

NINTH MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE Provisional agenda item 2

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Proposal for the WHO Pandemic Agreement

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The Parties to the WHO Pandemic Agreement,

- 1. *Recognizing* that States bear the primary responsibility for supporting the health and well-being of their peoples, and that States are fundamental to strengthening pandemic prevention, preparedness and response,
- 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 and technical 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 health products, and the serious shortcomings in 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 knowledge of indigenous peoples in strengthening pandemic prevention, preparedness, response and health systems recovery,
- 9. *Recognizing* the importance of ensuring political commitment, resourcing and action through cross-sector 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 One Health approach,

- 11. Recognizing the importance of rapid and unimpeded access of humanitarian relief in accordance with international law, including international human rights law and international humanitarian law, and the respect of the principles of humanity, neutrality, impartiality and independence for the provision of humanitarian assistance.
- 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 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, *recognizing* the concerns about its effects on prices and *recalling* that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) does not, and should not, prevent Member States from taking measures to protect public health,
- 15. 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, taking into account relevant national, domestic, and international laws.
- 16. 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
- 17. *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 produce pandemic-related health products [including for sale];
- (b) "[[One Health/one health] approach" means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent. [The approach mobilizes multiple sectors, disciplines, and communities [at varying levels of society [and their capacity] (DEL)/(RETAIN)] to work together (DEL)] (DEL)/(RETAIN)];

- (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 genebased 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 in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk of infection, severity, disease or mortality 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: 1 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.

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.

¹ Where appropriate, "national" will refer equally to regional economic integration organizations.

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

Article 3. Principles

To achieve the objective of the WHO Pandemic Agreement and to implement its provisions, the Parties shall be guided, inter alia, by the following:

- 1. the sovereign right of States to adopt, legislate and implement legislation, within their jurisdiction, in accordance with the Charter of the United Nations, the WHO Constitution and the principles of international law, and their sovereign rights over their biological resources;
- 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;
- 3. full respect of international humanitarian law for effective pandemic prevention, preparedness and response;
- 4. equity as a goal 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; and
- 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

- 3. 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.
- 4. 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 plans¹, programmes and/or other actions, that are consistent with the IHR and that cover, inter alia:
 - (a) prevention of the emergence and re-emergence of infectious diseases;
 - (b) Coordinated multi-sectoral surveillance and risk assessment;

¹ Cross reference to be provide in Article 17.4

- (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 zoonotic spill-over and transmission between humans and animals;
- (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 applicable international law.

5. 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.

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

- 1. The Parties shall promote a [One Health/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 applicable international and national law (DEL)], and taking into account national circumstances.
- 2. The Parties shall take measures, as appropriate aimed at identifying and addressing, [in line with national law and] subject to 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 appropriate measures / [measures, as appropriate] aimed at promoting human, animal and environmental health, with support, as necessary and upon request, from WHO and other relevant intergovernmental organizations (*insert footnote* competent intergovernmental organizations to be identified in the WHA resolution), including by:
 - (a) Developing, implementing and reviewing relevant national policies and strategies that reflect a [One Health/one health] approach as it relates to pandemic prevention, preparedness and response;

- (b) [[Promot[ing] the effective and meaningful engagement of communities in the development and implementation of policies, strategies and measures [related to One Health;] [to prevent, detect and respond to outbreaks (DEL)]; (DEL)] *Comment Refer to text in Art 17*] and
- (c) 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 the [One Health/one health] approach.
- 4. [[[The Parties shall further define] The modalities, terms and conditions and operational dimensions of a One Health approach [[, including prevention,] (DEL)] [within guidelines to be agreed by the COP] [for pandemic prevention, preparedness and response supportive of and consistent with [articles 4 and 5,](DEL)/this article][. shall be further defined in a[n] [legally binding] instrument [operational no later than 31 May 2026 and] that takes into consideration the provisions of the International Health Regulations (2005) [the first of which shall be operational by 31 May 2026] [and will be [operational] [to be agreed] by 31 May 2026]]. (DEL)] (DEL)]

