

EU Drafting suggestions on Articles 4 to 19 of the Intergovernmental Negotiating Body Bureau's proposal for negotiating text of the WHO Pandemic Agreement¹

The drafting suggestions outlined herein are the suggestions presented by the EU on Articles 4 to 19 of the Intergovernmental Negotiating Body (INB) Bureau's proposal for negotiating text of the WHO Pandemic Agreement¹. More specifically:

- The drafting suggestions for Article 4 represent a recasting and a revision of earlier EU proposals in light of current discussions. While the EU input includes some of the elements set out in Article 4 of the INB Bureau's proposal for negotiating text, we propose to revisit the structure of Article 4 to provide more clarity and details on the necessary elements for a robust pandemic prevention framework. The elements related to surveillance, which were included in previous EU proposals, and which are an essential component of any robust framework on pandemic prevention, have been set aside for the moment, to acknowledge the positions of several WHO Member States that these elements should be further considered within the framework of the Working Group on amendments to the International Health Regulations (2005) (WGIHR)².
- The drafting suggestions for Articles 5 to 19 are inserted in the INB Bureau's proposal for negotiating text. Proposals for additions are indicated in bold underlined, in square brackets. Proposals for deletion are set out by way of strike through, in square brackets. Comments or explanations are provided in blue italics.

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

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¹ Proposal for negotiating text of the WHO Pandemic Agreement (https://apps.who.int/gb/inb/pdf_files/inb7/A_INB7_3-en.pdf)

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

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Article 4. Preventing pandemic situations

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

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

Section A – Pandemic prevention strategies

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

Section B – Infection prevention

4. The Parties shall undertake actions to strengthen infection prevention and control, at all levels, including, but not limited to, households, communities and healthcare facilities, as well as in the veterinary sector, with the aim of preventing pandemic situations. To this end, each Party shall, within its territory:
 - (a) strengthen efforts to ensure access to safe water, sanitation and hygiene, as well as access to appropriate health services for diagnosis and treatment, including in hard-to-reach settings;
 - (b) strengthen efforts to guarantee timely access to effective immunization programmes;
 - (c) require healthcare facilities to adopt and regularly update an infection prevention and control programme, with appropriate resources and staff, and ensure the implementation of effective infection prevention and control measures applying the relevant international standards and guidelines; and
 - (d) strengthen efforts to ensure the appropriate management of waste from health facilities, veterinary practices, and live animal settings.

Section C – Preventing and controlling zoonotic spill-overs

5. The Parties shall, in accordance with their international obligations, undertake actions to strengthen animal disease preventive measures, with the aim of preventing and controlling the risk of zoonotic disease spill-over and spill-back. Such actions include:
 - (a) Adopting strategies aimed to mitigate the impacts of environmental factors on the risk of zoonotic diseases, including air-, vector- and water-borne pathogens and diseases, such as air and water pollution, climate change, biodiversity loss, land use change and ecosystem degradation;
 - (b) Promoting the adaption of farming practices, including within the context of intensive animal farming, also with the aim of preventing the emergence and spread of antimicrobial resistant pathogens;
 - (c) Establishing, strengthening, monitoring and enforcing as appropriate hygienic practices and risk management measures in markets handling live animals and live wildlife;
 - (d) Developing, strengthening and maintaining animal welfare policies and practices to ensure the humane and adequate treatment of wildlife, farm and companion animals at all stages of their

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trading, rearing, transport and slaughter, as well as to improve hygiene and, where possible, reduce long distance transportation of live animals; and

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

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

Section D – Control of wildlife trade

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

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

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

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

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

In order to promote prudent use of antimicrobials, each Party shall develop and implement measures to ensure that antimicrobials for human health and veterinary use are sold based on prescription of authorised professionals for health purposes.

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

11. Parties shall collect and report infection and AMR surveillance data in humans, animals, plants and the environment in line with minimum requirements established in Quadripartite organisations' standards and guidance, as well as data on antimicrobial use in humans, animals and plants. Parties shall apply relevant surveillance and data collection systems developed by intergovernmental bodies including, as appropriate, the Codex Alimentarius Commission and the Quadripartite organisations.

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Section F – Strengthening biosafety and biosecurity

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

Section G – Implementation support and capacity building

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

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

15. The support activities under this Article shall be closely coordinated with the provision of support under the IHR. The Parties and Secretariat shall report on the results obtained to the Conference of the Parties at least every two years. The reports shall be examined by the Implementation and Compliance Committee for the purpose of identifying general or specific problems requiring action by the Conference of the Parties or by the Parties concerned.

