World Health Organization

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

7 March 2024

REVISED Draft of the negotiating text of the WHO Pandemic Agreement

EU draft assessment (version of 12 March)

The EU proposals for additions are indicated in bold underlined, in square brackets. Proposals for deletion are set out by way of strike through, in square brackets. Comments or explanations are provided in light blue.

The Parties to the WHO Pandemic Agreement,

Recognizing that the World Health Organization is fundamental to strengthening pandemic prevention, preparedness and response, as it is the directing and coordinating authority on international health work,

EU NT comment: this paragraph should be placed last as it recalls an operational aspect.

Recalling the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition,

Recognizing that the international spread of disease is a global threat with serious consequences for lives, livelihoods, societies and economies that calls for the widest possible international cooperation in an effective, coordinated, appropriate and comprehensive international response, while reaffirming the principle of sovereignty of States Parties in addressing public health matters,

Deeply concerned by the gross inequities at national and international levels that hindered timely and equitable access to medical and other COVID-19 pandemic-related products, and the serious shortcomings in pandemic [**prevention and**] preparedness,

Recognizing the critical role of whole-of-government and whole-of-society approaches at country and community levels, and the importance of international, regional and cross-regional collaboration, coordination and global solidarity in achieving sustainable improvements in pandemic prevention, preparedness and response,

Recognizing the importance of ensuring political commitment, resourcing and attention across sectors for pandemic prevention, preparedness and response,

Reaffirming the importance of multisectoral collaboration at national, regional and international levels to safeguard human health, including through a One Health approach,

Reiterating the need to work towards building and strengthening resilient health systems, with skilled and trained health and care workers, to advance universal health coverage and to adopt an equitable approach to mitigate the risk that pandemics exacerbate existing inequities in access to health services,

Recognizing that the protection of intellectual property rights is important for the development of new medical products, and recalling that intellectual property rights do not, and should not, prevent Member States from taking measures to protect public health, and further recognizing concerns about the effects of intellectual property rights on prices,

Recognizing Member States' sovereign rights over their [~~genetic~~ Delete EU] **[natural]** resources **[in accordance with the Convention on Biological Diversity]** and *underscoring* the importance of promoting the early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens with pandemic potential, as well as the fair and equitable sharing of benefits arising therefrom, taking into account relevant national and international laws, regulations, obligations and frameworks,

Acknowledging that unequal development in different countries in the promotion of health and

control of disease, especially communicable disease, is a common danger that requires support through international collaboration, and that pandemic prevention, preparedness and response at all levels and in all sectors, particularly in developing countries, requires predictable. sustainable and sufficient financial, human, logistic and technical resources,

Have agreed as follows:

Chapter I. Introduction

Article 1. Use of terms

For the purposes of the WHO Pandemic Agreement:

(a) "biological materials" means clinical samples, specimens, isolates and cultures, either original or processed, of a pathogen;

(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 the order of nucleotides found in a molecule of DNA or RNA;[1]

EU NT comment: consider wider terminology, to capture not only DNA and RNA data, but also proteomic and metabolomic data or future analytical techniques. Waiting for the conclusion of discussions within the CBD does not seem to be a partible or timely option.

(d) "manufacturer" means any entity that produces, for commercial purposes, including by means of licensing agreements, diagnostics, therapeutics or vaccines for infectious diseases;

(e) "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;

EU NT comment: The One Health approach needs to guide the implementation of the agreement. We suggest moving the One Health Approach to Article 3.

(f) "PABS sequence databases" means publicly accessible databases that meet and agree to legally binding terms of reference that include arrangements to notify users of benefit-sharing provisions under the PABS system;

EU NT comment: Note that this issue is being discussed in the context of Article 12. The outcome of these discussions would need to be reflected here.

[1] Definition might need to be adjusted following finalisation of the negotiation within CBD on the scope of Digital Sequence Information, DSI, that, in addition to DNA and RNA, might include proteins and metabolites.

(g) "pandemic-related **[health]** products" means products that are needed for pandemic prevention, preparedness and response, which may include, without limitation, diagnostics, therapeutics, vaccines and personal protective equipment;

(h) "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;

(i) "pathogen with pandemic potential" means any pathogen that has been identified to infect a human and that is: novel (not yet characterized) or known (including a variant of a known pathogen), potentially highly transmissible and/or highly virulent with the potential to cause a public health emergency of international concern;

EU NT comment: Note that this issue is being discussed in the context of Article 12. The outcome of these discussions would need to be reflected here.

(j) "persons in vulnerable situations" means individuals, groups or communities with a disproportionate increased risk of infection, severity, disease or mortality in the context of a pandemic;

(k) "regional economic integration organization" means an organization that is composed of several sovereign states and to which its Member States have transferred competence over a range of matters, including the authority to make decisions binding on its Member States in respect of those matters;[1]

(l) "relevant diagnostic, therapeutic or vaccine" means a diagnostic, therapeutic or vaccine that is prequalified by WHO or has received a positive WHO Emergency Use Listing assessment or an authorization from a national regulatory authority for treatment, diagnosis or prevention of a disease in relation to which WHO has declared a public health emergency of international concern or characterized as a pandemic;

(m) "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; and

EU NT comment: Universal health coverage is mentioned only once in the instrument. The definition of the term does not therefore seem necessary.

(n) "WHO coordinated laboratory network" means laboratory alliances or networks coordinated by WHO in which each laboratory meets WHO standards and agrees to legally binding terms of reference that include arrangements to notify users of biological materials for pathogens with pandemic potential of benefit-sharing provisions under the PABS system.

EU NT comment: Note that this issue is being discussed in the context of Article 12. The outcome of these discussions would need to be reflected here.

[1] Where appropriate, 'national' will refer equally to regional economic integration organizations.

EU NT comment: we suggest adding the definition of "stakeholders", as follows, since the term recurs very frequently:

(o) **["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

The objective of the WHO Pandemic Agreement, guided by equity, and the **[other]** principles [~~and approaches~~ Delete EU] set forth herein, is to prevent, prepare for and respond to pandemics.

Article 3. Principles

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. full respect for the dignity, human rights and fundamental freedoms of all persons, and [**including**] the enjoyment of the highest attainable standard of health of every human being**[, as well as for international humanitarian law and principles]**;

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

EU NT comment: the issue is already addressed in the Preamble and the reference here to sovereign rights over biological resources needs to be deleted.

3. equity as the goal and outcome of pandemic prevention, preparedness and response, ensuring the absence of unfair, avoidable or remediable differences among groups of people;

4. [~~common but~~ Delete EU] [**the**] differentiated [~~responsibilities and respective~~ Delete EU] capabilities **[of Parties]** in pandemic prevention, preparedness, response and recovery of health systems;

EU NT comment: we suggest addressing CBDR within its appropriate context in the Preamble and modifying paragraph 5 as above. The Preambular paragraph could read as follows and be placed after the preambular paragraph on the sovereign rights of Parties over their natural resources:

[*Reaffirming* the common but differentiated responsibilities and respective capabilities to address environmental degradation and climate change, with a view to mitigating the risks of zoonotic spill-over due to such factors;]

5. solidarity, transparency and accountability to achieve the common interest of a more equitable and better prepared world to prevent, respond to and recover from pandemics; and

6. the best available science and evidence as the basis for public health decisions for pandemic prevention, preparedness and response.

[EU NT comment: The One Health approach needs to guide the implementation of the agreement. We suggest adding a paragraph 7 as follows, while deleting One Health from Article 1 on the use of terms:

[7. the "One Health" approach, as an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems, recognising that the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) is closely linked and interdependent]

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

Article 4. Pandemic prevention and surveillance

EU NT comments:

Some elements of Article 4 have been diluted, in particular the requirements related to IPC, immunization and vaccination, or access to water, sanitation and hygiene. The involvement and cooperation with the Quadripartite organizations has been kept to a minimum, with only one reference to "recommendations, guidelines and standards developed and adopted by WHO and other relevant intergovernmental organizations or bodies" under subparagraph 4(c).

The revised text includes two new subparagraphs:

- subparagraph 2(b) on community-based early detection and control measures and
- subparagraph 2(g) on vector-borne disease surveillance and prevention, with a requirement to 'develop, strengthen and maintain capacity to conduct risk assessments of vector-borne diseases that may lead to pandemic situations'.

Elements related to the monitoring of environmental factors, wildlife management or AMR, while being reflected in the text, are still in need of further specifications.

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 and coordinated multisectoral surveillance, taking into account national capacities and national and regional circumstances.

2. The Parties shall undertake to cooperate:

(a) in the implementation of the provisions of this Article, in particular through **[technical assistance and capacity building, taking into account especially the needs of the least developed country Parties and other Parties in need]** [~~enhancing financial and technical support to developing countries~~ Delete EU]; and

(b) in support of relevant global and[~~/or~~ Delete EU] regional [**and national**] initiatives aimed at preventing [~~pandemics~~ Delete EU] [**pandemic emergencies**], in particular those that improve surveillance, early warning and risk assessment; promote evidence-based actions, risk communication and community engagement; and identify settings and activities presenting a risk of emergence and re-emergence of pathogens with pandemic potential.