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, and as appropriate, participate in regional and global networks, through the application of relevant standards and protocols, including for laboratory biological risk management; 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. [The Parties, collaborating with WHO and relevant international organizations, shall endeavour to develop, strengthen and maintain health information systems, in accordance with national or domestic law [and to identify, promote and strengthen, relevant international data standards and interoperability that enable timely sharing of public health data] [based on good data governance] for preventing, detecting and responding to public health events. [The Conference of the Parties shall develop further

rules, norms and regulations regarding sharing of information by WHO to third Parties under this Agreement.] [The COP shall develop further the norms, rules and regulations through WHO...] (DEL)]

NOTE: Replace 3 with 3Alt

- 3 Alt. 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 [and responsible use], as appropriate, based on good data governance for preventing, detecting and responding to public health events.
- 4. 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.
- 5. With the aim of promoting and supporting learning among Parties, best practices, [and accountability(DEL)] and coordination of resources, the Conference of the Parties shall [consider to] determine an inclusive, transparent, effective and efficient [voluntary] pandemic prevention, preparedness and response [assessment] / [monitoring] [and evaluation (DEL)] system, complementing existing mechanisms, to be developed and implemented by WHO in partnership with relevant international organizations [[complementary to the IHR] (DEL)].

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

[The Conference of the Parties shall consider establishing an inclusive, transparent and effective monitoring and evaluation system for the implementation of the WHO Pandemic Agreement [, complementing existing mechanisms,] with the aim of promoting and supporting learning among parties, best practices, accountability and coordination of resources.]

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 and to protect the continued safety, mental health, wellbeing and 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.¹
- 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 subject to national law]:
 - (a) sustained investment in research and development for public health priorities, including for pandemic-related health products, [epidemiology, factors, and impacts of emerging diseases, and public health and social measures.] and support for research institutions and networks that

¹ [FOOTNOTE: Reference to the aforementioned Global Code of Practice does not alter its voluntary nature].

can rapidly adapt and respond to research and development needs in the event of a pandemic emergency;

- (b) scientific research programmes, projects and partnerships, including through technology co-creation[, open innovation,] 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;
- (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) the participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development; and

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

Note: RUS proposes deletion of (f)

- (g) [research on the causes and effects of pandemics, on their prevention and management, including: (i) the epidemiology of emerging diseases, factors driving disease spill-over or emergence, and social and behavioural science; (ii) public health and social measures used to control pandemics and their effect on the spread of disease and the burden imposed by these measures on society, including its economic cost impact; and (iii) relevant health products, with the aim of promoting equitable access, including their timely availability and affordability. DEL]
- 3. Each Party shall, in accordance with their national [or domestic] circumstances and law, and taking into account relevant national and international ethical guidelines and relevant guidance, promote the conduct of well-designed and well-implemented clinical trials in their jurisdiction, including by promoting representative study populations and [facilitating] access to [comparator][products needed to carry out trials] [and access for] such study populations of [to] the safe and [effective/efficacious] products that result from these trials.
- 4. Each Party shall, in accordance with [international standards,] national and/or domestic law and policies, support the transparent and public sharing of research results[, for the purposes of this Agreement]. /[The Parties in accordance with [international standards,] national and/or domestic law and policies shall facilitate the rapid and transparent publication of results and research including the results of clinical trials, related to the implementation of this Agreement.]
- 5. Each Party shall develop and implement[, as appropriate,] national [and/][or regional] policies [regarding the inclusion of] /[to include]/[on the inclusion of] provisions [in [publicly funded research and development agreements][particularly with private entities]/[with private and budgetary entities]/

[in research and development agreements in case of public-private partnerships/contracts] DEL] for the development of pandemic-related health products that promote timely and equitable global access to such products [during [public health emergencies of international concern and DEL] pandemics/[pandemic emergencies] DEL], and the publication of such terms. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) [voluntary] technology transfer [on mutually agreed terms]; (iv) publication of relevant information on research [inputs and DEL] outputs; and/or (v) adherence to product allocation frameworks adopted by WHO.

