

EU drafting suggestions on the refined textual proposals for the negotiating text of the WHO Pandemic Agreement, updated as of 27 February 2024

The drafting suggestions are set out below in blue characters by way of strike through (proposals for deletion) and bold underlined (proposals for additions). Comments or explanations are provided in light blue italics.

In light of further internal reflections, discussions with partners and development in the negotiations, the EU reserves the right to modify or withdraw the proposals below and to put forward additional proposals.

Chapter I. Introduction

Article 1. Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) “authorized national laboratory” means a laboratory authorized and designated by a Party to provide PABS Materials to the PABS System and recognized as part of the WHO Coordinated Laboratory Network.

[Comment: The EU notes that this issue is being discussed within the INB subgroup on Article 12. The outcome of these discussions would need to be reflected here.]

(b) “genetic sequence” means the order of nucleotides identified in a molecule of DNA or RNA, and contains the genetic information that determines the biological characteristics of an organism or a virus;

(c) “genetic sequence data” means data and associated data, information, and metadata generated through the use of sequencing technologies.

[Comment: For the EU, the reference to genetic sequence data does not appear necessary. If kept, we may need to consider wider terminology, to capture not only DNA and RNA data, but also proteomic and metabolomic data or future analytical techniques.]

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

[Comment: Reserve on the proposed definition. We note that the term was used only once in the proposed negotiating text, under paragraph 4 of Article 6. To be seen therefore if a definition is really needed.]

(e) “health worker” means individuals who provide assistance, surveillance and/or health care and are essential for health services to continue functioning during health emergencies;

[Comment: The EU notes that the term used in the agreement, under Article 7, is “health and care worker and that the definition may therefore require further revision.]

(f) “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;

[Comment: Reserve on the proposed definition. We note that the term was used only once in the proposed negotiating text, in Article 9 paragraph 2(d). To be seen therefore if a definition of this term is really needed.]

(g) “One Health” 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 needs to guide the implementation of the agreement. We suggest moving the One Health Approach to Article 3.]

(h) “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 of “pandemic”. We note that the definition for “pandemic emergency” under the WGIHR has received a certain degree of support at WGIHR 7. We consider that the exact same definition should be used in the two instruments (or a cross-reference between the two instruments).]

(i) “pandemic-related **[health]** products” means products that are needed for pandemic prevention, preparedness and response, which may include **[but is not limited to]** ~~[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]~~;

[Comment: we note that some elements of the proposed definition are unclear (e.g. partial overlap between “therapeutics” and “medicines”). The modifications above are suggested to improve clarity of the proposed definition.]

(j) “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;

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

[Comment: Reserve on the proposed definition. The EU notes that discussion on the scope of Article 12 is ongoing within the INB subgroup on Article 12. The outcome of these discussions would need to be reflected here.]

(l) “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, age, **[disability,]** 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];

(m) “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 EU notes that this issue is being discussed within the INB subgroup on Article 12. The outcome of these discussions would need to be reflected here.]

(n) “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;

[Comment: The need for such a definition should be assessed at a later stage.]

(o) “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: The EU notes that this issue is being discussed within the INB subgroup on Article 12. The outcome of these discussions would need to be reflected here. In addition, the definition appears too restrictive and not in line with the One Health approach.]

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

[Comment: We notes that this issue is being discussed within the INB subgroup on Article 12. The outcome of these discussions would need to be reflected here.]

[Comment: as noted at INB 7, we would suggest adding the definition of “stakeholders”, as follows, since the term recurs very frequently in the text of the agreement:

(q) “Stakeholders” means non-state actors as defined in the “Framework of Engagement with Non-State Actors”, in Annex 5 of resolution WHA69.10 (2016).]

Article 2. Objective [~~and scope Delete EU~~]

1. The objective of the WHO Pandemic Agreement, guided by [the principle of] 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 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. Delete EU]~~

[Comment: We reiterate the importance of including within the Pandemic Agreement a specific article on Human rights. The content of such article could be as follows. The EU would also be in favour of seeking the advice of the OHCHR for the drafting of such an article.]

[Article 2 bis. Respect of human rights and international humanitarian law

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. Guiding 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 following:

1. **Respect for human rights** – The implementation of this Agreement shall be with full respect for the dignity, human rights and fundamental freedoms of all persons, and the attainment by all people of the highest level of health. Each Party shall protect and promote non-discrimination, the respect for diversity, the promotion of gender equality and the protection of persons in vulnerable situations.

[Comment: as indicated above, the EU is of the view that human rights protection should be addressed in a specific article.]

2. **Sovereignty** – States have, in accordance with the Charter of the United Nations and the general principles of international law, the sovereign right to adopt, legislate and to implement legislation, within their jurisdiction, ~~[and have sovereign rights over their biological resources Delete EU]~~.

3. **Equity** – Equity is at the centre of pandemic prevention, preparedness and response, both at the national level within States, among and within countries or regions, and at the international level between States. Equity includes, but is not limited to, the ~~[unhindered Delete EU]~~, fair, equitable and timely access to safe, effective, quality and affordable pandemic-related [health] products and services, information, pandemic-related technologies and social protection, ~~[taking into account Delete EU]~~ [as well as] specific measures to protect persons in vulnerable situations.

[Comment: The EU proposes to use a shorter, and streamlined wording, as follows:]

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.]

4. **Responsibility** – Governments bear the primary responsibility for supporting the health

and wellbeing of their peoples, and effective pandemic prevention, preparedness and response require global collective action in support thereof.

5. **Recognition of different levels of capacity** – Unequal development in different countries in the promotion of health and control of disease, especially pandemic prevention, preparedness, and response, is a common danger. The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest cooperation of individuals and States.

~~6. **Common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems** – Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures. Given the unequal global development in the promotion of health and control of diseases, especially communicable disease, is a common danger, developed countries that hold more capacities and resources relevant to pandemics should bear a commensurate degree of differentiated responsibility regarding global pandemic prevention, preparedness, response and recovery through effective means of implementation, such as technology transfer and know-how as well as financial resources.~~

[Comment: The EU supports paragraph 5 on the recognition of different levels of capacity, with a preference for the wording proposed at INB 7. Paragraph 6 on the CBDR principle cannot be supported.]

7. **Solidarity** – [Embodies the need for] Effective collaboration, coordination and cooperation to achieve the common interest of a more equitable and better prepared world [able] to prevent, respond to and recover from pandemics.

[Alternative EU proposal for paragraphs 4 to 7:

We note that paragraphs 4 to 7 overlap in a significant measure. It may be preferable to consolidate these paragraphs as follows, using language currently included in paragraphs 4, 5 and 7.

[Responsibility and recognition of different levels of capacity – Governments bear the primary responsibility for the health and wellbeing of their peoples, which can be fulfilled only by the provision of adequate health and social measures. However, unequal development in different countries in the promotion of health and control of disease, especially pandemic prevention, preparedness, and response, is a common danger. This requires effective collaboration, coordination and cooperation to achieve the common interest of a more equitable and better prepared world able to prevent, respond to and recover from pandemics.]

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

9. **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, equitable, effective and timely pandemic prevention, preparedness and response. ~~[States Delete EU]~~ **[Governments and public authorities]** are accountable to provide specific measures to protect persons in vulnerable situations.

10. **Inclusiveness** – The full and active engagement with, and participation of, **[local]** communities and relevant stakeholders across all levels, 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 diverse and inclusive social participation ~~[, social capital, resources Delete EU]~~ and **[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.

11. **Science and evidence** – The best available science and evidence should inform and be the basis, **[together with the principle of freedom of scientific research,]** for pandemic prevention, preparedness and response, as well as public health decisions and development of plans.

[Comment: The EU can support the proposed text, but as indicated at INB 7, the EU considers that it would be important to add a reference to the principle of freedom of scientific research.]

12. **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 **[and international human rights law]**.

[Comment: The EU can support the proposed text, with the addition of a reference to international human rights law.]

13. **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]~~.

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

[16. 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.]

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

Definition of “pandemic” to be determined, including issue of whether to use “pandemic emergencies” or “pandemics”.

Article 4. Pandemic prevention and ~~[public health]~~ ~~EU~~ [collaborative] surveillance

1. The parties commit to [develop, implement and periodically review policies, strategies, and] ~~[take-Delete EU]~~-measures [in line with the One Health approach] to progressively strengthen pandemic prevention, taking into account the subnational, national and regional context.

2. The Parties shall cooperate:

- (a) in the implementation of the provisions of this article, in particular through [enhancing Delete EU] financial and technical support[, taking into account especially the needs of the least developed country Parties and other Parties in need] ~~[to developing countries Delete EU]~~ in line with Articles 16, 19 and 20;
- (b) in support of global, ~~[and/or Delete EU]~~ regional [and national] initiatives aimed at preventing ~~[pandemics Delete EU]~~ [pandemic emergencies], in particular those which improve data, surveillance, and early warning systems; promoting evidence-based action and risk communication; and identifying ~~[areas-and Delete EU]~~ activities [and settings that could pose a] ~~[at Delete EU]~~ risk of emergence and re-emergence of infectious [diseases/pathogens] with pandemic potential;
- (c) to develop, ~~[and Delete EU]~~ update [and implement] international standards and guidelines to prevent, detect and reduce the risks of zoonotic spillover, in collaboration with ~~[WHO and Delete EU]~~ [relevant international organizations or bodies including the Quadripartite organizations].

3. Each Party commits to progressively strengthen pandemic prevention, taking into account its national circumstances and capabilities, and drawing on the capacities set out in [paper/annex/list X - TBC], including through:

- (a) *Enhanced collaborative and integrated* surveillance, in line with the One Health approach and with applicable sharing of relevant benefits as set out in Article 12: (i) detect and conduct risk assessments of emerging or re-emerging pathogens which infect humans, in accordance with the International Health Regulations (2005); and (ii) detect and conduct risk assessments of [infectious] diseases in [livestock, wild and domestic] animal populations that present significant risks of zoonotic spillover; [and (iii) identify and monitor environmental factors contributing to those diseases, including through taking samples from specific environmental settings].
- (b) *Infection prevention and control*: (i) take measures to enable timely access to effective immunization and vaccination, which aim to reduce pandemic risks; (ii) enable access to safe water, sanitation and hygiene, including in hard-to-reach settings; (iii) require healthcare facilities and institutions to have in place a regularly updated infection prevention

and control programme, including sound management of health-care wastes; (iv) take measures to reduce the risks of infection spillover from animals to humans, **[including]** in live animal settings including veterinary practices; and (v) implement other infection prevention and control measures, in line with relevant international standards and guidelines.

