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## EU drafting suggestions to the Intergovernmental Negotiating Body Bureau's proposal for negotiating text of the WHO Pandemic Agreement<sup>1</sup>

The present document is a consolidation of the drafting suggestions submitted by the EU during or in the immediate aftermath of the 7<sup>th</sup> meeting of the Intergovernmental Negotiating Body (INB) on the INB Bureau's proposal for negotiating text of the WHO Pandemic Agreement<sup>1</sup>. More specifically:

- the drafting suggestions for all articles (except Articles 4 and 12) are inserted in the INB Bureau's proposal for negotiating text. Proposals for additions are indicated in bold underlined, in square brackets. Proposals for deletion are set out by way of strike through, in square brackets. Comments or explanations are provided in blue italics.
- Article 4 represent a recasting and a revision of earlier EU proposals in light of current discussions. While the EU input includes some of the elements set out in Article 4 of the INB Bureau's proposal for negotiating text, we have proposed to revisit the structure of Article 4 to provide more clarity and details on the necessary elements for a robust pandemic prevention framework. The elements related to surveillance, which were included in previous EU proposals, and which are an essential component of any robust framework on pandemic prevention, have been set aside for the moment, to acknowledge the positions of several WHO Member States that these elements should be further considered within the framework of the Working Group on amendments to the International Health Regulations (2005) (WGIHR)<sup>2</sup>.
- Article 12 represent a new proposal on access and benefit sharing prepared by the EU and its Member States considering development of the negotiations.

The drafting suggestions set forth in this paper are without prejudice to our ability to revise, improve or withdraw the text as discussions progress, as well as to put forward additional proposals.

<sup>1</sup> [Proposal for negotiating text of the WHO Pandemic Agreement \(https://apps.who.int/gb/inb/pdf\\_files/inb7/A\\_INB7\\_3-en.pdf\)](https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf)

<sup>2</sup> Working Group on Amendments to the International Health Regulations (2005) (<https://www.who.int/teams/ihr/working-group-on-amendments-to-the-international-health-regulations-%282005%29>).

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## Chapter I. Introduction

### Article 1. Use of terms

For the purposes of the WHO Pandemic Agreement:

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

~~[(b) “genomics” means the study of the total or part of the genetic or epigenetic sequence information of organisms and attempts to understand the structure and function of these sequences and downstream biological products. Genomics in health examines molecular mechanisms and the interplay of this molecular information, health interventions and environmental factors in disease; Delete EU] [Comment: we suggest deletion of the definition as the term is used only once in the text (in paragraph 4 of Article 6, which could be in our views deleted as it duplicates provisions set out in Article 4)]~~

[(c) “infodemic” means too much information, false or misleading information, in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviours that can harm health. It also leads to mistrust in health authorities and undermines public health and social measures; Reserve EU] [Comment: Reserve. We note that the term is used only once in the text, in Article 9 paragraph 2(d). We may therefore want to further reflect on whether a definition of this term is really needed.]

(d) “One Health approach” means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development; [Comment: we suggest moving the One Health Approach to Article 3]

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

(f) “pandemic-related **[health]** products” means products that are needed for pandemic prevention, preparedness and response, which may include ~~[, without limitation, Delete EU]~~ diagnostics, therapeutics, ~~[medicines, Delete EU]~~ vaccines, **[oxygen, equipment for the safe administration and disposal of medical products, equipment required for decontamination, as well as any relevant]** personal protective equipment ~~[, syringes and oxygen Delete EU]~~;

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

(h) “pathogen with pandemic potential” means any pathogen that has been identified to infect humans and that is potentially highly transmissible, capable of wide, uncontrollable spread in human

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populations, and highly virulent, making it likely to cause significant morbidity and/or mortality in humans; *[Comment: Reserve on the proposed definition. Further discussion and work needed]*

(i) “persons in vulnerable situations” means individuals, **[as well as persons belonging to]** groups or communities with ~~a disproportionate~~ ~~Delete EU~~ **[an]** increased **[or more severe]** risk of infection, ~~[severity, Delete EU]~~ disease or mortality in the context of a pandemic, including vulnerability due to **[underlying medical conditions, marginalization, or]** discrimination **[of any kind as to]** ~~on the basis of~~ ~~Delete EU~~ race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status **[or due to exposure to humanitarian, fragile or conflict-affected situations]**;

(j) “recipient” means receivers of WHO Pathogen Access and Benefit-Sharing (WHO PABS) Material from the WHO coordinated laboratory network, such as manufacturers of vaccines, diagnostics, pharmaceuticals and other products relevant to pandemic prevention, preparedness and response, as well as biotechnology firms, research institutions and academic institutions. Any manufacturer that enters into any contracts or formal agreements with recipients or laboratories in the WHO coordinated network for the purpose of using WHO PABS Material on the manufacturer’s behalf for commercialization, public use or regulatory approval of that manufacturer’s vaccines, diagnostics or pharmaceuticals shall also be considered a recipient for purposes of this Agreement; *[Comment: Reserve on the proposed definition. The definition needs to be assessed together with the text in article 12.]*

(k) “universal health coverage” means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care;

(l) “WHO coordinated laboratory network” means the international network of laboratories, coordinated by WHO, that conduct year-round surveillance of pathogens with pandemic potential, assessing the risk of an emerging pathogen with pandemic potential, and assisting in pandemic preparedness measures; and *[Comment: Reserve on the proposed definition. The definition needs to be assessed together with the text in article 12.]*

(m) “WHO PABS Material” means a pathogen with pandemic potential, as defined herein, and the genetic sequence data of such pathogens with pandemic potential. *[Comment: Reserve on the proposed definition. Needs to be assessed together with the text in article 12.]*

**[(n) “Stakeholders” means non-state actors as defined in the “Framework of Engagement with Non-State Actors”, in Annex 5 of resolution WHA69.10 (2016).]** *[Comment: we suggest adding the definition of “stakeholders”, since the term recurs very frequently]*

## Article 2. Objectives and scope

1. The objective of the WHO Pandemic Agreement, **[in accordance with the principle of]** ~~[guided by Delete EU]~~ equity~~[, the right to health and the principles and approaches set forth herein, Delete EU]~~ is to **[improve the Parties’ capacity to]** prevent, prepare for and respond to pandemics, with the aim of comprehensively and effectively addressing the ~~[systemic Delete EU]~~ gaps and challenges that exist in these areas, at **[local,]** national, regional and international levels.

2. In furtherance of its objective, the WHO Pandemic Agreement applies at all times.

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*[Comment: the EU is of the view that a specific article on Human Rights needs to be included in the Pandemic Agreement. The EU also notes that it could also be useful to seek the advice of the OHCHR for the drafting of such an article.]*

**[2bis Protection of human rights]**

**1. The implementation of this Agreement shall respect, protect and fulfil the human rights and fundamental freedoms of persons, and be in full compliance with international human rights law as well as international humanitarian law and principles.]**

**Article 3. General principles and approaches**

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

1. **Respect for human rights** – The implementation of this Agreement shall ~~[be with full Delete EU]~~ respect **[, protect and fulfil the]** for the dignity, human rights and fundamental freedoms of persons **[, and be in full compliance with international human rights law as well as international humanitarian law and principles]**. *[Comment: the EU believes that human rights protection should be addressed in a specific article, as indicated above (2bis). If reference is kept under Article 3, we suggest introducing a reference to the respect of international human rights law as well as humanitarian law and principles]*

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

3. **Equity** – Equity **[embodies the objective, both within countries and across countries, to reduce health inequalities. As such it is an integral component of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and of pandemic prevention, preparedness and response]** ~~[is at the centre of pandemic prevention, preparedness and response, both at the national level within States and at the international level between States. It requires, inter alia, specific measures to protect persons in vulnerable situations. Equity includes the unhindered, fair, equitable and timely access to safe, effective, quality and affordable pandemic related products and services, information, pandemic related technologies and social protection Delete EU].~~

4. **Responsibility** – Governments ~~[have a Delete EU]~~ **[bear the primary]** responsibility for the health of their peoples, and effective pandemic prevention, preparedness and response require global collective action **[in support thereof]**.

5. **Recognition of different levels of capacity** – Countries have varying levels of pandemic prevention, preparedness and response capacities, which presents a common danger such that support to countries with capacity needs is required, within the means and resources available.

6. **Solidarity** – **[Embodies the need for]** Effective ~~[national, international, Delete EU]~~ multilateral, **[regional,]** bilateral and multisectoral collaboration, coordination and cooperation to achieve the common interest of a safer~~[, fairer, Delete EU]~~ **[and]** more equitable **[world, which is]** ~~[and Delete EU]~~ better ~~[prepared world Delete EU]~~ **[able]** to prevent, **[be prepared for and]** respond to ~~[and recover from Delete EU]~~-pandemics.

7. **Transparency** – The effective prevention of, preparedness for and response to pandemics depends on the ~~[transparent, Delete EU]~~ open and timely sharing of, access to and disclosure of **[relevant]** ~~[accurate Delete EU]~~ information **[and]** ~~[, Delete EU]~~ data~~[,]~~ ~~[and other relevant elements that may come to light, for risk assessment, prevention and control measures, and the research and development of pandemic related~~

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products and services, including reports on sales revenues, prices, units sold, marketing costs and subsidies and incentives, consistent Delete EU] **[in compliance]** with **[applicable]** national, regional and international ~~[privacy and data protection rules, Delete EU]~~ regulations and laws.

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

9. **Inclusiveness** – The full~~[, equal, meaningful and]~~ active engagement with, and participation of, **[women, local]** communities and relevant stakeholders ~~[across all levels Delete EU]~~, consistent with ~~[relevant and Delete EU]~~ applicable **[national and]** international ~~[and national guidelines, Delete EU]~~ rules~~[,] [and Delete EU]~~ regulations **[and guidelines]** ~~[, including those relating to conflicts of interest, Delete EU]~~ is essential to ~~[mobilize social capital, resources and Delete EU]~~ **[promote]** adherence to public health and social measures, **[as well as]** ~~[and to gain Delete EU]~~ trust in governments and ~~[partners supporting Delete EU]~~ **[relevant national, regional and international agencies in support of]** pandemic prevention, preparedness and response.

10. **Science and evidence** – **[Freedom of scientific research is the precondition for the advancement of knowledge and the benefit of society.]** The best available science and evidence should inform and be the basis for pandemic prevention, preparedness and response, as well as public health decisions and development of plans.

11. **Proportionality** – Public health decisions for preventing, preparing for and responding to pandemics should be proportionate in a manner consistent with Article 2 of the International Health Regulations.

