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FOURTH MEETING OF THE INTERGOVERNMENTAL NEGOTIATING BODY TO DRAFT AND NEGOTIATE A WHO CONVENTION, AGREEMENT OR OTHER INTERNATIONAL INSTRUMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE Provisional agenda item 3

A/INB/4/3 1 February 2023

Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting

INB drafting group version: 4 April 2023 at 18:25 hours CEST

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, where 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 under 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 (referred to herein as the "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 will be without prejudice to the position of any delegation and following the principle that "nothing is agreed until everything is agreed".
- 4. Accordingly, the Bureau has prepared this zero draft of the WHO CA+ for consideration by the INB

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ZERO DRAFT, FOR THE CONSIDERATION OF THE INTERGOVERNMENTAL NEGOTIATING BODY AT ITS FOURTH MEETING

The Parties to this WHO CA+, 1

- 1. *Reaffirming* the principle of sovereignty of States Parties in addressing public health matters, notably pandemic prevention, preparedness, response and health systems recovery,
- 2. Recognizing the critical role of international cooperation and obligations for States to act in accordance with international law, including to respect, protect and promote human rights,
- 3. Recognizing that all lives have equal value, and that therefore equity should be a principle, an indicator and an outcome of pandemic prevention, preparedness and response,
- 4. Recalling the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, and that unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger,
- 5. Recognizing the central role of WHO, as the directing and coordinating authority on international health work, in pandemic prevention, preparedness, response and recovery of health systems, and in convening and generating scientific evidence, and, more generally, fostering multilateral cooperation in global health governance,
- 6. *Noting* that a pandemic situation is extraordinary in nature, requiring States Parties to prioritize effective and enhanced cooperation with development partners and other relevant stakeholders to address extraordinary challenges,
- 7. Recognizing that the international spread of disease is a global threat with serious consequences for public health, human lives, livelihoods, societies and economies that calls for the widest possible international cooperation and participation of all countries and relevant stakeholders in an effective, coordinated, appropriate and comprehensive international response,
- 8. Recalling the International Health Regulations of the World Health Organization and the role of States Parties and other stakeholders in preventing, protecting against, controlling and providing a public health response to the international spread of disease in ways that are commensurate with, and restricted to, public health risks, and which avoid unnecessary interference with international traffic and trade,
- 9. *Recognizing* that national action plans for pandemic prevention, preparedness, response and recovery of health systems should take into account all people, including communities and persons in vulnerable situations, places and ecosystems,
- 10. Recognizing that the threat of pandemics is a reality and that pandemics have catastrophic health, social, economic and political consequences, especially for persons in vulnerable situations, pandemic prevention, preparedness, response and recovery of health systems must be systemically integrated

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¹ The Bureau proposes, consistent with Member State submissions, that the preambular section be discussed at the appropriate point in the negotiations.

into whole-of-government and whole-of-society approaches, to ensure adequate political commitment, resourcing and attention across sectors, and thereby break the cycle of "panic and neglect",

- 11. Reflecting on the lessons learned from coronavirus disease (COVID-19) and other outbreaks with global and regional impact, including, inter alia, HIV, Ebola virus disease, Zika virus disease, Middle East respiratory syndrome and monkeypox/mpox, and with a view to addressing and closing gaps and improving future response,
- 12. Recognizing that urban settings are especially vulnerable to infectious diseases and epidemics, and the important role that communities have in preventing, preparing for and responding to health emergencies,
- 13. *Noting* with concern that the COVID-19 pandemic has revealed serious shortcomings in preparedness especially at city and urban levels for timely and effective prevention and detection of, as well as response to, potential health emergencies, indicating the need to better prepare for future health emergencies,
- 14. *Noting* that in 2021 women comprised more than 70% of the global health and care workforce and an even higher proportion of the informal health workforce, and during the COVID-19 response were disproportionately impacted by the burden of the pandemic, notably on health workers,
- 15. Reaffirming the importance of diverse, gender-balanced and equitable representation and expertise in pandemic prevention, preparedness, response and health system recovery decision-making, as well as in the design and implementation of activities,
- 16. Expressing concern that those affected by conflict and insecurity are particularly at risk of being left behind during pandemics,
- 17. Recognizing the synergies between multisectoral collaboration through whole-of-government and whole-of-society approaches at the country and community level and international, regional and cross-regional collaboration, coordination and global solidarity, and their importance to achieving sustainable improvements in pandemic prevention, preparedness and effective response,
- 18. Acknowledging that the repercussions of pandemics, beyond health and mortality, on socioeconomic impacts in a broad array of sectors, including economic growth, employment, trade, transport, gender inequality, food insecurity, education, environment and culture, require a multisectoral whole-of-society approach to pandemic prevention, preparedness, response and recovery of health systems,
- 19. Acknowledging the impacts of determinants of health across different sectors and communities on the vulnerability of communities, especially persons in vulnerable situations, to the spread of pathogens and the evolution of an outbreak,
- 20. *Underscoring* that multilateral and regional cooperation and good governance are essential to prevent, prepare for, respond to, and recovery of health systems from, pandemics that, by definition, know no borders and require collective action and solidarity,
- 21. *Emphasizing* that policies and interventions on pandemic prevention, preparedness, response and recovery of health systems should be supported by the best available scientific evidence and adapted to take into account resources and capacities at subnational and national levels,

- 22. Reaffirming the importance of access to timely information, as well as efficient risk communication that manages to counteract pandemics,
- 23. *Understanding* that most emerging infectious diseases originate in animals, including wildlife and domesticated animals, then spill over to people,
- 24. Recognizing the importance of working synergistically with other relevant areas, under a One Health approach, as well as the importance and public health impact of growing possible drivers of pandemics, which need to be addressed as a means of preventing future pandemics and protecting public health,
- 25. *Noting* that antimicrobial resistance is often described as a silent pandemic and that it could be an aggravating factor during a pandemic,
- 26. Reaffirming the importance of a One Health approach and the need for synergies between multisectoral and cross-sectoral collaboration at national, regional and international levels to safeguard human health, detect and prevent health threats at the animal and human interface, in particular zoonotic spill-over and mutations, and to sustainably balance and optimize the health of people, animals and ecosystems,
- 27. Acknowledging the creation of the Quadripartite (WHO, the Food and Agriculture Organization of the United Nations, the World Organisation for Animal Health and the United Nations Environment Programme) to better address any One Health-related issue,
- 28. Reiterating the need to work towards building and strengthening resilient health systems to advance universal health coverage, as an essential foundation for effective pandemic prevention, preparedness, response and recovery of health systems, and to adopt an equitable approach to prevention, preparedness, response and recovery activities, including to mitigate the risk that pandemics exacerbate existing inequities in access to services,
- 29. Recognizing that health is a precondition for, and an outcome and indicator of, the social, economic and environmental dimensions of sustainable development and the implementation of the 2030 Agenda for Sustainable Development,
- 30. Recognizing that pandemics have a disproportionately heavy impact on frontline workers, notably health workers, the poor and persons in vulnerable situations, with repercussions on health and development gains, in particular in developing countries, thus hampering the achievement of universal health coverage and the Sustainable Development Goals, with their shared commitment to leave no one behind,
- 31. Recognizing the need to enhance global solidarity and effective global coordination, as well as accountability and transparency, to avoid serious negative impacts of public health threats with pandemic potential, especially on countries with limited capacities and resources,
- 32. *Acknowledging* that there are significant differences in countries' capacities to prevent, prepare for, respond to and recover from pandemics,
- 33. *Deeply concerned* by the gross inequities that hindered timely access to medical and other COVID-19 pandemic-related products, notably vaccines, oxygen supplies, personal protective equipment, diagnostics and therapeutics,

- 34. Reiterating the determination to achieve health equity through resolute action on social, environmental, cultural, political and economic determinants of health, such as eradicating hunger and poverty, ensuring access to health and proper food, safe drinking water and sanitation, employment and decent work and social protection in a comprehensive intersectoral approach,
- 35. *Emphasizing* that, in order to make health for all a reality, individuals and communities need: equitable access to high quality health services without financial hardship; well-trained, skilled health workers providing quality, people-centred care; and committed policy-makers with adequate investment in health to achieve universal health coverage,
- 36. *Emphasizing* that improving pandemic prevention, preparedness, response and recovery of health systems relies on a commitment to mutual accountability, transparency and common but differentiated responsibility by all States Parties and relevant stakeholders,
- 37. Recalling the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and reiterating that the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) does not and should not prevent Members of the World Trade Organization from taking measures to protect public health,
- 38. Reaffirming that the TRIPS Agreement can and should be interpreted and implemented in a manner supportive of the right of Members of the World Trade Organization to protect public health and, in particular, to promote access to medicines for all,
- 39. Reaffirming that Members of the World Trade Organization have the right to use, to the full, the TRIPS Agreement and the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics,
- 40. Recognizing that protection of intellectual property rights is important for the development of new medical products, but also recognizing concerns about its effects on prices, as well as noting discussions/deliberations in relevant international organizations on, for instance, innovative options to enhance the global effort towards the production of, timely and equitable access to, and distribution of health technologies and know-how, by means that include local production,
- 41. *Recognizing* that protection of intellectual property rights is important for the development of new medicines, and also recognizing concerns about the negative effect on prices and on the production of, timely and equitable access to, and distribution of vaccines, treatments, diagnostics and health technologies and know-how,
- 42. Recognizing that intellectual property protection is important for the development of new medicines, and also recognizing concerns about its effect on prices, as well as noting discussions on enhancing global efforts towards the production of, timely and equitable access to, and distribution of health technologies and products,
- 43. Recognizing the concerns that intellectual property on life-saving medical technologies continues to pose threats and barriers to the full realization of the right to health and to scientific progress for all, particularly the effect on prices, which limits access options and impedes independent local production and supplies, as well as noting structural flaws in the institutional and operational arrangements in the global response to the COVID-19 pandemic, and the need to establish a future pandemic prevention, preparedness and response mechanism that is not based on a charity model,

- 44. *Reaffirming* the flexibilities and safeguards contained in the TRIPS Agreement and their importance for removing barriers to production of, and access to, pandemic-related products, as well as sustainable supply chains for their equitable distribution, while also recognizing the need for sustainable mechanisms to support transfer of technology and know-how to support the same,
- 45. Reaffirming the flexibilities and safeguards contained in the TRIPS Agreement and their importance for ensuring access to technologies, knowledge and full transfer of technology and knowhow for production and supply of pandemic-related products, as well as their equitable distribution,
- 46. Recalling resolution WHA61.21 (2008) on the global strategy and plan of action on public health, innovation and intellectual property, which lays out a road map for a global research and development system supportive of access to appropriate and affordable medical countermeasures, including those needed in a pandemic,
- 47. Recognizing that publicly funded research and development plays an important role in the development of pandemic-related products and, as such, requires conditionalities,
- 48. Underscoring the importance of promoting early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens, as well as the fair and equitable sharing of benefits arising therefrom, taking into account relevant national and international laws, regulations, obligations and frameworks, including the International Health Regulations, the Convention on Biological Diversity and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, and the Pandemic Influenza Preparedness Framework, and also mindful of the work being undertaken in other relevant areas and by other United Nations and multilateral organizations or agencies,
- 49. Acknowledging that pandemic prevention, preparedness, response and recovery of health systems at all levels and in all sectors, particularly in developing countries, require predictable, sustainable and sufficient financial, human, logistical and technical resources,

Have agreed as follows:

The world together equitably

Vision: The WHO CA+¹ aims for a world where pandemics are effectively controlled to protect present and future generations from pandemics and their devastating consequences, and to advance the enjoyment of the highest attainable standard of health for all peoples, on the basis of equity, human rights and solidarity, with a view to achieving universal health coverage, while recognizing the sovereign rights of countries, acknowledging the differences in levels of development among countries, respecting their national context and recognizing existing relevant international instruments. The WHO CA+ aims to achieve greater equity and effectiveness for pandemic prevention, preparedness and response through the fullest national and international cooperation.

¹ At its second meeting in July 2022, the INB identified that Article 19 of the WHO Constitution is the comprehensive provision under which the WHO CA+ should be adopted, without prejudice to also considering, as work progressed, the suitability of Article 21.

Chapter I. Introduction

Article 1. Definitions and use of terms

- 1. For the purposes of this WHO CA+:
 - (a) "[genomic DEL JPN/RETAIN IDN] [genetic ADD JPN, USA/ DEL IRN] sequences [of pathogens ADD IRN]" 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) "pandemic [emergency ADD USA/DEL SAU]" means the [simultaneous breakout and ADD NGA] [global spread DEL AUS, KEN, IND] [wide international spread ADD AUS, KEN, IND] of a [[novel ADD GBR] pathogen [or [a novel ADD GBR/DEL IND, RUS, BWA, COL] [viral ADD NGA] variant DEL MAR] DEL KEN] [disease ADD KEN] that infects human populations [with limited or no immunity DEL TGO] through sustained and high transmissibility [from person to person DEL AUS, FJI] [with the capacity to cause ADD AUS], [a global ADD SAU][overwhelming health systems with DEL AUS] severe morbidity and [high DEL AUS] mortality], [and causing DEL AUS] [social and economic disruptions DEL SAU, RUS, AUS][social disruption and economic downturn ADD SAU], all of which [require DEL AUS] [requiring ADD AUS] [equitable and ADD NAM, BWA] effective national [, regional ADD THA] and global [and multisectoral ADD GBR] collaboration [, coordination and response ADD NGA] [and coordination DEL NGA] for its control [and the mitigation of its adverse effects ADD THA] DEL MCO]; 1
- [ALT (b) BRN "pandemic" means a public health emergency of international concern caused by a pathogen or variant [representing a risk for global public health ADD MCO] [with the potential to overwhelm health systems, cause social and economic disruption DEL MCO], requiring effective national, [regional and ADD MCO] global [, and multisectoral collaboration and coordination;] [coordination and response; ADD MCO]
 - (c) "pandemic-related products" means [health related ADD JPN] products that may be needed for pandemic prevention, preparedness, response and/or [health system THA] recovery, and which may include, without limitation, diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen;
 - (d) [Persons in vulnerable situations means individuals or groups at increased risk of infection or increased risk of severe disease within the context of a pandemic [during peace, conflict, and post-conflict situations PSE]. This may include but is not limited to BRN] ["persons in vulnerable situations" [includes, but is not limited to BGD] [means vulnerable and [members of USA] marginalized groups DEL, NGA, KSA, TUR, UGA, TOG] [[includes in a pandemic and according to national context MOR], [people living in informal settlements KEN] [rural [and remote USA] communities ADD PRY, USA, COL] [persons belonging to GBR] Indigenous [People[s DEL, GBR/RETAIN PAR, CAN, BRA, AUS, NAM, COL]] DEL, USA] [persons USA], [as a collective or as individuals, BRA] [experiencing vulnerability CAN], [local communities IDN] persons belonging to national or ethnic, religious or linguistic minorities DEL TUR], [people under foreign occupation SYR, NAM, PSE], [prisoners, PSE,

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¹ 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 and other relevant mechanisms and instruments. In this connection see Article 15.2 hereof.

COL, PSE] [and detainees, PSE] refugees, [displaced persons, AUS] migrants [and migrant workers BGD] asylum seekers, stateless persons, persons in humanitarian settings and fragile [and conflict-stricken BGD] contexts, [marginalized communities DEL, NGA, KSA], older people, [gender-diverse persons AUS, BRA/DEL KSA] persons with disabilities, [indigents KEN] persons with health conditions, [women and girls including those who are AUS, BRA] pregnant [women DEL AUS, BRA], infants, children and adolescents, and those living in fragile areas, [such as DEL AUS/and] Small Island Developing States DEL ETH] [developing and landlocked countries ADD PRY] [,low and middle income countries PHL][among others ARG]; DEL RUS, IRN, MEX, ETH] DEL UGA]

- (a) "pathogen with pandemic potential" means...;
 - (e) "One Health approach" means...;
 - (f) "One Health surveillance" means...; [MERGE (f) and (g), SAU, MAR]
 - (g) "infodemic" means...;
 - (h) "inter-pandemic" means...;
 - (i) "current health expenditure" means...;
 - (j) "universal health coverage" means...; and
 - (k) "[health system ADD THA] recovery" means...
 - (1) [ADD DEF prevention, preparedness, response IDN]
 - (m) [ADD DEF "pandemic potential" means...; IDN]
- (n) [ADD DEF "medical countermeasures" means' SAU]
- (o) [ADD DEF "emerging and re-emerging" means ... SAU]
- (p) [ADD DEF "epidemic" means ... SAU]
- (q) [ADD DEF "outbreak" means ... SAU]

Article 2. Relationship with other international agreements and instruments

1. [[Nothing in the WHO CA+ is [meant DEL SAU] to conflict with the charter of the United Nations, the Constitution of the World Health Organization, or the International Health Regulations. USA, COL] [The implementation of the WHO CA+ shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization DEL USA, NZL, COL]]. The WHO CA+ [and [[the relevant international instruments DEL MCO], [including the DEL MCO] the International Health Regulations NZL] DEL USA]], should be interpreted so as to [not undermine the rights and obligations of States Parties to the International Health Regulations and other relevant international instruments USA] [[be complementary[,and JPN, MCO] compatible. [and synergistic DEL JPN, MCO, CHN], [coherent ISR] [and consistent with NZL, ISR] and the WHO CA+ should be interpreted [in a manner that promotes and supports the implementation and operationalization of the International Health

Regulations [and other relevant international instruments.¹ DEL USA]] DEL RUS] [The COP shall develop cooperative mechanisms with other organizations and treaty bodies COL], [[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 [examine overlaps and MOR] [avoid DEL] [unnecessary NGA, RUS, ETH, MOR] duplication and promote [synergies DEL CHN/RETAIN BGD], compatibility and coherence, with a common goal of strengthened pandemic [prevention NGA, ETH] preparedness, [prevention DEL NGA, ETH], response and health system recovery DEL NZL, IRN] DEL ESW].

[2 bis The WHO CA+ should be interpreted in a manner that promotes and supports the implementation and operationalization of the International Health Regulations and other relevant international instruments. 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 avoid duplication and promote synergies, compatibility and coherence, with a common goal of strengthened pandemic preparedness, prevention, response and health system recovery. ESW] RETAIN BGD]

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

Chapter II. Objective, guiding principles and scope

Article 3. Objective

The objective of the WHO CA+ [and its mechanisms IND] [is cooperation and implementation of international preparedness and response as supporting health systems in a post-pandemic situation RUS], guided by [equity DEL ISR/RETAIN PRY, ETH, PHL, BRA, IDN, TOG, MYS, EGY, PAK, HTI, IRN, CHN] [, human rights AUS] [the vision DEL AUS] [,and ISR] [guiding USA] principles [and rights DEL ISR, AUS/ RETAIN IDN] [and approaches USA] set out herein, is to [protect present and future generations from pandemics and their devastating consequences through the fullest national and international cooperation to AUS] prevent pandemics [and to rapidly and effectively respond to pandemic emergencies in a manner that USA], saves lives, reduces disease burden and protects livelihoods, through strengthening, proactively, the [world's capacities DEL TOG/the capacities of states and other stakeholders TOG, HTI] for preventing, preparing for and responding to, and recovery of health systems from pandemic [and other public health events of regional or global impact ETH] [emergencies USA]. [The objective of the WHO CA+, is to promote and implement effective international cooperation to prevent, prepare for and responding to, and recover of health systems from pandemics. RUS] [It recognises that pandemics have a disproportionate impact on women and girls, indigenous peoples, and all marginalized groups or people in vulnerable situations. CAN] The WHO CA+ aims to [protect and improve health and SAU] [comprehensively and DEL CAN/RETAIN SAU] effectively address systemic gaps and challenges that exist in these areas, at DEL USA] [focuses

¹ The INB is encouraged to conduct discussions on the matter of making explicit the synergies and concrete complementarity of the WHO CA+ with the International Health Regulations and other relevant mechanisms and instruments.

on] [[sub national, ETH] national, regional and international levels [through effective resource mobilization, coordinated and collaborative to KEN] [[including but not limited to gaps in production capacity, technology capacity, and in [equitable KEN, HTI] access to pandemic related products BRA, KEN, MYS, HTI], [through DEL USA/to] substantially reduce[ing/DEL USA] the risk [posed by USA] [of DEL USA] pandemic [including timely control of public health events before they become pandemics, ETH] [emergencies, including by USA] increasing pandemic [prevention, GBR, CAN] preparedness and response [capacities DEL /capabilities ADD USA], [and promoting rapid, effective and equitable coordinated, collaborative, transparent, [[progressive DEL MCO/RETAIN IRN, ARG] realization DEL THA] [equitable access to [quality and IDN] affordable pandemic related products and full and effective implementation THA, PRY, ETH, PHL, BRA, IDN, MYS, EGY, HTI] of universal health coverage and ensuring coordinated, collaborative and [best-available ISR] evidence-based [or scientific-based THA] pandemic [prevention, preparedness, CAN] response and [resilient DEL ETH] recovery [of DEL] [for ETH] health systems [resilience ETH] at community, national, regional and global levels. [NOTE: UGA proposes different distribution of the elements PPR]

[ALT The objective of the WHO CA+ is to provide a multilateral system coordinated by WHO for enabling adequate, prompt, and effective capacities for pandemic prevention, preparedness and response, and their operationalization including through [among others, building capacities of the health systems, BGD, PAK] mobilization of financial and technological resources, [and forging international cooperation, BGD] in accordance with the principles listed under Article 4, and complementing the International Health Regulations in order to save lives, reduce disease burden and protect livelihoods [aiming at the realization of universal health coverage ARM]. ESW, BGD, NAM, PAK, BWA, ARM, MOZ]

[ALT The objective of the WHO CA+ is to prevent pandemics, save lives, reduce disease burden and protect livelihoods through the strengthening of pandemic prevention, preparedness, response and recovery of health systems through global solidarity and cooperation towards equitably addressing systemic gaps and challenges that exist at national, regional, and international levels. FJI]

[ALT The objective of the WHO CA+, guided by equity, the vision, principles and rights set out herein, is to comprehensively and effectively prevent pandemics, save lives, reduce high transmissible viral disease burden and protect livelihoods, by strengthening of the global capacity for prevention, preparedness, response to and recovery of Health Systems through a multilateral collaboration, coordination and evidence based response to pandemics and health systems recovery at all levels, based on the principles of equity, including technology transfer, access to pandemic related products, research and training efforts that ensures total containment of pandemics. NGA]

Article 4. [[Guiding DEL NAM, BRA, CHN, COL, RUS, BGD, ETH, NGA, EGY, TGO, GHA, SWZ, PAK, KEN, AFR GROUP, MOZ, BDI, IDN, UGA/RETAIN USA, ISR, JPN] principles [of implementation SWZ] [[and rights SWZ, IDN] DEL ETH, USA, ISR, IRN, CHN] [and approaches USA, COL]

[[To DEL TUR] [For the purposes of TUR] achieve[ing TUR] the objective of the WHO CA+ and [to DEL TUR] implement[ing TUR] its provisions, the Parties [will DEL NAM, ETH, NGA, SWZ, KEN, IDN] [shall NAM, ETH, NGA, SWZ, KEN, AFR GROUP, MOZ, BDI, IDN] [act in accordance with NAM, BGD, ETH, NGA, KEN, AFR GROUP, MOZ, BDI] [[be guided SWZ, JPN], inter alia, by DEL NAM, COL, BGD, ETH, NGA, SWZ, KEN, AFR GROUP, MOZ, BDI, IDN/RETAIN JPN] the

principles [and rights DEL IRN] set out below: DEL PAK] [NOTE: split article 4 into principles (1, 2, 3, 4, 5, 6, 8, 11) and approaches (10, 14); the rest to be defined where to include them ARG, BRA]

