PERSONAL AND CONFIDENTIAL

From: Drs. Willem C. Engel
xxxxxxxxxx
xxxxxxxxx
xxxxxxxxx
xxxxxxxxxx

Also by e-mail:
xxxxxxxxxxx
Attn: Executive Board CBG
(Medicines Evaluation Board)
xxxxxxxxxxxxxxx
xxxxxxxxxxxxxxx

URGENT

Regarding: Letter of summons suspending Pfizer and Moderna marketing authorisations (October 2023)
Date: 1 October 2023

Dear Sir/Madam,

I would like to draw your attention to the following. The mRNA injections against C19 are inadequate because several sections from article 51 of the Medicines Act have been violated.

- the medicine is harmful
- the therapeutic effect is lacking
- the trade-off between benefits and risks is not favourable
- the medicinal product does not possess the declared qualitative and quantitative characteristics
- data submitted are incorrect
- checks have not taken place
- the package leaflet is not satisfactory

Last week, 4.8 million invitations were sent out by the RIVM to various residents of the Netherlands inviting them to take the repeat shot, to be taken from Monday 2 October 2023: https://www.rivm.nl/nieuws/coronaprik-voor-risicogroepen-60-plussers-griepprikgroep-zorgmedewerkers-en-zwangeren

This is problematic for several reasons, as will be explained below.

Reason why we hereby summon you (the Medicines Evaluation Board, hereinafter "CBG") to immediately proceed to suspend, pursuant to article 51 of the Medicines Act or article 23 of Directive 2001/83/EC, the marketing authorisations regarding the extension of the Marketing Authorisation as issued by the European Commission after positive advice from the European Medicine Agency (hereinafter "EMA"):

- Conditional Marketing Authorisation Pfizer (Comirnaty) dated 21 December 2020 (see https://ec.europa.eu/health/documents/community-register/2020/20201221150522/dec_150522_en.pdf

- Conditional Marketing Authorisation Moderna (Spikevax) dated 6 January 2021 (see https://ec.europa.eu/health/documents/community-register/2021/20210106150575/dec_150575_en.pdf
- Renewal of Marketing Authorisation Pfizer (Comirnaty-tozinameran) dated 31 August 2023 https://ec.europa.eu/health/documents/community-register/2023/20230831160389/dec_160389_en.pdf
- Renewal Marketing Authorisation Moderna (Spikevax-elasomeran) dated 15 September 2023 https://ec.europa.eu/health/documents/community-register/2023/20230915160561/dec_160561_en.pdf

Therapeutic indication: active immunisation

According to article 4.1 of the current authorisation (Marketing Authorisation) by the European Commission on 31 August 2023 (following a positive opinion from the EMA on 29 August 2023), Pfizer BioNTech's (Comirnaty) injections are only authorised for **active immunisation**.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Comirnaty 30 micrograms/dose concentrate for dispersion for injection is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2, in individuals 12 years of age and older.

The use of this vaccine should be in accordance with official recommendations.

https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_en.pdf

For Moderna (Spikevax), according to article 4.1 of that the current authorisation (Marketing Authorisation) was granted by the European Commission on 15 September 2023 (following a positive opinion from the EMA on 29 August 2023) and Moderna (Spikevax-elasomeran) injections are **also** authorised for **active immunisation** only.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Spikevax is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 6 months of age and older.

The use of this vaccine should be in accordance with official recommendations.

https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_en.pdf

You (the MEB) are obviously aware of the therapeutic indication of these drugs. In more understandable language, this boils down to:

> the drugs should **only** be used by people who want to protect **themselves** and that the drugs are **not** authorised to reduce transmission or numbers of infections (transmission control).

Your job is to communicate this to medics so that they can use it in their *informed consent* discussions (which they are legally obliged to do under Article 7:448 jo. 7:450 Civil Code). ***Off label*** application must **always be** done with *informed consent*.

Clinical trials

Clinical trials for the XBB.15 have only recently started and will not be completed until 2024, making it very premature to renew a licence when there is currently no PHEIC (Public Health Emergency of International Concern).

https://www.who.int/news/item/05-05-2023-statement-on-the-fifteenth-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-coronavirus-disease-(covid-19)-pandemic

https://www.clinicaltrials.gov/study/NCT05997290 Pfizer clinical trial (XBB)

Pfizer: 10.08.23 to 28.06.24 (phase 2/3)

Study Overview

Brief Summary:
The purpose of this clinical protocol is to learn about the safety, tolerability, and immunogenicity of new BNT162b2 RNA-based vaccine candidates targeting new variants of SARS-CoV-2 in healthy people.

Substudy A:

- This study will evaluate the safety, tolerability, and immunogenicity of BNT162b2 (Omi **XBB**.1.5) given as a single 30 µg dose,
  - in people who are 12 years of age and older,
  - who previously received at least 3 doses of a US-authorized mRNA COVID-19 vaccine, with...