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

**[13. One Health – The One Health approach means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development.]**

*[Comment: the One Health approach, as an overarching principle of the agreement, should preferably be included in Article 3, rather than in Article 1.]*

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

### **Article 4. Preventing pandemic situations**

*[Comment: recasting and revision of earlier EU proposals, as submitted to WHO on 27 November 2023, in light of the informal discussions held in the INB subgroup for Articles 4, 5 and 6.]*

1. The Parties agree that the actions set out in this article are necessary to progressively achieve an enhanced level of pandemic prevention in line with the One Health approach.
2. Without prejudice to their existing obligations under international law, the Parties should base the policies, strategies and measures in the areas covered in Article 4 on the recommendations, guidelines and standards adopted by the relevant international organizations and bodies, in particular the Quadripartite organizations and the Codex Alimentarius Commission, as well as by the Panel of Expert provided for in Article [...].

#### **Section A – Pandemic prevention strategies**

3. Each Party shall develop, strengthen, implement, periodically update and review comprehensive multisectoral national, and where applicable regional, pandemic prevention strategies, as part of the comprehensive pandemic prevention, preparedness and response plans referred to in Article [8 paragraph 1]. These strategies shall be consistent with, and supportive of, effective implementation of the International Health Regulations and take account of the One Health approach.

#### **Section B – Infection prevention**

4. 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 in the veterinary sector, with the aim of preventing pandemic situations. To this end, each Party shall, within its territory:

- (a) strengthen efforts to ensure access to safe water, sanitation and hygiene, as well as access to appropriate health services for diagnosis and treatment, including in hard-to-reach settings;
- (b) strengthen efforts to guarantee timely access to effective immunization programmes;
- (c) require healthcare facilities to adopt and regularly update an infection prevention and control programme, with appropriate resources and staff, and ensure the implementation of effective infection prevention and control measures applying the relevant international standards and guidelines; and
- (d) strengthen efforts to ensure the appropriate management of waste from health facilities, veterinary practices, and live animal settings.

#### **Section C – Preventing and controlling zoonotic spill-overs**

5. The Parties shall, in accordance with their international obligations, undertake actions to strengthen animal disease preventive measures, with the aim of preventing and controlling the risk of zoonotic disease spill-over and spill-back. Such actions include:

- (a) Adopting strategies aimed to mitigate the impacts of environmental factors on the risk of zoonotic diseases, including air-, vector- and water-borne pathogens and diseases, such as air and water pollution, climate change, biodiversity loss, land use change and ecosystem degradation;

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- (b) Promoting the adaption of farming practices, including within the context of intensive animal farming, also with the aim of preventing the emergence and spread of antimicrobial resistant pathogens;
- (c) Establishing, strengthening, monitoring and enforcing as appropriate hygienic practices and risk management measures in markets handling live animals and live wildlife;
- (d) 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; and
- (e) Monitoring the effectiveness of the adopted policies and measures for the purpose of constantly strengthening them and increasing their effectiveness.

6. On the basis of the findings and advice of the Panel of Experts provided for in Article [...] as well as of the advice of relevant international organizations, in particular the Quadripartite organisations, and other relevant organisations and bodies, and while respecting the mandate of such organisations, the Conference of the Parties shall adopt guidelines, recommendations, standards and other instruments, as necessary, to guide and support the Parties in undertaking national and where possible regional, measures aimed at reducing the of risks of zoonotic, including vector-borne, spill-over in accordance with the One Health approach.

#### **Section D – Control of wildlife trade**

7. The Parties shall undertake actions to ensure safe legal trade and prevent and prohibit national and international trade of animal and plant species and products thereof that may pose a higher risk of zoonotic diseases. For this purpose each Party shall put in place appropriate procedures for trade in such specimens of animal and plant species and products thereof to assess and mitigate the risks to human and animal health deriving from pathogens generally or likely hosted by the species to which the specimens in question belong. The Parties shall, in accordance with Article 12, facilitate the rapid and safe export of biological samples of domestic and wild animals for purposes of zoonotic disease research and effective response to pandemic situations.

8. 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 Peoples 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 Peoples, as well as local communities in the elaboration and implementation of the measures referred to in this section of Article 4.

#### **Section E – Preventing pandemic situations related to pathogens resistant to antimicrobial agents**

9. Each Party shall undertake actions to prevent the emergence and spread of pathogens that are resistant to antimicrobial agents. For this purpose, each Party shall, taking into account relevant international plans, guidance and recommendations, develop, maintain, implement and regularly update national, and where relevant regional, antimicrobial resistance plans. These plans shall include:

- (a) measures aimed at implementing internationally agreed commitments and targets on AMR, and
- (b) actions and initiatives that strengthen antimicrobial stewardship and infection prevention and control in the human, animal, plant and environmental sectors, promote the prudent use of antimicrobials and increase investment, where appropriate, in new and existing medicines, diagnostic tools, vaccines and other interventions, as well as affordable access to those.

In order to promote prudent use of antimicrobials, each Party shall develop and implement measures to



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ensure that antimicrobials for human health and veterinary use are sold based on prescription of authorised professionals for health purposes.

10. In order to contribute to the attainment of international targets, each Party shall set out its national targets, including on antimicrobial use in human, animal and plant health, based on its specific national situation. The targets shall be based on relevant data, including where available, national antimicrobial use, obtained through the nationally implemented One Health or sector specific AMR surveillance systems.

11. 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 use in humans, animals and plants. Parties shall apply relevant surveillance and data collection systems developed by intergovernmental bodies including, as appropriate, the Codex Alimentarius Commission and the Quadripartite organisations.

### **Section F – Strengthening biosafety and biosecurity**

12. Each Party shall undertake measures to strengthen laboratory biosafety and biosecurity, including in research facilities, in order to prevent the accidental exposure, misuse or inadvertent laboratory release of pathogens, through biosecurity and biosafety training and practices, regulating access to sensitive locations and strengthening transportation security and cross-border transfer, in accordance with applicable rules and standards. ....

### **Section G – Implementation support and capacity building**

13. The Parties shall cooperate, promote and facilitate the provision of technical assistance and capacity building, with the aim to assist developing country Parties in building sustainable capacity to implement their obligations and commitments under the Agreement, with particular regard to the needs of the least developed country Parties. In promoting such cooperation, special attention should be given to the development and strengthening of local, national, and where possible regional, capabilities, by means of human resources development and institution building.

14. The Secretariat, in collaboration with relevant international and regional organizations and other bodies, shall provide assistance in the identification of implementation support needs at national and regional level and in the organization of related technical assistance and capacity building activities, as well as in the related resource mobilisation in accordance with the provisions of Article 20.

15. 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. The reports shall 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 or by the Parties concerned.

16. The Secretariat shall support the Parties in the preparation of the plans, actions and initiatives referred to in this Article.

17. The Parties shall promote, establish or enhance One Health joint training programmes and continuing education programmes for human, animal and environmental health workforces, needed to build complementary skills, capacities and capabilities to prevent, detect, control, and respond to pandemic health threats.

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## Article 5. One Health

*[Comment: the drafting suggestions presented below for Article 5 were submitted to WHO on 7 November 2023 and therefore precede the submission of the EU proposals on Article 4 set out above. These drafting suggestions might be revisited in light of the informal discussions taking place in the INB subgroup for Articles 4, 5 and 6.]*

1. The Parties commit to promote and implement **[, at national, and as appropriate, regional and global levels]** a One Health approach for pandemic prevention, preparedness and response that is coherent, integrated, coordinated and collaborative among all relevant actors **[and sectors]** ~~[with the application of, and in accordance with, national law Delete EU].~~

~~[2.— The Parties shall promote and enhance synergies between multisectoral and transdisciplinary collaboration at the national level and cooperation at the international level, in order to identify, and conduct risk assessments at the interface between human, animal and environment ecosystems, while recognizing their interdependence, and with applicable sharing of the benefits, per the terms of Article 12 therein Delete EU].~~ *[Comment: main elements of this paragraph are already covered in a more specific way in other Articles.]*

~~[3.— The Parties commit to identify and address the drivers of pandemics and the emergence and re-emergence of disease at the human-animal-environment interface through the identification and integration of interventions into relevant pandemic prevention, preparedness plans, and, where appropriate, according to national legislation and capacity, through the strengthening of synergies with other relevant instruments Delete EU].~~ *[Comment: main elements of this paragraph are covered in a more specific way in Article 4 as per EU drafting proposals for this article.]*

~~[4.]~~ **[2.]** Each Party shall, in accordance with national context ~~[and to the extent necessary Delete EU],~~ protect human, animal, ~~[and Delete EU]~~ plant **[and environmental]** health by:

(a) implementing science-based actions, including but not limited to: improving infection prevention and control measures; antimicrobial research and development; access to and stewardship of antimicrobials; and harmonization of surveillance, in order to prevent, reduce the risk of, and prepare for, pandemics;

(b) fostering and implementing **[cross-sectoral]** actions at national and community levels that encompass whole-of- government and whole-of-society approaches to **[prevent, detect and]** control zoonotic outbreaks, **[epidemic-prone diseases and emerging, growing or evolving infectious disease threats with pandemic potential, notably at the human-animal-environment interface]**, including through the engagement of communities in surveillance to **[prevent and]** identify zoonotic outbreaks **[and antimicrobial resistance at source]**; *[Comment: subparagraph (b) has been merged with subparagraph 2(d) of Article 6 to avoid duplication]*

(c) ~~[taking a One Health approach into account in order to Delete EU]~~ produce science-based evidence, **[based on the One Health approach,]** including ~~[that which is related to Delete EU]~~ **[in relation to]** social and behavioural sciences and risk communication and community engagement; and

(d) promoting or establishing One Health joint training and continuing education programmes for human, animal and environmental health workforces, needed to build complementary skills, capacities and capabilities to prevent, detect, control, and respond to pandemic health threats.

~~[5.]~~ **[3.]** The Parties commit to develop, **[in line with the One Health approach and in collaboration and]** within the framework of relevant institutions, international norms and guidelines to prevent, **[detect and]**

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**control**] [~~zoonoses Delete EU~~] [**zoonotic spill-over**].

[6-] [4.] Pursuant to Article 21 herein [**and no later than [...] after the entry into force of the Agreement**], the Conference of the Parties shall, [**on the basis of the findings and recommendations of the Panel of Expert provided for Article [...], 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 provisions**] set forth in Articles 4 and 5 of this Agreement.

[7-] [5.] The Parties shall, in line with Article [~~46 Delete EU~~] [19] herein, develop and implement or strengthen, as appropriate, bilateral, regional, subregional and other multilateral channels to enhance financial and technical support, assistance and cooperation [~~in particular in respect of developing countries to strengthen surveillance systems and laboratory capacity in respect of promoting and implementing Delete EU~~] [**for the promotion and implementation of**] the One Health approach, [**with special attention to the needs of developing country Parties**] at the [**local and**] national level.

## Article 6. Preparedness, readiness and resilience

*[Comment: the drafting suggestions presented below for Article 6 were submitted to WHO on 8 November 2023 and therefore precede the submission of the EU proposals on Article 4 set out above. These drafting suggestions might need to be revisited in light of the informal discussions taking place in the INB subgroup for Articles 4, 5 and 6.]*

1. Each Party shall [~~continue Delete EU~~] [**take the necessary measures**] to strengthen [**and sustain**] its health system, including primary health care, for sustainable pandemic prevention, preparedness and response, taking into account the need for equity and resilience, with a view to the progressive realization of universal health coverage.

