

## **Bureau's text of the WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (WHO CA+)**

### **BACKGROUND, METHODOLOGY AND APPROACH**

1. In recognition of the catastrophic failure of the international community in showing solidarity and equity in response to the coronavirus disease (COVID-19) pandemic, the World Health Assembly convened a second special session in December 2021, at which it established an Intergovernmental Negotiating Body (INB) open to all Member States and Associate Members (and regional economic integration organizations, as appropriate) to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to its adoption under Article 19 or other provisions of the WHO Constitution, as may be deemed appropriate by the INB.
2. In furtherance of the above mandate, the INB established a process and systematic approach for its work and agreed, at its second meeting, that the instrument should be legally binding and contain both legally binding as well as non-legally binding elements. In that regard, the INB identified Article 19 of the WHO Constitution as the comprehensive provision under which the instrument should be adopted, without prejudice to also considering, as work progressed, the suitability of Article 21, and requested the Bureau to develop and present to the INB a conceptual zero draft of the instrument (WHO CA+) for discussion.
3. At its third meeting, the INB agreed that the Bureau, with support from the WHO Secretariat, would prepare the zero draft of the WHO CA+, based on the conceptual zero draft and input received during the third meeting of the INB, with legal provisions. The INB further agreed that the zero draft would be considered at its fourth meeting as a basis for commencing negotiations at that meeting, it being understood that the zero draft would be without prejudice to the position of any delegation and following the principle that "nothing is agreed until everything is agreed". Subsequently, at its fifth meeting, the INB requested the Bureau to provide a Bureau text, including options, where feasible, based on all submissions received and included in the compilation document, in order to facilitate the work of the drafting group, on the continued understanding that nothing is agreed until everything is agreed.
4. Accordingly, the Bureau has prepared a Bureau's text of the WHO CA+ for consideration by the INB Drafting Group in June 2023.

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The Parties to the WHO CA+,

[Preambular paragraphs to be addressed at a later time in the work of the INB.]

Have agreed as follows:

## **Chapter I. Introduction**

### **Article 1. Use of terms**

1. For the purposes of the WHO CA+:

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

(b) “infodemic” means too much information, including false or misleading information, in digital and physical environments during a disease outbreak. It causes confusion and risk-taking behaviours that can harm health. It also leads to mistrust in health authorities and undermines the public health response;<sup>1</sup>

(c) “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) are closely linked and interdependent;<sup>2</sup>

(d) “pandemic” means the global spread of a pathogen or variant that infects human populations with limited or no immunity through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and high mortality and causing social and economic disruptions, all of which require effective national and global collaboration and coordination for its control;<sup>3</sup>

(e) “pandemic-related products” means products that may be needed for pandemic prevention, preparedness, response and/or recovery, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;

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

(g) “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

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<sup>1</sup> [https://www.who.int/health-topics/infodemic#tab=tab\\_1](https://www.who.int/health-topics/infodemic#tab=tab_1).

<sup>2</sup> <https://www.who.int/news/item/01-12-2021-tripartite-and-unep-support-ohhlep-s-definition-of-one-health>.

<sup>3</sup> The INB is encouraged to conduct discussions on the matter of the declaration of a “pandemic” by the WHO Director-General under the WHO CA+ and the modalities and terms for such a declaration, including interactions with the International Health Regulations (2005) and other relevant mechanisms and instruments.

the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care.<sup>1</sup>

*[Other terms may be added, as appropriate, during the work of the INB.]*

## **Article 2. Objective and scope**

1. The objective of the WHO CA+, guided by equity, the right to health and the principles and approaches set out herein, is to prevent pandemics, save lives, reduce disease burden and protect livelihoods, through strengthening, proactively, the world's capacities for preventing, preparing for and responding to, and the recovery of health systems from, pandemics. The WHO CA+ aims to comprehensively and effectively address systemic gaps and challenges that exist in these areas, at national, regional and international levels, through substantially reducing the risk of pandemics; increasing pandemic preparedness and response capacities; the progressive realization of universal health coverage; and ensuring a coordinated, collaborative and evidence-based pandemic response and the resilient recovery of health systems at community, national, regional and global levels.
2. In furtherance of its objective, the WHO CA+ applies at all times, including during and between pandemics.

## **Article 3. General principles and approaches**

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

1. **Respect for human rights** – The implementation of the WHO CA+ shall be with full respect for the dignity, human rights and fundamental freedoms of persons, including the right to the enjoyment of the highest attainable standard of health, and each Party shall protect and promote such rights and freedoms, with due regard to the need for specific measures to ensure non-discrimination, the respect for diversity, the promotion of gender equality and the protection of persons in vulnerable situations.
2. **Sovereignty** – States have, in accordance with the Charter of the United Nations and the general principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so, they shall uphold the purposes and objectives of the WHO CA+ and carry out their obligations under the WHO CA+ in a manner consistent with the principles of the sovereign equality and the territorial integrity of States and that of non-intervention in the domestic affairs of other States.
3. **Equity** – Equity shall be at the centre of pandemic prevention, preparedness, response and recovery, both at the national level within States and at the international level between States. It requires, inter alia, specific measures to protect persons in vulnerable situations. Equity includes the unhindered, fair, equitable and timely access to safe, effective, quality and affordable pandemic-related products and services, information, pandemic-related technologies and social support. The Parties commit to promote, respect and facilitate equity in all phases of pandemic prevention, preparedness and response and recovery of health systems.

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<sup>1</sup> [https://www.who.int/health-topics/universal-health-coverage#tab=tab\\_1](https://www.who.int/health-topics/universal-health-coverage#tab=tab_1).

4. **Solidarity** – Effective national, international, multilateral, bilateral and multisectoral collaboration, coordination and cooperation to achieve the common interest of a safer, fairer, more equitable and better prepared world to prevent, respond to and recover from pandemics.

5. **Transparency** – The effective prevention of, preparedness for and response to pandemics depends on transparent, open and timely sharing of, access to and disclosure of accurate information, data and other relevant elements that may come to light, for risk assessment, prevention and control measures, and development of pandemic-related products and services, including reports on sales revenues, prices, units sold, marketing costs and subsidies and incentives, consistent with national, regional and international privacy and data protection rules, regulations and laws.

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

7. *Three options are presented for principle 7.*

**Option 7.A: Common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems** – Governments have a responsibility for the health of their peoples, which can be fulfilled only by the provision of adequate health and social measures. Given that the unequal development in different countries in the promotion of health and control of diseases, especially communicable diseases, is a common danger, Parties that hold more capacities and resources relevant to pandemics should bear a commensurate degree of differentiated responsibility regarding global pandemic prevention, preparedness, response and recovery.

**Option 7.B: Common responsibilities and different capabilities in pandemic prevention, preparedness, response and recovery of health systems** – Governments have a responsibility for the health of their peoples, which can be fulfilled only by the provision of adequate health and social measures. And the unequal development in different countries in the promotion of health and control of diseases, especially communicable diseases, is a common danger.

*Option 7.C: not to include as a principle.*

8. *Two options are presented for principle 8.*

**Option 8.A: One Health** – Multisectoral and transdisciplinary actions should recognize the interconnection between people, animals, plants and their shared environment, for which a coherent, integrated and unifying approach should be strengthened and applied with the aim of sustainably balancing and optimizing the health of people, animals and ecosystems, including through, but not limited to, by giving attention to the prevention of epidemics due to pathogens that are resistant to antimicrobial agents and zoonotic diseases.

*Option 8.B: not to include as a principle.*

9. **Inclusiveness** – The full and active engagement with, and participation of, representatives of communities and relevant stakeholders across all levels, consistent with relevant and applicable international and national guidelines, rules and regulations, including those relating to conflicts of

interest, is essential to mobilize social capital, resources and adherence to public health and social measures, and to gain trust in governments and partners supporting pandemic prevention, preparedness, response and health systems recovery.

10. **Science and evidence** – The best available science and evidence should inform and be the basis for pandemic prevention, preparedness, response and recovery of health systems, as well as public health decisions and development of plans.

11. **Central role of WHO** – As the directing and coordinating authority on international health work, and the leader of multilateral cooperation in global health governance, WHO is fundamental to strengthening pandemic prevention, preparedness, response and recovery of health systems.

12. **Proportionality** – Public health decisions for preventing, preparing for and responding to pandemics should be proportionate, such that the benefit of measures implemented outweigh their costs.

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

The WHO CA+ aims to achieve greater equity for pandemic prevention, preparedness and response through comprehensively and effectively addressing the systemic and capacity gaps and challenges that exist in these areas, at national, regional and international levels, with full respect for the dignity, human rights and fundamental freedoms of persons.

### **Article 4. Pandemic prevention and public health surveillance**

1. The Parties shall take prevention and surveillance measures that are consistent with and supportive of effective implementation of the International Health Regulations (2005).

*Two options are presented for the rest of Article 4.*

*Option 4.A: article ends here.*

#### **Option 4.B**

2. Each Party shall develop, strengthen, implement, periodically update and review comprehensive multisectoral national infection prevention and control measures, plans and programmes, including those addressing zoonotic diseases and pathogens. To this end, each Party shall, in accordance with its capabilities:

- (a) strengthen efforts to ensure access to safe water, sanitation and hygiene, and guarantee timely access to appropriate health services for diagnosis or treatment as measures to prevent the spread of disease in humans as well as animals;
- (b) ensure the implementation of infection prevention and control measures, applying as far as possible the latest international standards and guidelines;
- (c) strengthen efforts to ensure the sound management of wastes from health facilities, veterinary practices and live animal markets, contaminated by infectious pathogens;

(d) require health care institutions to have in place an infection prevention and control programme no later than [...] years after the entry into force of the WHO CA+; and

(e) strengthen animal disease preventive measures, including, but not limited to, measures concerning farms, the transport of animals, live animal markets, trade in wild animals and veterinary practices for both food-producing and companion animals, taking into account the relevant international standards. Those measures include water and feed hygiene, infection prevention and control measures, farm sanitation, hygiene and biosecurity, and animal welfare support measures.