3. Each Party commits to progressively strengthen pandemic prevention and coordinated multisectoral surveillance, taking into account its national capacities, including through:

(a) coordinated multisectoral surveillance[**, in line with the One Health approach]**: (i) detect[**ing**] and conduct[**ing**] risk assessments of emerging or re-emerging pathogens, including pathogens in **[livestock, wild and domestic]** animal populations that may present significant risks of zoonotic spillover, in accordance with the International Health Regulations (2005); **[(ii) identify and monitor environmental factors contributing to those diseases]**and (ii**[i]**) share the outputs of relevant surveillance and risk assessments within their territories with WHO and other relevant [**international organizations and**] agencies;

(b) community-based early detection and control measures: [~~leverage~~ Delete EU] [**strengthening**] community capacities, networks and mechanisms to detect unusual public health events and contain them at the source;

(c) water, sanitation and hygiene: [~~strengthen efforts~~ Delete EU] [**taking measures**] to ensure access to safe water, sanitation and hygiene, including in hard-to-reach settings;

(d) infection prevention and control: [**(i) taking measures to enable timely access to effective immunization and vaccination, which aim to reduce pandemic risks; and (ii)]** implement[**ing**] active infection prevention and control measures in all health care facilities and institutions, in line with relevant international standards and guidelines, [**including by requiring healthcare facilities and institutions to have in place a regularly updated infection prevention and control programme and by taking measure to support sound management of health-care wastes]**;

(e) zoonotic spillover and spillback prevention: (i) identify[**ing**] settings and activities that create or increase the risk of disease emergence and re-emergence at the human- animal-plant-environment interface; (ii) tak**[ing]** [**regulatory and other**] measures to reduce risks of zoonotic spillover and spillback associated with these settings and activities, including measures aimed at safe and responsible management [**and handling**] of [**livestock, wild and domestic]** [~~wildlife, farm and companion~~ Delete EU] animals, in line with relevant international standards and guidelines**[, as well as measures to address the health impact of environmental factors associated with the risk of zoonotic disease spill-over and spillback]**;

[(**f) Wildlife management: (i) taking action to prevent the development and spread of zoonotic disease arising from trade of wild animals, or products thereof, posing a high risk of zoonotic disease and (ii) facilitating, in line 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;]**

[~~f~~] [**g**] laboratory biosafety and biological risk management: develop[**ing**], strengthen[**ing**] and maintain[**ing**] biosafety and biological risk management, 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 facilities and ensuring the safety and security of transportation and cross-border transfer, in accordance]** [~~consistent~~ Delete EU] with applicable international and national rules, standards and guidelines;

[~~g~~] [**h**] vector-borne disease surveillance and prevention: develop[**ing**], strengthen[**ing**] and maintain[**ing**] capacity to conduct risk assessments of vector-borne diseases that may lead to pandemic situations; and

EU NT comment: suggest moving this subparagraph under subparagraph (a).

[~~h~~] [**i**] antimicrobial resistance (AMR): tak[**ing**] measures to address pandemic-related risks associated with the emergence and spread of pathogens that are resistant to antimicrobial agents, including through the development[**,**] [~~and~~ Delete EU] implementation [**and regular review**] of national and, where relevant, regional antimicrobial resistance action plans, taking into account relevant international guidelines [**and plans**], and with the aim

of facilitating affordable and equitable access to antimicrobials. **[For this purpose, the 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 antimicrobial research and development and 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:

(a) taking into account national capacities, ensure that relevant national, and where applicable regional, action plans, policies and/or strategies, include comprehensive, coordinated and multisectoral pandemic prevention measures and surveillance;

(b) develop, strengthen and maintain pandemic prevention capacities to complement the core capacities for surveillance, prevention and response as set out in the International Health Regulations (2005); and

(c) take into account recommendations, guidelines and standards developed and adopted by WHO and other relevant intergovernmental organizations or bodies, **[including the Quadripartite organizations,]** in the development of relevant national and, where applicable, regional policies, strategies and measures to prevent [~~pandemics~~ Delete EU] [**pandemic emergencies**].

5. The Parties recognize that environmental, climatic, social, anthropogenic and economic factors increase the risk of pandemics and endeavour to identify these factors and take them into consideration in the development and implementation of relevant policies, strategies and measures, including by strengthening synergies with other relevant international instruments and their implementation.

6. The Conference of the Parties may adopt, as necessary [**and in collaboration with relevant international organizations, in particular the Quadripartite organizations**], **[technical]** guidelines, recommendations and standards, including in relation to pandemic prevention capacities, to support the implementation of this Article.

Article 5. One Health approach to pandemic prevention, preparedness and response

EU NT comments:

The text of Article 5, and in particular paragraph 2, has been streamlined.

Previous paragraph 2(b), related to the implementation of scientific and evidence-based actions, and referring to IPC and AMR, has been removed from Article 5. In light of the requirement included in Article 16 for each Party to ensure that "policy actions are science- and evidence-based", the deletion of previous subparagraph 2(b) can be accepted, if stronger language on AMR is inserted in Article 4.

1. The Parties[**, recognizing the interconnection between people, animals and the environment,**] commit to promote a One Health approach for pandemic prevention, preparedness and response that is coherent, comprehensive, integrated, coordinated and collaborative among relevant actors and sectors.

2. For this purpose, each Party shall, taking into account its national circumstances and capacities, take measures to:

(a) implement relevant national[**, and where applicable, regional**] policies, strategies and measures [**for pandemic prevention, preparedness and response**] that reflect a One Health approach;

(b) [~~promote~~ Delete EU] [**ensure**] the effective and meaningful engagement of communities in the development and implementation of policies, strategies and measures to prevent, detect and respond to zoonotic outbreaks; and

(c) promote or establish, as necessary, One Health [**multidisciplinary**] workforce training and continuing education programmes for public health, animal health and environment sectors, to build complementary skills, capacities and capabilities.

3. The Parties shall contribute to the further development and updating of international standards and guidelines[**, based on the One Health approach,**] to detect, reduce risks of, monitor and manage zoonotic spillover and spillback, in collaboration with WHO and relevant intergovernmental organizations.

4. The Parties shall develop and implement or strengthen, as appropriate, bilateral, subregional, regional and other multilateral mechanisms to enhance financial and technical support, assistance and cooperation, in particular in respect of [~~developing countries~~ Delete EU] [**the needs of the least developed country Parties and other Parties in need**], in relation to promoting and taking measures towards One Health.

Article 6. Preparedness, health system resilience and recovery

EU NT comments:

Several of the comments submitted by the EU at INB 8 are reflected in the revised text for Article 6, in particular the inclusion of an explicit reference to persons in vulnerable situations in subparagraph 2(a), and to public health, animal health and environmental laboratory and diagnostic capacities in subparagraph 2(d).

Main differences to be noted are as follows:

- Previous subparagraph 2(b), related to the development, strengthening and maintaining of a multisectoral workforce, and which was overlapping with the requirements laid down under paragraph 1 of Article 7, has been removed.
- In subparagraph 2(d), the reference to the application of standards and protocols for infection prevention and control and to the prevention of AMR in relation to laboratory and diagnostic capacities has been removed. This should be reintroduced.
- In paragraph 4, the requirement is now to 'identify and promote', instead of 'develop and promote' relevant international data standards and interoperable systems.

1. Each Party commits to develop, strengthen and maintain its health system, including primary health care, for pandemic prevention, preparedness and response, taking into account the need for equity and resilience, with a view to the progressive realization of universal health coverage.

2. Each Party commits, in accordance with applicable laws and regulations, to strengthen and reinforce health system functions, including by adopting and[~~/or~~ Delete EU] developing policies,

plans, strategies and measures, as appropriate, for:

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

(b) developing, strengthening and maintaining health infrastructure as well as public and animal health institutions, including academic and research centres, at national, regional and international levels;

(c) developing post-pandemic health system recovery strategies;

(d) developing, strengthening and maintaining, as necessary, public health, animal health and environmental laboratory and diagnostic capacities, and associated national, regional and global networks, [**including**] through the application of relevant standards and protocols for [**infection prevention and control,**] laboratory biosafety and biological risk management[**, as well as the prevention of antimicrobial resistance**];

(e) developing, strengthening and maintaining: health information systems for early detection, forecasting, and timely information sharing; civil registration and vital statistics; and associated digital health and data science capacities; and

(f) promoting the use of social and behavioural sciences, risk communication and community engagement for pandemic prevention, preparedness and response.

3. The Parties commit to cooperate, within means and resources at their disposal, and with the support of the WHO secretariat and other relevant organizations, in order to provide or facilitate financial, technical and technological support, assistance, capacity-strengthening and cooperation, [~~in particular in respect of developing countries~~ Delete EU] [**with particular attention to the needs of the least developed country Parties**].

4. The Parties shall identify and promote relevant international data standards and interoperability that enable timely sharing of public health data for preventing, detecting and responding to public health events.

Article 7. Health and care workforce

EU NT comments:

The proposed text for Article 7 has been reworked and slightly reorganized in line with the advice of WHO experts (James Campbell, Director of the Health Workforce Department, and Scott Dowell, Global Health Emergency Corps lead), and based on the informal discussions held in the margins of INB 8 and led by Germany.

Several important EU proposals have been taken on board, such as the redrafting of paragraph 1(b), the establishment, as appropriate, of global health emergency teams (paragraph 4), as well as the insertion of the new paragraph 6, on ensuring a safe and healthy environment for other essential workers providing essential public goods and services during pandemic emergencies, which is to be welcomed.

1. Each Party, in accordance with its national circumstances, commits to take, where appropriate, the necessary measures to safeguard, protect, invest in, retain and sustain an adequate, skilled and trained health and care workforce, with the aim of strengthening 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 commits, where appropriate, to:

(a) protect the safety and security of the health and care workforce, including through strengthening decent work conditions, addressing mental health and wellbeing, ensuring priority access to necessary tools and supplies, including to pandemic- related [**health**] products during pandemic emergencies, as well as [**preventing and**] addressing harassment, violence and threats against health and care workers;

> **EU NT comment**: while we welcome shortening and streamlining of subparagraph 1(a), we would appreciate a clarification from the Bureau as to what the newly added "necessary tools and supplies" entail.

