

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

14 February 2024

# Proposal for negotiating text of the WHO Pandemic Agreement

Chapter II, Articles 10, 11 and 13 with refined textual proposals

## Article 10.1: Sustainable and *geographically diversified* production

1. The Parties, in collaboration with WHO and other relevant entities, with a view to achieving a more equitable geographical distribution of the global production of [product placeholder/ pandemic-related health products] and thus increasing equitable access to such products, thereby reducing the potential gap between supply and demand, shall endeavour to:

a. take measures, in cooperation with regional arrangements, to identify and/or designate support, maintain and strengthen production facilities at national and/or regional levels, particularly in developing countries, and to facilitate production of product placeholder, as appropriate;

b. in cases where the production capacity does not meet demand during a pandemic, take measures to identify and contract, as appropriate, with facilities other than those referred to in sub-paragraph (a) for scaling up the production of product placeholder; including through promoting and incentivizing public and private investment aimed at creating or expanding economically viable manufacturing facilities of relevant health products;

c. take measures, and encourage international organizations, to establish long-term contracts and make investments, especially in developing countries' facilities preferably with a regional scope of operation, that generate predictable demand for product placeholder produced by local and regional manufacturers. For this purpose, the Parties, as appropriate, should act individually and jointly by means of grants, loans, blended finance, taxation and other incentives and promotion measures;

\*Cross reference is made here to the negotiations on Articles 19 & 20 under Ambassador Tovar subgroup.

d. facilitate the continuous and sustainable operations of the facilities referred to in Paragraph 1.a of this Article, including through transparency of relevant data [unprotected]- information on pandemic-related health products and raw materials, across the value chain;

e. facilitate the transfer of relevant technology, know-how and licenses pooled in the mechanism referred to in Paragraph 2 of Article 11, to facilities referred to in Paragraph 1.a of this Article;

f. actively support and facilitate, as appropriate, skills development and capacity-building programmes and other initiatives aimed at enabling production facilities, particularly those referred to in Paragraph 1.a of this Article;

g. promote public and private sector investments aimed at creating or expanding manufacturing facilities for product placeholder, especially regional manufacturers based in developing countries; and

h. facilitate the necessary regulatory authorization of health products produced by facilities referred to in Paragraph 1.a of this Article.

Article 10.2

"Each Party is encouraged to cooperate further with the WHO to the conduct of global disease burden studies relevant to pathogens with pandemic potential, in collaboration with other relevant international organizations, with a view to promoting the sustainability of investments in facilities for the production of vaccines and therapeutics that could support pandemic response."

## Article 11: Transfer of Technology

1. In order to enable sufficient, sustainable, and geographically-diversified production of pandemicrelated products, each Party [especially developed countries], shall collaborate towards:

a) promoting and otherwise facilitating or incentivizing the transfer of technology and know-how for pandemic-related products on voluntary and mutually-agreed terms, including through the use of licensing and collaboration with regional or global technology transfer hubs partnerships and initiatives, and in particular for technologies that have resulted from public funding;

b) promoting the publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related health- products; without prejudice to applicable national laws;

c) license, on a non-exclusive basis and for the benefit of developing countries, government-owned pandemic-related technologies, on mutually agreed terms, and shall publish the terms of these licenses at the earliest reasonable opportunity and to the fullest extent possible in accordance with each Party's laws and regulations;

d) providing, within its capabilities, support for capacity-building for the development and transfer of technology and know-how on voluntary and mutually-agreed terms, and to facilitate access to other sources of support.

e) providing, within its capabilities, support for capacity-building for the development and transfer of technology and know-how on voluntary and mutually-agreed terms;

2. The Parties, in coordination with WHO and other relevant organizations, shall develop and strengthen multilateral mechanisms, as appropriate, that facilitate the transfer of technology and know-how for pandemic-related products on voluntary and mutually agreed terms;

3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall encourage holders of relevant patents related to the production of pandemic-related products, in particular those who received public funding, to waive/forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products.

4. The [XX Committee / [Conference of Parties / Governing Body of the CA+"] shall develop and adopt guidelines on the identification of technologies and know-how necessary to attain the objectives of this Agreement.

5. The Parties reaffirm recognize that WTO Members have the right to use to the full, the flexibilities inherent in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health of

2001 and subsequent relevant decisions\* which provide flexibility to protect public health including in future pandemics, since the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and that it can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

\* Reference is made here to what is known as Paragraph 6 System of the Declaration which was an amendment to the Agreement adopted by the WTO General Council on 30 August 2003, that became permanent by the GC Decision on 6 December 2005 and entered into force on 23 January 2017.

6. Each Party shall review and update as necessary its national legislation in order to ensure the implementation of such flexibilities in a timely and effective manner.