+ Show more

OFFICIAL TITLE

A PHASE 2/3 PROTOCOL TO INVESTIGATE THE SAFETY, TOLERABILITY, AND IMMUNOGENICITY OF BNT162b2 RNA-BASED VACCINE CANDIDATES FOR SARS-CoV-2 NEW VARIANTS IN HEALTHY INDIVIDUALS

CONDITIONS

SARS-CoV-2 Infection | COVID-19

INTERVENTION / TREATMENT

Biological: BNT162b2 (Omi **XBB**.1.5)

STUDY START (ACTUAL)
2023-08-10

PRIMARY COMPLETION (ESTIMATED)
2024-06-28

STUDY COMPLETION (ESTIMATED)
2024-06-28

ENROLLMENT (ESTIMATED)
700

STUDY TYPE
Interventional

PHASE
Phase 2
Phase 3

OTHER STUDY ID NUMBERS
C4591054

https://www.clinicaltrials.gov/study/NCT05765578 Moderna clinical trial (XBB)

Moderna: 08.03.23 to 31.12.24 (observational phase)

Study Overview

Brief Summary:
The goal of this observational study is to analyze binding antibody levels in adults in the United States (US) after receiving coronavirus disease 2019 (COVID-19) bivalent boosters (original and omicron BA.4/5) and updated COVID-19 vaccines (**XBB**.1.5).

OFFICIAL TITLE

DisCOVEries 2 - An Observational Study to Evaluate the Immunogenicity of mRNA **COVID-19** Bivalent Vaccines (Original and Omicron BA.4/BA.5) and 2023 Updated mRNA **COVID-19** Vaccines (**XBB**.1.5)

CONDITIONS

COVID-19

INTERVENTION / TREATMENT

Biological: Moderna COVID-19 Vaccine
Biological: Moderna mRNA1273.222 Booster
Biological: Pfizer COVID-19 Vaccine
Show 2 more interventions/treatments

STUDY START (ACTUAL)
2023-03-08

PRIMARY COMPLETION (ESTIMATED)
2023-10-01

STUDY COMPLETION (ESTIMATED)
2024-12-31

ENROLLMENT (ESTIMATED)
2850

STUDY TYPE
Observational

OTHER STUDY ID NUMBERS
mRNA-1273-P922

The main rule for the authorisation of Genetically Modified Organisms ("GMOs")

In Articles 6 to 11 of the Directive 2001/18/EC dated 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, the main rules for allowing GMOs into the environment can be found. It makes perfect sense that the rules for this are enormously strict as it can have a major impact on humans and the environment.

However, something strange happened on 15 July 2020. In connection with COVID, a new Regulation was suddenly created and came into force on 18 July 2020 (see Article 5). Articles 2(1) jo(2) and 4(1) of Regulation 2020/1043/EU on the conduct of clinical trials on medicinal products for human use containing or consisting of genetically modified organisms and intended for the treatment or prevention of coronavirus disease (COVID-19), as well as the supply of such medicinal products, are the most relevant provisions.

Article 2

1. All operations related to the conduct of clinical trials, including packaging and labelling, storage, transport, destruction, disposal, distribution, supply, administration or use of investigational medicinal products for human use containing or consisting of GMOs intended to treat or prevent COVID-19, with the exception of the manufacturing of the investigational medicinal products, shall not require a prior environmental risk assessment or consent in accordance with Articles 6 to 11 of Directive 2001/18/EC or Articles 4 to 13 of Directive 2009/41/EC when these operations relate to the conduct of a clinical trial authorised in accordance with Directive 2001/20/EC.

2. Sponsors shall implement appropriate measures to minimise foreseeable negative environmental impacts resulting from the intended or unintended release of the investigational medicinal product into the environment.

Article 4

1. This Regulation shall apply as long as WHO has declared COVID-19 to be a pandemic or as long as an implementing act by which the Commission recognises a situation of public health emergency due to COVID-19 in accordance with Article 12 of Decision No 1082/2013/EU of the European Parliament and of the Council (7) applies.

This Regulation allowed for a temporary derogation from the very strict rules of Directive 2001/18/EC.

Particularly important are Articles 6 and 9 of the Directive. These articles deal with the authorisation procedure and public consultation and information (see also the Aarhuus Convention on access to information, public participation in decision-making and access to justice in environmental matters, which entered into force for the Netherlands on 29 March 2005).

Article 9

Consultation of and information to the public

1. Member States shall, without prejudice to the provisions of Articles 7 and 25, consult the public and, where appropriate, groups on the proposed deliberate release. In doing so, Member States shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion.