(b) address disparities, inequalities, discrimination, stigma and bias, including [~~issues related to gender and youth and~~ Delete EU] unequal remuneration and opportunities, such as barriers faced by women to reaching leadership and decision-making roles, within the health and care workforce [~~particularly during health emergencies, to~~ Delete EU], [**and**] support the meaningful representation, engagement, consultation, participation and empowerment of all health and care workers;

(c) establish and maintain national workforce planning systems and strategies to rapidly, effectively and efficiently deploy health and care workers to maintain quality essential health services and essential public health functions, prior to and during [~~pandemics~~ Delete EU] [**pandemic emergencies**];

(d) take measures to ensure self-sufficiency in health and care workforce education, employment and retention in advance of public health emergencies; and

> **EU NT comment:** The paragraph is unclear and needs redrafting.

(e) strengthen, pre- and in- service competency-based education and training, deployment, remuneration, distribution and retention, including in rural and hard- to-reach areas, of the health and care workforce.

2. The Parties commit to assist [**within available resources,**] [~~and provide financial and technical support within means and resources at their disposal to~~ Delete EU] other Parties in need, with special attention to the needs of countries that are particularly vulnerable to the adverse effects of pandemics, [**with training and capacity building**] in order to strengthen and sustain a skilled and competent health and care workforce capable of maintaining quality essential health services, [~~essential~~ Delete EU] public health functions and emergency preparedness and response, at subnational, national and regional levels.

3. The Parties commit to collaborate, where appropriate, through multilateral and bilateral arrangements and [**in accordance**] [~~consistent~~ Delete EU] with [~~the WHO Global Code of Practice on the International Recruitment of Health Personnel and other~~ Delete EU] applicable international norms, codes and standards, promoting ethical[~~,~~] international recruitment principles and equity, to minimize the negative impact of health workforce migration on health systems while respecting the freedom of movement of health professionals.

> **EU NT comment**: We suggest not to refer to specific technical documents in the text of the agreement and we note that the WHO Global Code of Practice on the International Recruitment of Health Personnel would be covered under the reference to 'international

norms, codes and standards'.

4. The Parties, building on existing bilateral and multilateral networks, shall [**endeavor to**] [~~invest in~~ delete EU] establish[~~ing~~ Delete EU], sustain[~~ing~~ Delete EU], coordinat**[e]**[~~ing~~ Delete EU] and mobiliz**[e]**[~~ing~~ Delete EU] a skilled and trained multidisciplinary global public health emergency workforce that is able to manage health emergencies closest to where they start. For this purpose, Parties shall [~~invest in~~ Delete EU] [**endeavor to establish or**] designat**[e]**[~~ing~~ Delete EU], at national and where appropriate regional level, interdisciplinary emergency health teams[**, based on the One Health approach. Such teams shall]** [~~to~~ Delete EU] ensure the essential functions and surge capacities necessary [~~to deploy~~ Delete EU] in a pandemic emergency and **[shall]** [~~to~~ Delete EU] support Parties upon request. 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 organizations 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.**]

EU NT comment: emergency health teams are an essential component of a strong and efficient response to pandemic emergencies and the EU sees the revised Bureau's text as an improvement of the previous negotiating text. Nonetheless, we propose some additional clarifications, as indicated above.

5. The Parties shall develop[**,**] [~~**or**~~] strengthen [**and sustain**], leveraging or building on existing national and regional education institutions, centres of excellence and networks, a skilled and competent health and care workforce[**, including emergency health teams,**] at subnational, national and regional levels, with the capacity to maintain quality essential health services, essential public health functions and to respond rapidly to public health threats of pandemic potential.

6. Each Party commits to take the necessary steps to ensure decent work conditions and a safe and healthy environment for other essential workers that provide essential public goods and services during [~~pandemics~~ Delete EU] [**pandemic emergencies**].

Article 8. [~~**Preparedness**~~ **Delete EU] monitoring and functional reviews**

EU NT comments:

The proposed text for Article 8 has been considerably streamlined and shortened, visibly aiming to postpone the detailed discussions on the development of the monitoring and evaluation system to a later stage.

The Bureau has taken note of the comments of the EU on the duplications and overlaps between Article 8(1) and Article 17(4)(b)-(e) and paragraph 1 of Article 8 referring to national plans and strategies has been removed. The former paragraph 3, with small modifications, has become paragraph 1.

In paragraph 2, as already indicated during INB 8, in view of limited resources, the need to ensure complementarity with the IHR and to build on existing mechanisms under the IHR should be better reflected in the text. We also note that the reference to the conduct of

appropriate simulation or tabletop exercises has been removed.

1. 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.

2. Each Party shall assess, every five years, with technical support from the [~~WHO~~ Delete EU] Secretariat upon request, the functioning and readiness of, and gaps in, its pandemic prevention, preparedness and response capacity, based on the relevant tools and guidelines developed by WHO in partnership with relevant organizations at international, regional and sub-regional levels [**and by building on existing mechanisms under the International Health Regulations**].

Article 9. Research and development

EU NT comments:

The proposed text for Article 9 has been considerably shortened, in particular with regards to clinical trials. This in turn results in some missed opportunities, such as strengthening research workforce and infrastructure, as well as clinical trial policy and regulatory frameworks; reference to good scientific practice and international ethical guidelines; a registration of clinical trials prior to recruitment; promoting access to and facilitating use of comparator products needed for clinical trials, to allow for rapid development and comparison of products and technologies, as well as the interaction with regulatory bodies for guidance on optimal trial design to facilitate an efficient regulatory process.

None of the major EU proposals have been taken on board in Article 9. Thus, the most important EU proposals have been reiterated.

1. The Parties shall cooperate to build, strengthen and sustain national, regional and international capacities and institutions for research and development, particularly in developing countries, and shall promote scientific collaboration for the rapid sharing of information and access to research results and outcomes, including through open science approaches.

2. To this end, the Parties shall promote:

(a) sustained investment in research and development for public health priorities, including for pandemic-related [**health**] products, and support for research institutions and networks that can rapidly adapt and respond to research and development 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~~ Delete EU] research centres, particularly from developing countries, including from the public and, as appropriate, private sector;

(c) innovative research and development, including community-led and cross-sector collaboration, for addressing pathogens with pandemic potential;

(d) [~~equitable access to research knowledge, evidence synthesis,~~ Delete EU] knowledge translation and evidence-based communication tools, strategies and partnerships,

relating to pandemic prevention, preparedness and response;

EU NT comments: this new addition changes the meaning of paragraph 2(d) and therefore cannot be supported.

(e) capacity-building programmes, projects and partnerships, [~~and substantial and sustained support~~ Delete EU] for [~~research and~~ Delete EU] [**the**] development, [**dissemination and use of technical and scientific knowledge and research,**] including basic and applied research, such as early-stage research, product discovery, pre-clinical and translational research;

EU NT comments: paragraph 2(e) can be supported with the proposed modifications.

(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, [~~to develop~~ Delete EU] **[with the support of the Secretariat and with the view to pool expertise, avoid duplicating research efforts and facilitate the development of]** pandemic-related [**health**] products for diverse populations and settings [~~, with a central role for WHO~~ Delete EU];

EU NT comment: none the EU proposals have been taken on board, hence the proposed modifications. A clarification on what is meant by diverse populations would be useful.

(g) access for scientists and researchers, particularly from [~~developing countries~~ Delete EU] [**the least developed country Parties**], to relevant [~~international~~ Delete EU] scientific research programmes, projects and partnerships, including those referred to in this Article, as well as scientific publications;

(h) the sharing of information on national research agendas, capacity-building activities, and research and development priorities during pandemic emergencies [**with the support of existing expert bodies**]; and

(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) public health and social interventions used to control pandemics and their effect on the spread of disease and the burden imposed by these measures on society, including its economic cost; and (3) relevant **[pandemic related]** health products, with the aim of promoting equitable access, including their timely availability, affordability and quality.

3. The Parties shall, in accordance with [**domestic laws**], national circumstances and [~~mindful of~~ Delete EU] [**considering**] relevant international standards, take steps to strengthen international coordination and collaboration to support well-designed and well-implemented clinical trials, by developing, strengthening and sustaining clinical trial capacities and research networks at the national, regional and international levels.

EU NT comment: paragraph 3(a)-(i) of the refined Bureau's text for INB 8 has been significantly shortened, i.e. instead of quite detailed provisions of the former paragraph 3(a)-(i), this new paragraph 3 is a blend of the chapeau of paragraph 3 and of subparagraph 3(e). A clarification regarding the Bureau's rationale behind would be useful.

In light of these modifications, further assessment of paragraph 3 above and paragraph 4 below is needed.

4. The Parties shall support[:

(a)] 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 [**emergency; and**]

(b) **early interaction with regulatory bodies for guidance on optimal trial design to facilitate an efficient regulatory process.**

EU NT comment: the provisions in the current paragraph 4 are the same as in subparagraph 3(g) of the refined Bureau's proposal for INB 8. Further assessment is needed in view of the significant shortening of the text.

5. Each Party shall, in accordance with [~~national~~ Delete EU] [**domestic**] law, support the transparent and public sharing of research inputs and outputs from research and development of government-funded pandemic-related products, including scientific publications with data shared and stored securely.

EU NT comment: the language of this paragraph is unclear and needs to be redrafted.