- 1. **Respect for human rights [and fundamental freedoms USA/DEL IRN]** The implementation of the WHO CA+ shall be with full respect for the [dignity DEL AUS, NOR, IRN/RETAIN RUS], human rights [, mainly the right to health and the right to development. IRN] [[, dignity AUS] and fundamental freedoms of [all AUS, NOR] persons, [and [shall be guided by the Charter of the United Nations and the Constitution of the WHO RUS] the each Party shall protect and promote [universal human rights and freedoms AUS, NOR] DEL SGP, PAK] [such [human rights and fundamental USA/DEL SAU] [rights and GBR/DEL SAU] freedoms DEL ARG, SAU] [them ARG]. DEL IRN] [NOTE: Move to #3 ISR] [NOTE: Switch #1 and #2 NGA] [NOTE: keep original order of principles NOR, EGY]
- The right to [the highest attainable standard of GBR, CHE, BWA, USA, MOZ, ETH, ARM, NOR, PHL, CAN, MAR, TUN, ISR, USA/DEL IND | health - The enjoyment of the highest attainable standard of [physical and mental AUS, ARG, NZL, MEX, BGD, PAK, TUN, ECU, COL, ISR, USA, RUS, BRA, CAN, UGA, PER, SAU, TON, KOR, FJI, ZAF, AFR GROUP, CHE, BWA, IDN, BDI, NAM, MOZ, ETH, ARM, NOR, GBR, PHL, TUR, HTI, MAR, DOM, OMN health [without discrimination. SWZ][, [as PAK, TUN, TGO, SYR] [defined [by the Constitution of the WHO PAK, TUN, TGO, RUS, ETH, HTI, MAR, SYR] as a state of complete physical, mental and social well-being [and not merely the absence of disease or infirmity CHN, BGD, PAK, TUN, BRA, UGA, BWA, ARG, NAM, ETH, NOR, SYR, DOM], DEL AUS] is one of the fundamental rights of every human being without distinction [of any kind. FJI, DOM, TUN, MAR] [[[of [age, DEL CHN, BGD, PAK, SAU/RETAIN ARG, NOR] [gender, AUS, ARG, NZL, MEX, COL, ISR, USA, BRA, GBR, CAN, PER, FJI, CHE, BWA, NOR, PHL, OMN/DELETE SAU, EGY] [, disability [and sexual orientation DEL NGA, TGO, RUS, UGA, SAU, EGY, BDI, NAM, ETH, SYR, MAR, IRQ, OMN, PAK], NZL, MEX, COL, CAN, PER, BRA, FJI, USA, NOR, AUS] race, religion, political belief, economic or social condition. [[This right recognizes DEL ETH] [The right for health ETH] a legal obligation on States to ensure access to timely, acceptable, and affordable health care through the allocation of "maximum available resources" to progressively realize this right ZAF, AFR GROUP, MOZ, ETH] [[[This DEL ETH] [The right for health ETH, HTI] includes right of [timely UGA] access to pandemic related products such as vaccines, PPE, diagnostics and therapeutics [,etc. HTI] [technology and know-how UGA]. NGA, IDN, MOZ, ETH, ARM, UGA] NOTE: Move before previous sentence NGA] [NOTE: Move to #1 ISR, NGA, IRN, CHN, BGD, BWA, ARM] DEL PAK, IRN, SYR] DEL FJI, DOM, TUN] DEL MAR] DEL SWZ]
- 3. Sovereignty [and territorial integrity MAR] States have, in accordance with the Charter of the United Nations and the [general IRN] principles of international law, the sovereign right [, in full respect of their territorial integrity, MAR/DEL DZA] to determine and manage their approach to public health, notably pandemic prevention, preparedness, response and recovery of health systems, pursuant to their own policies and legislation, [provided that activities within their jurisdiction [or control DEL TUR] do not cause damage to their peoples [s' access to universal human rights or the universal human rights of those in AUS, COL] [and DEL AUS] other countries. DEL TGO, CHN, SGP, IRN, RUS, ETH, SYR] [In doing so they should uphold the objective of the WHO CA+ AUS, COL] [with due regard for other countries and their peoples. CHN] [States also have [the JPN] sovereign [rights DEL JPN] right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or areas beyond the limits of national jurisdiction JPN, NZL, TUR] over their biological [and natural ETH, TUR, NGA] resources. IDN, UGA, COL, NAM, BRA, IND, BGD, MYS, PRY, PHL, IRN, ARG, TUN, CHN, ETH, SYR, MAR, BWA, TUR, NGA, EGY, GHA, MOZ, OMN] [Sovereignty also covers the rights of States over their biological resources. DEL IDN, UGA, COL, NAM, BRA,

IND, BGD, MYS, PRY, PHL, IRN, ARG, TUN, CHN, ETH, SYR, MAR, BWA, TUR, NGA, EGY, GHA, MOZ, OMN/RES SGP] [NOTE: Move to #2 ISR, CHN] [Nothing in the WHO CA+ is meant to interfere in the internal affairs and the territorial integrity of States Parties IRN, SYR]

[ALT States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to legislate and to implement legislation in pursuance of their health policies. In doing so, they should uphold the [purposes DEL FJI] [objectives FJI] of this agreement. USA, CAN, SGP, NZL, GBR, FJI, KOR, ARG, TON]

- 4. Equity – The absence of [unfair, RES AUS/RETAIN HTI, EGY] avoidable or remediable differences, including in their capacities, among and within countries, including between groups of people, whether those groups are defined socially, economically, demographically, geographically or by other dimensions of inequality, is [the obstacle to achieve equity CHN, NAM, NGA] [central to equity DEL CHN, NAM, NGA]. Effective pandemic prevention, preparedness, response and [health system THA, CAN, TUN, HTI, ZAF, AFR GROUP, NGA, EGY, OMN, COL, TON, MOZ, FJI, PER] recovery cannot be achieved without political will and commitments in addressing the structural challenges in inequitable access to [global public goods, including through THA, MEX, BGD, PHL, MOZ, CHN, NAM, IDN, MYS, PAK, ARG, ZAF, AFR GROUP, OMN, DOM, BWA, ECU, DOM, UGA, FJI, HTI, PRY] [unhindered, BRA, SYR, IRN, MEX, BGD, PHL, MOZ, CHN, NAM, IDN, TUN, EGY, MYS, HTI, PAK, ZAF, AFR GROUP, BWA, PSE, COL, VEN, ARG, CUB/DEL USA, AUS] fair, equitable and timely access to [quality, THA, NGA] [affordable, DEL GBR, USA, AUS] safe [effective, quality, affordable essential GBR, USA, AUS, NGA, OMN, NOR,] [and efficacious DEL GBR, USA, AUS, NGA] [pandemic-related [health EGY] products RES JPN] and services, essential health services, information and social support, as well as tackling the inequities in terms of [access to technology on mutually agreed terms CAN, USA/DEL NAM, NGA, ARG] and in terms of capacities for research and development including on [voluntary CAN/DEL NGA, NAM, HTI, COL, ARG] transfer of technology and know-how ZAF, AFR GROUP, NGA, COL, ETH, UGA, MOZ, NAM, SWZ, PSE, EGY, IDN, PAK, IRN, SYR, ARG, PER, BRA, VEN, ECU, PHL] technology, health [and care ETH, MOZ] workforce, infrastructure and financing, among other aspects. [NOTE: Move to #1 IDN] [Within the present instrument the Parties commit to cooperate closely with a view to respecting equity in all the phases of prevention, preparedness, response and recovery in the phase of pandemics. TGO, ETH, HTI]
- 5. [International BGD, PAK, TUN, IRN, BRA, DOM, EGY]/[Global IRN] Solidarity [The parties commit, with this instrument, to show solidarity so as to ensure the protection and resilience of all during pandemics. TGO, HTI] The effective prevention, [of DEL NGA], preparedness, [for and DEL NGA] response, and [health system THA, EGY, HTI, OMN] recovery from NGA, OMN] [to DEL NGA] pandemics requires [national, DEL BGD, NGA, PAK, IRN, CHN, EGY/ RETAIN HTI, THA] [regional THA, IRN, TON, EGY, HTI] [international, multilateral, bilateral and [multisectoral DEL IRN] collaboration, coordination and cooperation, [through global [joint response NGA] [unity DEL NGA] DEL AUS] [and through recognition of different needs and capacities PAK, BRA, ECU, DOM], to achieve the common [public good NGA] [interest DEL NGA] [of DEL NGA] [for NGA] a fairer, [more DEL NGA] equitable and better prepared world. [NOTE: IRN reorder "...bilateral, regional and multilateral"]
- 6. **[Transparency** The effective prevention of, preparedness for and response to pandemics [and health system recovery THA] depends on [the safe CAN] [transparent DEL/rapid USA, CAN], open and timely sharing, access to and disclosure of accurate [and verified CHN] [and relevant THA] information, data [samples USA] [and other relevant elements that may come to light DEL USA] (including biological samples, genomic sequence data, [pathogens COL] [antimicrobial susceptibility data SAU] and clinical trial results [regulatory decisions, and procurement and supply chain information,

USA, AFR GROUP] [prices, [research and development MYS, THA, AFR GROUP] production costs, revenue from sale, and units sold of pandemic related products BRA, MYS, PHL, AFR GROUP] [, and relevant associated metadata AUS] [with due consideration to benefit sharing ETH, AFR GROUP] [through a fair and equitable benefit sharing system, IDN]), for risk assessment [and, DEL THA] control measures, [research and development THA] [and DEL CHN] development [and equally transparent open and timely sharing, access to and disclosure NAM] of pandemic-related products and [health THA] services [delivery THA], [and sharing of benefits derived from the utilization of those information, data and other relevant elements CHN, COL] notably through a whole-of-government and whole-of-society approach, based on, and guided by, the best-available scientific evidence [and information USA] [effective data governance IDN], consistent with [applicable USA] national [sovereignty CHN] [,regional and international privacy DEL CHN] and data [privacy CHN] protection rules, regulations and laws. DEL RUS]

- 7. [Accountability States are accountable for strengthening and sustaining their health systems' capacities and public health functions to provide adequate [early warnings and rapid, equitable, and effective responses, including through adequate USA] health and social measures by adopting and implementing legislative, executive, administrative and other measures [that seek to promote USA] [for DEL USA] fair, equitable, effective and timely pandemic prevention, preparedness, response and recovery of health systems. [All Parties shall cooperate with other States and relevant [international DEL/intergovernmental TUR] organizations, in order to collectively strengthen, support and [enhancing public and private sector support at all levels SAU] sustain capacities for [global DEL/pandemic THA] prevention, preparedness, response and recovery of health systems [at all levels THA]. DEL USA] DEL CHN/RETAIN CRI, UGA] [NOTE: Discuss accountability in Chapter 7 CHN]
- [Common [but differentiated DEL AUS, NZL, MCO, THA, EU/RETAIN EGY, CHN] responsibilities [and [respective PAK, NAM, PER, IRN, FJI, IND, BGD, SWZ] capabilities DEL/ but different capacities [and needs for support THA] AUS, NZL, MCO, THA, EU] in pandemic prevention, preparedness, response and recovery of health systems – All States are responsible for the health of their people, including pandemic prevention, preparedness, response and recovery, and previous pandemics have demonstrated that no one is safe until everyone is safe. Given that the health of all peoples is dependent on the fullest cooperation of individuals and States, all Parties are bound by the obligations of the WHO CA+ [, taking into account different national realities, capacities and levels of development [and needs for support THA] AUS, NZL, MCO, THA]. [States that hold more resources relevant to pandemics, including pandemic-related products and manufacturing capacity, should bear, where appropriate, a commensurate degree of differentiated responsibility with regard to global pandemic prevention, preparedness, response and recovery DEL AUS, NZL, MCO]. With the aim of supporting every Party to achieve the highest level of proven and sustained capacity, full consideration and prioritization are required of the specific needs and special circumstances of developing country Parties, especially those that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate capacities to respond to pandemics; and (iii) potentially bear a disproportionately high burden. DEL USA, ISR, JPN, CAN, GBR/ RETAIN BRA, UGA, AFR GROUP, TUN, PAK, DOM, EGY, SWZ, NAM, SYR, PRY, PER, HTI, IRN, NGA, OMN, CHN, FJI, ETH, IND, COL, GTM, BGD, PSE, MAR,

[ADD In implementing common but differentiated responsibilities, parties shall, among other things (i) develop, in accordance with article XX, a mechanism to verify needs and gaps of developing countries to fully implement the common obligations defined herein; (ii) develop an implementation plan with the resources provided in the financial mechanisms defined herein in article 19 to effectively address the needs and gaps in (i); (iii) allow time periods for the implementation of the obligation of this agreement in accordance with Annex XX. BRA, SYR, BGD]

- 9. [Inclusiveness The active engagement with, and participation of, all relevant stakeholders and partners across all levels [as applicable ISR], [consistent with relevant and applicable international [and national DEL TGO] guidelines [and contexts CAN], [and national TGO] rules and regulations (including those relating to conflicts of interest) DEL RUS], is fundamental for mobilizing resources and capacities to support pandemic prevention, preparedness, response and health systems recovery. [These efforts should be underpinned by the principle to leave no-one behind. AUS, KOR, HTI] [The idea is premised on the need to work together for common public good. NGA] RES NAM, SWZ, KEN]
- 10. [Community engagement [and participation BWA] Full engagement of communities [is essential for better TGO] in [pandemic AUS/DEL EGY] prevention, preparedness, [and TGO] response [to pandemics, as well as TGO] [and DEL TGO] recovery of health systems [is essential DEL TGO] to mobilize social capital, resources, adherence to public health and social measures, [for the achievement of universal health coverage BWA] and to gain trust in government. [Communities play a critical role in providing essential health services, particularly for vulnerable and marginalized groups. AUS/DEL EGY] RES CHN]
- 11. **Gender equality** Pandemic prevention, preparedness, response and recovery of health systems will be guided by and benefit from the goal of equal participation and leadership of men and women in decision-making with a particular focus on gender equality, taking into account the specific needs of all women and girls, using a country-driven, gender responsive/transformative, participatory and fully transparent approach.
- 12. **Non-discrimination and respect for diversity** All individuals should have fair, equitable and timely access to pandemic-related products, health services and support, without fear of discrimination or distinction based on race, religion, political belief, economic or social condition.
- 13. Rights of individuals and groups at higher risk and in vulnerable situations Nationally determined and prioritized actions, including support, will take into account communities and persons in vulnerable situations, places and ecosystems. Indigenous peoples, persons belonging to national or ethnic, religious or linguistic minorities, refugees, migrants, asylum seekers, stateless persons, persons in humanitarian settings and fragile contexts, marginalized communities, older people, persons with disabilities, persons with health conditions, pregnant women, infants, children and adolescents, for example, are disproportionately affected by pandemics, owing to social and economic inequities, as well as legal and regulatory barriers, that may prevent them from accessing health services.
- 14. 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 an aim to sustainably balance and optimize the health of people, animals and ecosystems, including through, but not limited to, attention to the prevention of epidemics due to pathogens resistant to antimicrobial agents and zoonotic diseases.
- 15. **Universal health coverage** The WHO CA+ will be guided by the aim of achieving universal health coverage, for which strong and resilient health systems are of key importance, as a fundamental aspect of achieving the Sustainable Development Goals through promoting health and well-being for all at all ages.
 - 50. **Science and evidence-informed decisions** Science, evidence and findable, accessible, interoperable and reusable data should inform all public health decisions and the development and implementation of guidance for pandemic prevention, preparedness, response and recovery of health systems.

- 51. **Central role of WHO** As the directing and coordinating authority on global health, and the leader of multilateral cooperation in global health governance, WHO is fundamental to strengthening pandemic prevention, preparedness, response and recovery of health systems.
- 52. **Proportionality** Due consideration should be given, including through regular monitoring and policy evaluation, to ensuring that the impacts of measures aimed at preventing, preparing for and responding to pandemics are proportionate to their intended objectives and that the benefits arising therefrom outweigh costs. RESERVE CHN, SWZ]

Article 5. Scope

The WHO CA+ applies to pandemic prevention, preparedness, response and health systems recovery at national, regional and international levels.

Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems

[[ADD EU:

G. Benefit sharing through equitable access to countermeasures

Article G1. General provisions

- 1. In case the Director General of the WHO declares a pandemic situation in accordance with Article 3, the Parties shall make all possible efforts to ensure that the relevant and most appropriate countermeasures are developed, manufactured, authorised and deployed as rapidly as possible and become available in sufficient quantities and at an affordable price to ensure an effective and equitable regional and international response to such pandemic situation.
- 2. To this effect the Parties shall ensure the rapid sharing of pathogen samples, genomic data and other relevant information as set out in article D.3. and section E, which is necessary to enable the fast development and manufacture of countermeasures.
- 3. The countermeasures covered by the provisions of this section/chapter shall be determined by the Countermeasure Expert Committee, as set out in Article P.5., as soon as possible after the declaration of a pandemic situation, on the basis of the characteristics of the pandemic situation, the needs for an effective response, as well as safety and efficacy requirements. The Committee shall also determine whether such countermeasures are in scarce supply for the purpose of an effective and equitable respose by each Party to the pandemic situation. Such determination shall be kept under review and the Committee shall determine when the situation of scarce supply has ended.
- 4. For this purpose the Parties shall cooperate to increase the transparency of market conditions prevailing in the markets for the countermeasures referred to in paragraph 3 and provide the Comittee with information on supply and demand forsuch countermeasures, to support the Committee in assessing their availability and affordability, possible supply chain vulnerabilities and mitigation measures.
- 5. In case a countermeasure referred to in paragraph 3 is developed making use of a pathogen sample, genomic sequence data or other information related to pathogens, any transfer agreement which may cover such sample or data, including an agreement between the Party where the sample or data originate and the countermeasure developer, should set out the general availability and affordability

commitments for the benefit of all countries in need as provided for in Articles G.2 and G.3. The transfer agreement should ensure that the countermeasure developer makes such general availability and affordability commitments applicable to the countermeasure manufacturer also in case the countermeasure manufacturer is a licensee of the countermeasure developer.

- 6. The Parties which are high income countries, and other Parties in a position to do so, shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to set out the availability and affordability commitments which will apply to the countermeasure manufacturer as provided for in Articles G.2 and G.3 in any purchase agreement that they conclude with such manufacturer.
- 7. The Parties which are high income countries, and other Parties in a position to do so, shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to set out the availability and affordability commitments which will apply to the countermeasure manufacturer as provided for in Articles G.2 and G.3, irrespective of whether the manufacturer is the countermeasure developer or a licensee of the countermeasure developer, in any agreement providing support to a countermeasure developer for research and development of new countermeasures.
- 8. The Parties shall encourage the countermeasure developers and manufacturers to commit to implementing the relevant provisions of this section and in particular the provisions set out in Articles G.2. and G.3. Such committments shall be received by the Director-General of the WHO who will keep them under review.
- 9. The Countermeasure Expert Committee shall develop model contract terms that may be used to ensure the rapid conclusion of agreements referred to in paragraphs 5, 6 and 7.
- 10. The Parties shall ensure delivery of medical countermeasures to persons in vulnerable situations and people living in hard-to-reach communities and humanitarian settings.

Article G.2. Availability of countermeasures

- 1. In case a countermeasure is in scarce supply, as determined in accordance with Article 1.3, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to ensure that countermeasure manufacturers reserve:
- a) no less than [...] percent of their production of such countermeasure on a quarterly basis for sale to Parties that are low income countries in accordance with the World Bank categorisation current at the time of the declaration, and
- b) no less than [...] percent of their production of such countermeasure on a quarterly basis for sale to Parties which are middle income countries in accordance with the World Bank categorisation current at the time of the declaration.
- 2. The WHO shall establish, in consulation with the Parties, a partnership and collaborate with the relevant organisations of the UN system, regional organisations and other relevant organisations, with particular attention to the needs of Parties, which are low or lower middle income countries, to:
- a) determine the equitable allocation of the reserved countermeasure quantities, taking into account factors, such as population size, demographic structure, epidemiological situation and and health system capabilities of beneficiary Parties and their readiness and capacity to utilize such countermeasures,

- b) facilitate, as appropriate, the conclusion of advance purchase commitments and purchase agreements of countermeasures,
- c) assist the buying countries in meeting the regulatory and logistic requirements for utilization of the specific countermeasure,
- d) facilitate or, as necessary, organise the efficient delivery and appropriate utilisation of the countermeasures in the beneficiary country or in humanitarian settings, and
- e) assist the buying countries on all matters related to the utilisation of the countermeasures.
- 3. The partnership modalities and collaboration guidelines for the organisations referred in paragraph 2 are set out in Annex 6. Such modalities shall aim at ensuring close consultation with the beneficiary Parties and that each function referred in paragraph 2 is discharged by the organisation best placed to perform it. Notwithstanding article ... (Amendments), the partnership modalities and guidelines may be modified by the member organisations of the partnership, in consultation with the Parties.
- 4. The Parties shall provide assistance to the partnership referred in paragraph 2.
- 5. In case the Director General of the WHO declares a pandemic situation in accordance with Article 3, the Parties in a position to do so shall make all possible efforts to donate countermeasures referred to in article G.1.3 to countries in need. Without prejudice to the possibility for the Parties to organise direct donations to countries in need, donations of countermeasures should be facilitated by and effected through, the partnership referred to in paragraphs 2 and 3 and in accordance with the provisions of this Article.

Article G.3. Affordability of countermeasures

- 1. With respect to sales to, or for the benefit of, Parties, which are low income countries, of countermeasures referred to in Article G.1.3 including, but not limited to, the reserved allocations referred to in Article G.2.1, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts, while a pandemic situation persist, to ensure that countermeasure manufacturers will provide them at not-for-profit price.
- 2. With respect to sales to, or for the benefit of, middle income countries, of countermeasures referred to in Article G.1.3 including, but not limited to, the reserved allocations referred to in Article G.2.1, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts, while a pandemic situation persist, to ensure that countermeasure manufacturers will apply tiered pricing, taking into consideration factors, such as population size, epidemiological situation, income level and capacity to pay of the buying countries.
- 3. The Countermeasures Expert Committee shall issue pricing guidelines including on not-for profit and tiered pricing, for each of the countermeasures referred to in Article G.1.3.
- 4. In case the Director General of the WHO declares a pandemic situation, the Parties in a position to do so shall cooperate, including with the private sector, take coordinated actions and make all possible efforts to make available financial resources for the acquisition of countermeasures referred to in Article 1.3 for the benefit of countries in need, with special attention to the needs and epidemiological situation

of the Parties which are low and lower middle income countries and of persons in vulnerable or humanitarian situations. For this purpose, Parties shall cooperate with the relevant multilateral and regional financial institutions.

Article G.4. Quality of countermeasures

- 1. In case the Director General of the WHO declares a pandemic situation, the Parties and the WHO shall cooperate to ensure the rapid availability of countermeasures by increasing the collaboration, including at regional level, among authorities competent to ensure the quality, safety and efficacy of the countermeasures referred to in Article G.1.3.
- 2. The Parties, with the support of the Secretariat, shall aim at aligning and, where possible, harmonising technical and regulatory requirements and procedures, promote the use of common technical documents, share relevant information and assessments concerning quality, safety and efficacy of countermeasures, including after regulatory approvals are granted.
- 3. The Parties shall promote and facilitate the use of regulatory reliance and mutual recognition, both at national and regional level, with the aim of expediting regulatory approvals and authorisations and ensuring quality, safety and efficacy of countermeasures.
- 4. The Parties, with the support of the Secretariat, shall promote the establishment or development of international and regional networks of scientific, research and regulatory institutions, as well as of international and regional protocols for the performance of clinical trials, with the aim of increasing the acceptability of trials results by the Parties' regulatory authorities. The Parties shall also promote access to relevant clinical data, including clinical trial eports and protocols, for the countermeasures referred to in Article G.1.3.
- 5. The Countermeasures Expert Committee shall issue guidelines for regulatory cooperation for each of the countermeasures referred to in Article G.1.3.
- 6. The Parties and the WHO shall collaborate with the aim of strengthening the capacities of regulatory authorities and systems, especially in case of pandemic situations, with particular attention to the needs of the Parties which are low and lower-middle income countries.

