all these alarm signals, an "abandonment of the exercise" should have taken place immediately with regard to the central protected good according to Art. 1 and Art. 3 para. 1 TPA - public health.

4.1.8. Massive underreporting impressively confirmed [ER N 1001]

612 The fact that massive underreporting was already known at the end of 2021 (front N 441 ff.) was once again impressively confirmed in 2022 by corresponding data and studies:

4.1.8.1 USA: "V-Safe" data reveals massive underreporting [ER N 1002 ff.].

613 Previously (N 537 ff.; N 544 ff.; N 563 ff.), it was explained in detail that the official adverse event reports had reached historic, unprecedented highs in 2022. However, the following fact also shows that even these high figures are still far too low: After months of litigation and subsequent access to the smartphone app "V-Safe" - with **more than 10 million users** - a US consumer protection organization was able to determine that **33% of all users** were **affected by side effects,** with **0.7%** having to be **hospitalized.** In contrast, the official

VAERS database shows only 0.025% hospitalized cases of side effects - **28 times less than with V-Safe. The problem of underreporting is evident from this example alone.**

4.1.8.2 USA: Only 61% of all side effects are correctly recorded in the VAERS [ER N 1006 ff].

614 Also in the USA, a random evaluation of 126 *VAERS reports* at the end of 2022 revealed massive inconsistencies that indicated that the underreporting of adverse events was not "only" due to completely inadequate passive reporting systems: Ultimately, **39%** of the **reports** made **in the VAERS *system*** were **not correctly listed publicly**.

615 The *CDC* and *FDA* were confronted with these figures on February 15, 2023 (at the latest). A response is still pending.

4.1.8.3 EU: Only 20% of all side effects are reported [ER N 1009 ff].

616 For the EU, there are considerable differences in reporting discipline between the member states for 2021. An in-depth, Europe-wide country comparison of this data by an association of over 80 renowned (German) scientists and professors revealed that **at least 80% of suspected cases** are **not reported to EudraVigilance.**

4.1.8.4 Germany: Only 20% of all adverse drug reactions reported [ER N 1012 ff].

617 According to the above analysis, Germany is exactly in line with the EU average: only around 20% of all adverse drug reactions are reported in Germany.

618 This high number of unreported cases was recently impressively confirmed by an analysis of German health insurance data: According to a corresponding extrapolation, around 2.5-3 million Germans affected by side effects must have been undergoing treatment in 2021. This is **ten times more than officially reported by the *Paul Ehrlich Institute (PEI)* based purely on spontaneous reports.**

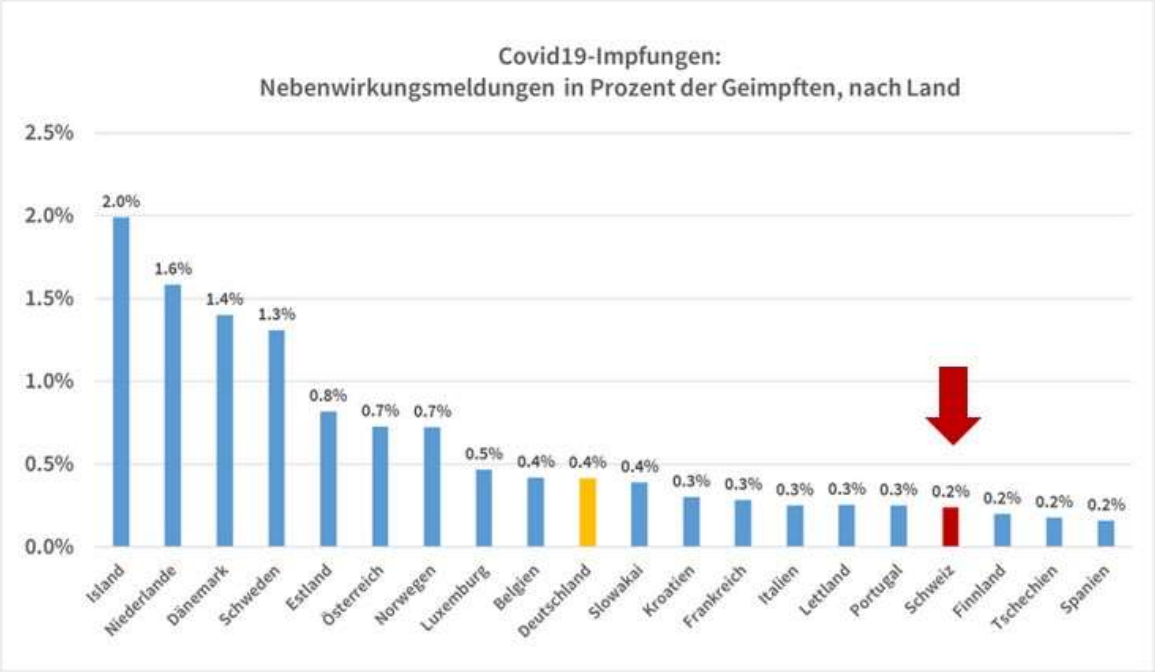
4.1.8.5 Germany: Sharp rise in hospital stays and deaths [ER N 1015 ff].

619 In August 2022 and December 2022, further health insurance data revealed that **medical treatments due to vaccine side effects increased by 3,000 percent** in 2021. In addition, **"sudden and unexpected" deaths also** increased **massively** with the start of the "vaccination campaign".

620 These data also represent a significant risk signal and indicate a massive underreporting of side effects by the regulatory authorities.

4.1.8.6 Switzerland: Only 10% of all adverse reactions are reported [ER N 1018 ff].

621 As already mentioned above (N 445), the reporting rate in Switzerland was already half that of Germany in mid-2021. In 2022, Swissmedic's reporting rate improved only marginally and stood at 0.97 suspected cases/1000 "vaccine doses" in May 2022. In comparison with the EU countries, Switzerland ranked only 17th in the reporting of adverse reactions: **Switzerland's percentage reporting rate was just 10% of Iceland's reporting rate, which can be clearly seen from the following graphical processing of the official figures:**



4.1.9. Manufacturer: disclosure of major risks in production and distribution [ER N 1022 et seq.]

622 As in 2019, Pfizer and BioNTech stated in their annual reports published at the beginning of 2022 that they may not be able to demonstrate sufficient efficacy or safety of their COVID "vaccine" to obtain permanent regulatory approval for 2021.

623 These warnings are absolutely justified: The fact that the requirements for conversion into an ordinary license are obviously not met is explained in the back (N 1068 ff., in particular N 1122 ff.) in detail.

4.1.10. Massive harm to children and young people [ER N 1025]

4.1.10.1 Worldwide: Far too many deaths among children and adolescents [ER N 1026 ff].

624 The regulatory authorities worldwide had published around 300 deaths as a result of COVID "vaccinations" in children and adolescents by spring 2022 (see also front N 560: 103 deaths as a result of mRNA injection), which should have led to an immediate ban on approvals - as these age groups are in no way at risk from SARS-CoV-2 (N 762 ff. [adolescents], N 771 ff. [children]) and the efficacy of mRNA injections for these age groups could not be proven (N 377 ff. [adolescents]; N 516 ff. [children]):

- EU: 168 deaths, 24 of which were infant deaths;
- USA: 112 deaths among children and adolescents;
- DE: 8-11 deaths in children and adolescents (and thus more deaths than due to COVID-19 disease);
- Switzerland: Allegedly no deaths.

625 The side effect reports concerning babies born to "vaccinated" mothers are particularly worrying: the risk of transmission through breast milk was already recognized at the end of 2021 (front N 480) - nevertheless, the human trial was continued. In Switzerland, as many as 7 cases of adverse reactions in infants were reported by May 2022. As there was already an international increase in stillbirths in 2022 (N 636 ff.) and declining live births (in particular N 644 f.), Swissmedic's figures are unlikely to reflect reality in any way here either.

626 The data on infant, child and adolescent deaths is clearly unpleasant for the responsible authorities: while the German *Paul Ehrlich Institute (PEI)*, for example, still provided detailed information on deaths in children and adolescents in its safety report at the end of 2021 (8 death reports), such information can no longer be found in the 2022 safety report. By mid-2022, the number is likely to have exceeded the previous figure of 10 death reports - meaning that **the number of deaths due to "vaccination" exceeded the official number of deaths in connection with "COVID-19"** (approx. 10) **in Germany.** The cost-benefit ratio for children and adolescents was therefore strikingly negative: under no circumstances is it permissible to kill as many or even more people with a drug than die from the disease it is supposed to prevent.

4.1.10.2 Experts and courts: mRNA injections in children irresponsible [ER N 1034 ff].

627 Given these facts, three authors from Wageningen University in the Netherlands, Johns Hopkins University in Baltimore and Oxford University in England came to the conclusion in a detailed statement on March 25, 2022 that **COVID-19 mRNA injections in healthy children cannot be justified on ethical grounds because the risks outweigh the minimal benefits.**

628 Other experts expressed very clear **criticism of the unit dose used** for adolescents, with which a completely unnecessary risk was taken, which was already evident in 2021 (front N 323 f.). In 2022, respected experts such as Klaus Stöhr (epidemiologist and long-standing head of the *WHO* and Novartis vaccination program) and virologist Alexander Kekulé publicly stated that it **was wrong to use the same dose for everyone aged 12 and over.** Susanne Wagner (biotech expert, consultant in the field of drug development and specialist for the test plans of new drugs with 30 years of experience in high-tech research) was also harsh on the regulatory authorities and marketing authorization holders: "**They should have reacted immediately after the first deaths of younger people following the first indications of the sometimes severe side effects such as heart muscle inflammation or strokes and reduced the dose."**

629 On December 5, 2022, a detailed benefit-risk analysis by renowned authors (including Harvard Medical School, Johns Hopkins University, Oxford University) was also published, which concluded that the **net benefit of a "booster injection" in the 18 to 29 age group** is **clearly negative.** According to the study, **over 31,000 people** would have to be **"vaccinated" to prevent a single COVID-19 hospitalization** over a six-month period. Each prevented hospitalization would lead to **18.5 serious adverse events** (such as myocarditis/pericarditis).

630 The mRNA "vaccines" are therefore in no way compatible with the welfare of children. This was already recognized by courts in Germany and Italy as well as the Florida Department of Health (USA) at the beginning of 2022. Their verdict: **the risk clearly outweighs the benefit, which is why "childhood vaccinations" should be avoided.**

4.1.11. Pregnant women: worrying number of miscarriages and stillbirths

4.1.11.1 Data still missing - delaying tactics by manufacturers [ER N 1046 ff.].

631 Even one year after approval, the manufacturers of Comirnaty and Spikevax still had to admit to the regulatory authorities at the beginning of 2022 that **"the safety profile of the vaccine in pregnant or breastfeeding women** is **not known ".**

632 This was because the pregnant women had been excluded from the pivotal clinical trial (see above 235). As a replacement, studies with pregnant women were started in February 2021. The corresponding results are - as far as can be seen - still not available. In any case, it is questionable whether these studies can provide any useful results at all, as the contract research institute *Ventavia* was once again commissioned for one of these core studies. In other words, the very institute that had obviously already falsified data in the approval studies (see N 398).

633 This **delaying tactic by manufacturers** in such a sensitive area is in no way compatible with an ongoing approval procedure. Especially in view of the fact that reports of premature births and stillbirths had already increased worldwide by the end of 2021 and unfortunately increased significantly again in 2022 (N 636), the question arises on what empirical data basis Swissmedic could justify the authorization of COVID "vaccines" for pregnant women in particular.

4.1.11.2 UK health authority warns against mRNA injections during pregnancy and breastfeeding [ER N 1049 ff].

634 In an updated summary of Comirnaty's assessment report on August 16, 2022, the *MHRA* pointed out the lack of data on the use of the COVID-19 "vaccine" in pregnant and breastfeeding women and advised against its use in these groups of people: There can currently **be "insufficient assurance of safe use of the vaccine in pregnant women"** and even **"women who are breastfeeding should not be vaccinated either".**

635 Although the data situation on use in pregnant women and breastfeeding mothers is the same internationally, Swissmedic did not take any steps to include corresponding information on the current data situation in the form of precautionary measures in the information for healthcare professionals for Comirnaty (see N 1198 ff.).

4.1.11.3 Massive increase in worldwide reports of miscarriages and stillbirths [ER N 1052 ff].

636 Already before (N 555), it was shown graphically that for Comirnaty and Spikevax in the EU and the USA, **1.4 to 2.8 stillbirths per 1 million "vaccine doses"** were already recorded in May 2022. In absolute figures, this already amounted to **2,135 stillbirths for Comirnaty** and **798 stillbirths for Spikevax in the** EU and the USA - not including underreporting.

637 The ***Open VAERS*** database finally reported **5,055 miscarriages** in connection with the COVID-19 "vaccines" as of September 23, 2022.

4.1.11.4 Austrian midwives sound the alarm: Increased miscarriages [ER N 1055 ff].

638 The fact that **many birth complications and deaths** are **not reported is** also shown by an appeal from over 200 concerned Austrian midwives at the beginning of 2022, which stated that **miscarriages, premature labor, early premature ruptures of the membranes, vaginal bleeding, premature births, growth retardation and eclampsia (seizures) occur frequently and are** not investigated further.

4.1.11.5 Worldwide: historic decline in live births [ER N 1056 ff].

639 Even before the COVID-19 "vaccines" were approved by Swissmedic, animal studies had already shown that mRNA injections significantly increased the rate of abortions and malformations (N 235 f.). It was later shown that COVID-19 mRNA injections had a lasting negative impact on sperm formation in young men (see N 649).

640 Historic declines in birth rates have been observed in many countries for 2022. These figures suggest that the COVID-19 "vaccinations" are very likely to be responsible for the decline in live births:

641 Data from the **EU** shows a marked decline in live births as of August 25, 2022, ranging from 1.3% to 19%. Compared to previous years, **more than 100,000 babies are "missing" in Europe in the first half of 2022,** with a significant correlation between "vaccination frequency" and a decline in births in 13 out of 18 countries. In contrast, a link between COVID-19 infections or COVID-19 hospitalizations and a decline in births could be ruled out.

642 A study by the *German Federal Institute for Population Research shows* for Germany and Sweden that around nine months after the "vaccination campaign" was extended to the younger population group, a significant decline in live births can be observed. **Compared to previous years, the decline in births in Germany is around 15% and in Sweden**

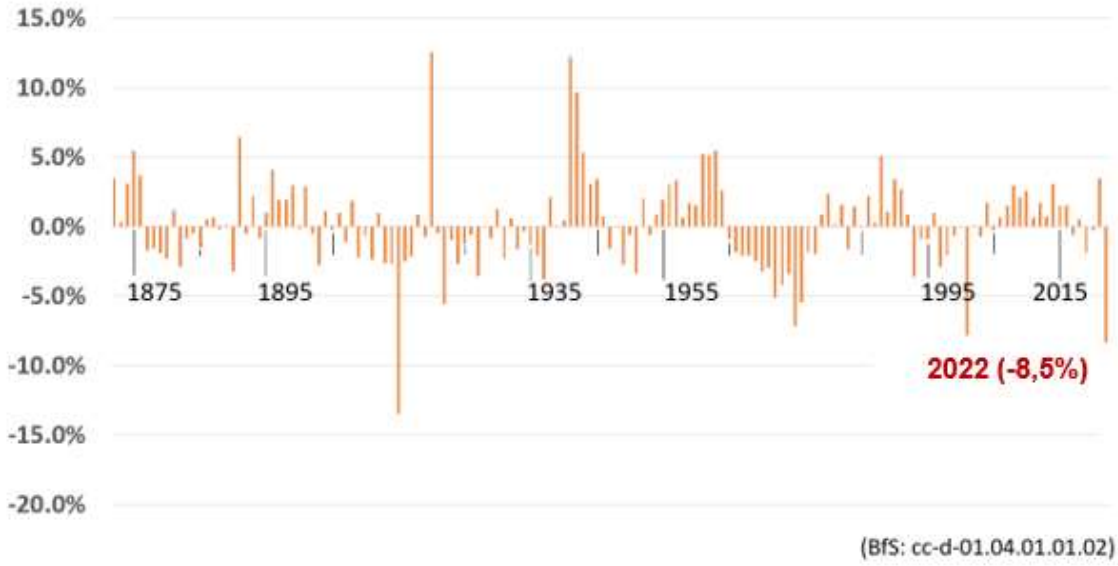
around 10%. In both countries, this decline in births occurred abruptly when the "pandemic-related" restrictions were largely lifted and social life had returned to normal. Neither country recorded a decline in the birth rate in 2020 and 2021 - which rules out the "pandemic" or COVID-19 as a cause. In addition, the birth rate in 2022 is significantly lower than in previous years.

643 In **Japan,** the number of live births in 2022 will fall below 800,000 for the first time since national birth statistics began in 1899.

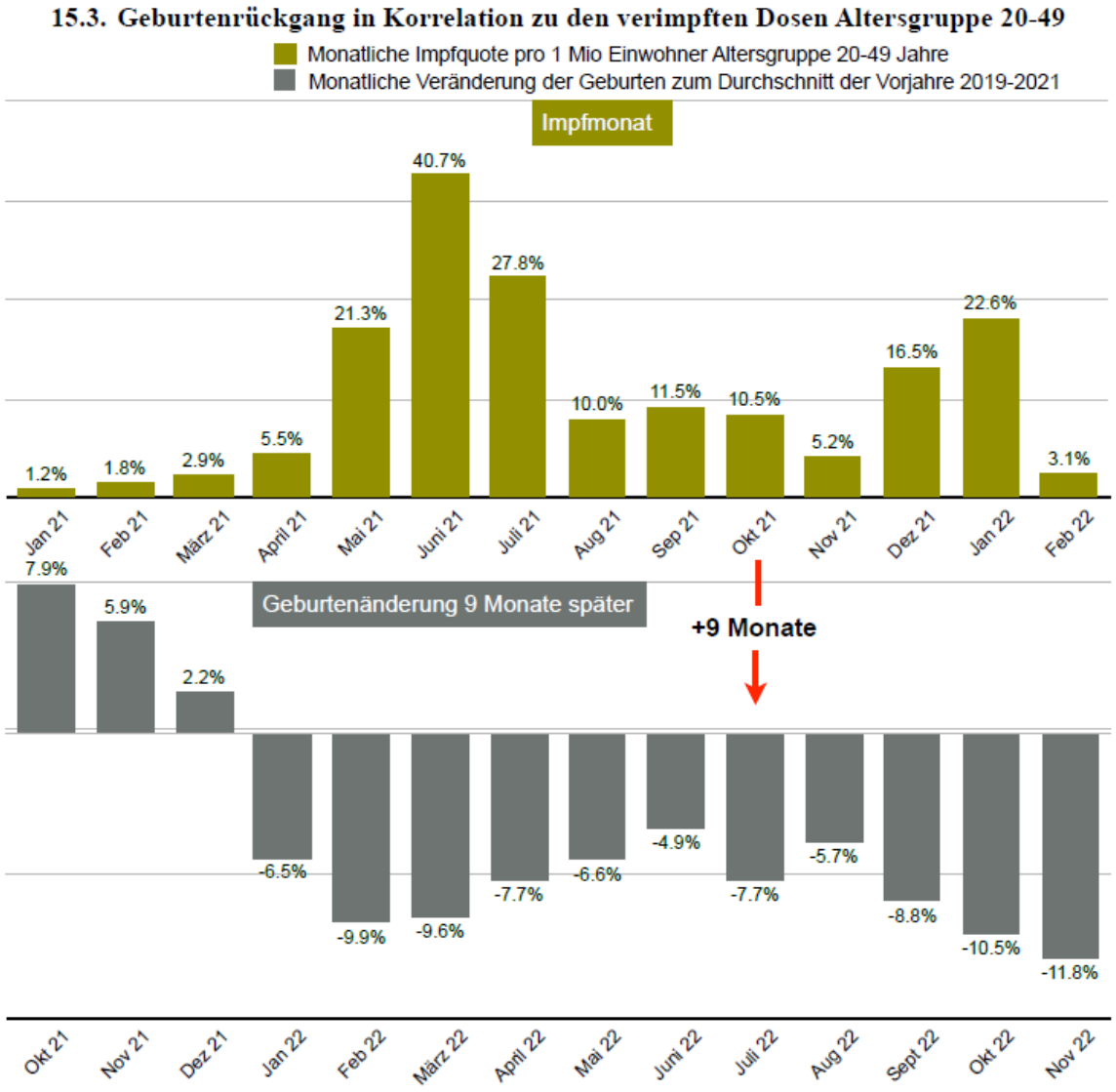
4.1.11.6 Switzerland: Historical decline in live births [ER N 1069 ff].

644 As an analysis by Prof. Beck presented in the Evidenzeport shows in detail, Switzerland experienced an **abrupt** and **historically unprecedented drop in birth rates in 2022** (apart from the First World War).

Abb. 3: Historisch nahezu einzigartiger Einbruch der Geburten 2022



645 **All publicly expressed theories for the cause** (such as "voluntary abstinence", "catch-up effect", "increased abortions", "COVID infections") **are either implausible, lead to contradictions or are even ruled out.** The correlation between "vaccination incidence" and the collapse in birth rates (as well as the increase in stillbirths in Germany), on the other hand, is obvious and **only the mRNA injections offer plausible reasons** for the historical collapse in birth rates.



4.1.11.7 Conclusion: Swissmedic bears direct responsibility for the decline in births [ER N 1101 ff].

646 What the preclinical data had already indicated has now unfortunately been confirmed worldwide: COVID-19 mRNA injections are associated with a high risk for pregnant women and their unborn children. The data worldwide shows an obvious correlation between "vaccination coverage" and the decline in live births. Since SARS-CoV-2 can be ruled out as a cause based on the data and no other plausible reasons can be identified so far, there is a strong suspicion that the **COVID-19 "vaccines" are causally linked to the decline in births**.

647 The fact that Swissmedic had covered up the obvious risks relating to pregnancy/fertility in the drug texts from the outset (see N 1199) is now taking its revenge in the form of a continuing decline in live births. Swissmedic also did not intervene with the *ECIF* to reverse the

recommendation for COVID-19 mRNA injections in pregnant women. **Swissmedic is therefore directly responsible for all complications in "vaccinated" pregnant women and in particular for the deaths of their unborn babies.**

648 Unsurprisingly, after the publication of the data on the decline in birth rates, Swissmedic denied - in a demonstrably false and unsubstantiated manner - any connection between COVID-19 "vaccinations" and a possible impairment of fertility (see N 655 et seq.).

4.1.12. Male fertility: decrease in sperm concentration by 15.9% [ER N 1104 f.].

649 A study on male fertility published in June 2022, which was conducted using 220 sperm samples, concluded that sperm concentration, motility and sperm count had not yet normalized even 150 days after "vaccination": **150 days after the 2nd "vaccination", sperm concentration was still 15.9% below the initial value.**

650 This is also a massive alarm signal, which the regulatory authority is aware of: The approval of the mRNA "vaccines" was nevertheless granted in an incomprehensible manner without a single investigation of the effects on (male) reproductive capacity (see in detail above N 253 ff.). This circumstance should obviously have been investigated.

4.1.13. Harm to newborn infants [ER N 1106]

651 Previously, selective reports of adverse reactions in infants worldwide had already been made (N 624 ff.). The following considerations could partly explain why newborns suffer adverse effects:

4.1.13.1 mRNA injection damages stem cells in umbilical cord blood of newborns [ER N 1107 f.].

652 On December 22, 2022, a study was published showing that COVID-19 mRNA injection significantly reduces blood-forming (hematopoietic) stem cells in the umbilical blood of newborn mice. The damage to stem cells is also more severe after mRNA injection than after COVID-19 disease. In the absence of stem cells of this type, **serious effects on the immune system are** to be expected, and in the case of defective function, serious blood diseases such as **leukemia.**

4.1.13.2 Increase in RSV cases in infants and young children correlates temporally with mRNA injection [ER N 1109 ff].

653 Infections with respiratory syncytial virus (RSV) are more severe if there are disorders of the hematopoietic stem cells. RSV can make hospitalization necessary in infants.

654 According to Prof. Berger, Head of Infectiology at the Children's Hospital Zurich, the RSV wave is "in a maximum range" compared to other years from November 2022. There is a lack of data to confirm or refute a correlation between this particularly severe RSV wave and the "mass vaccinations". **In any case, the RSV record figures correlate with the "vaccination campaign" of pregnant women,** whose infants and young children may fall ill with RSV and be hospitalized to a greater extent from autumn 2022.

4.1.14. Swissmedic covers up the influence of "vaccines" on fertility [ER N 1112 ff].

655 Based on the numerous indications and international data that clearly showed an impact of COVID-19 "vaccines" on fertility, Swissmedic should have suspended the authorization of mRNA injections for pregnant women long ago. However, confronted with the devastating facts, Swissmedic publicly claimed on September 30, 2022 that there was no evidence that fertility could be impaired by mRNA injections.

656 When asked on what Swissmedic based this bold claim, Swissmedic provided 11 studies that in no way stand up to an in-depth analysis:

4.1.14.1 Swissmedic's references for the purpose of proving "harmlessness" do not stand up to sound analysis [ER N 1116 ff].

657 **None of** the **11 publications** submitted by Swissmedic **stood up to a thorough analysis** by Dr. rer. nat. Hans-Joachim Kremer, a specialist in medical-scientific expert opinions with decades of experience:

- Surprisingly, the first study even confirms the **connection between the decline in birth rates and the "vaccination campaign"** with a time lag of around nine months, whereby a connection to unemployment, infection rates or COVID-19 deaths is ruled out. The risk of bias (errors in data collection that lead to incorrect results) is considered to be low.
- The second study then shows a **clear negative influence** of Comirnaty **on sperm count**, but there is a **high risk of bias.**
- In contrast, studies three and four show a (partial) **improvement in sperm quantity and quality,** which **does not** seem **very plausible,** however, as it is unclear on what

physiological-biological basis an mRNA injection should cause this effect. In addition, the **risk of bias is high or critical**.

- **No influences on sperm quality** were found in studies five to eight, although the studies were of extremely poor quality. The **risk of bias was** classified as **critical** three times and as **high** once.
- Study nine is based solely on the **results of an online survey** to investigate the possible influence of COVID-19 mRNA injection and disease on fertility. Furthermore, the study contains **numerous questionable aspects** and the **risk of bias** is **critical**.
- Study ten shows a possible influence of a SARS-CoV-2 infection on fertility, so there is no connection to the "vaccination".
- Overall, the last study has **numerous quality deficiencies** and should therefore not be taken into account.

658 **Conclusion: None of the 11 references is a prospective randomized placebo-controlled trial (RCT),** which is considered the "gold standard". Due to the methodology alone, all studies were susceptible to bias from the outset and thus to providing erroneous results. **The quality of these studies is comparable to the analyses conducted for Switzerland** (N 644 f.) **and Europe** (N 641)**, which confirm a relevant decline in birth rates**.

659 **Overall, the publications cited by Swissmedic are of insufficient quality and are not suitable for proving the safety of mRNA "vaccines" with regard to reproduction.**

4.1.14.2 Intervention of Prof. Beck and Prof. Vernazza at Swissmedic [ER N 1136 ff.].

660 **Professors Dr. Konstantin Beck and Prof. em. Dr. med. Pietro Vernazza** contacted Swissmedic in September 2022 with a **well-founded analysis** summarizing the animal studies, the current figures on the decline in births and the literature published in connection with this topic. They concluded that **the hypothesis that there is no causal relationship between mRNA injection and fertility decline must be rejected**. Accordingly, they called on Swissmedic to issue **an explicit warning** for the use of an mRNA-based COVID-19 "vaccine" **for people who do not wish to have children.**

661 In its response, Swissmedic continued to deny any negative impact on fertility by the mRNA injections and supported this with 12 references, 11 of which are identical to those mentioned above (N 657 ff.). Unsurprisingly, the added reference no. 12 was also unsuitable to prove the safety of COVID-19 "vaccines" in pregnancy, as it primarily investigated the influence of SARS-CoV-2 in pregnant women.

4.1.14.3 Conclusion: Swissmedic argues without a factual basis [ER N 1140]

662 From the outset, Swissmedic lied to the public about the dangers of mRNA injections in pregnancy, in particular by concealing alarming findings from animal studies on fertility (see above N 235 ff.; on the misleading technical information see below N 1198 ff.). Swissmedic is now even citing a **study** against the extensive analyses on the historical decline in birth rates, which **does not deny** the **connection between the decline in birth rates and the "vaccination campaign" with a time delay of around nine months, but actually confirms it**. Swissmedic also presents studies that do not stand up to closer scrutiny in any way. Swissmedic is thus arguing against all evidence instead of finally suspending the deadly approvals.

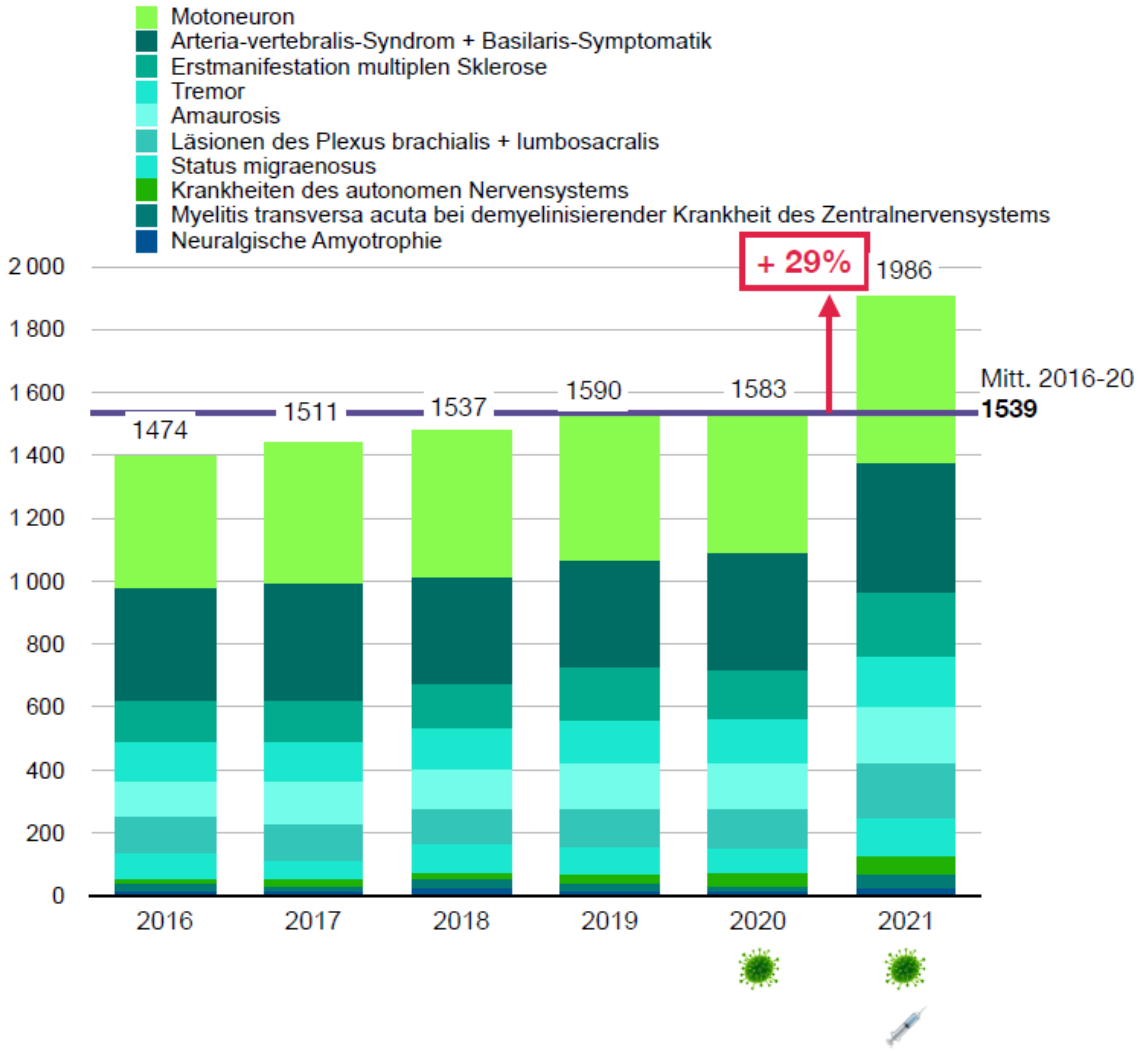
4.1.15. Switzerland: Conspicuous mortality in all age groups [ER N 1141]

663 In addition to the aforementioned historic decline in live births in Switzerland (N 644), another worrying trend became apparent in 2022 at the latest: Prof. Beck's in-depth analysis of the *BfS data using* a robust methodology revealed a **conspicuous and persistent mortality trend in <u>all</u> age groups in close temporal relation to "vaccination activity"** (back N 782).

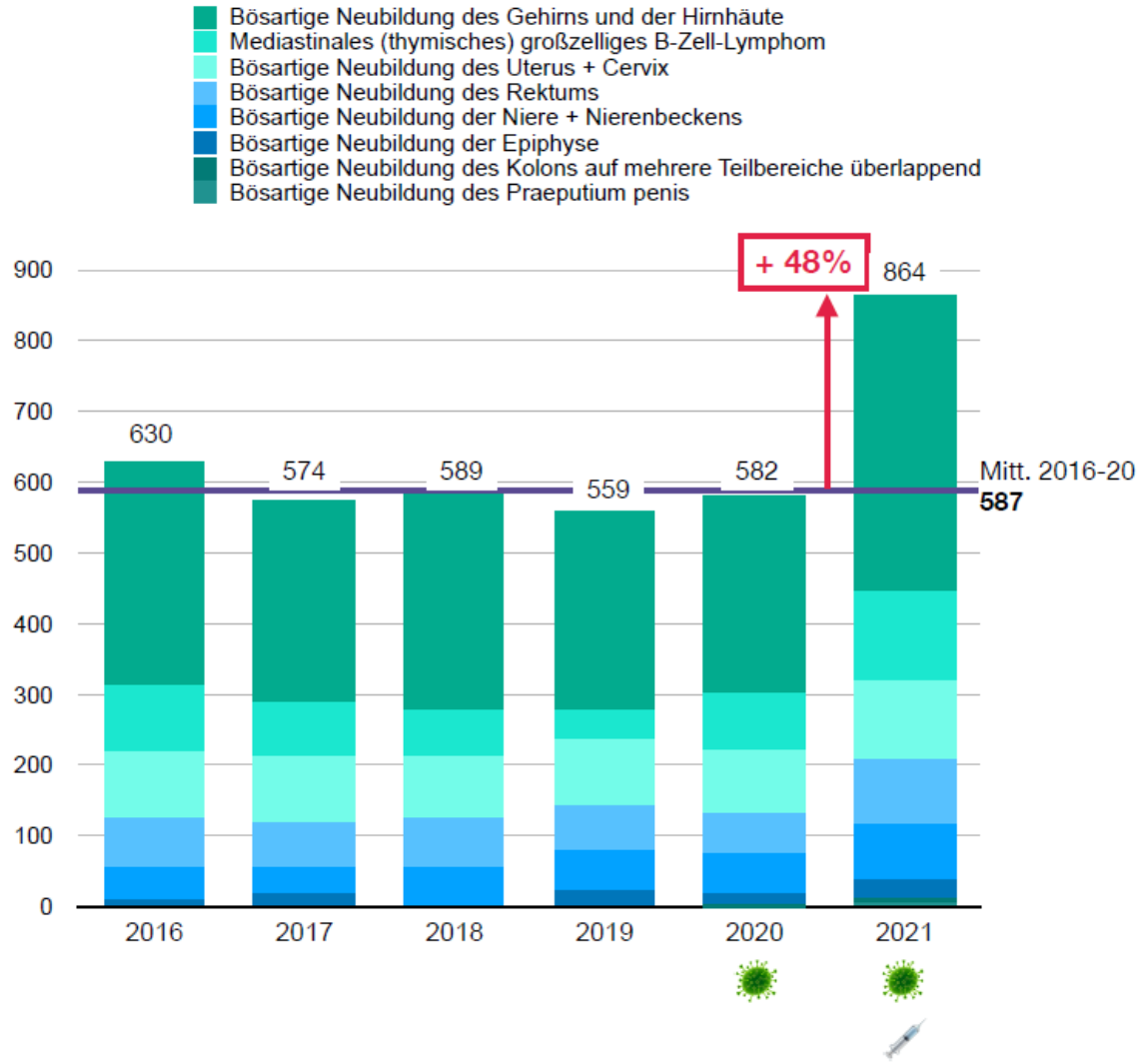
4.1.16. Switzerland: Massive increase in various disease diagnoses [ER N 1142 ff].

664 The "vaccination side effects" that occurred worldwide by the end of 2022 (front N 537 ff.) were then impressively confirmed by the *medical statistics of hospitals* for 2021, which the BfS published in November 2022: There was a **drastic increase in disease diagnoses in the area of "vaccination side effects" already in 2021 and thus a clear correlation with the mRNA injections.**

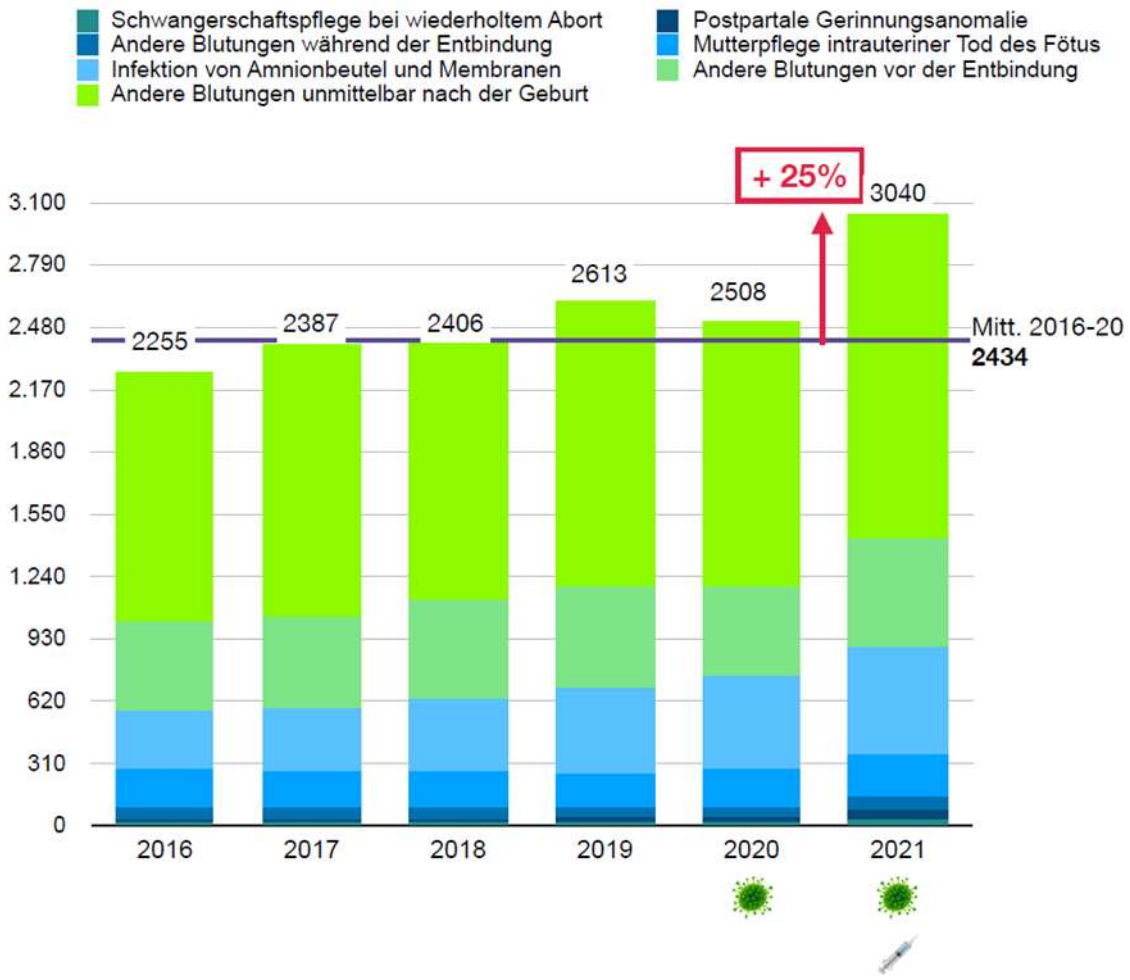
665 **Damage to the nervous system** increased marginally from 2016 to 2020, with a slight decrease in 2020. **In the "vaccination year" 2021, there was** then suddenly a **sharp increase of 29%** compared to the "pandemic year" 2020.



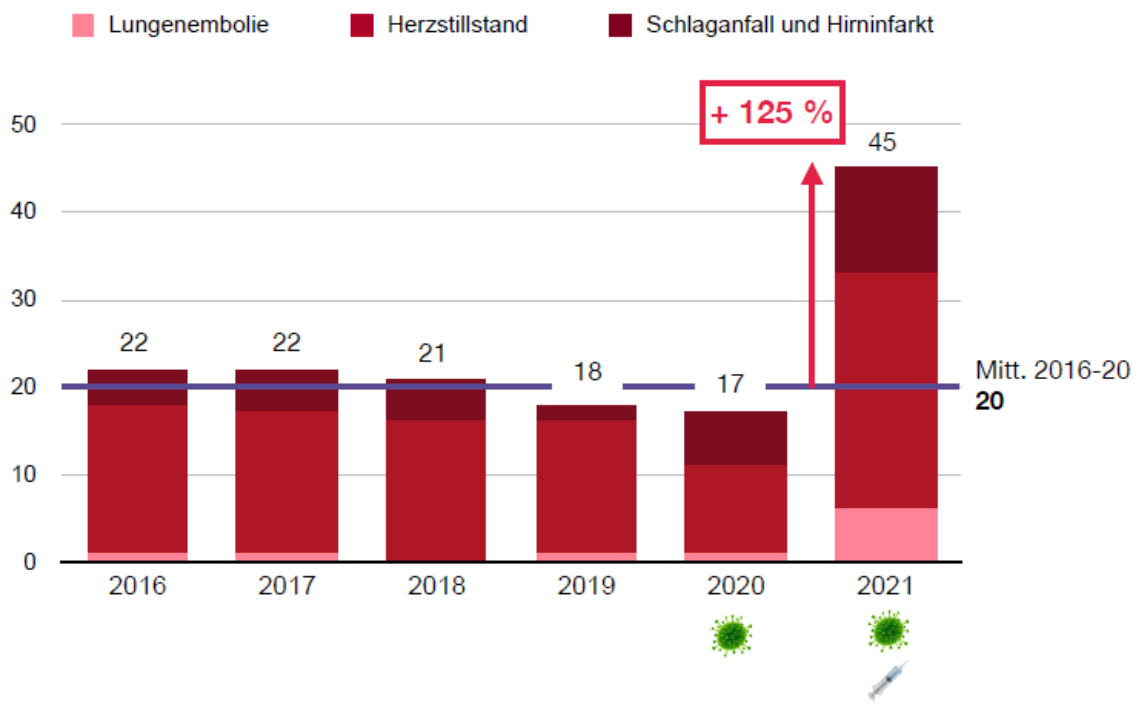
666 In the **15 to 39 age group, there was** a **marked increase of 48%** in a number of **cancers in the "vaccination year" 2021** compared to the "pandemic year" 2020. This is despite the fact that the number of such cancers has been very stable or even declining since 2016.



667 The picture is also dramatic in the area of **pregnancy/birth:** In the **15 to 39 age group**, **various disease diagnoses** increased slightly from 2016 to 2019 and then fell again slightly in the "pandemic year" 2020. **In the "vaccination year" 2021, however, they increase by 25% compared to the previous year, which is well above the average value for the previous 5 years.**



668 The data on **pulmonary embolism, cardiac arrest, stroke and cerebral infarction among <u>0 to 14-year-olds</u>** is particularly alarming. In the years 2016 to 2010, these disease diagnoses fell marginally at a constant rate. **However, in the "vaccination year" 2021** (mRNA injections for 12 to 15-year-olds from 04.06.2021), **the number of these diseases increased by 125%.**



4.1.17. Harmful to lethal mode of action of the spike protein [ER N 1154 ff].

669 The toxicity of the spike protein has been previously (N 391 ff.).

670 In early 2022, pathologists detected the spike protein in organs such as the liver, spleen and brain in people who had died after a COVID "vaccination" - in some cases **up to four months after the "vaccination".** It was also shown that **vascular damage** was attributable to the spike protein **in 12 out of 15 people who died**. In at least one of these cases, the **spike protein production** stimulated by the mRNA "vaccines" was **the causal cause of vascular lesions and the resulting myocarditis.** The spike protein (or the immune response triggered by it) was therefore proven to be the **cause of death.**

671 In addition, reports of **thromboembolic events (thromboses, embolisms, strokes) have** increased worldwide. According to one study, the **spike protein** can **induce clumping of red blood cells,** which could explain the massive increase in thromboembolic events.

672 Around July 2022, the *CDC* secretly removed the - obviously false - information published on its website stating that the mRNA and the spike protein would **not remain** in the body **"for long".** Shortly afterwards, in August 2022, the spike protein was detected not only in deceased people, but also in a person who was still alive - **a full nine months after the mRNA injection.** A further study at the beginning of 2023 showed that in 10 out of 108 patients examined, the **"vaccine" mRNA was still** circulating **in the blood 28 days after the injection.**

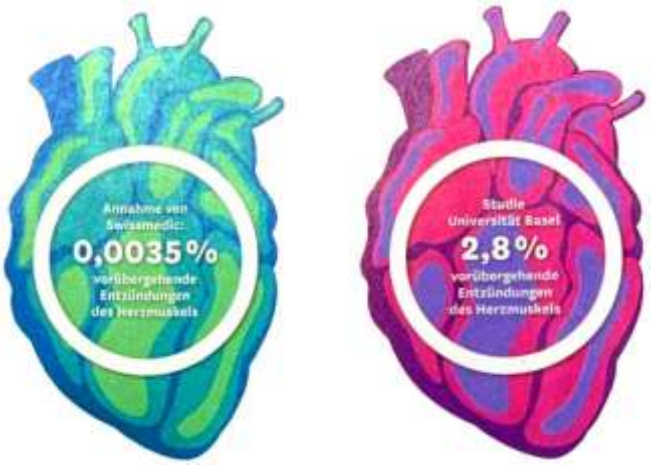
673 Also at the beginning of 2023, **Swissmedic** had to **admit that it has no idea how much spike protein is produced in a person.** The mRNA injections were therefore approved by Swissmedic, although Swissmedic is still unable to say how much of the actual active substance (spike protein) is actually produced in the body. Moreover, Swissmedic's statement that only **"minimal systemic exposure"** is to be expected is patently false: the spike protein is still detectable in the body after several months - and even contributes to the development of fatal vascular damage.

4.1.18. Alarm signal: myocarditis [ER N 1171 ff].

674 The risk of myocarditis - which can lead to death - was already evident in 2021 (front N 467 ff.).

675 Despite this, Swissmedic had not taken any adequate measures to effectively counter this development. This risk also manifested itself in 2022 in the form of additional adverse drug reaction reports (see above N 555 ff. above) made this danger very clear. In addition, more recent data has shown ever more clearly that mRNA injections can also frequently cause severe - fatal - cases of myocarditis/pericarditis:

- Cases of myocarditis have also increased in the EU despite adjustments to the "vaccination recommendations".
- In the US, 96% of all myocarditis cases are associated with hospitalization, two healthy teenagers died a few days after mRNA injection with Comirnaty and a US study showed that the unbound spike protein correlates with "vaccine"-induced myocarditis, confirming the toxic potential of the spike protein.
- In Japan, increased rates of myocarditis have been recognized and the risk of death associated with myocarditis has been found to be increased by a factor of 4 to 6.7 compared to a non-vaccinated reference population.
- In Scandinavia, a 5-fold increased risk after Comirnaty and an up to 15-fold increased risk of myocarditis after Spikevax were reported.
- In Germany, myocarditis has been identified as a potentially fatal "vaccination" side effect according to several autopsy results.
- **According to a globally recognized peer-reviewed Basel study, 2.8% of "vaccinated" people suffer from myocardial cell damage - 800 times more than the official figures from Swissmedic**, which once again shows the massive underreporting.



- In Israel, a large-scale study showed that myocarditis cannot be a consequence of COVID-19 disease, as myocarditis did not occur more frequently in an ("unvaccinated") group of around 197,000 COVID-19 sufferers than in an ("unvaccinated" and non-diseased) comparison group.
- Worldwide, "sudden and unexpected" deaths are at an all-time high, especially among previously healthy athletes - the term "sudden adult death syndrome" ("SADS") has even been introduced.

676 The occurrence of - in the worst case fatal - myocarditis in connection with a COVID-19 mRNA injection is therefore much more common than officially reported by the regulatory authorities. The increased incidence of myocarditis cannot be attributed to an infection with SARS-CoV-2, but obviously correlates with the worldwide "vaccination campaigns".

4.1.19. Alarm signal: V-AIDS [ER N 1220 ff].

677 In June 2022, the German law firm *Rogert & Ulbrich Rechtsanwälte in Partnerschaft mbB,* which specializes in the legal processing of vaccine damage, drew the public's attention to what it believes to be a widespread phenomenon that experts agree is due to "vaccination" with COVID "vaccines": damage to the immune system, which had already been described in the specialist literature in various publications as "Vaccine-Acquired Immune Deficiency Syndrome" (so-called **V-AIDS**). The publications had come to the conclusion that

- the COVID "vaccines" damage the immune system's communication system by suppressing the messenger substance interferon 1 and the mRNA "vaccines" can thus make "vaccinated" people more susceptible to infectious diseases and cancer.

- the spike proteins lead to "syncytia formation", where many human cells fuse to form a large cell, damaging the lymphocytes that are important for the immune defense, so that lymphocytopenia can develop.
- COVID "vaccines" can deactivate the function of natural T-killer cells and thus override the immune system's ability to recognize viruses and cancer cells.

678 The law firm had already noticed in a large number of individual cases that autoimmune diseases had been diagnosed following a "vaccination". In the blood tests that had been commissioned, the relevant markers indicating damage to the immune system were demonstrably altered.

679 The phenomenon of V-AIDS is of fatal importance because damage to the immune system is known to lead not only to an increased incidence of autoimmune diseases and cancer, but above all to an increased incidence of infectious diseases. In this context, it is relevant that, according to the statistics of numerous countries, COVID hospitalizations and deaths are driven by the vaccinated, which further supports the thesis of V-AIDS.

680 This means that there is increasing evidence pointing to a negative cost/benefit ratio of COVID "vaccinations". These indications are further reinforced by impressive official data from Israel and the US army:

4.1.20. Further data on the dangers of the "vaccines" [ER N 1229 ff].

681 In the USA, an evaluation of the **US military's medical epidemiology database (Defense Medical Epidemiology Database, *DMED***) showed an increase of **270% in heart attacks**, **460% in pulmonary embolisms**, **1000% in nerve diseases** since the start of the COVID "vaccination campaign", **breast cancer by 490%**, **facial nerve palsies** (facial paralysis) **by 290%**, **Guillain-Barré syndrome** (a severe neurological condition with paralysis that usually begins on both sides of the legs) **by 550%** and **miscarriages by 280%** compared to the five-year average. These figures only became public thanks to the US lawyer Renz, who was then accused of "misinformation" and defamed by the US government. Thanks to this active monitoring and recording system of the health status of all soldiers within the US Army, it is now clear to the general public and beyond reasonable doubt that **the negative effects of COVID "vaccinations" far outweigh the claimed benefits of COVID "vaccination" in this basically healthy group of people (active soldiers) who are not at significant risk from SARS-CoV-2**.

682 In February 2022, the Israeli Ministry of Health published the results of a study according to which **66% of Israelis who had received a "booster vaccination" suffered from side**

effects. This evaluation alone is cause for great concern, as it directly calls into question the cost-benefit ratio.

683 Worldwide, there is also still a clear **link between COVID "vaccinations" and an increase in emergency interventions** (see N 489 ff.). Compared to the time before the COVID "vaccinations", the increase in 4 countries considered is around **11% to 32%**. In a study, data from the Israeli rescue service also shows an increase of **25% for emergency calls in connection with cardiac arrest or acute coronary syndrome in the 16- to 39-year-old population** specifically for the period from January to May 2021.

684 Hospital infrastructures are clearly not prepared for the massive increase in "vaccine-injured" patients: A hospital outpatient clinic for "vaccine-injured" patients was established at the University of Marburg-Giessen, where as many as 200 affected "post-vac patients" were registered by May 2022 - a full 1,800 more patients were on the waiting list at that time.

4.1.21. Numerous other studies on heart problems, coagulation disorders and deaths [ER N 1241 ff].

685 By March 1, 2022, the previously (N 374, N 495), which indicate a link between the COVID "vaccines" and side effects, many more studies were added: limited to the mRNA "vaccines" Comirnaty and Spikevax, there were an additional 37 publications on heart problems, 14 publications on life-threatening coagulation disorders (thrombosis, etc.) and one publication on possible fatal consequences. Even at that time, the available studies alone were a considerable cause for alarm.

686 In total, at least **126 peer-reviewed publications on heart problems, 216 peer-reviewed publications on life-threatening coagulation disorders (thromboses etc.) and 6 peer-reviewed publications on possible deaths as a result of COVID "vaccinations" had** already appeared by March 2022 alone (a further systematic examination of the studies published worldwide was no longer pursued by the complainants).

687 In view of this flood of scientific studies, no one could seriously claim that the COVID or mRNA "vaccines" were not at least strongly suspected of causing serious side effects, including death. Insofar as these side effects have occurred and continue to occur in people who do not belong to the risk group (at risk from SARS-CoV-2), a negative net benefit of the COVID-19 "vaccines" is thus easily proven.

4.2. Effectiveness

4.2.1. Omicron variant: Rapid decrease in (relative) effectiveness (RRR) [ER N 1255 ff].

688 German, Swedish, Canadian and US studies came to the conclusion that although the mRNA "vaccines" also had a certain degree of initial protection against "Omikron", this protection declined sharply after just a few months. **Relative efficacy rates of 23%-59%** were calculated. In children, this even fell relatively quickly to 12-51% according to the US study. Once again: The RRR method leads - as before (N 300 f.) - leads to completely distorted data in the case of only a few proven infections. The absolute risk reduction (ARR) is therefore once again likely to be in the low single-digit percentage range. The mRNA "vaccines" therefore offered no "major therapeutic benefit" from the outset - they were simply unsuitable for protection against "Omikron" under the terms of Art. 9a TPA.

689 This became apparent very soon after: In Germany, the *RKI* officially stated on April 28, 2022:

> "What is **striking is the significant drop in the calculated vaccine effectiveness** of both the basic vaccination and the booster vaccination compared to a symptomatic infection in all age groups since the beginning of 2022, i.e. with the dominance of the Omikron variant."

690 The corresponding official graphs even showed that the "**vaccine effectiveness"** of the 5-59 age group **had been at zero since at least the end of March 2022**. However, instead of providing further information about the non-existent vaccination effectiveness, the *RKI* discontinued all information in this regard as of May 5, 2022. No comprehensible reasons were given for withholding this data and clearly do not exist. This once again demonstrates the **complete lack of transparency of the responsible authorities,** which are required by law to fully inform the population about all risks and (non-)effects of the experimental mRNA "vaccines".

691 In January 2023, the *UK Health Security Agency (UKHSA)* published calculations on the "number needed to vaccinate" ("NNV") of COVID-19 "vaccines". These show that, depending on age and risk, **tens of thousands to hundreds of thousands of people** need to be **"vaccinated"** to formally **prevent a single severe case of COVID-19**. For example, **34,200 children aged 5-11 years would have to be "primed" to statistically prevent a single COVID-19 hospitalization** Such high numbers for an "NNV" are far from the range normally accepted for a drug.

692 A well-founded risk-benefit analysis of COVID-19 "vaccines", published in the journal *Infosperber* on April 22, 2022, also concludes on the basis of official data that the ratio of benefit to harm for people under 30 is negative: if **all 540,000 men aged 20-29 living in Switzerland** were **"vaccinated"**, this would formally **prevent one COVID-19 death in only 0.25 men**. The author concludes that the protective effect of mRNA injections in young adults is so small that even a very small risk of side effects would likely reverse its benefits.

4.2.2. No protection against infection and transmission [ER N 1278 ff].

693 Neither the manufacturers nor the regulatory authorities have ever been able to prove that the mRNA "vaccines" protect against transmission and infection, as has been repeatedly demonstrated. On the contrary: the manufacturers themselves stated in their *assessment reports* to the *EMA* in November 2021 and March 2022 - i.e. after more than a year of the "vaccination campaign" - that it **was still not known to what extent the "vaccination" prevented further transmission** (see N 504). A study published in January 2022 also showed that **no significant difference was observed in the transmission of circulating variants of SARS-CoV-2 in "vaccinated" and "unvaccinated" people.** Accordingly, in March 2022, even the *RKI* had to admit that vaccination protection decreases over time and the probability of becoming PCR-positive despite "vaccination" increases. And Prof. A. Radbruch (immunologist and Vice President of the *Federation of European Immunological Societies [EFIS]) stated* unequivocally in March 2022 that the **viral load of infected "vaccinated" people is high** and that **protection from a "vaccination"** is **only short-term.**

694 In September 2022, there was a definitive official admission that the mRNA injections had never been tested for their effectiveness in protecting against transmission and that such protection against transmission had never been proven:

- The ***CDC acknowledged*** that the **circulating variants of SARS-CoV-2 can be spread by any person regardless of their "vaccination status"**.
- Prof. Berger, President of the *Federal Commission for Vaccination Issues,* ***EKIF***, also admitted: **"None of these [vaccines] protects well against a mild infection and also not against virus transmission"**.
- And finally, **Janine Small,** President of International Markets at the pharmaceutical company **Pfizer,** admitted in the EU Parliament that her COVID-19 "vaccine" **had never been tested to see whether or not it stopped virus transmission.**

695 Nevertheless, even at the beginning of 2023, Swissmedic still claims in its own "FAQ", without any evidence, that "the possibility of transmission of the coronavirus to other people after full vaccination is low" (see N 1204 ff.).

4.2.3. Negative effectiveness of the "booster": transfer period extended [ER N 1289 f.].

696 In July 2022, the results of a study were published in the *New England Journal of Medicine (NEJM)*, according to which it **took longer for people who had received a booster mRNA injection to be free** of **virus after an initial positive PCR test compared to those who had been "vaccinated" or "unvaccinated" twice.**

697 This study thus provides further data to prove that the mRNA injection does not have a positive effect on the transmission of the SARS-CoV-2 virus, but rather a negative effect.

4.2.4. Recovered people better protected against re-infection than "vaccinated " [ER N 1291 ff.].

698 By the end of 2021 (front N 521), more than 60 publications had already proven that **having had the disease reliably protected against re-infection and that the immunity acquired in this way** is **superior to a "vaccination".**

699 As a result of further studies, it was already noted in December 2021 that the antibody diversity was greater in those who had recovered than in those who had been "vaccinated". In a large-scale retrospective observational study by scientists at Oxford University in April 2022, it was also found that "**vaccinated" people had a 13-fold higher risk of reinfection** and a **7-fold higher risk of a new symptomatic disease with "Delta"** than "unvaccinated" people. There is no clearer proof than these results from scientists at one of the world's most renowned universities that COVID-19 "vaccinations" **weaken the natural immune system instead of strengthening it** - and thus have exactly the opposite effect to what they were actually intended to achieve. This observational study thus joins the many legally relevant facts and evidence that show that, on balance, the "vaccines" are a danger to public health.

700 This data situation, which was devastating for the "vaccination" strategy, led to a decision being made in Tennessee (USA) to legally equalize natural immunity and immunity acquired through "vaccination" against COVID-19.

4.2.5. Countries suspend COVID-19 "vaccinations" for certain population groups due to lack of benefit [ER N 1296 ff.]

701 In fall 2021, mRNA injections with Spikevax for young adults had already been suspended in various countries due to the apparently high risk of myocarditis (N 471).

702 From mid-2022, Denmark, England and Florida then established the completely negative benefit-risk profile for children, adolescents and younger adults and finally ended the failed "vaccination offer" or "vaccination campaign" for these population groups.

4.2.6. Inadequate recording of "vaccination breakthroughs" [ER N 1304 ff].

703 In Switzerland, so-called "vaccine breakthroughs" (more correctly, **infection breakthroughs**) - i.e. a lack of efficacy - are not adequately recorded in any way: Since the end of October 2021, such recording is only to take place for deaths and hospitalizations - all other cases are excluded. However, not even these two categories (deaths and hospitalizations) are strictly recorded:

704 This has already been described above (N 447 ff.) that **deaths** are not sufficiently recorded in any way.

705 There are also massive gaps in **hospitalizations**: some hospitals *did not* even start systematically recording the "vaccination status" *until* late summer 2021 *at the earliest.* Others did not start until the end of November 2021 at the earliest, with some only recording the certificate (and thus the "vaccination status") "if clinically relevant". Such instructions do not ensure that the "vaccination status" is systematically recorded. As a result of this **lax practice, it can still be** seen as at 31 January 2022 that the **"vaccination status"** was still **officially unknown** in **20%** of hospitalizations in connection with COVID disease.

706 **This proportion increased steadily over time until, in autumn 2022, the "vaccination status" of over 70% of COVID-19 hospitalized patients was unknown (N 713 ff.). Swissmedic did not take any measures to improve the recording of "vaccination status" in Swiss hospitals**.

707 Without strict recording of the "vaccine breakthroughs", precise analyses of the efficacy of the mRNA "vaccines" will be considerably more difficult - which is simply unacceptable in view of the fact that they are still in ongoing clinical trials.

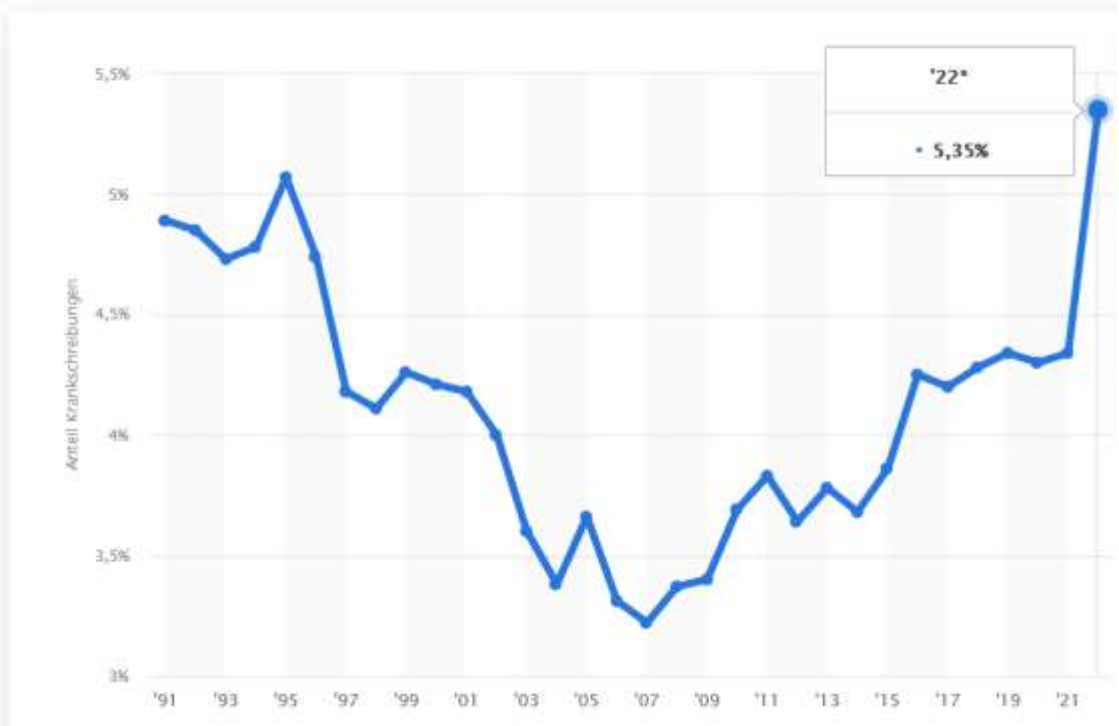
4.2.7. Increased incidence of disease and mortality in "vaccinated" patients [ER N 1315 ff].

708 The trend towards negative effectiveness was already evident in 2021 (front N 502 ff.) . This trend was impressively confirmed in 2022 according to new international data. The **mRNA injections** not only led to a **higher susceptibility to contracting severe COVID-19.** In connection with the introduction of mRNA injections, a generally **significantly increased mortality rate** can also be observed in many countries.

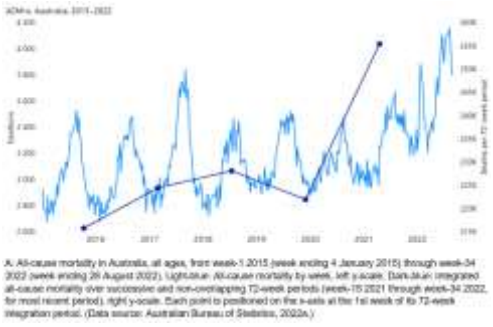
4.2.7.1 International data show negative effectiveness [ER N 1319 ff.].

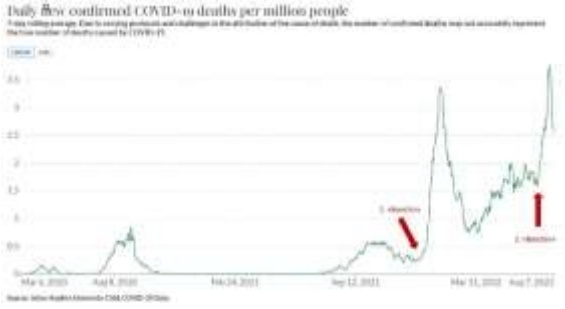
709 From 2022 in particular, there has been growing evidence worldwide that the "vaccinated" are more likely to contract COVID than the "unvaccinated" and are more likely to require hospital treatment or even die:

- In the *EU,* COVID-19 is the most common disease reported as a serious "vaccination side effect". In addition, COVID-19 also ranks among the top "fatal vaccination side effects". **Severe courses and deaths are therefore not prevented by mRNA injections** - moreover, the **conspicuous death rate among** the under 45s **correlates with the start of the "vaccination campaign"** in 2021 (and not with the start of the "pandemic" in 2020).
- In the *US,* Walgreens found that **double and triple "vaccinated" people** had **the highest rates of positive SARS-CoV-2 test results.** In addition, a report by US life insurance companies found that in the 3rd quarter of 2021 - the peak of the "vaccination campaign" - **deaths** in the 25-54 age group were **around 80% higher than expected.**
- In *Canada,* **97.7% of those who died from COVID** were **fully "vaccinated" or "boostered"** at the end of April 2022.
- In *England,* **9 out of 10 COVID deaths** in March 2022 were **in the vaccinated population** and 4 out of 5 COVID deaths were in the triple-vaccinated population.
- In Germany, mortality in 2021 and 2022 was at an unexplained high level. In addition, an analysis of German hospital billing data published in February 2022 showed that **hospitalizations with diagnosed vaccination side effects** were **11 times higher in 2021** than in previous years. The general **sickness rate in** 2021/2022 was also much higher than in the actual "pandemic year" 2020 and reached a **new high at the start of the "vaccination campaign"** compared to the twenty previous years.



- *Portugal* and *Malta* also experienced a similar development: With "vaccination coverage rates" of over 80%, these countries recorded a **significant increase in reported COVID deaths** from January 2022.
- In *Israel,* **70-80% of hospitalized patients seriously ill with COVID** were **"triple vaccinated"** at the beginning of February 2022. **In addition, the general mortality curve correlates impressively with the "vaccination incidence".**
- The data from "Zero COVID" *Australia* is also impressive*:* **overall mortality has increased since the end of 2022 and clearly correlates with the "booster campaign"** (for larger graphics see evidence report).





- The situation is similar in "Zero COVID" *New* Zealand: there, too, **deaths rose massively and sharply when the "booster campaign" began in spring 2022.**

4.2.7.2 Global analyses: "Vaccinations" cause more deaths than COVID-19 [ER N 1370 ff.]

710 On September 22, 2022, a **"mathematical modeling study"** was published which purports to show that the COVID-19 "vaccinations" had "significantly influenced" the course of the pandemic and **prevented 14.4 million "COVID-19 deaths".**

711 However, a careful analysis by the organization *Doctors for COVID-19 Ethics* (*D4CE*) revealed that the scientific basis of the "modelling study" was false, the **data** on which the calculations were based was **incorrect, outdated and even manipulated**, and that the publication was also tainted by **serious conflicts of interest.** According to the analysis, the COVID-19 "vaccinations" have **not prevented any deaths**, but on the contrary are associated with **negative efficacy** and **increased mortality.**

712 The *D4CE analysis* was impressively confirmed by a further study: Dr. RANCOURT et al. show a clear **correlation between "booster" campaign and unusual spikes in mortality** in Australia and Israel. The authors discuss the toxicity of the mRNA injections and calculate that **13 million people worldwide** have **died in connection with the COVID "vaccination".** A comparison with the 6.8 million official deaths from COVID according to the *WHO* ultimately shows a **clearly negative net benefit for the "vaccination"**.

