# COMPILATION TEXT REFLECTING DRAFTING GROUP INPUTS



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

WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response ("WHO CA+")

NB: Bold text reflects textual submissions received prior to and during INB5

Bold underline text reflects textual submissions received after INB5

#### BACKGROUND, METHODOLOGY AND APPROACH

- 1. In recognition of [the catastrophic failure of the international community in showing solidarity and equity in response <u>DEL CHI</u> [and recovery ADD AFR GROUP] to [the difficult situation faced by the international community in the face of ADD CHI]
- 2. 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. 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 [INB ADD CHI] 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 at its fourth meeting.

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

#### [RESERVE PREAMBULAR SECTION AFR GROUP]

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 **DEL SGP**] human rights,
- 3. Recognizing that all lives have equal value, and that [consequently, equity is a beginning and should be ADD CHI] [therefore equity should be a principle, DEL CHI] [an indicator and an outcome DEL SGP] of pandemic prevention, preparedness and response, [MOVE AND REPLACE AS PPI COSR]
- 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, [gender ADD CHI] religion, political belief, economic or social condition, [or of any other kind ADD CHI] and that unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger,

[PP4bis. Reaffirming the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the Convention on the Elimination of All Forms of Discrimination against Women, the Convention on the Rights of the Child, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Rights of Persons with Disabilities and all other relevant international human rights instruments ADD COSR]

- 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 **DEL SGP**] [and will require **ADD SGP**] States Parties to prioritize effective and enhanced cooperation with development partners and other relevant stakeholders to address extraordinary challenges, [**DEL WHOLE ARG**]
- 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,

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<sup>&</sup>lt;sup>1</sup> The Bureau proposes, consistent with Member State submissions, that the preambular section be discussed at the appropriate point in the negotiations.

[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 MOVED BY ARG FROM 17]

- 8. Recalling the [purpose and scope of the ADD SGP] International Health Regulations of the World Health Organization [and the role of States Parties and other stakeholders in <u>DEL SGP</u>] [to ADD SGP] [preventing, <u>DEL SGP</u>] protecting against, control[ling <u>DEL SGP</u>] and provid[ing <u>DEL SGP</u>] and provid[ing <u>DEL SGP</u>] as public health response to the international spread of disease in ways that are commensurate with[, <u>DEL SGP</u>] and restricted to[, <u>DEL SGP</u>] 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 **DEL CHI**] [especially ADD **CHI**] communities and persons in vulnerable situations, places and ecosystems,
- 10. Recognizing that the threat of pandemics is a reality[, ADD SGP] [and DEL SGP] that pandemics have catastrophic health, social, economic and political consequences, especially for persons in vulnerable situations, [and that ADD SGP] pandemic prevention, preparedness, response and recovery of health systems must be systemically integrated 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" DEL ARG],
- 11. Reflecting on the lessons learned from [the ADD SGP] 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 <u>DEL SGP</u>] with a view to addressing and closing gaps [in the global health architecture ADD SGP] 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,

[PP 12bis. Recognizing that pandemics put at particular risk people living in congregate settings including older persons, people with disabilities, people deprived of their liberty in prisons, residential institutions, migration and other centres of detention, COSR]

# [12ter. Expressing concern that those affected by conflict and insecurity are particularly at risk of being left behind during pandemics, (moved from 16) COSR]

- 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, **DEL SGP]** [**DEL WHOLE ARG**]

- 15. Reaffirming the importance of diverse, gender-balanced and equitable representation [participation ADD COSR] and expertise [including of those put at particular risk and in vulnerable situations COSR] in [decision-making for ADD SGP] pandemic prevention, preparedness, response and [recovery of ADD SGP] health system [s ADD SGP] [recovery decision-making, as well as in the design and implementation of activities DEL SGP],
- 16. *Expressing* concern that those affected by conflict and insecurity are particularly at risk of being left behind during pandemics, [MOVED TO PP12 COSR]
- 17. Recognizing the synergies between multisectoral collaboration [– through whole-of-government and whole-of-society [and One Health ADD ARG] approaches at the country and community level DEL SGP] 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,
- [17. 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, DEL AFR GROUP]
- 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, **DEL SGP**] require [a **DEL SGP**] multisectoral [whole-of-government and ADD SGP] whole-of-society approach[es at the country and community level ADD SGP] to pandemic prevention, preparedness, response and recovery of health systems,
- 19. Acknowledging the impacts of determinants of health across different sectors[, ADD SGP] [and DEL SGP] communities [and individuals ADD SGP] [on the vulnerability of communities DEL SGP], 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 <u>DEL SGP</u>] to counteract pandemics,
- 23. *Understanding* that most emerging infectious diseases originate in animals, including wildlife and domesticated animals, then spill over to [people **DEL SGP**] [humans SGP],
- 24. *Recognizing* the importance of working synergistically with other relevant [international organisations and stakeholders ADD SGP] [areas DEL SGP], 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 DEL SGP]

- 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 [emerging issues in the realm of animal-human-ecosystems interface, in the context of the ADD SGP] One Health[-related issue DEL SGP, AFR GROUP] [approach ADD SGP],
- 28. Reiterating the need [for States Parties ADD SGP] to work towards building and strengthening [their national ADD SGP] [resilient DEL SGP] 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, [most of which are women ADD COSR] 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,

[NEW PARA 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 ARG],

- 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, **RESERVE PHRASE SGP**] 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 [of States Parties ADD SGP] to [achieve DEL COSR][ ensure the highest attainable standard of ADD COSR] health [equity DEL COSR] through resolute action

on [social, environmental, cultural, political and economic <u>**DEL SGP**</u>] 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 <u>**DEL SGP**</u>] 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, [adequately remunerated, ADD ARG] skilled health workers [with safe and decent working conditions, ADD ARG] 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[, **DEL SGP**] [and ADD SGP] transparency [and common but differentiated responsibility **DEL SGP**] by all States Parties and relevant stakeholders,

[NEW PARA Emphasizing the need to improve access to quality, safe, effective and affordable medicines and other health technologies, inter alia, through building capacity for local production, especially in low and middle-income countries, technology transfer on voluntary and mutually agreed terms, cooperation with, support to and development of voluntary patent pools and other voluntary initiatives ARG]

