

**Onscreen text reflecting progress up to Thursday 19 September at  
17:30 CEST**



**SEVENTY-SEVENTH WORLD HEALTH ASSEMBLY  
Provisional agenda item 13.4**

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# **Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response**

## **Report by the Director-General**

1. The Director-General has the honour to transmit to the Seventy-seventh World Health Assembly the outcome of the Intergovernmental Negotiating Body (INB) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (see Annex), in line with decision SSA2(5) (2021).

### **ACTION BY THE HEALTH ASSEMBLY**

2. The Health Assembly is invited to consider the outcome of the INB, as contained in the Annex.

ANNEX

**OUTCOME OF THE INTERGOVERNMENTAL NEGOTIATING BODY (INB) TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE**

1. By decision SSA2(5) (2021), the Health Assembly, at its Second special session, decided, *inter alia*, to establish an intergovernmental negotiating body (INB) open to all Member States and Associate Members<sup>1</sup> to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. In decision SSA2(5), the Health Assembly also decided that the INB should submit its outcome for consideration by the Seventy-seventh World Health Assembly, with a progress report to the Seventy-sixth World Health Assembly.<sup>2</sup>
2. The INB undertook its work under the leadership of its Bureau, led by Ms Precious Matsoso of South Africa and Mr Roland Driee of the Kingdom of the Netherlands as Co-Chairs, and Vice-Chairs: Ambassador Tovar da Silva Nunes of Brazil; Ambassador Amr Ramadan of Egypt; Dr Viroj Tangcharoensathien of Thailand; and Ambassador Honsei Kozo of Japan, and supported by the Secretariat.
3. The INB held a total of nine meetings, including seven resumed sessions, various drafting and subgroups, working groups, informal consultations and briefings, including with the participation of experts and relevant stakeholders. These meetings discussed various iterations of a draft text towards a pandemic agreement and work from those meetings culminated in the outcome document presently submitted to the Health Assembly. The Bureau worked closely with the Bureau of the Working Group on Amendments to the International Health Regulations (2005) (WGIHR), and the two processes held two joint plenary sessions. Documents for the meetings of the INB, including the meeting reports, are available on the WHO website.<sup>3</sup>
4. Following its mandate as set out in decision SSA2(5), the INB drafted and negotiated the text of the WHO Pandemic Agreement, the draft of which, as at the conclusion of its ninth meeting, is contained in the Appendix. The INB did not reach consensus on the text.

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<sup>1</sup> And regional economic integration organizations, as appropriate.

<sup>2</sup> Document A76/37 Add.1.

<sup>3</sup> See <https://apps.who.int/gb/inb/>.

## Appendix

## Proposal for the WHO Pandemic Agreement

### **Draft text reflecting progress up to Thursday 19 September at 17:30 CEST**

Recalling that the INB did not reach consensus on the text of the WHO Pandemic Agreement, and worked on the basis of the principle that “nothing is agreed until everything is agreed”, highlighting and brackets in the text indicate the following:

- **Green** highlighting: text for which initial agreement was reached;
- **Yellow** highlighting: text for which initial convergence was reached;
- Text without highlighting: text for which no convergence was reached;
- Text in [brackets]: Text with respect to which there were divergent views.

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The Parties to the WHO Pandemic Agreement,

1. *Recognizing* that States bear the primary responsibility for the health and well-being of their peoples, and that States are fundamental to strengthening pandemic prevention, preparedness and response,

[*Ibis*. Recognizing that individuals, having duties to other individuals and to the community to which they belong, and that the relevant stakeholders, are under responsibility to strive for the observance of the objective of the present Agreement,]

2. *Recognizing* that differences in the levels of development of Parties engender different capacities and capabilities in pandemic prevention, preparedness and response and acknowledging that unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger that requires support through international cooperation, including the support of countries with greater capacities and resources, as well as predictable, sustainable and sufficient financial, human, logistical, technological, technical and digital health resources,

3. *Recognizing* that the World Health Organization is the directing and coordinating authority on international health work, including on pandemic prevention, preparedness and response,

4. *Recalling* the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,

5. [*Recalling* that the Convention on the Elimination of All Forms of Discrimination against Women, adopted by the United Nations General Assembly on 18 December 1979, provides that States Parties to that Convention shall take appropriate measures to eliminate discrimination against women in the field of health care, and that Sustainable Development Goal 5 aims “to achieve gender equality and empower all women and girls”,]

6. *Recognizing* that the international spread of disease is a global threat with serious consequences for lives, livelihoods, societies and economies that calls for the widest possible international and regional collaboration, cooperation and solidarity with all people and countries, especially developing countries, and notably least developed countries and small island developing States, in order to ensure an effective, coordinated, appropriate, comprehensive and equitable international response, while reaffirming the principle of the sovereignty of States in addressing public health matters,

7. *Deeply* concerned by the inequities at national and international levels that hindered timely and equitable access to [coronavirus disease (COVID-19) pandemic-related (DEL)] health products [during PHEIC and pandemic time], and the serious shortcomings in [global] pandemic prevention, preparedness and response,

8. *Recognizing* the critical role of whole-of-government and whole-of-society approaches at national and community levels, through broad social participation, and further recognizing the value and diversity of the culture and traditional knowledge of Indigenous Peoples as well as local communities [, including science and evidence-based traditional medicine,] in strengthening pandemic prevention, preparedness, response and health systems recovery,

9. *Recognizing* the importance of ensuring political commitment, resourcing and action through multisectoral collaborations for pandemic prevention, preparedness, response and health systems recovery,

10. *Reaffirming* the importance of multisectoral collaboration at national, regional and international levels to safeguard human health, including through a [o]One H[h]ealth approach,

11. *Recognizing* the importance of rapid and unimpeded access of humanitarian relief [in accordance (DEL)] [consistent] with international law, including international human rights law and international humanitarian law, [and the provision of humanitarian assistance in line with resolution A./RES46/182.] [and the respect of the [humanitarian (DEL)] principles of [sovereign equality,] humanity, neutrality, impartiality and independence for the provision of humanitarian assistance [with the consent of the affected country and in principle on the basis of an appeal by the affected country] (DEL)],

12. *Reiterating* the need to work towards building and strengthening resilient health systems, with adequate numbers of skilled, trained and protected health and care workers to respond to pandemics, to advance the achievement of universal health coverage, particularly through a primary health care approach [and equitable access to health products]; and to adopt an equitable approach to mitigate the risk that pandemics exacerbate existing inequities in access to health care services,

13. *Recognizing* the importance of building trust and ensuring the timely sharing of information to prevent misinformation, disinformation and stigmatization,

14. *Recognizing* that intellectual property protection is important for the development of new medicines and *recognizing* the concerns about its effects on prices, and *recalling* that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) [and its flexibilities] does not, and should not, prevent Member States

15. from taking measures to protect public health,

NOTE: Subject to consistency with related articles in this Agreement.

[(*New para. 14 bis*) *Emphasizing* the need to improve access to quality, safe, effective and affordable medicines and other health technologies, inter alia, through building capacity for local production, especially in developing countries [and notably least developed countries and small island developing states], technology transfer [on voluntary and mutually agreed terms] and cooperation, and other initiatives,

16. [Recalling the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the timely, safe, transparent, accountable and rapid sharing of materials and information on pathogens with pandemic potential for public health purposes, and, on an equal footing, the timely, fair and equitable sharing of benefits [arising therefrom (DEL)], taking into account relevant national, domestic, and international laws, (DEL / RETAIN)] NOTE: Upon finalization of Art 12.1

17. *Stressing* that adequate pandemic prevention, preparedness, response and health systems recovery is part of a continuum to combat other health emergencies and achieve greater health equity through resolute action on the social, environmental, cultural, political and economic determinants of health, and

18. Recognizing the importance and public health impact of growing threats such as climate change, poverty and hunger, fragile and vulnerable settings, weak primary health care and the spread of antimicrobial resistance.

Have agreed as follows:

## Chapter I. Introduction

### Article 1. Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) “manufacturer” means public or private entities that develop and/or (DEL)/(RETAIN)] produce pandemic-related health products [[including] (DEL)] [for sale] (DEL)];

(b) “[One Health/one health] approach” means an integrated multisectoral approach that aims to sustainably balance and optimize the health of people, animals and ecosystems including by addressing various social, economic and environmental determinants of health in an equitable manner. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent.

[ALT(b) One health approach means multisectoral approach to pandemic prevention, preparedness and response that recognise the risk of pandemics links and interdependents with health of animals and environment and requires integrated disease surveillance, prevention and control at the animal-human interface.]