6. Each Party [~~shall~~ Delete EU] **[should]** [~~develop national~~ Delete EU] [**in accordance with domestic laws and**] policies [~~to~~ Delete EU]:

(a) [~~include provisions in government-funded research and development agreements for the development of pandemic-related products that promote timely and equitable access to such products during public health emergencies of international concern and pandemics~~.—~~Such provisions may include: (i) licensing and/or sublicensing, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer on voluntary terms; (iv) publication of relevant information on research inputs and outputs; and/or (v) adherence to product allocation frameworks adopted by WHO~~ Delete EU]; and

EU NT comment: The second part of the current paragraph 6(a) appears too prescriptive and cannot be supported. We would favour reverting to the drafting of this provision in the refined Bureau's proposal for INB 8, namely:

"(a) include provisions to promote equitable access to pandemic-related health products in government-funded research and development agreements and in licensing of government-owned technology for such products; and".

(b) publish relevant terms of government-funded research and development agreements [**for pandemic-related health products,**] promoting equitable and timely access to such products during a pandemic emergency.

Article 10. Sustainable and geographically diversified production

1. The Parties commit to achieving [~~a more equitable geographical distribution and scaling up of the global~~ Delete EU] [**economically sustainable and geographically diversified**] production of pandemic-related **[health]** products, and **[thus]** increasing [~~sustainable~~ Delete EU], timely[~~, fair~~ Delete EU] and equitable access to such products[~~, as well as reducing the potential gap between supply and demand~~ Delete EU] during [~~pandemics~~ Delete EU] [**pandemic emergencies**].

2. The Parties, in collaboration with WHO and other relevant organizations, shall:

(a) take measures, in cooperation with regional organizations, to [~~provide support, maintain and strengthen~~ Delete EU] [**promote public and private investment aimed at creating or expanding economically sustainable and geographically diversified**] production facilities [**of health products**] [~~at national and/or regional levels~~ Delete EU], particularly in developing countries, [~~and to facilitate~~ Delete EU] **[which are capable of]** scaling up [~~of~~ Delete EU] production of pandemic-related **[health]** products during emergencies[~~, including through promoting and/or incentivizing public and private investment aimed at creating or expanding economically viable manufacturing facilities of relevant health products~~ Delete EU];

(b) facilitate the continuous and sustainable operations of the facilities referred to in subparagraph 2(a), including through promoting transparency of relevant unprotected information on pandemic-related products and raw materials across the value chain;

EU NT comment: We believe that "unprotected information on pandemic-related health product" may refer to information not protected by trade secret, but more clarification on what is meant would be useful.

(c) facilitate the [**voluntary**] transfer of relevant technology, know-how, and licenses pooled in relevant mechanisms (as referred to in Article 11), including during interpandemic times, to ensure the sustainability of the facilities referred to in subparagraph 2(a) ;

(d) [~~take measures, and~~ Delete EU] encourage international organizations, to establish long-term contracts and make investments, especially in developing countries' facilities preferably with a regional scope of operation, to ensure regular production of pandemic-related products produced by local and regional manufacturers;

(e) [**promote capacity building aimed at obtaining timely**] [~~facilitate and support~~ Delete EU] authorization of pandemic-related [**health**] products produced by the facilities referred to in subparagraph 2(a); and

(f) support and[~~/or~~ Delete EU] facilitate skills development, capacity-building and other initiatives for production facilities.

3. [~~Each Party shall promote public and private sector investments aimed at creating or expanding manufacturing facilities for pandemic-related products, especially regional manufacturers based in developing countries~~. Delete EU]

EU NT comment: the issue addressed in paragraph 3 is covered in paragraph 2(a).

Article 11. Transfer of technology and know-how

1. In order to enable [~~sufficient,~~ Delete EU] sustainable and geographically-diversified production of pandemic-related **[health]** products each Party, taking into account its national circumstances, shall:

(a) promote and otherwise facilitate or incentivize the [**voluntary**] transfer of technology and know- how for both pandemic-related and routine health products, including through the use of licensing and collaboration with regional or global technology transfer partnerships and initiatives, and in particular for the benefit of developing countries and for technologies that have received public funding for their development;

(b) promote the timely publication by private rights holders of the terms of licensing agreements and/or technology transfer agreements for pandemic-related **[health]** products, in accordance with [~~national~~ Delete EU] [**domestic**] laws [**and policy**];

(c) [~~make available licenses~~ Delete EU] **[promote the voluntary licensing]**, on a non-exclusive[~~, worldwide~~ Delete EU]and transparent basis and for the benefit of developing countries, [~~for~~ Delete EU] [**of**] government-owned pandemic-related **[health]** products, and [~~shall publish~~ Delete EU] [**the publication of**] the terms of these licenses at the earliest reasonable opportunity and in accordance with [~~national~~ Delete EU] [**domestic**] laws; and

(d) provide, within its capabilities, support for capacity-building for the [**voluntary**] transfer of technology and know-how for pandemic-related **[health]** products.

2. The Parties shall develop and strengthen, as appropriate, mechanisms [~~coordinated by WHO with the participation of other relevant technology transfer mechanisms as well as other relevant organizations,~~ Delete EU] to promote and facilitate the [**voluntary**] transfer of technology and know-how for pandemic-related **[health]** products to geographically diverse research and development institutes and manufacturers, particularly in developing countries, through the pooling of knowledge, intellectual property, know-how and data [~~to all developing countries~~ Delete EU].

EU NT comment: paragraph 2 largely overlaps with paragraph1(a).

3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:

~~(a)~~ encourage holders of relevant patents regarding pandemic-related **[health]** products, in particular those who received public funding, to 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 [**with the aim to increase the availability and affordability of such products to Parties in need**] [~~; and~~

~~(b)~~ [~~consider supporting, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic- related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products~~ Delete EU].

4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics[~~, and shall fully respect the use thereof by others~~ Delete EU].

5. Each Party shall, as necessary and appropriate, review [~~and update~~ Delete EU] its [~~national~~ Delete EU] [**domestic**] legislation in order to ensure the implementation of such flexibilities referred to in paragraph [~~5~~ Delete EU] [4] in a timely and effective manner.

6. The WHO Secretariat shall work towards the improvement of access to pandemic-related **[health]** products, especially during pandemic emergencies, through **[voluntary]** transfer of technology and know- how, including through cooperation with relevant international organizations.

Article 12. Access and benefit sharing

EU NT comment:

The Vice-chair has arguably made more changes to the text of 27 March than just the expected 'tweaks' in some paragraphs. The proposal now lands in between the EU and the AG approaches, but at the same time it represents neither of these approaches. Consequently, there is considerable vagueness and lack of clarity on how this PABS scheme would work in practice.

Conceptually, the EU's method of a threshold to put access and benefit sharing on equal footing has been deleted, suggesting that the scheme would become operational immediately following the entry into force of the agreement. With this approach it becomes, however, more difficult to understand why industry/manufacturers would want to participate in the system by concluding the PABS contracts. The Vice-chair has probably been driven by a wish to address the concerns expressed around free-riders and around the dependency on manufacturers for the entry into operation of the system. At the same time, with the current proposal it is not at all clear how benefit sharing would happen/be guaranteed with respect to manufacturers who would not sign PABS contracts. No clear/understandable SMTA model is foreseen or set out in the proposal (which is of course fortunate).

Furthermore, although the proposal specifically mentions, in para 3 b) and c), that all users "shall have legal obligations under PABS regarding benefit sharing" para 7 only refers to "entities that use biological materials and GSD **shared through the CLNs and SDBs**". Consequently, entities that have acquired the samples or GSD from other sources than the CLN or the SDBs are not covered by these benefit sharing provisions. Thus, in combination with the recognition that Parties are free to share beyond the CLNs and SDBs (which is of course also very welcome and as it should be), makes it very difficult, if not impossible, to understand how the benefit sharing obligations could possibly apply to "all users", as suggested in para 3 b) and c).

The risk is of course that the electronic notifications to be developed by the Parties will be seen/used as a method to 'fix' this deficiency by effectively turning the notifications into some sort of SMTAs. One can easily foresee very difficult discussions in this direction. So, the lack of the threshold to ensure that a critical mass of manufacturers is on board and thereby to guarantee that access and benefit sharing are on equal footing in the system, increases the risk for further appetite for an SMTA style approach. Therefore, it is very unfortunate that the Vice-chair has deleted the threshold provision.

Overall and in relation to the new text proposal, draft comments on the new text are set out below in connection to the relevant paragraphs identifying uncertainties, inconsistencies, and areas of concern to the EU. In these areas, alternative drafting will be needed and the EU will as relevant use and draw upon its previously submitted text proposal for these purposes. In a few cases, where the EU's PABS proposal does not necessarily address a specific issue in the current text, draft text suggestions are also set out in the text below. However, additional changes may be required.

1. The Parties hereby establish a multilateral system for access and benefit sharing for pathogens with pandemic potential: the WHO Pathogen Access and Benefit-Sharing System (PABS System).

2. The PABS System aims to ensure rapid, systematic and timely access to biological materials of pathogens with pandemic potential and the genetic sequence data (GSD) for such pathogens, which contributes to strengthened global surveillance and risk assessment, and facilitates research, innovation and development of health products; and on an equal footing,

equitable, fair and rapid sharing of monetary and non-monetary benefits, including timely, effective and predictable access to relevant diagnostics, therapeutics or vaccines, based on public health risks, needs and demand, contributing to the rapid and timely control of public health emergencies of international concern and pandemics.