Note: access to health products during pandemics must include "in all settings" in the definition.

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 in all settings, including through the measures provided in Articles 11 and 13.
- 2. The Parties, in collaboration with WHO and other relevant organizations, shall, subject to national law and available resources:
 - (a) take measures, as appropriate, to provide support, and/or strengthen existing or newly created production facilities of relevant health products in all settings, at national and regional levels, particularly in developing countries, with a view to promoting the sustainability of such geographically diversified production facilities, including, as appropriate, 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 in developing countries, including through promoting transparency of relevant unprotected information on pandemic-related health products and raw materials across the value chain;
 - (c) actively support, as it deems appropriate, relevant WHO technology, skills and knowledge transfer and local production programmes, including those referenced in Article 11, to facilitate strategically and geographically distributed production of pandemic-related health products, particularly in developing countries;
 - (d) endeavour to promote and 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, especially 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 pandemics, in cases where the capacity of facilities does not meet demand, take measures to identify and contract with manufacturers for rapid scaling up of the production of pandemic-related health products during pandemics.
- 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 pandemicrelated health products

Consensus-enabling language:

- 1. Each Party shall, in order to enable the sustainable and geographically diversified production of pandemic-related health products [for the attainment of the objectives of this instrument], and taking into account its national circumstances:
 - (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;

<u>note</u>: it is to be recalled that the chapeau of article 22 on "Cooperation in the scientific, technical, and legal fields and provision of related expertise" of the FCTC when dealing with transfer of technology, stated the following:

"1. The Parties shall cooperate directly or through competent international bodies to strengthen their capacity to fulfill the obligations arising from this Convention, taking into account the needs of developing country Parties and Parties with economies in transition. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, to establish and strengthen national tobacco control strategies, plans and programmes aiming at, inter alia:"

Also, the PIP Framework uses similar terminology under article 16:

"6.13.3 **Technology transfer** should be conducted in a manner consistent with applicable national laws and international laws and obligations, facilitated progressively over time, **on mutually agreed terms**, and be suitable to the..."

note: another option would be to add a definition on "transfer of technology", either:

1. Wherever the term transfer of technology is used in this agreement, it implies the transfer takes place under terms and conditions which are conducive to successful transfer;

Or:

2. Technology transfer is the process of sharing knowledge, skills, innovations, and technologies between governments, organizations, or institutions to ensure scientific and technological developments are available to those who need them.

Or:

3. When transfer of technology, including through licensing agreements, is referred to in this Agreement, such reference is generally understood to concern transfer of technology consensually negotiated and accepted among the parties. It is recognized that transfer of technology also may take place pursuant to domestic legislation or regulation of WHO members, provided that such legislation or regulation and actions taken pursuant to it is consistent with relevant international norms regarding intellectual property.

note: on "know-how", we can add a footnote:

For the purpose of this agreement, the transfer of technology includes the transfer of know-how [required to consistently manufacture and control the resulting product according to international standards].

