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

A/INB/9R/3
April 2024

Proposal for the WHO Pandemic Agreement

Contents

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, while achieving relevant commitments by all parties,

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 the Sustainable Development Goals aim to achieve gender equality and empower all women and girls,

Commented [A1]: Risk Assessmen Center on Food Chain under the Ministry of Agriculture and Food (RACFC) In any case, we suggest that the word "**directing**" be dropped. We support the position expressed in previous opinions that the texts disproportionately concentrate responsibility on the WHO. Such management judgments and decisions cannot be entrusted to a single organization to determine globally the same measures for all countries - the risk of making mistakes becomes incalculably high. It should be possible to deploy the wide variety of solutions and scientific achievements that countries can offer. We suggest that the WHO should not be burdened with such a concentrated responsibility and that its role should be coordinating, but not legally binding and mandatory. Other options can be sought in which there is a broad representation of countries to make such global decisions. There is such a note in the analysis of the EC. WHO could have a support and knowledge organization and possibly coordinate pandemic responses with advice.

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 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 crosssector 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 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, and to advance achievement of universal health coverage, particularly through a primary healthcare 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 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 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 own 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 of 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 social, environmental, cultural, political and economic determinants of health, and

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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;

(b) "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;

(c) "PABS Material and Information" means the biological material from a pathogen with pandemic potential, as well as sequence information relevant to the development of pandemic related health products;

(d) "pandemic-related health products" means safe, effective, quality and affordable products that are needed for pandemic prevention, preparedness and response, which may include, without limitation, diagnostics, therapeutics, vaccines and personal protective equipment;

(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" 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~~ proven to be highly transmissible and/or highly virulent with the potential to cause a public health emergency of international concern;

(g) "persons in vulnerable situations" means individuals, as well as persons belonging to 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; and [1]

(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

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

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Commented [A6]: RACFC – the term is too general and needs definition – it should cause high mortality, severe course, etc.

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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.

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 public health surveillance

1. The Parties shall cooperate with one another, in bilateral, regional and multilateral settings, to progressively strengthen pandemic prevention and public health surveillance capacities, consistent with the International Health Regulations (2005) (hereinafter IHR (2005)), and taking into account national and regional circumstances.

2. Each Party shall develop, strengthen, implement, periodically update and review comprehensive multisectoral national pandemic prevention and public health surveillance plans that are consistent with

and supportive of the effective implementation of the IHR (2005), and in accordance with its capacities, which cover, inter alia:

(a) collaborative surveillance;

(b) community-based early detection and control measures;

(c) water, sanitation and hygiene;

(d) routine immunization;

(e) infection prevention and control;

(f) zoonotic spill over and spillback prevention;

(g) laboratory biological risk management, in order to prevent the accidental exposure to, misuse or inadvertent release of pathogens;

(h) vector-borne disease surveillance and prevention; and

(i) antimicrobial resistance (AMR) to address pandemic-related risks associated with the emergence and spread of pathogens that are resistant to antimicrobial agents.

3. The Parties recognize that it is of great importance to identify those factors that s~~environmental, climatic, social, anthropogenic and economic factors~~ increase the risk of pandemics and endeavour to identify these factors and take them into consideration in the development and implementation of relevant policies, strategies and measures, at the international, regional and national levels, as appropriate, including by strengthening synergies with other relevant international instruments and their implementation.

4. The Conference of the Parties may adopt, as necessary, guidelines, recommendations and standards, including in relation to pandemic prevention capacities, to support the implementation of this Article.

Article 5. One Health

1. The Parties commit to promote a One Health approach for pandemic prevention, preparedness and response, recognizing the interconnection between people, animals and the environment, that is coherent, integrated, coordinated and collaborative among all relevant organizations, sectors and actors, taking into account national circumstances.

2. The Parties commit to identify and address the drivers of pandemics and the emergence and reemergence of disease at the human-animal-environment interface through the introduction and integration of interventions into relevant pandemic prevention, preparedness and response plans.

3. Each Party shall, in accordance with its national context, protect human, animal and plant health, with support from WHO and other relevant international organizations, by:

(a) implementing and regularly reviewing relevant national policies and strategies that reflect a One Health approach as it relates to pandemic prevention, preparedness and response;

(b) promoting the effective and meaningful engagement of communities in the development and implementation of policies, strategies and measures to prevent, detect and respond to outbreaks; and

Commented [A8]: disagree. The text as a whole is too comprehensive and vague. First, such a sweeping generalization that all these factors must be recognized as enhancing the risk of pandemics is factually incorrect. Second, the obligation for the parties to engage in such a comprehensive analysis is unenforceable and unacceptable. This will lead to a multiple increase in the administrative burden, commitment of a huge human and financial resource with an unclear positive result and duplication of already existing and built systems.