2. Each Party shall, [**including**] in accordance with [~~applicable laws, including, where appropriate, Delete EU~~] the International Health Regulations [**where appropriate**], adopt policies, strategies, [~~and/or Delete EU~~] [**legislative and administrative**] measures, as appropriate, [**aiming to**] [~~and strengthen and Delete EU~~] reinforce public health functions for:

(a) the continued [**timely**] provision of quality [~~routine and essential Delete EU~~] health services during pandemics [**with a focus on primary health care, immunization and mental health care, and with particular attention to people in vulnerable situations**];

(b) sustaining and strengthening the capacities of the multidisciplinary workforce [**and of emergency operation centres**] [~~needed Delete EU~~] during interpandemic periods, [~~and Delete EU~~] [**aiming to strengthen**] [~~preparing and ensuring Delete EU~~] surge capacity during pandemics; *[Comment: If focusing on workforce only, subparagraph (b) may be more appropriate under Article 7. Nonetheless, with the purpose of text streamlining, “emergency operational centres” has been moved to this subparagraph from subparagraph (i) of the Bureau’s proposal for negotiating text. Subparagraph (i) below is therefore deleted.]*

[~~(c) collaborative surveillance, outbreak detection, investigation and control, through interoperable early warning and alert systems, and timely notification; Delete EU~~] *[Comment: The EU strongly supports provisions aimed at strengthening surveillance capacities and requirements. Yet, deletion of subparagraph (c) is proposed to take into account the views expressed by several WHO Member States that these elements should be further considered within the framework of the Working Group*

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*on amendments to the International Health Regulations (2005) (WGIHR). Same rationale applies to the deleted subparagraphs (f) and (g), as well as paragraph 4 below.]*

~~[(d) multisectoral prevention of zoonoses, epidemic-prone diseases, and emerging, growing or evolving public health threats with pandemic potential, notably at the human-animal-environment interface; Delete EU] [Comment: see subparagraph 2(b) of Article 5.]~~

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

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

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

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

~~[(i) strengthening public health emergency operations centres' capacities during inter-pandemic periods and pandemic periods; and Delete EU] [Comment: see subparagraph (b).]~~

~~[(j) strengthening infection prevention and control. Delete EU] [Comment: IPC is already covered under Article 4].~~

3. The Parties shall cooperate, **[in line with Article 19.]** ~~[within available means and resources Delete EU],~~ to provide **[or facilitate the provision of,]** financial, technical and technological support, **[as appropriate]** ~~[assistance; Delete EU]~~ **[to strengthen]** the **[ir capacities]** ~~[capacity strengthening and cooperation Delete EU],~~ in particular in respect of **[the least developed country Parties]** ~~[developing countries Delete EU],~~ **[for sustainable pandemic prevention, preparedness and response]** ~~[in order to strengthen health emergency prevention, preparedness and response and health system recovery, consistent with the goal of universal health coverage Delete EU].~~

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

## Article 7. Health and care workforce

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

(a) strengthen, pre-, in- and post-service ~~[competency-based Delete EU]~~ education and training, deployment, **[competency-based]** remuneration, distribution and retention of the public health, health and care workforce, including community health workers and volunteers;

(b) address gender and ~~[youth Delete EU]~~ **[age-related]** disparities and inequalities and security concerns within the public health, health and care workforce, particularly in health emergencies, to support the meaningful representation, engagement, participation, empowerment, safety and well-being of all health and care workers, while addressing discrimination, stigma and inequality and eliminating bias, including ~~[unequal remuneration Delete EU]~~ **[gender-based pay discrimination]**, and noting that

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women still often face significant barriers to reaching leadership and decision-making roles;

(c) ~~[strengthen efforts to address Delete EU]~~ **[protect]** the safety of the health and care workforce, including by ensuring priority access to pandemic-related **[health]** products during pandemics, minimizing disruptions to the delivery of good quality essential health services, and developing and integrating effective measures to prevent and address violence and threats against health and care workers, their means of transport and equipment, as well as hospitals and other medical facilities, when preventing and responding to pandemics; and

(d) establish and maintain ~~[effective Delete EU]~~ **[agile national]** workforce planning systems to **[rapidly,]** effectively and efficiently deploy trained health and care workers during pandemics[; **and]**

**[(e) refrain from taking restrictive measures unduly preventing the movement of cross-border health workers].**

~~[2. The Parties shall commit financial and technical support, assistance and cooperation, in particular in respect of developing countries, in order to strengthen and sustain a skilled and competent public health, health and care workforce at subnational, national and regional levels. MOVE EU] [Comment: paragraph moved down as new paragraph 5 of this article.]~~

~~[3.— The Parties shall invest in establishing, sustaining, coordinating and mobilizing a skilled and trained multidisciplinary global public health emergency workforce that is deployable to support Parties upon request, based on public health need, in order to contain outbreaks and prevent the escalation of a small-scale spread to global proportions. Delete EU] [Comment: paragraph 3 is replaced by the two new paragraphs 3 and 4 below.]~~

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

**[3. Parties shall endeavour to establish or designate, by building on existing networks, emergency health teams at national and where appropriate regional level. Emergency health teams should be interdisciplinary, based on the 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 purpose of emergency health teams shall be to improve the timeliness, quality and coordination of health emergency services, as well as to support Parties affected by pandemic situations in assessing and responding to the public health risk. In this respect, the WHO in cooperation with relevant organisations and bodies shall promote coordination among the emergency health teams. They shall also assist Parties in the training of the emergency health teams, including with the aim to maintain the capacity for immediate deployment of such teams.]**

**4. Parties having established emergency health teams should inform WHO thereof and 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 WHO, in cooperation with relevant organisations and bodies, shall coordinate the deployment of emergency health teams in close coordination with the requesting Parties, including by selecting teams with the required expertise and appropriate equipment, and advising on the safety, modalities, location and duration of their deployment.]**

2.5. The Parties **[in a position to do so shall support and assist other Parties in need, at their request,]** ~~[commit financial and technical support, assistance and cooperation, Delete EU]~~ in particular ~~[in respect of Delete EU]~~ **[least developed country Parties]** ~~[developing countries Delete EU]~~, **[in training and capacity building]** in order to strengthen and sustain a skilled and competent public health, health and

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care workforce at subnational, national and regional levels, **[including emergency health teams]**.

## **Article 8. Preparedness monitoring and functional reviews**

*[Comment: Further reflection on where best to place this article under the Pandemic Agreement is required.]*

1. Each Party shall, in accordance with national ~~[laws Delete EU]~~ **[, and when appropriate regional, legislation]** and in the light of national **[and regional]** context[s], develop, **[regularly update]** and implement comprehensive, inclusive, multisectoral, resourced national **[, and where relevant regional,]** plans and strategies for pandemic prevention, preparedness and response ~~[and health system recovery Delete EU]~~ **[, that inter alia:]** *[Comment: elements from Article 17 paragraph 4 are moved to paragraph 1 of Article 8, as new subparagraphs (a) to (e) to avoid duplication between Article 8 and Article 17.]*

- [(a) identify and prioritize populations for access to pandemic-related health products and health services during a pandemic;**
- [(b) facilitate the timely allocation of resources to the frontline pandemic response;**
- [(c) review the status of stockpiles and the surge capacity of essential public health and clinical resources, and the surge capacity in production of pandemic-related health products;**
- [(d) facilitate the rapid and equitable restoration of public health capacities and routine and essential health services following a pandemic; and**
- [(e) promote collaboration and coordination with relevant stakeholders, including civil society, academic institutions and the private sector.**

**Such plans shall be consistent with and supportive of effective implementation of the International Health Regulations and shall pay particular attention to the respect for human rights, the needs of the persons in vulnerable situations and people living in humanitarian settings, as well as to the protection of health workers and other essential workers, including transport workers.]**

2. Each Party shall assess, no less than every five years, with technical support from the ~~[WHO Delete EU]~~ Secretariat upon request, **[and building on existing mechanisms under the IHR,]** the functioning and readiness of, and gaps in, its pandemic **[prevention,]** preparedness, ~~[surveillance Delete EU]~~ and ~~[multisectoral EU]~~ response capacity, logistics and supply chain management, and risk assessment. **[To this end, each Party shall, as appropriate,]** ~~[and Delete EU]~~ support the conduct of, inter alia, appropriate simulation or tabletop exercises, and intra- and after-action reviews, based on the relevant tools and guidelines developed by WHO in partnership with relevant organizations **[and stakeholders]**.

3. The Parties shall, building on existing tools, develop and implement an inclusive, transparent, effective and efficient pandemic prevention, preparedness and response monitoring and evaluation system. *[Comment: While the EU supports this paragraph, it is to be noted that the same requirements - in different words - appear to be laid down in paragraph 4. Repetition should be avoided.]*

4. The Parties shall establish, no later than 31 December 2026, a global peer review mechanism to assess pandemic prevention, preparedness and response capacities and gaps, as well as levels of readiness, with the aim of promoting and supporting learning among Parties, best practices, actions and accountability, at the national, regional and global levels, to strengthen national health emergency preparedness and readiness capacities. *[Comment: The deadline of 31 December 2026 appears not to take into consideration the entry into force date of the agreement, which remains to be determined. The need to establish a global peer review mechanism and possible parameters should be further discussed. Finally, the reference to "readiness" might be redundant.]*

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## Article 9. Research and development

1. The Parties shall cooperate to build strengthen and sustain geographically diverse capacities and institutions for research and development, particularly in developing countries, and shall promote research collaboration and access to research [**including**] through open science approaches for the rapid sharing of information and results.

2. To this end, the Parties shall promote:

- (a) sustained investment in the research and development of public health priorities, including for pandemic-related [**health**] products, aimed at improving equitable access to and delivery of such products, and support for national and regional research institutions that can rapidly adapt and respond to research and development needs in case of a pandemic;
- (b) technology co-creation and joint venture initiatives, actively engaging the participation of and collaboration among scientists and/or research centres [**from both public and private sector**], particularly from developing countries;
- (c) participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development, including community-led and cross-sector collaboration, [**including on activities involving animals that pose a risk of spillover of pathogens to humans,**] for addressing emerging and re-emerging pathogens with pandemic potential; [~~and Delete EU~~]
- (d) knowledge translation and evidence-based communication tools, strategies and partnerships relating to pandemic prevention, preparedness and response, including infodemic management, at local, national, regional and international levels[;]
- (e) joint scientific research programmes, projects and partnerships on the causes, enabling factors 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;
- (f) 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;
- (g) support and capacity building programmes, projects and partnerships for the development, dissemination and use of technical and scientific knowledge and research;
- (h) access for scientists and researchers from Parties, in particular parties which are Least Developed Countries, to scientific research programmes, projects and partnerships referred to in this article;
- (i) access to, and enhancement of, knowledge, skills and capacities through increased cooperation in the areas covered by the Agreement, and
- (j) collaboration, including with all relevant stakeholders, to set common objectives and research goals, pool expertise and avoid duplicating research efforts, especially in the field of countermeasures.