- (b) [Seek to] make available 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 urge private rights holders to do the same;
- (c) Ensure [seek to ensure/take measures to ensure] timely publication of the terms of its licensing agreements [on a non-exclusive and worldwide basis, particularly for the benefit of developing countries] 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 [Request] holders of relevant patents or licenses for pandemic-related health products, to charge reasonable royalties [in particular] to developing country manufacturers for the use of their technology and know-how 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 know-how for pandemic-related health products by private rights holders, on fair terms, including on concessional and preferential terms and in accordance with mutually agreed terms and conditions, to established regional or global technology transfer hubs, coordinated by WHO, or other [multilateral] mechanisms or networks, as well as the publication of those terms, in accordance with domestic law and policies; and
- (f) Encourage [seek to ensure] manufacturers within its jurisdiction to [voluntarily] share information [which they deem appropriate] during pandemics, [as appropriate], and in accordance with national law and policies, that is relevant to the production of pandemic-related health products with appropriate third parties, [when the withholding of such information prevents or hinders those parties] who [lack the know how needed] do not have the information for the urgent manufacturing of [pharmaceutical] such products that is necessary to respond to the pandemic.
- 2. Each Party shall provide, within its capabilities and subject to available resources and applicable law, support capacity-building, especially to local, subregional and/or regional developing country manufacturers [in] [from] developing countries, for the implementation of this Article.

Or:

Each Party shall provide, within its capabilities and subject to available resources and applicable law, support for capacity-building [for the], transfer of technology and know-how for pandemic-related health products [for the implementation of this article], on [voluntary and/or] mutually agreed terms, without prejudice to other measures a Party might take, especially to local, subregional and/or regional manufacturers from developing countries. [Nothing in this agreement shall prejudice the right of a Parties to support capacity building for transfer of technology or access to know-how.]

- 3. Each Party shall [consider] supporting, within the existing framework of relevant international and regional organizations, appropriate time-bound measures to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase, [on non-commercial terms], the availability [and adequacy] [and sustainability] of affordable pandemic-related health products during pandemics.
- 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, and they fully respect the use of [such flexibility] [these flexibilities] in conformity with the TRIPS Agreement. [and shall not exercise any direct or indirect pressure to that effect.]

Chair's simplified proposal for paragraph 5, following 7 May working group session:

- 5. The Parties shall, in collaboration with the WHO, identify, assess and, as appropriate, strengthen and develop multilateral mechanisms 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 shall be coordinated by the WHO, in collaboration with other relevant mechanisms and organizations, providing equal opportunities to manufacturers from developing countries to participate.
- 5. The Parties, working through the Conference of the Parties, agree to establish regional and/ or global technology and [know-how] transfer hubs, coordinated by the WHO and other relevant regional or international organizations, by providing equal participation opportunity for manufacturers and institutions in the developing countries to facilitate the [voluntary] transfer of technology and know-how [on mutually agreed terms] for the production of pandemic-related health products in particular the facilities in developing countries referenced under Article 10, which may include the pooling of knowledge, non-exclusive and transparent licensing of intellectual property, know-how and data. At least one such mechanism shall be established on or before the third Conference of the Parties.
- Alt 5. The Parties shall, in collaboration with the WHO, identify, assess, and as appropriate, [collaborate to facilitate the strengthening and developing of] [strengthen and develop] multilateral mechanisms that promote and facilitate the transfer of technology and know-how on [voluntary] [and mutually agreed terms] [, without prejudice to any other measures that a Party may take,] with a view to increasing access to pandemic-related products worldwide, particularly in developing countries, such mechanisms [shall be] [may be] coordinated with WHO, in collaboration with other relevant mechanisms and organizations [, providing equitable participation opportunities for developing countries,] [and may include the [pooling of knowledge,] non-exclusive and transparent licensing of intellectual property, know-how and data.]

Alt 5 bis [The WHO Secretariat shall work towards the improvement of access to pandemic-related health products, especially during pandemic emergencies, through transfer of technology and knowhow, including through cooperation with relevant international organizations.]

Chair's simplified proposal for paragraph 6, following 7 May working group session:

6. Each Party should review and consider amending, as appropriate, its national and/or domestic legislative law with a view to using the flexibility referred to in paragraph 4 in a timely and effective manner.