2. Without prejudice to the provisions of Article 25:

— Member States shall make available to the public information on all part B releases of GMOs in their territory;

— the Commission shall make available to the public the information contained in the system of exchange of information pursuant to Article 11.

(i) general information including information on personnel and training,

(ii) information relating to the GMO(s),

(iii) information relating to the conditions of release and the potential receiving environment,

(iv) information on the interactions between the GMO(s) and the environment,

(v) a plan for monitoring in accordance with the relevant parts of Annex III in order to identify effects of the GMO(s) on human health or the environment,

(vi) information on control, remediation methods, waste treatment and emergency response plans,

(vii) a summary of the dossier;

(b) the environmental risk assessment and the conclusions required in Annex II, section D, together with any bibliographic reference and indications of the methods used.

The main rule is that a GMO can only be authorised in the European Union after a technical dossier containing 7 documents has been provided (see below) as well as an environmental risk assessment.

Recently, however, a report "Resilient biotechnology policy; Lessons from the corona crisis: Opportunities for a more resilient biotechnology policy") by COGEM (Committee on Genetic Modification) was released on 11 October 2022 and published on 16 December 2022. Chapter 3 of this report shows that Regulation 2020/1043/EU is void because it is not based on the correct legal basis. Articles 114 or 168(4)(c) TFEU cannot be invoked in this case. This means that the rules of Directive 2001/18/EC continued to apply in full and that a technical dossier and an environmental report should therefore have been submitted. Having failed to do so, all the permits issued were thus unlawfully granted to the pharmaceutical companies.

Moreover, for the two extensions, even if Regulation 2020/1043 were **not invalid**, at least under Article 4(1) of the Regulation, **a technical dossier and an environmental risk assessment should**

have been submitted for the extensions, since the PHEIC was terminated by the WHO on 5 May 2023.

In addition, the public should have been informed and consulted in accordance with Article 9 of the Ordinance. As none of this happened, it means that there were very serious procedural errors, which meant that the permits should **never have been** granted. This means that an extension of the existing licence should not have been requested, but a **new** licence should have been applied for. Reason why you should immediately proceed with the suspension of the issued marketing authorisations.

Incidentally, the same also applies to Regulation 2019/5/EU; it too is based on the wrong legal ground; namely Articles 114 and 168(4)(c) TFEU. This means that this Regulation is also void.

Suspension ex article 51 Medicines Act

Under Section 51 of the Medicines Act, you are required to amend, **suspend** a marketing authorisation if the conditions are not met. In this case, 6 of the 10 conditions have not been met, as will be explained below.

Section 51 of the Medicines Act lists 10 categories (a to j) on the basis of which a marketing authorisation can be revoked, amended or suspended. As already discussed in sections 1.1 and 1.4, you (the MEB) only have the authority to suspend the marketing authorisation **within the Netherlands**, as the EMA is the body that issued the marketing authorisations for the EU.

> **Translation article 51 Dutch Medicine Law**
> The Board shall **suspend**, modify or revoke a marketing authorisation if:
>
> **a. the drug is harmful,**
> **b. it lacks therapeutic efficacy** or if **the balance of benefits and risks is not favourable**,
> **c.** the medicinal product does **not** possess the declared **qualitative and quantitative characteristics**,
> **d.** the **particulars and documents submitted** pursuant to Article 42 are **incorrect** or have not been amended in accordance with Article 49,
> **e.** the controls referred to in Article 28(1) have not been carried out,
> **f. the labelling or the package leaflet does not comply with the requirements laid down for this purpose** in Chapter 7,
> **g.** requirements pursuant to article 45a or 45b have not been complied with,
> **h.** the marketing authorisation holder fails to comply with the obligations laid down in Chapter 8,
> **i.** if the coordination group has so decided pursuant to Article 107g of Directive 2001/83, or
> **j. if the manufacturer's preparation or quality control is not in accordance with the requirements as described in the dossier on the basis of which the marketing authorisation in question was granted**.

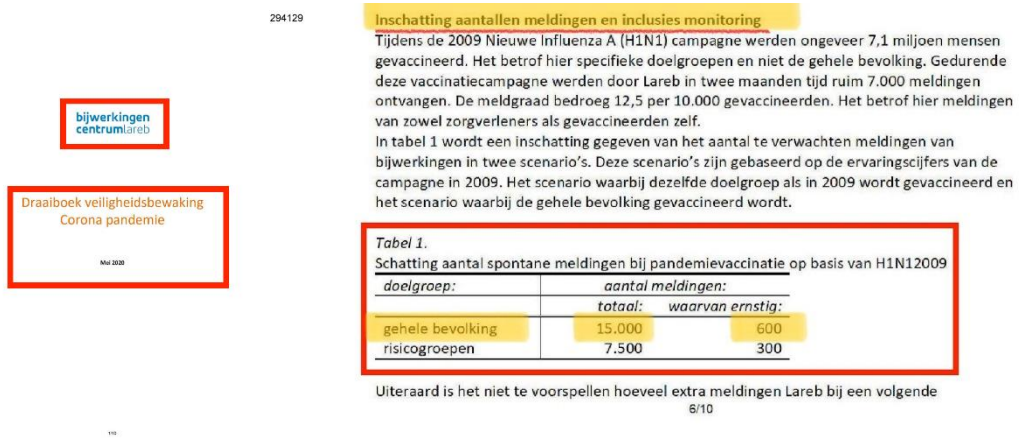
Section 51 of the Medicines Act requires you to amend, revoke **or suspend** a marketing authorisation if conditions are not met. The article will be reproduced below, followed by a specific explanation of the problems with existing marketing authorisations.

