

EIGHTH MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE

15 February 2024

Proposal for negotiating text of the WHO Pandemic Agreement

Chapter II, Article 9 with refined textual proposals

Chapter II. The world together equitably: Achieving equity in, for and through pandemic prevention, preparedness and response

Article 9. Research and development

1. To prevent, prepare for and enable a rapid, effective and equitable response to pandemics, the Parties shall cooperate to build, strengthen and sustain national, regional and international capacities and institutions for research and development (R&D), particularly in developing countries, and shall promote scientific collaboration for the rapid sharing of information and access to research results, including through open science approaches.

2. To this end, the Parties shall promote:

- (a) sustained investment in R&D for public health and clinical priorities, including for pandemic-related products, and support for research institutions and networks that can rapidly adapt and respond to R&D needs in the event of a pandemic emergency;
- (b) technology co-creation and joint venture initiatives, that engage the participation of and international collaboration among scientists and/or research centres, including from public and private sector, particularly from developing countries;
- (c) innovative R&D, including community-led and cross-sector collaboration, for addressing pathogens with pandemic potential;
- (d) knowledge translation and evidence-based communication tools, strategies and partnerships, relating to pandemic prevention, preparedness and response;
- (e) capacity-building programmes and partnerships for R&D, including early-stage research, such as discovery, pre-clinical, and translational research;
- (f) international collaboration and coordination, including with the private sector, to set common objectives, research goals and priorities, to develop pandemic-related products for diverse populations and diverse settings, with a central role for WHO;
- (g) access for scientists and researchers, particularly from developing countries, to relevant international scientific research programmes and partnerships, including those referred to in this Article:
- (h) the sharing of information on national research agendas, R&D priorities during pandemic emergencies, capacity-building activities and best practices on efficient and ethical clinical trials, including through the WHO Global Observatory on Health Research and Development;
- (i) research on the causes and effects of pandemics, on their prevention and management, including: (1) the epidemiology of emerging diseases, factors driving disease spillover or emergence, and behavioural science; (2) social interventions used to control pandemics and their effect on spread of disease and the burden imposed by these measures on society, including its economic cost; and (3) relevant medical and other countermeasures, with the aim of promoting equitable access, including their timely availability, affordability, and their quality.
- 3. The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop, strengthen and sustain clinical trial capacities at the national, regional and international levels, including by:
 - (a) building and maintaining a skilled research workforce and infrastructure, as appropriate;

- (b) strengthening clinical trial policy frameworks, particularly in developing countries;
- (c) investing in the infrastructure and training of clinical research networks and the coordination of clinical trials through existing, new or expanded clinical trial networks, including in developing countries;
- (d) ensuring that clinical trials are conducted in accordance with international ethical guidelines, including by guaranteeing:
 - i equitable representation, considering racial, ethnic and gender diversity across the life cycle, and are designed to help to address geographical, socioeconomic and health disparities, to promote a better understanding of the safety and efficacy of pandemic-related products for population subgroups; and
 - ii access to safe, effective, and quality assured interventions or products developed for the population or community in which the research is carried out;
- (e) strengthening international coordination and collaboration, through existing or new mechanisms and networks, to support well-designed and well-implemented clinical trials, including through trials facilitated and convened by WHO, whenever feasible;
- (f) developing national policies to support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications, while protecting privacy and health identifiers;
- (g) supporting new and existing mechanisms to facilitate the rapid reporting and interpretation of data from clinical trials, to develop or modify, as necessary, relevant clinical trial guidelines, including during a pandemic; and
- (h) promoting access to comparator products needed for clinical trials, to allow for rapid development and comparison of products and technologies.
- 4. Each Party shall develop and implement national policies to support the transparent, open public sharing of research inputs, outputs and processes from publicly funded pandemic related products R&D.
- 5. Each Party shall, in accordance with its national laws and considering the extent of funding provided:
 - include provisions to promote equitable access to pandemic-related products in government-funded R&D agreements and in licensing of government-owned technology for such products; and
 - b. publish relevant terms of government-funded R&D agreements for pandemic-related products, in particular, information on pricing policies for end-products; licensing to enable the development, manufacturing and distribution of pandemic-related products; and terms promoting equitable and timely access to such products during a pandemic emergency.
- 6. The Parties shall, with the support of the Secretariat, collaborate and assist each other in the implementation of this Article, in line with Articles 16 and 20, as well as relevant guidance from the [Governance mechanism of the WHO Pandemic Agreement].

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