3. When a Party has access to a pathogen with pandemic potential, it shall, using applicable biosafety, biosecurity and data protection standards:

(a) share with WHO any pathogen sequence information as soon as it is available to the Party;

(b) as soon as biological materials are available to the Party, provide the materials to one or more laboratories and/or biorepositories participating in WHO-coordinated laboratory networks (CLNs), which meet the [~~legally binding~~ Delete EU] terms of reference, as referenced below, with an electronic label of "PABS biological material" which will follow through to the end products and/or publications, and shall notify users of biological materials of the benefit-sharing provisions under the PABS System, recognizing that each Party may also share such biological materials to entities outside the CLNs. [~~All~~ Delete EU] [**These electronic label notifications shall serve to make**] users of biological materials [~~shall have legal obligations under~~ Delete EU] [**aware of the**] PABS [**system, including the provisions**] regarding benefit sharing; and

(c) as soon as pathogen GSD is available to the Party, upload the GSD and relevant metadata to one or more PABS sequence databases (SDBs) which meet the [~~legally binding~~ Delete EU] terms of reference, as referenced below, an electronic label of "PABS GSD" which will follow through to the end products and/or publications, and shall notify the users of GSD of the benefit-sharing provisions under the PABS System, recognizing that each Party may also share such GSD outside the SDBs. [**These electronic label notifications shall serve to make**] [~~All~~ Delete EU] users of GSD [~~shall have legal obligations under~~ Delete EU] [**aware of the**] PABS [**system, including the provisions**] regarding benefit sharing.

EU NT Comment regarding subparagraphs 3(a) and (b) above:

It is not possible to develop a system where 'all users' have legal obligations. This would presuppose a closed system combined with a SMTA-approach, alternatively the adoption of very far-reaching domestic legislation, neither of which are viable options to the EU. As these notifications do not form part of the EU's PABS proposal, alternative wording is therefore suggested in this regard.

4. The Parties consent to the further transfer and use of biological materials and GSD provided to the CLNs and SDBs, with an electronic label of "PABS biological material" or "PABS GSD", in accordance with the provisions of this Article including on benefit sharing, as well as applicable biosafety, biosecurity and data protection standards. Parties agree that intellectual property rights may not be sought on such materials and GSD.

5. The Parties agree that WHO shall develop, in accordance with the relevant templates to be developed by the Parties, as referenced in paragraph 11 below, as well as consistent with the WHO regulations for study, scientific groups, collaborating institutions and other mechanisms of collaboration, [~~legally binding~~ Delete EU] terms of reference for the CLNs and SDBs with [**appropriate**] arrangements to notify the users of biological materials and GSD of the benefit-sharing provisions of the PABS system.

EU NT comment:

The 'electronic label notifications are arguably too important for enabling certainty on how the system will function, to leave the development of these to future work. For the EU, the approach of an electronic notification conveyed in a way that is practically feasible for laboratories and databases is worth considering, but it must not be turned into a 'de facto' SMTA contract with legal consequences deriving solely from the sharing of a sample or GSD. Therefore, clarity around format and content of any such electronic notification is necessary. In addition, these terms of reference should not be labelled 'legally binding' as this would be misleading.

6. [**Following the adoption of this Agreement,**] WHO shall [**commence efforts aimed at**] conclud[e Delete EU][**ing**] legally binding standard PABS contracts with manufacturers[**. These contracts shall be agreed upon by the PABS system and the manufacturer and shall encompass**] [~~to provide~~ Delete EU] the following, taking into account the size, nature and capacities of the manufacturer:

EU NT comment:

The Parties cannot oblige the WHO, by way of a 'shall obligation' to conclude these contracts. These contracts are dependent on there being an interest from industry for their conclusion, i.e. the WHO alone cannot ensure that these contracts are concluded. In addition, the content of the contracts will have to be agreed upon mutually by the entity representing the PABS system and the manufacturer in question. Consequently, the details of the contracts cannot be set out in this article in an overly prescriptive manner.

(a) annual monetary contributions to support the PABS System and relevant capacities in countries; the determination of the annual amount, use, and approach for monitoring and accountability, shall be finalized by the Parties;

EU NT comment:

As we have been argued the annual contributions need to be set at a level that is perceived as reasonable by the manufacturers and that will still incentivize participation in the system. To ensure this the contributions should be decided between the representatives of the PABS system and the manufacturer. The size of the contributions should however be guided by specific aspects, to promote transparency and consistency with respect to manufacturers of similar size. It is not a useful way forward to try to decide amongst the Parties how much different manufacturers should contribute.

(b) real-time contributions of relevant diagnostics, therapeutics or vaccines produced by the manufacturer, 10% free of charge and 10% at not-for-profit prices during public health emergencies of international concern or pandemics, to be made available through the Network established under Article 13 for use on the basis of public health risks, needs and demand; and

EU NT comment: The set aside obligations are the same for pandemic situations as for PHEICs. As in the EU proposal, we suggest that there should be a difference between a pandemic situation and a PHEIC.]

(c) voluntary non-monetary contributions, such as capacity-building activities, scientific and research collaborations, non-exclusive licensing agreements, arrangements for transfer of technology and know-how in line with Article 11, tiered pricing for relevant diagnostics, therapeutics or vaccines.

EU NT comment: The word voluntary is key here and as long as that word is captured, this illustrative list of non-monetary benefits is agreeable.

7. The Parties agree on the following benefit-sharing provisions to be applied to users of biological materials and GSD shared through the CLNs and SDBs:

(a) entities that use biological materials and GSD shared through the CLNs and SDBs for commercial purposes, other than for the manufacture of diagnostics, therapeutics or vaccines, are to support the PABS System through voluntary contributions, taking into account the size, nature and capacities of the entity, such as monetary contributions, capacity-building activities, non-exclusive licensing agreements, arrangements for transfer of technology and know-how in line with Article 11, and/or scientific and research collaborations; and

EU NT comment: as the benefit sharing set out in (a) are all voluntary, and would therefore not build on an assumption of any legal obligations deriving from the usage as such, these suggested illustrative contributions could be acceptable.

(b) entities that use biological materials and GSD shared through the CLNs and SDBs for non-commercial purposes are to acknowledge the providers of the biological materials and GSD**[, where known,]** in relevant presentations or publications; contribute **[as relevant]** to public dissemination and transparency of research results; and, as appropriate, taking into account the size, nature and capacities of the entity, actively engage in scientific and academic collaborations, training and capacity-building activities, and consider voluntary monetary contributions to support the PABS System.

EU NT comment: if the providers are known to the entities, such acknowledgement could be acceptable. Qualifiers are however needed as suggested in (b).

Each Party, in respect of such a user operating within its jurisdiction, shall take all appropriate steps, in accordance with its relevant laws and circumstances, to encourage such a user to provide benefits in accordance with subparagraphs (a) and (b) above.

8. The Parties shall cooperate and take appropriate measures, such as conditions in public procurements or on public financing of research and development, prepurchase agreements, or regulatory procedures, to encourage and facilitate as many manufacturers as possible to enter into standard PABS contracts as early as possible.

EU NT comment: These measures are by and large acceptable as ways for Parties to encourage the conclusions of PABS contracts. The link to regulatory approval is however potentially problematic, as this would potentially open up for new requirements for such regulatory approvals.]

9. During a pandemic, each Party in a position to do so shall, within available resources and subject to applicable laws and in line with Article 13, set aside a portion of its total procurement of relevant diagnostics, therapeutics or vaccines in a timely manner for use in countries facing challenges in meeting public health needs and demand for relevant diagnostics, therapeutics or vaccines.

10. To support operationalization of the PABS System, WHO shall maintain updated lists of CLNs and SDBs, as well as of known pathogens that are pathogens with pandemic potential. WHO shall report regularly to the Parties on the conclusions of standard PABS contracts, and

shall make such contracts public, while respecting commercial confidentiality. WHO shall use measures such as prequalification and the WHO Emergency Use Listing Procedure to promote the PABS System and encourage manufacturers to conclude standard PABS contracts.

11. Templates for the standard PABS contracts and for legally binding terms of reference agreements with CLNs and SDBs shall be developed by the Parties.

EU NT comment:

Possibly the terms of reference for the CLNs and the SDBs could be developed by the Parties, after the adoption of the agreement. But as mentioned already, the contracts cannot be decided in all details by the Parties. They will ultimately have to be decided by the PABS system and the manufacturers who wish to enter such contracts. To provide transparency, predictability and consistency vis-à-vis different manufacturers, guidance can usefully be developed as part of the PABS system to this effect.

Comment on the lack of a paragraph with a threshold for PABS contracts: the important provision of the EU proposal of the threshold to ensure that a critical mass of the manufacturer would be on board, which was also reflected in para 11 of the text from 27 February, has been removed from this text. This would mean that there would be no guarantee of benefit sharing by way of concluded PABS contracts when the system enters into operation. This would mean that access and benefit sharing would not be on equally footing. Alternatively, it would presuppose a SMTA/PIP framework approach where the actual acquiring of a sample or GSD in itself would create legal obligations on benefit sharing. In line with the above, this is not a feasible option. Consequently, the threshold fills an important role in ensuring that access and benefit sharing are on equal footing, and it should therefore be brought back, in line with the EU's proposal.

12. The Parties who are Parties to the Convention on Biological Diversity and its Nagoya Protocol recognize that the PABS System, when fully operational, is consistent with and does not run counter to the objectives of the Nagoya Protocol; shall function as a specialized international access and benefit-sharing instrument; and is the applicable access and benefit- sharing system for biological materials and GSD for pathogens with pandemic potential. Accordingly, each such Party shall take effective legislative, executive, administrative or other measures at the appropriate government level to give effect to this recognition. Parties who are not Parties to the Convention on Biological Diversity and its Nagoya Protocol shall take such measures with respect to any relevant domestic legislation to ensure alignment with the objectives and implementation of this provision.

EU NT comment: it is not clear what the beginning of paragraph 12 means ("The Parties who are Parties to the Convention on Biological Diversity and its Nagoya Protocol recognize that the PABS System, when fully operational (…)"). The text opens for different interpretation, thus leading to uncertainty and significant lack of predictability, i.e. the opposite of the clarity around the application of NP that we hope to achieve with the PABS system.