- (c) *Zoonotic spillover prevention*: (i) identify settings and activities at high risk of disease emergence and re-emergence at human-animal-plant-environment interface; (ii) take **[regulatory and other]** measures to reduce risks of zoonotic **[disease emergence and]** spillover associated with these settings and activities, including measures aimed at **[prevention at source, as well as at]** safe and responsible management **[and handling]** of wildlife, farm and companion animals, in line with relevant international standards and guidelines.

[(c)bis Wildlife trade: (i) take action to prevent the development and spread of zoonotic disease arising from trade of animals, or products thereof, posing a high risk of zoonotic disease and (ii) facilitate, in accordance with Article 12, timely and safe sharing of biological samples of domestic and wild animals for zoonotic disease research. In taking such actions, the Parties shall involve indigenous peoples and local communities and 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.

- (d) **Health impact of environmental factors: take measures to address the health impact of environmental factors associated with the risk of zoonotic disease spill-over and spill-back;**

- (e) *Biosafety and biosecurity*: develop, strengthen, and maintain biosafety and biosecurity, in particular with regard to laboratories and research facilities in order to prevent the accidental exposure, misuse or inadvertent release of pathogens, including through biosafety and biosecurity training and practices, regulating access to sensitive ~~[locations]~~ **[facilities]** and ensuring the safety and security of transportation and cross-border transfer, consistent with applicable international and national regulations and standards; and

- (f) *Antimicrobial resistance(AMR)*: take measures to prevent the emergence and spread of pathogens that are resistant to antimicrobial agents, including **[by developing, implementing and regularly updating national, and where relevant regional]** ~~[through the prudent use of antibiotics in humans and animals in accordance with national~~ **[taking into account]** ~~EU]~~ AMR Action Plans ~~[and Delete EU]~~ relevant international guidelines and plans [footnote: Global Action Plan for AMR]. **[For this purpose, Parties shall: i) work towards implementing internationally agreed commitments and targets on AMR, including through setting out national or regional targets, ii) strengthen infection and prevention control, as well as antimicrobial stewardship, including through the prudent use of antimicrobials in humans and animals, and iii) increase investment, where appropriate, in new and existing medicines, diagnostic tools, vaccines and other interventions, as well as facilitating affordable access to same.]**

4. To implement the provisions in this Article, each party shall, consistent with the International Health Regulations and their effective implementation:

- (a) ensure that relevant national action plans, and where applicable regional, policies and ~~[and/or]~~ strategies⁵[and measures, as specified in paragraph 1 of this Article,] include comprehensive multisectoral pandemic prevention measures;
- (b) develop, strengthen and maintain the pandemic prevention capacities as set out in [list X / of capacities - TBC];
- (c) take into account recommendations, guidelines and policies developed and adopted by ~~[WHO and Delete EU]~~ relevant international organizations or bodies including the Quadripartite organizations (footnote) in the development of relevant national, [and where applicable regional,] policies, strategies, and measures to prevent pandemic. In this regard, the Secretariat and Quadripartite organizations may provide technical support as necessary. (footnote: The Quadripartite organizations shall mean FAO, UNEP, WHO and WOAH)
- (d) promote the effective and meaningful engagement of communities in whole society approach in the development and implementation of policies, strategies and measures related to pandemic prevention, in accordance with Article 17.

5. The Parties recognize that environmental, climatic, socio-economic and anthropogenic factors increase the risk of pandemics and endeavor to identify these and take them into consideration in the development and implementation of ~~[relevant Delete EU]~~ [pandemic prevention] policies, strategies and measures, including by strengthening synergies with other relevant international instruments and their implementation in accordance with Articles 17 and 25.

To be included in paper/annex/list X

[The Parties shall cooperate, with the support of the Secretariat, to strengthen and maintain public [and ~~[animal-Delete EU]~~ [veterinary] / and other relevant One Health] health laboratory and diagnostic capacities, [as stipulated in Annex 1 of the IHR,] especially in respect of the capacity to perform genetic sequencing, data science to assess the risks of detected pathogens and to safely [collect], handle [and store] samples containing pathogens.

Article 5. One Health approach

The Parties commit to promote and implement a One Health approach for pandemic prevention, preparedness and response that is coherent, integrated, coordinated and collaborative among all relevant actors and sectors.

1. For this purpose, each Party shall, taking into account its national circumstances and capabilities and drawing on the capacities set out in Paper/Annex/List and Annex 1 of the IHR:
 - (a) ensure that ~~[relevant Delete EU]~~ national[, and where applicable, regional] policies, strategies and measures [as specified in paragraph 1 of Article 4] adopt a One Health approach [to prevent and manage public health risks at the human-animal-plant-environment interface];
 - (b) implement scientific and evidence-based actions, including but not limited to: (i) improving infection prevention and control measures; (ii) antimicrobial research and development;

and (iii) ensuring equitable and timely access to, and prudent use of, antimicrobials in human and animal health sectors;

- (c) foster and implement actions at national and community levels that encompass whole-of-government and whole-of-society approaches to prevent, detect and ~~[respond to Delete EU]~~ **[control]** zoonotic outbreaks~~[, including through the engagement of communities in prevention at source and in surveillance to detect and identify those outbreaks];~~ and
- (d) promote or establish One Health joint training and continuing education programmes for human health, animal health and environmental **[sector]** workforces, in accordance with Article 7, to build complementary skills, capacities and capabilities.

2. [Pursuant to Article 21 herein, [the Governing Body] shall adopt as necessary guidelines, recommendations and standards as necessary to support the implementation of Articles 4 and 5 of this Agreement.](to be reviewed in light of Article 21 discussions.)

3. [The Parties shall 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 Delete EU]~~ **[taking into account especially the needs of the least developed country Parties and other Parties in need]** in relation to promoting and implementing a One Health approach **[at all levels]**, in line with Articles 16, 19 and 20.] (to be reviewed in light of Articles 16, 19 and 20 discussions.)

Article 6. Health system preparedness, ~~[readiness,]~~ resilience and recovery

1. Each Party commits to develop, strengthen and maintain its health system, including primary health care, for pandemic prevention, preparedness ~~[, readiness]~~ and response, taking into account the need for equity and resilience, with a view to the progressive realization of universal health coverage. (Note: need to consult WHO to determine whether “readiness” is redundant.)

2. Each Party commits, in accordance with applicable laws and regulations, to strengthen and reinforce health system functions, including by adopting and developing policies, strategies and measures, as appropriate, for:

- (a) sustaining the **[timely]** provision of, and equitable access to, quality routine and essential health services during pandemics, ~~[without exacerbating financial hardship Delete EU]~~ with a focus on primary healthcare, routine immunization and mental health care~~[, and with a particular attention to people in vulnerable situations];~~
- (b) developing, strengthening and maintaining a multisectoral and multidisciplinary workforce, which is able to respond effectively during pandemic~~[s]~~ **[emergencies]**, including by ensuring surge capacity, in accordance with Article 7;
- (c) developing post-pandemic health system recovery strategies;
- (d) developing, strengthening and maintaining **[public health, animal health and environmental]** laboratory and diagnostic capacities, and associated national, regional and global networks, **[including]** through the application of standards and protocols for infection prevention and control, laboratory biosafety and biosecurity, **[as well as the prevention of antimicrobial resistance]**.

- (e) developing, strengthening and maintaining: (i) health information systems for early detection, forecasting, and timely information sharing, (ii) civil registration and vital statistics, and (iii) associated digital health and data science capacities;
- (f) developing, strengthening and maintaining public and animal health institutions, including academic and research centres, at national, regional and international levels;
- (g) strengthening [~~leadership Delete EU~~], coordination, and management [~~structures Delete EU~~] capacities for pandemic prevention preparedness and response; and
- (h) promoting the production of science-based evidence, including that which is related to social and behavioural sciences, and risk communication and community engagement;

3. The Parties commit to cooperate, within available means and resources, with the support of the Secretariat and other relevant organizations, to provide or facilitate financial, technical and technological support, assistance, capacity-strengthening and cooperation, [~~in particular in respect to~~] with particular attention to the needs of the least developed country Parties [~~developing countries~~], in accordance with Articles 16, 19 and 20.

4. The Parties shall develop and promote relevant international data standards and interoperable systems that enable timely information-sharing for preventing, detecting, and responding to public health outbreaks, in accordance with International Health Regulations.

Article 7. Health and care ~~workforce~~ workers and other essential workers

1. Each Party, in line with its respective capacities, shall take the necessary measures to safeguard, protect, invest in, retain and sustain a skilled and trained 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 Delete EU~~] pandemic emergencies. To this end, each Party shall, in accordance with national law and practice:

- (a) strengthen, pre-, in- and post-service education and training, deployment, competency-based remuneration, distribution and retention of the health and care workforce, including community health workers and volunteers;
- (b) address disparities, [~~and Delete EU~~] inequalities, discrimination, stigma, and bias, including unequal remuneration and opportunities, as well as barriers faced by women to reaching leadership and decision-making roles [~~due to gender and age Delete EU~~] [~~particularly in health emergencies, to Delete EU~~] and support the meaningful representation, engagement, participation, empowerment, and well-being of all health and care workers [~~, while addressing discrimination, stigma and inequality and eliminating bias, including unequal remuneration and opportunities, and noting that women still often face significant barriers to reaching leadership and decision-making roles~~];

[Comment: the EU supports the intent of this paragraph but we suggest amendments to turn the text from a preambular style into a more operational requirement];

- (c) [~~increase Delete EU~~] protect the safety of the health and care workforce, including

through priority access to pandemic-related **[health]** products during ~~[pandemics Delete EU]~~ **[pandemic emergencies]**, minimizing disruptions to the delivery of good quality essential health services, and developing and integrating effective measures to prevent and address harassment, violence and threats against health and care workers, their means of transport and equipment, as well as hospitals and other medical facilities, when carrying out their duties; ~~[and]~~

[Comment: We note that the requirement to “increase” the safety of health and care workforce may be difficult to implement, hence the suggested modification of the verb “protect” instead of “increase”.]

(d) establish and maintain **[national]** workforce planning systems to rapidly, effectively and efficiently deploy trained health and care workers ~~[in times of need Delete EU]~~ **[during pandemic emergencies]**.

2. The Parties shall **[assist, within available resources, other Parties in need]** ~~[commit financial and technical support, assistance and cooperation, within the means and resources at their disposal Delete EU]~~, in particular ~~[in respect of developing countries]~~ **[the least developed country Parties]**, **[with training and capacity building]** in order to strengthen and sustain a skilled and competent health and care workforce at subnational, national and regional levels~~[, including emergency health teams]~~.