4.2.7.3 Same pattern in Switzerland: "Vaccinated" people fall ill and fill the hospitals [ER N 1383 ff.].

713 Unfortunately, Switzerland is also following this international trend:

714 As in Germany (N 709) - the Swiss population has also been "ailing" since the introduction of COVID-19 mRNA injections, as a health study by CSS *Insurance* shows. There has been a worrying **deterioration in the general state of health** of the Swiss population from 2020 to 2022 and a **marked increase in sick days** (particularly among **18 to 35-year-olds**).

715 COVID-19 disease is one of the most common "vaccination side effects " - the "vaccination" has therefore completely missed its target. Since spring 2022, the majority of "COVID-19 hospitalized" people have also been "vaccinated". And when it became clear that **the "vaccinated" were leading the COVID-19 hospitalizations by far,** the proportion of patients with "unknown vaccination status" was simply increased from 20.7% to **72.65%.** This enormous number of unreported cases is simply unacceptable - after all, it is easy to briefly enquire about and record the "vaccination status". Switzerland is thus deliberately **flying blind** - quite obviously in order to **cover up the presumably high proportion of "vaccinated" people in hospitals.**

716 Instead of simply allowing this blind flight, it would have long been up to Swissmedic to effectively monitor the effectiveness of the "vaccines" - among other things by recording "vaccination breakthroughs" (N 703 ff.). This is all the more the case as international data increasingly clearly demonstrates the ineffectiveness of the "vaccines" in preventing severe cases (N 502 f.).

717 Incidentally, the frequent assertion that the majority of "vaccinated" hospitalized people simply reflects the "vaccination coverage rate" is highly questionable from a medical point of view: if prevention is truly effective, it can of course be assumed that it is highly successful in preventing the disease against which it is used (with the exception of rare cases of "vaccination failure").

4.2.7.4 Conclusion: mRNA injections worsen health status [ER N 1404 ff].

718 Both the international and Swiss figures clearly show that COVID cases and the associated hospitalizations and deaths are driven by those who have been "vaccinated" several times.

719 **If the "vaccination" were effective and successfully prevented (severe) COVID-19 cases, COVID hospitalizations would have to be consistently led by unvaccinated people nationally and internationally**. Detailed analyses show that the global "vaccination campaigns" **correlate with unusual peaks in mortality.** Initial calculations show that - despite massive underreporting and all attempts at manipulation by the authorities - more people worldwide have died as a result of COVID "vaccinations" than as a result of the COVID-19 disease, resulting in a **clearly negative net benefit for the "vaccinations".**

4.2.8. Results of the published phase 1 to phase 4 studies by Comirnaty and Spikevax [ER N 1412 ff].

720 In September 2022, an **analysis of all completed and published study results from Comirnaty and Spikevax** was carried out, in which the available results were assessed in terms of their content and scientific value:

4.2.8.1 Comirnaty [ER N 1416 et seq.]

721 As of September 12, 2022, 27 of 138 Phase I/II/III/IV studies on Comirnaty had been completed, resulting in **37** preprints and peer-reviewed publications. None **of them stand up to even a brief analysis**, which is outlined in brief below:

- Observation period too short (1 publication);
- Mere review article without new findings (5 publ.);
- Immune response is comparable in pregnant, breastfeeding and non-pregnant women, no further safety data (1 Publ.);
- No statement regarding efficacy or safety of mRNA injections (14 publ.)
- Observation period too short and no investigation regarding correlation of observed increased antibody levels with reduced cases of disease (1 Pub.);
- Insufficient immunization against variants B.1.351 (1 Publ.);
- Moderna employees describe Spikevax as "superior" to Comirnaty on the basis of minimal incidence rates (1 Publ.);
- Observation period too short and inconsistent results (1 Publ.);
- Almost without exception, Pfizer/BioNTech employees report a "favorable benefit-risk profile" (1 Publ.);
- Use of different "vaccines" leads to more side effects (3 Publ.);
- Infection breakthroughs in "vaccinated" immunosuppressed patients are around three times higher than in non-immunosuppressed patients (1 Pub.);
- No study regarding correlation of observed increased antibody levels with reduced cases of disease (1 Pub.);
- Elevated antibody levels after mRNA injection in patients with chronic kidney disease, dialysis patients and kidney transplant patients, but no study on correlation of observed elevated antibody levels with reduced disease incidence (6 Pub.).

4.2.8.2 Spikevax [ER N 1440 et seq.]

As of September 12, 2022, 12 of 90 Phase I/II/III/IV studies on Spikevax had been completed, resulting in **17 preprints and peer-reviewed publications. All of these do not stand up to even a brief analysis**, which is outlined in brief below:

- Observation period too short and no study on correlation of generated "immunity" with reduced cases of disease (7 publ.);
- No study regarding correlation of observed increased antibody levels with reduced cases of disease (3 publ.);
- No statement regarding efficacy or safety of mRNA injections (5 Publ.);
- Moderna employees describe Spikevax as "superior" to Comirnaty on the basis of minimal incidence rates (1 Publ.);
- Simple comparison of side effects after basic immunization and after booster (1 Publ.).

4.2.8.3 Conclusion on the publications regarding Comirnaty and Spikevax [ER N 1451 et seq.]

722 All in all, **the 53 publications mentioned do not provide any new scientific findings that** would prove the **efficacy or safety of Comirnaty and Spikevax.** Either the publications had significant limitations, the observation period was too short or the studies investigated issues that have nothing to do with the efficacy or safety of the mRNA "vaccines". In particular, none of the studies proved that "generated immunity" correlates with an effective reduction in cases of disease.

4.2.9. Temporary authorization of the adapted bivalent Omikron booster "vaccines" [ER N 1454 f.].

723 On August 29, 2022 and October 10, 2022, two **bivalent COVID-19 "booster vaccines"**, Spikevax Bivalent Original/Omicron and Comirnaty Original/Omicron BA.1, were **temporarily authorized** by Swissmedic. These each contain half of the "vaccinations" initially approved for the basic immunization for a limited period of time. The findings regarding the efficacy and safety of the basic immunizations therefore also apply to the bivalent "vaccines".

4.2.9.1 Bivalent "Omikron vaccines" already obsolete at the time of approval [ER N 1456 ff].

724 At the time when the temporary authorizations for the bivalent "vaccines" updated with regard to BA.1 were granted, the BA.1 subline was no longer circulating in Switzerland to any

relevant extent. In other words, the "**vaccines" were already outdated at the time of approval** and therefore not suitable for the prophylactic treatment of a disease from the outset.

4.2.9.2 Manufacturer studies completely inadequate [ER N 1460 ff].

725 The **"efficacy data"** on these bivalent mRNA injections are also demonstrably **inadequate** and **completely unsuitable** for **demonstrating a benefit**:

726 First of all, it should be noted that various like-minded regulatory authorities (working together as the "Access Consortium") have created a joint position paper according to which, among other things, "**no** [extensive] **clinical studies**" are **required** for updated COVID-19 "vaccines", but **proof of an "immune response" is** sufficient. By means of a simple position paper, one of the most central safety mechanisms under therapeutic product law - proof of effective efficacy based on clinical studies - was thus simply removed (see N 1040 ff.).

727 According to the drug texts for the bivalent mRNA injections, the **increase in antibodies (AK) in the blood** was used as evidence of an "immune response". The detection of AK is a so-called "surrogate marker" that is used in a clinical trial as a substitute for a clinically relevant endpoint (e.g. mortality). However, this surrogate parameter is only useful if a causal relationship is proven; based on hard clinical endpoints in the approval studies, however, no relevant efficacy with regard to AK has been proven to date (see N 1052 and N 1098). The **surrogate marker "antibody"** is therefore **not validated.** Based on AK detection, therefore, no "major therapeutic benefit" (N 964 and N 1095 ff.) can be assumed.

728 The underlying animal study then shows that the bivalent Spikevax "vaccine" against newly circulating variants **does not** provide **any additional benefit**, but generates a comparable immune response to the original "vaccine". Swissmedic had obviously recognized this - and completely obscured this fact in the Information for healthcare professionals with barely comprehensible explanations (see below N 1198 ff.).

729 The basis for approval of the bivalent Comirnaty "vaccine" is an "interim analysis" in which AK values of different study groups were compared. Up to a few weeks after the injections, increased AK values were measured in "bivalently vaccinated" people, but it is **unknown how long the generated immune response lasted**. This would only be beneficial if the immune response lasts in the long term and if it also correlates with a reduction in (severe) cases of the disease. Neither has been proven to date.

730 It should only be mentioned in passing that the more recent bivalent Spikevax "vaccine" (Spikevax Bivalent Original / Omicron BA.4-5) is also based purely on AK measurements, which showed "non-inferiority" in an unblinded study compared with the basic immunization.

4.2.9.3 Study: Efficacy of bivalent "vaccines" insufficient at 20-39% [ER N 1482]

731 Finally, a study from December 19, 2022 also showed that the bivalent "vaccines" are associated with an insufficient **efficacy of only 20-39%.** The study also showed that the risk of **COVID-19 disease correlates positively with the number of "vaccine doses" administered.**

4.2.9.4 Conclusion: No effective proof of efficacy provided [ER N 1483]

732 The benefits of the bivalent Omikron booster "vaccines" were propagated solely on the basis of an increase in antibodies, although there has never been a well-founded investigation into whether this correlates with the prevention of COVID-19 cases and, in particular, severe cases. No proof of effective efficacy - let alone a "major therapeutic benefit" (Art. 9a TPA) - was ever provided by the manufacturers.

4.2.10. "Vaccine manufacturers" refuse to release data [ER N 1484 ff].

733 The phase 3 trials of Pfizer/Biontech and Moderna started in April 2020 and July 2020. According to the corresponding protocols, the duration of the phase 3 trials was originally set at a maximum of 26 months, but the end of the trial was subsequently postponed further and further without any plausible explanation.

734 This approach is justified in view of the manipulation of the study data already uncovered in 2021 (N 304), this approach must be regarded as a completely unacceptable cover-up tactic on the part of the marketing authorization holders.

4.3. Conclusion (end of 2022): Maximum risk with negative effectiveness [ER N 1489 ff.]

735 The devastating development that had already become apparent in 2021 continued in impressive fashion in 2022:

736 Alarm values for fatalities have been exceeded thousands of times - despite massive underreporting. Several studies have shown that the spike protein causes human deaths. Children die from mRNA "vaccinations" - the risk clearly exceeds the benefit for this population group. In general, "vaccinated" people die more often from COVID-19 than unvaccinated people. A conspicuous death rate has been observed worldwide since the start of the "vaccination campaigns".

737 The mRNA "vaccines" continue to be administered to pregnant women, even though not a single study on the effects on pregnant women has been successfully completed. The sad consequence of this is that thousands of stillbirths have been recorded worldwide - stillbirths which, like many other deaths, could have been prevented. There has been a historic decline in births worldwide. Studies presented by Swissmedic as supposed proof that "vaccinations" have no negative impact on fertility do not stand up to a thorough analysis.

738 The efficacy of the mRNA "vaccines" has not been proven in any way. With the Omikron boosters, there has even been a move to simply dispense with elementary clinical studies and rely on unvalidated surrogate markers instead. All manufacturer studies published up to September 2022 have failed to provide sufficient evidence of efficacy.

739 The risk-benefit ratio of mRNA "vaccines" is therefore not only close to zero - it is obviously negative.

5. Outlook: Use of self-replicating mRNA "vaccines"? [ER N 1503 ff.]

740 Despite the obvious failure of the mRNA "vaccines" and without waiting for the final results of the approval studies, mRNA technology continued to be pushed forward in the background: In the future, it is possible that not only non-replicating but even **"self-replicating mRNA"** (self-amplifying mRNA, "sa mRNA") will be used, as in the currently marketed "vaccines". These have the **ability to replicate independently in the human body.** If pharmacokinetic data is also to be dispensed with for these "vaccines", this would be extremely worrying, as it is virtually impossible to predict the quantity and duration of mRNA production in the human body in the case of self-replicating mRNA.

741 Vaccines with self-amplifying mRNA have already been tested in animal trials since 2015 for various infectious diseases such as Ebola, HIV, malaria, influenza rabies and Zika and for rabies and SARS-CoV-2 in initial human trials.

742 Results of a phase 1 trial with a self-amplifying mRNA COVID "vaccine" for SARS-CoV-2 were published in the journal Lancet on January 13, 2022:

743 The "vaccine" was administered to 192 volunteers twice in six different doses at four-week intervals. The generated immunity and side effects were subsequently observed over a period of eight weeks: The "vaccine" was deemed safe based on **six serious and 25 moderate adverse events,** all of which were classified as - allegedly - "not associated with the vaccine", but the generated immunity was deemed insufficient, which is why optimizations to the formulation were deemed necessary.

IV. Circumstances - "How dangerous was COVID-19 really?" [ER N 1507 f.]

744 All statements made in this section are based in full on the evidence report enclosed with this criminal complaint **(Enclosure 4),** which contains further discussions and lists the relevant supporting documents. The title structure in this section of the criminal complaint and the enclosed evidence report (section "*WHO pandemic* risk situation") correspond in terms of content, but are shifted by one level (e.g: Title level "**2nd** state of knowledge of Swissmedic mid-2020" of the criminal complaint corresponds to title level "**II** state of knowledge of Swissmedic mid-2020" of the evidence report). **Accordingly, reference is made in full to the detailed evidence report for proof and for more detailed explanations below.**

745 All approvals of the mRNA "vaccines" are under the impression of the "COVID pandemic": The aim of the mRNA "vaccinations" is to "combat" the so-called SARS-CoV-2 virus by immunizing the population against it and, in particular, to protect them from severe courses of the disease.

746 First of all, the (alleged) origin and (alleged) detection of SARS-CoV-2 will be discussed in a brief digression. There is no need for a conclusive classification here, as it will then be explained in detail - assuming that SARS-CoV-2 is actually the cause of the "COVID diseases" - that **SARS-CoV-2 has never** posed and does not pose **a life-threatening or disabling danger to the entire population** (target population).

1. Excursus: Origin and detection of SARS-CoV-2 [ER N 1509 ff].

747 The first "proof" of SARS-CoV-2 was already provided on January 10, 2020 by a working group led by Prof. ZHANG in Shanghai. However, the "proof" is based purely on computer models or bioinformatics (simplified below): Lung fluid was taken from a single person and - **without purification/centrifugation/sedimentation etc.** of the same - pieces of RNA of any chosen length contained therein were assembled using overlaps and "aligned" to two known gene sequences of corona viruses using two different (again arbitrarily chosen) "assemblers". In other words: Using certain software algorithms, **a "genome scaffold"** was **assembled** on the computer from a large number of unrelated short gene sequences **using "overlaps" and ultimately the "gene sequence" of SARS-CoV-2 was constructed using two known corona viruses (and specific PCR primers).** As a result, no precisely determined viral gene sequence was effectively isolated.

748 Whether strict proof - the detection of an isolate - of SARS-CoV-2 has been provided to date does not need to be conclusively clarified here. It is therefore assumed below that SARS-CoV-2 has been detected as a virus and as such causes the disease "COVID-19" .

2. Knowledge status Swissmedic mid-2020

2.1. Unscientific *FOPH* reporting *criteria* [ER N 1515 et seq.]

749 "COVID-19 cases" (and thus "COVID infections" but also "COVID-19 deaths") have been recorded worldwide from the outset according to the *WHO definition* and are based **almost exclusively** on the presence of a **positive PCR test result** (according to the *FOPH reporting criteria*). However, a positive PCR test result is **not a very meaningful "laboratory parameter"** per se and it is wrong from a medical and scientific point of view to diagnose a "COVID-19 case" based solely on a test result **without taking clinical symptoms into account**. Against this background, the **officially determined lethality of SARS-CoV-2** (which is based on the counting of "COVID-19 cases" and "COVID-19 deaths") must therefore be regarded as **inflated** (or, in the worst case, even completely false). To make matters worse, the *FOPH* defined unscientific reporting criteria, which inevitably led to an additional, systematic over-reporting of COVID-19 cases.

2.2. COVID-19: Not a life-threatening disease [ER N 1527 ff].

750 In mid-2020, a high to very high - demonstrably too high - **lethality of SARS-CoV-2** was assumed:

- In June/July 2020, an infection fatality rate (IFR) of **8%** (70-79 age group) and even **14.8%** (over 80 age group) was calculated for China;
- In July 2020, however, a lethality rate of "only" **0.6%** was calculated for the total population in Switzerland;
- In July 2020, the *CDC* assumed a death rate of **0.5-0.65%** of the total population;
- In August, the *WHO* put the lethality rate for the global population at **0.5 -1%.**

2.3. Conclusion: Unsuitable PCR test, overdetection of COVID-19 [ER N 1538 f.].

751 Despite the systematic overreporting of COVID-19 cases, it was therefore already apparent in summer 2020 that COVID-19, with an IFR of a maximum of 1% - which was far too high - was definitely not an unusually life-threatening disease of pandemic proportions.

3. Swissmedic's state of knowledge at the end of 2020 (first authorizations for adults)

3.1. Continued unscientific *BAG* reporting *criteria* [ER N 1540 ff].

752 On December 7, 2020, the ***WHO*** pointed out that a PCR test can give **false positive results** and that **clinical symptoms should** therefore **always be taken into account**. However, the **FOPH *reporting criteria*** were **not changed accordingly**.

3.2. COVID-19: Less dangerous than influenza for the majority of the population [ER N 1548 ff].

753 The first IFR figures were already massively revised downwards at the end of 2020: In October 2020, Prof. IOANNIDIS calculated a global mortality rate of just **0.15%-0.20%**; for people under the age of 70 it was as low as **0.03-0.04%.**

754 Even at this early stage, it was clear that the **"dangerousness" of SARS-CoV-2 was roughly equivalent to that of moderate flu:** according to the *WHO,* the mortality rate for seasonal flu (influenza, "flu") is normally less than 0.1%. In the USA, the *CDC* calculated a lethality rate of **0.1355% for** the total population for the last (moderate) flu epidemic of 2017-2018.

755 **There could therefore have been no question of a life-threatening or disabling disease for the entire adult population at the time of the first temporary approval.** If at all, the "vaccinations" could only have been considered for the more vulnerable people aged 70 and over.

3.3. Conspicuous mortality / excess mortality [ER N 1552 ff].

756 A detailed examination of publicly available sources, official statistics and other evidence carried out in the evidence report already produced the following findings for the end of 2020:

- The "excess mortality" calculations presented by the BfS must be put into perspective and cannot - in purely methodological terms - show any excess mortality in a historical comparison. In addition, the BfS is well aware of the fundamental difference between the methods (method [1] WHO vs. method [2] BfS), which was even communicated publicly in 2018 by means of a comparative graphic.
- COVID-19 was not a "pandemic of the century" - there was simply no historically relevant excess mortality in relation to the overall population.

- A conspicuous death rate was essentially limited to the over-65 age group, but COVID-19 in the "pandemic year" 2020 (already recognizable from the *BfS statistics)* could be ruled out as the sole cause of the increased death rate among the over-65s.
- The proportion of people who actually died predominantly as a result of COVID-19 was significantly lower than reported by the *FOPH* and *BfS,* based on the cause analysis described above, in particular because
  - a very large proportion of the "COVID-19 deaths" had already reached the age of average life expectancy,
  - the "COVID-19 measures" themselves also had harmful effects on health (in particular excessive use of invasive ventilation) and
  - ultimately, a large proportion of natural or alternative causes of death (especially serious pre-existing conditions) were recorded as "COVID-19 deaths" due to the misleading classification given by the *WHO*, but only a small fraction actually had COVID-19 as the predominantly causal cause of death.

757 All these circumstances were known to Swissmedic at the time of the first authorization of the mRNA injections, or had to be assumed to be known.

3.4. No overloading of hospitals in the "pandemic year" [ER N 1633 ff.]

758 The hospital system is designed (for cost reasons) in such a way that workload peaks can occur - especially in the winter months: In the past, for example, an **occupancy rate of around 90% in intensive care units** at university hospitals was definitely considered **normal**. A bed occupancy rate of "only" 80% was even classified as "unprofitable".

759 Despite this, Switzerland was sent into a second lockdown on 18 December 2020 due to an alleged "imminent overload of the healthcare system", even though the occupancy rate of intensive care beds was only around 75% and therefore within a completely normal range.

760 Despite repeated claims that the hospital system was overloaded, this was not the case throughout the entire "pandemic year" of 2020. There were always enough intensive care beds available during both lockdowns.

3.5. Conclusion at the end of 2020: No "pandemic" discernible [ER N 1643 ff].

761 At the end of 2020, the *FOPH* continued to maintain the obviously manipulative overreporting of COVID-19 cases. Nevertheless, the relevant data at the end of 2020 only allowed one conclusion to be drawn: there was simply no disease of "pandemic" proportions:

COVID-19 was no more dangerous than influenza, there was no historically conspicuous excess mortality in relation to the overall population and hospitals were never overcrowded.

4. Knowledge status Swissmedic mid-2021 (approval for adolescents)

4.1. *FOPH* sticks to unscientific reporting criteria despite *WHO appeal* [ER N 1647 ff.].

762 In January 2021, the ***WHO*** again drew attention to the fact that a **PCR test result** is **worthless on its own,** as it only serves as an **aid to diagnosis in connection with clinical observations** (= symptoms). Once again, this was **not taken into account in the *FOPH reporting criteria***.

763 The suitability of the PCR test for detecting the disease was also questioned by researchers based on new study results. The "high number of cases" was therefore already considered an irrelevant criterion in itself in June 2021.

4.2. COVID-19: Lack of threat, especially for young people [ER N 1651 ff.]

764 The lack of threat posed by SARS-CoV-2 to the Swiss population as a whole - and young people in particular - was already evident in June 2021: The global lethality rate (IFR) was revised downwards again by Prof. IOANNIDIS in March 2021 and set at **0.15%**. The *CDC* also adjusted its estimates downwards. **Even then, the IFR for adolescents was only 0.002% - so they were not at any risk from SARS-CoV-2.**

4.3. Conspicuous mortality / excess mortality [ER N 1657 ff].

765 As was already apparent at the end of 2020, there was no historical excess mortality for the total population (front N 756). The same finding was also confirmed for mid-2021:

- As of mid-2021, not even the official *BfS methodology* indicated a conspicuous mortality rate - and certainly no historical excess mortality was discernible.
- However, a closer analysis of the *BfS data* revealed **an increasingly striking increase in deaths from the end of 2020,** particularly in the **younger age groups that were virtually** unaffected by COVID-19. This increase was clearly closely linked in time to "vaccination activity".

766 These circumstances must also have been known to Swissmedic at the time of the first extension of the authorization for mRNA injections for adolescents.

4.4. No overloading of hospitals despite reduction in beds [ER N 1675 ff.].

767 Despite repeated predictions of horror scenarios, **Swiss hospitals were not overloaded** in winter 2020/2021**:** even at the "peak" of the crisis (December 2020), there was never a dangerous overload - despite politically forced bed reductions of 15-20% during the ongoing "pandemic" (!) .

4.5. Conclusion mid-2021: Young people in particular are not threatened in any way [ER N 1679 f.].

768 At the time the indication was extended to adolescents aged 12 and over, their IFR was in the region of 0.002% and therefore close to zero. In relation to the overall population, there was no historically conspicuous excess mortality. Despite the reduction in beds, there was never any threat of overloading Swiss hospitals. According to the data available at the time, no life-threatening or disabling disease could be identified that would have seriously threatened the entire target population of the COVID-19 "vaccinations".

769 However, there was a noticeable increase in the number of deaths, particularly in the younger age groups, which was clearly closely related to the "vaccination activity".

5. Status of knowledge at Swissmedic at the end of 2021 (approvals for "boosters" / children)

5.1. *FOPH reporting criteria* obsolete following Federal Supreme Court ruling [ER N 1681 et seq.]

770 On November 23, 2021, the **Federal Supreme Court stated** in a ruling that a **PCR test result "**is **not a diagnosis of disease and is of little significance on its own**". This announcement did not prompt the *FOPH* to act either: According to the ***FOPH* reporting *criteria,*** all positive PCR test results should continue to be reported, even **without taking the clinical picture into account**.

5.2. "Delta variant": Dangerousness of a mild flu; children not at risk [ER N 1684 ff].

771 The alleged threat posed by SARS-CoV-2 to the Swiss population as a whole was once again shown to be non-existent at the time the "booster" was approved: As early as July 2021, the lethality rate with the **"delta variant"** was ten times lower compared to the alpha/beta variant and still amounted to around **0.01-0.02% (IFR),** which corresponds to a

mild flu. This lower IFR was by no means due to the mRNA injections - these were already associated with a recognizably negative efficacy in 2021 (front N 502 f.; N 482 ff.; in particular for Switzerland N 494 and N 765 and N 774).

772 With regard to the "vaccination" for children, the following should also be noted:

- From the beginning of the "pandemic", children were never at risk of **mortality** above **0.0027%**. Children as the "target population" were therefore never threatened with death by SARS-CoV-2. In the official statistics of the *FOPH* and the Federal Statistical Office, four children who died from or with coronavirus were officially reported as deaths by the beginning of 2022. To date, however, despite relevant requests for evidence in over a dozen court cases brought by the co-signing attorney, the authorities have not provided evidence in a single case as to how many children in Switzerland have actually died or been hospitalized **predominantly as a result of infection with SARS-CoV-2**. [85]
- According to "Pediatrics Switzerland", "Long COVID" and "PIMS" pose no danger to children themselves, which means that there has never been a threat of a disabling disease.
- In September 2021, Pediatrics Switzerland also clarified that children - contrary to repeated claims - are not "superspreaders" and that the direction of infection is primarily from adults to children and not from children to adults.

773 **The risk of children becoming seriously ill with COVID-19 was close to zero at all times.** Accordingly, the requirement of Art. 9a para. 1 subpara. 1 TPA in conjunction with Art. Art. 18 lit. a VAZV, according to which the risk of severe disability or possible death must apply to all patients included in the target population - i.e. all children - was clearly not met at any time.

5.3. Conspicuous mortality / excess mortality [ER N 1705 ff].

774 In addition to the figures already reported at the end of 2020 (front N 756) and mid-2021 (front N 765), the following could be observed at the end of 2021:

- As at the end of 2021, no historical excess mortality could be identified for 2021 based on the age-standardized method.
- The supposed observation of an inconspicuous mortality rate in 2021 did not apply upon detailed analysis of the publicly available data with regard to the *BfS methodology* -

85 This delay in providing evidence on the part of the authorities is all the more relevant as the authorities are burdened with the burden of proof in proceedings to review the constitutionality of encroachments on fundamental rights within the meaning of Art. 36 of the Federal Constitution and encroachments on fundamental rights, particularly with regard to children (special protection of fundamental rights Art. 11 of the Federal Constitution), must be qualified as unconstitutional without proven necessity due to a breach of the principle of proportionality.

which Swissmedic could reasonably be expected to carry out: by mid-2021 at the latest, **an increasingly conspicuous increase in mortality was** observed **from the end of 2020**, particularly **in the age group that was virtually unaffected by COVID-19.** This increase in the number of deaths occurred in close temporal relation to "vaccination activity".

775 All these additional circumstances were known to Swissmedic at the time of the extensions of the authorization of the mRNA injections for children (as well as the "booster vaccinations" for adults), or had to be assumed as known.

5.4. No overloading of hospitals despite bed reductions; media campaign [ER N 1723 ff.].

776 Although hospital beds were further reduced, **the occupancy rate of intensive care units never exceeded 80% in** 2021. In addition, the officially reported **COVID patients** accounted for **only around 10% of hospitalizations overall, and significantly less during various periods.** Nevertheless, an unprecedented smear campaign against "unvaccinated" people, who would allegedly overload hospitals, was launched in the fall of 2021.

5.5. Conclusion at the end of 2021: no life-threatening / disabling illness [ER N 1735 f.]

777 At the latest with the "Delta" variant, whose IFR of 0.01-0.02% corresponded to a mild flu, a generally life-threatening or disabling disease that would have seriously threatened the entire target population of COVID-19 "vaccinations" and thus legitimized a temporary approval could not be identified from June/July 2021 onwards. For children in particular, the risk of serious illness was close to zero from the very beginning of the coronavirus crisis. In relation to the overall population, there was no historically conspicuous excess mortality. Despite the reduction in beds, there was never a risk of Swiss hospitals being overloaded.

778 However, there was a noticeable increase in the number of deaths, particularly in the younger age groups, which was clearly closely related to the "vaccination activity".

6. Swissmedic's state of knowledge as of 2022 ("Omikron variant") [ER N 1737]

6.1. PCR test: instrument for artificially inflating case numbers [ER N 1738 ff.].

779 The previously described unsuitability of the PCR test had clearly manifested itself by the end of 2021: the "laboratory-confirmed cases" had long since decoupled from the "laboratory-confirmed deaths". **The criterion of "case numbers" was therefore never suitable for effectively identifying a risk situation that needed to be combated.** Nevertheless, the *FOPH* stuck to the unscientific **reporting criteria.**

6.2. "Omicron variant": As dangerous as a cold [ER N 1742 ff].

780 With the "delta" variant of 2021 at the latest, there was no longer a disease threatening the population as a whole. The basic prerequisite of a life-threatening or disabling disease was clearly no longer met - indeed, it had not been met from the outset.

781 With the "Omikron" version, this realization was once again confirmed in all clarity:

- The lethality rate of the **"Omikron variant"** was still around **0.001-0.002% (IFR).** This means that "Omikron" is significantly **- at least 50 times - less dangerous** for the population as a whole **than normal influenza.**
- **Children**, in particular, were **never at serious risk of SARS-CoV-2** - the *CDC,* for example, was unable to document a single confirmed case of a healthy child aged 15 or younger dying from COVID-19 in March 2022.
- From 2022, there was also increasing evidence from studies carried out that **"Long COVID" and "PIMS"** do not pose any danger to the "unvaccinated", but that on the contrary, these symptoms are **much more likely to occur in the "vaccinated".** In August 2022, for example, it was shown that **a full 75% of the children treated in a specially established center for "post-COVID-19" children were "vaccinated".**

6.3. Conspicuous mortality / excess mortality [ER N 1762 ff].

782 The detailed examination of publicly available sources, official statistics and other evidence carried out in the evidence report - together with the results already presented above (end of 2020 [front N 756], mid-2021 [front N 765] and end of 2021 [front N 774]) - at the end of 2022, the following findings are mandatory:

- The "excess mortality" calculations presented by the BfS must be put into perspective and cannot - in purely methodological terms - show any excess mortality in a historical

comparison. In addition, the BfS is well aware of the fundamental difference between the methods (method [1] WHO vs. method [2] BfS), which was even communicated publicly in 2018 by means of a comparative graphic.

- COVID-19 was not a "pandemic of the century" - there was simply no historically relevant excess mortality in relation to the overall population.
- In the "pandemic year" 2020, COVID-19 can be ruled out as the sole cause of the increased death rate among the over 65s.
- In terms of excess mortality in an age-standardized comparison of the previous 12 years, 2021 is in second place .
- The year 2022 is in the fourth-best "place" in an identical analysis.
- According to *the BfS methodology,* from November 2021 to January 2023 there is a sustained mortality rate above the expected range (unique in a 12-year comparison).
- From January 2023, the *BfS* massively raised the expectation band for the over-65s, which was visible to the public.
- A detailed analysis of the *BfS data* and the application of a robust methodology reveals **a conspicuous and persistent mortality rate in all age groups** in close temporal relation to "vaccination activity" (Beck analysis).
- Prof. Beck's analysis reveals an obvious arbitrariness of methods on the part of the *BfS.*
- The proportion of people who actually died from COVID-19 was significantly lower than reported by the *FOPH* and *BfS* due to a detailed cause analysis, in particular because
  - a very large proportion of the "COVID-19 deaths" had already reached the age of average life expectancy,
  - the "COVID-19 measures" themselves also had harmful effects on health (in particular excessive use of invasive ventilation) and
  - ultimately, a large proportion of natural or alternative causes of death (especially serious pre-existing conditions) were recorded as "COVID-19 deaths" based on the *WHO's* classification, but only a small fraction actually had COVID-19 as the predominantly causal cause of death.

783 The special situation in 2022 could also be recognized by the fact that this year saw an abrupt and historically unprecedented drop in birth rates in Switzerland (apart from the First World War) and, after a detailed analysis, only the "vaccination event" can provide an explanation for this (above N 644 f.).

6.4. The 470 "COVID deaths" in the canton of Lucerne were primarily over 80-year-olds with a positive (PCR) test [ER N 1819 ff].

784 On September 30, 2022, the Government Council of the Canton of Lucerne published a report entitled "COVID-19 crisis management in the Canton of Lucerne". In the context of the "Initial situation", it states on p. 5: "470 people have died in the canton of Lucerne in connection with the virus up to August 2022."

785 On this basis, an interested resident put various questions to the State Chancellery of the Canton of Lucerne. The answers received can be summarized as follows: **Most of the "COVID-19 dead" in the canton of Lucerne died at an advanced age with a positive PCR test result and it is not known at all who died of COVID-19 as a cause and who did not.** This is yet another example of how the authorities are "informing" the population in a completely superficial manner - omitting elementary information - and are not even remotely willing to deal with the COVID crisis effectively.

6.5. No overloading of hospitals; manipulated case numbers [ER N 1824 ff.].

786 The situation in the area of (intensive care) hospital beds continued to develop in the winter of 2021/22 and thereafter in the completely normal range. In addition, from autumn 2021 at the latest, there was a **massive manipulation of the "case numbers" in hospitals: around 50% (!)** of the cases reported by the *FOPH* as "COVID-19 hospitalizations" were in fact not hospitalized due to a SARS-CoV-2 infection. This manipulation of figures led to an **unprecedented smear campaign** against the unvaccinated **("epidemic of the unvaccinated"), to** whom the "blame" for an - effectively unprecedented - overload of the hospital system was attributed.

6.6. Conclusion from 2022: No health risk whatsoever, measures obsolete [ER N 1831 f.].

787 By January 2022 at the latest, it was publicly known - and therefore generally accepted - that the **threat** posed by SARS-CoV-2 to **the healthcare system** (and therefore to people's health itself) had been **massively overstated.** In 2022, COVID-19 had demonstrably only reached the danger level of a common cold, which made any measures superfluous.

788 At the same time, however, there was a noticeable increase in the number of deaths, particularly in younger age groups. There was also a historically unprecedented slump in births. Both events are clearly closely linked in time to "vaccination activity", while COVID-19 can be ruled out as a cause after extensive analysis.

7. Overall conclusion: "COVID-19" was not a pandemic [ER N 1833 f.].

789 Even at the beginning of the "crisis" - i.e. in spring 2020 - SARS-CoV-2 did not pose a risk to the population as a whole that would exceed the level of a moderate flu. "Only" older people aged 70 and over were affected by a higher mortality rate. Children were not at risk at any time.

790 With the delta variant, the general "dangerousness" of SARS-CoV-2 was reduced to the level of a mild flu; with the Omikron variant, SARS-CoV-2 was around 50 times less deadly than a normal flu.

791 At no time was there a historically conspicuous excess mortality in the overall population. At no time were hospitals in Switzerland operating at more than 80% capacity.

792 **SARS-CoV-2 thus in no way represented a life-threatening or disabling disease for the entire adult population from the time of the "temporary" approval of the experimental mRNA therapies.**

793 On the other hand, **with the start of "vaccination activity", there has** been both a **noticeable increase in deaths** (especially in younger age groups) and a **historically unprecedented drop in birth rates**, while COVID-19 can be ruled out as the cause of these alarming developments.

V. Means of action/circumstances: Final risk-benefit analysis as at June 2023 [ER N 1835 ff.].

1. Preliminary remarks

794 In the context of the means and circumstances of the case, the legally relevant question to be assessed is, in particular, what a benefit/risk analysis carried out in accordance with the standards of the Therapeutic Products Act, on the basis of science and in accordance with previous practice should have looked like with regard to the mRNA-based COVID-19 "vaccines" from Pfizer and Moderna, and what conclusions an independent, qualified expert should have reached here by exercising the usual care. The rules applicable to Swissmedic and the resources and expertise available to it must be taken into account.

795 With regard to the risk/benefit assessment, the following legal framework conditions are relevant in advance:

796 According to Art. 1 of the Therapeutic Products Act (TPA, SR 812.21), "**only high-quality, safe and effective therapeutic products** may **be placed on the market** [and thus authorized] for the protection of human (and animal) health". Accordingly, the TPA sets a very

high standard of care for anyone who "handles therapeutic products" by requiring that these persons - including those authorized - "**take all measures that are necessary according to the state of the art in science and technology to ensure that *human and animal health is not endangered*".** (Art. 3 TPA). When carrying out any benefit/risk analysis, the focus must therefore always be on the potential hazard posed by medicinal products and on risk avoidance.

797 In the light of this general duty of care, for the purposes of (formally) temporary authorizations it must also always be checked whether the medicinal product to be authorized is "**compatible with the protection of health"** (Art. 9a para. 1 lit. a TPA) and whether "**a major therapeutic benefit** is **to be expected from its use**" (Art. 9a para. 1 lit. b TPA).

798 Furthermore, it is particularly relevant for "vaccines" that, according to the Federal Council Ordinance, their primary benefit and purpose should be [...] "to **generate active or passive immunity**" (Art. 2 of the Medicinal Products Licensing Ordinance; MPLO, SR 812.212.1). For the purposes of the benefit-risk analysis, proof that the mRNA-based COVID-19 "vaccines" actually generate active or passive immunity is therefore expected before any authorization of a "vaccine".

799 According to the principles mentioned above, the benefits and all risks of COVID-19 "vaccinations" must therefore first be determined separately and then compared with each other. This benefit/risk analysis must of course be carried out by the approval authority **before approval is granted** and taking into account the current "state of the art in science and technology", and not only from a historical perspective. Accordingly, it must also **continuously review** the accuracy of its analysis, as this is the only way to ensure that new scientific and technical findings are taken into account and that only effective and safe medicinal products are available on the market.

800 If the risks of a medicinal product outweigh the benefits, it is an unsafe medicinal product that contravenes the purpose of Art. 1 TPA. The authorization must be refused or withdrawn immediately and the medicinal product must be withdrawn from the market.

801 **The less serious the disease to be treated and the more robust the target population, the fewer risks may be created or accepted with a new medicinal product. Conversely, in exceptional cases, more severe side effects of a medicinal product may appear temporarily acceptable if the product is suitable for the treatment of a truly life-threatening or disabling disease and if a less risky treatment is not available** (Art. 9a TPA). This general risk-benefit analysis must be distinguished from the individual risk-benefit assessment, which is carried out by the treating physician for a specific patient in a specific case.

802 The relevant risk-benefit assessment must always be **carried out with regard to the relevant target population**. In doing so, it must be taken into account and specified which population groups are more or less affected by the respective disease. Authorization of a product is only possible for those populations that are significantly affected by the disease in question (so-called **indication**).

803 In the specific case of COVID-19 vaccines under the special pharmaceutical law regime of "temporary authorization" pursuant to Art. 9a TPA, a market authorization for all those population groups for which COVID-19 poses neither a life-threatening nor a disabling risk is therefore ruled out (see wording of Art. 9a para. 1 TPA; see in detail below N 1070 et seq.).

804 The benefit-risk analysis for the authorization of a medicinal product is generally based on the authorization dossier, which contains complete information on preclinical studies in animals, clinical studies in humans (phase 1-3) and the quality of the medicinal product. In addition, the authority must include all information available "according to the state of the art in science and technology" (Art. 3 TPA) in its analysis.

805 The regulatory authority may therefore only approve a medicinal product if the risk-benefit analysis **for the respective target group with the respective indication** is **clearly positive**, after taking into account all available knowledge on the possible risks "according to the state of the art in science and technology".

806 With regard to authorizations granted only "for a limited period" within the meaning of Art. 9a TPA, the law allows proof of safety and efficacy to be provided on the basis of short-term studies and long-term studies to be submitted at the end of the period. However, the **major therapeutic benefit of** the medicinal product required by Art. 9a para. 1 lit. b TPA must at least be recognizable and all other authorisation criteria must be fulfilled (see also N 1095 ff.).

2. Benefit/risk analysis [ER N 1835 ff. N 1845 ff.].

807 In order to subject Swissmedic's mRNA approval practice to a serious review, all aspects relevant to the decision with regard to the benefits and risks were presented in detail in the Evidence Report (Annex **13**) and ultimately summarized in **Chapter D. ("Final benefit/risk analysis as of March 2023").** To understand the legal assessment presented here, the explanations on the benefit/risk ratio in the evidence report, in particular in the aforementioned Chapter D. (ER N 1835 ff.) are therefore essential, with certain additions from the criminal complaint.

808 In addition, the **studies presented by Swissmedic as justification** were also reviewed in the evidence report, insofar as these studies were communicated by Swissmedic (ER N 1116 ff.).

809 To avoid unnecessary repetition, only the most important elements of the benefit/risk analysis from the evidence report are highlighted below. **The final explanation and argumentation on the legally relevant facts can be found in the evidence report**.

810 Any analysis carried out in accordance with the law and practice to determine the net benefit of the mRNA-based COVID-19 vaccines for the entire population would have had to take into account the facts presented in detail in the evidence report and not conclusively summarized below at the end of 2020 and in the following years.

2.1. Benefits of the "vaccination"?

2.1.1. Which potential hazards should be eliminated?

811 **The pathogen circulating in 2020 with the name "SARS-CoV-2" posed no extraordinary or extreme potential threat to Switzerland.** As documented in detail in the evidence report (summary: ER N 1833), this fact was readily apparent to Swissmedic at the end of 2020 and subsequently. In particular, at the time of the first authorizations of mRNA-based COVID-19 "vaccines", Swissmedic was well aware beyond reasonable doubt that

- **[i.]** that the PCR test procedure is unsuitable for reliable proof of COVID-19 as the predominant cause of illness or death without a detailed medical examination (ER N 1540 et seq.),
- **[ii.]** that the WHO guidelines (ER N 1610 et seq.) worldwide, as well as the FOPH's guidelines for Switzerland (ER N 1544, N 1619 et seq.), led to a **systematic overreporting** of COVID-19 disease and COVID-19 deaths (ER N 1540 et seq.; see also ER N 1650, N 1681 et seq., N 1738 et seq.),
- **[iii.]** that there was no **historical excess mortality** in Switzerland for the year 2020 and that there was no exceptional mortality of the total population up to at least 65 years of age (ER N 1576 et seq., N 1597 et seq.);
- **[iv.]** that the conspicuous death rate among the over-65s in Switzerland in the first two "COVID waves" (March and October/November 2020) was to a very large extent due to causes of death other than SARS-CoV-2 (ER N 1540 ff., N 1583 ff., N 1597 ff.),
- **[v.]** that the average age at death of all "persons who died with a positive PCR test" in 2020 was 83 years (men) and 86 years (women) according to the FOPH weekly reports (ER N 1592 ff., N 1605).

- **[vi.]** that despite continuous bed reductions from March 2020, the hospitals were never seriously overloaded throughout Switzerland , and that any short-term staff shortages were often due to overly cautious regulations in the event of positive PCR test results with subsequent quarantine or isolation (ER N 1633 ff.).
- **[vii.]** Moreover, at the end of 2020, alternative, effective treatment solutions were also available for the older population, but these were consistently excluded by Swissmedic (see N 1110 ff, N 1115 ff., N 1120 f.).

812 This means that, as at the end of 2020, no general serious threat from SARS-CoV-2 had ever been legally proven for healthy people under the age of 70 in Switzerland. **If the majority of the Swiss population, regardless of age, had been exposed to a generally life-threatening viral disease in 2020, the statistics [i.] - [vi.] mentioned above would have looked very different.**

813 These facts are absolutely legally relevant and documented in the evidence report. They would have been generally available to any specialist and must therefore also be considered known to all persons notified. There could be no question of an exceptional or even unique epidemiological threat to Switzerland from SARS-CoV-2 either at the end of 2020 or ever thereafter. **The risk potential of SARS-CoV-2 was demonstrably limited to the effects of a slightly more aggressive flu - depending on the age group and predisposition - in the population group over 65 years of age.**

2.1.2. Lack of benefit: No protective effect [ER N 1914 ff.]

814 Every medicinal product had to and must be measured against the actually identifiable COVID-19 risk potential described above (which was manageable in every respect). Authorization for vaccines against COVID-19 can only be considered for those medicinal products that actually and effectively reduce the identified - manageable - COVID-19 risk, but without creating new risks that could be greater than the risk originally identified for SARS-CoV-2.

815 The evidence report demonstrated in detail that the mRNA preparations were neither effective in preventing infection of the vaccinated persons nor in preventing transmission of the virus to third parties.

816 The approval studies corrupted by the manufacturers themselves only show benefits for minor events, but not for serious COVID diseases (ER N 1915 ff.; see also above N 296 ff, 376 ff, 498 ff, 688 ff.).

817 Significantly, the manufacturers have so far refrained from providing solid evidence of the benefits of the COVID-19 "vaccines" claimed by Swissmedic in the medium and long term

based on a **prospective randomized placebo-controlled trial (RCT)**, as would normally be a mandatory requirement for the proper approval of a medicinal product. Randomized controlled trials (RCTs) are still the gold standard and must never be replaced by methodologically clearly inferior studies such as database analyses, observational studies or even "modelling" (ER N 349 ff., N 1944).

818 The COVID-19 "vaccines" show negative efficacy overall and show a strikingly strong correlation with increased mortality (ER N 1923 ff.), see the following explanations.

2.2. New risks through mRNA technology

819 In view of the fact that SARS-CoV-2 was a phenomenon that could be controlled with existing preparations and existing forms of treatment even without special approvals for novel preparations (see N 1110 ff., N 1115 ff.), which had a perfectly manageable risk potential, **all those approaches to solutions that are associated with considerable risks and uncertainties are out of the question. Under no circumstances should the health of the population have been endangered by new risks**.

820 Unfortunately, the mRNA-based COVID-19 "vaccines" are a technology that dwarfs everything that has gone before in terms of risk factors, both qualitatively and quantitatively. In order to avoid repetition, only the most important categories of significant risk factors are recapitulated below, citing the corresponding references in the accompanying evidence report. The entire body of evidence presented in the evidence report is authoritative.

2.2.1. Fatal lack of controllability of mRNA technology [ER 1845 ff].

821 **All mRNA-based vaccinations are characterized by the fact that the production of the actual immunizing agent** (spike protein; so-called active pharmaceutical ingredient) **cannot be controlled in any way:** neither [i.] the quantitative dosage (ER N 51 ff.), [ii.] the duration of production and effect (ER N 77 ff.), [iii.] the site of production in the body (ER N 45 ff.) and not even [iv.] the quality of the spike protein produced (ER N 54 ff.) are controllable with mRNA technology. Even many months after the injection, non-endogenous spike proteins of unknown quality were detected in the brain, eyes, liver, ovaries and testicles (ER N 310 ff.). **This fundamental deficiency in all pharmacological parameters is due to the special mRNA technology itself and will never be remedied, neither with a perfected production process nor with large-scale randomized, controlled long-term trials.**

822 In addition, it was already known among experts at the end of 2020 that cells that carry the foreign spike protein on their surface are recognized as "foreign" by the immune system,

attacked and eliminated. The effect of the artificially produced spike protein is therefore fatally toxic. This mechanism of action was explained in detail in the ER (ER N 43 ff., ER 51 ff., N 594 ff., N 1155 ff.).

823 The evidence report also explained that the injected mRNA substances are packaged in **lipid nanoparticles**, which are highly toxic and have the potential to cause significant harm to the human body (ER N 118 ff., N 137 ff.).

824 In addition, Swissmedic has long been aware that mRNA products belong to the group of **Advance Therapy Medicinal Products** (ATMPs), i.e. are to be regarded as high-risk products because "**they contain nucleic acid, regulate gene expression and, as 'biologically active material' (i.e. RNA), are treated in the same way as genetically modified organisms (GMOs)**" (N 530 f.), and that for this reason alone and also in accordance with Art. 12 para. 5 lit. c and e of the Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Authorization of Medicinal Products and the Authorization of Medicinal Products under the Notification Procedure (VAZV, SR 812.212.23), a temporary authorization under Art. 9a TPA was simply inadmissible from the outset (see also N 526 ff., N 916 ff.).

825 For these reasons, Swissmedic must have been aware even before the start of the authorization procedure that **the mRNA products were highly risky experimental substances** whose risk to the healthy population under the age of 65 was obviously greater and significantly more threatening in several respects than the entirely manageable risk from SARS-CoV-2 infections alone. In **accordance with Art. 1, 3 and 7 TPA, Swissmedic would therefore have had a compelling reason to strictly refrain from authorizing the mRNA-based COVID-19 "vaccines" from the outset - regardless of the authorization title**.

826 **However, by authorizing mRNA-based COVID-19 vaccines, Swissmedic actually created new risks that were (and still are) many times greater and more unmanageable than the COVID-19 disease itself**:

2.2.2. Plethora of unprecedented special risk factors [ER N 1864 ff].

827 **DNA contamination**: Although the manufacturers are obliged to take measures to remove the DNA from the vaccines during production in purification steps (ER N 29 ff.), the mRNA "vaccines" of interest here are contaminated with DNA from bacterial E. coli cells far in excess of the permissible limits, which should have led to the refusal of authorization as an independent risk (ER N 196; N 207 ff.).

828 As the public only learned at the end of 2023 (but Swissmedic already knew from the end of 2020), the manufacturing process for the mRNA products actually administered

("manufacturing process 2" with plasmid DNA) differed fundamentally from the manufacturing process for the products formally approved by Swissmedic ("manufacturing process 1"; ER N 190, N 207 ff.). The administered products of manufacturing process 2 have a scandalously high level of bacterial autonomously replicating DNA impurities (so-called "plasmids"), so that consequently **all products according to manufacturing process 2** would have **to be considered as "never authorized".** However, Swissmedic tolerated this further massive risk factor without informing the public and without suspending the mRNA authorizations.

829 **Uncontrolled production (i.)**: As was to be expected after the historically uniquely short development period for mRNA preparations, the **quality of the batches produced** was extremely variable, as can be seen from the sometimes extremely different side effect patterns per batch. This shortcoming should never have been accepted by Swissmedic in view of the otherwise strict industry standards (see N 417 ff.; ER N 634 ff., N 651 ff.).

830 **Uncontrolled production (ii.):** Swissmedic allowed the injected starting substance (the modified mRNA) to exhibit large fluctuations in the range of 37-126% of the officially declared mRNA content per dose (above 225 ff.; ER N 174 ff.). With regard to the manufacturers' **dose-finding studies, which were** inadequate in every respect, and the associated risks, reference is made to the comments in the evidence report under N 1873 ff.

831 **Toxicity:** The aforementioned toxicity of **lipid nanoparticles** (ER N 137 ff.) and the **toxic effect of spike proteins** were not considered by Swissmedic as a risk factor at any time after authorization (ER N 43 ff., N 51 ff., N 594 ff., N 1155 ff.).

832 With regard to the **lack of safety evidence due to existing or inadequate animal studies,** please refer to the comments in the Evidence Report under N 265 ff, N 272 ff and N 280 ff.

833 Please refer to the comments in the Evidence Report under N 1878 ff. for the almost alarmingly numerous **adverse reaction reports from public** registers (in particular on blood coagulation disorders: ER N 1887 ff.), in each case with further references.

834 The fact that the manufacturers themselves also refer to exceptional and serious side effects is repeatedly explained in the evidence report: regarding **PSUR 1** from Pfizer/BioNTech (Comirnaty) see ER N 621 ff., N 644 ff., N 1880; regarding **PSUR 3** from Pfizer/BioNTech (Comirnaty) see ER N 970 ff., N 1882 (in each case with further references).

835 The striking **side effects in the area of myocarditis** are explained and demonstrated in detail in the evidence report under N 1171 ff. and N 1891 ff.

836 The **massive harm to children and adolescents is** dealt with in the Evidence Report under N 1025 ff. and the **side effects in infants** identified by Swissmedic are presented in the Evidence Report under N 1031 ff.

837 The striking **side effects in the area of fertility and fertility decline are** presented in the evidence report under N 1046 ff. and under N 1906 ff.

838 The strikingly frequent **damage to the immune system** after COVID "vaccination", which has already been described in the specialist literature in various publications as **"Vaccine-Acquired Immune Deficiency Syndrome" (V-AIDS), is** described in the evidence report under N 1220 ff.

839 The fact of **massive underreporting** of adverse mRNA side effects is demonstrated in detail in the evidence report under N 1001 ff.

840 With regard to Swissmedic's **product monitoring measures, which are inadequate in** every respect, reference is made to the comments in the Evidence Report under N 1864 ff. (see also ER N 1948 ff.; also N 1151 ff.).

841 Adverse events among mRNA-based preparations have long since reached historic highs, with **COVID-19 itself being** identified **as one of the most common side effects. Please refer to the** explanations in the evidence report under N 1878 ff. For **many** other risk factors, see N 1291, N 1298, N 1305 and N 1311.

842 The above list is by no means an exhaustive summary of the findings and evidence according to the evidence report. Rather, it serves as an introduction to the sheer endless mass of evidence on this topic. From this by no means exhaustive list and also from the evidence summarized at the beginning of the Executive Summary of this criminal complaint on the proof of risks and damage that has actually occurred, it is clear beyond any doubt: never before in the history of Switzerland has a medicinal product with such a negative benefit/risk profile been approved and administered to the general public - without indications of a specific life-threatening or seriously damaging disease for the entire population.

2.3. Experimental nature of COVID mRNA injections [ER N 1931 ff.]

843 Finally, it should be made clear why the vaccines discussed here are still obviously experimental in nature from various points of view:

844 The authorized substances initially have **an experimental character (I)** due to Swissmedic's authorization practice, which was contrary to its duties and which - as one lapse among many - already accepted fluctuations in the range of 37-126% of the officially

declared mRNA content per dose for the injected mRNA starting substance ("pro-drug") (see above N 225 ff.; ER N 174 ff.).

845 However, the authorised substances also have **an experimental character (II)** because the internal body cell production process for manufacturing the immunizing spike proteins forced by the mRNA injection provides anything but controllable production results, which was described in detail in the evidence report (ER N 43 ff., N 51 ff., N 77 ff., N 594 ff., N 1155 ff., N 1845 ff.). In response to an inquiry in January 2023, Swissmedic even explicitly admitted that it had no idea how much spike protein is produced in a person after an mRNA injection (ER N 1168).

846 Finally, these mRNA substances have **an experimental character (III) primarily because,** as already mentioned several times - after a record-breaking short development phase - the manufacturers have refrained from proving the benefits and safety of the COVID-19 "vaccines" claimed by Swissmedic based on **prospective randomized placebo-controlled trials (RCT)** with a sufficiently large number of participants over at least two years, as would normally be mandatory for proper approvals of any other medicinal product. (ER N 349 ff., N 1944).

847 **There can therefore be no doubt that the approval and administration of the COVID-19 "vaccines" is still predominantly experimental in nature, even if this has not been openly declared by the responsible authorities in any way.** This macabre experiment with our own population must be stopped immediately across the board after a full three years of approval.

2.4. Swissmedic's ineffectual defense and justification

2.4.1. Swissmedic's unsuitable claim that COVID-19 vaccines have no effect on fertility

848 In response to an individual inquiry as to which sources Swissmedic relied on when it concluded in its media release of 30 September 2022 that the COVID-19 "vaccines" had no impact on fertility (ER N 1112 et seq.), Swissmedic provided an excerpt of 11 references to studies that were allegedly intended to refute the feared impact of COVID-19 vaccinations on fertility.

849 These 11 studies were listed in the evidence report under ER N 1116. The validity of these 11 studies was clearly and verifiably refuted in the ER by means of an expert opinion by Dr. rer. nat. Hans-Joachim Kremer (ER N 1117 ff. and Supplement **54** to the ER; see also N 655 ff.). Swissmedic's attempt to disprove the influence of COVID-19 "vaccinations" on

fertility has failed, and the corresponding significant risks remain (see in detail above N 631 ff. [in particular N 644], N 649 f., N 651 ff., N 655 et seq.).

2.4.2. Corrupted "modeling study": "14.4 million deaths prevented"

850 A "modeling study" published in September 2022 was supposed to make it plausible to the world once and for all that the COVID "vaccines" would have prevented 14.4 million deaths. This study is repeatedly referred to both in the Swiss media and by the health authorities. The general opinion now prevails that this study has put any discussion about benefit and risk analyses to bed once and for all, and that everyone has empirical proof: "Look, the vaccine worked!"

851 The evidence report examined this study in detail and demonstrated that it is based on false and manipulated data and was written by authors with obvious conflicts of interest. For these reasons, this study is in no way to be classified as credible and is not suitable as court-proof evidence to prove an alleged positive benefit of COVID-19 vaccinations (ER N 1370 ff.).

3. Conclusion: Benefit/risk assessment NEGATIVE

852 The legally relevant facts explained in detail in the evidence report are sufficiently precise and comprehensively documented. After a detailed analysis of all legally relevant facts, it can only be concluded that **the risks associated with the mRNA substances** of contracting or dying from **serious side effects far exceed** the risk of contracting or dying from COVID-19 beyond any reasonable doubt**.** A benefit that is even halfway immunizing with these mRNA preparations - a protective effect against infection and transmission - has **never been proven by means of prospective randomized placebo-controlled long-term studies (RCT)**.

853 The "temporary" authorization pursuant to Art. 9a TPA (in the sense of a de facto "emergency authorization" or a de facto "pandemic authorization") for general use should not have been granted under any circumstances and should never have been extended due to the lack of any protective effect and the exorbitant risks.

854 **Consideration of the increasingly overwhelming data situation must necessarily lead to the conclusion [i.]** that the benefit of these mRNA "vaccines" was exclusively negative from the outset, **[ii.]** that all the facts must have been known to those responsible at Swissmedic from the outset; **[iii.]** that the mRNA substances should never have been authorized as COVID-19 "vaccines" due to the lack of controllability of the production process (and certainly not as ATMPs under the special temporary authorization procedure) and **[iv.]** that

- in order to prevent further harm to the population - they should have been withdrawn from circulation immediately .

855 In view of the extremely solid and comprehensively evaluated and processed facts, it can be ruled out that this negative benefit/risk assessment for the substances in question will ever turn positive. The "medicine" is far more dangerous than the "disease".

856 For all these reasons, all available mRNA preparations against COVID-19 must be **regarded** as unsuitable **NON-VALEUR with an unusually high risk content, both from** an epidemiological-medical and economic point of view, **and should finally be treated accordingly.**

VI. Swissmedic's criminal act - Illegal "pandemic authorizations"

857 Due to the legal explanations, this chapter is dealt with exclusively in the criminal complaint (and not also in the evidence report). For individual aspects, explicit reference is made to the evidence report where appropriate.

858 According to Art. 2 lit. b AMBV, vaccines are classified as medicinal products ("immunological medicinal products"). They are used "to produce active or passive immunity or to diagnose a state of immunity" and, according to Art. 1 TPA, may only be authorized in Switzerland for the protection of human and animal health if they are effective, safe and of high quality. In other words, the risk-benefit assessment by the authorization authority Swissmedic must be clearly positive. The smaller the expected benefit of a medicinal product, the more carefully potential risks must be analyzed and the suspected cases of adverse drug reactions observed after marketing authorization must be monitored. Risks and benefits must be weighted differently depending on the target population: In the case of a medicinal product that is used for advanced cancer, more and more severe side effects may generally be accepted than for a medicinal product that - as in the current case of COVID "vaccinations" - is only to be administered to a primarily healthy population, including children, for **preventive protection.**

859 Based on the above, it is clear that the **mRNA "vaccines" are drugs with a maximum risk profile and minimal to hardly any efficacy.** There were no circumstances at any time that would justify approval with such a devastating cost-benefit profile.

860 Nevertheless, Swissmedic granted a so-called "temporary" authorization for the mRNA "vaccines" for the first time in December 2020 and subsequently extended it several times. The following section therefore examines the characteristics and requirements of the "temporary authorization" and whether these were fulfilled. In order to better locate the "temporary" authorization in the system of the various authorization procedures under therapeutic

products law, the ordinary authorization procedure is described in detail below and then differentiated from the "simplified" and "temporary" authorization procedures.

861 It will become clear that **the "temporary" authorization of a medicinal product can circumvent practically all ordinary safety mechanisms under therapeutic products legislation.** And what's more: Swissmedic has even bypassed the few remaining safety requirements of the "temporary" authorization procedure - which Swissmedic has even imposed on itself - with regard to the mRNA "vaccines" and distorted them beyond recognition with actual "pandemic authorizations":

1. Usual admission procedure: Ordinary admission

862 In Switzerland, medicinal products are normally authorized "ordinarily" on the basis of Art. 9, 10, 11 and 16 TPA and the corresponding implementing provisions .[86]

1.1. Application for authorization with complete data

1.1.1. Development of a drug through to approval

863 **The development of a drug and especially a vaccine takes an average of ten to twenty years. It** regularly takes **over 13 years from the** idea to the approved drug.[87] During this time, scientists from different disciplines - chemists, biologists, doctors and pharmacists - work closely together. If all tests during the development phase have been successful, the manufacturer can apply for approval from the relevant authorities by submitting all the results documenting the preclinical and clinical development and production as an **"approval dossier".**

864 The success rate for the approval of a new drug is very low: **out of 10,000 drug candidates, only one actually reaches the market in the end.** Reasons for discontinuing the development of a new drug are often insufficient efficacy or serious side effects.[88]

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86 In particular the Ordinance on Medicinal Products (VAM; SR 812.212.21) and the Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorization of Medicinal Products (Ordinance on the Authorization of Medicinal Products; AMZV; SR 812.212.22).

87 vfa. Die forschenden Pharma-Unternehmen, "Klinische Studien zur Erprobung neuer Medikamente", 28.12.2016, https://www.vfa.de/de/arzneimittel-forschung/so-funktioniert-pharmaforschung/klinische-studien-uebersicht.html.

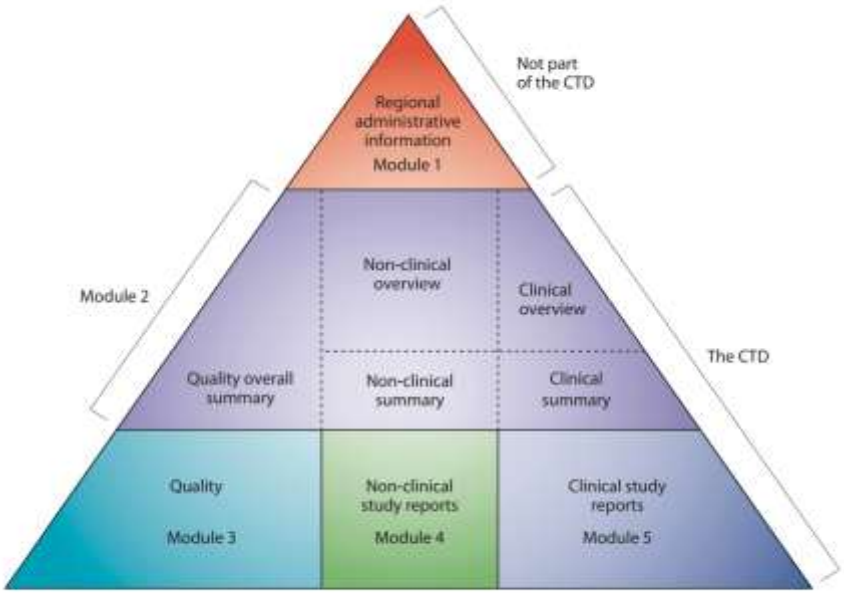
88 Infovac, "Development of vaccines", 04.10.2021, https://www.infovac.ch/de/faq/entwicklung-von-impfstoffen; Interpharma, "Approval and market launch", 09.06.2022, https://www.interpharma.ch/themen/fuhrend-in-forschung-entwicklung/der-weg-eines-medikaments/zulassung-und-markteinfuehrung-phase-iv/.

1.1.2. International standardization by means of CTD (modules 1-5)

865 An application for the authorization of a human medicinal product with a new active pharmaceutical ingredient must be submitted to the competent regulatory authority with an internationally uniformly defined structure in **5 modules**, in the so-called **"CTD" format** ("Common Technical Document" format). This is intended to ensure that an applicant does not have to compile the application documents anew for each authorization authority and that the applications can be compared. The CTD format was also implemented in Switzerland in 2003. The modules are structured as follows:[89]

- Module 1 contains administrative information and varies from country to country. Among other things, it contains a comprehensive table of contents of the entire dossier, regionally and administratively important information, various forms, as well as information on the use of the medicinal product such as medicinal product texts (Information for healthcare professionals, Patient information).
- Module 2 provides an overview of modules 3-5.
- **Module 3** deals with pharmaceutical **quality.** The chemical, pharmaceutical and biological information on the medicinal product can be found here - i.e. information on the manufacturing process, the control, characterization and specifications of the active pharmaceutical ingredient, the excipients and the finished medicinal product.
- **Module 4** deals with the **safety** of the medicinal product and contains all reports on the **preclinical studies** (studies "in vivo" on animals or "in vitro"). Among other things, the results of the pharmacology of the medicinal product (pharmacokinetics, pharmacodynamics) and the studies that have analyzed the safety of the medicinal product in "toxicity studies" can be found here.
- **Module 5** concerns the **efficacy of** the medicinal product and contains the study reports of the **clinical** trials conducted on humans.

89 ICH (The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), "M4: The Common Technical Document", 09.06.2022, https://www.ich.org/page/ctd. SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 10 f.; JORDAN, "An overview of the Common Technical Document (CTD) regulatory dossier", 2014, *https://journal.emwa.org/regulatory-writing-basics/an-overview-of-the-common-technical-document-ctd-regulatory-dossier/article/1693/2047480614z2e000000000207.pdf.*



The CTD triangle. The Common Technical Document is organized into five modules. Module 1 is region specific and modules 2, 3, 4 and 5 are intended to be common for all regions.

1.1.3. Legal regulation in the HMG

866 According to Art. 11 TPA, the application for authorization must "contain all information and documents essential for the assessment". Accordingly, a **complete authorization dossier** must be submitted, containing at least (Art. 11 para. 1 and para. 2 lit. a **no. 1-6 TPA**):[90]

1) the production method, composition, quality and shelf life [Module 2/3],
2) the results of the physical, chemical, galenic and biological or microbiological tests, **[Module 3]**
3) the results of the pharmacological, toxicological, **[Module 4]** and clinical trials **[Module 5]**, including all results from trials in special population groups,
4) the curative effects and the undesirable effects **[Module 5]**,
5) the labeling, the medicinal product information as well as the method of dispensing and use [Module 1],
6) an assessment of the risks and, where necessary, a plan for their systematic identification, clarification and prevention (pharmacovigilance plan) [Module 1],
7) the pediatric investigation plan in accordance with Article 54a TPA [Module 1].

867 For medicinal products with a new active pharmaceutical ingredient, a large amount of documentation must therefore be submitted, which includes all known product properties, the **results of years of research efforts in the context of preclinical and clinical trials,** the

90 Cf. SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 16.

complete patient and product information including packaging samples as well as **risk assessment plans** and test concepts.[91]

1.2. Main criteria: Quality, safety and efficacy

868 When a medicinal product is **authorized for the first time**, in addition to the analytical and technical information on the manufacturing process (quality; Module 3), the findings from the pharmacological-toxic (animal studies; Module 4) and clinical (human trials; Module 5) tests must also be available with regard to the desired and undesired effects of the product. This information is essential in order to prove efficacy in the sense of a statistically recorded positive therapeutic effect of a product. The clinical trials on humans are central to this: In particular, they comment on tolerability in humans, the character of the effect and adverse effects.[92]

869 Based on these documents, an **evaluation of the risk-benefit ratio** must be carried out, which is associated with considerable evaluation questions. With regard to efficacy, a medicinal product must be both **of high quality** (extensive achievement of the therapeutic objective) and **quantitatively effective** (high probability of efficacy). The **risks must be assessed according to** the severity and probability of occurrence or the frequency and severity of the adverse effects. It also plays a role whether or not **warning symptoms** are observed prior to the occurrence of the side effects.[93] Adverse drug reactions also include a lack of effect, which must be known for reasons of drug safety.[94] **Underestimated interactions of** a pharmacokinetic or pharmacodynamic nature with other medicinal products or with foodstuffs and stimulants also fall under adverse drug reactions.[95] The following should be noted in particular:

1.2.1. Quality: stability and purity

870 The documentation of the physical, chemical, galenic and biological or microbiological tests concerns the composition, manufacturing process, control of the starting materials, the intermediate products and the finished product, as well as the stability tests (Art. 11 para. 2 lit. a **no. 1** TPA; Art. 3 para. 1 TPLRO; **"Module 3"**). Appropriate analytical studies must demonstrate that the **quality of the preparation, i.e.** the degree of purity, composition and

91 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 8.
92 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 16.
93 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 17.
94 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 14, cf. also N 29a.
95 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 14.

galenic properties, remain **constant** during production.[96] In addition to stability, proof must also be provided that there are **no impurities.**[97]

871 The possibility of referring to individual analysis data of another medicinal product is not excluded. However, according to the Federal Supreme Court, it is not possible to make a blanket reference to the documents relating to another product for the quality assessment of a medicinal product, even if the composition is largely identical.[98]

1.2.2. Initial safety characteristics: Preclinical phase (animal studies)

872 The safety of a medicinal product is a relative characteristic: any adverse effects must be compared with the indication-related therapeutic effects, resulting in a favorable risk-benefit ratio. [99]

873 A medicinal product must necessarily be considered dangerous until its safety has been proven. Possible harmfulness and thus potential adverse effects are first determined on the basis of pharmacological and toxicological tests in **animal experiments** or validated alternative models (Art. 11 para. 2 lit. a **no. 2** TPA; Art. 4 para. 1 TPLRO; **"Module 4"**). The candidate medicinal product is tested **"in vitro"** (e.g. **cell cultures**) and **"in vivo" on animals.** This involves pharmacological questions, e.g. what happens to the drug or its components in cells or in an entire organism and what reactions are triggered. Furthermore, it is investigated exactly how long the effect lasts and what dose is necessary for the desired effect.