13. The Parties shall cooperate to support the effective operation of the PABS System, including by taking all necessary steps to facilitate the shipment of biological materials, and the export of necessary health products during a public health emergency of international concern or pandemic, in accordance with applicable international law.

14. The Conference of the Parties shall regularly review the operation, monitor adherence and effectiveness of the PABS System and shall take the decisions necessary to promote and support

its effective and sustainable implementation.

Article 13. Supply chain and logistics

1. The Global Supply Chain and Logistics Network (the Network) is hereby established[. ~~The Network shall be~~ Delete EU] [**as a partnership**] developed, coordinated and convened by WHO [~~in partnership with the Parties~~ Delete EU] and other relevant international and regional stakeholders, and shall be guided by the principles of equity, transparency, inclusivity, timeliness[~~, fairness~~ Delete EU] and consideration of public health needs. The Network shall pay particular attention to the needs of developing countries, including those in fragile and humanitarian settings.

2. The Conference of the Parties shall[~~, at its first meeting, define the structure and modalities of~~ Delete EU] [**provide guidance to**] the Network, [~~which shall~~ Delete EU] [**with the**] aim [~~at ensuring~~ Delete EU] [**to promote**] the following:

(a) collaboration among the Parties and other relevant stakeholders during and between pandemics;

(b) assignment of functions to stakeholders based on competencies and expertise; and

(c) accountability and transparency in the functioning of the Network.

3. The Parties shall periodically review the operationalization of the Network, including the support provided by Parties and other stakeholders during and between pandemics.

4. The functions of the Network shall include:

(a) identifying the types of pandemic-related [**health**] products and estimating the quantities needed and anticipated demand for robust pandemic prevention, preparedness and response;

(b) identifying[**, assessing and keeping under review]** the sources of safe, effective and quality assured pandemic-related products, including raw materials and potential surge capacities [~~as well as developing and maintaining a tool for this purpose~~ Delete EU];

(c) identifying, assessing, keeping under review and facilitating the most efficient means of procuring quality pandemic-related [**health**] products, [~~potentially~~ Delete EU] including pooled procurement and/or advance purchase agreements, to enhance equitable, timely and affordable access to these products;

(d) promoting transparency in cost, pricing and other relevant data on products, including raw materials, across the value chain;

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

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

(g) facilitating the equitable allocation of pandemic-related [**health**] products [**made**

available to] [~~, including those procured through the facilitation by~~ Delete EU] the Network[~~, acquired through the PABS or donated by countries as referred to in Article 13bis, subparagraph 2~~ Delete EU], based on public health risks and needs, and taking into account factors, such as 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, as appropriate, through regional stockpiles, consolidation hubs and staging areas, while taking into account specific requirements for [~~these pandemic-related~~ Delete EU] [**such**] products, including in humanitarian settings; and

(i) assisting countries in meeting the requirements for the effective utilization of specific pandemic-related products, as needed and requested.

5. The [~~WHO, as the convenor of the~~ Delete EU] Network[~~,~~] shall report regularly to the Conference of the Parties on all matters relevant to the implementation of this Article.

Article 13*bis*: National procurement- and distribution-related provisions

1. Each Party shall publish the terms of its government-funded purchase agreements for pandemic-related [**health**] products at the earliest reasonable opportunity [~~and in accordance with applicable laws,~~ Delete EU] and shall exclude confidentiality provisions that serve to limit such disclosure [**in accordance with domestic laws and policy**]. Each Party shall also encourage regional and global purchasing mechanisms to do the same.

2. Each Party, in accordance with [~~national~~ Delete EU] [**domestic**] laws [**and policy**], shall include 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 [**to such purchase agreements**] in order to address supply gaps around the world;

(c) [~~incentivize or otherwise~~ Delete EU] encourage [**voluntary**] licensing and other transfer of technology, in particular for the benefit of developing countries; and

(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 respond to a pandemic are targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.

4. The Parties 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 [~~of recognized humanitarian organizations~~ Delete EU] for the provision of humanitarian assistance.

5. 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, and taking into account the circumstances of recipient countries.

6. Each Party shall ensure that any national stockpiles do not unnecessarily exceed quantities needed for domestic public health emergency preparedness and response.

7. Whenever possible, when sharing pandemic [~~emergency response~~ Delete EU] [**related health products**] with countries, organizations or any mechanism that is facilitated by the Network, 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 with identified~~ Delete EU] [**take into account the**] 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 Parties 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 Parties 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 by essential ancillaries [**as far as possible**] and coordinated with the availability of support for distribution and administration, to ensure rapid allocation and absorption.

8. Each Party shall facilitate the effective distribution, delivery and administration of pandemic-related products in its domestic market.

Article 14. Regulatory systems strengthening

EU NT comment:

The proposed text for Article 14 is to be supported. It is largely based on the proposed text discussed at INB 8 and takes many suggestions presented by the EU into account.

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

2. Each Party shall take steps to ensure that it has legal, administrative and financial frameworks[~~, as appropriate,~~ Delete EU] in support of:

(a) issuing [~~emergency~~ Delete EU] [**urgent regulatory**] authorizations and approvals for pandemic-related **[health]** products and[~~/or~~ Delete EU], as appropriate, regulatory reliance processes for the timely authorization and approvals of such products, consistent with [~~national~~ Delete EU] [**domestic**] law, as well as systems to provide oversight of the quality, safety and efficacy of those products; and

(b) monitoring adverse events of such products through effective pharmacovigilance and post-marketing surveillance.

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

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

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

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

(b) information on the pandemic-related **[health]** products that it has authorized or approved, based on quality, efficacy and safety, and any other information on which the decision was based.

The Parties encourage WHO to facilitate access to the information referred to in this paragraph.

6. Each Party shall endeavor to, subject to [~~national~~ Delete EU] [**domestic**] laws:

(a) adopt, where needed, regulatory reliance processes in its national regulatory frameworks for use during pandemic emergencies, taking into account relevant guidelines;

(b) converge and/or align and, where possible, harmonize relevant technical and regulatory requirements, in accordance with applicable international standards and guidance; and

(c) provide support to help strengthen national regulatory authorities' and regional regulatory systems' ability to respond to pandemic emergencies, as appropriate, through [~~efforts such as~~ Delete EU] technical assistance, capacity-building, training and information exchange consistent with [~~national~~ Delete EU] [**domestic**] law.

7. Each Party may consider adopting, within the limits of its [~~national~~ Delete EU] [**domestic**] legislation, policies and legal practices, guidance and technical documents concerning medical products from relevant international regulatory harmonization initiatives or organizations and other relevant global or regional regulatory forums.

8. The Parties shall undertake to cooperate, to the extent possible, directly or indirectly and[~~/or~~ Delete EU] through relevant international bodies including WHO and other relevant partners, to support and improve regulatory capacity with the goal of enhancing the maturity level of the regulatory bodies, as assessed by WHO, and facilitating equitable geographical distribution and scaling up of the global production of medical products.

Article 15. Liability and compensation management

EU NT comments:

The proposed text for Article 15 has been further shortened and remains focused exclusively on vaccines. The new paragraph 1 is a streamlined version of the previous paragraphs 1 and 2 and can be considered as an improvement comparing to the previous version.

Only minor EU drafting suggestions have been taken on board. For example, the coverage of people in vulnerable and humanitarian situations remains addressed with relatively soft language under a new paragraph 2. To be noted that previous paragraph 3, laying down the requirement for indemnity clauses in supply/ purchase contracts to be exceptionally provided and be limited in time, has not been reintroduced despite the EU suggestion to do so.

1. Each Party shall consider developing, as necessary and in accordance with applicable law, national strategies for managing liability in its territory related to **[novel]** pandemic vaccines and shall make such strategies publicly available. Strategies may include, inter alia, legal and administrative frameworks; no-fault compensation mechanisms [**for serious adverse events resulting from the use and/or administration of novel vaccines developed for response to pandemics**], [~~potentially~~ Delete EU] [**including**] [~~funded by~~ Delete EU] private sector contributions; policies and other approaches for the negotiation of procurement and/or donation agreements. [**Such compensation mechanism(s) shall take into account the situation of individuals that are in humanitarian setting or in vulnerable situations.]**

EU NT comment: Paragraph 1 could be supported with the drafting suggestions above. More details on the added value and feasibility of making strategies publicly available would be needed.

2. The Parties, within the framework of the Conference of the Parties, in collaboration with relevant entities and multilateral organizations, as appropriate, shall develop recommendations [~~for~~ Delete EU] **[and facilitate]** the establishment and implementation of national, regional and/or global no-fault compensation mechanisms and strategies for managing liability during pandemic emergencies, including with regard to individuals that are in a humanitarian setting or vulnerable situations.

[**3. 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

EU NT comment:

While there have been some improvements for more specificity, our previous comments in relation to Article 16 still stand: Article 16 includes a set of general commitments for Parties, which are defined at a too high level, making it difficult to see how they would be implemented in a concrete manner.

Several EU comments have been taken on-board, such as removing unclear wording (e.g.: in subparagraph 2(b)). Subparagraph 2(c) referring to human rights and subparagraph 2(f) referring to ceasefires have been removed.

1. The Parties shall collaborate and cooperate in global coordinated actions, with WHO and other relevant international organizations, as well as among themselves, in pandemic prevention

preparedness and response, and in the implementation of this Agreement.

EU NT comment (same as last time): added value of paragraph 1 appears unclear in comparison to other more operational provisions included in the Agreement.