3. *[Comment: Reserve. The text of paragraph 3 is in large measure focused on clinical trials and needs further review.]* The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop and sustain, strong, resilient, and appropriately resourced, national, regional and

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international research capabilities. To this end, the Parties shall:

- (a) increase clinical trial capacities, including by:
  - i. building and maintaining a skilled research workforce and infrastructure, as appropriate;
  - ii. strengthening clinical trial policy [**and regulatory**] frameworks, particularly in developing countries;
  - iii. investing in the infrastructure and training of clinical research networks and the coordination of clinical trials through existing, new, or expanded clinical trial networks, including in developing countries, [~~to be prepared Delete EU~~] to provide timely[**, coordinated**] and appropriate responses to pandemics; and
  - iv. identifying and researching supply chain needs to rapidly mount and scale research responses during pandemic emergencies. [*Comment: sub-paragraph (iv) is unrelated to clinical trials and should be placed elsewhere*]
- (b) ensure that clinical trials have equitable representation, considering [**all relevant dimensions**] [~~racial, ethnic and gender diversity across the life cycle, and are designed Delete EU~~] to help to address geographical, socioeconomic and health disparities[~~, to Delete EU~~] [**and**] promote a better understanding of the safety and efficacy of pandemic-related [**health**] products for population subgroups;
- (c) promote the sharing of [**clinical trial protocols and**] information on national research agendas, including research and development priorities during pandemic emergencies, capacity-building activities and best practices on efficient and ethical clinical trials, including [~~through the WHO Global Observatory on Health Research and Development Delete EU~~] [**with the support of existing expert bodies**];
- (d) strengthen international coordination and collaboration in respect of clinical trials, through existing or new mechanisms, to support well-designed and well-implemented clinical trials;
- (e) develop national policies to support the transparent, public sharing of clinical trial protocols and results conducted either within their territories or through partnerships with other Parties, such as through open access publications, while [~~protecting privacy and health identifiers Delete EU~~] [**ensuring compliance with national law and international obligations regarding confidentiality, privacy and data protection**]; and
- (f) support new and existing mechanisms to facilitate the rapid reporting and interpretation of data from clinical trials, to develop or modify, as necessary, relevant clinical trial guidelines, including during a pandemic.
- [(g) support early interaction with regulatory bodies for guidance on optimal trial design to facilitate an efficient regulatory process.]**

4. [*Comment: Reserve. The text of paragraph 4 needs further review. The EU reserves its right to come back with drafting proposals at a later stage aimed at improving and streamlining the text*] Each Party shall, in accordance with national laws and considering the extent of public funding provided, publish the terms of government-funded research and development agreements for pandemic-related products, including information on:

- (a) research inputs, processes and outputs, including scientific publications and data repositories with data shared and stored securely in alignment with findability, accessibility, interoperability, and reusability principles;
- (b) the pricing of end-products, or pricing policies for end-products;



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- (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and
- (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic.

## Article 10. Sustainable production

*[Comment: The EU notes that many provisions under Article 10 are either unclear or represent a duplication of Article 11. We believe that it would be more useful to focus under Article 10 on provisions aimed at scaling up production and increasing the geographic diversification of production of pandemic-related health products.]*

1. The Parties, with a view to achieving a more equitable geographical and distribution of the global production of pandemic-related **[health]** products, and increasing **[sustainable,]** ~~[timely, fair, and~~ Delete EU] equitable **[and timely]** access to safe, effective, quality and affordable pandemic-related **[health]** products, thereby **[aiming to reduce]** ~~[reducing~~ Delete EU] the potential gap between supply and demand **[in]** ~~[at the time of a~~ Delete EU] pandemic **[situation,]** shall:

- (a) take measures to identify and maintain production facilities at national and regional levels, as well as to facilitate the production, as appropriate, and in furtherance of the provisions of Article 13 herein, of pandemic-related products therein; *[Comment: Reserve. As currently drafted, the EU cannot support this paragraph. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*
- (b) take measures to identify and contract with manufacturers other than those referenced in paragraph 1(a) of this Article, for scaling up the production of pandemic-related products, during pandemics, in cases where the production and supply capacity of the production facilities does not meet demand; *[Comment: Reserve. As currently drafted, the EU cannot support this paragraph. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*
- (c) strengthen ~~[coordination, with~~ Delete EU] **[collaboration between]** relevant international organizations, including United Nations entities **[as appropriate]**, on issues related to public health, intellectual property and trade, including ~~[the timely matching of supply to demand, and mapping~~ Delete EU] **[to assess]** manufacturing capacities and demand **[of pandemic-related health products]**;
- (d) encourage entities, including manufacturers within their respective jurisdictions, in particular those that receive significant public financing, to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licences to any manufacturers, particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries; *[Comment: Reserve. As currently drafted, the EU cannot support this paragraph. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*
- (e) ~~[actively~~ Delete EU] support ~~[, participate in and/or implement,~~ Delete EU] as appropriate, relevant ~~[WHO~~ Delete EU] technology, skills and know-how transfer programmes and initiatives aimed at enabling developing countries to produce pandemic-related **[health]** products, in order to facilitate ~~[strategically and geographically~~ Delete EU] **[regionally]** distributed production of pandemic-

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related **[health]** products; and

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

*[Comment on paragraphs 2 and 3: Reserve. As currently drafted, the EU cannot support paragraphs 2 and 3 below. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*

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

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

- (a) encourage research and development institutes and manufacturers, in particular those receiving significant public financing, to waive or manage, for a limited duration, royalties on the use of their technology for the production of pandemic-related products;
- (b) promote the publication, by private rights holders, of the terms of licensing agreements or technology transfer agreements for pandemic-related products; and
- (c) promote the voluntary licensing and transfer of technology and related know-how for pandemic-related products by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks.

## Article 11. Transfer of technology and know-how

**[1. The Parties shall promote and facilitate the transfer, on a voluntary basis, of technology, know-how and skills, that are necessary to improve the availability and affordability of effective and safe pandemic-related health products, and which are relevant to pandemic prevention, preparedness and response of Parties.]**

~~1. **[2.-To this end,]** the Parties ~~[, within a set time frame, working through the Conference of the Parties, Delete EU] shall [:]~~~~

**[(a) promote regional and international initiatives to facilitate the voluntary pooling of technologies and their voluntary licensing]** ~~[strengthen existing, and develop innovative, multilateral mechanisms, including through the pooling of knowledge, intellectual property and data, that promote the transfer of technology and know-how Delete EU] for the production of pandemic-related **[health]** products, ~~[on mutually agreed terms as appropriate, to manufacturers, Delete EU] particularly in developing countries.~~~~

~~[2. The Parties shall: Delete EU]~~

~~(a) [(b)] coordinate **[and]** ~~[with, Delete EU] collaborate with, facilitate and incentivize the manufacturers of pandemic-related **[health]** products to transfer **[on a voluntary basis]** relevant technology and know-how ~~[to manufacturer(s) on mutually agreed terms as appropriate, Delete EU] including through technology transfer ~~[hubs Delete EU and product development partnerships, ~~[and Delete EU] **[in order]** to address the need to develop new pandemic-related **[health]** products in a short time frame;~~~~~~~~~~

~~(b) [(c)] ~~[make available Delete EU] **[promote]** non-exclusive **[voluntary]** licensing of government-owned-technologies, on mutually agreed terms ~~[as appropriate Delete EU], for the development and manufacturing~~~~~~

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of pandemic-related **[health]** products, and publish the terms of these licences **[in accordance with each Party's laws and regulations:]**

(e) ~~[(d)]~~ **[provide assistance, as appropriate, in the establishment or development of national and regional regulatory frameworks aimed to facilitate the voluntary transfer of technology, skills and know-how. In this regard, the Parties reaffirm]** ~~[make use of Delete EU]~~ the flexibilities ~~[provided in Delete EU]~~ **[that Parties which are members of the World Trade Organization have under]** the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including those ~~[recognized Delete EU]~~ **[set out]** in the Doha Declaration on the TRIPS Agreement and Public Health ~~[and in Articles 27, 30 (including the research exception and “Bolar” provision), 31 and 31bis of the TRIPS Agreement, and fully respect the use thereof by others Delete EU];~~

~~(d)~~ **[(e)]** ~~[collaborate to ensure Delete EU]~~ **[facilitate]** equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities;

~~(e)~~ **[(f)]** develop, **[in collaboration with the World Intellectual Property Organization (WIPO) and the WHO,]** a database that ~~[provides the details of Delete EU]~~ **[collates publicly-available information on]** pandemic-related **[health]** products for all known **[diseases with]** pandemic-potential ~~[diseases, including the technological specifications and manufacturing process documents for each product Delete EU];~~ and *[Comment: the feasibility of the proposed provision needs to be checked with WIPO and WHO.]*

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

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

~~[(a) (h)]~~ **[(h)]** ~~[commit to agree upon, Delete EU]~~ **[consider]** within the framework of relevant institutions, ~~[time-bound waivers of intellectual property rights Delete EU]~~ **[appropriate measures]** to accelerate or scale up **[during a pandemic situation]** the manufacturing of pandemic-related products to the extent necessary to increase the availability and ~~[adequacy of affordable Delete EU]~~ **[affordability of]** pandemic-related products; Delete EU]

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

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

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

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## Article 12. Access and benefit sharing

*[Comment: Proposal on access and benefit sharing prepared by the EU and its Member States. The proposal is without prejudice to our ability to revise and improve the text as discussions progress]*

1. The Parties recognize that enhanced prevention, including surveillance, preparedness and response will benefit from an effective multilateral system enabling equitable and rapid access to pathogens and their genetic sequences, as well as the sharing of benefits, including more rapid and equitable access to products that derive from the utilization of such pathogens and their genetic sequences.

2. For these purposes, the Pathogen Access and Benefit-Sharing System (the “PABS System”) is hereby established. The PABS System shall act under the oversight of the [COP/governing body] and be authorised to enter into agreements, contracts or arrangements with Governments, organizations, institutions, firms or individuals and take other legal actions necessary to the performance of its functions for the purpose of carrying out its activities, in accordance with the rules, regulations and practice of the WHO. The PABS system shall be administered by the Partnership set out in article 13, bringing together the WHO, and the relevant organisations of the UN system, other relevant international organisations, regional organisations and stakeholders, including civil society and the private sector.<sup>3</sup>

3. The PABS System shall cover access to previously unknown pathogens, as defined in paragraph 4, their genetic sequence data and related available epidemiological and clinical information, subject to applicable domestic and international safety and security, as well as data protection laws and regulations, as well as the sharing of benefits that arise from the utilization of such pathogens and data.