New 6. Each Party [shall/should] review and [consider amending/, as appropriate, amend] its [national/domestic] [legislation/law] with a view to [using the flexibilities referred to in paragraph 4/ 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, [systematic] and timely [safe, transparent, and [accountable:], [open]] sharing of materials and information on pathogens with pandemic potential, to be covered by the instrument, pursuant to paragraph 2 (hereafter Materials and Information) and, on an equal footing, the rapid, [systematic,] timely, fair and equitable sharing of benefits [arising therefrom][related to the pathogens covered by the instrument] for public health purposes, [taking into account relevant national, domestic, and international laws,] the Parties [hereby establish] a multilateral system for access and benefit sharing for pathogens with pandemic potential, the 'WHO Pathogen Access and Benefit-Sharing System' (PABS System). The PABS System shall be coordinated and convened by WHO [working in cooperation with relevant stakeholders].
- 2. The provisions governing the PABS System, including scope, definitions [, including] [of pathogens with pandemic potential and] Material and Information,] modalities, terms and conditions, and operational dimensions shall be developed and agreed in a [legally binding] instrument (hereby called PABS Instrument). All elements of the PABS System shall come into operation simultaneously in accordance with the terms of such instrument. [[, which] [The instrument] [will] [should] come into force [for its parties] [no earlier than] [on] the date at which this Agreement comes into force].
- 3. The instrument referred to in paragraph 2, shall contain provisions regarding, inter alia, the following:
 - (a) access to Materials and Information, and on an equal footing, the fair and equitable sharing of benefits [arising therefrom];
 - (b) modalities on [legally binding terms and conditions on] access and benefit sharing that provide legal certainty to providers and users that could be implemented through standardized, legally binding contracts and users' registration [of the PABS System;] /
 - (b. alt.) [the [access and] benefits shall be implemented by [standardized] legally binding contracts between the [WHO and the users of the] PABS system and [private] entities which [voluntarily] conclude such contracts, taking into account the different nature, size and capabilities of such entities;]/[the access will be in accordance with terms and conditions to be agreed in the instrument, refer to paragraph 6']

b (alt) Processes that govern access to PABS Materials and Information and include, inter alia, terms and conditions for monitoring and accountability; processes that govern benefit sharing, including contracts concluded by WHO, and that take into account the nature, size and capacities of entities that decide to enter into such contracts.

- (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 [consistent with this Agreement,] complementary to the Pandemic Influenza Preparedness Framework [and other relevant ABS instruments, so as to avoid duplication] [and mutually supportive of other access and benefit instruments;
- (e) implementation in accordance with applicable laws, regulations, and standards, including as related to [export control,] safety, security and data protection;
- (f) robust [traceability mechanism], inclusive, transparent, and evidence-based governance, review, and accountability [mechanisms,] under the oversight of the parties to the Instrument, referred to in paragraph 2.
- (g) [intellectual property rights of [PABS] Materials and Information [shall be addressed in the instrument referenced in paragraph 2];][DEL]
- (h) [development and implementation in a manner that is consistent with and does 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, recognizing] / [the intention of recognition of] / [with the aim to recognize it] the PABS System as a specialized international access and benefit-sharing instrument, within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol, [including the process for such recognition,] noting that only states Party to the Nagoya Protocol are bound [thereby]/[by this sub-paragraph].[DEL]

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

- (a) The rapid [, systematic,] and timely, sharing of Materials and Information [, based on risk assessment,] [including, but not limited to,] through [existing] WHO coordinated laboratory networks, and relevant [and accountable] sequence databases [[based] on modalities, terms and conditions, to be [set out] / [agreed] in the [legally binding] contracts pursuant to paragraph X above];
- (b) The fair, equitable and rapid, [systematic] and timely sharing of benefits, both monetary and non-monetary [, free from disruptions of any kind] [[based] on modalities, terms and conditions, to be [set out] / [agreed] in the [legally binding] contracts pursuant to paragraph X above], including the following:
 - (i) in the event of a [PHEIC] and/or pandemic emergency, [provide access to WHO of] [expected rapid [access by] / [contribution by relevant manufacturers to] the PABS System to] [up to]/[at least] 20% of the [real time] production of each of safe, quality, efficacious and effective vaccines, therapeutics, and diagnostics [against][resulting from the sharing

of] pathogens to be covered by the Instrument;