a) The medicine is harmful

That this is the case is evidenced by the number of reports received in the Netherlands at the Centre for National Registration and Evaluation of Adverse Reactions ("LAREB") (overview dated 17 September 2023)

able ducer/Tradename	Total number of reports*	Number of adverse reactions reported	Number of reports with a serious adverse reaction**	Deceased
Pfizer (Comirnaty)	125.746	518.269	3.764	506
Pfizer herhaalprik	2.214	10.413	54	13
Moderna (Spikevax)	49.909	286.598	934	91
Moderna herhaalprik	3.592	17.791	88	12
AstraZeneca (Vaxzevria)	38.033	223.424	997	79
Janssen (Jcovden)	15.101	78.337	291	17
Novavax (Nuvaxovid)	60	277	-	-
Merk onbekend	584	2.439	95	33
Total	**235.239**	**1.137.548**	**6.223**	**751**

This is serious considering that in May 2020, the LAREB prepared a "Corona pandemic safety monitoring plan" in which it assumed that 15,000 reports would be received -600 of which were serious- if the *entire* population were injected with these drugs (see page 6 of 10 of the plan): https://voorwaarheid.nl/wp-content/uploads/2022/03/2022-03-09-Tuchtklacht-Pels-Rijcken-bijlage-2-WOB-Draaiboek-LAREB-Veiligheidsbewaking-Corona-pandemie-mei-2020.pdf



294129

bijwerkingen centrumlareb

Draaiboek veiligheidsbewaking Corona pandemie

Mei 2020

Inschatting aantallen meldingen en inclusies monitoring

Tijdens de 2009 Nieuwe Influenza A (H1N1) campagne werden ongeveer 7,1 miljoen mensen gevaccineerd. Het betrof hier specifieke doelgroepen en niet de gehele bevolking. Gedurende deze vaccinatiecampagne werden door Lareb in twee maanden tijd ruim 7.000 meldingen ontvangen. De meldgraad bedroeg 12,5 per 10.000 gevaccineerden. Het betrof hier meldingen van zowel zorgverleners als gevaccineerden zelf.
In tabel 1 wordt een inschatting gegeven van het aantal te verwachten meldingen van bijwerkingen in twee scenario's. Deze scenario's zijn gebaseerd op de ervaringscijfers van de campagne in 2009. Het scenario waarbij dezelfde doelgroep als in 2009 wordt gevaccineerd en het scenario waarbij de gehele bevolking gevaccineerd wordt.

Tabel 1.
Schatting aantal spontane meldingen bij pandemievaccinatie op basis van H1N12009

doelgroep:	*aantal meldingen:*	
	totaal:	*waarvan ernstig:*
gehele bevolking	15.000	600
risicogroepen	7.500	300

Uiteraard is het niet te voorspellen hoeveel extra meldingen Lareb bij een volgende

6/10

This means that the number of reports is a factor of 16 higher (235,239 / 15,000 = factor of 15.68) than LAREB itself had initially expected. For the number of serious adverse reactions, it is a factor of 10 (6,223 / 600 = factor of 10.37). It is incomprehensible that you (the MEB) did not suspend the marketing authorisations much earlier.

In addition, the side effects myocarditis and pericarditis are listed in the package leaflet of Pfizer Comirnaty (this search term occurs 20x) and that this is particularly at increased risk for boys and young men. Furthermore, **fatal cases** are reported, as shown below.