The PABS System aims to provide clarity and legal certainty for providers and users of pathogens and data, as well as of benefits, and to strengthen, expedite, and not impede research and innovation. The WHO in cooperation with the other Quadripartite organisations shall monitor the progressive development of the parties' laboratory capacities, and shall issue guidance on the interpretation on what constitutes an unknown pathogen.

4. For the purpose of this article:

“Pathogen” shall mean a virus or an organism that causes, or can cause, a disease to its human host and covers<sup>4</sup> unknown pathogens and unknown variants of known pathogens;

“Disease” shall mean an illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans;

“Unknown pathogen” shall mean a pathogen or a new variant of a pathogen that have not been identified and characterised at the date of entry into operation of the PABS System pursuant to paragraph 7(f). Unknown pathogens encompasses pathogens with public health emergency of international concern potential, according to assessment under the decision instrument contained in Annex 2 of the International Health Regulation (2005), as amended.

“Manufacturer” shall mean any entity that produces, including by means of licensing agreements, health

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<sup>3</sup> Such Partnership should be established in article 13, without prejudice to the financing of each Partnership members, although the additional tasks assigned to the Partnership members will call for additional resources.

<sup>4</sup> Possible coverage or exclusion of pandemic influenza pathogens as defined within the Pandemic Influenza Preparedness (PIP) Framework, as set out in Resolution 60.28 of the World Health Assembly will need to be further considered.

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products, namely vaccines, therapeutic or diagnostic products.

**5. Access to pathogens and genetic sequence data**

(a) Each Party, through one or more designated authorities, shall, in a safe, secure, rapid and systematic manner:

- (i) provide access to physical samples of pathogens within their control and available related epidemiological and clinical information useful for their utilisation (hereinafter the “samples”), to one or more laboratories or biorepositories participating in a network of laboratories coordinated by the WHO in cooperation with the other Quadripartite organisations, and, if it so decides, also to one or more laboratories recognised by the WHO or by any of the Party’s designated authorities (hereinafter collectively referred to as “recognised laboratories”); and
- (ii) provide access to the genetic sequence data and relevant metadata of pathogens within their control (hereinafter “sequence data”) by uploading them to one or more database(s), which are publicly accessible and recognised by the WHO or by any of the Party’s designated authorities (hereinafter “recognised databases”).

(b) In providing access to samples or sequence data consent is given to the further transfer and use of such samples and sequence data subject to applicable safety and security and data protection rules and standards, as well as the provisions of this article. The Parties and the recognised laboratories and recognised databases shall ensure the expeditious further transfer and use in accordance with paragraph 5(e) of this Article, and facilitate awareness of newly detected pathogens, as well as access to related samples and sequence data that may subsequently become available.

(c) For purposes hereof: “rapid” provision shall mean provision no later than [...] hours from the time of acquisition and identification by a Party through its designated authorities of a pathogen or from the time the relevant sequence data have become available to a Party. Parties may seek the cooperation and support of other Parties with available laboratory capacities in order to identify and characterize pathogens.

(d) The WHO and the other Quadripartite organisations in consultation with existing recognised laboratories shall set out the guidelines for individual or networks of national or regional laboratories or biorepositories to be recognised as capable of receiving and transferring samples in a timely, safe and secure manner, make these conditions publicly available, and keep a publicly accessible list of recognised laboratories. The Parties in cooperation with WHO and the other Quadripartite organisations shall provide technical assistance to national or regional laboratories from developing countries in need for the purpose of obtaining such recognition. The WHO and the other Quadripartite organisations in consultation with existing databases shall also set out the guidelines for a database to be recognised as publicly accessible and as capable of receiving and transferring sequence data in a secure manner, make these conditions publicly available and keep a publicly accessible list of recognised databases.

(e) In case that an institution, organisation or entity (hereinafter the “recipient”) makes a request for access to samples or sequence data, such access shall be accorded on an as expeditious basis as possible without conditions and with no discrimination by the recognized laboratory or recognised database as the case may be, to requesting recipients. For purposes hereof, “expeditious” provision shall mean provision no later than [...] hours from the time of the request for access samples or sequence data.

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In the event that a shortage of samples prevents a Party from fulfilling the obligations set out in this subparagraph, that Party shall inform the WHO and the PABS System of the situation and shall provide access as soon as it is practically possible.

(f) Notwithstanding paragraph 5(e) any access shall be subject to applicable safety, security and data protection rules and standards, as well as the provisions of this article including paragraph (h). Access to samples shall be free of charge, or, when a fee is charged, it shall be limited in amount to the approximate cost of services rendered.

(g) The PABS System shall be consistent with and mutually supportive of relevant international rules and guidelines, notably those for collection of patient specimens, material and data, as well as with open access and open science principles, and shall promote effective, standardized, global and regional databases that make findable, accessible, interoperable and reusable data available to all Parties and recipients.

(h) As an access condition under the PABS system, no entity shall claim any intellectual property rights on the unmodified sample or the unmodified sequence data as received pursuant to this paragraph. Samples or sequence data may otherwise be the subject of intellectual property rights, provided that the criteria relating to such rights are met. A recognised laboratory may have used technology protected by IPRs for the preparation of the sample. Any recipient of such sample acknowledges that such IPRs shall be respected.

## 6. **Multilateral benefit-sharing**

The Parties recognize that effective multilateral benefit sharing requires contributions from Parties as well as from stakeholders, and in particular from manufacturers of health products and pandemic-related health products. To this end, this paragraph sets out benefit sharing provisions applicable to Parties in A) pandemic situations and B) at all times. These provisions shall also form the basis for the benefit sharing commitments of manufacturers of health products and pandemic-related health products to be set out in the Standardised Benefit Sharing contracts between such manufacturers and the PABS System pursuant to paragraph 7(e).

### *A. Specifically during a pandemic situation*

In the case of a pandemic situation as declared pursuant to art ..., the Parties shall cooperate and take appropriate measures with the aim to ensure the following elements are set out in standardised benefit sharing contracts between the PABS System and manufactures pursuant to paragraph 7(e) or otherwise adhered to:

Manufacturers of pandemic-related health products shall make available to the Partnership for equitable distribution on the basis of public health risk, need and demand, [...%] percent of their production of safe and effective pandemic-related health products, as defined in paragraph 7(b), on a quarterly basis ([...%] free of charge and [...%] at not-for-profit prices), while a pandemic situation persists. Such products shall be made available and delivered only upon request of the Partnership in accordance with the provisions set out in the contracts concluded pursuant paragraph 7(e).

### *B. At all times*

The Parties shall cooperate and take appropriate measures with the aim to ensure the following elements are set out in standardised benefit sharing contracts between the PABS System and manufactures pursuant to paragraph 7(e) or otherwise adhered to:

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- i. Manufacturers of health products commit to engage in capacity-building and scientific and research collaboration on mutually agreed terms with scientists and researchers from developing countries, which are Parties to this Agreement, in the research, development or production phase of products related to the pathogen sample they acquired through the PABS System, with the aim to build technical skills and capacities. Such collaboration shall be facilitated by the PABS System and set out in the contracts concluded pursuant to paragraph 7(e);
- ii. Manufacturers of health products will contribute to support the WHO coordinated laboratory network, as well as capacity building activities, including to facilitate the participation of laboratories and biorepositories from developing countries in the network and their ability to rapidly detect and characterise pathogens and analyse genetic materials. Annual contributions for this purpose shall be set in the contracts pursuant to paragraph 7(e) and shall take into account the need to facilitate participation in the PABS System by manufacturers, which are medium and small size enterprises, as well as by manufacturers whose use of PABS System is limited to specific pathogen classes.
- iii. In case a public health emergency of international concern is declared pursuant to article 12 of the IHR, and unless a pandemic situation is declared [pursuant to article ... of the IHR as amended] and the provisions in paragraph 6.A. apply, the manufactures of relevant health products, as defined in paragraph 7(b), shall make available at not-for-profit prices to the Partnership, [...%] percent of safe and effective health products on a quarterly basis, while the public health emergency of international concern persists. Such products shall be made available for use on the basis of public health risk, need and demand, with particular attention to the needs of developing countries, and shall be delivered only upon request of the Partnership in accordance with the provisions set out in the contracts concluded pursuant paragraph 7(e).
- iv. If a public health emergency of international concern develops into a pandemic situation and the provisions of 6.A. become applicable, the amount of health products made available pursuant to paragraph 6.B.iii shall be counted against the amount due pursuant to paragraph 6.A.

## **7. General provisions and entry into operation of the PABS System**

- (a) Recipients which are not-for-profit institutions, organisations and entities, including academic or research institutions, and which are not engaged in the commercial use of samples or data shall be exempted from any sharing of benefits pursuant to paragraph 6, but shall be encouraged to make voluntary contributions to support the management and implementation of the PABS System, including through scientific collaborations, training and capacity building activities.
- (b) The health products, including pandemic-related products, covered by the provisions of this article are limited to vaccines, therapeutic and diagnostic products that are prequalified by the WHO or have received a positive WHO Emergency Use Listing assessment or an authorisation from a national regulatory authority for treatment, diagnosis/detection or prevention of the disease which has given rise to the declaration of a pandemic situation, or of a public health emergency of international concern.
- (c) Parties shall take all necessary steps to facilitate the export of pandemic-related products, in accordance with applicable international law.

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(d) The [COP/governing body], shall review the operationalization and functioning of the PABS System every four years, including the continuing fulfilment of the criteria set out in paragraph 7(f). Any modification to the provisions set out in this article shall be adopted by means of amendments to this Agreement.

(e) The Parties shall cooperate and take appropriate measures with the aim to encourage and facilitate the manufacturers of pandemic-related health products, including small and medium-sized enterprises which are active in the research and development of new health products, to commit to the relevant provisions of this Article, in particular the elements set out in paragraph 6.A. and 6.B., as early as possible and before a pandemic situation is declared with the aim of improving planning and preparedness. Such commitments shall be set out in legally binding, standardised benefit sharing contracts between relevant manufacturers of health products and the PABS System, who will keep their implementation under review and make them public, while respecting commercial confidentiality. The Director General shall report regularly to the Parties on the conclusions of such contracts.

(f) With the aim to ensure that the legally binding provisions related to both access to pathogens and genetic sequence data and multilateral benefit sharing take effect at the same time and actual benefits accrue the PABS System shall start to operate when the Director General of the WHO determines in consultation with the Panel of Experts for Scientific Advise and the Partnership members that:

i. the System is ready to do so, in particular with regard to the capacities of the networks of national and regional laboratories and repositories coordinated by the WHO, giving priorities to their capacity to handle pathogens with public health emergency of international concern potential, according to assessment under the decision instrument contained in Annex 2 of the IHR, and

ii. a sufficient number of manufacturers have concluded standardised benefit sharing contracts pursuant to paragraph 7(e). Such sufficient number shall include (1) manufacturers accounting for at least [...]% of sales of vaccines, [...]% of sales of therapeutics, and [...]% of sales of diagnostics, all measured on the basis of worldwide turn-over related to products for communicable diseases; and (2) at least the majority of the [10] largest vaccines manufacturers, the majority of the [15] largest therapeutics manufacturers, and the majority of the [15] largest diagnostics manufacturers, all measured by worldwide sales turn-over related to products for communicable diseases.