(i. alt) in the event of a [PHEIC] and/or pandemic emergency, [DEL expected rapid access by the PABS System] [ADD provide access to WHO of] [DEL up to]/][at least] 20% of [DEL the] *[ADD real-time] production [ADD (10% of production free of charge and 10% at not-for-profit prices)] of each of safe, quality, efficacious [DEL and effective] vaccines, therapeutics, and diagnostics [DEL against pathogens to be covered by the Instrument];

- o [No less than 10% of the production free of charge]
- o [[Up to] / [At least] 10% of the production at a not-for-profit price]

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.

(ii) Annual monetary contributions shall be administered by the PABS System[.] [, based on modalities, terms and conditions, to be defined according to paragraph 2b.]

[(NEW ii bis.) During a PHEIC and/or pandemic emergency, grant to WHO 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.]

- (c) [The Director General of WHO may initiate advance release of these pandemic related products to developing countries before PHEIC, to prevent outbreaks becoming PHEIC, in cases where concerned country lacks equitable access];
- (d) [that entities that use [PABS] Materials and Information for non-commercial purposes are to, at a minimum, acknowledge the providers of Materials and Information in relevant presentations and / or publications.]
- 5. The PABS System shall include additional benefit sharing provisions [. It shall also include specific benefit sharing provisions [promoting health emergency prevention, preparedness and response] [in the event of a PHEIC] [fn: flexibility is important as not all PHEICs develop into pandemic emergencies], which may include access to relevant vaccines, therapeutics, diagnostics. The [modalities of additional benefit sharing provisions] [modalities,] and a list of additional benefits, shall be defined in the Instrument referred to in paragraph 2.
- 6. Each Party that has manufacturing facilities in its jurisdiction that produce vaccines, therapeutics, and or diagnostics [resulting from the sharing of] pathogens to be covered by the Instrument shall take appropriate measures to facilitate the manufacture and export of such products [subject to national/domestic, and international law].

Article 13. Supply chain and logistics

1. The Global Supply Chain and Logistics Network (the GSCL Network) is hereby established to enhance equitable, timely and affordable [and unhindered DEL] access to pandemic-related health products [, as well as access to such products in [humanitarian settings DEL] in full respect of international [humanitarian DEL] law [and principles DEL]]. The GSCL Network shall be developed, coordinated, and convened by WHO in partnership with relevant [Parties and other] stakeholders [NOTE define stakeholders in Article 1] 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 [at all times DEL].

- 2. The Conference of the Parties [should] [shall DEL], at its first meeting, define [by consensus DEL] 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 [DEFINE RELEVANT STAKEHOLDERS] during and between pandemics;
 - (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 [vulnerable populations] [persons in vulnerable situations], 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 through 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.

3.The functions of the GSCL Network may include, subject to further decision making by the Conference of the Parties, for pandemic-related health products, the following: estimation of supply and demand; identification of product and relevant raw material sources; facilitation of procurement during PHEIC and pandemic emergencies including from facilities referenced under Article 10, coordination of relevant procurement agencies within the GSCL Network and pre-pandemic preparatory work; promotion of transparency across the value chain; collaboration on stockpiling; and facilitation of equitable [and unimpeded] access, including 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 operations of the GSCL Network, including the support provided by Parties and other stakeholders during and between pandemics.