3. The Parties shall take actions to prevent outbreaks or pandemics due to pathogens that are resistant to antimicrobial agents, and, in accordance with national context, shall develop and implement a national antimicrobial resistance plan that strengthens antimicrobial stewardship in the human, animal and environmental sectors and the prudent use of antibiotics.

4. The Parties shall take actions to strengthen laboratory biosafety and biosecurity in order to prevent the accidental exposure, misuse or inadvertent laboratory release of pathogens through biosecurity training and practices, regulating access to sensitive locations, and strengthening transportation security and cross-border transfer, in accordance with applicable rules and standards.

5. The Parties shall cooperate with one another and with the support of WHO to strengthen and maintain public health laboratory and diagnostic capacities, especially with respect to the capacity to perform genomic sequencing, data science to assess the risks of detected pathogens and to safely handle samples containing pathogens, and the use of related digital tools. The Parties shall also cooperate, as appropriate, to promote and facilitate the provision of necessary assistance by relevant international and regional organizations.

6. Each Party shall develop, strengthen and maintain the capacity to carry out integrated surveillance, including with respect to: (i) infectious diseases in humans; (ii) infectious diseases in animals that present significant risks for zoonotic, including vector-borne, spillover; and (iii) relevant samples taken from specific environmental settings for the purpose of preventing and controlling the spillover of potentially highly infectious pathogens, including antimicrobial resistant pathogens, across different animal species and between humans and animal populations.

#### **Article 5. Strengthening pandemic prevention and preparedness through a One Health approach**

*Two options are presented for Article 5.*

##### ***Option 5.A***

1. The Parties, recognizing that the majority of emerging infectious diseases and pandemics are caused by zoonotic pathogens, commit, in the context of pandemic prevention, preparedness, response and recovery of health systems, to promoting and implementing a One Health approach, at national, and, as appropriate, at regional and global levels, that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of, and in accordance with, domestic law and existing instruments and initiatives.

2. The Parties, with the aim of safeguarding human health and detecting and preventing health threats, shall promote and enhance synergies between multisectoral and transdisciplinary collaboration at the national level and cooperation at the international level, in order to identify, conduct risk



assessments of, and share pathogens with, pandemic potential at the interface between human, animal and environment ecosystems, while recognizing their interdependence.

3. The Parties will identify and integrate into relevant pandemic prevention and preparedness plans interventions that address the drivers of the emergence and re-emergence of disease at the human-animal-environment interface, including but not limited to climate change, land-use change, wildlife trade, desertification and antimicrobial resistance.

4. The Parties commit to regularly assessing One Health capacities, in so far as they relate to pandemic prevention, preparedness, response and recovery of health systems, and to identifying gaps, policies and the funding needed to strengthen those capacities.

5. The Parties commit to strengthening synergies with other existing relevant instruments that address the drivers of pandemics, such as climate change, biodiversity loss, ecosystem degradation and increased risks at the human-animal-environment interface due to human activities.

6. The Parties commit to strengthening multisectoral, coordinated, interoperable and integrated One Health surveillance systems, and to strengthening the laboratory capacity to identify and assess the risks and emergence of pathogens and variants with pandemic potential, in order to minimize spillover events, mutations and the risks associated with zoonotic neglected tropical and vector-borne diseases, with a view to preventing small-scale outbreaks in wildlife or domesticated animals from becoming a pandemic.

7. Each Party shall, in accordance with the national context and to the extent necessary, to protect human, animal or plant life or health:

(a) implement science-based actions, including but not limited to improving infection prevention measures, antimicrobial research and development, access to and stewardship of antimicrobials, harmonization of surveillance and management of environmental antimicrobial run-off, in order to prevent, reduce the risk of, and prepare for, pandemics from zoonotic pathogens and pathogens that are resistant to antimicrobial agents, taking into account relevant tools and guidelines, through a One Health approach, and shall collaborate with relevant partners, including the Quadripartite organizations;

(b) foster and implement actions at national and community levels that encompass whole-of-government and whole-of-society approaches to control zoonotic outbreaks (in wildlife and domesticated animals), including through the engagement of communities in surveillance that identifies zoonotic outbreaks and antimicrobial resistance at source;

(c) develop and implement a national One Health action plan on antimicrobial resistance that strengthens antimicrobial stewardship in the human and animal sectors, optimizes antimicrobial consumption, increases investment in, and promotes equitable and affordable access to, new medicines, diagnostic tools, vaccines and other interventions, strengthens infection prevention and control in health care settings and sanitation and biosecurity in livestock farms, and provides technical support to developing countries;

(d) implement One Health surveillance mechanisms using data collected from and shared across human, animal, and environmental sources for the purpose of preventing and controlling the spillover of pathogens with pandemic potential between humans and animal populations, as well as between different animal species;

- (e) take the One Health approach into account at national, subnational and facility levels in order to produce science-based evidence, including related to the social and behavioural sciences and risk communication and community engagement, and support, facilitate and/or oversee the correct, evidence-based and risk-informed implementation of infection prevention and control; and
- (f) promote or establish One Health joint training and continuing education programmes for human, animal and environmental health workforces, particularly for the veterinary and environmental services needed to prevent spillover events, in order to build complementary skills, capacities and capabilities to prevent, detect, control and respond to pandemic health threats.

8. In line with Article 15, the Parties shall develop and implement or strengthen, as appropriate, bilateral, regional, subregional and other multilateral channels to enhance financial and technical support, assistance and cooperation, in particular to developing countries to strengthen surveillance systems and laboratory capacity in promoting and implementing the One Health approach at the national level.

***Option 5.B: not to include as an Article.***

**Article 6. Preparedness, readiness and resilience**

1. Each Party shall take the necessary measures to strengthen their own health systems in order to strengthen and sustain pandemic prevention, preparedness and response, taking into account the need for equitable and resilient health systems, including primary health care with a view to the progressive realization of universal health coverage.
2. The Parties shall continue to cooperate on, and are encouraged to enhance, financial, technical and technological support, assistance, capacity-strengthening and cooperation, in particular to developing countries, in order to strengthen health emergency prevention and preparedness consistent with the goal of universal health coverage.
3. The Parties commit to establishing, or building on existing, genomics, risk assessment, and laboratory networks in order to conduct epidemiological genomic surveillance and the global sharing of emerging pathogens with pandemic potential, and drug-resistant pathogens.
4. Each Party shall, in accordance with applicable laws and supported by implementation plans, adopt policies, strategies and/or measures, as appropriate, that seek to integrate perspectives from public and private sectors and relevant agencies, consistent with relevant tools or other international agreements, including, but not limited to, the International Health Regulations (2005), and shall strengthen and reinforce public health functions for:
  - (a) the continued provision of quality routine and essential health services during pandemics, including clinical and mental health care and immunization, with a focus on primary health care, referral health services and community-level interventions, and the management of the backlog of, and waiting lists for, the diagnosis and treatment of, and interventions for, other diseases and health conditions, including care for patients with long-term effects from the pandemic disease;
  - (b) sustaining and strengthening the capacities of the multidisciplinary workforce needed during inter-pandemic periods, and preparing for and ensuring increased surge capacity during pandemics;

- (c) collaborative surveillance, outbreak detection investigation and control, through interoperable early warning and alert systems, and timely notification;
- (d) sustained national and/or regional laboratory capacity, including for genomic sequencing, as well as for analysing and sharing such information;
- (e) cross-sectoral prevention of zoonoses and epidemic-prone diseases, and emerging, growing or evolving [public health] / [infectious disease] threats with pandemic potential, notably at the human-animal-environment interface;
- (f) development of rehabilitation and post-pandemic health system recovery strategies;
- (g) strengthening public health laboratory and diagnostic capacities, and national, regional and global networks, through the application of standards and protocols for infection prevention and control, and public health laboratory biosafety and biosecurity;
- (h) 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;
- (i) creating and strengthening public health institutions at national, regional and international levels;
- (j) strengthening public health emergency operational centres' capacities during inter-pandemic periods and during pandemic periods; and
- (k) strengthening infection prevention and control.

#### **Article 7. Health and care workforce**

1. Each Party, in line with their respective capacities, shall take the necessary steps to safeguard, protect, invest in and sustain a skilled, trained, competent and committed health and care workforce, at all levels, in a [gender-responsive]/[gender-sensitive] manner, with due protection of employment, civil and human rights, and safety and well-being, consistent with applicable international obligations and relevant codes of practice, 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 its national law:

- (a) strengthen, pre-, in- and post-service, competency-based education and training, deployment, remuneration, distribution and retention of the public health, health and care workforce, including community health workers and volunteers;
- (b) address gender and youth 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 and safety, and well-being of all health and care workers, while addressing discrimination, stigma and inequality and eliminating bias, including unequal remuneration, and noting that women still often face significant barriers to reaching leadership and decision-making roles;
- (c) strengthen efforts to address the safety of the health and care workforce, including by ensuring that there is a conducive environment for frontline health and care workers and priority

access to pandemic-related products during pandemics, minimizing disruptions to the delivery of quality essential health services and protecting health and care workers from violence and intimidation in the course of carrying out pandemic prevention, response and recovery; and

(d) establish and maintain effective workforce planning systems to effectively and efficiently deploy trained health workers during pandemics.

2. The Parties [are encouraged to enhance]/[shall commit] financial and technical support, assistance and cooperation, in particular to developing countries, in order to strengthen and sustain a skilled and competent public health, health and care workforce at the subnational, national and regional levels.

3. The Parties shall invest in establishing, sustaining, coordinating and mobilizing an available, skilled and trained 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 small-scale spread to global proportions.

4. The Parties [will support] / [shall encourage] the development of a network of training institutions, national and regional facilities, and centres of expertise, leveraging and building on existing programmes in order to establish common guidance to enable more predictable, standardized, timely and systematic response missions and deployment of the aforementioned multidisciplinary public health emergency workforce.

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

1. Each Party, consistent with its national laws and context, shall undertake regular and systematic assessments in order to identify capacity gaps and develop and implement comprehensive, inclusive, multisectoral, resourced national plans and strategies for pandemic prevention, preparedness, response and health systems recovery, based on the relevant tools developed by WHO in partnership with relevant organizations.