Article G.5. Stockpiling of countermeasures

- 1. The Parties shall cooperate to ensure that international emergency stockpiles of countermeasures are established and existing ones supported or enlarged, with the objective of increasing the equitable availability and affordability of countermeasures, with special attention to the needs of Parties, which are low and lower middle income countries, and of persons in vulnerable situations living in their territories.
- 2. The Conference of the Parties shall take the necessary decisions with the aim of establishing international emergency stockpiles. The Countermeasures Expert Committee shall provide guidance on the types of countermeasures for which emergency stockpiles should be established or supported, where they should be located to facilitate equitable access, adequate financing measures, as well as on the management modalities of individual emergency stockpiles, with the aim of increasing equitable access and effective and efficient stockpiling operations.

Article G.6. Support for additional manufacturing facilities

- 1. In order to improve the availability and affordability of quality countermeasures, the Parties shall cooperate to support public and private sector investment aimed at creating or expanding manufacturing facilities of relevant countermeasures, especially facilities with a regional scope of operation in Parties which are low and middle income countries.
- 2. The Parties shall also promote the voluntary transfer of technology, know-how and skills that may be necessary to improve the availability and affordability of countermeasures.
- 3. For this purpose, the Parties should act individually and jointly by means of grants, loans, taxation and other incentive measures, as appropriate.
- 4. The Countermeasures Expert Committee shall provide advice to the Parties on the matters covered by this article.] RESERVE BRA, NAM, IDN, SWZ, BGD]
 - Article 6. [Predictable [, equitable, AF GROUP, HTI, TUN] global [production, distribution, SWZ, MYS, NAM, ETH, BGD] supply chain and logistics [network DEL AF GROUP, PAK, TUN] [mechanisms AF GROUP, PAK, BGD]
- 1. [The Parties [, recognizing the shortcomings of the preparedness for and response to the COVID-19 pandemic, DEL BRA, IDN, NAM, SWZ, PRY] agree on the need for an [adequate DEL BRA, NAM, PAK, DOM], [fair, IDN, BRA, NAM] equitable, transparent, robust, agile, effective and diverse global supply chain and logistics [network DEL ZAF, AFR GROUP] [mechanism ZAF, AFR GROUP] for pandemic prevention, preparedness, response and recovery [of health systems IDN, BRA, NAM, SAU, HTI] [, that ensure availability of and equitable access to pandemic related products, including pharmaceutical finished products for robust pandemic prevention, preparedness, response, and recovery. BRA, NGA, PAK, ETH, ECU, HTI, SAU, ARM, TUN, CHN] [and without interfering with the sovereignty of states to manage their own supply and logistics ISR] DEL BGD]
- [ALT 1. The Parties hereby establish a WHO Global Production, Distribution and Logistics Mechanism to realize pandemic-related products as global public goods by facilitating equitable access to pandemic-related products through diversified manufacturing bases of production and distribution. BGD]
- 2. [The WHO Global Pandemic Supply Chain and Logistics [Network (the "Network") DEL ZAF, AFR GROUP] [Mechanism ZAF, AFR GROUP] is hereby established DEL SWZ / RESERVE CHN, SAU] [to ensure the transparency and coordination of global sourcing and production of raw materials and other necessary inputs for sustainable and geographically distributed production of pandemic-related products PAK, EGY].
- [ALT 2. The Mechanism established pursuant to paragraph 1 shall carry out the following functions:
- (a) to facilitate the production of pandemic related products thorough designated production facilities at the national and regional level during inter-pandemic period as well as during pandemics based on the recommendations of the Intergovernmental Panel on Pandemic Science (IPPS) established under Article XX;
- (b) to perform supply chain mapping of raw materials, and their manufacturers, distributers, suppliers, and other necessary inputs, for sustainable production of pandemic-related products to effectively and efficiently carry out the recommendations of IPPS.

- (c) to map any potential manufacturers of pandemic related products other than the designated production facilities;
- (d) to assess the availability of the pandemic related products against the anticipated demand as identified by the IPPS and to develop a fair and equitable allocation plan in case of potential shortage.
- (e) to map the existing delivery and distribution options, and to establish or operationalize, as appropriate, international consolidation hubs, as well as regional staging areas to ensure that transport of supplies is streamlined;
- (f) to work with national and regional authorities to maintain the designated production facilities, and distribution systems including international consolidation hubs, and regional staging areas as well as training of their workforce;
- (g) to develop a dashboard that enables the real time information on pandemic-related products' production and supply capacity in different regions and countries, as well as real production and distribution status during the pandemic as well as strategic stockpiles during inter-pandemic period;
- (h) To facilitate technology transfer to the designated production facilities as well as the periodic maintenance and technological upgradation of the same;
- (i) To identify and contract manufacturers other than the designated production facilities for scaling up the production of pandemic related products during pandemics in cases where production and supply capacity of the designated facilities do not meet the demand, and to facilitate technology transfer, as appropriate;
- (k) To provide funding for the maintenance and upgradation of the designated production facilities in the developing countries.
- (l) to perform any other functions required for ensuring equitable access to pandemic related products as well as to carry out any other functions as may directed by the governing body of the WHO CA+. BGD]
- 3. The Parties shall support the [Network's DEL ZAF, AFR GROUP, AFR GROUP] [Mechanism's ZAF, AFR GROUP] development and operationalization [based on review and coordination JPN, AUS], and participate in the Network, within the framework of WHO [and other relevant organizations JPN, AUS], including through sustaining [and operating ETH] it, as appropriate THA] in inter-pandemic times as well as appropriate scale-up in the event of a pandemic [and timely control of other health emergencies of pandemic potential ETH]. [Taking into account their CBDRs, Parties shall provide WHO with timely information and ensure that national stakeholders make information available to States Parties for the adequate functioning of this mechanism/network. BRA] In that regard, the Parties shall:
 - (a) determine the types and size of products needed for robust pandemic prevention, preparedness and response, including costs and logistics for establishing and maintaining strategic stockpiles of such products [by working with relevant stakeholders and experts, guided by scientific evidence and regular epidemiological risk assessment and to be determined in an equitable manner ZAF, AFR GROUP], [including through predictable pre-purchase and long-term procurement contracts based on different types of demands THA] by working with relevant

stakeholders and experts, guided by scientific evidence and regular epidemiological risk assessments [, based on regular epidemiological risk and vulnerability assessment MAR];

- assess anticipated demand for, and map sources of, manufacturers and suppliers, including raw materials and other necessary inputs, for sustainable production of pandemic-related products [, including medical countermeasures JPN, AUS SAU] (especially active pharmaceutical ingredients [diagnostics and other therapeutics ZAF, AFR GROUP]), including manufacturing capacities [with an explicit goal of promoting distributed manufacturing capacities ETH, ZAF, AFR GROUP, NAM] [and a verification system that could be established for each of the supply chain processes. COL] [, [and DEL NGA, EGY] identify [and support NGA, EGY] the most [equitable and ETH, ZAF, AFR GROUP, NAM] efficient [multilateral and regional DEL JPN, AUS / RETAIN ETH, ZAF, AFR GROUP, NAM] purchasing mechanisms, including pooled mechanisms and in-kind contributions [ensuring that global procedures and pooled mechanisms purchased from local or regional manufacturers for global use to sustain broad manufacturing capacity ETH, ZAF, AFR GROUP, NAM] [, as well as [promoting DEL ETH, ZAF, AFR GROUP, NAM] [requiring ETH, ZAF, AFR GROUP, NAM] transparency in cost and pricing of all elements along the supply chain [procurement contracts, manufacturing cost and funding agreements ETH, ZAF, AFR GROUP, NAM]; DEL JPN, AUS / RETAIN ARG, BRA, COL, MEX, ECU, SLV, DOM, EGY, PRY]
- [(b bis) promote transparency by requiring that suppliers of products share information about patent status, subsidies received by government in the development of products, the results of clinical trials and the cost thereof and all other elements along the supply chain NAM, ETH, MEX, IDN]
- (c) develop [, strengthen and implement NGA, EGY] a mechanism to ensure the fair [and DEL ZAF, AFR GROUP] equitable [and context specific ZAF] allocation [at suitable cost EGY, NGA] of pandemic-related products based on [priorities for NGA, EGY] public health risks and [countries' EGY] needs [at suitable time EGY, NGA]; [for States Parties in particular requiring support to access medical countermeasures JPN, AUS, EGY, NGA]
- (d) map existing delivery and distribution options, and establish or operationalize, as appropriate, [strategically and equitably distributed ETH] international consolidation hubs, [with global geographic spread, NGA] as well as regional staging areas, [in compliance with transport safety regulations of the States Parties CHN] to ensure that transport of supplies is streamlined and uses the most appropriate means for the products concerned; and
- (e) develop [an interoperable PHL] [a DEL PHL] dashboard for pandemic-related [product DEL THA] [and life-support non-pandemic products THA] supply [and manufacturing MYS] capacity and availability, with regular reporting, and conduct regular tabletop exercises to test the functioning of the Network.]
- [(f) engage, as appropriate, with the commercial sector on business continuity systems to ensure the supply chain and logistics predictability and resiliency THA]
- [(g) design and implement programmes for more efficient and environmentally sustainable waste management practices in the pandemic response supply chain and logistic systems PHL]
- [ALT 3. The Parties shall support the operationalization and maintenance of the Mechanism and Network's development and operationalization, and participate in the Network, within the framework

of WHO, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic. In that in this regard, the Parties shall:

- (a) Designate production facilities at the national/regional level, as appropriate, that will undertake the production request from the Mechanism;
- (b) Make financial contribution and take part in the maintenance of the above-mentioned Designated Facilities based on the principle of CBDR;
- (c) Cooperate and coordinate with the Mechanism's allocation plans and implement its recommendations;
- (d) Provide the information at the request of the Mechanism for the implementation of its functions as mentioned in Paragraph 2;
- (e) Share with the Mechanism the technical specifications including regulatory dossiers of those pandemic related products that are under the mandate of Mechanism;
- (f) Ensure that their national intellectual property laws have provisions to expedite the production and distribution of pandemic related products by the Designated Production Facilities in an unhindered manner;
- (g) Transfer publicly funded technologies for production of pandemic related products to the Mechanism thorough the Technology Access Pool established pursuant to Article 7;
- (h) Facilitate the prompt supply of raw materials and ingredients needed for the production of the pandemic related products to the designated production facilities. BGD]
- 4. [The Parties [commit not to DEL IRN, BRA, SYR] [shall not IRN, BRA, SYR] impose [regulations DEL IRN, BRA, SYR] [restrictions of any kind IRN, BRA, SYR] that [unduly DEL CHN] interfere with the trade in, or of, pharmaceutical raw materials and ingredients [diagnostics and therapeutics ZAF, AFR GROUP] [, as appropriate, IDN] [and [finished HTI, BRA, FJI, MYS, IRN, BRA, PRY] pharmaceutical products MEX, BOL, CHL COL CRI, ECU, SLV, GTM, HDN, PAN, PER, DOM, VEN, BRN, ARG, HTI, BRA, NZL, FJI, EGY, MYS, IRN, NGA], mindful of the need for unhindered access to pandemic-related products [. DEL SAU] [, according to national circumstances, needs, and priorities SAU] DEL BGD]
- 5. [[In the event of a pandemic IDN, TUR] The Parties [commit to safeguard the humanitarian principles of humanity, neutrality, impartiality and independence, and [according to national law CHN] to facilitate DEL EU] [shall ensure [the [unimpeded DEL NGA, IRN] access of DEL CHN] humanitarian staff and cargo [consistent with international humanitarian law and principles EU]]. The commitment to facilitate such access is understood to be legally binding and [to apply in all circumstances, DEL TUR] consistent with humanitarian principles [. DEL NGA] [, subject to no local objections NGA] DEL BGD]
- [ALT 5. Parties shall cooperate to ensure universal and unhindered access of pandemic related products during a pandemic and to strategic stockpiles during inter-pandemic period. BGD]

6. [The Parties, working through the Governing Body for the WHO CA+, shall take all appropriate measures to establish and start functioning of the Network [immediately, but no later than six months THA] [no later than XX DEL THA [, one year after the entry into force of the pandemic treaty IDN]] DEL BGD]. [The Director General shall take measures to fully operationalize the mechanism established in paragraph 1 within 2 years of the adoption of the treaty. BGD] It is understood that giving effect to this Article immediately upon adoption of the WHO CA+ shall be considered pursuant to, and within the meaning of, Article 35 of the WHO CA+. RESERVE CHE, UK, USA, JPN, AUS, CAN, ZAF, AFR GROUP]

[New Para 7. Developed countries shall provide the financial resources for the functioning of the Mechanism under paragraph 2, especially for maintenance and technological upgradation of designated facilities in the developing countries. BGD, SWZ]

[New Para 8. Parties shall also legislative, administrative and policy measures for the full implementation of this provision and shall report to the governing body of WHO CA+. BGD, SWZ]

- Article 7. [[Access to technology DEL USA/RETAIL ARG, IDN] [and [to ARG] intellectual property ARG]: promoting sustainable and equitably distributed production and [voluntary CAN] transfer of technology and know-how [on voluntary and [mutually agreed terms EGY] USA, CAN] [retain original text for title AF GROUP, EGY]
- 1. [The Parties recognize that inequitable access to pandemic [emergency response USA]-related products [(including but not limited to vaccines, therapeutics and diagnostics) DEL USA] [during pandemic emergencies USA] [should DEL MEX] [shall MEX] be addressed by [but not limited to GBR] [inter alia, promoting investments to CAN] increased [quality and GBR] [sustainable GBR, CAN] manufacturing capacity that is more equitably, geographically [at regional and sub-regional levels SLV] and strategically distributed [for States Parties, in particular, those requiring support for access to medical countermeasures JPN][within the global community NGA]. SWZ] [In addition, other factors such as export restriction, delays in regulatory approval process and logistical problems should also be addressed to improve access to pandemic-related processes. CHE]
- 2. The Parties[, working through the Governing Body for the WHO CA+ DEL USA/ RETAIN and collaborating with WTO NGA], shall [consider USA] strengthen[ing USA] [existing DEL USA] [and develop DEL CHE] [developing USA] [innovative DEL USA] multilateral mechanisms that promote and incentivize [licensing and USA] relevant [voluntary CAN] transfer of technology [and know-how DEL JPN] for [geographically distributed and/or regional USA] production of pandemic [emergency response USA]-related products [during pandemic emergencies USA], on [voluntary and USA, JPN] mutually agreed terms, [as well as the objectives of this instrument COL] [to capable manufacturers RESERVE USA], [particularly DEL USA] [including USA] in developing countries.

[2bis The Parties shall ensure that capable manufacturers are strategically located in order to maximise access to complete pandemic-related products for countries where developing manufacturing capacity is not feasible. FJI]

3. [During inter-pandemic times DEL USA] [Between pandemic emergencies USA], [all DEL USA, CAN] [the USA] [the CAN] Parties [shall CHE] [[commit to establish these mechanisms and DEL CHE, CAN] shall DEL USA] [take measures to BRA]:

- (a) [[coordinate, collaborate, facilitate and incentivize DEL BRA] [ensure that BRA] manufacturers of pandemic-related products [especially those receiving public funding for research and development BRA] to [securely CAN] transfer [where appropriate and feasible, CAN] relevant technology and know-how [on a voluntary basis, CAN] to [capable DEL BRA] [other BRA] manufacturer(s) [[(as defined below) DEL IDN] on mutually agreed terms DEL BRA], including through technology transfer
- (b) hubs and product development partnerships, and [to address the needs to develop DEL BRA] new pandemic-related products in a short time frame, [to increase geographically distributed manufacturing capacity of pandemic-related products in a short time frame BRA] DEL JPN];
- [ALT 3(a) intend to coordinate, collaborate, facilitate and incentivize manufacturers of pandemic emergency response-related products to expand geographic diversification and capacity of manufacturing, in accordance with national law, through, for example, licensing agreements, contract manufacturing agreements, and product development partnerships [with capable manufacturer(s) as defined below) USA RESERVE ON "CAPABLE MANUFACTURERS"] on voluntary and mutually agreed terms USA]
- (c) [intend to USA] strengthen [coordination DEL USA/RETAIN CAN] [among the Secretariats of CAN] [cooperation USA], [with DEL CAN] relevant international organizations [as appropriate USA], [including United Nations agencies, DEL USA] on issues related to public health [(including as impacted by animal health and environmental health under the One Health principle), biosafety and security CAN], intellectual property and trade, including [with a view to ensuring that relevant technical experts are deployed to address these issues, reducing any duplication of work between all three organizations, CAN] [timely matching of supply to demand and DEL EU] mapping manufacturing capacities and demand [as well as ensuring transparency that will support and facilitate effective and timely notification of measures and coordination of rules and policies PHL];
- [ensure that international collaborations on research and development of pandemic-related products, especially with regard to vaccine, therapeutics and diagnostics development, include representation from low to middle income countries (LMICs) and PHL, SAU] [intend to USA] [encourage DEL PAK, EGY, IDN/RET USA, CAN] [require PAK, EGY] [where they deem appropriate CAN] entities, [including manufacturers [within their respective jurisdictions DEL PAK] DEL EU, USA], [that DEL PAK] [to PAK] conduct research and development of [relevant countermeasures EU] [[[pre-pandemic and DEL USA] pandemic [emergency response USA]related products DEL MEX], [in particular those that DEL EU] receive significant public financing for that purpose DEL PAK], to grant [non exclusive PAK], [on [voluntary and USA] mutually agreed terms DEL PAK / RETAIN USA], licences to [capable DEL PAK] [geographically distributed USA] [capable manufacturers RESERVE USA], [notably DEL USA] [including USA] from [low and lower-middle income EU] [developing DEL EU] countries, [with the aim to increase the affordability and availability of relevant countermeasures EU] [to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of [development and production of USA] [pandemic [emergency response-related USA] response product[s USA] DEL PAK] [research, development and production, [in particular for DEL PAK] [of PAK] pre-pandemic and pandemicrelated products DEL USA]; and DEL EU, JPN]

- [(c) bis make the best effort to adjust their national legislation to adapt to the full utilization of flexibilities, including compulsory licensing, as contained in the Doha Declaration on the TRIPS Agreement and Public Health of 2001; and IDN]
- [(c) bis shall review and amend their national legislation to adapt to the full utilization of flexibilities, including compulsory licensing, as contained in the Doha Declaration on the TRIPS Agreement and Public Health of 2001; and NAM]
- (e) Collaborate [with other Parties and relevant entities IDN] to [ensure DEL CAN] [support CAN] equitable [global pricing CAN] and affordable access to health technologies that promote the strengthening of national health systems [, including at primary health care level, CAN] [and mitigate social inequalities DEL IDN].
- [ALT 3(d) intend to promote best practices and information sharing among the Parties and between the Parties and relevant stakeholders, including the private sector, with regard to sustainable and equitably distributed production and transfer of technology and know-how on voluntary and mutually agreed terms. USA]
- 4. [In the event of a pandemic [emergency USA], DEL BRA] the Parties [: DEL BRA] [should make full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreements and Public Health of 2001 and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreements.]
- [4 ALT The Parties acknoledge the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreements and Public Health of 2001 and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreements. CAN]
 - (a) [[[will DEL NGA, IDN, ARM, EGY] [shall NGA, IDN, ARM, EGY] take appropriate measures to support time-bound waivers of intellectual property rights that can accelerate DEL CHE] [May use the inherent flexibilities contained in the WTO TRIPS Agreement, including exemptions which deal with specific public health emergency situations with the aim of accelerating or scaling CHE] [or scale DEL CHE] up manufacturing of pandemic-related products during a pandemic, to the extent necessary to [facilitate the manufacturing PHI] increase the availability and adequacy of affordable pandemic-related products [to complement existing relevant flexibilities under the TRIPS Agreement PHI]; DEL USA, GBR]
 - (b) [Affirm the right to use GBR] [[will DEL CHE, NGA, IDN, ARM] [shall NGA, IDN, ARM] [are entitled to CHE] [apply the full use of DEL GBR] the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 [and in Articles 27, 30 ([for example GBR] [including DEL GBR] the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement DEL CHE]; RESERVE USA] [NOTE: Delink from chapeau 7.4 ARG, BRA]
 - (c) [shall DEL USA] [intend to USA] encourage [all DEL USA] holders of patents related to the production of pandemic [emergency response USA]-related products [to take steps to promote equitable access via voluntary licensing arrangements] [to waive, or manage as appropriate, payment of royalties DEL USA] [including with USA] [by DEL USA] developing country manufacturers on the use, during the [declared USA] pandemic [emergency USA], of their technology for production of pandemic [emergency response USA]-related products, [and shall

require [, as appropriate, DEL IDN] those that have received public financing for the development of pandemic-related products to do so; DEL CHE, USA] and

(d) shall [ensure IDN] [encourage DEL IDN] 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. RESERVE EU/DEL JPN]

[ALT 4(d): intend to make available non-exclusive licensing of government-owned technologies that can be used for development and manufacturing pandemic emergency response-related products and publish the terms of these licenses at the earliest reasonable opportunity and to the fullest extent possible, in accordance with national laws. USA]

[NEW (e) The Parties shall work together to promote and facilitate, on a sustainable manner, knowledge and technology transfer regarding One Health, coordinated with other relevant organizations, including the creation and strengthening of multilateral mechanisms as well as establishing alliances for the development of new products MEX]

[ebis Once a pandemic is declared, a waiver under article 7 becomes automatic and shall be assumed to have been granted NGA]

[d(bis) shall review and amend their national laws to include exceptions to intellectual property rights for purposes of ensuring the transfer of relevant technology and now-how to manufacturers in developing countries NAM]

[4 bis the previous paragraph could be applied also during inter-pandemic times, as appropriate COL]

[NEW 5. In the event of a pandemic, the Parties (c) shall suspend the enforcement of IPRs that may create barriers to manufacture and supply of products during the pandemic. No Party shall challenge these measures based on international obligations that the Party suspending the obligation may have BRA]

- 5. [For purposes of this Article, "capable manufacturer" refers to an entity that operates in a manner that is consistent with national and [/or IDN] international guidelines and regulations, including biosafety and biosecurity standards. MOVE under Article 1 SWZ, ARG, IDN, CAN, ROK] RESERVE PARA 5 USA] RESERVE Article 7 AUS]
- [5 bis the inexistence of capable manufacturers cannot constitute a basis to deny the transfer of technology to a developing country. In that case, the modalities of technology transfer could be defined and adjust, depending the real capacities of that particular developing country. COL]

[NEW 6 The Parties shall 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 in accordance with national laws. USA]

[NEW 7 The Parties shall promote the voluntary engagement by private rights holders with established regional or global technology transfer hubs or other multilateral mechanisms or networks for voluntary licensing and voluntary transfer of technology on mutually agreed terms for pandemic emergency response-related products. USA]

Article 8. Regulatory strengthening

1. [[For the purposes of regulating pandemic-related products, AUS] The Parties shall strengthen the capacity and performance of [relevant AUS] national [and regional ETH] regulatory authorities [and endeavour to AUS] [and DEL PAK] [. Where appropriate, the Parties shall PAK] increase the [harmonization DEL AUS] [convergence AUS] of regulatory requirements [to support reliance-based decision making AUS, NZL] at the international [and DEL AUS] regional [and bilateral AUS] level[s AUS][, including, as applicable, through [capacity building cooperation between regulatory authorities and IDN] [facilitated THA] mutual recognition agreements DEL BGD] DEL AUS, NZL]. MOVE TO PREAMBLE BGD] [In addition to national regulatory authorities, regional regulatory authorities such as the African Medicines Agency Regulation (AMA) play an important role in harmonisation of registration of medicines or products and providing support to Member state. ZAF]

[1 alt. Parties hereby agree to establish a Inter Governmental Panel on Pandemic Science (IPPS) consisting of experts without conflict of interest to investigate the various science and technology aspects of pandemic with its Secretariat located at WHO HQ. WHO shall provide all the science for the IPPS to perform its function efficiently.