[4.bis the Parties of the agreement shall not apply any unilateral economic, financial or trade measures not in accordance with international law and the Charter of the United Nations that impede supply, distribution or procurement of any medical or health related goods [, including medicine, medical equipment, spare parts, raw materials, software, access codes etc. DEL] DEL]

- 5. During a pandemic, 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 facilitated in a manner consistent with international law [, including international humanitarian law, 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 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. [National (DEL)] 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, [within its available resources and subject to applicable law and policies, DEL] 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.
- 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.]
- 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 as appropriate, when sharing pandemic-related health products with countries, organizations or any mechanism that is facilitated by the Network, each Party shall endeavour to provide products that are unearmarked and accompanied by [essentially] [all appropriate and relevant conditions, requirements and characteristics, as well as DEL] ancillary products, that are necessary for their distribution, administration and dispensing.
- [7 Alt. When sharing pandemic-related health products with countries, organizations or any mechanism that is facilitated by the Network, each Party shall endeavour to provide products that are unearmarked and accompanied by all appropriate and relevant conditions, requirements and characteristics, including expiration dates as well as necessary for their distribution, and consideration for...]

- [7 Alt 2. Whenever possible and appropriate, when sharing pandemic-related health products with countries, organizations or any mechanism that is facilitated by the 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. [Each Party shall consider developing and making publicly available, as necessary and in accordance with applicable law, national strategies for managing liability, including indemnification clauses that are time-bound, in its territory related to novel pandemic vaccines. (DEL)]
- [8 Alt. [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.]

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, [including through regulatory reliance mechanisms, and oversight of pandemic-related health products]; 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. information on the pandemic-related health products that it has authorized or approved, [and, as appropriate, any information on which the decision was based DEL].
- 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 pandemic emergencies] [, subject to the availability of regulatory dossiers], [for pandemic-related health products] taking into account relevant guidelines.

- 5. Each Party shall, consistent with [applicable law (DEL)]/national and/or domestic law], encourage relevant developers and manufacturers of pandemic-related health products to diligently seek regulatory authorizations and approvals at national [regulatory] level, and as appropriate, pregulatification of pandemic-related health products with WHO and WHO listed authorities.
- 5alt. [Each Party shall, consistent with applicable law, encourage relevant developers and manufacturers of pandemic-related health products to diligently seek prequalification of pandemic-related health products with WHO, and regulatory authorizations and approvals at national level, and as appropriate,

 WHO listed authorities.]
- 5alt.2 Each Party shall, consistent with applicable law, encourage relevant developers and manufacturers of pandemic related health products to diligently seek regulatory authorizations, approvals and/or prequalification of pandemic-related health products with WHO, WHO listed authorities and other regional or national authorities as appropriate.
- 5bis WHO prequalification system and emergency use listing procedure shall be further improved by WHO with the aim to facilitate rapid approval of and timely access to pandemic related health products.
- 6. The Parties shall, as appropriate, monitor, [regulate (DEL)] and strengthen rapid alert systems [and regulate] against substandard and falsified pandemic-related health products.
- 7. [The Parties shall endeavour to, subject to applicable law:
 - a. [converge and/or align [and[/or harmonize, where appropriate,][, where possible, harmonize (DEL)] (DEL)] relevant technical and regulatory requirements, in accordance with applicable international standards and guidance; and (DEL)]
 - b. provide support to help strengthen national regulatory authorities' and regional regulatory systems' [ability/capacity] to respond to pandemic emergencies, as appropriate, consistent with applicable law and subject to available resources. (DEL)/(RETAIN)]