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(c) promoting or establishing One Health joint training and continuing education programmes for human, animal and environmental health workforces, to build relevant and complementary skills, capacities and capabilities.

4. The modalities, terms and conditions, and operational dimensions of a One Health approach shall be further defined in an instrument, that takes into consideration the provisions of the IHR (2005), and is operational by 31 May 2026.

Article 6. Preparedness, readiness and health system resilience

1. Each Party commits 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, with a view to achieving universal health coverage.

2. Each Party commits, in accordance with its national and / or domestic law, as appropriate and its capabilities, to develop or strengthen, sustain and monitor health system functions and infrastructure, including by adopting and/or developing policies, plans, strategies and measures, as appropriate, for:

(a) timely provision of, and equitable access to, scalable clinical care, quality routine and essential health care services during pandemics with a focus on primary health care, mental health and psychosocial support, and with particular attention to persons in vulnerable situations;

(b) post-pandemic health system recovery;

(c) laboratory and diagnostic capacities, and associated national, regional and global networks, through the application of relevant standards and protocols for laboratory biosafety and biosecurity; and

(d) promoting the use of social and behavioural sciences, risk communication and community engagement for pandemic prevention, preparedness and response.

4. The Parties, collaborating with WHO and relevant international organizations, shall endeavour to identify, promote and/or strengthen, as appropriate, in accordance with national and/or domestic law, as appropriate, relevant international data standards and interoperability that enable timely sharing of public health data for preventing, detecting and responding to pandemic public health events.

5. With the aim of promoting and supporting learning among Parties, best practices, ~~and accountability and coordination of resources~~, ~~an inclusive, transparent,~~to ensure effective and efficient pandemic prevention, preparedness and response WHO should organize conferences, seminars, international training courses, issue bulletins and manuals ~~monitoring and evaluation system shall be developed, implemented and regularly assessed, by WHO~~ in partnership with relevant organizations, building on relevant tools, ~~on a timeline to be agreed by the Conference of the Parties~~.

Article 7. Health and care workforce

1. Each Party, in line with its respective capacities and national circumstances, shall take the necessary steps to establish, safeguard, protect, invest in and sustain a multi-disciplinary, skilled, trained and diverse workforce to prevent, prepare for and respond to health emergencies closest to where they start, including in humanitarian settings, while maintaining quality essential health services and essential public health functions during pandemics.

Commented [A10]: RACFC - Text in this form is unacceptable. It must be specified exactly what health data is intended to be shared. Moreover, the term "public health events" is too general and unnecessarily broadens the scope of data to be shared. It should be replaced by "pandemic public health events".

Commented [A11]: RACFC – In connection with the objection already expressed above regarding the leading role of the WHO and the disproportionate concentration of powers to the WHO - we object to this text. **Bulgaria should impose a reservation**. It is unacceptable to give powers to a supranational, non-governmental organization to build such an evaluation system, which will bring a major administrative burden, but no benefits for the Bulgarian health care - humane and veterinary. It is unacceptable to give the WHO the power to single-handedly allocate resources to and between countries. Moreover, the construction of such a system contradicts the goal set at the beginning of the text. If the WHO wants to educate and support the training of countries, it should organize conferences, seminars, international training courses, to build a system for the exchange of best practices, without a mandatory and binding character, issue bulletins and manuals, and not build a control system. **In this case, it is a covert system of control over countries.** It duplicates, especially in the veterinary field, the role of the International Organization for Animal Health, which for many years has cooperated and assisted countries in animal health and the "One Health" approach.

Commented [A12]: RACFC - to be specified who these organizations are.

2. Each Party shall take appropriate measures to protect and ensure the continued safety, wellbeing and capacity of its health and care workforce, including by ensuring priority access to pandemic-related health products during pandemics, thereby minimizing disruptions to the delivery of good quality essential health services.

3. The Parties shall invest in establishing and sustaining, a skilled, trained, and coordinated multidisciplinary global health emergency workforce deployable to support Parties upon request, based on public health need, to contain outbreaks and prevent the escalation of a small-scale spread to global proportions.

