

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

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Proposal for negotiating text

of the WHO Pandemic Agreement

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The Parties to the WHO Pandemic Agreement,

- 1. *Recognizing* that the World Health Organization is fundamental to strengthening pandemic prevention, preparedness and response, as it is the directing and coordinating authority on international health work on human health which, alongside the World Organisation for Animal Health, the United Nations Environment Programme, and the Food and Agriculture Organisation, is a key member of the Quadripartite via which the four organizations signed an agreement to strengthen cooperation to sustainably balance and optimize the health of human, animal, plants and the environment.
- 2. *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,
- 3. *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 cooperation in an effective, coordinated, appropriate and comprehensive international response, while reaffirming the principle of sovereignty of States Parties in addressing public health matters,
- 4. *Noting* with concern that the coronavirus disease (COVID-19) pandemic revealed serious shortcomings in preparedness at national and global levels for the timely and effective prevention and detection of, and response to, health emergencies,
- 5. *Deeply* concerned by the gross inequities at <u>community</u>, national and international levels that hindered timely and equitable access to medical and other COVID-19 pandemic-related products, notably vaccines, oxygen supplies, personal protective equipment, diagnostics and therapeutics,
- 6. *Recognizing* the critical role of whole-of-government and whole-of-society approaches at country and community levels and the importance of international, regional and cross-regional collaboration, coordination and global solidarity in achieving sustainable improvements in pandemic prevention, preparedness and response,
- 7. *Recognizing* the importance of ensuring political commitment, resourcing and attention across sectors for pandemic prevention, preparedness and response,
- 8. *Reaffirming* the importance of multisectoral collaboration at national, regional and international levels to: safeguard human health; detect and prevent health threats at the animal, and human and environment interface, zoonotic spill-over and mutations; and to sustainably balance and optimize the health and well-being of people, animals and ecosystems in a One Health approach,

We would like to suggest including the following paragraph:

Noting that prevention at source costs a fraction of the cost of responding to a pandemic (source: Bernstein AS, Ando AW, Loch-Temzelides T, Vale MM, Li BV, Li H, Busch J, Chapman CA, Kinnaird M, Nowak K, et al. The costs and benefits of primary prevention of zoonotic pandemics. Sci Adv. 2022;4;8(5):eabl4183. https://www.science.org/doi/full/10.1126/sciadv.abl4183.).

- 9. *Reiterating* the need to work towards building and strengthening resilient health systems, with skilled and trained health and care workers, to advance universal health coverage and to adopt an equitable approach to mitigate the risk that pandemics exacerbate existing inequities in access to health services,
- 10. *Recognizing* that the protection of intellectual property rights is important for the development of new medical products, and *recalling* that intellectual property rights do not, and should not, prevent Member States from taking measures to protect public health, and further recognizing concerns about the effects

of intellectual property rights on prices,

- 11. *Underscoring* the importance of promoting the early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens with pandemic potential, as well as the fair and equitable sharing of benefits arising therefrom, taking into account relevant national and international laws, regulations, obligations and frameworks, including the International Health Regulations, the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and the Pandemic Influenza Preparedness Framework, and also mindful of the work being undertaken in other relevant areas and by other United Nations entities and multilateral organizations or agencies,
- 12. Acknowledging that pandemic prevention, preparedness and response at all levels and in all sectors, particularly in developing countries, require predictable, sustainable and sufficient financial, human, logistic and technical resources, and that unequal development across countries in the promotion of health and control of disease, especially communicable disease, is a common danger that requires support through international collaboration,
- 13. *Noting* the adoption of the Political Declaration of the United Nations General Assembly High-level Meeting on Pandemic Prevention, Preparedness and Response, during the 78th session of the United Nations General Assembly, which affirms the need to prioritize equity and respect for human rights and strengthen pandemic prevention, preparedness and response capacities,

We would like to suggest including the following paragraph:

<u>Recognizing</u> that the majority of emerging infectious diseases and pandemics are caused by zoonotic pathogens, and that preventing disease emergence and pathogen spillover at source represents the most effective and economic way of preventing future pandemics and achieving equity.

Have agreed as follows:

Chapter I. Introduction

Article 1. Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) "genetic sequences" means the order of nucleotides identified in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus;

(b) "genomics" means the study of the total or part of the genetic or epigenetic sequence information of organisms and attempts to understand the structure and function of these sequences and downstream biological products. Genomics in health examines the molecular mechanisms and the interplay of this molecular information, health interventions and environmental factors in disease;

(c) "infodemic" means too much information, false or misleading information, in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviours that can harm health. It also leads to mistrust in health authorities and undermines public health and social measures;

(d) "One Health approach" means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent. The approach mobilizes multiple sectors, disciplines and

communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development;

(e) "pandemic" means the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality and causing social and economic disruptions, all of which requires effective national and global collaboration and coordination for its control;

(f) "pandemic-related products" means products that are needed for pandemic prevention, preparedness and response, which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;

We would like to propose the inclusion of the following terms and definitions:

"pandemic prevention" - referring to the definition of "prevention of zoonotic spillover" by the One Health High Level Expert Panel means "prevention of pathogen spillover from animals to humans; shifting the infectious disease control paradigm from reactive to proactive (Primary prevention). Prevention includes addressing the drivers of disease emergence, namely ecological, meteorological and anthropogenic factors and activities that increase spillover risk, in order to reduce the risk of human infection. It is informed by, amongst other actions, biosurveillance in natural hosts, people and the environment, understanding pathogen infection dynamics and implementing intervention activities", i.e. measures taken by Parties in coordination with relevant stakeholders to address the root causes and drivers of infectious disease outbreaks as well as anticipate, contain, manage and eradicate the occurrence and spill-over of viruses and other pathogens from animals to other animals or humans in the first place. Preventing the spill-over of pathogens at their source aims to eliminate risk factors for the transmission of infectious diseases (which can turn into pandemics), especially through prolonged contact with animals at the time of pathogen shedding through handling, slaughter or consumption. Primary prevention aims to prevent disease before it occurs and therefore requires a just and equitable One Health approach that sustainably balances and optimizes the interdependent health of people, animals and ecosystems, and therefore addresses upstream factors, including supply-side and demand-side drivers of novel pathogens, emerging infectious diseases (EIDs) and pandemics at the human-animal-environment interface. This includes outcomes that promote better animal welfare and health as well as the cessation of high-risk practices including not trading in or marketing wild animals at regional, national, or international levels without first assessing the risks of any such practice to animal and/or human health and taking any necessary measures to mitigate such risks, implementing policies to enable a transition to sustainable, healthy and diverse food systems that are predominantly plant-based, by leveraging agroecology and high biodiversity practices for food and agriculture, phasing out fur farming and ending live animal markets including the dog and cat meat trade;

<u>"health for all" - defined by the WHO Council on Economics of Health for All, integrating</u> health, social, economic, financial and innovative aspects, bringing "health and well-being into the centre of how we think about purpose, value and development (...) building healthy societies that are just, inclusive, equitable and sustainable. (source: https://cdn.who.int/media/docs/defaultsource/council-on-the-economics-of-health-for-all/who-councileh4a_manifesto_09112021.pdf?sfvrsn=788671_5);

<u>"anti-microbial resistance (AMR)</u>" occurs when pathogens, such as bacteria and viruses, no longer respond to existing medicines. The more antimicrobials are used, the faster AMR develops. Intensive agriculture, accounting globally for over 70% of the use of antimicrobials is one of the leading causes of AMR, and it is recognised by experts and policymakers as a critical area of intervention to address this threat to public health (source:https://www.four-paws.org/get-involved/pandemics-and-animal-welfare/sustainable-food-systems-crucial-to-tackle-antimicrobial-resistance);

