World Health Organization

Seventy-eighth World Health Assembly

Provisional agenda item 16.2 A78/10

14 May 2025

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

Report by the Director-General

1. The Director-General has the honour to transmit to the Seventy-eighth World Health Assembly the outcome of the Intergovernmental Negotiating Body to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (see Annex), in line with decisions SSA2(5) (2021) and WHA77(20) (2024).

Action by the Health Assembly

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

Annex

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

1. By decision SSA2(5) (2021), the Health Assembly, at its Second special session, decided, inter alia, to establish an intergovernmental negotiating body (INB) open to all Member States and Associate Members[1] to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response. In decision SSA2(5), the Health Assembly also decided that the INB should submit its outcome for consideration by the Seventy-seventh World Health Assembly, with a progress report to the Seventy-sixth World Health Assembly.[2] The INB presented its work as of May 2024 to the Seventy-seventh World Health Assembly,[3] at which time the Health Assembly decided, through decision WHA77(20) (2024), to extend the mandate of the INB to finish its work as soon as possible, and submit its outcome for consideration by the Seventy-eighth World Health Assembly in 2025, or earlier by a special session of the World Health Assembly if possible in 2024 with only one agenda item dedicated to this outcome.

2. Since the Seventy-seventh World Health Assembly, the INB met an additional six times (INB10, 11, 12 and 13 with two resumed sessions) and held meetings of various drafting and subgroups and informal consultations and briefings, including the participation of experts and relevant stakeholders. At those various iterations of a draft text towards a pandemic agreement were discussed, culminating in the outcome document presently submitted to the Health Assembly. Documents for the sessions of the INB, including the meeting reports, are available on the WHO website.[4]

3. The INB undertook its work under the leadership of its Bureau, led by Ms Precious Matsoso of South Africa and Ambassador Anne-Claire Amprou of France as Co-Chairs, with Ambassador Tovar da Silva Nunes of Brazil, Ambassador Amr Ramadan of Egypt, Dr Viroj Tangcharoensathien of Thailand, and Ms Fleur Davies of Australia as Vice-Chairs, and supported by the Secretariat. Past members of the INB Bureau, who also contributed to the process, include Mr Roland Driece of the Kingdom of the Netherlands (previous Co-Chair), Ambassador Honsei Kozo of Japan (previous Vice-Chair), Mr Ahmed Salama of Egypt (previous Vice-Chair), and Mr Kazuho Taguchi of Japan (previous Vice-Chair).

4. Following its mandate as set out in decisions SSA2(5) and WHA77(20), the INB worked extensively on the outstanding articles in the draft WHO Pandemic Agreement. After intensive negotiations and cognizant of its mandate, at the resumed session of its thirteenth and final meeting, the INB reached consensus on the draft WHO Pandemic Agreement and decided to submit it, and an accompanying covering note, to the seventy-eighth World Health Assembly, the draft of which, inclusive of an editorial consistency review performed by the Bureau with support from the Secretariat, as decided by the INB at its thirteenth meeting, is contained in the Appendix.

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[1] And regional economic integration organizations, as appropriate.

[2] Document A76/37 Add.1, noted by the Health Assembly; see document WHA76/2023/REC/3, summary records of the sixth meeting, section 5, and seventh meeting, section 2.

[3] Document A77/10; see document WHA77/2024/REC/3, summary records of the third, fourth, thirteenth (section 10, and fourteenth (section 1) meetings).

[4] See https://apps.who.int/gb/inb/.

Appendix

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

Proposal for the WHO Pandemic Agreement

Outcome of the Intergovernmental Negotiating Body: agreed text on Wednesday, 16 April 2025 at 01:57 CEST

NOTE: Consistency review (25 April 2025)

- Green highlighting indicates text for which agreement has been reached by the Intergovernmental Negotiating Body.

Contents

The Parties to the WHO Pandemic Agreement,

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

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

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

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,

Recalling the Convention on the Elimination of All Forms of Discrimination against Women; the Convention on the Rights of the Child; the Convention on the Rights of Persons with Disabilities; and the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, as relevant to the context of pandemic prevention, preparedness and response,

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,

Deeply concerned by the inequities at national and international levels that hindered timely and equitable access to health products to address coronavirus disease (COVID-19), and recognizing the need to address the serious shortcomings at the national, regional and global levels in prevention, preparedness, response and health system recovery for public health emergencies of international concern, including pandemic emergencies,

Recognizing the need for resolute action to both strengthen pandemic prevention, preparedness and response and to improve equitable access to pandemic-related health products, as well as the importance of refraining from taking measures that adversely affect prevention, preparedness and response, while respecting States' rights to implement health measures in accordance with their relevant national law and obligations under international law, and *recalling* World Health Assembly decision SSA2(5) of 2021,

Recognizing the critical role of whole-of-government and whole-of-society approaches at national and community levels, through broad social participation, and further recognizing the value and diversity of the culture and traditional knowledge of Indigenous Peoples as well as local

communities, including traditional medicine, in strengthening pandemic prevention, preparedness, response and health systems recovery,

