EUROPEAN UNION *INITIAL* TEXTUAL PROPOSALS FOR AN AGREEMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE. (Proposals indicated in blue font)

THESE PROPOSALS ARE COMPLEMENTARY TO THE ZERO DRAFT AND THEY ARE NOT INTENDED TO ADDRESS ALL AREAS COVERED BY THE ZERO DRAFT.

IN LIGHT OF FURTHER INTERNAL REFLECTIONS, DISCUSSIONS WITH PARTNERS AND DEVELOPMENT IN THE NEGOTIATIONS, THE EU RESERVES THE RIGHT TO MODIFY OR WITHDRAW THE PROPOSALS BELOW AND TO PUT FORWARD ADDITIONAL PROPOSALS.

Outline of EU textual proposals in the Zero draft of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response ("WHO CA+")

The Parties to this WHO CA+,[I]

1. *Reaffirming* ....

Have agreed as follows:

The world together equitably

***Vision*:** The WHO CA+[II] aims for a world where pandemics are effectively controlled to protect present and future generations from pandemics and their devastating consequences, and to advance the enjoyment of the highest attainable standard of health for all peoples, on the basis of equity, human rights and solidarity, with a view to achieving universal health coverage, while recognizing the sovereign rights of countries, acknowledging the differences in levels of development among countries, respecting their national context and recognizing existing relevant international instruments. The WHO CA+ aims to achieve greater equity and effectiveness for pandemic prevention, preparedness and response through the fullest national and

[I] The Bureau proposes, consistent with Member State submissions, that the preambular section be discussed at the appropriate point in the negotiations.

[II] At its second meeting in July 2022, the INB identified that Article 19 of the WHO Constitution is the comprehensive provision under which the WHO CA+ should be adopted, without prejudice to also considering, as work progressed, the suitability of Article 21.

international cooperation.

Suggest deletion

Chapter I. Introduction

- Chapter I and II of the Zero Draft can be merged into one Chapter (Chapter I) entitled 'General provisions'

Article 1. Definitions and use of terms

1. For the purposes of this WHO CA+:

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

(b) "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 require effective national and global collaboration and coordination for its control;[III]

Suggeted definition:

"Pandemic situation" means a manifestation of a disease, irrespective of origin or source, that is spreading or is likely to spread over a wide geographical area, often worldwide, that is affecting or is likely to affect a large number of persons, and is creating or is likely to create a severe social disruption and economic loss.

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

Suggested definition:

"Countermeasures" means medical and other countermeasures necessary for the purpose of preparedness for and response to pandemic situations, including but not limited to, vaccines, therapeutics, diagnostics, medical devices, medical equipment and supplies, such as personal protective equipment.

(d) "persons in vulnerable situations" includes indigenous peoples, persons belonging to national

[III] The INB is encouraged to conduct discussions on the matter of the declaration of a "pandemic" by the WHO Director-General under the WHO CA+ and the modalities and terms for such a declaration, including interactions with the International Health Regulations and other relevant mechanisms and instruments. In this connection see Article 15.2 hereof.

or ethnic, religious or linguistic minorities, refugees, migrants, asylum seekers, stateless persons, persons in humanitarian settings and fragile contexts, marginalized communities, older people, persons with disabilities, persons with health conditions, pregnant women, infants, children and adolescents, and those living in fragile areas, such as Small Island Developing States;

(e) "pathogen with pandemic potential" means…;
(f) "One Health approach" means…;
(g) "One Health surveillance" means…;
(h) "infodemic" means…;
(i) "inter-pandemic" means…;
(j) "current health expenditure" means…;
(k) "universal health coverage" means…; and
(l) "recovery" means…

Additional proposals for definitions at this stage:

- "Quadripartite organisations" refer to World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (WOAH) and the United Nations Environment Programme (UNEP).

- "Low income countries", "lower middle income countries", "upper middle income countries", "higher income countries" refer to the Parties listed in the respective country group lists as prepared on an annual basis by the International Bank for Reconstruction and Development (the World Bank). "Middle income countries" refer to the Parties listed in either the list of lower middle income countries or in the list of upper middle income countries as prepared on an annual basis by the World Bank.

- One Health means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent.

Article 2. Relationship with other international agreements and instruments

1. The implementation of the WHO CA+ shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. The WHO CA+ and other relevant international instruments, including the International Health Regulations, should be interpreted so as to be complementary, compatible and synergistic, and the WHO CA+ should be interpreted in a manner that promotes and supports the implementation and operationalization of the International Health Regulations and other relevant international instruments.[IV] In the event that any part of the WHO CA+ addresses areas or activities that may bear on the field of competence of other organizations or treaty bodies, appropriate steps will be taken to avoid duplication and promote synergies, compatibility and coherence, with a common goal of strengthened pandemic preparedness, prevention, response and health system recovery.

[IV] The INB is encouraged to conduct discussions on the matter of making explicit the synergies and concrete complementarity of the WHO CA+ with the International Health Regulations and other relevant mechanisms and instruments.

2. The provisions of the WHO CA+ shall not affect the rights and obligations of any Party under other existing international instruments and shall respect the competencies of other organizations and treaty bodies.

3. The provisions of the WHO CA+ shall in no way affect the right of Parties to enter into bilateral or multilateral instruments, including regional or subregional instruments, on issues relevant or additional to the WHO CA+, provided that such instruments are compatible with their obligations under the WHO CA+. The Parties concerned shall communicate such instruments to the Governing Body for the WHO CA+ through the Secretariat.

[Article to be drafted when content of substantive provisions is known]

Declaring a pandemic: The task should be entrusted with the WHO Director-General. There could be two main options to be considered:

Option 1: pandemic determination procedure within the PA (identical definition of 'pandemic situation' to be included both in the PA and in the IHR)

Article 3 - Determination of a pandemic situation

1. The Director-General of the WHO shall assess and determine, on the basis of the information and advice received, whether an event constitutes a pandemic situation. The Director-General will make a determination whether an event constitutes a pandemic situation with regard to any event that is determined to be a public health emergency of international concern under Article 12 of the IHR.

2. If the Director-General considers that a pandemic situation is occurring, the Director-General shall immediately consult with the affected Parties. The Director-General shall, in accordance with the procedure set forth in Article 49 of the IHR, also seek the views of a Committee established in accordance with the provisions of Article 48 of the IHR (hereinafter the "Emergency Committee"), including on appropriate temporary recommendations. Notwithstanding Art. 49.4, the Director General shall invite representatives of the affected Parties to present their views to the Emergency Committee.

3. In determining whether an event constitutes a pandemic situation the Director-General shall consider:

(a) information provided by the affected Parties, including in accordance with Article D.2;
(b) the decision instrument contained in Annex 1 to this Agreement;
(c) the advice of the Emergency Committee; and
(d) scientific principles as well as the available scientific evidence and other relevant information.

4. If the Director-General, following consultations with the affected Parties, considers that a pandemic situation has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49 of the IHR.

Option 2: pandemic determination procedure within the IHR (identical definition of 'pandemic situation' to be included both in the PA and in the IHR)

Article 3 - Determination of a pandemic situation

For the purpose of this Agreement a pandemic situation shall be deemed to occur, or end, when the Director-General of the WHO so determines in accordance with the relevant provisions of the IHR (2005) as amended.

Chapter II. Objective, guiding principles and scope

Article 3. Objective

The objective of the WHO CA+, guided by equity, the vision, principles and rights set out herein, is to prevent pandemics, save lives, reduce disease burden and protect livelihoods, through strengthening, proactively, the world's capacities for preventing, preparing for and responding to, and recovery of health systems from, pandemics. The WHO CA+ aims to comprehensively and effectively address systemic gaps and challenges that exist in these areas, at national, regional and international levels, through substantially reducing the risk of pandemics, increasing pandemic preparedness and response capacities, progressive realization of universal health coverage and ensuring coordinated, collaborative and evidence-based pandemic response and resilient recovery of health systems at community, national, regional and global levels.

Proposed text:

The objective of the Agreement is to increase the capacity of the Parties to prevent, prepare for and respond to pandemic situations in an equitable, effective and efficient manner, with the aim of reducing morbidity, mortality and the social and economic impact of pandemics, at local, national, regional and international levels.

[An article along the lines of Zero Draft Article 14 on Human Rights could be placed here]

Proposed additional articles

Article … - General obligation

The Parties shall take all necessary measures and actions, individually and jointly, to apply and effectively implement at domestic, regional and international level the provisions of this Agreement, including the provisions set out in the Annexes to the Agreement, with the aim of preventing, preparing for and responding to pandemic situations.

Article … - Plans and measures

1. Each Party shall develop, implement, update and periodically review national, and where possible regional, action plans aimed to improving pandemic prevention, surveillance, early detection, preparedness and response, including emergency plans and measures, in accordance with the provisions of this Agreement and of the International Health Regulation (2005), in particular Annex 1 thereof. Parties shall prepare and adopt their action plans no later than [two] years after the entry into force of this Agreement, and review and update them at least every [three] years thereafter. Plans shall be prepared and updated as part of a continuous and transparent participatory process, taking into account the information gained from action on the ground, the results of research and the One health approach.

2. Such plan shall pay particular attention to the respect for human rights, the needs of the persons in vulnerable situations and people living in humanitarian settings, the protection of health and other essential workers, as well as to the aim to prevent the cross border spread of disease.

3. Parties shall establish or strengthen national, and where possible regional, mechanisms for institutional coordination, including the health, veterinary and environmental sectors, to prevent and fight pandemics, and shall provide adequate financial means therefor.

4. Responsible authorities set out under Article 4 of the IHR should be resposible also to ensure the implementation of this Agreement, as appropriate in view of national or regional responsibilities.

Article 4. Guiding principles and rights

To achieve the objective of the WHO CA+ and to implement its provisions, the Parties will be guided, inter alia, by the principles and rights set out below:

1. **Respect for human rights** – The implementation of the WHO CA+ shall be with full respect for the dignity, human rights and fundamental freedoms of persons, and each Party shall protect and promote such freedoms.

2. **The right to health** – The enjoyment of the highest attainable standard of health, defined as a state of complete physical, mental and social well-being, is one of the fundamental rights of every human being without distinction of age, race, religion, political belief, economic or social condition.

3. **Sovereignty** – States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to determine and manage their approach to public health, notably pandemic prevention, preparedness, response and recovery of health systems, pursuant to their own policies and legislation, provided that activities within their jurisdiction or control do not cause damage to their peoples and other countries. Sovereignty also covers the rights of States over their biological resources.

4. **Equity** – The absence of unfair, avoidable or remediable differences, including in their capacities, among and within countries, including between groups of people, whether those groups are defined socially, economically, demographically, geographically or by other dimensions of inequality, is central to equity. Effective pandemic prevention, preparedness, response and recovery cannot be achieved without political will and commitments in addressing the structural challenges in inequitable access to fair, equitable and

timely access to affordable, safe and efficacious pandemic-related products and services, essential health services, information and social support, as well as tackling the inequities in terms of technology, health workforce, infrastructure and financing, among other aspects.

5. **Solidarity** – The effective prevention of, preparedness for and response to pandemics requires national, international, multilateral, bilateral and multisectoral collaboration, coordination and cooperation, through global unity, to achieve the common interest of a fairer, more equitable and better prepared world.

6. **Transparency** – The effective prevention of, preparedness for and response to pandemics depends on transparent, open and timely sharing, access to and disclosure of accurate information, data and other relevant elements that may come to light (including biological samples, genomic sequence data and clinical trial results), for risk assessment and control measures, and development of pandemic- related products and services, notably through a whole-of-government and whole-of-society approach, based on, and guided by, the best-available scientific evidence, consistent with national, regional and international privacy and data protection rules, regulations and laws.

7. **Accountability** – States are accountable for strengthening and sustaining their health systems' capacities and public health functions to provide adequate health and social measures by adopting and implementing legislative, executive, administrative and other measures for fair, equitable, effective and timely pandemic prevention, preparedness, response and recovery of health systems. All Parties shall cooperate with other States and relevant international organizations, in order to collectively strengthen, support and sustain capacities for global prevention, preparedness, response and recovery of health systems.

8. **Common but differentiated responsibilities and capabilities in pandemic prevention, preparedness, response and recovery of health systems** – All States are responsible for the health of their people, including pandemic prevention, preparedness, response and recovery, and previous pandemics have demonstrated that no one is safe until everyone is safe. Given that the health of all peoples is dependent on the fullest cooperation of individuals and States, all Parties are bound by the obligations of the WHO CA+. States that hold more resources relevant to pandemics, including pandemic-related products and manufacturing capacity, should bear, where appropriate, a commensurate degree of differentiated responsibility with regard to global pandemic prevention, preparedness, response and recovery. With the aim of supporting every Party to achieve the highest level of proven and sustained capacity, full consideration and prioritization are required of the specific needs and special circumstances of developing country Parties, especially those that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate capacities to respond to pandemics; and (iii) potentially bear a disproportionately high burden.

9. **Inclusiveness** – The active engagement with, and participation of, all relevant stakeholders and partners across all levels, consistent with relevant and applicable international and national guidelines, rules and regulations (including those relating to conflicts of interest), is fundamental for mobilizing resources and capacities to support pandemic prevention, preparedness, response and health systems recovery.