<u>"zoonotic disease/ zoonosis" - as defined by the WHO: "zoonoses are defined as those diseases</u> and infections naturally transmitted between people and vertebrate animals":

<u>"integrated surveillance" means the systematic and timely collection, validation, analysis,</u> <u>interpretation and dissemination of data – collected from and shared across human, animal and</u> <u>environmental sources at local, national and international level – to inform cross sectoral actions to</u> <u>prevent, prepare for, respond and recover from zoonotic and anti-microbial resistance related events;</u>

<u>"One Health surveillance" includes "integrated surveillance for known and unknown</u> pathogens", "more traditional disease-based surveillance", as well as the "surveillance of drivers of disease emergence to improve prevention and mitigation of spill-over events". (source: One Health <u>High Level Expert Panel via</u> <u>https://www.sciencedirect.com/science/article/pii/S2352771423001374);</u>

<u>"precautionary approach" - refers to adopting precautionary measures when threats of serious</u> <u>risks, damage or harm are likely even though full scientific certainty of the extent of the risk is not in</u> <u>place.</u>

(g) "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;

(h) "pathogen with pandemic potential" means any pathogen that has been identified to infect humans and that is potentially highly transmissible, capable of wide, uncontrollable spread in human populations, and highly virulent, making it likely to cause significant morbidity and/or mortality in humans;

(i) "persons in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk of infection, severity, disease, <u>exposure to outbreaks at the human-animal-environment interface</u>, or mortality <u>and those known to be at disproportionate risk of marginalization, discrimination or exposure to a range of harms</u>, in the context of a pandemic, including vulnerability due to discrimination on the basis of race, colour, sex, <u>gender</u>, <u>age</u>, <u>disability</u>, language, religion, political or other opinion, national or social origin, property, birth or other status;

(j) "recipient" means receivers of WHO Pathogen Access and Benefit-Sharing (WHO PABS) Material from the WHO coordinated laboratory network, such as manufacturers of vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic prevention, preparedness and response, as well as biotechnology firms, research institutions and academic institutions. Any manufacturer that enters into any contracts or formal agreements with recipients or laboratories in the WHO coordinated network for the purpose of using WHO PABS Material on the manufacturer's behalf for commercialization, public use or regulatory approval of that manufacturer's vaccines, diagnostics or pharmaceuticals shall also be considered a recipient for purposes of this Agreement;

(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;

(1) "WHO coordinated laboratory network" means the international network of laboratories, coordinated by WHO, that conduct year-round surveillance of pathogens with pandemic potential, assessing the risk of an emerging pathogen with pandemic potential and assisting in <u>prevention and</u> preparedness measures; and

(m) "WHO PABS Material" means a pathogen with pandemic potential, as defined herein, and the genetic sequence data of such pathogens with pandemic potential.

Article 2. Objective and scope

- 1. The objective of the WHO Pandemic Agreement, guided by equity, the right to health and the principles and approaches set forth herein, is to prevent, prepare for and respond to pandemics, with the aim of comprehensively and effectively addressing the systemic gaps and challenges that exist in these areas, at <u>community</u>, national, regional and international levels <u>in order to save lives</u>, protect <u>livelihoods and achieve health for all</u>.
- 2. In furtherance of its objective, the WHO Pandemic Agreement applies at all times.

Article 3. General principles and approaches

To achieve the objective of the WHO Pandemic Agreement and to implement its provisions, the Parties will be guided, inter alia, by the general principles and approaches set forth below.

We would like to suggest the inclusion of the following approach:

One Health offers an integrated, unifying, multisectoral approach to prevention, preparedness and response of pandemics. It is rooted in collaboration, communication, coordination and capacity building and enables the achievement of equity and health for all. It calls for following whole-of-society and whole-of-government approaches and strengthens Parties' capacities to implement the provisions of the pandemic agreement.

1. **Respect for human rights** – The implementation of this Agreement shall be with full respect for the dignity, human rights and fundamental freedoms of persons.

2. **Sovereignty** – States have, in accordance with the Charter of the United Nations and the general principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies.

3. **Equity** – Equity is at the centre of pandemic prevention, preparedness and response, both at the national level within States and at the international level between States. It requires, inter alia, specific measures to protect persons in vulnerable situations. Equity is enabled by protecting communities at greatest risk of health, social and economic consequences of pandemics – the communities who are in contact with animals and their pathogens, through preventing pathogen emergence at source by reducing reliance on high-risk activities, and by transitioning those who rely on such activities to alternative livelihoods. Equity includes the unhindered, fair, equitable and timely access to safe, effective, quality and affordable pandemic-related products and services, information, research, pandemic-related technologies and social protection.

4. **Responsibility** – Governments have a responsibility for the health of their peoples, and effective pandemic prevention, preparedness and response require global collective action.

5. **Recognition of different levels of capacity** – Countries have varying levels of pandemic prevention, preparedness and response capacities, which presents a common danger such that support to countries with

capacity needs is required, within the means and resources available.

6. **Solidarity** – Effective national, international, multilateral, bilateral and multisectoral collaboration, coordination and cooperation to achieve the common interest of a safer, fairer, more equitable and better prepared world to prevent, respond to and recover from pandemics.

7. **Transparency** – The effective prevention of, preparedness for and response to pandemics depends on the transparent, open and timely sharing of, access to and disclosure of accurate information, data and other relevant elements that may come to light, for risk assessment, prevention and control measures, and the research and development of pandemic-related products and services, including reports on sales revenues, prices, units sold, marketing costs and subsidies and incentives, consistent with national, regional and international privacy and data protection rules, regulations and laws.

8. Accountability – States are accountable for strengthening and sustaining their health systems' capacities and public health functions to provide adequate public health and social measures by adopting and implementing legislative, executive, administrative and other measures for fair, equitable, effective and timely pandemic prevention, preparedness and response. States are accountable to provide specific measures to protect persons in vulnerable situations.

9. **Inclusiveness** – The full and active engagement with, and participation of, communities and relevant stakeholders across all levels, consistent with relevant and applicable international and national guidelines, rules and regulations, including those relating to conflicts of interest, is essential to mobilize social capital, resources and adherence to public health and social measures, and to gain trust in governments and partners supporting pandemic prevention, preparedness and response.

10. **Science and evidence** – The best available science and evidence should inform and be the basis for pandemic prevention, preparedness and response, as well as public health decisions and development of plans.

11. **Proportionality** – Public health decisions for preventing, preparing for and responding to pandemics should be proportionate in a manner consistent with Article 2 of the International Health Regulations which states: "The purpose and scope of these Regulations are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade", where public health risks constitute 'necessary interference' and include measures aimed at primary prevention which may require restriction on trade in wild animals or products derived from them based on perception or estimation of risk, and the transition of people away from related activities,

12. **Privacy, data protection and confidentiality** – Implementation of this Agreement shall respect the right to privacy, including as such right is established under international law, and shall be consistent with each Party's national laws and international obligations regarding confidentiality, privacy and data protection, as applicable.

We would like to propose the inclusion of the following principles:

Access to information – countries and stakeholders recognize the importance of free flow of knowledge and science-based information and materials, especially those aimed at the promotion of prevention, preparedness, and response to outbreaks and pandemics.

<u>Community engagement</u> – Parties are responsible to support communities in prevention, preparedness, response and recovery of health systems as part of the whole-of-society approach essential to mobilize social capital, resources, adherence to public health and social measures, and to support pandemic

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

Article 4. Pandemic prevention and <u>integrated and public health surveillance</u>

1. The Parties shall cooperate with one another in bilateral, regional and multilateral settings, in the development and strengthening of pandemic prevention and public health surveillance capacities.