874 According to Art. 4 para. 2 TPLRO, the corresponding documentation must contain in particular documents on **pharmacodynamics** (i.e. the relationship between the circulatory concentration of the active substance and the resulting effects on the organism), **pharmacokinetics** (i.e. the relationship between the dosage of an active substance and the resulting concentration in the blood, urine, body tissue and at the site of action), **toxicology** (i.e. tolerability in the organism) and **ecotoxicity** (i.e. tolerability in the environment). **These animal studies should already enable an initial risk-benefit analysis**[100] - although these preclinical studies can only provide rudimentary indications of possible (curative) effects in humans.

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96 SCHOTT/ALBERT, BSK HMG, 2nd edition, Basel 2022, Art. 11 N 28; see Swissmedic, "Wegleitung Zulassung Humanarzneimittel mit neuer aktiver Substanz HMV4", 15.09.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl101_00_005d_vwlnleitungfuerdiezulassungvonhumanarzneimittelnmi.pdf.download.pdf/zl101_00_005d_wlzulassungHumanneuerwirkstoff.pdf.

97 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 10.

98 Judgment 2A.16/2005 of the BGer of 04.08.2005, E. 2.2.

99 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 12.

100 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 30.

875 **Many drug candidates already fail these toxicity tests.** Only those drug candidates that pass all safety tests are allowed to enter the next development phase with studies on humans (clinical trials).[101]

1.2.3. Safety and efficacy: Clinical phases I-III

876 To prove the effect on humans, **clinical studies on humans are** also required, which provide information on clinical pharmacology as well as pharmacokinetic and pharmacodynamic interactions (Art. 11 para. 2 lit. a **no. 2** TPA; Art. 5 TPLRO; **"Module 5"**).

877 Clinical trials with therapeutic products on humans are regulated in Art. 53 ff. TPA, the Human Research Act (HRA; SR 810.30) and the Clinical Trials Ordinance (ClinO; SR 810.305). The definition in Art. 2 lit. a ClinO states that it is a **"research project involving human subjects"**, i.e. a "method-guided search for generalizable findings" (Art. 3 lit. a HRA). This means that scientifically recognized **procedures, in particular systematic and verifiable ones,** must be applied and the validity of the findings must extend beyond the context of the research project.[102] Research involving human subjects must comply with the international rules of good practice ("GCP") (Art. 10 para. 1 HRA; Art. 5 para. 1 and Annex 1 no. 2 ClinO), whereby reference is made to the Guideline on Good Clinical Practice of the International Conference on Harmonization in the version of 9 November 2016 (ICH Guideline).

878 Clinical trials on humans (**Module 5**) with medicinal products are only justified if, in animal experiments (preclinical; **Module 4**), cumulative[103]

1) direct or at least indirect evidence for the desired pharmacological efficacy of an active substance was found,
2) The speed and routes of drug absorption into and excretion from the organism (pharmacokinetics) were investigated,
3) no undesirable side effects have occurred in the range of pharmacologically effective normal doses and
4) dangerous or even lethal toxic organ and/or system damage has only been observed with overdoses that are many times higher than normal doses.

879 If the above premises are fulfilled, the **three phases of the clinical trial** can be started, which build on each other:[104]

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101 Netdoktor, "Arzneimittelzulassung", 10.08.2020, https://www.netdoktor.ch/medikamente/arzneimittelzulassung/.
102 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 3b.
103 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 9.
104 Netdoctor, FN 101.

1.2.3.1 Phase I: Safety (dose-finding study)

880 In **Phase I,** the tolerable dose and thus the **tolerability of** a test substance is tested for the first time in a small group of healthy volunteers (usually 60-80, regularly less than 100 volunteers) **(dose finding).** In up to 30 consecutive tests, phase I tests are carried out to determine whether the predictions from the animal studies are confirmed as to how quickly the active substance enters the bloodstream, how long it remains there, how it is metabolized in the body and how quickly and by what route it leaves the body again. In order to minimize the risk for the test subjects, new active substances may initially only be tested at a dose that is far below the dose that will later be contained in the drug. The dose is then gradually increased. If problems occur, the treatment of the test subjects is stopped immediately. If it becomes apparent that an active substance causes unacceptable side effects at the concentrations required for treatment, the entire development program is discontinued. If, on the other hand, it is tolerated, the clinical trial can be continued.[105]

1.2.3.2 Phase II: First signs of efficacy (first study in sick people)

881 **Phase II** is the first phase of testing with a small number of patients (usually 100-500 patients). This involves more detailed surveys on the occurrence of undesirable **side effects**. However, the main aim is to **be able to prove the efficacy and therapeutic benefit of a test substance statistically and thus generally valid for the first time.** This proof can only be provided by participating persons suffering from the disease to be treated.[106] In **Phase II,** the **immune response of vaccine candidates** is **observed in healthy individuals over several months, and in** particular, frequent side effects are also to be identified.

1.2.3.3 Phase III: Safety and efficacy: (double-blind study)

882 In **phase III,** the same is tested as in phase II, only with considerably more (**several 1,000 to several 10,000**) **study participants** and over an even longer period of time. Here, the clinical trials **that are decisive for approval are** carried out as so-called randomized**, controlled (double-blind)** trials (randomized control trials, RCT), which is considered the so-called "gold standard": one group receives a placebo, the other the drug to be tested, with the patients being randomly assigned to the groups.[107] This is intended to prevent hopes,

105 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 10 ff.; vfa. The research-based pharmaceutical companies, FN 87.

106 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 10 ff.; vfa. The research-based pharmaceutical companies, FN 87.

107 SCHNEIDER, BSK HMG, 2nd ed., Basel 2022, Art. 53 N 10 ff.; vfa. The research-based pharmaceutical companies, FN 87.

fears or skeptical attitudes on the part of doctors and patients from influencing the outcome of the treatment and thereby reducing the validity of the results.

883 The purpose of these comprehensive "approval studies" is to **find** out **whether the vaccine** really does **provide lasting protection against the disease** against which it was developed and, above all, **whether it is safe**. Only in such large-scale phase III studies, in which many study participants are observed over a sufficiently long period of time - usually **several years** - can rare side effects that only occur in the medium or long term be identified. Vaccination against a disease is only recommended if its benefits *far* outweigh the risk of adverse effects.[108]

1.2.3.4 Duration of clinical phases I-III

884 **Each of phases I-III should generally last at least one year, usually longer.**[109] Corresponding time specifications can hardly be found in the relevant literature or in the public domain. For phase I (dose finding), a few months may be sufficient, while phase II usually lasts up to a year. For Phase III, well over a year is regularly estimated - which is also shown by the "Phase I/II/III" study by Pfizer, which will last until 2024 and for which more than three years are planned.[110]

1.2.4. Assessment: Safety and efficacy only after completion of Phase III

885 Therefore, conclusive proof of the safety of a medicinal product can only be provided after all preclinical animal studies and clinical trials on humans (phases I-III) have been carried out.[111] Adverse drug reactions must be determined in particular on the basis of **clinical studies** and truthfully documented with information on frequency and severity (Art. 11 para. 2 lit. a **no. 2 and 3** TPA; Art. 5 TPLRO; **"Module 5"**). The **occurrence of adverse drug reactions is not a general reason for exclusion from authorization.** Even serious, life-threatening side effects are not *per se* a reason for rejecting an application. However, they must be taken into account as a central aspect when determining the risk-benefit ratio. [112]

886 The results of clinical trials are used on the one hand to determine the tolerability of a medicinal product and its side effects and interactions, and on the other hand to **assess its efficacy.**[113] Accordingly, the intended medical effects of the medicinal product for the

108 Infovac, FN 88.
109 vfa. The research-based pharmaceutical companies, FN 87.
110 NIH, "Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals," April 30, 2020, https://clinicaltrials.gov/ct2/show/NCT04368728.
111 See SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 13.
112 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 37.
113 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 33.

detection, prevention or treatment of a specific disease, as determined in clinical trials, must be stated in the application for authorization.[114] The so-called therapeutic efficacy is required. Based on the (clinical) studies conducted, **it must be demonstrated that the desired therapeutic, diagnostic or preventive effect is achieved in relation to the indication**.[115] **The mere presentation of the pharmacological effects determined on the basis of animal studies is not sufficient.**[116] Where proof of efficacy cannot be provided stringently, a statistical evaluation of the documented tests in the sense of a probability statement may suffice. However, it must be possible to derive the efficacy determined in this way with **sufficient probability** according to recognized scientific rules.[117]

1.3. Approval procedure and overall duration of the procedure

887 In order to **apply for** a **marketing authorization for a medicinal product, the complete "Phase II" study results** and the **12-month data of the "Phase III" studies are** usually submitted for review in the marketing authorization dossier in addition to the **documents on the quality of a medicinal product** and the **preclinical studies.**

888 The complete application is then subjected to a **comprehensive review** by Swissmedic with regard to the manufacturing method, composition, quality and shelf life as well as the desired and undesired effects based on the criteria according to Art. 10 TPA.[118] This examination as part of the ordinary authorization procedure takes around **330 calendar days**.[119] Accordingly, the 24-month data from the **"Phase III" studies** are normally available at the time of authorization, which additionally round off the picture with regard to efficacy and safety. The clinical trials alone (i.e. excluding preclinical animal trials), including the approval procedure, therefore take **at least two years**.

1.4. Approval, requirements and conditions

889 An ordinary marketing authorization is generally granted for five years (Art. 16 para. 2 sentence 1 TPA).

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114 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 35.
115 BGE 143 V 95 E. 3.2 p. 99 f.
116 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 15.
117 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 10 N 16; see judgment C-5649/2015 of the FAC of 24.07.2018, E. 5.3.
118 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 15.
119 Swissmedic, "Guidance on time limits for applications for authorization HMV4", 01.06.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_014d_wlfristenzulassungsgesuche.pdf.download.pdf/zl000_00_014d_wlfristenzulassungsgesuch.pdf, p. 10.

890 Each authorization can be linked to requirements and conditions (Art. 16 para. 1 sentence 2 TPA). Possible conditions mentioned by the legislator include the obligation to further evaluate a preparation (clarifications on interactions, adverse effects, regulations for special patient groups or on dosage)[120] or the prohibition of professional and public advertising for a specific medicinal product[121] . Swissmedic therefore has a certain amount of discretion to refuse authorization in a specific case or to approve it subject to conditions. **However, "serious deficiencies" in terms of safety or efficacy cannot be remedied by imposing conditions**[122] - and authorization must therefore be refused.

891 The results of the investigations that the medicinal product underwent in the preclinical and clinical phases can be viewed in the medicinal product information approved by Swissmedic (Information for healthcare professionals or Patient information), which is published for each medicinal product at www.swissmedicinfo.ch.

1.5. "Phase IV": Market surveillance

892 Relatively **rare side effects** - those that occur on average less than **once in 1,000 people treated** ("rare"; ≥1/10,000 to <1/1,000) - **are often not recognized in the studies prior to market launch.** A good dose of suspicion is therefore advisable at the beginning of the career of a - properly approved - drug.[123] Rare serious adverse drug reactions can hardly be detected in the run-up to the approval decision because the controlled clinical trials are only carried out with a relatively small number of test subjects and patients.[124] Despite these extensive (preclinical and) clinical trials conducted prior to proper approval, many side effects only become apparent after the drug has been approved, when the number of patients treated multiplies, which is why thorough market and therefore risk monitoring is still required even after proper approval.[125]

1.5.1. Risk management plan (and *PSUR/PBRER*)

893 The obligation to submit a pharmacovigilance plan in accordance with Art. 11 para. 2 lit. a no. 5 TPA (Art. 4 TPO) already exists in the authorization application (in "Module 1"). This requirement was newly introduced with the revision of the TPA on 1 January 2019 - in **response to serious incidents in the past in which risks** were **identified too late.** The aim is therefore to identify and name risk factors at an early stage in order to monitor them in

120 Message HMG, 3504.
121 Dispatch Revision HMG, 107.
122 SCHMID / UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 16 N 15.
123 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 18.
124 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 18.
125 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 36.

detail after market approval.[126] The risk management plan must meet the requirements of Good Vigilance Practice ("GVP") according to Annex 3 TPO and includes a summarized assessment of the important known, important potential and insufficiently investigated risks as well as a plan describing the follow-up of these risks and the measures to ensure the safe use of the medicinal product (Art. 5a para. 1 TPLRO).

894 Following approval of the application for authorization, the authorization holder is obliged to submit a summary of the risk management plan to the Agency (Art. 5a para. 2 TPLRO). This is then published publicly by Swissmedic as a supplement to the available information for healthcare professionals and patients.[127]

895 A risk management plan must be submitted in the ordinary procedure according to Art. 11 TPA for first authorization applications for medicinal products containing at least one new active substance (Art. 4 para. 1 lit. a TPO). According to Swissmedic, it also follows from Art. 11 TPA that a risk management **plan** is also mandatory for all applications for the authorization of medicinal products that do not qualify for a simplified authorization procedure (Art. 14 TPA, Art. 12 para. 5 TPLO), i.e. for "**vaccines**, serums and toxins", "medicinal products containing genetically modified organisms" and for "medicinal products for advanced therapies based on gene transfer methods (gene therapy medicinal products)".[128]

896 As part of the subsequent market surveillance, the marketing authorization holder of a medicinal product with a new active substance must submit **an updated report on the safety and benefit-risk ratio** of the medicinal product (so-called ***PSUR*** or *PBRER*) (Art. 60 para. 1 TPO) (at least) **once a year and without being requested to do so.**[129] An updated pharmacovigilance plan must also be submitted in the event of a significant change in risks or the emergence of new risks.[130]

897 Based on this data, Swissmedic must carry out an ongoing review of the benefit-risk profile of medicinal products (Art. 16c TPA [Review of authorization] in conjunction with Art. 14

126 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 14 and N 47 ff.; Swissmedic, "Wegleitung RMP ICH E2E Informationen Einreichung HAM", 01.03.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/MU_HMV4/mu103_10_001d_wlrmpiche2einformationeneinreichung-hmv4.pdf.download.pdf/MU103_10_001d_WL_RMP_ICH_E2E_Informationen_Einreichung_HMV4.pdf, p. 1.

127 Swissmedic, (FN 126), S. 1.

128 Swissmedic, (FN 126), S. 3.

129 For periodicity see: Art. 60 para. 2 VAM in conjunction with. Annex 3 TPO with reference to the periodic report on the safety of medicinal products and the benefit-risk ratio: Guideline E2C (R2) of the ICH in the version of December 17, 2012; Swissmedic, "Guidance PSUR PBRER Information Submission HAM", 01.04.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/MU_HMV4/mu103_10_002d_wlpsurpberinformationeinreichunghmv4.pdf.download.pdf/MU103_10_002d_WL_PSUR_PBRER_Information_Einreichung_HMV4.pdf.

130 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 53.

TPO).[131] Of course, the Agency cannot rely solely on the manufacturer's data: The obligation for subsequent market surveillance by the licensing authority is comprehensive in order to guarantee quality, efficacy and safety, which requires the maintenance of a close-meshed reporting and monitoring system that goes beyond mere manufacturer information:

1.5.2. Obligation to report

898 The notification obligation under Art. 59 para. 1-3 TPA is an important instrument of official, ex-post market surveillance.[132] As previously (N 892), subsequent market surveillance of medicinal products that have been (properly) authorized for the first time serves to identify **rare adverse reactions** that could not have been detected during preclinical and clinical studies. The reporting obligation is therefore one of the cornerstones for ensuring the protection of human (and animal) health (Art. 1 para. 1 TPA).[133]

1.5.2.1 Obligations of Swissmedic

899 According to Art. 58 para. 3 sentence 1 TPA, the Agency (Swissmedic) is responsible for monitoring the safety of therapeutic products. To this end, it collects reports in accordance with Art. 59 TPA, evaluates them and takes the necessary administrative measures. Ensuring the safety of therapeutic products within the framework of **ex-post market surveillance is** therefore just as much a core area of the Agency's activities as the area of authorization. The **Agency is obliged to identify and clarify risks as early as possible in order to take** the necessary measures to **ensure the safety of medicinal products** without delay.[134]

900 To this end, those who place therapeutic products on the market must ensure a functioning reporting system (Art. 59 para. 1 sentence 1 TPA).[135] In addition, quality defects (Art. 59 para. 2 TPA) and serious and unknown adverse reactions (Art. 59 para. 3 TPA) must be reported. On the basis of Art. 59 para. 1-3 in conjunction with Art. 58 para. 3 TPA, the Agency in turn has a duty to effectively enforce a **functioning reporting system** that

131 Swissmedic, "Guidance on medicinal product signals HAM", 01.02.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/mu/MU_HMV4/mu101_20_001d_wlarzneimittelsignalehmv4.pdf.download.pdf/MU101_20_001d_WL_Arzneimittelsignale_HMV4.pdf, p. 4.

132 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., 3540; SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19b.

133 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 1 N 12 and N 14 with explicit reference to the reporting obligations under Art. 58 et seq. HMG.

134 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., 3539; EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 16, Art. 59 N 2.

135 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19b.

ensures the early detection of potential risks. The Agency's responsibility for monitoring safety includes not only the reporting system in accordance with Art. 58 para. 3 sentence 2 TPA, i.e. that within the framework of pharmacovigilance and good vigilance practice (monitoring the risks of adverse reactions in connection with the use of medicinal products: Art. 61-66 VAM and Annex 3 VAM). According to the wording, meaning and purpose of Art. 58 para. 3 sentence 1, the **Agency's responsibility is to** be understood as a **comprehensive obligation in the context of monitoring the safety of therapeutic products**. [136]

901 In reality, the **reporting system** "set up" by Swissmedic is **purely passive in nature:** it is based on observed suspected cases for which spontaneous reports are (or should be) submitted to Swissmedic by those obliged to report, which Swissmedic then has to check and evaluate.[137] This makes it all the more important to **enforce this reporting obligation.** This is also a mandatory requirement for the **targeted imposition of administrative measures** in accordance with Art. 66 para. 2 TPA: Accordingly, the Agency is obliged, for example, to order "the distribution and dispensing of therapeutic products [...] and the immediate recall of therapeutic products from the market or the dissemination of recommendations for conduct to prevent harm" (lit. e), to confiscate "therapeutic products that are hazardous to health or do not comply with the provisions of this Act" (lit. d) or to suspend or revoke "authorizations and approvals" (lit. b). However, these means can only be used to achieve the purpose if the Agency ensures that it has the necessary information to do so. **Without the effective implementation of the legal obligation to enforce a functioning notification system, all efforts to ensure effective ex-post market surveillance to protect health will therefore come to nothing**. This refers to the relationship between efficacy and safety (see Art. 10 para. 1 lit. a and Art. 11 para. 2 lit. a no. 3 and 5 TPA). According to Art. 10 TPA, quality, safety and efficacy are prerequisites for authorization. **The potential benefit of a product must always exceed its potential risk.** If this **requirement is no longer met** due to new findings on the safety of the medicinal product, **the authorization must be revoked** or suspended (Art. 16, 16a and 16c TPA). [138]

902 Swissmedic is therefore responsible for the **comprehensive and effective monitoring of therapeutic product safety** and **rigorous enforcement of the reporting obligation** in the context of ex-post market surveillance.

136 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 15.
137 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 4.
138 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 16.

1.5.2.2 Obligations of manufacturers

903 The scope of the manufacturer's reporting obligation is very broad and is in principle not restricted at all at the legislative level.[139] Manufacturers must report **all adverse effects** and incidents that could endanger or impair the health of patients (Art. 59 para. 1 lit. b TPA).

1.5.2.3 Duties of medical personnel (medical profession)

904 Medical professionals, on the other hand, only have to report serious **and previously unknown adverse reactions**: According to Art. 59 para. 3 TPA, they must report serious or previously unknown adverse reactions and events, observations of other serious or previously unknown facts and quality defects to the Agency (Swissmedic).

905 Observations of **serious adverse drug reactions/facts must therefore be reported in all cases,**[140] which is also stated accordingly in Art. 63 para. 1 lit. a and lit. d TPO. Serious adverse drug reactions or observations of serious facts must be reported within 15 days (Art. 63 para. 3 sentence 1 TPO). A serious adverse reaction is deemed to exist if it is "**fatal or life-threatening**, requires **hospitalization** or prolongation of hospitalization, leads to **permanent or severe disability or incapacity**, or is a congenital anomaly or **birth defect**".[141]

906 However, previously **unknown adverse reactions** must be reported regardless of their severity (Art. 63 para. 1 lit. b TPO). Previously "unknown" or "new" adverse drug reactions are those that are **not or not sufficiently mentioned in the product information (Information for healthcare professionals).**[142] Such events must be reported within 60 days (Art. 63 para. 3 TPO).

907 According to Art. 59 para. 5 TPA, the reports according to paragraphs 1-3 must be submitted in accordance with the recognized rules of good vigilance practice. Accordingly, the reports in accordance with Art. 59 TPA should and must be submitted electronically in a standardized form and entered into the corresponding database (e.g. via the ElVis electronic vigilance reporting portal).[143]

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139 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 23, cf. also N 29 and N 12a/b.
140 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 58 N 16, N 44.
141 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 18a (cf. also N 40a); with reference to Art. 1 No. 12 of Directive 2001/83/EC and analogous to ICH Harmonized E2D Tripartite Guideline No. 2.3.
142 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 41.
143 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 3.

1.5.2.4 Threshold for mandatory reporting: degree of certainty

908 Depending on the scope of the adverse reactions to be reported (all or "only" serious and new) and the addressee of the reporting obligation, a **distinction must be made between the degree of certainty from which the reporting obligation applies:** is certain knowledge required or is the mere suspicion that an adverse reaction could be present sufficient?

909 The Dispatch and doctrine are in agreement on this point: the starting point for the reporting system is the **mere suspicion** of undesirable effects.[144] The Dispatch is unequivocal in this respect:

> "The timing and scope of the obligation to report depends on the degree of risk to health and the degree to which adverse effects and incidents of the therapeutic product are already known. The greater the risk to health and the less the adverse effect or incident is known, the sooner the event must be reported."[145]

910 A report must be made even if a signal is merely **suspected.**[146] A specific risk to public health is not necessary: **Even an abstract risk obliges the reporting and review of the safety of medicinal products on the market.** This means that any possible, relevant deterioration in the benefit-risk profile entails the legal obligations of Art. 59 TPA.[147]

1.5.3. International cooperation

911 **Collecting and evaluating all relevant data** as **completely** as possible is an indispensable prerequisite for implementation in terms of improving drug safety. To this end, an international data exchange takes place with the participation of Switzerland (Swiss access to "WHO Program for International Drug Monitoring [PIDM]"; "*EMA EudraVigilance System*").[148]

1.5.4. Special labeling requirement (black triangle) and advertising ban

912 Drug texts and also advertising materials for **drugs with new active substances** for which there is a **lack of information regarding** their **risks** because they have not yet been used

144 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., 3540; EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 3, N 24.

145 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., 3540.

146 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 4.

147 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 3, N 41.

148 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 5.

under real conditions and therefore rare allergic reactions, side effects or long-term effects have not yet been adequately recorded, must be marked with a **black triangle.**[149] The technical information of the **mRNA "vaccines" is** correctly marked with such a **black triangle.**[150]

913 In addition, there is a **ban on advertising to the public with** regard to prescription mRNA "vaccines" (see N 1385 et seq.).

1.5.5. Conditions and withdrawal of approval

914 According to Art. 66 TPA, Swissmedic has various options for intervention and sanctions if deficiencies are identified: Swissmedic can, for example, issue complaints and set a reasonable deadline for restoring the lawful status. For example, it can require the manufacturer to draw attention to newly discovered side effects in the medicinal product texts. However, it can also impose **restrictions on use:** If rare but serious side effects have been observed in certain patient groups, the authority can order that the medicinal product may no longer be used in these patient groups.[151]

915 Swissmedic can also suspend or revoke marketing authorizations if **unacceptable risks** have been identified over time. Sometimes the **manufacturer voluntarily withdraws** such a medicinal product **from the market.**

1.6. Additional requirements for *GMOs* and gene therapy medicinal products

916 Genetically engineered medicinal products, medicinal products containing genetically modified organisms (*GMOs*) and gene therapy medicinal products are not explicitly mentioned in the TPA.[152] However, in Art. 12 para. 5 lit. c and e TPLO, "medicinal products containing **genetically modified organisms**" and "advanced therapy medicinal products based on gene transfer methods **(gene therapy medicinal products)" are excluded from the simplified authorization procedure.**

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149 Swissmedic, "Pharmaceutical advertising: representation of the black triangle for medicinal products
under additional monitoring", 11.2019, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/marktueberwachung/werbung/darstellung-schwarzen-dreiecks.pdf.download.pdf/schwarzes-Dreieck.pdf.*

150 Swissmedicinfo, "Fachinformation Comirnaty", as of 04.2022, https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68225; Swissmedicinfo, "Fachinformation Spikevax", as of 05.2022 https://www.swissmedicinfo.ch/ShowText.aspx?textType=FI&lang=DE&authNr=68267.

151 Netdoctor, FN 101; Interpharma, FN 88.

152 See also SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 63, cf. also Art. 10 N 29 ff.

917 The requirements for conducting trials and placing *GMOs* and gene therapy medicinal products on the market are much stricter than for other medicinal products:

1.6.1. Swissmedic: Guidance document "Gene *therapy/GMO*" for clinical trials

918 According to Art. 54 TPA and Art. 35 ClinO, anyone wishing to conduct clinical trials with gene therapy products or *GMOs is* subject to authorization prior to the start of the trial.

919 On August 26, 2019, Swissmedic - together with the *FOPH*, the *FOEN* and the *Swiss Expert Committee for Biosafety (SECB)* - published a guidance document entitled "Gene therapy/GMO environmental data". This describes the information that must be submitted to the competent licensing authority (Swissmedic) for the purpose of assessing the risk to humans and the environment in clinical trials of somatic gene therapy (Art. 22 para. 1 ClinO) and therapeutic products containing genetically modified microorganisms (*GMOs*; Art. 22 para. 2 ClinO). [153]

920 According to Art. 22 para. 1 ClinO, clinical trials of **gene therapy are** trials in which genetic information is introduced into somatic cells (somatic gene therapy), which includes **mRNA technology** (Evidence Report, N 873 f.). With regard to the definition of ***GMOs*** (Art. 22 para. 2 ClinO), Swissmedic states that, in the context of clinical trials, this includes in particular viral vectors, naked nucleic acids (e.g. **plasmids**), complexed nucleic acids or bacteria.[154]

921 Swissmedic explains the problems associated with these preparations and the reason for the guidance issued:[155]

> "This guidance document takes into account the fact that the investigational medicinal products are usually viral vectors, plasmids or bacteria and therefore focuses on the **risks of possible excretion of the investigational medicinal product** by the test subjects and thus a potential release into the environment."

922 Swissmedic distinguishes between three hazard levels in its risk assessment: From the lowest risk ("investigational medicinal product is not excreted") to a medium risk

153 Internet Archive, Swissmedic, HD guidance gene therapy/GMO environmental data, 26.08.2019, p. 2, https://web.archive.org/web/20220816200115/https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/i-315/i-315_aa_01-a11dwegleitung-gentherapiegvoumweltdaten.pdf.download.pdf/i-315_aa_01-a11dwegleitunggentherapie-gvoumweltdaten.pdf.

154 Swissmedic, "HD guidance gene therapy/GMO environmental data", FN 153, S. 5.

155 Swissmedic, "HD guidance gene therapy/GMO environmental data", FN 153, S. 2.

("investigational medicinal product is excreted") to the highest risk ("investigational medicinal product is released into the environment").[156]

923 In order for a new preparation to be assigned to the lowest risk level (no excretion) for the conduct of a clinical trial, the following evidence*, among others,* can be provided:[157]

- Preclinical biodistribution studies with the investigational product (including data on excretion and the potential of the investigational product to integrate into the germline);
- Other justification for the assumption that no investigational medicinal products are excreted from subjects, such as:
  - favorable side effect profile - for example, **rapid degradation** - for certain experimental preparations;
  - Experimental preparation is **replication-deficient** with low probability of reversion and lack of recombination ability with wild type (in experimental subject);
  - Increased degradation or **reduced tissue distribution pattern** depending on the method and site of administration;
  - **lower stability** or increased degradation of the test preparation in test subjects in general;

924 The risk of a clinical trial is only considered to be "negligibly low" if it can be adequately demonstrated that the trial subject does not excrete the trial preparation and that there is "**no potential for integration into the germ line**" .[158]

925 If the above-mentioned evidence cannot be provided, the risk level increases and further measures (such as protection of contact persons, increased monitoring, etc.) must be taken.[159] Classification as a GMO therefore means that additional (and much stricter) regulatory requirements would have had to be observed for its authorization in Switzerland (see also ER N 74).

1.6.2. Special authorization requirements for the release

926 According to Art. 6 VAM, "medicinal products containing GMOs" must meet the requirements of Art. 28 FrSV (Release Ordinance; SR 814.911) in addition to those of the TPA. The application for authorization to place genetically modified organisms on the market must contain all the necessary information to demonstrate that the handling of the organisms cannot violate the requirements of Articles 7-11 (Art. 28 para. 1 FrSV), in particular

156 Swissmedic, "HD guidance gene therapy/GMO environmental data", FN 153, S. 2.
157 Swissmedic, "HD guidance gene therapy/GMO environmental data", FN 153, S. 7.
158 Swissmedic, "HD guidance gene therapy/GMO environmental data", FN 153, S. 8.
159 Swissmedic, "HD guidance gene therapy/GMO environmental data", FN 153p. 8 f.

- **the health of humans and animals must not be endangered,** in particular by toxic or allergenic substances or by the spread of antibiotic resistance;
- genetically modified organisms must **not be** allowed to **spread and multiply uncontrollably** in the environment;
- **no undesirable properties** may be **permanently passed on to other organisms.**

927 To provide this evidence, an application for authorization in accordance with Art. 28 para. 2 lit. a-i FrSV must contain, among other things, a **comprehensive technical dossier,** results of previous closed-system studies with the same organisms concerning hazards or adverse effects on humans, **authorizations for experimental releases** and for placing on the market, a monitoring plan, a proposal for **labelling** (Art. 10 FrSV), **information for recipients** (Art. 5 FrSV) and proof that the safety obligations have been fulfilled.

1.6.3. Special labeling requirements

928 In addition, there is an obligation to declare medicinal products that consist of *GMOs* or contain such organisms. The type of *GMO* and genetic modification must also be stated in the Information for healthcare professionals (Art. 27 para. 1 and 2 VAM).

929 Active substances and processing aids derived from *GMOs* must be declared in accordance with the provisions on the labeling of genetically modified foods (Art. 27 para. 3 VAM). According to Art. 8 para. 1, 2 and 6 VGVL[160] , foods, ingredients and processing aids that are *GMO products* must be labeled with the words **"genetically modified"** (see also Art. 10 FrSV).

1.6.4. Gene therapy medicinal products and GMOs: Ordinary procedure with increased requirements

930 The requirements for the authorization of gene therapy medicinal products and GMOs are the strictest stipulated by Swiss law for the authorization of medicinal products. Accordingly, Art. 12 para. 5 lit. c TPLO (SR 812.212.23) states unequivocally that "medicinal products containing genetically modified organisms" and "medicinal products for advanced therapies based on gene transfer methods (gene therapy medicinal products)" are **explicitly excluded from the simplified authorization procedure.**

1.7. Summary and assessment

931 The ordinary authorization procedure is dominated in its entirety by the guidelines of Art. 1 para. 1 TPA: With its high requirements for the necessary **quality tests, in-depth animal**

160 Ordinance of the FDHA on genetically modified foods (SR 817.022.51).

studies and **long-term studies on humans** and the thorough **one-year review phase by the Institute (Swissmedic),** it **ensures** that only high-quality, safe and effective therapeutic products are placed on the market.

932 For gene therapies (e.g. mRNA technology) and *GMOs* (e.g. plasmids), strict requirements already apply for the approval of clinical trials, which massively increase the hurdles for subsequent approval (which in turn is linked to stricter requirements).

933 Omitting necessary intermediate steps or replacing basic studies with other information is absolutely inadmissible. If a medicinal product fails even one of the necessary intermediate steps, market access is denied in order to protect the population.

2. Special authorization procedures

2.1. Overview

934 The following description is limited to the second form of authorization, which has been regulated in detail at the legislative level: The simplified authorization (Art. 14 TPA). The focus of the analysis is on answering the question as to the areas in which **significant shortcomings** can be identified **in comparison with the ordinary authorization procedure** and how these are **compensated for by alternative provisions.** The form of authorization chosen by Swissmedic in the present case, the "temporary authorization", which is a special form of simplified authorization, is then presented.

935 In addition to the three procedures described above (ordinary, simplified, time-limited), there are numerous other (sub)types of procedure such as the accelerated authorization procedure (Art. 7 TPO), the procedure with prior notification,[161] "off-label use" (Art. 3 and Art. 26 TPA) or "unlicensed use" (Art. 20 para. 1 TPA in conjunction with Art. 48 f. TPLRO). These are not discussed further below (among other things due to the lack of sufficient comparability of the differences in the areas of quality, safety and efficacy).

2.2. Simplified authorization (Art. 14 f. TPA)

936 According to Art. 14 para. 1 TPA, Swissmedic may provide for simplified authorization procedures for certain categories of medicinal products. This applies, for example, to the following categories:

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161 A "special offer from Swissmedic", according to Swissmedic, "Wegleitung Verfahren mit Voranmeldung HMV4", 01.03.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl101_00_013d_wlerlaeuterungenzumverfahren-mitvoranmeldungvmva.pdf.download.pdf/zl101_00_013d_mberlaeuterungenzumverfahren-mitvoranmeldungvmva.pdf, p. 2.

- Medicinal products with **known** active substances, **"generics"** (**lit. a**; Art. 12 ff. VAZV [SR 812.212.23]);
- Medicinal products that have been **authorized for** at least **10 years** in at least one **EU or EFTA** country, **"well-established use"** (**lit. a^{bis}** ; Art. 14a para. 1 lit. a TPA), or
- important medicinal products for rare diseases, so-called **"orphan drugs"** (lit. f.; Art. 4-8 and 24-26 VAZV).

937 The simplifications granted can be of a material (fee reduction) or documentary nature - in particular in the form of **reductions in the requirements for the authorization dossier to be submitted.** For example, only simplified proof of efficacy and tolerability can be provided.[162] In addition, a **pharmacovigilance plan** can be **waived**.[163]

938 Such a curtailment of the ordinary authorization procedure fundamentally means an **increase in risk.** Art. 14 para. 1 TPA therefore requires that the requirements for **quality, safety and efficacy must** be **guaranteed by other means**.[164] This necessary balance can be achieved, for example, by requiring **other documentation** to be submitted (known active substances and/or active substances already authorized in the EU) or by ensuring that **use is only** considered **in strictly limited cases** ("orphan drugs").

2.2.1. "Known active substances" (Art. 14 para. 1 lit. a TPA): "Generics"

939 According to Art. 14 para. 1 lit. a TPA, "medicinal products with known active substances" can be authorized in a simplified manner. This primarily includes so-called **"generics".**[165] They are characterized by the same active substance, the same pharmaceutical form, the same route of administration, the same dosage and the same indications (see Art. 4 para. 1 lit. $^{\text{asepties TPA}}$). In such cases, simplified authorization is justified by the fact that comprehensive documentation or complete authorization documents for an existing reference medicinal product can be used.[166]

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162 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 3.

163 Swissmedic, "Guidance document Authorization according to Art. 14 para. 1 let. a$^{\text{bis -quater}}$ TPA HMV4", 28.02.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_022d_wlzulassungart14abs1bstabis-quaterhmg.pdf.download.pdf/zl000_00_022d_wlzulassungart14abs1bstabisquaterhmg.pdf, para. 5.5; see also Swissmedic, "Guidance document Orphan Drug HMV4", 01.03.2021; *https://www.swissmedic.ch/dam/swissmedic/en/documents/authorization/zl_hmv_iv/zl100_00_002d_wle-orphandrugs.pdf.download.pdf/ZL100_00_002d_WL%20Orphan%20Drug.pdf*; see also: Art. 12-14 TPLO, which do not mention the pharmacovigilance plan; Art. 14a para. 1 lit a TPA, which refers to Art. 11 para. 1 and 2 letter a numbers 1-4 (but not number 5 [pharmacovigilance plan]). See also SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14a N 7.

164 Message HMG 1999, p. 3470; SCHMID / UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 3.

165 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 11.

166 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 14 f.

2.2.1.1 Renunciation of animal and human studies

940 Accordingly, pharmacological and toxicological tests (preclinical; **animal studies**) can be **waived** for "generics" if "sufficient evidence is available in the published literature" (Art. 13 para. 2 TPLRO).[167]

941 Proof of safety and therapeutic efficacy (comprehensive **clinical trials** phases I-III; human trials) can also be provided by alternative means, whereby Art. 14 para. 1 TPLO indicates corresponding possibilities. Essentially, it is a matter of **proving that the findings already obtained in the investigations of the reference medicinal product can be transferred with sufficient certainty to the new generic product to be authorized.**[168]

942 The previously described - costly and lengthy - studies of modules 4 and 5 can therefore be completely dispensed with by using established data. In other words, **the increased risk of missing studies is replaced by established and seamlessly transferable scientific findings.**

2.2.1.2 Not used for vaccines

943 However, an important exception to the simplified authorization procedure for medicinal products with known active substances is explicitly stated in Art. 12 para. 5 lit. a TPLO: **"The following cannot be authorized in a simplified procedure: Vaccines, serums and toxins".** Even for vaccines with known active substances, simplified authorization is therefore out of the question, as the **necessary risk compensation obviously cannot be provided.**

2.2.1.3 No use for GMOs and gene therapies

944 Art. 12 para. 5 lit. c and e TPLO contains a further important exception to the simplified authorization procedure for medicinal products with known active substances: Medicinal products containing genetically modified organisms (***GMOs***) and advanced therapy medicinal products based on gene transfer methods (**gene therapy medicinal products**) are **excluded** from the simplified authorization procedure.

2.2.2. "EU/EFTA" medicinal products (Art. 14 para. 1 lit. a^{bis} TPA): "well-established use"

945 According to Art. 14 para. 1 lit. a^{bis} TPA, there is also a simplified authorization for "medicinal products whose active substances are used in a medicinal product that has been

167 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 11 N 31.
168 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 16.

demonstrably authorized as a medicinal product in at least one EU or EFTA country for at least 10 years at the time of submission of the application and that is comparable in terms of indications, dosage and route of administration". This is the so-called **"well-established use"**,[169] i.e. an authorization based on proven use. In addition to **a 10-year application phase,** comparability is a prerequisite: this is the case if the medicinal products "can be regarded **as 'essentially the same'** regardless of the differences between them in terms of their **safety and efficacy**".[170]

2.2.2.1 Renunciation of animal and human studies

946 The exemptions granted essentially correspond to those for "known active substances": According to Art. 14a para. 1 lit. a TPA, the "results of pharmacological, toxicological and clinical trials" (Art. 11 para. 2 lit. a no. 2 TPA) can be replaced by a compilation of equivalent scientific evidence. It is necessary that sufficient evidence of the safety and efficacy of the medicinal product is available in the published literature (Art. 17b para. 1 TPLO).[171]

947 **Bibliographic evidence therefore also replaces the complex and lengthy studies of modules 4 and 5. This increase in risk is compensated for by the previous 10 years of successful application in humans.**

2.2.2.2 Use with vaccines and GMOs / gene therapeutics

948 This risk compensation - 10 years of use in humans - is apparently weighted so highly that Art. 14 para. 1 lit. a^{bis} TPA should be applicable to all medicinal product groups - i.e. also to **vaccines and *GMOs /* gene therapy medicinal products**.[172] This means that the simplified procedure appears to be available for GMOs and gene therapy medicinal products that have been used in humans in the EU/EFTA for many years , although this contradicts the ordinance provision of Art. 12 para. 5 lit. a TPLO.

2.2.3. "Orphan use (Art. 14 para. 1 lit. f TPA)

949 According to Art. 14 para. 1 lit. f TPA (Art. 4-8 TPLO; Art. 24-26 TPLO), "important medicinal products for rare diseases" can also be authorized in a simplified manner. These are medicinal products for diseases that are so rare ("orphan diseases") that it is not worthwhile for manufacturers to carry out research with regard to the comprehensive ordinary authorization procedure (so-called **"orphan use"**).[173] The purpose of simplified authorization in

169 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 18.
170 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 18. See also Art. 17a lit. b VAZV.
171 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14a N 7.
172 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 23.
173 BGE 139 V 375 E. 4.4. S. 378

this area is therefore to increase the chance that drugs for rare diseases will nevertheless be brought to market and research will be conducted in this area.[174]

2.2.3.1 Obtaining orphan drug status (ODS)

950 For a medicinal product to be recognized as an "orphan drug" for the first time, the manufacturer must prove on the basis of documentation (specialist literature, database information, etc.) (Art. 4 para. 1 and 2 TPLO in conjunction with Art. 4 para. 1 lit. adecies **no. 1** TPA) that

- it serves to detect, prevent or treat a **life-threatening or chronically disabling illness,**
- **which affects a maximum of five out of ten thousand people in Switzerland at the** time the application is submitted.

951 This is similar **in content to Art. 9a TPA,** which may also only be used for life-threatening or debilitating diseases. Accordingly, it is postulated in the doctrine that an authorization of "orphan drugs" is also possible within the framework of "temporary authorization" (if the conditions are met).[175]

952 Recognition is also possible if the medicinal product or its active substance has already been **granted** the **status** of an important medicinal product for rare diseases **by another country** with comparable medicinal product control within the meaning of Art. 13 TPA (Art. 4 para. 1 TPLO in conjunction with Art. 4 para. 1 lit. adecies **no. 2** TPA).

2.2.3.2 Monetary incentives and procedural assistance

953 Once orphan drug status (ODS) has been confirmed, monetary (and scientific) incentives and procedural support come into play:

- Waiver of state flat-rate fees for new registrations.[176]
- Extended document protection of fifteen years.[177]
- Possibility of preliminary clarifications by Swissmedic prior to submission of an application for authorization, which concern all relevant elements of an authorization (quality, safety and efficacy, in accordance with Art. 3-6 TPLRO and Modules 3-5).[178]

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174 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52.

175 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 6; SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52 *in fine*.

176 See Art. 65 para. 6 in conjunction with. Art. 9 lit. a and b GebV-Swissmedic (SR 912.214.5); SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52.

177 Art. 11b para. 4 HMG.

178 Art. 25 VAZV; SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 52.

954 In addition, the medicinal product can be granted a simplified authorization (Art. 24 para. 1 TPLO), whereby the authorization procedure (Art. 24-26 TPLO) is generally based on the procedural requirements for known active substances (simplified authorization)[179] or on those for new active substances (ordinary authorization) .[180][181] This means that, in principle, proof of quality, safety and efficacy must be provided for authorization.[182] However, with significant exceptions:

2.2.3.3 Renunciation of animal and human studies

955 According to Art. 26 para. 1 TPLRO, the rarity of the disease and the associated **difficulty in conducting clinical trials in accordance with Art. 5 TPLRO** is "appropriately" taken into account by Swissmedic with regard to the requirements for the scientific documentation for authorization. The difficulty in conducting trials is due in particular to the limited number of patients. In "justified" cases, this means that **complete study reports are not required,** although results published elsewhere must be provided.[183]

956 In its guidance document, Swissmedic even states that the rarity issue is also taken into account in the "assessment of **preclinical**" data. Accordingly, the study reports on pharmacological and toxicological tests (animal tests) would also be affected in accordance with Art. 4 TPLRO.[184]

957 If the medicinal product has already been authorized by another country with comparable medicinal product control, the applicant can submit to Swissmedic the documentation on quality, toxicology and clinical use that formed the basis for authorization in the third country (Art. 26 para. 2 TPLO).

2.2.3.4 Risk equalization: very limited scope of application

958 Medicinal products that have new active substances but whose efficacy and safety have not been verified to the same extent in animal trials (preclinical) or human trials (clinical) as would be the case under the ordinary procedure can therefore be placed on the market under the title "orphan use". Where there is no foreign authorization, risk compensation as

179 Swissmedic, "Guidance document Authorization of human medicinal products with known active substance HMV4", 01.03.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl101_00_007d_wlanleitungzulassungvonhumanarzneimitteln-mitbekann.pdf.download.pdf/ZL101_00_007d_WL%20Zulassung%20Humanarzneimittel%20mit%20bekanntem%20Wirkstoff.pdf, point 4

180 Swissmedic, (FN 96), para. 4.

181 Swissmedic, "Guidance document Orphan Drug HMV4" (FN 163), para. 7.1.

182 SCHMID/UHLMANN, BSK HMG, 2nd ed., Basel 2022, Art. 14 N 58.

183 Swissmedic, "Guidance document Orphan Drug HMV4" (FN 163), para. 7.2.

184 See Swissmedic, FN 183.

a result of years of use in humans is ruled out. Even if a new active substance is available, risk compensation through comparison with studies on known active substances is not guaranteed to the same extent as is the case with generics. **The relevant risk reduction therefore consists of the fact that "orphan drugs" may be used in a maximum of 0.05% (corresponding to 4320 people) of the total Swiss population.**[185]

2.2.3.5 Use with vaccines?

959 Whether vaccines could also be recognized as "orphan drugs" is not explicitly regulated. However, there are two circumstances that speak against this: If vaccines are already known active substances (Art. 14 para. 1 lit. a TPA; generics, see N 943) for safety reasons, this must *a fortiori* also be the case for vaccines that may be completely new. In addition, vaccines are intended to immunize against infectious diseases that affect tens of thousands of people, which means that it cannot be a "rare" disease that is to be combated. **A simplified approval of vaccines under the title "orphan use" must therefore be ruled out from the outset.**

2.2.3.6 Application for gene therapies

960 The factual situation in the field of gene therapies is at least different: The first gene therapies have already been recognized worldwide as "orphan drugs". Gene therapy drugs are generally only administered once at a young age for rare hereditary diseases in the hope that this treatment will be sufficient for the patient's entire life.[186]

2.2.4. Interim conclusion

961 In all the simplified authorization procedures examined, the animal and human studies (Modules 4 and 5) that are mandatory in the ordinary procedure can be dispensed with. This waiver results in an increase in risk, which is counteracted with various compensatory measures depending on the medicinal product. The missing studies are replaced in this way

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185 "Five out of ten thousand people" corresponds to 0.05%; total Swiss population currently approx. 8,637,000.

186 KERPEL-FRONIUS, "Development and Use of Gene Therapy Orphan Drugs-Ethical Needs for a Broader Cooperation Between the Pharmaceutical Industry and Society", 23.12.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7785873/; HUTTON, "Adverum Biotechnologies gets Orphan Drug Designation from FDA for gene therapy candidate", 06.01.2022, https://www.ophthalmologytimes.com/view/adverum-biotechnologies-gets-orphan-drug-designation-from-fda-for-gene-therapy-candidate; PARK, "Gene Therapy Candidate Designated Orphan Drug for Buerger Disease", 20.10.2021, https://www.empr.com/home/news/drugs-in-the-pipeline/gene-therapy-candidate-designated-orphan-drug-for-buerger-disease/.

- through established and seamlessly **transferable scientific findings** with a restriction on authorized medicinal products (known active substances; generics) or
- knowledge gained through **more than 10 years of application in humans** ("well-established use") or
- by **restricting the application** to a small target population ("orphan use").

962 Since none of these criteria are applicable to the mRNA technology to be assessed here or to SARS-CoV-2, the simplified procedure with the associated simplifications was and is not available for the approval of this new type of "vaccine" against SARS-CoV-2.

2.3. "Temporary authorization" (Art. 9a HMG; Art. 18 - 22 VAZV)

963 In regulatory terms, the "temporary authorization" as an actual emergency authorization was separated from the ordinary and simplified authorization by the legislator and regulators and regulated specifically in Art. 9a TPA, specified and supplemented in Art. 18 - 22 TPLO [187][188] and presented in a Swissmedic guidance document. [189]

964 According to Art. 9a TPA, a "medicinal product for diseases that are **life-threatening or** result in **disability**" can be **authorized "for a limited period" in a "simplified" procedure** according to Art. 14 TPA - if this is compatible with the protection of health, a major therapeutic benefit is to be expected and no alternatives are available.

965 As can already be seen from the legal definition, the *technical term* "temporary authorization" chosen by the legislator has no meaningfulness whatsoever to describe the special features of this specially regulated authorization procedure. Due to the characteristics described below, this specific form of authorization is rather a special authorization, *de facto* an actual emergency authorization.

2.3.1. Narrow scope of application: pre-existing life-threatening diseases

2.3.1.1 History of origin

966 Art. 9a TPA emerged from the former Art. 9 para. 4 a TPA. This read:

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187 Ordinance of the Swiss Agency for Therapeutic Products on the Simplified Authorization of Medicinal Products and the Authorization of Medicinal Products under the Notification Procedure (VAZV; SR 812.212.23).

188 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 17.

189 Cf. also Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", status: 01.01.2022, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl109_00_001d_wl_befristete_zl_ham_hmv4_ab_010121.pdf.download.pdf/ZL109_00_001d_WL_Befristete_Zulassung_Humanarzneimittel_HMV4.pdf* , p. 4 ff.

> "The Agency may **authorize** the distribution or dispensing of unauthorized medicinal products for **life-threatening** diseases **for a limited period** if this is compatible with the protection of health, if a major therapeutic benefit is to be expected from their use and if no comparable medicinal product is available."

967 According to the 1999 dispatch at the time, this original standard was created in response to a motion "in the interests of patients with life-threatening diseases", "which sought to enable the use of unregistered medicinal products in public hospitals under strict medical supervision".[190] And further: "It should be possible to make **promising new medicines for life-threatening diseases available to patients without a marketing authorization.** Since submitting a complete application for authorization is a time-consuming and costly activity, it should be possible to authorize distribution and dispensing under the aforementioned conditions. [...] These **exceptional authorizations** are intended for the use of a medicinal product **for individual patients,** for a specific patient group or for patients who cannot participate in ongoing studies."[191]

968 In the dispatch on the new Art. 9a TPA, the extension to disabling diseases was justified by the fact that, with regard to the benefit/risk assessment, "it is hardly possible to differentiate between life-threatening diseases and diseases leading to disability".[192] However, this was actually an **adjustment to the legal situation in the EU**.[193] In addition, "for reasons of consistency", the "temporary authorization" was changed to a "temporary authorization", which could be granted on the basis of "simplified conditions". This is because **placing a product on the market "for an unspecified number of patients" is** terminologically not an "authorization" but an "approval". [194]

969 The **originally** narrowly defined scope of application of the "temporary authorization" - as an **exception for individual patients without regular authorization** - was thus largely emptied of its meaning with the supposedly mere transfer to Art. 9a TPA: **There was now suddenly talk of a broadly effective "authorization".** Temporary authorization, on the other hand - which in material terms corresponds much more closely to the old Art. 9 para. 4 a TPA - was now included in Art. 9b TPA.

970 Under the guise of a mere rewording, a new type of "simplified" or "temporary authorization" was created, which came into force as Art. 9a TPA on 1 January 2019. It was still stated

190 Message HMG 1999, p. 3470.
191 Message HMG 1999, p. 3496 f. (emphasis added).
192 Message HMG 2012, p. 62.
193 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 42b.
194 Message HMG 2012, p. 62 f.

that "temporary authorizations according to Art. 9a" may only ever be granted for a "shorter duration" due to their **"exceptional nature".**[195]

2.3.1.2 Reason prerequisite: "Life-threatening, disabling illness"

971 According to Art. 9a TPA, the possibility of a temporary authorization in a simplified procedure is only open to medicinal products that are to be used against life-threatening or debilitating diseases, if this is compatible with the protection of health (lit. a), if the corresponding medicinal product is expected to have a major therapeutic benefit (lit. b) and if no authorized, alternative and equivalent medicinal product is available in Switzerland (lit. c).[196]

972 The overriding aim of the temporary authorization is to make a medicinal product available immediately and pragmatically for a **life-threatening, disabling disease** for which no treatment options are available on the market and which is expected to be of great benefit based on initial provisional data. It is therefore argued that Art. 9a TPA would regulate the so-called **"compassionate use".**[197] This is defined in the EU as follows:

> "[...] 'compassionate use' means that a [...] medicinal product is made available for humane considerations to a group of patients **suffering from a debilitating chronic or serious disease** or **whose disease is considered life-threatening** and who cannot be treated satisfactorily with an authorized medicinal product."

973 The object of compassionate use - and thus also of Art. 9a TPA - must therefore **be diseases from which patients are already suffering.** The application of compassionate use to illnesses that may only occur or are possibly imminent - i.e. **for prophylaxis in healthy people - is definitely not envisaged in principle.**

974 This finding is in line with the case law of the Federal Supreme Court: according to this, the **risk of severe disability or possible death** must apply to all patients in the target population and must **not** appear to **be a mere possibility.** Rather, it must be **seriously likely to materialize** based on the specific circumstances.[198]

2.3.1.3 Interim conclusion

975 The legislative history, doctrine and case law therefore indicate a narrow scope of application of Art. 9a TPA to **pre-existing life-threatening or disabling diseases.**

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195 Message HMG 2012, p. 70.
196 For all requirements, see N 963 ff., N 992 ff.
197 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 42a, Art. 9a N 4.
198 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 20; judgment 8BC_523/2106 of the Federal Supreme Court of 27.10.2016, E. 5.2.1.

2.3.2. Massively divergent regulatory requirements: Forecasts instead of facts

976 Due to the independent standardization in Art. 9a TPA (and Art. 18 - 22 TPLO), the "temporary authorisation" differs significantly in regulatory terms from the previously discussed ordinary and simplified forms of authorisation. While the law and ordinance explicitly define which central elements of the ordinary authorization can be waived for the simplified authorizations described above, this is not the case for the temporary authorization. Accordingly, it is virtually impossible to demonstrate the difference between ordinary and temporary authorization procedures directly on the basis of the legal and regulatory standards.

977 While the **ordinary and simplified procedure sets out clear requirements for the documents to be submitted (quality tests, animal studies, clinical studies)**, such information is completely absent from the legal and regulatory provisions of the "temporary authorization". **As a "substitute" for the hard facts, the "temporary authorization" is partly based on forecasts:** A cost-benefit analysis is not carried out conclusively, but in the hope that the criterion of **efficacy in** particular will still be able to be strictly proven in the **future.** Legislators and regulators have attempted to take this into account with various test criteria, all of which must be met *cumulatively at the* time of initial approval:

- Pre-existing life-threatening or disabling illness
  (Art. 9a para. 1 **subpara. 1** HMG in conjunction with Art. 18 lit. a VAZV)
- Compatibility with the protection of health
  (9a para. 1 lit. a HMG)
- Major therapeutic benefit **expected**
  (Art. 9a para. 1 **lit. b** TPA in conjunction with Art. 18 lit. c TPLRO)
- Lack of alternative treatment
  (Art. 9a para. 1 **lit. c** TPA in conjunction with Art. 18 lit. b TPLRO)
- Subsequent delivery of complete (study) data **probably** possible
  (Art. 9a HMG in conjunction with Art. 18 **lit. d** VAZV)
- Temporal urgency
  (Art. 9a HMG in conjunction with Art. 18 **lit. e** VAZV)

978 It follows from this: Even if, according to the will of the legislator, some compromises can be made with regard to the **efficacy** criterion, the other core criteria of Art. 1 TPA - **quality and basic safety** - of a medicinal product to be authorized must **always be demonstrated**.

2.3.3. Massively shortened process duration; incomplete data

979 In order to be able to help patients in life-threatening situations quickly, the procedure for **"temporary approval" takes** just **140 calendar days.**[199] In addition, there is a massive acceleration due to the fact that the temporary approval can also be granted on the basis of **limited data and corresponding studies that have not yet been carried out**. [200]

980 According to Swissmedic, the following documents, among others, must therefore be submitted:[201]

- complete data relating to pharmaceutical quality (Module 3),
- complete preclinical data (animal studies; Module 4),
- available relevant top-line results of ongoing studies as supporting information,
- Draft of a risk management plan (RMP).

981 "Top-line results" are the results of the phase II studies. As these do not have to be available in full (but only "available relevant" results), two conclusions can be drawn from this: On the one hand, **definitive study results for clinical phases II and III are not available in the case of a "temporary authorization" - in deviation from the ordinary authorization procedure.** On the other hand, at least the results of the completed clinical phase I trial (dose-finding) must be submitted as the absolute minimum standard (basic safety).

982 Accordingly, the **clinical documentation** (Module 5) on the efficacy and safety of COVID "vaccines" is **largely incomplete.** A "temporary authorization" can therefore be granted **without the most elementary safety precautions** - namely the broad testing of a drug on healthy and sick people over usually several years (phase II/III studies).

983 In principle, the only **compensation for this massive increase in risk** is therefore that **"temporary authorization" is only permitted for diseases that are life-threatening for the entire target population or result in disability** (Art. 9a para. 1 TPA). Unlike in the cases of simplified authorization, in which corresponding study protocols or literature can be provided due to known active substances and years of use in humans, such empirical values are lacking for medicinal products authorized for the first time under Art. 9a TPA. A

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199 Swissmedic, "Guidance on time limits for applications for authorization HMV4", FN 119.

200 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, before Art. 8-17 N 42a.

201 Swissmedic, "Wegleitung Befristete Zulassung Humanarzneimittel HMV4", status: 01.01.2022, para. 5.5., *https://www.*swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl109_00_001d_wl_befristete_zl_ham_hmv4_ab_010121.pdf.download.pdf/ZL109_00_001d_WL_Befristete_Zulassung_Humanarzneimittel_HMV4.pdf.; Swissmedic, information event on the revision of the Therapeutic Products Act "Temporary authorization", 25.10.2018, *https://www.swissmedic.ch/dam/swissmedic/de/dokumente/stab/veranstaltung/hmg/befristetezulassung.pdf.download.pdf/09_Befristete%20Zulassung_J%C3%B6rg%20Schl%C3%A4pfer.pdf.*

risk reduction as in the case of "orphan use" - i.e. a very limited application in a small number of people - is also ruled out.

2.3.4. Risk compensation through time limits?

984 As a **further risk compensation,** the restriction in the name would also come into play, according to which the "temporary" approval can only be granted for **a maximum of two years** with special conditions. The results of the ongoing approval study must be submitted on an ongoing basis during this period in a "rolling procedure" so that the "temporary" approval can be converted into a full approval based on **complete clinical documentation after two years at the latest** (Art. 21 TPLO)[202] - or must be suspended immediately.

985 However, this supposed **risk compensation** is immediately **invalidated** by Art. 21 Para. 3 VAZV. This states that the "temporary" authorization "may be extended upon reasoned request". In 2018, Swissmedic stated that the **possibility of extension** could only be granted with "scientific justification" and "fulfillment of [all] conditions" (Annex **16,** slide 9).

BO: Enclosure **16:** Swissmedic, Information event on the revision of the Therapeutic Products Act (TPA), Temporary authorization, 25.10.2018

986 Both of the "prerequisites" for an extension mentioned by Swissmedic are undoubtedly flexible: Swissmedic could both control the conditions imposed on manufacturers on its own authority and accept "scientific justifications" of all kinds, but this would in no way comply with the law. In fact, Swissmedic is only obliged to authorize medicinal products in accordance with Art. 9a TPA if the requirements for this are actually met. This applies both to the first authorization and to each renewal.

987 **The time limit therefore does not effectively reduce the risk,** as the experimental substances are already being used on humans without restriction during this period. Added to this is the **possibility of extension, which is accompanied by unclear requirements and** immediately robs the "temporary" authorization of its essence.

988 Effective compensation for the increased risks associated with the temporary authorization in order to protect public health can therefore only be achieved in two areas: (i.) Particularly **careful information of the patient about all risks** and all aspects of the benefit/risk ratio; (ii.) **Particularly careful and effective pharmacovigilance,** which allows any undesirable side effects to be identified immediately so that the temporary authorization can be revoked immediately if the benefit/risk ratio is negative (see N 1151 ff.).

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202 Swissmedic, "Guidance document Temporary authorization of human medicinal products HMV4", FN 201.

2.3.5. Careful consideration of interests and only cautious application

989 The limited data situation is accompanied by possible health risks, which must be weighed against the potential health benefits of using the preparation in question.[203] The balancing of interests to be carried out therefore affects the right to life and the right to self-determination of the individual patient (Art. 10 para. 2 BV) on the one hand, and the public interest in protection against potentially unsafe or ineffective medicinal products (Art. 118 para. 1 BV; Art. 1 HMG) and the associated right to physical integrity of the individual (Art. 10 para. 2 BV) on the other. [204]

990 If a regular authorization procedure is dispensed with in favour of a temporary authorization, the patient is exposed to a risk due to the incomplete documentation on efficacy and safety, as it may turn out in the course of time that the medicinal product is not effective after all or is associated with serious side effects. **Consequently, a temporary authorization can only be justified if the expected benefit and the potential harm resulting from withholding the therapy are very high. In** such a case, due diligence requirements must be given very high priority and potential risks must be carefully and comprehensively monitored in parallel - both in the Phase III trial that has not yet been completed and among users in the real world - so that safety signals can be detected immediately and measures can be taken against them if necessary.

991 Not least because of these uncertainties, the possibility of **compassionate use** (or Art. 9a TPA) should **only be used with caution** according to Federal Supreme Court case law, as otherwise the purpose of the general authorization requirement could be undermined.[205]

3. "Pandemic approval" for mRNA "vaccines"

3.1. Massive deviations from the planned approval procedure

992 As before (963 ff.), the authorization requirements pursuant to Art. 9a TPA deviate considerably from the requirements of the ordinary authorization procedure. The correct application of the "temporary authorization" standards is therefore already associated with a considerable increase in risk.

993 In this case, the fact that Swissmedic had not even adhered to the requirements of Art. 9a TPA (and the corresponding implementing provisions), but had once again fallen

203 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 2.
204 Similarly SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 3.
205 Judgment 2A.469/2003 of 06.09.2004, E. 3.3.

significantly - illegally - below these minimum requirements in the form of actual "pandemic authorizations", made matters worse:

3.1.1. 2019: Swissmedic sets the course for the abolition of therapeutic products legislation

994 As before (N 966 ff.), the scope of application of Art. 9a TPA is limited to **pre-existing (currently existing) life-threatening or disabling diseases**. This narrow scope of application of Art. 9a TPA was obviously an obstacle for Swissmedic:

3.1.1.1 Application of Art. 9a TPA also for vaccines (for prophylaxis)?

995 Less than three months after the new Art. 9a TPA came into force (January 1, 2019), Swissmedic felt compelled to publish the following on its website in March 2019: [206]

> "**Temporary authorizations also possible for vaccines (i.e. for prophylaxis)?**
>
> Yes
>
> A-154
>
> Last change 20.03.2019"

996 This "clarification" was apparently necessary from the point of view of the manufacturers of the mRNA "vaccines" and the licensing authority in order to be prepared for pandemics such as the "COVID pandemic" that was declared just under a year later. However, the basis for this clarification is in open contradiction to the legal basis: **Both the history of the creation of Art. 9a TPA and the meaning of the guiding basic idea of compassionate use rule out the mere prophylactic use of mRNA "vaccines" in a healthy population from the outset** (see N 966 ff.)**.**

997 A systematic interpretation of the law also leads to the same conclusion: According to the wording, the "temporary" authorization pursuant to Art. 9a TPA is granted "in a simplified procedure pursuant to Art. 14 para. 1". **However,** according to Art. 12 para. 5 lit. a TPLO, **"vaccines" in particular cannot be authorized in a simplified procedure** (see N 943 [Generics]; above N 959 ["orphan use"]. Only vaccines that have been authorized in the EU/EFTA for many years (over 10 years) are apparently exempted in this respect (see N 948). This is understandable in principle, as the fact that a vaccine has been (successfully) authorized for more than 10 years is sufficient proof of a significant risk reduction (see above

206 Swissmedic, "Temporary authorizations also possible for vaccines", 20.03.2019, https://www.swissmedic.ch/swissmedic/de/home/news/specials/hmv4-ambvmedicrime-info/tpa-revision-faq/fragen-infoanlass-1/a-154.html.

N 961 f.). **However,** such proof of risk reduction could **not be provided** for the **novel mRNA "vaccines" . The unfounded opening of Art. 9a TPA for vaccinations was thus clearly aimed at removing the final safety hurdles of therapeutic products legislation that would have applied in the context of simplified authorization.**

998 The fact that clear standards for the protection of public health cannot under any circumstances be weakened or repealed by the competent administrative authority on its own authority, contrary to the clear hurdles of the wording of the TPA, the principle of legality and the principles of delegation derived from this by the Federal Supreme Court, has already been explained above (N 177). Swissmedic can therefore under no circumstances evade the minimum requirements laid down by the federal legislator for the protection of public health by means of a simple reference on its own website.

3.1.1.2 Application of Art. 9a TPA for gene therapy medicinal products?

999 Should Swissmedic take the view that the mRNA injections are not "vaccines" but "gene therapy medicinal products", the following should be noted:

1000 Neither the law nor the ordinance explicitly regulates whether Art. 9a TPA can also be applied to gene therapy medicinal products. Analogous to the (non-)regulation of "orphan use"[207] and the de facto authorization of gene therapy medicinal products there (see N 960), it should therefore be concluded that at least gene therapy medicinal products could be authorized under Art. 9a TPA. However, a broad application - as is now erroneously practised in Art. 9a TPA with the authorization of mRNA "gene therapies" - lacks precisely the elementary protective element of the very limited scope of application of "orphan use" to a maximum of 0.05% of the total population (see above N 958). A temporary authorization of "gene therapies" can therefore be ruled out without further ado for the very reason of population-wide application.

1001 In addition, there is once again the fact that Art. 9a TPA is not designed for medicinal products for prophylactic purposes, which has already been explained with regard to "vaccines" (see above N 995 ff.). However, the mRNA technology now being used in the context of the COVID crisis is precisely not used as a "therapy" for people who are already ill. Rather, these mRNA-based substances are generally only used in healthy people and for preventive purposes, which is why it would be downright misleading to claim that these mRNA substances are used to "treat" a disease or defect (see evidence report N 24 ff.). For an application to mRNA "gene therapy medicinal products" for prophylactic purposes, Art. 9a TPA would therefore have to read: "whose use is expected to have a major therapeutic **or**

207 On the concept of "orphan use" in front N 949 ff.

prophylactic benefit". This is clearly not the case, which is why even a possible classification of mRNA "vaccines" as "gene therapy medicinal products" would not change the fact that their authorization under Art. 9a TPA is out of the question from the outset.

1002 In addition, the strict regulatory requirements that the legislator imposes on gene therapy medicinal products and that Swissmedic has imposed on itself, for example with regard to the conduct of clinical trials (see N 916 ff.), clearly cannot be complied with in the context of Art. 9a TPA.

3.1.1.3 Application of Art. 9a TPA for GMOs?

1003 As in the Evidence Report (N 96 ff.; see also above N 203), there are even clear indications that the mRNA injections could qualify as *GMOs*: to date, it has not been ruled out that reverse transcription into human DNA might not be possible after all. There are also indications that at least the bivalent "vaccines" contain plasmids that qualify as *GMOs* (Evidence Report N 214 f.; see also N 233).

1004 As long as this possibility of genetic modification cannot be ruled out, the precautionary principle dictates that the strictest safety measures should be applied to any authorization. In other words, the precautionary measures previously applied to *GMOs* (N 916 ff.) described for GMOs (e.g: Proof of rapid degradation of the preparation and lack of integration potential in the germ line) should have been complied with - or at least their application should have been checked - from the outset. A waiver of protection via Art. 9a TPA would clearly contradict the above-mentioned intentions of the legislator, particularly in the case of substances for which a permanent gene-modifying effect cannot be ruled out. Nevertheless, Swissmedic has recognized the demonstrably real risk of permanent gene modification by mRNA substances (see above N 200 ff.) was simply ignored.