10. **Community engagement** – Full engagement of communities in prevention, preparedness, response and recovery of health systems is essential to mobilize social capital, resources, adherence to public health and social measures, and to gain trust in government.

11. **Gender equality** – Pandemic prevention, preparedness, response and recovery of health systems will be guided by and benefit from the goal of equal participation and leadership of men and women in decision-making with a particular focus on gender equality, taking into account the specific needs of all women and girls, using a country-driven, gender responsive/transformative, participatory and fully transparent approach.

12. **Non-discrimination and respect for diversity** – All individuals should have fair, equitable and timely access to pandemic-related products, health services and support, without fear of discrimination or distinction based on race, religion, political belief, economic or social condition.

13. **Rights of individuals and groups at higher risk and in vulnerable situations** – Nationally determined and prioritized actions, including support, will take into account communities and persons in vulnerable situations, places and ecosystems. Indigenous peoples, persons belonging to national or ethnic, religious or linguistic minorities, refugees, migrants, asylum seekers, stateless persons, persons in humanitarian settings and fragile contexts, marginalized communities, older people, persons with disabilities, persons with health conditions, pregnant women, infants, children and adolescents, for example, are disproportionately affected by pandemics, owing to social and economic inequities, as well as legal and regulatory barriers, that may prevent them from accessing health services.

14. **One Health** – Multisectoral and transdisciplinary actions should recognize the interconnection between people, animals, plants and their shared environment, for which a coherent, integrated and unifying approach should be strengthened and applied with an aim to sustainably balance and optimize the health of people, animals and ecosystems, including through, but not limited to, attention to the prevention of epidemics due to pathogens resistant to antimicrobial agents and zoonotic diseases.

15. **Universal health coverage** – The WHO CA+ will be guided by the aim of achieving universal health coverage, for which strong and resilient health systems are of key importance, as a fundamental aspect of achieving the Sustainable Development Goals through promoting health and well-being for all at all ages.

16. **Science and evidence-informed decisions** – Science, evidence and findable, accessible, interoperable and reusable data should inform all public health decisions and the development and implementation of guidance for pandemic prevention, preparedness, response and recovery of health systems.

17. **Central role of WHO** – As the directing and coordinating authority on global health, and the leader of multilateral cooperation in global health governance, WHO is fundamental to strengthening pandemic prevention, preparedness, response and recovery of health systems.

18. **Proportionality** – Due consideration should be given, including through regular monitoring and policy evaluation, to ensuring that the impacts of measures aimed at preventing, preparing for and responding to pandemics are proportionate to their intended objectives and that the benefits arising therefrom outweigh costs.

Article 5. Scope

The WHO CA+ applies to pandemic prevention, preparedness, response and health systems recovery at national, regional and international levels.

Propose to introduce a new Chapter II entitled 'Preventing, detecting and reporting pandemic situations'

A. Preventing pandemic situations

Article A.1. - Preventing pandemic situations

1. The Parties shall undertake actions to strengthen infection prevention and control, at all levels, including, but not limited to, households, communities and healthcare facilities, as well as the veterinary sector, with the aim of preventing pandemic situations. In particular:

a) Parties shall strengthen efforts to ensure access to safe water, sanitation and hygiene and guarantee access to appropriate health services as a preventive infection control measures for the general public, including hard-to-reach settings in the Parties' territory, as well as animals.
b) Parties shall ensure the implementation of infection prevention and control measures applying as far as possible the latest WHO, FAO, Codex Alimentarius, International Plant Protection Convention (IPPC), and WOAH standards and guidelines.
c) Parties shall strengthen efforts to ensure the sound management of healthcare and protective equipment waste, which may be contaminated.
d) Parties shall require healthcare institutions to have in place an infection prevention and control programme no later than […] years after the entry into force of the Agreement.
e) Parties shall strengthen animal disease preventive measures, including, but not limited to, on farms, transport of animals, live animal markets, trade in wild animals and in veterinary practices both for food-producing and companion animals taking into account the relevant WOAH standards. Those measures include water and feed hygiene, infection prevention and control measures, biosecurity and animal welfare support measures.

2. Parties shall take actions to prevent pandemic situations due to pathogens resistant to antimicrobial agents in accordance with the provisions set out in Annex 2.

3. Parties shall take actions to prevent the inadvertent laboratory release of pathogens in accordance with the provisions set out in Annex 3.

B. Surveillance

Article B.1. - Pathogen surveillance and identification

1. Each Party shall within its territory develop, strengthen and maintain the capacity to detect, identify and characterize pathogens presenting significant risks, including pathogens in animal population presenting a zoonotic risks, and vector-borne diseases, and to assess as much as possible their likelihood to cause spread in human and animal populations and serious diseases leading to pandemic situations.

2. Without prejudice to existing reporting and notification obligations, each Party shall inform the Secretariat of this Agreement (hereinafter the "Secretariat") in a rapid and effective manner about the pathogens referred to in paragraph 1 that it has detected, and communicate the information and data on their characteristics that it has been able to assemble. The Party shall communicate in a rapid and effective manner to the Secretariat new or updated data or information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international and regional organizations. For purposes hereof, "rapid" shall be understood to mean within […] hours from the time of identification of a pathogen with pandemic potential or from the time the relevant data or information have become available.

"Effective" shall be understood as sufficient information on the specific geaographic localisation, all information already available on the original infection case or cases, on risks of contamination and on all actions already undertaken for preventing the spread of the outbreak.

3. The Parties shall cooperate with one another and with the support of the Secretariat, in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of Parties which are low and lower middle income countries, especially with respect to the capacity to perform genetic sequencing of detected pathogens and safely handle samples containing pathogens, as well as to use related digital tools. The Parties shall also promote and facilitate the provision of necessary assistance by relevant international and regional organizations.

Article B.2. - Surveillance at the wildlife-livestock-human interface

1. In view of the objective set out in article B.1., each Party shall develop, strengthen and maintain the capacity to carry out integrated surveillance of infectious diseases in humans, of infectious diseases in animals presenting significant risks for zoonotic, including vector-borne, spillover, as well as of relevant environmental indicators, and samples taken from specific environmental settings, for the purpose of preventing and controlling the spillover of potentially dangerous pathogens, including antimicrobial resistant pathogens, between humans and animal populations, as well as between different animal species. For this purpose the Parties shall ensure the cooperation and exchange of information among national and regional authorities responsible for surveillance. Such surveillance shall encompass livestock, companion animals, high-risk wildlife and vectors as defined by the Conference of the Parties. Parties shall promptly communicate to the Secretariat new or updated data, analysis and information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international and regional organizations, especially for the purpose of early warning and detection.

2. Parties shall cooperate with one another in bilateral, regional and multilateral settings in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of low and lower middle-income countries which are Parties to the Agreement. In particular, Parties shall cooperate to strengthen public health laboratory and diagnostic capacities, including capacities for genomic sequencing, as well as digital health and data science capacities. Parties shall coordinate surveillance activities as appropriate taking into account the decisions of the Conference of the Parties and the recommendations of relevant international organizations and bodies.

3. The Conference of the Parties shall adopt recommendations on the harmonization and standardization of information and data arising out of their surveillance activities to ensure the interoperability of data information systems and the comparability and integration of information and data for the purpose of an effective assessment of national, regional and international risks of zoonotic and vector-borne diseases, while maintaining appropriate standards of data protection.

C. *Preventing and controlling zoonotic spill-overs through the One Health approach*

Article C.1. - Control of wildlife trade

1. Subject to their international obligations, Parties shall adopt legislative, administrative and technical measures to ensure safe legal trade and prohibit and prevent the illicit national and international trade of animal and plant species that may pose a higher risk of zoonotic diseases based on the result of their surveillance under Articles B.1. (Pathogen surveillance and identification) and B.2. (Surveillance at the wildlife-livestock-human interface).

2. The Parties shall put in place export and import authorisation procedures for specimens of animal and plant species mentioned in paragraph 1 to assess the risk to human and animal health deriving from pathogens generally or likely hosted by the species to which the specimens in question belong, or from laboratory testing of the specimens. They shall not allow or, as the case may be, subject the export or import authorization to specific risk mitigation measures to prevent or reduce the risk of emergence and spread of disease into human or other animal populations. The Parties shall facilitate the rapid export of biological samples of wild animals for purposes of zoonotic disease research and effective response to pandemic situations.

Article C.2. - International standards and national measures

1. The Conference of the Parties shall, on the basis of the findings and advice of the Panel of Expert provided for in Article P.3 (*Scientific advice*) as well as of the advice of relevant international organizations, in particular the Quadripartite organisations, and other relevant organisations and bodies, adopt guidelines, recommendations, standards and other instruments, as necessary, to guide and support the Parties in the adoption of national measures aimed at the implementation of the provision under Section B, and more generally to the reduction of risks of zoonotic, including vector-borne, spillover in accordance with the One Health approach.

2. The Parties shall, in accordance with their international obligations, adopt policies and measures of a legislative, regulatory, administrative and technical nature for the purpose of:

a) Identification and mapping of geographical areas, animal and plant species, activities and practices within their jurisdiction which may require particular surveillance;

b) Monitoring environmental factors associated with the risk of zoonotic diseases, such as vector- and water-borne pathogens and diseases, water quality, unsustainable land uses or deforestation, predictive climatic, entomology or vegetation indices;

c) On the basis of their activities under sub-paragraphs a) and b), reducing as much as possible the risk of zoonotic diseases by controlling and adapting relevant activities and practices, such as certain unsustainable land uses and wildlife consumption practices;

d) Adapting farming practices, including within the context of large-scale animal farming, aimed at preventing the insurgence of antimicrobial resistant pathogens;

e) Establishing, strengthening, monitoring and enforcing as appropriate hygienic practices and risk management measures in markets selling live animals and live wildlife;

f) Developing, strengthening and maintaining animal welfare policies and practices to ensure the humane and adequate treatment of wildlife, farm and companion animals at all stages of their trading, rearing, transport and slaughter, as well as to improve hygiene and, where possible, reduce long distance transportation of live animals.

g) Monitoring the effectiveness of the adopted policies and measures for the purpose of constantly strengthening them and increasing their effectiveness.

3. Without prejudice to their existing obligations under international law the Parties shall base the policies and measures provided for under this Article on the recommendations, guidelines and standards adopted by the Panel of Expert provided for in Article P.3 (Scientific advice), as well as by relevant international organizations and bodies, with particular regard to WHO, WOAH and the Codex Alimentarius Commission.

4. The Parties shall fully take into account the rights, as set out in the UN Declaration on the Rights of Indigenous Peoples, needs and traditional practices of indigenous and local communities under their jurisdiction in order to avoid any discrimination or depriving such communities of their livelihood and traditional knowledge. The Parties shall consult and involve indigenous and local communities in the elaboration and implementation of the measures referred to in this Article.

5. Each Party shall report specifically on the national or regional measures adopted and implemented under this Article to the Conference of the Parties every […] years after the entry into force of the Agreement for that Party as part of their reporting under article P.2. The Conference of the Parties shall specify the information required from Parties, with particular regard to the challenges encountered and assistance needed. The reports shall also be examined by the Implementation and Compliance Committee for the purpose of identifying general or specific problems requiring action by the Conference of the Parties and by the Parties concerned.

6. Each Party shall promote technical, scientific and research cooperation with other Parties in implementing the provisions of this Article, inter alia, through the development and implementation of national and where possible regional policies and measures. In promoting such cooperation, special attention should be given to the development and strengthening of national, and where possible regional, capabilities, by means of human resources development and institution building, especially in low and lower-middle income countries, as well as other middle income countries in need.

D. Early detection and reporting of pandemic situations

Article D.1. - Applicability

This section shall apply between Parties to the Agreement without prejudice to the International Health Regulations (2005), and in particular Part II thereof.

Article D.2. - Early Detecting and Reporting

1. Notwithstanding Article 6.1 of the IHR, in case of an event which may constitute a pandemic situation in accordance with Article 3 (*Determination of a pandemic situation*), the Party within which such event or occurrence is taking place shall immediately provide the Secretariat with all relevant information and respond promptly to requests for consultation by the WHO and the Parties likely to be affected.

2. Notwithstanding Article 10.2 of the IHR, the same Party shall also verify and provide within the shortest possible period and in no case later than 24 hours any other information or report as requested by the WHO with a view to allowing the WHO to assess the public health threat and inform other Parties accordingly.

3. The Secretariat, in cooperation with Parties in a position to do so, and in accordance with Article D.4., shall offer its assistance to the Party concerned for the purpose of collecting and analyzing relevant information, making full use of an integrated One Health approach.

4. Notwithstanding Article 10.4 and 11 of the IHR, if the Party concerned does not provide or verify the information as provided for in paragraphs 1 and 2, the Secretariat shall be allowed to share with other Parties, relevant international organizations and the public the information available to it, and independently assessed by it, in accordance with established epidemiological principles.

5. As part of the provision of information in accordance with paragraph 1, the Party concerned may make a request for emergency health and other support. In accordance with article I.1., all Parties in a position to provide such support, shall cooperate with the requesting Party and the WHO, which shall facilitate and coordinate, together with other relevant international, regional and non-governmental organisations, the provision of emergency medical and other assistance.