2. Each Party shall periodically assess the functioning, readiness and gaps of its pandemic preparedness, surveillance capacity and multisectoral response, logistics and supply chain management, and risk assessment, through, among others, appropriate simulation or tabletop exercises, and intra- and after-action reviews. These efforts are for the purposes of helping to identify gaps and bottlenecks, share lessons learned and improve national pandemic prevention, preparedness and response.

3. The Parties will convene multi-country or regional multisectoral tabletop exercises no less than every five years, with technical support from the WHO Secretariat, with the aim of identifying gaps in multi-country response capacity.

4. Each Party shall provide regular reporting, building on existing relevant reporting, where possible, on its pandemic prevention, preparedness, response and health systems recovery capacities.

5. 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, which includes targets and national, regional and global standardized indicators, with necessary and predictable resources for developing countries for this purpose.

6. The Parties shall consider and endeavour to implement the recommendations generated from reviews, including the prioritization of activities for immediate action, in accordance with their nationally determined health priorities.

*Three options are presented for the rest of Article 8.*

*Option 8.A: the Article ends here.*

*Option 8.B: Parties propose to establish a peer review mechanism.*

7. The Parties shall establish, regularly update and broaden the implementation of a universal preparedness peer review mechanism that leverages the use of existing monitoring and evaluation tools to assess national, regional and global preparedness capacities and gaps, through whole-of-government and whole-of-society approaches, in order to strengthen capacities for pandemic prevention, preparedness, response and health systems recovery, through technical and financial cooperation, mindful of the need to integrate available data and to engage national leadership at the highest level.

*Option 8.C: Parties propose to establish a universal health and preparedness review mechanism.*

8. The Parties agree to establish a universal health and preparedness review mechanism, a regular intergovernmental dialogue among Member States that aims to promote collective global action and accountability for preparedness by bringing them together with stakeholders at the national, regional and global levels to comprehensively review their national health emergency preparedness capacities.

9. Each Party shall conduct a national review and participate in a global peer review between Parties in order to share national practices, gaps in preparedness, and opportunities for improving health capacities and emergency preparedness.

#### **Article 9. Research and development**

1. The Parties shall cooperate to build, strengthen and sustain capacities and institutions for research and development for pandemic-related products, particularly in developing countries, including for related clinical trials and information-sharing through open science approaches for rapid sharing of scientific findings and research results.

2. With a view to promoting greater sharing of knowledge and transparency, each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, in accordance with national laws and, as appropriate, taking into account the extent of public funding:

(a) promote the public dissemination of the results of government-funded research for the development of pandemic-related products, in accessible languages and formats;

(b) publish the terms of government-funded research and development agreements for pandemic-related products, as appropriate, including:

(i) research inputs, processes and outputs;

(ii) pricing of end-products, or pricing policies for end-products;

(iii) licensing to enable development, manufacturing and distribution, especially in developing countries; and

(iv) terms regarding affordable, equitable and timely access to pandemic-related products at the time of a pandemic;

- (c) promote, facilitate and incentivize technology co-creation and joint venture initiatives, actively engaging the participation of scientists and/or research centres, particularly from developing countries; and
  - (d) promote and prioritize investment in the research and development of pandemic-related products that can promote equitable access.
- 3. Each Party shall increase, the transparency of information about research and development for pandemic-related products by:
  - (a) sharing information on research agendas, including national research and development priorities, during pandemic emergencies, as appropriate;
  - (b) sharing information on national efforts and plans for building or strengthening national, regional and global research and development capacity, including by building and maintaining a skilled research workforce and research infrastructure, and by researching supply chain needs in order to rapidly mount and scale research responses during pandemic emergencies; and
  - (c) ensuring that resources are directed to well-designed projects that can produce robust and reliable evidence.
- 4. The Parties shall encourage the participation of relevant stakeholders, consistent with national biosafety and biosecurity laws and regulations, in order to accelerate innovative research and development, including community-led and cross-sector collaboration, for addressing emerging and re-emerging pathogens with pandemic potential.
- 5. Each Party shall implement and apply relevant international standards for the biorisk management of laboratories and research facilities that carry out research to better understand the pathogenicity and transmissibility of pathogens with pandemic potential, and to prevent the unintended consequences of such research, while minimizing unnecessary administrative hurdles for research.
- 6. The Parties [commit to]/[are encouraged to] promote, cooperate and strengthen knowledge translation and evidence-based communication tools and strategies relating to pandemic prevention, preparedness, response and recovery of the health system, at local, national, regional and international levels.
- 7. The Parties, in accordance with their national and regional legal and regulatory frameworks and contexts, and as appropriate, shall increase clinical trial capacity and strengthen clinical trials policy frameworks, particularly in developing countries, in order to enable a greater number of clinical trial sites that can conduct well-designed and well-implemented clinical trials, and to ensure readiness for the coordination of trials through existing, new or expanded clinical trial networks that meet relevant regulations and internationally harmonized standards, promoting the sharing of information and best practices on efficient and ethical clinical trial design and delivery, and in designing, preparing and conducting clinical trials that ensure human subject protections.
- 8. The parties will develop national policies to support the transparent, public sharing of clinical trial results conducted within their territories, such as through open source publication.

9. The Parties shall take steps, individually and collectively, to develop strong, resilient national, regional and international, appropriately resourced research ecosystems, including national and global clinical research networks. In that regard, the Parties, as appropriate, commit to:

- (a) investing in the infrastructure and training of clinical research networks in developing countries in order to be prepared to provide timely and appropriate responses to pandemics;
- (b) further strengthening international coordination and collaboration on clinical trials, through existing mechanisms, where established, to support well-designed and well-implemented trials, including new clinical trial platforms operating on multi-country footprints, where scientifically appropriate, to address priority infectious and non-infectious diseases, with mechanisms to pivot protocols to support pandemic response, where necessary and appropriate;
- (c) supporting new and existing mechanisms to facilitate the rapid interpretation of data from clinical trials to develop or amend, as necessary, relevant clinical guidelines, including during a pandemic; and
- (d) ensuring that clinical trials conducted during health emergencies are equitable, address geographical, socioeconomic and health disparities, and promote racial, ethnic and gender diversity for a better understanding of the safety and efficacy of new vaccines and treatments in subgroups of the population.

#### **Article 10. Liability risk management**

1. The Parties shall establish, no later than XX, using existing relevant models as a reference, regional or international vaccine injury compensation scheme(s) for injuries resulting from the use and/or administration of vaccines developed for response to pandemics that is/are transparent and complement(s) any liability protections and/or other liability risk management mechanisms.
2. Each Party shall consider implementing and/or participating in vaccine injury compensation scheme(s) for injuries resulting from the use and/or administration of vaccines developed for response to pandemics, and shall consider developing strategies for sufficiently funding the scheme(s).
3. Each Party shall develop national strategies for managing liability risks in its territory regarding the manufacture, distribution, administration and use of the vaccines developed for response to pandemics. Strategies could include, for example, 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 the vaccines developed in response to pandemics, and building expertise for contract negotiations in this matter.
4. Each Party shall endeavour to ensure that in contracts for the supply or purchase of vaccines developed in response to pandemics, buyer/recipient indemnity clauses, if any, are exceptionally provided as a last resort arrangement, and are reasonably time-bound, with the end-date expressly defined from the outset. The Parties further agree that such buyer/recipient indemnity clauses should be accepted for novel products only.
5. The Parties shall work with WHO and other relevant organizations and entities on the foregoing, including to develop recommendations for, and capacity-building tools on, liability risk management during pandemic emergencies, regarding the manufacture, distribution, administration or use of pandemic-related products.

6. In accordance with national laws, each Party shall make publicly available information regarding any global, regional or country-level liability frameworks and vaccine compensation schemes that apply to the manufacture, distribution, administration or use of pandemic-related products during pandemic emergencies in its jurisdiction.

**Article 11. Co-development and transfer of technology and know-how**

*Two options are presented for Article 11.*

**Option 11.A**

1. The Parties recognize that inequitable access to pandemic-related products (including but not limited to vaccines, therapeutics and diagnostics) should be addressed by increased manufacturing capacity that is more equitably, geographically and strategically distributed.
2. The Parties, working through the Conference of the Parties, shall strengthen existing and develop innovative multilateral mechanisms, including through the pooling of knowledge, intellectual property and data, that promote the relevant transfer of technology and know-how for the production of pandemic-related products, on mutually agreed terms as appropriate, to manufacturers, particularly in developing countries.
3. The Parties shall ensure that manufacturers of pandemic-related products are strategically and geographically distributed in order to maximize access to complete pandemic-related products for countries in which developing manufacturing capacity is not feasible.
4. During inter-pandemic periods, all Parties commit to establishing these mechanisms and shall:
  - (a) coordinate, collaborate, facilitate and incentivize the manufacturers of pandemic-related products to transfer the relevant technology and know-how to manufacturer(s) (as defined below) on mutually agreed terms as appropriate, including through technology transfer hubs and product development partnerships, and to address the need to develop new pandemic-related products in a short time frame;
  - (b) strengthen coordination, with relevant international organizations, including United Nations agencies, on issues related to public health, intellectual property and trade, including the timely matching of supply to demand and mapping manufacturing capacities and demand;
  - (c) encourage entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms as appropriate, licences to manufacturers, notably 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 response product research, development and production, in particular for pre-pandemic and pandemic-related products;
  - (d) collaborate to ensure equitable and affordable access to health technologies that promote the strengthening of national health systems and mitigate social inequalities; and



(e) develop a database that provides the details of pandemic-related products for all known pandemic potential diseases, including the technological specifications and manufacturing process documents for each product.