1 alt(bis). IPPS shall meet minimum once in a year and assess various scientific aspects related to pandemic prevention, preparedness, response and recovery including the evaluation of pandemic threat, R&D prioritization, coordination, regulation and oversight of genetic engineering of organisms, health technology assessment of pandemic related products and any other aspects of pandemic prevention, preparedness, response and recovery referred by the governing body. Towards its function IPPS is free to create working groups or tasks forces as appropriate.

1 alt (ter). Parties hereby decided to establish a dedicated section in WHO's Global Observatory on Research and Development on pandemic related products and WHO shall submit annual report to the IPPS to facilitate prioritization and coordination of research and development pandemic related products. BGD]

2. [Each Party shall build and strengthen its country [and/or regional ETH] regulatory capacities [, reliance practices AUS] and performance for DEL CHN] [Each party shall facilitate CHN] timely approval of [safe and high-quality AUS] pandemic-related products and, in the event of a pandemic, accelerate the process of approving and licensing [safe and high-quality AUS] pandemic-related products for emergency use in a timely manner, including [where applicable, AUS] the sharing of [[regulatory [dossiers DEL AUS] DEL THA, BRN] RES JPN] [information AUS] [relevant information regarding the safety and clinical effectiveness of health products, including after regulatory approvals during the post-marketing phase BRN] [unredacted, full assessment reports THA] [and other relevant technical information MEX, EGY] with [other DEL THA, CHN] [relevant THA, CHN] [regulatory ETH] institutions [in a way that respects confidentiality of data NZL]. [Each Party shall support capacity building to address the shortage of the well-trained and experienced regulatory professionals to adopt and promote good timely evaluation of medical products. ZAF]

[2 alt. In a pandemic situation States Parties shall promptly share with the Technology Access Pool established under Article 7, all regulatory dossier information of all pandemic related products for which the regulatory authority of the State Party has given authorization. BGD]

[2 bis: The Parties shall establish a program of work, including a timeline, for the alignment of the key regulatory requirements and practices for multi-regional and multi-country clinical trials so that, in the

face of new public health emergencies, countries are ready to offer an immediate regulatory response. BRA]

[2 ter The WHO shall develop global regulatory standards and shall also develop capacities for national as well as regional regulatory authorities including in quality of products to reach higher WHO maturity levels. The WHO shall also create and maintain a regulatory database for countries to deposit their data. AF Group, ZAF]

3. The Parties shall, as appropriate, monitor and regulate against substandard and falsified pandemic-related products, [including AUS] through existing [Member State DEL CHN] mechanisms on substandard and falsified medical products.

[NEW 4 The Parties shall strengthen the existing rapid alert systems among neighbouring countries in reporting sub-standard and falsified pandemic-related products. PHL]

[NEW 4. WHO shall establish regulatory pathways based on the scientific evidence and technological advancement for accelerating the non-originator (generic) production of pandemic related products with quality. For the purposes of this paragraph, the Director General shall convene expert committees including WHO Expert Committee on Biological Standardization to develop the required regulatory guidelines. BGD]

[NEW 4. Each party shall evolve public awareness measures to promote research and evidence-based perspectives on pandemic and discourage wrong information dissemination on pandemic-related products, in line with local realities. NGA]

[NEW 4 bis. The Parties shall facilitate, based on country-specific analysis on the needs, feasibility and implementability of health products, cooperation of manufacturers of pandemic-related health products, with the assistance of WHO, as appropriate, by utilizing mechanisms such as WHO prequalification and the WHO Emergency Use Listing and other health products lists authorized by relevant international organizations, during pandemics and inter-pandemic times, to promote equitable access to health products through the mutual recognition of health products JPN]

[ALT ARTICLE 8 TEXT:

- 1. Each Party shall strengthen the capacity and performance, as appropriate, of its national authorities responsible for authorizing or approving the use of pandemic emergency response-related products and for providing oversight of the quality, safety, and efficacy of such products.
- 2. Each Party shall make publicly available online the following information, and shall ensure that such information is kept updated in a timely manner:
 - a. any national and/or regional processes for authorizing or approving use of pandemic emergency response-related products during a pandemic emergency;
 - b. any additional relevant regulatory flexibilities or programs that may be activated during pandemic emergencies; and
 - c. a contact point within each relevant national and/or regional regulatory authority for inquiries concerning its pandemic emergency processes and procedures.

The Parties request that WHO compile on its website links to Parties' websites containing such information.

3. Each Party shall make publicly available online, on a timely basis, its rationale for authorizing or approving pandemic emergency response-related products, including the evidence, analysis of data, and other information on which the decision was based, in accordance with relevant laws. The Parties request that WHO compile on its website links to Parties' websites containing such information.

4. Each Party:

- a. intends to encourage manufacturers, as appropriate, to generate the relevant data and request in a timely manner and diligently pursue regulatory authorizations and approvals of pandemic emergency response-related products with stringent regulatory authorities, other priority authorities, and WHO.
- b. shall seek to increase the harmonization or convergence of regulatory requirements at the global and regional level, as consistent with applicable law;
- c. shall adopt and implement, when practicable and consistent with national laws and procedures, guidance and technical documents concerning medical products from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the International Medical Device Regulators Forum (IMDRF) or their successor organizations;
- d. intends to include, as appropriate, its national authorities responsible for authorizing or approving the use of pandemic emergency response-related products in government decision-making processes related to preparedness and response to pandemic emergencies in support of a whole-of-government approach.

5. In addition, each Party shall consider:

- a. adopting reliance processes in its national regulatory frameworks for use during pandemic emergencies, and incorporating relevant principles from the WHO Good Reliance Practices Guidelines;
- b. working with relevant stakeholders and international organizations on approaches to enhance the efficiency of regulatory processes for pandemic emergencies and promote greater cooperation and collaboration to prepare for and respond to pandemic emergencies;
- c. providing support to help strengthen national regulatory authorities and regional regulatory systems' ability to respond to pandemic emergencies, on mutually agreeable terms and as appropriate, through efforts such as technical assistance, capacity building activities, training on a national or regional basis, or information exchange consistent with applicable law
- 6. The Parties shall work together to develop and support strategies for strengthening WHO processes for Emergency Use Listing, Prequalification and any other relevant processes for

recommending the use and continued regulatory oversight of pandemic emergency responserelated products.

7. The Parties, as appropriate, intends to seek to prevent, detect, and respond to substandard and falsified pandemic emergency response-related products, including through national-level regulatory oversight, national enforcement authorities, as appropriate, relevant regional forums, and the WHO Member State Mechanism on Substandard and Falsified Medical Products.

USA]

[ALT ARTICLE 8 TEXT G.4. Quality of countermeasures

- 1. In case the Director General of the WHO declares a pandemic situation, the Parties and the WHO shall cooperate to ensure the rapid availability of countermeasures by increasing the collaboration, including at regional level, among authorities competent to ensure the quality, safety and efficacy of the countermeasures referred to in Article G.1.3.
- 2. The Parties, with the support of the Secretariat, shall aim at aligning and, where possible, harmonising technical and regulatory requirements and procedures, promote the use of common technical documents, share relevant information and assessments concerning quality, safety and efficacy of countermeasures, including after regulatory approvals are granted.
- 3. The Parties shall promote and facilitate the use of regulatory reliance and mutual recognition, both at national and regional level, with the aim of expediting regulatory approvals and authorisations and ensuring quality, safety and efficacy of countermeasures.
- 4. The Parties, with the support of the Secretariat, shall promote the establishment or development of international and regional networks of scientific, research and regulatory institutions, as well as of international and regional protocols for the performance of clinical trials, with the aim of increasing the acceptability of trials results by the Parties' regulatory authorities. The Parties shall also promote access to relevant clinical data, including clinical trial eports and protocols, for the countermeasures referred to in Article G.1.3.
- 5. The Countermeasures Expert Committee shall issue guidelines for regulatory cooperation for each of the countermeasures referred to in Article G.1.3.
- 6. The Parties and the WHO shall collaborate with the aim of strengthening the capacities of regulatory authorities and systems, especially in case of pandemic situations, with particular attention to the needs of the Parties which are low and lower-middle income countries. EU]

Article 9. Increasing research and development capacities [in support of equitable access to pandemic-related products CAN, ROK]/RETAIN ORIGINAL TEXT EGY]

1. The Parties recognize the need to build and strengthen [cross-sectoral UK] capacities and institutions for [innovative DEL ETH, USA, PAK] [well-designed and well-implemented USA] research and development for pandemic [emergency response USA] -related products, [in non-pandemic periods, including those which may be needed in the animal health sector UK] [particularly in DEL USA] [including clinical trials; sustainable, geographically diverse regional or USA] developing countr[ies DEL USA] [y USA] [capacities, which would require sustained [national, regional, or global]

commitments between pandemic emergencies; USA] [and responding to the needs of developing countries ETH], [and the need for [collaboration and PAK] information sharing [in a voluntary manner JPN] through [, wherever possible and prudent, USA] open science approaches for rapid sharing of scientific findings and [both positive and negative THA] research results.]DEL UK] [ADD, and such sharing should not be imposed as preconditions for either provision or receipt of assistance CHN]

[NEW PARA: Ensure and promote, including via conditions in funding agreements, wide and rapid registration of health tools, including where clinical trials have been conducted

New PARA: To provide financial mechanism for R&D and manufacturing for at-risk event of outbreak with transparent and predefined triggers MYS]

NEW PARA: 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. UK]

[1 alt. Parties hereby agree to establish a Inter Governmental Panel on Pandemic Science (IPPS) consisting of experts without conflict of interest to investigate the various science and technology aspects of pandemic with its Secretariat located at WHO HQ. WHO shall provide all the science for the IPPS to perform its function efficiently. BGD]

[1 alt(bis)]. IPPS shall meet minimum once in a year and assess various scientific aspects related to pandemic prevention, preparedness, response and recovery including the evaluation of pandemic threat, R&D prioritization, coordination, regulation and oversight of genetic engineering of organisms, health technology assessment of pandemic related products and any other aspects of pandemic prevention, preparedness, response and recovery referred by the governing body. Towards its function IPPS is free to create working groups or tasks forces as appropriate. BGD]

[1 alt (ter). Parties hereby decided to establish a dedicated section in WHO's Global Observatory on Research and Development on pandemic related products and WHO shall submit annual report to the IPPS to facilitate prioritization and coordination of research and development pandemic related products. BGD]

- 2. [With a view to promoting greater sharing of knowledge and transparency [in patent landscape, pricing and public funding that goes into research and development ZAF], DEL THA] [efficiency of R&D, and equitable access to health tools MYS] each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, [shall DEL USA] [intends to USA], [include binding terms and conditions on recipients of publicly funded research and development, MYS] [taking into account the extent of the public funding [received DEL THA] [provided THA] DEL BGD]:
 - (a) [promote DEL ETH] [require ETH] the [open innovation ensuring freedom of operation to all BGD] [free, DEL JPN] public dissemination of the results of [publicly and DEL USA] government-funded research [and promote the same for research that is not publicly funded ETH] for the development of pandemic [emergency response USA] -related products [at the earliest reasonable opportunity and to the fullest extent possible in accordance with national laws in a pandemic emergency; USA] [except for patent-protected information JPN];

- (b) [[endeavour to DEL ETH, IDN, BGD] [ensure IDN] include terms and conditions on prices of products, allocation, data sharing and transfer of technology, as appropriate, and publication of contract terms DEL JPN];
- [b (bis) making it compulsory for manufacturers that receive public funding to disclose information about the prices and contractual terms for public procurement, patent status approval and marketing approval status of health products, the results and costs from human subject clinical trails and reports on subsidies, incentives, sales revenue, units sold and marketing costs. NAM]
- [ALT (b): consider publishing the terms of government funded R&D agreements for pandemic emergency response-related products, at the earliest reasonable opportunity and to the fullest extent possible in accordance with national laws. USA]
- (c) [ensure that promoters of research for pandemic-related products assume an appropriate level of the associated risk DEL USA];
- (d) [consider USA] promote[ing USA] [, facilitate IDN] and incentivize[ing USA] technology co-creation and joint venture initiatives [with developing State Parties THA] [as needed and create public research and development initiatives ETH]; and
- (e) [[consider including [through effective regulations and policies IDN] provisions promoting global access in USA] [establish [and enact ETH] [appropriate DEL BGD] conditions [in the grant agreement BGD] [for publicly DEL USA] [government USA] funded research DEL BGD] and development [agreements and in licensing of government-owned technology for pandemic emergency response-related products USA] [, including on DEL USA] [such as clauses promoting publication of research and clinical trial results, USA] [distributed manufacturing, DEL USA] licensing [and sublicensing of innovations USA], technology transfer [on voluntary and mutually agreed terms USA], know how THA] and pricing [policies DEL IDN] [during pandemic emergencies USA]. DEL JPN]
- [NEW f) consider promoting and prioritizing investment in research and development of pandemic emergency response-related products that can expand accessibility across diverse settings and among diverse populations. USA]
- [NEW f) affordable pricing of end products, including on a no-profit or no-loss basis upon PHEIC determination
- NEW g) granting of non-exclusive licenses, including provisions for data sharing, technology transfer, and waiving or managing royalties as appropriate, to enable development, manufacturing, and distribution, especially in developing countries
- NEW h) adherence to allocation frameworks as determined by WHO when PHEIC is declared; and
- NEW i) retention of rights by the funder, through ownership or licensing of research results, for use, licensing, or assignment, as necessary, to ensure affordable, equitable, and timely access MYS]
- [NEW f) States Parties shall ensure that in the contracts with the recipients of any public funding, government shall retain the rights as funders. ZAF]

[NEW g) States Parties shall strengthen their contracts with recipients of public funding to builtin the contract that funding for research and development become conditional with an obligation for technology transfer. ZAF]

[NEW f) provide all required information to the dedicated page of WHO's Global Observatory on Research and Development on pandemic related products' research and development including funding provided. BGD]

- 3. [Each USA] Part[y USA] [ies shall DEL USA] [intends to USA] [increase DEL CAN, BGD] [improve CAN / maintain BGD] [, as appropriate, USA] the transparency of information about [funding for DEL USA] research and development for pandemic [emergency response USA] -related products [while balancing transparency with security CAN] by:
 - (a) [disclosing DEL USA] [sharing USA] information[, in a timely manner ETH] on public funding for research and development of potential pandemic [emergency response USA] -related products [and provisions to enhance the availability and accessibility of the resulting work, including [freely available and DEL JPN] publicly accessible publications and public reporting [publications JPN] of the relevant patents DEL USA] [licensing and funding agreements ETH];
 - (b) [making it compulsory for manufacturers [that receive public funding for the production DEL ETH] of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics[, taking into account the extent of the public funding received DEL ETH]; and DEL CAN, JPN, SAU, USA]
 - (c) [[encouraging DEL BRA] [ensuring BRA] manufacturers that receive other funds, external to the manufacturer, for the production of pandemic-related products to disclose prices and contractual terms for public procurement in times of pandemics. DEL ETH, JPN, SAU /RETAIN BRA]
 - [NEW (d): strengthening, through international cooperation, the monitoring and traceability of technologies and intellectual property rights of pandemic-related products that have received public funding, at any stage of their development. COL]
 - [NEW (d) sharing information on research agendas, including national research and development priorities, during pandemic emergencies, as appropriate USA]
 - [NEW (e) sharing information on national efforts and plans for building or strengthening national, regional and global research and development capacity, including building and maintaining a skilled research workforce, research infrastructure, and research supply chain needs to rapidly mount and scale research responses during pandemic emergencies USA]
- 4. [Each Party DEL USA] [The Parties intend to USA] [should DEL USA] encourage [participation of relevant stakeholders USA] [non-State actors DEL USA, TUR] [including private sector URY] to participate in {efforts to USA] [and DEL USA] accelerate innovative research and development [in a safe and secure manner USA] [, particularly research that responds to the needs of developing countries ETH] for addressing [novel pathogens, pathogens resistant to antimicrobial agents and DEL USA] emerging and re-emerging [diseases DEL USA] [pathogens USA] with pandemic potential. [This would include community-led research and cross-sector collaborative research. NZL] [The NSA should have capacities as required by and compliance with the national

biosafety and biosecurity laws and regulations, and accept the national supervision and inspection CHN]

- 5. [The Parties shall establish, no later than [XX 12 months following the treatz entrz into forceNGA, with reference to existing models, a global compensation mechanism for injuries resulting from pandemic vaccines [to which Parties shall contribute based on the principle of Common but Differentiated Responsibilities BGD]. DEL CAN, RUS, USA, SAU, CHN]
- 6. [Pending establishment of such global compensation mechanism, each Party shall, in contracts for the supply or purchase of pandemic-related products, [endeavour to DEL IDN, BGD] exclude buyer/recipient indemnity clauses of indefinite or excessive duration. [Till the establishment of global compensation mechanism parties shall prevent pharmaceutical companies from insisting indemnity clauses of indefinite or excessive duration in supply contracts with other parties. BGD] DEL CAN, RUS, USA, JPN, SAU, CHN]
- 7. [In the conclusion of contracts for the supply or purchase of pandemic-related products, each Party shall [endeavour to DEL ETH, BRA, IDN, BGD] exclude confidentiality provisions that serve to limit disclosure of terms and conditions. DEL USA, JPN, SAU, CHN]
- 8. [Each Party shall [, as applicable, DEL BGD] implement and apply [relevant USA] international standards for [Biorisk management, including USA], oversight of and reporting on laboratories and research facilities that carry out [pandemic prevention, preparedness, and response-related research and development, USA] [work to genetically alter organisms to increase their pathogenicity and transmissibility, DEL USA] in order to prevent [accidental release DEL USA] [unintended or deliberate misuse USA] of [these DEL USA] pathogens, while [ensuring that these measures do not create any DEL USA] [minimizing USA] unnecessary administrative hurdles for research. DEL RUS]

[NEW PARA: The parties are encouraged to support research to further our shared understanding of the epidemiology of emerging diseases, factors driving disease spillover or emergence, and associated strategies to reduce or mitigate the risks of disease spillover or emergence associated with these drivers, and embed new evidence into policy making. UK]

- 9. The Parties are encouraged to promote [, cooperate IDN] and strengthen knowledge translation and evidence-based communication tools [, USA] [and DEL USA] strategies[, and partnerships USA] relating to pandemic prevention, preparedness, response and recovery [of health systems IDN], [and infodemic management USA] at local, national, regional and international levels.
- 10. The Parties acknowledge the need to take steps, individually and collectively, to develop strong, resilient national, regional and international [clinical DEL USA] research ecosystems, [including national and global clinical research networks USA] [and ensure international standards for ethical research and procedures PHL]. In that regard, the Parties[, as appropriate DEL BGD] [, commit to DEL USA]:

[NEW PARA: Prioritize the development and strengthening of clinical trial research capabilities, including clinical trials, that comply with international standards of trial design, conduct and human subject protections. UK]

[NEW PARA: 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. UK]

[NEW PARA: endeavor to invest in national research and development efforts, including clinical networks that can rapidly transition from supporting routine healthcare research and development to developing pandemic emergency response-related products, as well as non-pharmaceutical interventions and social science research; USA]

[NEW PARA: endeavor to strengthen national research capacities and national and international research networks that are responsive to local research priorities, can develop country-led research agendas, and that can effectively execute prioritized national and global research and development agendas during pandemic emergency responses and promote coordination; USA]

[NEW PARA: endeavor to incorporate research as an integral element in their national and regional pandemic and epidemic preparedness and response planning, and to align their research efforts to be compliant with international norms and standards for biosafety and biosecurity USA]

- (a) [intend to promote regional and global research networks that are capable of high-quality clinical trials, in accordance with Good Clinical Practices and other International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) standards, for pandemic emergency response-related products; and USA] foster[ing DEL USA] and coordinat[e USA] [ing DEL USA] clinical research and clinical trials [including identification of shared priorities and by coordinating funding to support multi-country working, where appropriate UK][during pandemic emergencies USA][, including, as appropriate, DEL UK] through [new and MYS] [existing DEL USA] coordination mechanisms [, especially those based in developing countries MYS] [which are ready to respond timely when outbreaks begin through measures such as standardized templates, tools, funding mechanisms, and standard operating procedures ETH] [and guidelines PHL];
- (b) [ensuring equitable access to resources (funding or in-kind), clinical research and clinical trials [and sufficient quantities of tested products ETH], so that resources are deployed optimally [equitably ETH] [and DEL IDN] efficiently [as well as geographically and strategically distributed IDN] DEL JPN, SAU, USA];
- (c) [supporting DEL USA] [intend to promote, in accordance with national laws, USA] transparent and rapid reporting of clinical research and clinical trial results, [including data, underlying findings, and results ETH] [including posting of aggregate results data from clinical trials related to pandemic emergency response-related products in a publicly accessible registry that is affiliated with the WHO International Clinical Trials Registry Platform (ICTRP), USA] to ensure evidence is available in a timely manner to inform national, regional and international decision-making; and
- (d) [without prejudice to existing protocols on health ethics and human rights NGA] [intend to USA] disclos[e USA] [ing DEL USA] disaggregated information, for instance by gender and

age, to the extent possible and as appropriate, on the results of clinical research and clinical trials relating to pandemic prevention, preparedness, response and recovery [of health systems THA].

[NEW PARA: endeavor to coordinate and improve communications, dissemination, and training on international guidelines and standards for conducting ethical and scientifically valid clinical trials by convening, periodically and as needed, relevant bodies responsible for promoting guidelines and standards for clinical trials, as well as governmental, private sector, and civil society stakeholders. USA]

[NEW PARA: Developing national policies to promote streamlined approaches to clinical trial governance whilst maintaining the highest possible standards, considering more coordinated regulatory and ethical review processes, including proportionate approaches for facilitating multicenter research and mechanisms to support emergency governance approaches during a pandemic to support expedited review where necessary. UK]

[NEW PARA[ADD: including and actively engaging research partners with local expertise in the design of research, based on national research priorities, to ensure the experiences of under-represented populations are understood and their unique research priorities are considered to help ensure that pandemic related products address their needs. UK]

[NEW PARA: 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. UK]

[NEW PARA: The treaty's independent funding mechanisms shall provide funding support for research and development capacity processes for developing countries NGA]

[9 bis The parties should strengthen the knowledge base for public health and social interventions by developing enabling legal frameworks and enhancing capacities for such research NOR, BRN]

[RELATED TO THE ABOVE 9 BIS:

[PROPOSED ADDITIONAL PREAMBULAR PARAGRAPH Recognising that while public health and social measures are indispensable for responding to pandemics, evidence on their effectiveness and unintended negative consequences remain scarce. NOR]

[PROPOSED ADDITIONAL DEFINITION Article 1: [m "public health and social measures" means non-pharmaceutical interventions that can be taken by individuals, institutions, communities, local and national governments and international bodies to slow or stop the spread of an infectios disease. NOR]

[PROPOSED ADDITIONAL GUIDING PRINICPLE: [Research agendas and frameworks should be strategically shaped to enhance the PPR evidence base. NOR]

NEW ARTICLE 9. Scientific and research cooperation

 The Parties shall cooperate to advance knowledge and scientific research in the areas covered by the Agreement, at national, regional and international levels, directly or through international and regional organizations and other relevant bodies. The Parties shall ensure the freedom of scientific research.