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

Reaffirming the importance of multisectoral collaboration at national, regional and international levels to safeguard human health,

Recognizing the importance of rapid and unimpeded access of humanitarian relief consistent with national and international law, as applicable, including applicable international humanitarian law and international human rights law,

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 the need to adopt an equitable approach to mitigate the risk that pandemics exacerbate existing inequities in access to health care services and health products,

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

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 World Trade Organization 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, and which provides flexibility to protect public health, as recognized in the Doha Declaration on the TRIPS Agreement and Public Health,

Emphasizing the need to improve access to quality, safe, effective and affordable medicines and other health technologies, inter alia, through building capacity for local production, especially in developing countries, transfer of technology as mutually agreed,[1] cooperation, strengthened legal and regulatory frameworks and other initiatives,

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

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

[1] See footnote 8.

Have agreed as follows:

Chapter I. Introduction

Article 1 Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) "humanitarian settings" refers to settings in which an event or series of events, such as armed conflicts, natural disasters, or other emergencies, have resulted in a critical threat to the life, health, safety, security or well-being of a community or other large group of people in need of humanitarian assistance. This is without prejudice to rights and obligations under applicable international humanitarian law;

(b) "One Health approach" for pandemic prevention, preparedness and response recognizes that the health of humans is closely linked and interdependent with the health of domestic and wild animals, as well as plants and the wider environment (including ecosystems), aiming for a sustainable balance, and uses an integrated multisectoral and transdisciplinary approach to pandemic prevention preparedness and response, which contributes to sustainable development in an equitable manner;

(c) "pandemic emergency" means a public health emergency of international concern, that is caused by a communicable disease and:

(i) has, or is at high risk of having, wide geographical spread to and within multiple States; and

(ii) is exceeding, or is at high risk of exceeding, the capacity of health systems to respond in those States; and

(iii) is causing, or is at high risk of causing, substantial social and/or economic disruption, including disruption to international traffic and trade; and

(iv) requires rapid, equitable and enhanced coordinated international action, with whole-of-government and whole-of-society approaches;[2]

(d) "pandemic-related health products" means those relevant health products[3] that may be needed for prevention, preparedness and response to pandemic emergencies;

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

(f) "persons in vulnerable situations" and "people in vulnerable situations" mean individuals, including persons in groups or in communities or in emergency, and/or humanitarian settings,

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[2] Pursuant to the International Health Regulations (2005). The Conference of the Parties shall consider any further amendments to the International Health Regulations (2005) modifying this term, with the aim to ensure consistency in the use of terms between the International Health Regulations and the WHO Pandemic Agreement.

[3] See footnote 2.

with a disproportionate increased risk of infection, morbidity, or mortality, as well as those likely to bear a disproportionate burden owing to social determinants of health in the context of a public health emergency of international concern, including a pandemic emergency;

(g) "public health emergency of international concern" means an extraordinary event which is determined:

(i) to constitute a public health risk to other States through the international spread of disease; and

(ii) to potentially require a coordinated international response;[4]

(h) "public health risk" means a likelihood of an event that may affect adversely the health of human populations, with an emphasis on one which may spread internationally or may present a serious and direct danger;[5]

(i) "relevant stakeholders" in the context of their engagement with the World Health Organization is understood in accordance with the Constitution of the World Health Organization and applicable principles, norms and standards of the World Health Organization;

(j) "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;[6] and

(k) "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 across the life course.

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 and approaches

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, in accordance with the Charter of the United Nations and the principles of international law to legislate and to implement legislation, within their jurisdiction.

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[4] See footnote 2.

[5] See footnote 2.

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

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

3. full respect for international humanitarian law as relevant to effective pandemic prevention, preparedness and response;

4. equity as a goal, principle and outcome of pandemic prevention, preparedness and response, striving in this context 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, as well as 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, particularly of developing countries, including landlocked developing countries, as well as the special circumstances of small island developing States and of least developed countries, in relation to pandemic prevention, preparedness and response; 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

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

2. Each Party shall progressively strengthen measures and capacities for pandemic prevention and coordinated multisectoral surveillance, taking into account its national circumstances**.** In this regard**,** each Party shall, in accordance with its national and/or domestic law and applicable international law, and subject to the availability of resources, develop or strengthen, and implement comprehensive multisectoral national pandemic prevention and surveillance plans,[7] programmes and/or other actions, that are consistent with the International Health Regulations (2005), and take into account its public health priorities and relevant international standards, and guidelines, and that cover, inter alia:

(a) prevention of emerging and re-emerging infectious diseases, by taking measures to promote collaboration across relevant sectors to identify and address drivers of infectious disease at the human-animal-environment interface, with the aim of early prevention of pandemics;

[7] See Article 15.4.