3. The Parties shall collaborate, through multilateral and bilateral arrangements and in accordance with ~~[relevant and Delete EU]~~ applicable international norms and standards, to minimize the negative impact of health workforce migration on health systems while respecting the freedom of ~~[mobility Delete EU]~~ **[movement]** of health professionals ~~[, during pandemics Delete EU]~~.

4. 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.

[Comment: Possible alternative text to paragraph 4 (a merging of our alternative proposal and the original paragraph 4 could also be envisaged)

4. Parties shall endeavour to establish or designate, at national and where appropriate regional level, and by building on existing networks, interdisciplinary emergency health teams, based on the One Health approach. Emergency health teams should include public health expertise and logistics support and ensure the essential functions and capacities for responding to a pandemic emergency. 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 a pandemic emergency in assessing and responding to the public health risk.

5. Parties having established emergency health teams should inform WHO thereof and make best efforts to respond to requests for deployment by Parties affected by a pandemic emergency 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. They shall also assist Parties in the training of the emergency health teams.]

~~[5:]~~ [6.] The Parties shall develop or strengthen, leveraging and building on existing training infrastructure, a network of training institutions, national and regional facilities, and centres of expertise to strengthen and sustain a skilled and competent health and care workforce at subnational, national and regional levels, [, including emergency health teams] ~~[with the capacity to respond rapidly to public health threats of pandemic potential]~~.

7. Each Party shall take the necessary steps to ensure decent working conditions and a safe and healthy environment for essential workers as they continue to provide essential public goods and services during pandemic emergencies.

Article 8. Preparedness monitoring and functional reviews

1. Each Party shall, in accordance with national ~~[or]~~ [, and when appropriate] regional laws, ~~[as applicable Delete EU]~~, 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]~~ [, that inter alia:]

[Comment: the EU proposes to move subparagraphs (a) to (e) of Article 17 paragraph 4 related to the development of comprehensive national pandemic prevention, preparedness and response plans to paragraph 1 of Article 8, as new subparagraphs (b) to (f) to avoid duplication between Article 8 and Article 17.]

- [(a) new subparagraph include comprehensive multisectoral pandemic prevention measures, based on the One Health approach, in line with the requirements set out under Articles 4 and 5;
- (b) identify and prioritize populations, based on public health risk and need, for access to pandemic-related health products and health services;
- (c) facilitate the timely allocation of resources to the frontline pandemic response;
- (d) 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;
- (e) facilitate the rapid and equitable restoration of public health capacities and routine and essential health services during and following a pandemic emergency; and
- (f) promote collaboration with relevant stakeholders, including civil society, academic institutions and the private sector.

New paragraph: Such plans and strategies shall be consistent with and supportive of effective implementation of the International Health Regulations. These plans shall in addition be consistent with international human rights law and pay particular attention to the needs of the persons in vulnerable situations and people living in humanitarian settings, as well as to the protection of health and care 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 International Health Regulations,] the functioning and readiness of, and gaps in, its pandemic [prevention,] preparedness, ~~[surveillance Delete EU]~~ and ~~[multisectoral Delete EU]~~ response

capacity, [including] logistics and supply chain management, and risk assessment[.] [To this end, each Party shall, as appropriate,] ~~[and shall 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.

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

[Comment on paragraphs 2 and 3: the EU notes that complementarity with the IHR needs to be considered, to avoid duplication and waste of limited resources.]

Article 9. Research and development

1. To prevent, prepare for and enable a rapid, effective and equitable response to pandemics, the Parties shall cooperate to build, strengthen and sustain national, regional and international capacities and institutions for research and development (R&D), particularly in developing countries, and shall promote scientific collaboration for the rapid sharing of information and access to research results, including through open science approaches.

2. To this end, the Parties shall promote:

- (a) sustained investment in R&D for public health ~~[and clinical Delete EU]~~ priorities, including for pandemic-related [health] products, and support for research institutions and networks that can rapidly adapt and respond to R&D needs in the event of a pandemic emergency;
- (b) technology co-creation and joint venture initiatives, that engage the participation of and international collaboration among scientists and/or research centres, including from public and private sector, particularly from developing countries;
- (c) innovative R&D, including community-led and cross-sector collaboration, for addressing pathogens with pandemic potential;
- (d) knowledge translation and evidence-based communication tools, strategies and partnerships, relating to pandemic prevention, preparedness and response;
- (e) capacity-building programmes~~[, projects]~~ and partnerships for ~~[R&D Delete EU]~~ [the development, dissemination and use of technical and scientific knowledge and research], including early-stage research, such as discovery, pre-clinical, and translational research;
- (f) [regional and] international collaboration and coordination, including with ~~[the private sector Delete EU]~~[all relevant stakeholders], to ~~[set Delete EU]~~[identify] common objectives, research goals and priorities, [with the support of the Secretariat and with the view to pool expertise, avoid duplicating research efforts and facilitate the development of] ~~[to develop Delete EU]~~ pandemic-related [health] products for diverse populations and diverse settings~~[, with a central role for WHO]~~;

[Comment: clarification on what is meant by diverse populations would be useful.]

- (g) access for scientists and researchers, particularly from [the least developed] ~~[developing countries Delete EU]~~ [country Parties], to relevant ~~[international Delete EU]~~ scientific research programmes [, projects] and partnerships, including those referred to in this Article;
- (h) the sharing of information on national research agendas, R&D priorities during pandemic emergencies, capacity-building activities and best practices on efficient and ethical clinical trials, ~~[through the WHO Global Observatory on Health Research and Development Delete EU]~~ [with the support of existing expert bodies];
- (i) research on the causes [, enabling factors] and effects of ~~[pandemics Delete EU]~~ [pandemic emergencies], on their prevention and management, including: (1) the epidemiology of emerging diseases, factors driving disease spillover or emergence, and behavioural science; (2) social interventions used to control pandemics and their effect on spread of disease and the burden imposed by these measures on society, including its economic cost; and (3) relevant [pandemic related health products] ~~[medical and other countermeasures-Delete EU]~~, with the aim of promoting equitable access, including their timely availability, affordability, and their quality.

3. The Parties shall, in accordance with national laws and regulatory frameworks and contexts, take steps to develop, strengthen and sustain clinical [research and] trial capacities at the national, regional and international levels, [and in accordance with the standards established by WHO,] including by:

- (a) building and maintaining a skilled research workforce and infrastructure, as appropriate;
- (b) strengthening clinical trial policy [and regulatory] frameworks, particularly in developing countries;
- (c) 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;
- (d) ensuring that clinical trials are conducted in accordance with [good scientific practice and] international ethical guidelines, including by guaranteeing:

- i 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; and

- ii [access to safe, effective, and quality assured interventions or products developed for the population or community in which the research is carried out; Reserve EU]

[Comment: Additional clarifications on the intent behind the proposal would be needed.]

- (e) strengthening [regional and] international coordination and collaboration, through existing or new mechanisms and networks, to support well-designed and well-

implemented clinical trials, including through trials facilitated and convened by WHO, ~~[whenever feasible Delete EU]~~ **[as appropriate]**;

- (f) developing 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]**;
- (g) supporting 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; and
- (h) promoting access to **[and facilitating use of]** comparator products needed for clinical trials, to allow for rapid development and comparison of products and technologies.
- (i) **[support early interaction with regulatory bodies for guidance on optimal trial design to facilitate an efficient regulatory process.]**

4. Each Party shall **[promote]** ~~[develop and implement national policies to support Delete EU]~~ the transparent, open public sharing of research inputs, outputs and processes from publicly funded pandemic related products R&D.

5. Each Party ~~[shall Delete EU]~~ **[should]**, in accordance with ~~[its national Delete EU]~~ **[domestic]** laws **[and policies]** ~~[and considering the extent of funding provided Delete EU]~~:

- a. include provisions to promote equitable access to pandemic-related **[health]** products in government-funded R&D agreements and in licensing of government-owned technology for such products; and
- b. publish relevant terms of government-funded R&D agreements for pandemic-related **[health]** products, in particular **[where relevant]**, information on pricing policies for end-products; licensing to enable the development, manufacturing and distribution of pandemic-related **[health]** products; and terms promoting equitable and timely access to such products during a pandemic emergency.

6. The Parties shall, with the support of the Secretariat, collaborate and assist each other in the implementation of this Article, in line with Articles 16 and 20, as well as relevant guidance from the [Governance mechanism of the WHO Pandemic Agreement].

Article 10.1: ~~[Sustainable and Delete EU]~~ **[Support for] *geographically diversified production***

1. The Parties, in collaboration with WHO and other relevant ~~[entities Delete EU]~~ **[international and regional organizations and stakeholders]**, with a view to achieving a more equitable geographical distribution of ~~[the global Delete EU]~~ production of ~~[[product placeholder Delete EU]~~ pandemic-related health products] and thus increasing equitable access to such products, ~~[thereby reducing the potential gap between supply and demand Delete EU]~~,

shall [cooperate and] endeavour to:

- a. ~~[take measures, in cooperation with regional arrangements, to identify and/or designate support, maintain and strengthen production facilities at national and/or regional levels, particularly in developing countries, and to facilitate production of product placeholder, as appropriate Delete EU];~~
- b. ~~[in cases where the production capacity does not meet demand during a pandemic, take measures to identify and contract, as appropriate, with facilities other than those referred to in sub-paragraph (a) for scaling up the production of product placeholder; including through Delete EU] promot[e][ing] and incentiviz[e][ing] public and private investment aimed at creating or expanding economically viable manufacturing facilities of relevant health products[, including pandemic-related ones, especially facilities with a regional scope of operation, with particular regard to the preparedness and response needs of the least developed country Parties and other Parties in need.-For this purpose, the Parties should act individually and jointly by means of grants, loans, blended finance, taxation and other incentive and promotion measures, as appropriate and in accordance with domestic laws.];~~

[Comment: We suggest an alternative drafting for subparagraphs a. and b.]

- c. ~~take measures, and encourage international organizations, to establish long-term contracts and make investments, especially in developing countries' facilities preferably with a regional scope of operation, that generate predictable demand for product placeholder produced by local and regional manufacturers. For this purpose, the Parties, as appropriate, should act individually and jointly by means of grants, loans, blended finance, taxation and other incentives and promotion measures;]~~

**Cross reference is made here to the negotiations on Articles 19 & 20 under Ambassador Tovar subgroup.*

- d. facilitate the continuous and [economically] sustainable operations of the facilities referred to in Paragraph 1.a of this Article, including through transparency of relevant ~~data~~ [unprotected] information on pandemic-related health products and raw materials, across the value chain;

[Comment: A clarification of the term "unprotected information on pandemic-related health product" would be necessary.]