5. In the event of a pandemic, the Parties shall:

(a) take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate or scale up the manufacturing of pandemic-related products during a pandemic, to the extent necessary to increase the availability and adequacy of affordable pandemic-related products;

(b) apply the full 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 of 2001 and in Articles 27, 30 (including the research exception and the “Bolar” provision), 31 and 31bis of the TRIPS Agreement;

(c) encourage all holders of patents related to the production of pandemic-related products to waive or manage, as appropriate, the payment of royalties by developing country manufacturers on the use, during the pandemic, of their technology for the production of pandemic-related products, and shall require, as appropriate, those that have received public financing for the development of pandemic-related products to do so; and

(d) encourage all research and development institutes, including manufacturers, in particular those receiving significant public financing, to waive or manage, as appropriate, royalties on the continued use of their technology for production of pandemic-related products.

6. The Parties shall ensure, when engaged in bilateral or regional trade or investment negotiations, that 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 of 2001.

### ***Option 11.B***

1. Capacity-building and the transfer of technologies, skills, knowledge and know-how relevant to pandemic prevention, preparedness and response should be a country-driven, transparent, effective and iterative process. To this end, the Parties shall:

(a) cooperate, directly or through relevant legal instruments and frameworks and relevant global, regional, subregional and sectoral bodies, to assist Parties, in particular developing country Parties, in achieving the objectives of this WHO CA+ through capacity-building and the development and transfer of technologies, skills, knowledge and know-how relevant to pandemic prevention, preparedness and response;

(b) provide, within their capabilities, resources to support such capacity-building and the development and transfer of relevant technology, and to facilitate access to other sources of support, taking into account their national policies, priorities, plans and programmes; and

(c) monitor and review periodically, within the framework of the Conference of the Parties, capacity-building and the transfer of the technologies, skills, knowledge and know-how relevant

to pandemic prevention, preparedness and response, based on and responsive to the needs and priorities of developing countries.

2. The Parties also recognize the importance of manufacturers and other entities with access to relevant technologies in respect of pandemic-related products making specific efforts to transfer these technologies, skills, knowledge and know-how to countries, particularly developing countries, that do not have access to such technologies, skills, knowledge and know-how.

3. At all relevant times, particularly during pandemics, each Party shall, subject to its national laws:

(a) take steps to urge the manufacturers of pandemic-related products, such as but not limited to diagnostics, vaccines and therapeutics, to grant, subject to any existing licensing restrictions, on mutually agreed terms, [as appropriate,] a non-exclusive, royalty-free licence to any such manufacturers 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;

(b) urge the manufacturers of pandemic-related products, such as but not limited to diagnostics, vaccines and therapeutics, to transfer, under mutually agreed terms as appropriate, the relevant technologies, skills, knowledge and know-how to countries without such manufacturing capacities, particularly developing countries; and

(c) actively support, participate in and/or implement, as appropriate, relevant WHO technology transfer programmes and initiatives aimed at enabling developing countries to produce their own vaccines, medicines and diagnostics to address health emergencies, including strategies to build new production facilities in developing and/or industrialized countries, and on the transfer of technology, skills and know-how.

4. The transfer of technology, skills, knowledge and know-how for the manufacture of pandemic-related products shall be conducted in a manner consistent with applicable national laws and international laws and obligations, facilitated progressively over time on mutually agreed terms as appropriate, and shall be suitable to the capacity of recipient countries to empower them to manufacture pandemic-related products.

5. In the event of a pandemic, each Party shall, in accordance with national laws:

(a) make available non-exclusive licensing of government-owned technologies on mutually agreed terms as appropriate, that can be used for the development and manufacturing of pandemic-related products, and publish the terms of these licences at the earliest reasonable opportunity and to the fullest extent possible;

(b) promote the publication, by private rights holders, of the terms of voluntary licensing agreements or technology transfer agreements for pandemic emergency response-related products, at the earliest opportunity and to the fullest extent possible;

(c) promote the voluntary engagement of private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks for the voluntary licensing and voluntary transfer of technology on mutually agreed terms as appropriate, for pandemic emergency response-related products;

(d) ensure equitable and timely access to health technologies, in particular in developing countries, without discrimination; and

(e) *Two options are presented for subparagraph 5(e) of Option 11.B.*

**Option A for 5(e):** suspend the application of intellectual property rights, through time-bound waivers, in order to facilitate the scaling-up, production, manufacture and supply of the products that are especially meant for a pandemic. Neither Party shall challenge these measures based on any international obligations that the Party suspending the obligation may have.

**Option B for 5(e):** not to include a subparagraph.

6. *Two options are presented for paragraph 6 of Option 11.B*

**Option A:** The Parties shall take into account the rights and obligations in the TRIPS Agreement, including those affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, in order to promote access to medicines and other health technologies for all.

**Option B:** The Parties [may]/[shall, as they deem appropriate,] make use of the full flexibilities provided in the TRIPS Agreement, including those affirmed by the Doha Declaration on the TRIPS Agreement and Public Health, without interferences.

**Article 12. Access and benefit-sharing**

*Two options are presented for Article 12.*

**Option 12.A**

1. The Parties agree that pandemic prevention, preparedness, response and health system recovery requires the rapid, systematic, and timely sharing of biological materials with epidemic and pandemic potential, as well as [genetic sequence data and relevant information]/[digital sequence information] (WHO CA+ biological material). The Parties also agree that a multilateral access and benefit-sharing system(s) is/are needed for timely, effective, predictable and equitable access to pandemic-related products, as well as other benefits, both monetary and non-monetary, that strengthen pandemic prevention, preparedness, response and health system recovery based on public health risks and needs.

2. The Parties agree to establish such a system(s), consistent with applicable and relevant national, regional and international laws and regulations, as well as existing international instruments, which is/are implementable at all times, both during and between pandemics. This will provide certainty and legal clarity for the providers and users of biological materials, and will strengthen, expedite and not impede research and innovation. Recognizing that biological materials-sharing and multilateral benefit-sharing are equally important parts of the collective action for global public health, the Parties are mindful that the system(s) could be structured as either a unified system or two mutually supportive systems, and all or parts thereof could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed. The Parties will ensure that such system(s) is/are consistent with, supportive of, and do not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol thereto.

3. The Parties shall further develop the details of the access and benefit-sharing system(s) through the Conference of the Parties, recognizing that biological materials-sharing and multilateral

benefit-sharing are equally important parts of the collective action for global public health. The system(s) shall be operational no later than xxx.

**Option 12.B**

1. The Parties recognize that global pandemic prevention, preparedness and response requires multilateral, fair, equitable and timely sharing of, on an equal footing, pathogens with pandemic potential, including their genomic sequences, components and related information, and their benefits, monetary and non-monetary, including access to pandemic-related products, [arising therefrom]/[that arise from the utilization of such pathogens].

2. The Parties hereby establish the WHO Pathogen Access and Benefit-Sharing System (PABS system) under the WHO CA+. The Parties agree that the PABS system is structured as [a unified system]/[two mutually supportive systems].

3. The PABS system aims to ensure timely access to pathogens with pandemic potential and the corresponding benefit-sharing. The PABS system shall cover all pathogens with pandemic potential, including their genomic sequences, as well as access to benefits [arising therefrom] / [that arise from the utilization of such pathogens], be consistent and supportive of, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol or any other international access and benefit-sharing instruments. This will provide certainty and legal clarity for the providers and users of biological materials, and will strengthen, expedite and not impede research and innovation. The Parties, working through the Conference of the Parties, shall review the operationalization and functioning of the PABS system every five years, and may take steps, as appropriate, to recognize the PABS system as a specialized international access and benefit-sharing instrument within the meaning of paragraph 4 of Article 4 of the Nagoya Protocol, as necessary.

4. The Parties shall further develop the details of the PABS system through the Conference of the Parties, recognizing that biological materials-sharing and multilateral benefit-sharing are equally important parts of collective action for global public health. The PABS system shall be operational no later than xxx, in conformity with the provisions set out below.

5. Biological materials-sharing:

(a) Each Party, through its relevant public health authorities and authorized laboratories, shall, in a rapid, systematic and timely manner: (i) provide pathogens with pandemic potential from early infections due to pathogens with pandemic potential or subsequent variants to a laboratory recognized or designated as part of an established WHO coordinated laboratory network; and (ii) upload the genomic sequence of such pathogens with pandemic potential to one or more publicly accessible database(s) of its choice.

(b) The PABS system will be consistent with international legal frameworks, notably those for the collection of patient specimens, material and data, and will promote effective, standardized, real-time global and regional platforms that promote findable, accessible, interoperable and reusable data available to all Parties.

(c) Access shall be accorded expeditiously by the laboratory recognized or designated as part of an established WHO coordinated laboratory network, subject to the conclusion of a Standard Material Transfer Agreement, which will be agreed upon by the Parties, developed for the purposes of the PABS system, with the recipient in accordance with subsection (i) below. Any

such access shall be subject to applicable biosafety and biosecurity rules and standards, and free of charge, or, when a fee is charged, it shall not exceed the minimal cost involved.

(d) Recipients of materials shall not claim any intellectual property or other rights in respect of the pathogens with pandemic potential, or their genomic sequences, components or related information.

(e) Access to pathogens with pandemic potential protected by intellectual and other property rights shall be consistent with relevant international agreements and with relevant national laws.

6. Multilateral benefit-sharing:

(a) The Parties agree that the benefits, both monetary and non-monetary, arising from facilitating access to pathogens with pandemic potential shall be shared fairly and equitably, in accordance with the provisions of the PABS system. Accordingly, it is understood that the production of pandemic vaccines or other pandemic-related products, irrespective of the technology, information or material used, implies the utilization of pathogens with pandemic potential, their genomic sequence, components and related information.

(b) Facilitated access shall be provided pursuant to a Standard Material Transfer Agreement, the form of which shall be set out in the PABS system and shall contain the benefit-sharing obligations that the access to pathogens with pandemic potential is subject to.

(c) *Three options are presented for subparagraph 6(c) of Option 12.B.*

**Option 6(c).X:** The benefit-sharing obligations [of manufacturers of pandemic-related products developed from the utilization of pathogens with pandemic potential] will include, but not be limited to: (i) real-time access by WHO to a minimum of 20% of the production of safe, efficacious and effective pandemic-related products, in order to support their equitable distribution through the WHO allocation mechanism, in particular to developing countries, [according to public health risk and need]/[that are Parties to this WHO CA+]. The pandemic-related products shall be provided to WHO on the following basis: 10% as a donation and 10% at affordable prices to WHO; and (ii) collaboration with manufacturers from developing countries and WHO initiatives to transfer technology and know-how and strengthen capacities for the timely scale-up of production of pandemic-related products.