- 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, [RESERVE SGP]
- 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, [RESERVE SGP] [DEL WHOLE ARG] 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, [RESERVE SGP]
- 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, [DEL WHOLE ARG]
- 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, [DEL WHOLE ARG, SGP]
- 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, [DEL WHOLE ARG, SGP]
- 43. Recognizing the concerns [regarding the effect ADD SGP] 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 DEL SGP] [have on ADD SGP] the effect on prices, which [may ADD SGP] limit[s DEL SGP] 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 [past public health emergency of international concern such

- <u>us H5N1, H1N1 and recently the ADD ARG</u>] [the <u>DEL ARG</u>] 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, **DEL WHOLE SGP**]
- 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 [with a view to identifying gaps in research and development on diseases that disproportionately affect developing countries ADD SGP] [system supportive of access to appropriate and affordable medical countermeasures, including those needed in a pandemic, DEL SGP]
- 47. *Recognizing* that publicly funded research and development plays an important role in the development of pandemic-related products and, as such, requires conditionalities, **RESERVE TUN**]

[PP47bis(new) Recognizing that in the context of pandemics, the most important priority of the global community is to halt its rapid transmission and reverse the trend of consequential global distress by ensuring that everyone, everywhere can access the health technologies they need for detection, prevention, treatment and response ADD COSR].

[PP47ter: (new) Recalling the Solidarity Call to Action and the WHO COVID-19 Technology Access Pool (C-TAP) initiative efforts and challenges to support restoring global health security during the COVID-19 pandemic through voluntarily pooling knowledge, intellectual property and data necessary for the pandemic response and to advance scientific discovery, technology development and broad sharing of the benefits of scientific advancement and its applications based on the right to health. ADD COSR]

- 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, <u>DEL SGP1</u> 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,
- 50. [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 [at the global, national, and community level CAN] with an aim to sustainably balance DEL THA] and optimize the health of people, [animals and ecosystems DEL THA] [, including through, but not limited to, attention to the prevention of [and response to THA] epidemics due to [novel THA] pathogens [resistant to antimicrobial agents DEL THA] and zoonotic diseases [and their spillover THA] [and food safety TUN] DEL BRA] AFR GROUP]

[ALT [NEW PARA ZAF [ADD 50 Emphasizing that transnational corporations and other business enterprises have a responsibility to respect human rights]

51. [Universal health coverage – The WHO CA+ [will DEL THA] [shall THA] be guided by the aim of achieving universal health coverage [focusing on primary health care THA], for which strong and resilient health systems [based on primary health care AUS, BRA] are of key importance, as a fundamental aspect of achieving [human development including THA] [the Sustainable Development Goals DEL THA] through promoting [good THA] health and well-being for all at all ages AFR GROUP]

[ALT [NEW PARA ZAF [ADD 51 Recognizing the need for continuity of essential health services during a pandemic]

52. [Science and evidence-informed [policies and THA] decisions – Science, evidence and findable, accessible, interoperable and reusable data should inform all public health [policies and THA] decisions and the development and implementation of guidance for pandemic prevention, preparedness, response and recovery of health systems [shall be based on science, evidence, and findable accessible, interoperable and reusable data THA] AFR GROUP].

[ALT [NEW PARA ZAF [ADD 52 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]

53. [Central role of WHO – DEL AUS] [Coordination in global health governance – The implementation of the WHO CA+ is advanced in coordination with the respective roles, mandates, and work of global health actors. AUS] As the directing and coordinating authority on [global health DEL AUS] [international health work AUS], and the leader of multilateral cooperation in global health governance, WHO,[working together with regional organizations] ADD AFRICA GROUP, is fundamental to strengthening pandemic prevention, preparedness, response and recovery of health systems. [NOTE IRN, AFR GROUP]

[NEW PARA ZAF [ADD 53 Reaffirming States' obligation to proactively ensure the accessibility of all public health information necessary in pandemic preparedness and responses, including through public dissemination of any relevant, disaggregated public health data necessary for the realization of the right to health].

[NEW PARA ZAF [ADD 54 Reaffirming that States are required to make provision for and ensure that any and all restrictive legal regulations enacted in order to respond to pandemics and health emergencies do not have a disproportionate impact on the full range of human rights, including economic, social, and cultural rights (ESCR)].

*Have* agreed as follows:

[MOVED FROM ART 9 (1) The Parties recognize the need to build and strengthen capacities and institutions for innovative research and development for pandemic-related products, particularly in developing countries, and the need for information sharing through open science approaches for rapid sharing of scientific findings and research results DEL BGD]

## The world together equitably

[Vision: The WHO CA+¹ aims [to achieve greater equity and effectiveness for pandemic prevention, preparedness and response through the fullest national and international cooperation ADD SGP] [for a world where pandemics are effectively controlled to protect present and future generations from pandemics and their devastating consequences, DEL SGP] 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. DEL COSR] [The WHO CA+ aims to achieve greater equity and effectiveness for pandemic prevention, preparedness [and DEL AFR GROUP] response through the fullest national and international cooperation DEL SGP]. DEL EU AUS, BRN, IND, JAM / RETAIN AFR GROUP,]

## [USA PROPOSED ARTICLES]

[Proposed Article A. Multilateral Pandemic Prevention, Preparedness, and Response Benefit Sharing System

- 1. The Parties agree that the Multilateral Pandemic Prevention, Preparedness, and Response Benefit Sharing System ("the Benefit Sharing System") is to be established. Furthermore, the Parties agree that the Benefit Sharing System shall be established with the voluntary participation of relevant stakeholders, including participants of health partnerships, the private sector, civil society, and international organizations, on terms to be determined by Member States. The Parties emphasize that the role of relevant stakeholders in the development of this system is to be prioritized immediately.
- 2. The Parties affirm that both the benefits and the Benefit Sharing System are intended to be used to support more rapid, effective, and equitable pandemic prevention, preparedness and response based on public health needs, including, inter alia, health emergency workforce, populations most at-risk for severe illness or death, and responses in complex humanitarian crisis settings.
- 3. The Parties intend for the Benefit Sharing System to:
- a. be efficient, feasible, practical, and effective;
- b. generate more benefits, including both monetary and non-monetary, than costs;
- c. be implementable during and between pandemic emergencies;
- d. provide certainty and legal clarity for providers and users of biological materials and genetic sequence data from pathogens with pandemic potential;

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<sup>&</sup>lt;sup>1</sup> 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.