4. The Parties shall commit to develop, as necessary, and implement coordinated policies and measures for the safety and protection of workers who are essential for the normal functioning of critical supply chains during pandemics, such as seafarers and cross-border transport workers, among others, facilitating their transit and transfer, as well as ensuring their access to medical care, as appropriate.

~~5. The Parties shall collaborate, as appropriate, through multilateral and bilateral mechanisms, to minimize the negative impact of health workforce migration on health systems while respecting the freedom of movement of health professionals, taking into account the applicable international codes and standards.~~

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Article 8. *Preparedness monitoring and functional reviews – provisions of this article were moved to Article 6 (retained for numbering purposes only)*

Article 9. Research and development

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

2. To this end, the Parties shall promote, within means and resources at their disposal:

   (a) sustained investment in research and development for public health priorities;

   (b) technology co-creation and joint venture initiatives, actively engaging the participation of scientists and/or research centres from developing countries;

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

   (d) participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development.

3. The Parties shall, in accordance with national circumstances and mindful of relevant international standards and obligations, take steps to strengthen international coordination and collaboration to support well-designed and well-implemented clinical trials, by developing, strengthening and sustaining clinical trial capacities and research networks, at the national, regional and international levels, and facilitating the rapid reporting and interpretation of data from such trials.

4. Each Party shall ensure that government-funded research and development agreements for development of pandemic-related health products include, if~~as~~ appropriate, provisions that promote timely and equitable access to such products and shall publish the relevant terms. Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer on mutually agreed terms; (iv) publication of relevant information on research inputs and outputs; and/or (v) adherence to product allocation frameworks adopted by WHO.

Article 10. Sustainable and geographically diversified production, and technology transfer and know-how

1. The Parties commit to achieving more equitable geographical distribution and scaling up of the global production of pandemic-related health products, and increasing sustainable, timely, fair and equitable access to such products, as well as reducing the potential gap between supply and demand during pandemics, through voluntary transfer of relevant technology and know-how on mutually agreed terms.

2. The Parties, in collaboration with WHO and other relevant organizations, shall:

(a) Take measures to provide support for, maintain and/or strengthen, as appropriate, facilities at national and regional levels, particularly in developing countries, and those that have conducted disease burden studies relevant to pathogens with pandemic potential, with a view to promoting the sustainability of such investments, for the production, or scaling up of production, of relevant pandemic-related health products;

(b) take measures, in accordance with national and/or domestic laws, as appropriate, and regulations, to identify and contract with manufacturers other than those referenced in paragraph 2(a) of this Article, for scaling up the production of pandemic-related health products, during pandemics, in cases where the production and supply capacity of the production facilities does not meet demand;

(c) actively support, participate in and/or implement, as appropriate, relevant WHO technology, skills and know-how transfer programmes to facilitate strategically and geographically distributed production of pandemic-related health products; and

(d) promote and incentivize public and private sector investments and/or partnerships aimed at creating or expanding manufacturing facilities or capacities for pandemic-related health products, especially facilities with a regional operational scope that are based in developing countries.

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

1. Each Party shall, in order to enable sufficient, sustainable and geographically-diversified production of pandemic-related health products, and taking into account its national circumstances:

(a) promote and otherwise facilitate or incentivize the voluntary 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 funding for their development, through a variety of measures such as licensing, on mutually agreed terms;

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СЗО не е търговска организация!

(b) publish the terms of its licenses for pandemic-related health technologies in a timely manner and in accordance with applicable law, and shall encourage private rights holders to do the same;

(c) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to forgo or reduce, for a limited duration, royalties on the use of their technology for the production of pandemic-related health products;

(d) promote the voluntary transfer of relevant technology and related know-how for pandemic-related health products, by private rights holders, on fair and most favourable terms, including on concessional and preferential terms and in accordance with mutually agreed terms and conditions, to established regional or global technology transfer hubs or other multilateral mechanisms or networks, as well as the publication of the terms of such agreements;

(e) encourage holders of relevant patents that received public funding, and where appropriate, other holders of relevant patents for pandemic-related health products, to forgo royalties or otherwise license any relevant patents at reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related health products; and

(f) encourage manufacturers within its jurisdiction to share as appropriate, during pandemics, information that is relevant to the production of pandemic-related health products when the withholding of such information prevents or hinders urgent manufacture of a pharmaceutical product 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 for capacity-building for the voluntary transfer of technology and know-how for pandemic-related health products on mutually agreed terms, especially to local, sub-regional and/or regional manufacturers based in developing countries.