- 2. Cooperation in research shall address fields such as biological, biotechnological, medical, pharmaceutical, environmental and behavioural research, including human and animal health and epidemiology, so as to strengthen and advance scientific knowledge, aimed at preventing, be prepared for and respond to pandemic situations. The Parties shall pay particular attention to the needs of parties which are low and lower middle income countries and seek the advice of the Panel of Experts provided for in Article P.3.
- 3. The Parties shall promote, in particular:
- a. national and regional research institutions which are able to rapidly respond to research and development needs in case of a pandemic situation;
- b. joint scientific research programmes, projects and partnerships on the causes and effects of pandemics, on their prevention and management, and on relevant medical and other countermeasures, including preventive, diagnostic and therapeutic countermeasures, with the specific aim to increase the availability, affordability and quality of such countermeasures;
- regional and international collaboration and exchange of information between research institutions, funding organisations as well as individual scientists, including national, regional and international research and development networks that are able to rapidly respond in case of a pandemic situation;
- d. support and capacity building programmes, projects and partnerships for the development, dissemination and use of technical and scientific knowledge and research;
- e. access for scientists and researchers from Parties, which are low and middle income countries, to scientific research programmes, projects and partnerships referred to under b), c) and d);
- f. access to, and enhancement of, knowledge, skills and capacities through increased cooperation in the areas covered by the Agreement, and
- g. collaboration, including with the private sector, to set common objectives and research goals, pool expertise and avoid duplicating research efforts, especially in the field of countermeasures. EU; BRN support, with reservation on with respect to references in the proposal on the differentiation of responsibilities and benefits based solely on income categorization]

RESERVE: UK on all paragraphs in this Article 9 for which they did not provide textual amendments.

Article 10. [[[WHO Pathogen Access and Benefit-Sharing System

1. The [Parties recognize that global pandemic preparedness and response BRA, PAK, DOM, HTI, CHN] [need for a DEL BRA,PAK, DOM, CHN] [requires BRA, PAK DOM, HTI, CHN] multilateral, fair, equitable and timely [system for DEL BRA, PAK, DOM, CHN] sharing of, on an equal footing, pathogens with pandemic potential [[and DEL BRA] [including their BRA, PAK, DOM, CHN] [genomic DEL] [genetic COL] sequences [and digital sequence information BRA, PAK, DOM, CHN] DEL JPN], and benefits [monetary and non monetary COL] [that BRA, PAK, DOM, CHN] aris[e BRA, PAK, DOM, CHN] [ing there DEL BRA, PAK, DOM, CHN] from [their utilization BRA, PAK, DOM, CHN], [that applies and operates in both inter-pandemic and pandemic times, is hereby recognized DEL BRA, PAK, DOM, CHN] [including access to pandemic-related products BRA, PAK, DOM, CHN]. In pursuit thereof, [the Parties agree BRA, PAK, DOM, CHN] [it is agreed DEL BRA, PAK, DOM, CHN]

to establish the WHO Pathogen Access and Benefit-Sharing System (the "PABS System") [under this WHO CA+. The Parties are mindful that the PABS System, or parts thereof, could be adopted under Article 21 of the WHO Constitution, should such an approach be agreed. The terms of the PABS System shall be developed no later than XX with a view to their provisional application consistent with Article 35 hereof DEL BRA, PAK, DOM, TUN, CHN, IRN].

[NEW PARA The PABS system aims to ensure timely, public access to pathogens with pandemic potential and the corresponding benefit sharing. BRA, PAK, DOM, TUN, CHN]

- 2. [The PABS System shall [cover all pathogens with pandemic potential, including their genomic sequences, as well as access to benefits arising therefrom, and ensure that it DEL BRA, PAK, DOM, CHN] [be consistent and support, and not run counter to, the objectives of the Convention on Biological Diversity and the Nagoya Protocol nor any other BRA, PAK, DOM, CHN] [operates synergistically with other relevant DEL BRA, PAK, DOM, CHN] access and benefit-sharing instruments [agreed in other international agreements COL] DEL JPN].
- 3. The PABS System shall include the following elements and shall be regulated as follows:

[Access to pathogens with pandemic potential

- (a) Each Party, through its relevant 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 [in accordance with national regulations and laws on data privacy SAU, TUN] 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 of its choice [DEL BRA, PAK, DOM, CHN] [a designated database(s) BRA, PAK, DOM, CHN] DEL JPN]. [For purposes hereof, "rapid" shall be understood to mean within XX hours from the time of identification of a pathogen with pandemic potential; DEL BRA, SAU, PAK, DOM, TUN, CHN]
- (b) [The PABS System will be consistent with international [, regional and national SAU] legal frameworks, notably those for collection of patient specimens, [material [and data DEL JPN] DEL SAU] [and information related to SAU], and will promote effective, standardized, real-time global and regional platforms that promote findable, accessible, interoperable and reusable data available to all Parties; DEL BRA, PAK, DOM, CHN]
- (c) Access shall be accorded expeditiously by the laboratory recognized or designated as part of an established WHO coordinated laboratory network, subject to conclusion of a Standard Material Transfer Agreement, 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 [which shall not include operational costs of the PABS System JPN];
- (d) [Recipients of materials shall not claim any intellectual property or other rights [that limit the facilitated access DEL BRA, PAK, DOM, CHN] to pathogens with pandemic potential, or their genomic sequences or [their BRA, PAK, DOM, CHN] components, [or digital sequence information BRA, IDN, PAK, DOM, CHN] [in the form received DEL BRA, PAK, DOM, CHN]; and DEL JPN]

(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 [regional SAU] laws. DEL BRA, PAK, DOM, CHN] RESERVE ON SECTION, IRN]

Fair and equitable benefit-sharing

- (f) The Parties agree that benefits [monetary and non monetary COL] arising from facilitating access to pathogens with pandemic potential [and to the relevant traditional knowledge COL] shall be shared fairly and equitably in accordance with the provisions of the PABS System. Accordingly, it is understood that production of pandemic vaccines or other pandemic-related products, irrespective of the technology, information or material used, implies [use DEL BRA, PAK, DOM, CHN] [utilization BRA, PAK, DOM, CHN] of pathogens with pandemic potential, [[including the DEL BRA, PAK, DOM, CHN] [their BRA, PAK, DOM, CHN] genomic sequence[, components and digital sequence information BRA, PAK, DOM, CHN] DEL JPN];
- (g) 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 that shall contain the benefit-sharing [options available to entities accessing DEL BRA, PAK, DOM, CHN] [obligations that the access to BRA, PAK, DOM, CHN] pathogens with pandemic potential [is subject to BRA, PAK, DOM, CHN]; and
- (h) [[Such options shall include, but not be limited to DEL BRA, PAK, DOM, CHN] [The benefit sharing obligations by manufacturers of pandemic-related products developed from the utilization of pathogens with pandemic potential will include: BRA, PAK, DOM, CHN] DEL JPN]
- (1) [real-time access by DEL BRA, PAK, DOM, CHN] [reserve for BRA, PAK, DOM, CHN] WHO [to DEL BRA, PAK, DOM, CHN] [a minimum of BRA, PAK, DOM, CHN] 20% of the production of [safe, efficacious and effective pandemic-related products, including diagnostics, vaccines, personal protective equipment and therapeutics, DEL BRA, PAK, DOM, CHN] [pandemic-related products BRA, PAK, DOM, CHN] to enable equitable distribution, in particular to developing countries, according to public health risk and need and national plans that identify priority populations. The pandemic-related products shall be provided to WHO [on the following basis: 10% as a donation and 10% at affordable prices to WHO DEL BRA, PAK, DOM, CHN]; (ii) [commitments by the countries where manufacturing facilities are located that they will facilitate the shipment to WHO of these pandemic-related products by the manufacturers within their jurisdiction, according to schedules to be agreed between WHO and manufacturers DEL BRA, PAK, DOM, CHN.] [Collaborate 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. BRA, PAK, DOM, CHN]

[NEW PARA The benefit-sharing options for any entity accessing covered pathogen material or digital sequence information access may include, among other:

- access fees/fee per sample collected or otherwise acquired
- sharing of research and development results
- collaboration, cooperation and contribution in scientific research and development programmes

- collaboration, cooperation and contribution in education and training. BRA, PAK, DOM, CHN]

[Recognition of the PABS System as a specialized international instrument

- (i) [[The PABS System, adopted under the WHO Constitution, is established with a view to its recognition as a specialized international access and benefit-sharing instrument within the meaning of the Nagoya Protocol; RESERVE TUR, IRN] DEL SAU, IRN]
- (j) [Upon adoption, each Party shall, in accordance with its national law, adopt and implement effective legislative, executive, administrative or other measures to give effect to such recognition at the domestic level and/or with respect to its relations with all other States and regional economic integration organizations, as appropriate; and DEL BRA, PAK, DOM, CHN]
- (k) [The Parties shall support the further development and operationalization of the PABS System, including appropriate governance mechanisms, and participate in its operation, including through sustaining it in inter-pandemic times as well as appropriate scale-up in the event of a pandemic. DEL BRA, PAK, DOM, CHN]

[New section: Access and benefit-sharing committee

- (X) An access and benefit-sharing committee is hereby established. It shall serve, inter alia, as a means for establishing guidelines for benefit-sharing, providing transparency and ensuring a fair and equitable sharing of benefits.
- (X)The access and benefit-sharing committee shall be composed of XX members possessing appropriate qualifications in related fields so as to ensure the effective exercise of the functions of the committee. The members shall be nominated by Parties and elected by the Conference of the Parties, taking into account gender balance and equitable geographic distribution, and providing for representation on the committee from developing States. The terms of reference and modalities for the operation of the committee shall be determined by the Conference of the Parties.
- (X) The committee may make recommendations to the Conference of the Parties on matters relating to the PABS. BRA, PAK, DOM, CHN] RESERVE ON SECTION, IRN]
- 4. The Parties [agree that the PBAS system will constitute a Protocol to the WHO CA+, and BRA, PAK, DOM, CHN], working through the Governing Body for the WHO CA+, shall develop and finalize additional elements and tools necessary to fully implement, operationalize and sustain the PABS System, no later than XX. RESERVE CHE, PHL, UK] [All parts of the PABS should come into force simultaneously. BRA, PAK, DOM, CHN] RESERVE ARTICLE 10 AUS] RETAIN NGA]

[NEW ARTICLE 10

E. Access to and sharing of pathogen samples and data

Article E.1. - Access to and sharing of pathogen samples, pathogen genomic sequence data and other relevant information related to pathogens

With a view to fostering international cooperation and coordination in the surveillance and control of pathogens and in scientific research and technological development of medical and other

countermeasures, and in accordance with article D.3. (Support to detection capacities) and B.1. (Pathogen surveillance and identification), Parties shall ensure either directly or through the Secretariat or other existing mechanisms the free and rapid access to, and sharing of, pathogen samples, pathogen genomic sequence data and other relevant information related to pathogens obtained through their surveillance and detection activities. Parties may seek the cooperation of other Parties with more advanced technological capacities in order to fully identify and characterize the pathogens in question. The Parties should use of the model agreements set out in Annex 5, as appropriate.

The Conference of the Parties shall as soon as possible but no later than two years after the entry into force of this Agreement adopt rules or guidelines to facilitate and support the access to, and sharing and storage of, pathogen samples, as well as the generation, storage and sharing of pathogen genomic sequence data and other relevant information related to pathogens, in accordance with international law.

Parties shall equitably share the relevant medical countermeasures, including the ones produced with the assistance of pathogen samples, pathogen genomic surveillance data and other relevant information related to pathogens shared in accordance with paragraph 1 and the provisions set out in Section G. The Parties agree and affirm that the relevant provisions of this Agreement, in particular sections E and G, constitute a specialised access and benefit-sharing instrument.

The Conference of the Parties shall consider the establishment, or development of, one or more international repositories of pathogen samples and pathogen genomic sequence data falling under the present Agreement. This may include the utilization of existing national, regional or international repositories on the basis of agreements concluded with the Parties concerned. Repositories shall be accessible to Parties on an equitable and transparent basis, clear conditions and without discrimination. They shall be accessible to non-Parties on conditions to be decided by the Conference of the Parties. Data repositories shall comply with global norms and standards established by WHO.

G. Benefit sharing through equitable access to countermeasures

Article G1. General provisions

- 1. In case the Director General of the WHO declares a pandemic situation in accordance with Article 3, the Parties shall make all possible efforts to ensure that the relevant and most appropriate countermeasures are developed, manufactured, authorised and deployed as rapidly as possible and become available in sufficient quantities and at an affordable price to ensure an effective and equitable regional and international response to such pandemic situation.
- 2. To this effect the Parties shall ensure the rapid sharing of pathogen samples, genomic data and other relevant information as set out in article D.3. and section E, which is necessary to enable the fast development and manufacture of countermeasures.
- 3. The countermeasures covered by the provisions of this section/chapter shall be determined by the Countermeasure Expert Committee, as set out in Article P.5., as soon as possible after the declaration of a pandemic situation, on the basis of the characteristics of the pandemic situation, the needs for an effective response, as well as safety and efficacy requirements. The Committee shall also determine whether such countermeasures are in scarce supply for the purpose of an effective and equitable respose by each Party to the pandemic situation. Such determination shall be kept under

review and the Committee shall determine when the situation of scarce supply has ended.

- 4. For this purpose the Parties shall cooperate to increase the transparency of market conditions prevailing in the markets for the countermeasures referred to in paragraph 3 and provide the Comittee with information on supply and demand forsuch countermeasures , to support the Committee in assessing their availability and affordability, possible supply chain vulnerabilities and mitigation measures.
- 5. In case a countermeasure referred to in paragraph 3 is developed making use of a pathogen sample, genomic sequence data or other information related to pathogens, any transfer agreement which may cover such sample or data, including an agreement between the Party where the sample or data originate and the countermeasure developer, should set out the general availability and affordability commitments for the benefit of all countries in need as provided for in Articles G.2 and G.3. The transfer agreement should ensure that the countermeasure developer makes such general availability and affordability commitments applicable to the countermeasure manufacturer also in case the countermeasure manufacturer is a licensee of the countermeasure developer.
- 6. The Parties which are high income countries, and other Parties in a position to do so, shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to set out the availability and affordability commitments which will apply to the countermeasure manufacturer as provided for in Articles G.2 and G.3 in any purchase agreement that they conclude with such manufacturer.
- 7. The Parties which are high income countries, and other Parties in a position to do so, shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to set out the availability and affordability commitments which will apply to the countermeasure manufacturer as provided for in Articles G.2 and G.3, irrespective of whether the manufacturer is the countermeasure developer or a licensee of the countermeasure developer, in any agreement providing support to a countermeasure developer for research and development of new countermeasures.
- 8. The Parties shall encourage the countermeasure developers and manufacturers to commit to implementing the relevant provisions of this section and in particular the provisions set out in Articles G.2. and G.3. Such committments shall be received by the Director-General of the WHO who will keep them under review.
- 9. The Countermeasure Expert Committee shall develop model contract terms that may be used to ensure the rapid conclusion of agreements referred to in paragraphs 5, 6 and 7.

10. The Parties shall ensure delivery of medical countermeasures to persons in vulnerable situations and people living in hard-to-reach communities and humanitarian settings.

Article G.2. Availability of countermeasures

- 1. In case a countermeasure is in scarce supply, as determined in accordance with Article 1.3, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts to ensure that countermeasure manufacturers reserve:
- a. no less than [...] percent of their production of such countermeasure on a quarterly basis for sale to Parties that are low income countries in accordance with the World Bank categorisation current at the time of the declaration, and
- b. no less than [...] percent of their production of such countermeasure on a quarterly basis for sale to Parties which are middle income countries in accordance with the World Bank categorisation current at the time of the declaration.
- 2. The WHO shall establish, in consulation with the Parties, a partnership and collaborate with the relevant organisations of the UN system, regional organisations and other relevant organisations, with particular attention to the needs of Parties, which are low or lower middle income countries, to:
- a. determine the equitable allocation of the reserved countermeasure quantities, taking into account factors, such as population size, demographic structure, epidemiological situation and and health system capabilities of beneficiary Parties and their readiness and capacity to utilize such countermeasures,
- b. facilitate, as appropriate, the conclusion of advance purchase commitments and purchase agreements of countermeasures,
- c. assist the buying countries in meeting the regulatory and logistic requirements for utilization of the specific countermeasure,
- d. facilitate or, as necessary, organise the efficient delivery and appropriate utilisation of the countermeasures in the beneficiary country or in humanitarian settings, and
- e. assist the buying countries on all matters related to the utilisation of the countermeasures.
- 3. The partnership modalities and collaboration guidelines for the organisations referred in paragraph 2 are set out in Annex 6. Such modalities shall aim at ensuring close consultation with the beneficiary Parties and that each function referred in paragraph 2 is discharged by the organisation best placed to perform it. Notwithstanding article ... (Amendments), the partnership modalities and guidelines may be modified by the member organisations of the partnership, in consultation with the Parties.
- 4. The Parties shall provide assistance to the partnership referred in paragraph 2.

5. In case the Director General of the WHO declares a pandemic situation in accordance with Article 3, the Parties in a position to do so shall make all possible efforts to donate countermeasures referred to in article G.1.3 to countries in need. Without prejudice to the possibility for the Parties to organise direct donations to countries in need, donations of countermeasures should be facilitated by and effected through, the partnership referred to in paragraphs 2 and 3 and in accordance with the provisions of this Article.

Article G.3. Affordability of countermeasures

- 1. With respect to sales to, or for the benefit of, Parties, which are low income countries, of countermeasures referred to in Article G.1.3 including, but not limited to, the reserved allocations referred to in Article G.2.1, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts, while a pandemic situation persist, to ensure that countermeasure manufacturers will provide them at not-for-profit price.
- 2. With respect to sales to, or for the benefit of, middle income countries, of countermeasures referred to in Article G.1.3 including, but not limited to, the reserved allocations referred to in Article G.2.1, the Parties shall cooperate and take coordinated actions with the aim to ensure availability and affordability in access to countermeasures, and to this effect shall make all possible efforts, while a pandemic situation persist, to ensure that countermeasure manufacturers will apply tiered pricing, taking into consideration factors, such as population size, epidemiological situation, income level and capacity to pay of the buying countries.
- 3. The Countermeasures Expert Committee shall issue pricing guidelines including on not-for profit and tiered pricing, for each of the countermeasures referred to in Article G.1.3.
- 4. In case the Director General of the WHO declares a pandemic situation, the Parties in a position to do so shall cooperate, including with the private sector, take coordinated actions and make all possible efforts to make available financial resources for the acquisition of countermeasures referred to in Article 1.3 for the benefit of countries in need, with special attention to the needs and epidemiological situation of the Parties which are low and lower middle income countries and of persons in vulnerable or humanitarian situations. For this purpose, Parties shall cooperate with the relevant multilateral and regional financial institutions.

Article G.4. Quality of countermeasures

1. In case the Director General of the WHO declares a pandemic situation, the Parties and the WHO shall cooperate to ensure the rapid availability of countermeasures by increasing the collaboration, including at regional level, among authorities

competent to ensure the quality, safety and efficacy of the countermeasures referred to in Article G.1.3.

- 2. The Parties, with the support of the Secretariat, shall aim at aligning and, where possible, harmonising technical and regulatory requirements and procedures, promote the use of common technical documents, share relevant information and assessments concerning quality, safety and efficacy of countermeasures, including after regulatory approvals are granted.
- 3. The Parties shall promote and facilitate the use of regulatory reliance and mutual recognition, both at national and regional level, with the aim of expediting regulatory approvals and authorisations and ensuring quality, safety and efficacy of countermeasures.
- 4. The Parties, with the support of the Secretariat, shall promote the establishment or development of international and regional networks of scientific, research and regulatory institutions, as well as of international and regional protocols for the performance of clinical trials, with the aim of increasing the acceptability of trials results by the Parties' regulatory authorities. The Parties shall also promote access to relevant clinical data, including clinical trial eports and protocols, for the countermeasures referred to in Article G.1.3.
- 5. The Countermeasures Expert Committee shall issue guidelines for regulatory cooperation for each of the countermeasures referred to in Article G.1.3.
- 6. The Parties and the WHO shall collaborate with the aim of strengthening the capacities of regulatory authorities and systems, especially in case of pandemic situations, with particular attention to the needs of the Parties which are low and lower-middle income countries.

Article G.5. Stockpiling of countermeasures

- 1. The Parties shall cooperate to ensure that international emergency stockpiles of countermeasures are established and existing ones supported or enlarged, with the objective of increasing the equitable availability and affordability of countermeasures, with special attention to the needs of Parties, which are low and lower middle income countries, and of persons in vulnerable situations living in their territories.
- 2. The Conference of the Parties shall take the necessary decisions with the aim of establishing international emergency stockpiles. The Countermeasures Expert Committee shall provide guidance on the types of countermeasures for which emergency stockpiles should be established or supported, where they should be located to facilitate equitable access, adequate financing measures, as well as on the management modalities of individual emergency stockpiles, with the aim of increasing equitable access and effective and efficient stockpiling operations.

Article G.6. Support for additional manufacturing facilities

- 1. In order to improve the availability and affordability of quality countermeasures, the Parties shall cooperate to support public and private sector investment aimed at creating or expanding manufacturing facilities of relevant countermeasures, especially facilities with a regional scope of operation in Parties which are low and middle income countries.
- 2. The Parties shall also promote the voluntary transfer of technology, know-how and skills that may be necessary to improve the availability and affordability of countermeasures.
- 3. For this purpose, the Parties should act individually and jointly by means of grants, loans, taxation and other incentive measures, as appropriate.
- 4. The Countermeasures Expert Committee shall provide advice to the Parties on the matters covered by this article.

EU]

Chapter IV. Strengthening and sustaining capacities for pandemic prevention, preparedness, response and recovery of health systems

Article 11. Strengthening and sustaining [core USA] preparedness and health systems' resilience

1. The Parties recognize the need for [resilient health systems [, including the ability to pivot in virtual care options in countries where capabilities allow for it CAN] [, rooted in DEL USA, EU] [strengthening core [essential THA, HTI] [aiming at EU] [a primary health care-based approach, and CAN] health system capacities, including those established under the International Health Regulations, that are needed for pandemic preparedness to prevent, detect, and respond to future pandemic threats and for primary health care, which is critical for frontline emergency detection and response and to achieving USA, HTI] universal health coverage, to [prevent and EU] mitigate the shocks caused by pandemics and DEL BGD, PAK] to ensure continuity of [quality CHN] health services [and creating resiliency USA] [[, thus preventing health systems from becoming DEL BGD, PAK] [without being BGD, PAK] overwhelmed DEL EU] [in the times of pandemic outbreaks and spread BGD, PAK] [during pandemic emergencies USA]. [Parties shall take all necessary steps to organize, strengthen and sustain their health systems at national level EU]. [[The Parties shall strive to accelerate the achievement of universal health coverage, and ensure continued provision of quality routine and essential health services during pandemics. NOR]

[Para 1 ALT proposal Each Party shall take the necessary measures to strengthen their own health systems in order to strengthen and sustain the pandemic prevention, preparedness and response, taking into account the need for equitable and resilient health systems, with a view to sustaining universal health coverage. JPN]

[Para 1 ALT ALT The Parties recognize the need to develop, enhance and sustain strong, resilient, and inclusive human, animal and environment health systems, and progressive realisation of universal health coverage to support pandemic prevention, enable early detection and response for emerging health threats, to mitigate the shocks caused by pandemics, ensure continuity of health services, and prevent health systems from becoming overwhelmed. UK]

2. [[The [developed country BGD] Parties [shall provide BGD, PAK, THA, HTI, IRN] [are encouraged to enhance DEL BGD, IDN, PAK, THA, HTI, NGA, EGY, TUN] [WHO's six pillars of health systems strengthening AF Group] [commit NGA] [shall take necessary measures IDN, EGY] [shall continue to cooperate on and are encouraged UK] financial, [and CHN] technical [and technological DEL CHN] support, [through international assistance and capacity building IDN] [promote sharing of experiences and best practices MYS] assistance and cooperation, in particular to developing countries, to strengthen [health system [capacities for health UK] capacity and resilience, including MYS] [primary health care and hospital care facilities and to achieve BGD, PAK] [[health emergency DEL THA, HTI] [pandemic THA, HTI] prevention [and DEL THA, HTI] preparedness[, [response CHN, UK] and health system recovery THA, HTI, UK] [consistent with the goal of DEL BGD, PAK] universal health coverage. [[Consistent with the commitments made in 'Transforming our world: the 2030 Agenda for Sustainable Development' and the 'Political declaration of the high-level meeting on universal health coverage' UK] [The Parties shall strive to accelerate the achievement of universal health coverage. DEL USA, THA, HTI] DEL CHN] DEL EU, NOR, JPN]

NOTE: UK Will propose 12.2. alt.