- e. strengthen, expedite, and not impede research and innovation;
- f. be consistent with open access to genetic sequence data (GSD) and related metadata from pathogens with pandemic potential;
- g. incorporate practices to ensure biosafety and biosecurity; and
- h. be implemented in a manner consistent with applicable national and international laws, regulations, and other obligations.
- 4. The Parties intend for the Benefit Sharing System to perform the following functions:
- a. provide, where appropriate, surveillance, risk assessment, and early warning information and related services to all countries with regard to pathogens with pandemic potential;
- b. provide, where appropriate, capacity building in surveillance, risk assessment, and early warning information and related services to the Parties with regard to pathogens with pandemic potential;
- c. Facilitate, where appropriate, the safe and secure conduct of basic, applied, translational and clinical research regarding pathogens with pandemic potential;
- d. prioritize during a pandemic emergency, rapid and equitable access to safe and effective diagnostics, therapeutics, and vaccines against pathogens with human pandemic potential, particularly to populations of concern affected by the pandemic emergency, according to public health risk and needs and particularly where those countries do not have their own capacity to produce or access vaccines, diagnostics, and pharmaceuticals;
- e. build capacity in countries over time, in particular for low- and middle-income countries (LMICs), with the voluntary participation of relevant stakeholders and commensurate with the country capabilities, including through: technical assistance; regulatory strengthening; transfer of technology, skills, and know-how on voluntary and mutually agreed terms; and geographically distributed manufacturing and supply chains, tailored to the country's public health risk and needs.
- 5. The Parties recognize that the WHO CA+ conveys numerous benefits, which the Parties consider to be benefits also conveyed by the Benefit Sharing System to be established in accordance with Article X, Section/Paragraph 1. These benefits, as identified in the WHO CA+, may include but are not limited to the following:
- a. sharing of biological materials, GSD and related metadata from pathogens with pandemic potential; b. transparency and coordination on global supply chains for pandemic emergency response-related products, including with the voluntary participation of relevant stakeholders;
- c. national measures that promote timely and equitable access to pandemic emergency responserelated products during a pandemic emergency based on public health risks and needs, including through provisions in publicly funded purchase agreements and the use of pooled procurement mechanisms for pandemic emergency response-related products;
- d. support for building and strengthening capacities, based on need, mutual agreement, and as appropriate. Such capacity building could include, inter alia:
  - i. core capacity requirements for surveillance and response, as outlined in Annex 1 of the International Health Regulations (2005);
  - ii. regulatory systems;
  - iii. biosafety, biosecurity, and biorisk management;
  - iv. basic, applied, translational, and clinical research;
  - v. health emergency workforce development; vi. manufacturing of pandemic emergency response-related products, including regionally distributed manufacturing, tailored to public health risk and need and considering the capacity of the Party for long-term sustainable funding
- <u>e. coordination, collaboration, and cooperation in scientific research and responserelated activities;</u>

- <u>f. licensing and technology transfer for pandemic emergency response-related products on</u> voluntary and mutually agreed terms;
- g. related bilateral, regional, or global capacity building and technical support and assistance;
- h. support for establishing and maintaining regional stockpiles of pandemic emergency responserelated products and products for other health emergencies;
- i. financing for pandemic prevention, preparedness, and response; and j. sharing of research results.
- 6. The Parties recognize that contributions of monetary and non-monetary benefits to be shared by relevant stakeholders shall be considered as part of the Benefit Sharing System.
- 7. In part to support the Benefit Sharing System, the Parties intend to urge, direct the WHO to urge, and request other relevant global partners to urge, manufacturers of pandemic emergency response-related products to:
- a. set aside a portion of each production cycle of these products for procurement by/for LMICs;
  b. implement tiered pricing for these products, based on income level of countries;
- c. engage rapidly with any relevant global, regional, or other access mechanisms, including those that provide these products to LMICs;
- d. at the earliest opportunity, develop, publish, and implement global access plans that are designed to facilitate timely and equitable global access to their products, and include provisions in purchase agreements that further these goals; e. support WHO in strengthening regulatory (prequalification and Emergency Use Listing) capacities and in supporting in-country activities that promote reliance on these authorizations during health emergencies; and
- f. support financing for strengthening pandemic preparedness and IHR core capacities.
- 8. In part to support the Benefit Sharing System, the Parties intend to urge nongovernmental entities, global health actors, and regional entities that procure pandemic emergency related response products, including personal protective equipment, to include provisions that facilitate timely and equitable global access to those products in those entities' purchase agreements.
- 9. The Parties agree the WHO CA+ in its entirety shall function, in conjunction with the International Health Regulations (2005), and contributions of relevant stakeholders to support pandemic prevention, preparedness, and response, as a specialized international instrument[s] for access and benefit sharing for human and zoonotic pathogens. USA]

#### **[USA Proposed Article B. Sample and Data Sharing**

- 1. The Parties recognize the need for rapid and transparent sharing of biological materials 1, including samples of human and potential zoonotic pathogens, particularly those with epidemic and pandemic potential, as well as genetic sequence data (GSD) and relevant metadata from human and potential zoonotic pathogens, as a key component of pandemic prevention, preparedness, and response.
- 2. The Parties also recognize that the distribution of genetic sequence data and the practices of biological material and genetic sequence data sharing require appropriately designed solutions for facilitating access and for benefit sharing to prepare for and respond to health emergencies.

## Access to human and potential zoonotic pathogens

3. The Parties, through their national health authorities, shall share, in a rapid and timely manner, biological material with established laboratory networks, laboratories, and biorepositories,

subject to applicable national and international laws, regulations, rules, and standards, including relating to biosafety, biosecurity, and transport, and consistent with relevant national and international frameworks for collection of patient specimens and epidemiological data.

- 4. The Parties intend to share biological material pursuant to paragraph 3 in accordance with the following:
- a. Access to biological material is accorded expeditiously and free of charge, or, when a fee is charged, it does not exceed the minimal cost involved;
- b. Access to biological materials related to an outbreak or health emergency, or response to an outbreak or health emergency, is to be accorded the highest priority, and shared as quickly as possible by amending standard procedures as needed.
- c. Information related to the biological material be similarly shared with high priority, subject to applicable law;
- d. Access is provided for any legitimate purpose related to pandemic prevention, preparedness, or response.
- 5. The Parties recognize the potential benefits of using a Standard Material Transfer Agreement (SMTA) to cover all transfers of biological materials within the scope of the WHO CA+. The SMTA in Annex X is an example based on an SMTA that some WHO Member States used during COVID-19.