(b) prevention of infectious disease transmission between animals and humans, including, inter alia, zoonotic disease spill-over, by taking measures to identify and reduce pandemic risks associated with human-animal interactions, and relevant settings, as well as measures aimed at prevention at source, while recognizing the importance of safeguarding communities' livelihoods and food security;

(c) coordinated multisectoral surveillance to detect and conduct risk assessment of emerging or re-emerging pathogens with pandemic potential, including those pathogens that may present significant risks of zoonotic spillover and those pathogens that are resistant to antimicrobial agents, as well as sharing of the outputs of relevant surveillance and risk assessments amongst relevant sectors within its territory to enhance early detection;

(d) early detection and control measures at the community level, through strengthening mechanisms and enhancing capacities at the community level, to prevent, detect and report unusual public health events to relevant authorities within its territory, in order to facilitate actions for early containment at the source;

(e) strengthening efforts to ensure access to safe water, sanitation and hygiene for all, including in hard-to-reach areas;

(f) measures to strengthen effective routine immunization programmes especially by increasing and/or maintaining high immunization coverage, and timely supplementary vaccination to reduce public health risks and to prevent outbreaks, promoting public awareness of the importance of immunization, and strengthening supply chains and immunization systems;

(g) infection prevention and control measures, including safe management of medical waste, in all health care facilities, and infection prevention and control measures in long-term care facilities;

(h) surveillance, risk assessment and prevention of vector-borne diseases that may lead to pandemic emergencies, including by developing, strengthening and maintaining capacities, and by taking into account social, demographic and/or environmental factors that can impact vector distribution and disease transmission;

(i) laboratory biological risk management, including through biosafety and biosecurity training and practices, and ensuring the safety and security of transportation, in accordance with applicable international and national regulations and standards; and

(j) measures to address public health risks associated with the emergence and spread of pathogens that are resistant to antimicrobial agents, facilitating affordable and equitable access to antimicrobials and promoting appropriate, prudent, and responsible use across relevant sectors

3. The Parties recognize that a range of environmental, climatic, social, anthropogenic and economic factors, including hunger and poverty, 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 and/or domestic law and applicable international law.

4. The Conference of the Parties shall develop and adopt guidelines, recommendations and other non-binding measures as necessary, to promote the effective implementation of the provisions set out in paragraphs 1 and 2 of this Article, consistent with the provisions of the International Health Regulations (2005), following, as appropriate, a One Health approach, with full consideration of the national circumstances and the different capacities and capabilities of Parties, as well as the need for capacity-building and implementation support for developing country Parties.

5. The Conference of the Parties, through its work in relation to the provisions of this Article, shall address, inter alia, cooperation for implementation, in particular through technical assistance, capacity-building, research collaboration, facilitating equitable access to relevant products and tools, technology transfer as mutually agreed,[8] and financing in line with the provisions of the WHO Pandemic Agreement; and cooperation to support global, regional and national initiatives aimed at preventing public health emergencies of international concern, including pandemic emergencies, with particular consideration given to developing country Parties.

6. Technical support in implementing this Article, in particular to developing country Parties, as appropriate and upon request, shall be facilitated by the World Health Organization, in collaboration with other relevant intergovernmental organizations.

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

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

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

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

(a) developing, implementing and reviewing relevant national policies and strategies that reflect a One Health approach as it relates to pandemic prevention, preparedness and response, including promoting engagement of communities, in accordance with Article 15.3(a); and

[8] For the purposes of the WHO Pandemic Agreement, “as mutually agreed” means willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements.

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

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 17, to achieve universal health coverage.

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

(a) the timely provision of equitable access to scalable clinical care and quality routine essential health care services, while maintaining public health functions and, as appropriate, social measures during pandemics, with a focus on primary health care, mental health and psychosocial support and with particular attention to persons in vulnerable situations;

(b) national or, as appropriate, regional capacities to adopt transparent, cost-effective procurement practices and supply chain management of pandemic-related health products;

(c) laboratory and diagnostic capacities, through the application of relevant standards and protocols, including for laboratory biological risk management, and as appropriate, participation in regional and global networks;

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

(e) post-pandemic health system recovery.

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

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

Article 7 Health and care workforce

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

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

(a) facilitating priority access to pandemic-related health products during pandemic emergencies;

(b) eliminating all forms of inequalities and discrimination and other disparities, such as unequal remuneration and barriers faced by women;

(c) addressing harassment, violence and threats;

(d) supporting individual and collective empowerment; and

(e) developing policies for work-related injury, disability or death during emergency response.

3. Each Party shall endeavour 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 World Health Organization 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 and/or domestic law, 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 World Health Organization health workforce support and safeguards list and applicable international codes and standards, including those of a voluntary nature, such as the World Health Organization Global Code of Practice on the International Recruitment of Health Personnel.[9]

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 who 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 8 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 the World Health Organization,

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

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

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

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

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

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

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

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

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

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

6. The Parties shall collaborate, as appropriate, towards improving the World Health Organization processes for Emergency Use Listing, prequalification and any other relevant World Health Organization processes for recommending the use of pandemic-related health products.