(g) The PABS System shall report yearly to the Parties on its operation, including on the use of the annual contributions provided for in article 6.B.ii.

(h) The Parties agree and affirm that the PABS System constitutes a specialised access and benefit-sharing instrument within the meaning of Article 4.4 of the Nagoya Protocol. The Parties further agree that relevant domestic and regional access and benefit sharing rules and legislation shall not apply to the sharing of pathogen samples or sequence data as well as benefits, which is carried out pursuant to the PABS System.

### Article 13. Global Supply Chain and Logistics Network

1. The WHO [~~Global Supply Chain and Logistics Network (the WHO SCL Network) is hereby established. The WHO SCL Network will operate within the framework of WHO in Delete EU~~] **[shall establish, in consultation with the Parties, and coordinate a]** partnership [~~and collaboration Delete EU~~] with **[relevant organizations of the UN system]**, relevant international **[and]**; Delete EU] regional **[organizations]** [~~and~~



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Delete EU] **as well as** other relevant organizations[;Delete EU] and **stakeholders. The Partnership shall** be guided by equity and public health needs, paying particular attention to the needs of **least developed country** [developing country Delete EU] Parties.

2. The [~~Conference of the Parties~~] **Partnership organisations** shall develop **operational** guidelines [~~on~~ Delete EU] **and** modalities [~~and~~ Delete EU] **for** collaboration, [~~for the WHO SCL Network~~ Delete EU] which shall [~~be~~ Delete EU] aim[ed Delete EU] at ensuring close consultation [~~among~~ Delete EU] **with the** Parties and that functions are discharged by the organizations best placed to perform them.

3. The Parties shall support the [~~WHO SCL Network's~~ Delete EU] **Partnership's** development and operationalization [~~and participate in the WHO SCL Network, including through sustaining it at all times~~ Delete EU]. The [~~terms~~ Delete EU] **functions** of the [~~WHO SCL Network~~ Delete EU] **Partnership** shall include:

- (a) estimating, or, where possible, determining, the most likely types and [~~size/~~ Delete EU] volume of products needed for robust pandemic prevention, preparedness and response, including the costs and logistics for establishing and maintaining strategic stockpiles of such products;
- (b) assessing the [~~anticipated demand for, mapping the sources of, and maintaining a dashboard of manufacturers and suppliers,~~ Delete EU] **available production and supply capacities**, including surge capacities and relevant [~~necessary~~ Delete EU] raw materials, for the sustainable production of pandemic-related **health** products;
- (c) identifying the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms;
- (d) working with national authorities to establish and maintain national and/or regional stockpiles of various pandemic response-related products, as well as maintaining the relevant logistic capacities and assessing them at regular intervals, and specifying the criteria to ensure that stockpiling is used only to address public health needs **and that unnecessary accumulation of products not linked to the actual needs of a Party is avoided**;

**[(d) bis determine the equitable allocation of the reserved quantities of pandemic-related health products, based on public health risks and 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 products,]**

- (e) facilitating the negotiation and agreement of advance purchase commitments and procurement contracts for pandemic-related products;
- (f) promoting transparency [~~in cost, pricing and all other relevant contractual terms~~ Delete EU] **of market conditions** along **relevant** [~~the~~ Delete EU] supply chain[s];
- (g) coordinating to avoid competition for resources among procuring entities, including regional organizations and/or mechanisms;
- (h) mapping existing, and identifying needed, delivery and distribution options;
- (i) establishing or operationalizing, as appropriate, international or regional stockpiles, consolidation hubs and staging areas;
- (j) assisting buying countries in meeting the logistic requirements for the utilization of specific pandemic-related **health** products; and
- (k) facilitating or, as necessary, organizing the efficient delivery and appropriate utilization of pandemic-related **health** products in beneficiary countries or in humanitarian settings.

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

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

6. Each Party shall, in its government-funded purchase agreements for pandemic-related products, to the fullest extent possible and in accordance with applicable laws, exclude confidentiality provisions that serve to limit the disclosure of terms and conditions. *[Comment: Text needs to be reviewed, and duplication with other provisions avoided.]*

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

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

[9. The Parties shall enable inclusive, equitable and effective cooperation and participation, and shall take all appropriate measures to undertake the foregoing no later than 31 May 2025. RESERVE EU] *[Comment: While the EU supports the rapid application of the provisions of this Agreement, we note that the timeframe suggested appears unfeasible.]*

#### Article 14. Regulatory strengthening

*[Comment: the EU suggests re-ordering the paragraphs in Article 14, to start with the requirement for Parties to have legal, administrative and financial frameworks in place to support emergency regulatory approvals in case of a pandemic.]*

**[1.]** *[Comment: Paragraph 5 of the Bureau's proposal for negotiating text moved as a new paragraph 1.]* Each Party shall take steps to ensure that it has the legal, administrative and financial frameworks **[necessary for]** ~~[in place to support Delete EU]~~ emergency regulatory approvals **[or]** for **[regulatory reliance aimed at]** the effective and timely ~~[regulatory Delete EU]~~ approval of **[safe and efficacious]** pandemic-related **[health]** products during a pandemic.

~~[1-]~~ **[2.]** The Parties **[and WHO]** shall **[collaborate, including through technical assistance, with the aim of]** strengthen**[ing the capacities of]** their national and regional regulatory authorities[, **with particular attention to the needs of the developing country Parties]** ~~[including through technical assistance, with the aim of expediting regulatory approvals and authorizations and ensuring the quality, safety and efficacy of pandemic related products. Delete EU]~~ *[Comment: the second half of this paragraph is moved to paragraph 4 below.]*

~~[2-]~~ **[3.]** The Parties shall **[aim at]** align**[ing]** and, where possible, harmoniz**[ing]** technical and regulatory

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requirements ~~[and procedures Delete EU]~~, in accordance with applicable international standards, guidance and protocols, including those covering regulatory reliance and mutual recognition, and shar[ing] relevant information and assessments concerning the quality, safety and efficacy of pandemic-related [health] products with other Parties.

~~[3. The Parties shall, as appropriate, monitor, regulate and strengthen rapid alert systems, against substandard and falsified pandemic-related products.] [Comment: see paragraph 5.]~~

4. **[The Parties shall promote and facilitate, as appropriate, the use of regulatory reliance and mutual recognition, both at national and regional level, with the aim of ensuring quality, safety and efficacy of pandemic-related health products and expediting regulatory approvals or authorisations. To this end,]** each Party shall, in accordance with relevant laws, publicly disclose information on national, and, if applicable, regional processes for authorizing or approving use of pandemic-related [health] products, and any additional relevant regulatory pathways for such pandemic-related [health] products that may be activated during a pandemic to increase efficiency, and update such information in a timely manner.

~~5. Each Party shall take steps to ensure that it has the legal, administrative and financial frameworks in place to support emergency regulatory approvals for the effective and timely regulatory approval of pandemic-related products during a pandemic. [Comment: see paragraph 1.]~~

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

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

## Article 15. Compensation and liability management

1. Each Party shall develop, **[as necessary and in accordance with national and regional legislation,]** ~~[national Delete EU]~~ strategies for managing liability risks in its territory regarding the ~~[manufacturing, distribution, Delete EU]~~ administration and use of novel vaccines developed in response to pandemics. **[In doing so, Parties will ensure that both the risks and benefits from these novel vaccines are shared in a balanced manner between the public and private sector.]** ~~[Strategies may include, inter alia, the development of model contract provisions, vaccine injury compensation mechanisms, insurance mechanisms, policy frameworks and principles for the negotiation of procurement agreements and/or the donation of novel vaccines developed in response to pandemics, and building expertise for contract negotiations in this matter. Delete EU]~~

2. The ~~[Conference of the Delete EU]~~ Parties shall ~~[establish, within two years of the entry into force of the WHO Pandemic Agreement, Delete EU]~~ **[facilitate the delivery of pandemic-related health products including by humanitarian organisations. In this regard,]** using ~~[existing Delete EU]~~-relevant models as a reference, **[the Parties shall promote the establishment of regional or international schemes for]** no-fault vaccine injury compensation mechanism(s), with the aim of **[ensuring]** ~~[promoting access to Delete EU]~~ financial remedy for individuals experiencing serious adverse events resulting from **[the delivery and administration of]** a [novel] pandemic vaccine **[with particular regards to the needs of individuals that are in humanitarian setting or in vulnerable situations.]** ~~[as well as more generally promoting pandemic~~

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~~vaccine acceptance. The Conference of the Parties shall further develop the mechanism(s), which may be regional and/or international, including strategies for funding the mechanism(s), through the modalities provided for in Article 20 herein. Delete EU]~~

3. Each Party shall endeavour to ensure that in contracts for the supply or purchase of novel pandemic vaccines, [~~buyer/recipient indemnity Delete EU]~~ **[indemnification]** clauses **[in favour of manufacturers]**, if any, are exceptionally provided, and are time-bound.

## Article 16. International collaboration and cooperation

1. The Parties shall collaborate and cooperate with competent international and regional intergovernmental organizations and other bodies, as well as among themselves, in the formulation of cost-effective measures, procedures and guidelines for pandemic prevention, preparedness and response. *[Comment: the added value of paragraph 1 seems to be limited, in comparison to other more operational provisions included in the Agreement. It might be more useful to place it earlier in the text.]*

2. The Parties shall:

- (a) promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness and response;
- (b) support mechanisms that ensure that policy decisions are science- and evidence-based;
- (c) develop, as necessary, and implement policies, that respect, protect and fulfil the human rights of all people; *[Comment: provisions of subparagraph (c) appear to be a repetition of the general principle already set out under Article 3 paragraph 1 of the Bureau's proposal for negotiating text. The EU would in addition be in favour of having a specific article on the protection of human rights<sup>5</sup>.]*
- (d) promote equitable representation on the basis of gender, geographical and socioeconomic status, as well as the equal and meaningful participation of young people, [~~and Delete EU]~~ **and people living with disability, in national, regional and global decision-making processes, global networks and technical advisory groups**];
- ~~[(e) assist developing countries through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs for pandemic prevention, preparedness, and response in line with the provisions set forth in Article 19 herein; and Delete EU] *[Comment: while the EU support the objective of the provision, we suggest deletion, as it duplicates the provisions of Article 19.]*~~
- [(f) encourage ceasefires in affected countries during pandemics to promote global cooperation against common global threats. Reserve EU] *[Comment: Reserve on text. While the EU sympathises with the spirits of the proposal, the text needs to be further considered.]*

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

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

<sup>5</sup> “EU proposal for a specific article on the protection of human rights:

### Article 2 bis Protection of human rights

1. The implementation of this Agreement shall respect, protect and fulfil the human rights and fundamental freedoms of persons, and be in full compliance with international humanitarian law and principles.”