Sharing of human and potential zoonotic pathogen genetic sequence data

- 6. The Parties shall share, and shall encourage others to share, in a rapid, systematic, frequent, and transparent manner, sufficient and representative human and potential zoonotic pathogen genetic sequence data and analyses arising from that data, and relevant metadata, consistent with applicable laws and regulations, relating to human and potential zoonotic pathogens in public databases that can be accessed by the global scientific community, with appropriate biosecurity practices, without a requirement to track and trace the use of human and potential zoonotic pathogen GSD.
- 7. The Parties intend to share, and intend to encourage others to share, human and potential zoonotic pathogen genetic sequence data and relevant metadata in a rapid, systematic, and transparent manner and by the most effective means that promote responsible use and findable, accessible, interoperable and reusable (FAIR) data.

Annex: Example Template Standard Material Transfer Agreements

The "BIOLOGICAL MATERIAL [insert description of material]" is being made available by the PROVIDER to the RECIPIENT under the terms below. "BIOLOGICAL MATERIAL" as used in this agreement means the original material or any unmodified progeny transferred and excludes any derivatives made by the RECIPIENT:

- 1. The BIOLOGICAL MATERIAL is made available for any legitimate purpose required to rapidly prevent, detect, prepare for, and respond to, the spread or transmission of [insert pathogen].
- 2. THIS BIOLOGICAL MATERIAL IS NOT FOR USE IN HUMAN SUBJECTS.

- 3. The BIOLOGICAL MATERIAL may not be further distributed to other entities unless it is for the purpose described in Article 1 and under terms no more restrictive than this Agreement. To ensure compliance with this, copies of MTAs recording all further transfers must be sent back to [insert email of agreed upon POC].
- 4. The RECIPIENT agrees to acknowledge the source of the BIOLOGICAL MATERIAL in any publications reporting use of it, including any open or publicly available deposit of genetic sequence data from the BIOLOGICAL MATERIAL. [Insert name and contact information for source of the BIOLOGICAL MATERIAL]
- 5. Any MATERIAL delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
- 6. The RECIPIENT and PROVIDER agree to transfer, use, manage, and control the BIOLOGICAL MATERIAL in compliance with all applicable laws and regulations of [INSERT COUNTRY].

The following terms are added if the BIOLOGICAL MATERIAL is [regulated by national biosafety and biosecurity related export control measures]:

- 7. The RECIPIENT will immediately notify the PROVIDER [insert contact information] if the BIOLOGICAL MATERIAL becomes lost or stolen.
- 8. These commodities, technology, or software are exported from the [INSERT COUNTRY] in accordance with their BIOSAFETY AND BIOSECURITY EXPORT REGULATIONS. The RECIPIENT agrees to comply with all terms and conditions of the export license. Diversion contrary to [INSERT COUNTRY] law is prohibited.
- 9. Unless either party requires this Agreement to be executed by signature, no further evidence of acceptance is required.
- (FN (1) "Biological materials" for the purposes of this instrument includes human and potential zoonotic pathogens, related clinical specimens, related environmental samples, and modified pathogens prepared from isolates of human and potential zoonotic pathogens or related clinical specimens. USA]

# Chapter I. Introduction [LAYOUT PROPOSAL MERGE CHAPTERS 1 AND 2 INTO ONE CHAPTER (CHAPTER I) ENTITLED 'GENERAL PROVISIONS' EU]

#### 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 **DEL ARG**] genetic information that determines the biological characteristics of an organism or a virus[; **DEL PAK**] [. They may take the form of Digital Sequence Information ADD **PAK**]
- [(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; DEL AFR GROUP]

[NEW PARA A).Genomic and genetic sequence data and other forms of digital sequence information on genetic resources. It is not necessary to define these terms but if INB insists on definitions AG suggests that INB defines the terms provided. AFR GROUP] [ALT (a) "event" means a manifestation of disease arising from the spread of a pathogen or variant that infects human populations JAM]

"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 [including variants of known pathogens, and novel or newly recognised agents UK] [[or [a novel ADD GBR/DEL IND, RUS, BWA, COL] [viral ADD NGA]variant DEL MAR] DEL KEN] [disease ADD KEN] that infects DEL UK] [to which UK] human populations [possess UK] [[with DEL UK] limited or no [natural or acquired UK] immunity DEL TGO, PAK] [through DEL UK] [and limited or no available medical countermeasures in the presence of UK] sustained [and high DEL UK] transmissibility [from person to person DEL AUS, FJI, PAK, UK] [with the capacity to cause ADD AUS], [a global ADD SAU] [to people UK], [capable of severe morbidity and mortality, with the potential to cause disruption of UK] [[overwhelming DEL **UK**] health [systems [with **DEL PAK**] DEL AUS] [severe morbidity and [high DEL AUS] mortality **DEL PAK, UK**], [and causing DEL AUS, **UK**] [social and economic [systems UK] [disruptions DEL UK] DEL SAU, RUS, AUS][social disruption and economic downturn ADD SAU], [all of DEL AUS] which [require DEL AUS] [requiring ADD AUS] [requires ADD AUS] [equitable and ADD NAM, BWA] effective national [, regional ADD THA] and global [and multisectoral ADD GBR, AUS, UK] collaboration [, coordination and response ADD NGA] [and coordination DEL NGA, RETAIN AUS] for its control [and the mitigation of its adverse effects ADD THA] DEL MCO, RUS]; [A pandemic

<sup>&</sup>lt;sup>1</sup> The INB is encouraged to conduct discussions on the matter of the declaration of a "pandemic" by the WHO Director-General under the WHO CA+ and the modalities and terms for such a declaration, including interactions with the International Health Regulations and other relevant mechanisms and instruments. In this connection see Article 15.2 hereof.

is determined by the declaration of a Public Health Emergency of International Concern (PHEIC) under the International Health Regulations (2005). ADD PAK]

[ALT (b) DEF [Pandemic is an outbreak of a disease caused by a new or existing pathogen or variant. This can include viruses, bacteria, fungi, and parasites. It spreads rapidly and easily due to human activities such as travel, trade, and animal-to-human transmission, and can affect a large portion of the population across multiple continents or worldwide. This leads to a high number of cases, overwhelming healthcare systems and resulting in severe morbidity and increased mortality rates. Pandemics also cause significant social and economic disruptions, requiring effective collaboration and coordination between nations and globally to prevent, control, and treat the disease. The impact of pandemics may also result in long-term changes in society and public health practices. ADD SAU]

[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]

[ALT (b) BRN ALT 1(b) "pandemic" means a Public Health Emergency of International Concern (as determined under the IHR) arising from an emerging or re-emerging infectious disease with the potential to overwhelm health systems, requiring effective national, regional, and global collaboration and coordination for its control.]