(c) [“PABS material and [PABS] information” [shall be defined in the instrument as referred to in Article 12]/ means the biological material from a pathogen with pandemic potential [shared through the PABS system], [as well as (DEL)/(RETAIN)] [[its] (DEL)] [or its sequence] [digital] [[sequencing/sequence] information [relevant to the development of pandemic-related health products] (DEL)];

(d) [[“pandemic-related health products” [means [safe, effective, quality and affordable] health products, including medicines, vaccines, medical devices including diagnostics, personal protective equipment, decontamination products, assistive products, antidotes, cell- and gene-based therapies, and other health technologies that are needed to respond to public health emergencies of international concern, including pandemic emergencies;] [means the safe, effective, quality and affordable products that are needed for pandemic prevention, preparedness and response, [which may include, without limitation (DEL)/(RETAIN)/including], diagnostics, therapeutics, vaccines and personal protective equipment [and ancillary supplies [[and other health technologies] (DEL)];]]

(e) [“Party” means a State or regional economic integration organization that has consented to be bound by this Agreement, in accordance with its terms, and for which this Agreement is in force;]

(f) [“pathogen with pandemic potential” [shall be defined in the instrument as referred to in Article 12]/ means any pathogen that has been identified to infect a human and that is novel (not yet characterized) or known [(including a variant of a known pathogen), potentially highly transmissible and/or highly virulent, with the potential to cause a public health emergency of



international concern (DEL)] [(including existing pathogens with a change in disease severity, mode of transmission, or evasion from an existing medical countermeasure), and (2) likely to be both highly transmissible with the potential for uncontrolled spread and sufficiently virulent that it has the potential to cause a public health emergency of international concern or pandemic emergency]];

(g) “[persons (DEL)/(RETAIN)] [people] in vulnerable situations” means individuals, [as well as persons in] groups or communities with a disproportionate increased risk of infection, severity, disease or mortality [, as well as those likely to bear a disproportionate burden owing to social determinants of health] in the context of a pandemic. This is understood to include persons in fragile and humanitarian settings;

(h) “[regional economic integration organization” means an organization that is composed of several sovereign States and to which its Member States have transferred competence over a range of matters, including the authority to make decisions binding on its Member States in respect of those matters;<sup>1</sup> and]

(i) “universal health coverage” means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care.

*Foot note:* To be inserted with the first mention of the term “relevant stakeholders”

The term “relevant stakeholders” is understood in the context of article 2(b) of the WHO Constitution, as well as the WHO Framework of Engagement with Non-State Actors.

(new j) “Transfer of technology” For the purposes of this Agreement, references to the transfer of technology implies consensually negotiated and accepted terms among the contracting parties without prejudice to other measures that State Parties may take pursuant to their domestic legislation, provided that such legislation and actions are consistent with relevant international norms regarding intellectual property.

(new k) “Know-how” For the purpose of this agreement, the transfer of technology is understood to include the sharing of know-how which covers knowledge and skills required to manufacture and control the resulting product according to international standards.

## **Article 2. Objective**

1. The objective of the WHO Pandemic Agreement, guided by equity and the principles further set forth herein, is to prevent, prepare for and respond to pandemics.

2. In furtherance of this objective, the provisions of the WHO Pandemic Agreement apply both during and between pandemics, unless otherwise specified.

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<sup>1</sup> Where appropriate, “national” will refer equally to regional economic integration organizations.

### Article 3. **Principles** [and approaches] (DEL)]

To achieve the objective of the WHO Pandemic Agreement and to implement its provisions, the Parties shall be guided, inter alia, by the following [principles (DEL)] [and approaches] (DEL)]:

1. The sovereign right of States, in accordance with the principles of international law, as enshrined in the Charter of the United Nations and the WHO Constitution, to legislate and to implement legislation, within their jurisdiction, [and their sovereign rights over their biological resources (DEL)/(RETAIN)];

2. Full respect for the dignity, human rights and fundamental freedoms of all persons, and the enjoyment of the highest attainable standard of health of every human being [as well as the right to development] [as well as full respect for non-discrimination, gender equality and the protection of persons in vulnerable situations] (DEL)];

3. Full respect [for the principles and applicable rules] of international humanitarian law for effective pandemic prevention, preparedness and response;

4. Equity as a goal [, principle] and outcome of pandemic prevention, preparedness and response, striving for the absence of unfair, avoidable or remediable differences among and between individuals, communities and countries;

5. Solidarity with all people and countries in the context of health emergencies, inclusivity, transparency and accountability to achieve the common interest of a more equitable and better prepared world to prevent, respond to and recover from pandemics, recognizing different levels of capacities and capabilities [, as well as the special circumstances of small island developing States]; and

[5bis. Full recognition of the special circumstances of [developing countries, in particular] (DEL)] small island developing States and of least developed countries in relation to pandemic prevention, preparedness and response;]

6. The best available science and evidence as the basis for public health decisions for pandemic prevention, preparedness and response.

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

### Article 4. Pandemic prevention and surveillance

1. The Parties shall take steps, individually and through international collaboration, in bilateral, regional and multilateral settings, to progressively strengthen pandemic prevention and surveillance capacities, consistent with the International Health Regulations (2005) and taking into account national capacities and national and regional circumstances.

2. Each Party shall, in accordance with its national laws and subject to the availability of resources, develop, strengthen and implement, comprehensive multisectoral national pandemic prevention and surveillance plans<sup>1</sup>, programmes and/or other actions, that are consistent with the IHR and that cover, inter alia:

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<sup>1</sup> Cross reference to be provide in Article 17.4

- (a) prevention of the emergence and re-emergence of infectious diseases;
- (b) coordinated multi-sectoral surveillance and risk assessment;
- (c) early detection and control measures including at community level;
- (d) water, sanitation and hygiene;
- (e) routine immunization;
- (f) infection prevention and control;
- (g) prevention of infectious disease transmission between animals and humans, including zoonotic disease spill-over;
- (h) vector-borne disease surveillance and prevention;
- (i) laboratory biological risk management;
- (j) prevention of antimicrobial resistance

2bis. The Parties recognize that a range of environmental, climatic, social, anthropogenic and economic factors may increase the risk of pandemics, and shall endeavour to consider these factors in the development and implementation of relevant policies, strategies, plans, and/or measures, at the international, regional and national levels as appropriate, in accordance with national law, and [subject to (DEL)] applicable international law.

3. The Conference of the Parties may adopt, as necessary, [and without prejudice to the instrument referred to in Article 5.3 (DEL) / (RETAIN)] guidelines, recommendations and other non-binding measures, including in relation to pandemic prevention capacities, to support the implementation of this Article.

[3 *Alt.* The functional dimensions and details of paragraph 2 shall be further defined in an Annex to this Agreement that takes into consideration a One Health approach and the provisions of the IHR (2005). The Annex shall give full consideration to the national circumstances and the differentiated capacities of developing country Parties, as well as the need for capacity building and implementation support to enable developing country Parties to effectively implement the provisions of the instrument and progressively strengthen pandemic prevention.]

[3 *Alt. Bureau proposal:* The Conference of the Parties shall further develop the provisions of this Article in an instrument in accordance with Chapter III, consistent with the provisions of the amended IHR (2005) and taking into consideration a One Health approach, and may also adopt, as necessary, guidelines, recommendations and other non-binding measures, including in relation to pandemic prevention capacities, to support the implementation of this Article, with full consideration to the national circumstances and the different capacities of developing country Parties, as well as the need for capacity building and implementation support for developing country Parties.]

3 *Alt. Bureau proposal – with revisions:* ~~The Conference of the Parties shall further develop the provisions of this Article~~ **The provisions of this Article including functional dimensions shall be further developed and agreed** in an instrument in accordance with Chapter III, consistent with the

provisions of the amended IHR (2005) and taking into consideration a One Health approach, and **the Conference of the Parties** may also adopt, as necessary, guidelines, recommendations and other non-binding measures, including in relation to pandemic prevention capacities, to support the implementation of this Article, with full consideration to the national circumstances and the different capacities **and capabilities** of ~~developing country~~ Parties, as well as the need for capacity building and implementation support for developing country Parties.

### **Article 5. One Health approach for Pandemic Prevention, Preparedness and Response**

1. The Parties shall promote a One Health approach for pandemic prevention, preparedness and response, recognizing the interconnection between the health of people, animals and the environment, that is coherent, integrated, coordinated and collaborative among all relevant organizations, sectors and actors, as appropriate, in accordance with national and/or domestic law, and applicable international law, and taking into account national circumstances.

2. The Parties shall take measures, as appropriate aimed at identifying and addressing, in accordance with national and/or domestic law, and applicable international law, the drivers of pandemics and the emergence and re-emergence of infectious disease at the human-animal-environment interface, through the introduction and integration of interventions into relevant pandemic prevention, preparedness and response plans subject to the availability of resources.