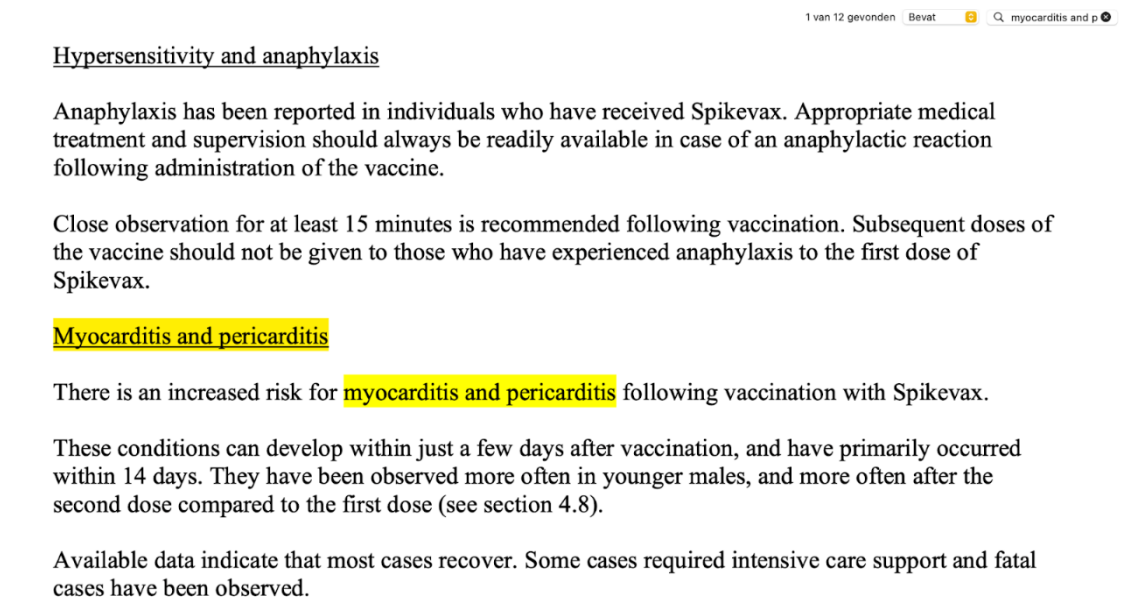
Myocarditis and pericarditis

There is an increased risk of myocarditis and pericarditis following vaccination with Comirnaty. These conditions can develop within just a few days after vaccination and have primarily occurred within 14 days. They have been observed more often after the second vaccination, and more often in younger males (see section 4.8). Available data indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. Vaccinees (including parents or caregivers) should be instructed to seek immediate medical attention if they develop symptoms indicative of myocarditis or pericarditis such as (acute and persisting) chest pain, shortness of breath, or palpitations following vaccination.

Healthcare professionals should consult guidance and/or specialists to diagnose and treat this condition.

The leaflet for Moderna (Spikevax) also mentions the risk of myocarditis and pericarditis (this search term appears 12x), and **fatal cases are reported**, as shown below.



Hypersensitivity and anaphylaxis

Anaphylaxis has been reported in individuals who have received Spikevax. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following administration of the vaccine.

Close observation for at least 15 minutes is recommended following vaccination. Subsequent doses of the vaccine should not be given to those who have experienced anaphylaxis to the first dose of Spikevax.

Myocarditis and pericarditis

There is an increased risk for myocarditis and pericarditis following vaccination with Spikevax.

These conditions can develop within just a few days after vaccination, and have primarily occurred within 14 days. They have been observed more often in younger males, and more often after the second dose compared to the first dose (see section 4.8).

Available data indicate that most cases recover. Some cases required intensive care support and fatal cases have been observed.

b) Lack of therapeutic efficacy and unacceptable risks of side effects

A vaccine should induce long-term immunity: https://www.cdc.gov/vaccines/vac-gen/imz-basics.htm#diseases

The moment a vaccine would provide protection for less than a year, this is not met. Immunity involves creating a long-term defence and this is not met.

c) The medicinal product does not possess the declared qualitative and quantitative properties
Qualitatively: the drugs do not prevent transmission and therefore the *slogan "You're doing it for someone else"* does not apply. Therefore, the drugs are prescribed *off label*, which means that informed consent must always take place in which the conversation must make it clear that there is a risk of death and that the drug is not approved to prevent transmission.

Quantitative: the previous claim made, namely that 70% to 95% could no longer become infected after injection, has not been fulfilled: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9115787/

d) The documents submitted are incorrect
Through irregularities and illegalities in changing the categorisation (classification/classification) of medicines, drugs that lack much of the safety research have mistakenly entered the market. By changing the *rolling review* and *conditional marketing authorisation* procedure and changing the definition of vaccine and immunity, the criteria are no longer adequate. Gross irregularities have also been found in *clinical trial* data. This has been published several times in the *British Medical Journal* (BMJ). See: https://www.bmj.com/content/375/bmj.n2635

f) Inserts do not meet requirements
The *Summary of Product Characterisations* (hereafter: "SMPCs"; also called leaflets for *professionals*) submitted by Pfizer and Moderna are so **voluminous** that they have become *de facto* **illegible** for both doctors and citizens, thus rendering ***informed consent*** **impossible**.