**Option 6(c).Y:** In accordance with national laws, each Party shall include provisions in government-funded purchase agreements for pandemic-related products that promote timely and equitable global access to such products, including, as appropriate, provisions that:

- (i) permit the donation of products outside its territories;
- (ii) facilitate potential delivery swaps or other modifications in order to address supply gaps around the world, including in developing countries;
- (iii) promote or incentivize the increased production capability of pandemic-related products, for example through subcontracting, licensing or technology transfer on voluntary and mutually agreed terms as appropriate; and

- (iv) incentivize or otherwise encourage the formulation and sharing of global access plans for the products.

**Option 6(c).Z:** In case the Director-General of the WHO declares a pandemic in accordance with Article XX:

- (i) the Parties in a position to do so shall make all possible efforts to donate pandemic-related products to countries in need, without prejudice to the possibility for the Parties to organize direct donations to countries in need; and
- (ii) in case pandemic-related products are in scarce supply, the Parties shall cooperate and take coordinated actions with the aim of ensuring availability and affordability in access to pandemic-related products, and to this effect shall make all possible efforts to ensure that pandemic-related product manufacturers reserve:
  - (a) no less than [...] % of their production of such pandemic-related products on a quarterly basis for sale to Parties that are least developed countries; and
  - (b) no less than [...] % of their production of such pandemic-related products on a quarterly basis for sale to developing country Parties.

7. Each Party which has manufacturing facilities that produce pandemic-related products in its jurisdiction shall facilitate the shipment to WHO of such pandemic-related products, according to schedules to be agreed between WHO and manufacturers.

### **Article 13. Supply chain and logistics**

1. The Parties agree on the need for transparent, robust, agile, effective, coordinated and diverse global supply chain and logistics functions for pandemic prevention, preparedness, response and health system recovery in order to ensure the availability, affordability of, and equitable access to, pandemic-related products. The Parties commit to working in a participatory manner, with a range of partners and relevant stakeholders at the community, national, regional and global levels, to strengthen the enabling environment for more rapid, equitable, and effective access for pandemic prevention, preparedness and response.

*Three options are presented for paragraph 2 of Article 13.*

#### ***Option 13.A: establish a network***

2. The [WHO Global Pandemic-Related Product Network]/[WHO Global Pandemic Supply Chain and Logistics Network] (the Network) is hereby established. The Network will operate within the framework of WHO, linked with other international organizations and relevant institutions, and will leverage existing regional and international mechanisms.

*2 bis* The Parties shall support the Network's development and operationalization and participate in the Network, including through sustaining it at all times, both during and between pandemics. The Network shall:

- (a) determine the types and size 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) assess the anticipated demand for, map the sources of, and maintain a dashboard of manufacturers and suppliers, including surge capacities, for, the sustainable production of pandemic-related products;
- (c) identify the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms;
- (d) promote transparency in cost, pricing and all other relevant contractual terms along the supply chain;
- (e) develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;
- (f) map existing delivery and distribution options;
- (g) establish or operationalize, as appropriate, international or regional consolidation hubs and staging areas; and
- (h) establish appropriate measures to reduce the unnecessary waste of government-procured pandemic-related products, including through considering the sharing of products in order to maximize their use.

***Option 13.B: no network is established.***

2. The Parties commit to increasing global supply chain transparency and coordination. The Parties recognize the need to undertake the following for robust, resilient, equitable, transparent, agile, geographically distributed and diverse pandemic prevention, preparedness, response and health system recovery:

- (a) determine the types and size of products needed for robust pandemic prevention, preparedness and response, including the costs and logistics of establishing and maintaining strategic stockpiles of such products;
- (b) assess the anticipated demand for, map the sources of, and maintain a dashboard of manufacturers and suppliers for, the sustainable production of pandemic-related products;
- (c) identify the most efficient multilateral and regional purchasing mechanisms, including pooled mechanisms;
- (d) promote the transparency of costs, pricing and all other relevant contractual terms along the supply chain;
- (e) develop a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;
- (f) map existing delivery and distribution options;
- (g) establish or operationalize, as appropriate, international or regional consolidation hubs and staging areas; and

- (h) establish appropriate measures to reduce the unnecessary waste of government-procured pandemic-related products, including through considering the sharing of products in order to maximize their use.

***Option 13.C: a partnership is established.***

2. WHO shall establish, in consultation with the Parties and consistent with Article 14 of this WHO CA+, a partnership, and shall collaborate with the relevant organizations of the UN system, regional organizations and other relevant organizations, paying particular attention to the needs of the Parties that are developing countries, to:

- (a) determine the equitable allocation of the reserved pandemic-related product quantities, taking into account factors such as the population size, demographic structure, epidemiological situation and health system capabilities of beneficiary Parties and their readiness and capacity to utilize such pandemic-related products;
- (b) facilitate, as appropriate, the conclusion of advance purchase commitments and purchase agreements of pandemic-related products;
- (c) assist the buying countries in meeting the regulatory and logistical requirements for the utilization of specific pandemic-related products;
- (d) facilitate or, as necessary, organize the efficient delivery and appropriate utilization of pandemic-related products in beneficiary countries or in humanitarian settings; and
- (e) assist buying countries on all matters related to the utilization of pandemic-related products.

*2 bis* The partnership modalities and collaboration guidelines for the organizations referred to in paragraph 2 shall aim at ensuring close consultation with the beneficiary Parties and ensuring that each function referred in paragraph 2 is discharged by the organization best placed to perform it. Notwithstanding Article 32, the partnership modalities and guidelines may be modified by the member organizations of the partnership, in consultation with the Parties.

*2 ter* The Parties shall provide assistance to the partnership referred to in paragraph 2.

3. Each Party shall, at the earliest reasonable opportunity and in accordance with applicable laws, make publicly available online the terms of government-funded purchase agreements for pandemic-related products in those instances in which the Party is directly entering into the purchase agreement.

4. 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 disclosure of terms and conditions.

5. Each Party shall consider participating in the pooled procurement of pandemic-related products, as appropriate.

6. The Parties [recognize the importance of ensuring]/[commit to ensuring] that any emergency trade measures in the event of a pandemic are targeted, proportionate, transparent and temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.



7. The Parties commit to safeguarding the humanitarian principles of humanity, neutrality, impartiality and independence, and to facilitating the unimpeded access of humanitarian staff and cargo.

8. The Parties shall enable inclusive, equitable and effective cooperation and participation, and shall take all appropriate measures to undertake the foregoing no later than XX.

#### **Article 14. Regulatory strengthening**

1. The Parties shall align and, where possible, harmonize technical and regulatory requirements and procedures; promote and facilitate the use of regulatory reliance and mutual recognition; use common technical documents; and share relevant information and assessments concerning the quality, safety and efficacy of pandemic-related products, including after regulatory approvals are granted.

2. The Parties, for the purposes of regulating pandemic-related products, shall strengthen the capacity and performance of relevant national and regional regulatory authorities, including through technical assistance, with the aim of expediting regulatory approvals and authorizations and ensuring the quality, safety and efficacy of pandemic-related products.

3. Each Party shall make publicly available information on national and/or regional processes, in accordance with relevant laws, for authorizing or approving use of pandemic-related products during a pandemic, and any additional relevant regulatory pathways that may be activated during a pandemic to increase efficiency, and shall ensure that such information is kept updated in a timely manner.

4. The Parties shall, as appropriate, monitor, regulate and strengthen the existing rapid alert systems among neighbouring countries, against substandard and falsified pandemic-related products, including through existing Member State mechanisms on substandard and falsified medical products.

5. Each Party shall take steps to ensure that it has 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.

6. Each Party shall, in accordance with national laws, encourage manufacturers, as appropriate, to generate relevant data and diligently pursue regulatory authorizations and/or approvals of pandemic-related products with WHO-listed authorities, other priority authorities and WHO.

#### **Article 15. International collaboration and cooperation**

1. The Parties shall coordinate, 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, response and recovery of health systems, and to this end shall:

(a) promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness, response and recovery, by means that include establishing appropriate governance arrangements;

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

(c) develop, as necessary, and implement policies, drawing on international guidance, that recognize the rights and specific needs, and ensure the protection of all people, in particular persons in vulnerable situations, those living in fragile environments or areas and small island

developing States, and those who face multiple threats simultaneously, by gathering and analysing data, including data disaggregated by gender, age, geography, socioeconomic status and other relevant population subcategories, to show the impact of policies on different groups;

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

(e) ensure solidarity with, and prevent the stigmatization of, countries that report public health emergencies, and collectively develop collaboration mechanisms as an incentive to facilitate transparency and the timely reporting and sharing of information;

(f) ensure solidarity by providing universal and equitable access to pandemic-related products, technologies and know-how, including through the diversification of production to developing countries, as well as technology transfer;

(g) where appropriate and with due regard for the principle of sovereignty, facilitate WHO's rapid access to outbreak areas within the Party's jurisdiction or control, including through the deployment of rapid response and expert teams, to assess and support the response to emerging outbreaks;

(h) assist developing countries through multilateral and bilateral partnerships that focus on developing capacities for effectively addressing health needs for pandemic prevention, preparedness, response and health system recovery; and

(i) ensure ceasefires in affected countries during pandemics to promote global cooperation against common global threats.

*Two options are presented for the rest of Article 15.*

*Option 15.A: the Article ends at paragraph 1.*

*Option 15.B: the Article continues with the following paragraph 2.*

2. Recognizing the central role of WHO as the directing and coordinating authority on international health work, and mindful of the need for coordination with regional organizations, entities in the United Nations system and other intergovernmental organizations, the WHO Director-General shall determine whether to declare a pandemic.