3. Each Party shall, in accordance with national or domestic law and taking into account national and regional contexts, and subject to the availability of resources, take [measures, as appropriate,] [measures that it considers appropriate] [appropriate measures] aimed at promoting human, animal and environmental health, with support, as necessary and upon request, from WHO and other relevant intergovernmental organizations, including by:

(a) Developing, implementing and reviewing relevant national policies and strategies that reflect a One Health approach as it relates to pandemic prevention, preparedness and response, including promoting engagement of communities, in accordance with 17.3(a); and

(b) Promoting or establishing joint training and continuing education programmes for the workforce at the human, animal and environmental interface to build relevant and complementary skills, capacities and capabilities, in accordance with a One Health approach.

(NOTE: Relevant intergovernmental organizations to be identified in the WHA resolution)

### **Article 6. Preparedness, readiness and health system resilience**

1. Each Party, within the means and resources at its disposal, shall take appropriate measures to develop, strengthen and maintain a resilient health system, particularly primary health care, for pandemic prevention, preparedness and response, taking into account the need for equity and in line with Article 19, to achieve universal health coverage.

2. Each Party, within the means and resources at its disposal, shall take appropriate measures, in accordance with its national and/or domestic law, to develop or strengthen, sustain and monitor health system functions and infrastructure for:

- (a) the timely provision of equitable access to scalable clinical care and quality routine essential health care services, while maintaining public health functions and, as appropriate, social measures during pandemics, with a focus on primary health care, mental health and psychosocial support and with particular attention to persons in vulnerable situations;
- (b) national or, as appropriate, regional capacities to adopt transparent, cost-effective procurement practices and supply chain management of pandemic-related health products;
- (c) laboratory and diagnostic capacities, through the application of relevant standards and protocols, including for laboratory biological risk management, and as appropriate, participate in regional and global networks; and
- (d) promoting the use of social and behavioural sciences, risk communication and community engagement for pandemic prevention, preparedness and response;
- (e) post-pandemic health system recovery.

3. Each Party, collaborating with WHO, shall endeavour towards developing, strengthening and maintaining national health information systems, in accordance with national or domestic law, subject to availability of resources, including through use of relevant international data standards for interoperability, as appropriate, based on good data governance for preventing, detecting and responding to public health events.

3. Each Party shall monitor its preparedness capacities, and periodically assess, if needed with technical support from the WHO Secretariat upon request, the functioning and readiness of, and gaps in, its pandemic prevention, preparedness and response capacities.

## **Article 7. Health and care workforce**

1. Each Party, in line with its respective capacities and national circumstances, shall take the appropriate measures with the aim to develop, strengthen, protect, safeguard, retain and invest in a multi-disciplinary, skilled, adequate, trained, domestic health and care workforce to prevent, prepare for and respond to health emergencies, including in humanitarian settings, while maintaining essential health care services and essential public health functions at all times and during pandemic emergencies.

2. Each Party, taking into account its national circumstances, and in accordance with its international obligations, shall take appropriate measures to ensure decent work, protect the continued safety, mental health, wellbeing, and strengthen capacity of its health and care workforce, including by:

- (a) facilitating priority access to pandemic-related health products during pandemic emergencies;
- (b) eliminating all forms of inequalities and discrimination and other disparities, such as unequal remuneration and barriers faced by women;
- (c) addressing harassment, violence and threats;
- (d) supporting individual and collective empowerment; and
- (e) developing policies for work-related injury, disability or death during emergency response.

3. Each Party shall endeavor to strengthen national capacities and designate or establish, as appropriate, national, subnational and/or regional level multidisciplinary, emergency health teams. Building on this, the Parties shall take measures, within their capacities and capabilities, in coordination with the WHO and other relevant international and regional organizations, with the aim to strengthen, sustain and mobilize a skilled, trained and multidisciplinary global health emergency workforce to support Member States, including through deployment, upon their request.

4. The Parties shall collaborate, as appropriate, and in accordance with their national laws, through multilateral and bilateral mechanisms, to minimize the negative impact of health and care workforce migration on health systems while respecting the freedom of movement of health professionals, taking into account the WHO support and safeguard list and applicable international codes and standards, including those of voluntary nature, such as the WHO Global Code of Practice on the International Recruitment of Health Personnel.<sup>1</sup>

5. The Parties, taking into account national circumstances, shall take appropriate measures in order to ensure decent work and a safe and healthy environment for other essential workers that provide essential public goods and services during pandemic emergencies. The Parties, taking into account national circumstances, shall also take measures to develop and implement coordinated policies for the safety and protection of transport and supply chain workers, as appropriate, by facilitating the transit and transfer of seafarers and transport workers among others, and their access to medical care.

## Article 9. Research and development

1. The Parties shall cooperate, as appropriate, to build, strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, and shall promote research collaboration and access to research, including through open science approaches for the rapid sharing of information and results, especially during pandemics.

*Note: open science will be further discussed in the definitions (cf UNESCO definition).*

2. To this end, the Parties shall promote, within means and resources at their disposal, and in accordance with national and/or domestic law and policy:

(a) sustained investment and support for research institutions and networks that can rapidly adapt and respond to research and development needs in the event of a pandemic emergency, and for research and development for public health priorities, including: (i) the epidemiology of emerging infectious diseases, factors driving zoonotic disease spill-over or emergence, and social and behavioural science; (ii) the management of pandemics, such as public health and social measures as well as their effects and socioeconomic impacts; and (iii) pandemic-related health products, including promoting equitable access.

(b) scientific research programmes, projects and partnerships, including through technology co-creation, and joint venture initiatives, with the active participation of, and international and regional collaboration with, scientists and research institutions and centres, particularly from developing countries;

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<sup>1</sup> FOOTNOTE: Reference to the aforementioned Global Code of Practice does not alter its voluntary nature.

(c) generation of and equitable access to evidence synthesis, knowledge translation and evidence-based communication tools, strategies and partnerships, relating to pandemic prevention, preparedness and response;

(d) the sharing of information on research agendas, priorities, capacity-building activities, and best practices, relevant to the implementation of this Agreement, including during pandemic emergencies;

(e) capacity-building programmes, projects and partnerships, and sustained support for all phases of research and development, including basic and applied research;

(f) accelerating innovative research and development consistent with applicable biosafety and biosecurity obligations, laws, and regulations, including biosecurity precautions, as well as taking into account relevant standards, guidance [, as appropriate];

[(f bis) the participation of relevant stakeholders in accelerating research and development];

*Note: relevant stakeholders will be considered in the definitions of article 1.*

[ALT 3. Each Party shall [, as appropriate], in accordance with their national or domestic circumstances and law, and taking into account relevant national and international ethical guidelines and guidance, promote, during PHEIC and pandemic emergencies, the conduct of well-designed and well-implemented clinical trials in their jurisdiction, including by [ensuring / promoting / enabling] *inter alia*: (i) representative study populations; (ii) access to safe and effective products that result from these trials for such study populations, including communities; and (iii) access to comparator products as required in the clinical trial to assess candidate pandemic-related health products.]

4. Each Party shall, pursuant to paragraph 1, in accordance with national and/or domestic law and policies, and taking into account relevant international standards, support the rapid and transparent publication of clinical trial protocols and other research results related to the implementation of this Agreement.

5. Each Party shall develop and implement national and/ or regional policies regarding the inclusion of provisions in research and development agreements, particularly publicly funded research of private entities and public-private partnerships, for the development of pandemic-related health products, that promote timely and equitable access to such products, particularly for developing countries, during public health emergencies of international concern including pandemic emergencies, and the [publication of] such [terms or provisions]. Provisions in the R&D agreements may include: (i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer; (iv) publication of relevant information on clinical trial protocols and relevant research results; and (v) adherence to product allocation frameworks adopted by WHO.

Note1: Pending discussion in Article 11 regarding licensing and tech transfer

Note 2: Access to health products during pandemics must include “in all settings” in the definition

*Original*                      *para*                      *from*                      *Bureau's*                      *proposal*  
5. Each Party shall develop and implement national and/ or regional policies regarding the inclusion of provisions in publicly funded research and development agreements, particularly with private entities

and public-private partnerships, for the development of pandemic-related health products that promote timely and equitable access to such products during public health emergencies of international concern including pandemic emergencies. Such provisions may include: (i) licensing and/or sublicensing, particularly to developing countries, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer [reference to a footnote in Article XX]; (iv) publication of relevant information on clinical trial protocols and other research results; and (v) adherence to product allocation frameworks adopted by WHO.