In addition, it is **not allowed to** create 1 package leaflet for different products. The XBB.15 *boosters qualify as a* new medicine, for which a separate leaflet should therefore be designed. The pharmacist cannot expect the doctor and the patient to figure out *for themselves* which part of such extensive SMPCs (package leaflets), namely 574 pages or 224 pages is about the XBB.15 booster, as shown below.

SMPC Pfizer (574 pages): (https://www.ema.europa.eu/en/documents/product-information/comirnaty-epar-product-information_nl.pd)

SMPC Moderna (224 pages): (https://www.ema.europa.eu/en/documents/product-information/spikevax-previously-covid-19-vaccine-moderna-epar-product-information_nl.pdf

The information must be clear and also easily accessible. It is not permissible to lump everything together in the proverbial "big heap", even if the same excipients are used. A separate leaflet should be prepared for each variation. After all, even a small change in sequence can have major consequences. (such as thalidomide where the stereoisomer is teratogenic)

The current leaflets list the variants interchangeably. This is insufficiently specific and therefore not permitted. Thus, the regulation on informed consent (*informed consent*) article 7:448 jo. 7:450 BW (Book 7, Title 7, Section 5: the medical treatment agreement) cannot be complied with. This can be called highly problematic.

j) There was a breach of Good Manufacturing Practices

Emails sent within the EMA show that there were 3 problems shortly before authorisation. These problems were mainly in Good Manufacturing Practices.

Wathion Noel

Mon 11/16/2020 12:42 PM

Inbox

Time for decision-making at EU; tomorrow phone call with Olga et al to prepare for EU Exe SG on Wednesday.

Wednesday EU Exe SG with HoAs.

Thursday TC with Commissioner.

The feasibility to "adapt" the CMA to these extraordinary circumstances will be key for determining the approach.

This email argues that the ability to amend the terms of a Conditional Marketing Authorisation is important to the approach. https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-4.png

Nolte Alexis

Mon 23/11/2020 10:48

Sent Items

To:

Korakianiti Evdokia;

Evdokia,

One way to understand how the lower mRNA level in the finished product translates to efficacy would be to measure whether it affects significantly levels of protein expression. It could be that the level of antigenic protein expressed is not significantly affected. However, I don't know whether there is a test that would allow to predict impact on efficacy without clinical trial for comparability.

Alexis

This e-mail states that the lower amount of intact mRNA in the *finished* product might translate into lesser efficacy, thus making the 95% claim underlying the media statements a priori misleading. https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-7.png

Boone Hilde

ma 23/11/2020 14:26

Dear Marco & Irene,

In the EC table, CHMP opinion is presented for 21 December, whereas this morning 23rd was mentioned as per current timetable, I understand.

But, indeed we agreed trying to bring Opinion forward by a few days eg to 21 or even 18 Dec.

So, what response should we give back to EC now:

Current EMA planning is 23 Dec for Opinion, but we are looking into bringing adoption forward?

Or

Do we already say that 21 Dec for Opinion, as listed in the EC table, is correct, but that we are looking into bringing adoption forward even more?

I take it that the Eudralink TT request that we just received, replaces Olga's question below (as it is in essence the same).

Best, Hilde

In this email, it is clear that rather than being guided by thorough research to arrive at an opinion, the EMA is interfering in the substantive process and indicating that approval should be given sooner. This did happen, the Conditional Marketing Authorisation was awarded to Pfizer on 21 December 2020. See: https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-14.png

Conclusions: a number of major concerns remain that impact the benefit/risk of the vaccine (efficacy/safety) most notably the comparability issue around % mRNA integrity. These concerns are shared by most member states. **An approval by the end of the year could potentially be possible, if these concerns + GMP will be resolved**. Any remaining Quality issues will need to be considered in the context of overall B/R (& could potentially be addressed via specific obligations/Annex II conditions/recommendations).

The BWP report reflecting these conclusions is undergoing written adoption today.