Article D.3. - Sharing of information and data

In accordance with the provisions of Article E.1. (Sharing of pathogen samples, genetic sequences and equitable sharing of benefits), the Party within which an event or occurrence as referred to in Article D.2. (Early Detecting and Reporting) is taking place shall make available, in accordance with open access and open science principles, relevant international and national practices and data protection rules, any scientific findings, surveillance and diagnostic data, research results and samples, including when stored in relevant data repositories, and agree on access conditions that allow for their reuse for research and development purposes with the aim of informing public health responses, limiting the spread of diseases and enabling the rapid development of safe and efficacious medical and other counter-measures.

Article D.4. - Field missions for the purpose of verification and support

1. Notwithstanding Article 10.3 and 4 of the IHR, WHO should offer to deploy field missions including, as necessary, experts from other relevant international organizations, in particular the Quadripartite organisations, for the purpose of supporting a Party in the verification of an event, investigation about its origins, assessment of the public health risk and evaluation of the effectiveness of the public health measures implemented by that Party.

2. Parties shall not unjustifiably refuse an offer by WHO to deploy the field mission referred to in paragraph 1 and shall strive to agree on the timing and terms of reference of the mission within 24 hours from receipt of the offer. Parties and the WHO should to the extent possible make use of the standard terms of reference set out in Annex 4 to this Agreement.

3. If a Party rejects the offer, it shall provide WHO within 24 hours with the reasons for its refusal and may at the same time request additional information from WHO about the purpose and objective of the field mission. WHO shall respond to any such request within 12 hours. If the Party

rejects the offer or does not respond within 12 hours from the provision by WHO of the required information, WHO shall inform other Parties and report to the Conference of the Parties.

4. A Party receiving a WHO field mission shall collaborate in good faith to ensure the effectiveness of the mission, shall make information available and provide access to sites and facilities, shall ensure the security of the visiting team and shall respect the privileges and immunities of WHO and those of other organizations involved. WHO shall inform other States Parties about the outcome of the mission, including any refusal by the Party to collaborate with the visiting team.

Article D.5. - Support to detection capacities

1. WHO should provide, or facilitate the provision of, technical cooperation to assist Parties, with particular regard to Parties which are low and lower middle income countries, in strengthening their capacities for the surveillance, detection, reporting and verification of public health threats which may cause pandemic situations, including the provision of necessary equipment.

2. WHO should consult with relevant international organizations and bodies, such as the Quadripartite organizations, as well as the secretariats of relevant multilateral environmental conventions with a view to securing their participation and collaboration in the activities provided in this section, including field missions. Agreements to this effect with the relevant organizations shall be approved by the Conference of the Parties.

Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems

Proposal on access and benefit-sharing

E. Access to and sharing of pathogen samples and data

Article E.1. - Access to and sharing of pathogen samples, pathogen genomic sequence data and other relevant information related to pathogens

1. With a view to fostering international cooperation and coordination in the surveillance and control of pathogens and in scientific research and technological development of medical and other countermeasures, and in accordance with article D.3. (Support to detection capacities) and B.1. (Pathogen surveillance and identification), Parties shall ensure either directly or through the Secretariat or other existing mechanisms the free and rapid access to, and sharing of, pathogen samples, pathogen genomic sequence data and other relevant information related to pathogens obtained through their surveillance and detection activities. Parties may seek the cooperation of other Parties with more advanced technological capacities in order to fully identify and characterize the pathogens in question. The Parties should use of the model agreements set out in Annex 5, as appropriate.

2. The Conference of the Parties shall as soon as possible but no later than two years after the entry into force of this Agreement adopt rules or guidelines to facilitate and support the access to, and sharing and storage of, pathogen samples, as well as the generation, storage and sharing of pathogen genomic sequence data and other relevant information related to pathogens, in accordance with international law.

3. Parties shall equitably share the relevant medical countermeasures, including the ones produced with the assistance of pathogen samples, pathogen genomic surveillance data and other relevant information related to pathogens shared in accordance with paragraph 1 and the provisions set out in Section G. The Parties agree and affirm that the relevant provisions of this Agreement, in particular sections E and G, constitute a specialised access and benefit-sharing instrument.

4. The Conference of the Parties shall consider the establishment, or development of, one or more international repositories of pathogen samples and pathogen genomic sequence data falling under the present Agreement. This may include the utilization of existing national, regional or international repositories on the basis of agreements concluded with the Parties concerned. Repositories shall be accessible to Parties on an equitable and transparent basis, clear conditions and without discrimination. They shall be accessible to non-Parties on conditions to be decided by the Conference of the Parties. Data repositories shall comply with global norms and standards established by WHO.

G. Benefit sharing through equitable access to countermeasures

Article G1. General provisions

1. In case the Director General of the WHO declares a pandemic situation in accordance with Article 3, the Parties shall make all possible efforts to ensure that the relevant and most appropriate countermeasures are developed, manufactured, authorised and deployed as rapidly as possible and become available in sufficient quantities and at an affordable price to ensure an effective and equitable regional and international response to such pandemic situation.

2. To this effect the Parties shall ensure the rapid sharing of pathogen samples, genomic data and other relevant information as set out in article D.3. and section E, which is necessary to enable the fast development and manufacture of countermeasures.

3. The countermeasures covered by the provisions of this section/chapter shall be determined by the Countermeasure Expert Committee, as set out in Article P.5., as soon as possible after the declaration of a pandemic situation, on the basis of the characteristics of the pandemic situation, the needs for an effective response, as well as safety and efficacy requirements. The Committee shall also determine whether such countermeasures are in scarce supply for the purpose of an effective and equitable respose by each Party to the pandemic situation. Such determination shall be kept under review and the Committee shall determine when the situation of scarce supply has ended.

4. For this purpose the Parties shall cooperate to increase the transparency of market conditions prevailing in the markets for the countermeasures referred to in paragraph 3 and provide the Comittee

with information on supply and demand forsuch countermeasures , to support the Committee in assessing their availability and affordability, possible supply chain vulnerabilities and mitigation measures.

5. In case a countermeasure referred to in paragraph 3 is developed making use of a pathogen sample, genomic sequence data or other information related to pathogens, any transfer agreement which may cover such sample or data, including an agreement between the Party where the sample or data originate and the countermeasure developer, should set out the general availability and affordability commitments for the benefit of all countries in need as provided for in Articles G.2 and G.3. The transfer agreement should ensure that the countermeasure developer makes such general availability and affordability commitments applicable to the countermeasure manufacturer also in case the countermeasure manufacturer is a licensee of the countermeasure developer.

6. The Parties which are high income countries, and other Parties in a position to do so, shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to set out the availability and affordability commitments which will apply to the countermeasure manufacturer as provided for in Articles G.2 and G.3 in any purchase agreement that they conclude with such manufacturer.

7. The Parties which are high income countries, and other Parties in a position to do so, shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to set out the availability and affordability commitments which will apply to the countermeasure manufacturer as provided for in Articles G.2 and G.3, irrespective of whether the manufacturer is the countermeasure developer or a licensee of the countermeasure developer, in any agreement providing support to a countermeasure developer for research and development of new countermeasures.

8. The Parties shall encourage the countermeasure developers and manufacturers to commit to implementing the relevant provisions of this section and in particular the provisions set out in Articles G.2. and G.3. Such committments shall be received by the Director-General of the WHO who will keep them under review.

9. The Countermeasure Expert Committee shall develop model contract terms that may be used to ensure the rapid conclusion of agreements referred to in paragraphs 5, 6 and 7.

10. The Parties shall ensure delivery of medical countermeasures to persons in vulnerable situations and people living in hard-to-reach communities and humanitarian settings.

Article G.2. Availability of countermeasures

1. In case a countermeasure is in scarce supply, as determined in accordance with Article 1.3, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to ensure that countermeasure manufacturers reserve:

a) no less than […] percent of their production of such countermeasure on a quarterly basis for sale to Parties that are low income countries in accordance with the World Bank categorisation current at the time of the declaration, and
b) no less than […] percent of their production of such countermeasure on a quarterly basis for sale to Parties which are middle income countries in accordance with the World Bank categorisation current at the time of the declaration.

2. The WHO shall establish, in consulation with the Parties, a partnership and collaborate with the relevant organisations of the UN system, regional organisations and other relevant organisations,with particular attention to the needs of Parties, which are low or lower middle income countries, to:

a) determine the equitable allocation of the reserved countermeasure quantities, taking into account factors, such as population size, demographic structure, epidemiological situation and and health system capabilities of beneficiary Parties and their readiness and capacity to utilize such countermeasures,
b) facilitate, as appropriate, the conclusion of advance purchase commitments and purchase agreements of countermeasures,
c) assist the buying countries in meeting the regulatory and logistic requirements for utilization of the specific countermeasure,
d) facilitate or, as necessary, organise the efficient delivery and appropriate utilisation of the countermeasures in the beneficiary country or in humanitarian settings, and
e) assist the buying countries on all matters related to the utilisation of the countermeasures.

3. The partnership modalities and collaboration guidelines for the organisations referred in paragraph 2 are set out in Annex 6. Such modalities shall aim at ensuring close consultation with the beneficiary Parties and that each function referred in paragraph 2 is discharged by the organisation best placed to perform it. Notwithstanding article ... (Amendments), the partnership modalities and guidelines may be modified by the member organisations of the partnership, in consultation with the Parties.

4. The Parties shall provide assistance to the partnership referred in paragraph 2.

5. In case the Director General of the WHO declares a pandemic situation in accordance with Article 3, the Parties in a position to do so shall make all possible efforts to donate countermeasures referred to in article G.1.3 to countries in need. Without prejudice to the possibility for the Parties to organise direct donations to countries in need, donations of countermeasures should be facilitated by and effected through, the partnership referred to in paragraphs 2 and 3 and in accordance with the provisions of this Article.

Article G.3. Affordability of countermeasures

1. With respect to sales to, or for the benefit of, Parties, which are low income countries, of countermeasures referred to in Article G.1.3 including, but not limited to, the reserved allocations referred to in Article G.2.1, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all

possible efforts, while a pandemic situation persist, to ensure that countermeasure manufacturers will provide them at not-for-profit price.

2. With respect to sales to, or for the benefit of, middle income countries, of countermeasures referred to in Article G.1.3 including, but not limited to, the reserved allocations referred to in Article G.2.1, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts, while a pandemic situation persist, to ensure that countermeasure manufacturers will apply tiered pricing, taking into consideration factors, such as population size, epidemiological situation, income level and capacity to pay of the buying countries.

3. The Countermeasures Expert Committee shall issue pricing guidelines including on not-for profit and tiered pricing, for each of the countermeasures referred to in Article G.1.3.

4. In case the Director General of the WHO declares a pandemic situation, the Parties in a position to do so shall cooperate, including with the private sector, take coordinated actions and make all possible efforts to make available financial resources for the acquisition of countermeasures referred to in Article 1.3 for the benefit of countries in need, with special attention to the needs and epidemiological situation of the Parties which are low and lower middle income countries and of persons in vulnerable or humanitarian situations. For this purpose, Parties shall cooperate with the relevant multilateral and regional financial institutions.

Article G.4. Quality of countermeasures

1. In case the Director General of the WHO declares a pandemic situation, the Parties and the WHO shall cooperate to ensure the rapid availability of countermeasures by increasing the collaboration, including at regional level, among authorities competent to ensure the quality, safety and efficacy of the countermeasures referred to in Article G.1.3.

2. The Parties, with the support of the Secretariat, shall aim at aligning and, where possible, harmonising technical and regulatory requirements and procedures, promote the use of common technical documents, share relevant information and assessments concerning quality, safety and efficacy of countermeasures, including after regulatory approvals are granted.

3. The Parties shall promote and facilitate the use of regulatory reliance and mutual recognition, both at national and regional level, with the aim of expediting regulatory approvals and authorisations and ensuring quality, safety and efficacy of countermeasures.

4. The Parties, with the support of the Secretariat, shall promote the establishment or development of international and regional networks of scientific, research and regulatory institutions, as well as of international and regional protocols for the performance of clinical trials, with the aim of increasing the acceptability of trials results by the Parties' regulatory authorities. The Parties shall also promote access to relevant clinical data, including clinical trial eports and protocols, for the countermeasures referred to in Article G.1.3.

5. The Countermeasures Expert Committee shall issue guidelines for regulatory cooperation for each of the countermeasures referred to in Article G.1.3.

6. The Parties and the WHO shall collaborate with the aim of strengthening the capacities of regulatory authorities and systems, especially in case of pandemic situations, with particular attention to the needs of the Parties which are low and lower-middle income countries.

Article G.5. Stockpiling of countermeasures

1. The Parties shall cooperate to ensure that international emergency stockpiles of countermeasures are established and existing ones supported or enlarged, with the objective of increasing the equitable availability and affordability of countermeasures, with special attention to the needs of Parties, which are low and lower middle income countries, and of persons in vulnerable situations living in their territories.

2. The Conference of the Parties shall take the necessary decisions with the aim of establishing international emergency stockpiles. The Countermeasures Expert Committee shall provide guidance on the types of countermeasures for which emergency stockpiles should be established or supported, where they should be located to facilitate equitable access, adequate financing measures, as well as on the management modalities of individual emergency stockpiles, with the aim of increasing equitable access and effective and efficient stockpiling operations.