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

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

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Article 5. One Health

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

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

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

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

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

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

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

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

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

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

~~[6.]~~ **[4.]** Pursuant to Article 21 herein **[and no later than [...] after the entry into force of the Agreement]**, the Conference of the Parties shall, **[on the basis of the findings and recommendations of the Panel of Expert provided for Article [...], as well as of the advice of relevant international organizations, in particular the Quadripartite organisations, and other relevant organisations and bodies, adopt guidelines, recommendations, standards and other instruments, as necessary, to guide**

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and support the Parties in the adoption of national] measures **[aimed at the implementation of the provisions]** set forth in Articles 4 and 5 of this Agreement.

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

Article 6. Preparedness, readiness and resilience

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

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

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

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

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

~~[(c) collaborative surveillance, outbreak detection, investigation and control, through interoperable early warning and alert systems, and timely notification; Delete EU]~~ *[Comment: The EU strongly supports provisions aimed at strengthening surveillance capacities and requirements. Yet, deletion of subparagraph (c) is proposed to take into account the views expressed by several WHO Member States that these elements should be further considered within the framework of the Working Group on amendments to the International Health Regulations (2005) (WGIHR). Same rationale applies to the deleted subparagraphs (f) and (g), as well as paragraph 4 below.]*

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

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

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

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

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

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

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

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

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

Article 7. Health and care workforce

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

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

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

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

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

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

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

~~[3. The Parties shall invest in establishing, sustaining, coordinating and mobilizing a skilled and~~

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

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

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

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

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

Article 8. Preparedness monitoring and functional reviews

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

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

- [(a) identify and prioritize populations for access to pandemic-related health products and health services during a pandemic;
- (b) facilitate the timely allocation of resources to the frontline pandemic response;
- (c) review the status of stockpiles and the surge capacity of essential public health and clinical resources, and the surge capacity in production of pandemic-related health products;
- (d) facilitate the rapid and equitable restoration of public health capacities and routine and essential health services following a pandemic; and

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(e) promote collaboration and coordination with relevant stakeholders, including civil society, academic institutions and the private sector.

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

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

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

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

Article 9. Research and development

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

2. To this end, the Parties shall promote:

- (a) sustained investment in the research and development of public health priorities, including for pandemic-related **[health]** products, aimed at improving equitable access to and delivery of such products, and support for national and regional research institutions that can rapidly adapt and respond to research and development needs in case of a pandemic;
- (b) technology co-creation and joint venture initiatives, actively engaging the participation of and collaboration among scientists and/or research centres **[from both public and private sector]**, particularly from developing countries;
- (c) participation of relevant stakeholders, consistent with applicable biosafety and biosecurity obligations, laws, regulations and guidance, to accelerate innovative research and development, including community-led and cross-sector collaboration, **[including on activities involving animals that pose a risk of spillover of pathogens to humans,]** for addressing emerging and re-emerging pathogens with pandemic potential; ~~[and Delete EU]~~
- (d) knowledge translation and evidence-based communication tools, strategies and partnerships relating to pandemic prevention, preparedness and response, including infodemic management, at local, national, regional and international levels[.];

[(e) joint scientific research programmes, projects and partnerships on the causes, enabling factors and effects of pandemics, on their prevention and management, and on relevant

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medical and other countermeasures, including preventive, diagnostic and therapeutic countermeasures, with the specific aim to increase the availability, affordability and quality of such countermeasures;

- (f) regional and international collaboration and exchange of information between research institutions, funding organisations as well as individual scientists, including national, regional and international research and development networks that are able to rapidly respond in case of a pandemic situation;
- (g) support and capacity building programmes, projects and partnerships for the development, dissemination and use of technical and scientific knowledge and research;
- (h) access for scientists and researchers from Parties, in particular parties which are Least Developed Countries, to scientific research programmes, projects and partnerships referred to in this article;
- (i) access to, and enhancement of, knowledge, skills and capacities through increased cooperation in the areas covered by the Agreement, and
- (j) collaboration, including with all relevant stakeholders, to set common objectives and research goals, pool expertise and avoid duplicating research efforts, especially in the field of countermeasures.

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

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

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- (f) support new and existing mechanisms to facilitate the rapid reporting and interpretation of data from clinical trials, to develop or modify, as necessary, relevant clinical trial guidelines, including during a pandemic.

[(g) support early interaction with regulatory bodies for guidance on optimal trial design to facilitate an efficient regulatory process.]

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

- (a) research inputs, processes and outputs, including scientific publications and data repositories with data shared and stored securely in alignment with findability, accessibility, interoperability, and reusability principles;
- (b) the pricing of end-products, or pricing policies for end-products;
- (c) licensing to enable the development, manufacturing and distribution of pandemic-related products, especially in developing countries; and
- (d) terms regarding affordable, equitable and timely access to pandemic-related products during a pandemic.

