WHO convention, agreement or other international instrument on

pandemic prevention, preparedness and response WHO CA+

Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting

Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how

1. The Parties recognize that inequitable access to pandemic-related products (including but not limited to vaccines, therapeutics and diagnostics) should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed.

2. The Parties, working through the Governing Body for the WHO CA+, shall strengthen existing and develop innovative multilateral mechanisms that promote and incentivize relevant transfer of technology and know-how for production of pandemic-related products, on mutually agreed terms, to capable manufacturers, particularly in developing countries.

3. During inter-pandemic times, all Parties commit to establish these mechanisms and shall:

(a) coordinate, collaborate, facilitate and incentivize manufacturers of pandemic-related products to transfer relevant technology and know-how to capable manufacturer(s) (as defined below) on mutually agreed terms, including through technology transfer hubs and product development partnerships, and to address the needs to develop new pandemic-related products in a short time frame;

(b) strengthen coordination, with relevant international organizations, including United Nations agencies, on issues related to public health, intellectual property and trade, including timely matching of supply to demand and mapping manufacturing capacities and demand;

(c) encourage entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms, licences to capable manufacturers, notably from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic response product research, development and production, in particular for pre-pandemic and pandemic-related products; and

(d) collaborate to ensure equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities.

Article 8. Regulatory strengthening

1. The Parties shall strengthen the capacity and performance of national regulatory authorities and increase the harmonization of regulatory requirements at the international and regional level, including, as applicable, through mutual recognition agreements.

2. Each Party shall build and strengthen its country regulatory capacities and performance for timely approval of pandemic-related products and, in the event of a pandemic, accelerate the process of approving and licensing pandemic-related products for emergency use in a timely manner, including the sharing of regulatory dossiers with other institutions.

3. The Parties shall, as appropriate, monitor and regulate against substandard and falsified pandemic-related products, through existing Member State mechanisms on substandard and falsified medical products.

Article 18. One Health

1. The Parties, recognizing that the majority of emerging infectious diseases and pandemics are caused by zoonotic pathogens, commit, in the context of pandemic prevention, preparedness, response and recovery of health systems, to promote and implement a One Health approach that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing instruments and initiatives.

Article 2. Relationship with other international agreements and instruments

1. The implementation of the WHO CA+ shall be guided by the Charter of the United Nations the Constitution of the World Health Organization. The WHO CA+ and other relevant internati instruments, including the International Health Regulations, should be interpreted so as to

[1] The INB is encouraged to conduct discussions on the matter of the declaration of a "pandemic" by the WHO Director-General under the WHO CA+ and the modalities and terms for such a declaration, including interactions with tl International Health Regulations and other relevant mechanisms and instruments. In this connection see Article 15.2 her

complementary, compatible and synergistic, and the WHO CA+ should be interpreted in a manner that promotes and supports the implementation and operationalization of the International Health Regulations and other relevant international instruments.[1] In the event that any part of the WHO CA+

Notes on the IHR

Article 3

1. The implementation of these Regulations shall be ~~with full respect for the dignity, human rights and fundamental freedoms of persons~~ **based on the principles of equity, inclusivity, coherence and in accordance with their common but differentiated responsibilities of the States Parties, taking into consideration their social and economic development**.

(…)

Article 12 Determination of a public health emergency of international concern public health emergency

of regional concern, or intermediate health alert

2. If the Director-General considers, based on an assessment under these Regulations, that a **potential or actual** public health emergency of international concern is occurring, the Director-General shall **notify all States Parties and seek to** consult with the State Party in whose territory the event arises regarding this preliminary determination **and may, in accordance with the procedure set forth in Article 49, seek the views of the Committee established under Article 48 (hereinafter the "Emergency Committee")** . If the Director-General **determines that the event constitutes a public health emergency of international concern,** ~~and the State Party are in agreement regarding this determination~~, the Director-General shall **notify all the States Parties**, in accordance with the procedure set forth in Article 49, seek the views of ~~the Committee established under Article 48 (hereinafter the~~ "Emergency Committee") on appropriate temporary recommendations.

~~3. If, following the consultation in paragraph 2 above, the Director-General and the State Party in whose territory the event arises do not come to a consensus within 48 hours on whether the event constitutes a public health emergency of international concern, a determination shall be made in accordance with the procedure set forth in Article 49.~~

NEW Article 13A WHO Led International Public Health Response

1. States Parties recognize WHO as the guidance and coordinating authority of international public health response during public health Emergency of International Concern and undertake to follow WHO's recommendations in their international public health response.