#### **Article 16. Whole-of-government and whole-of-society approaches at the national level**

1. The Parties recognize that pandemics begin and end in communities and are encouraged to adopt a whole-of-government and whole-of-society approach, including to empower and ensure communities' ownership of, and contribution to, community readiness and resilience for pandemic prevention, preparedness, response and recovery of health systems.

2. Each Party shall, in keeping with national capacities, establish, implement and adequately finance an effective national coordinating multisectoral mechanism, with the meaningful representation, engagement and participation of key actors of communities, as appropriate.

3. Each Party shall, in accordance with its national context, promote the effective and meaningful engagement of communities, civil society and other relevant stakeholders, including the private sector, as part of a whole-of-society response in decision-making, implementation, monitoring and evaluation, and shall also provide effective feedback opportunities.
4. Each Party shall develop, in accordance with its national context, comprehensive national pandemic prevention, preparedness, response and health systems recovery plans pre-, post- and inter-pandemic that, inter alia: (i) identify and prioritize populations for access to pandemic-related products and health services; (ii) 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; (iii) 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 products; (iv) facilitate the rapid and equitable restoration of public health capacities and routine health services following a pandemic; and (v) promote collaboration with relevant stakeholders, including the private sector and civil society.
5. Each Party, based on national capacities, shall take the necessary steps to address the social, environmental and economic determinants of health, and the vulnerability conditions that contribute to the emergence and spread of pandemics, and shall prevent or mitigate the socioeconomic impacts of pandemics, including but not limited to those affecting economic growth, the environment, employment, trade, transport, gender equality, education, social assistance, housing, food insecurity, nutrition and culture, especially for persons in vulnerable situations.
6. Each Party shall take effective measures to strengthen its national public health and social policies to facilitate a rapid, resilient response, especially for persons in vulnerable situations, including by mobilizing social capital in communities for mutual support.

**Article 17. Implementation, acknowledging differences in levels of development**

*Three options are presented for Article 17.*

***Option 17.A***

1. All Parties shall fully implement the WHO CA+, recognizing their different levels of development and respectful of their national sovereignty.
2. The specific needs and special circumstances of developing country Parties to support the implementation of the provisions of this WHO CA+ should be given full consideration for financial and technical assistance, technology transfer and support for sustainable capacity-building.
3. Where a developing country Party lacks the necessary capacity to implement the specific provision(s) of the WHO CA+, the Parties shall work together to identify the most relevant partner(s) that can support the development of such capacities and shall cooperate to ensure that the necessary financial and human resources are made available.

**Option 17.B**

1. The provisions contained in this WHO CA+ shall be implemented by developing country Parties in accordance with this Article.
2. The specific needs and special circumstances of developing country Parties, especially those that are particularly vulnerable to the adverse effects of pandemics and other public health emergencies of international concern and those that would have to bear a disproportionate or abnormal burden under the WHO CA+, should be given full consideration.
3. Financial assistance, technology transfer, technical assistance and support for capacity-building shall be provided by developed country Parties to help developing country Parties to implement the provisions of the WHO CA+. The extent and the timing of implementation of the provisions of the WHO CA+ shall be related to the implementation capacities of developing country Parties, recognizing that enhanced support for developing country Parties will allow for higher ambition in their actions. Other Parties are encouraged to provide or continue to provide such support voluntarily.
4. Where a developing country Party continues to lack the necessary capacity, the implementation of the provision(s) concerned will not be required until implementation capacity has been acquired. Where a developing country Party continues to lack the necessary primary health care and hospital care capacities to the resilience levels as determined under Article 6, the implementation of other capacity-building shall not be required in such a manner that investments will be diverted away from primary health care or hospital care capacities.
5. The extent to which developing country Parties will implement their commitments under the WHO CA+ will depend on the effective implementation by developed country Parties of their commitments under this Article related to financial resources, the transfer of technology, technical assistance and support for capacity-building for developing country Parties, and will fully take into account their administrative and institutional capabilities, as well as the fact that economic and social development and poverty eradication are the first and overriding priorities of developing country Parties.
6. Developing country Parties shall have full flexibility in the implementation of the WHO CA+ in light of their capacities, avoiding undue burden and respectful of their national sovereignty, in accordance with their national capacities and priorities premised upon their sovereign prerogatives.

**Option 17.C: not to include an article.**

**Article 18. Communication and public awareness**

1. The Parties shall strengthen science, public health and pandemic literacy in the population, as well as access to information on pandemics and their effects and drivers, combat the infodemic, and tackle false, misleading, misinformation or disinformation, including through the promotion of international cooperation. In that regard, each Party shall:
  - (a) promote and facilitate, in accordance with national approaches, laws and regulations, the development and implementation of risk communication, community engagement, infodemic management, and educational and public awareness programmes on pandemics and their effects, in a way that is broadly accessible;
  - (b) conduct regular community outreach, social listening, and periodic analysis and consultations with civil society organizations and media outlets in order to identify the prevalence

and profiles of misinformation, which will contribute to design communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust and promoting adherence to public health and social measures;

(c) promote communications on scientific, engineering and technological advances that are relevant to the development and implementation of national and international rules and guidelines for pandemic prevention, preparedness, response and recovery of health systems, based on science and available evidence, when appropriate; and

(d) take effective measures to increase digital health literacy among the public and within the health sector through education and meaningful engagement, including with 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, including confidence, the uptake of and demand for vaccines, the use of appropriate therapeutics, the use of non-pharmaceutical interventions, and trust in science and government institutions.

3. The Parties shall promote a science and evidence-informed approach to effective and timely risk assessment, mindful of the uncertainty and the evolving nature of data and evidence during a pandemic, when communicating such risks to the public.

#### **Article 19. Financing**

1. The Parties recognize the important role that sustainable financial resources play in achieving the objective of the WHO CA+ and the primary financial responsibility of national governments in protecting and promoting the health of their populations. In that regard, each Party shall:

(a) cooperate with other Parties, as appropriate and within the means and resources at its disposal, to raise sustainable financial resources for the effective implementation of the WHO CA+ through bilateral and multilateral, regional or subregional funding mechanisms;

(b) plan and provide adequate financial support, in line with its national fiscal capacities, for: (i) strengthening and sustaining capacities for pandemic prevention, preparedness, response and recovery of health systems; (ii) implementing its national plans, programmes and priorities; and (iii) strengthening health systems and the progressive realization of universal health coverage for pandemic prevention, preparedness and response;

(c) prioritize and increase or maintain, including through greater collaboration between the health, finance and private sectors, as appropriate, domestic funding for pandemic prevention, preparedness, response and health systems recovery, notably for improving and sustaining relevant capacities and working to achieve universal health coverage;

(d) mobilize financial resources for international cooperation and assistance on pandemic prevention, preparedness, response and health systems recovery, in accordance with its respective capacities and based on the principle of solidarity, particularly for developing countries, including through international organizations and existing and new mechanisms; and

(e) provide, within the means and resources at its disposal, support and assistance to other Parties, at their or at WHO's request, in emergencies to facilitate containment at the source.

2. The Parties shall endeavour to ensure, through innovative existing and/or new mechanisms, the sustainable and predictable financing of global, regional and national systems, capacities, tools and global public goods, while avoiding duplication, promoting synergies and enhancing transparent and accountable governance of these mechanisms in order to support the strengthening of pandemic prevention, preparedness, response and recovery of health systems, based on public health risk and need, particularly in developing countries.

3. The Parties agree to establish funding mechanisms to support implementation of this WHO CA+. The mechanisms should avoid duplication and ensure complementarity and coherence among the utilization of the funds within the mechanisms and other existing funds. The mechanisms shall ensure the provision of adequate, accessible, new and additional, and predictable financial resources, and shall include the following:

- (a) A fund shall be established that shall be funded, inter alia, through the following sources:
  - (i) annual contributions by Parties to the WHO CA+, within their respective means and resources;
  - (ii) contributions from pandemic-related product manufacturers; and
  - (iii) voluntary contribution by Parties and other stakeholders.
- (b) A voluntary fund shall be established for pandemic prevention, preparedness, response and recovery of health systems, with contributions from all relevant sectors that benefit from good public health (travel, trade, tourism, transport).
- (c) The aforementioned fund will provide resources to assist Parties, in particular developing countries, in meeting their obligations under the WHO CA+, in particular with regard to capacity-building, the strengthening of health systems and laboratory capacities for pandemic prevention, preparedness response and recovery of health systems, research and development for pandemic related-products, and technology transfer. The fund will also finance the WHO allocation mechanism, as well as the Secretariat of the WHO CA+.
- (d) The Parties shall promote, as appropriate, the use of bilateral, regional, subregional and other appropriate and relevant channels to provide funding for the development and strengthening of pandemic prevention, preparedness, response and health system recovery programmes of developing country Parties.

4. The Parties will [mobilize]/[facilitate] additional financial resources, including from international financing facilities, for the affected countries, based on public health risk and need, in order to maintain and restore routine public health functions and other essential health services during and in the aftermath of a pandemic response.

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

*Two options are presented for paragraph 6 of Article 19.*

***Option 19.A***

6. The Parties agree that the funding models for pandemic prevention, preparedness and response need to take into account national financial capacity and capabilities, and to this extent shall:

(a) establish programmes that convert debt repayment into pandemic prevention, preparedness, response and recovery investments in health, to be attained under individually negotiated “debt swap” agreements; and

(b) commit to expanding partnerships with development finance institutions for providing additional funding to developing countries, through prioritized debt relief, debt restructuring and the provision of grants rather than loans that will guarantee that programmes protect essential health and related spending from encroachment, as well as to take advantage of the economic benefits of frontloading finance for prevention and preparedness or support investments.

***Option 19.B: not to include a paragraph.***

### **Chapter III. Institutional arrangements and final provisions**

#### **Article 20. Conference of the Parties**

1. A Conference of the Parties is hereby established. The Conference of the Parties shall be comprised of delegates representing the Parties to the WHO CA+. The Conference of the Parties shall also include observers as follows:

(a) representatives of the United Nations and its specialized and related agencies, as well as representatives of any State Member thereof or observers thereto that are not Party to the WHO CA+; and

(b) representatives of any body or organization, whether national or international, governmental or nongovernmental, private sector or public sector, which is qualified in matters covered by the WHO CA+, provided that observers pursuant to this subparagraph may be admitted as an observer, upon formal application, in accordance with the terms and conditions to be adopted by the Conference of the Parties, to be renewable every three years, unless at least one third of the Parties object.