3.1.1.4 Effective scope of application of Art. 9a TPA: Pre-existing diseases

1005 This absolutely unusual - and inadmissible - extension of the scope of application of Art. 9a TPA to "vaccinations" and "gene therapy medicinal products" (possibly *GMOs*) is also reflected in Swissmedic's authorization practice in connection with Art. 9a TPA (or with the predecessor provision of Art. 9 para. 4 a TPA; for the history of its origins, see N 966 ff.) before the coronavirus pandemic:

1006 According to the Basel Commentary, the Swissmedic website once (presumably before December 2020) listed "only four temporarily authorized medicinal products" on the publication list in accordance with Art. 22 para. 1 TPLO.[208]

1007 As of February 2022, this same list of "*Temporarily authorized medicinal products for life-threatening* diseases"[209] already contained **20 medicinal products in** addition to COVID "vaccines", which are authorized as antidotes for snake bites (2 medicinal products) or for excessive blood thinning (1 medicinal product) or as therapy for severe osteoporosis (1 medicinal product), cancer (13 medicinal products), a severe form of muscle atrophy in young children up to 2 years of age (1 medicinal product) and for the treatment of COVID disease (2 medicinal products).

1008 It is striking that the **COVID "vaccines" on this list** are **an absolute exception: They are the** only drugs approved for a limited period of time that have been and are used **preventively** and in principle for the **healthy population as a whole.** And this for a disease with a **very high survival rate of approx. 99.85% (see** N 750 ff.). In contrast, the other medicinal products are used to treat individual patients who are already seriously ill and whose chances of survival (cancer, snakebite) are already massively reduced.

1009 By May 31, 2023, the **list of "temporary" approved medicinal products had** even grown to **well over 40 approvals.**[210]

1010 Until the beginning of the COVID crisis, the only exception for "prophylactic" use in humans as part of a "temporary authorization" was probably the swine flu vaccine *Pandemrix,* whose hasty approval in 2009 caused immense suffering worldwide due to unforeseen side effects (see N 357 ff.). It is simply incomprehensible why this serious mistake had to be repeated in 2020 and why this wrong decision is still being upheld.

3.1.1.5 Conclusion: Illegal temporary authorization for "vaccines" and "gene therapeutics"

1011 The authorization of vaccines was fundamentally inadmissible under any simplified procedure and, as was the case until 2019, should only have been carried out in compliance with the strictest rules of therapeutic products law in the ordinary procedure. With a simple "clarification" in March 2019, Swissmedic simply removed this important safety barrier on its own authority: From then on, vaccines were no longer subject to the strictest requirements of the

208 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 8.

209 Swissmedic, "Temporarily authorized medicinal products for life-threatening diseases", 02.2022, https://www.swissmedic.ch/swissmedic/de/home/services/listen_neu.html.

210 Swissmedic, "Extended list of authorized human medicinal products", 31.05.2023, https://www.swissmedic.ch/swissmedic/de/home/services/listen_neu.html.

ordinary procedure, nor to the somewhat more stringent requirements of the simplified procedure, but instead to the minimum authorization requirements of Swiss therapeutic products legislation with the rules of Art. 9a TPA on "temporary" authorization.

1012 The mere fact that Swissmedic opened the "temporary" authorization according to Art. 9a TPA for supposed "vaccines" - in fact: mRNA injections to be administered purely for prophylactic purposes to a healthy general population - without objective justification and contrary to all legal methods of interpretation, represents a serious breach of the most important principles of the Therapeutic Products Act. This breach of law would be all the more serious if the mRNA injections were even to be classified as *GMOs*.

3.1.2. Autumn 2020: Massive erosion of "temporary admission"

1013 As if the granting of "temporary authorizations" for "vaccinations" (and "gene therapies") were not already an unacceptably risk-increasing procedure, Swissmedic further undermined the "temporary" procedure in September 2020 with an amended "Guidance on the authorization procedure for COVID-19 medicinal products in the event of a pandemic" - allegedly based on the COVID Act, but in particular based on a Federal Council decree:

3.1.2.1 COVID Act: No free pass for the Federal Council and Swissmedic

1014 With Art. 3 para. 2 lit. c of the COVID-19 Act, Parliament has authorized the Federal Council to provide for exemptions from the authorisation requirement for medicinal products or to adapt the authorisation requirements or the authorisation procedure. However, this is only for the purpose of "ensuring an adequate supply of important medical goods to the population".

1015 It follows from this wording alone that an exception to the licensing requirements is only possible if the supply of the population cannot be ensured in any other way **and** if the safety of the population is not jeopardized by new risks as a result of these exceptions. As stated at the end (N 1104 ff.), there are already a large number of treatment alternatives for COVID-19 disease. In addition, Swissmedic was already sufficiently aware at the time of the initial authorizations that the particular mechanism of action of the mRNA-based COVID preparations was associated with unknown risks, see for example the problems of

- of the special risks associated with "gene therapy/ATMP" front N 824 f. (N 526 ff., N 916 ff.);
- the lack of controllability of artificially forced spike production in front N 821 et seq. [ER N 1845 et seq;]
- of the toxic spike proteins in front N 391 ff. and N 822 [ER 594 ff;]

- toxicity of the lipid nanoparticles in front N 212 ff. and N 823 [ER N 118 ff;]
- the extremely short development period and the lack of randomized controlled long-term studies before N 270 ff., N 275 ff. [ER N 349 ff., N 1944];
- of the other significant risk factors identified by Swissmedic at the front N 827 ff. and at the back N 1291, N 1298, N 1305 and N 1311ER N 196, N 207 ff., N 1835 ff., N 1845 ff;
- the ineffectual attempts at justification on the part of Swissmedic above N 655 ff. and N 848 ff;
- the absence of an extraordinary threat to the general population from SARS-CoV-2" front N 744 ff. and N 811 ff.

1016 **Due to their special technical expertise, the persons responsible for Swissmedic can therefore in no way invoke this ordinance provision to justify the risky mRNA authorizations for the entire population. Swissmedic should have known better than the Federal Council.**

1017 It is therefore exclusively the idea of protecting public health that Art. 3 para. 2 lit. c COVID-19 Act follows. Under no circumstances did the legislator intend to authorize the Federal Council or Swissmedic to dispense with basic protective measures such as preclinical and clinical studies in the context of the authorisation of medicinal products and the consideration of all other risk-relevant facts. **The provision does not constitute a free pass for the Federal Council or Swissmedic to approve any mRNA gene therapy under the pretext of "pandemic control" and without further risk/benefit analysis, disregarding the most important pillars of the Therapeutic Products Act** - on the contrary: even under the COVID-19 Act, the Federal Council and Swissmedic are obliged to observe the principles of subsidiarity, effectiveness and proportionality. Any strategy to combat COVID-19 must be geared towards the mildest and shortest possible restriction [...] (Art. 1 para. 2bis COVID-19 Act). Accordingly, the Federal Council was in no way authorized to arbitrarily abandon the therapeutic products mandate under Art. 1 TPA to protect public health from ineffective or unsafe medicinal products.

3.1.2.2 Federal Council COVID ordinance as a gateway

1018 However, based on Art. 3 para. 2 lit. c COVID-19 Act, the **Federal Council** then provided for **various exceptions to the authorization requirements for medicinal products** in the **COVID-19 Ordinance 3 of 19 June 2020** (SR 818.101.24) - for example in **Art. 21 para. 2,** which is quite likely to jeopardize the protection of public health from unsafe medicinal products:

> "Variations to the authorization of a medicinal product authorized in Switzerland with an active substance according to Annex 4 Number **1 [No. 41: "COVID-19 vaccines"]**, on the basis of which the medicinal product can be used for the treatment of COVID-19 patients in Switzerland, **may be implemented immediately after submission of a corresponding variation application pending Swissmedic's decision. On the basis of a benefit/risk analysis, Swissmedic** may approve deviations from the applicable provisions of therapeutic products legislation in the case of variations to the authorization of medicinal products with an active substance according to Annex 4 number 1."

1019 The same applies to Art. 21 para. 4 COVID-19 Ordinance 3 of June 19, 2020:

> "On the **basis of a benefit/risk analysis,** Swissmedic may authorize **deviations** from the **manufacturing process** approved as part of the authorisation for medicinal products for the prevention and control of the coronavirus in Switzerland. It defines criteria under which the person responsible for technical matters can grant **early market release** for medicinal products for the prevention and control of the coronavirus in Switzerland."

1020 It should be emphasized that in both provisions of COVID-19 Ordinance 3 relating to public health, the Federal Council explicitly adheres to the pre-existing basic order by repeating the principle that **Swissmedic must carry out a benefit/risk analysis before each authorisation.** As Swissmedic has been the highest technically and objectively competent authority for years to correctly identify medicinal product risks and take appropriate precautions, the Federal Council ordinance in question does not change Swissmedic's legal mandate to ensure the protection of public health from ineffective and unsafe medicinal products.

3.1.2.3 "Pandemic" guidelines V.3.0: Massive acceleration

1021 However, instead of applying the Federal Council's requirements as a (supposedly) independent approval authority in accordance with the provisions of therapeutic products legislation, Swissmedic interpreted the authorizations contained in Art. 21 of COVID-19 Ordinance 3 of 19 June 2020 as a free pass to adapt a guidance document that had been in place since 2012 to the "COVID-19 pandemic" as of 15 September 2020 and to abandon existing safety mechanisms:[211] According to the adapted **"Guidance document**

211 Internet archive, "Guidance on the authorization procedure for COVID-19 medicinal products in the HMV4 pandemic", V.3.1, 01.12.2020 (see V.3.0 as of 15.09.2020: "Orientation towards the COVID-19 pandemic"),

Authorization procedure for COVID-19 medicinal products in the event of a pandemic", Swissmedic wants to create the conditions "**in the exceptional situation of a pandemic"** to "handle authorization applications for medicinal products that serve to prevent and treat a pandemic disease as quickly as possible" (p. 2).

1022 In this "pandemic" guidance document, Swissmedic stated, reiterating the legal requirements of Art. 9a TPA, that such a "temporary authorization of medicinal products for life-threatening diseases" could also be granted ex officio (p. 6). At the same time, **however, Swissmedic removed various safety mechanisms** in order to speed up the "temporary authorization" even further, such as

- Deviation from the usual deadlines for the processing of applications for admission (p. 6 para. 9);
- Waiver of the "classic milestone LoQ [List of Questions]" (p. 5 para. 7.4);
- "Approval" of "deviations from the applicable legal requirements for therapeutic products" as part of the review of applications for authorization (p. 4 no. 7).

1023 The **irresponsible increase in risk (**which is **neither covered by the Therapeutic Products Act nor by the delegation standard of Art. 3 para. 2 lit. c COVID-19 Act)** associated with these three "acceleration processes" alone is described below (N 1024 ff., N 1028 ff. and N 1031 et seq.):

3.1.2.4 Massively reduced processing time

1024 Swissmedic immediately made use of the "pandemic" guidance mentioned above:

1025 Pfizer had submitted the application for the approval of Comirnaty on October 16, 2020, whereupon Swissmedic had already granted the "temporary" approval by letter dated December 19, 2020. **Swissmedic "reviewed" the application within a processing period of just 45 working days (corresponding to 63 calendar days).**[212]

1026 The same applies to Moderna's application for authorization: The application for authorization of Spikevax was submitted on November 9, 2020. Swissmedic issued the "temporary" approval by letter dated January 12, 2021, which **also results in** a **processing period of exactly 45 working days.**[213]

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https://web.archive.org/web/20210119193829/https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_044d_wl_zulassungsverfahren_covid-19.pdf.download.pdf/ZL000_00_044d_WL_Zulassungsverfahren_f%C3%BCr_Covid_19_Arzneimittel_im_Pandemiefall.pdf.

212 Evidence Report, N 1970.

213 Evidence report, N 1990.

1027 Both represent a massive undercutting of the company's own requirements for the temporary approval procedure (processing in normally 140 calendar days; see N 979), and it is obvious that the risk was once again massively increased in a completely unnecessary manner, which Swissmedic was of course aware of.

3.1.2.5 Omission of answers to elementary questions ("List of Questions")[214]

1028 In addition, the approval letter from Swissmedic to Pfizer shows that the **answers to the "List of questions" ("LoQ")** regarding preclinical, quality and clinical aspects were **not yet available** from Pfizer at the time of approval. This is also a clear violation of the normal authorization procedure according to the previously applicable guidelines: Until now, the answers to the LoQ were listed as a prerequisite for the preliminary decision and, accordingly, for the subsequent "temporary authorization".

1029 According to the guidance document "*Time limits for applications for authorization HMV4*" dated 28 February 2022, not all application types have to go through all procedural stages and milestones. If **no questions arise** from the assessment, the "LoQ" milestone may be skipped according to Swissmedic. In the present case, however, it is clear from the approval letter from Swissmedic to Pfizer that **there were serious uncertainties and thus unanswered questions** regarding quality, preclinical and clinical aspects (see below N 1191; in detail Evidence Report N 1974). The granting of the temporary authorization without waiting for the open questions to be answered ("LoQ") therefore clearly contradicts the clear requirements of the Therapeutic Products Act, to which Swissmedic itself had committed itself before the "pandemic".

1030 Swissmedic was obviously aware of this problem and - as mentioned above (N 1022) - stated in the "Pandemic" guidance document: "The classic LoQ milestone of the standard procedure does not apply." However, it is incomprehensible how a careful weighing of benefits and risks could have taken place without this central milestone and the corresponding answers to such open questions. By taking this fatal step, Swissmedic has deprived itself of one of its most fundamental means of enforcing drug safety - namely by asking questions and carrying out checks on efficacy and safety. This approach reveals Swissmedic's intention to dispense with a **fundamentally important legal obligation under the TPA** (to review the efficacy and safety of the substances to be authorized) in advance for an indefinite number of procedures with the stroke of a pen.

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214 On the whole Evidence Report, N 1974 ff.

3.1.2.6 Waiver of elementary studies on quality and safety: "deviations"?

1031 As before (N 980), the documentation for Module 3 (**quality**), Module 4 (**safety**; preclinical/animal studies) and at least one Phase I study from Module 5 is mandatory for a "temporary authorization".

1032 At the time of the first approval of the mRNA "vaccines", not even these minimum requirements were met. It follows from the above that

- purity (module 3) was obviously not guaranteed in view of various **impurities** (front N 231 ff.) and
- no or no adequate animal studies (Module 4) - namely on pharmacokinetics and toxicology - had been carried out (before N 250 ff.).

1033 After all, two-month data from telescoped phase I/II/III studies were submitted. However, these data and the corresponding analyses - as previously shown in detail (see for example N 397 ff. and N 297 ff.) - were either **falsified** or prepared in a scientifically untenable manner. Accordingly, although the requirements for Phase I were formally fulfilled, the studies all failed in material terms.

1034 Swissmedic may argue that these "deviations" are based on its own "pandemic" guidance (see N 1022) or the Federal Council's COVID Ordinance (see N 1019) had been able to "approve" them. **However, drug impurities and falsified studies are by no means any negligible "deviations", but such serious misconduct that official "approval" is simply out of the question. Swissmedic's indifference to impurities that are hazardous to health is clearly incompatible with the protective purpose of the Therapeutic Products Act.** Without elementary study data, it is objectively impossible to carry out even a rudimentary, useful "benefit/risk analysis".

3.1.2.7 Interim conclusion: "Acceleration" leads to fatal security gaps

1035 At the time of the "temporary" first authorizations at the end of 2020 / beginning of 2021, Swissmedic had already deviated from the legal requirements in the maximum conceivable way. **Practically all relevant safety mechanisms were arbitrarily undermined by Swissmedic in the name of "acceleration" in the face of an alleged "pandemic".** Key safety questions remained unanswered and acute alarm signals such as impurities or falsified studies - both of which are real killer criteria for approval - were simply ignored.

1036 Given this initial situation, there is a strong suspicion that Swissmedic **has** deliberately thrown **overboard** all essential instruments for reviewing and enforcing the always necessary **"benefit/risk analysis" and** has **not even begun to pay sufficient legal attention**

to mandatory authorization requirements. Swissmedic has thus already granted the first authorizations - even taking into account all "pandemic" regulations by the Federal Council and Swissmedic - in deliberate violation of the most fundamental legal hurdles to protect public health from ineffective and unsafe medicinal products.

3.1.2.8 Addendum: "Extension of approval" for adolescents, children, "boosters"

1037 Also in September 2020, Swissmedic had already stated in the quickly amended "pandemic" guidance document based on Art. 21 COVID-19 Ordinance 3 that **"extensions of authorizations"** and **"extensions of indications"** for "COVID-19 vaccines" (Annex 4 No. 1 COVID-19 Ordinance 3) would be **"implemented immediately"** after submission of a corresponding variation application.[215] Swissmedic (and apparently also the Federal Council) therefore expected that the first "temporary authorisation" of mRNA injections would not be limited to "basic immunization".

1038 Swissmedic probably made use of this option for the first time on June 4, 2021, when it extended the "temporary" authorizations to adolescents **after less than a month's review.** Subsequently, this "immediate implementation" was probably also applied to "booster" and children's authorizations following a simple application for a variation.

1039 In doing so, Swissmedic, which is exclusively geared towards speed, ignored a large number of alarm signals with each of these "authorization extensions" (see N 319 ff.; N 388 ff.; N 526 ff.) - **the cost-benefit ratio had long been obviously negative** (see above N 807 ff.). It should therefore be noted that Swissmedic also illegally granted all "extensions of authorization" - even taking into account all "pandemic" regulations by the Federal Council - in deliberate violation of the relevant statutory hurdles to protect public health from ineffective and unsafe medicinal products.

3.1.3. 2021: Elimination of central security mechanisms

1040 As early as spring 2021 - i.e. even before the authorization extensions to adolescents - Swissmedic was already preparing to eliminate the most central of all safety mechanisms in therapeutic products legislation: A **complete waiver of large-scale pivotal clinical trials (Phase III)** for variant-adapted "COVID vaccines" (on the crucial importance of Phase III trials, see N 882 f.).

1041 This step is hardly surprising, as the manufacturers had already *de facto* discontinued the - mandatory - "Phase I/II/III" studies for the first registrations by removing the control group ("unblinding") at the beginning of 2021 (see N 275 ff.). A "solution" therefore had to be found

215 Swissmedic, 01.12.2020 (FN 211), p. 3 no. 3.

to at least completely dispense with the very costly "Phase III" studies without having to carry them out *pro forma.*

3.1.3.1 Guideline "Pandemic" V.4.0: Waiver of phase III clinical trials

1042 For the planned waiver, Swissmedic relied on a **declaration by the "Access Consortium**"[216] dated March 4, 2021, which was attached as **Annex 1** to the "Pandemic" guidance document (in German) in version 4.0 dated May 15, 2021.[217] As of August 2022, this statement was removed from the guidance document and can apparently only be found in English on the Swissmedic website,[218] , which is definitely not conducive to transparency.

1043 Under the title "Guidelines for adapting approved COVID-19 vaccines for SARS-CoV-2 mutations during a pandemic", the declaration of the "Access Consortium" (Annex 1) justifies the **waiver of clinical trials** for the adapted "vaccines" right at the beginning as follows (point 11):

> "Extensive safety experience has already been gained with SARS-CoV-2 vaccines during the course of the pandemic and vaccine deployment due to mass vaccination, and **efficacy has been demonstrated for the original drug candidate with extensive Phase III clinical trials.**"

1044 This was already a blatant lie at the time: the regulatory authorities had long been aware that the aforementioned Phase III trials had been "unblinded" months ago and thus largely deprived of their informative value (see N 275 ff.). There was no proof of efficacy at the end of 2020 (see N 296 ff.) - nor has such evidence been submitted to date (see N 376 et seq., N 498 ff., N 688 et seq.).

1045 Nevertheless, Swissmedic took up this fatal lie and repeated it in the "Pandemic" guidance (V.4.0; 15.05.2021) under point 8.1[219] as follows:

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216 Cf. on this front N 726.

217 Internet archive, "Guidance on the approval procedure for COVID-19 medicinal products in the HMV4 pandemic", V. 4.0, 15.05.2021, https://web.archive.org/web/20210607143824/https://www.swissmedic.ch/dam/swissmedic/de/dokumente/zulassung/zl_hmv_iv/zl000_00_044d_wl_zulassungsverfahren_covid-19.pdf.download.pdf/ZL000_00_044d_WL_Zulassungsverfahren_f%C3%BCr_Covid_19_Arzneimittel_im_Pandemiefall.pdf.

218 Swissmedic, "ACCESS Consortium - Points to consider for strain changes in authorized COVID-19 vaccines in an ongoing SARS-Cov2 pandemic", 04.03.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/stab/networking/access-consortium-points-strain-changes-covid-19-vaccines-sars-cov2.pdf.download.pdf/OFF-SEN%20-%20Final%20ACCESS%20Guidance_Covid-19%20vaccine%20strain%20changes.pdf.

219 Swissmedic, 15.05.2021 (FN 217).

> "The **evidence** gathered in the **large clinical trials for first licensure** and through mass vaccination campaigns provides a **solid basis** for this approach [...]"

1046 On the basis of this deliberate false assertion, Swissmedic then decided without further ado to no longer classify the variant-adapted "vaccines" as novel products (para. 8.1), but as a substance that was supposedly sufficiently well known in the meantime:[220]

> "For public health and scientific reasons, the regulatory authorities **do not consider** an **updated coronavirus vaccine to be a completely novel product with the resulting requirement for lengthy, comprehensive clinical trials."**

1047 Swissmedic quickly reclassified such "updates" - i.e. actually completely new products - as "Type II variations" (para. 8.2):[221]

> "Variations related to the **replacement** or addition of a serotype, **strain**, antigen or coding region or combination of serotypes, strains, antigens or coding regions of a human coronavirus vaccine are **classified** as a **type II variation.**"

1048 Swissmedic and the Access Consortium themselves disclose in the aforementioned declaration of March 4, 2021 (Annex 1, p. 11, no. 3) that this approach is beyond all therapeutic product regulations:[222]

> "Under **a more restrictive interpretation, regulators would consider an adaptation of an authorized vaccine to a new strain as a new product and require new clinical trials to demonstrate safety, immunogenicity and efficacy.** This would result in a significant delay before such a new version of the vaccine would be ready for distribution, as the time-limiting step is the collection of efficacy data, which requires spontaneous infections and a comparator group."

1049 Swissmedic itself thus concedes that under normal circumstances such fundamental manipulations to a "vaccine" would necessarily make it a new product that would have to undergo a complete authorization procedure - with time-consuming and comprehensive clinical trials.

220 Swissmedic, 15.05.2021 (FN 217).
221 Swissmedic, 15.05.2021 (FN 217).
222 Swissmedic, 15.05.2021 (FN 217).

1050 Swissmedic stated in the "Pandemic" guidance (V.4.0; 15.05.2021) under point 8.3[223] on the question of what type of proof of efficacy still needs to be provided:

> "From a clinical perspective, **clinical efficacy studies** are **not required prior to approval.** Regulatory authorities require **bridging immunogenicity data** from a sufficient number of subjects; an immunogenicity and reactogenicity study may include both vaccine-naïve subjects and subjects already vaccinated with the current version of the vaccine."

1051 "Bridging data" is thus understood to mean immunogenicity data (antibody measurements) based on the original vaccines - thus enabling approval without any clinical proof of efficacy, which must normally be based on a hard clinical endpoint. For such "immunogenicity and reactogenicity studies", a "non-inferiority study" should be sufficient, which is stated in Annex 1 No. 25 (Statement of the "Access Consortium" of March 4, 2021):[224]

> "If the design of a non-inferiority trial is chosen, in which the titers of neutralizing antibodies against the variant formed after administration of the adapted vaccine are compared with the titers of antibodies against the original strain formed after administration of the previous vaccine [...]"

1052 This is problematic in two ways: Firstly, in such a **"non-inferiority study"** it only has to be shown that the new medicinal product is "not significantly worse" than the previous medicinal product.[225] Secondly, as explained in detail in the Evidence Report (N 1466 ff.) (see also N 727) - such antibody proofs are merely so-called "surrogate markers": However, if - as in the case of mRNA "vaccines" - they have not been validated on the basis of previous studies, **such "surrogate markers" cannot be used to provide any reliable proof of efficacy.** It has been known for 30 years that reliance on surrogate endpoints can be unjustified despite a strong correlation with the clinical endpoint - with potentially fatal consequences .

1053 In spring 2021, Swissmedic thus created the basis for **authorizing all conceivable manipulations of these "vaccines" based on the already massively accelerated "temporary" first authorizations of the mRNA "vaccines" in order to then be able to inject these modified mRNA "vaccines" directly into humans, omitting central safety mechanisms and without even rudimentary proof of efficacy (replacement of high-quality "Phase III" studies with largely useless "non-inferiority studies").**

223 Swissmedic, 15.05.2021 (FN 217).
224 Swissmedic, 15.05.2021 (FN 217).
225 DATAtab, "Equivalence and non-inferiority", 2023.

3.1.3.2 Implementation from 2022: Swissmedic dispenses with strict proof of efficacy

1054 Swissmedic could have refrained from this planned project: In 2022, when the Omikron variant, which was obviously safe for the general population, was already circulating (front N 779 ff.) and even the Federal Council had lifted the "special situation" as of April 1, 2022 - and thus declared the alleged "pandemic" to be over -[226] **there was no longer any reason for "pandemic approvals" from then at the very latest.**

1055 Nevertheless, Swissmedic announced on 1 May 2022 that it would continue to "prioritize" and "expedite appropriately to the pandemic situation" applications for the authorisation of medicinal products "for the prevention and treatment of a pandemic disease (e.g. COVID-19)" so that effective and safe medicinal products would be available to patients as quickly as possible.[227] **Swissmedic therefore remained in "pandemic mode" for no understandable reason.**

1056 The demands of the "vaccine" manufacturers were not long in coming: On June 18, 2022, **Uğur Şahin** - CEO of BioNTech - blatantly **demanded that the global regulatory authorities completely dispense with clinical trials for "vaccine adaptations".**[228] He was thus demanding nothing less than the undermining of the very last elementary safety mechanisms of therapeutic products legislation, even in the endemic normal state - and Swissmedic was quite obviously prepared to comply with this devastating - criminal - demand: Thus, on June 24, 2022, Swissmedic announced that Moderna had submitted an application for an authorization extension for a corona vaccine against Omikron.[229] Swissmedic seriously stated the same:

> "Swissmedic examines the application for an extension of authorization on a rolling basis. Applicants **do not** have to submit a **complete dossier to** Swissmedic with the initial submission of the application. Instead, they submit the **first available data packages** and submit a plan with deadlines for the subsequent submission of further data packages. Data submitted so

226 Federal Council, "MM Return to the normal situation", 30.03.2022.

227 Swissmedic, "Adaptation of the guidance document Authorization procedure for COVID-19 medicinal products in the pandemic HMV4", 01.05.2022, *https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/authorisations/informationen/anpassung-wl-covid-19-im-pandemiefall.html* .

228 FINANCIAL TIMES, "BioNTech chief calls for speedy ruling on Covid vaccines that target latest strains", 18.06.2022, https://www.ft.com/content/1c1bcc16-afe6-4a13-8278-b2ee925f7f75; WIESBADENER KURIER, "Coronavirus: BioNTech-Chef switches to alarm mode", 21.06.2022, https://www.wiesbadener-kurier.de/lokales/rhein-main/coronavirus-biontech-chef-schaltet-in-den-alarmmodus-1789803.

229 Swissmedic, "Moderna submits application for extension of authorization for a corona vaccine against Omikron", 24.06.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/moderna-zulassungserweiterung-impfstoff-corona-omikron.html.

far, which are now being reviewed, include investigations from **laboratory studies (preclinical)** and **initial data on manufacturing and quality (CMC).**"

1057 Swissmedic thus complied with the manufacturers' purely economically motivated demands for the complete **abandonment of clinical trials** without any resistance - virtually at the first call. Moreover, it can even be inferred from the press release that **not even complete documentation on quality and preclinical studies was available**.

1058 Nevertheless, Swissmedic granted "temporary" approvals (extensions) for "Spikevax Bivalent Original/Omicron" and "Comirnaty Original/Omicron BA.1" on August 29, 2022 and October 10, 2022. And this without any useful proof of efficacy (non-validated surrogate markers) and despite the fact that these bivalent "vaccines" were already outdated at the time of approval (N 723 ff.).

1059 The first Omikron approvals therefore lacked the most fundamental data. According to the laws of logic, it is virtually impossible that Swissmedic could have carried out an examination of quality, safety, let alone efficacy, in accordance with therapeutic product legislation, given this absolutely inadequate data situation.

3.1.4. Conclusion: Swissmedic is gradually sliding into illegality

1060 From 2019 onwards, Swissmedic did everything in its power to gradually undermine and ultimately completely ignore the central legal norms of therapeutic products legislation and ordinances, which were created to protect the public from poor-quality, ineffective and unsafe medicinal products:

- In 2019, Swissmedic created the basis for issuing "temporary authorizations" for "vaccinations" - contrary to all scientific logic and legal interpretation methodology - by means of a simple declaration on its own website (see N 995 ff.);
- In 2020, Swissmedic issued a "Pandemic case" guideline - allegedly based on the Federal Council's Art. 21 COVID-19 Ordinance 3, which in turn is allegedly based on Art. 3 para. 2 lit. c COVID-19 Act - in order to further undermine the already very lax regulations on "temporary authorization" (see N 1013 ff., in particular N 1021 et seq.);
- At the end of 2020, Swissmedic then issued the first "pandemic authorizations" (disguised as "temporary" or even supposedly "regular"[230] authorizations) - with a massive reduction in processing time (see N 1024 ff.), omitting elementary questions (see N 1028 ff.) and omitting elementary studies on quality and safety (see N 1031 ff.), although none

230 For this deceptive act, see N 1191.

of the legal requirements for the granting of a "temporary authorization" were met (see in detail below N 1068 ff.);

- In 2021, Swissmedic amended the "Pandemic" guidance document and removed (further) key safety mechanisms such as the - mandatory - requirement for comprehensive clinical trials (see N 1040 ff.);
- Although there was clearly no question of a "pandemic" in 2022, Swissmedic also implemented this illegal waiver of central safety mechanisms and granted "temporary" authorizations (authorization extensions) for the bivalent "Omikron booster BA.1" without any useful proof of efficacy (without phase I/II/III clinical trials) - even though these bivalent "vaccines" were already outdated at the time of authorization (see N 1054 ff.);

1061 Swissmedic's approach represents a deliberate and continued acceptance of unmanageable risks. The modifications made to the therapeutic products authorization system since 2019 and the persistence in "pandemic mode" against all evidence form the illegal basis for the **continued "authorization" of untested medicinal products and thus for the continued violation of the most fundamental legal duties of protection and care with regard to public health, which serve only one interest: the economic interest of manufacturers.**

3.2. Comparison of the procedures and interim conclusion

1062 As described in detail (see N 992 ff.), Swissmedic has therefore completely ignored all the central requirements of both the "temporary" and the "ordinary" authorization procedure in the present mRNA "pandemic authorizations" . This deviation from the statutory requirements is illustrated once again in the following titles as a summary:

3.2.1. Comparison of development times

1063 In terms of time, a comparison of the development time of a medicinal product within the scope of regular approval with the "pandemic" approvals of the mRNA "vaccines" at the end of 2020 gives the following picture:

BO: Supplement **17:** CCCA, Pfizer did not follow established protocols, 02.12.2022 (original source in English: CCCA, "The Pfizer Inoculations for COVID-19, More Harm than Good", 16.12.2021, p. 14, *https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf)*

1064 This alone shows the **high risk** Swissmedic has taken with the **massively accelerated "pandemic approvals"** disguised as "temporary approvals".

3.2.2. Comparison: Requirements for studies and approval procedures

1065 A direct comparison of the mRNA "pandemic approvals" with the legally prescribed approval forms of temporary, simplified and regular approval also shows what **compromises** were made **in terms of quality, safety and efficacy** in view of this acceleration. It is evident that the "pandemic approval" of mRNA "vaccines" fails completely in practically all areas examined:

Necessary studies for **authorization application**	Ord.	**Temporary**		Simplified		
		mRNA	9a	Bek.	EU	Orph.
Module 3 *(Quality)*						
Stability	YES	NO	YES	YES	YES	YES
Purity	YES	NO	YES	YES	YES	YES
Module 4 *(Preclinical)*						
Pharmacology	YES	NO	YES	NO*	NO*	NO*
Toxicology	YES	NO	YES	NO*	NO*	NO*
Module 5: (Clinic)						
Phase I (usually 2-4 months)	YES	YES	YES	NO*	NO*	NO*
Phase II (usually 1 year)	YES	NO	YES	NO*	NO*	NO*
Phase III (at least 1 year)	YES	NO	NO	NO*	NO*	NO*
Admission modalities						
Procedure						

Duration in calendar days	330	63	140	--	--	210
Answer "LoQ"	YES	NO	YES	--	--	--
Medicines **excluded** for:						
Vaccines	NO	NO	(NO)	YES	NO	(YES)
Gene therapy and GMOs	NO	NO	(YES)	YES	NO	NO
Population-wide application	NO	NO	YES*	NO	NO	YES
Mandatory "conditions"						
"Risk management plan" & PSUR	YES	YES	YES	NO	NO	NO
NO*: Under replacement of studies by literature, alternative studies, previous approvals						
YES*: only for life-threatening or disabling diseases in the target population						

1066 The various "pandemic authorizations" repeatedly granted for the mRNA "vaccines" therefore deviate from the ordinary authorization in all key safety aspects. Indeed, they do not even meet the reduced requirements of a simplified authorization and even fall short of the minimum requirements for "temporary authorization" under Art. 9a TPA. As explained in detail above,

- deviated massively from the usual release specifications in the area of stability (225 ff.) and there are considerable indications of irregularities in production (see N 417 ff.),
- the purity was obviously not given in view of the impurities (front N 231 ff.),
- no sufficient preclinical studies are available (prior N 250 ff.),
- the clinical trials were only conducted fully blinded for just over two months and then sabotaged by "unblinding" (breaking up the control groups) (front N 270 ff., N 275 ff.),
- the procedure for "temporary" approval was carried out in a rush and undercut its own requirements (N 992 ff.),
- risky substances (vaccines, gene therapy, possibly even *GMOs*) were approved for use on a healthy population in an already risky procedure (see N 186 ff., N 200 ff.),
- notifications from manufacturers (e.g. via *PSUR*) were ignored by Swissmedic and withheld from the public (see N 405 ff, 595 ff.; cf. also below on the misleading product information N 1198 ff.), and
- has never been shown to be sufficiently effective (front N 296 ff., N 376 ff., N 498 ff., N 688 et seq.).

1067 The manufacturers were unable to provide any studies in their applications for approval that would meet the requirements for the elementary modules 3 and 4 (and 5). With this **blatant omission of the most elementary information on safety and efficacy, the greatest possible risk was** taken. To make matters worse, the planned duration of the procedure was again massively undercut and important intermediate steps were simply omitted, contrary to the company's own specifications. The risk is further increased by the fact that the mRNA "vaccines" are being used for mere prophylaxis in a basically healthy population and that there is also the suspicion that they represent genetically modified organisms.

3.3. Examination of the legal requirements for "temporary admission"

1068 Now - as before (N 963 ff., in particular N 977), "temporary admission" is not primarily defined on the basis of the requirements of ordinary/simplified admission, but follows its own rules to a certain extent by working with **forecasts.**

1069 For this reason, the mRNA authorizations are examined below on the basis of the formal requirements of the legislator and regulators. All of the following criteria must be met **cumulatively** for a legally compliant "temporary authorization". However, not a single one of these criteria was or is ever actually met:

3.3.1. Life-threatening or disabling illness?

3.3.1.1 Clear legal requirements in the HMG

1070 According to Art. 9a para. 1 **subpara. 1** TPA in conjunction with Art. Art. 18 lit. a VAZV, the medicinal product must be used for life-threatening or disabling diseases. As previously (N 971 ff.), **this risk** must be **seriously expected to materialize in the entire target population**. According to the traditional view, it must therefore be a matter of **pre-existing diseases that pose an** immediate life-threatening or disabling risk to the entire population - approval for mere prophylaxis is therefore ruled out from the outset.

1071 SARS-CoV-2 has never posed a greater risk to the general population - which is the target population for COVID "vaccinations" - than seasonal moderate influenza (front N 750 ff.). Based on data from the Federal Statistical Office, it was already clear at the end of 2020 that there was no historically relevant excess mortality in 2020 compared to the 10 previous years (see N 756 f.). Even with the delta variant, SARS-CoV-2 corresponded to mild influenza (see N 770), with the "Omikron" variant the **lethality of SARS-CoV-2** was **even 50 times lower than that of seasonal influenza** (front N 779 f.). There was no danger for children and adolescents at any time: with a lethality rate of 0.0027%, their "COVID-19 risk" tended towards zero from the outset (front N 772). **From the outset, COVID-19 was therefore never a disease that would lead to severe disability, severe suffering with possible fatal consequences or short-term death in a relevant part of the target population.** The first criterion for the temporary approval of the COVID "vaccines" was therefore never met. **The trial could therefore already be terminated at this point: The "temporary" approval for the general population was simply unlawful due to the lack of a fatal or disabling disease.**

1072 However, even if COVID-19 were similarly lethal or slightly more lethal than severe influenza, a lethality of 0.15-0.2%, for example, would never - really never - be sufficient to

assume a life-threatening (or disabling) disease for the population as a whole. Assuming such a danger with such a low lethality rate would mean that a "temporary authorization" could always be applied for all conceivable infectious diseases. **The purpose of the ordinary authorization requirement would be permanently undermined.** However, this is precisely what the Federal Supreme Court has ruled must not happen under any circumstances (see N 991). Added to this is the fact that, according to the traditional view, a temporary authorization was **never** intended **for prophylaxis,** but only in the case of diseases from which the individual patient was already suffering and therefore threatened with death (or severe disability). This basic prerequisite of compassionate use was abandoned by Swissmedic in 2019 without any comprehensible reasons - although this cannot be deduced either from the legislative process or from European regulation (see N 971 ff., N 995 ff.). **The "temporary" approval of the mRNA "vaccines" under the impression of a non-threatening disease that has been tested proves to be a Trojan horse for undermining and undermining the most central safety mechanisms under therapeutic products law** (see above N 1060 et seq.). Incidentally, this undermining is already evident from the fact that the **number of "temporarily" authorized medicinal products** has **risen exponentially from 4 to currently over 40 (!) since the "pandemic" was declared** (see above N 1006 ff.). This development is absolutely devastating for patient safety and must be stopped immediately.

3.3.1.2 WHO "pandemic" automatically leads to application of Art. 9a TPA?

1073 As far as can be seen, Swissmedic has not yet explained why it considers the requirement of a "life-threatening or disabling disease" to be met. Even in its "Pandemic Guidance", it only states that this applies to the "exceptional situation of a pandemic" (see N 1021).

1074 On June 23, 2021, Swissmedic responded as follows to a private individual who had submitted a corresponding request on June 10, 2021:

> "In addition, we would like to point out that the declaration of a 'public health emergency of international concern' (the highest alert level according to the International Health Regulations) by the WHO also justifies the application of Art. 9a para. 1 TPA."

BO: Enclosure **18**: Mail correspondence Swissmedic Art. 9a WHO pandemic, 24.11.2022

1075 Swissmedic had therefore claimed that the declaration of a "WHO pandemic" automatically led to the application of Art. 9a TPA. On November 17, 2022, the same private individual followed up again and requested to receive "the legal treatise stating the reasons why the

declaration of a public health emergency of international concern justifies the application of Art. 9a para. 1 TPA". On November 24, 2022, Swissmedic communicated (Annex **18**):

> "Our internal investigations have shown that Swissmedic has no official document on this [...]."

1076 Swissmedic is clearly not in a position to justify the existence of a "life-threatening or disabling disease". The claim made in 2021 of an alleged automatism between the "WHO pandemic" and the application of Art. 9a TPA does not stand up to scrutiny in any way:

3.3.1.3 No automatism: WHO does not give orders to Swissmedic

1077 An interpretation of Art. 9a TPA according to the methods of the Federal Supreme Court[231] leads to the clear conclusion that the automatism claimed by Swissmedic simply does not exist:

1078 There is not the slightest indication of any automatism between the declaration of a "pandemic" by the *WHO* and the applicability of Art. 9a TPA, if only because of the **wording of** Art. 9a TPA: no such link is evident at all. The **historical** interpretation (for the history of the origins of Art. 9a TPA, see N 966 ff.) does not provide any indication of such automatism. An **objective, contemporary** interpretation does not lead to any other conclusion either: There is no evidence that Swissmedic could blindly follow a declared "WHO pandemic" to activate Art. 9a TPA.

1079 Only a **systematic** interpretation could justify such an approach: However, this would require leaving therapeutic products law behind and referring to the Epidemics Act (EpG; SR 818.101). In **Art. 6 para. 1 lit. b EpG,** this states that a "special situation" exists if "the World Health Organization (WHO) has determined that a health emergency of international concern exists and that this threatens public health in Switzerland". However, even this article **does not** establish **an automatic link between a WHO pandemic and the declaration of a "special situation"** by the Federal Council. This can already be seen from the fact that the Federal Council lifted the "special situation" on April 1, 2022,[232] whereas the *WHO* itself continued to adhere to its invented "pandemic" in 2023, ironclad and far removed from any reality.[233] The same can be seen from a detailed legal analysis of the "special situation": there is no such automatic mechanism under either national law (Art. 6 EpG) or international law.[234]

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231 So-called "methodological pluralism": BGE 142 III 557 E. 8.3 p. 560 f., BGE 139 II 173 E. 2.1 p. 175.
232 Federal Council, "MM Return to the normal situation", 30.03.2022.
233 WHO, "Statement on the fourteenth meeting", 30.01.2023.
234 Committee of Jurists, "Special situation, analysis and consequences", 10.03.2022, N 18 ff.

1080 However, if there is not even an automatic link between Art. 6 para. 1 lit. b EpG and a "WHO pandemic", such a link can certainly not be invoked in conjunction with Art. 9a TPA. The declaration of a "public health emergency with international implications" by the *WHO* therefore does not justify the application of Art. 9a para. 1 TPA. Swissmedic's corresponding assertion in the email of June 23, 2021 is therefore without foundation.

3.3.1.4 No automatism: Federal Council does not give orders to Swissmedic

1081 The last remaining lifeline for Swissmedic would be the possible assertion that the declaration of a "special situation" in accordance with Art. 6 para. 1 lit. a TPA by the Federal Council would result in the automatic application of Art. 9a TPA.

1082 But here too: Such a link is simply not apparent. At the latest since the Federal Council ended the "special situation" on April 1, 2022, this possible argument has also ceased to apply. Apart from that, a special risk situation pursuant to Art. 6 para. 1 lit. a no. 1-3 EpG was no longer seriously recognizable *by* the end of January 2021 *at the latest* and had not been sufficiently proven by the *FOPH* in any way.[235]

3.3.1.5 Conclusion

1083 The basic requirement of a life-threatening or disabling illness is therefore already lacking for the application of Art. 9a TPA.

1084 It is also not possible to deviate from this requirement by blindly linking it to a declared "WHO pandemic": The *WHO* does not give orders to Swissmedic. The same applies to a "special situation" declared by the Federal Council. Swissmedic must itself clarify the factual and legal requirements for the applicability of Art. 9a TPA and take the appropriate precautions under its own responsibility in accordance with Swiss legislation. Swissmedic has clearly not fulfilled this obligation.

3.3.2. Compatibility with the protection of health?

1085 According to Art. 9a para. 1 **lit. a** TPA, the use of the medicinal product must be compatible with the protection of health. This requirement must be met even if the Federal Council Ordinance is applied, as it is a central requirement of any benefit-risk analysis (see N 1018 ff.). This means that the medicinal product must meet **the most basic safety standards** - which is normally checked in detail on the basis of animal and human trials (see above N 872 ff.). As previously (N 250 ff.), such tests were dispensed with to an alarming extent prior

235 See in detail Juristen-Komitee, "Besondere Lage, Analyse und Konsequenzen", 10.03.2022, N 6 ff. See also above N 744 ff.

to the "temporary" authorizations. In addition, there are a large number of other **risks** that made the **incompatibility of mRNA "vaccines" with human health apparent** from the outset:

3.3.2.1 Identifiable risks at the time of initial registration en end of 2020

1086 At the time of the first registrations **at the end of 2020**, a large number of risks were already openly recognizable. These had already been identified before (N 186 ff.) and are described in detail below (N 1291 ff.) in the context of the alleged breaches of duty of care. In order to avoid repetition, reference is made to the relevant statements and only key points are referred to below:

1087 At the end of 2020, gene therapy was already a new mode of action that had never before been tested on a healthy population (front N 186 ff.). In addition, the mRNA "vaccines" contained toxic lipid nanoparticles (see N 212 ff.) and toxic, potentially mutagenic and carcinogenic impurities were already detected at that time (see N 231 ff.). The mere existence of these alarm signals (there were many more) should have led to the authorization documents being evaluated particularly carefully with regard to these identifiable risks and linked to conditions. But this is exactly what did not happen: Rather

- the first registrations were rushed through (front N 1024 ff.),
- important milestones were omitted (front N 1028 f.),
- the release specifications have been massively reduced (front N 224 ff.),
- Animal studies omitted or their alarming results ignored (front N 250 ff.),
- *de facto* discontinued clinical trials simply accepted (N 269 ff.)
- severely inadequate pharmacovigilance systems tolerated (front N 284 ff.) and
- does not communicate the internally identified risks to the public or does so in an absolutely trivializing manner (see in particular N 1190 et seq.).

3.3.2.2 Additional identifiable risks in mid-2021

1088 Unfortunately, things continued in the same vein after the first "temporary" approvals. By mid-2021, various risks had already materialized and new ones had even been added: these had already been identified before (N 319 ff.) and are described in detail below (N 1298 ff.) in the context of the alleged breaches of duty of care. In order to avoid repetition, reference is made to the relevant statements.

1089 At this point, it should only be emphasized that by June 2021, a total of 517,768 side effects had already been reported in Switzerland, the EU and the USA for Comirnaty and Spikevax alone - including 136,543 serious side effects and 7,242 deaths. This meant that even at

that time, the standard global **alert value** of 50 deaths had already been exceeded by **a factor of 150** worldwide **- which should have led to an immediate ban on approval** (see N 341 f.). The COVID "vaccines" showed - after only a few months of use - an absolutely devastating result compared to other vaccines: **For every million doses vaccinated, the reported serious side effects were at least 30 times higher and the reported death rates were at least 20 times higher than for the flu vaccines** (front N 366 ff.).

3.3.2.3 Additional identifiable risks at the end of 2021

1090 Although the reported side effects had already exceeded all known levels by June 2021 and thousands of people had already died or suffered severe side effects as a result of the mRNA "vaccines", there was no "exercise termination". Instead, the process continued in the same style. By the end of 2021, various risks had once again manifested themselves in an obvious manner and the **alarm signals for those responsible at Swissmedic were unmistakable** - for example with **reports of falsified studies and massive underreporting of side effects**. These had already been reported before (N 388 ff.) and are described in detail below (N 1305 ff.) in the context of the alleged breaches of the duty of care. In order to avoid repetition, reference is made to the relevant statements.

1091 By the end of 2021, the correlation between mRNA "vaccinations" and serious side effects, including death, was so obvious that **causality** could be assumed: **mRNA "vaccines" are almost certain to lead to serious side effects, including death.** And not in isolated cases, but in such an **overwhelming number of cases that had never been seen since systematic records of side effects began.** At the same time, **a conspicuous and persistent incidence of death in close temporal relation to "vaccination activity"** was also observed in **younger age groups in Switzerland** (front N 494 with reference to N 765 and N 774).

3.3.2.4 Additional identifiable risks from 2022

1092 Against this background, it is incomprehensible how the vaccination campaign could have been continued at all. Even when "Omikron" was used to "combat" a pathogen that was 50 times less deadly than normal flu (front N 779 ff.), the demonstrably toxic, disabling and deadly mRNA preparations were not withdrawn from the market. On the contrary, the enormous mountain of risks continued to pile up. These had already been identified before (N 537 ff.) and are described in detail below (N 1311 ff.) in the context of the alleged breaches of duty of care. In order to avoid repetition, reference is made to the relevant statements.

3.3.2.5 Conclusion

1093 In view of the novel medicinal products, the potential health risks were already very high at the time of authorization. A temporary authorization should therefore never have been granted from the outset for this reason.

1094 However, at the latest when the risks manifested themselves openly in June 2021 and then in an overwhelming manner at the end of 2021 in the form of the most severe side effects, including death, to an alarming and unprecedented extent, while at the same time the dangerousness of the COVID-19 pathogen was steadily decreasing, any initial, extended and maintained approval was in no way compatible with the protection of public health.

3.3.3. Great therapeutic benefit?

1095 According to Art. 9a para. 1 **lit. b** TPA in conjunction with Art. Art. 18 lit. c TPLO, a major therapeutic benefit must be expected from the use of the temporarily authorized medicinal product. This requirement must be met even if the Federal Council Ordinance is applied, as it is a central requirement of any benefit-risk analysis (see above N 1018 ff.). A clear definition of this term has not yet been provided either in the text of the ordinance, in Swissmedic's explanatory notes or in the case law.

1096 The concept of major therapeutic benefit is linked to that of **efficacy** within the meaning of Art. 10 para. 1 lit. a TPA. A medicinal product is effective if it produces the intended therapeutic, diagnostic or preventive effect in relation to the indication. Proof of efficacy must be provided using scientific methods. The applicant must therefore demonstrate in a clinically and scientifically convincing manner that the medicinal product has the desired effect in the target population. The assessment of clinical relevance is based on the respective clinical picture and the associated clinical and scientific practice.[236]

3.3.3.1 Basic requirement: vaccines must immunize

1097 According to Art. 2 lit. b AMBV, vaccines are "medicinal products used to induce active or passive immunity". Accordingly, the *WHO* definition states that vaccinations use the body's natural defenses "to build up resistance to certain infections and strengthen the immune system".[237] Even this central basic function - immunity against an infection - is obviously not

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236 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 28.

237 WHO, "Vaccines and immunization: What is vaccination?", 30.08.2021, *https://www.who.int/news-room/questions-and-answers/item/vaccines-and-immunization-what-is-vaccination* : "Vaccination is a simple, safe, and effective way of protecting people against harmful diseases, before they come into contact with them. It uses your body's natural defenses to build resistance to specific infections and makes your immune system stronger."

fulfilled by the COVID "vaccines": they neither immunize nor protect against disease, nor do they protect against a severe course or even death (see N 498 ff., N 693 ff.).

1098 Even if an increase in antibodies ("*surrogate markers*") has been shown in studies and this can be formally interpreted as "immunization", neither in approval studies nor in other prospective studies based on hard, meaningful clinical endpoints (e.g. reduction of COVID diseases or COVID hospitalizations; see N 709 ff.) that an increase in antibodies correlates with a resulting protection of vaccinated persons and that COVID "vaccinations" are associated with a benefit in this regard.

3.3.3.2 Unclear therapeutic benefit from the outset

1099 However, the lack of therapeutic benefit did not only manifest itself in the course of the use of COVID "vaccinations", but was already sufficiently apparent at the time of the first temporary approval, as has been shown in detail: The study endpoint (= primary efficacy endpoint) selected in the Pfizer and Moderna approval studies was **not clinically relevant** from the outset, as it primarily **recorded** mild "confirmed COVID diseases" and thus **trivial events** that do not burden either the individual or the healthcare system. In addition, the events assigned to the study endpoints did not occur with sufficient frequency: "confirmed COVID illnesses" occurred in only around 1%, "severe COVID illnesses" in just ≤0.2% of study participants (front N 296 ff.).

1100 The mRNA "vaccines" were therefore not suitable for protection against fatal or disabling diseases from the outset. And even against these trivial events, the mRNA "vaccines" provided minimal protection at best - when it came to protection against "severe COVID diseases", they failed completely (see N 305 ff.).

1101 Even in subsequent studies, it was never possible to prove a benefit that even remotely deserved the rating "great". In particular, the approval studies of the "COVID vaccines" had already shown no relevant efficacy for a booster vaccination ("booster"), a 3rd dose in immunocompromised patients or in children aged 5 and over at the time of approval (front N 508 ff., N 516 ff.). In 2022, there was increasing evidence worldwide that vaccinated people fall ill and die from COVID more frequently than unvaccinated people - which means that the efficacy would even be negative worldwide (see N 709 ff.).

1102 In fact, in Switzerland, by 2022 at the latest, **a conspicuous and persistent death rate was observed in <u>all</u> age groups in close temporal relation to the general Swiss-wide "vaccination activity"** (front N 663 and N 782). Switzerland also recorded a **historically unprecedented drop in births** in 2022, for which only the mRNA injections can provide plausible reasons (front N 644 f.). The mRNA injections are thus obviously associated with

a **negative** therapeutic benefit (see the evidence report on the negative risk/benefit ratio in detail, in particular N 1835 ff.

3.3.3.3 Conclusion

1103 The COVID "vaccines" were not expected to have a *major* clinical benefit at any time, which means that this condition for temporary approval is also not met. Rather, it became apparent from 2022 at the latest that the mRNA injections were associated with **negative efficacy.**

3.3.4. Lack of an alternative treatment?

1104 According to Art. 9a para. 1 **lit. c** TPA in conjunction with Art. Art. 18 lit. b TPLRO, no authorized, alternative and equivalent medicinal product may be available in Switzerland.

3.3.4.1 Cost-benefit ratio

1105 Where another treatment approach already exists, the lack of a treatment alternative is generally to be affirmed where the new therapy in question has a significantly better cost-benefit ratio.[238] With regard to the individual reimbursement of medicinal products (Art. 71 a ff KVV [SR 832.102]), the Federal Supreme Court stated that a high therapeutic benefit presupposes a favorable therapeutic benefit-cost ratio, in the sense that "the higher the costs, the greater the therapeutic benefit must be expected".[239] It continued:[240]

> "Only by comparing different cost-benefit ratios can it be decided whether a particular cost-benefit ratio is favorable or unfavorable. If there are no significant differences between two alternative treatment methods from a medical point of view, the more cost-effective and therefore more economical application should always be chosen. However, if a certain treatment method has advantages over other applications in diagnostic or therapeutic terms (e.g. lower risks, fewer complications, more favorable prognosis with regard to side effects and long-term consequences), this may justify covering the costs of this more expensive application or this must be taken into account when comparing the prices of the medicinal products."

1106 However, unlike in health insurance law, an alternative therapy cannot be disregarded because it is more complicated or more expensive and therefore does not have a favorable cost-benefit risk. There is no room for cost-related considerations in the context of approval

238 See SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 25.
239 BGE 143 V 130 E. 11.2 S. 136.
240 BGE 142 V 26 E. 5.2.1 P. 35.

procedures under therapeutic products law.[241] "Costs" are therefore not to be understood in "monetary terms" in the present case, but in a comprehensive sense, also taking into account side effects and other risks when using the medicinal product. **The expected benefits of a vaccine would therefore have to outweigh the benefits of other treatment methods.**

1107 Accordingly, Swissmedic also states in its guidance document "Temporary authorization for human medicinal products HMV4"[242] that, based on the clinical documentation submitted, it must be possible to estimate "without evaluating the detailed data that the therapeutic benefit is clinically relevant and exceeds the benefit of the previously authorized therapy/standard therapy (basis for comparison)." The basis for comparison included "all therapies with approved medicinal products available in Switzerland at the time of submission of the application".

3.3.4.2 Costs/benefits of COVID "vaccines"

1108 If - as in the present case - the use of COVID "vaccines" is associated with side effects of an unprecedented magnitude and therefore with a **very high risk** (see N 1085 ff.), the COVID "vaccines" would therefore have to have a huge advantage over other methods in order to make up for these immense "costs".

1109 This is clearly not the case: not only do the COVID "vaccines" not even begin to contribute to sustainable immunization, they also do not protect against infection, transmission and disease. They are largely **ineffective** in "combating" SARS-CoV-2 and therefore useless - indeed, they are even associated with a clearly **negative benefit** (see N 1095 ff. with further references). In contrast, there are several alternative drugs and treatment protocols that are highly effective, one of which is discussed below as an example:

3.3.4.3 Ivermectin as an inexpensive, safe and effective alternative

1110 Early drug treatment protocols for SARS-CoV-2, such as that of the *FLCCC,* which includes ivermectin, have been in place since around mid-2020, but at the latest since the start of the vaccination campaign. [243]The strong antiviral activity of ivermectin against SARS-CoV-

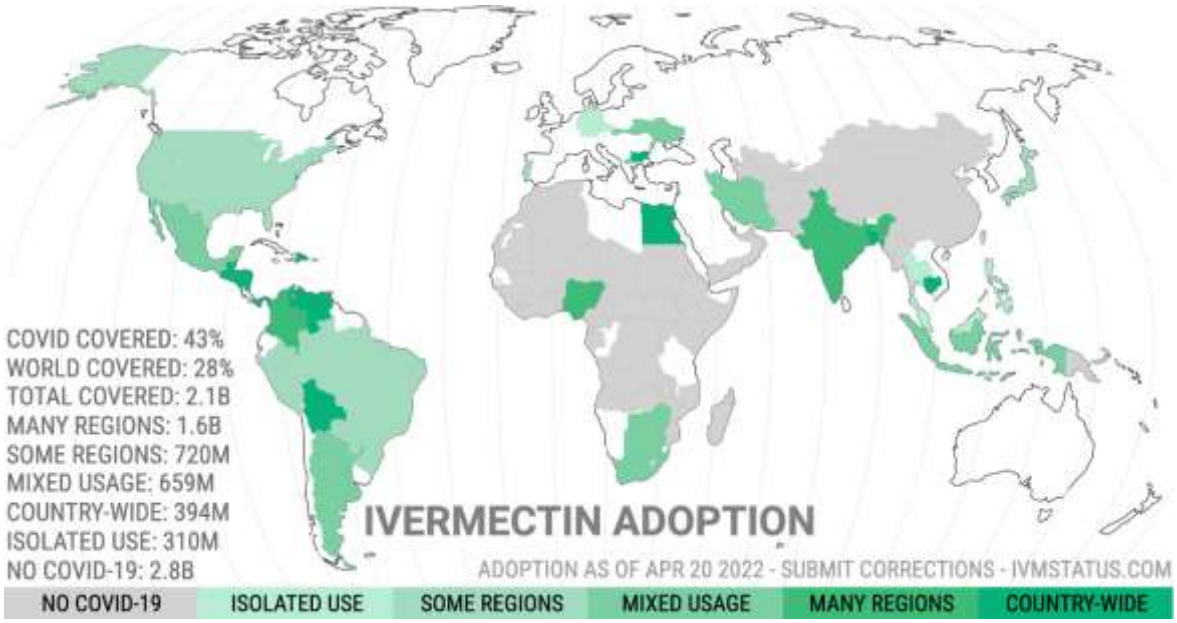
241 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 26.

242 Swissmedic, "Guidance document Temporary authorization of human medicinal products HMV4", (FN 201), S. 5.

243 See for example: Front Line COVID-19 Critical Care Alliance, "Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19", 16.01.2021, https://covid19criticalcare.com/wp-content/uploads/2020/11/FLCCC-Ivermectin-in-the-prophylaxis-and-treatment-of-COVID-19.pdf; Front Line COVID-19 Critical Care Alliance, "Prevention and Treatment Protocols for COVID-19", 10.06.2022, https://covid19criticalcare.com/covid-19-protocols/; WHO, "WHO advises that ivermectin only be used to treat

2 *in vitro* was already demonstrated in June 2020.[244] Since then, **the efficacy of ivermectin against COVID-19 has been demonstrated in 67 studies,** 31 of which were prospective randomized trials (RCT = gold standard of studies). A meta-analysis, which includes data from 3406 patients from 24 RCTs, concludes that ivermectin reduces the risk of death and reduces severe courses if used early.[245]

1111 **Ivermectin** is currently being **used successfully in more than 20 countries for the treatment of COVID-19:** In Europe, for example, it is approved for isolated use ("some regions") in Portugal, Germany, the Czech Republic, Slovakia, Ukraine and Macedonia. **In Bulgaria - an EU member state - ivermectin has been used country-wide for the treatment of SARS-CoV-2 since January 15, 2021.**[246]



COVID-19 within clinical trials", 31.03.2021, https://www.who.int/news-room/feature-stories/detail/who-advises-that-ivermectin-only-be-used-to-treat-covid-19-within-clinical-trials.

244 CALY et al, "The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro", 03.04.2020, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7129059/.

245 BRYANT/LAWRIE et al, "Ivermectin for Prevention and Treatment of COVID-19 Infection: A Systematic Review, Meta-analysis, and Trial Sequential Analysis to Inform Clinical Guidelines", 21.06.2021, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8248252/; HOFT, "There Are Now 365 Studies that Prove the Efficacy of Ivermectin and HCQ in Treating COVID-19 - Will Anyone Confront Fauci and The Medical Elites on Their Deception?", 25.11.2021, https://www.thegatewaypundit.com/2021/11/now-365-studies-prove-efficacy-ivermectin-hcq-treating-covid-19-will-anyone-confront-fauci-medical-elites-deception/.

246 Ivmstatus, "Global ivermectin adoption for COVID-19", 10.06.2022, https://ivmstatus.com.

1112 Despite this, Merck, the manufacturer of ivermectin, claims that ivermectin has not been proven to be effective.[247] Meanwhile, evidence has emerged that the study on which these claims are primarily based was manipulated.[248]

1113 Merck's denial of efficacy can only be explained by the fact that Merck has submitted applications for approval in various countries, including Switzerland, for the presumably very expensive molnupiravir, which is to be used to treat COVID-19. While the manufacturing costs for a therapeutic dose of molnupiravir are USD 17.80, it is expected to cost USD 712.00 for the patient in the USA. Merck is therefore charging a 40-fold price premium.[249] Preclinical studies indicate that molnupiravir can even damage the genome.[250] It is incomprehensible how, given this data situation, approval of molnupiravir can be seriously considered while the same is denied to ivermectin, a drug that has been tried, tested and safe for decades.

1114 In stark contrast to the COVID "vaccinations", there is therefore strong evidence that ivermectin is highly effective, safe and even harmless - and this will be the case at the latest when ivermectin is approved in the EU country of Bulgaria in January 2021. **Accordingly, Swissmedic's duty to minimize risk should have meant that approval in Switzerland should have been suggested by Swissmedic, applied for by Merck and quickly approved by Swissmedic as part of the simplified approval procedure (Art. 14 TPA).** Instead, Swissmedic claims in an almost grotesque manner that "no scientific evidence" is available on the efficacy of Ivermectin - only to then publicly warn against taking the drug, which is defamed as a mere "dewormer", on the basis of this allegedly non-existent evidence.[251] If Swissmedic already warns against allegedly ineffective medicinal products, it should also have issued such a warning about the obviously ineffective and also deadly COVID "vaccines" long ago.

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247 Merck, "Merck Statement on Ivermectin use During the COVID-19 Pandemic", 04.02.2021, https://www.merck.com/news/merck-statement-on-ivermectin-use-during-the-covid-19-pandemic/.

248 WORLD COUNCIL FOR HEALTH, "Scientific Misconduct Uncovered in the TOGETHER Ivermectin Trial", 12.6.2022, https://worldcouncilforhealth.org/news/2022/06/together-trial/75890/.

249 SCHEPIS, "Serious deficiencies in the approval study of the corona vaccine. Where are the consequences?", 04.11.2021, https://www.nebelspalter.ch/gravierende-maengel-bei-zulassungsstudie-des-corona-impfstoffes-wo-bleiben-die-konsequenzen.

250 ZHOU et al, "β-D-N4-hydroxycytidine Inhibits SARS-CoV-2 Through Lethal Mutagenesis But Is Also Mutagenic To Mammalian Cells", 07.05.2021, https://academic.oup.com/jid/article/224/3/415/6272009.

251 Swissmedic, "Swissmedic warns: Do not buy medicines to treat or prevent COVID-19 infection online", 02.11.2021, https://www.swissmedic.ch/swissmedic/de/home/humanarzneimittel/marktueberwachung/arzneimittel-aus-dem-internet/drug-safety-current-threats/vorbeugung-covid-19.html.

3.3.4.4 Other alternatives

1115 Based on international recommendations, **remdesivir**, **dexamethasone** (a cortisone) and **heparin** for blood thinning were also used in Swiss hospitals in **2020 for the treatment of COVID patients** with severe cases.[252] Remdesivir (Veklury) was temporarily approved for the treatment of COVID patients on November 25, 2020.[253] The treatment recommendations have been expanded over time to include toculizumab, monoclonal antibodies and "convalescent plasma therapy", depending on the individual clinical situation.[254]

1116 Olumiant was approved for the treatment of COVID-19 in August 2021, Ronapreve in December 2021 and Xevudy (time-limited) and Regkirona (time-limited) in January 2022.[255] With the active substances molnupiravir, toculizumab, favipiravir, nirmatrelvir/ritonavir (paxlovid) and tixagevimab/cilgavimab, five further potential medicinal products for the treatment of COVID-19 were in the review process at Swissmedic as at May 2022.[256]

1117 If the current and future therapeutics have a better cost-benefit ratio compared to the COVID "vaccines", there is no longer any basis for a temporary authorization of the COVID "vaccines" for "prophylactic" administration to a largely harmless target population. For this reason alone, Swissmedic should not have granted an authorization for the novel mRNA injections at any time, thereby failing to meet the authorization requirement pursuant to Art. 9a para. 1 lit. c TPA in conjunction with Art. 18 lit. b TPO. Art. 18 lit. b TPLRO.

3.3.4.5 Federal Council overrides requirement of no alternative treatment

1118 However, a highly worrying development emerged towards the end of 2021: By ordinance of October 27, 2021, the Federal Council inserted a rule that came into force on October 28, 2021, which simply nullified the - legal (!) - requirement of no alternative treatment (Art. 21 para. 5 COVID-19 Ordinance 3):

> "By way of derogation from Article 9a paragraph 1 letter c of the Therapeutic Products Act of 15 December 2000, temporary authorizations may be granted even if an authorized, alternative and equivalent medicinal product

252 USZ, "Revised therapy recommendations for nephrological patients with proven SARS-CoV-2 infection, with special consideration of the adaptation of immunosuppression", 12.2020, https://www.usz.ch/app/uploads/2021/03/Therapieempfehlungen-COVID-22.12.20.pdf.

253 Swissmedic, "Status of authorizations to combat COVID-19", as at 10.06.2022, https://www.swissmedic.ch/swissmedic/de/home/news/coronavirus-covid-19/stand-zl-bekaempfung-covid-19.html.

254 USZ, "Coronavirus SARS-CoV-2 and COVID-19: Treatment", 10.06.2022, https://www.usz.ch/fachbereich/infektiologie/angebot/coronavirus-sars-cov-2-und-covid-19-behandlung/.

255 Swissmedic, FN 253.

256 Swissmedic, FN 253.

is available in Switzerland, provided that the authorizations serve to ensure the supply of medicinal products to prevent and combat the coronavirus in Switzerland"

1119 The Federal Council probably based its highly questionable approach on Art. 3 para. 2 lit. c of the COVID-19 Act (SR 818.102), which authorizes Parliament to provide for exemptions from the authorisation requirement for medicinal products or to adapt the authorisation requirements or the authorisation procedure (see in detail above N 1013 ff.). **However, the fact that the Federal Council is undermining the requirement for alternative treatment methods of all things speaks volumes: such alternatives obviously exist and should have been approved long ago instead of the experimental, dangerous and useless mRNA "vaccinations".**

3.3.4.6 Conclusion

1120 There would therefore have been very good reasons to at least examine the approval of ivermectin and other promising (drug-based) early treatment protocols for SARS-CoV-2 instead of relying completely one-sidedly on the experimental and dangerous COVID "vaccination" as the only "game changer" - even with "indefinite" approval.

1121 The requirement of a lack of treatment alternatives was already not met in December 2020. In view of the lack of efficacy and safety of the COVID "vaccines" and the increasing availability of alternative therapies, prioritizing the mRNA "vaccines" also violates this condition of "temporary" approval.

3.3.5. Subsequent delivery of complete data?

1122 Furthermore, according to Art. 9a TPA in conjunction with Art. Art. 18 **lit. d TPLO,** the applicant must be in a position to provide the necessary data in accordance with Section 2 or Section 3 of the TPLO. This means that the studies required for a regular authorization must be submitted within two years at the latest (cf. Art. 21 para. 1 TPLO) after the temporary authorization.[257]

1123 As before (N 275 ff.), the manufacturers have "unblinded" their own approval studies (dissolution of the control groups), which the approval authorities knew by the beginning of 2021 at the latest. Without a comparator arm (placebo group), the initial situation for the temporary authorization granted has changed fundamentally and the requirements for converting the temporary authorizations into an ordinary authorization are no longer met. The marketing authorization holders will not be able to submit data comparing efficacy and safety

257 SCHOTT/ALBERT, BSK HMG, 2nd ed., Basel 2022, Art. 9a N 35.

between vaccine and placebo over a period longer than a few months. In addition, there were protocol deviations, falsification of data and other irregularities (see N 397 ff.). All of this was known to the regulatory authorities and it was obvious that the manufacturers would not be able to provide the necessary studies.

1124 In addition, manufacturers are pushing back the end of phase III trials further and further - currently until 2024 (front N 247, 293, 884). However, they should have been in a position to provide the final data within two years - i.e. by the end of 2022. They also clearly failed to meet this target - despite this, Swissmedic continued to grant further authorizations up to and including "ordinary" authorizations (see N 1131 ff.). Complete documentation is therefore not available even in 2023. This mandatory requirement for "temporary" approval was and is therefore clearly not fulfilled.

