

"Pandemic Situation"

 jamesroguski.substack.com/p/pandemic-situation

The European Union has created and defined a new term, "Pandemic Situation" as part of their 20+ page addition to the Zero Draft of the proposed "Pandemic Treaty." Things just keep getting crazier!

On March 28, 2023, the European Union quietly published the following page, that neither you nor I are "authorized" to access:

https://www.eeas.europa.eu/delegations/un-geneva/european-union-initial-textual-proposals-agreement-pandemic-prevention_en

Here is the document that you and I are apparently NOT "authorized" to see:

<https://www.eeas.europa.eu/sites/default/files/documents/2023/EU%20proposals%20integrated%20into%20the%20ZD%2028%20March.pdf>

The document includes additional text that the European Union seeks to add to the Zero Draft of the proposed "Pandemic Treaty."

Below is a summary of the 20+ additional pages that the European Union has proposed in secret.

The European Union created a new term, and seeks to give Tedros Adhanom Ghebreyesus the brand new power to declare a "Pandemic Situation."

Apparently, the European Union felt that the authority given by the International Health Regulations to the Director General of the WHO that enables him to declare a Public Health Emergency of International Concern (PHEIC) needed to be enhanced.

“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.

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 European Union wants to control infection prevention and control in your household...

Article A.1. - Preventing pandemic situations

1. 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**.

The European Union stated the obvious...

Parties shall take actions to prevent the inadvertent laboratory release of pathogens. 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 European Union wants to control “unsustainable land uses” and “wildlife consumption practices”...

Control of wildlife trade

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.

The European Union would like to create a Countermeasure Expert Committee...

Countermeasures Expert Committee shall issue pricing guidelines... It shall pay particular attention to the needs of Parties which are low and lower middle income countries;

The European Union would like to create a “Panel of Experts to oversee the “One Health Approach”...

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;

The European Union would like to censor misinformation, disinformation and false news...

Each Party shall...

promote regular analysis and consultations with 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...

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.

The European Union would like to empower the “Quadripartite”...

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 European Union would like to inspect your waste...

The Parties shall monitor, and regularly report to the relevant Quadripartite organisations Anti Microbial Resistance 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 Organisation's Secretariats.

The European Union wants to control “antimicrobials”...

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.

Does this mean that the European Union would like to control the use of over-the-counter anti-microbial products such as silver, chlorine dioxide, food grade hydrogen peroxide and garlic?

The entire Zero Draft, including the proposals made by the European Union is available here:

<https://www.eeas.europa.eu/sites/default/files/documents/2023/EU%20proposals%20integrated%20into%20the%20ZD%2028%20March.pdf>

I have extracted the proposals made by the European Union and made them available below:

EUROPEAN UNION *INITIAL* TEXTUAL PROPOSALS FOR AN AGREEMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE.

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.

~~The world together equitably~~

Vision: ~~The WHO CA+H 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 international cooperation.~~

[The European Union] Suggest[ed] deletion [of the above text.]

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

Suggested 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.

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.

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 to be drafted when content of substantive provisions is known]

[NEW] 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.

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. Objective

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 responsible also to ensure the implementation of this Agreement, as appropriate in view of national or regional responsibilities.

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. 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:
 1. 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.
 2. 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 WOAHA standards and guidelines.
 3. c) Parties shall strengthen efforts to ensure the sound management of healthcare and protective equipment waste, which may be contaminated.
 4. 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.

5. 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 WOAHS 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.
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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 geographic 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, WOAHA 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.
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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 response 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 Committee with information on supply and demand for such 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 commitments 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 consultation 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 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 reports 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.

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 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 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.

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 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, multidisciplinary, 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, multidisciplinary, 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.

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.

The Secretariat shall support the Parties in the preparation of the AMR One Health action. 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, WOAHA 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 [Anti Microbial Resistance] targets

1. Parties commit to working towards the following global AMR outcome targets:
 - a. For high income countries:
 1. 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;

2. 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:

1. 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;

2. 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 paragraph 1 shall be reviewed by the Conference of 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.

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 WOA 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;

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;

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. 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

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