2. Only delegates representing Parties will participate in any decision-making of the Conference of the Parties, whether by consensus, voting or otherwise.

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

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

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

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

(d) in the event that the World Health Assembly does not establish such a third main committee of the World Health Assembly by the date of the entry into force of the WHO CA+, the Conference of the Parties shall agree on the framework in which the Conference of the Parties shall operate.

4. 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 CA+, which may, if so determined by the World Health Assembly, be outside the regular cycle of meetings of such a third main committee of the World Health Assembly under which the Conference of the Parties operates.

5. Following the first session of the Conference of the Parties:

(a) subsequent regular sessions of the Conference of the Parties shall be held at the time and date of such a third main committee of the World Health Assembly within which the Conference of the Parties operates; and

(b) extraordinary sessions of the Conference of the Parties shall be held at such a time and date as may be deemed necessary by the Conference of the Parties or at the written request of any Party, provided that, within six months of the request being communicated to them by the Secretariat, it is supported by at least one third of the Parties; the date and time of any such extraordinary sessions would be outside the regular cycle of meetings of such a third main committee of the World Health Assembly within which the Conference of the Parties operates.

6. The Conference of the Parties shall keep under regular review the implementation of the WHO CA+ and take the decisions necessary to promote its effective implementation, and may adopt protocols, annexes and amendments to the WHO CA+, in accordance with Articles 32, 33 and 34. To this end, it shall:

(a) consider reports submitted by the Parties in accordance with Article 21 and adopt regular reports on the implementation of the WHO CA+;

(b) oversee the bodies referred to in paragraph 9 of this Article, including by establishing their rules of procedure and working modalities and, if so decided, by establishing other subsidiary bodies as are necessary to achieve the objective of the WHO CA+;

(c) promote and facilitate the mobilization of financial resources for the implementation of the WHO CA+, in accordance with Article 19;



(d) request, where appropriate, the services and cooperation of, and information provided by, the competent and relevant organizations and bodies of the United Nations system and other international and regional intergovernmental organizations and nongovernmental organizations and bodies, as a means of strengthening the implementation of the WHO CA+; and

(e) consider other action, as appropriate, for the achievement of the objective of the WHO CA+, in the light of experience gained in its implementation.

7. The Conference of the Parties shall keep under regular review, every three years, the implementation and outcome of the WHO CA+ and any related legal instruments that the Conference of the Parties may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO CA+.

8. The work of the Conference of the Parties shall be carried out by the following bodies, as further described in this Chapter, as well as by any other bodies the Conference of the Parties may establish, in accordance with the terms of the WHO CA+:

- (a) the Implementation and Compliance Committee, as set out in Article 22;
- (b) the Panel of Experts to provide scientific advice, as set out in Article 23;
- (c) the Pandemic-Related Products Expert Committee, as set out in Article 24; and
- (d) the Benefit-Sharing Expert Committee, as set out in Article 25.

#### **Article 21. Periodic reports to the Conference of the Parties**

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

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

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

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

4. The periodic reports submitted by the Parties shall be made publicly available online by the Secretariat.

#### **Article 22. Implementation and Compliance Committee**

1. An Implementation and Compliance Committee to facilitate and consider the implementation of, and promote compliance with, the provisions of the WHO CA+ is hereby established as a subsidiary body of the Conference of the Parties.

2. The Implementation and Compliance Committee is mandated to promote the implementation of, and review compliance with, the provisions of the WHO CA+, including by addressing matters related to possible non-compliance.

3. The Implementation and Compliance Committee shall be facilitative in nature and function in a manner that is transparent, non-adversarial and non-punitive, and shall pay particular attention to the respective national and regional capabilities and circumstances of Parties, in particular the needs of Parties that are developing countries. The Implementation and Compliance Committee shall provide notification in writing with respect to the actions of any Party that it may be considering.

4. The Implementation and Compliance Committee shall consider issues of implementation and compliance at the individual and systemic levels, inter alia, and shall report periodically and make recommendations, as appropriate, while cognizant of the respective national circumstances, to the Conference of the Parties. Such recommendations may include proposals for the consideration of the Conference of the Parties aimed at facilitating and providing support for the implementation of the WHO CA+, paying particular attention to the needs of Parties that are developing countries.

5. The Committee shall consist of [...] members, [which are independent experts,] [possessing appropriate qualifications and experience,] nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality and equitable geographical representation. The first members of the Implementation and Compliance Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to Article 20. The members of the Implementation and Compliance Committee shall have recognized competence in fields relevant to the WHO CA+ and shall reflect an appropriate balance of expertise.

6. The Implementation and Compliance Committee shall consider:

- (a) written submissions from any Party with respect to compliance with the provisions of the WHO CA+;
- (b) periodic reports by the Parties submitted in accordance with Article 21;
- (c) any issue submitted to it by the Conference of the Parties; and
- (d) other relevant information.

7. The Implementation and Compliance Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Implementation and Compliance Committee.

8. The Implementation and Compliance Committee shall make every effort to adopt its recommendations by consensus. In the absence of consensus, the recommendations shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two thirds of the members.

9. The Implementation and Compliance Committee shall collaborate with relevant monitoring and review bodies and mechanisms that may be established by the World Health Assembly or by States Parties to the International Health Regulations (2005), including by providing for joint sessions.

10. In the course of its work, the Implementation and Compliance Committee may draw on appropriate information from any bodies established under the WHO CA+ or the World Health Organization, as well as from any information submitted to the WHO by Parties through other mechanisms.

### **Article 23. Panel of Experts to provide scientific advice**

1. An expert body to provide scientific advice is hereby established as a subsidiary body of the Conference of the Parties to provide the Conference of the Parties with information, science-based and other technical advice on matters relating to the WHO CA+. The Panel of Experts shall comprise independent experts competent in the relevant fields of expertise and sitting in their individual expert capacity. It shall be multidisciplinary, in line with the One Health approach. It shall report regularly to the Conference of the Parties on all aspects of its work. The body shall:

- (a) collect, consider and evaluate the most advanced and recent information and scientific knowledge available on the origins, prevention, surveillance, control and impacts of pandemics;
- (b) provide or compile assessments of the state of scientific knowledge relating to zoonotic and other risks, in accordance with the One Health approach;
- (c) prepare scientific and evidence-based assessments on the effects of the measures taken in the implementation of the WHO CA+ and make recommendations, as appropriate;
- (d) provide advice, as appropriate, on scientific programmes and international cooperation in research and development related to matters covered by the WHO CA+, as well as on ways and means of supporting endogenous capacity-building in developing countries;
- (e) respond to scientific, technological and methodological questions that the Conference of the Parties or other subsidiary body may put forward;
- (f) assess the status of available scientific knowledge and evidence relating to pandemics' causes, predictability, prevention measures, and preparedness and response requirements;
- (g) assess global and regional situations, and may forecast emerging pandemic threats, the level of risk they possess, and the need for any specific preparedness programme or response options, including the availability or need for new research on the health products and technologies;
- (h) assess the threats and prepare a R&D Blueprint for pandemics;
- (i) prepare strategies and guidelines for preparedness and response for various known pandemics;

- (j) conduct health technology assessments of pandemic-related products and share the results with Parties and WHO mechanisms;
- (k) act in coordination with the R&D observatory, as well as the R&D Blueprint, in the development of prioritization of R&D objectives and targets;
- (l) stocktake and monitor all types of genetic research and big data analysis associated with highly transmissible pathogens, alert the scientific community about any potential biosecurity concerns, and develop standards and operating procedures to avoid any such concerns;
- (m) develop guidelines on research involving pandemic potential pathogens, including genetic engineering, with a view to avoiding biosafety and biosecurity concerns, including accidental laboratory leakages of disease-causing agents; and
- (n) provide advice and recommendations on any matter, as requested by the Conference of the Parties.

2. The Panel of Experts shall take due account of relevant work by, and allow for the participation in its proceedings of, relevant international and regional intergovernmental organizations, governmental and nongovernmental organizations and bodies, and academic experts.

3. The Panel of Experts shall consist of [...] independent experts selected by common accord by the Heads of the Quadripartite organizations, on the basis of the criteria of competence, independence, multidisciplinary, gender equality and equitable geographical representation. Its composition may be modified by the Conference of the Parties.

4. The Panel of Experts shall elaborate its rules of procedure, which shall be approved by the Conference of the Parties at its second session.

5. The Conference of the Parties shall ensure the availability of the resources necessary to enable the Panel of Experts to achieve its objectives and perform its tasks.

#### **Article 24. Pandemic-Related Products Expert Committee**

1. A Pandemic-Related Products Expert Committee is hereby established as a subsidiary body of the Conference of the Parties.

2. The Pandemic-Related Products Expert Committee is mandated to monitor and analyse issues related to the availability, affordability and quality of pandemic-related products, and to report to the Conference of the Parties, discharge all functions set out in the WHO CA+ and respond to the requests of the Conference of the Parties. It shall pay particular attention to the needs of Parties that are developing countries.

3. The Pandemic-Related Products Expert Committee shall consist of [...] members, who are independent experts nominated by Parties and elected by the Conference of the Parties, with due consideration for gender equality, multidisciplinary, including legal, economic and industrial organization expertise, and equitable geographical representation. The initial members of the Pandemic-Related Products Expert Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 4 of this Article. The members of the Pandemic-Related

Products Committee shall have recognized competence in fields relevant to the WHO CA+ and shall reflect an appropriate balance of expertise.

4. The Pandemic-Related Products Expert Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Pandemic-Related Products Expert Committee.

5. The Pandemic-Related Products Expert Committee shall make every effort to deliberate by consensus. In the absence of consensus, its recommendations or decisions shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two thirds of the members.