### **Article 10. Sustainable and geographically diversified local production**

1. The Parties shall take measures, as appropriate, to achieve more equitable geographical distribution and rapid scale-up of the global production of pandemic-related health products and increase sustainable, timely and equitable access to such products, as well as reduce the potential gap between supply and demand during pandemic emergencies, including through the measures provided in Articles 11 and 13.
2. The Parties, in collaboration with WHO and other relevant organizations, shall, as appropriate and subject to national and/or domestic law:
  - (a) take measures, to provide support, and/or strengthen existing or newly created production facilities of relevant health products, at national and regional levels, particularly in developing countries, with a view to promoting the sustainability of such geographically diversified production facilities, including through supporting and/ or facilitating skills development, capacity-building and other initiatives for production facilities;
  - (b) facilitate the continuous and sustainable operations of local and regional manufacturers, especially of developing countries, including through promoting transparency of relevant information on pandemic-related health products and raw materials across the value chain that is not subject to protection under relevant domestic and international law;
  - (c) actively support, relevant WHO technology, skills and knowledge transfer and local production programmes, including those referenced in Article 11, and other relevant programmes, to facilitate sustainable, strategically and geographically distributed production of pandemic-related health products, particularly in developing countries;
  - (d) endeavour to promote and/or incentivize public and private sector investments, purchasing arrangements, and partnerships, including public-private partnerships, aimed at creating or expanding manufacturing facilities or capacities for pandemic-related health products, including facilities with a regional operational scope in developing countries;
  - (e) encourage international organizations and other relevant organizations to establish arrangements, including appropriate long-term contracts for pandemic-related health products, including through procurement from facilities referenced under paragraph 2(a) and pursuant to the objectives of Article 13, especially those produced by local and/or regional manufacturers in developing countries; and



(f) during pandemic emergencies, in cases where the capacity of facilities referred to above does not meet demand, take measures to identify and contract with manufacturers with the aim of rapidly scaling up the production of pandemic-related health products.

3. WHO shall, upon request of the Conference of the Parties, provide assistance to the facilities referenced under paragraph 2 above, including, as appropriate, with respect to training, capacity-building, and timely support for development and production of pandemic-related products, especially in developing countries, with the aim to achieve geographically diversified production.

### **Article 11. Transfer of technology and know-how for the production of pandemic-related health products**

1. Each Party shall, in order to enable the sustainable and geographically diversified production of pandemic-related health products for the attainment of the objective of this Agreement, as appropriate:

(a) Promote and otherwise facilitate or incentivize transfer of technology, skills and [know-how] [which may include know-how, as appropriate,] on [voluntary and mutually agreed terms, without prejudice to other measures a Party might take,] for pandemic-related health products, in particular for the benefit of developing countries [and for technologies that have received public/government funding for their development], through a variety of measures such as licensing, capacity building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding, regulatory policies, and/or fiscal policies;

*After agreeing to the definition/footnote on technology transfer and know how, article 11.1 (a) can read:*

Promote and otherwise facilitate or incentivize transfer of technology and know-how for pandemic-related health products, in particular for the benefit of developing countries, [and for technologies that have received public/government funding for their development in line with Article 9] through measures which may include, *inter alia*, licensing, capacity building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding and regulatory policy measures;

New 1(j) Alt / footnote under Article 11:

Transfer of Technology is understood to mean non-coercive transfer and on mutually agreed terms. This understanding is without prejudice to other measures that parties may take pursuant to their domestic and/or national legislation, provided that such measures are consistent with their relevant international obligations regarding intellectual property,

*Revised New 1(j) Alt / footnote under Article 11 following consultations on Monday 16 September:*

For the purposes of this Agreement, Transfer of Technology means a mutually agreed process where Parties share technology without coercion. This understanding is without prejudice to measures that Parties may take in accordance with their domestic or national legislation and does not affect any rights they may exercise under it, provided that these measures are in line with their relevant international obligations regarding intellectual property rights.

And a New 1(k) Alt on know-how:

Know-how refers to knowledge and skills required to manufacture products.

(b) ~~Seek to~~ Make available, during a PHEIC including a pandemic emergency, licences on a non-exclusive, worldwide and transparent basis and for the benefit of developing countries for government-owned pandemic-related technologies, in accordance with national or domestic, and international law and encourage ~~urge~~ private rights holders to do the same;

(c) take measures to ensure timely publication of the terms of its licensing agreements relevant to promoting timely and equitable global access to pandemic-related health technologies, in accordance with applicable law and policies, and shall encourage private rights holders to do the same;

(d) Encourage / urge holders of relevant patents or licenses for the production of pandemic-related health products to forgo or otherwise charge reasonable royalties in particular to developing country manufacturers during a pandemic emergency, with the aim to increase the availability and affordability of such products to populations in need;

(e) Promote the transfer of relevant technology [and related knowledge and skills] [and know-how] for pandemic-related health products by private rights holders, to established regional or global technology transfer hubs, coordinated by WHO, or other mechanisms or networks; and

*Note: pending resolution of discussion on VMAT and use of term 'know-how' as per the footnotes above.*

(f) Urge manufacturers within its jurisdiction to voluntarily share information, in accordance with national laws and policies during pandemic emergencies, relevant to the production of pandemic-related health products.

*Alt (f)* Urge manufacturers within its jurisdiction to voluntarily share information, during pandemic emergencies, relevant to the production of pandemic-related health products.

2. Each Party shall provide, as appropriate and subject to available resources and applicable law, support for capacity-building, especially to local, subregional and/or regional developing country manufacturers, for the implementation of this Article.

3. Each Party shall, within the ~~existing~~ framework of relevant international and regional organizations, ~~consider supporting~~ ~~adopts~~ ~~consider adopting~~ ~~review and consider~~ ~~endeavour to undertake~~ [support, as] appropriate, time-bound measures to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase the availability, accessibility and affordability of pandemic-related health products during pandemic emergencies.

4. The Parties that are World Trade Organization (WTO) members reaffirm that they have the right to use, to the full, the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics. The Parties respect the use of the TRIPS flexibilities. [that are consistent with the TRIPS Agreement] [and shall not exercise any direct or indirect pressure [to that effect (DEL)] [to discourage the use of such flexibilities].

5. The Parties shall, in collaboration with WHO, identify, assess and, as appropriate, strengthen and/or develop mechanisms and initiatives that promote and facilitate the transfer of technology with a view to increasing access to pandemic-related products, particularly in developing countries, including through the pooling of intellectual property, know-how and data and transparent, non-exclusive licensing. Such mechanisms may, where appropriate, be coordinated by the WHO, in collaboration with

other relevant mechanisms and organizations, enabling equitable / equal / increased participation of manufacturers from developing countries.

*\*Transfer of technology is in yellow pending agreement on paragraph 11.1 a)*

6. Each Party should review and consider amending, as appropriate, its national and/or domestic legislation with a view to ensuring that it is able to implement this Article in a timely and effective manner.

## Article 12 Pathogen Access and Benefit-Sharing System

1. Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the rapid, and timely sharing of materials and sequence information on pathogens with pandemic potential, to be covered by the instrument, pursuant to paragraph 2 (hereafter PABS Materials and Sequence Information) and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits [arising therefrom (BUREAU)] [[covered by the PABS System] [[including] arising from the sharing] of PABS Materials and Sequence Information, for public health purposes.

DEL BUREAU: [taking into account] / [in accordance with] relevant national, domestic, and [applicable] international laws].

the Parties [agree to establish (BUREAU)] [hereby establish (DEL BUREAU)] a multilateral system for safe, transparent, and accountable, access and benefit sharing for pathogens with pandemic potential, the 'WHO Pathogen Access and Benefit-Sharing System' (PABS System). The PABS System shall be [[administered (DEL BUREAU)] coordinated [and convened (DEL BUREAU)] by WHO. [working in cooperation with relevant stakeholders – *Note: move to new paragraph 3h*] (DEL BUREAU)].

2. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, shall be developed and agreed in an instrument in accordance with Chapter III (hereinafter the 'PABS Instrument'). All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument. [The PABS Instrument shall come into force no earlier than the date on which the WHO Pandemic Agreement comes into force.]