[ALT [Pandemic means a public health emergency of an international concern which is determined, as provided in this instrument and or IHR: i) to constitute a public health risk to other states through the international spread of disease, ii) to require a coordinated, collaborative and equitable international response; and iii) to potentially cause a higher level of social and economic disruption and impact AFR GROUP]. [ALT "pandemic" means the global spread of a pathogen or variant that infects human populations through sustained and high transmissibility from person to person, overwhelming health systems with severe morbidity and or high mortality, and causing social and economic disruptions. ADD JAM]

[NEW PARA "public health emergency" means an event detected by the national surveillance systems in a Country and which has the potential for a serious public health impact;. JAM]

- (c) "pandemic-related products" means [[health related ADD JPN] [health-related pandemic ADD AUS] products [and technologies ADD ARG] that may be needed for [use according to the capacity of the country ADD PRY] pandemic prevention, preparedness, response and/or [health system THA, JAM] recovery, and which may include, without limitation, [reagents and laboratory supplies ADD MEX] diagnostics, therapeutics, medicines, vaccines, personal protective equipment, syringes and oxygen; DEL RUS]
- (d) [Persons in vulnerable [situations <u>DEL JAM</u>] [historically discriminated ADD ARG] [groups <u>ADD JAM</u>] 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[<u>s ADD JAM</u>] but is not limited to BRN, JAM] ["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, UK/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, COL, PSE] [and detainees, PSE] refugees, [and ADD ARG] [displaced persons, AUS] migrants [and migrant workers BGD] [regardless of their migratory status ADD ARG] asylum seekers, stateless persons, persons in humanitarian settings and fragile [and conflict-stricken BGD] contexts, [persons belonging to UK] [marginalized communities DEL, NGA, KSA, CHI], older people, [gender-diverse persons AUS, BRA/DEL KSA] persons with disabilities, [indigents KEN] persons with health conditions, [transgender people ADD ARG] [women and girls including those who are AUS, BRA] [who may be at an increased risk during a pandemics ADD JAM] pregnant [women DEL AUS, BRA], infants, children and adolescents, [rural communities, indigenous and remote communities ADD PRY] [[and DEL AUS] those living in fragile areas, DEL CHI] [such as DEL AUS/and] [and ADD AUS 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, SGP][ and such other persons as may be identified in accordance with national policies and systems; ADD JAM] [considered by the State party to be at greater risk pathogen infection or greater risk to health as a result of this infection ADD RUS]

[Persons in vulnerable situations means individuals or groups [Who according to disease epidemiology **AFR GROUP**], are 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, 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, [genderdiverse 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] DEL AFR GROUP],** [Article 1 (d) "persons in vulnerable situations" [includes those groups and individuals who are rendered vulnerable due to inequality in the enjoyment and exercise of their human rights, access to services and participation in decision-making, ADD **COSR**] including [women, ADD COSR] 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, [persons deprived of liberty, homeless persons, people living in poverty, ADD COSR] marginalized communities, older people, persons with disabilities, persons with health conditions, [LGBTQI+ persons, ADD COSR] pregnant women, infants, children and adolescents, and those living in fragile areas, such as Small Island Developing States, and [those at the intersections of these identities, ADD COSR]

[ALT 1(d) BRN "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, including but not limited to ....]

[ALT "persons in vulnerable situations " subject to member states' national law includes 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, and those living in fragile areas, such as Small Island Developing States; NGA]

"pathogen with pandemic potential" means...;

# [SUGGESTION "pathogen with pandemic potential" means...; [definition to include "drug resistant pathogens" ADD SGP]

(f) "One Health approach" means...;

[NEW PARA 'an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development AUS]

[ALT 1(f) BRN "One Health" means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals, and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. In this context, the approach mobilizes multiple sectors, disciplines, and communities at varying levels of society to work together to prevent pandemic threats at source, as well as prepare for, respond to, and recover from pandemics.]

[ALT 1(F) MEX "One Health approach" means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and interdependent.]

[ALT (f) "One Health approach" [The One Health approach is a collaborative, cross-sectoral, and multidisciplinary approach to addressing health challenges at the human-animal-environment interface. ADD SAU];

[ALT (f) NEW [One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. The approach mobilizes multiple

sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development. ADD UK]

(g) ["One Health surveillance" means...; [MERGE (f) and (g), SAU, MAR] **DEL RUS**]

#### [ALT "Collaborative Surveillance" IND]

[NEW PARA "One Health surveillance" means...; an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. The approach mobilizes multiple sectors, disciplines and communities at varying levels of society to work together to foster well-being and tackle threats to health and ecosystems, while addressing the collective need for clean water, energy and air, safe and nutritious food, taking action on climate change, and contributing to sustainable development ARG]

[ALT 1(g) BRN "One Health surveillance" means the systematic and timely collection, validation, analysis, interpretation, and dissemination of information collected from and shared across human, animal, and environmental sources at local, national, and international level - to inform cross-sectoral action to prevent, prepare for, respond, and recover from zoonotic and anti-microbial resistance related events.]

(h) ["infodemic" means...; **DEL MEX**]

[[ADD DEF (h) [Medical countermeasures (MCMs) are products such as drugs, vaccines, diagnostic tests, and other medical supplies that can be used to prevent, mitigate, or treat the health effects of chemical, biological, radiological, or nuclear (CBRN) incidents or other public health emergencies. ADD SAU]

(i) "inter-pandemic" means...;

[ADD DEF (i) [Emerging diseases are diseases that have recently appeared or are newly identified in a population. ADD SAU]

(j) ["current health expenditure" means...; **DEL RUS**]

# [ ADD DEF (j) [Re-emerging diseases are diseases that were previously under control or eliminated but haverecently resurfaced or increased in incidence. ADD SAU]

(k) ["universal health coverage" means [A situation where all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative, rehabilitative and palliative essential health services, and essential, safe, affordable, effective and quality medicines and vaccines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable, and marginalized segments of the population; JOINT PROPOSAL BRA, JPN, THA]...; and **DEL RUS**]

[ALT 1(k) BRN "Universal health coverage" means ensuring that all people can use the promotive, preventive, curative, rehabilitative, and palliative health services they need, of

sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.]