3. Consider supporting, within the framework of relevant organizations, appropriate measures to accelerate or scale up the manufacturing of pandemic related health products, to the extent necessary to increase the availability and adequacy of affordable pandemic-related health products during pandemics.

4. The Parties that are WTO Members reaffirm that they have the right to use, to the full, flexibilities in the TRIPS Agreement, including those reaffirmed in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health in future pandemics, and shall fully respect the use of the TRIPS flexibilities by WTO members.

5. The Parties shall, working through the Conference of the Parties, establish regional or global technology and know-how transfer hubs, coordinated by WHO, to increase and geographically diversify the transfer of technology and know-how for the production of pandemic-related health products, by manufacturers in developing countries.

Article 12. Access and benefit sharing

1. A multilateral access and benefit sharing system for pathogens with pandemic potential, the "WHO Pathogen Access and Benefit-Sharing System" (PABS System), is hereby established to ensure rapid, systematic and timely sharing of PABS Material and Information for, inter alia, public health risk assessment, and, on an equal footing, timely, effective, predictable and equitable

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СЗО не е търговска организация!

access to pandemic related health products, and other benefits, both monetary and non-monetary, arising from such sharing. The PABS System shall be coordinated and convened by WHO.

2. The PABS System shall have the following foundations:

(a) the commitment of Parties to share, on an equal footing, PABS Material and Information and the benefits arising therefrom, considering these as equally important parts of the collective action for global public health;

(b) its implementation in a manner to strengthen, expedite and not stifle research and innovation;

(c) its implementation in a manner to ensure mutual complementarity with the Pandemic Influenza Preparedness Framework;

(d) its implementation in accordance with applicable biosafety, biosecurity and data protection standards and internaltional law;

(e) the development of a robust, inclusive, transparent, Member State-led, and science-based governance, review, and accountability mechanism(s);

(f) not seeking to obtain intellectual property rights on PABS material and information; and

(g) its implementation in a manner to be consistent with, and does not run counter to, the objectives of the The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, 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 a view to providing legal certainty to PABS System providers and users, and with the aim of the recognition of the System as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol.

3. The WHO PABS System shall have, at a minimum, the following components and elements:

(a) The rapid, systematic and timely sharing of PABS Material and Information, and all relevant information, in accordance with modalities, terms and conditions to be determined and agreed; and

(b) The fair, equitable and timely sharing of benefits, both monetary and non-monetary, arising from access to PABS Material and Information, in accordance with modalities, terms and conditions to be determined and agreed, and which shall include, at a minimum, the following:

(i) in the event of a pandemic, real-time access by WHO to 20% (10% as a donation and 10% at affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related health products; and

(ii) annual monetary contributions from PABS System users shall be administered by WHO, based on modalities, terms and conditions to be defined, per paragraph 6 of this Article .

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(c) A mechanism to ensure the fair and equitable allocation and distribution of the pandemic related health products in paragraph 3(b) above, shall be developed taking into account public health risks, needs, and demand, per paragraph 6 of this Article.

4. The PABS System will also have additional benefit-sharing options, which may include:

(a) voluntary non-monetary contributions, such as capacity-building activities, scientific and research collaborations, non-exclusive licensing agreements, arrangements for voluntary transfer of technology and know-how of relevant diagnostics, therapeutics or vaccines in line with Article 11; Tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related health products during PHEICs or pandemics; and

(b) encouraging of laboratories in the WHO coordinated laboratory network to actively seek the participation of scientists from developing countries in scientific projects associated with research on PABS Material and Information.

5. Each Party that has manufacturing facilities that produce pandemic-related health products in its jurisdiction shall take all necessary steps to facilitate the export of such products, in accordance with timetables to be agreed between WHO and the relevant manufacturers.

6. The modalities, terms and conditions, and operational dimensions of the PABS System shall be further defined in a legally-binding instrument, that is operational no later than 31 May 2026.

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Article 13. Supply chain and logistics

1. The Global Supply Chain and Logistics Network (the Network) is hereby established to enhance equitable, timely and affordable access to pandemic-related health products. The Network shall be developed, coordinated and convened by WHO in partnership with the Parties and other relevant international and regional stakeholders. The Parties shall prioritize sharing through the Global Supply Chain and Logistics Network for equitable allocation based on public health risk and need over bilateral donation agreements.