- e. facilitate the [voluntary] transfer of relevant technology, [and] know-how [on mutually agreed terms, including through] ~~[and Delete EU]~~ licenses pooled in the mechanism [and initiatives] referred to in Paragraph [1.a and] 2 of Article 11, to facilities referred to in Paragraph 1.a of this Article;
- f. ~~[actively Delete EU]~~ support and facilitate ~~[, as appropriate, Delete EU]~~ skills development and capacity-building programmes and other initiatives aimed at [enabling Delete EU] [creating or expanding] production facilities, particularly those referred to in Paragraph 1.a of this Article;

g. ~~[promote public and private sector investments aimed at creating or expanding manufacturing facilities for product placeholder, especially regional manufacturers based in developing countries; and Delete EU]~~

h. **[promote capacity building aimed at obtaining timely]** ~~[facilitate the necessary-Delete EU]~~ regulatory authorization~~[s]~~ ~~[of]~~ **[for the pandemic-related]** health products produced by facilities referred to in Paragraph 1.a of this Article.

~~{Article 10.2~~

~~“Each Party is encouraged to cooperate further with the WHO to the conduct of global disease burden studies relevant to pathogens with pandemic potential, in collaboration with other relevant international organizations, with a view to promoting the sustainability of investments in facilities for the production of vaccines and therapeutics that could support pandemic response.” Delete EU]~~

Article 11: Transfer of Technology

1. In order to enable ~~[sufficient, Delete EU]~~ sustainable, and geographically-diversified production of pandemic-related products, each Party ~~[especially developed countries]~~, shall collaborate towards:

a) promoting and otherwise facilitating or incentivizing the transfer of technology and know-how for pandemic-related **[health]** products on voluntary and mutually-agreed terms, including **[for technologies that have resulted from public funding and]** through the use of licensing and collaboration with regional or global technology transfer hubs partnerships and initiatives, ~~[and in particular for technologies that have resulted from public funding Delete EU];~~

b) promoting the publication by private rights holders of the terms of licensing agreements and~~[or Delete EU]~~ technology transfer agreements for pandemic-related health- products; without prejudice to applicable ~~[national Delete EU]~~ **[domestic]** laws;

c) **[promoting the voluntary licensing]** ~~[license Delete EU]~~, on a non-exclusive basis and for the benefit of developing countries, ~~[of]~~ government-owned pandemic-related technologies, on mutually agreed terms, and ~~[shall publish Delete EU]~~ **[the publication of]** the terms of these licenses at the earliest reasonable opportunity and to the fullest extent possible in accordance with each Party’s laws and regulations;

[Comment: clarifications on what is meant by ‘government-owned’ technologies would be important.]

d) providing, within **[their respective]** ~~[its Delete EU]~~ capabilities, support for capacity-building for the development and transfer of technology and know-how on voluntary and mutually-agreed terms ~~[, and to facilitate access to other sources of support Delete EU].~~

e) ~~[providing, within its capabilities, support for capacity building for the development and transfer of technology and know-how on voluntary and mutually agreed terms Delete EU];~~
[Comment: duplicates subparagraph d).]

2. The Parties, in coordination with WHO and other relevant organizations, shall develop and strengthen multilateral mechanisms, as appropriate, that facilitate the transfer of technology and knowhow for pandemic-related **[health]** products on voluntary and mutually agreed terms;

3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall encourage holders of relevant patents related to the production of pandemic-related **[health]** products, **[including]** ~~[in particular Delete EU]~~ those who received public funding, to ~~[waive/ Delete EU]~~ forgo or otherwise ~~[charge reasonable Delete EU]~~ **[limit]** royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related **[health]** products.

4. The ~~[XX Committee / [Conference of Parties / Governing Body of the CA+]]~~ shall develop and adopt **[technical]** guidelines on the identification of technologies and know-how necessary to attain the objectives of this Agreement.

5. The Parties ~~reaffirm~~ recognize that **[Parties which are]** WTO Members have the right to use to the full, the flexibilities **[set out]** ~~[inherent Delete EU]~~ in the TRIPS Agreement, **[as recognised in]** the Doha Declaration on the TRIPS Agreement and Public Health of 2001 ~~[and subsequent relevant decisions* Delete EU]~~ which provide flexibility to protect public health including in future pandemics, since the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and that it can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

** Reference is made here to what is known as Paragraph 6 System of the Declaration which was an amendment to the Agreement adopted by the WTO General Council on 30 August 2003, that became permanent by the GC Decision on 6 December 2005 and entered into force on 23 January 2017.*

6. Each Party shall review ~~[and update Delete EU]~~ as ~~[necessary Delete EU]~~ **[appropriate]** its national legislation in order to ~~[ensure enable]~~ the implementation of such flexibilities in a timely and effective manner.

Article 13: **[Support for]** Global Supply ~~[Chain Network Delete EU]~~

[Supply chain network provisions:]

1. The ~~[Global Supply Chain and Logistics Network] (the Network) Delete EU]~~ **[A Partnership coordinated and operated by WHO in collaboration with other relevant international and regional organizations and stakeholders, including [.....]]**, is hereby established **[(hereinafter the “Partnership”)]**.

The ~~[Network Delete EU]~~**[Partnership]** shall ~~[be developed and operated by WHO Delete EU]~~ **[act]** in ~~[partnership Delete EU]~~ **[consultation]** with the Parties ~~[and other relevant international and regional organizations and stakeholders Delete EU]~~, and shall be guided by the principles of equity, transparency, inclusivity, and public health needs. The ~~[Network shall consider the experiences of other mechanisms in procurement, allocation and distribution of product placeholder in health emergencies, and Delete EU]~~ **[Partnership]** shall pay particular attention to the needs of **[the least developed]** ~~[developing Delete EU]~~ countries and others with increased needs, including those in fragile and humanitarian settings.

The ~~[governance structure of the Delete EU]~~ **[consultation modalities between the Parties and the Partnership]** ~~[Network Delete EU]~~ shall be defined in the first meeting of the governing body. ~~[, allowing for equitable representation of the WHO regions. Delete EU]~~

2. The ~~[Network Delete EU]~~ **[Partnership]** shall develop modalities aimed at ensuring the following:

- a) collaboration among the Parties and other relevant stakeholders during and between pandemics,
- b) assignment of functions to stakeholders based competencies and expertise, and
- c) accountability and transparency in the functioning of the ~~[Network Delete EU]~~ **[Partnership]**.

3. The Parties shall periodically review the operationalization of the ~~[Network Delete EU]~~ **[Partnership]**, including the support provided by Parties and other stakeholders ~~[during and between pandemics Delete EU]~~.

The functions of the ~~[Network Delete EU]~~ **[Partnership]** shall include:

- a) identifying the types of pandemic-related health products and estimating the quantities needed for robust pandemic prevention, preparedness and response;
- b) identifying **[, assessing and keeping under review]** the sources of safe, effective and quality assured **[pandemic-related health]** product**[s]** ~~[placeholder Delete EU]~~, including the necessary raw materials and potential surge capacities ~~[as well as developing and maintaining a tool for this purpose [e.g. a dashboard] Delete EU]~~.

**potential cross-reference to article 10.*

- c) identifying, assessing, keeping under review ~~[and facilitating Delete EU]~~ the most efficient means of procuring quality **[pandemic-related health]** products ~~[placeholder, potentially Delete EU]~~ including pooled procurement and ~~[/or Delete EU]~~ advance purchase agreements, to enhance equitable, timely and affordable access to these products;
- d) promoting transparency in cost, pricing and other relevant data on **[pandemic-related]**

health] products, including raw materials, across the value chain;

[Comment: additional clarifications would be needed on what type of data should be provided under subparagraph (d).]

e) promoting ~~[and coordinating Delete EU]~~ [coordination] ~~[within the Network Delete EU]~~ to avoid competition for resources among international procuring entities, including regional organizations and ~~[or Delete EU]~~ mechanisms;

f) collaborating with relevant authorities and organizations ~~[/institutions, as appropriate Delete EU]~~, and taking into account national and regional circumstances to establish, strengthen ~~[,]~~ ~~[and Delete EU]~~ maintain [and regularly assess] national, regional, and ~~[or Delete EU]~~ international stockpiles of various [pandemic-related health] product ~~placeholder~~, including stockpiles earmarked for humanitarian settings, as well as to maintain related logistic capacities ~~[and assess them at regular intervals Delete EU]~~; and

g) facilitating the equitable allocation of [pandemic-related health] product [s made available to the Partnership,] ~~placeholder Delete EU]~~ based on public health risks and needs, taking into account factors, such as [humanitarian needs,] population size, demographic structure, epidemiological situation and health system capabilities of beneficiary countries and their readiness and capacity to utilize such products;

h) facilitating the most efficient delivery and distribution of pandemic-related health products, including [in humanitarian settings], ~~[as appropriate Delete EU]~~, through regional stockpiles, consolidation hubs, ~~[and Delete EU]~~ staging areas [and other appropriate means] ~~[, while taking into account specific requirements for these products Delete EU]~~;

i) assisting countries in meeting the requirements for the effective utilization of specific [pandemic-related health] product [s] ~~placeholder Delete EU]~~, as needed and requested.

j) the ~~[Network Delete EU]~~ [Partnership] shall report regularly to the COP/ Governing Body its activities and on any information obtained that is of significant interest to the parties;

[Procurement/Trade/Other provisions]

1. Each Party shall publish the terms of its government-funded purchase agreements for pandemic- related health productions ~~[, in accordance with applicable laws, Delete EU]~~ and shall endeavour to exclude unwarranted confidentiality provisions that serve to limit such disclosure [in line with applicable domestic laws].