2. The Parties shall:

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

[**(a bis) develop and implement policies that respect, protect and fulfil the human rights of all people;**]

(b) ensure that policy decisions are science- and evidence-based;

(c) promote equitable representation as well as the equal and meaningful participation in national, regional and global decision-making processes; and

(d) provide support to countries, upon request, through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs for pandemic prevention, preparedness and response; and develop[**, in cooperation with WHO and other relevant international organizations, and while taking into account the International Health Regulations,**] measures aimed at preventing the stigmatization of, and promoting solidarity with, countries that report public health emergencies.

EU NT comment (same as last time):

As previously commented, the EU supports the objective of the first sentence, related to the provision of capacity building. However this sentence duplicates the provisions of Article 19 paragraph 2 and its added value is therefore unclear.

The second part of the subparagraph can overall be supported, with drafting suggestions. WHO should have a strong role for preventing stigmatization by fighting disinformation.

Article 17. Whole-of-government and whole-of-society approaches

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 establish or strengthen, and maintain, a national [**, and where possible regional,**] [~~coordination~~ Delete EU] multisectoral [~~body~~ Delete EU] [**mechanism**] for [**institutional coordination, of**] pandemic prevention, preparedness and response.

3. Each Party shall, taking into account its national circumstances, promote the effective and meaningful engagement of communities, and other relevant stakeholders, as part of a whole- of-society approach in planning, decision-making, implementation, monitoring and evaluation, and shall also provide effective feedback opportunities.

4. Each Party shall develop, [**regularly update and implement**] in accordance with [**domestic laws, and in the light of**] national [**and regional**] context[**s**], comprehensive[**, multisectoral and resourced**] national [**, and where relevant regional,**] pandemic prevention, preparedness and response plans that [~~address pre-, post- and interpandemic periods that,~~ Delete EU] inter alia:

EU NT comment: Given that paragraph 1 referring to the preparedness plans and strategies has

been deleted from Article 8 of the revised Bureau's proposal, we suggest the equivalent drafting suggestions under Article 17 paragraph 4 below. In view of scarce resources, we need to consider the complementarity with the IHR, as well as coherence with the requirements under the EU Regulation on serious cross-border health threats (2022/2371).

[(a) include comprehensive multisectoral pandemic prevention measures, based on the One Heath approach, in line with the requirements set out under Articles 4 and 5;]

[~~(a)~~] **[(b)]** identify and prioritize, as appropriate, populations, based on public health risk and need, for access to pandemic-related **[health]** products and health services;

[~~(b)~~] **[(c) facilitate the timely allocation of resources to the frontline pandemic response]** [~~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~~ Delete EU];

EU NT comment: We suggest deleting the reference to the mobilisation of resources in order to avoid duplication with provisions under Articles 7, 19 and 20.

[~~(c)~~] **[(d)]** 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 **[health]** products;

[~~(d)~~] **[(e)]** facilitate the rapid and equitable restoration of public health capacities and routine and essential health services during and following a pandemic **[emergency]**; and

[~~(e)~~] **[(f)]** promote collaboration with relevant stakeholders, including the private sector[**, academic institutions**] and civil society, [**while**] avoiding all forms of conflicts of interest[~~, in a~~ Delete EU] [**and ensuring**] transparen[~~t~~ Delete EU][**cy**] [~~manner~~ Delete EU].

[**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.**]

5. Each Party, based on national capacities, shall take the necessary steps to address the social, environmental and economic determinants of health and shall work to prevent or mitigate the socioeconomic impacts of pandemics.

6. 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

EU NT comment:

Article 18 has been condensed, taking on-board very few of the suggestions submitted by the EU at INB 8.

References to public health education, literacy and awareness in the population, which were previously included under paragraphs 1 and 5 of Article 18 have disappeared (previous paragraph 5 has been entirely removed). The EU considers that these are important elements that should be reflected in Article 18. The simplification of the language in paragraph 1 can therefore be supported, provided that the main elements of the previous paragraph 5 are reintroduced.

1. Each Party shall promote 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 on the efficacy and safety of pandemic-related health products,**] with the aim of countering and addressing misinformation or disinformation, particularly through risk communication and effective community-level engagement.

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

3. The Parties shall promote and apply science- and evidence-based approaches**[, including in relation to social and behavioral sciences,]** to effective and timely risk assessment, and culturally appropriate public communications.

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

5. **[The Parties shall promote and facilitate, in accordance with domestic law and approaches, the development and implementation of risk communication strategies and education and public awareness programmes on outbreaks and pandemic emergencies, with the participation of all stakeholders, including health professionals, communities and civil society, and in a way that is broadly accessible, including to persons in vulnerable situations and people living in humanitarian settings.]**

Article 19. Implementation and support

EU NT comments:

- *Overall comment on the link between articles 19 and 20 of the draft PA and article 44 of the draft amendments to the IHR:*

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 that will be agreed in articles 19 and 20 of the PA should, as relevant, be replicated also in article 44 of the amended IHR to ensure that the arrangements will apply to both instruments alike. With such approach to ensure consistency across the PA and the amended IHR, there is no need for the proposal of referring to the "Cooperating Parties" etc.

- *On the new version of articles 19 and 20***:**

As regards articles 19 and 20 the new version from the bureau presented on 8 March is very similar to the previous version presented by the vice chair of the sub group on articles 19 and 20. Consequently, our previous EU-text proposals are still very valid and relevant, with only a need for some minor adjustments here and there to adapt to the small adjustments that have been made by the bureau in this new version.

1. The Parties shall cooperate, directly [~~and/~~ Delete EU] or through relevant regional or international [~~bodies~~ Delete EU] [**organizations**], to sustainably strengthen **[their]** pandemic prevention, preparedness and response capacities [~~in countries, particularly developing countries,~~

~~which are Parties to the WHO Pandemic Agreement or the International Health Regulations (2005) (hereinafter referred to collectively as "Cooperating Parties")~~ Delete EU], taking into account especially the needs of [~~developing countries~~ 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 (2005). Such cooperation shall promote the [**voluntary**] sharing or transfer of technology and technical, scientific and legal expertise, 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**].

3. The [~~WHO~~ Delete EU] Secretariat, [~~supporting the WHO Pandemic Agreement and the International Health Regulations (2005),~~ Delete EU] following the guidance of the Governing Bodies, [**and**] 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,~~ Delete EU] [**in the identification of support needs in implementing the commitments under the Pandemic Agreement**], and [~~organize~~ Delete EU] [**in the organization of**] the technical [~~and financial~~ Delete EU] assistance [**and capacity building activities provided for in this Article, with particular regard to the needs of the least developed country Parties and other Parties in need**] [~~necessary to address such gaps and needs in implementing the commitments agreed upon under the Pandemic Agreement and the International Health Regulations (2005)~~ Delete EU].

EU NT 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.

Article 20. Sustainable financing

EU NT comment regarding the link between articles 19 and 20 of the draft PA and article 44 of the draft amendments to the IHR:

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 that will be agreed in articles 19 and 20 of the PA should, as relevant, be replicated also in article 44 of the amended IHT to ensure that the arrangements will apply to both instruments alike. With such approach to ensure consistency across the PA and the amended IHR, there is no need for the proposal of referring to the "Cooperating Parties" etc.

1. The Parties commit to working together to strengthen sustainable financing [~~for~~ Delete EU]

[**of**] 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**]:

EU NT comment: In line with the overall introductory comment above, the financial strategy could also encompass the IHR 2005 as amended and if so the text of paragraph 1, as well as the relevant provision in the IHR as amended, should reflect this.

(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 (2005); (ii) implementing national plans, programmes and priorities; and (iii) strengthening health systems resilience;

(b) mobilize financial resources through all sources, including existing and [~~new~~ Delete EU] [**future**] bilateral, sub-regional, regional and multilateral funding mechanisms, [**in complementarity with domestic funding as outlined under subparagraph (a),**] to assist in particular [~~developing~~ Delete EU] [**the least developed**] country Parties [**and other Parties in need**], in the implementation of the WHO Pandemic Agreement, including through grants and concessional loans;

(c) promote, within relevant bilateral, regional and/or multilateral mechanisms, innovative [**means of**] financing [~~measures, including but not limited to debt relief, based on transparent financial reprogramming plans for pandemic prevention, preparedness, response and recovery of health-system related actions, for affected countries whose debt payment might affect expenditures on pandemic prevention, preparedness and response, and in the case of pandemics, take measures for debt relief, including the suspension of debt servicing and debt cancellation~~ Delete EU]; and

EU NT comment: as currently drafted, subparagraph (c) cannot be supported. 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 governing bodies of the [~~Cooperating Parties~~ Delete EU] [**Conference of the Parties**] shall adopt, [**by consensus**] every five years a Financial and Implementation Strategy [~~on pandemic prevention, preparedness and response~~ Delete EU] [**of the WHO Pandemic Agreement**]. The Parties[~~, particularly those providing financial support for the strengthening of pandemic prevention, preparedness and response,~~ Delete EU] shall [~~align with~~ Delete EU] [**take into account**] the Financial and Implementation Strategy [**defined by the Conference of the Parties**] while financing [**pandemic prevention, preparedness and response**] [~~the relevant funding mechanisms, both within and outside WHO~~ Delete EU].