Article G.6. Support for additional manufacturing facilities

1. In order to improve the availability and affordability of quality countermeasures, the Parties shall cooperate to support public and private sector investment aimed at creating or expanding manufacturing facilities of relevant countermeasures, especially facilities with a regional scope of operation in Parties which are low and middle income countries.

2. The Parties shall also promote the voluntary transfer of technology, know-how and skills that may be necessary to improve the availability and affordability of countermeasures.

3. For this purpose, the Parties should act individually and jointly by means of grants, loans, taxation and other incentive measures, as appropriate.

4. The Countermeasures Expert Committee shall provide advice to the Parties on the matters covered by this article.

N. Scientific and research cooperation

Article N.1. Scientific and research cooperation

1. The Parties shall cooperate to advance knowledge and scientific research in the areas covered by the Agreement, at national, regional and international levels, directly or through international and

regional organizations and other relevant bodies. The Parties shall ensure the freedom of scientific research.

2. Cooperation in research shall address fields such as biological, biotechnological, medical, pharmaceutical, environmental and behavioural research, including human and animal health and epidemiology, so as to strengthen and advance scientific knowledge, aimed at preventing, be prepared for and respond to pandemic situations. The Parties shall pay particular attention to the needs of parties which are low and lower middle income countries and seek the advice of the Panel of Experts provided for in Article P.3.

3. The Parties shall promote, in particular:

a) national and regional research institutions which are able to rapidly respond to research and development needs in case of a pandemic situation;

b) joint scientific research programmes, projects and partnerships on the causes and effects of pandemics, on their prevention and management, and on relevant medical and other countermeasures, including preventive, diagnostic and therapeutic countermeasures, with the specific aim to increase the availability, affordability and quality of such countermeasures;

c) regional and international collaboration and exchange of information between research institutions, funding organisations as well as individual scientists, including national, regional and international research and development networks that are able to rapidly respond in case of a pandemic situation;

d) support and capacity building programmes, projects and partnerships for the development, dissemination and use of technical and scientific knowledge and research;

e) access for scientists and researchers from Parties, which are low and middle income countries, to scientific research programmes, projects and partnerships referred to under b), c) and d);

f) access to, and enhancement of, knowledge, skills and capacities through increased cooperation in the areas covered by the Agreement, and

g) collaboration, including with the private sector, to set common objectives and research goals, pool expertise and avoid duplicating research efforts, especially in the field of countermeasures.

Article 6. Predictable global supply chain and logistics network

1. The Parties, recognizing the shortcomings of the preparedness for and response to the COVID-19 pandemic, agree on the need for an adequate, equitable, transparent, robust, agile, effective and diverse global supply chain and logistics network for pandemic prevention, preparedness, response and recovery.

2. The WHO Global Pandemic Supply Chain and Logistics Network (the "Network") is hereby established.

3. The Parties shall support the Network's development and operationalization, and participate in the Network, within the framework of WHO, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic. In that regard, the Parties shall:

(a) determine the types and size of products needed for robust pandemic prevention, preparedness and response, including costs and logistics for establishing and maintaining strategic stockpiles of such

products, by working with relevant stakeholders and experts, guided by scientific evidence and regular epidemiological risk assessments;

(b) assess anticipated demand for, and map sources of, manufacturers and suppliers, including raw materials and other necessary inputs, for sustainable production of pandemic-related products (especially active pharmaceutical ingredients), including manufacturing capacities, and identify the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms and in-kind contributions, as well as promoting transparency in cost and pricing of all elements along the supply chain;

(c) develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;

(d) map existing delivery and distribution options, and establish or operationalize, as appropriate, international consolidation hubs, as well as regional staging areas, to ensure that transport of supplies is streamlined and uses the most appropriate means for the products concerned; and

(e) develop a dashboard for pandemic-related product supply capacity and availability, with regular reporting, and conduct regular tabletop exercises to test the functioning of the Network.

4. The Parties commit not to impose regulations that unduly interfere with the trade in, or of, pharmaceutical raw materials and ingredients, mindful of the need for unhindered access to pandemic-related products.

5. The Parties commit to safeguard the humanitarian principles of humanity, neutrality, impartiality and independence, and to facilitate the unimpeded access of humanitarian staff and cargo. The commitment to facilitate such access is understood to be legally binding and to apply in all circumstances, consistent with humanitarian principles.

6. The Parties, working through the Governing Body for the WHO CA+, shall take all appropriate measures to establish and start functioning of the Network no later than XX. It is understood that giving effect to this Article immediately upon adoption of the WHO CA+ shall be considered pursuant to, and within the meaning of, Article 35 of the WHO CA+.

Article 7. Access to technology: promoting sustainable and equitably distributed production and transfer of technology and know-how

1. The Parties recognize that inequitable access to pandemic-related products (including but not limited to vaccines, therapeutics and diagnostics) should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed.

2. The Parties, working through the Governing Body for the WHO CA+, shall strengthen existing and develop innovative multilateral mechanisms that promote and incentivize relevant transfer of technology and know-how for production of pandemic-related products, on mutually agreed terms, to capable manufacturers, particularly in developing countries.

3. During inter-pandemic times, all Parties commit to establish these mechanisms and shall:

(a) coordinate, collaborate, facilitate and incentivize manufacturers of pandemic-related products to transfer relevant technology and know-how to capable manufacturer(s) (as defined below) on mutually agreed terms, including through technology transfer hubs and product development partnerships, and to address the needs to develop new pandemic-related products in a short time frame;

(b) strengthen coordination, with relevant international organizations, including United Nations agencies, on issues related to public health, intellectual property and trade, including timely matching of supply to demand and mapping manufacturing capacities and demand;

(c) encourage entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms, licences to capable manufacturers, notably 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 response product research, development and production, in particular for pre-pandemic and pandemic-related products; and

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

4. In the event of a pandemic, the Parties:

(a) will take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;

(b) will apply 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 of 2001 and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement;

(c) shall encourage all holders of patents related to the production of pandemic-related products to waive, or manage as appropriate, payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for 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

(d) shall encourage all research and development institutes, including manufacturers, in particular those receiving significant public financing, to waive, or manage as appropriate, royalties on the continued use of their technology for production of pandemic-related products.

5. For purposes of this Article, "capable manufacturer" refers to an entity that operates in a manner that is consistent with national and international guidelines and regulations, including biosafety and biosecurity standards.

Article 8. Regulatory strengthening

- **(See above proposal: Article G4 – Quality of countermeasures)**

1. The Parties shall strengthen the capacity and performance of national regulatory authorities and increase the harmonization of regulatory requirements at the international and regional level, including, as applicable, through mutual recognition agreements.

2. Each Party shall build and strengthen its country regulatory capacities and performance for timely approval of pandemic-related products and, in the event of a pandemic, accelerate the process of approving and licensing pandemic-related products for emergency use in a timely manner, including the sharing of regulatory dossiers with other institutions.

3. The Parties shall, as appropriate, monitor and regulate against substandard and falsified pandemic-related products, through existing Member State mechanisms on substandard and falsified medical products.

Article 9. Increasing research and development capacities

- **(See above proposal: Article N1– Scientific and research cooperation)**

1. The Parties recognize the need to build and strengthen capacities and institutions for innovative research and development for pandemic-related products, particularly in developing countries, and the need for information sharing through open science approaches for rapid sharing of scientific findings and research results.

2. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, taking into account the extent of the public funding received:

(a) promote the free, public dissemination of the results of publicly and government-funded research for the development of pandemic-related products;

(b) endeavour to include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms;

(c) ensure that promoters of research for pandemic-related products assume an appropriate level of the associated risk;

(d) promote and incentivize technology co-creation and joint venture initiatives; and

(e) establish appropriate conditions for publicly funded research and development, including on distributed manufacturing, licensing, technology transfer and pricing policies.

3. Parties shall increase the transparency of information about funding for research and development for pandemic-related products by:

(a) disclosing information on public funding for research and development of potential pandemic-related products and provisions to enhance the availability and accessibility of the resulting work, including freely available and publicly accessible publications and public reporting of the relevant patents;

(b) making it compulsory for manufacturers that receive public funding for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics, taking into account the extent of the public funding received; and

(c) encouraging manufacturers that receive other funds, external to the manufacturer, for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics.

4. Each Party should encourage non-State actors to participate in and accelerate innovative research and development for addressing novel pathogens, pathogens resistant to antimicrobial agents and emerging and re-emerging diseases with pandemic potential.

5. The Parties shall establish, no later than XX, with reference to existing models, a global compensation mechanism for injuries resulting from pandemic vaccines.

6. Pending establishment of such global compensation mechanism, each Party shall, in contracts for the supply or purchase of pandemic-related products, endeavour to exclude buyer/recipient indemnity clauses of indefinite or excessive duration.

7. In the conclusion of contracts for the supply or purchase of pandemic-related products, each Party shall endeavour to exclude confidentiality provisions that serve to limit disclosure of terms and conditions.

8. Each Party shall, as applicable, implement and apply international standards for, oversight of and reporting on laboratories and research facilities that carry out work to genetically alter organisms to increase their pathogenicity and transmissibility, in order to prevent accidental release of these pathogens, while ensuring that these measures do not create any unnecessary administrative hurdles for research.

9. The Parties are encouraged to promote and strengthen knowledge translation and evidence-based communication tools and strategies relating to pandemic prevention, preparedness, response and recovery, at local, national, regional and international levels.

10. The Parties acknowledge the need to take steps, individually and collectively, to develop strong, resilient national, regional and international clinical research ecosystems. In that regard, the Parties, as appropriate, commit to:

(a) fostering and coordinating clinical research and clinical trials, including, as appropriate, through existing coordination mechanisms;

(b) ensuring equitable access to resources (funding or in-kind), clinical research and clinical trials, so that resources are deployed optimally and efficiently;

(c) supporting transparent and rapid reporting of clinical research and clinical trial results, to ensure evidence is available in a timely manner to inform national, regional and international decision-making; and

(d) disclosing disaggregated information, for instance by gender and age, to the extent possible and as appropriate, on the results of clinical research and clinical trials relating to pandemic prevention, preparedness, response and recovery.

Article 10. WHO Pathogen Access and Benefit-Sharing System

1. The need for a multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with pandemic potential and genomic sequences, and benefits arising therefrom, that applies and operates in both inter-pandemic and pandemic times, is hereby recognized. In pursuit thereof, it is agreed to establish the WHO Pathogen Access and Benefit-Sharing System (the "PABS System") under this WHO CA+. The Parties are mindful that the PABS System, or parts thereof, could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed. The terms of the PABS System shall be developed no later than XX with a view to their provisional application consistent with Article 35 hereof.

2. The PABS System shall cover all pathogens with pandemic potential, including their genomic sequences, as well as access to benefits arising therefrom, and ensure that it operates synergistically with other relevant access and benefit-sharing instruments.

3. The PABS System shall include the following elements and shall be regulated as follows:

Access to pathogens with pandemic potential

(a) Each Party, through its relevant and authorized laboratories, shall, in a rapid, systematic and timely manner: (i) provide pathogens with pandemic potential from early infections due to pathogens with pandemic potential or subsequent variants to a laboratory recognized or designated as part of an established WHO coordinated laboratory network; and (ii) upload the genomic sequence of such pathogens with pandemic potential to one or more publicly accessible databases of its choice. For purposes hereof, "rapid" shall be understood to mean within XX hours from the time of identification of a pathogen with pandemic potential;

(b) The PABS System will be consistent with international legal frameworks, notably those for collection of patient specimens, material and data, and will promote effective, standardized, realtime global and regional platforms that promote findable, accessible, interoperable and reusable data available to all Parties;

(c) Access shall be accorded expeditiously by the laboratory recognized or designated as part of an established WHO coordinated laboratory network, subject to conclusion of a Standard Material Transfer Agreement, developed for the purposes of the PABS System, with the recipient in accordance with subsection (i) below. Any such access shall be subject to applicable biosafety and biosecurity rules and standards, and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved;

(d) Recipients of materials shall not claim any intellectual property or other rights that limit the facilitated access to pathogens with pandemic potential, or their genomic sequences or components, in the form received; and

(e) Access to pathogens with pandemic potential protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws.

Fair and equitable benefit-sharing

(f) The Parties agree that benefits arising from facilitating access to pathogens with pandemic potential shall be shared fairly and equitably in accordance with the provisions of the PABS System. Accordingly, it is understood that production of pandemic vaccines or other pandemic- related products, irrespective of the technology, information or material used, implies use of pathogens with pandemic potential, including the genomic sequence;

(g) Facilitated access shall be provided pursuant to a Standard Material Transfer Agreement, the form of which shall be set out in the PABS System and that shall contain the benefit-sharing options available to entities accessing pathogens with pandemic potential; and

(h) Such options shall include, but not be limited to: (i) real-time access by WHO to 20% of the production of safe, efficacious and effective pandemic-related products, including diagnostics, vaccines, personal protective equipment and therapeutics, to enable equitable distribution, in particular to developing countries, according to public health risk and need and national plans that identify priority populations. The pandemic-related products shall be provided to WHO on the following basis: 10% as a donation and 10% at affordable prices to WHO; (ii) commitments by the countries where manufacturing facilities are located that they will facilitate the shipment to WHO of these pandemic-related products by the manufacturers within their jurisdiction, according to schedules to be agreed between WHO and manufacturers.