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

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

(a) cooperate with a view to align, where appropriate, relevant technical and regulatory requirements in accordance with applicable international standards and guidance; and

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

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, access to research, and rapid sharing of research information and results, especially during public health emergencies of international concern, including pandemic emergencies.

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

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

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

(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 the WHO Pandemic Agreement, including during pandemic emergencies;

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

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

(g) the participation of relevant stakeholders in accelerating research and development.

3. Each Party shall, in accordance with its national or domestic circumstances and law, and taking into account relevant national and international ethical guidelines and guidance, promote, during public health emergencies of international concern, including pandemic emergencies, the conduct of well-designed and well-implemented clinical trials in its jurisdiction, including by: (i) promoting representative trial populations; (ii) promoting, as appropriate, sharing of pandemic-related vaccines, therapeutics and diagnostics for use as comparator products[10] in the conduct of clinical trials of pandemic-related vaccines, therapeutics and diagnostics; and (iii) promoting access

[10] For the purposes of this paragraph, "comparator product" means an investigational or marketed product (i.e., active control), or placebo, used as a reference in a clinical trial.

to safe and effective products that result from these trials for such trial populations and for populations at risk in its communities.

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

5. Each Party shall develop and implement national and/or regional policies, adapted to its domestic circumstances, regarding the inclusion of provisions in publicly funded research and development grants, contracts, and other similar funding arrangements, particularly with private entities and public-private partnerships, for the development of pandemic-related health products, that promote timely and equitable access to such products, particularly for developing countries, during public health emergencies of international concern, including pandemic emergencies, and regarding the publication of such provisions. Such provisions may include: (i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) provisions enabling access to technology to facilitate research and development and geographically diversified local production (iv) publication of relevant information on clinical trial protocols and relevant research results; and (v) adherence to product allocation frameworks adopted by the World Health Organization.

Article 10 Sustainable and geographically diversified local production

1. The Parties shall take measures, as appropriate, to achieve more equitable geographical distribution and rapid scale-up of the global production of pandemic-related health products and increase sustainable, timely and equitable access to such products, as well as reduce the potential gap between supply and demand during pandemic emergencies, including through the measures provided in Articles 11 and 13.

2. The Parties, in collaboration with the World Health Organization and other relevant organizations, shall, as appropriate and subject to national and/or domestic law:

(a) take measures, to provide support for, and/or strengthen, existing or newly created production facilities of relevant health products, at national and regional levels, particularly in developing countries, with a view to promoting the sustainability of such geographically diversified production facilities, including through supporting and/or facilitating skills development, capacity-building and other initiatives for production facilities;

(b) facilitate the continuous and sustainable operations of local and regional manufacturers, especially of developing countries, including through promoting transparency of relevant information on pandemic-related health products and raw materials across the value chain that is not subject to protection under relevant domestic and international law;

(c) actively support relevant World Health Organization technology, skills and knowledge transfer and local production programmes, including those referenced in Article 11, and other relevant programmes, to facilitate sustainable, and strategically and geographically distributed, production of pandemic-related health products, particularly in developing countries;

(d) promote or incentivize public and private sector investments, purchasing arrangements, and partnerships, including public-private partnerships, aimed at creating or expanding manufacturing facilities or capacities for pandemic-related health products, including facilities with a regional operational scope in developing countries;

(e) encourage international organizations and other relevant organizations to establish arrangements, including appropriate long-term contracts for pandemic-related health products, including through procurement from facilities referenced under subparagraph 2(a) of this Article and pursuant to the objectives of Article 13, especially those produced by local and/or regional manufacturers in developing countries; and

(f) during pandemic emergencies, in cases where the capacity of facilities referred to in subparagraph 2(a) of this Article does not meet demand, take measures to identify and contract with manufacturers with the aim of rapidly scaling up the production of pandemic-related health products.

3. The World Health Organization shall, upon request of the Conference of the Parties, provide assistance to the facilities referenced under paragraph 2 of this Article, 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 cooperation on related know-how for the production of pandemic-related health products

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

(a) promote and otherwise facilitate or incentivize, transfer of technology as mutually agreed,[11] including transfer of relevant knowledge, skills, technical expertise, and cooperation on any other related know-how for production of pandemic-related health products, in particular for the benefit of developing countries, through measures which may include, inter alia, licensing, capacity-building, relationship facilitating, incentives or conditions linked to research and development, procurement or other funding and regulatory policy measures;

(b) take measures to enhance the availability of licences for pandemic-related health technologies to which it owns the rights, on a non-exclusive, transparent and broad geographic basis and for the benefit of developing countries, where and as feasible, in accordance with national and/or domestic law, and international law and encourage private rights holders to do the same;

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

[11] See footnote 8.

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

(e) promote the transfer of relevant technology as mutually agreed,[12] including transfer of relevant knowledge, skills and technical expertise, for pandemic-related health products by private rights holders, to established regional or global technology transfer hubs, coordinated by the World Health Organization, or other mechanisms or networks; and

(f) during pandemic emergencies, encourage manufacturers to share information, relevant to the production of pandemic-related health products, in accordance with national and/or domestic law and policies.

