PROPOSAL FROM THE CO-FACILITATORS FROM NORWAY AND MEXICO TO RE-ORGANIZE THE CURRENT ELEMENTS OF ARTICLE 9, BASED ON COMMENTS FROM MEMBER STATES AT THE "PILOT" INFORMAL CONSULTATIONS (14 AND 15 JUNE)

CLEAN VERSION.

1. The Parties shall cooperate to build, strengthen and sustain capacities and institutions for research and development for pandemic-related products, particularly in developing countries, including for related clinical trials and information-sharing through open science approaches for rapid sharing of scientific findings and research results.

2. The Parties shall:

a. promote and prioritize investment in the research and development of pandemic-related products that can promote equitable access.

b. promote, facilitate and incentivize technology co-creation and joint venture initiatives, actively engaging the participation of scientists and/or research centres, particularly from developing countries;

c. encourage the participation of relevant stakeholders, consistent with national biosafety and biosecurity laws and regulations, to accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential.

d. [commit to/are encouraged to] promote, cooperate and strengthen knowledge translation and evidence-based communication tools and strategies relating to pandemic prevention, preparedness, response and recovery of the health system, at local, national, regional and international levels.

e. ensure that resources are directed to well-designed projects that can produce robust and reliable evidence.

3. The Parties, in accordance with their national and regional legal and regulatory frameworks and contexts, and as appropriate, shall:

a. increase clinical trial capacity and strengthen clinical trials policy frameworks, particularly in developing countries;

[in order to enable a greater number of clinical trial sites that can conduct well-designed and well-implemented clinical trials, and to ensure readiness for the coordination of trials through existing, new or expanded clinical trial networks that meet relevant regulations and internationally harmonized standards];

b. promote~~ing~~ the sharing of information and best practices on efficient and ethical clinical trial design and delivery, and ~~i~~on designing, preparing and conducting clinical trials that ensure human subject protections;

c. develop national policies to support the transparent, public sharing of clinical trial results conducted within their territories, such as through open source publication.

4. The Parties shall take steps, individually and collectively, to develop strong, resilient national, regional and international, appropriately resourced research ecosystems, including national and global clinical research networks.

In that regard, the Parties, as appropriate, commit to:

(a) investing in the infrastructure and training of clinical research networks in developing countries in order to be prepared to provide timely and appropriate responses to pandemics;
(b) further strengthening international coordination and collaboration on clinical trials, through existing mechanisms, where established, to support well-designed and well-implemented trials, including new clinical trial platforms operating on multi-country footprints, where scientifically appropriate, to address priority infectious and non-infectious diseases, with mechanisms to pivot protocols to support pandemic response, where necessary and appropriate;
(c) supporting new and existing mechanisms to facilitate the rapid interpretation of data from clinical trials to develop or amend, as necessary, relevant clinical guidelines, including during a pandemic; and
(d) ensuring that clinical trials conducted during health emergencies are equitable, address geographical, socioeconomic and health disparities, and promote racial, ethnic and gender diversity for a better understanding of the safety and efficacy of new vaccines and treatments in subgroups of the population.

5. Each Party shall increase, the transparency of information about research and development for pandemic-related products by:

(a) promoting the public dissemination of the results of government-funded research for the development of pandemic-related products, in accessible languages and formats;

(b) sharing information on:

i. research agendas, including national research and development priorities, during pandemic emergencies, as appropriate;

ii. national efforts and plans for building or strengthening national, regional and global research and development capacity, including by building and maintaining a skilled research workforce and research infrastructure, and by

researching supply chain needs in order to rapidly mount and scale research responses during pandemic emergencies;

6. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, in accordance with national laws and, as appropriate, taking into account the extent of public funding, publish the terms of government-funded research and development agreements for pandemic-related products, as appropriate, including:

(i) research inputs, processes and outputs;
(ii) pricing of end-products, or pricing policies for end-products;
(iii) licensing to enable development, manufacturing and distribution, especially in developing countries; and
(iv) terms regarding affordable, equitable and timely access to pandemic-related products at the time of a pandemic;

7. Each Party shall implement and apply relevant international standards for the biorisk management of laboratories and research facilities that carry out research to better understand the pathogenicity and transmissibility of pathogens with pandemic potential, and to prevent the unintended consequences of such research, while minimizing unnecessary administrative hurdles for research.