[ALT ARG "universal health coverage" means that all people have access to the full range of quality health services they need, when and where they need them, without financial hardship. It covers the full continuum of essential health services, from health promotion to prevention, treatment, rehabilitation and palliative care]

[ALT PRY- ADD 'without access to universal, timely and effective, it is not possible to achieve universal coverage']

[ALT AUS (k) "universal health coverage" means... that all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative, rehabilitative and palliative essential health services, and essential, safe, affordable, effective and quality medicines and vaccines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable, and marginalized segments of the population; and ]

[ALT JAM "universal health coverage" means all people and communities have access, without any kind of discrimination, to comprehensive, appropriate and timely, quality promotive, preventative, curative, rehabilitative and palliative health services determined at the national level according to needs, as well as access to safe, effective, and affordable quality medicines, while ensuring that the use of such services does not expose users to financial difficulties, especially groups in conditions of vulnerability...; and]

[ALT [universal health coverage implies that all people have access, without discrimination, to nationally determined sets of the needed promotive, preventive, curative, rehabilitative and palliative essential health services, and essential, safe, affordable, effective and quality medicines and vaccines, while ensuring that the use of these services does not expose the users to financial hardship, with a special emphasis on the poor, vulnerable, and marginalized segments of the population ADD UK].

#### [ALT (k) (k) [Pandemic declaring criteria must meet the following: ADD SAU]

- 1- Easy geographic spread of the pathogen: The pathogen has demonstrated a highly contagious nature, with the potential to rapidly spread across multiple countries within the same region or across at least two countries in different WHO regions, posing significant challenges to containment efforts. ADD SAU]
- 2- Severity: The pathogen's severity should be evaluated based on its potential to cause a significant global health crisis, taking into account factors such as its transmission rate, mortality rate, and available treatments and vaccines. ADD SAU]
- 3- Impact on healthcare systems: The impact of the pathogen on healthcare systems in affected countries has been significant, resulting in an overwhelming surge of patients that have made it difficult for healthcare providers to deliver adequate care to all patients. 4- Containment efforts: such as travel restrictions and quarantine protocols, have proven ineffective in mitigating the spread of the pathogen. ADD SAU]
- (l) ["[health system ADD THA] recovery" means... **DEL RUS**]

- (m) [ADD DEF prevention, preparedness, response IDN]
- (n) [ADD DEF "pandemic potential" means...; IDN]
- (o) [ADD DEF "medical countermeasures" means ....' SAU]
- (p) [ADD DEF "emerging and re-emerging" means ... SAU]
- (q) [ADD DEF "epidemic" means ... SAU]
- (r) [ADD DEF "outbreak" means ... SAU]
- (s) [ADD DEF "pandemic situation" means manifestation of a disease, irrespective of origin or source, that is spreading or is likely to spread over a wide geographical area, often worldwide, that is affecting or is likely to affect a large number of persons, and is creating or is likely to create a severe social disruption and economic loss. EU, NGA]
  - (r) [ADD DEF "pandemic situation" means manifestation of a disease, irrespective of origin or source, that is spreading or is likely to spread over a wide geographical area, often worldwide, that is affecting or is likely to affect a large number of persons, and is creating or is likely to create a severe social disruption and economic loss. EU, NGA] [RESERVE AFR GROUP]
- (t) [ADD DEF "countermeasures" / "quadripartite organizations" / "low income countries" / "One Health" means [see EU proposal] EU]
  - [ADD DEF "Countermeasures" means medical and other countermeasures necessary for the purpose of preparedness for and response to pandemic situations, including but not limited to, vaccines, therapeutics, diagnostics, medical devices, medical equipment and supplies, such as personal protective equipment. EU]
- [ADD DEF "Quadripartite organisations" refer to World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (WOAH) and the United Nations Environment Programme (UNEP). EU]
- [ADD DEF "Low income countries", "lower middle income countries", "upper middle income countries", "higher income countries" refer to the Parties listed in the respective country group lists as prepared on an annual basis by the International Bank for Reconstruction and Development (the World Bank). "Middle income countries" refer to the Parties listed in either the list of lower middle income countries or in the list of upper middle income countries as prepared on an annual basis by the World Bank, EU]
- [ADD DEF One Health means an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems. It recognizes the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent. EU]
- (s) [ADD DEF ["countermeasures" DEL AFR GROUP] / ["quadripartite organizations" Reserve AFR GROUP]/ ["low income countries" DEL AFR GROUP]/ "One Health" means [see EU proposal] EU] [Reserve EU PROPOSAL: AFR GROUP]

#### [ADD DEF "whole of government and whole of society approach" means... JAM]

## [NEW PARA (t) ADD Health Products AFR GROUP]

[NEW PARA Add definition of "Quadripartite Organizations – organizations made up of the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), the World Organization for Animal Health (WOAH) and the United Nations Environment Programme (UNEP) ARM]

[ADD DEF 'Prevention'; - 'Preparation'; - 'Response'; - 'Good Governance'. ADD CHE]

[ADD DEF Health and care workforce BRN]

[ADD DEF Health literacy BRN]

[ADD DEF "Continuity of essential health service"; ZAF]

[ADD DEF "Benefit sharing" ZAF]

[ADD DEF "Community" TUR]

## Article 2. Relationship with other international agreements and instruments

[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 WHO CA+ shall not conflict with the charter of the United Nations, the Constitution of the World Health Organization, or the International Health Regulations and its ADD JAM] [The DEL JAM] implementation [of the WHO CA+ DEL JAM] shall be guided by the Charter of the United Nations [international human rights law ADD PAK] and the Constitution of the World Health Organization DEL USA, NZL, COL]]. The WHO CA+ [and [[the relevant [international DEL CAN] [WHO ADD CAN] instruments DEL MCO, UK], [including the DEL MCO, UK | 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 **DEL SGP, UK]** [,and JPN, MCO] compatible. [and synergistic DEL JPN, MCO, CHN, UK], [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 DEL CAN, PAK] [WHO ADD CAN] instruments. DEL SGP, UK] [adopted by the WHO ADD PAK] 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 [and agreed upon ADD SAU] steps will be taken to [examine overlaps and MOR] [avoid DEL] [unnecessary NGA, RUS, ETH, MOR] duplication and promote [synergies DEL CHN, SGP/RETAIN BGD], compatibility [and coherence DEL SGP], 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, UK].