2. The Conference of the Parties shall, at its first meeting, define the structure and modalities of the Network, which shall aim at ensuring the following:

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

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

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

(d) equitable allocation of pandemic-related health products; and

(e) accountability and transparency in the functioning and governance of the Network.

3. The Parties shall periodically review the operations of the Network, including the support provided by Parties and other stakeholders during and between pandemics.

4. During a pandemic, emergency trade measures shall be targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or disruptions in supply chains of pandemicrelated health products.

5. During a pandemic, rapid and unimpeded access of humanitarian relief personnel, their means of transport, supplies and equipment, and to pandemic-related health products, shall be facilitated in a manner consistent with relevant provisions of international law, including humanitarian law, and in respect of the principles of humanity, neutrality, impartiality and independence for the provision of humanitarian assistance.

6. A multilateral system for managing vaccine and therapeutic related compensation and liability during pandemics shall be considered.

7. The WHO, as the convenor of the Network, shall report regularly to the Conference of the Parties on all matters relevant to the implementation of this Article.

Article 13bis: National procurement and distribution

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1. Each Party shall publish the relevant terms of its purchase agreements with manufacturers for pandemic-related health products at the earliest reasonable opportunity, and shall exclude confidentiality provisions that serve to limit such disclosure, and in accordance with applicable laws, and as appropriate. Regional and global purchasing mechanisms shall also be encouraged to do the same.

2. During a pandemic, each Party in a position to do so shall, within available resources and subject to applicable laws, set aside a portion of its total procurement of relevant diagnostics, therapeutics or vaccines in a timely manner for use in countries facing challenges in meeting public health needs and demand.

3. Each Party shall take appropriate measures to promote rational use and reduce waste of pandemic related health products.

4. Each Party undertakes to avoid having national stockpiles of pandemic-related health products that unnecessarily exceed quantities anticipated to be needed for domestic pandemic preparedness and response.

5. When sharing pandemic-related health products with countries, organizations, or any mechanism that is facilitated by the Network, such products will be unearmarked and accompanied by all appropriate and relevant conditions, requirements and characteristics, as well as ancillary products, necessary for their distribution, administration and dispensing.

6. Each Party shall endeavour to ensure that, in contracts for the supply or purchase of novel pandemic vaccines, buyer/recipient indemnity clauses, if any, are exceptionally provided and are timebound.

Article 14. Regulatory strengthening

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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 and cooperation with WHO, other Parties and relevant organizations, as and when requested, with the aim of ensuring the quality, safety and efficacy of such products.

2. Each Party shall take steps to ensure that it has the legal, administrative and financial frameworks in place to support emergency regulatory authorizations for the effective and timely approval of pandemic-related health products during a pandemic, monitoring adverse events, and sharing of regulatory dossier through WHO, as appropriate.

3. Each Party shall, in accordance with relevant laws:

   (a) encourage manufacturers of pandemic-related health products to generate and submit in a timely manner, relevant regulatory data, contribute to the development of common technical documents, and diligently pursue national regulatory authorizations and approvals, and, as appropriate, prequalification with WHO and WHO listed authorities; and

   (b) publicly disclose information on national and, if applicable, regional processes for authorizing or approving use of pandemic-related health products, and adopt regulatory reliance processes or other relevant regulatory pathways, as appropriate, for such pandemic related health products that may be activated during a pandemic to increase efficiency, and update such information in a timely manner.

4. The Parties shall, as appropriate, monitor, regulate and strengthen rapid alert systems against substandard and falsified pandemic-related health products.

5. The Parties shall align and, where possible, harmonize technical and regulatory requirements and procedures, in accordance with applicable international standards, guidance and protocols, including those covering regulatory reliance and mutual recognition, and make publicly available relevant information, data and assessments concerning the quality, safety and efficacy of pandemic-related health products with other Parties.

Article 15. Compensation and liability management – *provisions of this article were integrated into Article 13 and 13bis (retained for numbering purposes only)*

Article 16. International collaboration and cooperation– *provisions of this article were integrated with Article 19 (retained for numbering purposes only)*

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

1. The Parties are encouraged to adopt whole-of-government and whole-of-society approaches at national level, including to empower and enable community ownership of, 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 the effective and meaningful engagement of communities, and other relevant stakeholders, as part of a whole-of-society approach in planning, decision-making, implementation, monitoring and evaluation, and shall also provide effective feedback opportunities; and

   (b) take appropriate measures to mitigate the socioeconomic impacts of pandemics and strengthen national public health and social policies to facilitate a rapid, 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 national pandemic prevention, preparedness and response plans that address pre-, post- and interpandemic periods, in a transparent manner that promotes collaboration with relevant stakeholders, including the private sector and civil society, avoiding all forms of conflicts of interest.