With thanks to Ton, Brian and Claudio,

Kind regards,

Veronika

Veronika Jekerle, PhD

Head of Pharmaceutical Quality Office

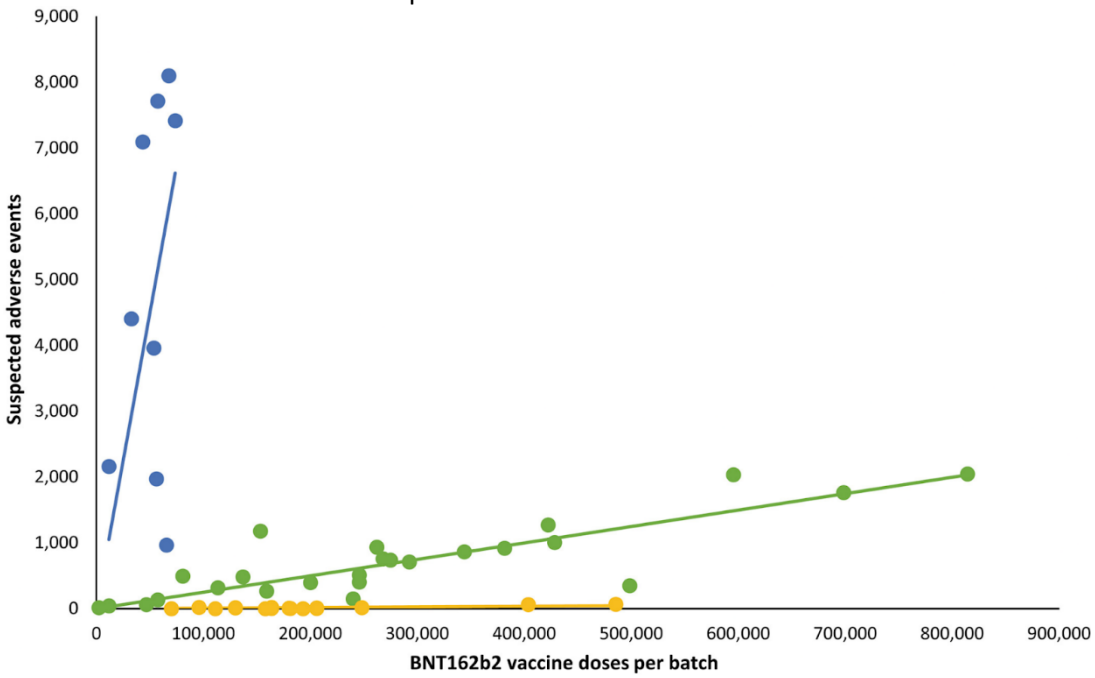
Quality and Safety of Medicines

Office: 09-N-02

Extension: 8438

On 24 November 2020, there was still talk of 3 Major Objections;
1. The mRNA integrity depends on Good Manufacturing Practices (GMP). A problem was identified with mRNA integrity.
2. The *clinical batches* used for the *clinical trials* differed significantly from the *commercial batches*.
3. Finally, there was also a lot of difference between different production facilities.See: https://voorwaarheid.nl/wp-content/uploads/2022/12/E-mail-9.png

The batch homogeneity did not appear to be in order. That this in turn affected the benefit/risk ratio, aka efficacy/safety ratio was shown in the publication: Batch-dependent safety of the BNT162b2 mRNA COVID-19 vaccine, Maniche et al, 30 March 2023, see:
https://onlinelibrary.wiley.com/doi/10.1111/eci.13998
In this publication, reports of adverse events depend on batch number. This correlation is significant. 4% of doses account for 70% of reports.



A drug so diverse in action cannot be authorised, if only because of the impossibility of informed consent. In addition, as a precautionary principle, the highest category of side effects must be assumed. This makes an effectiveness/safety trade-off negative for each specific target group.

Interim conclusion: As many as 6 out of 10 categories have not been met, which is why you should proceed to immediate suspension.

Union licence for Pfizer and Moderna

The Conditional Marketing Authorisation for Pfizer and Moderna awarded on 21 December 2020 and 6 January 2021 do not meet the requirements as Regulation 2019/5/EU & Regulation 2020/1043/EU & Regulation 2021/756/EU do not meet the framework laid down:

- On environmental risk assessment and reporting in Regulation2001/18/EC & Directive 2009/41/EC
- On safety for medicinal products laid down in Directive 2001/83/EC & 2003/63/EC & 2007/1394/EC
- Concerning the granting of a union licence laid down in Regulation 2004/726/EC & Regulation 2008/1234/EC

The changes in Regulation 2019/5/EU should not be used to go outside the framework of existing classification and categorisation, only clarification is allowed, no categories can be added that conflict with the current system, full legislation is needed for that.

The temporary suspension of the environmental risk assessment and reporting (2020/1043) appears to be null and void with this (see chapter 3 of the report Resilient Biotechnology Policy dated 11 October 2022 by COGEM published on 16 December 2022 https://cogem.net/app/uploads/2022/12/CGM-2022-05-Veerkrachtig-biotechnologiebeleid.pdf Particular reference is made to pages 36-38 of the report.

The changes in Regulation 2021/756/EU were done **AFTER** the first Conditional Marketing Authorisation grant. Article 19 of Regulation 2008/1234 clearly states that follow-up licences should be assessed according to the criteria of the first licence.

CHAPTER IV

SECTION 1

Special procedures

Article 19

Extensions of marketing authorisations

1. An application for an extension of a marketing authorisation shall be evaluated in accordance with the same procedure as for the initial marketing authorisation to which it relates.

2. An extension shall either be granted a marketing authorisation in accordance with the same procedure as for the granting of the initial marketing authorisation to which it relates or be included in that marketing authorisation.