3. The instrument referred to in paragraph 2, shall contain provisions regarding, inter alia, the following:

(a) access to PABS Materials and Sequence Information, and on an equal footing, the fair and equitable sharing of benefits [arising from sharing];

(b) modalities, terms and conditions on access and benefit sharing that provide legal certainty;

(c) implementation in a manner to strengthen, facilitate and accelerate research and innovation, as well as the fair and equitable sharing and distribution of benefits;

(d) implementation in a manner, complementary to, and not duplicative of, the Pandemic Influenza Preparedness Framework and other relevant access and benefit sharing instruments where applicable;

(e) implementation in accordance with national, domestic, and applicable international law, regulations, and standards, including as related to export control [and traceability of relevant pathogens] [and PABS Materials and Sequence Information], biosafety and biosecurity of pathogens, and data protection;

(f) robust [inclusive], transparent, and evidence-based governance, review, and accountability under the oversight of the parties to the Instrument, referred to in paragraph 2, including the consideration of a traceability mechanism [, as well as consistency with open access data];

NEW PARA: The provisions governing the PABS System shall be agreed such that they are consistent with, and do not run counter to the objectives of the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, with the aim to recognize the PABS System, [with respect to Parties to the Nagoya Protocol and] [once fully developed] [and operational], as a specialized international access and benefit-sharing instrument, within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol [, taking into account relevant decisions of the Meeting of the Parties to the Nagoya Protocol, and noting that only Parties to the Nagoya Protocol and the PABS Instrument are bound thereby. (DEL / RETAIN)] [The PABS System shall be operationalized once the System is recognised as a specialized international access and benefit-sharing instrument. (DEL)]

[alt(g) the provisions governing the PABS System shall be agreed in a specialised international access and benefit sharing instrument within the meaning of Paragraph 4 of Article 4 of the Nagoya Protocol.]

*Note: suggestion to make this into separate paragraph (1bis or 3bis)*

[Para 3(h) engagement with relevant stakeholders in accordance with norms and standards on WHO's engagement with non-state actors.]

[Para 3(i) Development and implementation in a manner that is consistent with and does not run counter to the objectives of Article X of the Biological Toxin Weapons Convention;]

4. The PABS System, as set out in the Instrument referred to in paragraph 2, shall provide, inter alia, the following:

(a) The rapid [, voluntary,] and timely sharing of PABS Materials and Sequence Information, [informed by risk assessment,] including, [but not limited to,] through WHO coordinated laboratory networks, and relevant [and accountable] sequence databases [, the modalities, terms and conditions of which shall be agreed in legally binding contracts]; NOTE: Taking note of the *unyellowing* of this paragraph

(b) The fair, equitable and rapid, and timely sharing of benefits [free from disruptions (DEL / RETAIN)], both monetary and non-monetary, the modalities, terms and conditions, of which shall be set out in [a prior and informed consent and mutually agreed terms] legally binding contracts between the PABS system, administered by WHO, and [entities (DEL)] [users] that [voluntarily] decide to [use PABS Material and Information] [enter into such contracts, (DEL)] taking into account the different nature, [size and capabilities (DEL)] of such [entities (DEL)] [users], including the following:

[i. in the event of a PHEIC, contribution by manufacturers to WHO for allocation and

distribution through the GSCL Network of reasonable real-time production in a range [of 3%–10% (DEL)] [of 10%–15%] of safe, quality, efficacious vaccines, therapeutics, and diagnostics needed during a PHEIC, on a free-of-charge basis or at not-for-profit prices. Such products shall be made available for use on the basis of public health risk and need, and upon request, with particular attention to the needs of developing countries. (DEL / RETAIN)]

[The Director General of WHO may initiate advance release of vaccines, therapeutics and diagnostics in paragraph (i) [to developing countries before PHEIC, (DEL)] to prevent outbreaks becoming PHEIC, [in developing countries] [in cases where concerned countries lack equitable access (DEL)] and/or for WHO stockpiles. Manufacturers shall comply with the DG's request for advance release.]

ii. in the event of a pandemic emergency, contribution by manufacturers to WHO for allocation and distribution through the GSCL Network of [their] reasonable real-time production [at least 20% of real-time production, and no less than 10% of production provided free of charge, and 10% production at not-for-profit prices] [up to 20%] of safe, quality, efficacious vaccines, therapeutics, and diagnostics needed during pandemic emergency, on a free-of-charge basis or at [not-for-profit or affordable] prices, recognizing that flexibility is important in negotiating in the above referenced range with all manufacturers. Such products shall be made available for use on the basis of public health risk and need, [and] upon request, with particular attention to the needs of developing countries.

iii. Annual monetary contributions to the WHO from relevant commercial users of the PABS System, including relevant manufacturers of vaccines, therapeutics and diagnostics based on modalities, terms and conditions, to be defined according to paragraph 3 of this Article.

5. The PABS System shall include additional benefit sharing provisions which may include the granting to WHO, during a PHEIC and/or pandemic emergency, of royalty free, non-exclusive manufacturing licences that can be sub-licensed to manufacturers in developing countries for the production of vaccine therapeutics and/or diagnostics. Such additional benefits shall be defined in the PABS Instrument referred to in paragraph 2.

6. Each Party that has manufacturing facilities in its jurisdiction that produce vaccine, therapeutic and/or diagnostics for pathogens covered by the PABS Instrument, shall take appropriate measures to facilitate the manufacture and export of such products, in accordance with its national/domestic and relevant international law.

[6 bis. This Article is without prejudice to consideration of other elements for the effective operationalization of the PABS System for pathogens with pandemic potential and sequence information, in a fair, transparent, accountable and equitable manner. (RESERVE)]

### **Article 13. Supply chain and logistics**

1. The Global Supply Chain and Logistics Network (the GSCL Network) is hereby established to enhance, facilitate, and work to remove barriers to, equitable, timely and affordable [and unhindered] access to pandemic-related health products, as well as to enable access to such products in humanitarian settings, in accordance with international law. The GSCL Network shall be developed, coordinated and

convened by WHO in full consultation with the Parties, WHO Member States, and in partnership with relevant stakeholders, under the oversight of the Conference of the Parties. The Parties shall prioritize, as appropriate, sharing pandemic-related health products through the GSCL Network for equitable allocation based on public health risk and need, in particular during pandemic emergencies.

2. The Conference of the Parties shall, at its first meeting, define [by consensus] the structure, functions and modalities of the GSCL Network, with the aim of ensuring the following:

(a) collaboration among the Parties and other relevant stakeholders during and between pandemic emergencies;

*(the issues of defining different relevant stakeholders might need further work)*

(b) the functions of the GSCL Network are discharged by the organizations best placed to perform them;

(c) consideration of the needs of developing countries and the needs of [persons in vulnerable situations] [those in vulnerable situations] [vulnerable populations], including those in fragile and humanitarian settings;

(d) the equitable and timely allocation of pandemic-related health products, based on public health risk and need, including through procurement from the facilities referenced under Article 10; and

(e) accountability, transparency, and inclusiveness in the functioning and governance of the GSCL Network allowing for equitable representation of the WHO Regions.

Article 13.3 is displayed as subparagraphs as suggested by the EU:

3. The functions of the GSCL Network shall include, *inter alia*, subject to further decision making by the Conference of the Parties:

a) identification of pandemic-related health products and relevant raw material sources including co-sourcing or co-allocation;

b) identification of barriers to their access;

c) estimation of supply and demand;

d) facilitation of procurement during PHEIC and pandemic emergencies including from facilities referenced under Article 10;

e) coordination of relevant procurement agencies within the GSCL Network and pre-pandemic preparatory work;

f) promotion of transparency across the value chain;

g) collaboration on stockpiling both during pandemic emergencies and inter-pandemic periods;

h) facilitation of, and working to remove barriers to equitable [and unimpeded] access, including [through] allocation, distribution, delivery, and assistance with utilization, including for products provided to the PABS system, during a PHEIC and a pandemic emergency.

4. The Conference of the Parties shall periodically review the functions and operations of the GSCL Network, including the support provided by the Parties, WHO Member States and relevant stakeholders, during and between pandemic emergencies and may provide further guidance related to its operations, should the need arise as relevant.

*Note: The Bureau would consider the issue of what exactly the three consecutive events in 1, 2 and 4 (defining the structure of the GSCL, first COP, and periodical review) would entail in terms of functions.*

5. During a pandemic emergency and PHEIC, the rapid and unimpeded access of humanitarian relief personnel, their means of transport, supplies and equipment and their access to pandemic-related health products shall be allowed and facilitated in accordance with national and international law, and the principles contained in Article 3 of this Agreement. [including international humanitarian law] [and principles] [the Charter of the United Nations.] [and its purposes and principles, [with respect for sovereignty, and the principle of sovereign equality].

6. [The GSCL Network may consider developing recommendations, for the consideration of the Conference of the Parties, [for a possible no-fault compensation mechanism] ~~[multilateral mechanism for liability risk management]~~ for novel pandemic vaccines allocated through the GSCL Network, with particular regard for persons in humanitarian settings.]

7. WHO, as the convener of the GSCL Network, shall report to the Conference of the Parties, at intervals to be determined by the Conference of the Parties.

### **Article 13bis. Procurement and distribution**

1. Each Party shall endeavour, as appropriate, during a pandemic, in accordance with national and/or domestic law and policies, to publish the relevant terms of its purchase agreements with manufacturers for pandemic-related health products at the earliest reasonable opportunity, and to exclude confidentiality provisions that serve to limit such disclosure. The Parties shall take steps to encourage regional and global purchasing mechanisms to do the same.