2. The Parties should take actions to strengthen multisectoral, coordinated data interoperability and support the adoption of relevant international data standards in the development of the prevention and <u>integrated One Health and public health surveillance capacities</u>, with particular regard to the strengthening of developing countries' capacities.

3. The Parties shall cooperate, with the support of the WHO Secretariat <u>and relevant institutions</u>, to strengthen and maintain <u>veterinary and</u> public health laboratory and diagnostic capacities, especially in respect of the capacity to perform genetic sequencing, data science to assess the risks of detected pathogens and to safely handle samples containing pathogens, and the use of related digital tools.

4. Each Party shall develop, strengthen, implement, periodically update and review comprehensive multisectoral national prevention and <u>integrated One Health and public</u> health surveillance plans, that are <u>complementary to</u>, consistent with and supportive of the effective implementation of the International Health Regulations <u>and other relevant instruments</u>. To this end, each Party shall, in accordance with its capabilities <u>and where needed</u>, through bilateral, regional and multilateral cooperation including the support of the Quadripartite institutions, as well as means of implementation:

We would like to suggest adding the following paragraphs:

<u>develop a national multisectoral coordinating mechanism to develop and implement</u> <u>effective holistic strategies</u>

develop primary prevention strategies to prevent pathogen spill-over and address anthropogenic drivers of outbreaks, including through the adoption of a highly precautionary approach to high-risk activities, such as wildlife trade, habitat destruction or intensive animal agriculture, and the elimination or reduction of such activities and the transition of people reliant on them to alternative activities;

(a) develop, strengthen and maintain the capacity to: (i) detect, identify and characterize pathogens presenting significant risks; and (ii) conduct risk assessment of such pathogens and vectorborne diseases to <u>identify factors that must be addressed to</u> prevent spill-over in human and animal populations and cause serious diseases leading to pandemic situations,

(b) strengthen efforts to ensure access to safe water, sanitation and hygiene, including in hard-toreach settings in the Party's territory;

(c) ensure the implementation of effective infection prevention and control measures, applying as far as possible the applicable international standards and guidelines <u>as well as calling for the</u> <u>development of standards and guidelines where necessary;</u>

(d) strengthen efforts to ensure the sound management of wastes from health facilities and require health care institutions to have in place a regularly updated infection prevention and control programme;

(e) strengthen animal <u>health and welfare and</u> disease preventive measures <u>including but not</u> <u>limited to biosecurity, nutrition, keeping and breeding conditions of animals, access to animal health</u> <u>services for communities, surveillance at critical points such as farms, markets and border crossings</u> and monitor and mitigate environmental factors associated with the risk of zoonotic disease spillover and spill-back <u>taking into account the relevant international standards</u>;

(f) strengthen laboratory biosafety and biosecurity, including in research facilities, in order to prevent the accidental exposure, misuse or inadvertent laboratory release of pathogens, through biosecurity training and practices, regulating access to sensitive locations and strengthening transportation security and cross-border transfer, in accordance with applicable rules and standards; and

(g) take actions to prevent outbreaks due to pathogens that are resistant to antimicrobial agents, and, in accordance with national context, develop and implement a national One Health action plan for pandemic prevention, preparedness and response that includes an antimicrobial resistance component

(h) strengthen protocols for intelligence and data sharing across human health, animal health and environment sectors at all levels for effective surveillance.

5. Each Party shall develop, strengthen and maintain capacity to carry out integrated public health surveillance, including in respect of infectious diseases in humans, and animals that present significant risks of zoonotic diseases spill-over and incorporate preventive measures in their national plans.

Article 5. One Health

1. The Parties commit to promote and implement a One Health approach for pandemic prevention, preparedness and response <u>at national</u>, regional and global level, that is coherent, integrated, coordinated and collaborative among all relevant actors <u>including the Quadripartite institutions</u>, with the application of, and in accordance with, national law, and existing instruments and relevant international guidelines such as the One Health Joint Plan of Action in order to prevent and mitigate the transmission and further spread of <u>diseases</u>.

2. The Parties shall promote and enhance synergies between multisectoral and transdisciplinary collaboration at the national level and cooperation at the international level, in order to identify and conduct risk assessments at the interface between human, animal and environment ecosystems, while recognizing their interdependence with the aim of addressing those risks, and with applicable sharing of the benefits, per the terms of Article 12 herein.

3. The Parties commit to identify and address the <u>hotspots and</u> drivers of pandemics and the emergence and re- emergence of disease at the human-animal-environment interface through the identification and integration of interventions into relevant pandemic prevention, preparedness plans, and, where appropriate, according to national legislation and capacity, <u>and</u> through the strengthening synergies with other relevant instruments <u>in order to reduce the likelihood of zoonotic outbreaks in animal and human populations and spillover events</u>. <u>These drivers include but are not limited to commercial wildlife trade and husbandry, live</u> <u>animal markets</u>, factory farming, habitat encroachment and biodiversity loss</u>.

4. Each Party shall, in accordance with national context and to the extent necessary, protect human, animal, and plant and environmental health by:

(a) implementing science-based actions, <u>including focusing on</u> but not limited to: <u>identifying and</u> <u>addressing drivers and hotspots</u>, improving<u>-infection</u> <u>spill-over</u> prevention <u>and infection</u> and control

measures; antimicrobial research and development; access to, <u>prudent use</u> and stewardship of antimicrobials<u>in animal and human health sectors</u>; and harmonization of surveillance, in order to prevent, reduce the risk of, and prepare for, pandemics;

(b) fostering and implementing actions at national and community levels that encompass wholeof-government and whole-of-society approaches to <u>prevent control</u> zoonotic outbreaks, including through the engagement of communities to identify high-risk activities and a transition to alternative behaviours and livelihoods, and in surveillance to identify zoonotic outbreaks;

(c) taking a One Health approach into account in order to produce <u>and share knowledge and</u> science-based evidence, including that which is related to social and behavioural sciences, and risk communication and community engagement; and

(d) promoting or establishing One Health joint training and continuing education programmes for human, animal and environmental health workforces <u>including frontline workers interacting with</u> <u>wildlife or domesticated animals</u>, needed to build complementary skills, capacities and capabilities to prevent, detect, control and respond to pandemic health threats.

5. The Parties commit to develop, within the framework of relevant institutions, international norms and guidelines to prevent <u>pathogen spillover at source and zoonoses</u>tic <u>outbreaks in animal populations and spill-over events to human populations</u>.

6. Pursuant to Article 21 herein, the Conference of the Parties shall develop appropriate modalities to address the measures set forth in Articles 4 and 5 of this Agreement.

7. The Parties shall, in line with Article 16 herein, develop and implement or strengthen, as appropriate, bilateral, regional, subregional and other multilateral channels to enhance financial and technical support, assistance and cooperation, in particular in respect of developing countries, to <u>enable the implementation of</u> <u>One Health and prevention plans, as well as strengthen integrated One Health</u> surveillance systems and <u>public health and veterinary</u> laboratory capacity in respect of promoting and implementing a One Health approach at the national level.

Article 6. Preparedness, readiness and resilience

1. Each Party shall continue to strengthen its health system, including primary health care, for sustainable pandemic prevention, preparedness and response, taking into account the need for equity and resilience, with a view to the progressive realization of universal health coverage, and foster collaboration between human and animal health and care sectors to ensure preparedness across the human-animal interface.