Article 31

Digital health documents must incorporate means to verify their authenticity via retrieval

from an official web site, such as a QR code.

Article 44 Collaboration and assistance

1. States Parties shall ~~undertake to~~ collaborate with **and assist** each other**, in particular developing counties States Parties, upon request,** ~~to the extent possible~~, in:

new (a) strengthening regional planning, preparedness and response, in close cooperation with WHO Regional Offices and relevant international and regional organizations;

(a) the detection and assessment of, and response to, events as provided under these Regulations;

(b) the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under these Regulations **and in particular as provided in Annex 1** ;

(c) the mobilization of financial resources to facilitate implementation of their obligations under these Regulations; and **to establish an international financial mechanism for providing financial assistance to developing countries in the development, strengthening and maintenance of core capacities required under these Regulation sand functioning health systems resilient to the public health emergencies.**

(c) (New) building capacity to identify emerging public health threats, including through laboratory methods and genome sequencing;

(c) (new) strengthening capacity to identify health threats including through surveillance, research and development cooperation, technological and information sharing.

(g) (new) developing recommendations and guidance on the use of the digital technologies to improve and modernize communication for preparedness and response to health emergencies, including to better meet the obligations of these Rules

(h) (new)in countering the dissemination of false and unreliable information about public health events, preventive and anti-epidemic measures and activities in the media, social networks and other ways of disseminating such information

(i) (d) the formulation of proposed laws and other legal and administrative provisions for the implementation of these Regulations.

(f)(c) the mobilization of financial resources to support developing countries in building, strengthening and maintaining the capacities provided for in Annex 1 **and Annex 6 through the financial mechanism established under Article 44A and to establish an international financial mechanism for providing financial assistance to developing countries State Parties for the said purpose** ;

(g) (New) support to States Parties in enhancing reporting capabilities in accordance with the requirements of these Regulations, including the simplification and harmonization of reporting processes by States Parties;

(h) (New) facilitation of the development of national public health emergency response plans by developing, disseminating and updating policy documents and technical guidance, training materials, data and science to enable response;

(i) (New) strengthening the capacity of Focal Points, including through regular and targeted training events and workshops, consultations;

(j) (New) ensuring that differences in contexts and priorities among different States Parties, respect for their sovereignty, including health system strengthening, are taken into account when developing recommendations and supporting their implementation by WHO in order to improve pandemic preparedness and effective response for public health emergencies.

New (d) the formulation of laws and other legal and administrative provisions for the implementation of these Regulations;

New (e) training health and supportive workforce in the implementation of these Regulations;

New (f) the facilitation of accessibility and affordability of health products, including sharing of technologies and know-how, establishment and maintenance of the local production and distribution facilities.

New (d) in providing equitable access to health products such as diagnostics, therapeutics, vaccines, personal protective equipment and other tools required for responding to public health emergencies of international concern to frontline workers, vulnerable populations and general public of all countries in order, as well as in prioritizing access to such health products for health workers of all countries in rolling out distribution plans and production capacity.

(Article 53 bis-quater): The Compliance Committee

NEW Chapter IV (Article 53 bis-quater): The Compliance Committee

53 bis Terms of reference and composition

1. The State Parties shall establish a Compliance Committee that shall be responsible for:

(a) Considering information submitted to it by WHO and States Parties relating to compliance with obligations under these Regulations;

(b) Monitoring, advising on, and/or facilitating assistance on matters relating to compliance with a view to assisting States Parties to comply with obligations under these Regulations;

(c) Promoting compliance by addressing concerns raised by States Parties regarding implementation of, and compliance with, obligations under these Regulations; and

(d) Submitting an annual report to each Health Assembly describing:

(i) The work of the Compliance Committee during the reporting period;

(ii) The concerns regarding non-compliance during the reporting period; and

(iii) Any conclusions and recommendations of the Committee.

2. The Compliance Committee shall be authorized to:

(a) Request further information on matters under its consideration;

(b) Undertake, with the consent of any State Party concerned, information gathering in the territory of that State Party;

(c) Consider any relevant information submitted to it;

(d) Seek the services of experts and advisers, including representatives of NGOs or members of the public, as appropriate; and