2. Each Party shall, in accordance with national and/or domestic law and policies, consider including provisions in its publicly funded purchase agreements for pandemic-related health products that promote timely and equitable [unhindered] [global] access especially for developing countries, such as provisions regarding donation, delivery modification, licensing and global access plans.

3. During a pandemic, each Party shall consider, setting aside a portion of its total procurement of, or making other necessary arrangements for the procurement of, relevant diagnostics, therapeutics or vaccines in a timely manner for use in countries facing challenges in meeting public health needs and demand. [RESERVE 1 Member State]

4. [[The Parties recognize the importance of ensuring that (DEL)] [During a pandemic,] emergency trade measures designed to respond to a pandemic emergency are targeted, proportionate, transparent

and temporary, and do not create [unnecessary (DEL)] barriers to trade or disruptions in supply chains [of pandemic related health products (DEL)], [taking into account the IHR, with particular consideration for products allocated through the PABS System or GSCL Network.]]

*Alt*

4:

The Parties recognize that during a pandemic emergency, it is important that trade measures designed to respond to a pandemic emergency are targeted, proportionate, transparent and temporary, as well as being in line with GATT Article XX on General Exceptions including to protect human health and national security on an indiscriminate basis. In doing so, the Parties also recognize the need not to create unjustifiable barriers to trade or disruption in supply chains of pandemic-related health products, including products allocated through the PABS System or GSCL Network.

5. [Each Party shall take measures, as appropriate, including with support of the GSCL Network, to promote rational use and reduce the waste of pandemic-related health products ~~in its domestic market (DEL)~~, in order to support and facilitate the effective global distribution, delivery, and administration of pandemic-related health products.]

6. During a pandemic emergency, each Party should avoid maintaining national stockpiles of pandemic-related health products that unnecessarily exceed the quantities anticipated to be needed for domestic pandemic preparedness and response.

7. Whenever possible and appropriate, when sharing pandemic-related health products with countries, organizations or any mechanism that is facilitated by the GSCL Network, each Party shall endeavour to do the following: provide product that is unearmarked and accompanied by necessary ancillaries, has sufficient shelf life, and is in line with the needs and capacities of recipients; provide recipients with expiration dates, information about required ancillaries, and other similar information; coordinate between and among the Parties and any access mechanism; and provide product in large volumes and in a predictable manner.

8. *Proposal by USA:* Each Party shall develop, as appropriate and in accordance with applicable law, national strategies for managing liability in its territory related to pandemic vaccines, including those received through the GSCL Network, and shall make such strategies publicly-available. Strategies may include, inter alia, legal and administrative frameworks; no-fault compensation mechanisms, potentially funded by private sector contributions; and policies and other approaches for the negotiation of procurement and/or donation agreements, including circumstance-based time limitations, model contract provisions, and building expertise in relevant agencies; and insurance policies.]

9. [Request] WHO, [working (DEL)] in collaboration with relevant entities and multilateral organizations as appropriate, [shall (DEL)] [to] develop recommendations [for (DEL)] [and encourage, when needed,] the establishment and implementation of national, regional and/or global no-fault compensation mechanisms and other strategies for managing liability related to novel pandemic vaccines during pandemic emergencies, including for the GSCL Network and with [particular] regard to persons in vulnerable situations.] (DEL)]

#### **Article 14. Regulatory systems strengthening**

1. Each Party shall strengthen its national and, where appropriate, regional regulatory authority responsible for the authorization and approval of pandemic-related health products, including through technical assistance from, and cooperation with WHO, and other international organizations upon



request and other Parties as appropriate, with the aim of ensuring the quality, safety and efficacy of such products.

2. Each Party shall take steps towards ensuring that it has the technical capacity, and legal, administrative, and financial frameworks, as appropriate, in support of:

a. expedited regulatory review and/or emergency regulatory authorization, and oversight of pandemic-related health products, consistent with applicable law; and

b. effective vigilance to monitor the safety and effectiveness of pandemic-related health products.

3. Each Party shall, in accordance with applicable national and/or domestic law, as appropriate, make publicly available and keep updated:

a. information on national and, if applicable, regional regulatory processes for authorizing or approving the use of pandemic-related health products; and

b. [relevant] information on the pandemic-related health products that it has authorized or approved, [including information about the authorization or approval].

4. Each Party shall endeavour to, subject to applicable national and/or domestic law, adopt, where needed, regulatory reliance mechanisms in its national and, where appropriate, regional regulatory frameworks for use during PHEICs including pandemic emergencies for pandemic-related health products taking into account relevant guidelines.

5. Each Party shall, as appropriate and consistent with applicable law, encourage relevant developers and manufacturers of pandemic related health products to diligently seek regulatory authorizations and approvals from national and/or regional regulatory authorities, including WHO listed authorities, and prequalification of such products by WHO.

5bis *alt* [The Parties shall collaborate, as appropriate, towards [improving / strengthening / enhancing] WHO processes for Emergency Use Listing, prequalification and any other relevant WHO processes for recommending the use of pandemic-related health products.]

6. The Parties shall, as appropriate, monitor and strengthen rapid alert systems and take regulatory measures to respond to substandard and falsified pandemic-related health products.

7. The Parties shall endeavour to, subject to applicable law:

a. [cooperate with a view to] [converge or align, where appropriate, relevant technical and regulatory requirements in accordance with applicable international standards and guidance. (DEL para a)]

[*Alt a.* Ensure consistent regulatory processes, sound regulatory decision-making, and increased efficiency of regulatory system by implementing Good Regulatory Practices.]

b. provide support to help strengthen national regulatory authorities' and regional regulatory systems' capacity to respond to pandemic emergencies, subject to available resources.

### **Article 17. Whole-of-government and whole-of-society approaches**

1. The Parties are encouraged to apply whole-of-government and whole-of-society approaches at national level, including, according to national circumstances, to empower and enable community ownership, and contribution to, community readiness for and resilience to pandemic prevention, preparedness and response.
2. Each Party is urged to establish or strengthen, and maintain, a national multisectoral coordination mechanism for pandemic prevention, preparedness and response.
3. Each Party shall, taking into account its national circumstances:
  - (a) promote and facilitate the effective and meaningful engagement of Indigenous Peoples, communities, including local communities as appropriate, and relevant stakeholders, including through social participation, as part of a whole-of-society approach in planning, decision-making, implementation, monitoring and evaluation of policies, strategies and measures, and also provide feedback opportunities;
  - (b) take appropriate measures to mitigate the socioeconomic impacts of pandemics and strengthen national public health and social policies including those for social protection, to facilitate a rapid, inclusive, resilient response to pandemics, especially for compin vulnerable
  - (c) situations, including by mobilizing social capital in communities for mutual support.
4. Each Party shall develop, in accordance with national and/or domestic context, comprehensive, multisectoral, and, as appropriate, regional, and national pandemic prevention, preparedness and response plan(s) that address pre-, post- and interpandemic periods, in a transparent and inclusive manner that promotes collaboration with relevant stakeholders.
5. Each Party shall promote and facilitate, where appropriate, and in accordance with national and/or domestic law, and policy, the development and implementation of education and community engagement initiatives and programmes on pandemic and public health emergencies, with the participation of relevant stakeholders in a way that is inclusive and accessible, including to persons in vulnerable situations.

### **Article 18. Communication and public awareness**

1. Each Party shall, as appropriate, take measures to strengthen science, public health and pandemic literacy in the population, as well as access to transparent, timely, accurate, science- and evidence-based information on pandemics and their causes, impacts and drivers, as well as on the efficacy and safety of pandemic related health products, particularly through risk communication and effective community-level engagement.
2. Each Party shall, as appropriate, conduct research and inform policies on factors that hinder or strengthen adherence to public health and social measures in a pandemic and trust in science and public health institutions, authorities and agencies.

3. In furtherance of Paragraph 1 and 2 of this Article, WHO shall, as appropriate and upon request, continue to provide technical support to States Parties, especially developing countries towards communication and public awareness of pandemic related measures.

### **Article 19. International cooperation and support for implementation**

1. The Parties shall cooperate, directly or through relevant international organizations, subject to national law and available resources, to sustainably strengthen the pandemic prevention, preparedness and response capacities of all Parties, particularly developing country Parties. Such cooperation shall include, *inter alia*, the promotion of the [voluntary] transfer of technology and [know-how] on mutually agreed terms and the sharing of technical, scientific and legal expertise, as well as financial assistance and support for capacity-strengthening for those Parties that lack the means and resources to implement the provisions of this Agreement, and shall be facilitated, as appropriate, by WHO in collaboration with relevant organizations upon the request of the Party, to fulfil the obligations arising from this Agreement.