3.3.6. Time urgency?

1125 Finally, according to Art. 9a TPA in conjunction with Art. Art. 18 **lit. e** TPLRO, the collection of all necessary data and the processing and evaluation of the data in accordance with Art. 11 lit. d TPA (ordinary authorization) would have to take so long that irreversible damage would occur or intensify as a result or that this would be associated with severe suffering for the patient.

1126 It is not to be expected that the collection of all necessary data within the framework of a proper approval procedure would have been associated with the occurrence of irreversible damage or severe suffering in patients suffering from SARS-CoV-2. For example, in front (N 1070 ff.) that at no time was there a life-threatening or disabling disease threatening the entire target population. At most, there was a risk for older people, but they could have been adequately protected in other ways. In particular, alternative treatment methods would have existed practically from the beginning of the coronavirus crisis - i.e. as early as mid-2020 - that could have been approved quickly and with a side effect profile that had already been known for many years (see N 1104 ff.).

1127 Waiting until all the data required for a proper procedure was available would not have been associated with a disadvantage for COVID sufferers, nor with the occurrence of irreversible damage or severe suffering, which means that this condition for temporary approval is also not met.

3.4. Conclusion: Requirements for "temporary approvals" never fulfilled

1128 This means that not a single one of the six cumulative requirements for "temporary" approvals will be met even in 2023. Even worse: at the **time of the first "temporary" approvals**

at the end of 2020, not a single one of the cumulative requirements had been met. With a lot of "goodwill", it could be argued that no alternative treatment methods existed in December 2020 and that older people in particular were exposed to an increased risk, which is why there was at most a certain urgency for a short time. But even then, the temporary authorizations fail completely in the other three conditions **(not compatible with the protection of health; no major therapeutic benefit; no subsequent delivery of complete data).**

4. Overall conclusion: Illegal "pandemic approvals"

1129 The "pandemic approval" of the mRNA "vaccines" deviates in all essential safety aspects from the regular, and even the simplified and temporary approval. The approval of the mRNA "vaccines" was therefore **accompanied by** a **blatant omission of the most elementary safety and efficacy tests, thereby** taking **the greatest possible risk of all. The requirements for the ("temporary") authorizations of the COVID "vaccines" were therefore never met - the granting and maintenance of these by Swissmedic is simply unlawful.**

1130 This massive risk could only be counteracted to some extent with **rigorous pharmacovigilance** and **transparent information for the public.** However, Swissmedic has also criminally neglected these duties of care, as the following comments show (N 1151 ff. [inadequate risk monitoring]; N 1187 ff. [misleading the public]). In combination of all misconduct, Swissmedic's actions must even be classified as an **illegal experiment on humans (**back N 1211 ff.).

VII. Swissmedic's criminal act - illegal establishment of the mRNA platform

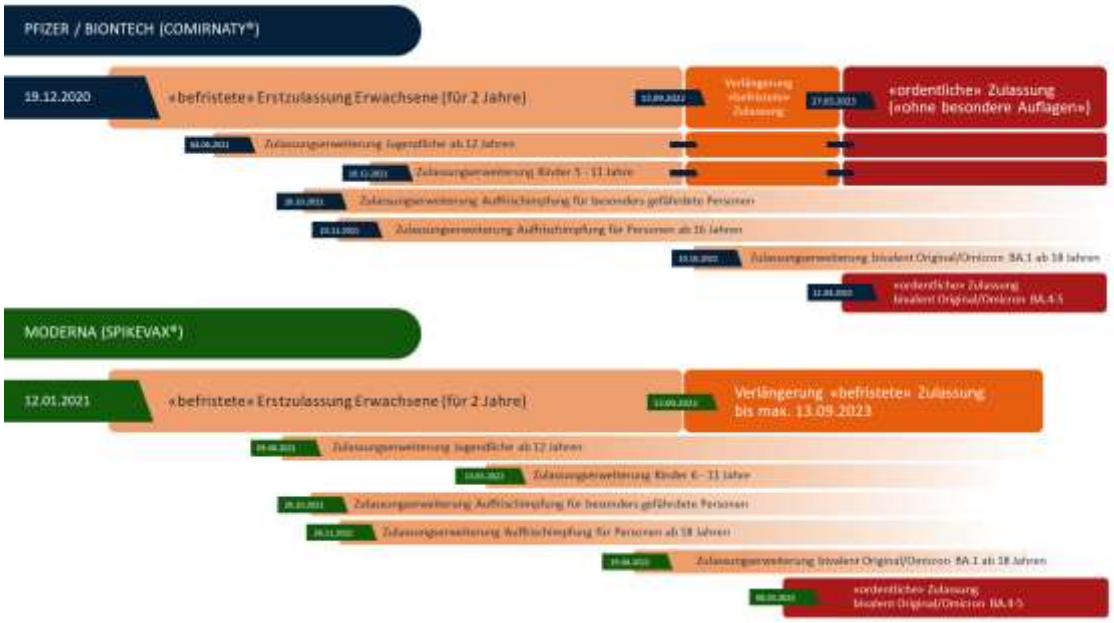
1131 Due to the legal explanations, this chapter is dealt with exclusively in the criminal complaint (and not also in the evidence report). For individual aspects, explicit reference is made to the evidence report where appropriate.

1. Expiry of the "temporary" approvals on 19.12.2022 and 12.01.2023 respectively

1132 The two-year "temporary" approvals for Comirnaty and Spikevax (including all extensions based on them) would have expired on December 19, 2022 and January 12, 2023 respectively. From these dates, the medicinal products in question could no longer have been used on the market. Exceptions would only have been possible if the prescribing doctor had explicitly informed the patient in writing of the particular risks associated with use after expiry of the "temporary" approval (so-called "off-label use"). Without further active action by the

regulatory authority, use for the general public would therefore have been possible under the illegal regime of "pandemic approvals" (see N 857 ff., in particular N 992 ff.) would no longer have been possible.

1133 However, instead of immediately suspending the "temporary" authorizations or at least allowing them to expire, Swissmedic accommodated the manufacturers to the maximum extent possible and - despite the lack of requirements - granted an extension of the authorizations and ultimately even issued "full" authorizations (graphic in full resolution: Evidence Report, Supplement **71**):



1134 By autumn 2022 at the latest, Swissmedic had therefore made a new fundamental decision ("How do we proceed?") and created new legal acts in the form of new authorization decisions, which are discussed below:

2. Autumn 2022: Extensions of the "temporary" approvals

1135 In September 2022, Swissmedic ***de facto*** **tacitly** extended the "temporary" "pandemic" authorizations for Comirnaty and Spikevax until 13 September 2023 without providing transparent information to the public. Swissmedic thus extended the legally stipulated time limit by a whole nine months or almost 40%.[258] As a result, these actually "temporary" authorizations came closer and closer to a full authorization in terms of duration (initial granting for 5 years; Art. 16 para. 2 TPA), although the requirements for a full authorization were and are not even remotely fulfilled.

258 Evidence Report, N 2031 ff.

1136 As before (N 984 ff.), such an extension would only be permissible with "scientific justification" and only if "all conditions are met". When asked, Swissmedic refuses to provide any information as to the "scientific justification" on which these outrageously long extensions were granted.[259] Due to the numerous conditions still imposed even in 2023 (see N 1141 ff.), it can be assumed that the manufacturers were even further away from fulfilling Swissmedic's requirements in September 2022. However, even these requirements are completely inadequate: in particular, the continued toleration of "unblinded" and falsified "Phase I/II/III" studies (see N 275 ff. and N 397 et seq.) is not an acceptable act under therapeutic products law in "pandemic times", let alone in times when there is no health risk. The requirements for the transfer to an ordinary marketing authorization are therefore simply unattainable for the medicinal products of interest here.

1137 The extension of the "pandemic" authorization beyond the 2 years already (illegally) granted is once again a blatant violation of the most important provisions of the TPA for the protection of public health (in particular Art. 1, Art. 3, Art. 9a, Art. 10 para. 1 lit. a TPA). At the end of 2022, it had long been obvious that

- COVID-19 is neither a life-threatening nor a disabling disease for the general public (see N 750 ff., N 753 et seq,764 ff., N 771 et seq,780 ff. and summarizing N 789 ff.),
- the mRNA-based novel "COVID-19 vaccines" do not guarantee an immunizing protective effect against SARS-CoV-2 and the necessary characteristics of a vaccination within the meaning of Art. 2 lit. b AMBV are not present (see above N 297 ff., N 376 ff., N 498 ff., N 688 ff.) and
- the publicly available data painted an almost devastating picture of the alleged "safety" of the drugs under discussion here (see N 186 ff., N 319 ff., N 388 ff., N 526 ff.) - in particular, there was a conspicuous death rate in Switzerland (see above N 663 with reference) and a massive increase in various disease diagnoses (see N 664 ff.) were openly recognizable from the official BfS data.

1138 The fact that the manufacturers could still provide the cumulative evidence of quality, safety and efficacy required by law within the grace period granted must be regarded as completely illusory, if not objectively impossible. **At the end of 2022, Swissmedic therefore had every reason by law to immediately discontinue this ongoing experiment on humans - instead of extending it. The extension, which nevertheless took place, goes hand in hand with a threat to public health that can no longer be tolerated under any title.**

259 Evidence report, N 2033.

3. From March 2023: Issue of "quasi-regular" authorizations

1139 In March and April 2023 - just in time before the *WHO* lifted the international public health emergency ("PHEIC") on May 5, 2023 - Swissmedic literally took a "flight forward" and began issuing much longer-term authorizations, apparently even "ordinary" authorizations - once again with a completely misleading orientation of the population:[260]

3.1. Spikevax Bivalent BA.4-5: "Open-ended" approval as a new form of approval?

1140 On March 8, 2023, Swissmedic surprised everyone with a press release stating that it had issued an "unlimited authorization" for "Spikevax Bivalent Original / Omicron BA.4-5". It should be noted that half of this mRNA injection is based on the "temporary" first authorization. It is already completely unclear on what legal basis a medicinal product can be authorized "for an indefinite period", which itself consists of 50% of a "temporary" authorized medicinal product. It is even less clear what Swissmedic means by an "unlimited" authorization. In response to repeated requests for the relevant legal standard, Swissmedic resorts to meaningless excuses and, in the end, seriously claims that this is an "ordinary authorization" - although it is obvious that there has been a maximum deviation from the strict requirements applicable there. **Swissmedic is thus deceiving the public once again** and is once more attempting to conceal its own actions - now by **inventing a simply non-existent form of authorization.**[261]

3.2. Comirnaty: conversion of the "temporary" license into a "regular" license

1141 In March 2023, Swissmedic followed up again and (partially) put an end to the (tacit) extension of **Comirnaty.** However, not by revoking the authorization, but by **granting a 5-year "authorization without special conditions**" - namely for the initial authorization of 19 December 2020 and the extensions to adolescents of 4 June 2021 and children of 10 December 2022. The corresponding media release of 27 March 2023 is once again written in such a confusing way that it is not clear to the addressee on what benefit-risk assessment and on what legal basis this authorization was granted. Only a glance at the recently issued authorization decision of 17 March 2023 reveals that Swissmedic actually proceeded to convert the "temporary" authorization into an "ordinary" authorization - although there was no basis whatsoever for doing so:

1142 Various **preclinical and quality** requirements may not even have been met - yet Swissmedic claims that all requirements have been met. In doing so, Swissmedic is - once again

260 See evidence report N 2038 ff.
261 For the whole, see Evidence Report N 2039 ff.

- relying on false information from the manufacturers and ignoring all the alarm signals that have emerged worldwide. Swissmedic is therefore - once again - concealing its own control failure with a brief reference to allegedly fulfilled requirements and allowing the manufacturers to continue.

1143 In addition, the public was once again massively misled: Swissmedic claimed in the press release that it had **"approved** an **authorization without special conditions".** In reality, however, Swissmedic simply extended several conditions of the "temporary" authorization for the **clinical trials** for the "ordinary" authorization. Clinical trials - especially phase III trials - are mandatory for a regular authorization (Art. 11 para. 2 lit. a no. 2 TPA). Such elementary studies therefore represent the prerequisite - the condition - for an authorization and can of course not be redefined as mere conditions (on the admissibility of conditions, see above N 890 and N 914 f.). However, this is precisely what Swissmedic has done. The "ordinary" authorization for children aged 5-12 years is particularly objectionable: The (clinical) data situation for an authorization in children is completely inadequate. Accordingly, on January 27, 2023, Swissmedic made it a mandatory requirement that **Pfizer at least provide "real world" data before the temporary authorization would be converted into a regular authorization. Less than two months later, Swissmedic completely abandoned this condition for a regular authorization: Pfizer was also granted regular approval for children and is now to be able to submit these same centralized data at its discretion ("as soon as available").** In view of the devastating data situation and the danger posed by mRNA injections for this population group, which was demonstrably never threatened by SARS-CoV-2, this is simply an unacceptable approach.

1144 Swissmedic blatantly lied to the public with this media release of 27 March 2023, according to which it had issued an authorization for Comirnaty "without special conditions". As explained in detail above, **Swissmedic simply extended several unfulfilled (special) conditions of the temporary authorization and regarded unfulfilled conditions as fulfilled without further ado.** The requirements for a regular authorization according to Art. 9 / 11 TPA are in no way fulfilled.

1145 It can be seen that Swissmedic was obviously under enormous "pressure to act". For example, it backed away "just like that" from central requirements, which it had considered to be a mandatory condition for ordinary approval only a few months previously, and made maximum concessions to Pfizer, as if the supervisory authority was solely concerned with satisfying the needs of the manufacturers. Obviously, in view of the fact that the "temporary" approval could no longer be maintained due to the lack of a disease threatening the entire target population with death or disability, a quick solution had to be found. However, instead of finally suspending the approvals, Swissmedic issued the full approval without further ado

- and just "in time" before even the *WHO* had officially declared the "pandemic" over as of May 5, 2023.[262]

3.3. Comirnaty: "Approval" for "bivalent COVID-19 Original / Omicron BA.4-5"

1146 On 11 April 2023, Swissmedic published a press release stating that it had now also authorized the "Bivalent Original / Omikron BA.4-5 mRNA vaccine" - again without specifying which form of authorization it had chosen. In response to a private inquiry, Swissmedic stated on 21 April 2023 that the authorization was based **"on Art. 11 TPA"** - without using the word "ordinary authorization". Swissmedic claimed that **"the applicant** had **submitted all the data required for the authorization".** As *explained in detail in the Evidence Report (N 2087 ff.) (with direct references),* Swissmedic once again omits all warning signals and once again presents the mRNA injection in a completely untruthful and embellished manner. In particular, the following statements made by Swissmedic (in the media release and/or in the response to the private inquiry) should be emphasized:

- Contrary to Swissmedic's assertion, the *"efficacy and safety"* of the monovalent "vaccines" was not proven in any way in the *"double-blind controlled randomized studies".* Furthermore, Swissmedic once again fails to mention that these very studies were actively sabotaged by unblinding (breaking up the control groups) and largely deprived of their informative value.
- Swissmedic refers to a definition of criteria at *"international level",* namely for the purpose of authorizing *"a SARS-CoV2 variant vaccine generally on the basis of immunogenicity data"*. However, higher antibody concentrations alone can by no means prove sufficient efficacy against a disease. The fact that the *"antibody concentration measured protective effect of the bivalent vaccine against the omicron variants BA.4 and BA.5 of the SARS-CoV-2 virus"* is higher is therefore once again a misleading euphemism, as it suggests an allegedly "higher" efficacy, while not even sufficient efficacy of the monovalent mRNA injections has been proven.
- Swissmedic refers to a *"considerable amount of data from controlled clinical studies*" - but fails to mention that the sheer amount of data is not a quality feature per se. On the contrary, the studies produced by the manufacturers proved to be useless for sufficient proof of efficacy and safety, while Swissmedic apparently consistently ignored independent - and equally solid and worrying - studies , according to
  - the 53 publications on completed phase I/II/III/IV studies published by the manufacturers up to September 2022 are all subject to considerable limitations and are

262 For the full title, see Evidence Report N 2045 ff.

unable to make any substantial contribution to the question of the efficacy and safety of mRNA injections,
    - available manufacturer studies on the "Omikron booster" are completely inadequate to prove safety and efficacy,
    - the 11 studies cited by Swissmedic on request for the alleged proof of harmlessness with regard to fertility are qualitatively inadequate,
    - and instead, by March 2022 alone, there were over 300 independent studies on heart problems, coagulation disorders and deaths as a result of COVID "vaccinations".
- Swissmedic also refers to collected *"Real World Evidence (RWE) data and pharmacovigilance reports" and* claims that *"no new safety signals"* can be identified. However, it is precisely this "real world" data that shows, for example,
    - that - despite massive underreporting - reports of serious to fatal side effects have reached unprecedented highs and thus relevant alarm values have long been exceeded,
    - that the mRNA injections are significantly more dangerous than the flu vaccines,
    - that even the manufacturers' interim reports were alarming in every respect,
    - that a potentially even negative effectiveness of the entire mRNA "vaccination campaign" can be identified.

4. Conclusion: Swissmedic operates without law and far from reality

1147 Although it had long since been confirmed and confirmed in both qualitative and quantitative terms over a period of around two years that the mRNA technology used in the context of the COVID crisis was neither of high quality, nor safe, nor effective, Swissmedic fatally made new fundamental decisions from the end of 2022 onwards to extend the authorization (and later also on actual ordinary authorizations) of these same mRNA-based medicinal products. The requirements for extensions of these "temporary" authorizations, and indeed for the granting of supposedly "ordinary" (Art. 9 / 11 TPA) authorizations, were not even remotely met.

1148 By granting these latest extensions and authorizations - under whatever title - for an "indefinite" period (see N 1140) or even as "ordinary" authorizations (see N 1141 ff.), the highest supervisory and licensing authority for therapeutic products is operating outside of its core mandate under therapeutic products legislation and far removed from any reality. Swissmedic has evidently decided to approve the novel, still experimental **mRNA therapy/prophylaxis** (see above N 193 f., 200 ff., N 526 ff.) **in the sole interest of the manufacturers as a new platform for widespread use** - and not only in disregard of the

mandatory requirements of the ordinary approval procedure (see above N 862 ff.), but also in disregard of all other requirements that the legislator has set for gene therapies and GMOs (see N 916 ff.) to protect the population from poor-quality, unsafe and ineffective medicinal products.

1149 **Those responsible at Swissmedic have thus disregarded the law to an unprecedented extent and confirmed that they will not shy away from putting the interests of manufacturers above the legally enshrined right to protection of the Swiss population, regardless of the consequences.**

1150 **With their illegal authorizations, those responsible at Swissmedic have also created the dangerous illusion of efficacy and safety. As a** result, they are still preventing people in Switzerland from being able to consider the true extent of the drug risks when making their personal vaccination decisions.

VIII. Swissmedic's offense - inadequate risk monitoring

1151 Some of the statements made in this section are **supplements to the information previously provided in this criminal complaint**, **to which explicit reference** is made **in each case**.

1152 Other statements are based on the **evidence report v2.0 (enclosure 13)** attached to this criminal complaint, which contains further discussions where necessary and lists the relevant supporting documents. The title structures in this section of the criminal complaint and the enclosed evidence report (section "Inadequate risk monitoring") correspond in terms of content, but are shifted by one level (e.g.: Title level "**1.** No active monitoring" of the criminal complaint corresponds to title level "**I.** No active monitoring" of the evidence report).

1153 Based on the above (N 857 ff., in particular N 992 ff.), Swissmedic has created an ongoing risk to the health of the Swiss population that far exceeds the health risk posed by the SARS-CoV-2 pathogen. The only possible way to minimize the risk would therefore be risk management after approval that is beyond all doubt - but even there, Swissmedic does not meet the most basic requirements with its massive underreporting of side effects:

1. No active monitoring [ER N 1948 f.].

1154 To date, Swissmedic has limited itself to a purely passive reporting system, which in no way adequately takes into account the risk created by the emergency authorizations granted hastily and without any reliable study: As is well known, the traditional *passive reporting system* is designed for drugs that have previously been thoroughly tested on humans in

order to be able to detect any rare side effects that have remained undetected - which may have been overlooked in studies (see N 898 ff).

1155 Swissmedic itself had already clearly recognized in the aftermath of swine flu 2010 (concerning Pandemrix) that a passive reporting system for the purpose of monitoring drug safety for new drugs launched on the market at short notice had to be classified as inadequate (see N 361 f.). Swissmedic therefore already had the experience and knowledge before the COVID crisis that only active monitoring was suitable in such situations to quickly and reliably identify the risks associated with novel medicinal products that had never been tested before.

1156 However, even without these historical empirical values from the "Pandemrix" approval phase, the need for proactive monitoring arises purely logically from the fact that when a substance is dispensed to the general population without sufficiently conducted medical-scientific studies, there is just as little reliable knowledge on the question of efficacy and safety as before the start of clinical phase III. The dispensing of a corresponding substance to the general population is therefore equivalent to the approval stage of clinical phase III. Risk monitoring and safety management by the regulatory authority must therefore be carried out according to similar principles as an actual human trial in clinical phase III. Risk-adequate pharmacovigilance would therefore have to ensure that the risks and side effects associated with the new substance are identified at an early stage so that the authorization can be revoked immediately if necessary.

1157 In view of the hasty "pandemic approval" of the completely new medicinal products, Swissmedic could not leave it at a purely passive reporting system: The mRNA "vaccines" are - as previously (N 186 ff., N 389 ff.; see also N 999 ff.) - as **gene therapy for prophylactic use in a healthy population are** highly experimental and **have not been validated by a single (long-term) study in humans.** Rather, they are still in the clinical phase, which is expected to continue until (at least) 2024 (see N 247, N 293, N 884). The initial situation with the "temporary" authorized mRNA therapies is therefore in no way comparable to that of regularly authorized new medicinal products. On the contrary, Swissmedic has created an **unprecedented risk** with the approval of mRNA therapies and has repeatedly renewed it despite constantly increasing evidence regarding a lack of efficacy and unprecedented side effects, which would have **to be compensated for by substitute measures to minimize the risk.**

1158 In view of the fact that there are still no scientifically reliable long-term clinical phase III studies available for the mRNA "vaccinations", and in view of the fact that a drug with a new mode of action (in this context: preventive use for the healthy general public) new mode of

action (production of the spike protein in the human body; uncertainty regarding the body cells involved in the production; uncertainty regarding the duration, quality and quantity of the spike protein), **the mRNA "vaccinations" should have been subjected to proactive pharmacovigilance from the outset - as is mandatory under study conditions.** However, Swissmedic failed to do so, contrary to its duty.

2. Massive underreporting in Switzerland - complete passivity at Swissmedic [ER N 1950 ff].

2.1. Unsustainable number of unreported cases of at least 90%

1159 The fact that the passive reporting system is not even remotely sufficient to capture the massive risk potential is also shown by the underreporting that has already been pointed out several times: In Switzerland, **at best 10% of all adverse drug reactions** are **reported - which leads to an unsustainable number of unreported cases of at least 90%** (front N 441 ff., N 612 ff., in particular N 621 et seq.).

2.2. More active design of the passive reporting system

1160 There are certainly ways to improve at least the passive reporting system a little: in the USA, for example, the *CDC provided* an app, "V-Safe", which enables "vaccinated" people to report adverse effects simply and easily (front N 613).

1161 Germany had also introduced an app to monitor the safety of COVID-19 vaccines with "SaveVac 2.0". When asked by the *Tages-Anzeiger* why Switzerland did not have such an app, Swissmedic responded as follows on July 2, 2021:[263]

> "Such extended monitoring was also discussed for Switzerland, but could not be implemented for the current vaccination campaign, mainly for technical reasons."

1162 An obvious and untenable excuse, as one potential app provider made clear in the same *Tages-Anzeiger* article: his company could have overcome any technical obstacles "within a reasonable period of time". In fact, it is by no means comprehensible why Swissmedic, which is trimmed for speed everywhere and, according to its own statements, has an excellent international network, should not have been able to ensure monitoring comparable to that in the USA or Germany.

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263 Tagesanzeiger, Germany has this vaccination app, but it's missing in Switzerland, 02.07.2021 .

2.3. Unsuitable design of the passive reporting system

1163 However, it is not only objectionable that Swissmedic did not take sufficient steps to make the passive reporting system a little more active. Swissmedic limited itself to a completely user-unfriendly passive reporting system until 2022, which once again unnecessarily increased the hurdles for reporting by private individuals:

2.3.1. Until 2022: Incorrect online form as well as PDF and Word form

1164 If a private individual wanted to submit a report to Swissmedic in 2021 - the year of "mass vaccinations" - it would be a real ordeal given today's technical possibilities:

1165 Via the homepage *www.swissmedic.ch*, the link "Report adverse drug reactions" led to a subpage "Reporting of suspected adverse drug reactions by patients". There was also an "FAQ" under the heading "How to report":

> "Adverse drug reactions can be reported using a **form.**"

1166 Clicking on the link under "**Form**" did not lead to an effective online reporting form - as one would have expected - but to a "General information contact form". This form was (as the title suggests) completely unsuitable for reporting side effects.

1167 Back to the subpage mentioned above: In addition to the "FAQ", there were two PDF and Word forms with identical content for downloading. These could be completed manually or electronically and then sent by email to vigilance@swissmedic.ch.

BO: Enclosure **19**: Swissmedic, Reporting system before July 2022, Local safety, 30.03.2022, consisting of:
Reporting system 01, Start page;
Reporting system 02-01, Patient notification;
Reporting system 02-02, Patient form PDF;
Reporting system 02-03, Patient form Word;
Reporting system 03, Contact form General information.

1168 As far as can be seen, this **confusing and unnecessarily complicated presentation** was the only way for patients to be able to notify Swissmedic, especially during the peak phase of "mass vaccinations" in 2021. In view of the fact that **Swissmedic has had time to take appropriate precautions since the beginning of 2020 at the latest, this technical "reporting offer" is inadequate in every respect, even counterproductive.**

2.3.2. From July 2022: Swissmedic improves far too late

1169 It was not until July 14, 2022 that Swissmedic announced: "New online reporting form for affected persons or their relatives". Since then, the direct link "Online reporting form" has

taken reporters to a **functioning online reporting form.** Relatively harmless side effects such as "fever" or "redness" can be quickly recorded in this form. Serious side effects such as myocarditis, periocarditis, pulmonary embolisms or herpes zoster, on the other hand, must be entered manually.

BO: Enclosure **20**: Swissmedic, reporting system from July 14, 2022, 23.08.2022, consisting of:
Reporting system 04, Media release 'Online reporting form' (14.07.2022);
Reporting system 05, Reporting of suspected adverse drug reactions;
Reporting system 06, Online reporting of adverse
drug
reactions - start;
Reporting system 07, Details of the reporting person (step 1_5);
Reporting system 08, Affected person (step 2_5); Reporting system
09-01, Adverse reactions (step 3_5);
Reporting system 09-02_Swissmedic, Nw (step 3_5), Aufgel. Adverse reactions;
reporting system
09-03_Swissmedic, Nw (step 3_5), Manual intervention serious NW;
reporting system 09-04_Swissmedic, Nw (step 3_5), Severity of effect;
reporting system 10, Drug _ Vaccination (step 4_5);
reporting system 11, Online reporting of adverse reactions - summary.

1170 This solution, which is not particularly innovative and technically very easy to implement - certainly within weeks, if not faster - came far too late, indeed it **came far too late 18 months after the start of "mass vaccination". In view of the lead time of several months and the warning signals that were already recognizable before the approval date, Swissmedic should have provided such a passive online registration form at the absolute minimum for the start of the "mass vaccinations" at the end of 2020.**

2.4. Lack of enforcement of the reporting obligation

1171 Swissmedic should also - if it wanted to maintain the completely inadequate passive reporting system - have made every effort to ensure that the doctors involved at least fulfilled their passive reporting obligations with the greatest possible care. However, the opposite was the case: **it is not apparent that Swissmedic ever urged the doctors subject to the reporting obligation to strictly comply with the reporting obligation.** Nor is it evident that any administrative or criminal proceedings were initiated against non-reporting physicians. On the other hand, in the course of their legal work, the undersigned lawyers are regularly told by hospital staff that it is virtually impossible to persuade the doctors on duty - even in very clear cases - to investigate a possible connection between COVID "vaccinations" and unusual clinical pictures (myocarditis; thromboses; permanent inflammation, etc.) at the request of affected (often young) patients. Instead of investigating such cases, the pure dogma "that what must not be cannot be" is applied.

BO: Interviewing the hospital staff on duty

2.5. Conclusion

1172 Swissmedic has failed in every respect to consistently enforce at least the passive reporting system and to properly adapt it to the special situation. In particular, the uncomplicated recording of adverse reaction reports during the peak phase of "mass vaccinations" in 2021 was not guaranteed. In addition, Swissmedic clearly failed to encourage the medical profession to strictly comply with the reporting obligation.

1173 This form of pharmacovigilance is inadequate in every respect in view of the massive increase in risk due to the hasty "pandemic approval" of a completely new medicinal product. **Swissmedic has thus virtually prevented the efficient reporting of side effects instead of encouraging reporting behavior.**

3. Swissmedic approves removal of the control group in the approval studies [ER N 1955 ff.]

1174 By the end of 2020 - i.e. at the time of the first approvals - the manufacturers had already almost completely "unblinded" the "Phase III" studies required for approval, which is tantamount to a ***de* facto *discontinuation*** (see N 275 ff.).

1175 Swissmedic was already aware of this fact at the time of the first authorizations. Swissmedic wrote to Moderna in the approval decision of January 12, 2021:

> "The open questions on the duration of protection will depend heavily on a non-blinded control group. ... This question could alternatively be answered with a household contact study."

1176 And Swissmedic wrote to Pfizer in the approval decision of December 18, 2020:

> "It is reasonable to assume that once vaccination is available, it will not be possible to maintain a control group. A study with an alternative study design, e.g. a blinded crossover design or any study design that can circumvent this problem, is strongly recommended".

1177 The fact that Swissmedic describes the dissolution of the control group as "reasonable" is simply untenable. Every new medicinal product must be tested for safety and efficacy in a double-blind study. There is simply no justification whatsoever for dispensing with this elementary requirement - and certainly not with the succinct "assumption" that a control group cannot be maintained.

1178 The unblinding of the "phase 3" studies and the associated obvious refusal of the manufacturers to provide solid data for the final assessment of the safety and efficacy of the mRNA "vaccines" seems downright brazen. The fact that Swissmedic has accepted such an attitude of refusal must, against the background of the clear legal duty of care within the meaning of Art. 3 para. 1 TPA, once again be classified as a downright obvious breach of duty. Here too, Swissmedic demonstrated a complete lack of will, or at least a pure inability, to effectively review the safety and efficacy of the "temporary" authorized mRNA "vaccines".

4. Ignored messages from manufacturers [ER N 1959 f.].

1179 As already shown in several places (see for example above N 275 ff., N 405 ff., N 475, N 595 ff.), the manufacturers themselves had reported massive side effects and other serious anomalies (such as the **unblinding of the approval studies or relevant quality problems in production)** to the international approval authorities and thus also to Swissmedic. None of this prompted Swissmedic to demand the most elementary safety standards, or even the mandatory suspension of the "temporary" authorizations.

1180 And even more serious: the relevant reports were not only ignored by Swissmedic, they were also not communicated to the public in any way - or if they were communicated, they were presented in a glossed-over manner (see N 1187 ff.).

5. Ignored third-party studies [ER N 1961 ff].

1181 However, Swissmedic not only ignored warnings from the manufacturers, but also from third parties who had studied the benefit-risk profile of the mRNA "vaccines" in detail. Swissmedic even ignored the fact that Pfizer falsified data in the approval studies - a circumstance that should have led to the immediate suspension of the approval (see N 397 ff., N 400 ff.).

1182 All of this was repeatedly rejected by Swissmedic over a period of well over 2 years. For example, Swissmedic was still incoherently holding on to the well-founded criticism of the *Canadian COVID Care Alliance* ("*CCCA*") regarding Comirnaty's 6-month data on February 1, 2022:

> "As you can see, the assessment, evaluation and ultimately the decision on the authorization and life cycle of medicinal products in general and COVID-19 relevant medicinal products in particular is in good hands with Swissmedic, the only legitimate authority under therapeutic products legislation to ensure the safety, efficacy and quality of these therapeutic products for patients."

1183 As a further study among hundreds of studies with alarm signals, Swissmedic's handling of the Basel study on heart damage (800 times more side effects compared to the official Swissmedic figures) is an example of how inadequately Swissmedic is able or willing to record the numerous warning signals as required (front N 675; Evidence Report N 1199 ff.).

6. Insufficient batch testing? [ER N 1964]

1184 Previously (N 321 f.), the suspicion was discussed that Swissmedic may even have failed to adequately check the Spikevax batches manufactured in Switzerland. However, without the relevant documentation - which is only available to Swissmedic and possibly other regulatory authorities - this allegation can neither be substantiated nor refuted.

7. Conclusion

1185 While Swissmedic repeatedly assures the public that it will continue to monitor the mRNA "vaccines" "very closely",[264] it has in fact taken no measures whatsoever to ensure pharmacovigilance.

1186 Well-founded indications of serious alarm signals are invariably brushed aside without any substantive debate - and the *de facto* emergency approvals are maintained without any visible risk reduction measures.

IX. Swissmedic's criminal act - misleading the public

1187 Some of the statements made in this section are **supplements to the information previously provided in this criminal complaint**, **to which explicit reference** is made **in each case**.

1188 Other explanations are based on the **evidence report v2.0 (Annex 13)** enclosed with this criminal complaint, which contains more detailed discussions and lists the relevant evidence where applicable. The title structure in this section of the criminal complaint and the enclosed evidence report (section "Misleading the public") correspond in terms of content, but are shifted by one level (e.g.: Title level "**1. Misleading** communication of licensing decisions" of the criminal complaint corresponds to title level "**I.** Misleading communication of licensing decisions" of the evidence report).

1189 The very last way for Swissmedic to minimize the new risks to public health created by the approval and lack of product monitoring is to provide the public with fully transparent information so that they can make an error-free vaccination decision. However, with its

[264] See the multiple announcements in Swissmedic's media releases, Evidence Report N 2008, N 2017, N 2024, N 2045.

misleading information strategy, Swissmedic has further increased the health risk for the Swiss population, which is massively increased by each authorization:

1. Misleading communication of licensing decisions [ER N 1965 ff.].

1190 Since the end of 2020, Swissmedic has published several **media releases on** its own website about authorizations and extensions of authorizations for the mRNA "vaccines" Comirnaty and Spikevax .

1191 In the individual communications addressed to the public, Swissmedic chose formulations that obviously deviated from the established state of knowledge attributable to Swissmedic at the time of the respective communication. The misleading communications are listed in full in the Evidence Report and compared directly with the state of knowledge available to Swissmedic at the time. Reference is therefore made in full to the corresponding explanations **(ER N 1965-2096),** with particular emphasis on the following misleading statements:

- First approval Pfizer 19.12.2020:
  - The description of the first illegal mRNA "pandemic approval" as having taken place "in an orderly procedure" is a sheer lie (ER, N 1968 ff.).
  - The omission of elementary test steps (such as "LoQ") is not mentioned at all. On the contrary, the public is led to believe that a "careful weighing of benefits and risks" has taken place, which demonstrably never existed (ER, N 1975 ff.).
  - Swissmedic simply suppressed the fact that when Comirnaty was first authorized, there were over 40 unresolved questions on key points such as quality, efficacy and safety (for example: lack of information on the efficacy of the "vaccine"; Pfizer's refusal [!] to set up a replacement study for the "unblinded" authorization study; lack of information on pregnancy and breastfeeding) (ER, N 1979 ff.).
  - Despite the lack of data, Swissmedic claimed in its own communications an alleged efficacy of over 90%, which has never been proven (ER, N 1982 ff.).
  - The trivialization of the side effects, in particular the concealment of the fact that over 1,200 deaths had occurred within a very short time (ER, N 1986 ff.).
- First registration Moderna 12.01.2021:
  - Once again, Swissmedic claimed to have carried out a "thorough review" despite the massive acceleration of the procedure - but again failed to mention that there were still over 60 unresolved questions regarding quality, efficacy and safety (ER N 1990 ff.).
  - Particularly brazen is the concealment of the fact that an inspection of Moderna had revealed numerous serious defects (ER N 1997 f.).

- Once again, a never proven high efficacy of 94% was propagated (ER, N 1999).
- Once again, Swissmedic trivialized side effects (ER N 2000 f.).

- Extensions to young people (from 04.06.2021):
  Here, Swissmedic has once again propagated high efficacy claims of 93-100%, which were based on obvious misrepresentations by the manufacturers. In addition, Swissmedic completely ignored the problem of unit dosing (and thus overdosing), failed to address the lack of risk to adolescents from SARS-CoV-2 and made no mention whatsoever of the serious to fatal side effects (ER N 2003 ff.).
- "Booster" extensions (from 26.11.2021; ER N 2010 ff.):
  - Swissmedic claimed an alleged protection against severe courses, although such proof had never been adequately provided.
  - Swissmedic converted barely usable efficacy data from completely inadequate studies into an alleged proof of efficacy.
  - Swissmedic continued to withhold serious risk signals from the public (falsified data from manufacturers, serious to fatal side effects, etc.) and at the same time claimed to be monitoring risks and benefits "very closely" to reassure the public.
- Extensions to children (from 10.12.2021: ER N 2019 ff.):
  - At no point did Swissmedic write that this was merely an extension of authorization for a medicinal product that was still authorized for a limited period, and made statements such as "all data" had been "carefully checked", which once again gave the completely false impression that everything was proceeding as in an ordinary procedure.
  - Swissmedic pointed out several times that the "vaccination" for children was "effective" and had even shown "high clinical efficacy in younger children", although the clinical studies had only shown minimal therapeutic benefit for minor events (such as sore throats/headaches).
  - Swissmedic even claimed that Comirnaty could "virtually completely prevent severe courses of disease caused by the SARS-CoV-2 virus". "Virtually completely" implies 100% efficacy against serious illnesses. This can hardly be surpassed in terms of audacity, as no "severe" illnesses occurred in children in the approval studies carried out. Due to a lack of available data, no statement could be made about the prevention of severe disease progression, which Swissmedic turned into the complete opposite of "virtually complete" protection.
  - Once again, Swissmedic played down the side effects and completely ignored the numerous serious side effects that occurred - in particular the massive exceedance

of the alarm values in the case of deaths. Nor did Swissmedic say a word to the public about the fact that children were and are in no way threatened by SARS-CoV-2.

1192 Swissmedic's misinformation reached a sad climax with the media releases on the authorization extensions for children. The fact that this serious misinformation was made precisely with regard to the weakest members of society - children and their worried parents - makes Swissmedic's behavior all the more reprehensible. In view of the virtually complete lack of benefit of the mRNA "vaccines", Swissmedic exposed **this youngest and least threatened population group to SARS-CoV-2 to the risk of serious side effects and deaths without need and in an absolutely misleading manner.**

1193 However, Swissmedic went even further and decided to authorize further "boosters": On August 29, 2022 (Spikevax; ER N 2026 ff.) and October 10, 2022 (Comirnaty; ER 2030 ff.), it granted approvals for the first "bivalent" boosters for the "Omikron" variant BA.1, once again misleading the public:

- According to Swissmedic, the alleged efficacy of the new "boosters" is proven in the form of "higher antibody concentrations", although strict proof of efficacy cannot be provided in this way, as these are not validated surrogate markers (see above N 723 ff., N 1058). Swissmedic completely fails to mention that the manufacturers had at the same time completely dispensed with detailed clinical studies.
- Swissmedic once again trivializes the side effects: Swissmedic writes of a "similar side effect profile", of no new "safety signals" and that it is fulfilling its duty to monitor the market. None of this is correct: the (serious) side effects and deaths reported worldwide were at a tragic high and various safety signals (birth losses/miscarriages/dead births, massively increased myocarditis rates, etc.) were obvious - but were blatantly ignored by Swissmedic.
- Swissmedic also made no mention of the fact that data from various countries had shown an increased incidence of illness and death in "vaccinated" people - in other words, a potentially negative effect of the entire mRNA vaccination campaign.
- Swissmedic had also completely ignored the fact that the "pandemic" had finally lost its (alleged) dangerousness with the appearance of the "Omikron variant": Omikron was as dangerous as a mild cold infection - the requirements for "pandemic" approval were therefore simply not met.

1194 And as if this disinformation were not enough, Swissmedic did not adequately inform the public about the extensions of the "temporary" authorizations at the end of 2022 / beginning

of 2023, but *de facto* tacitly extended them by several months (ER N 2033 ff.; above N 1131 et seq.).

1195 In spring 2023, Swissmedic even granted "ordinary" authorizations:

- On 8 March 2023, it granted a supposedly "regular" approval for the second bivalent "booster" from Moderna, which cannot be lawful in purely conceptual terms if half of this "vaccine" is based on the original active ingredient, which is still only approved for a "limited period" (ER N 2040 ff.; N 1140).
- On March 27, 2023, Swissmedic even converted Comirnaty's "temporary" approval into a supposedly "regular" approval - even though key quality, preclinical and clinical requirements had clearly not been met. In the corresponding media release, Swissmedic had even twisted this fact into the complete opposite and communicated to the public an authorization "without special conditions" (ER N 2047 ff.; in detail above N 1141 ff.).
- On 11 April 2023, Swissmedic then also granted an allegedly "ordinary" marketing authorization for Pfizer's second bivalent "booster", although the requirements were by no means met here either (ER N 2089 ff.; in detail above N 1146).

1196 As already mentioned above (N 1147), Swissmedic is operating outside the Therapeutic Products Act and far removed from reality. With each further authorization, Swissmedic moved further and further away from the legal requirements - without even beginning to inform the public about this. As a result, Swissmedic always deluded the public into believing that the same strict requirements were *de facto* met as those that must be fulfilled for a properly authorized medicinal product. In reality, however, Swissmedic had omitted elementary steps in all critical areas - quality, efficacy, safety - and completely undermined central safety mechanisms of Swiss therapeutic products legislation.

1197 With its illegal authorizations and misleading communication, **Swissmedic created the dangerous illusion of efficacy and safety. It is** particularly serious that this deception emanates from the authority responsible for ensuring the safety of medicines, on which all stakeholders (other authorities, media, politicians, etc.) rely. Swissmedic thus prevented people in Switzerland from being able to consider the true extent of the drug risks when making their personal vaccination decisions, which constitutes **a serious breach of duty of care within** the meaning of Art. 3 para. 1 TPA on the part of Swissmedic to the detriment of public health.

2. Information for healthcare professionals on mRNA "vaccines": Inadequate, incorrect and misleading texts [ER N 2097 et seq.].

1198 The Evidence Report lists the information for healthcare professionals on Comirnaty and Spikevax that is still publicly available (ER N 2097). The applicable requirements for the information for healthcare professionals - which Swissmedic has imposed on itself with its own guidance document - are then shown for individual sections (such as "Contraindications" or "Adverse effects") (ER N 2098 ff.).

1199 It is then explained in detail how Swissmedic itself has grossly disregarded these requirements through omissions, embellishments and false information. This is particularly serious with regard to drug safety: **Information for healthcare professionals is the central source of information for the "vaccinating" medical profession,** which in turn must fully inform patients about the benefits and risks (see N 1325). At this point, reference is made in full to the corresponding explanations regarding Swissmedic's misconduct **(ER, N 2111-2239),** whereby the following misleading statements in the information for healthcare professionals should be particularly emphasized:

- Missing or trivializing information on serious side effects:
  - Complete lack of references to **"thromboembolic side effects"**, although these should at least be reported as "very rare" (<1/10,000) - or even as "occasional" (≥1/1,000 to <1/100) (ER N 2115 ff.).
  - Complete lack of references to **"herpes zoster"** as an adverse reaction, although this should be included in the Information for healthcare professionals as a "very rare" adverse reaction (<1/10,000) (ER N 2126 ff.).
  - Complete lack of references to **"hearing loss/tinnitus"**, although this is obviously to be classified as "very rare" (<1/10,000) (ER N 2136 ff.).
  - Complete lack of references to **"COVID-19 disease"** as a side effect, although even Swissmedic reported this "vaccination failure" ("vaccination breakthrough") in 7th place among the most common side effects (ER N 2141 ff.).
  - Completely inadequate warning about the side effect **"myocarditis/pericarditis"**, in particular by using far too low frequency data (ER N 2152 ff.).
- Important warnings are missing completely or are misleading and incorrect:
  - The information for healthcare professionals published by Swissmedic on **"Pregnancy" and "Fertility"** ("no direct or indirect harmful effects"; "no vaccine-related effects on female fertility, pregnancy or embryo-fetal development or on the development of offspring observed") are completely trivializing and directly contradict the

study results, which show an increased miscarriage and malformation rate (ER N 2168).

- There are no warnings for **"breastfeeding women",** although the risk of mRNA "vaccines" passing into breast milk is known and other health authorities explicitly advise against "vaccinating" breastfeeding women (ER N 2178).
- Complete lack of warnings about **deaths,** although several deaths have already been clearly attributed to mRNA injections internationally, even the Federal Statistical Office reports "19 vaccination deaths" for Switzerland and although Swissmedic has already included corresponding warnings for other medicinal products (namely COVID-19 Vaccine Janssen) from a single death, which means that Swissmedic is also glossing over the mRNA injections here (ER N 2184).
- Lack of warnings for patients with an increased **risk of thrombosis**, although such a risk has long been identified (ER N 2190).
- Lack of warnings regarding **elderly and previously ill people,** especially as there is no information available on the effects of mRNA "vaccines" on this group of people - the study situation is completely inadequate (ER N 2195 f.).
- Inadequately communicated warning regarding immunosuppressed patients, in that they were invited to be "vaccinated" in a publicity-effective manner in the face of completely inadequate data (ER N 2197 ff.).

- In the "preclinical data" section, the toxicity of the mRNA injections - massive alarm signals in animal studies regarding the toxicity of the lipid nanoparticles and the spike protein - is played down, even suppressed, and safety is postulated based on non-existent data (ER N 2201 ff.).
- In the "Pharmacokinetics" section, Swissmedic suppresses alarming data from animal studies and at the same time claims - also untruthfully - that there is no obligation to carry out pharmacokinetic studies anyway (ER N 2207 ff.).
- Swissmedic publishes illusory claims of efficacy that have long since been refuted and conceals the lack of efficacy (ER N 2222 ff.).
- Swissmedic fails to mention the risk of reverse transcription and does not adequately inform the addressees that mRNA injections are actual gene therapies, or even genetically modified organisms (*GMOs*), although Swissmedic itself has considered "mRNA products" to be "equivalent" to *GMOs* since 2022 (ER N 2228 ff.).

1200 The technical information for the two COVID-19 "vaccines" Comirnaty and Spikevax is incomplete, incorrect and misleading overall. Safety signals from the post-marketing phase were demonstrably ignored and drug texts were not updated with regard to recognized risks.

1201 Accordingly, the medical profession was not adequately informed about hazards in the information for healthcare professionals and did not receive any appropriate recommendations on what to do, which made it impossible to properly inform the people to be "vaccinated" and exposed them to completely unnecessary risks. Swissmedic massively misled the addressees (the medical profession; the general public) by publishing the aforementioned information for healthcare professionals.

1202 The **concealment of all these legally relevant and risk-relevant facts** in its information for the Swiss public constitutes a **serious breach of duty of care within the** meaning of Art. 3 para. 1 TPA on the part of Swissmedic to the detriment of public health.

1203 This list of missing and euphemistically presented side effects and warnings could be extended indefinitely - for which, however, more detailed investigations and analyses are necessary.

3. Deception through "FAQ" on Swissmedic website [ER N 2240 ff.].

1204 Swissmedic publishes *questions and answers about COVID-19 "vaccinations*" ("*FAQ on COVID-19 vaccines*") on its own website for the general public, where it has been disseminating misleading information on a permanent basis since 2020.

1205 The evidence report (ER N 2240 ff.) shows in detail why Swissmedic's answers to none of the questions examined on the core topics of "efficacy" and "safety" correspond to the truth. Truthful, critical information on mRNA preparations is sought in vain here, and known risks are concealed. This deprives the general public of the factual basis for an informed decision and for a personal risk-benefit assessment.

1206 This is particularly evident in Swissmedic's answer to the first "FAQ" question: "**Are the COVID-19 vaccines safe?"** (ER 2241 f.). Until March 2023, Swissmedic's answer to this question was as follows (emphasis added)

> "The vaccines against COVID-19 were already thoroughly tested during their development and then carefully reviewed by Swissmedic experts. Only vaccines that are **proven to be safe, effective and of high quality** are licensed in Switzerland. **So far, there is no evidence of lasting negative consequences for health.**"

1207 This response was therefore maintained at a time when there could no longer be the slightest doubt about the lack of efficacy and safety. It is symptomatic of an actual **policy of permanent disinformation** on the part of the highest supervisory authority for drug safety. With this "**FAQ**", Swissmedic once again confirmed and cemented its misleading

information policy, instead of finally informing the Swiss public transparently and truthfully about the risks of mRNA injections in accordance with due diligence (Art. 3 para. 1 TPA).

4. Further omissions and appeasements by Swissmedic [ER N 2266 ff].

1208 Swissmedic did not stop at misleading media releases, technical information and statements on its own website such as the "FAQ". Swissmedic also continuously spread misinformation about mRNA injections through numerous other channels (magazines, television, e-mail correspondence) - quite obviously with the aim of reassuring the Swiss population and maintaining "willingness to vaccinate".

1209 The evidence report (ER N 2266 ff.) lists a selection of almost a dozen such false statements in detail. At this point, reference is made in full to the corresponding explanations, whereby the following misleading statements in particular should be emphasized:

- Swissmedic untruthfully claims that there is "no evidence of accumulation of LNP" (ER N 2266 ff.), that these lipid nanoparticles are "not harmful" (ER N 2291) and "pose no risk to humans" (ER N 2282 ff.).
- Swissmedic untruthfully claims that the spike protein is only produced for a "short time" and that "physiological damage caused by the spike protein [...] is not to be expected" (ER N 2286 ff.).
- Swissmedic untruthfully claims that there are "no proven deaths" (in Switzerland) - and that even internationally there are "no indications" of an increased rate of deaths (ER N 2269 ff.).
- Swissmedic trivializes (serious) side effects several times: for example in the *"Vigilance News"* addressed to the specialist public (ER N 2278 ff.) or in a media release with the blatantly false claim that COVID-19 "vaccines" have "no influence on fertility" (ER N 2281).

1210 This list of misleading communication is also by no means exhaustive , but underlines Swissmedic's consistently deceptive information policy. Accordingly, Swissmedic has failed to inform the Swiss public transparently and truthfully about the risks of mRNA injections through all available communication channels in a diligent manner (Art. 3 para. 1 TPA).

X. Swissmedic's criminal act - unauthorized human experimentation

1211 As before (N 843 ff.), the general approvals of mRNA preparations by Swissmedic and their administration by doctors still have all the characteristics of a human experiment, as it is still

not possible to make reliable statements in advance about the respective protective and side effects of these substances.

1212 Swissmedic's approach - illegal "pandemic authorizations" (front N 857 ff.) and their illegal perpetuation (see N 1131 ff.), inadequate risk monitoring (see N 1151 ff.) and massive misleading of the public (see N 1187 ff.) - is therefore not only fundamentally contrary to all principles of public health law, but also to mandatory international law: The legal obligations that Switzerland must fulfill in the context of "pandemics" (i.e. "PHEIC" ["Public Health Emergency of International Concern"] declared by the *WHO General Secretariat*) are defined by the International Health Regulations (IHR; SR 0.818.103). Art. 3 para. 1 IHR explicitly stipulates that states must uphold the fundamental rights of citizens even in times of pandemic:

> "These provisions shall be implemented with full respect for human dignity, human rights and fundamental freedoms."

1213 It follows from Art. 3 para. 4 and Art. 57 para. 1, 2nd sentence of the IGA that the legal obligations of states under the IGA in no way restrict the legal obligations arising from other international agreements:

> "The IHR shall not affect the rights and obligations of States Parties under other international agreements."

1214 The UN Covenant on Civil and Political Rights is therefore also applicable (SR 0.103.2). Its Art. 7 stipulates:

> "No one shall be subjected to torture or to cruel, inhuman or degrading treatment or punishment. In particular, **no one shall be subjected to medical or scientific experimentation without their voluntary consent.**"

1215 This provision also applies in times of emergency, which is explicitly stated in Art. 4 para. 1 and para. 2 of the aforementioned UN Covenant and makes this provision **mandatory international law**:

> "In the event of a public emergency which threatens the life of the nation and which is officially proclaimed [...]"
>
> "On the basis of the above provision [*1], Articles 6, 7, 8 (paragraphs 1 and 2), 11, 15, 16 and 18 may not be repealed [...]"

1216 This means that **the absolute ban on human trials without informed consent also applies in these special situations.** Under the guise of a "pandemic", Swissmedic has actually dared to authorize novel medicinal products without even the slightest indication of adequate studies and without mandatory warnings that are understandable and transparently

communicated to everyone. The corresponding "authorizations" thus led to a human experiment to which no one can validly consent due to a lack of sufficient information. With the chosen procedure, Art. 7 of the UN Covenant - i.e. mandatory international law - was blatantly undermined to the detriment of potentially the entire population of Switzerland.

1217 Without the necessary information about all risks and side effects relevant to the decision - in particular about the experimental nature of the mRNA substances themselves - any injection of mRNA-based COVID-19 preparations based on Swissmedic's approvals and their misinformation constitutes an act of "cruel, inhuman or degrading treatment or punishment" within the meaning of the UN Covenant and also within the meaning of Art. 10 para. 3 of the Federal Constitution. There can be no justification for a violation of this principle, which is mandatory under international and constitutional law, because this is the actual core content of the human right to life.

XI. Swissmedic's actions: overall conclusion

1218 The responsible persons at Swissmedic were and are aware that Swissmedic is **the highest responsible authority** in Switzerland due to the legal competencies and obligations to protect public health (against ineffective and harmful therapeutic products and against false information) as described above. By virtue of special legislation on therapeutic products, Swissmedic has the actual key role in Switzerland in the areas of authorization, placing on the market and subsequent market surveillance of therapeutic products and is responsible for the accuracy of the relevant product information.

1219 For this reason, politicians, officials, the courts, the media and the public place particular reliance on information and the assessment by Swissmedic when it comes to the quality, efficacy and safety of new medicinal products. They attach particular importance to the credibility and truthfulness of the decisions and public communication of this regulatory authority and its representatives.

1220 The people responsible at the regulatory authority were also aware that the marketing authorizations of the mRNA "vaccines" and the associated official information from Swissmedic are relevant for the individual benefit/risk analysis and therefore play a crucial role for Switzerland as a whole.

1221 **Despite this, Swissmedic has continuously, repeatedly and deliberately violated fundamental standards of protection and due diligence under therapeutic products legislation** that serve to protect public health. In particular, it granted a temporary authorization in accordance with Art. 9a TPA despite the absence of all essential requirements - neither formal nor material. The risks and dangers to public health created by this were not

adequately and effectively taken into account in accordance with the high standard of care set out in Art. 3 para. 1 TPA:

1222 Swissmedic has consistently and regularly ignored essential information on the lack of efficacy and safety and concealed it from the public. For example, it has misled the public about the true nature of these authorizations by presenting them on its website as the "world's first authorization in the ordinary procedure" and repeatedly and constantly emphasizing that the substances in question had been tested for efficacy and safety with the conscientiousness required by law and met the strict standards of Art. 1 of the Therapeutic Products Act.

1223 Swissmedic has consistently suppressed, concealed and obfuscated virtually all significant evidence of lack of efficacy and lack of safety from the public, thereby permanently and repeatedly misleading Swiss politicians and the public about the extent of the actual and imminent risks of the mRNA "vaccines".

1224 At the same time, at no time since the first authorization was granted in December 2020 has Swissmedic effectively ensured that it has itself obtained an accurate picture of the constantly increasing adverse side effects. It has either completely failed to impose effective requirements on manufacturers or has failed to enforce them or to revoke the temporary authorization if the requirements are not met. Nor has it ensured that adverse drug reactions are recorded effectively and as promptly as possible and that they are published (active market surveillance or pharmacovigilance).

1225 With the repeated, repeated and serious violations of the most fundamental duties of care under therapeutic products law and standards for the protection of public health (illegal "pandemic approvals" [front N 857 ff.] and their perpetuation [see N 1131 ff.], inadequate risk monitoring [front N 1151 ff.], misleading the public (see N 1187 ff.), Swissmedic is not only in breach of Swiss law, but there is also a **suspicion** that, in view of the ongoing human experiment and the lack of possibility of consent due to the misleading nature of the experiment, a **breach of mandatory international law** - in particular Art. 7 of the UN Covenant on Civil and Political Rights - has occurred (see N 1211 et seq.). This stipulates that **no one may be subjected to medical or scientific experiments without their voluntary consent - not even in "emergency situations".**

XII. Medical malpractice - "vaccination" without sufficient information

1226 Front (N 84 ff.), the facts concerning the private plaintiff have already been presented in brief.

1227 The detailed facts and the corresponding actions of the medical profession (and also of Swissmedic) in specific relation to the private plaintiffs are set out in Annex **3** (**"List and documentation of private plaintiffs"),** which is attached to this criminal complaint and still needs to be supplemented and expanded.

1. Classification of COVID "vaccines": Medicinal products category B

1228 When deciding on the authorization application, Swissmedic assigns the medicinal product to a dispensing category (Art. 40 para. 1 TPO). According to Swissmedic's list of "Temporarily authorized human medicinal products for life-threatening diseases"[265] , all mRNA "vaccines" are assigned to the "dispensing category medicinal products" B. According to Art. 42 TPO, a medicinal product is assigned to the **category of prescription-only medicinal products (dispensing category B) if,** among other things, it is recommended for the treatment of diseases for which a **medical diagnosis or monitoring** is required (lit. a), it contains active substances or preparations of active substances whose effects and undesirable effects still need to be researched in more detail (lit. d) and its dispensing requires **specialist advice from** a medical professional (lit. f).

1229 Pursuant to Art. 24 TPA (as implemented by the Federal Council in Art. 45 TPO), exceptions to the medical prescription requirement are also provided for, which means that **pharmacists** can also dispense certain human medicinal products in dispensing category B.[266] The mRNA "vaccines" do not appear to meet the requirements set out in Art. 45 VAM. Accordingly, the canton of Zurich, for example, has explicitly regulated in Section 24 para. 3 lit. e MedBV (LS 811.11) as of February 17, 2021 that pharmacists with the approval of the Health Directorate may administer "vaccinations against COVID-19" to persons aged 16 and over without a doctor's prescription. Of course, this delegation to pharmacists does not exempt them from complying with the aforementioned other requirements (diagnosis, monitoring, specialist advice) that are placed on category B prescription-only medicines.

2. Lack of information, missing and inadequate forms

1230 The legal requirements for information and consent are set out below (N 1322 ff. and N 1589 ff.) are discussed in detail. At this point, it should be noted that, according to the current state of knowledge, the documentation of the "vaccination acts" concerning the private claimant is extremely incomplete: there are **hardly any information and consent forms**

265 Swissmedic, "Temporarily authorized human medicinal products for life-threatening diseases", 31.05.2022, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/internetlisten/befristete_ham.xlsx.download.xlsx/Befristet_zugelassene_Arzneimittel%20HAM.xlsx.

266 On this innovation, see BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 24 N 14a f.

(see "Documentation of the private claimant" [Exhibit **3**]). It is also unknown whether the Swiss authorities had provided the relevant forms.

1231 Information and consent forms would obviously have been available: At the request of a citizen, the Federal Republic of Germany released "all e-mail and correspondence with representatives of BioNTech, including companies commissioned by BioNTech, such as consulting firms or foundations".[267] Many documents were (once again) blacked out, but among the more than 200 files released, there were also some whose contents were fully visible - such as an "Anamnesis consent form" and a two-page "Information sheet on vaccination against COVID-19 (Corona Virus Disease 2019) - with mRNA vaccine".[268] However, it is not known whether these forms were used at all in Germany. Furthermore, at least these forms (as of December 2020) do not in any way satisfy the requirement for full information, as key information (such as the completely inadequate study situation) is once again concealed and the mRNA injections are presented in an absolutely euphemistic manner (e.g. "mostly mild or moderate" "vaccination reactions").

1232 However, even if standardized forms that fully meet the requirements for comprehensive information had been used (see also N 1235 f.): They can never replace the individual consultation (see below N 1324 et seq.).

3. Case groups

1233 In the following, the private plaintiffs are assigned to individual case groups on the basis of the information in the "Private plaintiff documentation":

3.1. Case group 1: Cursory information, contraindications not taken into account

3.1.1. "Vaccination" by general practitioners (and in individual vaccination centers)

1234 Insofar as the private plaintiffs received the mRNA injections from their **general practitioners** (and at most in individual vaccination centers), there is at least minimal documentation

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267 Federal Ministry of Health, reply regarding "Correspondence with BioNTech" dated 25.04.2022, https://fragdenstaat.de/anfrage/briefverkehr-mit-biontech/#nachricht-692047.

268 Federal Ministry of Health, 026_AW_Aufklärungsbögen_finale_Version_Redacted_geschw.pdf, 08.02.2023, *https://fragdenstaat.de/anfrage/briefverkehr-mit-biontech/#nachricht-771058;* Federal Ministry of Health, 026a-covid-19-aufklaerung-2020-12-09-002, 08.02.2023, *https://fragdenstaat.de/anfrage/briefverkehr-mit-biontech/#nachricht-771058*; Federal Ministry of Health, 026b-covid-19-hinweise-zur-aufklaerung-2020-12-09-002, 08.02.2023, *https://fragdenstaat.de/anfrage/briefverkehr-mit-biontech/#nachricht-771058;* Federal Ministry of Health, 026c-covid-19-impfeinwilligung-anamnese-2020-12-09-002, 08.02.2023, https://fragdenstaat.de/anfrage/briefverkehr-mit-biontech/#nachricht-771058.

available of a brief - approximately five-minute - explanation (written information and declaration of consent).

1235 **However, none of the private plaintiffs was - to the best of our current knowledge - sufficiently informed about**

- that without a COVID "vaccination" their health is in no way significantly at risk due to SARS-CoV-2, and that there were and are perfectly valid alternatives for the prevention and treatment of serious illness due to infection with SARS-CoV-2,
- that the authorizations of the COVID-19 "vaccines" are by no means ordinary authorizations within the meaning of Art. 9, 10, 11 and 16 TPA, but only so-called "temporary authorizations" within the meaning of Art. 9a TPA,
- that these approvals were granted on the basis of **incomplete clinical data** according to the information for healthcare professionals and patients,
- that there was a limited ("unblinded") study population and a massively shortened study duration,
- that due to the complete lack of long-term studies, not all risks and side effects were known and are still not known,
- that it is therefore an experimental "vaccine" which is still in the test phase of human trials (clinical phase III trials).

1236 This important information alone (see N 1322 ff.) concern essential risk factors and are simply indispensable for a free decision on vaccination. Without this knowledge and individual consideration, any consent is based on an error of fact.

1237 The following private plaintiffs generally fall into this group - subject to completion of the "private plaintiff documentation":

- Private plaintiff 1,
- (Private plaintiff 3),
- Private plaintiff 6.

3.1.2. "Vaccination" by pharmacists

1238 As explained above, "COVID vaccinations" could apparently also be carried out by pharmacists in accordance with cantonal regulations - in **compliance with all requirements (in particular diagnosis, monitoring, specialist advice) that are placed on category B prescription-only medicines.** In a corresponding leaflet "Vaccination in pharmacies"[269] , the

[269] Canton of Zurich, Cantonal Medicines Control, leaflet "Vaccination in pharmacies - target group: public pharmacies", as of March 1, 2021, https://www.zh.ch/content/dam/zhweb/bilder-dokumente/themen/gesundheit/gesundheitsberufe/pharmazie/MKB_40708_Impfen_in_Apotheken_D.pdf

Cantonal Therapeutic Products Control of the Canton of Zurich also states that questionnaires are provided to clarify the necessity of the "vaccination", which are to be filed in **patient documentation. In** addition, section 4.5 "Patient **consent**" expressly states this:

> "Consent is understood to mean the agreement given by the patient that they wish to be vaccinated in the pharmacy.
>
> Consent is lawful if the following conditions are met:
>
> a. The patient is capable of judgment.
>
> b. The patient has **been fully informed** about:
>
> - Type or effect of the vaccination, number of injections as well as advantages and disadvantages of a vaccination (e.g. side effects or tolerance)
>
> - Alternatives to vaccination (natural diseases, drug treatment)
>
> - Procedure in the event of side effects
>
> - Costs of the vaccination (assumption of costs, amount)
>
> To safeguard the pharmacist, it is advisable to confirm this consent by means of a signature."

1239 In this absolutely minimal "clarification" - should this actually have taken place - there is therefore no reference to the fact that the mRNA "vaccines" were only approved on the basis of **incomplete clinical data** and are still at the human trial stage.

1240 This group currently does not include any private plaintiffs - subject to error and completion of the "private plaintiff documentation".

3.2. Case group 2: Absence of any vaccination history

1241 Insofar as the private plaintiffs received the mRNA injections in **"vaccination centers", it** should be noted that in most cases there is no documentation of any kind regarding the vaccination history. There is not even any evidence that information was provided, let alone a declaration of consent. Individual vaccination centers were only able to provide mere "vaccination documentation" that only commented on the injection dates and the mRNA "vaccines" administered.

1242 The following private plaintiffs generally fall into this group - subject to completion of the "private plaintiff documentation":

- Private plaintiff 2,

- (Private plaintiff 3),
- Private plaintiff 4,
- Private plaintiff 5.

4. Insel Gruppe: Misleading information

1243 To make matters worse, in addition to the usually completely inadequate information, misleading false information is being spread. For example, the Insel Gruppe is still spreading "facts about COVID vaccination" on its website under "Every vaccination counts"[270] in a six-page brochure in June 2022,[271] which - as explained in detail above - have long been refuted:

1244 Under #2 "Fertility" is stated without any evidence:

> "Vaccination has no effect on fertility. [...] The vaccination also has no influence on the future development of the placenta or the course of a future pregnancy."

1245 Under #3 "Long-term safety of vaccines", despite all the serious side effects that have already occurred, including death:

> "Late effects of mRNA vaccines are not to be expected. [...] Experience has shown that serious adverse vaccination reactions are very rare and have historically occurred within one to two months after vaccination. This period has already been carefully checked in the authorization studies. [...] Any side effects are carefully analyzed and reviewed. No long-term effects are known to date."

1246 Under #6 "Risk vs. benefit of vaccination:" is again presented in complete denial of thousands of death reports and millions of reported side effects:

> "The benefits of vaccination massively outweigh the potential risks. [...] If severe side effects were to occur, this would be known by now with such a high number of vaccinated people. [...] The mRNA vaccines offer robust protection against both severe disease progression and long-term consequences."

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270 Insel Gruppe, "Every vaccination counts", 05.04.2022, 15.06.2022, 20.06.2022, 27.06.2022, https://www.insel.ch/de/patienten-und-besucher/coronavirus/covid-impfzentrum-auf-dem-inselcampus.

271 Insel Gruppe, "Facts about the COVID vaccination", 09.09.2021, https://www.insel.ch/fileadmin/Inselspital/Bilder/Patienten_und_Besucher/Corona/Fakten_COVID-Impfung_Insel_Gruppe.pdf.

1247 Further statements under #1 "DNA" ("Our genes are not changed by the mRNA vaccine"), #4 "Speed of development of the vaccine" and #5 "Virus variants" also lack any critical appraisal of the mRNA "vaccines" and contain only euphemistic and trivializing "facts".

C. LEGAL ASSESSMENT

1248 In the first section of the following examination, the penal provisions of the TPA are presented first: First, the abstract and concrete endangering offenses of Art. 86 TPA concerning the authorization of therapeutic products, followed by the offense of Art. 87 TPA concerning the supervision of therapeutic products. This is followed in the second section by the dangerous offenses of the SCC and finally in the third section by the (more serious) penal provisions of the SCC, all of which are designed as successful offenses. The fourth section then deals with the punishable preparatory acts.

I. Penal provisions HMG

1249 The penal sanctions of Chapter 8 of the TPA serve to realize the central concerns of protecting human (and animal) health and protecting against deception.[272] Among other things, they are intended to ensure that only high-quality, safe and effective therapeutic products are placed on the market (Art. 1 para. 1 TPA).[273]

1250 The dispatch explains Swissmedic's key role in the areas of authorization, placing on the market and subsequent market surveillance of therapeutic products:

> "In order to ensure that only high-quality, safe and effective therapeutic products are placed on the market, it is essential to have an efficient, independent and binding therapeutic product control system for the whole of Switzerland."[274]
>
> "With the creation of a Swiss Institute of Therapeutic Products, the existing forces with their knowledge and experience are to be effectively bundled. [...]. The Institute is primarily responsible for the authorization and manufacturing authorization of medicinal products and, in cooperation with the cantons, for the subsequent market surveillance of therapeutic products."[275]

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272 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, before chapter 8 N 16.

273 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., 3456 f.

274 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3484.

275 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3467.