2. Each Party, in accordance with ~~[national Delete EU]~~ [domestic] laws, shall include [to the extent possible] provisions in government-funded purchase agreements for pandemic-related health products that promote timely and equitable ~~[global Delete EU]~~ access to such products, ~~[such as Delete EU]~~ [including] provisions that:

- a) ~~[permit Delete EU]~~ **[facilitate]** the donation of such products outside of its territories;
 - b) facilitate potential modifications **[, including to delivery schedules]** ~~[(e.g., delivery swaps and schedules Delete EU)]~~, in order to address supply gaps around the world;
 - c) ~~[incentivize or otherwise Delete EU]~~ encourage **[voluntary]** licensing and other **[voluntary]** transfer of technology **[on mutually agreed terms]**, in particular for the benefit of low-and middle-income countries;
 - d) ~~[incentivize or otherwise Delete EU]~~ encourage the formulation and sharing of global access plans for the products.
3. The Parties ~~[recognize the importance of ensuring Delete EU]~~ **[agree]** that any emergency trade measures designed to tackle a pandemic, if deemed necessary, shall be targeted, proportionate, transparent, temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.
4. Whenever possible, each Party shall take appropriate measures to promote rational use and reduce waste of pandemic-related **[health]** products, including through the sharing of products, while taking into account the circumstances of recipient countries.
5. Each Party shall ensure **[, in accordance with applicable domestic laws,]** that any national stockpiles do not unnecessarily exceed quantities needed for domestic public health emergency preparedness and response.
6. Whenever possible, when sharing pandemic ~~[emergency response Delete EU]~~-related **[health]** products with recipient countries, organizations, or the Partnership ~~[collaboration Delete EU]~~, each Party shall abide by the following:
- a) The selection and shelf life of pandemic ~~[emergency response Delete EU]~~-related **[health]** products ~~[are data driven and in alignment Delete EU]~~ **[take into account the [with identified Delete EU] needs [and the Delete EU] distribution and administration [dispensing Delete EU] timelines and capabilities of the recipients, [as well as demand],**
 - b) Prospective recipients are made aware of any expiration dates, availability of the products, and required ancillaries as far in advance as possible;
 - c) As appropriate, sharing countries coordinate with each other and with other global or regional access mechanisms, to maximize allocation to populations with the highest risk and greatest public health need and to facilitate rapid ~~[absorption/ Delete EU]~~ administration;
 - d) Products shared with global or regional access mechanisms are unearmarked for

greatest effectiveness and to support long-term planning;

- e) Sharing countries release products [~~in large volumes and Delete EU~~] in a predictable manner, in order to reduce [~~transaction Delete EU~~] costs and facilitate recipient planning; and
- f) Shared products are accompanied with essential ancillaries [as far as possible], and coordinated with the availability of support for distribution and administration, to ensure rapid allocation and absorption.

[7. 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.]

Article 14. Regulatory Systems Strengthening

1. Each Party shall strengthen its national[,] and [~~/or Delete EU~~] [where appropriate] regional[,] regulatory authority responsible for the approval or authorization of [pandemic emergency response-related [health] products], including through technical assistance and [~~/or Delete EU~~] cooperation with WHO and relevant organizations, as appropriate, with the aim of ensuring the quality, safety, and efficacy of such products.

2. Each Party shall take [the appropriate] steps to ensure that it has legal, administrative, and financial frameworks necessary for:

- a) [~~emergency Delete EU~~][urgent] regulatory authorizations and approvals for [pandemic emergency response-related [health] products] and [~~/or Delete EU~~], as appropriate, regulatory reliance processes aimed at the timely approvals and authorizations of such products, as well as systems-to provide oversight of the quality, safety, and efficacy of those products, and

[Comment: Preference for the use of the wording: 'urgent' instead of 'emergency', given that the focus should be on the possibility to authorise in a 'timely' manner. This seems to be better captured by the word 'urgent'.]

- b) [~~taking actions to Delete EU~~]prevent[ing], detect[ing], and respond[ing] to substandard and falsified versions of [~~such Delete EU~~] [pandemic emergency response-related health] products including having mechanisms for notifying relevant regional or global rapid alert systems when such substandard or falsified products are confirmed.

3. Each party shall, in accordance with [~~national Delete EU~~] [domestic] laws, with the aim of enhancing transparency and regulatory reliance, make publicly available [~~online Delete EU~~] and keep updated in a timely manner:

- a) information on national and, if applicable, regional regulatory processes for authorizing or approving use of [pandemic emergency response-related [health]

products], and

- b) information on the [pandemic emergency response-related **[health]** products] that it has authorized or approved and its rationale for such decision(s), including the evidence, analysis of data, and other information on which the decision was based.

The Parties [~~request that Delete EU~~] **[encourage the]** WHO **[to facilitate access to the information referred to in this paragraph]** [~~compile and maintain on its website links to Parties' websites containing such information~~ Delete EU].

4. Each Party shall, in accordance with [~~national~~ Delete EU] **[domestic]** laws, encourage **[and support developers and]** manufacturers¹ **[of pandemic emergency response-related health products]**, as appropriate, to generate and submit in a timely manner relevant data and diligently pursue regulatory authorizations and/or approvals of [pandemic emergency response-related **[health]** products] with WHO listed authorities, other priority authorities, and WHO.

5. Each Party shall consider:

- a) [~~adopting~~ Delete EU] **[enabling and promoting, where needed, the use of]** regulatory reliance processes in its national regulatory frameworks for use during [pandemic emergencies] [~~incorporating principles from~~] **[taking into account]** relevant guidelines [~~such as the WHO Good Reliance Practices Guidelines, among others~~].

[Comment: The EU suggests the modifications indicated above to capture the possibility for mature regulators like WHO-listed authorities to make arrangements allowing other regulatory authorities to benefit from their work.]

- b) providing support to help strengthen national regulatory authorities and regional regulatory systems' ability to respond to pandemic emergencies, on mutually agreeable terms and as appropriate, through [~~efforts such as~~] technical assistance, capacity building, training, and information exchange consistent with applicable law.

6. The Parties shall [~~work together~~ Delete EU] **[cooperate]** to develop and support strategies for strengthening WHO processes for Emergency Use Listing, Prequalification and any other relevant processes [~~for recommending the use and~~ Delete EU] **[aimed at ensuring]** continued regulatory oversight of [pandemic emergency response- related **[health]** products].

7. Each Party shall consider adopting and implementing, when practicable and consistent with national law and procedures, guidance and technical documents concerning medical products developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF) or their successor organizations.

Article 15. Compensation and Liability Management

1. In order to increase **[the use of quality, safe, effective vaccine]** [~~confidence~~ Delete EU],

¹ We will need a definition that includes sponsors and marketing authorization holders as part of a definition for manufacturers.

each Party shall consider, where necessary, establishing ~~implement and/~~ Delete EU or participat~~e~~ing in a transparent no-fault compensation mechanism(s), established at a national, regional or global level, for serious adverse events resulting from the use and/or administration of novel vaccines developed for response to pandemics and shall consider developing strategies for funding the mechanism(s), ~~potentially~~ Delete EU including through private sector contributions. Such compensation mechanism(s) shall take into account the situation of individuals that are in humanitarian setting or in vulnerable situations.

2. In order to facilitate timely access to vaccines developed for response to pandemics, each Party shall also consider developing, as necessary and in accordance with national and regional legislation, ~~national strategies for managing liability in its territory related to pandemic vaccines. Such strategies may include, inter alia,~~ Delete EU model contract indemnification provisions, insurance mechanisms, policy frameworks and principles for the negotiation of procurement and/or donation agreements ~~including circumstance-based time limitations and building expertise for contract negotiations in this matter~~ Delete EU.
3. Each Party shall make information about ~~its participation in~~ Delete EU available no-fault compensation mechanism(s) and other strategies for liability management publicly-available, in accordance with domestic ~~national~~ Delete EU law.
4. WHO, in collaboration with other relevant organizations and entities, shall develop recommendations ~~for~~ Delete EU and facilitate the establishment and implementation of regional and/or global no-fault compensation mechanisms ~~funds~~ Delete EU and ~~for~~ Delete EU strategies for managing liability during pandemic emergencies, ~~including coverage of~~ Delete EU to cover individuals that are in a humanitarian setting or vulnerable situations.
5. Each Party shall endeavour to ensure that in contracts for the supply or purchase of novel pandemic vaccines, 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 in global coordinated actions, with relevant international and regional intergovernmental organizations and other ~~bodies~~ Delete EU stakeholders, as well as among themselves, in the formulation of ~~cost-~~effective, high-impact, public health needs-based and inclusive 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; *[Comment: it is not clear for the EU what mechanisms are covered by this provision]*

(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 rights².]*

(d) promote equitable representation on the basis of gender, geographical and socioeconomic status, as well as the equal and meaningful participation of young people, women, and people living with disability, in national, regional and global decision-making processes, global networks and technical advisory groups;

(e) assist ~~[developing countries Delete EU]~~ **least developed country Parties and other Parties in need** 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; *[Comment: The EU supports the objective of the provision. However, subparagraph (e) duplicates the provisions of Article 19 and may therefore not be necessary.]*

(f) encourage ceasefires in **[conflict]** affected countries during pandemic **[emergencies]** ~~[to promote global cooperation against common global threats Delete EU];~~

(g) ensure solidarity with, and prevent the stigmatization of, countries that report public health emergencies, and collectively develop collaboration mechanisms as an incentive to facilitate transparency and the timely reporting and sharing of information *[Comment: The EU supports the objective of the proposed text, which is to develop collaboration mechanisms and avoid risk of conflicting measures between States. While the EU sympathises with the objectives of the proposal regarding the need to ensure solidarity with countries that report public health emergencies, we note that it is unclear what such requirement would entail. In addition, it might be useful to provide more clarification on how such collaboration mechanisms would be developed. The EU has proposed a mechanism for enhanced consultation under the IHR (article 43(7) of IHR, which has however not met much interest so far.]*

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 enable community ownership of, and contribution to, community readiness for and resilience to pandemic prevention, preparedness and response.
2. Each Party shall ~~[, in keeping with national capacities, Delete EU]~~ establish, implement and adequately finance an effective **[and where relevant regional,]** ~~[coordinating multisectoral]~~

² “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.”

Delete EU] [coordination] mechanism [, with multisectoral and transdisciplinary engagement,] for pandemic prevention, preparedness and response.

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 emergency, as well as when implementing,] ~~[implementation Delete EU]~~, monitoring and ~~[evaluation Delete EU]~~ [evaluating these measures] ~~[and shall also provide Delete EU]~~, [while also providing] effective feedback opportunities.

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

- ~~(a) identify and prioritize populations, based on public health risk and need, 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 during and following a pandemic; and~~
- ~~(e) promote collaboration with relevant stakeholders, including the private sector and civil society, avoiding all forms of conflicts of interest.] [Comment: the EU suggests moving paragraph 4 and its subparagraphs to Article 8, paragraph 1, as subparagraphs (b) to (f) to avoid duplications of requirements between Articles 8 and 17.]~~

~~[5.]~~[4.] Each Party, based on national capacities, shall take the necessary steps to address the social, environmental and economic determinants of health, and the vulnerability conditions~~[,~~ [including in humanitarian settings,] that contribute to the emergence, escalation or spread of outbreaks [with pandemic potential] ~~[to global proportions Delete EU]~~, and shall work to prevent or mitigate the socioeconomic impacts ~~[of pandemics Delete EU]~~ [thereof].