Recognition of the PABS System as a specialized international instrument

(i) The PABS System, adopted under the WHO Constitution, is established with a view to its recognition as a specialized international access and benefit-sharing instrument within the meaning of the Nagoya Protocol;

(j) Upon adoption, each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures to give effect to such recognition at the domestic level and/or with respect to its relations with all other States and regional economic integration organizations, as appropriate; and

(k) The Parties shall support the further development and operationalization of the PABS System, including appropriate governance mechanisms, and participate in its operation, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic.

4. The Parties, working through the Governing Body for the WHO CA+, shall develop and finalize additional elements and tools necessary to fully implement, operationalize and sustain the PABS System, no later than XX.

Chapter IV. Strengthening and sustaining capacities for pandemic prevention, preparedness, response and recovery of health systems

Article 11. Strengthening and sustaining preparedness and health systems' resilience

1. The Parties recognize the need for resilient health systems, rooted in universal health coverage, to mitigate the shocks caused by pandemics and to ensure continuity of health services, thus preventing health systems from becoming overwhelmed.

2. The Parties are encouraged to enhance financial, technical and technological support, assistance and cooperation, in particular to developing countries, to strengthen health emergency prevention and preparedness consistent with the goal of universal health coverage. The Parties shall strive to accelerate the achievement of universal health coverage.

3. The Parties are encouraged to establish global, regional and national collaborative genomics networks that are dedicated to epidemiological genomic surveillance and the global sharing of emerging pathogens with pandemic potential.

4. Each Party shall, in accordance with national law, adopt policies and strategies, supported by implementation plans, across the public and private sectors and relevant agencies, consistent with relevant tools, including, but not limited to, the International Health Regulations, and strengthen and reinforce public health functions for:

(a) continued provision of quality routine and essential health services during pandemics, including clinical and mental health care and immunization, with a focus on primary health care and community-level interventions, and management of the backlog of and waiting lists for the diagnosis and treatment of, and interventions for, other illnesses, including care for patients with long-term effects from the pandemic disease;

(b) strengthening human resource capacities during inter-pandemic times and during pandemics;

(c) surveillance (including using a One Health approach), outbreak investigation and control, through interoperable early warning and alert systems;

(d) sustained laboratory capacity for genomic sequencing, as well as for analysing and sharing

such information;

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

(f) post-emergency health system recovery strategies;

(g) strengthening public health laboratory and diagnostic capacities, and national, regional and global networks, including standards and protocols for infection prevention and control, and public health laboratory biosafety and biosecurity; and

(h) creating and maintaining up-to-date, universal platforms and technologies for forecasting and timely information sharing, through appropriate capacities, including building digital health and data science capacities.

Article 12. Strengthening and sustaining a skilled and competent health and care workforce

1. Each Party shall take the necessary steps to safeguard, protect, invest in and sustain a skilled, trained, competent and committed health and care workforce, at all levels, in a gender-responsive manner, with due protection of its employment, civil and human rights and well-being, consistent with international obligations and relevant codes of practice, with the aim of increasing and sustaining capacities for pandemic prevention, preparedness and response, while maintaining essential health services. This includes, subject to national law:

(a) strengthening in- and post-service training, deployment, remuneration, distribution and retention of the health and care workforce, including community health workers and volunteers; and

(b) addressing gender disparities and inequalities within the health and care workforce, to ensure meaningful representation, engagement, participation and empowerment 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 taking leadership and decision-making roles.

2. The Parties are encouraged to enhance financial and technical support, assistance and cooperation, in particular to developing countries, to strengthen and sustain a skilled and competent health and care workforce at the national level.

3. The Parties shall invest in establishing, sustaining, coordinating and mobilizing an available, skilled and trained 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 an escalation of smallscale spread to global proportions.

4. The Parties will support the development of a network of training institutions, national and regional facilities and centres of expertise in order to establish common guidance to enable more predictable, standardized, timely and systematic response missions and deployment of the aforementioned public health emergency workforce.

Additional article to be introduced in Chapter IV expanding on Article 12(2):

Article I.1 - Enhancing and coordinating emergency preparedness and response measures

1. Parties shall endeavor to establish or designate emergency health teams at national and where appropriate regional level. Emergency health teams should be multi-disciplinary, based on a One Health approach, and ensure the essential functions and capacities for responding to a pandemic situation. Emergency health teams should include public health expertise and logistics support. The role of emergency health teams shall be to improve the timeliness, quality and coordination of health and emergency services.

2. Parties in a position to do so shall support and assist other Parties in need, at their request, in particular Parties which are low or lower middle income countries, in training and capacity building for their local or regional emergency health teams. The Secretariat in cooperation with relevant organisations and bodies shall also provide regular training and assist local and regional emergency medical teams of Parties in maintaining the capacity for immediate deployment at national and regional level.

3. Parties having established emergency health teams shall make best efforts to respond to requests for deployment by Parties affected by pandemic situations to which they are not able to fully respond with their national resources. The Secretariat shall coordinate the deployment of emergency health teams in close coordination with the requesting Parties and the WHO, including by selecting teams with the required expertise and appropriate equipment, and advising on the modalities, location and duration of their deployment.

Article 13. Preparedness monitoring, simulation exercises and universal peer review

1. Each Party shall undertake regular and systematic capacity assessments in order to identify capacity gaps and develop and implement comprehensive, inclusive, multisectoral national plans and strategies for pandemic prevention, preparedness and response, based on relevant tools developed by WHO.

2. Each Party shall periodically assess the functioning, readiness and gaps of its preparedness and multisectoral response, logistics and supply chain management, through appropriate simulation or tabletop exercises, that include risk and vulnerability mapping. Such exercises may consist of afteraction reviews of actual public health emergencies that can support identifying gaps, share lessons learned and improve national pandemic prevention, preparedness and response.

3. The Parties will convene multi-country or regional tabletop exercises every two years, with technical support from the WHO Secretariat, with an aim to identify gaps in multi-country response capacity.

4. Each Party shall provide annual (or biennial) reporting, building on existing relevant reporting where possible, on its pandemic prevention, preparedness, response and health systems recovery capacities.

5. The Parties shall develop and implement a transparent, effective and efficient pandemic prevention, preparedness and response monitoring and evaluation system, which includes targets and national and global standardized indicators, with necessary funding for developing countries for this purpose.

6. The Parties should establish, regularly update and broaden implementation of a universal peer review mechanism to assess national, regional and global preparedness capacities and gaps, by bringing nations together to support a whole-of-government and whole-of-society approach to strengthen national capacities for pandemic prevention, preparedness, response and health systems recovery, through technical and financial cooperation, mindful of the need to integrate available data and to engage national leadership at

the highest level.

7. The Parties shall endeavour to implement the recommendations generated from review mechanisms, including prioritization of activities for immediate action.

Article 14. Protection of human rights

Suggest moving up under Chapter I – General provisions

1. The Parties shall, in accordance with their national laws, incorporate non-discriminatory measures to protect human rights as part of their pandemic prevention, preparedness, response and recovery, with a particular emphasis on the rights of persons in vulnerable situations.

2. Towards this end, each Party shall:

(a) incorporate into its laws and policies human rights protections during public health emergencies, including, but not limited to, requirements that any limitations on human rights are aligned with international law, including by ensuring that: (i) any restrictions are non-discriminatory, necessary to achieve the public health goal and the least restrictive necessary to protect the health of people; (ii) all protections of rights, including but not limited to, provision of health services and social protection programmes, are non-discriminatory and take into account the needs of people at high risk and persons in vulnerable situations; and (iii) people living under any restrictions on the freedom of movement, such as quarantines and isolations, have sufficient access to medication, health services and other necessities and rights; and

(b) endeavour to develop an independent and inclusive advisory committee to advise the government on human rights protections during public health emergencies, including on the development and implementation of its legal and policy framework, and any other measures that may be needed to protect human rights.

Chapter V. Coordination, collaboration and cooperation for pandemic prevention, preparedness, response and health system recovery

Article 15. Global coordination, collaboration and cooperation

1. The Parties recognize the need to coordinate, collaborate and cooperate, in the spirit of international solidarity, with competent international and regional intergovernmental organizations and other bodies in the formulation of cost-effective measures, procedures and guidelines for pandemic prevention, preparedness, response and recovery of health systems, and to this end shall:

(a) promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness, response and recovery by means that include establishing appropriate governance arrangements;

(b) support mechanisms that ensure global, regional and national policy decisions are science and evidence-based;

(c) develop, as necessary, and implement global policies that recognize the specific needs, and ensure the protection of, persons in vulnerable situations, indigenous peoples, and those living in fragile environments or areas, such as Small Island Developing States, who face multiple threats simultaneously, by gathering and analysing data, including data disaggregated by gender, to show the impact of policies on different groups;

(d) promote equitable gender, geographical and socioeconomic status, representation and participation, as well as the participation of youth and women, in global and regional decisionmaking processes, global networks and technical advisory groups;

(e) ensure solidarity with, and prevent stigmatization of, countries that report public health emergencies, as an incentive to facilitate transparency and timely reporting and sharing of information; and

(f) facilitate WHO with rapid access to outbreak areas within the Party's jurisdiction or control, including through the deployment of rapid response and expert teams, to assess and support the response to emerging outbreaks.

2. Recognizing the central role of WHO as the directing and coordinating authority on international health work, and mindful of the need for coordination with regional organizations, entities in the United Nations system and other intergovernmental organizations, the WHO Director-General shall, in accordance with terms set out herein, declare pandemics.[V]

Article 16. Whole-of-government and whole-of-society approaches at the national level

1. The Parties recognize that pandemics begin and end in communities and are encouraged to adopt a whole-of-government and whole-of-society approach, including to empower and ensure communities' ownership of, and contribution to, community readiness and resilience for pandemic prevention, preparedness, response and recovery of health systems.

2. Each Party shall establish, implement and adequately finance an effective national coordinating multisectoral mechanism with meaningful representation, engagement and participation of communities.

3. Each Party should promote effective and meaningful engagement of communities, civil society and non-State actors, including the private sector, as part of a whole-of-society response in decisionmaking, implementation, monitoring and evaluation, as well as effective feedback mechanisms.

4. Each Party shall develop, in accordance with its national context, comprehensive national pandemic prevention, preparedness, response and recovery plans pre-, post- and inter-pandemic that, inter alia: (i) identify and prioritize populations for access to pandemic-related products and health services; (ii) support timely and scalable mobilization of multidisciplinary surge capacity of human and financial resources, and facilitate timely allocation of resources to the frontline pandemic response; (iii) review the status of stockpiles and surge capacity of essential public health and clinical resources, and surge capacity in production of pandemic-related products; (iv) facilitate rapid and equitable restoration of public health capacities following a pandemic; and (v) promote collaboration with nonState actors, the private sector and civil society.

5. Each Party will take steps to address the social, environmental and economic determinants of health, and vulnerability conditions that contribute to the emergence and spread of pandemics, and prevent or mitigate the socioeconomic impacts of pandemics, including but not limited to, those affecting economic growth, the environment, employment, trade, transport, gender equality, education, social assistance, housing, food insecurity, nutrition and culture, and especially for persons in vulnerable situations.

6. Each Party should strengthen its national public health and social policies to facilitate a rapid, resilient response, especially for persons in vulnerable situations, including mobilizing social capital in communities

[V] Reference is made to footnote 3 (Article 1), which invites the INB to propose and consider the development of modalities and terms for this provision.

for mutual support.

Article 17. Strengthening pandemic and public health literacy

➢ Expanded and restructured proposal

Article M.1 Addressing misinformation and disinformation

1. The Parties should act independently and jointly to increase public health education, literacy and awareness in the population, and access to information on pandemics and their causes and effects, as well as on the efficacy of medical and other countermeasures, with the aim to counter misinformation or disinformation, including through promotion of international cooperation. In that regard, each Party shall:

(a) promote and facilitate, at all appropriate levels, in accordance with national law, development and implementation of educational and public awareness programmes on pandemics and their effects, by informing the public, communicating risk and providing evidence- and science-based information about pandemics and relevant countermeasures through effective channels, including social media, in cooperation with all stakeholders, including health professionals, local communities and civil society and the private sector;

(b) promote regular analysis and consultations with civil society organizations and media outlets to identify the prevalence and profiles of misinformation and design communications and develop messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust and promoting prevention of pandemic risks; and

(c) promote effective and accessible communication specifically aimed at informing persons in vulnerable situations and people living in humanitarian settings;

2. The Parties shall exchange information and cooperate, in accordance with national law, in preventing and investigating incidents of misinformation and disinformation. They shall endeavor to harmonize best practices to increase the accuracy and reliability of crisis communication, promoting health literacy and developing effective tools to identify and counteract misinformation and disinformation.

3. The Conference of the Parties shall promote cooperation among the Parties for the implementation of this article and consider adopting additional measures, as appropriate.

4. The Secretariat shall, at the request of the Conference of the Parties, develop technical guidance, consult with experts, civil society organizations, the media and monitor social media to identify relevant patterns of communication and need for information. It shall report to the Conference of the Parties on its activities.