EU NT comment: in line with the overall introductory comment above, 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 is hereby defined. The Conference of the Parties 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 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 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:

(a) **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;**

(b) **facilitate coordination among existing sources of financing to fund implementation support activities;**

(c) **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;**

(d) **increase the transparency, accountability, inclusiveness, efficiency and effectiveness of financing for implementation;**

(e) **report periodically to the Conference of Parties 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:

(a) voluntary monetary contributions from Parties;

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

[~~3. A Coordinating Financial Mechanism (the "Mechanism") is hereby established to support the implementation of both the WHO Pandemic Agreement and the International Health Regulations (2005) in a sustainable, predictable, inclusive and transparent manner and accountable to the governing bodies of the Cooperating Parties. The mechanism aims to increase the effectiveness and efficiency of existing and future financial mechanisms, 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.~~ Delete EU]

EU NT 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. The Mechanism shall include a pooled fund to provide financing to support, strengthen and expand capacities for pandemic prevention, preparedness and response, and as necessary for day zero surge response, in Cooperating Parties that require financial support. The fund may include sources from 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 Conference of the Parties.~~

~~5. The Mechanism will also promote harmonization and coordination for financing pandemic prevention, preparedness and response and International Health Regulations related capacities.~~ Delete EU]

EU NT comment: paragraph 4 appears to be redundant as this provision will also be included in the IHR as amended.

[~~6. The Mechanism shall, inter alia:~~

~~(a) identify financing instruments and mechanisms that are available to serve the purposes of pandemic prevention, preparedness and response, 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 Conference of the Parties, working arrangements with relevant identified financing instruments and entities to facilitate their alignment with the Financial and Implementation Strategy;~~

~~(c) provide advice and support, upon request, to Cooperating Parties in identifying and applying in order to obtain access to financial resources in accordance with national pandemic prevention, preparedness and response priorities and identified needs;~~

~~(d) assess the availability of funds, and support the mobilization of financial resources free from conflict of interest; and~~

(e) ~~conduct relevant analyses on needs and gaps, in addition to tracking cooperation efforts, to inform the development of the Financial and Implementation Strategy, guide Cooperating Parties and recommend course corrections as necessary.~~ Delete EU]

[~~7~~][**6.**] The [**Coordinating**] Mechanism[~~, including its fund,~~ Delete EU] shall function under [~~the authority and~~ Delete EU] guidance of the Conference of the Parties and be accountable to it. [~~The Conference of the Parties 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]

[**7. The Conference of the Parties and the entity or entities entrusted with the operation of the coordination mechanism shall agree upon arrangements to give effect to the above paragraphs.**]

EU NT comment:

We propose adding a new paragraph 7 to address the need for a link to be established between the COP 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 UNFCC. This paragraph will need to be revised in light of the further drafting of the institutional arrangements applicable to the COP, to ensure consistency.

4. The Conference of the Parties shall periodically review the effectiveness of the [**Coordinating**] Mechanism, such as policies, operational modalities and activities, and its first revision should be carried out no less than two years after its establishment.

Chapter III. Institutional and final provisions

Article 21. Conference of the Parties

1. A Conference of the Parties is hereby established.

EU NT comment: the denomination (COP/ Governing Body) remains to be discussed.

2. The Conference of the Parties 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 reports submitted by the Parties in accordance with Article 23 and adopt regular reports on the implementation of the WHO Pandemic Agreement;

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

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

(d) [~~consider and review developed countries' reports on their contribution to the implementation of the WHO Pandemic Agreement or any other assistance offered towards developing countries 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]

EU NT comment: Reporting of Parties is covered by subparagraph 2(a). Delete subparagraph (d).

(e) 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;

(f) 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;

(g) provide guidance to the WHO Director-General and to Parties, on effective implementation of the WHO Pandemic Agreement including the matters considered in paragraph[~~s~~] (a) [~~and (d)~~ Delete EU]; and

(h) 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. The first session of the Conference of the Parties shall be convened by the World Health Organization not later than one year after the entry into force of the WHO Pandemic Agreement. The Conference of the Parties will determine the venue and timing of subsequent regular sessions at its first session.

4. Extraordinary sessions of the Conference of the Parties shall be held at such other times as may be deemed necessary by the Conference of the Parties, or at the written request of any

Party, provided that, within six months of the request being communicated in writing to the Parties by the Secretariat, it is supported by at least one-third of the Parties. **[Such extraordinary sessions may be called at the level of Heads of State or Governments.]**

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

6. **[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 Conference of the Parties as observers. Any other body or agency, whether national or international, governmental or non-governmental, including civil society and the private sector, that is qualified in areas covered by the Agreement and has requested the Secretariat to participate in the sessions of the Conference of the Parties as an observer, is admitted unless 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 Conference of the Parties.**] The Conference of the Parties shall establish the [~~criteria for~~ Delete EU] [**rules applicable to**] the participation of observers at its proceedings.

7. The Conference of the Parties shall by consensus adopt financial rules for itself as well as governing the funding of any subsidiary bodies it may establish as well as financial provisions governing the functioning of the Secretariat. At each ordinary session, it shall adopt [**by consensus**] a budget for the financial period until the next ordinary session.

8. The Conference of the Parties may establish subsidiary bodies, as it deems necessary, and on terms and modalities to be defined by the Conference of the Parties.

EU NT comment: The EU will continue to support the establishment of a Scientific Committee and of an Implementation Committee.

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 organisation 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 organisation 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 Conference of the Parties

1. Each Party shall submit to the Conference of the Parties, through the Secretariat, periodic reports on its implementation of the WHO Pandemic Agreement.

2. The frequency and format of the reports submitted by all Parties shall be determined by the Conference of the Parties.

3. The Conference of the Parties 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~~ Delete EU] [**the least developed**] country Parties.

4. The reporting and exchange of information under the WHO Pandemic Agreement shall be subject to [~~national~~ Delete EU] [**domestic**] law regarding confidentiality and privacy. The Parties shall protect[~~, as mutually agreed,~~ Delete EU] any confidential information that is exchanged.

Article 24. Secretariat

1. Secretariat functions for the WHO Pandemic Agreement shall be provided by the Secretariat of 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 technical, administrative, and logistic support to the Conference of the Parties and its subsidiary bodies as may be established under the WHO Pandemic Agreement or by the Conference of the Parties for the purpose of the implementation of the WHO Pandemic Agreement;

(b) make arrangements for the sessions of the Conference of the Parties 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~~ Delete EU] [**including**] developing country Parties [**and with particular attention to the needs of least developed country Parties**], in implementing the WHO Pandemic Agreement, including the compilation and communication of information required in accordance with the provisions of the WHO Pandemic Agreement or pursuant to requests of the Conference of the Parties;prepare reports on its activities under the WHO Pandemic Agreement under the guidance of the Conference of the Parties, and to submit them to the Conference of the Parties;

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

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

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

Article 25. 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 continuing to seek to resolve it**[, including, if they so agree, 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]**.

~~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 ad hoc arbitration in accordance with the Permanent Court of Arbitration Rules of 2012.~~ Delete EU]

EU NT comment: added value unclear.

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

Article 26. Relationship with other international agreements and instruments

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.

EU NT comment: paragraph 1 could be moved to Article 3.

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

3. 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.

Article 27. Reservations

1. Reservations may be made to the WHO Pandemic Agreement unless incompatible with the object and purpose of the WHO Pandemic Agreement.

2. [Notwithstanding paragraph 1 above, no reservation may be made to Article XX, Article YY, or Article ZZ of the WHO Pandemic Agreement. Reserve EU]

EU NT Comment: Reserve on paragraph 2. Whether to exclude the possibility to lodge reservations will need to be assessed on a case-by-case basis.

Article 28. Declarations and statements

1. Article 27 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 29. Amendments

1. Any Party may propose amendments to the WHO Pandemic Agreement, including its annexes and protocols. Such amendments shall be considered by the Conference of the Parties.

2. The Conference of the Parties 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.

5. An 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 30. Annexes

1. Annexes to the WHO Pandemic Agreement shall be proposed, adopted and shall enter into force in accordance with the procedure set forth in Article 29.

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.

Article 31. Protocols

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

2. The Conference of the Parties may adopt protocols to the WHO Pandemic Agreement. In adopting these protocols, every effort shall be made to reach consensus. If all efforts at consensus have been exhausted and no agreement has been reached, the protocol 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.

EU NT comment: the last sentence 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 Conference of the Parties 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.

5. Any protocol to the WHO Pandemic Agreement shall be binding only on the Parties to the protocol in question. Only Parties to a protocol may take decisions on matters exclusively relating to the protocol in question.

6. The requirements for entry into force of any protocol shall be established by that instrument.

Article 32. Withdrawal

1. At any time after two years from the date on which the WHO Pandemic Agreement has entered into force for a Party, that Party may withdraw from the 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. A State shall not be discharged by reason of the withdrawal from the obligations which accrued while it was a Party to the WHO Pandemic Agreement, nor shall the withdrawal affect any right, obligation or legal situation of that State created through the execution of this Agreement prior to its termination for that State.

4. 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 33. 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 34. 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 Depositary.

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]**. These organizations shall also inform the Depositary, who shall in turn inform the Parties, of any substantial modification in the extent of their competence.

Article 35. Entry into force

1. This Agreement shall enter into force on the thirtieth day following the date of deposit of the fortieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary.

2. For each State that ratifies, accepts or approves the WHO Pandemic Agreement or accedes thereto after the conditions set forth in paragraph 1 of this Article for entry into force have been fulfilled, the WHO Pandemic Agreement shall enter into force on the thirtieth day following the date of deposit of its instrument of ratification, acceptance, approval or accession.

3. For each regional economic integration organization depositing an instrument of formal confirmation or an instrument of accession after the conditions set forth in paragraph 1 of this Article for entry into force have been fulfilled, the WHO Pandemic Agreement shall enter into force on the thirtieth day following the date of deposit of its instrument of formal confirmation or of accession.

4. For the purposes of this Article, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by Member States of

that regional economic integration organization.

Article 36. 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 37. 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.

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