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 [[as appropriate](DEL)] of Indigenous Peoples, communities, including local communities, and [relevant stakeholders], including through social participation, as part of a whole-of-society approach in [assessment,] planning, decision-making, implementation, monitoring and evaluation [of policies, strategies and measures], [and also] [in order to (DEL)] provide [effective (DEL)] 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 persons in vulnerable situations, including by mobilizing social capital in communities for mutual support.
- 4. Each Party shall develop, in accordance with national context, comprehensive, multisectoral, national pandemic prevention, preparedness and response plan(s) that address pre-, post- and interpandemic periods, in a transparent and inclusive manner that promotes collaboration relevant stakeholders, including the private sector, and civil society.
- 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 [under and] 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, [in accordance with] [subject to DEL] [domestic and] national law and available resources, shall [endeavour to]:
 - (a) maintain or increase, [to the extent feasible,] domestic funding for pandemic prevention, preparedness and response;
 - (b) mobilize additional financial resources to assist 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 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.]
- 3. A Coordinating Financial Mechanism (the Mechanism) is hereby established to promote sustainable financing support, strengthen and expand capacities for pandemic prevention, preparedness and response, and to [facilitate]/[promote]/[contribute to] [provide] any surge response necessary for day zero, particularly in developing country Parties. [Its operation shall be entrusted to one or more international entities to be selected, by consensus, by the Conference of the Parties at its first meeting.] 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;
 - (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) [establish, as necessary, following a mandate from the Conference of the Parties, working arrangements with relevant identified financing instruments and entities to facilitate their support of the financial and implementation strategy;]
- (e) provide advice and support, upon request, to Parties in identifying and applying for financial resources for strengthening pandemic prevention, preparedness and response; and
- (f) 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. The Conference of the Parties shall adopt [, by consensus,] terms of reference for the Mechanism and modalities for its operationalization and governance, [including the necessary working arrangements with the entity/entities referred to in Para 3,] within 12 months after the entry into force of the WHO Pandemic Agreement.
- 5. The Conference of the Parties shall [request the Fund established pursuant to Article 44 of the International Health Regulations, to mobilize additional financial resources to be allocated for the purposes of this Agreement to its Parties. The Conference of Parties shall consider creation of an additional fund accountable to it, after 5 years of review, if the then existing funds are not assisting the Parties in the implementation of this Agreement comprehensively.] take appropriate measures to give effect to this Article, including the possibility of exploring, [at its first session and thereafter as appropriate,] 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 DEL] 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.
- 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 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. At each ordinary session, it shall adopt [by consensus] a budget for the financial period until the next ordinary session. (DEL)]
- 7. The Conference of the Parties may establish subsidiary bodies, as well as decide upon delegating functions to bodies established under other agreements adopted under the WHO Constitution, as it deems necessary, and determine the terms and modalities of such bodies.

[[7bis The sub-committee on implementation and compliance established by the amended International Health Regulations (2005) shall also consider implementation of, and promote compliance with, the provisions of this agreement and report, if requested, to 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 Secretariats of other competent international and regional intergovernmental 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 ad hoc 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 provision 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. DEL]

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 Depositary 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 [States] 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.

[5bis. For the purposes of paragraphs 4 and 5 above, 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

- 3. Any Party may propose protocols to the WHO Pandemic Agreement. Such proposals shall be considered by the Conference of the Parties.
- 4. 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. In the event that a protocol is proposed for adoption under Article 21 of the Constitution of the World Health Organization, it shall further be presented to the World Health Assembly for consideration for adoption.
- 5. 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.
- 6. [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.]
- 7. 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.
- 8. [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 Depositary.
- 2. Any such withdrawal shall take effect upon expiry of one year from the date of receipt by the Depositary of the notification of withdrawal, or on such later date as may be specified in the notification of withdrawal.
- 3. [A State shall not be discharged by reason of the withdrawal from the obligations which accrued while it was a Party to the WHO Pandemic Agreement, nor shall the withdrawal affect any right, obligation or legal situation of that State created through the execution of this Agreement prior to its termination for that State.]
- 4. [Any Party that withdraws from the WHO Pandemic Agreement shall not be considered as having also withdrawn from any protocol to which it is a Party, or from any related instrument, unless such a Party formally withdraws from such other instruments and does so in accordance with the relevant terms, if any, thereof.] [NOTE: proposed revert to INB9 text]

Article 33. Signature

- 1. This Agreement shall be open for signature by all [States, including,] Members of the World Health Organization and any States that are not Members of the World Health Organization [but are Members or non-Member Observer States of the United Nations (DEL)], 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 Depositary.]
- 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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