3. [[[[The Parties [are encouraged DEL IDN, THA, HTI] [shall explore IDN, NGA] [commit NGA] [shall consider THA, HTI] to [collaborate and work with relevant stakeholders to support existing or USA] establish[ing THA, HTI] [new USA] global, regional and national collaborative [genomics DEL UK] [epidemic intelligence UK] [and laboratory USA] networks[, using a One Health approach USA] [, without duplicating those already in existence CAN] [that are dedicated DEL USA] to [plant, animal, and human disease UK] [conduct USA] epidemiological [genomic DEL UK] surveillance and [promote the rapid, transparent, and systematic open USA] [the global DEL USA] sharing of [samples and genetic sequence data from notifiable events under the IHR, including USA] [emerging DEL THA, HTI] pathogens with pandemic potential [, in a safe and secure manner USA] [and antimicrobial resistance and increase efforts to make better use of advances in the ability to collect, analyze, use and share human, animal, plant and environment health data in order to anticipate, assess the risk of, and respond to, health security threats CAN]. DEL BGD, CHN, ARM, PAK] MOVE RUS] DEL EU] DEL JPN] [including emerging and re-emerging zoonoses UK]

[RESERVE PARA 3 IRN, AF GROUP (AF Group noting to cross reference Art 10)]

- [3 bis The Parties shall establish intersectoral mechanisms to fulfill the commitments regarding the strengthening and sustaining capacities for pandemic prevention, preparedness, response, and recovery of health systems. MEX]
- 4. [Each Party shall[, in accordance with [national DEL USA] [applicable USA] law DEL EU] [and supported by implementation plans USA], adopt policies and strategies, [as appropriate USA] [supported by implementation plans, across the DEL USA] [that seek to integrate perspectives from USA] public and private sectors [and relevant agencies [including accelerated clinical research, USA] [, consistent with relevant tools, including, but not limited to, the International Health Regulations [, [the Terrestrial Animal Health Code and the Aquatic Animal Health Code and their associated manuals,

the Performance of Veterinary Services pathway, and the Wildlife Health Framework and UK] [, the One Health Joint Plan of Action and international animal health standards and codes CAN], and DEL BGD, PAK] DEL EU] strengthen[, upgrade BGD, PAK] [and DEL UK] reinforce [and where relevant integrate, UK] [health systems, primary health care, and JPN] [capacities mentioned in Annex 1 of the IHR 2005 to the resilience levels determined by the national authorities taking into account the standards advise by the WHO, and ensure BGD, PAK] public health functions [for DEL BGD, PAK] [in the human and animal sectors UK] [such as BGD, PAK] [the following 6 building blocks JPN]:

[NEW PARA: the parties are encouraged to put in place the necessary tools to ensure good governance of their health systems MAR]

[NEW PARS (a): "Ensuring the full and effective implementation of universal health coverage, including continuing to extend its benefits package based on the real need of the population". THA, HTI]

- (a) [[Service Delivery: JPN][continued provision of quality routine and essential health services [including home care BRA] during pandemics [emergencies USA], including[, for example, USA] clinical [sexual and reproductive health services CAN] and [preventive care such as JPN] mental health care and immunization, [sexual and reproductive health services and maternal, neonatal and child health services FJI, AUS, NZL] [with a focus on primary health care [referral health services IDN] and community-level interventions, [[and particular attention to people in vulnerable situations EU] [[expansion of the access to health systems, ensuring the reception and control of suspected cases during the pandemics BRA] and management of the backlog of and waiting lists for the diagnosis and treatment of, and interventions for, other illnesses, including care for patients with long-term effects from the pandemic disease; DELINK as SEPARATE point under Article 11.4 ARM] DEL JPN] DEL EU] RESERVE UK]
 - [(a) bis Health Workforce: strengthening and sustaining a skilled and competent health and care workforce (as stipulated in Article 12.) JPN];
- (b) [strengthening [human resource DEL USA, UK] [and animal health workforce UK] [and mapping CAN] capacities [in relation to pandemic preparedness, prevention, preparedness and response UK] [at national and subnational level to identify, track, test and treat, as well as contain and control public health risks, in particular those of pandemic potential EU] [of the multidisciplinary workforce needed USA] [during inter-pandemic times and [preparing for and ensuring surge capacity BRN] during pandemics [, including capacities to protect human resources from health risks PHL] [emergencies, including, for example, protection from the impact of pandemic emergencies USA]; MOVE RUS/ALT MOVE to Art 12 CHN] [including the establishment of mechanisms or arrangements for emergency hiring of health professionals at local and national levels BRA] [including to support timely access to comprehensive, integrated, and person-centred primary health services CAN] DEL EU]

[new (b) bis providing multi-disciplinary training for health, veterinary, environmental experts and supportive workforce, with aim to ensure integrated capacities for a One Health approach; EU]

(c) [Health Information Systems: JPN] [conducting EU] [enhancing CHN] surveillance [(including using a One Health approach[, when appropriate USA]) DEL CHN], [horizon scanning, BRN] outbreak [detection CAN] investigation and control, through [interoperable DEL USA] early warning and alert systems[, with the goal of interoperability, as well as with

other sectors, as appropriate for national priorities and needs USA] [and timely notification BRA] [JPN: text as stipulated in Parts B and D of EU proposal] [as well as strengthening early warning, surveillance, and response capacity for emerging zoonoses at the community level CAN];

- [(c) alt Strong multisectoral One Health surveillance systems, including the monitoring of drug-resistant pathogens, at all levels, across human, animal, plant and broader environment health to facilitate rapid detection of health threats, monitoring of long-term trends and sharing of intelligence.

 UK]
- [(c) bis multi-sectoral early warning and risk communication systems which incorporate disease surveillance, including drug-resistant pathogens, alongside monitoring of environmental, climatic and anthropogenic drivers of disease, linked to cross-sectoral risk assessment and response functions. UK]
- (d) [strengthening public health CHN] [sustained DEL CHN] laboratory [and its CHN] [capacity DEL CHN] [capacities, including capacities CHN] for [testing BRN] genomic sequencing [and collecting pathogens and clinical samples USA], as well as for [establishing new technologies ISR] analysing and sharing [and safeguarding IDN] such information [in real time ISR] [through a good data governance IDN] [for samples USA];
- (e) [cross sectoral UK] prevention of [zoonoses and BRN] epidemic-prone diseases, and emerging, growing or evolving [public health DEL CAN] [infectious disease CAN] threats with pandemic potential, notably at the human-animal-environment interface [including through implementation of appropriate infection prevention and control standards at both healthcare institutions and within the community, biosecurity, waste management, and animal disease preventive measures BRN] [including through community-based One Health approaches CAN];
- [NEW (e) bis health emergency workforce and response system, to co-ordinate and implement public health response including surge capacity and response capacities of Parties; EU]
- [NEW (e) ter management of the backlog of and waiting lists for the diagnosis and treatment of, and interventions for, conditions for continued provision of quality routine and essential health services during pandemics; JPN]
- [NEW (e) quater Medical products, vaccines, and technologies: achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems (as stipulated in Chapter III); access to and sharing of pathogen samples and data as well as benefit sharing through equitable access to countermeasures (as stipulated in part E and G of EU proposal); JPN]
- (f) [[development of IDN] post-[emergency DEL THA, HTI] [pandemic THA, HTI] health system recovery strategies [and action plans CHN] [including care for patients with long-term effects from the pandemic disease itself or from a disruption in care caused by the burden of the pandemic situation on the health care system; and EU] [taking into consideration national contexts and the specific neds of communities, at risk populations (e.g. frontline workers) CAN] RESERVE UK];

- (g) [strengthening [public health [and animal health USA, BRN] [One Health CAN] laboratory [and diagnostic DEL BRN] [, diagnostic, and reporting BRN] capacities, [retention of laboratory staff THA, HTI] and DEL CHN] national, regional and global networks[, including DEL USA] standards and protocols for infection prevention and control, and public [and animal CAN] health laboratory biosafety and biosecurity [including mitigating the risk of intentional theft or release of pathogens CAN] [Specific emphasis will be given to pre-analytical processes, international standardizations of serological and molecular assays and analysis of pathogens with pandemic potential in the frame of the clinical setting and the environmental setting including but not only wastewater; water sources and different matrixes of water and food ISR]; and MERGE with 4.(d) CHN] [during inter-pandemic times, during and after pandemics THA, HTI] [MERGE 4(g) with 4(d) TUN]
- (h) [creating and maintaining up-to-date, [networked USA] [universal DEL USA] platforms and technologies for forecasting[, where possible, USA] and timely information sharing, [including human, animal, and environmental data, pathogens and clinical samples, USA] through appropriate capacities, including [open data infrastructures, CAN] building digital health [including telemedicine services IDN] and [open BRA] data science capacities [(open science) BRA] [to modernize data management CAN] RESERVE UK].

NEW listed letter items proposed in this paragraph ((i), (j), (k), etc, et seq), with proposing delegation(s):

[create and strengthen public health institutions at national, regional and international levels AF GROUP]

[primary health care strengthening ARM]

[strengthened infection prevention and control USA]

[To strengthen WHO role in providing normative, policy, and technical guidance to build health system capacity and resilience MYS]

[strengthened infection prevention and control USA]

[Health financing: sustainable and predictable financing, recognizing the important role that 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 (as stipulated in Article 19); enhancing financial, technical and technological support, assistance and cooperation, in particular to developing countries, to strengthen health emergency prevention and preparedness consistent with the goal of universal health coverage. The Parties shall strive to accelerate the achievement of universal health coverage; JPN]

[Leadership and governance: coordination, collaboration and cooperation for pandemic prevention, preparedness, response and health system recovery as well as whole-of-government and whole-of-society approaches at the national level (as stipulated in Chapter V); and preparedness monitoring, simulation exercises and universal peer review (as stipulated in Article 13); JPN]

[NOTE: JPN proposes to add bullet / listed headings for the sub entries (reflected in above, see also written comments]

[measures to promote infection prevention and control (IPC) / water, sanitation and hygiene, including in primary health care facilities, and at the community level CAN]

[measures to develop prevention strategies targeting the emergence and spread of antimicrobial resistance, including by promoting effective antimicrobial stewardship and appropriate use of antimicrobials across One Health sectors CAN]

[Measures to improve health data governance and management, including through common standards and policies to improve how health information is collected, shared, used and reported. CAN]

[strengthening research and development capacities for evidence-based decision-making CAN]

[systematically evaluating, exchanging and utilizing scientific evidence to inform decision-making CAN]

[DEL BGD original listed items under 3]

[NEW SUBPARAS / listed items under 3 (replacing originals):

- (a) Assuring quality of and access to health care facilities;
- (b) Maintaining adequate quantity and quality of health workforce;
- (c) Ensuring equitable access to medicines and other health products and technologies;
- (d) Maintaining laboratories and other facilities with adequate diagnostics capacities;
- (e) Maintenance of regulation information dissemination channels for early warning and timely information sharing;
- (f) Protocols and standards for infection prevention and control;
- (g) Advancing public health research;
- (h) Addressing socio-economic and cultural determinants of the health and reduction of health inequities;
- (i) Ensuring community participation in line with Alma-Ata and Asthana Declarations.;
- (j) Public Health Emergency Management protocols and stimulation exercises [especially rapid response teams TUN]. BGD, PAK]

NEW PROPOSED ARTICLE 11 PARAS, (FOLLOWING 4):

- [xx. The Parties shall enhance cooperation with Parties which are low and middle income countries with an aim to strengthen the capacity of their health systems for prevention, preparedness of and response to pandemic situations.
- xx. The Secretariat shall support the Parties in the implementation of this Article, with particular regard to the needs of Parties which are low and lower middle income countries. The Secretariat in close cooperation with relevant international, regional organisations and other relevant non-governmental entities shall provide capacity building, training and support, relying as much as possible on existing training and capacity building facilities.
 - xx. The Conference of the Parties may adopt as appropriate protocols, annexes and guidelines for the implementation of the provisions of this Article.
 - xx. This article is without prejudice to the provisions of the International Health Regulations (2005), in particular Articles 5 and 13 as well as Annex 1. The Parties acknowledge the need to ensure that the implementation and interpretation of this Articles is complementary and supportive of the International Health Regulations (2005) as amended. The Conference of the Parties shall consult regularly with WHO to this end and shall propose measures and adopt decisions to address possible problems in this regard. EU]
 - [xx. The Parties request that WHO promote the use of assessment tools, guidance documents, and other resources, including the IHR Monitoring and Evaluation Framework tools, to facilitate Member State assessment of and targeted improvements to core preparedness. USA]

[NEW PROPOSED ARTICLE 11 BIS, PROPOSED TO PRECEDE CURRENT PARAGRAPH 1

Article 11 bis Pandemic prevention

- 11.1 Each Party shall undertake actions within their territories to prevent the introduction and spread of emerging and re-emerging infectious diseases, and other threats with pandemic potential, notably at the human-animal-environment interface through the use of appropriate domestic legal instruments that identify the relevant authorities for domestic surveillance and control of communicable diseases, health emergency declaration, preparedness, and operational readiness and response planning.
- 11.2 Each Party shall develop and implement appropriate multisectoral coordination mechanisms that address pandemic prevention at the human-animal-environment interface including through risk assessment procedures based on the drivers of emerging and re-emerging infectious diseases within their territories.
- 11.3 In accordance with their international obligations, each Party shall adopt legal or other administrative measures for the purposes of pandemic prevention through:
- a. Implementing appropriate and risk-based infection prevention and control measures at all levels, including but not limited to laboratories, healthcare facilities, communities, and within the animal health sector, in line with international best practices and standards.

- b. Strengthening animal disease preventive measures including sustainable animal welfare, farming and land use practices, feed hygiene, biosecurity in the production, transportation, slaughter and retailing of animals and animal products, and implementing infection prevention and control measures throughout the food chain, taking into account relevant guidelines and instruments such as the World Organisation for Animal Health's Terrestrial Animal Health code and Performance of Veterinary Services tool.
- c. Applying appropriate risk reduction and risk management practices to manage the trade of live animals both within and between countries and ensure the prevention of illicit trade of animal and plant species that may pose a pandemic risk.
- d. Implementing 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. BRN]

Article 12. Strengthening and sustaining a skilled and competent [and motivated AF GROUP, SWZ, ETH] health and care workforce

- [Each Party [in line with their respective capacities PAK, IRN] shall [, subject to national laws NGA, EGY] [take the [necessary DEL SAU] steps DEL THA] [to DEL USA] [with respect to regional and country-specific workforce [emergency medical teams MEX, URY, TUN, DOM, HTI] approaches, to USA] safeguard, protect, invest in scale up recruitment of THA] and sustain a skilled, trained, competent and committed [ADD CAN] [human UK] health and care workforce [and animal health workforce UK] [, at all levels DEL USA], [including migrant health workers, PHL, PAK] [including emergency medical teams, [at all levels, DEL IRN] MEX, URY, TUN, DOM, HTI], [in a genderresponsive manner DEL RUS, IRN, NGA / RETAIN CAN] [in a gender sensitive manner NGA, EGY], with due protection of [its DEL BGD] [employment, [safety, IDN] [civil DEL USA] and human rights and well-being DEL IRN] [rights, safety and well-being IRN] [of health workers BGD] [including physical, mental and social well-being, USA], consistent with international obligations [and in accordance with the international labor standards and the Declaration of Fundamental Principles and Right to Work PSE] [and the WHO global code of practice on international recruitment of health personnel PHL, MOR] [and bearing mind USA] [and relevant codes of practice DEL PHL, MOR] [under relevant international laws THA, with the aim of increasing and sustaining capacities for pandemic prevention, preparedness and response [and recovery of health system IDN, THA], [while DEL UK] [including UK] maintaining essential health services [during pandemics UK] [in both, source and destinations countries PHL, ISR]. [This DEL USA] [These steps may USA] includes, subject to [national DEL USA] [applicable USA] law:
 - (a) strengthening [prevention and MEX, URY, TUN, DOM, HTI] [in- and post-service DEL UK] [pre- and in- service competency-based education and UK] training, [supportive supervision, UK] deployment, remuneration, distribution and retention of the health and care workforce, including community health workers and volunteers; and
 - [(a) bis strengthening efforts to address the issue of safety of health and care workforce, including and; IDN]
 - (b) addressing gender disparities[, USA] [and DEL USA] inequalities[, and security concerns USA] within the health and care workforce, to ensure meaningful representation, engagement,

participation[, USA] [and DEL USA] empowerment[, and safety USA] of all health [emergency USA] [and care DEL USA] workers, while addressing [violent harassment CAN] discrimination, stigma [from chat BRA] and inequality and eliminating bias, including unequal remuneration, and noting that women still often face significant barriers to taking leadership and decision-making roles.

[NEW 12(b) promoting and protecting the safety and wellbeing of health and care workers, particularly in health emergencies, through the provision of occupational health and safety, protection from violence in the workplace, improvement of mental health and psychological well-being of health and care workers, and protection from physical and biological hazards, including the implementation of minimum patient safety and infection prevention and control practices, ensuring the availability of personal protective equipment of acceptable quality, and provision of adequality environmental services, including water, sanitation and hygiene, disinfection, and ventilation in relevant settings. UK]

[1 bis. Parties, acting together through the governing bodies of WHO CA+, ensure that frontline health workers of all Parties have priority access to pandemic response products including but not limited to PPEs, diagnostics, vaccines, and therapeutics during pandemics, especially when WHO reports a shortage and starts implementing its allocation plan. BGD]

- [(b) bis Ensuring meaningful representation, engagement, participation and empowerment of all health and care workers without discrimination IRN]
- [(c) intensify efforts and create policies that ensure the availability of health professionals in all regions and localities, especially in the most vulnerable and difficult to access territories and respond also the need to retain health professionals in these areas. BRA]

[1 bis 1BIS The Parties shall, as appropriate, monitor and regulate labor conditions of health and care workers in order to protect this workforce, especially from risk of contagion, exhausting working hours and participation in experimental procedures unapproved by government agencies. BRA] RESERVE RUS]

[1bis Parties shall establish a strategy for training their health and care work force in field epidemiology, risk management, incident management systems, and biosecurity, with the objective of increasing their capacities in the fields of preparedness and response. COL, TUN]

2. [The [developed country BGD, IRN] Parties [in line with their respective capacities PAK] [[are encouraged DEL NGA, PHL, IDN, THA, AF GROUP] [shall AF GROUP] [commit NGA] [shall PHL, THA]] [shall take necessary measures IDN] to enhance DEL BGD, IRN] [shall provide BGD, IRN] financial and technical support, assistance and cooperation, in particular to developing countries, to strengthen [, retain PHL] and sustain a skilled and competent health and care workforce [as well as other relevant sectors for the response and recovery phases MEX, URY, TUN, DOM] [with public health emergency competence THA] at the [subnational, USA] national[, and regional USA] level. [During pandemics and in case of shortages, WHO and Mechanism under Article 6 shall prioritize the need of frontline health workers. Frontline Healthcare Workers shall be protected adequate insurance. BGD, IRN] [The Parties are also encouraged to enhance education and medical training for health professionals. BRA] RESERVE PARA 2 JPN]

[2bis Each party commit to take the necessary measures to reverse and reduce the negative impact of the migration of highly qualified and trained health personnel on countries of origin, with the aim of

implementing principles and practices for the ethical international recruitment of health personnel taking into account the rights and obligations of countries of origin, countries of destination and migrant health workers, and also to establish financial and technical support mechanisms to address the negative effects of migration on health systems of countries of origin, especially developing countries, as stipulated in the WHO Global Code of Practice for the International Recruitment of Health Personnel and supported by the Global Strategy on Human Resources for Health on the Horizon 2030. MAR, TUN, HTI]

- 3. The Parties [shall DEL USA] [are encouraged to USA] [shall consider, as appropriate, the establishment of global public health emergency THA] invest in establishing, [sustaining, coordinating and mobilizing an available, skilled and trained DEL THA] global public health emergency workforce that is deployable [on voluntary basis ISR] [through the networks of WHO collaborating Centres IDN] to support [pandemic affected IDN] Parties upon request, [and is accountable for preventing and responding to sexual abuse and harassment CAN] based on public health need[, in order to contain outbreaks[, USA] [and DEL USA] prevent an escalation of small-scale spread to global proportions DEL BGD] [, and minimize disruptions to the delivery of quality essential health services USA] [Parties shall develop, working through the governing body of WHO CA+, a code of conduct for the personnel of the global public health emergency workforce BGD]. [EU I.1 to be pasted]
- 4. The Parties [will DEL PHL, THA] [shall PHL, THA] [support DEL NGA, SAU, USA] [commit to NGA] [shall encourage USA] the development of a network of training institutions, national and regional facilities and centres of expertise[, leveraging and building off of existing of existing training infrastructure and programs, USA] in order to establish common guidance[, taking in account the regional, national and local context and experiences including any indigenous medical knowledge systems for enabling BGD] [, with respect to national and regional contexts, USA] [to enable more DEL BGD] predictable, standardized, [as well as THA] timely and systematic response missions [and deployment of the aforementioned [multi-disciplinary AF GROUP] public health emergency workforce DEL THA] [under the auspices of and coordination of the WHO IDN]. [EU I.1 to be pasted]

[NEW PARA 4. without prejudice to the contents of article 12, mobilization of health workforce shall not be carried out in a manner that drains health workforce on a permanent basis from countries or regions with acute shortage of health workforce and/or undermine local health operations. NGA]

[ADD definitions of health care workforce and veterinary workforce in Article 1 BRN, PER, AUS]

[FN: ADD on Gender SAU]

Article 13. [[Preparedness monitoring, simulation exercises and [universal peer review DEL CHN, IRN] DEL IND, HTI, PAK] [Health systems performance assessment IND, HTI, FJI, PAK] [Preparedness monitoring, evaluation and review TUN]

[[In the event of a pandemic, THA] Each Party shall undertake regular [and systematic DEL THA] [national IDN] capacity assessments in order to identify capacity gaps [and enhance response readiness, by USA] [and DEL USA] develop[ing USA] and implement comprehensive, inclusive, multisectoral national plans and strategies for pandemic prevention, preparedness [and DEL THA] [, THA] response, [and health system recovery THA] based on [relevant DEL THA] [existing and new THA] [tools DEL BGD] [indicators BGD] developed by WHO[, FAO, WOAH, and UNEP, including but not limited to those established by the International Health Regulations Monitoring and Evaluation Framework, in partnership with relevant organizations USA] DEL RUS].