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<sup>&</sup>lt;sup>1</sup> 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.

[[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, COL11. 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, AFR GROUP]].

The implementation of the WHO CA+ shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. The WHO CA+ and other relevant international instruments, including the International Health Regulations, should be interpreted so as to be complementary, compatible and synergistic, 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, [including the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the International Covenant on Civil and Political Rights, the Convention on the Elimination of All Forms of Discrimination against Women, the Convention on the Rights of the Child, the International Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Rights of Persons with Disabilities and other relevant international human rights instruments. ADD COSR 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 [uphold the highest standard of human rights, ADD **COSR**] promote synergies, compatibility and coherence, with a common goal of strengthened pandemic preparedness, prevention, response and health system recovery.]

[ALT NZL The implementation of the WHO CA+ shall be guided by the Charter of the United Nations and the Constitution of the World Health Organization. The WHO CA+ and other relevant international instruments, including the International Health Regulations, should be interpreted so as to be complementary and compatible]

[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 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 <u>DEL AFR GROUP</u>] promote synergies, compatibility and coherence, with a common goal of strengthened pandemic preparedness, prevention, response and health system recovery. ESW] RETAIN BGD, **AFR GROUP**]

- 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.
- [ 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. **DEL AFR GROUP**]
- 3. The provisions of the WHO CA+ shall in no way affect the [right <u>DEL CAN</u>] [ability <u>ADD CAN</u>] of Parties to enter into bilateral or multilateral [instruments <u>DEL AUS</u>] [agreements <u>ADD AUS</u>], including regional or subregional [instruments <u>DEL AUS</u>] [agreements <u>ADD AUS</u>], on issues relevant or additional to the WHO CA+, [provided that such [instruments <u>DEL AUS</u>] [agreements <u>AUS</u>] are compatible with their obligations under the WHO CA+ <u>DEL CAN</u>]. The Parties concerned shall communicate such [instruments <u>DEL AUS</u>] [agreements <u>AUS</u>] to the Governing Body for the WHO CA+ through the Secretariat.
- [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 sub-regional 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. **RETAIN Africa Group**]

[NEW PARA 4 The WHO shall maintain its fundamental role in pandemic prevention, preparedness and recovery of health systems as the directing and coordinating authority on global health and the leader of multilateral cooperation in global health governance NZL]

#### 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, JAM, SGP/RETAIN PRY, ETH, PHL, BRA, IDN, TOG, MYS, EGY, PAK, HTI, IRN, CHN, RETAIN AUS] [, human rights AUS] [the vision DEL AUS, IND, JAM, **SGP** [,and ISR, AUS] [guiding USA] [the ADD JAM] 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 **DEL** AUS] AUS] [prevent DEL JAM] [protect against, and control ADD JAM] pandemics [and to rapidly and effectively respond to pandemic emergencies in a manner that USA], [saves lives, reduces disease burden and protects livelihoods, through **DEL SGP**] strengthen[ing, proactively, **DEL SGP**] the [world's DEL JAM] [by providing a framework for the implementation of coordinated and evidenced based measures to strengthen national, regional and international ADD JAM] 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 [, DEL AUS] 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 on] [[sub national, ETH, DEL TUR] 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] [prevention UK] [and emergency situation ADD PRY] preparedness and response [capacities DEL /capabilities ADD USA], [and promoting rapid, effective and equitable coordinated, collaborative, transparent, [[progressive DEL MCO/RETAIN IRN, ARG] [ensure the progressive ADD 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] [science and ADD AUS] evidence-based [or scientific-based THA] pandemic [and emergency situation ADD PRY [prevention, preparedness, CAN] response and [resilient DEL ETH] recovery [of DEL] [for ETH] health systems [resilience ETH] at community, national, regional and global levels. DEL JAM][ Ensuring the discovery, development, availability, and unhindered timely and equitable access to affordable medical and other pandemic response products. ADD **SAU**] [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 provide a multilateral system coordinated by WHO for enabling adequate, prompt, and effective capacities for pandemic prevention, preparedness [and DEL AFR GROUP] response, [and AFR GROUP] [recovery AFR GROUP], and their operationalization including through [among others, building capacities of the health systems, BGD, PAK] mobilization of financial [resources, access to health products, technology and know - how and their equitable deployment AFR GROUP], [and 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, AFR GROUP]

[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]

[The objective of the WHO CA+, guided by equity, the vision, principles and rights set out herein, is to prevent pandemics, save lives, reduce disease burden and protect livelihoods, through strengthening, proactively, the world's capacities for preventing, preparing for and responding to, and recovery of health systems from, pandemics. The WHO CA+ aims to comprehensively and effectively address systemic gaps and challenges that exist in these areas, at national, regional and international levels, through substantially reducing the risk of pandemics, increasing pandemic preparedness and response capacities, [progressive DEL ARG] [ensure the progressive ARG] realization of universal health coverage and ensuring coordinated, collaborative and evidence-based pandemic response and resilient recovery of health systems at community, national, regional and global levels].

[ALT The objective of the Agreement is to increase the capacity of the Parties to prevent, prepare for and respond to pandemic situations in an equitable, effective and efficient manner, with the aim of reducing morbidity, mortality and the social and economic impact of pandemics, at local, national, regional and international levels. EU]

[ALT The objective of the WHO CA+, and its mechanisms guided by equity, principles and rights set out herein, is to prevent pandemics, remain prepared for and respond to pandemics in a manner to save lives, reduce disease burden and protect livelihoods, through identifying systemic gaps and challenges that exist at national, regional and international levels and address them effectively through strengthening, proactively, the world's capacities for preventing, preparing for and responding to, and recovery of health systems from pandemics including through progressive realization of universal health coverage and and equitable access to essential health tools and pandemic related products through a coordinated, and collaborative action at all levels IND].

## [ALT BRN Article 3. Purpose and scope

The aim of the of the WHO CA+ is to prevent pandemics, save lives, reduce disease burden, and protect livelihoods through strengthening pandemic prevention, preparedness, response, and recovery of health systems.

#### The specific objectives are to:

- (a) Establish a multilateral system coordinated by WHO that enables adequate, prompt, and effective capacities for pandemic prevention, preparedness, and response, and recovery at the national and global level.
- (b) Provide for the appropriate mobilization of resources to sustain the aforementioned multilateral system.
- (c) Complement the International Health Regulations through addressing systemic barriers to pandemic prevention, preparedness, response, and recovery that exist at the national and global level.