2. Each Party shall, in accordance with applicable laws, including, where appropriate, the International Health Regulations, adopt policies, strategies and/or measures, as appropriate, and strengthen and reinforce public health functions for:

(a) the continued provision of quality routine and essential health services during pandemics;

(b) sustaining and strengthening the capacities of the multidisciplinary workforce needed during inter- pandemic periods, and preparing for and ensuring surge capacity during pandemics;

(c) collaborative <u>and integrated</u> surveillance <u>including but not limited to at critical points such as</u> <u>farms</u>, <u>live animal markets and border crossings</u>, outbreak detection, investigation and control, through interoperable early warning and alert systems, and timely notification;

(d) multisectoral prevention of zoonoses, epidemic-prone diseases and emerging, growing or evolving public health threats with pandemic potential, notably at the human-animal-environment interface;

(e) the development of rehabilitation and post-pandemic health system recovery strategies;

(f) strengthening public health laboratory and diagnostic capacities, and national, regional and global networks, through the application of standards and protocols for public health laboratory biosafety and biosecurity;

(g) creating and maintaining up-to-date, universal, interconnected platforms and technologies for early detection, forecasting and timely information sharing, through appropriate capacities, including building digital health and data science capacities;

(h) creating and strengthening public health institutions at national, regional and international levels;

(i) strengthening public health emergency operations centres' capacities during interpandemic periods and during pandemic periods; and

(j) strengthening infection prevention and control.

3. The Parties shall cooperate, within available means and resources, to provide financial, technical and technological support, assistance, capacity-strengthening and cooperation, in particular in respect of developing countries, in order to strengthen health emergency prevention, preparedness and response and health system recovery, consistent with the goal of universal health coverage.

4. The Parties shall establish, building on existing arrangements as appropriate, genomics, risk assessment and laboratory networks in order to conduct surveillance and sharing of emerging pathogens with pandemic potential, pursuant to the terms and modalities established in Article 12 herein.

Article 7. Health and care workforce

1. Each Party, in line with its respective capacities, shall take the necessary steps to safeguard, protect, invest in and sustain a skilled, trained, competent and committed <u>multidisciplinary</u> health and care workforce, with the aim of increasing and sustaining capacities for pandemic prevention, preparedness and response, while maintaining quality essential health services and essential public health functions during pandemics. To this end, each Party shall, in accordance with national law:

(a) strengthen, pre-, in- and post-service competency-based education and training, deployment, remuneration, distribution and retention of the public health, health, <u>One Health</u> and care workforce, including community health workers and volunteers;

(b) address gender and youth disparities and inequalities and security concerns within the public health, health and care workforce, particularly in health emergencies, to support the meaningful representation, engagement, participation, empowerment, safety and well-being of all health and care workers, while addressing discrimination, stigma and inequality and eliminating bias, including unequal remuneration, and noting that women still often face significant barriers to reaching leadership and decision-making roles;

(c) strengthen efforts to address the safety of the health and care workforce, including by ensuring priority access to pandemic-related products during pandemics, minimizing disruptions to the

delivery of good quality essential health services, and developing and integrating effective measures to prevent and address violence and threats against health and care workers, their means of transport and equipment, as well as hospitals and other medical facilities, when preventing and responding to pandemics; and

(d) establish and maintain effective workforce planning systems to effectively and efficiently deploy trained health and care workers during pandemics;

We would like to suggest including the following paragraph:

Strengthen the animal health and care workforce capacity, and its collaboration with the human health workforce.

2. The Parties shall commit financial and technical support, assistance and cooperation, in particular in respect of developing countries, in order to strengthen and sustain a skilled and competent public health, health, veterinary, One Health and care workforce at the subnational, national and regional levels.

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

4. The Parties shall develop a network of training institutions, national and regional facilities, and centres of expertise to strengthen and sustain a skilled and competent public health, health and care workforce at subnational, national and regional levels.

Article 8. Preparedness monitoring and functional reviews

1. Each Party shall, in accordance with national laws and in the light of national context, develop and implement comprehensive, inclusive, multisectoral, resourced national plans and strategies for pandemic prevention, preparedness, response and health systems recovery, through collaboration between authorities responsible for human, animal and environmental health and well-being.

2. Each Party shall assess, no less than every five years, with technical support from the WHO Secretariat upon request, the functioning and readiness of, and gaps in, its pandemic preparedness, surveillance and multisectoral response capacity, logistics and supply chain management, and risk assessment, as well as measures to contain pathogen spread through identification and mitigation of high-risk activities involving animals, and shall support the conduct of, inter alia, appropriate simulation or tabletop exercises, and intra- and after-action reviews, based on the relevant tools and guidelines developed by WHO in partnership with relevant organizations.

3. The Parties shall, building on existing tools, develop and implement an inclusive, transparent, effective and efficient pandemic prevention, preparedness and response monitoring and evaluation system.

4. The Parties shall establish, no later than 31 December 2026, a global peer review mechanism to assess pandemic prevention, preparedness and response capacities and gaps, as well as levels of readiness, with the aim of promoting and supporting learning among Parties, best practices, actions and accountability, at the national, regional and global levels, to strengthen national health emergency preparedness and readiness capacities.

Article 9. Research and development

1. The Parties shall cooperate to build, strengthen and sustain geographically diverse capacities and

institutions for research and development, particularly in developing countries, and shall promote research collaboration and access to research through open science approaches for the rapid sharing of information and results.

2. To this end, the Parties shall promote:

(a) sustained investment in the research and development of <u>animal and</u> public health priorities, including for pandemic-related products, aimed at improving equitable access to and delivery of such products, and support for national and regional research institutions that can rapidly adapt and respond to research and development needs in case of a pandemic;

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

(c) participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential; and

(d) knowledge translation and evidence-based communication tools, strategies and partnerships relating to pandemic prevention, preparedness and response, including infodemic management, at local, national, regional and international levels.

3. The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop and sustain strong, resilient and appropriately resourced, national, regional and international research capabilities. To this end, the Parties shall:

- (a) increase clinical trial capacities, including by:
 - i. building and maintaining a skilled research workforce and infrastructure, as appropriate;
 - ii. strengthening clinical trial policy frameworks, particularly in developing countries;
 - iii. investing in the infrastructure and training of clinical research networks and the coordination of clinical trials through existing, new, or expanded clinical trial networks, including in developing countries, to be prepared to provide timely and appropriate responses to pandemics; and
 - iv. identifying and researching supply chain needs to rapidly mount and scale research responses during pandemic emergencies.

We would like to suggest to include the following paragraph:

In implementing Article 9 paragraphs 1-3 above, the Parties shall acknowledge the risks associated with research work and clinical trials involving animals, given the potential animal welfare, conservation and biodiversity impacts, which could in turn increase the risk of pathogen spillover to people involved in securing, producing, researching on and caring for those animals, and apply the 3Rs approach to the use of animals in research.

(b) ensure that clinical trials have equitable representation, considering racial, ethnic and gender diversity across the life cycle, and are designed to help to address geographical, socioeconomic and health disparities, to promote a better understanding of the safety and efficacy of pandemic-related

products for population subgroups;

(c) promote the sharing of information on national research agendas, including research and development priorities during pandemic emergencies, capacity-building activities and best practices on efficient and ethical clinical trials, including through the WHO Global Observatory on Health Research and Development;

(d) strengthen international coordination and collaboration in respect of clinical trials, through existing or new mechanisms, to support well-designed and well-implemented clinical trials;

(e) develop national policies to support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publication, while protecting privacy and health identifiers; and

(f) support new and existing mechanisms to facilitate the rapid reporting and interpretation of data from clinical trials, to develop or modify, as necessary, relevant clinical trial guidelines, including during a pandemic.

4. Each Party shall, in accordance with national laws and considering the extent of public funding provided, publish the terms of government-funded research and development agreements for pandemic-related products, including information on:

(a) research inputs, processes and outputs, including scientific publications and data repositories, with data shared and stored securely in alignment with findability, accessibility, interoperability, and reusability principles;

(b) the pricing of end-products, or pricing policies for end-products;

(c) licensing to enable development, manufacturing and distribution of pandemic-related products, especially in developing countries; and

(d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic.