2. Particular consideration shall be given to the specific needs and special circumstances of developing country Parties, identifying and enabling access to sustainable and predictable means necessary to support the implementation of the provisions of this Agreement.

3. The Parties shall collaborate and cooperate for pandemic prevention, preparedness and response through strengthening and enhancing cooperation among relevant legal instruments and frameworks, and relevant organizations [and stakeholders,] [as appropriate,] in the achievement of the objectives of this Agreement, while closely coordinating support with that provided under the International Health Regulations (2005).

### **Article 20. Sustainable financing**

1. The Parties shall strengthen sustainable and predictable financing to the extent feasible, in an inclusive and transparent manner, for implementation of this Agreement and the International Health Regulations (2005).

2. In this regard, each Party, subject to national and/or domestic law and available resources, shall:

(a) maintain or increase domestic funding, as necessary, for pandemic prevention, preparedness and response;

(b) [to the extent possible,] mobilize additional financial resources to support Parties, in particular developing country Parties, in the implementation of the WHO Pandemic Agreement, including through grants and concessional loans;

(c) promote, as appropriate, within relevant bilateral, regional and/or multilateral funding mechanisms, innovative financing measures, including transparent financial reprogramming plans for pandemic prevention, preparedness and response, especially for developing country Parties experiencing fiscal constraints; and

(d) encourage inclusive and accountable governance and operating models of existing financing entities to minimize the burden on countries, offer improved efficiency and coherence at scale, enhance transparency and be responsive to the needs and national priorities of developing countries.

[2.bis The Parties shall refrain from taking any measures that may adversely affect the sustainable and predictable financing of other Parties for the purposes of this Agreement. (DEL / RETAIN)]

3. A Coordinating Financial Mechanism (the Mechanism) [is hereby established] to:

(a) promote sustainable financing for the implementation of this Agreement and the IHR to support strengthening and expanding capacities for pandemic prevention, preparedness and response; and

(b) contribute to the [availability of] surge financing response necessary [for day zero], particularly in developing country Parties.

*Note: 'is hereby established' and 'for day zero' – questioned by one Member State*

3 Bis. The Mechanism shall, inter alia:

(a) conduct relevant needs and gaps analyses to support strategic decision-making and develop every five years a financial and implementation strategy for the Pandemic Agreement, and submit it to the Conference of the Parties for its consideration;

*Note: Paragraph not accepted by one Member State*

(b) promote harmonization, coherence and coordination for financing pandemic prevention, preparedness and response and International Health Regulations (2005)-related capacities;

(c) identify all sources of financing that are available to serve the purposes of supporting the implementation of this Agreement and the International Health Regulations (2005), and maintain a dashboard of such instruments and related information and the funds allocated to countries from such instruments;

(d) provide advice and support, upon request, to Parties in identifying and applying for financial resources for strengthening pandemic prevention, preparedness and response; and

(e) leverage voluntary monetary contributions for organizations and other entities supporting pandemic prevention, preparedness and response, free from conflicts of interest, from relevant stakeholders, in particular those active in sectors that benefit from international work to strengthen pandemic prevention, preparedness and response.

4. The Mechanism shall function under the authority and guidance of the Conference of the Parties and be accountable to it. Its operation may be supported by one or more international entities to be selected by the Conference of the Parties. The Conference of the Parties shall adopt [, by consensus,] terms of reference for the Mechanism and modalities for its operationalization and governance, within 12 months after the entry into force of the WHO Pandemic Agreement, and may adopt necessary working arrangements with other international [financial] entities.

5. The Conference of the Parties shall take appropriate measures to give effect to this Article, including the possibility of exploring, additional financial resources to support the implementation of this Agreement [through new or existing funds].

6. The Conference of the Parties shall periodically consider, as appropriate, the financial and implementation strategy for the Pandemic Agreement referred to in paragraph 3(a) of this Article. The Parties shall endeavour to align with it, as appropriate, when providing external financial support for the strengthening of pandemic prevention, preparedness and response.

### **Chapter III. Institutional arrangements and final provisions**

#### **Article 21. Conference of the Parties**

1. A Conference of the Parties is hereby established.

2. The Conference of the Parties shall regularly take stock of the implementation of the WHO Pandemic Agreement and review its functioning every five years, and shall take the decisions necessary to promote its effective implementation. To this end, it shall take actions, as appropriate, for the achievement of the objective of the WHO Pandemic Agreement.

Note: Add a new para 2 bis in article 21:

The Conference of the Parties shall [, at its first meeting,] consider establishing an inclusive, transparent and effective [voluntary] [monitoring [and evaluation DEL] DEL] [assessment and support] system for the implementation of the WHO Pandemic Agreement [, complementing existing mechanisms, DEL] with the aim of promoting and supporting learning among parties, best practices, [accountability DEL] and coordination of resources, in a manner that is consistent with the IHR.]

3. The first session of the Conference of the Parties shall be convened by the World Health Organization not later than one year after the entry into force of the WHO Pandemic Agreement. The Conference of the Parties will determine the venue and timing of subsequent regular sessions at its first session.

4. Extraordinary sessions of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference of the Parties or at the written request of any Party, provided that, within six months of the request being communicated in writing to the Parties by the Secretariat, it is supported by at least one third of the Parties. Such extraordinary sessions may be called at the level of heads of state or government.

[[4bis. All decisions of the Conference of the Parties shall be taken by consensus unless otherwise specified by Articles of this agreement [or the rules of procedure adopted pursuant to paragraph 5].] (DEL)]

5. The Conference of the Parties shall, at its first session, adopt by consensus its rules of procedure and its criteria for the participation of observers at its proceedings.

6. [The Conference of the Parties shall [apply the Financial Regulations and Rules of the World Health Organization (VC Proposal)] [by consensus adopt financial rules for itself, as well as governing the funding of any subsidiary bodies it may establish and the functioning of the Secretariat (DEL)]. [At each ordinary session, it shall adopt [by consensus] a budget for the financial period until the next ordinary session (RETAIN) (DEL).] RETAIN Bureau's text

7. The Conference of the Parties may establish subsidiary bodies, and determine the terms and modalities of such bodies, as well as decide upon delegating functions to bodies established under other

agreements adopted under the WHO Constitution, [including the Sub-committee on Implementation established under the IHR,] as it deems necessary.

[[7bis [The COP may request that] The sub-committee on implementation [and compliance (DEL)] established by the amended International Health Regulations (2005) [shall (DEL)] also consider implementation of [, and promote compliance with, (DEL)] the provisions of this agreement and report, if requested, [by] [to (DEL)] the Conference of the Parties.] (DEL)]

## Article 22. Right to vote

1. Each Party to the WHO Pandemic Agreement shall have one vote, except as provided for in paragraph 2 of this Article.

2. A regional economic integration organization that is Party to the WHO Pandemic Agreement, in matters within its competence, shall exercise its right to vote with a number of votes equal to the number of its Member States that are Parties to the WHO Pandemic Agreement ~~[duly accredited and present during the voting]~~. Such an organization shall not exercise its right to vote if any of its Member States exercises its right to vote, and vice versa.

## Article 23. Reports to the Conference of the Parties

1. Each Party shall report periodically to the Conference of the Parties, through the Secretariat, on its implementation of the WHO Pandemic Agreement. The Secretariat shall report to the Conference of the Parties on its activities with respect to the implementation of this agreement.

2. The information required, frequency and format of the reports in paragraph 1 shall be determined by the Conference of the Parties.

3. The Conference of the Parties shall adopt appropriate measures to assist Parties, upon request, in meeting their obligations under this Article, with particular attention to the needs of developing country Parties.

4. The reporting and exchange of information by the Parties under the WHO Pandemic Agreement shall be subject to national and/or domestic law, as appropriate, regarding confidentiality and privacy. The Parties shall protect, as mutually agreed, any confidential information that is exchanged.

5. Subject to paragraph 4 of this article, the reports submitted pursuant to this Article shall be made publicly available online by the Secretariat.

## Article 24. Secretariat

1. The WHO Secretariat shall function as the Secretariat of the WHO Pandemic Agreement and shall perform the functions assigned to it under this Agreement and such other functions as may be determined by the Conference of the Parties. In performing these functions, the WHO Secretariat shall, under the guidance of the Conference of the Parties, ensure the necessary coordination, as appropriate, with the competent international and regional inter-governmental organizations and other relevant [international] bodies.

2. Nothing in the WHO Pandemic Agreement shall be interpreted as providing the WHO Secretariat, including the WHO Director-General, any authority to direct, order, alter or otherwise prescribe the

national and/or domestic laws, as appropriate, or policies of any Party, or to mandate or otherwise impose any requirements that Parties take specific actions, such as ban or accept travellers, impose vaccination mandates or therapeutic or diagnostic measures or implement lockdowns.