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

3. The Parties shall cooperate, as appropriate, with regard to time-bound measures to which they have agreed within the framework of relevant international and regional organizations to which they are a party, to accelerate or scale up the manufacturing of pandemic-related health products, to the extent necessary to increase the availability, accessibility and affordability of pandemic-related health products during pandemic emergencies.

4. The Parties that are World Trade Organization members reaffirm that they have the right to use, to the full, the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights and the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics. The Parties shall respect the use of these flexibilities that is consistent with the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights.

5. The Parties shall, in collaboration with the World Health Organization, identify, assess and, as appropriate, strengthen and/or develop mechanisms and initiatives that promote and facilitate the transfer of technology as mutually agreed,[13] with a view to increasing access to pandemic-related health products, particularly in developing countries, including through the pooling of intellectual property, relevant knowledge, skills and technical expertise and data and transparent, non-exclusive licensing. Such mechanisms may, where appropriate, be coordinated by the World Health Organization, in collaboration with other relevant mechanisms and organizations, enabling increased participation of manufacturers from developing countries.

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

[12] See footnote 8.

[13] See footnote 8.

Article 12 Pathogen Access and Benefit-Sharing System

1. Recognizing the sovereign right of States over their biological resources and the importance of collective action to mitigate public health risks, and underscoring the importance of promoting the rapid and timely sharing of "materials and sequence information on pathogens with pandemic potential" (hereinafter "PABS Materials and Sequence Information") and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes, the Parties hereby establish a multilateral system for safe, transparent, and accountable access and benefit-sharing for PABS Materials and Sequence Information, the "WHO Pathogen Access and Benefit-Sharing System" (hereinafter the "PABS System"), to be developed pursuant to paragraph 2 of this Article.

2. The provisions governing the PABS System, including definitions of pathogens with pandemic potential and PABS Materials and Sequence Information, modalities, legal nature, terms and conditions, and operational dimensions, shall be developed and agreed in an instrument in accordance with Chapter III (hereinafter the "PABS Instrument") as an annex. The PABS Instrument shall also define the terms for the administration and coordination of the PABS System by the World Health Organization. For the purposes of the coordination and operation of the PABS System, the World Health Organization shall collaborate with relevant international organizations[14] and relevant stakeholders. All elements of the PABS System shall come into operation simultaneously in accordance with the terms of the PABS Instrument.

3. Taking into account the differences in the use of PABS Materials and Sequence Information, the development of a safe, accountable and transparent PABS System shall address traceability measures and open access to data.

4. Having regard to Article 4.4 of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their utilization to the Convention on Biological Diversity (hereinafter the "Nagoya Protocol"), the PABS Instrument shall be consistent with, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol, recognising that nothing in this paragraph creates obligations under these instruments for non-Parties thereto.

5. The PABS Instrument referred to in paragraph 2 of this Article, shall contain provisions regarding, inter alia, the following:

(a) the rapid and timely sharing of PABS Materials and Sequence Information and, on an equal footing, the rapid, timely, fair and equitable sharing of benefits, both monetary and non-monetary, including annual monetary contributions, vaccines, therapeutics and diagnostics arising from the sharing and/or utilization of PABS Materials and Sequence Information for public health purposes;

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

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

[14] In the context of collaboration with the World Health Organization, "relevant international organizations" is understood in accordance with the Constitution of the World Health Organization.

(d) development and implementation in a manner:

(i) complementary to, and not duplicative of, the access and benefit sharing measures and obligations of the Pandemic Influenza Preparedness Framework and other relevant international access and benefit sharing instruments, where applicable; and

(ii) to ensure that each Party reviews and, as it deems appropriate, aligns its national and/or regional access and benefit sharing measures applicable to PABS Materials and Sequence Information within the scope of the PABS Instrument, so that measures that are contrary to, or inconsistent with, or duplicative of, the PABS Instrument will not be applied upon entry into operation of all elements of the PABS System.

(e) implementation consistent with applicable international law and with applicable national and/or domestic law, regulations and standards related to risk assessment, biosafety, biosecurity and export control of pathogens, and data protection; and

(f) implementation in a manner to facilitate the manufacture and export of vaccines, therapeutics and diagnostics for pathogens covered by the PABS Instrument.

6. The PABS System, as set out in the Annex referred to in paragraph 2 of this Article, shall provide, inter alia, that in the event of a pandemic emergency, as determined in accordance with Article 12 of the International Health Regulations (2005):

(a) each participating manufacturer[15] shall make available to the World Health Organization, pursuant to legally binding contracts signed with the World Health Organization, rapid access targeting 20% of their real time production of safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the pandemic emergency, provided that a minimum threshold of 10% of their real time production is made available to the World Health Organization as a donation, and the remaining percentage, with flexibility based on the nature and capacity of each participating manufacturer, is reserved at affordable prices to the World Health Organization; and

(b) the distribution of these vaccines, therapeutics, and diagnostics shall be on the basis of public health risk and need, with particular attention to the needs of developing countries, and the Global Supply Chain and Logistics Network referred to in Article 13 may be used to this end.