1. The Parties commit to increase science, public health and pandemic literacy in the population, as well

as access to information on pandemics and their effects, and tackle false, misleading, misinformation or disinformation, including through promotion of international cooperation. In that regard, each Party is encouraged to:

(a) promote and facilitate, at all appropriate levels, in accordance with national laws and regulations, development and implementation of educational and public awareness programmes on pandemics and their effects, by informing the public, communicating risk and managing infodemics through effective channels, including social media;

(b) conduct regular social listening and analysis to identify the prevalence and profiles of misinformation, which contribute to design communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust; and

(c) promote communications on scientific, engineering and technological advances that are relevant to the development and implementation of international rules and guidelines for pandemic prevention, preparedness, response and recovery of health systems, based on science and evidence.

2. The Parties will contribute to research and inform policies on factors that hinder adherence to public health and social measures, confidence and uptake of vaccines, use of appropriate therapeutics and trust in science and government institutions.

3. The Parties shall promote science and evidence-informed effective and timely risk assessment, including the uncertainty of data and evidence, when communicating such risk to the public.

Article 18. One Health

- **One Health issues are covered throughout the various sections of the EU proposals. We will come back on the content of Article 18.**

1. The Parties, recognizing that the majority of emerging infectious diseases and pandemics are caused by zoonotic pathogens, commit, in the context of pandemic prevention, preparedness, response and recovery of health systems, to promote and implement a One Health approach that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing instruments and initiatives.

2. The Parties, with an aim of safeguarding human health and detecting and preventing health threats, shall promote and enhance synergies between multisectoral and transdisciplinary collaboration at the national level and cooperation at the international level, in order to identify, conduct risk assessment of and share pathogens with pandemic potential at the interface between human, animal and environment ecosystems, while recognizing their interdependence.

3. The Parties will identify and integrate into relevant pandemic prevention and preparedness plans interventions that address the drivers of the emergence and re-emergence of disease at the humananimal-environment interface, including but not limited to climate change, land use change, wildlife trade, desertification and antimicrobial resistance.

4. The Parties commit to regularly assess One Health capacities, insofar as they relate to pandemic prevention, preparedness, response and recovery of health systems, and to identify gaps, policies and the funding needed to strengthen those capacities.

5. The Parties commit to strengthen synergies with other existing relevant instruments that address the drivers of pandemics, such as climate change, biodiversity loss, ecosystem degradation and increased risks

at the human-animal-environment interface due to human activities.

6. The Parties commit to strengthen multisectoral, coordinated, interoperable and integrated One Health surveillance systems and strengthen laboratory capacity to identify and assess the risks and emergence of pathogens and variants with pandemic potential, in order to minimize spill-over events, mutations and the risks associated with zoonotic neglected tropical and vector-borne diseases, with a view to preventing small-scale outbreaks in wildlife or domesticated animals from becoming a pandemic.

7. Each Party shall:

(a) implement actions to prevent pandemics from pathogens resistant to antimicrobial agents, taking into account relevant tools and guidelines, through a One Health approach, and collaborate with relevant partners, including the Quadripartite;

(b) foster actions at national and community levels that encompass whole-of-government and whole-of-society approaches to control zoonotic outbreaks (in wildlife and domesticated animals), including engagement of communities in surveillance that identifies zoonotic outbreaks and antimicrobial resistance at source;

(c) develop and implement a national One Health action plan on antimicrobial resistance that strengthens antimicrobial stewardship in the human and animal sectors, optimizes antimicrobial consumption, increases investment in, and promotes equitable and affordable access to, new medicines, diagnostic tools, vaccines and other interventions, strengthens infection prevention and control in health care settings and sanitation and biosecurity in livestock farms, and provides technical support to developing countries;

(d) enhance surveillance to identify and report on pathogens resistant to antimicrobial agents in humans, livestock and aquaculture that have pandemic potential, building on the existing global reporting systems; and

(e) take the One Health approach into account at national, subnational and facility levels in order to produce science-based evidence, and support, facilitate and/or oversee the correct, evidence-based and risk-informed implementation of infection prevention and control.

Additional article:

Article O.1. Provision of implementation support

1. The Parties shall cooperate for the implementation of the Agreement.

2. The Parties shall promote and strengthen cooperation between their competent bodies and authorities in order to fully achieve the objective of the Agreement.

3. The Parties shall facilitate the provision of technical assistance and capacity building, with particular attention to the needs of Parties which are low and lower middle income countries and with the aim to assist them in building sustainable capacity to implement their obligations and commitments under the Agreement.

4. The Parties shall promote, establish or enhance joint training programmes between, and continuing education of, human, animal and environmental health professionals and the inclusion of the One Health approach in health-related educational programmes.

5. The Parties shall cooperate, including with the private and philanthropic sectors, to secure the financial resources necessary for the provision of adequate assistance aimed at the effective implementation of the Agreement. For this purpose the Conference of the Parties shall, at its first session, define a financial mechanism functioning under its guidance. It shall select the existing entities providing multilateral, regional and bilateral financial and technical assistance to be entrusted with the operation of the mechanism and set out the necessary arrangements for cooperation with these entities in order to enable its effective and equitable operation.

6. Where relevant and appropriate, assistance activities shall address regional and sub-regional implementation problems and promote regional and sub-regional capacities.

7. The Secretariat, in collaboration with relevant international and regional organizations and other bodies, shall provide assistance in the identification of support needs and organization of the technical assistance and capacity building activities provided for in this Article, with particular regard to the needs of the Parties which are low or lower-middle income countries. The support activities under this Article shall be closely coordinated with the provision of support under the IHR. The Parties and Secretariat shall report on the results obtained to the Conference of the Parties at least every two years as part of the report provided for in Article P.2.

8. The Conference of the Parties shall hold at least one dedicated meeting within the yearly ordinary session to:

(a) discuss any problems regarding the implementation of provisions of this Agreement;

(b) review progress in the provision of technical assistance and capacity building to support the implementation of the Agreement, including any Party, especially low and lower middle income not receiving adequate support;

(c) share experiences and information on ongoing assistance and support for capacity building and implementation programmes, including challenges and successes;

(d) review the reports provided by the parties and the Secretariat in accordance with paragraph 7.

Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems

Article 19. Sustainable and predictable financing

1. The Parties recognize the important role that financial resources play in achieving the objective of the WHO CA+ and the primary financial responsibility of national governments in protecting and promoting the health of their populations. In that regard, each Party shall:

(a) cooperate with other Parties, within the means and resources at its disposal, to raise financial resources for effective implementation of the WHO CA+ through bilateral and multilateral funding mechanisms;

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

(c) commit to prioritize and increase or maintain, including through greater collaboration between the health, finance and private sectors, as appropriate, domestic funding by allocating in its annual budgets not lower than 5% of its current health expenditure to pandemic prevention, preparedness, response and health systems recovery, notably for improving and sustaining relevant capacities and working to achieve universal health coverage; and

(d) commit to allocate, in accordance with its respective capacities, XX% of its gross domestic product for international cooperation and assistance on pandemic prevention, preparedness, response and health systems recovery, particularly for developing countries, including through international organizations and existing and new mechanisms.

2. The Parties shall ensure, through innovative existing and/or new mechanisms, sustainable and predictable financing of global, regional and national systems, capacities, tools and global public goods, while avoiding duplication, promoting synergies and enhancing transparent and accountable governance of these mechanisms, to support strengthening pandemic prevention, preparedness, response and recovery of health systems, based on public health risk and need, particularly in developing countries.

3. The Parties shall promote, as appropriate, the use of bilateral, regional, subregional and other appropriate and relevant channels to provide funding for the development and strengthening of pandemic prevention, preparedness, response and health system recovery programmes of developing country Parties.

4. The Parties will facilitate rapid and effective mobilization of adequate financial resources, including from international financing facilities, to affected countries, based on public health need, to maintain and restore routine public health functions during and in the aftermath of a pandemic response.

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

Chapter VII. Institutional arrangements

Proposal on institutional arrangements

Article P.1. Conference of the Parties

1. A Conference of the Parties is hereby established as the main body responsible for promoting and supporting the implementation of this Agreement.

2. The first session of the Conference of the Parties shall be convened by the Director General of the World Health Organization not later than six months after the entry into force of the Agreement. Thereafter, ordinary sessions of the Conference of the Parties shall be held every year or as otherwise decided by the Conference.

3. As requested by at least one fourth of the Parties or by the Director-General of the WHO, the Conference of the Parties may be convened at the level of Heads of State and Government with the aim to provide political support for the implementation of the Agreement and for the effective and equitable improvement of pandemic prevention, preparedness and response.

4. Extraordinary sessions of the Conference of the Parties, including at the level of Heads of States and Government, shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party or of the Director General of the WHO, provided that, within four weeks of the request being communicated to them by the Secretariat, it is supported by at least one fourth of the Parties.

5. At its first session, the Conference of the Parties shall adopt by consensus:

a) its Rules of Procedure;

b) its financial rules, which shall also apply to the funding of its subsidiary bodies, as well as financial provisions governing the functioning of the Secretariat.

6. At each ordinary session, the Conference of the Parties shall adopt a budget for the financial period until the next ordinary session.

7. The Conference of the Parties shall review and assess the implementation of the Agreement and take any decisions necessary to achieve its objective. To that end, it shall:

a) perform the functions assigned to it by the Agreement,

b) consider ways to facilitate the effective implementation of the Agreement, with particular attention to the needs of Parties which are low and lower middle income countries;

c) promote, at national, regional and international levels, the development, implementation and evaluation of multisectoral strategies, plans and programmes, as well as policies, legislation and other measures to ensure the implementation of the Agreement, following the “One Health” approach;

d) consider the periodic reports submitted by the Parties in accordance with Article P.2;

e) consider the recommendations and advice transmitted to it by the panel of Experts and the Implementation and Compliance Committee;

f) promote and facilitate the mobilization of financial resources for the implementation of the Agreement;

g) establish such subsidiary bodies as are necessary to achieve the objective of the Agreement;

h) consider and adopt, as appropriate, protocols and annexes in accordance with Article…;

i) consider ways to enhance the coordination in the implementation of the IHR and the implementation of the Agreement;

j) cooperate with relevant international organizations and intergovernmental and non-governmental bodies, including those operating at the regional level; and

f) consider and take any other action or decision required for the achievement of the objective of the Agreement.

8. Organizations, institutions, programmes, funds and entities of the United Nations system, the World Trade Organization, the World Organization for Animal Health, any other relevant international organisations, as well as any State not a Party to the Agreement, may be represented at sessions of the Conference of the Parties as observers. Any other body or agency, whether national or international, governmental or non-governmental, including civil society and the private sector, that is qualified in areas covered by the Agreement and has requested the Secretariat to participate in the sessions of the Conference of the Parties as an observer, is admitted unless one third of the Parties present object. This provision shall also apply to the admission and participation of observers to the subsidiary bodies of the Conference of the Parties.

9. In order to ensure the best possible cooperation and coordination of actions to achieve the objective of the Agreement, the Conference of the Parties shall establish and strengthen regular cooperation with relevant international and regional intergovernmental organizations, including, but not limited to the World Health Organization, the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health, the United Nations Environment Programme, the World Intellectual Property Organization, the World Trade Organization, the International Monetary Fund and the World Bank.

Article P.2. Periodic 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 Agreement, which shall include the following:

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

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

c) information on implementation support received under the Agreement; and

d) other information as required by specific provisions of the Agreement.

2. The frequency, conditions and format of the periodic reports submitted by the Parties shall be determined by the Conference of the Parties at its first session, with the aim to facilitate reporting by the Parties and avoid 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, with particular attention to the needs of Parties which are low and lower middle income countries.

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

Article P.3. Scientific advice

1. An expert body to provide scientific advice is hereby established as a subsidiary body of the Conference of the Parties to provide the Conference of the Parties with information, science-based and other technical advice on matters relating to the Agreement. This Panel of Experts shall comprise independent experts competent in the relevant fields of expertise and sitting in their individual expert capacity. It shall be multidisciplinary in line with the One Health approach. It shall report regularly to the Conference of the Parties on all aspects of its work. The body shall:

a) Collect, consider and evaluate the most advanced and recent information and scientific knowledge available on the origins, prevention, surveillance, control and impacts of pandemics;

b) Provide or compile assessments of the state of scientific knowledge relating to zoonotic and other risks in accordance with the One Health approach;

c) Prepare scientific and evidence-based assessments on the effects of measures taken in the implementation of the Agreement and make recommendations as appropriate;

d) Provide advice as appropriate on scientific programmes, international cooperation in research and development related to matters covered by the Agreement, as well as on ways and means of supporting endogenous capacity building in low and lower-middle income countries, as well as other middle income countries in need;

e) Respond to scientific, technological and methodological questions that the Conference of the Parties or other subsidiary body may put forward, and

f) Provide advice and recommendations on any matter as requested by the Conference of the Parties.

2. The Panel of Experts shall take due account of relevant work by, and allow for the participation in its proceedings of, relevant international and regional intergovernmental organizations, governmental and non-governmental organisations and bodies, as well as academic experts.

3. The Panel of Experts shall consist of […] independent experts selected by common accord by the Heads of the Quadripartite Organisations on the basis of criteria of competence, independence, multidisciplinarity, gender equality and equitable geographic representation. Its composition may be modified by the Conference of the Parties.