#### **Article 25. Settlement of disputes**

1. In the event of a dispute between two or more Parties concerning the interpretation or application of the WHO Pandemic Agreement, the Parties concerned shall seek through diplomatic channels a settlement of the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation, or conciliation. In case of failure to reach a solution by the methods mentioned above, the Parties, if they so agree in writing, may resort to arbitration in accordance with the Permanent Court of Arbitration Rules 2012 or its successor rules unless the disputing Parties agree otherwise.

2. The provisions of this Article shall apply with respect to any protocol adopted under Article [31] within the scope of this Agreement as between the Parties to the protocol, unless otherwise provided therein.

#### **Article 26. Relationship with other international agreements and instruments**

1. The interpretation and application of the WHO Pandemic Agreement shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.

2. The Parties recognize that the WHO Pandemic Agreement, and the International Health Regulations (2005) should be interpreted so as to be compatible.

[3. The provisions of the WHO Pandemic Agreement shall not affect the rights and obligations of any Party under other existing legally binding international instrument to which it is a Party, provided that the exercise of those rights and obligations is compatible with the objective of this instrument.

*Alt 3.* This Agreement shall not alter the rights and obligations of Parties which arise from other agreements compatible with this Agreement and which do not affect the enjoyment by other Parties of their rights or the performance of their obligations under this Agreement.]

#### **Article 27. Reservations**

Reservations may be made to the WHO Pandemic Agreement unless incompatible with the object and purpose of the WHO Pandemic Agreement.

#### **Article 28. Declarations and statements**

1. Article 27 does not preclude a State or regional economic integration organization, when signing, ratifying, approving, accepting or acceding to the WHO Pandemic Agreement, from making declarations or statements, however phrased or named, with a view, inter alia, to the harmonization of its laws and regulations with the provisions of the WHO Pandemic Agreement, provided that such declarations or statements do not purport to exclude or to modify the legal effect of the provisions of the WHO Pandemic Agreement in their application to that State or regional economic integration organization.

2. A declaration or statement made pursuant to this Article shall be circulated by the Depository to all Parties to the WHO Pandemic Agreement.

### **Article 29. Amendments**

1. Any Party may propose amendments to the WHO Pandemic Agreement, including its annexes and such amendments shall be considered by the Conference of the Parties.
2. The Conference of the Parties may adopt amendments to the WHO Pandemic Agreement. The text of any proposed amendment to the WHO Pandemic Agreement shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption. The Secretariat shall also communicate proposed amendments to the signatories of the WHO Pandemic Agreement and, for information, to the Depositary.
3. The Parties shall make every effort to adopt any proposed amendment to the WHO Pandemic Agreement by consensus. If all efforts at consensus have been exhausted and no agreement has been reached, the amendment may as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session. For the purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote. Any adopted amendment shall be communicated by the Secretariat to the Depositary, which shall circulate it to all Parties for acceptance.
4. Instruments of acceptance in respect of an amendment shall be deposited with the Depositary. An amendment adopted in accordance with paragraph 3 of this Article shall enter into force, for those Parties having accepted it, on the ninetieth day after the date of receipt by the Depositary of an instrument of acceptance by at least two thirds of the Parties to the WHO Pandemic Agreement at the date of the adoption of the amendment.
5. An amendment shall enter into force for any other Party on the ninetieth day after the date on which that Party deposits with the Depositary its instrument of acceptance of the said amendment.
6. For the purposes of this Article, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by the Member States of that organization.

### **Article 30. Annexes**

1. Annexes to the WHO Pandemic Agreement shall be proposed, adopted and shall enter into force in accordance with the procedure set forth in Article 29.
2. Annexes to the WHO Pandemic Agreement shall form an integral part thereof and, unless otherwise expressly provided, a reference to the WHO Pandemic Agreement constitutes at the same time a reference to any annexes thereto.

### **Article 31. Protocols**

1. Any Party may propose protocols to the WHO Pandemic Agreement. Such proposals shall be considered by the Conference of the Parties.
2. The Conference of the Parties may adopt protocols to the WHO Pandemic Agreement. In adopting these protocols, the decision-making terms of Article 29(3) shall apply, mutatis mutandis.
3. The text of any proposed protocol shall be communicated to the Parties by the Secretariat at least six months before the session of the Conference of the Parties at which it is proposed for adoption.



4. [States that are not Parties to the WHO Pandemic Agreement may be Parties to a Protocol, provided the Protocol so provides (DEL).] [Only Parties to the WHO Pandemic Agreement may be Parties to a protocol.]

5. Any protocol to the WHO Pandemic Agreement shall be binding only on the Parties to the protocol in question. Only Parties to a protocol may take decisions on matters exclusively relating to the protocol in question.

[5 bis. Any protocol to this Agreement shall be interpreted together with this Agreement taking into account the purpose of that protocol.]

6. The requirements for entry into force of any protocol, and the procedure for the amendment of any protocol, shall be established by that protocol.

### **Article 32. Withdrawal**

1. At any time after two years from the date on which the WHO Pandemic Agreement has entered into force for a Party, that Party may withdraw from the Agreement by giving written notification to the Depository.

2. Any such withdrawal shall take effect upon expiry of one year from the date of receipt by the Depository of the notification of withdrawal, or on such later date as may be specified in the notification of withdrawal.

3. A Party's withdrawal shall not in any way affect the duty of any Party to fulfil any obligation embodied in this Agreement to which it would be subject under international law independently of this Agreement.

4. Any Party that withdraws from the WHO Pandemic Agreement shall be considered as also having withdrawn from any Protocol to which it is a Party, unless the said Protocol requires its Parties to formally withdraw in accordance with its relevant terms. NOTE: Link with Art 31 para 4.

### **Article 33. Signature**

1. This Agreement shall be open for signature by all Members of the World Health Organization and by any States that are not Members of the World Health Organization but are Members or non-Member Observer States of the United Nations, and by regional economic integration organizations.

2. This Agreement shall be open for signature at the World Health Organization headquarters in Geneva, following its adoption by the World Health Assembly at its Seventy-seventh session, from XX May 2024 to XX June 2024, and thereafter at United Nations Headquarters in New York, from XX June 2024 to XX June 2025.

### **Article 34. Ratification, acceptance, approval, formal confirmation or accession**

1. The WHO Pandemic Agreement and any protocol thereto shall be subject to ratification, acceptance, approval or accession by [all States] and to formal confirmation or accession by regional economic integration organizations. This Agreement and any protocol thereto shall be open for accession from the day after the date on which the Agreement is closed for signature. Instruments of ratification, acceptance, approval, formal confirmation or accession shall be deposited with the Depository.

2. Any regional economic integration organization that becomes a Party to the WHO Pandemic Agreement, without any of its Member States being a Party shall be bound by all the obligations under the WHO Pandemic Agreement or any protocol thereto. In the case of those regional economic integration organizations for which one or more of its Member States is a Party to the WHO Pandemic Agreement, the regional economic integration organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the Agreement. In such cases, the regional economic integration organization and its Member States shall not be entitled to exercise rights under the WHO Pandemic Agreement concurrently.

3. Regional economic integration organizations shall, in their instruments relating to formal confirmation or in their instruments of accession, declare the extent of their competence with respect to the matters governed by the WHO Pandemic Agreement and any protocol thereto. These organizations shall also inform the Depositary, who shall in turn inform the Parties, of any substantial modification in the extent of their competence.

### **Article 35. Entry into force**

1. This Agreement shall enter into force on the thirtieth day following the date of deposit of the sixtieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary.

2. For each State that ratifies, accepts or approves the WHO Pandemic Agreement or accedes thereto after the conditions set forth in paragraph 1 of this Article for entry into force have been fulfilled, the WHO Pandemic Agreement shall enter into force on the thirtieth day following the date of deposit of its instrument of ratification, acceptance, approval or accession.

3. For each regional economic integration organization depositing an instrument of formal confirmation or an instrument of accession after the conditions set forth in paragraph 1 of this Article for entry into force have been fulfilled, the WHO Pandemic Agreement shall enter into force on the thirtieth day following the date of deposit of its instrument of formal confirmation or of accession.

4. For the purposes of this Article, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by Member States of that regional economic integration organization.

[NOTE: to be revisited pending protocol discussions]

### **Article 36. Depositary**

The Secretary-General of the United Nations shall be the Depositary of the WHO Pandemic Agreement and amendments thereto and of any protocols and annexes adopted in accordance with the terms of the WHO Pandemic Agreement.

### **Article 37. Authentic texts**

The original of the WHO Pandemic Agreement, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

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