Article 10. Sustainable production

1. The Parties, with a view to achieving a more equitable geographical distribution of the global production of pandemic-related products, and increasing the timely, fair and equitable access to safe, effective, quality and affordable pandemic-related products, thereby reducing the potential gap between supply and demand at the time of a pandemic, shall:

(a) take measures to identify and maintain production facilities at national and regional levels, as well as to facilitate the production, as appropriate, and in furtherance of the provisions of Article 13 herein, of pandemic-related products therein

(b) take measures to identify and contract with manufacturers other than those referenced in paragraph 1(a) of this article, for scaling up the production of pandemic-related products, during pandemics, in cases where the production and supply capacity of the production facilities does not meet demand;

(c) strengthen coordination with relevant international organizations, including <u>but not limited to</u> United Nations entities, on issues related to public health, intellectual property and trade, including the timely matching of supply to demand and mapping manufacturing capacities and demand; (d) encourage entities, including manufacturers within their respective jurisdictions, in particular those that receive significant public financing, to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licences to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries;

(e) actively support, participate in and/or implement, as appropriate, relevant WHO technology, skills and know-how transfer programmes and initiatives aimed at enabling developing countries to produce pandemic-related products, in order to facilitate strategically and geographically distributed production of pandemic-related products; and

(f) support public and private sector investments aimed at creating or expanding manufacturing facilities of pandemic-related products, especially facilities with a regional operational scope that are based in developing countries.

2. Each Party shall initiate or strengthen, as appropriate, the conduct of disease burden studies relevant to pathogens with pandemic potential, with a view to ensuring the sustainability of investments in facilities for the production of vaccines and therapeutics that could support pandemic response.

3. Each Party, in addition to the undertakings in paragraph 2 of this Article, shall:

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

(b) promote the publication, by private rights holders, of the terms of licensing agreements or technology transfer agreements for pandemic-related products; and

(c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks.

We would like to suggest to include the following paragraph:

In implementing Article 10 paragraphs 1-3 above, Parties shall acknowledge the need to develop manufacturing and distribution methodologies for pandemic-related products that minimise wider environmental impacts.

Article 11. Transfer of technology and know-how

1. The Parties, within a set time frame, working through the Conference of the Parties, shall strengthen existing, and develop innovative, multilateral mechanisms, including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how for the production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries.

2. The Parties shall:

(a) coordinate with, collaborate with, facilitate and incentivize the manufacturers of pandemic-related products to transfer relevant technology and know-how to manufacturer(s) on mutually agreed

terms as appropriate, including through technology transfer hubs and product development partnerships, and to address the need to develop new pandemic-related products in a short time frame;

(b) make available non-exclusive licensing of government-owned technologies, on mutually agreed terms as appropriate, for the development and manufacturing of pandemic-related products, and publish the terms of these licences;

(c) make use of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31*bis* of the TRIPS Agreement, and fully respect the use thereof by others;

(d) collaborate to ensure equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities;

(e) develop a database that provides the details of pandemic-related products for all known pandemic-potential diseases, including the technological specifications and manufacturing process documents for each product; and

(f) provide, within their capabilities, resources to support capacity-building for the development and transfer of relevant technology, skills and know-how, and to facilitate access to other sources of support.

3. During pandemics, each Party shall, in addition to the undertakings in paragraph 2 of this Article:

(a) commit to agree upon, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;

(b) encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, for a limited duration, the payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for the production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so; and

(c) encourage manufacturers within its jurisdiction to share undisclosed information, in accordance with paragraph 2 of Article 39 of the TRIPS Agreement, with qualified third-party manufacturers when the withholding of such information prevents or hinders urgent manufacture by qualified third parties of a pharmaceutical product that is necessary to respond to the pandemic.

4. The Parties shall, with a view to effective pandemic response, when engaged in bilateral or regional trade or investment negotiations, take steps so that the negotiated provisions do not interfere with the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health.

Article 12. Access and benefit-sharing

1. The Parties hereby establish a multilateral system for access and benefit sharing, on an equal footing, the WHO Pathogen Access and Benefit-Sharing System (WHO PABS System), to ensure rapid and timely risk assessment and facilitate rapid and timely development of, and equitable access to pandemic-related products for pandemic prevention, preparedness and response.

2. The WHO PABS System shall ensure rapid, systematic and timely sharing of WHO PABS Material, as well as, on an equal footing, timely, effective, predictable and equitable access to pandemic-related products, and other benefits, both monetary and non-monetary, based on public health risks and needs, to strengthen pandemic prevention, preparedness and response.

- 3. The Parties shall implement the WHO PABS System:
 - (a) in a manner to strengthen, expedite and not impede research and innovation;
 - (b) at all times, both during and between pandemics;
 - (c) in a manner to ensure mutual complementarity with the Pandemic Influenza Preparedness Framework; and
 - (d) with governance and review mechanisms, to be determined by the Conference of the Parties.
- 4. The WHO PABS System shall have the following components:
 - (a) WHO PABS Materials sharing:
 - i. Each Party, through its relevant public health authorities and authorized laboratories, shall, in a rapid, systematic and timely manner: (1) provide WHO PABS Material to a laboratory recognized or designated as part of an established WHO coordinated laboratory network; and (2) upload the genetic sequence of such WHO PABS Material to one or more publicly accessible database(s) of its choice, provided that the database has put in place an appropriate arrangement in respect of WHO PABS Materials.
 - ii. The WHO PABS System shall be consistent with international legal frameworks, notably those for the collection of patient specimens, material and data, and will promote findable, accessible, interoperable and reusable data available to all Parties.
 - iii. The Parties shall develop and use a Standard Material Transfer Agreement (a PABS SMTA), which may be concluded through electronic means, and which shall include relevant biosafety and biosecurity rules, to be used with the transfer of WHO PABS Materials from a laboratory recognized or designated as part of an established WHO coordinated laboratory network to any Recipient.
 - iv. Recipients of WHO PABS Material shall not seek to obtain any intellectual rights on WHO PABS Material.
 - (b) PABS multilateral benefit sharing:
 - i. Benefits, both monetary and non-monetary, arising from access to WHO PABS Materials, shall be shared fairly and equitably, pursuant to a PABS SMTA, which may be concluded through electronic means.
 - ii. The PABS SMTAs shall include, but not be limited to, the following monetary and nonmonetary benefit-sharing obligations:
 - 1. in the event of a pandemic, real-time access by WHO to a minimum of 20% (10% as a donation and 10% at affordable prices to WHO) of the production of safe, efficacious and effective pandemic-related products for distribution based on public health risks and needs, with the understanding that each Party that has manufacturing facilities that produce pandemic-related products in its jurisdiction shall take all necessary steps to facilitate the export of such pandemic-related products, in accordance with timetables to be agreed between WHO and

manufacturers; and

- 2. on an annual basis, contributions from Recipients, based on their nature and capacity, to the capacity development fund of the sustainable funding mechanism established in Article 20 herein.
- (c) The Parties shall also consider additional benefit-sharing options, including:
 - i. encouraging manufacturers from developed countries to collaborate with manufacturers from developing countries through WHO initiatives to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products;
 - ii. tiered-pricing or other cost-related arrangements, such as no loss/no profit loss arrangements, for purchase of pandemic-related products, that consider the income level of countries; and
 - iii. encouraging <u>of</u> laboratories in the WHO coordinated laboratory network to actively seek the participation of scientists from developing countries in scientific projects associated with research on WHO PABS Materials.