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and resilience to pandemic prevention, preparedness and response.

2. Each Party shall [~~in keeping with national capacities, Delete EU~~] establish, implement and adequately finance an effective national, [**and where relevant regional,**] [~~coordinating multisectoral Delete EU~~] [**coordination**] mechanism[, **with multisectoral and transdisciplinary engagement, to prevent, prepare for and respond to pandemics**].

3. Each Party shall, in accordance with national context, promote the effective and meaningful engagement of [**local**] communities, civil society and other relevant stakeholders, [~~including the private sector, as part of a whole of society response in decision-making Delete EU~~] [**when deciding on measures to prevent, prepare for and respond to a pandemic, as well as when implementing,**] [~~implementation Delete EU~~], monitoring and [~~evaluation Delete EU~~] [**evaluating these measures.**] [~~and shall also provide e Delete EU~~] [**E**]ffective feedback opportunities [**should be provided.**]

[~~4. Each Party shall develop, in accordance with national context, comprehensive national pandemic prevention, preparedness, and response plans pre-, post- and interpandemic that, inter alia:~~

- (a) [~~identify and prioritize populations for access to pandemic-related products and health services;~~
- (b) [~~support the timely and scalable mobilization of the multidisciplinary surge capacity of human and financial resources, and facilitate the timely allocation of resources to the frontline pandemic response;~~
- (c) [~~review the status of stockpiles and the surge capacity of essential public health and clinical resources, and surge capacity in the production of pandemic-related products;~~
- (d) [~~facilitate the rapid and equitable restoration of public health capacities and routine and essential health services following a pandemic; and~~
- (e) [~~promote collaboration with relevant stakeholders, including the private sector and civil society. Delete EU~~] [*Comment: paragraph 4 and its subparagraphs are moved to Article 8, paragraph 1, as subparagraphs (a) to (e).*]

[~~5.~~]**[4.]** Each Party, based on national capacities [**and priorities**], shall take the necessary steps to address the social, environmental, [**humanitarian**] and economic determinants of health, and the vulnerability conditions that contribute to the emergence and spread of [**outbreaks with**] pandemic [**potential**], and shall [**work to**] prevent or mitigate the socioeconomic impacts [~~of pandemics Delete EU~~] [**thereof, including through measures aimed at transitioning people away from activities that increase risk of pathogen spill-over**].

[~~6.~~]**[5.]** Each Party shall take appropriate measures to strengthen national public health and social policies to facilitate a rapid, resilient response to pandemics, especially for persons in vulnerable situations, including by mobilizing [~~social capital in Delete EU~~] [**support of local**] communities [~~for mutual support Delete EU~~].

## Article 18. Communication and public awareness

1. The Parties [~~shall strengthen Delete EU~~] [**should act independently and jointly to increase**] [~~science, Delete EU~~] public health [**education,**] [~~and pandemic Delete EU~~] literacy [**and awareness**] in the population [**and**] [~~as well as Delete EU~~] access to [**evidence-based and transparent**] information on pandemics and their [**causes, drivers and**] effects [~~and drivers Delete EU~~], [**as well as on the efficacy and safety of pandemic-related health products, with the aim to counter**] [~~and combat false, misleading, Delete EU~~] misinformation or disinformation, including through effective international collaboration and cooperation, as referred to in Article 16 herein. [**In that regard, each Party shall, in accordance with national, and**

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**when applicable regional, approaches, law and regulations:**

- (a) **promote and facilitate the development and implementation of public awareness programmes on pandemics and their effects, in cooperation with all stakeholders, as well as health professionals and local communities;**
- (b) **promote, including through community stakeholder engagement, effective, transparent and accessible communication specifically aimed at informing persons in vulnerable situations and people living in humanitarian settings; and**
- (c) **take effective measures to increase digital health literacy among the public and within the health sector through education and meaningful engagement, including clinicians, health sector stakeholders, and decision-makers, to foster trust.]**

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

3. The Parties shall promote and apply a science and evidence-informed approach to effective and timely risk assessment and public communication.

**[4. The Parties shall exchange information and cooperate, in accordance with national law, in preventing and investigating incidents of misinformation and disinformation. They shall endeavour 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.]**

#### **Article 19. Implementation capacities and support**

1. The Parties shall cooperate, directly or through competent international bodies, to strengthen their capacity to fulfil the obligations arising from this Agreement [**while closely coordinating their support activities under this Article with the provision of support under the IHR,**] [~~taking into account especially the needs of developing country Parties Delete EU~~]. Such cooperation shall promote the transfer of technical, scientific and legal expertise [~~and, Delete EU~~] [**as well as the voluntary transfer of**] technology [~~, as mutually agreed, Delete EU~~] to establish and strengthen sustainable pandemic prevention, preparedness and response capacities of all Parties [**in line with the One Health approach**]. [*Comment: The deletion of "taking into account especially the needs of developing country Parties" is suggested only to avoid duplication with paragraph 2 below.*]

~~[2. Each Party shall, within the means and resources at their disposal, cooperate to raise financial resources for the effective implementation of the WHO Pandemic Agreement through bilateral and multilateral funding mechanisms. [*Comment: duplication with subparagraph (a) of Article 20.*]~~

~~[3.] [2.]~~ The Parties shall give particular consideration to the specific needs and special circumstances of [**the least developed**] [~~developing Delete EU~~] country Parties [**and other Parties in need**] for financial and technical assistance [**with the aim to assist them in building sustainable capacity**] to [~~support the implementation of Delete EU~~] [**fulfil their obligations arising under**] this Agreement.

~~[4.] [3.]~~ The Parties shall, where a Party lacks the necessary capacity to implement specific provision(s) of this Agreement, work together [**and with the support of the Secretariat**] to identify the most relevant partner(s) that can support the development of such capacities and shall cooperate to ensure that the mechanism(s) identified in Article 20 herein provides the necessary financial resources.

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**[4. 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 least developed country Parties and other Parties in need.]**

**Article 20. Financing [implementation support]**

1. The Parties commit to sustainable financing for strengthening pandemic prevention, preparedness and response. In this regard, each Party, within the means and resources at its disposal, shall:

(a) cooperate with other Parties, as appropriate, to raise sustainable financial resources for the effective implementation of this Agreement through [existing] bilateral and multilateral, regional or subregional funding mechanisms;

(b) plan and provide adequate financial support, in line with national fiscal capacities, for: (i) strengthening and sustaining [national, and where appropriate regional,] capacities for pandemic prevention, preparedness and response; (ii) implementing national plans, programmes and priorities; and (iii) strengthening [its] health system[s Delete EU] and the progressive realization of universal health coverage for pandemic prevention, preparedness and response;

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

~~[(d) mobilize financial resources for international cooperation and assistance in respect of pandemic prevention, preparedness and response, in accordance with its capacities and based on the principle of solidarity, particularly for developing countries, including through international organizations and existing and new mechanisms; and Delete EU] [Comment: we suggest deleting subparagraph (d) to avoid duplication with subparagraph (a).]~~

~~[(e) provide support and assistance to other Parties, upon request, to facilitate the containment of spill-over at the source. Delete EU] [Comment: we suggest deleting subparagraph (e), because it is unclear why "containment of spill-over at source" is singled out.]~~

2. ~~[A sustainable funding mechanism shall be established by the Conference of the Parties no later than 31 December 2026. The mechanism shall ensure the provision of adequate, accessible, new and additional and predictable financial resources, and shall include the following. Delete EU] [The Parties shall cooperate, including with all relevant stakeholders, to secure the financial resources necessary for the provision of adequate assistance aimed at the effective implementation of the Agreement. For this purpose, a coordination mechanism functioning under the guidance of the Conference of the Parties/Governing Body is hereby defined. The Conference of the Parties/ Governing Body shall, at its first session, select by consensus one or more existing entities providing multilateral, regional and bilateral financial and technical assistance to be entrusted with the operation of the coordination mechanism. The Conference of the Parties/Governing Body shall also set out the necessary arrangements for cooperation and coordination with other entities providing such assistance in order to enable transparent, effective and equitable operation of the coordination mechanism, in line with the provisions in this Article. The Conference of the Parties/Governing Body shall review the operation of the coordination mechanism every [...] years and make any necessary modifications by consensus.~~

**3. The coordination mechanism, through the selected entity or entities entrusted with its operation, shall:**

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**i. assist developing country Parties in identifying and mobilising all sources of financing to fund implementation support activities necessary to meet their obligations under the WHO Pandemic Agreement and the IHR (2005) as amended and related activities for pandemic prevention, preparedness and response, with particular regard to the needs of the least developed country Parties;**

**ii. facilitate coordination among existing sources of financing to fund implementation support activities;**

**iii. promote the mobilisation of financing, including from all relevant stakeholders, to fund implementation support activities.**

**iv. increase the transparency, accountability, inclusiveness, efficiency and effectiveness of financing for implementation.**

**v. report periodically to the [COP/Governing Body] on the operation of the coordination mechanism.]**

~~(a) [A capacity development fund that shall be resourced, inter alia, through the following: Delete EU]~~

**[4. All Parties, within their capabilities, shall endeavour to contribute to the funding of the activities aimed at the effective implementation of this Agreement. The coordination mechanism shall encourage the provision of resources from all sources, including:]**

~~[(i) annual monetary contributions by Parties to the WHO Pandemic Agreement; Delete EU]~~

~~[(ii) monetary contributions from recipients pursuant to Article 12; and Delete EU] [*Comment: to be discussed in the context of art 12*]~~

~~[(iii)] [(i) **annual**] voluntary monetary contributions from Parties [to the WHO Pandemic Agreement Delete EU]~~

~~[(b) — An endowment for pandemic prevention, preparedness and response, resourced, inter alia, through the following Delete EU]~~

~~[(+)] [(ii)] voluntary monetary contributions from [all Delete EU] relevant [**stakeholders, in particular those active in**] sectors that benefit from international work to strengthen pandemic prevention, preparedness and response; [and~~

~~— [(ii) [(ii)] donations from philanthropic organizations and foundations and other voluntary monetary contributions. Delete EU]~~

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

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



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~~resourcing of the funding mechanism, with due regard to the avoidance of conflicts of interest.~~  
*[Comment: subparagraph (d) is unnecessary and should be deleted in light of the proposed redrafting of the chapeau of paragraph 2.]*

[3] [5] The Parties represented in relevant regional and international intergovernmental organizations and financial and development institutions shall encourage, as appropriate, these entities to provide additional financial assistance for developing country Parties to support them in meeting their obligations under the WHO Pandemic Agreement~~[, without limiting their participation in or membership of these organizations Delete EU].~~

### Chapter III. Institutional arrangements and final provisions

*[EU comment: In general, discussions and revision of Chapter III need to be done at a later stage, once there is a higher level of convergence on the content of the provisions under Chapter II. In further discussing the institutional set up, it will also be important to consider the potential cost and administrative implications of the establishment of any new proposed bodies, as well as any opportunity to make use of existing bodies whose mandates may be adapted to the need of this agreement.]*