4. The Panel of Experts shall elaborate its rules of procedure, which shall be approved by the Conference of the Parties at its second session.

5. The Conference of the Parties shall ensure the availability of the resources necessary to enable the Panel of Experts to achieve its objectives and perform its tasks.

Article P.4. Implementation and Compliance Committee

1. An Implementation and Compliance Committee is hereby established as a subsidiary body of the Conference of the Parties.

2. The Committee is mandated to promote implementation of, and review compliance with, the provisions of the Agreement, including by addressing matters related to possible non-compliance. It shall be facilitative in nature and shall pay particular attention to the respective national and regional capabilities and circumstances of Parties, in particular the needs of Parties which are low and lower middle income countries;

3. For that purpose, the Committee shall make recommendations to the Conference of the Parties. Such recommendation may include proposals for consideration of the Conference of the Parties aimed at facilitating and providing support for the implementation of the Agreement, with particular attention to the needs of Parties which are low and lower middle income countries;

4. The Committee shall consist of […] members, which are independent experts, nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality and equitable geographical representation. The first members of the Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 6. The members of the Committee shall have recognized competence in fields relevant to the Convention and reflect an appropriate balance of expertise.

5. The Committee shall consider:

a) written submissions from any Party with respect to compliance with the provisions of the Agreement;

b) periodic reports by the Parties submitted in accordance with Article P.2.;

c) any issue submitted to it by the Conference of the Parties; and

d) other relevant information.

6. The Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Committee.

7. The committee shall collaborate with relevant monitoring and review bodies and mechanisms that may be established by the World Health Assembly or by the Parties of the IHR including by providing for joint sessions.

8. The Committee shall make every effort to adopt its recommendations by consensus. In the absence of consensus, the recommendations shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two-thirds of the members.

Article P.5. Countermeasures Expert Committee

1. A Countermeasures Expert Committee is hereby established as a subsidiary body of the Conference of the Parties.

2. The Committee is mandated pursuant to Article G.1. to monitor and analyse issues related to the availability, affordability and quality of countermeasures and report to the Conference of the Parties, discharge all functions set out in the Agreement and respond to requests from the Conference of the Parties. It shall pay particular attention to the needs of Parties which are low and lower middle income countries;

3. The Committee shall consist of […] members, which are independent experts, nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality, multidiciplinarity, including legal, economic and industrial organisation expertise, and equitable geographical representation. The initial members of the Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 4. The members of the Committee shall have recognized competence in fields relevant to the Agreement, and in particular section G thereof, and reflect an appropriate balance of expertise.

4. The Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Committee.

5. The Committee shall make every effort to deliberate by consensus. In the absence of consensus, its recommendations or decision shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two-thirds of the members.

Article P.6. Secretariat

1. A Secretariat is hereby established.

2. Secretariat functions under the Agreement shall be provided by the World Health Organization in cooperation with the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health and the United Nations Environment Programme. The Heads of the respective organizations will determine the modalities of their cooperation in discharging the Secretariat functions under the Agreement. Such modalities shall be approved by the Conference of the Parties at its first session.

3. Secretariat functions shall be:

a) to make arrangements for sessions of the Conference of the Parties and its subsidiary bodies and to provide them with services as required;

b) to assist the Parties, particularly Parties which are low and lower middle income countries, in implementing the Agreement;

c) to ensure coordination and cooperation with the secretariats of relevant international and regional organizations and with other relevant bodies;

d) to enter into such administrative or contractual arrangements as may be required for the effective discharge of its functions;

e) to perform other secretariat functions specified by the Agreement and any additional functions entrusted to it by the Conference of the Parties.

Article 20. Governing Body for the WHO CA+

1. A governing body for the WHO CA+ is established to promote the effective implementation of the WHO CA+ (hereinafter, the "Governing Body").

2. The Governing Body shall be composed of:

(a) the Conference of the Parties (COP), which shall be the supreme organ of the Governing Body, composed of the Parties and constituting the sole decision-making organ; and

(b) the Officers of the Parties, which shall be the administrative organ of the Governing Body.

3. The COP, as the supreme policy setting organ of the WHO CA+, shall keep under regular review every three years the implementation and outcome of the WHO CA+ and any related legal instruments that the COP may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO CA+. The COP shall:

(a) be composed of delegates representing Parties;

(b) convene regular sessions of the Governing Body; the first of which shall take place not later than one year after the date of entry into force of the Convention, at a time and place to be determined by the WHO Secretariat, with the time and place of subsequent ordinary sessions to be determined by the COP upon a proposal of the Officers of the Parties;

(c) convene special sessions of the Governing Body at such other times as may be deemed necessary by the COP, or at the written request of any Party, provided that, within 30 days of such a request being communicated to the Party/Parties by the Secretariat, it is supported by at least one third of the Parties; and

(d) adopt its rules of procedure, as well as those of the other bodies of the Governing Body, which shall include decision-making procedures. Such procedures may include specified majorities required for the adoption of particular decisions.

4. The Officers of the Parties, as the administrative organ of the Governing Body, shall:

(a) be composed of two Presidents, four Vice-Presidents and two rapporteurs, serving in their individual capacity and elected by the COP for XX years; and

(b) endeavour to make decisions by consensus; however, if efforts to reach consensus are deemed by the Presidents to be unavailing, decisions may be taken by voting by the President and

Vice-Presidents.

5. The Governing Body may further develop proposals for consideration by the WHO Executive Board, including to promote coordination and synergies between its Standing Committee on Health Emergency Prevention, Preparedness and Response and the Governing Body for the WHO CA+.

Article 21. Consultative Body for the WHO CA+

1. A consultative body for the WHO CA+ (the "Consultative Body") is established to provide advice and technical inputs for the decision-making processes of the COP, without participating in any decision-making.

2. The Consultative Body will provide opportunity for broad, fair and equitable input to the COP for the decision-making processes of the COP. Further, the Consultative Body will provide opportunity for facilitation of implementation of COP decisions through modalities to be established by the COP. For the avoidance of doubt, it is understood that the Consultative Body will not participate in any decision-making, whether by consensus, voting or otherwise, of the COP.

3. The Consultative Body shall be composed of (i) delegates representing Parties; and (ii) representatives of the United Nations and its specialized and related agencies, as well as any State Member thereof or observers thereto not Party to the WHO CA+. Further, representatives of any body or organization, whether national or international, governmental or nongovernmental, private sector or public sector, which is qualified in matters covered by the WHO CA+, may be admitted upon formal application, in accordance with terms and conditions to be adopted by the COP, renewable every three years, unless at least one third of the Parties object.

4. The Consultative Body shall be subject to the oversight of the COP, including rules of procedure adopted by the COP.

Article 22. Oversight mechanisms for the WHO CA+

1. The Governing Body, at its first meeting, shall consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of the WHO CA+ and also address cases of non-compliance.

2. These measures, procedures and mechanisms shall include monitoring provisions and accountability measures to systematically address the achievement and gaps of capacities for prevention, preparedness, response and recovery of health systems, and the impact of pandemics, by means that include submission of periodic reports, reviews, remedies and actions, and to offer advice or assistance, where appropriate. These measures shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under the WHO CA+.

Article 23. Assessment and review

The Governing Body shall establish a mechanism to undertake, three years after the entry into force of the WHO CA+, and thereafter every three years and upon modalities determined by the Governing Body, an evaluation of the relevance and effectiveness of the WHO CA+, and recommend corrective measures, including, if deemed appropriate, amendments to the text of the WHO CA+.

Article 24. Secretariat

1. A Secretariat for the WHO CA+ shall be provided by the Director-General of the World Health Organization. Secretariat functions shall be:

(a) to make arrangements for sessions of the Governing Body and any subsidiary bodies and to provide them with services as required;

(b) to transmit reports received by it pursuant to the WHO CA+;

(c) to provide support to the Parties, on request, in the compilation and communication of information required in accordance with the provisions of the WHO CA+;

(d) to prepare reports on its activities under the WHO CA+ under the guidance of the Governing Body, and submit them to the Governing Body;

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

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

(g) to perform other secretariat functions specified by the WHO CA+ and such other functions as may be determined by the Governing Body.

Chapter VIII. Final provisions

Article 25. Reservations

1. No reservations or exceptions may be made to this WHO CA+ unless expressly permitted by other articles of this WHO CA+.

2. A reservation incompatible with the object and purpose of the WHO CA+ shall not be permitted.

3. Reservations that are receivable in accordance with the above, once made, may be withdrawn at any time by notification to this effect addressed to the Depositary, who shall then inform all Parties thereof. Such notification shall take effect on the date on which it is received.

Article 26. Confidentiality and data protection

Any exchange of data or information by the Parties pursuant to the WHO CA+ shall respect the right to privacy, including as such right is established under international law, and will be consistent with each Party's national law, as applicable, regarding confidentiality and privacy.

Article 27. Withdrawal

1. At any time after two years from the date on which the WHO CA+ has entered into force for a Party that Party may withdraw from the WHO CA+ 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 CA+ 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. Right to vote

1. Each Party to the WHO CA+ shall have one vote in the COP, 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 CA+. Such an organization shall not exercise its right to vote if any of its Member States exercises its right, and vice versa.

Article 29. Amendments to the WHO CA+

1. Any Party may propose amendments to the WHO CA+. Such amendments will be considered by the COP, which may invite views of the Consultative Body.

2. Amendments to the WHO CA+ shall be adopted by the COP. The text of any proposed amendment to the WHO CA+ shall be communicated to the Parties by the Secretariat at least three months before the session at which it is proposed for adoption. The Secretariat shall also communicate proposed amendments to the signatories of the WHO CA+ and, for information, to the Depositary.

3. The Parties shall make every effort to reach agreement by consensus on any proposed amendment to the WHO CA+. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-thirds majority vote of the Parties present and voting at the session. For 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. 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.

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 30. Adoption and amendment of annexes to the WHO CA+

1. The COP may adopt annexes to the WHO CA+ and amendments thereto.

2. Annexes to the WHO CA+ shall form an integral part thereof and, unless otherwise expressly provided, a reference to the WHO CA+ 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 31. Protocols to the WHO CA+

1. Any Party may propose protocols to the WHO CA+. Such proposals will be considered by the COP, which may invite the views of the Consultative Body.

2. The COP may adopt protocols to the WHO CA+. In adopting these protocols every effort shall be made to reach consensus. If all efforts at consensus have been exhausted and no agreement reached, the protocol shall as a last resort be adopted by a two-thirds 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.

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

4. States that are not Parties to the WHO CA+ may be Parties to a protocol thereof, provided the protocol so provides.

5. Any protocol to the WHO CA+ 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 32. Signature

The WHO CA+ shall be open for signature by all Members of the World Health Organization, any States that are not Members of the World Health Organization but are members of the United Nations, and by regional economic integration organizations, 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 July 2024, and thereafter at United Nations Headquarters in New York, from XX August 2024 to XX November 2024.

Article 33. Ratification, acceptance, approval, formal confirmation or accession

1. The WHO CA+ shall be subject to ratification, acceptance, approval or accession by States, and to formal confirmation or accession by regional economic integration organizations. It shall be open for accession from the day after the date on which the WHO CA+ 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 CA+ without any of its Member States being a Party shall be bound by all the obligations under the WHO CA+. In the case of those organizations, where one or more of its Member States is a Party to the WHO CA+, the organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the WHO CA+. In such cases, the organization and the Member States shall not be entitled to exercise rights under the WHO CA+ 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 CA+. 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 34. Entry into force

1. The WHO CA+ shall enter into force on the thirtieth day following the date of deposit of the thirtieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary.

2. For each State that ratifies, accepts or approves the WHO CA+ or accedes thereto after the conditions set out in paragraph 1 of this Article for entry into force have been fulfilled, the WHO CA+ 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 out in paragraph 1 of this Article for entry into force have been fulfilled, the WHO CA+ shall enter into force on the thirtieth day following the date of its depositing of the 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 the Organization.

Article 35. Provisional application by the Parties, and actions to give effect to the provisions of the WHO CA+ by the World Health Assembly

1. The WHO CA+ may be applied provisionally, in whole or in part, by a signatory and/or Party that consents to its provisional application by so notifying the Depositary in writing at the time of signature of the instrument, or signature or deposit of its instrument of ratification, acceptance, approval, formal confirmation or accession. Such provisional application shall become effective from the date of receipt of the notification by the Secretary-General of the United Nations.

2. Provisional application by a signatory and/or Party shall terminate upon the entry into force of the WHO CA+ for that Party or upon notification by that signatory and/or Party to the Depositary in writing of its intention to terminate its provisional application.

3. Provisions of the WHO CA+ may be given effect as recommendations for all Member States of the World Health Organization under Article 23 of the WHO Constitution, and given effect as policies of the World Health Organization, understood as authoritative with respect to the Director-General, under Articles 18(a), 28(a) and 31 of the WHO Constitution.

Article 36. Settlement of disputes

1. In the event of a dispute between two or more Parties concerning the interpretation or application of the WHO CA+, 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 agreement by good offices, mediation or conciliation shall not absolve 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 CA+, or at any time thereafter, a Party 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: (i) submission of the dispute to the International Court of Justice; and/or (ii) ad hoc arbitration in accordance with procedures to be adopted by consensus by the Governing Body.