In addition, the addition of 'codes/sequences' in Regulation 2021/756/EU conflicts with the classification and categorisation of Directive 2001/83/EC & Directive 2003/63/EC & Regulation 2007/1394.

Regulation 2009/120/EC making change to Annex part IV namely art 2.1 *"Gene therapy medicinal products shall not include vaccines against infectious diseases"* offers no relief, the last rule should be

seen as mutually exclusive. After all, vaccine is already defined by the regulations that appeared before.

A vaccine must induce immunity appears from Article 1(4) Directive 2001/83/EC:

4. *Immunological medicinal product:*

Any medicinal product consisting of vaccines, toxins, serums or allergen products:

(a) vaccines, toxins and serums shall cover in particular:

(i) agents used to produce active immunity, such as cholera vaccine, BCG, polio vaccines, smallpox vaccine;

(ii) agents used to diagnose the state of immunity, including in particular tuberculin and tuberculin PPD, toxins for the Schick and Dick Tests, brucellin;

(iii) agents used to produce passive immunity, such as diphtheria antitoxin, anti-smallpox globulin, antilymphocytic globulin;

(b) 'allergen product' shall mean any medicinal product which is intended to identify or induce a specific acquired alteration in the immunological response to an allergizing agent.

Article 1.4 (immunological medicine) of this Regulation says "immune response" , but immunity. These are two completely different things. Immunity is a specific immune response where infection is prevented in the future, in the current injections there is no evidence of that.

In addition, a vaccine must contain an antigen; this antigen requires its own registration in the Vaccine Antigen Master File (VAMF) laid down in Directive 2003/63/EC. The reason for this method is that homogeneity and quality and active dose can be determined per treatment. This is not the case with coding sequences.

The recommendations for categorisation and interpretation of the law is reflected in the EMA's *guidelines*.
Reflection paper on classification of advanced therapy medicinal products 2015
https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-classification-advanced-therapy-medicinal-products_en-0.pdf especially 2.3.3 where mRNA is chosen as an example of gene therapy.

Reflection paper on criteria to be considered for the 6 evaluation of new active substance (NAS) status of 7 biological substances 2023
https://www.ema.europa.eu/en/documents/scientific-guideline/reflection-paper-criteria-be-considered-evaluation-new-active-substance-nas-status-biological_en.pdf especially 5.8 which states that any significant change in the sequence of mRNA requires a new application.

Thereby, it must be established that parts of Regulation 2020/1043/EU and Regulation 2021/756/EU are contrary to the classification system and the security system, as argued in the COGEM report, they are thus contrary to Articles 141 and 168 TFEU.

In addition, 2019/5 was used in violation of Article 290(1) of the Treaty on the Functioning of the European Union ("TFEU"):

> *"A legislative act may delegate to the Commission the power to adopt non-legislative acts of general application to supplement or amend certain non-essential elements of the legislative act."*

It is clearly stated that delegation of powers is not about legislative acts. If classification and categorisation acts and provision are in conflict with existing classification and categories it is WELL legislation, thus all such acts are null and void. In addition, the same line can be followed as the changes lead to a greater risk to public health (see Article 168 TFEU).

The issues are discussed in detail in this publication by Helene Banoun, 9 June 2023, *International Journal of Molecular Sciences. Zie:* https://www.mdpi.com/1422-0067/24/13/10514

Conclusion
You should immediately suspend the trade licences issued. If you fail to do so, you are acting unlawfully and will be liable for the damage that occurs as a result.

You can interpret this request as an enforcement request to -in accordance with your statutory duty under Section 2 jo. 9 jo. 51 jo. 79 Medicines Act- immediately suspend the marketing authorisations issued by the European Commission, as 6 of the 10 criteria of Section 51 Medicines Act have **not been** met, as will be explained below.

I hereby inform you that the **failure to take a decision on time** (no later than Monday 2 October 2023 as the pricking round for the XBB.15 booster will start on Monday 2 October 2023) is considered equivalent to a decision in the sense of administrative law, against which objection and appeal may be lodged (possibly accompanied by the filing of a preliminary injunction in view of the urgent interest in this matter) within the meaning of Article 1:3(1) jo. 6:2 opening words and under b of the General Administrative Law Act (Awb). In your decision, you must observe the requirements of due care and weigh up the interests in accordance with Articles 3:2 to 3:4 of the Awb.

In addition, a decision not to proceed immediately with enforcement and suspension may qualify as an unlawful (government) act within the meaning of Section 6:162 of the Civil Code, which can also trigger civil proceedings.

We would like to receive an acknowledgement of receipt and a substantive response to this summons as soon as possible, as the puncture campaign starts again tomorrow (Monday, 2 October 2023). In the absence of a response within 48 hours, you may face a summons.

Sincerely,

VoorWaarheid's legal and medical team