> "However, safe use also means ensuring that, as far as possible, no harm is caused by therapeutic products. This is achieved by evaluating the risk-benefit ratio at the time of authorization, the dosage instructions and information on undesirable interactions with other medicinal products or foods or in the case of certain genetic dispositions. Information on adverse effects also indicates in which cases medicinal products should not be used or should be used with particular caution."[276]

1. Breach of the duty of care (Art. 86 para. 1 lit. a TPA)

1.1. Misdemeanors and crimes against the HMG

1.1.1. Basic offense: Abstract endangerment (misdemeanor)

1251 According to Art. 86 para. 1 lit. a TPA, anyone who intentionally **manufactures, places** on the market, **uses,** prescribes, imports, exports or trades abroad in medicinal products without the required authorization or licence, contrary to the requirements and conditions attached to an authorization or licence or **contrary to the duties of care laid down in Articles 3, 7**, 21, 22, **26**, 29 and 42 is liable to a custodial sentence not exceeding three years or a monetary penalty.

1.1.2. Qualification: Concrete danger (crime)

1252 According to Art. 86 para. 2 lit. a TPA, anyone who knows or must assume that conduct contrary to the duty of care within the meaning of Art. 1 para. 1 lit. a TPA **poses a specific risk to** human health is liable to a custodial sentence not exceeding ten years, which may be combined with a monetary penalty, or to a monetary penalty.

1.2. Objective basic facts (Art. 86 para. 1 lit. a TPA)

1253 As far as **Swissmedic** is concerned, the alternative offense of **manufacturing** in violation of the duties of care stipulated in Art. 3 TPA and Art. 7 TPA must be examined in particular.

1254 With regard to **the medical profession,** the offense variant of **use** in violation of the duty of care stipulated in Art. 26 TPA is examined in particular.

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276 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3484.

1.2.1. Object of the crime: Pharmaceuticals

1255 Medicinal products are products of chemical or biological origin that are intended or advertised to have a medicinal effect on the human organism, in particular for the prevention or treatment of diseases (Art. 4 para. 1 lit. a TPA). Medicinal products must be "ready for use", which also includes, for example, freeze-dried products that must be dissolved with a solvent immediately before administration.[277] The two elements of "being advertised" and "being intended" are in tension. Because the public interest in protecting the health of patients and consumers of medicinal products is of great importance, the objective intended purpose is primarily decisive for the legal nature of a product. A purely subjective approach based solely on the supplier's advertising would not meet the requirements of therapeutic products legislation.[278]

1256 Swissmedic and the manufacturers promoted the mRNA preparations in question as alleged "vaccines". "Vaccines" are defined as medicinal products "used to produce active or passive immunity" (Art. 2 lit. b AMBV).[279] As previously (N 1097), the mRNA preparations do not immunize. The subjective intended purpose of the manufacturers and Swissmedic is therefore clearly incorrect. Rather, the mRNA preparations are to be classified as gene therapy medicinal products (possibly even as GMOs) due to their mode of action (see above N 191 ff.; see also N 916 ff., N 999 ff.). However, as such they also fall under the definition of medicinal products (see, for example, Art. 12 para. 5 lit. e TPLO: "gene therapy medicinal products" as "medicinal products with known active substances"). As ready-to-use products with a medical effect on the human organism, mRNA injections therefore constitute medicinal products within the meaning of the TPA.

1.2.2. Swissmedic: "Manufacture of " as an offense variant

1257 The punishable acts are described in Art. 86 para. 1 lit. a TPA, whereby the "manufacture" variant of the offence is of particular interest to Swissmedic:

1.2.2.1 Concerning batches produced in Switzerland (Moderna: Spikevax)

1258 Manufacturing" is defined as "all operations involved in the production of therapeutic products, from the procurement of starting materials to processing, packaging, storage and delivery of the end product, as well as quality control and release" (Art. 4 para. 1 lit. c TPA).

277 EGGENBERGER/KESSELRING, BSK HMG, 2nd ed., Basel 2022, Art. 4 N 8 ff. on the definition of a medicinal product in detail.

278 EGGENBERGER/KESSELRING, BSK HMG, 2nd ed., Basel 2022, Art. 4 N 19.

279 See also EGGENBERGER/KESSELRING, BSK HMG, 2nd ed., Basel 2022, Art. 4 N 22 with specific reference to vaccinations as medicinal products.

This also includes **batch release.**[280] According to the Federal Supreme Court, it is **part of the manufacturing process:**[281] "La libération des lots fait partie du processus de fabrication".[282] If the manufacture of a medicinal product requires special measures, in particular to ensure safety - protection of the legal interest of health -,[283] a release must be obtained from the Swiss Agency for Therapeutic Products for each batch prior to distribution in accordance with Art. 17 TPA. According to Art. 18 para. 1 lit. b of the Ordinance of the Swiss Agency for Therapeutic Products on the Requirements for the Authorization of Medicinal Products (Ordinance on the Authorization of Medicinal Products, AMZV; SR 812.212.22), "vaccines" are subject to batch release. The assessment of a batch is usually carried out by the Swissmedic testing laboratory (the Official Medicines Control Laboratory [OMCL]) within 30 days of submission of the manufacturer's batch documentation and the samples by the marketing authorization holder.[284] If the quality requirements are met, Swissmedic (or its OMCL test laboratory) issues the batch release and issues a certificate to the marketing authorization holder (Art. 21 para. 1 TPLRO).[285]

1259 As before (N 321 f.), at least the mRNA active ingredient Spikevax was manufactured in Switzerland by Moderna. **Swissmedic is responsible for the release of the vaccine batches manufactured in Switzerland, has obviously also issued the corresponding releases and is still issuing them. The competent persons acting on behalf of Swissmedic thus fulfill the offence of "manufacturing" within the meaning of Art. 86 para. 1 lit. a TPA, insofar as the batches of the mRNA "vaccine" manufactured in Switzerland by Spikevax (Moderna) are concerned.**

1260 **Swissmedic was at least obliged to have the quality of the batch samples received from the manufacturer for each (Spikevax) batch checked by the laboratory test center.** Such test reports are not available, at least not publicly. Instead, there is even the suspicion that Swissmedic limited itself to a mere random check (N 321 f.). This alleged procedure is particularly questionable in view of the fact that very large fluctuation ranges in the area of quality and thus, in extreme cases, an **active substance content of just 37% were**

280 For the term "batch", see Art. 2 lit. h TPLRO: "a homogeneous and defined quantity of starting material, medicinal product or packaging material manufactured in one operation or in a series of operations".

281 EGGENBERGER/KESSELRING, BSK HMG, 2nd ed., Basel 2022, Art. 4 N 159.

282 Judgment 2F_17/2019 of the FSC of December 29, 2019, E. 3.2; see also judgment 2C_600/2018 of the FSC of May 13, 2019, E. 11.2.

283 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 10.

284 Swissmedic, Laboratory Division (OMCL) "Official batch release of vaccines and blood products", status 16.06.2021, https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/labor_omcl/23_vz_03_d_behoerdlichechargenfreigabe.pdf.download.pdf/23_vz_03_d_behoerdlichechargenfreigabe.pdf, p. 4; BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 19.

285 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 14 f.

accepted (see above N 226), is simply unacceptable: This massive undercutting of the usual quality criteria entails a massive increase in risk, which was and is to be countered with corresponding additional controls.

1.2.2.2 Concerning imported batches (probably Pfizer: Comirnaty): MRA recognition ?

1261 The production sites of the batches of Comirnaty (Pfizer) destined for Switzerland are not known to the complainants. At least in Switzerland, it appears - error and publication of the batch release protocols (see above N 107 f.) - there does not appear to be one. It can presumably be assumed that Comirnaty is manufactured entirely abroad and imported into Switzerland.

1262 Insofar as the **production** of the imported commercial batches took place **in the EU**, direct batch release by Swissmedic is no longer necessary: According to Art. 17 para. 1 sentence 2 TPA, "international agreements on the recognition of batch releases" are reserved. One such agreement is the bilateral agreement between the Swiss Confederation and the EU/EEA on the mutual recognition of conformity assessments of June 21, 1999 (Agreement on mutual recognition in relation to conformity assessment, "MRA"). This provides for the mutual recognition of official batch release for products manufactured industrially in Switzerland or the EU (Chapter 15 and "Explanatory Notes" to Chapter 15),[286] the so-called MRA recognition procedure.

1263 Accordingly, Swissmedic can also issue the batch release certificate (Art. 21 para. 1 TPLRO) on the basis of a batch release from an EU authority, provided that the industrial production of the product took place in the EU/EEA area (Art. 21 para. 2 TPLRO).[287] This means that for medicinal products that are subject to official batch release in Switzerland and in at least one EU member state and that have already been tested and released by an OMCL of an EU member state, no additional sample test is carried out by the OMCL and the batch release of the EU OMCL is fully recognized if these medicinal products are to be placed on the Swiss market. **According to the agreement, only one notification of the batch is made by the marketing authorization holder to the OMCL.** Within 7 working days of receipt of the necessary documents (notification form [Marketing Information Form, MIF], copy of the EU Batch Release Certificate and, if applicable, a "Certificate of Analysis") by the OMCL, the marketing authorization holder receives confirmation by e-mail that the batch can be distributed in Switzerland. [288]

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286 Agreement between the Swiss Confederation and the European Community on Mutual Recognition in relation to Conformity Assessment (SR 0.946.526.81).

287 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 14b.

288 Swissmedic, Laboratory Division (OMCL) "Official batch release of vaccines and blood products", status 16.06.2021,

1264 **MRA recognition therefore replaces the actual batch test.** However, like batch testing, the MRA recognition procedure is also an essential prerequisite for the authorization of the mRNA "vaccines" to be imported onto the Swiss market. The batch release - or in this case: the MRA recognition - does not replace the authorization of a medicinal product according to Art. 16 ff. TPA.[289] In individual cases, official batch release can also be a condition of an authorization decision.[290] Accordingly, if Swissmedic had sufficient reason to withdraw the authorization granted to Pfizer/BioNTech for Comirnaty in the context of the MRA recognition of a batch, no MRA recognition of the batch should have been granted.

1265 The opposite view would mean that the status of manufacturer would depend randomly on where a medicinal product is produced: If it is produced within Switzerland or outside the EU, Swissmedic is the "manufacturer" - if it is produced within the EU, Swissmedic could attempt to evade responsibility as the manufacturer. This would open the door to circumvention of the safety mechanisms under therapeutic products legislation. For the Swiss market, however, **Swissmedic is the "gatekeeper" stipulated by the legislator: by delegating elementary supervisory and testing duties, such as batch testing, to a foreign authority, Swissmedic cannot absolve itself of its own responsibility.**

1266 **As the final and highest supervisory authority, Swissmedic also remains responsible for the release of vaccine batches not manufactured in Switzerland.** This means that the competent persons acting on behalf of Swissmedic also fulfill the definition of "manufacturing" within the meaning of Art. 86 para. 1 lit. a TPA with regard to Comirnaty (Pfizer/BioNTech).

1.2.3. Swissmedic: "Import" offense variant "

1267 If - contrary to the view expressed here (N 1261 ff.) - the MRA recognition is not to be subsumed under the concept of (batch) release in the sense of the manufacturing concept, the offense variant of "import" must be examined:

1268 The term "import" is not explicitly defined in Art. 4 TPA. Based on Art. 4 para. 2 TPA, the Federal Council has defined importation in Art. 2 lit. m in conjunction with lit. l MPLO as "all [...] activities in connection with the transportation of medicinal products into Switzerland".

1269 The import of medicinal products into Switzerland is subject to authorization, with **Swissmedic issuing the import authorization** (Art. 18 para. 1 lit. a TPA). In principle,

https://www.swissmedic.ch/dam/swissmedic/de/dokumente/bewilligungen/labor_omcl/23_vz_03_d_behoerdlichechargenfreigabe.pdf.download.pdf/23_vz_03_d_behoerdlichechargenfreigabe.pdf, p. 4 f.; BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 11, N 14b, N 29 ff.

289 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 3.

290 BECK / BRAUN, BSK HMG, 2nd ed., Basel 2022, Art. 17 N 3.

Swissmedic issues an importer with an **unlimited authorization** (see, for example, Art. 42 MPLO).[291] However, according to Art. 20 para. 3 lit. a TPA, the Federal Council can stipulate that the import of certain medicinal products that require special control to protect health must be authorized by the Agency **in individual cases.**[292] In Art. 44 TPA, the Federal Council has provided for a principle, an exception and an optional counter-exception with regard to "immunological medicinal products": In principle, an authorization is required for "immunological medicinal products" "for each individual consignment" (Art. 44 para. 1 lit. a MPLO; **individual import authorization).** An exception applies, for example, where "an official batch release from an inspection authority belonging to the OCABR network is available for the batch to be imported" (Art. 44 para. 2 lit. c MPLO). As a counter-exception, Swissmedic "may" require an individual import authorization even if an OCABR batch release is available - **"for the protection of health" (Art.** 44 para. 3 MPLO).

1270 In the letters of authorization to Pfizer (Evidence Report, Supplement 2, p. 8) and Moderna (Evidence Report, Supplement 3, p. 11), Swissmedic issued the following decision:

> "An individual import permit must be applied for for each import into Switzerland (Article 44 para. 2 letter c of the Medicinal Products Licensing Ordinance [MPLO])." (Pfizer)
>
> "For each importation into Switzerland, it must be verified that a request for authorization to import into the unit must be submitted (see art. 44 de l'ordonnance sur les autorizations dans le domaine des médicaments [OA-Méd])." (Moderna; translated: *"For each import into Switzerland, it must be checked whether an application for an individual import authorization must be submitted ([...])."*).

1271 Swissmedic therefore demanded an **individual import authorization** for each imported batch, at least from Pfizer, even if an official batch release (e.g. from the *EMA*) was available. Swissmedic is therefore not only responsible for issuing individual import licenses, but has also explicitly demanded that they be obtained. Its activities are therefore **the central prerequisite for any import of** (immunological) medicinal products into Switzerland. However, the same would also apply if Swissmedic had limited itself to issuing an unlimited authorization: This activity of Swissmedic also represents the basic prerequisite for any import activity of the manufacturers.

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291 STRAUB, BSK HMG, 2nd ed., Basel 2022, Art. 18 N 11 et seq.
292 STRAUB, BSK HMG, 2nd ed., Basel 2022, Art. 18 N 9a.

1272 **The competent persons acting on behalf of Swissmedic thus fulfilled the offence of "importation" within the meaning of Art. 86 para. 1 lit. a TPA, insofar as they had issued import authorizations for batches from the manufacturers Pfizer and Moderna.**

1.2.4. Swissmedic: "Placing on the market" offense variant

1273 If neither of the two offense variants ("manufacture" in front of N 1257 et seq.; "importation" above N 1267 ff.) is deemed relevant, the further offense of "placing on the market" would have to be examined in detail.

1.2.5. Swissmedic: "Duty of care according to Art. 3 and Art. 7 TPA" offense variant

1274 The duties of care subject to criminal prosecution are also described in Art. 86 para. 1 lit. a TPA, whereby the duties of care under Art. 3 TPA (general duty of care) and Art. 7 TPA (duty of care during manufacture) are of primary interest to Swissmedic. In principle, the duties of care contained in the implementing provisions issued on the basis of the TPA are also covered. Those **duties that aim to prevent risks to human health** are subject to criminal sanctions.[293] In principle, anyone can be a perpetrator; even **merely limited actions (division of labor) are sufficient** as contributions to the offense and are to be considered criminal.[294] However, if specific duties (of care) are involved, only the bearers of these duties can be considered perpetrators.[295] Duties of care are breached if they are not fulfilled **in full and on time.**[296]

1.2.5.1 Art. 3 TPA - (General) duty of care

1275 Anyone handling therapeutic products must take all measures that are necessary according to the state of the art in science and technology to ensure that human and animal health is not endangered (Art. 3 para. 1 TPA).

1276 The addressees of the general duty of care include, in particular, authorities such as Swissmedic as the licensing and supervisory authority.[297]

1277 Art. 3 TPA is the general duty of care standard. The general clause of Art. 3 TPA only applies if (1) a duty of care required by the current state of science and technology has been breached when handling a therapeutic product (2) and (3) the health of a person has been endangered in concrete or abstract terms as a result, i.e. with adequate causation.[298] A

293 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 27.
294 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 84, N 86.
295 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 86.
296 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 29.
297 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 37b.
298 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 59a/60.

breach of the required or conceivable duty of care is - similar to the application of the hazard rate[299] - not to be assumed lightly. For example, it is not sufficient for a lack of care to be inferred from the mere fact that a health hazard has actually occurred.[300]

1278 The use of therapeutic products should **not pose a risk to** human **health**, which is already clear from Art. 1 TPA.[301] Safety is at the heart of this: this is not only the aim of Art. 1 and 3 TPA, but is also declared an explicit authorization requirement for medicinal products in Art. 3 para. 1 TPA.[302] Absolute safety cannot be achieved and therefore cannot be demanded.[303] However, due consideration must be given to all the circumstances of the specific case: if a hazard potentially affects a very large group of people (entire population), if this hazard lasts for several years and if the potential risk to health associated with the action to be assessed (authorization decision; information to the public; passive pharmacovigilance, etc.) must be taken into account.If the potential risk to health (e.g. for children and adolescents) associated with the action to be assessed is considerable in individual cases (e.g. increase in rare diseases), a stricter standard of due diligence must be applied to the actions of the responsible highest supervisory authority due to the danger created than in the case of actions that only affect a few people, only take place over a short period of time and which themselves remain trivial in individual cases.

1279 Accordingly, there is an **obligation to minimize risk** when handling therapeutic products, which requires that appropriate risk analyses are carried out.[304] The **risk profile of a therapeutic product must therefore** be **reviewed on an ongoing basis.** This must be done by systematically weighing up and assessing the risks and benefits of a therapeutic product. The efficacy must be set in relation to the risks and undesirable effects, whereby in individual cases the **benefits must outweigh the disadvantages.**[305] Only if this assessment results in an **acceptable risk** of the therapeutic product may it be **described as "safe"** in the sense of the TPA.[306] As long as the benefits outweigh the risks in the individual case, a risk to health is acceptable and does not constitute a breach of due diligence.[307]

1280 The core of the risk analysis required under Art. 3 TPA is therefore the **regular, systematic, forward-looking search for hazards.**[308] This means that the requirements for the duty of

299 To this rear N 1506 ff.
300 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 74.
301 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 13.
302 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 14.
303 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 14.
304 Message on a Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA) of June 1, 1999, BBl 1999 III 3453 ff., p. 3487.
305 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 17, cf. also N 24.
306 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 18.
307 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 24.
308 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 56 f.

care are based on the **current** state of science and technology and not on the state at the time the medicinal product was first authorized.[309] The current **findings of theoretical science** and current **practical experience must be taken into account.**[310] **This also means that this search for risks must be actively pursued**. Swissmedic must therefore not wait until other government bodies or a manufacturer or another authorization authority abroad approaches Swissmedic and presents it with evidence of an overriding risk. Such behavior would already be a serious breach of duty under therapeutic products legislation because Swissmedic has been appointed as the highest professional supervisory authority for the enforcement of the principles and duties of care defined in the TPA, and because its professional judgment and public communication form the basis for political decisions by the Federal Council, the Federal Office of Public Health, for information by the media, for the educational work of doctors, and ultimately for the vaccination decision of each individual person.

1281 In view of its far-reaching statutory responsibility for public health, Swissmedic must therefore - in line with the principle of proportionality - take all measures necessary to protect public health in a proactive and above all impact-oriented manner in order to avoid a risk to health.[311] In particular, this also means that information on undesirable side effects must be provided **transparently** in the information for healthcare professionals (Art. 13 and Annex 4 TPLRO) and patients (Art. 14 and Annex 5 TPLRO).[312] If this is not done, the justified safety expectations of the public (politicians, media, doctors and especially patients) will be violated on a large scale and **existing risks** concealed. [313]

1282 **However, if essential information on the lack of efficacy or safety of mRNA "vaccinations" is withheld from the public or not communicated with the necessary clarity, each** individual benefit/risk assessment **based on this erroneous information** and ultimately the resulting and each **individual consent to "vaccination" must be considered invalid** if it would have been refused with full knowledge of all the facts.[314]

1283 The standard of due diligence for medicinal product information is specified in more detail in Art. 28 TPO, among other things, in concretization of the general duty of due diligence in Art. 3 TPA: According to this, the marketing authorization holder is obliged to adapt the **medicinal product information to the current state of science and technology as well as new events** and assessments on an ongoing basis and without being requested to do

309 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 42.
310 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 43.
311 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 50 ff.
312 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 14.
313 Cf. JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 54 f.
314 For details on information and consent, see N 1322 ff. and N 1589 ff.

so.[315] If, for example, the risk assessment has changed after market authorization, this must lead to an amendment of the medicinal product information: Under normal circumstances - i.e. for duly authorized medicinal products - in Switzerland and the EU, for example, the inclusion of newly discovered adverse drug reactions is mandatory if a causal relationship between the administration of the medicinal product and the adverse drug reaction can at least reasonably be assumed ("Adverse Drug Reaction" [ADR]).[316] The **requirement of a presumption of causality** makes perfect sense in the area of duly authorized or simplified authorized medicinal products, as these have been tested on humans for many years and many side effects could already be determined prior to authorization. However, the situation is completely different in the case of the **mRNA "vaccines" approved for a limited period of time** on a completely inadequate database and in the complete absence of long-term human trials: **The search could essentially only begin after approval. Under these circumstances, the precautionary principle dictates that all side effects that have occurred must be strictly recorded and reported to the public**.

1284 The limit to what is at best just permissible passivity in the area of recording and publishing side effects is exceeded at the very latest where **there is a risk of misleading the public:** If experience, findings and assessments in practical implementation show, for example, that a statement in a medicinal product information is misunderstood by experts, the marketing authorization holder must **immediately ensure,** together with the **Institute,** that clarity is created by **eliminating** the **risk of misleading information by making the necessary clarifications**.[317] The same applies a fortiori to objective misinformation.

1.2.5.2 Art. 7 (Requirements for manufacture)

1285 Art. 86 para. 1 lit. a TPA explicitly refers to Art. 7 TPA. In Art. 7 para. 1 TPA and Art. 4 of the Medicinal Products Licensing Ordinance (MPLO), the general standard of care for the **manufacture of a medicinal product is** specified in more detail.[318] According to Art. 7 para. 1 TPA, medicinal products and pharmaceutical excipients whose manufacture requires authorization must be manufactured in accordance with the recognized rules of good manufacturing practice (Art. 7 para. 1 TPA).

1286 The legislator therefore refrains from regulating this special area and restricts itself to declaring technical standards to be legally binding.[319] The rules of good manufacturing practice are accordingly specified at ordinance level (AMBV) with reference to the European

315 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 11.
316 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 10.
317 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 65, Art. 32 N 35.
318 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 61.
319 JAISLI/SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 48.

directives. Despite these further references, the Federal Supreme Court assumes that the **TPA thus satisfies the requirement of certainty**.[320] In view of the group of addressees of the TPA - qualified persons from the therapeutic products sector - the doctrine also assumes that the requirement of certainty has been satisfied. This is particularly true in view of the fact that "the complexity of the regulation of therapeutic products is due to the complexity of the subject matter and that there are no reasonable alternatives to the currently practiced method of graduated legislation in the area of therapeutic products".[321]

1287 The rules of good manufacturing practice contain regulations that must be guaranteed throughout the entire manufacturing process and can basically be divided into nine categories: **Quality assurance system,** sufficient and qualified personnel, suitable premises and equipment, documentation obligation, clearly defined production processes, independent **quality control,** clear contract design, complaint and recall system, self-inspection.[322] Although these rules formally relate primarily to **quality**, according to the Federal Supreme Court, the other mandatory elements of **safety and efficacy** required by Art. 1 TPA must of course also be guaranteed at all times.[323]

1288 The elements of quality assurance and quality control mentioned above should be emphasized here in particular: the manufacturer must effectively ensure that the medicinal products are of the quality (as well as safety and efficacy) required for use.[324] This includes minimizing the risk of errors in order to **avoid impurities**, cross-contamination and, in general, effects that impair the quality of the product.[325] As part of **quality control, it** must be ensured that the necessary tests are carried out - for example as part of the **release procedure** - and that **no products are released for delivery until their quality (and safety and efficacy) has been assessed as satisfactory. Samples of each batch** of a starting material or finished product must be **kept for** a certain period of time.[326] Swissmedic therefore plays a key role in quality control within the scope of batch release: without its approval, the products cannot be placed on the market (for batch release, see also N 1258).

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320 Judgment 6B_600/2020 of the Federal Supreme Court of 07.09.2020, E. 5.6.
321 SUTER/PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 17.
322 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 5 ff.
323 Judgment 2C_424/2018 of the BGer of 05.03.2019, E. 3.3., E. 3.5.1; see DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 5.
324 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 6.
325 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 8 with reference to judgment 2A.156/2004 of the BGer of 25.03.2004, E. 2.2, and judgment C-3214/2009 of the BVGer of 10.06.2010.
326 DUPASQUIER/BOEHM, BSK HMG, 2nd ed., Basel 2022, Art. 7 N 11.

1.2.6. Swissmedic: Duty of care under therapeutic products legislation repeatedly violated

1289 According to Art. 3 TPA and Art. 7 TPA, Swissmedic is therefore obliged to review the risk-benefit profile for each authorization of mRNA "vaccines" and the batch releases issued on this basis as part of the manufacturing process on an ongoing, comprehensive and timely basis. Swissmedic is **required to carry out regular, systematic and forward-looking risk assessments.** The benefit of the "vaccines" must always outweigh the risk taken, whereby there is a mandatory obligation to minimize the risk. For each batch release, it must therefore be ensured that at least the quality and safety requirements are met - and that the medicinal product is also ideally effective. In addition, Swissmedic is **required to provide the public with transparent information at all times, in particular on side effects and contraindications, in accordance with the current state of theoretical science and practical experience;** misleading reports must be removed and clarified immediately.

1290 Swissmedic has breached each of these duties of care under Art. 3 and 7 TPA:

1.2.6.1 Breaches of duty for first-time adult registrations (end of 2020)

1291 At the end of 2020 and the beginning of 2021, Swissmedic granted "temporary" authorization for Comirnaty and Spikevax for all adults aged 18 and over ("first and second vaccinations") in a fast-track procedure: The applications for approval were "reviewed" **in just 63 calendar days**. An ordinary procedure would take 330 days, a procedure for "temporary approval" would usually take 140 days, **whereby all possible safety mechanisms** ("list of questions", omission of elementary studies on quality and safety) were **omitted in a maximum deviation from an ordinary approval procedure** (see N 992 ff.). Swissmedic did so even though the following **risk-increasing and therefore legally relevant facts** were already known or should have been known beyond reasonable doubt to the licensing authority at the time, namely:

- that the technology in question was a novel mRNA technology, also known as **gene therapy**, which until now had only been used in individual cases in cancer patients, i.e. only in people with severe previous illnesses and only on a trial basis; even in the context of such use, no relevant efficacy had been demonstrated to date, and to date no pharmaceutical product with mRNA technology had ever received marketing authorization for purely prophylactic use in healthy population groups (see N 186 ff.),
- that to date the suspicion that this drug could even be a **genetically modified organism** has by no means been sufficiently dispelled (see N 200 ff.), which is why this medicinal

product should never have been authorized under a "temporary authorization" (see N 926 ff., N 999 f.),

- that mRNA "vaccines" for healthy individuals therefore represented an absolute **abnormality** in comparison to all other drugs that had previously been authorized on a regular or "temporary" basis (front N 966 ff., in particular N 995 ff.),
- that this medicinal product is **not a vaccination in the conventional sense** due to the lack of evidence of an immunizing effect and should therefore never have been sold to the public as a COVID-19 "vaccination" (see N 498 ff., N 693 ff., N 1097 f., N 1256),
- that the **dose-finding studies** for Spikevax were carried out **inadequately and** thus a **much too high mRNA dose** was **approved**, particularly for adolescents (front N 208 ff.),
- that the present new mRNA technology is characterized by the fact that the production process of the actual active substance (the spike protein) is transferred to the human body, whereby **this active substance would not be produced itself without this intervention and no sufficient empirical data were available which made this endogenous production of the spike protein and its novel mode of action in the body appear to be controllable** with regard to: (1) duration of production (2) location of production in the body (affected organs); (3) quality; (4) quantity of production and with regard to (5) the efficacy and safety of the active substance produced for the purely prophylactically treated and otherwise healthy population (front N 272 ff., N 391 ff.; see also N 191 et seq.),
- that due to the lack of controllability of dosage and quality of this drug and due to the lack of sufficient evidence of a significant protective effect against infection with SARS-CoV-2, the most essential requirements for a general marketing authorization for the prevention of a healthy population were obviously not fulfilled, neither for a proper (see N 862 ff., in particular N 1065) nor for a "temporary authorization" (above N 963 ff., N 992 ff., in particular N 1068 et seq.),
- that the mRNA "vaccines" with the **toxic lipid nanoparticles** (LNP) contain new, as yet untested ingredients that have not been approved in humans and are potentially carcinogenic **according to the manufacturer's description** (and EMA), presumably impair fertility and can damage the unborn child - and damage the central nervous system, kidneys, liver and respiratory system with prolonged or repeated exposure, whereby a small number of **animal studies** conducted prior to market approval **confirmed the considerable potential for damage** (see N 212 ff.),
- that the release specifications, with a minimum required active ingredient content of just 37%, deviated drastically from all previously established rules, which meant that the **quality of the drugs** could **not be guaranteed in any way**, with the correspondingly

high proportion of **non-intact mRNA** harboring a considerable risk of **genotoxicity and carcinogenicity** (front N 225 ff.),

- that the mRNA "vaccines" with nitrosamine, benzene and bacterial DNA contained **toxic, mutagenic and carcinogenic impurities** (see N 231 ff.), which means that there is also an urgent suspicion of **non-GMP-compliant production**, i.e. the **quality** (Module 3: including purity) of the "vaccines" is already **inadequate** (front N 870 ff.),
- that despite the unresolved suspicion of the presence of a genetically modified organism and the reported toxic properties of LNP, **no animal studies on genotoxicity and carcinogenicity** had been carried out (see for example above N 217, N 222 and N 223; cf. also re. mRNA N 229),
- that preclinical studies (animal studies) had identified a **possible risk in pregnancies** (twofold increase in preimplantation losses, malformations), which is why the *Human Medicines Experts Committee (HMEC)* commissioned by Swissmedic urgently advised at the end of 2020 to explicitly list "pregnancy" under **"precautions"** in the product information (see N 235 ff.), but Swissmedic subsequently failed to do so,
- that the animal studies were not carried out "GLP-compliant" and that in the few animal studies on pharmacokinetics - which were terminated far too early - a **worrying accumulation of toxic lipid nanoparticles (LNP)** in the liver, spleen and other organs such as the ovaries was found (front N 251 ff., N 258 ff.),
- that marketing authorizations for novel medicinal products are normally only granted on the basis of clinical trials with an observation period of 24 months, but that the study participants in the mRNA "vaccines" were observed for only **two months** in the clinical approval studies (see N 247 ff.; on the proper development of a medicinal product, see N 863 et seq.),
- that the production of the spike protein in the human body had apparently never been adequately investigated in any clinical manufacturer's study with regard to the quality, duration and location of the production of the allegedly immunizing protein, despite the explicit requirement of the HMEC (front N 272 ff.),
- that clear risk signals such as **indications of increased morbidity in the "vaccination group" were** already present in the clinical approval studies (front N 278 ff.),
- that these very same **clinical approval studies** had been "unblinded" by the manufacturers **by removing the control groups**, thus de facto terminated and therefore **sabotaged** themselves (see N 275 ff.), which made it highly unlikely - if not downright impossible by the manufacturer - that useful and complete data would ever be available in the absence of a control group, which would be a mandatory prerequisite for a temporary authorization (see N 1122 ff.),

- that the studies submitted by the manufacturers (both animal and human studies) were completely inadequate in terms of quality and quantity to provide sufficient evidence of a significant protective effect and safety (front N 250 ff., N 269 ff.),
- that there were already indications of possible **late effects such as blood diseases, neurodegenerative diseases or autoimmune diseases** (in particular ADE) at the end of 2020 and that these could not be refuted even by means of completely inadequate animal studies (front N 242 ff., N 290 ff.),
- that **Moderna's** proprietary **pharmacovigilance system (PVS)** had proven to be **completely unsuitable** for monitoring drug safety (front N 284 ff.),
- that against the background of the facts listed above, the release of the mRNA "vaccines" for the entire population by means of "temporary" authorization within the meaning of Art. 9a TPA in December 2020 meant nothing other than that the Swiss population was participating without its knowledge in **the** largest clinical experiment **ever conducted in Switzerland** (and at the same time worldwide) (see N 292 ff.).

1292 At the same time, it was already clear at the end of 2020 that **"COVID-19" never posed a "life-threatening or disabling" disease** or threat to the general public as a whole, which would have been *the first* main prerequisite for "temporary approval". Even at the end of 2020, COVID-19 was clearly no more dangerous than influenza, there was no historically conspicuous excess mortality in relation to the overall population and hospitals were never overcrowded throughout Switzerland (front N 752 ff.). Swissmedic therefore authorized a highly experimental and dangerous medicinal product for a disease that did not pose a significant threat to the population as a whole (with the exception of the elderly population).

1293 The only last "lifeline" left for Swissmedic was to prove that a **"major therapeutic benefit"** for protection against SARS-CoV-2 could have been expected, at least for the very small population group of elderly *and* previously ill people. But even this was clearly not the case at the end of December 2020,

- especially since the "vaccinations" should protect against serious (fatal or disabling) diseases - but the (still ongoing, but sabotaged) approval studies primarily investigated whether the "vaccinations" protect against headaches and other minor events in combination with a positive PCR test result (front N 297 f.),
- especially since the reported effectiveness figures of up to 100% only related to **minor events** and were based on calculations that in no way reflect reality, which is why - if at all - an **effectiveness in the low single-digit percentage range** was to be assumed (see N 299 et seq.),

- especially since even the FDA had announced in June 2020 that it would accept an extremely low efficacy of only 50%, which meant that a "major therapeutic benefit" could not be assumed under any circumstances (front N 311 f.),
- especially since **no single study had even come close to proving protection against serious illness**, as the few cases examined were in the range of statistical chance (front N 305 ff.),
- especially since the "vaccinations" obviously did not offer any protection against the transmission of SARS-CoV-2 (see N 309 f.) and were therefore simply unsuitable for "pandemic control",
- especially since "vaccinations" must "immunize" in the long term (see N 1097), but in view of the "booster vaccinations" already planned from the outset (see N 508) and the obviously large-scale occurrence of so-called "vaccination breakthroughs", this was not an achievable goal,
- especially as there had been **effective and safe alternatives** to experimental mRNA injections, but these were actively suppressed - almost ridiculed - by Swissmedic (see N 1110 ff., N 1115 ff.).

1294 Swissmedic has therefore approved a medicinal product on the Swiss market with a **devastatingly negative risk-benefit profile from the outset**. Against this background, the plan to authorize the mRNA "vaccines" for all adults in Switzerland from December 2020 must be qualified as a **project with maximum, unprecedented risk content,** whereby the **lack of protective effect** of the mRNA "vaccines" was evident from the outset. A drug risk to public health that had never before been taken in the history of Switzerland was therefore offset by a **benefit that was** not **measurable** or **barely measurable** - especially as there was clearly no disease that posed a sufficient threat to the population as a whole. At the same time, **effective and safe alternatives** existed, which were actively suppressed by Swissmedic.

1295 A "gene therapy" that has not yet been sufficiently tested in humans and has the maximum risk potential summarized above should never have been approved. The approvals that were nevertheless granted constitute *per se* a **massive breach of due diligence on the part of Swissmedic** and **created considerable new dangers for public health in Switzerland, which would not have threatened the vast majority of the population without this approval of the mRNA substances, or through SARS-CoV-2 alone.**

1296 At the same time, however, Swissmedic **did not take any sufficiently risk-reducing measures** to minimize the risk to the population as a whole posed by these mRNA "vaccines", which were authorised in contravention of the law and the recognized rules of good

manufacturing practice. **In particular, Swissmedic failed (1) to ensure rigorous monitoring and (2) to provide the population with transparent information:**

- Despite the negative experience with Pandemrix, Swissmedic was content with a purely passive reporting system for market surveillance (see N 1154 ff.), which can in no way be considered risk-adequate for a completely new active substance that is still in the phase of the first ever human trial, or is simply inadequate - especially since the problem of "underreporting" in passive reporting systems has long been known (see N 441 ff.; above N 1159). **Instead, the mRNA "vaccines"** should have **been subject to active pharmacovigilance - as under study conditions - from the outset** (on the requirements for a functioning reporting system, see N 899 ff.; on the violation of reporting obligations see below N 1364 ff., in particular N 1374).
- At the end of 2020 and the beginning of 2021, Swissmedic approved the practically complete discontinuation of the approval studies, thereby unnecessarily relinquishing the control instrument for checking efficacy and safety that is crucial for any approval procedure (see N 1174 ff.; see also above N 275 ff.). The manufacturers will obviously not be in a position to ever provide complete data (see above N 1122). The omission of this elementary requirement is in no way justifiable and the approval of this illegal procedure by the highest supervisory authority responsible for drug safety in Switzerland constitutes a serious violation of Art. 9a TPA (and Art. 3 TPA).
- Swissmedic probably also failed to ensure rigorous batch testing from the outset (see N 1184 with reference to N 321 f.), which meant that the quality of the experimental mRNA medicinal products could in no way be checked independently of the manufacturers.
- Swissmedic informed the Swiss population about the first authorizations by means of **media releases,** which contained a **whole range of misleading information** (front N 1191). For example, Swissmedic announced that had been authorized by Comirnaty in an "orderly" procedure, which is an **outright lie.** Swissmedic also propagated a never proven high efficacy and concealed the fact that there were dozens of unresolved questions about quality, efficacy and safety. As this and other misinformation came from the highest regulatory and licensing authority itself - and because it has still not been corrected - the resulting misleading effect on the will and opinion of health authorities, the medical profession and the population is particularly great.
- In the absence of an immunizing effect of the mRNA medicinal products, which is mandatory for the qualification as a **"vaccination" in the legal sense** pursuant to Art. 2 lit. b AMBV (see above N 1097 f.), **Swissmedic's** continued use of the term "COVID-19 vaccination" alone constitutes **serious misinformation on the part of the Federal Council, health authorities, doctors and patients, which was fatal for their**

decisions. This misinformation was adopted by all of the country's health authorities in reliance on Swissmedic's special expertise and driven into the public's consciousness by means of continuous media campaigns on all channels.

- Swissmedic also scattered all kinds of information in the **information for healthcare professionals** for the attention of doctors and patients who were obliged to provide information, which was already blatantly false at the end of 2020 (see in detail above N 1199):
  - For example, in the information for healthcare professionals on Comirnaty, Swissmedic published in December 2020 - contrary to the recommendation of its own expert committee HMEC - that "no vaccine-related effects on female fertility, pregnancy or embryo-fetal development or on the development of offspring have been identified", which is in stark **contradiction to the** manufacturers' **study results** and explicit warnings from its own expert committee. Swissmedic has thus even thrown well-founded **manufacturer and expert warnings to** the wind.
  - In the "preclinical data" section, Swissmedic downplayed or even concealed the toxicity of the mRNA injections - massive alarm signals in animal studies regarding the toxicity of the lipid nanoparticles and the spike protein - and postulated safety based on non-existent data.
  - In the "Pharmacokinetics" section, Swissmedic suppressed alarming data from animal studies and at the same time claimed - also untruthfully - that there was no obligation to carry out pharmacokinetic studies anyway.
  - Swissmedic also published the illusorily high efficacy claims in the information for healthcare professionals.
  - Swissmedic concealed the real danger of reverse transcription and did not adequately inform the addressees that the mRNA injections are actual gene therapies, possibly even genetically modified organisms (*GMOs*), i.e. medicinal products that have the potential to cause lasting damage to the patient's genetic material.
- Swissmedic also published a **"FAQ" on** its own website aimed at the public, which **contained countless pieces of misleading information.** Based on the data already available internally at the end of 2020, Swissmedic was able to recognize this as clearly false information. For example, the answer to the first question ("Are COVID-19 vaccines safe?") - there is **"no evidence to** date **of any lasting negative consequences for health "** - is particularly factually incorrect and manipulative in every respect. Even the publication of such a false claim ("fake news") should never have happened. In addition, Swissmedic even emphasized this false claim by placing it at the top of the FAQ and incomprehensibly maintained it unchanged until the beginning of 2023. Its influence on the formation of public opinion on the vaccination decision in this prominent position

must be classified as considerable. **Against the background of all the circumstances, this breach of duty must be classified as particularly serious, but as explained above and in the evidence report, it was unfortunately not an isolated case** (above N 1204 ff.).

1297 The data situation presented as at the end of 2020 is based primarily on Swissmedic's high-profile information and Pfizer's approval documents, which have so far only been published very sparsely; Moderna's approval documents are - as far as can be seen - hardly available to the public (see above N 102). The present list of serious violations of the duties of care under therapeutic products law is therefore likely to become more extensive once all the authorization documents have been secured and evaluated (on the corresponding application, see N 102 et seq.), the list is likely to be considerably longer. Even without this additional information, however, there is clearly a strong suspicion that **the defendants acting on behalf of Swissmedic** had **already grossly violated their duties of care by the end of 2020**, thereby endangering the health of an increasingly large proportion of the population.

1.2.6.2 Breaches of duty with extension to young people (June 2021)

1298 Without effectively countering the breaches of the duty of care described above - i.e. eliminating them or compensating for them by taking appropriate measures (informing the public; monitoring) - Swissmedic took the step of extending authorizations to adolescents aged 12 and over in June 2021. And this despite the fact that, in addition to all previous legally relevant **risk-increasing facts,** it was known by mid-June 2021 that

- that Swissmedic and other regulatory authorities had apparently failed to ensure rigorous **batch testing** in view of the novel mRNA medicinal products, with the result that those responsible continued **their irresponsible blind flight** due to **a lack of quality control** (see N 321 f.),
- that, due to poorly conducted dose-finding studies, the dose approved for adolescents was **half** (Comirnaty) or **five times** (Spikevax) **higher than the recommended dose** (front N 323 f.),
- that as many as **42,086 side effects (including heart failure, facial paralysis, herpes zoster and thromboembolic events) and over 1,200 deaths** had been reported with Comirnaty by February 2021 alone - i.e. within just a few months (front N 325 ff.), which in earlier times (approx. 5,000 serious side effects or approx. 50 deaths) would have led to the **immediate withdrawal of** the drug in question or the **immediate discontinuation of the study** (see N 354 ff.),

- that a strikingly high number of adverse event reports were recorded for breastfed infants (front N 328),
- that the **safety concerns about ADE (disease exacerbation through "vaccination"; see** N 242) were in no way dispelled (see above N 329),
- that even Pfizer had identified and communicated a **negative impact on male fertility** as a potential risk (front N 333 f.),
- that by June 2021, global reports of adverse reactions (517,768) and deaths (7,242) had already reached a level (front N 341 f.), at which the aforementioned **alarm value of 50 deaths** - which would lead to the immediate discontinuation of studies or withdrawal of approval - had already been **exceeded by a factor of 150,**
- that the COVID-19 "vaccines" had already proven to be significantly more dangerous than flu, swine flu and measles vaccines in view of these massive side effect reports in May 2021 (front N 364 ff.),
- that around 20 **peer-reviewed** studies had already shown a potential link between the mRNA "vaccines" and serious side effects such as heart problems, thrombosis and death (front N 373 f.).

1299 It had long been obvious that a high **therapeutic benefit** had **not been proven,**

- especially since in the approval studies, in view of the complete lack of "danger" of SARS-CoV-2, **not a single adolescent was seriously ill with corona,** which meant that the **"vaccinations" could not satisfy the legal purpose from the outset** (because no protection against "life-threatening or disabling disease") and any approval for adolescents was therefore unlawful (see N 379 f.),
- especially since the efficacy data of up to 93% reported by the manufacturer again only referred to **minor events** and were based on figures that were in the realm of statistical chance, which means that any calculation of efficacy based on this is dubious, unscientific and misleading (see N 377 f.) - and once again showed that these drugs should never have been qualified and approved as a vaccination in the conventional sense due to their lack of immunizing effect,
- especially as the extensive **ineffectiveness of the mRNA injections** had already been **confirmed** in February 2021 **on the basis of the manufacturer's data and the increasingly generally available empirical data,** as the most common side effects included the lack of effectiveness of the "vaccination" and COVID disease (front N 317).

1300 At the same time, it was already obvious at the time that there was **no life-threatening or disabling illness to be combated** - especially in young people**,**

- as this target population with a mortality rate of **0.002% (IFR)** was never significantly threatened by SARS-CoV-2 (N 764),
- since even according to the official BfS methodology, no historical excess mortality could be identified even in absolute figures, while **an increasingly conspicuous increase in mortality** was **only** observed **in younger age groups from the end of 2020 - i.e. only since the start of "vaccination activity**" (front N 765), and
- as, despite predicted horror scenarios and politically forced bed reductions, even at the "peak" of the crisis in December 2020, there was never a dangerous overload of hospitals throughout Switzerland (front N 767),

1301 The high risk potential of the "vaccines", which had already been identified at the time of initial approval in December 2020, had been realized in the most impressive way by June 2021, **all alarm values had been exceeded:** thousands of people died in close connection with the administration of the mRNA "vaccines", tens of thousands suffered serious side effects. This development was not only reflected in absolute figures, but was also very strikingly reflected by June 2021 in the alarmingly high increase in the rates of severe side effects and deaths **per million doses administered** (front N 343 ff.). Swissmedic had therefore taken a high risk that could no longer be justified in any way - while at the same time the mRNA injections were largely ineffective and there was no threat posed by COVID-19.

1302 Despite this serious development, Swissmedic once again failed to provide the public **with clear and truthful information about** the **risk factors that were** already known from the outset and the new **risk factors that have emerged** since December 2020 when the authorization was extended**; indeed, it once again published misleading information and still failed to ensure rigorous monitoring :**

- Despite all the alarm signals, Swissmedic continued to make do with a purely passive and **completely user-unfriendly reporting system** (see N 1164 ff.), while other countries (such as the USA and Germany) had at least developed their reporting system somewhat more actively (see N 1160 et seq.).
- Swissmedic apparently failed to enforce even this passive reporting system adequately and **neglected to urge doctors to comply with the reporting obligation** (see N 1171).
- Swissmedic probably still **did not carry** out **any rigorous batch testing** (front N 1184 with reference to N 321 f.).
- Swissmedic informed the Swiss population about the authorization for adolescents by means of a **press release,** which once again contained a **whole range of misleading information** (see N 1191). For example, Swissmedic had once again propagated high

efficacy claims of 93-100%, which were based on obviously false information from the manufacturers. In addition, Swissmedic had completely ignored the problem of unit dosing (and thus overdosing), failed to address the lack of risk to adolescents from SARS-CoV-2 and made no mention whatsoever of the serious to fatal side effects. Swissmedic also maintained the highly misleading designation of the mRNA injections as "COVID-19 vaccination", even though the manufacturers had still not been able to demonstrate the legally relevant quality characteristics (Art. 2 lit. b AMBV) that are mandatory for this term.

- Swissmedic also scattered all kinds of information in the **information for healthcare professionals** for the attention of doctors and patients who were obliged to provide information, which was already obviously incorrect in mid-2021 (front N 1199):
  - **Despite the thousands of reports received, there was no information on serious side effects** such as "thromboembolic side effects", "herpes zoster", "hearing loss/tinnitus", "myocarditis/pericarditis" or "COVID-19 disease" ("vaccination failure").
  - **Important warnings** - for example on pregnancy, fertility, for nursing mothers, on deaths, on the increased risk of thrombosis, for elderly and previously ill people, for immunosuppressed people - were **completely missing or were misleading and incorrect.**
  - Swissmedic had still omitted the toxicity of the mRNA injections in the "preclinical data" section.
  - In the "Pharmacokinetics" section, Swissmedic is still suppressing alarming data from animal studies.
  - Swissmedic also published the illusorily high efficacy claims in the information for healthcare professionals, which had been calculated using a downright misleading methodology.
  - Swissmedic still failed to mention the danger of reverse transcription and did not adequately inform the addressees that the mRNA injections are actual gene therapies, possibly even genetically modified organisms (*GMOs*), i.e. medicinal products that have the potential to cause lasting damage to the patient's genetic material.
- Swissmedic left the misleading **"FAQ"** unchanged on its own website, in which, among other things, it **continued to explicitly deny** the crucial question for the public regarding **indications of lasting negative consequences for health.** It thus continued to actively maintain this and other deceptions of alleged efficacy and safety contrary to all the facts (see N 1204 ff.).
- Swissmedic disseminated all kinds of **further untruthful information** in public and also in response to private inquiries (see N 1209):

- In May 2021, for example, Swissmedic claimed, contrary to the data available to it, that "physiological damage caused by the spike protein [...] is not to be expected".
- Swissmedic also issued a press release on May 7, 2021, stating that there was **"no international evidence" of an increased rate of deaths** following mRNA injection - which, given the **high** global **reporting rates of 17.1-32.1 deaths per million doses administered to** date (before N 343), this once again constituted **blatantly misleading misinformation to the public**.
- In the same press release, Swissmedic also stated that "a clearer picture of the safety of the vaccines" was available as a result of the suspicion reports and that the "known positive risk-benefit ratio" had not changed. These empty claims have nothing in common with the reality of the escalating reports of side effects - once again, this is a thoroughly **embellished, untrue and misleading presentation of the actual situation.**

1303 So instead of finally withdrawing the toxic, suspected carcinogenic and potentially mutagenic drugs from the market immediately, their **approval** was **extended in a further risk-increasing and misleading manner** - by spreading false information, the demonstrably dangerous mRNA substances were now also approved for administration to adolescents who are in no way threatened by SARS-CoV-2, even at the same - potentially lethal - dose.

1304 Accordingly, there is also a strong suspicion in mid-2021 that **the persons acting on behalf of Swissmedic** had **grossly violated their duties of care** and in doing so had irresponsibly extended the scope of their pre-existing serious breaches of duty of care .

1.2.6.3 Breaches of duty with "booster" / children admission (end of 2021)

1305 Without finally effectively countering the breaches of the duty of care described above, Swissmedic took the step at the end of 2021 of extending the authorizations to a third dose ("booster") and to children from the age of five. And this despite the fact that, in addition to all the legally relevant **risk-increasing facts** listed above, this was known by the end of 2021,

- that even representatives of the pharmaceutical industry openly described mRNA injections as what they are - namely a gene therapy (or gene prophylaxis; see above N 194) - and not a vaccination in the conventional sense (see N 389 f.),
- that the **presence and mode of action of the toxic spike protein** in the human body, **which cannot be controlled** in terms of time, quantity and quality, presumably leads to a large number of serious side effects (including death) (front N 391 ff.),

- that the rules of *"Good Clinical Practice (GCP)"* were violated several times in the course of the Comirnaty **approval study**, and that - as it turned out in the course of 2021 - **data had** even been **falsified**, which meant that the data integrity of the Pfizer/BioNTech approval study was no longer guaranteed in any way at the time of the extension of approval (see N 397 et seq.),
- that **Pfizer/BioNTech** had **even falsified death reports** to hide the fact that **more deaths** occurred **in the vaccine group** than in the placebo group (front N 400 ff.),
- that Comirnaty experienced **four times more adverse events** and almost two times more serious adverse events in the **vaccine group** than in the placebo group as a result of the medication (front N 403 ff.),
- that **Pfizer/BioNTech** had presented an alarming interim report (*PSUR*) at the end of August 2021, according to which **46 cases** had ended fatally **in the clinical trials** and **5,069 cases (1.6%)** had ended **fatally** in the so-called **"postmarketing phase"** (front N 406),
- that **Pfizer/BioNTech** explicitly pointed out the complete lack of data ("missing information") in the same interim report (*PSUR*) concerning the effect of the "vaccination" on frail patients with concomitant diseases (see N 408 ff.),
- that the same interim report (*PSUR*) showed that the **age group of 13 to 50-year-olds was most affected by the side effects** - i.e. precisely the age group that was never threatened by COVID-19 (front N 411),
- that **Pfizer/BioNTech** revealed in this same interim report (*PSUR) that* **19 batches** had led to an **above-average number of cases of side effects** - another strong indication of massive quality problems (front N 412),
- that of these 19 batches, only **7 batches** had been **delivered to Switzerland** - an alarm signal that should have led Swissmedic to issue an immediate **warning to the population, including a batch recall** (see N 413),
- that **Pfizer/BioNTech** stated in this same interim report (*PSUR),* contrary to all data already available at that time on reported side effects, that reports of **thrombosis** or **herpes zoster**, for example, would not constitute risk signals (front N 414),
- that the data available on the "booster" with Spikevax is extremely sparse, but that the few data already **showed** the severe and potentially **frequent side effect of pericarditis** (anterior N 416),
- that, according to initial investigations, the **individual vaccine batches** were responsible for the occurrence of severe side effects to a **very different extent**, which indicates an **uneven production** and thus a **serious quality problem** and a **serious violation of GMP *rules*** (front N 417 ff.), which is highly alarming as quality must be strictly

guaranteed as an absolutely mandatory element of every marketing authorization (see N 870 ff.; above N 963 ff., in particular N 980),

- that in Switzerland, the EU and the USA a total of **1,066,217 adverse reactions** - including **274,054 serious adverse reactions** and **12,807 deaths - had** already been reported for Comirnaty and Spikevax alone, whereby the absolute **alarm value of 50 deaths** had already been **exceeded by a factor of 250** (front N 425 ff.),
- that **at least 60 deaths** were recorded in children in Switzerland, the EU and the USA for Comirnaty and Spikevax alone (front N 438 f.; see also above N 459 ff.), which means that the absolute **alarm value of 50 deaths - which should lead to an immediate stop of any authorization of medicinal products - was clearly exceeded** in this target group alone, which is in no way endangered by SARS-CoV-2,
- that the mRNA "vaccines" (Comirnaty and Spikevax) had received **60 times as many reports of serious side effects** and **20 times as many death reports per million doses administered as** compared to the influenza vaccines as of the end of 2021 (front N 427 ff., in particular N 429 f.),
- that there was a **massive underreporting of side effects** worldwide (front N 441 ff.) and that the reporting rate in Switzerland was conspicuously low only in comparison with Germany (front N 445 f.),
- that massive underreporting has been criticized worldwide, particularly in the case of deaths, which can be attributed to the largely **absent or merely superficial performance of autopsies** and the premature exclusion of a connection between mRNA injection and death (see N 447 ff.),
- that **children who are in no way threatened by COVID-19 have been exposed without need to the risk** of frequent serious to fatal side effects such as myocarditis/pericarditis - and not "only" by Spikevax, but also - and apparently even to a greater extent - by Comirnaty (front N 467 ff.),
- that even at the end of 2021, manufacturers were still unable to provide usable data on the tolerability of mRNA "vaccines" in pregnant women (and breastfeeding mothers), while by the end of 2021 **over 2,000 premature and stillbirths** after mRNA injection had already been reported in the USA and the EU alone (front N 473 ff., in particular N 478),
- that several studies and now well over 100 **peer-reviewed** studies have shown a link between the mRNA "vaccines" and serious side effects such as heart problems, thrombosis and death (see 482 ff.),
- that in Switzerland in particular, a worrying trend was already evident in 2021, namely a **conspicuous and persistent mortality rate in younger age groups in close temporal relation to "vaccination activity"** (front N 494; rear N 765 and N 774).

1306 There was also simply **no high therapeutic benefit**,

- especially as there was still **no effective proof of efficacy** and **no evidence of protection against transmission** (see N 498 ff.), whereby on August 3, 2021, even the FOPH publicly admitted that "a vaccinated person who becomes infected [...] is just as infectious as an unvaccinated person who becomes infected" (front N 505).
- especially as the protective effect of the "booster" and the "3rd dose in immunosuppressed patients" had not been proven in any way in view of inadequate studies and misleading calculations (see N 508 ff.),
- especially in **children and adolescents** in the complete absence of a threat from SARS-CoV-2 (front N 764, N 771 ff.), with virtually non-existent efficacy of the mRNA "vaccines" (see N 377 ff., N 516 ff.) and with **over 50 deaths already reported** worldwide as a result of mRNA injections (see N 438 f., N 459 ff.) in this age group alone, a risk/benefit assessment had to be obviously negative,
- Moreover, teenagers are **six times more likely to** suffer from **heart problems (myocarditis) caused by COVID "vaccines"** than the likelihood of severe COVID disease progression (anterior N 467 ff.), which is another reason why a risk/benefit assessment obviously had to be negative.

1307 There was now an obvious lack of a **life-threatening or disabling illness to be combated,**

- as "Delta" was a variant that corresponded to a normal **mild flu** in terms of danger (front N 771 ff.),
- as **no historical excess mortality** could be identified in Switzerland for the year 2021 (front N 774),
- as **intensive care units in Switzerland** were **never over 80% utilized in** 2021 (front N 776).

1308 The already known risks had therefore been confirmed or even exacerbated - and a large number of new risks had emerged. At the same time, in view of the lack of proof of efficacy and the lack of threat, there was no justification whatsoever for extending the authorizations at the end of 2021. In fact, **Swissmedic should have finally revoked all "temporary" authorizations of the mRNA "vaccines" immediately.** However, this did not happen - instead, **Swissmedic once again published misleading information in order to conceal its own wrong decisions from the public , and still failed to ensure rigorous monitoring:**

- Despite all the alarm signals, Swissmedic continued to make do with a purely passive and **completely user-unfriendly reporting system** (see N 1164 ff.). Accordingly, it can

be assumed that a large number of other side effects were and are not or not sufficiently recognized.

- Swissmedic **apparently continued to fail to urge doctors to comply with the reporting obligation** (see N 1171), which led to the massive underreporting of side effects (N 441 ff., N 612 ff.) is further reinforced.
- Swissmedic **even ignored the manufacturers' reports** - for example about massive side effects or serious quality problems during production (see N 1179 f.).
- Swissmedic **also ignored high-quality third-party studies** and the fact that Pfizer falsified data in the pivotal studies (front N 1181 ff.).
- Swissmedic probably still **did not carry out any rigorous batch testing** (front N 1184 with reference to N 321 f.).
- Swissmedic informed the Swiss population about the "booster" authorization and the authorization for children by means of **media releases,** which once again contained a **whole range of misleading information** (see N 1191). In particular, Swissmedic communicated a **"high clinical efficacy in younger children",** whereby severe courses of disease were "practically completely" prevented, completely distorting and glossing over all the facts. A "virtually complete" - i.e. 100% - efficacy against serious illnesses is **diametrically opposed to the study results. Swissmedic thus exposed the least threatened population group to the risk of serious side effects and deaths without need and in an absolutely misleading manner.** At the same time, Swissmedic continued to maintain the highly misleading designation of the mRNA injections as "COVID-19 vaccination", even though the manufacturers had clearly not been able to demonstrate the legally relevant quality characteristics (Art. 2 lit. b AMBV) that are mandatory for this term.
- Swissmedic also scattered all kinds of information in the **information for healthcare professionals** for the attention of doctors and patients who were obliged to provide information, which was obviously incorrect at the end of 2021 (front N 1199):
  - **Despite the thousands of reports received, there were still no references to serious side effects** such as "thromboembolic side effects", "herpes zoster", "hearing loss/tinnitus" or "COVID-19 disease" ("vaccination failure"), while the serious side effect **"myocarditis/pericarditis"** was **included in a completely trivialized manner.**
  - **Important warnings** - for example on pregnancy, fertility, for breastfeeding women, on deaths, on the increased risk of thrombosis, for elderly and previously ill people, for immunosuppressed people - were **still missing completely or were misleading and incorrect,** although these side effects had long been recognized as a potential risk signal. For example, despite explicit reference by the manufacturers to

missing data ("missing information") concerning the **older, previously ill population**, Swissmedic **did not include a corresponding warning in Comirnaty's Information for healthcare professionals**, whereupon the "booster" was even recommended as a priority for this age group. The suppression of this elementary information in the Information for healthcare professionals and the toleration of the priority recommendation of the "booster" for the elderly population once again represents an open violation of Swissmedic's duty of care under therapeutic products legislation (Art. 3 para. 1 TPA).

- Swissmedic had still omitted the toxicity of the mRNA injections in the "preclinical data" section.
- In the "Pharmacokinetics" section, Swissmedic is still suppressing alarming data from animal studies.
- Swissmedic also continued to publish the illusorily high efficacy claims in the information for healthcare professionals.
- Swissmedic still failed to mention the danger of reverse transcription and did not adequately inform the addressees that the mRNA injections are actual gene therapies, possibly even genetically modified organisms (*GMOs*), i.e. medicinal products that have the potential to cause lasting damage to the patient's genetic material.

- Swissmedic still left the misleading **"FAQ"** unchanged on its own website and thus also maintained this deception (in particular the **false claim regarding the allegedly still missing indications of lasting negative consequences for health**) in a prominent public place (see N 1204 ff.).
- Swissmedic disseminated all kinds of **further untruthful information** in public and also in response to private inquiries (see N 1209):
  - In December 2021, for example, Swissmedic claimed that lipid nanoparticles were "not harmful", contrary to all factual evidence.
  - Swissmedic also claimed that there were no proven deaths (in Switzerland) - ignoring the fact that such deaths following an mRNA injection had simply not been adequately investigated in any way.

1309 Although there was therefore every reason to immediately withdraw the dangerous and largely ineffective mRNA injections from the market in view of the complete lack of threat to the population as a whole, Swissmedic **even extended** their **authorization to children in a further risk-increasing and misleading manner** - obviously deceiving the public about the quality, efficacy and safety of the authorized medicinal products.

1310 Accordingly, at the end of 2021, there is also a strong suspicion that **the persons acting on behalf of Swissmedic** had **grossly violated their duty of care** and, in doing so,

extended the circle of their already existing serious breaches of duty of care to an irresponsible extent.

1.2.6.4 Breaches of duty from 2022

1311 In 2022, Swissmedic maintained all "temporary" authorizations, even though the administration of mRNA injections had manifested enormous risks that are unparalleled in the pharmaceutical sector. In addition to all the legally relevant **risk-increasing facts** mentioned above, this became known in the course of 2022,

- that even Swissmedic conceded that **"preparations such as mRNA"** are **"comparable to gene therapy products"**, and the FOEN even stated that the **combination of mRNA with lipid nanoparticles** leads to the assumption of a **genetically modified organism (GMO)** (see N 526 ff.) - which means that the strictest safety regulations (which even go beyond the requirements of an ordinary approval procedure) should have been applied from the outset (see N 916 ff.), although Swissmedic did not apply these from the outset by switching to an allegedly "temporary" authorization procedure and even successively undermined the remaining minimal safety mechanisms (see N 992 ff.),
- that the evidence for a **lack of GMP** *(Good Manufacturing Practice)* **compliance of the mRNA injections** became even stronger, as both manufacturers and regulatory authorities refuse any access to the relevant documentation (front N 532 ff.; see also N 542 f.),
- that almost four million adverse reactions to all COVID "vaccines" had already been reported worldwide (Switzerland, EU, USA) by May 2022 (front N 538 ff.), with Comirnaty and Spikevax alone accounting for **over 1.7 million side effects** - including **464,971 serious side effects** and **20,886 deaths** (front N 548 ff.) - which meant **that** the **alarm value of 50 deaths was exceeded more than 400 times** worldwide at that time,
- that these figures continued to rise in the following months (front N 562 ff.) and by the end of February 2023, Comirnaty and Spikevax alone accounted for **over 2.1 million side effects**, of which **597,000 were serious** side effects and **24,959 deaths** (front N 548 ff.) - and this despite conspicuous "adjustments", particularly in the EU (front N 335 ff.),
- that the mRNA "vaccines" (Comirnaty and Spikevax) received **100 times the number of reports of severe side effects** and **20 times the number of deaths** per million doses administered compared to the flu vaccines (front N 550 ff., N 566 ff., N 582 et seq.),

- that another alarming interim report (PSUR No. 3) had been published on Comirnaty (front N 595 ff.), from which it emerged that
  - that **the under-50 age group** was **disproportionately affected by side effects**, i.e. a population group that was in no way threatened by COVID-19 (front N 597 ff.),
  - that **information** on the safe use of Comirnaty in **pregnant women**, breastfeeding women and other patient groups **was still lacking** (front N 605 ff.),
  - that the indications of **massive quality differences** between the individual batches were increasingly confirmed and that **many dangerous batches** were again delivered to **Switzerland** (front N 608 ff.),
- that several studies showed that in the EU at best 20% of all side effects, and in Switzerland probably **only 10% of all side effects were reported at all** (front N 612 ff.), **which means that Swissmedic allows the public to be massively misled about the true extent of side effects,**
- that the **manufacturers** again stated in their 2021 **annual reports that** they may **not be able to demonstrate sufficient efficacy or safety of their COVID "vaccine" to** obtain permanent regulatory approval (front N 622 f.),
- that by 2022, the number of suspected cases of **(very young) children** killed by the mRNA "vaccines" worldwide - i.e. a population group in no way threatened by COVID-19 - will continue to accumulate to around **300 deaths** (front N 624 ff.), whereby **in Germany it can even be assumed that, despite underreporting, the number of child deaths due to "vaccination" significantly exceeds the official statistics of deaths due to "COVID-19"** (front N 626),
- that according to a detailed benefit-risk analysis by renowned authors (including Harvard Medical School, Johns Hopkins University, Oxford University), the **net benefit of a "booster injection" in the 18 to 29 age group** is **clearly negative** (front N 629),
- that despite Swissmedic's statements that the mRNA "vaccines" had no effect on pregnancy, **2,135 stillbirths with Comirnaty** and **798 stillbirths with Spikevax** and **5,055 miscarriages with all COVID-19 "vaccines**" - not including underreporting - had already been reported by May 2022 in the EU and the USA alone (front N 636 f.), with the manufacturers still openly admitting in 2022 that **- due to a lack of corresponding studies - "the safety profile of the vaccine in pregnant or breastfeeding women** is **not known"** (front N 631 ff.), which is why, since August 2022, even the British Health Authority has warned against mRNA injections during pregnancy and breastfeeding (see N 634 f.),
- that in 2022 there was a **massive decline of 10-15% in live births** worldwide (front N 639 ff.),

- **that Switzerland** also experienced **a historic decline in live births of 8.5% in 2022,** for which, after excluding all other hypotheses, **mRNA injections** remain **the only plausible reason** (front N 644 f.),
- that according to a study on male fertility published in June 2022, the **sperm concentration 150 days after the 2nd "vaccination" was still 15.9% below the initial value** (front N 649 ff.), which means that not only female but also male fertility is potentially negatively affected by the "vaccination",
- that the **mRNA injections damage the stem cells in the umbilical cord blood of newborns** (anterior N 651 f.) and that the RSV record numbers correlate with the "vaccination campaign" of pregnant women (front N 653 f.),
- that Swissmedic ignores all these massive risk signals in the area of human reproduction and tries to downplay them with all kinds of untenable justifications - and even (probably inadvertently) cites a study that does not deny the **connection between the decline in birth rates and the "vaccination campaign"** with a time lag of about nine months, but rather confirms it (see N 655 ff.),
- that an in-depth analysis of the *BfS data* using a robust methodology by Prof. Beck revealed a **conspicuous and persistent mortality pattern in all age groups in close temporal relation to "vaccination activity"** (front N 663 ff.),
- that based on the *BfS data* in Switzerland - especially in age groups not threatened by COVID-19 in any way - a massive increase in various disease diagnoses **(damage to the nervous system: +29%; cancers: +48%; pregnancy complications: +25%; pulmonary embolism, cardiac arrest, stroke and cerebral infarction in 0- to 14-year-olds: +125%) can** be identified for 2021 since the start of the "vaccination campaign" (front N 664 ff.),
- that the **"vaccine" spike protein** (or the immune response triggered by it) has been proven to be **the cause of death** according to several autopsy results and that - contrary to Swissmedic's official statements - it is by no means only detectable **in the human body** for a short time, but for **up to nine months** (see N 669 ff.),
- that the occurrence of **myocarditis in** connection with COVID-19 mRNA injections, which can be fatal in the worst case, is much **more frequent** - according to a now peer-reviewed **Basel study up to 800 times more frequent -** than officially reported by the regulatory authorities (front N 674 ff.),
- that with **V-AIDS**, a long-suspected and since 2022 now emerging serious side effect has made itself felt, which results in permanent **damage to the immune system,** which can lead not only to an increased incidence of autoimmune diseases and cancer, but above all to an increased incidence of infectious diseases (front N 677 ff.),

- that the reports of side effects and devastating health consequences are virtually overflowing worldwide: **Around 66% of Israelis who had received a "booster shot" suffered from side effects -** and in the US military, a massive **increase of 270% in heart attacks**, **460% in pulmonary embolisms**, **1000% in nerve diseases**, **490% in breast cancer**, **290% in facial paresis** (facial paralysis), **550%** in **Guillain-Barré syndrome** and **280% in miscarriages** was recorded (front N 681 ff.),
- that by March 1, 2022, a total of at least **126 peer-reviewed publications on heart problems, 216 peer-reviewed publications on life-threatening coagulation disorders (thrombosis, etc.) and six peer-reviewed publications on possible deaths as a result of COVID vaccinations had** been published (front N 685 f.).