#### **Article 25. Benefit-Sharing Expert Committee**

1. A Benefit-Sharing Expert Committee is hereby established as a subsidiary body of the Conference of the Parties.

2. The Benefit-Sharing Expert Committee is mandated to establish guidelines for benefit-sharing, providing transparency and ensuring a fair and equitable sharing of benefits, and to report to the Conference of the Parties, discharge all functions set out in the WHO CA+ and respond to the requests of the Conference of the Parties. It shall pay particular attention to the needs of Parties that are developing countries.

3. The Benefit-Sharing Expert Committee shall consist of [...] members, who are independent experts nominated by Parties and elected by the Conference of the Parties, with due consideration for gender equality, multidisciplinary, including legal, economic and industrial organization expertise, and equitable geographical representation. The initial members of the Benefit-Sharing Expert Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 4 of this Article. The members of the Committee shall have recognized competence in fields relevant to the WHO CA+, and shall reflect an appropriate balance of expertise.

4. The Benefit-Sharing Expert Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Benefit-Sharing Expert Committee.

5. The Benefit-Sharing Expert Committee shall make every effort to deliberate by consensus. In the absence of consensus, its recommendations or decisions shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two thirds of the members.

#### **Article 26. Secretariat**

*Two options are presented for paragraph 1 of Article 26.*

##### *Option 26.A*

1. A Secretariat for the WHO CA+ is hereby established. The Secretariat functions for the WHO CA+ shall be provided by the World Health Organization.

**Option 26.B**

1. A Secretariat for the WHO CA+ is hereby established. The Secretariat functions of the WHO CA+ shall be provided by the World Health Organization, in cooperation with the Food and Agriculture Organization of the United Nations, the World Organisation for Animal Health and the United Nations Environment Programme. The heads of the respective organizations will determine the modalities for their cooperation in discharging the Secretariat functions under the Agreement. Such modalities shall be approved by the Conference of the Parties at its first session.
2. The Secretariat functions shall be:
  - (a) to provide administrative and logistic support to the Conference of the Parties for the purpose of the implementation of this agreement and to make arrangements for the sessions of the Conference of the Parties and any subsidiary bodies and to provide them with services, as required;
  - (b) to transmit reports and other relevant information regarding the implementation of this agreement received by it pursuant to the WHO CA+;
  - (c) to provide support to the Parties, [on request,] particularly developing country Parties and Parties with economies in transition, in implementing the WHO CA+, including the compilation and communication of information required in accordance with the provisions of the WHO CA+ or pursuant to requests of the Conference of the Parties;
  - (d) to prepare reports on its activities under the WHO CA+ under the guidance of the Conference of the Parties, and submit them to the Conference of the Parties;
  - (e) to ensure, under the guidance of the Conference of the Parties, the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;
  - (f) to enter, under the guidance of the Conference of the Parties, into such administrative or contractual arrangements as may be required for the effective discharge of its functions;
  - (g) to cooperate and coordinate with other United Nations agencies in related areas; and
  - (h) to perform other Secretariat functions specified by the WHO CA+ and such other functions as may be determined by the Conference of the Parties.

**Article 27. Relationship with other international agreements and instruments**

1. The implementation of the WHO CA+ shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. The WHO CA+ and other relevant international instruments, including the International Health Regulations (2005), should be interpreted so as to be complementary and compatible.
2. The provisions of the WHO CA+ shall not affect the rights and obligations of any Party under other existing international instruments and shall respect the competencies of other organizations and treaty bodies. In the event that any part of the WHO CA+ addresses areas or activities that may bear on the field of competence of other organizations or treaty bodies, appropriate steps will be taken to promote synergies, compatibility and coherence, with the common goal of strengthened pandemic preparedness, prevention, response and health system recovery.

3. The provisions of the WHO CA+ shall in no way affect the ability of Parties to enter into bilateral or multilateral agreements, including regional or subregional agreements, on issues relevant or additional to the WHO CA+, provided that such agreements are compatible with their obligations under the WHO CA+. The Parties concerned shall communicate such agreements to the Conference of the Parties, through the Secretariat.

#### **Article 28. Reservations**

*Three options are presented for Article 28.*

##### ***Option 28.A***

No reservations may be made to the WHO CA+.

##### ***Option 28.B***

1. No reservations may be made to the WHO CA+, unless explicitly permitted by other articles of the WHO CA+. Such reservations shall not be incompatible with the object and purpose of the WHO CA+.

2. Reservations that are permitted in accordance with paragraph 1 of this Article, once made, may be withdrawn at any time by notification to this effect addressed to the Depositary, who shall then inform all Parties thereof. Such notification shall take effect on the date on which it is received by the Depositary.

##### ***Option 28.C***

1. The Parties may make reservations to the WHO CA+. Such reservations shall not be incompatible with the object and purpose of the WHO CA+.

2. Reservations that are permitted in accordance with paragraph 1 of this Article, once made, may be withdrawn at any time by notification to this effect addressed to the Depositary, who shall then inform all Parties thereof. Such notification shall take effect on the date on which it is received by the Depositary.

#### **Article 29. Confidentiality and data protection**

Any exchange of data or information by the Parties pursuant to the WHO CA+ shall respect the right to privacy, including as such right is established under international law, and shall be consistent with each Party's national law and international obligations regarding confidentiality, privacy and data protection, as applicable.

#### **Article 30. Withdrawal**

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

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

3. Any Party that withdraws from the WHO CA+ shall be considered as having also withdrawn from any protocol(s) to the WHO CA+ to which it is a Party.

**Article 31. Right to vote**

1. Each Party to the WHO CA+ shall have one vote in the Conference of the Parties, except as provided for in paragraph 2 of this Article.

2. Regional economic integration organizations, in matters within their competence, shall exercise their right to vote with a number of votes equal to the number of their Member States that are Parties to the WHO CA+, duly accredited and present during the voting. Such an organization shall not exercise its right to vote if any of its Member States exercises its right, and vice versa.

**Article 32. Amendments to the WHO CA+**

1. Any Party may propose amendments to the WHO CA+. Such amendments shall be considered by the Conference of the Parties. Amendments to the WHO CA+ shall be adopted by the Conference of the Parties.

2. The text of any proposed amendment to the WHO CA+ shall be communicated to the Parties by the Secretariat at least three months before the session at which it is proposed for adoption. The Secretariat shall also communicate proposed amendments to the signatories of the WHO CA+ and, for information, to the Depositary.

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

4. 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 two thirds of the Parties.

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

**Article 33. Annexes to the WHO CA+**

1. Annexes to the WHO CA+ and amendments thereto shall be proposed, adopted and shall enter into force in accordance with the procedure set out in Article 34.

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

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



**Article 34. Protocols to the WHO CA+**

1. Any Party may propose protocols to the WHO CA+. Such proposals will be considered by the Conference of the Parties.
2. The Conference of the Parties may adopt protocols to the WHO CA+. In adopting these protocols, every effort shall be made to reach consensus. If all efforts at consensus have been exhausted and no agreement has been reached, the protocol shall as a last resort be adopted by a two-thirds 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.
3. The text of any proposed protocol shall be communicated to the Parties by the Secretariat at least three months before the session at which it is proposed for adoption.
4. Only Parties to the WHO CA+ may be Parties to a protocol.

**Article 35. Signature**

The WHO CA+ shall be open for signature by all Members of the World Health Organization, any States that are not Members of the World Health Organization but are members of the United Nations, and regional economic integration organizations, at 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 July 2024, and thereafter at United Nations Headquarters in New York, from XX August 2024 to XX November 2024.

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

1. The WHO CA+ shall be subject to ratification, acceptance, approval or accession by States and to formal confirmation or accession by regional economic integration organizations. The WHO CA+ shall be open for accession from the day after the date on which the WHO CA+ 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 CA+ without any of its Member States being a Party shall be bound by all the obligations under the WHO CA+. In the case of those regional economic integration organizations for which one or more of its Member States is a Party to the WHO CA+, the regional economic integration organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the WHO CA+. In such cases, the regional economic integration organization and its Member States shall not be entitled to exercise rights under the WHO CA+ 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 CA+. 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 37. Entry into force**

1. The WHO CA+ shall enter into force on the thirtieth day following the date of deposit of the thirtieth instrument of ratification, acceptance, approval, formal confirmation or accession with the Depositary.

2. For each State that ratifies, accepts or approves the WHO CA+ or accedes thereto after the conditions set out in paragraph 1 of this Article for entry into force have been fulfilled, the WHO CA+ 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 out in paragraph 1 of this Article for entry into force have been fulfilled, the WHO CA+ shall enter into force on the thirtieth day following the date of deposit of its instrument of formal confirmation or of accession.

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

#### **Article 38. Provisional application**

1. Before its entry into force, the WHO CA+ may be applied provisionally, in whole or in part, by a State or regional economic integration organization that consents to its provisional application by so notifying the Depositary in writing at the time of signature or deposit of its instrument of ratification, acceptance, approval, formal confirmation or accession. Such provisional application shall become effective from the date of receipt of the notification by the Depositary.

2. Provisional application by a State or regional economic integration organization shall terminate upon the entry into force of the WHO CA+ for that State or regional economic integration organization, or upon written notification by that State or regional economic integration organization to the Depositary of its intention to terminate its provisional application.

#### **Article 39. Settlement of disputes**

1. In the event of a dispute between two or more Parties concerning the interpretation or application of the WHO CA+, 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 Parties to the dispute from the responsibility of continuing to seek to resolve it.

2. When ratifying, accepting, approving, formally confirming or acceding to the WHO CA+, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory *ipso facto* and without special agreement, in relation to any Party accepting the same obligation: (i) submission of the dispute to the International Court of Justice; and/or (ii) ad hoc arbitration in accordance with procedures to be adopted by consensus by the Conference of the Parties.

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 40. Depositary**

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

**Article 41. Authentic texts**

The original of the WHO CA+, 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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**Annexes**

*[Several Member States proposed text for, or suggested the inclusion of, annexes to the WHO CA+. It is suggested to discuss the inclusion of possible annexes in a later stage, as appropriate and as decided by the INB.]*