#### Article 21. Conference of the Parties

*[EU comment: The denomination “Conference of the Parties” and its organisation and functions will need to be further considered.]*

1. A Conference of the Parties is hereby established. The Conference of the Parties shall be comprised of ~~[delegates representing Delete EU]~~ **[representatives of]** the Parties to the WHO Pandemic Agreement. Only ~~[delegates representing Delete EU]~~ **[representatives of]** Parties will participate in any of the decision-making of the Conference of the Parties. The Conference of the Parties shall establish the criteria for the participation of observers at its proceedings.
2. With the aim of promoting the coherence of the Conference of the Parties and the Health Assembly, as well as coherence in respect of relevant instruments and mechanisms within the framework of the World Health Organization, the Conference of the Parties shall operate in coordination with the Health Assembly. In particular, the Conference of the Parties~~[, where feasible and appropriate,]~~ shall hold its regular sessions immediately before or after regular sessions of the Health Assembly, and in the same location and venue as the Health Assembly~~[, where feasible. Delete EU]~~
3. The first session of the Conference of the Parties shall be convened by the World Health Organization not later than one year after the entry into force of the WHO Pandemic Agreement.
4. Following the first session of the Conference of the Parties:
  - (a) subsequent regular sessions of the Conference of the Parties shall be held annually; and
  - (b) extraordinary sessions of the Conference of the Parties shall be held at such other times, without reference to the regular sessions of the Health Assembly, as may be deemed necessary by the Conference of the Parties, or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties.
5. The Conference of the Parties shall adopt by consensus its Rules of Procedure at its first session.
6. The Conference of the Parties shall by consensus adopt financial rules for itself as well as governing the funding of any subsidiary bodies of the Conference of the Parties that are or may be established, as well as financial provisions governing the functioning of the Secretariat. It shall also adopt a biennial budget **[by**

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consensus].

7. The Conference of the Parties shall keep under regular review[, every three years,] the implementation of the WHO Pandemic Agreement [and any related instruments] and take the decisions necessary to promote [~~its Delete EU~~] [their] effective implementation, and may adopt amendments, annexes and protocols to the WHO Pandemic Agreement, in accordance with Articles 28, 29, and 30 herein. To this end, it shall:

- (a) consider reports submitted by the Parties in accordance with Article 23 herein and adopt regular reports on the implementation of the WHO Pandemic Agreement;
- (b) oversee any subsidiary bodies, including by establishing their rules of procedure and working modalities;
- (c) promote and facilitate the mobilization of financial resources for the implementation of the WHO Pandemic Agreement, in accordance with Article 20 herein;
- (d) request, where appropriate, the services and cooperation of, and information provided by, the competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies, as a means of strengthening the implementation of the WHO Pandemic Agreement; and
- (e) consider other action, as appropriate, for the achievement of the objective of the WHO Pandemic Agreement in the light of experience gained in its implementation.

8. [~~The Conference of the Parties shall keep under regular review, every three years, the implementation and outcome of the WHO Pandemic Agreement and any related legal instruments that the Conference of the Parties may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO Pandemic Agreement. Delete EU~~] [*EU comment: duplication with paragraph 7.*]

9. The Conference of the Parties shall establish subsidiary bodies [as are necessary to achieve the objectives of the Agreement] [~~to carry out the work of the Conference of the Parties, as it deems necessary, Delete EU~~] [and define their] [~~on Delete EU~~] terms and modalities [~~to be defined by the Conference of the Parties Delete EU~~]. [~~Such subsidiary bodies may include, without limitation, an Implementation and Compliance Committee, a panel of experts to provide scientific advice and a WHO PABS System Expert Advisory Group. Delete EU~~]

*[EU comment: We suggest adding the following two paragraphs, 10 and 11, under Article 21.]*

10. 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.

11. 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

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## **Monetary Fund and the World Bank.**

*[EU comment: We suggest inserting new Articles 21bis and 21 ter.]*

### **[Article 21 bis. Implementation and Compliance Committee**

**1. A mechanism to facilitate implementation of and promote compliance with the provisions of this Agreement is hereby established.**

**2. The mechanism referred to in paragraph 1 of this Article shall consist of a committee, as a subsidiary body to the Conference of the Parties, that shall be expert-based and facilitative in nature and function in a manner that is supportive, transparent, non-adversarial and non-punitive. The committee shall address generic issues related to implementation and compliance as well as individual cases. In doing so, the committee shall pay attention to the respective circumstances and capabilities of Parties.**

**3. The committee shall operate under the modalities and procedures to be adopted by the Conference of the Parties at its first session and report annually to the Conference of the Parties.**

### **Article 21 ter. 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 operate under the modalities and procedures to be adopted by the Conference of the Parties at its first session.]**

### **Article 23. Reports to the Conference of the Parties**

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

- (a) information on good practices, legislative, executive, administrative or other measures taken to implement the WHO Pandemic Agreement;
- (b) information on any constraints or difficulties encountered in the implementation of the WHO Pandemic Agreement and on the measures taken or under consideration to overcome them;
- (c) information on implementation support received under the WHO Pandemic Agreement; and
- (d) other information as required by specific provisions of the WHO Pandemic Agreement.

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

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

4. The periodic reports submitted by the Parties shall be made publicly available [~~online~~ Delete EU] by the Secretariat.

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#### Article 24. Secretariat

1. A Secretariat for the WHO Pandemic Agreement is hereby established. Secretariat functions for the WHO Pandemic Agreement shall be provided by the World Health Organization. **[In performing its Secretariat functions the WHO shall cooperate, as appropriate, with relevant international organisations, including the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health and the United Nations Environment Programme.]**

2. Secretariat functions shall be to:

- (a) provide administrative and logistic support to the Conference of the Parties for the purpose of the implementation of this Agreement and to make arrangements for the sessions of the Conference of the Parties and any subsidiary bodies and to provide them with services, as required;
- (b) transmit reports and other relevant information regarding the implementation of this Agreement received by it pursuant to this Agreement;
- (c) provide support to the Parties, upon request, particularly developing country Parties and Parties with economies in transition, in implementing the WHO Pandemic Agreement, including the compilation and communication of information required in accordance with the provisions of the WHO Pandemic Agreement or pursuant to requests of the Conference of the Parties;
- (d) prepare reports on its activities under the WHO Pandemic Agreement under the guidance of the Conference of the Parties, and to submit them to the Conference of the Parties;
- (e) ensure, under the guidance of the Conference of the Parties, the necessary coordination with competent international and regional intergovernmental organizations and other bodies;
- (f) enter, under the guidance of the Conference of the Parties, into such administrative or contractual arrangements as may be required for the effective discharge of its functions;
- (g) cooperate and coordinate with other United Nations entities in related areas; and
- (h) perform other secretariat functions specified by the WHO Pandemic Agreement and such other functions as may be determined by the Conference of the Parties.

#### Article 26. Reservations

*[EU comment: Reserve. Whether to introduce or not the possibility to lodge reservations will need to be assessed later in the process, when the content of the substantive provisions will become clearer.]*

No reservations may be made to the WHO Pandemic Agreement.

#### Article 29. Annexes

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

2. Annexes to the WHO Pandemic Agreement shall form an integral part thereof and, unless otherwise expressly provided, a reference to the WHO Pandemic Agreement constitutes at the same time a reference to any annexes thereto.

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

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### Article 30. Protocols

*[EU comment: we consider that Article 30, in particular the last sentence of paragraph 2, needs to be discussed at a later stage.]*

1. Any Party may propose protocols to the WHO Pandemic Agreement. Such proposals will be considered by the Conference of the Parties.
2. The Conference of the Parties may adopt protocols to the WHO Pandemic Agreement. In adopting these protocols, every effort shall be made to reach consensus. If all efforts at consensus have been exhausted and no agreement has been reached, the protocol shall as a last resort be adopted by a three- quarters majority vote of the Parties present and voting at the session. For the purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote. In the event a protocol is proposed for adoption under Article 21 of the Constitution of the World Health Organization, it shall further be considered for adoption by the Health Assembly.
3. The text of any proposed protocol shall be communicated to the Parties by the Secretariat at least six months before the session at which it is proposed for adoption.
4. States that are not Parties to the WHO Pandemic Agreement may be parties to a protocol thereof, provided the protocol so provides.
5. **[Subject to Article 32,]** ~~[A]~~**[a]**ny protocol to the WHO Pandemic Agreement shall be binding only on the parties to the protocol in question. Only parties to a protocol may take decisions on matters exclusively relating to the protocol in question.
6. The requirements for entry into force of any protocol shall be established by that instrument.

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

1. The WHO Pandemic Agreement~~[, and any protocol thereto,]~~ shall be subject to ratification, acceptance, approval or accession by States and to formal confirmation or accession by regional economic integration organizations. The WHO Pandemic Agreement shall be open for accession from the day after the date on which the WHO Pandemic Agreement is closed for signature. Instruments of ratification, acceptance, approval, formal confirmation or accession shall be deposited with the Depository.
2. Any regional economic integration organization that becomes a Party to the WHO Pandemic Agreement~~[, or any protocol thereto,]~~ without any of its Member States being a Party shall be bound by all the obligations under the WHO Pandemic Agreement~~[, or any protocol thereto as the case may be]~~. In the case of those regional economic integration organizations for which one or more of its Member States is a Party to the WHO Pandemic Agreement, the regional economic integration organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the WHO Pandemic Agreement. In such cases, the regional economic integration organization and its Member States shall not be entitled to exercise rights under the WHO Pandemic Agreement concurrently.
3. Regional economic integration organizations shall, in their instruments relating to formal confirmation or in their instruments of accession, declare the extent of their competence with respect to the matters governed by the WHO Pandemic Agreement~~[, or any protocol thereto as the case may be]~~. These organizations shall also inform the Depository, who shall in turn inform the Parties, of any substantial modification in the extent of their competence.

### Article 34. Settlement of disputes

1. In the event of a dispute between two or more Parties concerning the interpretation or application of

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the WHO Pandemic Agreement, the Parties concerned shall seek through diplomatic channels a settlement of the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach a solution by good offices, mediation or conciliation shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.

2. When ratifying, accepting, approving, formally confirming or acceding to the WHO Pandemic Agreement, or at any time thereafter, a Party which is not a regional economic integration organization may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory *ipso facto* and without special agreement, in relation to any Party accepting the same obligation: (a) submission of the dispute to the International Court of Justice; and/or (b) ad hoc arbitration in accordance with ~~[procedures to be adopted by consensus by the Conference of the Parties. Delete EU]~~ **[the Permanent Court of Arbitration Rules 2012. The Parties that have agreed to accept arbitration as compulsory shall accept the arbitral award as binding and final]**. A Party which is a regional economic integration organization may make a declaration with like effect in relation to arbitration in accordance with the procedures referred to in paragraph 2(b) of this Article.

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