5. In the event that pandemic-related products are produced by a manufacturer that does not have a PABS SMTA under the WHO PABS System, it shall be understood that the production of pandemic-related products requiring the use of WHO PABS Materials, implies the use of the WHO PABS System. Accordingly, each Party, in respect of such a manufacturer operating within its jurisdiction, shall take all appropriate steps, in accordance with its relevant laws and circumstances, to require such a manufacturer to provide benefits in accordance with paragraph 4(b)(ii) of this Article.

6. The Parties shall develop a mechanism to ensure the fair and equitable allocation of pandemic-related products, based on public health risks and needs.

7. The Parties shall ensure that all components of the WHO PABS System are operational no later than 31 May 2025. The Parties shall review the operation and functioning of the WHO PABS System every five years.

8. The Parties shall ensure that the WHO PABS System is consistent with, supportive of, and does not run counter to the objectives of the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization thereto. The WHO PABS System will provide certainty and legal clarity to the providers and users of WHO PABS Materials. The WHO PABS System shall be recognized as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol.

Article 13. Global Supply Chain and Logistics Network

1. The WHO Global Supply Chain and Logistics Network (the WHO SCL Network) is hereby established. The WHO SCL Network will operate within the framework of WHO, in partnership and collaboration with relevant international, regional and other organizations, and be guided by equity and public health needs, paying particular attention to the needs of developing country Parties, while also taking into account the potential environmental impacts of pandemic-related product development and distribution, with a view to minimising such impacts.

2. The Conference of the Parties shall develop guidelines on modalities and collaboration for the

WHO SCL Network, which shall be aimed at ensuring close consultation among Parties and that functions are discharged by the organizations best placed to perform them.

3. The Parties shall support the WHO SCL Network's development and operationalization and participate in the WHO SCL Network, including through sustaining it at all times. The terms of the WHO SCL Network shall include:

(a) estimating, or, where possible determining, the most likely types and size/volume of products needed for robust pandemic prevention, preparedness and response, including the costs and logistics for establishing and maintaining strategic stockpiles of such products;

(b) assessing the anticipated demand for, mapping the sources of and maintaining a dashboard of manufacturers and suppliers, including surge capacities and relevant necessary raw materials, for the sustainable production of pandemic-related products;

(c) identifying the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms;

(d) working with national authorities to establish and maintain national and/or regional stockpiles of various pandemic response-related products, as well as maintaining the relevant logistic capacities and assessing them at regular intervals, and specifying the criteria to ensure that stockpiling is used only to address public health needs;

(e) facilitating the negotiation and agreement of advance purchase commitments and procurement contracts for pandemic-related products;

(f) promoting transparency in cost, pricing and all other relevant contractual terms along the supply chain;

(g) coordinating to avoid competition for resources among procuring entities, including regional organizations and/or mechanisms;

(h) mapping existing, and identifying needed, delivery and distribution options;

(i) establishing or operationalizing, as appropriate, international or regional stockpiles, consolidation hubs and staging areas;

(j) assisting buying countries in meeting the logistic requirements for the utilization of specific pandemic-related products; and

(k) facilitating or, as necessary, organizing the efficient delivery and appropriate utilization of pandemic-related products in beneficiary countries or in humanitarian settings.

4. Each Party shall take appropriate measures to reduce waste of pandemic-related products, including through the exchange and/or donation of products in order to maximize their use, while taking account of the needs of recipient countries.

5. Each Party shall, at the earliest reasonable opportunity and in accordance with applicable laws, make publicly available online the terms of government-funded purchase agreements for pandemic-related products in those instances in which the Party is directly entering into such purchase agreements.

6. Each Party shall, in its government-funded purchase agreements for pandemic-related products, to the fullest extent possible and in accordance with applicable laws, exclude confidentiality provisions that serve to limit the disclosure of terms and conditions.

7. The Parties recognize that any emergency trade measures in the event of a pandemic shall be targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.

8. The Parties shall commit to ensure rapid and unimpeded access of humanitarian relief personnel, as well as their means of transport, supplies and equipment, in accordance with international humanitarian law, and to respect the principles of humanity, neutrality, impartiality and independence for the provision of humanitarian assistance.

9. The Parties shall enable inclusive, equitable and effective cooperation and participation, and shall take all appropriate measures to undertake the foregoing no later than 31 May 2025.

Article 14. Regulatory strengthening

1. The Parties shall strengthen their national and regional regulatory authorities, including through technical assistance, with the aim of expediting regulatory approvals and authorizations and ensuring the quality, safety and efficacy of pandemic-related products.

2. 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 share relevant information and assessments concerning the quality, safety and efficacy of pandemic-related products with other Parties.

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

4. Each Party shall, in accordance with relevant laws, publicly disclose information on national and, if applicable, regional processes for authorizing or approving use of pandemic-related products, and any additional relevant regulatory pathways for such pandemic-related products that may be activated during a pandemic to increase efficiency, and update such information in a timely manner.

5. Each Party shall take steps to ensure that it has the legal, administrative and financial frameworks in place to support emergency regulatory approvals for the effective and timely regulatory approval of pandemic-related products during a pandemic.

6. Each Party shall, in accordance with relevant laws, encourage manufacturers to generate relevant data, contribute to the development of common technical documents, and diligently pursue regulatory authorizations and/or approvals of pandemic-related products with WHO listed authorities, other priority authorities and WHO.

Article 15. Compensation and liability management

1. Each Party shall develop national strategies for managing liability risks in its territory regarding the manufacturing, distribution, administration and use of novel vaccines developed in response to pandemics. Strategies may include, inter alia, the development of model contract provisions, vaccine injury compensation mechanisms, insurance mechanisms, policy frameworks and principles for the negotiation of procurement agreements and/or the donation of novel vaccines developed in response to pandemics, and

building expertise for contract negotiations in this matter.

2. The Conference of the Parties shall establish, within two years of the entry into force of the WHO Pandemic Agreement, using existing relevant models as a reference, no-fault vaccine injury compensation mechanism(s), with the aim of promoting access to financial remedy for individuals experiencing serious adverse events resulting from a pandemic vaccine, as well as more generally promoting pandemic vaccine acceptance. The Conference of the Parties shall further develop the mechanism(s), which may be regional and/or international, including strategies for funding the mechanism(s), through the modalities provided for in Article 20 herein.

3. 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 time-bound.

Article 16. International collaboration and cooperation

1. The Parties shall collaborate and cooperate with competent international and regional intergovernmental organizations and other bodies, <u>such as the Quadripartite</u>, as well as among themselves, in the formulation of cost-effective measures, procedures and guidelines for pandemic prevention, preparedness and response.

2. The Parties shall:

(a) promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness and response;

(b) support mechanisms that ensure that policy decisions are <u>coherent</u>, science- and evidence-based, <u>while adopting a precautionary approach to risk</u>;

(c) develop, as necessary, and implement policies that respect, protect and fulfill the human rights of all people;

(d) promote equitable representation on the basis of gender, geographical and socioeconomic status, as well as the equal and meaningful participation of young people and women;

(e) assist developing countries through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs for pandemic prevention, preparedness and response in line with the provisions set out in Article 19 herein; and

(f) encourage ceasefires in affected countries during pandemics to promote global cooperation against common global threats-; and

We would like to suggest adding the following paragraph:

ensure alignment with the SDGs and policy coherence and alignment between science-based objectives on prevention, preparedness and response with relevant institutions including the Quadripartite as well as international instruments and multilateral environmental agreements, including CBD, CITES and CMS.

Article 17. Whole-of-government and whole-of-society approaches at the national level

1. The Parties are encouraged to adopt whole-of-government and whole-of-society approaches, including to empower and ensure community ownership of, and contribution to, community readiness for and resilience to pandemic prevention, preparedness and response.

2. Each Party shall, in keeping with national capacities, establish, implement and adequately finance an effective national coordinating multisectoral mechanism.