1312 Moreover, even in the course of the second year of the global COVID-19 vaccination campaign, **no "major therapeutic benefit"** (Art. 9a para. 1 lit. b TPA) could be determined or proven. On the contrary, the evidence showed that as the "vaccination campaign" progressed, **the negative effects of the mRNA injections became** increasingly evident,

- especially since the **mRNA "vaccines" obviously no longer offered any immunizing protective effect even against the "Omikron" variant** (see N 688 ff.),
- especially since in 2022 it was finally officially acknowledged - both by the manufacturer and the approval authorities - that **protection against transmission** could **never be proven** (see N 693 ff.),
- especially since **a negative effect** was **even** observed with regard to **"boosters"**, as the transmission time was not shortened but extended (see N 696 f.),
- especially since, according to dozens of studies, recovered people are better protected against re-infection than "vaccinated" people (front N 698 ff.),
- especially since several countries had long since suspended the approval of COVID-19 "vaccinations" in certain population groups due to a lack of benefit (see N 701 f.),
- especially since **an increased incidence of disease and deaths** can be observed **worldwide**, which correlates permanently **with the start of the "vaccination campaign"** in 2021 (and not with the start of the "pandemic" in 2020), which clearly indicates a **negative effectiveness of the mRNA injections** (front N 708 ff., N 782 f.),
- especially since **53 studies published by the manufacturer** were **not able to** provide any **new scientific evidence that** would strictly prove the efficacy or safety of Comirnaty and Spikevax (see N 720 ff.),
- especially since **no strict proof of efficacy** had **ever been provided** for the adapted bivalent Omikron booster "vaccines" (see N 723 ff.),

- especially as the manufacturers are pushing back the end of the phase 3 studies further and further - in view of the manipulation of the study data already uncovered in 2021 (N 304), this is a completely **unacceptable cover-up tactic** (front N 733 f.).

1313 In addition, in 2022, as the virulence (danger) of the SARS-CoV-2 variants still circulating at that time - i.e. in the third year of the "pandemic" - decreased, there was a much greater lack of a **life-threatening or disabling disease to be combated** than in previous years,

- since with the **"Omikron variant"** the lethality of SARS-CoV-2 was only about **0.001-0.002% (IFR),** which means that "Omikron" is significantly - namely at least **50 times - less dangerous** for the population as a whole **than a normal flu** and **definitely does not** represent a **life-threatening or disabling disease** (front N 780 f.), which would justify an emergency authorization according to Art. 9a TPA,
- since **COVID-19** was **obviously not a "pandemic of the century"** - there was simply no historically relevant excess mortality in relation to the total population and a very large proportion of the "COVID-19 deaths" had already reached the **age of average life expectancy** (front N 782 and N 784 f.),
- as there was never an overload in the hospital system despite a **massive manipulation of the COVID "case numbers" in the hospitals** that became public (front N 786 ff.), which once again confirmed the largely harmless nature of SARS-CoV-2.

1314 **A revocation of all "temporary" authorizations of the mRNA "vaccines" was therefore long overdue in 2022.** However, this still did not happen - instead, **Swissmedic once again published new misleading information and continued to maintain the misleading information already published without corrections in order to continue to conceal its own wrong decisions from the public . Furthermore,** in the second year of the "vaccination" campaign, **the people in charge at Swissmedic failed to ensure rigorous monitoring that** would have been appropriate to the ever-increasing risk created by Swissmedic :

- Far too late - only in July 2022 - Swissmedic made its completely user-unfriendly reporting system somewhat more user-friendly - but - despite all the alarm signals - continued to make do with a purely passive **reporting system** (see N 1164 ff.). Accordingly, it can be assumed that a large number of other side effects were and are still not or not sufficiently recognized.
- Swissmedic **apparently continued to fail to urge doctors to comply with the reporting obligation** (see N 1171), which led to the massive underreporting of side effects (N 441 ff., N 612 ff.) is further reinforced.

- Swissmedic **continued to ignore the manufacturers' reports** - for example, of massive side effects or serious quality problems during production (front N 1179 f.).
- Swissmedic **also ignored high-quality third-party studies** and continued to ignore the fact that Pfizer falsified data in the pivotal studies (front N 1181 ff.).
- Swissmedic probably still **did not carry out any rigorous batch testing** (front N 1184 with reference to N 321 f.).
- Swissmedic informed the Swiss population about the "booster" authorization and the authorization for children by means of **media releases,** which again contained a **whole range of misleading information** (see N 1191). In particular, Swissmedic communicated a **"high clinical efficacy in younger children",** whereby severe courses of disease were "practically completely" prevented, completely distorting and glossing over all the facts. A "virtually complete" - i.e. 100% - efficacy against serious diseases is **diametrically opposed to the study results. Swissmedic thus exposed the least threatened population group to the risk of serious side effects and deaths without need and in an absolutely misleading manner.** At the same time, Swissmedic continued to maintain the highly misleading designation of the mRNA injections as "COVID-19 vaccination", even though the manufacturers had clearly not been able to demonstrate the legally relevant quality characteristics (Art. 2 lit. b AMBV) that are mandatory for this term.
- Swissmedic also scattered all kinds of information in the **information for healthcare professionals** for the attention of doctors and patients who were obliged to provide information, which was obviously incorrect in 2022 (front N 1199):
  - For example, **despite the thousands of reports received, there was incomprehensibly still no mention of serious side effects** such as "thromboembolic side effects", "herpes zoster", "hearing loss/tinnitus" or "COVID-19 disease" ("vaccination failure"), while the serious side effect **"myocarditis/pericarditis"** was **included in a completely trivialized manner.**
  - **Important warnings** - for example on pregnancy, fertility, for breastfeeding women, on deaths, on the increased risk of thrombosis, for elderly and previously ill people, for immunosuppressed people - were **also still completely missing or were misleading and false,** although these side effects had long been identified as a potential risk signal worldwide. In particular, Swissmedic continued to uphold the "vaccination recommendation" for pregnant women without even the slightest evidence of safety and in the knowledge that reports of stillbirths were increasing worldwide and that many countries (not just Switzerland) were experiencing a historic drop in birth rates.

- Swissmedic had still omitted the toxicity of the mRNA injections in the "preclinical data" section.
- In the "Pharmacokinetics" section, Swissmedic is still suppressing alarming data from animal studies.
- Swissmedic also continued to publish the illusorily high efficacy claims in the information for healthcare professionals.
- Swissmedic still failed to mention the danger of reverse transcription and did not adequately inform the addressees that the mRNA injections are actual gene therapies, possibly even genetically modified organisms (*GMOs*), i.e. medicinal products that have the potential to cause lasting damage to the patient's genetic material.

- Swissmedic still left the misleading **"FAQ"** unchanged on its own official website and thus also maintained this deception (in particular the false claim regarding the alleged lack of evidence of lasting negative consequences for health) with publicity (see N 1204 ff.).
- Swissmedic disseminated all kinds of **further untruthful information** in public and also in response to private inquiries (see N 1209):
  - In 2022, for example, Swissmedic falsely claimed that there was "no evidence of accumulation of LNPs" and that they "pose no risk to humans".
  - Swissmedic also claimed, contrary to all evidence, that the spike protein was only produced for a "short time".
  - Swissmedic downplayed (serious) side effects several times - both to the specialist public (in the "Vigilance News") and to the general public.
  - Swissmedic still claimed that there were no proven deaths (in Switzerland) - although even the BfS had reported 19 deaths in Switzerland as a result of mRNA injections.

1315 Swissmedic therefore made every effort to present the maintenance of the authorizations and the extensions of the authorizations in 2022 as an absolutely normal procedure - which it was in no way, since **Swissmedic fundamentally deviated from all principles of therapeutic products law** (see N 992 ff.). By concealing key information on safety and efficacy - and even by disseminating massive misinformation - **Swissmedic continued to give the public the illusion of a "courant normal", which has in no way been the case since the end of 2020.**

1.2.6.5 Breaches of duty from 2023

1316 As above (N 1131 ff.), Swissmedic did not take the decision at the end of 2022 to cancel the illegal pandemic authorizations (see N 857 ff., in particular N 992 ff.) immediately or at

least allow them to expire, but even took the step of perpetuating the experimental mRNA technology with new - allegedly "ordinary" - authorizations with a duration of well over 2 years in the sole interest of the manufacturers as a new platform for broad-based use. It goes without saying that the requirements for extensions of these "temporary" authorizations, and indeed for the granting of supposedly "ordinary" (Art. 9 / 11 TPA) authorizations, were not even remotely met in 2023, meaning that those acting on behalf of Swissmedic violated their duty of care under Art. 3 TPA and Art. 7 TPA in an almost unimaginable manner - and to an even greater extent than in previous years, which is relevant under criminal law.

1.2.6.6 Result

1317 As already mentioned above (N 807 ff.), the plan to authorize the mRNA "vaccines" for all adults in Switzerland from December 2020 must be qualified as a **project with an increasing, unprecedented risk character** for public health. Swissmedic had several opportunities to take corrective action after the first wrong decision was made at the end of 2020, i.e. to withdraw the temporary authorizations, to point out the lack of evidence of efficacy and safety to the public with the necessary clarity, and to effectively adapt the risk monitoring system (pharmacovigilance) throughout Switzerland to the risk created by the authorizations. However, none of these measures were taken and none of the numerous opportunities to protect public health from the risks of mRNA medicinal products were seized. As a result, the risk and the damage caused to public health increased massively with each extension of the authorization because the responsible magistrates, the health authorities, the media, the medical profession and above all the population (or patients) relied on the correctness of the information provided by Swissmedic in connection with the authorization of mRNA preparations with regard to their protective effect and safety.

1318 The breaches of duty in connection with the authorizations of mRNA-based preparations, which Swissmedic continued to issue under the title "COVID-19 vaccination" or "booster vaccination" after the first temporary authorizations expired at the end of 2022 (beginning of 2023), are of particular, almost outstanding relevance under criminal law. As described above (N 1131 ff.), the corresponding authorization orders are to **be assessed** as **independent new criminal acts.** All breaches of duty committed in this context are of particular importance under criminal law because at the time of those new approval orders from the end of 2022, all facts relevant to the decision to assess efficacy and safety (in contrast to the situation at the end of 2020) **were available conclusively and with all the necessary clarity, both** qualitatively and quantitatively. It was clear by that time at the latest that the manufacturers would never again be able to provide the legally required proof of efficacy

and safety for these mRNA-based substances (**objective impossibility;** see for example N 1034, N 1122 ff., N 1138).

1319 **And there is no longer any reasonable justification for describing these mRNA-based preparations as "vaccines" in the legal sense, let alone advertising them to the public.**

1.2.7. Medical profession: "Application" offense variant (duty to inform)

1320 With regard to the medical profession, the punishable acts ("use") and duties of care are also described in Art. 86 para. 1 lit. a TPA, whereby the duties of care under Art. 26 TPA (duties of care when prescribing, dispensing and using) are of particular interest in the present case.

1.2.7.1 The term "levy" includes application

1321 The term "dispensing" covers the final stage, i.e. the transfer or provision of a ready-to-use medicinal product to the end user. The prescribing of a medicinal product itself is not yet considered a dispensing; only the filling of a prescription leads to the actual dispensing of the medicinal product. The term "dispensing" also includes administration **to third parties** (Art. 4 para. 1 lit. f TPA).[327] The persons responsible for injecting the mRNA "vaccines" into the patient (**doctors**) therefore fulfill the definition of "use" within the meaning of Art. 86 para. 1 lit. a TPA.

1.2.7.2 Art. 26 - Requirements for dispensing (application): Duty to provide information

1322 With regard to the duties of care to be fulfilled, the previously (N 1274) (avoidance of risks to human health; limited actions sufficient; fully timely fulfillment) apply equally and analogously to the medical profession.

1323 When prescribing, **dispensing and using** medicinal products, the recognized rules of medical and pharmaceutical science must be observed (Art. 26 para. 1 TPA). **Before any** prescription-only human medicinal product **is dispensed** (and used), a person authorized to prescribe and dispense it must **issue a prescription** to the patient (Art. 26 para. 4 TPA). A medicinal product may only be prescribed (and used) if the **patient's state of health is known** (Art. 26 para. 2 TPA).

1324 In the interests of drug safety and **patient protection,** the dispensing system of the Therapeutic Products Act is based on **specialist advice** in the form of appropriate instructions

327 Message HMG, p. 3491; BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 24 N 5, Art. 26 N 6.

when prescribing and dispensing.[328] The patient must therefore be informed individually and during a consultation: Information forms or the information for healthcare professionals can at best take on a supporting function and serve as a basis for the discussion, but cannot replace the personal discussion and individual explanation.[329] The medicinal product must therefore be prescribed by a doctor in full knowledge of the patient's **vital signs**, state of health, any **allergies**, **drug intolerances** and the **potential for interaction** with other active ingredients in medicines or foodstuffs.[330] The doctor's duty of care in general and within the framework of the recognized rules of medical science also entails an **obligation to provide** the patient with **sufficient information** before the procedure.[331] As part of the treatment, the doctor must inform the patient about the correct therapeutic behavior and must draw attention to known dangers (so-called **safety information**).[332] In particular, information must be provided not only about frequently occurring risks, but also about rare risks, insofar as these are known and may have serious consequences.[333]

1325 **Prescription medicines** such as those in dispensing category B (COVID "vaccines") are generally[334] only available after **consultation with a doctor** and on the basis of **advice** and **examination** by a specialist doctor. The doctor must make a decision based on knowledge of all preparations available on the market with the same indication and knowledge of their positive and negative effects - primarily **on the basis of the information for healthcare professionals.** The safety expectations of a prescription-only medicine are therefore based on those of the prescribing doctor and not those of the patient.[335] In the case of prescription medicines, the doctor must weigh up the **opportunities and risks** of the various products available on the market on the basis of the information for healthcare professionals with regard to the specific application and **discuss** this **with the patient.**[336] Accordingly, it is essential that the doctor informs the patient about all aspects that are important for the patient and which are (only) listed in the information for healthcare professionals. The **duty to inform lies with the doctor,** who cannot relieve himself by asking his patient to inform

328 BGE 142 II 80 E. 2.2 p. 87; BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 26 N 6.
329 HOFMANN, "COVID-19-Impfung: Aufklärung und Urteilsfähigkeit", FMH Recht 2021, p. 158-159, p. 159.
330 BGE 142 II 80 E. 2.1 p. 86; see EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 14.
331 See BGE 134 IV 175 E. 4.1. p. 180; also BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 26 N 9.
332 BGE 116 II 519 E. 3b p. 521; judgment 4C.229/2000 of the Federal Supreme Court of 27.11.2000 E. 3a/aa.
333 HOFMANN, "COVID-19-Impfung: Aufklärung und Urteilsfähigkeit", FMH Recht 2021, p. 158-159, p. 159.
334 For the possible exceptions, according to which a prescription including administration by pharmacists is also possible, see above N 1229.
335 Cf. judgment 4A_365/2014 of the Federal Supreme Court of January 5, 2015, E. 5, with reference to judgment LB130045-O/U of the High Court of the Canton of Zurich of May 7, 2014, p. 18 f.
336 Judgment 4A_365/2014 of the Federal Supreme Court of January 5, 2015, E. 9.2.

himself or to read the medical instructions on the package leaflet of the medicine.[337] In addition, the patient must also be informed of any risks that are not yet included in the information for healthcare professionals but have been scientifically proven.[338]

1326 The requirement for comprehensive information must be given particular weight if little is scientifically known about the use of a medicinal product: if a **therapy is** still **purely experimental in nature** due to a lack of scientifically proven findings, the **pre-invasive information and risk assessment obligations** must **be observed with particular care.**[339] This requirement clearly applies to the completely new mRNA therapies: they are in no way a common form of therapy - and certainly not for prophylactic and experimental use in a healthy population. They have never been tested extensively in humans before and are still at the human trial stage, which was warned about in the specialist information, at least to some extent - but openly recognizable for experts (front N 912 [black triangle], N 1235 [incomplete clinical data situation]). Accordingly, the references in the information for healthcare professionals to a **limited study population** - if the patient to be vaccinated belongs to this population - and any **shortened study duration** or other **special circumstances during the approval procedure must** be mentioned. The patient must also be informed that **not all risks and side effects** are **known** if this is the case due to **a lack of long-term studies** de r.[340] This additional duty to provide information is particularly relevant in the case of so-called **"off-label use", i.e.** the prescription and administration of a medicinal product outside the scope of its marketing authorization: this circumstance itself must be properly explained, as well as the associated consequences such as the lack of cost coverage by the health insurance fund (Art. 71a ff KV) and the threat of the manufacturer's product liability ceasing to apply.[341]

1327 The patient must therefore be informed about the nature and risks of the proposed "vaccination" in such a way that they can give their informed consent in full knowledge of the facts.[342] The content of the information must be based on the information leaflet accompanying the vaccine. At the very least, the patient **must** therefore be informed about all **side effects, contraindications, intolerances and other warnings** contained in the

337 Judgment 4C.229/2000 of the Federal Supreme Court of 27.11.2000, E. 3a/bb.
338 HOFMANN, "COVID-19-Impfung: Aufklärung und Urteilsfähigkeit", FMH Recht 2021, p. 158-159, p. 159.
339 See BGE 134 IV 175 E. 4.1 f. p. 180.
340 HOFMANN, "COVID-19-Impfung: Aufklärung und Urteilsfähigkeit", FMH Recht 2021, p. 158-159, p. 159.
341 See BÜRGI, BSK HMG, 2nd ed., Basel 2022, Art. 26 N 9.
342 HOFMANN, "COVID-19-Impfung: Aufklärung und Urteilsfähigkeit", FMH Recht 2021, p. 158-159, p. 159.

information for healthcare professionals **- and in particular about the gaps in the clinical data** .

1328 In view of the novelty of the mRNA "vaccines" and the still ongoing "rolling" approval procedure, **every doctor** was also **obliged to provide particularly careful and detailed information.** Accordingly, the patient also had to be informed that not all risks and side effects are yet known due to the lack of studies, i.e. that the information for healthcare professionals is not complete and is constantly being supplemented on the basis of new findings.

1.2.8. Medical profession: Duty of care under therapeutic products law violated in various ways

1329 As before (N 1233 ff.), the duty of care (in particular the duty to provide information) was exercised to varying degrees depending on the location and the medical professional responsible for the "vaccination". Accordingly, an attempt is made to group the cases:

1.2.8.1 Case group 1 - Cursory information, contraindications not taken into account

1330 With regard to case group 1 (above N 1234 f.), it should be noted that a five-minute explanation is hardly ever sufficient in view of the established complexity of the mRNA "vaccines". As already mentioned above (N 1235), as far as can be seen, no private plaintiff was sufficiently informed about the existence of a "temporary" authorization within the meaning of Art. 9a TPA with the associated **incomplete data situation**. No information was provided about the fact that this is an experimental "vaccine" that is still in the **test phase of human trials** (clinical phase III trials). There was also no information about the **lack of long-term studies** and the associated **uncertainty about possible side effects.** However, it was mandatory to provide information about all these circumstances - in particular because the doctor had specialist knowledge after consulting the information for healthcare professionals, which he had to pass on to the patient. Furthermore, nothing is known about the private plaintiffs having been correctly informed that their health is in no way significantly at risk without a COVID "vaccination" due to SARS-CoV-2, and what **valid alternatives** there were and are for prevention or treatment of the disease. In addition, it would have been imperative to at least provide information about the **warnings and side effects** already **contained in the information for healthcare professionals.** However, in view of the publicly available data on risks and side effects, simply relying on the information contained in the information for healthcare professionals clearly did not go far enough: it was therefore also imperative to provide information on the fact that the **worldwide reports of side effects had** already reached a level in mid-2021 that - as far as can be seen - had not previously been the case for a single medicinal product.

1331 A consideration of the "vaccination" of a person willing to be vaccinated therefore had to be made in detail after complete information about the most elementary principles of the "temporary" approval, such as the incomplete clinical data situation and all possible - even theoretically possible - side effects and in relation to the underlying diseases, risk factors and existing medication. Failure to comply with these mandatory elements therefore primarily constitutes inadequate information in these cases.

1332 Secondarily, it must also be examined whether the acting GP should have recognized contraindications based on the patient's medical history and should have advised his patient against the "vaccination", or even refused it. In view of the fact that the "vaccines" are still in the experimental phase, these clarifications had to be carried out with particular care. Where contraindications were identified on the basis of the specialist and patient information provided by Swissmedic, the family doctor was obliged to carry out further clarifications.

1333 Based on the documents available to date, there is a strong suspicion that in the aforementioned cases (front N 1234 f.) **no clarification had taken place that met the necessary requirements as described above** (see N 1322 ff.)**.**

1.2.8.2 Case group 2 - Absence of any vaccination history"

1334 With regard to case group 2 (above N 1241), it should be noted that **no clarification was documented in any way.** Until proven otherwise, it must therefore be assumed that in the cases mentioned above no information was actually provided. **Without information, however, any administration of a prescription-only medicinal product is simply unlawful.** The examination of further actions by the responsible doctors (or any responsible pharmacist) is therefore generally unnecessary in these cases.

1.2.9. Constitutive "success"?

1335 As mentioned at the beginning (front N 150 f.), the basic provision of Art. 86 para. 1 lit. a TPA is an abstract endangering offense - a factual "success" is therefore not necessary. The abstract endangerment is presumed on the basis of the previously described criminal act and does not have to be proven as an additional element of the objective offense in individual cases.

1.3. Qualification (Art. 86 para. 2 lit. a TPA)

1336 According to Art. 86 para. 2 lit. a TPA, manufacturing in breach of due diligence (Swissmedic) or use in breach of due diligence (medical profession) is subject to a qualified penalty

if it poses a specific risk to human health. As mentioned at the beginning (above N 153 ff.), proof of an actual **risk to the health of at least one person** must be provided.

1337 The front alone (N 86 ff.) were not only specifically endangered in their health by the mRNA "vaccines" authorized by Swissmedic and administered by doctors, but were even injured.

1338 There is therefore a strong suspicion that the defendants have specifically endangered people's health.

1.4. Causality between action and success

1.4.1. Connection between HMG action and health hazard

1339 There must be a legally relevant causal link between the handling (manufacture/use) of a therapeutic product and the abstract (para. 1) or concrete (para. 2) health risk. The consequence of this causality requirement is that only those duties of care that could actually lead (para. 1) or did lead (para. 2) to a health hazard are covered by Art. 3 TPA. In the case of the omission of legally required actions, the omission in question must have been adequately causal for the occurrence of the health risk to be assessed.[343] The same applies mutatis mutandis to Art. 7 TPA and Art. 26 TPA.

1.4.2. Causality theories

1.4.2.1 Active action: "conditio sine qua non"

1340 According to the conditional or equivalence theory, a cause is any condition that cannot be removed without the result being omitted *("conditio sine qua non").* Causality is therefore given regardless of the type of action of the perpetrator if this was only *a* condition for the success that occurred (so-called natural causality). Neither the number nor the weight of any (contributory) causes is relevant.[344]

1.4.2.2 Passive behavior: Hypothetical causal link

1341 In the case of passive conduct - i.e. an offense of omission - the hypothetical causal link must be determined. According to the prevailing case law and the case law of the Federal Supreme Court, this assessment must be made according to the so-called theory of

343 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 3 N 53; see also BGE 135 IV 37 E. 2.4.1 p. 40.

344 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 103 f.

probability: The required connection is given if the required action could not be added without the success most likely being omitted.[345]

1.4.3. Causality at Swissmedic

1342 The breaches of duty by Swissmedic described above cannot be ignored without eliminating the abstract and concrete health risks described above: The misguided choice of procedure for "temporary authorization" alone, and in particular the completely erroneous determination of the cost-benefit ratio, represent the central prerequisite for the authorization of the dangerous and useless mRNA "vaccines" in Switzerland, as a result of which a large number of people's health was endangered in both abstract and concrete terms. The same applies to the actions of the multiple extensions and maintenance of the authorizations.

1343 If the maintenance were to be seen as passive behavior, a corresponding hypothetical causal link would also exist: If Swissmedic had intervened and correctly revoked the illegal authorizations, further damage would obviously have been averted, or at least most likely.

1344 The actions (and omissions) of the persons responsible at Swissmedic are therefore by far the most important cause of the occurrence of the abstract and concrete health hazards.

1.4.4. Causality in the medical profession

1345 The same applies in principle to the medical profession: a careful medical history and thorough information for the patient are key to preventing health risks.

1346 If the **medical history** had been taken correctly - especially in the case of patients with a history of infection - the doctor acting correctly would have recognized the various general risks associated with the mRNA injection and those contained in the information for healthcare professionals, compared them with the low actual risk of SARS-CoV-2 infection in each individual case, refrained from injecting mRNA and thus prevented a (concrete) health hazard (for the time being).

1347 Furthermore, if the **patients** had been **informed** correctly, taking into account all the facts essential for their personal benefit/risk assessment (lack of data on efficacy and safety; trial stage of clinical phase III; approval only "temporary"; publicly available data on risks and side effects conspicuously negative, etc.), the patients would very likely have recognized, taking into account their personal circumstances, that an mRNA injection would in no way reliably improve the protection of their health against severe courses of COVID-19 infection. Due to the numerous risk and uncertainty factors and with correct information about the

345 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 325 f.

actual - rather weak - threat posed by SARS-CoV-2 (including the prevention and treatment alternatives available in this context), a different picture would have emerged in the end - weighing up all the circumstances in the context of an individual benefit/risk analysis - and many of the patients concerned would probably have refrained from the mRNA "vaccination".

1.5. Subjective facts

1348 For the distinction between contingent intent and negligence, see below N 1533.

1.5.1. Preliminary assessment concerning Swissmedic

1.5.1.1 With regard to the basic offense (para. 1 lit. a)

1349 Subjectively, intent, at least contingent intent, is required. [346]

1350 By the time the thousands of adverse reactions occurred worldwide since spring 2021 at the latest, it was clear to the notified parties acting at Swissmedic that all the risk signals that were already apparent at the end of 2020 had manifested themselves in an overt manner. From spring 2021 at the latest, the notified parties could therefore no longer trust that a possible "success" in the sense of a risk would not occur - it had obviously already occurred. In view of the overwhelming evidence already now - without having the complete approval documents at their disposal - the existence of the abstract health risk must therefore have been so obvious to them that the **willingness to simply accept this risk** can **reasonably only** be interpreted **as accepting it**.

1351 However, it was previously explained in detail that Swissmedic already had information internally at the end of 2020 that was highly worrying. Swissmedic had simply brushed aside all these alarm signals and had not communicated them publicly in any way. There are therefore already strong indications of a willingness on the part of the accused to have willingly and knowingly accepted health risks to a very large number of people as early as the end of 2020.

1352 There is therefore a strong suspicion that the persons acting on behalf of Swissmedic had already accepted an abstract health risk to a very large proportion of the Swiss population at the end of 2020, or at the latest from spring 2021 (approx. June 2021). Based on the seizures and confiscations to be carried out, the investigation must also examine what additional internal knowledge Swissmedic already had at an earlier point in time.

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346 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 92.

1.5.1.2 With regard to qualification (para. 2 lit. a)

1353 Here too, intent, or at least contingent intent, is required. The intent must at least include the concrete endangerment of the health of **at least one person.**[347]

1354 With regard to qualification, the above applies in principle. Depending on the evaluation of further documents - in particular the complete approval documents - an acceptance in favor of the defendants can at best be assumed from June 2021 at the earliest. However, by this time at the latest, the international data situation was almost overwhelming and thousands of specific health risks had to be assumed.

1.5.1.3 Possibly: Negligent commission?

1355 According to Art. 86 para. 4 TPA, negligent commission of the offense is also punishable.

1356 According to the above, there is hardly any room for a merely negligent commission of the offence, at most at the time of the first admissions at the end of 2020 or beginning of 2021. Due to the large amount of incriminating material already available as of December 2020 (as evidence of possible intent as of December 2020), it is to be expected that this strong suspicion of possible intent will be substantiated even after the requested investigative measures have been carried out, whereby new, exculpatory evidence would have to be taken into account ex officio (cf. Art. 6 para. 2 StPO).

1.5.2. Preliminary assessment regarding the medical profession

1357 In principle, a similar chronological sequence can also be assumed for the "vaccinating" medical profession: The more overwhelming the evidence, the more likely it is to assume intent instead of negligence. What the doctors knew or should have known must be investigated in the course of the criminal proceedings to be opened.

1.6. Justification Reason: consent?

1358 It should be noted in advance that the location of the examination of consent is dogmatically controversial: some doctrines consider consent to be a feature that excludes the offense, while others examine consent under the heading of unlawfulness.[348] In the present case, consent is examined - admittedly in a dogmatically unclean way - both in the area of the facts of the case (breach of duty of care due to lack of information) and under the heading of justification.

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347 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 94, N 100 (and N 4.)

348 In detail NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 10 ff.

1359 A more detailed description of the issue of consent is given in the case of the offense of (negligent) grievous bodily harm (see N 1589 ff.).

1360 The Basel Commentary on the Therapeutic Products Act takes the view that under Art. 86 TPA, the consent of (abstractly or specifically) endangered persons should in principle be considered as a justification.[349] **However, consent is only permissible where the person giving consent may dispose of the good alone** - which is only possible in the case of offenses against the individual (i.e. in particular Art. 111 ff. of the Swiss Criminal Code).[350] The individual cannot validly dispose of legal interests of the general public.[351] How an individual should be able to consent to an offense that endangers the common good of the **health of all people** in abstract or concrete terms (see in detail above N 149 ff.) is not comprehensible. The validity of the consent of an individual - let alone a somehow fictitious consent of the "general public" - to the criminal acts of **Swissmedic** under Art. 86 TPA can therefore be ruled out. The objectively ascertainable breaches of the duty of care committed by Swissmedic, as set out in detail above, are decisive (see above N 1289 ff.).

1361 With regard to the criminal liability of the **medical profession,** it should be noted that a valid consent would already exclude the criminal liability: If there was a consent after sufficient information, the "vaccinating" persons would not have acted carelessly. Previously (N 1322 ff, N 1329 ff.) it has already been explained in detail that there is a lack of sufficient information, which rules out valid consent.

1.7. Grounds for exclusion of guilt

1362 No grounds for exclusion of guilt are apparent.

1.8. Conclusion

1363 There is a strong suspicion that the persons reported and the other perpetrators still to be identified have committed an offense under Art. 86 para. 1 lit. a and para. 2 lit. a TPA (possibly Art. 86 para. 4 TPA).

2. Violation of reporting obligations (Art. 87 para. 1 lit. c TPA)

1364 According to Art. 87 para. 1 lit. c TPA, anyone who intentionally violates reporting obligations under the Therapeutic Products Act is liable to a fine of up to CHF 50,000.

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349 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 95.
350 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 18.
351 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 25.

1365 Art. 87 para. 1 lit. c TPA includes, in particular, reporting obligations pursuant to Art. 59 para. 1-3 TPA.[352] These were discussed in detail above (N 898 ff.).

2.1. Objective facts

2.1.1. Perpetrators

1366 The group of perpetrators is open ("who"): It is a matter of reporting obligations that must be fulfilled by anyone who carries out their own activities with therapeutic products and thereby possibly creates a dangerous situation themselves. [353]

2.1.1.1 Swissmedic

1367 As before (N 899 ff.), Swissmedic is responsible within the framework of ex-post market surveillance for the **situation-specific - comprehensive and effective - monitoring of therapeutic product safety** and **strict enforcement of the obligation to notify.** If the Agency violates this obligation, it creates a risk to public health, which means that the persons acting on behalf of the Agency are potential offenders with regard to the violation of reporting obligations within the meaning of Art. 87 para. 1 lit. c TPA in conjunction with Art. 59 para. 1-3 TPA. Art. 59 para. 1-3 TPA in conjunction with Art. 58 para. 3 TPA. Art. 58 para. 3 TPA.

2.1.1.2 Medical profession

1368 As before (N 904 ff.), medical professionals (physicians) must report, among other things, all **serious** side effects as well as all **unknown** side effects that are not listed in the information for healthcare professionals. Doctors therefore belong to the potential group of offenders with regard to the violation of reporting obligations within the meaning of Art. 87 para. 1 lit. c TPA in conjunction with Art. 59 para. 3 TPA. Art. 59 para. 3 TPA.

2.1.2. Object of the crime: Pharmaceuticals

1369 With regard to the therapeutic products mentioned in Art. 59 para. 1-3 TPA, the legal definitions according to the TPA apply.[354] In the present case, only the definition of "medicinal products" pursuant to Art. 2 para. 1 lit. a in conjunction with Art. 4 para. 1 lit. a TPA is of interest. Art. 4 para. 1 lit. a TPA, which has already been described above (N 1255 ff.) have

352 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 18.
353 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19.
354 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 19.

already been described above: The mRNA injections are medicinal products within the meaning of the TPA.

2.1.3. Criminal offense: violation of the duty to report

2.1.3.1 On the part of Swissmedic

1370 At no time did Swissmedic fulfill its obligations to install a **situation-appropriate - comprehensive and functioning - monitoring of therapeutic product safety** and **strict enforcement of the reporting obligation:**

1371 The passive reporting systems are not appropriate for an active substance that is still in the phase of the first ever human trial, and which from the outset exhibited so conspicuously many and so strikingly serious risk characteristics (front N 185 ff. and N 1291 ff.), is simply inadequate. With the mRNA "vaccinations", Swissmedic has for the first time ever approved a gene therapy for prophylaxis in a healthy population for a "limited period" (i.e. on the basis of completely inadequate data) - and has taken the greatest possible risk. Given this initial situation, **the mRNA "vaccines" should have been subjected to active pharmacovigilance from the outset - similar to that under study conditions** (see N 1151 ff., in particular N 1154 ff.).

1372 To make matters worse, Swissmedic does not even come close to enforcing the passive reporting system to the extent required by law: In Switzerland, **only around 10% of all adverse drug reactions** are **reported at all,** which represents **massive underreporting** (front N 1159 f.; see also N 441 ff., N 612 ff.). Swissmedic clearly does not require those obliged to report to comply with strict reporting discipline, or does not do so to a sufficient degree - which the present situation with the novel mRNA "vaccines" would absolutely require. This **massive underreporting** makes it impossible for Swissmedic (and the public) to recognize the full extent of the devastating consequences in order to take appropriate safety measures (such as the mandatory adaptation of the information for healthcare professionals).

1373 There is therefore a strong suspicion that Swissmedic has breached its due diligence obligations in the area of therapeutic products reporting obligations on several occasions and, above all, on an ongoing basis.

1374 If the reporting system does not meet the legal requirements of Art. 59 SCC or if the medicinal product information is not adapted in good time as a result, **criminal liability under Art. 86 para. 1 lit. a** (or even para. 2) may also apply if there is a **risk to health.**[355]

355 EICHENBERGER, BSK HMG, 2nd ed., Basel 2022, Art. 59 N 31a.

Accordingly, the violated reporting obligations have already been discussed previously (N 1296, N 1302, N 1308, N 1314) are cited.

2.1.3.2 On the part of the medical profession (medical staff)

1375 The medical profession is obliged to treat even **mere suspicions** (see N 908 ff.) **of serious or new side effects.**

1376 From the massive underreporting in Switzerland alone, it can be concluded that the medical profession complies with this reporting obligation in a completely inadequate manner.

1377 This is exemplified by the case of private claimant 3: None of the doctors treating her felt compelled to submit a report to Swissmedic, despite their existing obligation to do so. In the end, she even had to submit the report herself.

1378 There is therefore a strong suspicion that a large number of doctors have breached their duty of care in the area of reporting obligations under therapeutic products law.

2.2. Subjective facts

2.2.1. Intention

1379 Subjectively, the facts of Art. 87 para. 1 lit. c TPA require intent, whereby contingent intent is sufficient.[356] For the distinction between contingent intent and negligence, see below N 1533.

1380 In view of the months - indeed years - of tolerated and obvious underreporting of side effects, it must now be assumed that all those involved accepted the consequences. The corresponding suspicion must be substantiated (or rejected) as part of the criminal proceedings to be conducted.

2.2.2. Negligence

1381 If no intent can be proven, it should be noted that negligence is also covered by Art. 87 para. 3 TPA.[357]

356 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 39.
357 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 44.

2.3. Forms of participation

1382 It should also be noted that - despite the mere offense (cf. Art. 105 para. 2 SCC) - attempt and aiding and abetting are also punishable (Art. 87 para. 4 TPA).[358]

2.4. Grounds for justification and exclusion of guilt

1383 There are no apparent grounds for justification or exclusion of guilt.

2.5. Conclusion

1384 There is a strong suspicion that the persons reported and the other perpetrators still to be identified have committed an offense under Art. 87 para. 1 lit. c TPA.

3. Violation of the ban on advertising (Art. 87 para. 1 lit. b HMG)

1385 According to Art. 87 para. 1 lit. b TPA, anyone who violates the provisions on the advertising of medicinal products is liable to a fine of up to CHF 50,000.

3.1. Objective facts

3.1.1. Perpetrators: Swissmedic and Insel Group

1386 The group of offenders is openly formulated ("who"). According to Art. 31 para. 3 TPA, the object of protection of the provisions on the advertising of medicinal products is health and protection against deception or misleading information. The provisions on the advertising of medicinal products are violated by anyone who

- does not comply with the limits of permissible advertising in professional advertising in accordance with Art. 32 para. 1 TPA and Art. 3-13 of the Medicinal Products Advertising Ordinance (AWV; SR 812.212.5) or
- does not comply with the limits of permissible advertising in advertising to the public in accordance with Art. 32 para. 1 and 2 TPA and Art. 14-22 and Art. 23 para. 1 AWV.[359]

1387 Everyone is therefore an addressee of this provision - including those acting on behalf of Swissmedic and the Insel Group.

358 See SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 46 ff.
359 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 14.

3.1.2. Object of the crime: Pharmaceuticals

1388 The mRNA injections are medicinal products within the meaning of the HMG (see N 1255 ff.; N 1369).

3.1.3. Offenses

3.1.3.1 Prohibited advertising to the public

1389 **Advertising to the general public** is only permitted for non-prescription medicinal products in dispensing categories C, D and E (Art. 31 para. 1 lit. b TPA; Art. 14 AWV). As **mRNA "vaccines"** belong to category B (prescription-only; see N 1228 f.), they are subject to a **strict ban on advertising to the general public.** Advertisements in newspapers, brochures or posters (lit. a) and also advertising via electronic media (lit. c) are considered to be advertising to the public according to Art. 15 AWV. The ban on advertising to the general public therefore also applies to prescription-only medicinal products on the **Internet**. [360]

1390 Medicinal product advertising includes all information, marketing and incentive measures aimed at promoting the prescription, dispensing, sale, consumption or use of medicinal products (Art. 2 lit. a AWV). The intention to promote sales is the essential criterion here: this includes **all sales-promoting measures that are** likely to infringe one of the interests of public health (e.g. **protection against deception** or **protection against inappropriate use of medicinal products**).[361] According to Swiss case law, an activity qualifies as pharmaceutical advertising if a large number of people are influenced by certain measures or if **incentives are created that are intended to cause these people to change their consumption behavior.**[362] Even the mere provision of information about possible uses of medicinal products constitutes advertising if it is intended and suitable to influence consumer behavior.[363] Advertising does not have to refer directly to a medicinal product: It is also sufficient if it is clear and unambiguous to an averagely educated and interested addressee of the advertisement which specific medicinal product is being advertised on the basis of their prior knowledge or further information.[364] A distinction must be made between drug advertising and drug information: If the active pharmaceutical ingredients are uprated compared to other effective active pharmaceutical ingredients or other active pharmaceutical ingredients are neglected and/or **undesirable side effects are**

360 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 82, Art. 32 N 43a.
361 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 21a.
362 Judgment C-5490/2015 of the FAC of March 28, 2017, E. 6.4.1; Judgment C-3090/2014 of the FAC of March 4, 2016, E. 4.3.4.
363 Judgment C-5490/2015 of March 28, 2017, E. 6.4.1.
364 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 21b.

concealed, the ban on advertising to the general public stands in the way of such an approach.[365] Such unbalanced and incomplete information cannot meet the requirements for permissible information of a general nature within the meaning of Art. 1 para. 2 lit. c AWV.[366] Moreover, it was probably misleading advertising anyway:

3.1.3.2 Misleading specialist advertising

1391 **Specialist advertising** - i.e. advertising in specialist journals or via electronic media (Art. 4 lit. a and c TPA) - is also permitted for category B medicinal products (Art. 31 para. 1 lit. a TPA). The specialist advertising must be **accurate, balanced, factually correct and verifiable**; in addition, the statements must **not be misleading (**Art. 5 para. 3 TPA; see also Art. 32 para. 1 lit. a TPA). The misrepresentation or suppression of facts is considered to be misleading.[367] **Healthcare professionals have a health policy-based interest in factually correct advertising of medicinal products: the** aim is to prevent healthcare professionals from being misled and thereby prescribing or dispensing unnecessary or unsuitable medicinal products.[368] If, for example, experience, findings and assessments in practice show that a **statement in a medicinal product information** is misunderstood by healthcare professionals, patients or competitors, the marketing authorization holder, together with the Agency, must immediately ensure that clarity is created by **eliminating** the risk of **misleading information by making the necessary clarifications**. This is a concretization of the duty of care contained in Art. 3 TPA (see above N 1284).[369]

3.1.4. Acts of Swissmedic

3.1.4.1 Prohibited advertising to the public

1392 As before (N 1190 ff.), Swissmedic has published every single authorization decision by means of misleading **media releases** and continues to maintain these publications to this day. With this misleading communication, Swissmedic **created the dangerous illusion of efficacy and safety in the population.**

1393 As before (N 1204 ff.), **Swissmedic** has also maintained a **"FAQ"** on its own website since the start of the "vaccination campaign", which is aimed at the entire population. This contains blatantly false information ("So far there are no indications of lasting negative

365 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 33.
366 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 33.
367 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 32 N 11, cf. also Art. 31 N 49.
368 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 32 N 16.
369 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 32 N 35.

consequences for health"; false quality information; false efficacy information; false risk information) and completely lacks sufficient risk information on serious side effects and the special nature of the present procedure, which undermines almost all safety mechanisms. Swissmedic therefore presents the mRNA "vaccines" in a completely unbalanced, even misleading manner.

1394 Swissmedic thus gives the public the - demonstrably untrue - impression that mRNA "vaccines" are of high quality, safe and largely free of side effects, **which is likely to persuade consumers (misled in this way) to change their consumption behavior - to take a (regular) "vaccination".**

3.1.4.2 Misleading specialist advertising

1395 Previously (N 1198 ff.), it was explained in detail that Swissmedic had published inadequate, incorrect and misleading texts in the information for healthcare professionals on the mRNA "vaccines" from the outset. Even after two years, Swissmedic had not adequately updated these texts and had **omitted** various (serious) **side effects** whose occurrence was so frequent that they had to be included as risk signals as early as 2021. Important **warnings are** also still completely missing - or are misleading and incorrect - even though numerous publications, international adverse reaction reports and other sources made their (correct) inclusion in the information for healthcare professionals mandatory. **The information for healthcare professionals on the two COVID-19 "vaccines" Comirnaty and Spikevax is therefore incomplete, incorrect and misleading overall.**

1396 As before (N 1209 *in fine)*, **Swissmedic** also disseminates **blatant trivializations and blatant misinformation** in other publications such as the "Vigilance News" for the attention of the specialist public**.**

1397 Through these deceptions, which have been repeatedly renewed and reinforced since the end of 2020, **Swissmedic** has **deliberately misled the professional public,** which is particularly serious, as it has allowed healthcare professionals to administer the unsuitable - indeed dangerous - mRNA injections to patients.

3.1.5. Offenses Island Group: Prohibited advertising to the public

1398 As before (N 1243 ff.), the Insel Gruppe also publishes information on its own website which is used to present the mRNA "vaccines" in a completely unbalanced, even misleading manner. In this way, the Insel Gruppe also gives the public willing to be vaccinated the impression that the mRNA "vaccines" are safe and largely free of side effects in order to persuade

the (misled) consumer to change their consumption behavior - to take a regular "vaccination".

3.2. Subjective facts

3.2.1. Intention

1399 Subjectively, the facts of Art. 87 para. 1 lit. b TPA require intent, whereby contingent intent is sufficient.[370] For the distinction between contingent intent and negligence, see below N 1533.

1400 In particular, in view of the embellished and downright misleading public advertising of the mRNA "vaccines" on **Swissmedic'**s own website, which has continued **since December 2020 to the present day** (i.e. for more than 18 months), and the completely misleading specialist advertising even in 2022, there is considerable suspicion that the persons acting on behalf of **Swissmedic** have at least accepted the possibility of violating advertising bans under therapeutic products law. The corresponding suspicion must be substantiated (or rejected) as part of the criminal proceedings to be conducted.

1401 The same applies with regard to advertising to the public for those acting on behalf of the **Insel Group.**

3.2.2. Negligence

1402 If no intent can be proven, it should be noted that negligence is also covered by Art. 87 para. 3 TPA.[371]

3.3. Forms of participation

1403 It should also be noted that - despite the mere offense (cf. Art. 105 para. 2 SCC) - attempt and aiding and abetting are also punishable (Art. 87 para. 4 TPA).[372]

3.4. Grounds for justification and exclusion of guilt

1404 There are no apparent grounds for justification or exclusion of guilt.

370 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 31 N 21a.
371 SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 44.
372 See SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 87 N 46 ff.

3.5. Conclusion

1405 There is a strong suspicion that the persons reported and the other perpetrators still to be identified have committed an offense under Art. 87 para. 1 lit. b TPA.

II. Dangerous offenses of the StGB

1406 Due to the close factual connection to the provisions of the TPA and the structure of the offense as an endangering offense, Art. 230bis StGB (concrete endangering offense), Art. 317 StGB (abstract endangering offense) and Art. 129 StGB (concrete endangering offense) will be discussed first. The next section describes the successful offenses under the SCC.

1. Danger from *GMOs* or pathogenic organisms (Art. 230bis StGB)

1407 According to Art. 230bis para. 1 lit. a StGB, anyone who intentionally releases genetically modified or pathogenic organisms if they know or should know that they are endangering the life and limb of humans through these actions is liable to prosecution. According to para. 2, negligence is also punishable.

1.1. Objective facts

1.1.1. Means of crime

1.1.1.1 Genetically modified organisms

1408 In the substantive part, it was explained in detail that the mRNA "vaccines" are a "**gene therapy**" - i.e. an endogenous production of a spike protein of unknown quality and unknown quantity, forced by mRNA substances, over an unknown period of time, which would not be produced by the human body itself without this intervention (see N 186 f.; ER N. 25 ff. and N 34 ff.). It was shown that both the manufacturers and the regulatory authorities of the USA (FDA) and the EU (EMA) had - correctly - equated mRNA preparations with gene therapies and classified them as Advance Therapy Medicinal Products (ER N 20 ff.). With reference to Swissmedic, it was shown that the supreme regulatory and supervisory authority for medicinal products had created a new department for "Advanced Therapy Medicinal Products" (ATMP) in January 2022 (front N 527) and stated in this context that it was "responsible for products and procedures with **properties comparable to gene therapy products**", which would also include "preparations [...] such as [...] mRNA". Swissmedic thus made it clear enough that the mRNA-based COVID-19 preparations were to be assigned to the special risk class of ATMPs.

1409 It was also shown that both the Federal Office of Public Health (FOEN; front N 528) and Swissmedic (front N 529 f.) unanimously came to the conclusion that these vaccines are genetically modified organisms (*GMOs*). In particular, the FOEN openly stated that **"mRNA vaccines are biologically active genetic material", which is why they are "legally equivalent to an organism"** (see N 528). Both authorities thus recognized that these mRNA active substances are to be regarded as genetically modified organisms within the meaning of Art. 5 para. 2 of the Gene Technology Act (GTG, SR 814.91) as well as within the meaning of Art. 230bis StGB, which is why a market authorisation of these products in the simplified authorisation procedure (Art. 9a TPA) would be completely excluded (see above N 531, N 926 ff., N 944, N 948, N 1003).

1410 **The mRNA active substances in question are therefore also to be regarded as genetically modified organisms and therefore as a means of committing an offense within the meaning of Art. 230bis StGB.**

1411 In addition, it was explained that a transcription of mRNA into DNA (so-called "reverse transcription") has not yet been ruled out due to a lack of corresponding studies (see N 200 ff.). The enclosed evidence report also explains in detail, with reference to initial studies, how and where such an incorporation of "vaccine" mRNA into human DNA could occur, that such a risk cannot be categorically ruled out, and that this risk had also been recognized by Swissmedic (on so-called reverse transcription: ER N 81 ff.).

1.1.1.2 Pathogenic organisms

1412 It should also be checked whether pathogenic organisms could also be involved if pathogenicity can be demonstrated:

1413 Organisms are pathogenic if they can cause diseases (Art. 7 para. ^{5quater} USG). Pathogenicity results from the abstract potential of the introduced organism to cause transmissible diseases. These must be diseases that are triggered by the biological effect of the microorganism in the host, in that the organisms multiply or produce toxic substances that cause the host to become ill.[373]

1414 The evidence report explained in detail that the injected mRNA substances are packaged in lipid nanoparticles, which are highly toxic and have the potential to cause significant harm to the human body (ER 118 ff., N 137 ff.; above N 212 ff.). The evidence report also showed that the manufacturers had selected a substance with a demonstrably toxic effect in the form of the spike protein (ER 51 ff., N 594 ff., N 1155 ff.; foreground N 391 et seq.).

373 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 10.

Therefore, there is also a strong suspicion here that the mRNA "vaccines" could be pathogenic organisms within the meaning of Art. 230bis para. 1 lit. a SCC.

1.1.1.3 Further requirements for the instrumentality?

1415 Furthermore, the wording of the law does not impose any special requirements on the organisms as means of committing an offense pursuant to Art. 230bis . In particular, it is not required that the organism itself must already have a certain minimum degree of dangerousness. Rather, the potential for harm and thus the criminally relevant danger results from the respective criminal conduct. The success of the endangerment can, of course, result from the criminal handling of an organism that is already dangerous in itself. However, it is also conceivable that only the corresponding conduct - such as the release of a pathogenic organism in a certain quantity or into a certain environment - causes the endangerment, whereas the organism itself would not be dangerous in the criminal law sense if used differently.[374]

1.1.2. Criminal act

1416 The criminal act of releasing organisms pursuant to Art. 230bis StGB covers both the experimental release and the placing on the market of the organisms.[375] **Authorized release is also an offence.**[376] Initially, however, "unauthorized release" was still required as an offence.[377,378] "Release" is defined as any "handling of organisms in the environment", i.e. outside of "closed systems".[379]

1417 The mRNA "vaccines" have already been used millions of times on humans in Switzerland on the basis of a "temporary" authorization by Swissmedic, which violates fundamental legal duties of care, and have thus been placed on the market.

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374 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 11.

375 WBK-S, minutes of the meeting of 2/3 April 2001, 79 f.; cf. also BARBEZAT, ZStrR 2011, 378. In the GTG and the USG, a distinction is made between these types of release, cf. Art. 11 and 12 GTG, Art. 29c and 29d USG.

376 Supplementary Report II of the Administration of 27. 3. 2001, No. 3, WBK-S, Minutes of the meeting of 2/3. 4. 2001, Annex.

377 Cf. for example WBK-S, minutes of the meeting of 14. 12. 2000, 4; report of the administration of 16. 1. 2001, para. 3.1; WBK-S, minutes of the meeting of 22. 1. 2001, 21, 23; supplementary report of the administration of 16. 2. 2001, para. 3, WBK-S, minutes of the meeting of 19./20. 2. 2001, appendix; WBK-S, minutes of the meeting of 19./20. 2. 2001, 5 ff.

378 On the whole ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 14; gl. M. BARBEZAT, ZStrR 2011, 378; see also PK3-TRECHSEL/CONINX, Art. 230bis N 4.

379 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 13.

1.1.3. Factual "success "

1418 Art. 230bis para. 1 lit. a StGB requires a threat to the life and limb of people as a constituent element of the offense.

1419 A **specific** risk is required. The probability of the damage occurring is decisive. A specific risk exists if, in the normal course of events, there is a probability or a remote possibility that the protected legal interest will be infringed. A particularly imminent, acute risk of injury is required.[380] To establish a common risk, it is sufficient that an individual person has been specifically endangered, but only if they are not individually determined from the outset in the sense of the theory of representation, but are selected by chance.[381]

1420 As a result, the same concrete risk is required as under Art. 86 para. 2 lit. a TPA. This is - as previously (N 1336 ff.) - is given.

1.2. Subjective facts

1.2.1. Intention

1421 Intent is required, whereby contingent intent is sufficient. Contingent intent must also include endangerment: the perpetrator must have recognized that an endangerment could possibly occur and must have accepted it.[382]

1422 As explained above, the FOEN pointed out in January 2022 that mRNA products should be considered (*genetically modified) organisms* (GMOs) (see N 528). And in response to a private request, Swissmedic also stated in November 2022 that it equated mRNA products with GMOs and also assigned them to the ATMP risk group (see N 529):

> "However, **mRNA products** are **ATMPs** because they contain nucleic acid, regulate gene expression and **are considered 'biologically active material' (i.e. RNA) equivalent to genetically modified organisms (GMOs).** Thus, the vaccines are not defined as therapy, but due to their **classification as GMOs** in the category **Advanced Therapy Medicinal Products.**"

1423 In addition, Swissmedic was already aware of the risk of mRNA integration into the human genome at the end of 2020; the regulatory authority described this possibility as "very low" (front N 204). This at least "very low" (but possibly also somewhat greater) risk did not

380 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 18, N 23.

381 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th ed., Basel 2019, Art. 230bis StGB N 18, N 24.

382 ACKERMANN / SCHRÖDER BLÄUER, in: BSK StGB, 4th edition, Basel 2019, Art. 230bis StGB N 31 ff.

subsequently prompt Swissmedic to take any safety measures, which means that any realization of this risk was obviously accepted.

1.2.2. Negligence

1424 If intent cannot be proven, it should be noted that Art. 230bis para. 2 SCC also covers the negligent commission of the offense.

1.3. Grounds for justification and exclusion of guilt

1425 There are no apparent grounds for justification or exclusion of guilt.

1.4. Conclusion

1426 **There is sufficient suspicion that the persons reported and the other perpetrators still to be identified have committed an offense under Art. 230bis para. 1, or possibly para. 2, SCC**.

2. Falsification of documents in office (Art. 317 StGB)

1427 According to Art. 317 para. 1 SCC, anyone who, as a public official or person of public faith, intentionally forges or falsifies a document is guilty of forgery in office. If the offender acts negligently, the penalty is a fine (Art. 317 para. 2 SCC). Forgery of documents is an abstract endangering offense.[383] .

2.1. Objective facts

2.1.1. Perpetrators

1428 Civil servants within the meaning of Art. 317 SCC are civil servants and employees of a public administration and the administration of justice as well as persons who provisionally hold an office or are provisionally employed by a public administration or the administration of justice or temporarily exercise official functions (Art. 110 para. 3 SCC). The decisive factor is the function in the service of the public.[384]

1429 The persons notified by Swissmedic work for Swissmedic in a managerial capacity. Swissmedic is an independent institution under public law and fulfills a public service mandate, which means that the notified persons are considered public officials within the meaning of the Swiss Criminal Code.

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383 BGE 129 IV 53 E. 3.2 P. 58.
384 BGE 135 IV 201.

2.1.2. Criminal act

1430 The offenses under Art. 317 para. 1 SCC correspond to forgery of documents under Art. 251 para. 1 SCC[385] . Only documents that are intended and suitable to prove a fact of legal significance are deemed to be documents (Art. 110 para. 4 SCC). Facts are legally significant if they alone or in conjunction with other facts have the effect of creating, maintaining, establishing, changing, transferring or rescinding a right or an obligation.[386] False certification is the **creation of** a genuine but **untrue deed,** i.e. where the actual facts and the facts contained in the deed do not correspond. The truth of the declaration is protected: a deed is true if its content gives rise to ideas that correspond to reality according to the public perception of the addressee. **It is untrue if the facts to which it refers did not occur at all or occurred in a different way**.[387] False certification requires a qualified written lie. According to the case law of the Federal Supreme Court, this is assumed to be the case if the document has **increased credibility** and the addressee therefore places particular trust in it: Generally valid objective guarantees that ensure the truth of the declaration are necessary.[388] False certification is also possible by omission.[389]

1431 According to Art. 67 para. 1 TPA, Swissmedic is obliged to inform the public truthfully about special events in connection with therapeutic products:

> "The Agency ensures that the public is informed about special events in connection with therapeutic products that endanger health and receives recommendations for action. It publishes information of general interest from the therapeutic products sector, in particular on authorization and revocation decisions as well as findings in the context of market surveillance."

1432 Art. 67 para. 1 TPA in conjunction with Art. 67 para. 1bis and Art. 67 para. 8 and para. 9 TPA form the formal legal basis, which imposes **overall responsibility on** the "Agency" **Swissmedic for the completeness and correctness of the collection of all medicinal product information** relating to preparations authorized by it, including information on ingredients, indications and contraindications. The medicinal product information (information for healthcare professionals and patient information) is published in the form of an electronic directory **(**www.swissmedicinfo.ch) and at the expense of the marketing authorization holders. [390]

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385 BGE 117 IV 286 E. 6b p. 290 f.
386 BGE 113 IV 77 E. 3a, with further references.
387 BSK-StGB, BOOG, N 66 to Art. 251.
388 BGE 132 IV 12 E. 8.1 p. 14 f.; 129 IV 130 E. 2.1 p. 133 f.
389 Judgment 6P.76/2004 of the BGer of 01.10.2004, E. 6.4
390 MEYER / PFENNINGER-HIRSCHI, BSK HMG, 2nd ed., Basel 2022, Art. 67 N 7b.

1433 The publication of all information for healthcare professionals and patient information in the electronic directory must always be complete, up-to-date and in a suitable and structured form. Publication is based on the **medicinal product information approved by the Agency (Swissmedic) as** part of the authorization or variation decisions.[391] If, for example, experience, findings and assessments during practical implementation indicate that a **statement in a medicinal product information** is misunderstood by healthcare professionals, patients or competitors, the marketing authorization holder, **together with the Agency,** must immediately ensure that clarity is provided by **eliminating** the risk of **misleading information by making the necessary clarifications**.[392]

1434 With the **approval** and publication, Swissmedic, as a particularly qualified specialist authority, lends an "official seal of approval" to the specialist and patient information provided to the public, which gives it **increased credibility.** As previously (N 1198 ff.; see also N 1395; in detail ER N 2111 ff.), the **information for healthcare professionals** (and thus also the far less detailed patient information based on it) **on the two COVID-19 "vaccines" Comirnaty and Spikevax** are **incomplete, incorrect and misleading overall - in particular, there is a lack of mandatory information on known and unknown risks and contraindications.** Swissmedic has therefore produced several untrue documents. Swissmedic has also continuously underpinned these multiple acts of deception with various other deceptive information (see above N 1289 ff. with further references; **see in particular the detailed catalog in ER N 1964 ff**.) - instead of informing the public truthfully without delay.

1435 **Swissmedic therefore created and published untrue documents within the meaning of Art. 317 SCC on a large scale and with effect for practically the entire population of Switzerland with the specialist and patient information on Comirnaty and Spikevax, and maintained this deceptive effect over a long period of time.**

2.1.3. No "successful offense" necessary

1436 As an abstract endangerment offense, the offense is already completed when the false documents are put into circulation.[393] It is not necessary for a person to actually be deceived.[394]

1437 Nevertheless, it should be noted at this point that the untrue and misleading information in the information for healthcare professionals and patients had **fatal consequences** for a not inconsiderable proportion of the population: this is key information that is capable of

391 MEYER / PFENNINGER-HIRSCHI, BSK HMG, 2nd ed., Basel 2022, Art. 67 N 18c.
392 JAISLI / SCHUMACHER-BAUSCH, BSK HMG, 2nd ed., Basel 2022, Art. 32 N 35.
393 BGE 113 IV 77 E. 4 P. 82.
394 BGE 121 IV 216 E. 4 p. 223 with reference.

significantly influencing the **decision to give consent.** The information approved by Swissmedic was - as explained in detail (N 1198 ff.; see also N 1395; in detail ER N 2111 ff.) - were **in massive contradiction to reality and misled the public, as well as healthcare professionals, in a legally relevant manner and permanently about the low to complete lack of efficacy and about the actual severity of the risks associated with these products.**

2.2. Subjective facts

1438 Intent is given if the perpetrator, in his capacity as a public official, deliberately states legally significant facts that are untrue in a document that he knows is suitable or intended to prove those facts.[395] In addition, the perpetrator must act with the **intention to deceive in legal transactions.** The intention to deceive arises from the intention of the perpetrator to use the documents as genuine.[396] The perpetrator must intend to deceive legal transactions or at least accept it. [397]

1439 Those responsible at Swissmedic deliberately allowed and continue to allow the publication of specialist and patient information with untrue content in order to facilitate and maintain the approval of the mRNA "vaccines" and to promote their administration. And this despite the fact that they have long known or should have known that the cost-benefit profile for the average population in general (see N 1289 ff.) is clearly to the disadvantage of the mRNA "vaccines" and that they should therefore have been withdrawn from the market long ago. They are therefore aware of the falsity of the content and nevertheless want to convey the safety of the "vaccines" to the general public, thereby acting with the intention to deceive.

2.3. Grounds for justification and exclusion of guilt

1440 There are no apparent grounds for justification or exclusion of guilt.

2.4. Privilege: Negligence

1441 In the alternative, negligent commission of the offense must be examined in accordance with Art. 317 no. 2 StGB.

395 BGE 100 IV 182.
396 BGE 135 IV 198, unpublished E. 9.4
397 BGE 100 IV 180 E. 3a p. 182.

2.5. Conclusion

1442 There is a strong suspicion that the persons reported and the other perpetrators still to be identified are liable to prosecution under Art. 317 para. 1 SCC, or possibly para. 2.

3. Endangering life (Art. 129 StGB)

1443 According to 129 StGB, anyone who unscrupulously puts a person's life in imminent danger is liable to prosecution.

1444 The legal interest covered by Art. 129 SCC is life (not health). Because this must actually be put in immediate danger, it is a specific endangering offense.[398]

3.1. Objective facts

1445 What is required is the causing of a concrete, direct danger to the life of another person. The latter must be specifically identifiable, or it must at least be a clearly defined group of people.[399] Not every, but only an immediate danger to life is sufficient. This is the case if "in the normal course of events, there is a probability or a remote possibility of injury to the protected legal interest".[400] In road traffic, this imminent possibility can be, for example, the "high probability" of a serious accident with potentially fatal consequences.[401]

1446 In the present case, at least the case of private claimant 1 is on record, who suffered a grade III anaphylactic shock immediately after the mRNA injection and only survived thanks to immediate hospitalization. Due to her previous (two) grade III anaphylactic shocks after ingesting peanuts, the (very) remote possibility of a fatal consequence of the injection was a definite possibility and had manifested itself accordingly. In view of the numerous reports of potentially fatal cases of myocarditis and other serious side effects, the number of people actually at risk is likely to increase many times over.

1447 The objective facts are therefore likely to be fulfilled in a large number of cases without further ado.

3.2. Subjective facts

1448 It is more difficult to prove the subjective element of the offense, as this requires both direct intent and unscrupulousness:

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398 MAEDER, in: BSK StGB, 4th edition, Basel 2019, Art. 129 StGB N 6 and N 12.
399 MAEDER, in: BSK StGB, 4th edition, Basel 2019, Art. 129 StGB N 8 and N 10.
400 BGE 133 IV 1, E. 5.1 P. 8; BGE 94 IV 60, P. 62.
401 MAEDER, in: BSK StGB, 4th edition, Basel 2019, Art. 129 StGB N 21.

3.2.1. Direct intent

1449 Art. 129 SCC requires direct intent; contingent intent with regard to endangerment is not sufficient according to doctrine, materials and case law of the Federal Supreme Court.[402]

1450 To take the example of private plaintiff 1: According to previous knowledge, her "vaccinating" family doctor was aware that she had already suffered grade III anaphylactic shocks twice after ingesting peanuts. There was therefore no doubt that she was aware of this. However, whether the family doctor also wanted to endanger the life of the private plaintiff 1 must be determined.

1451 The same applies to those acting on behalf of Swissmedic: they must have been aware of the potential lethal risks. The will side, on the other hand, must be determined. The same applies to those acting on behalf of the "Insel Gruppe".

3.2.2. Unscrupulousness

1452 However, not only direct intent is required, but also "unscrupulousness". There must therefore be a qualified degree of reproachability - such as a particular lack of restraint and recklessness on the part of the perpetrator, a danger that lacks any consideration for the lives of other people.[403]

1453 Such evidence is likely to be provided first and foremost by "vaccinating" doctors who acted almost "on a piecework basis" and omitted all basic safety mechanisms (in particular a complete lack of information). The same applies to those acting on behalf of Swissmedic and the "Insel Gruppe".

3.3. Grounds for justification and exclusion of guilt

1454 With regard to the justification of consent, it should be noted that the principle of "volenti non fit iniuria" does not apply to Art. 129 SCC: the unscrupulous offender - and only the unscrupulous offender is punishable under Art. 129 SCC - cannot exculpate himself by referring to the consent of the victim.[404] The justification of consent is, moreover, discussed at the back (N 1589 ff.) (see also N 1522).

1455 There are also no apparent grounds for exclusion of guilt.

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402 MAEDER, in: BSK StGB, 4th ed., Basel 2019, Art. 129 StGB N 57, inter alia with reference to BGE 133 IV 1 E. 5.1 p. 8.
403 MAEDER, in: BSK StGB, 4th edition, Basel 2019, Art. 129 StGB N 51.
404 MAEDER, in: BSK StGB, 4th edition, Basel 2019, Art. 129 StGB N 54.

3.4. Conclusion

1456 There is at least sufficient suspicion within the meaning of Art. 309 para. 1 lit. a of the Code of Criminal Procedure that the persons reported and the other perpetrators still to be identified have committed an offense under Art. 129 of the Swiss Criminal Code.

III. Successful offenses of the StGB

1. Attribution of criminal acts

1457 What the offences reported in the present case have in common is that - as far as can be seen - they were not committed directly by the defendants acting in a managerial capacity, but by medical staff in vaccination centers, pharmacies or GP practices.

1458 For a corresponding accusation to be made against the defendants who are not themselves "vaccinating", the "success of the offense" must therefore be attributed, which can be done, for example, on the basis of the non-genuine offense of omission (e.g. in the form of principal liability) or - if a corresponding accusation can be substantiated - on the basis of indirect perpetration.

1.1. False omission offenses (and principal's liability)

1459 In the case of criminal liability of those acting on behalf of Swissmedic, the attribution is made via the non-genuine offense of omission, since according to Art. 11 SCC, a guarantor position exists by law or due to the creation of a risk.

1460 In principle, the same also applies to persons in management positions outside Swissmedic who are responsible for "vaccinating" personnel. Particular attention must be paid here to the instructions given to the "vaccinating" personnel and the precautionary and safety measures taken in the area of mandatory information. Attribution is not made here directly via Art. 11 StGB, but via the principal's liability, which is also structured as a non-genuine offense of omission.

1.1.1. Non-genuine offense of omission: position of guarantor

1461 A felony or misdemeanor can also be committed by failing to act in breach of duty (Art. 11 para. 1 SCC). According to Art. 11 para. 2, anyone who fails to prevent the endangerment or violation of a criminally protected legal interest, although they are obliged to do so due to their legal status, in particular on the basis of a criminal offense, is in breach of duty:

- a. of the law;
- b. a contract;

- c. a voluntarily entered into joint venture; or
- d. the creation of a hazard.

1462 Anyone who fails to act in breach of duty is only liable to prosecution on the basis of the relevant offense if, according to the circumstances of the offense, he can be accused of the same offense as if he had committed the offense by actively doing it (Art. 11 para. 3 SCC).

1.1.1.1 Guarantor obligation

1463 The bringing about of the success that constitutes the offense by means of omission is only equivalent to an active act if someone has the duty to act accordingly due to a special legal position.[405] There are two basic types of guarantor status. The duty can relate to

- that someone must avert all dangers and damage that threaten certain legal interests of individual persons (duty of care or duty to protect) or
- that the person concerned must keep a certain source of danger under control in order to prevent damage to the legal interests of any party (duty to safeguard or monitor).[406]

1464 According to Art. 11 para. 2 lit. a StGB, guarantor **positions** can arise **from the law.** Whether a statutory duty qualifies as a guarantor duty must be determined on the basis of criminal law assessments. Relevant standards are, for example, statutory duties that require a person to **monitor a source of danger** (principal's liability Art. 55 CO; animal keeper's liability Art. 56 CO; plant owner's liability Art. 58 CO). A **guarantor position** can also arise **from official and professional duties**:[407] For example, the Anti-Money Laundering Act and the FINMA guidelines establish a guarantor position, which is why a financial intermediary can be guilty of money laundering by omission.[408] The **criminal provisions of Art. 86 f. TPA (in conjunction with the due diligence obligations of Art. 3 and Art. 7 TPA)** oblige the persons acting on behalf of Swissmedic to ensure that only high-quality, safe and effective therapeutic products are placed on the market in order to protect the health of the Swiss population. In other words, they are responsible for one of the greatest assets - human health. In doing so, they must strictly monitor all possible sources of danger emanating from medicinal products and contain them in order to minimize risks. The authorized persons acting on behalf of Swissmedic thus have a **position of guarantor with regard to the physical and health integrity of people** (as specified by law in Art. 3 para. 1 TPA,

405 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 310.
406 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 310.
407 On the whole DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 312 ff.
408 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 315 with reference to BGE 136 IV 188.

among others) - the very same legal interests that are also protected by the offences of success under Art. 111 ff. StGB[409] and Art. 122 ff. StGB[410] are protected.