**Article 13: Global Supply Chain Network** 

### Supply chain network provisions:

1. The [Global Supply Chain and Logistics Network] (the Network) is hereby established.

The Network shall be developed and operated by WHO in partnership with the Parties and other relevant international and regional organizations and stakeholders, and shall be guided by the principles of equity, transparency, inclusivity, and public health needs. The Network shall consider the experiences of other mechanisms in procurement, allocation and distribution of product placeholder in health emergencies, and shall pay particular attention to the needs of developing countries and others with increased needs, including those in fragile and humanitarian settings.

The governance structure of the Network shall be defined in the first meeting of the governing body, allowing for equitable representation of the WHO regions.

- 2. The Network shall develop modalities aimed at ensuring the following:
  - a) collaboration among the Parties and other relevant stakeholders during and between pandemics,
  - b) assignment of functions to stakeholders based competencies and expertise, and
  - c) accountability and transparency in the functioning of the Network.
- 3. The Parties shall periodically review the operationalization of the Network, including the support provided by Parties and other stakeholders [during and between pandemics].

The functions of the Network shall include:

- a) identifying the types of pandemic-related health products and estimating the quantities needed for robust pandemic prevention, preparedness and response;
- b) identifying the sources of safe, effective and quality assured product placeholder, including the necessary raw materials and potential surge capacities as well as developing and maintaining a tool for this purpose [e.g. a dashboard].
  \*potential cross-reference to article 10.
- c) identifying, assessing, keeping under review and facilitating the most efficient means of procuring quality products placeholder, potentially including pooled procurement and/or advance purchase agreements, to enhance equitable, timely and affordable access to these products;
- d) promoting transparency in cost, pricing and other relevant data on products, including raw materials, across the value chain;
- e) promoting and coordinating within the Network to avoid competition for resources among international procuring entities, including regional organizations and/or mechanisms;
- f) collaborating with relevant authorities and organizations/institutions, as appropriate, and taking into account national and regional circumstances to establish, strengthen and maintain national, regional, and/or international stockpiles of various product placeholder, including stockpiles earmarked for humanitarian settings, as well as to maintain related logistic capacities and assess them at regular intervals; and
- g) facilitating the equitable allocation of product placeholder based on public health risks and needs, taking into account factors, such as population size, demographic structure, epidemiological situation and health system capabilities of beneficiary countries and their readiness and capacity to utilize such products;
- h) facilitating the most efficient delivery and distribution of pandemic-related health products, including, as appropriate, through regional stockpiles, consolidation hubs, and staging areas, while taking into account specific requirements for these products;
- i) assisting countries in meeting the requirements for the effective utilization of specific product placeholder, as needed and requested.

j) the Network shall report regularly to the COP/ Governing Body its activities and on any information obtained that is of significant interest to the parties;

#### **Procurement/Trade/Other provisions**

- 1. Each Party shall publish the terms of its government-funded purchase agreements for pandemicrelated productions, in accordance with applicable laws, and shall endeavour to exclude unwarranted confidentiality provisions that serve to limit such disclosure.
- 2. Each Party, in accordance with national laws, shall include provisions in government-funded purchase agreements for pandemic-related products that promote timely and equitable global access to such products, such as provisions that:
  - a) permit the donation of such products outside of its territories;
  - b) facilitate potential modifications (e.g., delivery swaps and schedules, in order to address supply gaps around the world;
  - c) incentivize or otherwise encourage licensing and other transfer of technology, in particular for the benefit of low-and middle-income countries;
  - d) incentivize or otherwise encourage the formulation and sharing of global access plans for the products.
- 3. The Parties recognize the importance of ensuring that any emergency trade measures designed to tackle a pandemic, if deemed necessary, shall be targeted, proportionate, transparent, temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.
- 4. Whenever possible, each Party shall take appropriate measures to promote rational use and reduce waste of pandemic-related products, including through the sharing of products, while taking into account the circumstances of recipient countries.
- 5. Each Party shall ensure that any national stockpiles do not unnecessarily exceed quantities needed for domestic public health emergency preparedness and response.

- 6. Whenever possible, when sharing pandemic emergency response-related products with recipient countries, organizations, or the partnership collaboration, each Party shall abide by the following:
  - a) The selection and shelf life of pandemic emergency response-related products are data driven and in alignment with identified needs and the distribution and administration/dispensing timelines and capabilities of the recipients,
  - b) Prospective recipients are made aware of any expiration dates, availability of the products, and required ancillaries as far in advance as possible;
  - c) As appropriate, sharing countries coordinate with each other and with other global or regional access mechanisms, to maximize allocation to populations with the highest risk and greatest public health need and to facilitate rapid absorption/administration;
  - d) Products shared with global or regional access mechanisms are unearmarked for greatest effectiveness and to support long-term planning;
  - e) Sharing countries release products in large volumes and in a predictable manner, in order to reduce transaction costs and facilitate recipient planning; and
  - f) Shared products are accompanied with essential ancillaries, and coordinated with the availability of support for distribution and administration, to ensure rapid allocation and absorption.

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