~~[6.]~~[5.] Each Party shall take appropriate measures to strengthen national public health and social policies to facilitate a rapid, resilient response to ~~[pandemics Delete EU]~~ [pandemic emergencies], 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, by increasing timely access to ~~[credible Delete EU]~~ [transparent] and evidence-based information on ~~[pandemics Delete EU]~~ [pandemic

emergencies] and their causes, effects and drivers, [as well as on the efficacy and safety of pandemic-related health products.] with the aim of countering and combatting ~~[false, misleading, Delete EU]~~ misinformation or disinformation, including through effective international collaboration and cooperation as referred to in Article 16 herein, as well as through effective community-level engagement.

2. The Parties shall, as appropriate, promote and/or conduct research and inform policies on factors that hinder or strengthen and promote adherence to public health and social measures in a ~~[pandemic Delete EU]~~ [pandemic emergency] and trust in science and public health institutions.

3. The Parties shall promote and apply a science- and evidence-informed approach[, including in relation to social and behavioural sciences,] to effective and timely risk assessment and public communication.

4. The Parties shall exchange information and cooperate, in accordance with national law, in preventing misinformation and disinformation, and endeavour to harmonize best practices to increase the accuracy and reliability of crisis communication[, to promote health literacy and to develop effective tools to identify and counteract misinformation and disinformation].

5. The Parties shall promote and facilitate, in accordance with national [, and when applicable regional,] approaches, laws and regulations, the development and implementation of risk communication, community engagement, infodemic management, and education and public awareness programmes, ~~co-created~~ with [the participation of all stakeholders, including health professionals,] communities and civil society, on outbreaks and ~~[pandemics Delete EU]~~ [pandemic emergencies], in a way that is broadly accessible[including to persons in vulnerable situations and people living in humanitarian settings].

Article 19. Implementation capacities and support

[Comment: To ensure consistent application of the financial arrangements between the Pandemic Agreement and the amended IHR, and to enable an efficient institutional arrangement for both instruments, the text in articles 19 and 20 could, as relevant, be replicated in both instruments or cross-referenced.]

1. The Parties shall cooperate, directly or through relevant international bodies, to sustainably strengthen pandemic prevention, preparedness and response capacities in ~~[countries, particularly developing countries, which are Delete EU]~~ Parties to the WHO Pandemic Agreement, ~~[or the International Health Regulations (hereinafter referred to collectively as “Cooperating Parties”); Delete EU]~~ *[Comment: to be replicated in the International Health Regulations as amended, with consequential adjustments of the text]* taking into account especially the needs of ~~[developing Delete EU]~~ [the least developed] country Parties [and other Parties in need], while closely coordinating support provided under ~~[this Delete EU]~~ Article[s 19 and 20] with the provision of support under the International Health Regulations. Such cooperation shall promote the [voluntary] sharing or transfer of technical, scientific and legal expertise and technology, as well as ~~[financial assistance and support for Delete EU]~~ capacity-strengthening to those ~~[Cooperating Delete EU]~~ Parties which lack the means and resources to implement the provisions of this Agreement.

2. [Where a Party lacks the necessary capacity to implement specific provision(s) of this

Agreement,] ~~[T]~~~~[t]~~he Parties shall~~[, upon request, Delete EU]~~ [cooperate and, with the help of the Secretariat,] facilitate the provision of technical assistance and support ~~[for those Cooperating Delete EU]~~ [to such] Parties ~~[that have requested such assistance or support Delete EU]~~, in particular [to the least developed] ~~[developing countries Delete EU]~~ [country Parties or other Parties in need], either bilaterally or through relevant regional ~~[and/ Delete EU]~~ or international organizations [and taking into account the Coordinating mechanism set out in Article 20]. The Parties shall, upon request, facilitate the provision of technical assistance and support for those Cooperating Parties that have requested such assistance or support, in particular developing countries, either bilaterally or through relevant regional and/or international organizations.

3. The Secretariat ~~[of the WHO Pandemic Agreement as established in article 24 Delete EU]~~, in collaboration~~[, as appropriate, Delete EU]~~ with relevant regional and international organizations and other relevant bodies, shall provide assistance to [Parties] ~~[all countries that so request, particularly developing countries, to identify Delete EU]~~ [in the identification of] pandemic prevention, preparedness and response ~~[gaps and Delete EU]~~ [support] needs, and ~~[organize Delete EU]~~ [in the organization of] the technical ~~[and financial Delete EU]~~ assistance [and capacity building activities provided for in this Article] ~~[necessary to address such gaps and needs Delete EU]~~[, with particular regard to the needs of the least developed country Parties and other Parties in need].

[Comment: The EU proposes to revise paragraph 3 as indicated above. In addition, we trust the Secretariat will be clearly defined in the institutional chapter of the Pandemic agreement. The overall role and tasks of the Secretariat will have to be reviewed also in light of the further work on the institutional arrangement, to ensure consistency as well as resource efficiency.]

4. [The Parties shall annually submit to the Governing Body of the WHO Pandemic Agreement a report on all implementation support provided or received under the WHO Pandemic Agreement.]³

Article 20. Financing [implementation support]

1. The Parties commit to working together to strengthen sustainable financing [of] ~~[for Delete EU]~~ health emergencies as well as for pandemic prevention, preparedness and response [for the purpose of the effective implementation of this Agreement [and the IHR 2005 as amended]]. In this regard, each Party, within the means and resources at its disposal, shall [endeavor to]:

- a. prioritize and maintain or increase, as necessary, domestic funding for pandemic prevention, preparedness and response, without undermining other domestic public health priorities including for (i) strengthening and sustaining capacities for the prevention, preparedness and response to health emergencies and pandemics, in particular the core capacities of the International Health Regulations; (ii) implementing national plans, programmes and priorities; and (iii) strengthening health systems and the progressive realization of universal health coverage ~~[for Delete EU]~~[enabling] pandemic prevention, preparedness and response;

³ Paragraph could be moved to Article 23, in case there is a decision to concentrate all the reporting requirements at that article.

- b. mobilize financial resources through all sources, including existing and [future] ~~[new Delete EU]~~ bilateral, subregional, regional and multilateral funding mechanisms, [in complementarity with domestic funding as outlined under subparagraph a.] to assist in particular [the least developed] ~~[developing Delete EU]~~ country Parties [and other Parties in need], in the implementation of the WHO Pandemic Agreement, including through grants and concessional loans;
- c. ~~[take measures or develop mechanisms, including, as appropriate, within relevant bilateral, regional and/or multilateral mechanisms, for debt relief, including suspension of debt servicing and/or debt cancellation, based on transparent financial reprogramming plans for pandemic prevention, preparedness and response related actions, for affected countries whose debt payment might affect expenditures on pandemic prevention, preparedness and response; Delete EU]~~ and
[Comment: the EU cannot support the proposed paragraph as currently drafted. Further clarification and discussions are needed with regards to subparagraph c.]
- d. encourage governance and operating models of existing financing entities to ~~[minimize>Delete EU]~~ [share] the burden on countries [according to their capacities], offer improved efficiency and coherence at scale, enhance transparency and be responsive to the needs and national priorities of developing countries.

2. The [Conference of Parties/]Governing Body of the WHO Pandemic Agreement shall adopt [by consensus], every 5 years, taking fully into account the International Health Regulations, a Financial Strategy ~~[on prevention, preparedness and response to health emergencies and pandemics Delete EU]~~ [for the implementation of the WHO Pandemic Agreement, based on financial gaps analysis and programmed expected outcome]. The Parties~~[-, particularly those providing support for the implementation of pandemic prevention, preparedness and response, Delete EU]~~ shall ~~[align with Delete EU]~~ [take into account] the Financial Strategy [defined by the Conference of Parties/Governing body] while financing ~~[the relevant funding mechanisms, both within and outside WHO Delete EU]~~ [pandemic prevention, preparedness and response].

[Comment: in line with the overall introductory comment above under Article 19, the financial strategy, if agreed, could also encompass the IHR as amended and if so, the text of paragraph 2, as well as the relevant provision in the IHR as amended, should reflect this.]

3. [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 Coordinating 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 Coordinating 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 Coordinating mechanism, in line with the provisions in this Article. The Conference of the Parties/Governing Body shall review the operation of the Coordinating mechanism every [...] years and make any necessary modifications by consensus.]

4. The Coordinating mechanism, through the selected entity or entities entrusted with its operation, shall:

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 and through innovative sources of financing, such as social bonds and blended finance, to fund implementation support activities;

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

v. report periodically to the [Conference of Parties/Governing Body] on the operation of the Coordinating mechanism, including on the use of funds provided.

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

(i) voluntary monetary contributions from Parties;

(ii) voluntary monetary contributions from relevant stakeholders, in particular those active in sectors that benefit from international work to strengthen pandemic prevention, preparedness and response.]

~~[A Coordinating Financial Mechanism (the “Mechanism”) is hereby established to support implementation of the WHO Pandemic Agreement and increase the effectiveness and efficiency of existing and future financial mechanisms, within or outside WHO, including by providing additional financial resources to strengthen and expand capacities for pandemic prevention, preparedness and response in Cooperating Parties, in particular in developing country Parties. The Mechanism will also contribute to funding the Secretariat of the WHO Pandemic Agreement. Delete EU]~~

[Comment: The financing of the running cost of the Pandemic Agreement, including funding to the Secretariat, should be separated from the financing of the implementation of the Agreement and be dealt with in another article.]

~~[4] [6.]~~ The **[coordination]** Mechanism shall ~~[operate in accordance with Delete EU]~~ **[be guided by]** the principles of equity and fairness, predictability, sustainability, efficiency, effectiveness, transparency, accountability and inclusive governance.