7. The PABS Instrument shall also include benefit sharing provisions, in the event of a public health emergency of international concern as determined in accordance with Article 12 of the International Health Regulations (2005), including options regarding access to safe, quality and effective vaccines, therapeutics, and diagnostics for the pathogen causing the public health emergency of international concern, pursuant to legally binding contracts signed by participating manufacturers with the World Health Organization.

[15] The term “participating manufacturer” to be defined in the PABS instrument.

8. The PABS Instrument shall also include additional benefit sharing provisions to be set out in legally binding contracts signed with the World Health Organization, including options for:

(a) Capacity-building and technical assistance;

(b) research and development cooperation;

(c) facilitating rapid access to available vaccines, therapeutics and diagnostics with a view to responding to public health risks and events in the context of Article 13.3 of the International Health Regulations (2005);

(d) the granting of non-exclusive licences to manufacturers in developing countries, for the effective production and delivery of vaccines, therapeutics and diagnostics; and

(e) other forms of transfer of technology as mutually agreed,[16] including transfer of relevant knowledge, skills and technical expertise.

9. This Article is without prejudice to consideration of other elements for the effective operationalization of the PABS System in a fair, transparent, accountable and equitable manner.

Article 13 Supply chain and logistics

1. The "Global Supply Chain and Logistics Network" (hereinafter the "GSCL Network") is hereby established to enhance, facilitate, and work to remove barriers and ensure equitable, timely, rapid, safe, and affordable access to pandemic-related health products for countries in need during public health emergencies of international concern, including pandemic emergencies, and for prevention of such emergencies. The GSCL Network shall be developed, coordinated and convened by the World Health Organization in full consultation with the Parties, World Health Organization Member States that are not Parties, and in partnership with relevant stakeholders, under the oversight of the Conference of the Parties. The Parties shall prioritize, as appropriate, sharing pandemic-related health products through the GSCL Network for equitable allocation based on public health risk and need, in particular during pandemic emergencies.

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

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

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

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

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

[16] See footnote 8.

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

3. The functions of the GSCL Network shall include, inter alia, subject to further decision-making by the Conference of the Parties with respect to further tasks that may be assigned to the GSCL Network:

(a) identification of pandemic-related health products and relevant raw material sources;

(b) identification of barriers to their access;

(c) estimation of their supply and demand;

(d) facilitation of procurement of pandemic-related health products and relevant raw materials, including from facilities referenced under Article 10, during public health emergencies of international concern, including pandemic emergencies;

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

(f) promotion of transparency across the value chain;

(g) collaboration on stockpiling both during pandemic emergencies and inter-pandemic periods to, inter alia, promote the establishment of international and regional emergency stockpiles, strengthen existing stockpiles, facilitate effective and efficient stockpiling operations and increase equitable and timely access to pandemic-related health products;

(h) initiation and facilitation of the rapid release from international stockpiles of relevant health products in the event of outbreaks, especially to developing countries, to prevent outbreaks from progressing into public health emergencies of international concern, including pandemic emergencies; and

(i) facilitation of, and working to remove barriers to, timely and equitable access to pandemic-related health products, through allocation, distribution, delivery, and assistance with utilization, including for products provided to the PABS System, during public health emergencies of international concern, including pandemic emergencies, with special regard to needs in humanitarian settings.

4. The Conference of the Parties shall periodically review the functions and operations of the GSCL Network, including the support provided by the Parties, World Health Organization Member States that are not Parties to the WHO Pandemic Agreement, and relevant stakeholders, during and between pandemic emergencies and may provide further guidance related to its operations.

5. The World Health Organization, 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 14 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 access especially for developing countries, such as provisions regarding donation, delivery modification, licensing and global access plans.

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

4. The Parties recognize the importance of ensuring that emergency trade measures designed to respond to a pandemic emergency are targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or disruptions in supply chains.

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 order to support and facilitate the effective global distribution, delivery, and administration of pandemic-related health products.

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

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

Article 15 Whole-of-government and whole-of-society approaches

1. The Parties are encouraged to apply whole-of-government and whole-of-society approaches at the national level, including, according to national circumstances, 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 and facilitate the effective and meaningful engagement of Indigenous Peoples, communities, including local communities as appropriate, and relevant stakeholders, including through social participation, as part of a whole-of-society approach in planning, decision-making, implementation, monitoring and evaluation of policies, strategies and measures, and also provide feedback opportunities; and

(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 people in vulnerable situations, including by mobilizing social capital in communities for mutual support.

4. Each Party shall develop, in accordance with national and/or domestic context, comprehensive, multisectoral, and, as appropriate, regional, and national pandemic prevention, preparedness and response plan(s) that address pre-, post- and inter-pandemic periods, in a transparent and inclusive manner that promotes collaboration with relevant stakeholders.