5. The Parties shall promote and facilitate, in accordance with national and/or domestic law, as appropriate, and policy, the development and implementation of education and community engagement programs on pandemic and public health emergencies with the participation of all relevant stakeholders, in a way that is accessible, including to persons in vulnerable situations.

Article 18. Communication and public awareness

1. The Parties shall strengthen science, public health and pandemic literacy in the population, as well as access to transparent, accurate, science- and evidence-informed information on pandemics and their causes, impacts and drivers, particularly through risk-communication and effective communitylevel engagement.

2. The Parties shall, as appropriate, conduct research to 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.

Article 19. International cooperation and support for implementation

1. The Parties shall cooperate, directly or through relevant international organizations, within the means and resources at their disposal, to sustainably strengthen the pandemic prevention, preparedness and response capacities of all Parties, particularly developing country Parties. Such cooperation shall promote the transfer of technology on mutually agreed terms, and sharing of technical, scientific and legal expertise, as well as financial assistance and support for capacity-strengthening to those Parties that lack the means and resources to implement the provisions of this Agreement, and shall be facilitated and provided by WHO, in collaboration with relevant organizations, as appropriate, upon 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, in order to enable them to implement 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 global, regional, subregional and sectoral organizations and stakeholders, 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

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

2. In this regard, each Party, within the means and resources at its disposal, shall:

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

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

(c) explore, and as appropriate, promote, 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.

3. A Coordinating Financial Mechanism (the "Mechanism") is hereby established to provide sustainable financing support, to strengthen and expand capacities for pandemic prevention, preparedness and response, and necessary for day zero surge response, particularly in developing country Parties. 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 IHR (2005) related capacities;

(c) identify all sources of financing that are available to serve the purposes of supporting the implementation of this Agreement, 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 conflict 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 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.

5. The Conference of the Parties shall periodically consider, as appropriate, the Financial and Implementation Strategy for the Pandemic Agreement referred to in paragraph 2(a) above. 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

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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 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.

5. The Conference of the Parties shall, at its first session, adopt by consensus its Rules of Procedure and 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 as well as financial provisions governing the functioning of the Secretariat. At each ordinary session, it shall adopt a budget for the financial period until the next ordinary session.

7. The Conference of the Parties may establish subsidiary bodies, as it deems necessary, and determine the terms and modalities of such bodies.

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 their Member States that are Parties to the WHO Pandemic Agreement. 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.

2. The frequency and format of the reports submitted by all Parties 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 under the WHO Pandemic Agreement shall be subject to national and/or domestic law, as appropriate, regarding confidentiality and privacy. The

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Parties shall protect, as mutually agreed, any confidential information that is exchanged. The periodic reports submitted by the Parties shall be made publicly available online by the Secretariat.

Article 24. Secretariat

1. Secretariat functions for the WHO Pandemic Agreement shall be provided by the WHO Secretariat.

2. Secretariat shall perform functions specified by the WHO Pandemic Agreement, as appropriate and such other functions as may be determined by the Conference of the Parties or assigned to it under the WHO Pandemic Agreement.

3. Nothing in the WHO Pandemic Agreement shall be interpreted as providing the WHO Secretariat, including the WHO Director-General, Conference of the Parties and World Health Assembly, 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 may continue to seek solutions to the dispute through joint consultations, including, if they so agree, by resorting to ad hoc arbitration in accordance with the Permanent Court of Arbitration Rules 2012 or successor rules. The Parties that have agreed to arbitration shall accept the arbitration award as binding and final.

2. The provisions of this Article shall apply with respect to any protocol 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 IHR (2005) should be interpreted so as to be compatible and mutually reinforcing.

Article 27. Reservations

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

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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 Parties to the WHO Pandemic Agreement.

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.

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. 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.

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.

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4. States that are not Parties to the WHO Pandemic Agreement may be Parties to a protocol, provided the protocol so provides.

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.

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

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.

Article 33. Signature

1. This Agreement shall be open for signature by all 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, 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 17 June 2024 to 28 June 2024, and thereafter at United Nations Headquarters in New York, from 8 July 2024 to 7 July 2025.

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

1. The WHO Pandemic Agreement 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.

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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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