- 2. [Each Party shall periodically assess the functioning, readiness and gaps of its [pandemic emergency USA] [pandemic prevention THA] preparedness [and DEL THA] [, THA] [multisectoral DEL THA] response, [and health system recovery THA] [logistics and supply chain management DEL THA], [and risk assessment USA] through appropriate simulation [or tabletop DEL CHN] exercises, [and intra-and after-action reviews. These efforts are for the purposes of helping to USA] [[that include DEL THA] [taking into account THA] risk and vulnerability mapping [Personnel responsible for critical functions, decision-making or communication with the public shall participate in these simulations and exercises on a regular basis. CAN] [, and CHN] [. Such exercises [may DEL THA] [shall THA] consist of DEL CHN] [the conduct of intra- PHI] after-action reviews of [actual public health emergencies DEL THA] [pandemic THA] that [can support DEL USA] identify[ing DEL USA] DEL THA] [help to address THA] gaps [and bottlenecks USA], share lessons learned and [thus USA] improv[e DEL USA] [ing USA] national pandemic prevention, preparedness [and DEL THA] [, THA] response [and health system recovery THA] [in accordance with the monitoring and evaluation tools of the International Health Regulations MAR, TUN]. DEL RUS]
- 3. The Parties [are encouraged to consider USA] [will DEL USA, THA] [shall THA] conven[e DEL USA] [ing USA] [or participate CHN] multi-country or regional [, and when appropriate, border COL] [tabletop DEL CHN] [simulation CHN] exercises [every two years, DEL USA, THA] [no later than XX after the declaration of a public health emergency with pandemic potential THA] with technical support from the WHO Secretariat [and its regional offices COL] [, as appropriate CHN] with an aim to identify gaps in multi-country [preparedness COL] response capacity.
- 4. [Each Party shall provide [annual (or DEL THA] biennial[) DEL THA] reporting, building on existing relevant reporting where possible, on [implementation of articles of the WHO CA+ USA] [its pandemic prevention, preparedness, response and health systems recovery capacities DEL USA]. RESERVE RUS, ETH, IRN]
- 5. [Building on existing tools available through the IHR Monitoring and Evaluation Framework (MEF), USA] The Parties shall [building on the Joint External Evaluation and other assessment tools, CAN] [refine USA] [develop DEL USA] and implement [a DEL THA] [an inclusive THA] transparent, effective and efficient pandemic prevention, preparedness [and DEL THA] [, THA] response [and health system recovery THA] monitoring and evaluation system, which includes targets and national[, regional THA] and global standardized indicators [and the ability to gather, analyse, and report disaggregated data, including sex- and age-disaggregated data,] for the purpose of the effectiveness of pandemic-related health interventions among different groups CAN], [such as those in the IHR MEF, endeavoring to facilitate USA] [[with necessary DEL USA] funding[, both external and domestic, USA] for developing countries DEL THA] for this purpose.
- 6. [[The Parties [shall USA, THA] [should DEL USA, THA] establish, regularly update and broaden implementation of a universal [health and preparedness USA] peer review [(UHPR) USA] mechanism[, which draws upon findings from the IHR MEF tools, USA] to [review USA] [assess DEL USA] national, regional and global [public health THA] [preparedness DEL THA] capacities and gaps, [by bringing nations together to support a DEL THA] [through THA] whole-of-government and whole-of-society approach[es THA] to strengthen [national DEL THA] capacities for pandemic prevention, preparedness, response [, sustained delivery of quality health and other essential services during a pandemic, USA] 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. DEL CHN] DEL THA] RESERVE PAK, ETH, IRN]
- 7. [The Parties shall [consider USA] [endeavour to implement DEL USA] the recommendations generated from review mechanisms, including prioritization of activities for immediate action [, as

appropriate to their nationally determined public health priorities BGD, EGY] RESERVE PAK, ETH, IRN]

RESERVE ARTICLE 13: CHN, NAM, EGY.

[NEW 8. The Parties shall establish a committee of independent experts that would assess the state of global pandemic prevention, preparedness, response and health systems recovery to complement and inform the global peer review mechanism; CAN]

NEW TEXT

"Plans and Measures"

- 1. Each Party shall develop, implement, update and periodically review national, and where possible regional, action plans aimed to improving pandemic prevention, surveillance, early detection, preparedness and response, including emergency plans and measures, in accordance with the provisions of this Agreement and of the International Health Regulation (2005), in particular Annex 1 thereof. Parties shall prepare and adopt their action plans no later than [two] years after the entry into force of this Agreement, and review and update them at least every [three] years thereafter. Plans shall be prepared and updated as part of a continuous and transparent participatory process, taking into account the information gained from action on the ground, the results of research and the One health approach.
- 2. Such plan shall pay particular attention to the respect for human rights, the needs of the persons in vulnerable situations and people living in humanitarian settings, the protection of health and other essential workers, as well as to the aim to prevent the cross border spread of disease.
- 3. Parties shall establish or strengthen national, and where possible regional, mechanisms for institutional coordination, including the health, veterinary and environmental sectors, to prevent and fight pandemics, and shall provide adequate financial means therefor.
- 4. Responsible authorities set out under Article 4 of the IHR should be resposible also to ensure the implementation of this Agreement, as appropriate in view of national or regional responsibilities. EU]

ALT ARTICLE 13. UNIVERSAL HEALTH AND PREPAREDNESS REVIEW (UHPR)

- 1. The Parties agree to establish the Universal Health and Preparedness review mechanism. The Universal Health and Preparedness Review (UHPR) is a regular intergovernmental dialogue between Member States on their respective national capacities for health emergency preparedness. It is organized in two phases: a national review phase and a global peer-review phase.
- 2. Each Party shall undertake a regular and transparent national and peer-review of their comprehensive national health emergency preparedness capacities. The UHPR aims to promote collective global action

for preparedness, by bringing Member States and stakeholders together at national, regional and global levels.

- 3. Each Party shall provide a national report, based on a review of relevant data for key indicators extracted from available sources. The national report will be the result of an inclusive and broadly-based consultation process. State Parties will make the necessary institutional arrangements to undertake the national review.
- 4. Each Party shall then participate in a global peer-review mechanism between State Parties. State Parties shall present evidence gathered in their national evaluation and report and share their national practices, the gaps identified in preparedness and the opportunities for improvement. State Parties will present the actions taken to improve health capacities and emergency preparedness in their country. CHE

Article 14. [[Prioritization and AF GROUP] Protection [and promotion AUS, NZL] of human rights

1. The Parties shall [ensure that all EU] [[, in accordance with their [national laws DEL CAN, ARG] DEL AUS, NZL, PHI] [obligations under international human rights law, CAN, ARG] [and international obligations AF GROUP] [incorporate DEL THA] [implement public health THA] [or implement URY] [non-discriminatory DEL THA, AF GROUP] DEL EU] measures [, in a non-discriminatory manner and in respect of THA] [related to EU] [[to [protect DEL THA] [and promote AUS, NZL] human rights DEL AF GROUP] [promote the right to health AF GROUP] [and fundamental freedoms USA] [without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status PHI] as part of DEL EU] their pandemic prevention, preparedness[, DEL EU] [and EU] response [and [health system IDN, CAN, THA] recovery, DEL EU] [efforts shall be undertaken in accordance with human rights obligations EU] [with a particular emphasis on the [rights of DEL THA] DEL USA] [taking into account the challenges faced by USA] persons in vulnerable situations [and by health and other essential workers USA].

2. [Towards this end, each Party shall:

[endeavour to IDN] incorporate into its laws and policies [and practices NZL] human rights protections [and the right to health AF GROUP] [and preserving the right of every person to quality, accessible and affordable healthcare PHI during [pandemics THA, BGD, AF GROUP] [[public health emergencies DEL BGD, AF GROUP], including, but not limited to, requirements that DEL THA any limitations on human rights are [aligned DEL THA] [consistent THA] with international [and international humanitarian PSE] law, [including by ensuring DEL THA] that: (i) any restrictions [to human rights are consistent with the Party's obligations under international human rights law AUS] [are non-discriminatory, necessary], proportionate and the least restrictive THA to achieve the public health goal [and the least restrictive necessary to protect the health of people DEL THA] [such restrictions should be of limited duration and subject to review NZL] DEL AUS]; (ii) all protections of rights, including [but not limited to DEL THA], [the right to health and social security, AUS] [provision of health services[, education IDN] and social protection programmes DEL AUS], are non-discriminatory and take into account the needs of people at high risk and persons in vulnerable situations; [and DEL PHI] (iii) people living under any restrictions on the freedom of movement, such as quarantines and isolations, have sufficient access to [pandemic-related products THA] [medication DEL THA], health services and other necessities [and rights DEL IDN, AUS, THA]; and [(iv) when addressing prevention, preparedness, response, and recovery, to respect the special needs of Indigenous People and vulnerable populations, including access to health services BRA, COL] [; and (iv) ensuring that migrants, including the sea-based workers, are not left behind in multi-level and multi-disciplinary approaches;]

(b) [[[endeavour to [develop DEL IDN] [engage with communities, civil societies, and other relevant stakeholders, to support a whole-of-government and whole-of-society approach IDN] [an independent and inclusive advisory committee to [give relevant advice to THA] advise the government DEL IDN] [and other relevant stakeholders THA] [in developing legal and policy framework IDN] on human rights [promotion and THA] protections during [public health emergencies DEL THA] [pandemics THA], [[including on the development and implementation of its legal and policy framework, DEL IDN] and any other measures that may be needed to protect [and promote AUS] human rights DEL THA] DEL BGD] [in times of pandemic IDN]. MOVE to INTRO SECTION USA, CAN] DEL AF GROUP] DEL CHN] [ensure any measures taken by them to address pandemic shall not impede the enjoyment of human rights of the populations living in other Parties' territory BGD] DEL 2(b) AF GROUP]

[ALT 2(b): to ensure any measures taken by Parties to address pandemic shall not impede the enjoyment of human rights to health of the populations living in other Parties' territories. AF GROUP]

[new (c): ensure that all information concerning government policy during health emergencies be publicized to everyone through the appropriate channels, including by making it fully accessible to persons with disabilities, and by translating it to the necessary languages in order to make it reach persons belonging to national or linguistic minorities and migrants. ISR]

[new (c, 2): implement measures to address sexual and gender-based violence in pandemic prevention, preparedness and response and prevent and respond to sexual exploitation, abuse and sexual harassment AUS]

[NEW (c) take measures such that the actions of Non-State Actors within their territory shall not impede the enjoyment of the human rights in the territories of other BGD]

DELETE ART 14, PARA 2: USA, CAN

DELETE ART 14 (IN FULL): RUS, IRN

[NEW 3. During Pandemics, Parties undertake to prioritize protection of right to health of people, both within and outside jurisdictions, by creation of conditions which would assure to all free medical service and medical attention. In this regard, Parties undertake to provide "march-in clauses" in the relevant national legislations so as to temporarily acquire rights or to take up or oversee the management of necessary health care facilities, including any health products manufacturing facilities or any required intellectual property rights, within their jurisdiction solely for the purpose of providing effective pandemic response for a specified time. BGD]

[NEW 4. During Pandemics, Parties shall also take measures to protect people from the commercial exploitation if they are seeking medical care from private sector establishments, within their jurisdiction. BGD]

[NEW 5. Parties with capabilities in the development or manufacturing of new pandemic-related products shall provide for capacity building, transfer of technology and financial assistance to developing countries through WHO or other channels to ensure full realization of right to enjoy benefits of the scientific progress and its applications, in particular equitable access to pandemic related products BGD]

Chapter V. Coordination, collaboration and cooperation for pandemic prevention, preparedness, response and health system recovery

Article 15. Global coordination, collaboration and cooperation

- 1. The Parties [subject to Member States national laws and practice NGA, MAR] [recognize the need to DEL AF GROUP] [shall AF GROUP] coordinate, collaborate and cooperate, in the spirit of international solidarity [and full respect for national sovereignty CHN, IRN, MAR] [and territorial dignity of states ETH]], with competent international and regional intergovernmental organizations and other bodies [as well as among themselves MEX] in the formulation [and/or implementation BGD, BRA, HTI, THA, EGY] of cost-effective [and evidence-based ETH] measures, [interventions, THA] procedures and guidelines [and protocols URY] for pandemic prevention, preparedness, response and recovery of health systems, and to this end shall:
 - (a) [promote DEL THA] [elevate THA] global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness, response and [health system THA] recovery [by means that include establishing appropriate governance arrangements DEL THA] [as well as mechanisms to monitor bilateral, and multilateral international cooperation and assistance BGD, BRA, HTI, PAK, EGY];
 - (b) support mechanisms that ensure global, regional and national policy decisions [are DEL THA] [based on THA] science [and DEL BGD, BRA, HTI, PAK, EGY] evidence[, and equity BGD, BRA, HTI, PAK, EGY]-based [based on the evidence available at the current time ISR];
 - [(b bis) support each other the implementation of the plans developed under Article 16(4). BGD, BRA, HTI, PAK, EGY]
 - [ALT (b) Enable science and evidence-informed decisions at global, regional and national level, including by enabling and conducting research on public health and social interventions; NOR]
 - (c) develop, as necessary, and implement global policies that recognize the specific needs, and ensure the protection of, persons in vulnerable situations [, indigenous peoples, and those living in fragile environments or areas, such as Small Island Developing States, [and landlocked developing countries PRY] IDN] who face multiple threats simultaneously, by gathering and analysing data, including data disaggregated by gender, to show the impact of policies on different groups;
 - (d) promote [all human SAU] [equitable [gender DEL RUS, IRN], [race, color, ethnic, BRA] [geographical and socioeconomic status, DEL RUS, IRN] DEL SAU] representation and participation, [as well as the participation of youth and women, DEL RUS, SAU, IRN] in global [and DEL FJI] regional [and national FJI] decision-making processes, global [[taskforces FJI] and technical advisory groups;
 - (e) ensure solidarity [by identifying incentives for reporting BWA] with, and prevent stigmatization [and discrimination THA] [misinformation, disinformation, CHN] of countries that

report public health emergencies [with pandemic potential THA], as an incentive to facilitate transparency and timely reporting and sharing of [verified CHN] information; and

[(e bis) ensure solidarity with and provide universal and equitable access to health products, technologies and know-how, including through diversification of production to developing countries, technology transfer and by ensuring supply of the health products are unobstructed universally BGD, BRA, HTI, PAK, IDN, EGY, MYS, IRN, NAM]

(f) facilitate [at the invitation of the party RUS, CHN, IRN] WHO['s BGD, BRA, HTI, PAK, CHN, EGY, IRN, MAR] [with rapid DEL BGD, BRA, HTI, PAK, CHN, EGY, IRN, MAR] access to outbreak areas within the Party's jurisdiction or control, [including through the deployment of rapid response and expert teams, DEL BGD, BRA, HTI, PAK, CHN, EGY, IRN, MAR] to assess and support the response to emerging outbreaks[, in cases where Parties are unable to carry out the necessary assessments or response as the case may be BGD, CHN, EGY, IRN, MAR] [upon prior request of the Party and in coordination with the national government. BRA, CHN, IRN].

[NEW (g) develop with the support of the four international agencies of the Quadripartite the necessary measures to strengthen One Health capacities to enable Parties to prevent and address health threats at the human-animal-interface CAN]

[NEW (g) evolve multilateral and bilateral partnerships that focus on assisting developing countries on developing capacities for effectively addressing health needs for Pandemic Prevention, preparedness, response and recovery. AF GROUP]

2. [[Recognizing the central role of WHO as the directing and coordinating authority on international health work, [as established in Article 2 of the WHO Constitution MEX] 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, in accordance with terms set out herein, declare [public health emergencies with pandemic potential and THA] pandemics. COMMENT MEX MOVE TO PREAMBLE] [The Health Assembly may approve agreements on pandemic PPRR which WHO may sign with other international organizations which would guarantee WHO's primacy in identifying and defining the global health policy priorities and in directing the partnering international organizations pandemic response policies. BGD, BRA, HTI, PAK, EGY] RESERVE JPN, CAN, SAU, RUS, IRN]

[NEW 3. Parties agree to exclude any measure taken in pursuance of WHO CA+ or IHR 2005 from the scope of the dispute settlement provisions of under investment protection agreements. BGD, BRA, HTI, PAK, EGY]

[NEW 4. Parties agree not to sue other Parties or take retaliatory measures against a Party failing to debt service during a pandemic nor shall they charge defaults with further interests. BGD, BRA, HTI, PAK, EGY]

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¹ Reference is made to footnote 3 (Article 1), which invites the INB to propose and consider the development of modalities and terms for this provision.

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 establish, implement and adequately finance an effective national [and/or subnational AUS, CAN] coordinating multisectoral mechanism with meaningful representation, engagement and participation of [local authorities and TUR] communities [, in accordance with Alma Ata and Astana Declarations BGD, PAK] [, as appropriate IDN]. DEL SAU]
- 3. [[Each Party [should DEL IDN, TUN] [shall IDN, TUN] promote effective and meaningful engagement of [local authorities, TUR] communities, civil society and [non-State actors DEL IDN, TUR, MAR, EGY, TUN] [other relevant stakeholders IDN, TUR, MAR, EGY, TUN], [including the private sector[, subject to national law CHN, IRN, NGA], as part of a [whole-of-government TUR] whole-of-society response DEL EU] in decision-making [when deciding on measures to prevent, prepare for and respond to a pandemic, as well as when EU], implement[ation DEL EU] [ing EU], monitoring and evaluati[on DEL EU] [ing of these measures EU], [as well as DEL EU] effective feedback mechanisms [should also be provided EU]. [, avoiding conflicts of interests BGD] MOVE to General Provisions EU] DEL RUS]
- 4. Each Party shall develop, in accordance with its national context, comprehensive[, multisectoral AUS] national pandemic prevention, preparedness, response and [health system THA] recovery plans pre-, post- and inter-pandemic that, inter alia: [NEW sub-bullet identify and mitigate high risk practices for spillover and transmission of pathogens of pandemic potential; AUS] (i) identify [and prioritize DEL JPN] [vulnerable JPN] populations [who would most benefit from earliest access to medical countermeasures while ensuring equity JPN] [for access to pandemic-related products[, social protection PHL] and health services [in particular persons in vulnerable situations AUS] DEL JPN]; (ii) support timely and scalable mobilization of multidisciplinary surge capacity of human and financial resources, and facilitate timely allocation of resources to the frontline pandemic response; (iii) review the status of stockpiles and surge capacity of essential public health and clinical resources, and surge capacity in production of pandemic-related products; (iv) facilitate rapid and equitable restoration of public health capacities following a pandemic; and (v) promote collaboration with [non-State actors DEL IDN, TUR, MAR, EGY] [relevant stakeholders, including IDN, TUR, MAR, EGY], the private sector and civil society. [ADD [, avoiding conflict of interests BGD ???]
- 5. Each Party [will DEL THA, IDN] [shall THA, IDN] take steps to address [the social, environmental and economic DEL THA] [relevant THA] determinants of health, [intersectional inequalities AUS] [and vulnerability conditions DEL THA] that contribute to the emergence and spread of pandemics [and ensure strong social protection measures PHL], and [prevent or DEL THA] mitigate the socioeconomic impacts of pandemics [arising from pandemic prevention, preparedness, response and health system recovery. THA] [, including but not limited to, those affecting economic growth, the environment, employment, trade, transport, gender equality, [social inclusion, AUS] education, social assistance, housing, food insecurity, nutrition and culture, and especially for persons in vulnerable situations [in line with national context NGA]. DEL THA] [ADD definition of person in vulnerable situations in Article 1 NGA]
- 6. Each Party [should DEL IDN] [shall endeavour IDN] strengthen its national public health and social policies to facilitate [a DEL THA] [an inclusive THA] rapid, resilient response, especially for

persons in vulnerable situations [in line with national context NGA], including mobilizing social capital in communities for mutual support. DELETE ARTICLE 16 RUS and move PARAs 1 & 2 to general provisions or principles section]

Article 17. [Strengthening pandemic and public health literacy

1. The Parties [commit to DEL THA, ETH] [shall THA, ETH] increase science, public health [outbreak and ETH] and pandemic literacy [and countering mis- and dis-information and strengthening public trust SAU] in the population [on an ongoing basis ETH], as well as [timely THA, ETH] access to [and dissemination of THA] information on pandemics [, their causes AUS] and their effects, and tackle [[false, misleading, DEL AUS] misinformation [and AUS] or DEL PHL] disinformation [or false and misleading information PHL], including through [engagement with communities, civil societies, and private sectors, as well as IDN] promotion of international cooperation. In that regard, each Party [is encouraged to DEL NGA] [shall THA, NGA]:

[new sub para 0: deliver concise, accurate and real time information by employing trusted sources of information, such as professional societies or WHO to support delivery of health information and risk messages THA]

[new sub para 0bis utilize communication networks and ability to pass through message to subnational and local level THA]

(a) promote and facilitate, at all appropriate levels, in accordance with national [approaches CAN] laws and regulations, [and in cooperation with diverse groups, the CAN] development and implementation of educational and public awareness programmes [co-created with communities on outbreaks and ETH] [on DEL ETH] pandemics[, their causes AUS] and their [drivers and CAN] effects, by informing the public, communicating risk [translating science, CAN] and managing infodemics [without delay THA] through effective [bidirectional ETH] [meaningful engagement and accessible CAN] channels [and communication infrastructure THA], including social media[,in a way that is broadly accessible, including to persons in vulnerable situations AUS];

[NEW (a) bis ensure alignment and consistency of risk information from all official sources THA]

- (b) conduct regular [community outreach, IDN] [social listening DEL AUS] [research AUS] and analysis to identify the prevalence and profiles of [misinformation DEL PHL] [disinformation including false news PHL], [[which DEL AUS] [to AUS] contribute to [design DEL AUS] DEL PHL] [as reference for the design of PHL] communications and messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust; and
- (c) promote communications on scientific, engineering and technological advances that are relevant to the development and implementation of [national and AUS] international rules and guidelines for pandemic prevention, preparedness, response and recovery of health systems, based on science and [available JPN] evidence[, when appropriate JPN].