3. Each Party shall, in accordance with national context, promote the effective and meaningful engagement of communities, civil society and other relevant stakeholders, including the private sector, as part of a whole-of-society approach in decision-making, implementation, monitoring and evaluation, and shall also provide effective feedback opportunities.

4. Each Party shall develop, in accordance with national context, comprehensive national <u>One Health</u> pandemic prevention, preparedness and response plans pre-, post- and interpandemic <u>inline with the One</u> <u>Health Joint Plan of Action</u> that, inter alia:

We would like to suggest adding the following paragraph:

include assessment of activities that increase risk, and measures to mitigate such risk thereby addressing pathogen spillover at source, adopting a precautionary approach;

(a) identify and prioritize populations for access to pandemic-related products and health services;

(b) support the timely and scalable mobilization of the multidisciplinary surge capacity of human and financial resources, and facilitate the timely allocation of resources to the frontline pandemic response;

(c) review the status of stockpiles and the surge capacity of essential public health and clinical resources, and surge capacity in the production of pandemic-related products;

(d) facilitate the rapid and equitable restoration of public health capacities and routine and essential health services following a pandemic; and

(e) promote collaboration with relevant stakeholders, including the private sector and civil society.

5. Each Party, based on national capacities, shall take the necessary steps to address the social, environmental and economic determinants of health, and the vulnerability conditions that contribute to the emergence and spread of pandemics, and shall prevent or mitigate the socioeconomic impacts of pandemics, including through measures aimed at transitioning people away from activities that increase risk of pathogen spillover, such as wildlife trade and intensive animal production.

6. Each Party shall take appropriate measures to 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.

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 information on pandemics and their effects and drivers, and combat false, misleading, misinformation or disinformation, including through effective international collaboration and cooperation as referred to in Article 16 herein.

2. The Parties shall, as appropriate, conduct research and inform policies on factors that hinder adherence to public health and social measures in a pandemic and trust in science and public health institutions.

3. The Parties shall promote and apply a <u>precautionary</u>, science- and evidence-informed approach to effective and timely risk assessment and public communication.

Article 19. Implementation capacities and support

1. The Parties shall cooperate, directly or through competent international bodies, <u>specifically the</u> <u>Quadripartite</u>, to strengthen their capacity to fulfill the obligations arising from this Agreement, taking into account especially the needs of developing country Parties. Such cooperation shall promote the transfer of technical, scientific and legal expertise and technology, as mutually agreed, to establish and strengthen sustainable pandemic prevention, preparedness and response capacities of all Parties.

2. Each Party shall, within the means and resources at their disposal, cooperate to raise financial resources for the effective implementation of the WHO Pandemic Agreement through bilateral and multilateral funding mechanisms.

3. The Parties shall give particular consideration to the specific needs and special circumstances of developing country Parties for financial and technical assistance to support the implementation of this Agreement.

4. The Parties shall, where a Party lacks the necessary capacity to implement specific provision(s) of this Agreement, work together to identify the most relevant partner(s) that can support the development of such capacities, and shall cooperate to ensure that the mechanism(s) identified in Article 20 herein provides the necessary financial resources.

Article 20. Financing

1. The Parties commit to sustainable financing for strengthening pandemic prevention, preparedness and response, noting that prevention costs a fraction of pandemic response and should therefore be prioritised. In this regard, each Party, within the means and resources at its disposal, shall:

(a) cooperate with other Parties, as appropriate, to raise sustainable financial resources for the effective implementation of this Agreement, especially supporting developing countries where needed, through bilateral and multilateral, regional or subregional funding mechanisms and matching activities that require support with respective funds through coordination among funding mechanisms that support activities that strengthen pandemic prevention, preparedness and response;

(b) plan and provide adequate financial support, in line with national fiscal capacities, for: (i) strengthening and sustaining capacities for pandemic prevention, preparedness and response; (ii) implementing <u>pandemic prevention</u>, <u>preparedness and response</u> national plans, programmes and priorities; and (iii) strengthening health systems and the progressive realization of universal health coverage for pandemic prevention, preparedness and response;

(c) prioritize and increase or maintain, including through greater collaboration between the health, finance and private sectors, as appropriate, domestic funding for pandemic prevention, preparedness and response;

(d) mobilize financial resources for international cooperation and assistance in respect of pandemic prevention, preparedness and response, in accordance with its capacities and based on the principle of solidarity, particularly for developing countries, including through international organizations and existing and new mechanisms; and

(e) provide support and assistance to other Parties, upon request, to facilitate <u>prevention of</u> <u>pathogen spill-over at source</u>, and the containment of spill-over <u>should it occurat the source</u>.

2. A sustainable funding mechanism shall be established by the Conference of the Parties no later than 31 December 2026. The mechanism shall ensure the provision of adequate, accessible, new and additional and predictable financial resources, and shall include the following:

- (a) A capacity development fund that shall be resourced, inter alia, through the following:
 - i. annual monetary contributions from Parties to the WHO Pandemic Agreement;
 - ii. monetary contributions from recipients pursuant to Article 12 herein; and
 - iii. voluntary monetary contributions from Parties to the WHO Pandemic Agreement.

(b) An endowment for pandemic prevention, preparedness and response, resourced, inter alia, through the following:

- i. voluntary monetary contributions from all relevant sectors that benefit from international work to strengthen pandemic prevention, preparedness and response; and
- ii. donations from philanthropic organizations and foundations, and other voluntary monetary contributions.

(c) The funding mechanism will provide resources to assist Parties, in particular developing countries, in meeting their obligations under the WHO Pandemic Agreement and related activities for pandemic prevention, preparedness and response. The funding mechanism will contribute to funding support of the Secretariat of the WHO Pandemic Agreement.

(d) For the purposes of this Agreement, the mechanism shall function under the authority of the Conference of the Parties, and shall be accountable thereto. The Conference of the Parties shall further define and provide guidance on overall strategies, policies, programme priorities and eligibility for access to and utilization of financial resources, including in respect of the compensation mechanism(s) referred to in Article 15 herein, and shall also monitor outcomes and address the operation and resourcing of the funding mechanism, with due regard to the avoidance of conflicts of interest.

3. The Parties represented in relevant regional and international intergovernmental organizations and financial and development institutions shall encourage, as appropriate, these entities to provide additional financial assistance for developing country Parties to support them in meeting their obligations under the WHO Pandemic Agreement, without limiting their participation in or membership of these organizations.

Chapter III. Institutional arrangements and final provisions

Article 21. Conference of the Parties

1. A Conference of the Parties is hereby established. The Conference of the Parties shall be comprised of delegates representing the Parties to the WHO Pandemic Agreement. Only delegates representing Parties will participate in any of the decision-making of the Conference of the Parties. The Conference of the Parties shall establish the criteria for the participation of observers at its proceedings.

2. With the aim of promoting the coherence of the Conference of the Parties and the Health Assembly, as well as coherence in respect of relevant instruments and mechanisms within the framework of the World Health Organization, the Conference of the Parties shall operate in coordination with the Health Assembly. In particular, the Conference of the Parties shall hold its regular sessions immediately before or after regular

sessions of the Health Assembly, and in the same location and venue as the Health Assembly, where feasible.

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.

4. Following the first session of the Conference of the Parties:

(a) subsequent regular sessions of the Conference of the Parties shall be held annually; and

(b) extraordinary sessions of the Conference of the Parties shall be held at such other times, without reference to regular sessions of the Health Assembly, 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 to them by the Secretariat, it is supported by at least one third of the Parties.

5. The Conference of the Parties shall adopt by consensus its Rules of Procedure at its first session.

6. The Conference of the Parties shall by consensus adopt financial rules for itself as well as governing the funding of any subsidiary bodies of the Conference of the Parties that are or may be established, as well as financial provisions governing the functioning of the Secretariat. It shall also adopt a biennial budget.