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 37. Depositary

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

Article 38. Authentic texts

The original of the WHO CA+, 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.

Propose the introduction of the following annexes:

ANNEX 1 – Decision instrument for the assessment of events that may constitute a pandemic situation

To be developed under the PA [However, in case option 2 is chosen, it will likely need to be developed as a further amendment/addition to the IHR]

ANNEX 2 - Preventing pandemic situations due to pathogens resistant to antimicrobial agents through the One Health approach

Article 1 - Action plans

1. Each Party shall develop and implement an AMR One Health national, and where possible regional, strategy or action plan, as part of, or complement to, the plan referred to in Article 6, taking into account relevant international plans, guidance documents and recommendations, especially from the Quadripartite organisations.

2. The Secretariat shall support the Parties in the preparation of the AMR One Health action plans. The Parties shall pay particular attention to the needs of Parties which are low and lower middle income countries, in particular through the relevant Quadripartite organisations mechanisms.

Article 2 - Surveillance of AMR and of antimicrobials consumption/use (AMC/AMU)

1. Parties shall collect and report infection and AMR surveillance data in humans, animals, plants and the environment in line with minimum requirements established in Quadripartite organisations standards and guidance, as well as data on antimicrobial consumption in human and veterinary medicine. They shall enroll in and report to the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS), and apply other relevant surveillance systems developed by intergovernmental bodies like the Codex Alimentarius Commission and the Quadripartite organisations.

2. Starting no later than […] years after the entry into force of this Agreement, the Parties shall monitor, and regularly report to the relevant Quadripartite organisations AMR surveillance data in the environment, such as in urban wastewater, surface and groundwater bodies, sewage sludge and soil and make such surveillance data available through the Quadripartite Organisations Secretariats.

3. The Secretariats of the Quadripartite Organisations are encouraged to further develop the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) standards, Codex Alimentarius, WOAH and other protocols and databases to cover AMR surveillance in animals,

plants, the environment, as well as AMC in animals, and enable integrated One Health surveillance. Where applicable, this should be done either by integrating or establishing links with other existing AMR and AMU data collection mechanisms.

4. The Quadripartite organisations Secretariats should provide, every 2 years, an analysis of the data provided under paragraphs 1 and 2 and Parties should take this evidence into consideration, in addition to any analysis of data performed at national or regional level, as a basis for improving existing AMR measures and developing and implementing new measures against AMR.

5. Parties that are not low and lower middle income countries should undertake to support the design and implementation of infection and AMR and AMC surveillance activities in low and lower middle-income countries through relevant Quadripartite Organisations mechanisms and by facilitating national and regional capacity strengthening activities throughout the relevant parts of the health, environment, food and medicines safety system and by developing national and regional laboratory infrastructure.

Article 3 - AMR targets

1. Parties commit to working towards the following global AMR outcome targets:

a. For high income countries:

i. Reduce by […%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for E. coli resistant to 3rd generation cephalosporin, as calculated and reported by WHO for the year […], within a period of [… years] after entry into force of this Agreement;

ii. Reduce by […%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for methicillin-resistant S. aureus (MRSA), as calculated and reported by WHO for the year […], within a period of [… years] after entry into force of this Agreement.

b. For upper middle income countries:

i. Reduce by […%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for E. coli resistant to 3rd generation cephalosporin, as calculated and reported by WHO for the year […], within a period of [… years] after entry into force of this Agreement;

ii. Reduce by […%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for methicillin-resistant S. aureus (MRSA), as calculated and reported by WHO for the year […], within a period of [… years] after entry into force of this Agreement.

c. For low and lower middle-income countries:

i. Reduce by […%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for E. coli resistant to 3rd generation cephalosporin, as calculated and reported by WHO for the year […], within a period of [… years] after entry into force of this Agreement;

ii. Reduce by […%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for methicillin-resistant S. aureus (MRSA), as calculated and reported by WHO for the year […], within a period of [… years] after entry into force of this Agreement.]

2. The targets set out in paragraphs 1 shall be reviewed by the Conference of the Parties at least every […] years and adapted if necessary.

3. In order to contribute to the attainment of targets referred to in paragraph 1, Parties shall set out their national targets within their AMR One Health plans, including on antimicrobial consumption/use in human, animal and plant health, based on their specific national situation. The targets shall be based on relevant data, including national antimicrobial consumption/use, obtained through the nationally implemented One Health or sector specific AMR surveillance systems as specified in Article 2. The national targets may differ from the global target defined under point 1 for the relevant group of countries. It should however be developed in a spirit consistent with the global targets.

4. The Panel of Experts referred to in Article P.5. should monitor progress made towards achieving the global targets. Based on this evidence, and in collaboration with relevant scientific bodies, the Panel should formulate recommendations for action. The analysis and recommendations of the Panel shall be made public. Parties should revise their targets and AMR strategies as necessary, taking into account the recommendations of the Panel.

Article 4 - Enhanced efforts to the implementation of infection prevention and treatment measures

1. Parties shall ensure that their husbandry systems provide for a high level of animal health and welfare allowing a reduce need for the antimicrobial treatment of animals.

2. Parties shall make use of standards and guidance of the Quadripartite organisations, including the WHO Access, Watch, Reserve (AWaRe) classification of antibiotics, to ensure effective treatments of infections as well as prudent distribution and use of quality-assured antimicrobial medicines.

3. Parties shall promote the inclusion of training on IPC/biosecurity and appropriate management and treatment of infections, including antimicrobial stewardship, in all settings, including medical, veterinary, phytosanitary, agricultural nursing, pharmacy, dentistry, and midwifery schools. This training, which may be supported by the WHO Academy, should include a strong practical component, use a One Health approach and be inter-professional whenever possible

4. Parties shall undertake to raise public awareness on infection prevention and control, antimicrobial resistance and the prudent use of antimicrobials in human, animal and plant health, as well as the consequences of self-medication of antibiotics.

5. Parties shall take steps to introduce appropriate disposal systems in healthcare settings, pharmacies and the community setting, and inform the general public on the correct disposal methods for antimicrobial drugs.

Article 5 - Incentives for the development and availability of medical countermeasures relevant to combat AMR including manufacturing of new antimicrobials

1. Parties should support the development and availability of preventive, diagnostic, and therapeutic medical countermeasures relevant to combat AMR, notably old and new antimicrobials, innovative diagnostic tests, and alternatives to antimicrobials for human and animal use.

2. Parties should enhance R&D, production and distribution of vaccines, improving effective vaccines coverage and fostering awareness and acceptance in the population since vaccination is one of the tools to combat AMR.

3. Parties should support global initiatives for the establishment of regional and global priority lists of resistant pathogens, such as the WHO Bacterial Priority Pathogens List (WHO BPPL), and medical countermeasures, pipeline analyses, and the establishment of target product profiles.

4. Parties should take into account the priorities established in accordance with point 3 in their national research priority setting, funding and policy efforts.

5. Parties should coordinate, where possible, their research efforts with each other, and with global research initiatives, notably on the development of medical countermeasures relevant to combat AMR.

6. Parties should cooperate to foster the resilience of international supply chains, and expand global, regional and local production capacity to ensure availability and accessibility of quality-assured antimicrobials and other medical countermeasures relevant to combatting AMR.

7. Parties should coordinate their initiatives and partnerships, including with the private sector, to incentivize antimicrobial research, development, manufacturing and distribution. Wherever possible, incentives should be linked to conditions that promote stewardship.

Article 6 - Prudent use of antimicrobials in human medicine

1. Each Party shall, within a period of [… years] after entry into force of this Agreement, adopt and implement measures to prohibit the sale and use of antimicrobials for humans without prescription. Proportionate exemptions may be considered for antimicrobials as listed in the Appendix to this Annex [*to be developed*], including situations of emergencies and exceptional circumstances. Parties that are not low and lower-middle income countries undertake to support the low and lower middle-income countries to implement this measure.

2. Each Party shall, within a period of [… years] after entry into force of this Agreement, adopt and implement national clinical guidelines for the treatment of main infections taking into account antimicrobial stewardship principles, in particular in first line/primary health care settings, hospitals and long-term care facilities.

3. Parties shall promote, monitor and incentivize the use of diagnostic or susceptibility tests before antibiotics are used in human medicine.

Article 7 - Prudent use of antimicrobials in the veterinary field

1. Within a period of [2 years] after the entry into force of this Agreement, each Party shall implement measures to apply standards of the WOAH and Codex Alimentarius on the use of antimicrobial in animals, in particular the Codex Code of Practice to Minimise and Contain Foodborne Antimicrobial Resistance" (CXC 61-2005).

2. Each Party shall adopt measures to phase out the use of antimicrobials for growth promotion, starting with medically important antimicrobials.

3. Each Party shall adopt measures to ensure that all antimicrobials are administered only based on a prescription by a veterinarian, starting with medically important antimicrobials.

4. Parties shall report on the use of antimicrobials in veterinary medicines under the Quadripartite organisations monitoring systems.

5. Parties shall promote, monitor and incentivize the use of rapid diagnostic or susceptibility tests before antibiotics are used in veterinary medicine.

Article 8 - Responsible and prudent use of antimicrobials in the plant protection/health fields

1. Within a period of [2 years] after the entry into force of this Agreement, each Party shall implement measures to apply the Codex Code of Practice to Minimise and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) on the use of antimicrobials in plant protection.

2. Antimicrobials shall not be applied routinely, nor used to prevent plant diseases or to compensate for poor agricultural or plant protection practices, inadequate or lack of care, or for poor management. They shall only be applied based on a recommendation of a plant protection/health professional.

3. Each Party shall, within a period of [… years] after entry into force of this agreement, ensure that the use of antimicrobials in plants for the purpose of prevention or yield increase has been phased out.

4. Antimicrobials shall be used for prophylaxis only under specific and strictly limited circumstances, which shall be clearly defined in applicable legislation.

5. Parties shall promote, monitor and incentivize the use of rapid diagnostic or susceptibility tests before antibiotics are used for plant protection/health purposes.

ANNEX 3 - *Preventing inadvertent laboratory release of pathogens*

Article 1 - Biosecurity and Biosafety Standards

1. The Conference of the Parties shall:

a) Decide the information to be submitted by each Party with regard to the laboratories or other similar institutions to which the provisions of this Annex apply, including the biosafety and biosecurity measures applied at each laboratory and the security level attributed to it; the list

of laboratories or other similar institutions submitted by each Party should be periodically revised;

b) Specify the groups of pathogens and biological agents and the type of laboratories requiring the application of the biosafety and biosecurity standards adopted pursuant to this Annex;

c) Adopt and revise, as appropriate and while taking into account relevant international regulations, guidelines and standards, necessary minimum biosafety and biosecurity standards to be applied by each Party to the pathogens specified in this Article related to acquisition, storage, handling, experimentation, transfer, transport, both within the jurisdiction of the Party as well as to another Party, and destruction.

2. The standards referred to in subparagraph c) above shall be elaborated drawing upon best practices developed by Parties as well as relevant international and scientific organizations, having particular regard to their resource implications and the limitations they may impose on the activities carried out in the laboratories concerned.

Article 2 - Reporting by Parties

1. Each Party shall report to the Secretariat at intervals to be decided by the Conference of the Parties on its application of the standards referred in Article 1 (Biosecurity and Biosafety Standards), paragraph 2, the reasons for any significant deviation, from them as well as challenges and problems encountered in their application.

2. The Secretariat shall submit a summary report to the Conference of the Parties, reflecting in particular progress and challenges encountered by Parties in securing increasingly higher levels of biosafety and biosecurity.

3. Each Party shall report immediately to the Secretariat accidents within the laboratories listed under Article 1 (Biosecurity and Biosafety Standards), paragraph 1 with regard to the pathogens referred to in Article 1.2. that have resulted or may result in the release of those pathogens in the environment and may pose a risk to health. The Secretariat shall immediately inform the other Parties and offer or facilitate the provision of technical assistance to the Party or Parties concerned. The Secretariat shall report to the Conference of the Parties about any such accident.

Article 3 - Implementation support

The Secretariat shall periodically visit the laboratories listed under Article 1.1. for the purpose of supporting the Parties in the effective implementation of the biosafety and biosecurity standards adopted by the Conference of the Parties and of recommending possible improvements in the application of such standards. The conditions and modalities for carrying out visits under this Article shall be decided by the Conference of the Parties. The specific timing of such visits and the composition of the visiting team will be agreed upon with the Party concerned in accordance with such conditions and modalities.

Article 4 - Technical Assistance

The Secretariat shall provide, or facilitate the provision of, technical assistance upon the request of any Party in order to assess and improve the biosafety and biosecurity features of any laboratory and

other similar institutions. Parties shall collaborate with each other for the same purpose.

Article 5 – National laws

The provisions of this Annex are without prejudice to the application of relevant national laws.

ANNEX 4 - Field missions for the purpose of verification and support: Standard terms of reference

To be developed

ANNEX 5 - Model agreements

5.1 Model transfer agreements (for pathogen samples)
5.2 Framework agreement (for pathogen data)

To be developed

ANNEX 6 – Equitable access to countermeasures: Partnership modalities and guidelines

To be developed