[NEW (d) further engage with the private sector and civil society for better and faster risk communications to keep up with social trend THA]

- [NEW (e) promote community education for handling medical waste management and elimination of pandemic-related products THA]
- [NEW (f) increase health data literacy among the public and within the health sector through education and meaningful engagement, including clinicians, health sector stakeholders, and decision-makers, to foster trust CAN]
- 2. The Parties [will contribute DEL THA] [shall conduct THA] to research and inform policies on factors that hinder [social appropriation of knowledge COL] [pandemic-related measures such as THA] adherence to public health and social measures, confidence and uptake of vaccines, use of appropriate therapeutics and trust in science and government institutions [while strengthening digital health operations and infrastructure THA].
- 3. The Parties shall promote science and evidence-informed effective and timely risk assessment, including the uncertainty of data and evidence, when communicating such risk to the public. DEL EU
- [4. Adequate allocation of resources including financial shall be used by the Governing bodies to promote public awareness XXX AF GROUP]

[ALTERNATIVE TEXT

Addressing misinformation and disinformation

- 1. The Parties should act independently and jointly to increase public health education, literacy and awareness in the population, and access to information on pandemics and their causes and effects, as well as on the efficacy of medical and other countermeasures, with the aim to counter misinformation or disinformation, including through promotion of international cooperation. In that regard, each Party shall:
 - a. promote and facilitate, at all appropriate levels, in accordance with national law, development and implementation of educational and public awareness programmes on pandemics and their effects, by informing the public, communicating risk and providing evidence- and science-based information about pandemics and relevant countermeasures through effective channels, including social media, in cooperation with all stakeholders, including health professionals, local communities and civil society and the private sector;
 - b. promote regular analysis and consultations with civil society organizations and media outlets to identify the prevalence and profiles of misinformation and design communications and develop messaging strategies for the public to counteract misinformation, disinformation and false news, thereby strengthening public trust and promoting prevention of pandemic risks; and
 - c. promote effective and accessible communication specifically aimed at informing persons in vulnerable situations and people living in humanitarian settings;

- 2. The Parties shall exchange information and cooperate, in accordance with national law, in preventing and investigating incidents of misinformation and disinformation. They shall endeavor to harmonize best practices to increase the accuracy and reliability of crisis communication, promoting health literacy and developing effective tools to identify and counteract misinformation and disinformation.
- 3. The Conference of the Parties shall promote cooperation among the Parties for the implementation of this article and consider adopting additional measures, as appropriate.
- 4. The Secretariat shall, at the request of the Conference of the Parties, develop technical guidance, consult with experts, civil society organizations, the media and monitor social media to identify relevant patterns of communication and need for information. It shall report to the Conference of the Parties on its activities. EU, CHE]

Article 18. [One Health

- 1. The Parties, [recognizing that the majority of emerging [and re-emerging BRA] infectious diseases and pandemics are caused by zoonotic [pathogens DEL CHN] DEL BGD] [and also recognizing the human right to a clean, healthy and sustainable environment COL] [spill-overs that are influenced by climate change, loss of biodiversity and other epidemiological and environmental processes BGD], [commit to DEL MEX, SLV] [shall establish coordination, guaranteeing the interoperability of surveillance systems at the human-animal-environmental interface MEX, SLV], in the context of pandemic prevention, preparedness, response and recovery of health systems, [and in line with the guidance of the Quadripartite, CAN] to promote and implement a One Health approach [, with clear access and benefit sharing rules NAM, BRA, IDN] that is coherent, integrated, coordinated[, equitable BGD, NAM, IDN] and collaborative among all relevant actors, [in order to sustainably balance and optimise the health of people, animals, plants and ecosystems COL] [[with the application of existing instruments and initiatives DEL NAM, BRA, IDN] [such as the One Health Joint Plan of Action CAN] DEL BGD] [in accordance with national circumstances and legislations taking into account the principles and recommendations that may be adopted by the governing bodies of WHO CA+ BGD, NAM, BRA, IDN].
- 2. The Parties, with an aim of safeguarding human health and detecting and preventing health threats, shall promote and enhance synergies between multisectoral and transdisciplinary collaboration [and cooperation JPN] at the national [level DEL JPN] and [cooperation at DEL JPN] the international level [, in order to identify, conduct risk assessment of and share [pathogens with pandemic potential DEL BGD] [while sharing benefits derived from and improving equity related access to medical counter measurement and R&D, CHN] [information about the unusual events BGD] at the interface between human, animal and environment ecosystems, [that may cause a pandemic or that may be early sign of imminent pandemic outbreak BGD] [while recognizing their interdependence DEL BGD]. DEL BRA]
- 3. The Parties[, within their national capacities, BGD, IRN] 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 [, biodiversity loss ISR / ALT pressure on biodiversity COL] and antimicrobial resistance DEL CHN] [and social determinants of health and economic development ARG, BRA] [commensurate with the international cooperation and assistance provided by developed countries and WHO, especially in terms of finance, technology and other means

of implementation or mitigation of economic or other losses the Party may face in implementation of interventions BGD]. [

- 4. [The Parties commit to regularly assess [their RUS] One Health capacities [according to national needs RUS][, insofar as they relate to pandemic prevention, preparedness, response and recovery of health systems DEL BGD] [as specified in Annex XX BGD], and to identify gaps, policies and the funding needed to strengthen those capacities [without prejudicing the national investments and international assistance in building, strengthening and development of health systems capacities as identified in Annex 1 of IHR 2005 BGD]. DEL PARA 4 CHN]
- 5. [The Parties [commit to DEL MEX] [shall MEX] strengthen synergies with other existing relevant [international legal BGD] instruments that address the drivers of pandemics[, such as climate change, biodiversity loss, [wildlife trade COL] [ecosystem degradation DEL SAU] and increased risks at the human-animal-environment interface due to human activities [and social determinants of health and economic development ARG, BRA] taking into consideration social, economic, political, cultural and commercial determinants of health, socioeconomic inequities between developing and developed countries, particularly health inequities, and the need for equity and solidarity BGD]. DEL PARA 4 CHN, IRN]
- 6. [The Parties commit to strengthen multisectoral, coordinated, interoperable and integrated One Health surveillance systems and strengthen laboratory capacity to identify and assess the risks and emergence of pathogens and variants with pandemic potential, in order to minimize spill-over events, mutations and the risks associated with [pandemic potential diseases IDN] [[zoonotic, other tropical and vector-borne diseases BRA / DEL MEX, EGY] [emerging and re-emerging diseases MEX, EGY], with a view to preventing small-scale outbreaks in wildlife or domesticated animals from becoming a pandemic DEL IDN]. DELETE PARA 6 BGD, CHN]
- [ALT 6. The Parties commit to strengthen national One Health surveillance systems and strengthen laboratory capacity to identify and assess the risks posed by unusual public health events at the human-animal-environment interface that may cause or lead to a pandemic outbreak in humans. Each State Party shall notify WHO, by the most efficient means of communication available, by way of the National IHR Focal Point, and within x days of assessment of public health information, of all events within its territory that may cause a pandemic in accordance with the decision instrument annexed1 as well as any public health measure to be implemented in response to those events. BGD]
- [NEW 6 bis. Any sharing of pathogens with human pandemic potential from the human-animal-environment interface including its genomic sequence data by the Parties shall only be through WHO PABS System established under Article 10, subject to standard material transfer agreements, governing access to and use of PABS materials as well as fair and equitable sharing of benefits arising from their utilization, including products, technologies and know how BGD]
 - 7. [Each Party[, within its national capacity and condition, CHN, IRN] [shall DEL IRN] [will commit to IRN]:
 - (a) [implement [science-based ARG, BRA] actions to prevent pandemics from pathogens resistant to antimicrobial agents, taking into account relevant tools and guidelines[, through a One Health approach, and collaborate with relevant partners, including the Quadripartite DEL BRA] DEL CHN];

- [(a)bis take measures to promote public awareness on zoonotic and emerging disease risks and preventive method, with the aim of building widespread support for risk reduction regulations NGA]
- (b) foster [science-based ARG, BRA] actions at national [and community DEL CHN] levels that encompass whole-of-government and whole-of-society approaches to control zoonotic outbreaks [(in wildlife and domesticated animals), including engagement of communities in surveillance that identifies zoonotic outbreaks and antimicrobial resistance at source DEL CHN];
- (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, DEL CHN] and provides [technical DEL CHN] support [of affordable access to, medicines, diagnostic tools, vaccines and other interventions, CHN] to developing countries DEL BRA, MEX];
- (d) [enhance surveillance to identify and report on pathogens resistant to antimicrobial agents in humans, livestock and aquaculture that have pandemic potential, building on the existing global reporting systems; and [promote food quality and safety; and SAU] DEL sub-para (d) BRA, CHN, IRN / RETAIN SWE, FRA, NOR, ITA, SAU]
- (e) take the One Health approach into account at national, subnational and facility levels in order to produce science-based evidence, and support, facilitate and[/or DEL NGA] oversee the correct, evidence-based and risk-informed implementation of infection prevention and control. DELETE PARA 7 BGD] RESERVE CHN, URY, PRY / MOVE to Article 4 RUS]
- [(f) Support other States Parties, in particular developing countries parties in establishing and maintaining One Health surveillance systems and laboratory capacities BRA, IDN, IRN]
- [(g) Support equitable and affordable access to medicines, diagnostic tools, vaccines and any other pandemic-related products to fight endemic zoonotic, neglected tropical and vector-borne diseases BRA, IDN, IRN]
- [NEW (f) Share with all the Parties in real time knowledge and troubleshooting in order to build and sustain 6 &7 ISR]

[NEW (xx) Prioritize One Health in the international political agenda, increase understanding and advocate for the adoption and promotion of the enhanced intersectoral health governance; Strengthen national One Health policies, strategies and plans; Accelerate the implementation of One Health plans; Build intersectoral One Health workforces; Increase investment and financing of One Health strategies and plans. SAU]

Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems

Article 19. [Sustainable and predictable financing

1. The Parties recognize the important role that 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 DEL USA] [intends to USA]:

- (a) [cooperate with other Parties, within the means and resources at its disposal, to raise [sustainable PAK, AUS] financial resources for effective implementation of the WHO CA+ through [domestic, USA] bilateral and multilateral [a new or existing SAU] [regional and subregional NZL] funding mechanisms [including the Pandemic Fund IDN]; RESERVE 1.a USA]
- (b) plan and provide [domestic USA] [adequate DEL USA] financial support in line with its national fiscal capacities [and as appropriate USA] [and programs SAU] for: (i) strengthening [and sustaining core capacities for USA] pandemic prevention, preparedness, response and recovery of health systems [in alignment with the IHR Monitoring and Evaluation Framework and associated metrics USA]; (ii) implementing its national plans, programmes and priorities; [and DEL CHN] (iii) strengthening [public and animal USA] health systems and progressive realization of universal health coverage [for pandemic prevention, preparedness, response and health system recovery USA] [and; (iv) increasing concerted financial support for health care workforce CHN];
- (c) [[intend to USA] [[commit DEL PHL] [endeavour PHL] to [finance necessary amount domestically, JPN] [prioritize and increase or DEL US] maintain DEL JPN] [and, where possible to increase USA], including through greater collaboration between the health, finance [and DEL USA] private[, and other USA] sectors, and other USA] as appropriate, [domestic funding [[by [a significant allocation USA] [allocating DEL USA] in its annual budgets [for USA] [not lower than 5% of its current health expenditure DEL JPN, CHN, NZL, UK, NOR, AUS, TUN, SAU, MEX, CAN, EU, ECU] DEL USA DEL PAK] [in accordance withs its respective capacities PAK] to pandemic prevention, preparedness, response and health systems recovery, notably for improving and sustaining relevant capacities and working to achieve universal health coverage; and RESERVE 19.1.c AUS]

[NEW PARA intend to develop a coordinated and standardized approach to publish, as appropriate, existing national investments in pandemic prevention, preparedness, and response, both in national budgets and expenditure tracking, in alignment with appropriate evaluation mechanisms and national action plans, on a predefined regular basis USA]

- (d) [intend USA] [[commit DEL USA] to [allocate DEL JPN, CHN] [provide JPN], in accordance with its respective capacities, [funding USA] [XX% of its gross domestic product DEL USA, JPN, CHN, NZL, UK, NOR, TUN, MEX, EU] [provide financial support CHN] for international cooperation and assistance on pandemic prevention, preparedness, response and health systems recovery, particularly for developing countries, including through international organizations and existing and new mechanisms DEL AUS] [particularly for developed countries to commit XX% of its gross domestic product to support developing countries in this regard CHN].
- [(d) ALT: facilitate the mobilization of financial resources, in accordance with its respective capacities, to pandemic prevention, preparedness, response and health systems recovery, particularly for developing countries, including through international organizations and existing and new mechanisms. CHE]
- 2. The Parties [recognize the importance of coordination of USA] [[shall DEL JPN] ensure, through [innovative DEL SAU, NZL] DEL USA] existing [and/or new DEL CHE, AUS] mechanisms, sustainable and predictable financing of global, regional and national systems, capacities, [and USA] tools [and global public goods DEL USA], while avoiding duplication, promoting synergies [for USA] and enhancing transparent and accountable governance of these mechanisms, to support strengthening

pandemic prevention, preparedness, response and recovery of health systems, based on public health risk and need, particularly in developing countries.

[NEW 2. bis The Parties agree to establish the CA+ fund to support countries in the implementation of this agreement. The terms of reference of such fund are part of Annex XX. Resources for such fund should be as follows:

- (a) Annual participation contribution by pandemic vaccine, diagnostic and therapeutic manufacturers which use the PABS;
- (b) Annual contribution by the States Parties to the CA+, in accordance with the principle of "common but differentiated responsibilities and respective capabilities"; and
- (c) Voluntary contribution by States Parties and other stakeholders.

The aforementioned fund will provide resources to assist Parties, in particular developing countries, in meeting their obligations under the CA+, in particular with regards to capacity building, strengthening of health systems and laboratory capacities for PPRR, R&D for pandemic related-products and technology transfer. The fund will also finance the WHO allocation mechanism, as well as the Secretariat of the CA+. BRA]

- 3. The Parties shall promote, as appropriate, the use of [domestic USA] bilateral, regional, subregional and other appropriate and relevant channels to provide funding [at all levels USA] for the development and strengthening of pandemic prevention, preparedness, response and health system [capacity building and USA] recovery programmes of developing country Parties.
- 4. [The Parties [intend to encourage USA] [will facilitate DEL USA] [will endeavour to AUS] rapid and effective mobilization of [adequate DEL USA] financial resources [via transparent domestic financing mechanisms for responding to health emergencies allowing for timely execution of funds by relevant sectors USA][, including DEL USA] [in addition to funding USA] from international financing facilities, [including but not limited to the Financial Intermediary Fund for Pandemic Prevention, Preparedness and Response (also known as the Pandemic Fund) PAK] to affected [countries DEL CHN] [developing Parties CHN], based on public health [risk and PHL] need, [and their nationally determined priorities PAK] [to maintain and restore routine public health functions during and in the aftermath of a pandemic response RESERVE USA]. DEL PARA 4 SAU]

[NEW 4 bis. The Parties shall not impose any restrictions, including through the application of Unilateral Coercive Measures, that may interfere with the timely delivery of international financial and development supports to affected countries. IRN]

5. The Parties represented in relevant regional and international intergovernmental organizations and financial and development institutions [shall DEL JPN] [encourage DEL PHL] [ensure that PHL] [as appropriate USA] these entities [to DEL PHL] provide financial assistance for developing country Parties to support them in meeting their obligations under the WHO CA+ [to the extent consistent with the objectives and mandate of these entities, and JPN][, without limiting their participation in or membership of these organizations DEL USA].

RESERVE ARTICLE 19 COL, URY, ECU, GTM, PER

[NEW ARTICLE O.1. Provision of implementation support

- 1. The Parties shall cooperate for the implementation of the Agreement.
- 2. The Parties shall promote and strengthen cooperation between their competent bodies and authorities in order to fully achieve the objective of the Agreement.
- 3. The Parties shall facilitate the provision of technical assistance and capacity building, with particular attention to the needs of Parties which are low and lower middle income countries and with the aim to assist them in building sustainable capacity to implement their obligations and commitments under the Agreement.
- 4. The Parties shall promote, establish or enhance joint training programmes between, and continuing education of, human, animal and environmental health professionals and the inclusion of the One Health approach in health-related educational programmes.
- 5. The Parties shall cooperate, including with the private and philanthropic sectors, to secure the financial resources necessary for the provision of adequate assistance aimed at the effective implementation of the Agreement. For this purpose the Conference of the Parties shall, at its first session, define a financial mechanism functioning under its guidance. It shall select the existing entities providing multilateral, regional and bilateral financial and technical assistance to be entrusted with the operation of the mechanism and set out the necessary arrangements for cooperation with these entities in order to enable its effective and equitable operation.
- 6. Where relevant and appropriate, assistance activities shall address regional and sub-regional implementation problems and promote regional and sub-regional capacities.
- 7. The Secretariat, in collaboration with relevant international and regional organizations and other bodies, shall provide assistance in the identification of support needs and organization of the technical assistance and capacity building activities provided for in this Article, with particular regard to the needs of the Parties which are low or lower-middle income countries. The support activities under this Article shall be closely coordinated with the provision of support under the IHR. The Parties and Secretariat shall report on the results obtained to the Conference of the Parties at least every two years as part of the report provided for in Article P.2.
- 8. The Conference of the Parties shall hold at least one dedicated meeting within the yearly ordinary session to:
 - (a) discuss any problems regarding the implementation of provisions of this Agreement;
 - (b) review progress in the provision of technical assistance and capacity building to support the implementation of the Agreement, including any Party, especially low and lower middle income not receiving adequate support;
 - (c) share experiences and information on ongoing assistance and support for capacity building and implementation programmes, including challenges and successes;
 - (d) review the reports provided by the parties and the Secretariat in accordance with paragraph 7.

EU NEW ARTICLE]

Chapter VII. Institutional arrangements

Article 20. Governing Body for the WHO CA+

- 1. A governing body for the WHO CA+ is established to promote the effective implementation of the WHO CA+ (hereinafter, the "Governing Body").
- 2. The Governing Body shall be composed of:
 - (a) the Conference of the Parties (COP), which shall be the supreme organ of the Governing Body, composed of the Parties and constituting the sole decision-making organ; and
 - (b) the Officers of the Parties, which shall be the administrative organ of the Governing Body.
- 3. The COP, as the supreme policy setting organ of the WHO CA+, shall keep under regular review every three years the implementation and outcome of the WHO CA+ and any related legal instruments that the COP may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO CA+. The COP shall:
 - (c) be composed of delegates representing Parties;
 - (d) convene regular sessions of the Governing Body; the first of which shall take place not later than one year after the date of entry into force of the Convention, at a time and place to be determined by the WHO Secretariat, with the time and place of subsequent ordinary sessions to be determined by the COP upon a proposal of the Officers of the Parties;
 - (e) convene special sessions of the Governing Body at such other times as may be deemed necessary by the COP, or at the written request of any Party, provided that, within 30 days of such a request being communicated to the Party/Parties by the Secretariat, it is supported by at least one third of the Parties; and
 - (f) adopt its rules of procedure, as well as those of the other bodies of the Governing Body, which shall include decision-making procedures. Such procedures may include specified majorities required for the adoption of particular decisions.
- 4. The Officers of the Parties, as the administrative organ of the Governing Body, shall:
 - (g) be composed of two Presidents, four Vice-Presidents and two rapporteurs, serving in their individual capacity and elected by the COP for XX years; and
 - (h) endeavour to make decisions by consensus; however, if efforts to reach consensus are deemed by the Presidents to be unavailing, decisions may be taken by voting by the President and Vice-Presidents.
- 5. The Governing Body may further develop proposals for consideration by the WHO Executive Board, including to promote coordination and synergies between its Standing Committee on Health Emergency Prevention, Preparedness and Response and the Governing Body for the WHO CA+.

Article 21. Consultative Body for the WHO CA+

- 1. A consultative body for the WHO CA+ (the "Consultative Body") is established to provide advice and technical inputs for the decision-making processes of the COP, without participating in any decision-making.
- 2. The Consultative Body will provide opportunity for broad, fair and equitable input to the COP for the decision-making processes of the COP. Further, the Consultative Body will provide opportunity for facilitation of implementation of COP decisions through modalities to be established by the COP. For the avoidance of doubt, it is understood that the Consultative Body will not participate in any decision-making, whether by consensus, voting or otherwise, of the COP.
- 3. The Consultative Body shall be composed of (i) delegates representing Parties; and (ii) representatives of the United Nations and its specialized and related agencies, as well as any State Member thereof or observers thereto not Party to the WHO CA+. Further, 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+, may be admitted upon formal application, in accordance with terms and conditions to be adopted by the COP, renewable every three years, unless at least one third of the Parties object.
- 4. The Consultative Body shall be subject to the oversight of the COP, including rules of procedure adopted by the COP.

Article 22. Oversight mechanisms for the WHO CA+

- 1. The Governing Body, at its first meeting, shall consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of the WHO CA+ and also address cases of non-compliance.
- 2. These measures, procedures and mechanisms shall include monitoring provisions and accountability measures to systematically address the achievement and gaps of capacities for prevention, preparedness, response and recovery of health systems, and the impact of pandemics, by means that include submission of periodic reports, reviews, remedies and actions, and to offer advice or assistance, where appropriate. These measures shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under the WHO CA+.

Article 23. Assessment and review

The Governing Body shall establish a mechanism to undertake, three years after the entry into force of the WHO CA+, and thereafter every three years and upon modalities determined by the Governing Body, an evaluation of the relevance and effectiveness of the WHO CA+, and recommend corrective measures, including, if deemed appropriate, amendments to the text of the WHO CA+.

Article 24. Secretariat

- 1. A Secretariat for the WHO CA+ shall be provided by the Director-General of the World Health Organization. Secretariat functions shall be:
 - (a) to make arrangements for sessions of the Governing Body and any subsidiary bodies and to provide them with services as required;
 - (b) to transmit reports received by it pursuant to the WHO CA+;

- (c) to provide support to the Parties, on request, in the compilation and communication of information required in accordance with the provisions of the WHO CA+;
- (d) to prepare reports on its activities under the WHO CA+ under the guidance of the Governing Body, and submit them to the Governing Body;
- (e) to ensure, under the guidance of the Governing Body, the necessary coordination with the competent international and regional intergovernmental organizations and other bodies;
- (f) to enter, under the guidance of the Governing Body, into such administrative or contractual arrangements as may be required for the effective discharge of its functions; and
- (g) to perform other secretariat functions specified by the WHO CA+ and such other functions as may be determined by the Governing Body.

Chapter VIII. Final provisions

Article 25. Reservations

- 1. No reservations or exceptions may be made to this WHO CA+ unless expressly permitted by other articles of this WHO CA+.
- 2. A reservation incompatible with the object and purpose of the WHO CA+ shall not be permitted.
- 3. Reservations that are receivable in accordance with the above, 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.

Article 26. 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 will be consistent with each Party's national law, as applicable, regarding confidentiality and privacy.

Article 27. 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 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 not be considered as having also withdrawn from any protocol to which it is a Party, or from any related instrument, unless such a Party formally withdraws from such other instruments, and does so in accordance with the relevant terms, if any, thereof.

Article 28. Right to vote

1. Each Party to the WHO CA+ shall have one vote in the COP, 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+. Such an organization shall not exercise its right to vote if any of its Member States exercises its right, and vice versa.

Article 29. Amendments to the WHO CA+

- 1. Any Party may propose amendments to the WHO CA+. Such amendments will be considered by the COP, which may invite views of the Consultative Body.
- 2. Amendments to the WHO CA+ shall be adopted by the COP. 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 reach agreement by consensus on any proposed amendment to the WHO CA+. If all efforts at consensus have been exhausted, and no agreement reached, the amendment shall as a last resort be adopted by a two-thirds majority vote of the Parties present and voting at the session. For 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 at least 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 30. Adoption and amendment of annexes to the WHO CA+

- 1. The COP may adopt annexes to the WHO CA+ and amendments thereto.
- 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 31. Protocols to the WHO CA+

- 1. Any Party may propose protocols to the WHO CA+. Such proposals will be considered by the COP, which may invite the views of the Consultative Body.
- 2. The COP 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 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. States that are not Parties to the WHO CA+ may be Parties to a protocol thereof, provided the protocol so provides.
- 5. Any protocol to the WHO CA+ shall be binding only on the Parties to the protocol in question. Only Parties to a protocol may take decisions on matters exclusively relating to the protocol in question.
- 6. The requirements for entry into force of any protocol shall be established by that instrument.

Article 32. 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 by regional economic integration organizations, at the World Health Organization headquarters in Geneva, immediately following its adoption by the World Health Assembly at the Seventy-seventh World Health Assembly, from XX May 2024 to XX July 2024, and thereafter at United Nations Headquarters in New York, from XX August 2024 to XX November 2024.

Article 33. 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. It 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 organizations, where one or more of its Member States is a Party to the WHO CA+, the 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 organization and the 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 34. 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 its depositing of the 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 the Organization.

Article 35. Provisional application by the Parties, and actions to give effect to the provisions of the WHO CA+ by the World Health Assembly

- 1. The WHO CA+ may be applied provisionally, in whole or in part, by a signatory and/or Party that consents to its provisional application by so notifying the Depositary in writing at the time of signature of the instrument, or 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 Secretary-General of the United Nations.
- 2. Provisional application by a signatory and/or Party shall terminate upon the entry into force of the WHO CA+ for that Party or upon notification by that signatory and/or Party to the Depositary in writing of its intention to terminate its provisional application.
- 3. Provisions of the WHO CA+ may be given effect as recommendations for all Member States of the World Health Organization under Article 23 of the WHO Constitution, and given effect as policies of the World Health Organization, understood as authoritative with respect to the Director-General, under Articles 18(a), 28(a) and 31 of the WHO Constitution.

Article 36. 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 agreement 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 Party may declare in writing to the Depositary that, for a dispute not resolved in accordance with paragraph 1 of this Article, it accepts, as compulsory *ipso facto* and without special agreement, in relation to any Party accepting the same obligation: (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 Governing Body.
- 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 37. Depositary

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

Article 38. 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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