5. Each Party shall promote and facilitate, where appropriate, and in accordance with national and/or domestic law and policy, the development and implementation of education and community engagement initiatives and programmes on pandemic and public health emergencies, with the participation of relevant stakeholders in a way that is inclusive and accessible, including to people in vulnerable situations.

Article 16 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 paragraphs 1 and 2 of this Article, the World Health Organization shall, as appropriate and upon request, continue to provide technical support to Parties, especially developing countries towards communication and public awareness of pandemic-related measures.

Article 17 International cooperation and support for implementation

1. The Parties shall cooperate, directly or through relevant international organizations, subject to national and/or domestic 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 transfer of technology as mutually agreed,[17] including transfer of relevant knowledge, skills, and technical expertise, 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 the WHO Pandemic Agreement, and shall be facilitated, as appropriate, by the World Health Organization in collaboration with relevant organizations upon the request of the Party, to fulfil the obligations arising from this Agreement.

[17] See footnote 8.

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

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

Article 18 Sustainable financing

1. The Parties shall strengthen sustainable and predictable financing to the extent feasible, in an inclusive and transparent manner, for the implementation of the WHO Pandemic Agreement.

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

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

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

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

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

3. A “Coordinating Financial Mechanism” (hereinafter “the Mechanism”) is hereby established to promote sustainable financing for the implementation of the WHO Pandemic Agreement, to support strengthening and expanding capacities for pandemic prevention, preparedness and response, and contribute to the prompt availability of surge financing response necessary as of day zero, particularly in developing country Parties. The Coordinating Financial Mechanism established under the International Health Regulations (2005) shall be utilized as the Mechanism to serve the implementation of the WHO Pandemic Agreement, in a manner determined by the Conference of the Parties. In this regard, and for the purposes of the implementation of the WHO Pandemic Agreement:

(a) the Mechanism shall function under the authority and guidance of the Conference of the Parties and be accountable to it;

(b) the Mechanism’s operation may be supported by one or more international entities to be selected by the Conference of the Parties. The Conference of the Parties may adopt necessary working arrangements with other international entities; and

(c) the Conference of the Parties shall adopt by consensus terms of reference for the Mechanism and modalities for its operationalization and governance in relation to the implementation of the WHO Pandemic Agreement, within 12 months after entry into force of the WHO Pandemic Agreement.

4. In giving effect to paragraph 3 of this Article, the Conference of the Parties shall request the Mechanism to, 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 WHO Pandemic Agreement, which shall be submitted to the Conference of the Parties for its consideration;

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

(c) identify all sources of financing that are available to serve the purposes of supporting the implementation of the WHO Pandemic Agreement, and maintain a dashboard of such sources and related information and the funds allocated to countries from these sources;

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

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

5. The Conference of the Parties shall take appropriate measures to give effect to this Article, including the possibility of exploring additional financial resources to support the implementation of the WHO Pandemic Agreement, through all sources of funding, existing and new, including innovative sources and those beyond official development assistance.

6. The Conference of the Parties shall periodically consider, as appropriate, the financial and implementation strategy for the WHO Pandemic Agreement referred to in subparagraph 4(a) of this Article. The Parties shall endeavour to align with the aforementioned strategy, as appropriate, when providing external financial support for the strengthening of pandemic prevention, preparedness and response.

Chapter III. Institutional arrangements and final provisions

Article 19 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, including by engaging with the States Parties Committee for the Implementation of the International Health Regulations (2005).

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. The Conference of the Parties may establish subsidiary bodies, and determine the terms and modalities of such bodies, as well as decide upon delegating functions to bodies established under other agreements adopted under the Constitution of the World Health Organization, as it deems appropriate.

5. The Conference of the Parties at its second meeting shall consider and approve the establishment of a mechanism to facilitate and strengthen effective implementation of the provisions of the WHO Pandemic Agreement. In doing so, the Conference of the Parties may take into account other relevant mechanisms, including those under the International Health Regulations (2005).

6. This mechanism shall:

(a) be facilitative in nature, and function in a manner that is transparent, cooperative, non-adversarial, non-punitive and cognizant of respective national circumstances;

(b) consider the reports referred to in Article 21.1, and make non-binding recommendations, including on support to be given to a Party to facilitate implementation;

(c) operate under the rules of procedure/terms of reference adopted by consensus by the Conference of the Parties at its second meeting; and

(d) report periodically to the Conference of the Parties.

7. 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.

8. 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.

9. The Conference of the Parties shall adopt by consensus its financial rules, which shall be applied to any subsidiary bodies it may establish, and shall consider for that purpose the Financial Regulations and Rules of the World Health Organization. It shall adopt by consensus a budget for each financial period.

Article 20 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. 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 21 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 the WHO Pandemic Agreement.