Article 10. Sustainable production

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

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

- (a) take measures to identify and maintain production facilities at national and regional levels, as well as to facilitate the production, as appropriate, and in furtherance of the provisions of Article 13 herein, of pandemic-related products therein; *[Comment: Reserve. As currently drafted, the EU cannot support this paragraph. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*
- (b) take measures to identify and contract with manufacturers other than those referenced in paragraph 1(a) of this Article, for scaling up the production of pandemic-related products, during pandemics, in cases where the production and supply capacity of the production facilities does not meet demand; *[Comment: Reserve. As currently drafted, the EU cannot support this paragraph. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*
- (c) strengthen ~~[coordination, with Delete EU]~~ **[collaboration between]** relevant international organizations, including United Nations entities **[as appropriate]**, on issues related to public health, intellectual property and trade, including ~~[the timely matching of supply to demand, and mapping Delete EU]~~ **[to assess]** manufacturing capacities and demand **[of pandemic-related health products]**;
- (d) encourage entities, including manufacturers within their respective jurisdictions, in particular those that receive significant public financing, to grant, subject to any existing licensing restrictions, on mutually agreed terms, non-exclusive, royalty-free licences to any manufacturers,

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particularly from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic-related product development and production, in particular for pre-pandemic and pandemic diagnostics, vaccines and therapeutics for use in agreed developing countries; *[Comment: Reserve. As currently drafted, the EU cannot support this paragraph. We reserve our right to, as an alternative to the deletion of the paragraph to extent other Member States want to retain it, come back with drafting proposals at a later stage aimed at improving the text and making it acceptable.]*

- (e) ~~[actively Delete EU] support[, participate in and/or implement, Delete EU]~~ as appropriate, relevant ~~[WHO Delete EU]~~ technology, skills and know-how transfer programmes and initiatives aimed at enabling developing countries to produce pandemic-related **[health]** products, in order to facilitate ~~[strategically and geographically Delete EU]~~ **[regionally]** distributed production of pandemic-related **[health]** products; and
- (f) support public and private sector investments aimed at creating or expanding manufacturing facilities for pandemic-related **[health]** products, especially facilities with a regional operational scope that are based in developing countries.

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

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

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

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

Article 11. Transfer of technology and know-how

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

~~1.2. To this end,~~ the Parties~~[, within a set time frame, working through the Conference of the Parties, Delete EU]~~ shall~~[:]~~

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

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

~~[(a)]~~ **[(b)]** coordinate **[and]** ~~[with, Delete EU]~~ collaborate with, facilitate and incentivize the

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

- ~~[(b)]~~ **[(c)]** ~~[make available Delete EU]~~ **[promote]** non-exclusive **[voluntary]** licensing of government-owned technologies, on mutually agreed terms ~~[as appropriate Delete EU]~~, for the development and manufacturing of pandemic-related **[health]** products, and publish the terms of these licences **[in accordance with each Party's laws and regulations:]**

~~[(e) make use of the flexibilities provided in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement, and fully respect the use thereof by others; Delete EU]~~
[Comment: The EU proposes moving this paragraph (as reformulated) to the preamble³.]

- (d) ~~[collaborate to ensure Delete EU]~~ **[facilitate]** equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities;
- (e) develop~~[],~~ **[in collaboration with the World Intellectual Property Organization (WIPO) and the WHO,]** a database that ~~[provides the details of Delete EU]~~ **[collates publicly-available information on]** pandemic-related **[health]** products for all known **[diseases with]** pandemic-potential ~~[diseases, including the technological specifications and manufacturing process documents for each product Delete EU]; and~~ *[Comment: the feasibility of the proposed provision needs to be checked with WIPO and WHO.]*
- (f) provide, within their capabilities, resources to support capacity-building for the development and **[voluntary]** transfer of relevant technology, skills and know-how, and to facilitate access to other sources of support.

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

~~[(a) commit to agree upon, 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]~~

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

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

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

³ We propose a reformulated subparagraph (c) for the preamble: "10 bis. Reaffirming that members of the World Trade Organization have the right to use, to the full, the provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), which provide flexibility to protect public health and, in particular, to promote access to medicines for all."

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Article 12. Access and benefit sharing

[Comment: The EU continues to study the issue and for the moment we reserve our position as well as our right to put forward proposals on the matter.]