1465 According to Art. 11 para. 2 lit. d StGB, the person who has **created or increased dangers to a legal interest** is also obliged to ensure that these dangers do not materialize. It is possible for conduct to be qualified as an omission due to its social significance if certain activities (i.e. active actions) are associated with it. **A guarantor obligation exists even if a risk was created in a permissible manner and in compliance with the prescribed safety regulations.**[411]

1.1.1.2 Concrete danger situation and power to act

1466 Insofar as non-genuine injunctions can be considered, the duty to intervene presupposes that a **specific risk situation** has arisen with regard to the legal interests to be protected, i.e. that there is a threat of the occurrence of the criminal offense.[412]

1467 Only this triggers the duty to intervene in favor of endangered legal interests. The party failing to act must therefore have the **power to** avert the danger.[413]

1.1.1.3 Occurrence of success and causal link

1468 Insofar as non-genuine offences of omission are to be assessed, the objective elements of the offense require the occurrence of the **actual success.**[414]

1469 There must be a causal link between the occurrence of this event and the omission. In the case of non-genuine acts of omission, the **hypothetical causal link must be** determined. According to the prevailing case law and the case law of the Federal Supreme Court, this assessment must be made according to the so-called theory of probability: The required connection is given if the required action could not be added without the success most likely being omitted.

1.1.1.4 Swissmedic: Notified parties in breach of duty, inactive guarantors

1470 From their position at Swissmedic alone, the defendants held a position of guarantor for the protection of the health of the Swiss population, which results directly from the main purpose of this authority as described in Art. 1 TPA and Art. 3 para. 1 TPA. The serious breach of

409 SCHWARZENEGGER / STÖSSEL, in: BSK StGB, 4th edition, Basel 2019, before Art. 111 StGB N 1.
410 ROTH / BERKEMEIER, in: BSK StGB, 4th ed., Basel 2019, before Art. 122 StGB N 6.
411 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 319 f.
412 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 324.
413 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 324 f.
414 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 325.

the duties of care incumbent on them under therapeutic products legislation already created a concrete risk situation by allowing a substance to be used for the general healthy population whose risk/benefit profile was almost devastatingly negative due to the risk factors described in detail in the facts of the case.

1471 Furthermore, by completely failing to take the necessary and adequate measures to contain the danger created - such as (1) providing transparent and clear information to the public and also to the medical profession about the relevant risk factors mentioned; (2) strictly enforcing the reporting obligations and (3) revoking authorizations - those acting on behalf of Swissmedic have exacerbated the already existing danger to the legal right to human integrity.

1472 This risk situation was openly recognizable to the defendants from June 2021 at the latest (front N 1298 ff.), whereby the power to avert the "successes" that occurred, such as serious bodily injury and homicide, lay entirely with the accused.

1473 If they had compensated for the - uniquely large - risk created by the "temporary" license in good time, they would have had to actively ensure the following:

1) Risk-adequate and risk-focused requirements for manufacturers and effective enforcement of the same; in particular with regard to the completion of incomplete application documentation (complete declaration of all ingredients; proof of the quality of the manufacturing process; proof of methodologically correct and still correctly conducted clinical studies, etc.);
2) risk-adequate education of the population and the medical profession about the true extent of the risks and side effects;
3) a risk-adequate, effective system for the timely, complete and prompt recording and reporting of serious and as yet unknown side effects in particular;
4) risk-adequate monitoring of all publicly available information on the risks and side effects of authorized substances;
5) an immediate suspension or revocation of "temporary" authorizations as soon as there are grounds for concern that the benefit/risk ratio is no longer clearly positive.

1.1.2. Principal's liability

1.1.2.1 Control competence regarding typical operational risks

1474 If the principal himself is *actively* involved in an offense, the following questions do not arise. However, if a principal remains inactive - i.e. if there is potentially a non-genuine *offense of*

omission - it is disputed in case law and doctrine under which conditions a guarantor obligation can be assumed due to the principal's position:

1475 There is broad agreement that a principal cannot be held responsible for all criminal offenses committed in his company.[415] Rather, it is necessary that the offenses are related to the **risks typical for the business** and that these offenses are committed by persons who are responsible **for controlling** the relevant area of responsibility.[416]

1476 If typical operational risks emanate from a company, the principal is responsible for controlling and, if necessary, minimizing them. Under the heading of principal's liability, this means that the principal Swissmedic - in addition to ensuring appropriate organization - must also be responsible for the existence and implementation of a safety **concept** to the extent necessary. In addition to senior managers, the guarantors for the existence, content and implementation of the safety plan are those persons who, according to the organizational structure of the company, are responsible for the control or minimization of typical operational hazards or who should have ordered the safety precautions according to the relevant specifications.[417]

1477 The principal may and - if he wishes to fulfill his management duties in larger companies - must delegate tasks. In general, the **delegation** - provided it is permissible or valid and is actually carried out by the delegatee - results in an extensive exemption from liability under civil law and therefore also under criminal law.[418] The main prerequisite for this exemption from liability is that the delegating party cannot be accused of having acted in breach of duty when selecting (cura in eligendo), informing (cura in instruendo) and monitoring (cura in custodiendo) the delegatee.[419]

1.1.2.2 Swissmedic: Notified parties in breach of duty, inactive guarantors

1478 The position of guarantor of the notified persons acting on behalf of Swissmedic already arises from their legal duty to protect the health of the Swiss population (see above N 1463 et seq.). Alternatively, a guarantor position also arises from principal's liability: unintended side effects of medicinal products that occur primarily because authorizations were granted unjustifiably or because the public was not informed in a risk-adequate manner or because risk-adequate pharmacovigilance was waived are to be regarded as "hazards typical of the

415 See BGE 105 IV 176 Regeste, E. 4a p. 176 f.

416 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, Art. 11 N 104. See also DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 p. 381 f. with reference to BGE 105 IV 176 f. and BGE 96 IV 155, 173 ff.

417 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 p. 383.

418 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 p. 384.

419 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 35 p. 384; SUTER / PIELES, BSK HMG, 2nd ed., Basel 2022, Art. 86 N 89.

business", which must be identified and proactively excluded as far as possible by the notified persons acting on behalf of Swissmedic by means of risk-adequate measures or at least minimized as far as possible. These minimal requirements were clearly not met by the notified parties, which is why their position as guarantors also arises from principal's liability.

1.1.2.3 Senior medical staff

1479 The medical directors in question are obliged to counteract typical operational risks with appropriate safety concepts. As part of the investigation, it must be determined what specific precautions have been taken, in particular to ensure that patients are fully informed. If the corresponding precautions are inadequate - for which the sometimes complete lack of documentation is a first indication - and are not only attributable to conduct in breach of duty on the part of the "vaccinating" staff, then according to the guarantor duty, complicity on the part of the senior medical staff is indicated.

1.1.3. Intentional or negligent omission

1480 The perpetrator must know or at least be aware of the possibility that the actual conditions for his position as guarantor exist. He must also realize that the danger has occurred, that he has the possibility of eliminating it and that if he continues to stand by and watch, the offence could be committed.[420] The perpetrator must also have at least accepted all of this.[421]

1481 If the perpetrator fails to recognize one or more of these circumstances, his conduct must be assessed according to the rules of **mistake of fact. In** particular, a **negligent success offense may be** considered.[422]

1.1.3.1 Swissmedic: Those notified presumably acted with intent

1482 Swissmedic's assessors were and are well aware of their position as guarantors of the health of the Swiss population, as they refer in their mission statement to their function of ensuring safe and effective therapeutic products (see N 174). In view of the overwhelming facts, the defendants must have realized by June 2021 at the latest that they had made a serious mistake in approving the mRNA "vaccines". Added to this is the withholding of warnings and the dissemination of various pieces of misinformation (see N 1187 ff.), which indicates at least possibly intentional action.

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420 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 327 f.
421 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 329; BGE 105 IV 176 Regeste, E. 4b p. 177 f.
422 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 30 p. 328.

1.1.3.2 Senior medical staff

1483 In view of the misleading information provided by Swissmedic, it is not readily apparent to what extent the medical management was aware of the extent of misconduct in the area of mRNA approvals. However, it must also have been clear to the medical management that SARS-CoV-2 was in no way a life-threatening or disabling disease for the population as a whole, given the low mortality rates. This fundamental prerequisite alone is missing, which means that a "temporary approval" should never have been granted, as the leading medical team must have known. Moreover, if the investigation were to reveal that the medical directors had not even taken the most basic organizational safety precautions with a view to providing fully transparent and documented information, it would not only be out of the question to invoke the three curae - the serious breach of duty would also indicate acceptance of the corresponding consequences.

1.2. Indirect perpetration?

1484 In view of the massively misleading public statements made by Swissmedic, the question also arises as to whether there could be indirect perpetration:

1485 An indirect offender is someone who uses another person as an "unwilling or at least not intentionally acting instrument in order to have him carry out the intended criminal act" (BGE 101 IV 306 p. 310 E. 8b).

1486 The indirect perpetrator causes the "person in front" ("mediator") to make an error that excludes his intent or exploits an already existing misconception of this kind in order to cause him to realize the objective elements of the crime or at least individual elements of it. It must be an error of fact.[423] According to Art. 13 para. 1 StGB, an error of fact exists if the perpetrator acts "in a mistaken idea of the facts". The error may relate to the means used by the perpetrator. For example: someone puts a substance into drinking water that they do not know is harmful to health.[424]

1487 For his part, the **person in front** can only be held liable for **negligently** bringing about a criminal act caused by him (see Art. 13 para. 2 StGB), namely if he acted under the influence of an error caused by the "person behind" and this must be charged to him as carelessness in breach of duty. Otherwise, the "tool" remains unpunished. [425]

423 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 15 p. 189.
424 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 10 p. 129.
425 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 15 p. 188 f.

1488 Therefore, if the misleading information provided by Swissmedic led to a misapprehension of the facts on the part of the doctors in charge and also the "vaccinating" doctors, this may constitute contributory negligence.

1.3. Other forms of offense

1489 If the person in front (e.g. the "vaccinating" staff) commits the act with at least contingent intent (which means there is no indirect perpetration), either aiding and abetting or complicity must be examined. [426]

1490 An accomplice is a person who intentionally and significantly cooperates with other perpetrators in the determination, planning or execution of an offense, so that he is the main participant (BGE 130 IV 58 p. 66 E. 9.2.1). An accomplice is anyone who intentionally assists in a felony or misdemeanor (Art. 25 StGB).

1491 Moreover, incitement could also be relevant in the case of corresponding intent (Art. 24 para. 1 StGB).

1492 We will not go into more detail at this point, as it will only be possible to determine who acted intentionally and who was negligent at what time on the basis of the investigation to be carried out.

2. Negligent homicide (Art. 117 StGB)

1493 Anyone who negligently causes the death of a person is punished under Art. 117 StGB.

2.1. Achievement of the success of the offense

2.1.1. Criminal act: Causing death

1494 Any form of causing the death of a living person is sufficient as a criminal offense, whereby the perpetrator can use any means. The acceleration of death is sufficient to fulfill this success-oriented offence. Homicide by non-genuine omission is also covered.[427]

1495 Based on international surveys and studies, there are numerous indications that the mRNA "vaccinations" have led to deaths (front N 374, N 495, N 669 ff. and N 685). By authorizing the mRNA "vaccines" under Art. 9a TPA and repeatedly extending or not revoking their authorization - with completely neglected monitoring and misleading information to the

426 FORSTER, BSK StGB, 4th ed., Basel 2019, before Art. 24 N 30, cf. also N 35.
427 SCHWARZENEGGER, BSK StGB, 4th edition, Basel 2019, Art. 111 N 4.

public - and by administering the mRNA "vaccines" through the **medical profession**, the deaths of people in Switzerland are potentially being caused or accelerated.

2.1.2. Factual success

1496 Negligent homicide is completed with the occurrence of death.

1497 Even if Swissmedic wants to deny this for Switzerland (on the complete lack of warnings on **deaths,** see N 1199), it seems rather unlikely that none of the 236 reports of suspected deaths in Switzerland to date (see N 580) as a result of mRNA "vaccination" could be substantiated. As already explained in detail on several occasions (see N 1296 with further references), Swissmedic has not adequately taken into account the particular risks associated with these substances when designing the monitoring of mRNA "vaccines". This complete passivity in the area of pharmacovigilance - with the reliance on a completely inadequate passive reporting system resulting in massive underreporting - is a clear indication that Swissmedic is not willing to ensure complete transparency.

1498 As far as can be seen, Swissmedic has made no discernible efforts to date to work towards the consistent performance of professional autopsies in suspected cases of mRNA injections resulting in death - for example, through appropriate high-profile publications or direct recommendations to the public prosecutor's offices and forensic medicine institutes. This is exemplified by the specific case of private claimant 5, in which an autopsy that was inadequate in every respect had taken place (see N 95 f., N 449 ff.): Limiting the examination to obvious final causes of death (such as organ damage and bleeding) is simply not sufficient to determine vascular damage caused by the mRNA "vaccines", which then lead to the final causes of death.

2.1.3. Causality

1499 In the case of successful offenses, the question arises as to whether the actor caused the success in its concrete form. According to the conditional or equivalence theory, a cause is any condition that cannot be removed without the result being omitted *("conditio sine qua non").* In the case of passive conduct by omission, a hypothetical causal link as defined above may be considered (N 1341 and N 1469). Causality is thus given regardless of the type of action of the perpetrator if this was only *a* condition for the success that occurred (so-called natural causality). Neither the number nor the weight of any (contributory) causes is relevant.[428]

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428 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 8 p. 103 f.

1500 The approval of the mRNA "vaccines" by the persons acting on behalf of Swissmedic is the central prerequisite for their use by the medical profession in Switzerland. The authorization, its repeated maintenance, the omission of any risk-adequate measures to avert danger and the "vaccination actions" that took place cannot be ignored without the "success" in the sense of the harmful "vaccination" side effects being omitted. The actions (and omissions) of the responsible persons thus represent one - probably by far the most important - cause of the "vaccine damage" that has occurred.

2.2. Disregard of a duty of care

1501 A person commits an act negligently if he fails to consider or take into account the consequences of his conduct due to carelessness contrary to his duty. Carelessness is contrary to duty if the perpetrator fails to observe the caution to which he is obliged under the circumstances and according to his personal circumstances (Art. 12 para. 3 StGB).

1502 It must first be examined whether the breach of duty "objectively" created an impermissible risk, and then whether this breach of duty is "subjectively" reproachable under the specific circumstances and personal circumstances of the perpetrator.

2.2.1. Creation of an unauthorized risk

2.2.1.1 Violation of general-abstract standard

1503 Where specific standards require certain behavior, the degree of care to be observed is determined primarily by these regulations.[429]

1504 General abstract standards that deal with risky behavior are often found in special laws in the form of abstract dangerous offenses. The maximum permissible risk is therefore at least indirectly defined in these. If a criminal offense occurs, there is a certain probability that the duty of care under Art. 12 para. 3 SCC has been disregarded if the special statutory provision is disregarded.[430]

1505 As before (N 1289 et seq.), there is a strong suspicion that the defendants violated several duties of care (and standardized endangerment offences) of the TPA and thus disregarded the maximum permissible risk. In addition, there are strong indications (see N 1336 et seq.) that this risk materialized in the form of injury to the physical integrity of a large number of people , meaning that an actual "success" occurred. There is therefore a considerable probability that the care required under Art. 12 para. 3 SCC was not exercised.

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429 BGE 140 II 7 E. 3.4 P. 10.
430 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 348 f.

2.2.1.2 General hazard rate and permitted risk

1506 If a general, abstract standardized duty has not been breached, the general principle of danger or the principle of "neminem laedere" can also be applied on a subsidiary basis.[431] According to this, the person carrying out a dangerous act must do everything reasonable to ensure that the danger does not lead to injury to the legal interests of others.[432] In doing so, the actor must ensure that any unnecessary increase in danger is avoided and that the limits of the permitted (maximum permissible) risk are not exceeded.[433] The decisive factor here is which risks to legal interests protected by criminal law may be accepted in a certain area of conduct (high-risk versus low-risk activities) according to general opinion.[434]

1507 If, contrary to expectations, the actions of the defendants can in any way be classified as just about due diligence on the basis of the vast number of legal standards on the level of laws and ordinances as well as other recommendations, the following should be pointed out:

1508 In the present case, activities such as the approval of medicinal products, which are not in breach of duty per se, but involve a certain risk to the legal interests of third parties, must be examined. Any regulation and documentation cannot conceal the fact that the core issue is whether, with the initial and ongoing approval of the mRNA "vaccinations", those responsible have created an unacceptable risk that has led to injury to human health. As explained in detail above, the benefit of the "vaccines" tends towards zero (see N 296 ff., N 376 ff., N 498 f.), while at the same time the risks that can already be identified dwarf anything that has gone before and the medium to long-term consequences cannot be assessed in any way due to the lack of any studies (end of 2020: N 185 ff. and N 1291 ff.; mid-2021: N 318 ff. and N 1298 ff.; end of 2021: N 387 ff. and N 1305 ff.; from 2022: N 525 ff. and N 1311 ff.). In addition, the defendants acting on behalf of Swissmedic have exacerbated this already alarming risk situation through their own actions (such as inadequate requirements for manufacturers, misleading information for the public and the medical profession, completely inadequate monitoring, etc.; see N 1151 ff. and N 1187 et seq.) are exacerbated. Given this initial situation, it is obvious that the defendants have not done and are not doing everything reasonable to protect the endangered and already violated legal interests with due diligence.

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431 BGE 140 II 7 E. 3.4 p. 10; BGE 121 IV 14 f.; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 349 and p. 351.

432 BGE 135 IV 64; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 351.

433 BGE 140 II 7 E. 3.4 p. 10; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 343.

434 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 354.

2.2.1.3 Insert: Principle of trust

1509 In this case, the defendants could invoke the principle of trust. According to the principle of trust, everyone may in principle assume that their fellow citizens will behave in accordance with their duties. This applies in particular to cooperation based on the division of labor. However, there are important restrictions: If someone is obliged to supervise another person, or if several people work together as part of a multiple security system, none of the persons involved can exonerate themselves from having relied on the dutiful conduct of the other participants. In addition, if there are concrete indications that another person is behaving in a manner contrary to due diligence, the person behaving correctly is required to take special precautions. This means that in such a case, when assessing the duty of care, a lower risk than the maximum permissible risk must be assumed.[435]

1510 Accordingly, those acting on behalf of **Swissmedic** cannot claim to have relied on the fact that the manufacturers would act with due diligence. On the contrary: as senior members of the supervisory authority, it is part of their fundamental duty to supervise the manufacturers. In view of the complete novelty of the mRNA "vaccines" and the numerous alarm signals that have emerged (end of 2020: N 185 ff. and N 1291 ff.; mid-2021: N 318 ff. and N 1298 ff.; end of 2021: N 387 ff. and N 1305 ff.; from 2022: N 525 ff. and N 1311 ff.), the notified parties were also required to exercise particular care in connection with the authorization and monitoring of COVID "vaccines".

1511 The same applies to the **medical profession:** insofar as the doctors complied with Swissmedic's requirements and fulfilled all their duties to provide information, the question arises as to whether - despite the misleading information provided by Swissmedic - they should not have known better as specialists. The international study situation on side effects (front N 374, N 495 and N 685) and the obvious lack of a "pandemic" (above N 744 ff.) must have given rise to justified doubts in every doctor's mind as to the accuracy of the information provided by Swissmedic. Accordingly, they could not blindly trust Swissmedic's specifications, but would have had to carry out their own investigations.

2.2.2. Attribution of success

1512 According to the above, there is a strong suspicion that the defendants exceeded the maximum permissible risk and thereby created a hazardous situation resulting in injury. However, in order to justify a breach of the duty of care, the risk created must have been both

[435] On the whole DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 352 f.

foreseeable and *avoidable* for the parties involved, whereby the care to be exercised is measured according to an objective, individual standard.[436]

2.2.2.1 Foreseeability: Social adequacy

1513 The sequence of events leading to success must be foreseeable for the specific perpetrator, at least in its essential features[437] - including any special knowledge.[438] In order to answer the question of whether the risk of success was foreseeable for the perpetrator, the standard of adequacy applies, i.e. his conduct must be capable of bringing about or at least facilitating a success such as the one that occurred, according to the normal course of events and the experiences of life.[439] Whether an act in the sense of the **theory of adequacy** is suitable in the ordinary course of events and according to general life experience to bring about or favor a success of the kind that occurred must be decided *ex ante, i.e. from the* time of the act; because subsequent (better) knowledge of the context cannot decide whether an act was permitted or prohibited at the time it was carried out.[440]

1514 As before (N 1289 et seqq.), the persons acting on behalf of **Swissmedic had** different data at different times - or, given their position, should necessarily have had it. As time went on, knowledge of the lack of danger posed by COVID-19 solidified, and it became increasingly clear that the mRNA "vaccinations" were not only not as effective as promised, but that the risk associated with the authorization was beyond what had ever been assumed in previous drug authorizations. At the time of the first "temporary" approval in December 2020 - but at the latest at the time of the "temporary" approval for adolescents aged 12 and over in June 2021 - there were already so many warnings that were known or should have been known to the notified parties that these "temporary" approvals should never have been granted. Accordingly, it was already apparent to the notified parties - in particular due to their specialist knowledge - that the approval of the experimental gene therapy involved a considerable risk potential, which was disproportionate to the expected benefit in view of the low mortality rate in the overall population due to COVID-19. As specialists, they had to recognize that the approval of such a "vaccine" was outside the permissible risk range and was likely to cause massive damage to the physical integrity of the vaccinated people. The foreseeability of the outcome was therefore given. According to the normal course of events and the experience of life (at the time), the conduct of the defendants was likely to at least

436 BGE 140 II 7 E. 3.4 P. 10
437 BGE 129 IV 282 E. 2.1 P. 284.
438 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 355 f.
439 BGE 129 IV 282 E. 2.1 p. 284 f.; BGE 121 IV 10 E. 3 p. 15; DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 353.
440 BGE 135 IV 56 E. 2.2 P. 65.

favor an outcome such as the one that occurred. Accordingly, the defendants should have oriented their conduct towards the known risk.

1515 The same applies to the **medical profession** - albeit with a slight time lag at best: by June 2021 at the latest, the excessive side effects were obvious to everyone, including doctors (see N 318 ff. and N 1298 ff.). The same applies to the lack of danger of SARS-CoV-2 and the (largely) uselessness of the mRNA "vaccinations". Anyone still "vaccinating" from this point onwards must have been aware of the devastating risk-benefit ratio with the potential for fatal consequences - even if they strictly adhered to Swissmedic's guidelines. Irrespective of this, those cases in which elementary anamnesis and information obligations were violated must be assessed (see above N 1322 ff.): Any doctor (or pharmacist) who did not properly clarify and inform the patient created a risk in every case that could adequately lead to death.

2.2.2.2 Avoidability: Individual ability to fulfill obligations

1516 For the occurrence of the outcome to be attributable to the offender's conduct in breach of duty, its foreseeability alone is not sufficient. A further prerequisite is that the outcome was also individually avoidable: a course of events is only controllable if the perpetrator has the ability to eliminate the danger associated with his conduct - whether by taking appropriate precautions or by refraining from the risky action.[441] A hypothetical course of causation is examined and it is checked whether the outcome would not have occurred if the perpetrator had acted in accordance with his duties, whereby this must be answered by evaluating all known circumstances *ex post.* The success is to be attributed to the perpetrator if his conduct was the cause of the success with at least a high degree of probability or with a probability bordering on certainty.[442] It should be noted that in emergency situations and when an intervention is urgent, depending on the circumstances, it is not always possible to demand that the most objectively expedient of the various possible measures be taken.[443]

1517 With regard to those acting on behalf of **Swissmedic,** it should be noted that in December 2020 there was considerable media and political pressure to approve the experimental mRNA "vaccines". However, the licensing authority must under no circumstances bow to media or political pressure, but must strictly comply with the law and ensure that "only high-quality, safe and effective therapeutic products are placed on the market to protect the health of the people of this country" (Art. 1 para. 1 TPA). Nor can the defendants seriously argue that an actual emergency situation or even urgency existed: As already explained in

441 STRATENWERTH, AT I, 4th edition, Bern 2011, § 16 N 10
442 BGE 140 II 7 E. 3.5 P. 11; BGE 135 IV 56 E. 2.1 P. 65.
443 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 344.

detail (above N 750 ff.), there was no mortal danger whatsoever, at least with regard to the population as a whole. Those at risk, if at all, were people over the age of 70 who were previously ill. The damage to physical integrity caused unnecessarily by the "vaccinations" could therefore have been prevented if the defendants had behaved properly. This possibility of preventing harm was readily available to the notified parties, as they are the "gatekeepers" in Switzerland as far as the authorization (and monitoring) of medicinal products is concerned. The fact that the notified parties nevertheless decided otherwise can only be attributed to political pressure or other - in no way medically or epidemiologically indicated - motives.

1518 With regard to **the medical profession,** a distinction must again be made: Insofar as duties to take a medical history and provide information were breached, the corresponding conduct was easily avoidable. There was also no "temporal urgency" or even an "emergency situation" that would have prevented compliance with at least the most elementary duties of care in the context of providing information. It was possible and reasonable for any doctor practicing in Switzerland to present and explain to their own patient all the essential general facts as the basis for an informed decision on the benefit/risk assessment in a specific consultation. By virtue of their special professional competence and their obligation to serve the well-being of their patients, doctors can be expected and demanded to think independently in this respect, even if in individual cases this results in a decision that deviates from the generally prevailing schematized general vaccination recommendation of Swissmedic (and other administrative units). By refraining from the obviously risky action of "vaccination" with an experimental gene therapy, any "vaccinating" doctor (and also the doctor promoting the "vaccination" in a management function) could have prevented the successful outcome.

2.2.2.3 Insertion: no serious contributory negligence of third parties

1519 In the present case, the defendants could still argue that all vaccinated persons "consented" to the "vaccination" and the associated possible side effects. However, the adequacy of the cause to be assessed for the success can only be denied if very exceptional circumstances, such as the contributory negligence of a third party or material or construction defects, are added as contributory causes which could not have been expected and which weigh so heavily that they appear to be the most probable and direct cause of the success and thus push all other contributory factors - namely the behavior of the defendants - into the background.[444] It would be necessary for the person concerned to have endangered their legal interests of health and physical integrity in such a responsible manner that this would

444 BGE 135 IV 56 E. 2.2 P. 65.

correspond to actual self-harm.[445] The decisive factor here is whether it would have been possible and reasonable for the potential perpetrator to inform the person concerned about the risks of their actions. Both presuppose superior risk reduction skills - in particular superior knowledge of the dangers in question.[446] The criminal liability of the perpetrator who promotes self-endangerment for the result that has occurred therefore begins if the victim does not recognize the danger, for example due to their inexperience or youth, if the perpetrator understands the risk better than the person endangering themselves due to their superior knowledge or if they have a guarantor position in favour of the victim.[447]

1520 With the approval, the inadequate to non-existent monitoring and the associated maintenance of the approval, as well as the misleading public communication, the notified parties acting on behalf of **Swissmedic were** the main reason why people in Switzerland were "vaccinated" against COVID-19. However, the notified persons did not stop at mere approval decisions: They publicly "informed" the population (including doctors and medical staff) about the alleged safety and supposedly high effectiveness of the "vaccinations" - and did so in a blatantly misleading manner (front N 1187 ff.). The defendants had specific specialist knowledge (on the additional position of guarantor, see N 1463 ff.) and would therefore have had a duty to inform those willing to be vaccinated in a transparent manner - which they did not do. Against this backdrop, any "consent" on the part of the injured parties is completely irrelevant. The same also applies in principle to intermediate actions by the medical profession, provided that they acted in accordance with Swissmedic's recommendations and provided sufficient information. There are therefore simply no recognizable "exceptional" circumstances in the sense of self-inflicted or third-party negligence that would make the actions of the defendants recede into the background. The most probable and direct cause of the vaccination damage appears to be Swissmedic's approval decisions, for which the defendants are jointly responsible.

1521 With regard to the medical profession, a distinction must again be made between those doctors who have strictly adhered to Swissmedic's requirements and have complied with all duties to provide information, and those doctors who have largely or even completely dispensed with medical histories and information in breach of their duties. The former can - up to a certain point - claim to have been misinformed by Swissmedic, although they must also take credit for their specialist knowledge in this case. The latter have, through their own gross misconduct (breach of the duty to take a medical history and provide information),

445 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 358.
446 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 32 p. 359.
447 BGE 125 IV 189 E. 3a p. 194.

been such a significant contributory cause that it is not possible to invoke third-party negligence from the outset.

2.3. Justification: Consent ?

1522 Consent to one's own killing is not legally possible: Art. 114 StGB declares the killing of another person to be punishable, even if the person concerned seriously and insistently requests it.[448]

2.4. Grounds for exclusion of guilt

1523 No grounds for exclusion of guilt are apparent.

2.5. Conclusion

1524 There is a strong suspicion that the persons reported and the other perpetrators still to be identified have committed multiple offenses under Art. 117 SCC for the period from December 2020 - at the latest from June 2021.

3. Intentional homicide (Art. 111 SCC) and murder (Art. 112 SCC)

1525 Anyone who intentionally kills a person is liable to prosecution under the basic offense of Art. 111 StGB. Intentional homicide can also be committed as an indirect perpetrator.[449]

1526 If qualifying elements of the offense are present, the elements of the offense of murder under Art. 112 StGB must be examined.

3.1. Objective basic offense (Art. 111 StGB)

3.1.1. Achievement of the success of the offense

1527 With regard to the offense, success of the offense and natural causality, please refer to vorn (N 1494 ff.).

3.1.2. Excursus: Objective attribution

1528 In the event that the very far-reaching attribution of success via natural causality appears unreasonable, the examination of objective attribution is an option.[450] A result is objectively

448 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 27.
449 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [ed.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd edition, Zurich / St. Gallen 2013, Art. 111 N 1.
450 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 88.

imputable if the perpetrator has created a legally relevant danger that is realized in the result that constitutes the offence.[451]

1529 The objective imputability of the result is lacking, for example, if the result is not or no longer covered by the *scope of protection of the norm* that the offender has violated through his action.[452] Like the criminal provisions of the TPA, which serve to protect human health (Art. 1 TPA), the offences of injury under the SCC also protect human health - in the form of the protection of life itself (Art. 111 et seq. SCC)[453] and the protection of physical and health integrity (Art. 122 et seq. SCC).[454] By authorizing and administering the COVID "vaccinations", those responsible have created precisely the legally relevant danger that has materialized in the factual success of injuring people's health.

1530 However, the scope of protection of a norm ends where the *personal responsibility of* the victim begins: Self-inflicted, conscious self-harm by people who are capable of judgment and informed therefore generally leads to a restriction of the attribution of success.[455] However, if the person involved in creating the risk has *superior knowledge* compared to the victim, the principle of personal responsibility must be carefully examined.[456] This means that the elements of "guarantor status" and "third-party fault" also come into play under the title of objective attribution,[457] as they have previously been used under the titles of injunctive relief (N 1463 ff.) and negligence offenses (N 1519 ff.) were examined. Both a guarantor position and superior knowledge on the part of the defendant were affirmed. A restriction of the attribution of success is therefore not appropriate.

3.2. Subjective facts

1531 Homicide under Art. 111 SCC must be committed intentionally, whereby contingent intent is sufficient.

1532 A felony or misdemeanor is committed intentionally by anyone who carries out the act with knowledge and intent (Art. 12 para. 2 sentence 1 StGB). In addition to knowledge of the real possibility of committing the offence, intent also requires the will to commit the offence. The offender must decide against the legally protected good. This will is given in the sense of **direct intent if the realization of the offence** is the perpetrator's actual goal or appears to him to be a necessary prerequisite for achieving his goal. The same applies if the

451 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 88.
452 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 88 f.
453 SCHWARZENEGGER / STÖSSEL, in: BSK StGB, 4th ed., Basel 2019, before Art. 111 StGB N 1.
454 ROTH / BERKEMEIER, in: BSK StGB, 4th ed., Basel 2019, before Art. 122 StGB N 6.
455 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 89.
456 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 89.
457 DONATSCH / TAG, Strafrecht I, 9th ed., Zurich/Basel/Geneva 2013, § 7 p. 90, inter alia with reference to BGE 125 IV 189 E. 3a p. 194 (regarding *negligent* bodily harm).

realization of the offence is a necessary secondary consequence for the perpetrator, even if it is indifferent or even undesirable.[458]

1533 Any person who considers the realization of the act to be possible and accepts it (Art. 12 para. 2 sentence 2 StGB) acts **with contingent intent.** Both those acting with contingent intent and those acting with conscious negligence are aware of the possibility of success. However, there are differences in the element of intent. The deliberately negligent perpetrator trusts (due to carelessness in breach of duty) that the result he foresees as possible will not occur.[459] Contingent intent, on the other hand, is given if the perpetrator considers the occurrence of the outcome or the realization of the offence to be possible, but nevertheless acts because he accepts the outcome in the event that it occurs, comes to terms with it, even if it is undesirable. The court may infer intent from the offender's knowledge if the occurrence of the outcome is so likely that the offender's willingness to accept it as a consequence can only reasonably be interpreted as an acceptance of the outcome.[460] The external circumstances from which the conclusion can be drawn that the perpetrator accepted the realization of the offence include, among other things, the extent of the risk of the offence being realized known to the perpetrator and the severity of the breach of the duty of care. The greater the probability of the offence being committed and the more serious the breach of the duty of care, the closer the actual conclusion that the offender accepted the commission of the offence.[461]

3.2.1. Concerning first and second "vaccinations"

1534 As before (N 1291), the defendants acting on behalf of **Swissmedic** were already in gross breach of their duties of care under therapeutic products law at the end of 2020. In particular, their internal level of knowledge - based only on the few documents currently available - differed blatantly from the information communicated to the outside world, which suggests the existence of contingent intent. In the criminal investigation, it is therefore essential to determine what other documents (authorization documents, e-mail communication, internal memos, etc.) Swissmedic had at its disposal.

1535 In view of the widespread misinformation from Swissmedic and the lack of publicly available data on side effects, it is hardly possible to prove that a doctor acted with intent.

458 BGE 130 IV 58 E. 8.2 p. 60 f.
459 BGE 143 V 285 E. 4.2.2 S. 291.
460 BGE 137 IV 1 p. 4 E. 4.2.3; see also BGE 130 IV 58 E. 8.3 p. 61.
461 BGE 130 IV 58 E. 8.4 P. 62.

3.2.2. Further approvals from June 2021 and from fall 2021

1536 At least as of June 2021, it was obvious to those acting on behalf of **Swissmedic** that they had authorized a medicinal product for the prophylactic treatment of a disease that is hardly life-threatening or disabling and that is neither effective nor safe. Accordingly, they knew that none of the requirements for a "temporary authorization" had (ever) been met. Under these circumstances, the defendants' knowledge gives rise to the strong suspicion that the occurrence of completely avoidable side effects, including the unnecessary death of vaccinated persons, was so likely that their actions to the contrary could only reasonably be interpreted as acceptance of this very "success".

1537 The same applies to the **medical profession,** although a corresponding contingent intent can only be assumed from fall 2021 (approval of booster and pediatric "vaccinations"): By that time at the latest, it was openly recognizable to any independently thinking and informed doctor that SARS-CoV-2 is not a dangerous disease for the population as a whole, that the mRNA "vaccinations" in no way sufficiently immunize in view of the "necessity" of "boosters" and that the reports of side effects worldwide had reached an unprecedented number. To continue to "vaccinate" in the face of this overwhelming evidence can only be interpreted as accepting the most serious consequences.

3.2.3. From the prevalence of the "Omikron" variant

1538 By 2022, SARS-CoV-2 with "Omikron" had lost all danger for the entire target population of the mRNA "vaccinations". At the same time, global reports of side effects reached new highs. In addition, the lack of effectiveness of the mRNA "vaccinations" was demonstrated by the fact that even those who had been vaccinated three times repeatedly fell ill with "COVID-19" (front N 709 ff.). The mRNA "vaccinations" are therefore - as has been obvious to everyone since 2022 at the latest - useless and also dangerous and even fatal.

1539 Under these circumstances, the knowledge of the defendants gives rise to the strong suspicion that the occurrence of completely avoidable side effects, including the unnecessary death of vaccinated persons, was so likely that their actions to the contrary can only reasonably be interpreted as acceptance of this very "success". In view of the overwhelming facts, it must even be assumed that this absolutely irresponsible action was **directly intentional.**

3.3. Qualification: Murder (Art. 112 StGB)

1540 Murder first requires intentional homicide, whereby contingent intent is sufficient;[462] reference is made to the preceding remarks (see above N 1533).

1541 If the perpetrator also acts in a particularly unscrupulous manner, in particular if his motive, the purpose of the act or the manner in which it is carried out are particularly reprehensible, then the qualifying criteria for murder under Art. 112 SCC are present.

1542 The use of poison, for example, is considered a particularly reprehensible form of execution: however, this alone should not be sufficient to assume particular unscrupulousness.[463] The use of poison is particularly reprehensible if it is used in an insidious manner. Insidiousness exists if the perpetrator first gains the victim's trust in order to then kill them by taking advantage of their helplessness.[464] For example, it was qualified as murder when poison was administered under the pretext of caring for the victim.[465]

1543 The mRNA "vaccines" lead to the body's own production of the so-called spike protein, which has a pathogenic - i.e. disease-causing - effect that, in the worst case, can lead to death (see N 391 ff., N 669 ff.). Added to this are the toxic, potentially carcinogenic and mutagenic lipid nanoparticles (LNP), which can also cause devastating damage to the body (see N 212 ff.). In addition, toxic, carcinogenic and mutagenic impurities such as benzene and nitrosamine were found in the mRNA "vaccines" (see N 231 ff.) - such substances simply have no place in a "vaccine". Despite all these known circumstances, those responsible at **Swissmedic** praised the "vaccinations" as "carefully tested" and with "high clinical efficacy" (see N 1190, 1199), without even pointing out the possible fatal consequences in a single place that was easily understandable and visible to patients (front N 1199, N 1204 ff.). In doing so, they created false confidence in the dangerous "vaccination" among those affected, which they exploited against their better judgment in view of the overwhelming facts.

3.4. Grounds for justification and exclusion of guilt

1544 There are no apparent grounds for justification or exclusion of guilt.

1545 In particular, valid consent to one's own killing is not possible (see N 1522).

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462 BGE 112 IV 65 E. 3b; SCHWARZENEGGER, in: BSK StGB, 4th edition, Basel 2019, Art. 112 StGB N 26.

463 SCHWARZENEGGER, in: BSK StGB, 4th edition, Basel 2019, Art. 112 StGB N 23.

464 TRECHSEL / FINGERHUTH in: in: Trechsel / Pieth [eds.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed., Zurich / St. Gallen 2013, Art. 112 N 21.

465 BGE 77 IV 57 E. 3 p. 64: "[...] the use of poison speaks for their malice.".

3.5. Conclusion

1546 There is at least sufficient suspicion that the persons acting on behalf of **Swissmedic** and the other perpetrators still to be identified have committed multiple offenses under Art. 111 SCC, or possibly under Art. 112 SCC.

1547 In addition, there is a strong suspicion that the medical practitioners involved and the other perpetrators still to be identified have committed multiple offenses under Art. 111 SCC.

4. Criminal abortion (Art. 118 StGB)

1548 Under Art. 118 para. 2 SCC, anyone who terminates a pregnancy without the consent of the pregnant woman is liable to a custodial sentence of one to ten years.

4.1. Objective facts

4.1.1. Criminal act: Termination of pregnancy

1549 The act consists of terminating the pregnancy.[466] This includes any killing of an embryo or fetus between nidation and the onset of labor. [467]

1550 Both acts that lead to the premature separation of the fruit and subsequently to its death, as well as the killing of the fruit in the womb, constitute an offense. [468]

1551 Induced premature births are also punishable: both induced premature births in the early and middle stages of pregnancy (non-viable fetuses) and in the late stages of pregnancy (basically viable fetuses) are punishable if the (contingent) intent of the perpetrator was to kill the nascent fetus.[469]

4.1.1.1 Acts of Swissmedic

1552 As guarantor (front N 1461 ff.), Swissmedic was and is obliged to prevent damage such as premature births and miscarriages in connection with mRNA "vaccinations". Instead, Swissmedic committed the following serious breaches of its duty of care:

1553 At the end of 2020 and the beginning of 2021, Swissmedic also granted Comirnaty and Spikevax "temporary" authorization for pregnant women and stated in the information for healthcare professionals on Comirnaty that "no direct or indirect adverse effects" on

466 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 16.
467 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 4.
468 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 4.
469 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 4.

pregnancy and fertility had been identified (see N 1199), although this was already known at the time,

- that the lipid nanoparticles SM-102 contained in Spikevax can probably impair fertility and damage the child in the womb (anterior N 212 ff., in particular N 219) and
- that preclinical studies (animal studies) had identified a possible risk in pregnancies (two-fold increase in preimplantation losses, malformations) (front N 235 ff.).

1554 At the end of 2021, Swissmedic continued to maintain the completely trivializing and misleading texts in the information for healthcare professionals, although it was also clear at the time,

- that, according to the manufacturers, the effects of the mRNA "vaccines" on pregnancy, the fetus or a nursing child were not known (front N 473 f.),
- that more than 2,000 miscarriages or premature births have already been reported worldwide (front N 475 ff., in particular N 478),
- that numerous complications and deaths of newborns breastfed by recently vaccinated mothers have already been recorded worldwide (front N 480).

1555 In the course of 2022, Swissmedic continued to maintain the completely trivializing and misleading texts in the information for healthcare professionals, even though it was now also clear,

- that the safety profile of the "vaccine" in pregnant or breastfeeding women was still not known and that a manufacturer had again commissioned the necessary studies from a research institute known for falsifying data (front N 631 ff.),
- that only until May 2022, **1.4-2.8 stillbirths per 1 million "vaccine doses"** were recorded for Comirnaty and Spikevax in the EU and the USA (front N 636), and
- that there was a massive decline in live births worldwide (front N 639 ff.),
- that there had also been **a historical decline in live births in Switzerland,** whereby this not only obviously correlates with the "vaccination campaign", but after excluding all other possible explanations, **only the mRNA injections** remain **as the most plausible cause** (front N 644 f.).

1556 In addition, despite all these circumstances, Swissmedic has apparently been publishing a false and completely misleading text on its own website ("FAQ") for the attention of the public since the beginning of the "vaccination campaign" (front N 1204 ff. with reference to evidence report): "The vaccine has no effect on your body's ability to become pregnant. It also has no influence on the future development of the placenta or the course of a future pregnancy. In addition, the vaccine has no negative effects on you or your child if you are breastfeeding.") - and has still not removed this text.

1557 By allowing pregnant women to be "vaccinated" with the mRNA "vaccines" and also by disseminating false and misleading information instead of explicitly warning of the suspected - and now proven - danger, the people acting on behalf of the regulatory authority have contributed to a huge number of abortions in Switzerland.

4.1.1.2 Medical malpractice

1558 Corresponding acts by the medical profession should also be investigated.

4.1.2. Lack of consent

1559 An abortion induced in accordance with Art. 118 para. 2 SCC must be performed without the consent of the pregnant woman.[470] The general requirements for the consent of the injured party are decisive for the validity of the consent (see in detail below N 1589 ff.), which presupposes full disclosure (see in detail above N 1322 ff.). First of all, the pregnant woman must be capable of judgment, i.e. she must be able to correctly assess the purpose and scope of the medical intervention. The consent must be free of any lack of will, i.e. the pregnant woman must have full knowledge of the nature and scope of the intervention (without coercion, threat or deception). Consent can be expressed or implied, but the perpetrator must be aware of it before the act is carried out.[471]

1560 In view of the misleading information provided by Swissmedic with regard to the alleged safety of mRNA "vaccinations" during pregnancy and breastfeeding, there is a legally relevant deception, which means that any declarations of consent are tainted by a serious lack of intent. Under these circumstances, no valid consent is conceivable - unless an individual doctor had provided correct and comprehensive information beyond the specialist information.

1561 Added to this is the considerable pressure exerted by 3G and 2G certification requirements on people to be "vaccinated". Without "vaccination", there was a threat of far-reaching consequences ranging from social ostracism to job loss with corresponding existential fears. Even under this impression of latent coercion to be "vaccinated", no pregnant woman was able to give valid consent.

4.1.3. Factual success

1562 The actual result is the killing of the embryo or fetus.[472]

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470 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 17.

471 On the whole SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 5

472 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th ed., Basel 2019, Art. 118 N 19 i.V.m. N 10.

1563 As outlined above, international reports suggest that mRNA "vaccinations" are probably linked to unwanted abortions. There is therefore a strong suspicion that such cases have also occurred in Switzerland.

4.1.4. Causality (and objective attribution)

1564 The authorization and administration of the mRNA "vaccines" are one - probably by far the most important - cause of the vaccine damage that has occurred (see N 1499 f.), which are also objectively attributable to the perpetrators (see above N 1528 et seq.).

4.2. Subjective facts

1565 The subjective element of the offense requires (contingent) intent. The perpetrator must know or at least accept that he is performing the abortion against the will of the pregnant woman.[473] In addition, he must at least accept that his action may lead to an unwanted abortion (see above N 1551).

1566 At the end of 2020, **Swissmedic** was already spreading false information against its better judgment (front N 1552 et seq.). In view of this circumstance, there is a strong suspicion that the defendants had at least accepted that their actions would lead to unwanted abortions in vaccinated pregnant women when the COVID "vaccines" were first approved in December 2020 - or at the latest from the end of 2021.

1567 A corresponding intent can also be determined in the **medical profession.**

4.3. Grounds for justification and exclusion of guilt

1568 There are no apparent grounds for justification or exclusion of guilt.

1569 In particular, there are no consents (front N 1559 ff.)

4.4. Competitions

If a pregnancy is brought about by killing the pregnant woman herself, the perpetrator is to be punished under Art. 111-113 and Art. 118 para. 2 SCC (genuine competition).[474]

4.5. Conclusion

1570 There is a strong suspicion that the persons reported and the other perpetrators still to be identified have committed multiple offenses under Art. 118 para. 2 SCC.

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473 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 20.
474 SCHWARZENEGGER / HEIMGARTNER, BSK StGB, 4th edition, Basel 2019, Art. 118 N 19, N 32.

5. Intentional and negligent (grievous) bodily harm

1571 If the COVID "vaccination" has not (yet) led to the death of the vaccinated person, bodily injury offenses must be examined. The following explanations are limited to official offenses:

5.1. Negligent grievous bodily harm (Art. 125 StGB)

1572 According to Art. 125 para. 1 in conjunction with para. Para. 2 StGB, anyone who negligently causes serious bodily injury or damage to the health of a person is liable to prosecution and will be prosecuted ex officio.

5.1.1. Achievement of the success of the offense

5.1.1.1 Criminal act

1573 Bodily injury can be committed both by active action and by failure to act in breach of duty (on the non-genuine offences of omission, see N 1459 et seq.).

1574 Both on the basis of national (and international) notifications to Swissmedic (see for example above N 325 ff., N 341 ff., N 537 ff. and N 595 ff.) as well as on the basis of national (see for example N 674 et seq. [Basel Study]) and international (see, for example, N 374, N 495 and N 685) Surveys and studies provide numerous indications that COVID "vaccinations" have led to considerable damage to physical integrity. In Switzerland, there has been a massive increase in various serious disease diagnoses - damage to the nervous system, cancer - in connection with the "vaccination campaign" (see N 664). By authorizing the mRNA "vaccines" in accordance with Art. 9a TPA and repeatedly extending or not revoking their authorization - with completely neglected monitoring and misleading information to the public - and by administering the mRNA "vaccines" through the **medical profession,** people's physical integrity has been and continues to be violated.

5.1.1.2 Consequence of the offense: Serious bodily injury

1575 The bodily injury is serious if it corresponds to the objective elements of Art. 122 StGB.[475] According to Art. 122 StGB, grievous bodily harm exists, among other things, if either a *life-threatening* injury was caused (para. 1), an *important organ* of a person was mutilated or rendered unusable (para. 2) or if a person was rendered *permanently incapacitated or infirm* (para. 3).

475 BGE 109 IV 18 E. 2a p. 18 f.

1576 *The danger to life* required by law must be immediate. It is not sufficient for the injury to be reasonably dangerous and for the possibility of death to be somewhat close, as may be the case with a broken leg, for example. Life-threatening bodily injury can only be said to have occurred if the injury has led to a condition in which the possibility of death has increased to such an extent that it has become a serious and urgent probability.[476] A danger to life of short duration is sufficient.[477]

1577 *A* kidney, *an* eye or *an* ear are already considered *important organs*;[478] the heart or brain are therefore also considered important organs. Organs are already mutilated or rendered useless if their function is permanently impaired, such as in the case of a stiffened elbow.[479] A permanent but only minor restriction of function is not sufficient.[480]

1578 *Permanent incapacity to work or frailty* only exists in the case of irreversible impairment of health. Frailty means a state of permanent illness or permanent impairment of health such as poisoning. In practice, this variant is to be read with the *general clause in para. 3* ("other serious damage to the body or to physical or mental health").[481] In particular, the duration of the hospital stay, the (full or partial) inability to work, as well as the degree and duration of the disability and the pain suffered must be taken into account.[482]

5.1.1.3 "Tater success" using the example of myocarditis

1579 Only the cases of myocarditis in all the variants listed above easily reach the necessary degree of severity:

1580 There is simply no such thing as "mild" myocarditis. Myocarditis can lead to cardiogenic shock, cardiac arrhythmia or cardiac arrest (front N 467 ff., N 674 ff.) and thus lead to immediate death. There is therefore a serious risk of death from COVID "vaccinations".

1581 But even those who survive this first immanent risk of death in the acute phase of myocarditis remain scarred for life: The survival rate after myocarditis drops massively - the damage to the heart muscle is permanent and leads to a massively increased mortality rate for

476 BGE 109 IV 18 E. 2c p. 20.
477 BGE 91 IV 193 E. 2 P. 194.
478 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [ed.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd edition, Zurich / St. Gallen 2013, Art. 122 N 5.
479 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [ed.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd edition, Zurich / St. Gallen 2013, Art. 122 N 6.
480 BGE 129 IV 1 E. 3.2 p. 3 (fanned and bifurcated urinary stream).
481 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [ed.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd edition, Zurich / St. Gallen 2013, Art. 122 N 7.
482 TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [ed.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd edition, Zurich / St. Gallen 2013, Art. 122 N 9.

those affected in the years that follow (see N 467 ff.). The heart as a vital human organ is therefore seriously - life-threateningly - and permanently damaged.

1582 It goes without saying that this is accompanied by irreversible and serious damage to health.

5.1.1.4 "Successful offense" using the example of other cases

1583 The necessary degree of severity is also likely to be reached in other cases: For example, in the case of irreparable autoimmune diseases, serious strokes or cancer (see in detail above N 290 ff., N 664 ff., N 677 ff.).

1584 In the present case, several private plaintiffs have suffered such serious damage that their ability to work will probably be impaired for the rest of their lives.

1585 The complainants reserve the right to introduce and present further cases of aggrieved private claimants in detail in the course of the present criminal proceedings.

5.1.1.5 Causality

1586 The causality *("conditio sine qua non")* between authorization and administration on the one hand and vaccination side effects on the other is given (N 1499 f.).

5.1.2. Disregard of a duty of care

5.1.2.1 Creation of an unauthorized risk

1587 The approval, lack of adequate monitoring and administration of the mRNA "vaccines" created an unlawful risk, which materialized in the injury to the physical integrity of a large number of people (see in detail N 1503 ff.).

5.1.2.2 Attribution of success

1588 The risk created was both foreseeable and avoidable for the parties involved (see in detail above N 1512 et seq.).

5.1.3. Justification: Consent

1589 In principle, consent must be examined as a justification (for the dogmatic classification, see above N 1358).

1590 Consent is not expressly standardized in the Criminal Code. However, it is generally recognized and also standardized in civil law (Art. 28 para. 2 ZGB) that the consent of the person

with legal interests excludes the wrongfulness of the act ("volenti non fit iniuria").[483] Consent is only valid under three cumulative conditions:[484]

- the consenting party must be allowed to **dispose** of the **legal interest;**
- consent must be given in full **knowledge of the facts and before the act is committed;**
- consent must be given **voluntarily.**

5.1.3.1 Power of disposition: consent to grievous bodily harm permissible?

1591 With regard to the possibility of consent in cases of serious bodily injury, some scholars are of the opinion that this is only possible if the acceptance of the injury serves a moral, ethically recognized purpose (such as organ donation).[485] However, this restriction of freedom of disposition cannot be substantiated (subject to exceptions): The decisive factors are capacity for understanding and voluntariness. According to the correct view, consent to grievous bodily harm can therefore be given in principle.[486] In doing so, the Federal Supreme Court and the prevailing opinion assume that a medical "healing intervention" is always a bodily injury that requires the consent of the injured person.[487] Because medical interventions in physical integrity can be serious and permanent, there are particularly high requirements for consent, especially with regard to information:[488]

5.1.3.2 Knowledge of the facts: Prior and complete clarification

1592 The person giving consent must know what they are doing; it is therefore imperative that they have at least the **capacity to make a judgment.**[489] When absolute legal interests are violated, the patient's prior consent is central: he or she must be sufficiently informed about the intended intervention. The requirement for the patient's consent and the associated **right to information are** based on the patient's general right of personality and serve to protect both the patient's freedom of will and their right to self-determination and physical integrity.[490] **Prior, proper and complete information** about the procedure and its possible

483 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 8.
484 See NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 23.
485 ROTH / BERKEMEYER, BSK StGB, 4th ed., Basel 2019, before Art. 122 N 21; TRECHSEL / FINGERHUTH, in: Trechsel / Pieth [eds.], Schweizerisches Strafgesetzbuch, Praxiskommentar, 2nd ed., Zurich / St. Gallen 2013, before Art. 122 N 8.
486 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 31-33.
487 BGE 99 IV 208 (concerning injection), confirmed in BGE 124 IV 258 E. 2 p. 260; ROTH / BERKEMEYER, BSK StGB, 4th ed., Basel 2019, before Art. 122 N 21, N 26; NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 51.
488 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 31-33.
489 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 34 f.
490 BGE 115 Ib 180/81, BGE 114 Ia 358 E. 6, BGE 112 II 128, BGE 108 II 61 et seq. E. 2 and 3.

consequences is required. The decisive factor here is whether and to what extent the patient, as a layperson, understands and is able to grasp the medical information and thus the implications of the planned intervention.[491] The exclusion of wrongdoing only extends as far as the consent. What the person giving consent does not know, does not recognize and does not foresee cannot be validly permitted.[492]

5.1.3.3 Voluntariness

1593 Consent must be freely given and must not suffer from any relevant lack of will.[493] The relevant will may be missing or distorted in the following cases in particular:

1594 A lack of voluntariness exists in particular in the case of direct **threats and coercion.** "Forced" consent is not consent.[494]

1595 If the person concerned is **deceived, the** decisive factor is whether the deception relates to the legal interest in question and affects the content, extent or scope of the consent. If the deception is relevant to the legal interest, there is no valid consent.[495] Accordingly, it is also possible to deceive with **partial truths** if these give the impression that the whole truth is involved.[496] Deception by omission is also possible, especially if an error is not corrected. However, this is only possible if there is a **guarantor obligation to rectify the error.** A qualified legal obligation to take action is necessary.[497]

5.1.3.4 Burden of proof on the attending physician

1596 The doctor must prove that the patient has been properly informed and has given consent as a justification.[498] The requirements for documentation and the scope of the information have been set out above (N 1322 ff.) have been described in detail above. From the point of view of probative value, it is therefore not sufficient to merely make a general note in the medical history that the patient was informed about the planned procedure and the possible complications. Rather, the information must be fully documented in the medical records and, in particular, it must be briefly noted which aspects of the specialist information were explained.[499]

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491 ROTH / BERKEMEYER, BSK StGB, 4th ed., Basel 2019, before Art. 122 N 21, N 24.
492 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 40.
493 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 47.
494 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 42.
495 NIGGLI / GÖHLICH, BSK StGB, 4th ed., Basel 2019, before Art. 14 N 45.
496 See MAEDER / NIGGLI, BSK StGB, 4th ed., Basel 2019, Art. 146 N 50.
497 See MAEDER / NIGGLI, BSK StGB, 4th ed., Basel 2019, Art. 146 N 56-58.
498 BGE 115 Ib 181, 113 Ib 425.
499 HOFMANN, "COVID-19-Impfung: Aufklärung und Urteilsfähigkeit", FMH Recht 2021, p. 158-159, p. 159.

5.1.3.5 Swissmedic: Deceptive information makes valid consent impossible

1597 Any appeal by Swissmedic to the justifying consent of the "vaccinated" would be misguided: With its misleading information policy, Swissmedic has largely made it impossible for the "vaccinated" to have been fully and transparently informed. The deception about the safety and efficacy of the "vaccination" is significant - with full knowledge, hardly anyone willing to be vaccinated would have consented to be part of a world-first human trial with an ineffective and dangerous to fatal drug.

5.1.3.6 Medical profession: Incomplete information makes valid consent impossible

1598 As before (N 1329 et seq.), various doctors violated their most basic duties of information and care under therapeutic products law. In none of the cases described is there sufficient information, which means that there is also a lack of valid consent.

5.1.4. Grounds for exclusion of guilt

1599 No grounds for exclusion of guilt are apparent.

5.1.5. Conclusion

1600 There is a strong suspicion that the persons reported and the other perpetrators still to be identified have committed multiple offenses under Art. 125 para. 1 in conjunction with para. 2 StGB. para. 2 of the Swiss Criminal Code.

5.2. Intentional grievous bodily harm (Art. 122 StGB)

1601 According to Art. 122 StGB, anyone who intentionally causes serious bodily harm or damage to the health of another person is liable to prosecution.

5.2.1. Objective facts

1602 For details of the elements of the offense of grievous bodily harm, see N 1575 ff.

5.2.2. Subjective facts

1603 With regard to contingent intent from June 2021 at the latest and possibly even direct intent from 2022 at the latest of the defendants, see N 1534 et seq.

5.2.3. Grounds for justification and exclusion of guilt

1604 On the lack of justification for consent, see in detail above N 1589 ff.

1605 There are also no apparent grounds for exclusion of guilt.

5.2.4. Conclusion

1606 There is at least sufficient suspicion that the persons reported and the other perpetrators still to be identified committed multiple offenses under Art. 122 SCC from June 2021 at the latest.

5.3. Qualified simple bodily harm (Art. 123 No. 1 / 2 StGB)

1607 Pursuant to Art. 123 No. 1 para. 1 in conjunction with. No. 2 para. 1 and 2 StGB, anyone who intentionally harms a person's body or health in a manner other than that specified in Art. 122 StGB and uses poison to do so is liable to prosecution ex officio.

5.3.1. Objective facts

5.3.1.1 Basic offense

1608 Art. 123 no. 1 para. 1 SCC covers all bodily injuries that are not yet considered serious within the meaning of Art. 122 SCC, but are also no longer considered mere assault within the meaning of Art. 126 SCC.[500] Physical integrity is impaired in the sense of bodily injury if internal or external injuries or damage are inflicted that require at least a certain amount of treatment and healing time, such as broken bones, concussions or bruises with bruising.[501] In addition, there are disorders of well-being that are equivalent to an actual pathological condition, which is the case, for example, when considerable pain is caused.[502]

1609 Already before (N 1579, N 1583) it was established that in a large number of cases serious bodily injury is to be assumed; these cases therefore also easily fulfill the basic offence of simple bodily injury.

1610 Added to this are all the simple bodily injuries that were unnecessarily inflicted on people in the form of "frequent side effects": Reactions at the injection site such as pain, redness and swelling, muscle and joint pain and chills/fever. In addition, all other bodily injuries that do not yet reach the level of serious bodily injury are also included.

500 ROTH / BERKEMEIER, BSK StGB, 4th edition, Basel 2019, Art. 123 N 3.
501 ROTH / BERKEMEIER, BSK StGB, 4th edition, Basel 2019, Art. 123 N 4.
502 ROTH / BERKEMEIER, BSK StGB, 4th edition, Basel 2019, Art. 123 N 5.

5.3.1.2 Qualification: Use of poison

1611 No. 2 of Art. 123 StGB qualifies the particularly dangerous or reprehensible act by dispensing with the application requirement while the threat of punishment remains the same.[503] The explicitly mentioned "poison" is a substance that is intended or capable of harming the human body. This includes drugs, toxins, viruses and bacteria.[504]

1612 As before (N 1543), the mRNA "vaccines" are toxic substances.

5.3.2. Subjective facts

1613 For more information on contingent intent from June 2021 at the latest and even direct intent from 2022 at the latest, see N 1538 et seq.

5.3.3. Grounds for justification and exclusion of guilt

1614 On the lack of justification for consent, see in detail above N 1589 ff.

1615 There are also no apparent grounds for exclusion of guilt.

5.3.4. Conclusion

1616 There is a strong suspicion that the accused persons and the other perpetrators still to be identified committed multiple offenses under Art. 123 para. 1 (1) in conjunction with para. 2 (1) and (2) SCC from June 2021 at the latest. No. 2 para. 1 and 2 of the Swiss Criminal Code.

IV. Criminal preparatory acts (Art. 260bis StGB)

1617 According to Art. 260bis para. 1 lit. a-c StGB, anyone who takes specific technical or organizational precautions, the nature and extent of which show that he is preparing to carry out an intentional homicide (Art. 111 StGB), murder (Art. 112 StGB) or grievous bodily harm (Art. 122 StGB) is punished.

1. Objective facts

1618 Preparatory acts under criminal law are understood to be precautions that are intended to enable or facilitate a subsequent offense. Preparations are **planned** if several interrelated acts are directed towards a common goal, namely the preparation of the criminal offense. The preparation must be carried out systematically and over a certain period of time. The preparations are **specific if** they are recognizably related to one of the aforementioned

503 ROTH / BERKEMEIER, BSK StGB, 4th ed., Basel 2019, Art. 123 N 11 f.
504 ROTH / BERKEMEIER, BSK StGB, 4th edition, Basel 2019, Art. 123 N 14.

offenses (homicide, bodily harm, etc.). Sufficiently concrete are preparatory acts which, according to the normal course of events and general life experience, appear suitable for the realization of the relevant facts. **Organizational** measures are measures that are taken to ensure the smooth execution of the crime plan. In terms of **time,** the nature and extent of the preparations must be such that it can reasonably be assumed that the offender will continue to pursue his intention to commit the offense without further ado. However, the offender does not have to be in the immediate process of committing the offense.[505]

1619 As before (N 857 ff., in particular N 992 ff.), Swissmedic has been pursuing a plan since May 2021 at the latest - and possibly even since 2019 - to completely undermine all safety mechanisms of therapeutic products legislation: Swissmedic has prepared everything in its own announcements and regulations to authorize experimental gene therapies as "vaccinations" and to be able to completely dispense with clinical trials for "updated coronavirus vaccines". Based on the illegal "temporary" initial approvals of mRNA "vaccines", which have already been accelerated to an unprecedented extent, **Swissmedic** now considers itself authorized to approve every conceivable manipulation of these "vaccines" so that it can then inject these modified mRNA "vaccines" directly into humans without any safety mechanisms such as preclinical and clinical trials. In doing so, it is clearly complying with all the manufacturers' demands and **has recently even been granting "proper" approvals without sufficient clinical studies - i.e. approvals based on completely inadequate data on quality and safety.** This no longer has anything to do with ensuring the safety of medicinal products - the corresponding authorizations even violate the absolute ban on human trials without "informed consent" if the absolute lack of transparency in informing the public continues. In view of all the experience gained since the end of 2020 with the useless, high-risk to fatal mRNA "vaccines", Swissmedic's long-planned approach, which is still being implemented, is obviously likely to cause further deaths and bodily harm.

2. Subjective facts

1620 The preparatory acts must be intentional; contingent intent is not sufficient. There must be an intention to commit one of the listed offenses.[506]

1621 In view of the large number of previously (end of 2020: N 185 ff. and N 1291 ff.; mid-2021: N 318 ff. and N 1298 ff.; end of 2021: N 387 ff. and N 1305 ff.; from 2022: N 525 ff. and N 1311 ff.) and the unwavering continuation of the useless and dangerous "vaccination campaign", there is a strong suspicion that the people responsible at Swissmedic have either long since lost their senses - or are pursuing deeply malicious intentions. The documents

505 On the whole ENGLER, BSK StGB, 4th ed., Basel 2019, Art. 260bis N 1-9.
506 On the whole ENGLER, BSK StGB, 4th ed., Basel 2019, Art. 260bis N 12.

to be seized and the interviews to be conducted will help to determine which of the two variants applies.

3. Grounds for justification and exclusion of guilt

1622 There are no apparent grounds for justification or exclusion of guilt.

4. Conclusion

1623 There is a strong suspicion that the accused persons and the other perpetrators still to be identified are planning to make specific technical or organizational arrangements to carry out an intentional homicide (Art. 111 StGB), murder (Art. 112 StGB) or grievous bodily harm (Art. 122 StGB).

Conclusion

In conclusion, I kindly ask you to consider my submissions favorably and to approve the requests made at the outset.

Yours sincerely

Attorney Ph. Kruse, LL.M.

List of enclosures Criminal complaint

Enclosure **1**:	"List of sources for the criminal complaint", 14.07.2022
Enclosure **2**:	List of notifying parties, 14.07.2022
Enclosure **3**:	List and documentation of private plaintiffs, 14.07.2022
Enclosure **4**:	Evidence report, 14.07.2022
Enclosure **5**:	Analysis of 15 deaths, 14.07.2022
Enclosure **6**:	Data DVD Sources, 14.07.2022
Enclosure **7**:	Request from University of L. to Paul-Ehrlich Institute, "Subject: Our request pursuant to §1 IFG of 3.3.2022 [...]", 13.04.2022
Enclosure **8**:	Law firm R.: "Inquiry of the professors Prof. Dr. M. et al. [...]", 14.04.2022
Enclosure **9**:	Law firm R.: "Inquiry from Professors Prof. Dr. M. et al. [...] - My letter dated April 13, 2022", 29.04.2022
Enclosure **10**:	"List of addresses of vaccination centers CH", 01.04.2022
Enclosure **11**:	Autopsy protocol Prof. Dr. A. Burkhardt, "Notes and recommendations for conducting post-mortem examination (autopsy) of persons deceased in connection with COVID vaccination", March 17, 2022
Supplement **12**:	"List of sources for criminal charges" 2.0, 14.12.2023
Supplement **13**:	Evidence report 2.0, 07.02.2024
Enclosure **14**:	Analysis of deaths in the Canton of Bern, 24.08.2022
Enclosure **15**:	USB stick, complete digital dossier, 07.02.2024
Enclosure **16**:	Swissmedic, Information event on the revision of the Therapeutic Products Act (TPA), Temporary authorization, 25.10.2018
Supplement **17**:	CCCA, Pfizer did not follow established protocols, 02.12.2022 (original source in English: CCCA, "The Pfizer Inoculations for COVID-19, More Harm than Good", 16.12.2021, p. 14, https://www.canadiancovidcarealliance.org/wp-content/uploads/2021/12/The-COVID-19-Inoculations-More-Harm-Than-Good-REV-Dec-16-2021.pdf)
Enclosure **18**:	Mail correspondence Swissmedic Art. 9a WHO pandemic, 24.11.2022
Enclosure **19**:	Swissmedic, Reporting system before July 2022, Local safety, 30.03.2022, consisting of: Reporting system 01, Start page; Reporting system 02-01, Patient notification; Reporting system 02-02, Patient form PDF; Reporting system 02-03, Patient form Word; Reporting system 03, Contact form General information.
Enclosure **20**:	Swissmedic, reporting system from July 14, 2022, 23.08.2022, consisting of: Reporting system 04, Media release 'Online reporting form' (14.07.2022); Reporting system 05, Reporting of suspected adverse drug reactions; Reporting system 06, Online reporting of adverse drug reactions - start; Reporting system 07, Details of reporting person (step 1_5); Reporting system 08, Affected person (step 2_5); Reporting system 09-01, Adverse drug reactions (step 3_5); Reporting system 09-02_Swissmedic, Nw (step 3_5), Reverse drug reactions (step 3_5); Reporting system 09-03_Swissmedic, Nw (step 3_5), Adverse drug reactions (step 3_5). Adverse reactions; reporting system 09-03_Swissmedic, Nw (step 3_5), Manual intervention serious NW; reporting system 09-04_Swissmedic, Nw (step 3_5), Severity of effect; reporting system 10, Drug _ Vaccination (step 4_5); reporting system 11, Online reporting of adverse reactions - summary.