~~[5. The Mechanism shall consist of a pooled fund to provide targeted, supplementary financing to support strengthen and expand capacities for pandemic prevention, preparedness and~~

~~response, and as necessary for day zero surge response, in Cooperating Parties when other resources are not accessible through existing financing entities. It shall be sourced through monetary contributions received as part of operations of the PABS System, voluntary funds from both States and Non State Actors and other contributions to be agreed upon by the Governing Body of the Pandemic Agreement.~~

~~6. The Mechanism will also promote harmonization and coordination for financing prevention, preparedness and response to health emergencies and pandemics with other funding mechanisms, both within and outside WHO.~~

~~7. In order to support the Mechanism, the Secretariat of the WHO Pandemic Agreement shall, *inter alia*:~~

- ~~a. identify financing instruments and mechanisms, within or outside WHO, that are available to serve the purposes of prevention, preparedness and response to health emergencies and pandemics, and maintain a dashboard of such instruments, and related information such as eligibility criteria, modalities and levels of funding available, priorities and process requirements, including financial contributions made by Parties and non State Actors, as applicable, to such instruments, and the funds allocated to countries from such instruments;~~
- ~~b. establish, as necessary, following a mandate from the Governing Body of the WHO Pandemic Agreement, working arrangements with relevant identified financing instruments and entities to facilitate their alignment with the Financial Strategy;~~
- ~~c. provide advice and support, upon request, to Cooperating Parties in identifying and applying to obtain access to financial resources in accordance with national pandemic prevention, preparedness and response priorities and identified needs; and~~
- ~~d. assess the availability of funds, and support the mobilization of financial resources free from conflict of interest. Delete EU]~~

~~[8][7.] The [Coordinating] Mechanism shall function under the authority and guidance of the [Conference of Parties/]Governing Body of the WHO Pandemic Agreement and be accountable to it. [The Governing Body of the WHO Pandemic Agreement shall adopt modalities for the operationalization of the Mechanism, including eligibility criteria and the establishment of a governing board of the Mechanism, with balanced representation of WHO regions and developed and developing country Parties, within 12 months after the entry into force of the Pandemic Agreement. Delete EU]~~

[9. Conference of Parties/ Governing Body and the entity or entities entrusted with the operation of the coordination mechanism shall agree upon arrangements to give effect to the above paragraphs.]

[Comment: We propose adding a new paragraph 9 to address the need for a link to be established between the COP/Governing Body and the entity/entities entrusted with the operation of the coordinating mechanism as well as the arrangements and tasks that will apply. The suggested text is based on text to this effect in MEAs and this text is taken from the UNFCCC. This paragraph will need to be revised in light of the further drafting of the institutional

arrangements applicable to the COP/Governing Body, to ensure consistency.]

[9.][10.] The [**Conference of Parties**]/Governing Body of the WHO Pandemic Agreement shall periodically review the effectiveness of the [**Coordinating**] Mechanism, such as policies, operational modalities and activities, and its first revision should occur no less than two years after its establishment.

Chapter III. Institutional arrangements, Dispute settlement, and Final provisions

Institutional arrangements

Article 21. Governing Body

[Comment: Before considering drafting in detail, a discussion on the governing bodies of the pandemic agreement and the IHR should be conducted also on the basis of the Note of 26 January prepared by the Secretariat. Based on the outcomes of such discussion, paragraph 3 would need to be redrafted or deleted.]

1. A Governing Body is hereby established.

2. The Governing Body shall keep under regular review [, every three years,] the implementation of the WHO Pandemic Agreement and take the decisions necessary to promote its effective implementation. To this end, it shall:

(a) consider [the] report[s] of its subsidiary bodies ~~[submitted by the {Implementation and Compliance Committee} {Parties in accordance with Article 23 [and adopt regular reports]} on the implementation of the WHO Pandemic Agreement];~~

(b) ~~consider the report of WHO Director General on the overall implementation of the WHO Pandemic Agreement, as well as reports from WHO Production and Distribution Mechanism, Pandemic Technology Access Pool, WHO SCD Network, {and the} Financial Committee {, and the Scientific Advisory Committee}; Delete EU]~~

[Comment: Suggest rephrasing and merging subparagraphs 2(a) and (b) as indicated above]

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

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

(e) ~~[consider and review developed countries' reports on their contribution to the implementation of the WHO Pandemic Agreement pursuant to {the Articles on financial mechanism, technology access pool transfer of technology otherwise, technical assistance, capacity building} or any other assistance offered towards the [developing countries][parties or countries that need assistance based on WHO SCL Network mapping] and reports submitted by such parties or countries on receiving such offers, their acceptance, rejection or implementation, both submitted pursuant to Article 19 and provide specific recommendations to the parties concerned on enhancing such cooperation and assistance; Delete EU] *[Comment: the paragraph as drafted is not acceptable.]*~~

(f) invite, where appropriate in order to strengthen the implementation of the WHO Pandemic Agreement, the services and cooperation of, and information provided by, competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies;

(g) promote, including by establishing appropriate processes, cooperation and coordination with and among relevant legal instruments and frameworks and relevant global, regional, subregional and sectoral bodies, with a view to promoting coherence among efforts for pandemic prevention, preparedness and response;

(h) provide guidance to the WHO Director-General and to Parties, on effective implementation of the WHO Pandemic Agreement including the matters considered in paragraphs (a) and (e); and

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

3. [With the aim of promoting the coherence of the Governing Body and the Health Assembly, as well as coherence in respect of relevant instruments and mechanisms within the framework of the World Health Organization, the Governing Body shall operate within a third main committee of the World Health Assembly, subject to the establishment of such a committee by the World Health Assembly. In particular:

(a) decision-making within such a third main committee of the World Health Assembly will be adjusted, as appropriate, to accommodate the membership of the committee and the Governing Body;

(b) the Governing Body shall operate under the rules of procedure of such a third main committee of the World Health Assembly, provided that the Governing Body may agree to amend, supplement or revise such rules of procedure with a view to facilitating the dispatch of its business, with the aim of facilitating reporting by the Parties and avoiding duplication;

(c) in the event that the States Parties to the International Health Regulations (2005) determine that a Meeting of States Parties under that instrument will also operate within such a third main committee of the World Health Assembly, further steps will be agreed, as necessary, to accommodate, as appropriate, decision-making within such a third main Committee of the World Health Assembly; and

(d) in the event that the World Health Assembly does not establish such a third main committee of the World Health Assembly by the date of the entry into force of the WHO Pandemic Agreement, the Governing Body shall agree on the framework in which the Governing Body shall operate. [RESERVE EU](#)

4. The first session of the Governing Body shall be convened by the World Health Organization not later than one year after the entry into force of the WHO Pandemic Agreement.

5. Following the first session of the Governing Body:

(a) subsequent regular sessions of the Governing Body shall be held [bi-] annually] at the time and date of such a third main committee of the World Health Assembly within the Governing Body operates; and

(b) extraordinary sessions of the Governing Body shall be held at such other times, without reference to the regular sessions of the Health Assembly, as may be deemed necessary

by the Governing Body, or at the written request of any Party, provided that, within six months of the request being communicated in writing to the Parties by the Secretariat, it is supported by at least [one third] [a majority] of the Parties.

6. The Governing Body shall adopt by consensus its Rules of Procedure at its first session.

7. [Organizations, institutions, programmes, funds and entities of the United Nations system, as well as 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 Governing Body 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 Governing Body as an observer, is admitted unless two third of the Parties present object. This provision shall also apply to the admission and participation of observers to the subsidiary bodies of the Governing Body.] The Governing Body shall establish the [~~criteria for Delete EU~~] [rules applicable to] [~~the criteria for Delete EU~~] the participation of observers at its sessions.

8. The Governing Body shall by consensus adopt a biennial budget, as well as financial rules for itself, rules governing the funding of any subsidiary bodies of the Governing Body, and financial provisions governing the functioning of the Secretariat [and promoting participation from [developing [~~countries Delete EU~~] [country] parties [~~or countries that need assistance based on WHO SCL Network mapping Delete EU~~], [with particular attention to the needs of least developed country Parties]].

9. The Governing Body may establish subsidiary bodies, as it deems necessary, and on terms and modalities to be defined by the Governing Body. [Such subsidiary bodies may include an Implementation and Compliance Committee, a panel of experts to provide scientific advice [a Data Interoperability & Standards Committee] and a [WHO PABS System Expert Advisory Group].]

[Comment: Paragraph 9 needs to be revised in light of relevant content of substantive provisions.]

Article 22. Right to vote

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

2. A regional economic integration organisations that is Party to the WHO Pandemic Agreement, in matters within its competence, shall exercise its right to vote with a number of votes equal to the number of their Member States that are Parties to the WHO Pandemic Agreement. Such a regional economic integration organisations shall not exercise its right to vote if any of its Member States exercises its right to vote, and vice versa.

Article 23. Reports to the Governing Body

1. Each Party shall submit to the Governing Body periodic reports on its implementation of the WHO Pandemic Agreement.

2. The frequency, conditions and format of the reports submitted by the Parties shall be determined by the Governing Body [at its first session].

3. The Governing Body shall adopt appropriate measures to assist Parties, upon request, in meeting their obligations under this Article, [including developing country Parties and] with particular attention to the needs of [developing] [least developed] country Parties.

[Article 24. Scientific Advisory Committee

[Comment: The EU reserves its position on Article 24, which will need to be significantly redrafted in light of relevant content of substantive provisions.]

1. The Parties hereby establish a Scientific Advisory Committee as a subsidiary body of the Governing Body, to ~~[assess the science related to pandemic prevention, preparedness, response and recovery Delete EU]~~ [provide the Governing Body with information, scientific and technical advice on matters relating to the Agreement and its effective implementation].

2. The Scientific Advisory Committee shall consist of independent experts from various disciplines related to pandemic prevention, preparedness, response and recovery. The experts shall be nominated by the Parties, and appointed by the Director General [, based on criteria of competence, independence, multidisciplinary, gender equality and equitable geographic representation].

3. The Scientific Advisory Committee shall perform the following functions:

(a) assess the status of available scientific knowledge and evidence relating to pandemics, its causes, predictability, prevention measures, preparedness and response requirements and report the same to the Governing Body;

(b) assess global and regional situations and may forecast the emerging pandemic threats, level of risk such threats possess, or the need for any specific preparedness programme or response options for the Mechanism and its PTAP established under Articles 10 and 11 respectively;

(c) assess the availability of pandemic-related [health] products and provide recommendations for strategic stockpiling during inter-pandemic periods to the Mechanism established under Article 10 as well as the WHO SCD Network under Article 13;

(d) assess the need for pandemic-related [health] products during a novel pathogen outbreak and make recommendations for the Mechanism established under Article 10;

(e) coordinate with the Global Health R&D Observatory for prioritization and coordination of R&D, including through the development of R&D blueprints for pandemic-related [health] products and to submit such blueprints to the Governing Body;

(f) prepare strategies and guidelines for [prevention,] preparedness and response for various known pandemics and to submit such strategies and guidelines to the Governing Body;

(g) conduct health technology assessments of pandemic-related [health] products and share the results of such assessments with the Parties and relevant WHO Mechanisms;

(h) monitor of all types of genetic research, including “gain of function” research and big data analyses associated with highly transmissible pathogens, alert the scientific community about any potential biosecurity concerns and develop standards and operating procedures to avoid such biosecurity concerns;

(i) supervise research involving pandemic potential pathogens including genetic engineering and “gain of function” research with a view to avoiding biosafety and biosecurity concerns, including accidental laboratory leakages of disease-causing agents and in this regard, develop guidelines and submit to the Governing Body; and

(j) Any other tasks so entrusted to the Scientific Advisory Committee by the Governing Body or the World Health Assembly.