Article 13. Global Supply Chain and Logistics Network

1. The WHO ~~[Global Supply Chain and Logistics Network (the WHO SCL Network)]~~ is hereby established. The WHO SCL Network will operate within the framework of WHO in Delete EU] **[shall establish, in consultation with the Parties, and coordinate a]** partnership ~~[and collaboration Delete EU]~~ with **[relevant organizations of the UN system]**, relevant international ~~[and]~~; Delete EU] regional **[organizations]** ~~[and Delete EU]~~ **[as well as]** other relevant organizations~~[Delete EU]~~ and **[stakeholders. The Partnership shall]** be guided by equity and public health needs, paying particular attention to the needs of **[least developed country]** ~~[developing country Delete EU]~~ Parties.

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

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

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

[(d) bis determine the equitable allocation of the reserved quantities of pandemic-related health products, based on public health risks and taking into account factors, such as population size, demographic structure, epidemiological situation and health system capabilities of beneficiary Parties and their readiness and capacity to utilize such products.]

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

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- (j) assisting buying countries in meeting the logistic requirements for the utilization of specific pandemic-related **[health]** products; and
- (k) facilitating or, as necessary, organizing the efficient delivery and appropriate utilization of pandemic-related **[health]** products in beneficiary countries or in humanitarian settings.

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

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

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

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

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

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

Article 14. Regulatory strengthening

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

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

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

~~[2-]~~ **[3.]** The Parties shall **[aim at]** align~~[ing]~~ and, where possible, harmoniz~~[ing]~~ technical and regulatory requirements ~~[and procedures Delete EU]~~, in accordance with applicable international standards,

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guidance and protocols, including those covering regulatory reliance and mutual recognition, and shar[ing] relevant information and assessments concerning the quality, safety and efficacy of pandemic-related [health] products with other Parties.

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

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

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

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

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

Article 15. Compensation and liability management

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

2. ~~The [Conference of the Delete EU] Parties shall [establish, within two years of the entry into force of the WHO Pandemic Agreement, Delete EU]~~ **[facilitate the delivery of pandemic-related health products including by humanitarian organisations. In this regard,]** using ~~[existing Delete EU]~~ relevant models as a reference, **[the Parties shall promote the establishment of regional or international schemes for]** no-fault vaccine injury compensation mechanism(s), with the aim of **[ensuring]** ~~[promoting access to Delete EU]~~ financial remedy for individuals experiencing serious adverse events resulting from **[the delivery and administration of]** a **[novel]** pandemic vaccine**[with particular regards to the needs of individuals that are in humanitarian setting or in vulnerable situations.]** ~~[as well as more generally promoting pandemic vaccine acceptance. The Conference of the Parties shall further develop the mechanism(s), which may be regional and/or international, including strategies for funding the mechanism(s), through the modalities provided for in Article 20 herein. Delete EU]~~

3. Each Party shall endeavour to ensure that in contracts for the supply or purchase of novel pandemic

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vaccines, [~~buyer/recipient indemnity Delete EU~~] **[indemnification]** clauses **[in favour of manufacturers]**, if any, are exceptionally provided, and are time-bound.

Article 16. International collaboration and cooperation

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

2. The Parties shall:

- (a) promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness and response;
- (b) support mechanisms that ensure that policy decisions are science- and evidence-based;
- (c) develop, as necessary, and implement policies, that respect, protect and fulfil the human rights of all people; *[Comment: provisions of subparagraph (c) appear to be a repetition of the general principle already set out under Article 3 paragraph 1 of the Bureau's proposal for negotiating text. The EU would in addition be in favour of having a specific article on the protection of human rights⁴.]*
- (d) promote equitable representation on the basis of gender, geographical and socioeconomic status, as well as the equal and meaningful participation of young people, [~~and Delete EU~~] **women [and people living with disability, in national, regional and global decision-making processes, global networks and technical advisory groups];**
- ~~[(e) assist developing countries through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs for pandemic prevention, preparedness, and response in line with the provisions set forth in Article 19 herein; and Delete EU]~~ *[Comment: while the EU support the objective of the provision, we suggest deletion, as it duplicates the provisions of Article 19.]*
- [(f) encourage ceasefires in affected countries during pandemics to promote global cooperation against common global threats. Reserve EU] *[Comment: Reserve on text. While the EU sympathises with the spirits of the proposal, the text needs to be further considered.]*

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

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

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

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

⁴ “EU proposal for a specific article on the protection of human rights:

Article 2 bis Protection of human rights

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

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shall also provide ~~e-Delete EU~~ **[E]ffective** feedback opportunities **[should be provided.]**

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

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

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

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

Article 18. Communication and public awareness

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

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

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

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

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

Article 19. Implementation capacities and support

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

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

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

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

[4. The Secretariat, in collaboration with relevant international and regional organizations and other bodies, shall provide assistance in the identification of support needs and organization of the technical assistance and capacity building activities provided for in this Article, with particular regard to the needs of the least developed country Parties and other Parties in need.]