7. The Conference of the Parties shall keep under regular review the implementation of the WHO Pandemic Agreement and take the decisions necessary to promote its effective implementation, and may adopt amendments, annexes and protocols to the WHO Pandemic Agreement, in accordance with Articles 28, 29, and 30 herein. To this end, it shall:

(a) consider reports submitted by the Parties in accordance with Article 23 herein and adopt regular reports on the implementation of the WHO Pandemic Agreement;

(b) oversee any subsidiary bodies, including by establishing their rules of procedure and working modalities;

(c) promote and facilitate the mobilization of financial resources for the implementation of the WHO Pandemic Agreement, in accordance with Article 20 herein;

(d) request, where appropriate, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies as a means of strengthening the implementation of the WHO Pandemic Agreement; and

(e) consider other action, as appropriate, for the achievement of the objective of the WHO Pandemic Agreement in the light of experience gained in its implementation.

8. The Conference of the Parties shall keep under regular review, every three years, the implementation and outcome of the WHO Pandemic Agreement and any related legal instruments that the Conference of the Parties may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO Pandemic Agreement.

9. The Conference of the Parties shall establish subsidiary bodies to carry out the work of the Conference of the Parties, as it deems necessary, on terms and modalities to be defined by the Conference of the Parties. Such subsidiary bodies may include, without limitation, an Implementation and Compliance Committee, a panel of experts to provide scientific, <u>policy and technical</u> advice, <u>designated expert</u> implementing agencies including the Quadripartite to assist member states in implementing the provisions

of the agreement, and a WHO PABS System Expert Advisory Group.

Article 22. Right to vote

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

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

Article 23. Reports to the Conference of the Parties

1. Each Party shall submit to the Conference of the Parties periodic reports on its implementation of the WHO Pandemic Agreement, which shall include the following:

(a) information on good practices, legislative, executive, administrative or other measures, taken to implement the WHO Pandemic Agreement;

(b) information on any constraints or difficulties encountered in the implementation of the WHO Pandemic Agreement and on the measures taken or under consideration to overcome them;

- (c) information on implementation support received under the WHO Pandemic Agreement; and
- (d) other information as required by specific provisions of the WHO Pandemic Agreement.

2. The frequency, conditions and format of the reports, including periodic reports, submitted by the Parties shall be determined by the Conference of the Parties at its first session, with the aim of facilitating reporting by the Parties and avoiding duplications. These reports shall be drawn up in a clear, transparent and exhaustive manner, without prejudice to respect for applicable rules on confidentiality, privacy and data protection.

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

4. The periodic reports submitted by the Parties shall be made publicly available online by the Secretariat.

Article 24. Secretariat

1. A Secretariat for the WHO Pandemic Agreement is hereby established. The Secretariat functions for the WHO Pandemic Agreement shall be provided by the World Health Organization, in consultation with members of the Quadripartite.

2. The Secretariat functions shall be to:

(a) provide administrative and logistic support to the Conference of the Parties for the purpose of the implementation of this Agreement, and to make arrangements for the sessions of the Conference of the Parties and any subsidiary bodies and to provide them with services, as required;

(b) transmit reports and other relevant information regarding the implementation of this Agreement received by it pursuant to this Agreement;

(c) provide support to the Parties, upon request, particularly developing country Parties and Parties with economies in transition, in implementing the WHO Pandemic Agreement, including the compilation and communication of information required in accordance with the provisions of the WHO Pandemic Agreement or pursuant to requests of the Conference of the Parties;

(d) prepare reports on its activities under the WHO Pandemic Agreement under the guidance of the Conference of the Parties, and submit them to the Conference of the Parties;

(e) ensure, under the guidance of the Conference of the Parties, the necessary coordination with competent international and regional intergovernmental organizations and other bodies;

(f) enter, under the guidance of the Conference of the Parties, into such administrative or contractual arrangements as may be required for the effective discharge of its functions;

(g) cooperate and coordinate with other United Nations entities in related areas; and

(h) perform other secretariat functions specified by the WHO Pandemic Agreement and such other functions as may be determined by the Conference of the Parties.

Article 25. Relationship with other international agreements and instruments

1. The implementation 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 other relevant international instruments, including the International Health Regulations, should be interpreted so as to be complementary and compatible. The provisions of the WHO Pandemic Agreement shall not affect the rights and obligations of any Party under other existing international instruments.

3. The provisions of the WHO Pandemic Agreement shall in no way affect the ability of Parties to enter into bilateral or multilateral agreements, including regional or subregional agreements, on issues relevant or additional to the WHO Pandemic Agreement, provided that such agreements are compatible with their obligations under the WHO Pandemic Agreement. The Parties concerned shall communicate such agreements to the Conference of the Parties, through the Secretariat.

Article 26. Reservations

No reservations may be made to the WHO Pandemic Agreement.

Article 27. 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 WHO Pandemic 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. 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 28. Amendments

1. Any Party may propose amendments to the WHO Pandemic Agreement. Such amendments shall be considered by the Conference of the Parties.

2. Amendments to the WHO Pandemic Agreement shall be adopted by the Conference of the Parties. 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 shall 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 amendments shall be communicated by the Secretariat to the Depositary, who 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. The 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 29. Annexes

1. Annexes to the WHO Pandemic Agreement and amendments thereto shall be proposed, adopted and shall enter into force in accordance with the procedure set forth in Article 28 herein.

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.

3. Annexes shall be restricted to lists, forms and any other descriptive material relating to procedural, scientific, technical or administrative matters, and shall not be substantive in nature.

Article 30. Protocols

1. Any Party may propose protocols to the WHO Pandemic Agreement. Such proposals will 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, every effort shall be made to reach consensus. If all efforts at consensus have been exhausted and no agreement has been reached, the protocol shall as a last resort be adopted by a threequarters 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. In the event that a protocol is proposed to be adopted under Article 21 of the Constitution of the World Health Organization, it shall further be considered for adoption by the Health Assembly.

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

4. States that are not Parties to the WHO Pandemic Agreement may be parties to a protocol thereof, 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 shall be established by that instrument.

Article 31. Signature

The WHO Pandemic Agreement shall be open for signature by all Members of the World Health Organization, by States that are not Members of the World Health Organization but are member or nonmember observer states of the United Nations, and by regional economic integration organizations. The WHO Pandemic Agreement shall be open for signature at the World Health Organization headquarters in Geneva, immediately following its adoption by the World Health Assembly at the Seventy-seventh World Health Assembly, from XX [May] 2024 to XX [June] 2024, and thereafter at United Nations Headquarters in New York, from XX [June] 2024 to XX [June] 2025.

Article 32. Ratification, acceptance, approval, formal confirmation or accession

1. The WHO Pandemic Agreement shall be subject to ratification, acceptance, approval or accession by 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 the WHO Pandemic 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. 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 WHO Pandemic 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. 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 fortieth 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. 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. Failure to reach a solution by good offices, mediation or conciliation shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

2. When ratifying, accepting, approving, formally confirming or acceding to the WHO Pandemic Agreement, or at any time thereafter, a Party which is not a regional economic integration organization may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory *ipso facto* and without special agreement, in relation to any Party accepting the same obligation: (a) submission of the dispute to the International Court of Justice; and/or (b) ad hoc arbitration in accordance with procedures to be adopted by consensus by the Conference of the Parties. A Party which is a regional economic integration organization may make a declaration with like effect in relation to arbitration in accordance with the procedures referred to in paragraph 2(b) of this Article.

3. The provisions of this Article shall apply with respect to any protocol as between the parties to the protocol, unless otherwise provided therein.

Article 35. Depositary

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

Article 36. Authentic texts

The original of this 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.