4. In accordance with its functions as set out in paragraph 3 above, the Scientific Advisory Committee shall:

(a) carry out the systematic review of the published scientific and public health literature and develop recommendations ensuring highest levels of scientific quality, independence and credibility at all stages of its functioning;

(b) take into account the information provided to it by the Parties and the institutional mechanisms established under the WHO Pandemic Agreement;

(c) take into account the need for exploring different disciplines and knowledge systems, gender balance, and effective contribution and participation by experts from [developing countries][parties or countries that need assistance based on WHO SCL Network mapping]; and

(d) perform any other relevant activities to fulfil its mandate, as appropriate.

[Comment: Paragraphs 3 and 4 need to be redrafted at a higher level of generality. As drafted, they appear quite prescriptive and, in some respect, not acceptable.]

5. The Scientific Advisory Committee shall meet at least once annually and may set up committees or panels of experts, as appropriate, to carry out its functions. The Scientific Advisory Committee shall carry out its functions in a transparent way and its meetings shall be open to all WHO Member States, and NSAs in official relation with WHO.]

[Placeholder for Article XX. Other technical committees.]

[Article 25. Implementation and Compliance Committee

1. The Parties hereby establish an Implementation and Compliance Committee as a subsidiary body of the Governing Body, to facilitate and consider the implementation of and promote compliance with the provisions of the WHO Pandemic Agreement. The committee shall be facilitative in nature and function in a manner that is transparent, non-adversarial and non-punitive.

2. The Implementation and Compliance Committee shall consist of members possessing appropriate qualifications and experience, nominated by the Parties and elected by the

Conference of the Parties, with due consideration to [competence, independence, multidisciplinary,] gender [~~balance~~ Delete EU] [equality] and equitable geographical representation. [*Comment: drafting suggestions to ensure consistency with Article 24.*]

3. The Implementation and Compliance Committee shall operate under the modalities and rules of procedure adopted by the Governing Body at its first meeting, consider issues of implementation and compliance at the individual and systemic levels, inter alia, and report periodically and make recommendations, as appropriate while cognizant of respective national circumstances, to the Governing Body.

4. In the course of its work, the Implementation and Compliance Committee may draw on appropriate information from any bodies established under the WHO Pandemic Agreement or the WHO, as well as from any information submitted to the WHO by Parties through other mechanisms.

5. The Implementation and Compliance Committee shall meet jointly, as appropriate with any Committee that may be established to review IHR implementation and compliance.]

Article 26. 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 Governing Body and its subsidiary bodies as may be established under the WHO Pandemic Agreement or by the Governing Body for the purpose of the implementation of the WHO Pandemic Agreement, and

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

(c) transmit reports and other relevant information regarding the implementation of the WHO Pandemic Agreement received by it pursuant to the WHO Pandemic Agreement;

(d) 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 Governing Body;

(e) prepare reports on its activities under the WHO Pandemic Agreement under the guidance of the Governing Body, and to submit them to the Governing Body;

(f) ensure, under the guidance of the Governing Body, the necessary coordination with

the Secretariats of other competent international organizations, regional intergovernmental organizations, and other bodies;

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

(h) perform other secretariat functions specified by the WHO Pandemic Agreement and such other functions as may be determined by the Governing Body or assigned to it under the WHO Pandemic Agreement.

3. Nothing in the WHO Pandemic Agreement shall be interpreted as providing the Secretariat of the World Health Organization, including the WHO Director-General, any authority to direct, order, alter or otherwise prescribe the domestic laws or policies of any Party, or to mandate or otherwise impose any requirements that Parties take specific actions, such as ban or accept travellers, impose vaccination mandates or therapeutic or diagnostic measures, or implement lockdowns.

Dispute settlement

Article 27. Settlement of disputes

1. In the event of a dispute between two or more Parties concerning the interpretation or application of the WHO Pandemic Agreement, the Parties concerned shall seek through diplomatic channels a settlement of the dispute through negotiation or any other peaceful means of their own choice, including good offices, mediation or conciliation. Failure to reach a solution by good offices, mediation or conciliation shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it **[, including by resorting to ad hoc arbitration in accordance with the Permanent Court of Arbitration Rules 2012 or its successor rules. The Parties that have agreed to arbitration shall accept the arbitral award as binding and final].**

[Comment: Acceptance of compulsory jurisdiction is highly unlikely. Paragraph 2(b) could be deleted, in particular if the suggested addition to paragraph 1 is accepted. If paragraph 2(b) stays, we suggest choosing the following drafting from the options proposed by the Bureau in square brackets for paragraph 2(b):

2. When ratifying, accepting, approving, formally confirming or acceding to the WHO Pandemic Agreement, or at any time thereafter, a Party may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory ipso facto and without special agreement, in relation to any Party accepting the same obligation: (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 Governing Body. 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.]**

[Comment: Acceptance of compulsory jurisdiction is highly unlikely. Paragraph 2(b) could be deleted, in particular if the suggested addition to paragraph 1 is accepted. If paragraph 2(b) stays, we suggest choosing the drafting as indicated above from the options proposed by the Bureau in square brackets for paragraph 2(b).]

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

Final provisions

[Propose that it be stated in Chapter I that: “1. The interpretation and application of the WHO Pandemic Agreement shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization.”]

Article 28. Relationship with other international agreements and instruments

1. The Parties recognize that the WHO Pandemic Agreement and the International Health Regulations should be interpreted so as to be [complementary and] compatible.

2. The provisions of the WHO Pandemic Agreement shall not affect the rights and obligations of any Party under other legally binding international instruments to which it is party.

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

Article 29. Reservations

[Comment: The EU reserves its position on Article 29. 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 be clearer.]

No reservations may be made to the WHO Pandemic Agreement [unless permitted by other articles of the WHO Pandemic Agreement **RESERVE EU**].

[Article 30. Declarations and statements

1. Article 29 does not preclude a State or regional economic integration organization, when signing, ratifying, approving, accepting or acceding to the WHO Pandemic Agreement, from making declarations or statements, however phrased or named, with a view, inter alia, to the harmonization of its laws and regulations with the provisions of the WHO Pandemic Agreement, provided that such declarations or statements do not purport to exclude or to modify the legal effect of the provisions of the WHO Pandemic Agreement in their application to that State or regional economic integration organization.

2. A declaration or statement made pursuant to this Article shall be circulated by the

Depositary to all Parties to the WHO Pandemic Agreement.]

Article 31. Amendments

1. Any Party may propose amendments to the WHO Pandemic Agreement, [including its annexes and protocols]. Such amendments shall be considered by the Governing Body.

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

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

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

[Comment: the brackets should be deleted. The amendment should enter into force for the Parties having accepted it.]

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

Article 32. [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 31 (Amendments).

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 procedural, scientific, technical or administrative matters. Delete EU]~~

[Comment: Paragraph 3 appears to be unnecessarily restrictive.]

Article 33. [Protocols]

1. Any Party may propose protocols to the WHO Pandemic Agreement. Such proposals shall be considered by the Governing Body.

2. The Governing Body 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 may as a last resort be adopted by a three-quarters majority vote of the Parties present and voting at the session. For the purposes of this Article, Parties present and voting means Parties present and casting an affirmative or negative vote. In the event that 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.

[Comment: the last sentence of paragraph 2 needs to be revisited.]

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

4. [States that are not Parties to the WHO Pandemic Agreement may be Parties to a protocol, provided the protocol so provides.][Only Parties to the WHO Pandemic Agreement may be Parties to a protocol.]

5. [Subject to article 36, any] [~~Any Delete EU~~] 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 34. Withdrawal

1. At any time after [two][one] years from the date on which the WHO Pandemic Agreement has entered into force for a Party, that Party may withdraw from the Agreement by giving written notification to the Depositary.

2. Any such withdrawal shall take effect upon expiry of one year from the date of receipt by the Depositary of the notification of withdrawal, or on such later date as may be specified in the notification of withdrawal.

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

Article 35. Signature

1. This Agreement shall be open for signature by all States, and by regional economic integration organizations.

2. This Agreement shall be open for signature at the World Health Organization headquarters

in Geneva, immediately following its adoption by the World Health Assembly at the Seventy-seventh World Health Assembly, from XX [May] 2024 to XX [June] 2024, and thereafter at United Nations Headquarters in New York, from XX [June] 2024 to XX [June] 2025.

Article 36. Ratification, acceptance, approval, formal confirmation or accession

1. This Agreement [, and any protocol thereto,] shall be subject to ratification, acceptance, approval or accession by all States and to formal confirmation or accession by regional economic integration organizations. This Agreement shall be open for accession from the day after the date on which the 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. 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 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 37. Entry into force

[Comment: This article, as well as the one related to signature, ratification, and a few others need to be further discussed.]

1. This Agreement shall enter into force on the thirtieth day following the date of deposit of the [XXX] instrument of ratification, acceptance, approval, formal confirmation or accession with the Depository.
2. For each State that ratifies, accepts or approves the WHO Pandemic Agreement or accedes thereto after the conditions set forth in paragraph 1 of this Article for entry into force have been fulfilled, the WHO Pandemic Agreement shall enter into force on the thirtieth day following the date of deposit of its instrument of ratification, acceptance, approval or accession.
3. For each regional economic integration organization depositing an instrument of formal confirmation or an instrument of accession after the conditions set forth in paragraph 1 of this Article for entry into force have been fulfilled, the WHO Pandemic Agreement shall enter into force on the thirtieth day following the date of deposit of its instrument of formal confirmation or of accession.
4. For the purposes of this Article, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by Member States

of that regional economic integration organization.

Article 38. Depositary

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

Article 39. Authentic texts

The [original of the WHO Pandemic Agreement, of which the] Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic[, shall be deposited with the Secretary-General of the United Nations].