2. The information required, frequency and format of the reports in paragraph 1 of this Article 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 22 Secretariat

1. The Secretariat of the World Health Organization 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 Secretariat of the World Health Organization shall, under the guidance of the Conference of the Parties, ensure the necessary coordination, as appropriate, with the competent international and regional intergovernmental organizations and other relevant bodies.

2. Nothing in the WHO Pandemic Agreement shall be interpreted as providing the Secretariat of the World Health Organization, including the Director-General of the World Health Organization, any authority to direct, order, alter or otherwise prescribe the national and/or domestic law, 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 23 Settlement of disputes

1. In the event of a dispute between two or more Parties concerning the interpretation or application of the WHO Pandemic Agreement, the Parties concerned shall seek through diplomatic channels a settlement of the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation, or conciliation. In case of failure to reach a solution by the methods mentioned above, the Parties, if they so agree in writing, may resort to arbitration in accordance with the Permanent Court of Arbitration, 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 29 within the scope of the WHO Pandemic Agreement as between the Parties to the protocol, unless otherwise provided therein.

Article 24 Relationship with other international agreements

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) and other relevant international agreements should be interpreted so as to be compatible.

3. The provisions of the WHO Pandemic Agreement shall not affect the rights and obligations of any Party deriving from other international agreements and legal instruments.

Article 25 Reservations

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

Article 26 Declarations and statements

1. Article 25 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 27 Amendments

1. Any Party may propose amendments to the WHO Pandemic Agreement, including its annexes, and such amendments shall be considered by the Conference of the Parties.

2. The Conference of the Parties may adopt amendments to the WHO Pandemic Agreement. The text of any proposed amendment to the WHO Pandemic Agreement shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption. The Secretariat shall also communicate proposed amendments to the signatories of the WHO Pandemic Agreement and, for information, to the Depositary.

3. The Parties shall make every effort to adopt any proposed amendment to the WHO Pandemic Agreement by consensus. If all efforts at consensus have been exhausted and no agreement has been reached, the amendment may as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session. For the purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote. Any

adopted amendment shall be communicated by the Secretariat to the Depositary, which shall circulate it to all Parties for acceptance.

4. Instruments of acceptance in respect of an amendment shall be deposited with the Depositary. An amendment adopted in accordance with paragraph 3 of this Article shall enter into force, for those Parties having accepted it, on the ninetieth day after the date of receipt by the Depositary of an instrument of acceptance by at least two thirds of the Parties to the WHO Pandemic Agreement at the date of the adoption of the amendment.

5. An amendment shall enter into force for any other Party on the ninetieth day after the date on which that Party deposits with the Depositary its instrument of acceptance of the said amendment.

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

Article 28 Annexes

1. 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.

2. Annexes to the WHO Pandemic Agreement proposed after its entry into force shall be proposed, adopted and shall enter into force in accordance with the procedure set forth in Article 27.

3. Notwithstanding paragraph 2 of this Article, for annexes of a procedural, scientific, technical or administrative nature, the Conference of the Parties may decide that the following procedure for acceptance and entry into force applies:

(a) Any Party that does not accept such an annex or its amendment shall so notify the Depositary of its non-acceptance, in writing, within six months from the date of the communication of the adoption by the Depositary. The Depositary shall without delay notify all Parties of any such notification received. A Party may at any time substitute an acceptance for a previous notification of non-acceptance and the annex shall thereupon enter into force for that Party;

(b) On the expiry of six months from the date of the communication of the adoption by the Depositary, the annex shall enter into force for all Parties which have not submitted a notification of non-acceptance in accordance with the provision of subparagraph 3(a) of this Article.

4. The same procedure shall also apply for any amendments to such annexes of a procedural, scientific, technical or administrative nature.

Article 29 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 27.3 shall apply, *mutatis mutandis*.

3. The text of any proposed protocol shall be communicated to the Parties by the Secretariat at least six months before the session of the Conference of the Parties at which it is proposed for adoption.

4. Only Parties to the WHO Pandemic Agreement may be parties to a protocol to the WHO Pandemic Agreement.

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. Any protocol to the WHO Pandemic Agreement shall be interpreted together with the WHO Pandemic Agreement, taking into account the purpose of the WHO Pandemic Agreement and of that protocol.

7. 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 30 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 this 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 Party's withdrawal shall not in any way affect the duty of any Party to fulfil any obligation embodied in the WHO Pandemic Agreement to which it would be subject under international law independently of this Agreement.

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

Article 31 Signature

1. The WHO Pandemic Agreement shall be open for signature by all States and by regional economic integration organizations.

2. The WHO Pandemic Agreement shall be open for signature after adoption of the Annex described in Article 12.2 of this Agreement by the Health Assembly, at the World Health Organization Headquarters in Geneva, and thereafter at the United Nations Headquarters in New York, on dates to be determined by the Health Assembly.

Article 32 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. The WHO Pandemic Agreement shall be open for accession from the day after the date on which this 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 this 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 this 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 33 Entry into force

1. The WHO Pandemic 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.

Article 34 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 35 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.