<u>The scope of the WHO CA+ applies to pandemic prevention, preparedness, and response at</u> national, regional, and global levels.]

#### [ALT Article 3 EU - Determination of a pandemic situation

- 1. The Director-General of the WHO shall assess and determine, on the basis of the information and advice received, whether an event constitutes a pandemic situation. The Director-General will make a determination whether an event constitutes a pandemic situation with regard to any event that is determined to be a public health emergency of international concern under Article 12 of the IHR.
- 2. If the Director-General considers that a pandemic situation is occurring, the Director-General shall immediately consult with the affected Parties. The Director-General shall, in accordance with the procedure set forth in Article 49 of the IHR, also seek the views of a Committee established in accordance with the provisions of Article 48 of the IHR (hereinafter the "Emergency Committee"), including on appropriate temporary recommendations. Notwithstanding Art. 49.4, the Director General shall invite representatives of the affected Parties to present their views to the Emergency Committee.
- 3. In determining whether an event constitutes a pandemic situation the Director-General shall consider: (a) information provided by the affected Parties, including in accordance with Article D.2; (b) the decision instrument contained in Annex 1 to this Agreement; (c) the advice of the Emergency Committee; and (d) scientific principles as well as the available scientific evidence and other relevant information.
- 4. If the Director-General, following consultations with the affected Parties, considers that a pandemic situation has ended, the Director-General shall take a decision in accordance with the procedure set out in Article 49 of the IHR.]

#### [ALT Article 3 EU Article 3 - Determination of a pandemic situation

For the purpose of this Agreement a pandemic situation shall be deemed to occur, or end, when the Director-General of the WHO so determines in accordance with the relevant provisions of the IHR (2005) as amended.]

#### [ADD ARTICLE EU Article ... - General obligation

The Parties shall take all necessary measures and actions, individually and jointly, to apply and effectively implement at domestic, regional and international level the provisions of this Agreement, including the provisions set out in the Annexes to the Agreement, with the aim of preventing, preparing for and responding to pandemic situations.]

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

# [ALT SPLIT ARTICLE INTO GUIDING PRINCIPLES AND RIGHTS IN ORDER TO CLARIFY THE PROVISIONS]

[[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 DEL COSR] [and fundamental freedoms USA/ DEL IRN] [Human Rights-based Approach ADD COSR] — The implementation of the WHO CA+ shall be [applied, guaranteeing, respecting, protecting and promoting ADD CHI] [with full respect DEL CHI] 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, ZAF] [such DEL ARG [human rights and fundamental USA/DEL SAU] [rights and GBR, UK/DEL SAU] freedoms DEL ARG, SAU, SGP] [them ARG]. DEL IRN] [in a manner consistent with national and international laws. ADD JAM] [NOTE: Move to #3 ISR] [NOTE: Switch #1 and #2 NGA] [NOTE: keep original order of principles NOR, EGY]

[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] **DEL AFR GROUP**]

[ALT 1: The implementation of the WHO CA+ shall be with full respect for the dignity and human rights, including the right of everyone to the enjoyment of the highest attainable standard of physical and mental health without distinction of race, religion, political belief, economic or social condition. [AFR Group Replaces 1 and 2][ALT 1 Respect for human rights – Each Party shall respect, promote and protect the dignity, and human and fundamental rights and freedoms of persons, including the right to enjoyment of the highest attainable Page 2 of 4 standard of health, in implementing the WHO CA+ NZL]

[ALT ZAF [ADD protect and fulfil human rights] – [ADD The implementation of the WHO CA+ shall include the obligation to respect, protect and fulfil human rights and fundamental freedoms in accordance with international human rights law especially the rights of individuals at greater risk of human rights violations, such as those who are criminalized, marginalized and/or groups vulnerable to poor health outcomes as a result of structural barriers].

[The right to DEL CAN] [[promotion of the enjoyment of ADD CAN] the highest attainable standard of GBR, CHE, BWA, USA, MOZ, ETH, ARM, NOR, PHL, CAN, MAR, TUN, ISR, **USA, UK/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, UK] [physical or mental ADD ARG] 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 **DEL AUS**] [and not merely the absence of disease or infirmity CHN, BGD, PAK, TUN, BRA, UGA, BWA, ARG, NAM, ETH, NOR, SYR, DOM, SGP], 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, SGP/RETAIN ARG, NOR] [gender, AUS, ARG, NZL, MEX, COL, ISR, USA, BRA, GBR, CAN, PER, FJI, CHE, BWA, NOR, PHL, OMN, COSR/DELETE SAU, EGY, UK] [, disability ADD COSR [and sexual orientation DEL NGA, TGO, RUS, UGA, SAU, EGY, BDI, NAM, ETH, SYR, MAR, IRQ, OMN, PAK, UK], NZL, MEX, COL, CAN, PER, BRA, FJI, USA, NOR, AUS] race, religion, political belief, economic or social condition[. DEL ARG, NZL, CHE] [without any distinction ADD CHE [,migratory status, among others. This includes the allocation of "maximum available resources" to progressively realize this goal ADD ARG]. [[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]

[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 AFRICA GROUP]

[ALT The right to health – The enjoyment of the highest attainable standard of health, [physical or mental ARG], defined as a state of complete physical, mental and social well-being [and not merely the absence of disease or infirmity ARG], is one of the fundamental rights of every human being without distinction of age, [gender ARG], race, religion, political belief, economic or social condition, [migratory status, among others.. This includes the allocation of ARG] ["maximum DEL ARG] [available resources" to progressively realize this goal ARG].

[ALT ZAF 2. THE RIGHT TO HEALTH – The enjoyment of the highest attainable standard of physical and mental, and social well-being [ADD defined as a wide range of socioeconomic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and portable water and adequate sanitation, safe and healthy working conditions, and a healthy environment], is one of the fundamental rights of every human being without distinction of age, race, religion, political belief, economic or social condition.]

[ALT (2) CHI Right to health – The enjoyment of the highest level of health that can be achieved, defined as a state of complete physical, mental and social well-being, is one of the fundamental rights of every being regardless of age, race, gender, religion, political ideology or economic or social condition or of any other nature.]

**Sovereignty** [and territorial integrity MAR] – States have, in accordance with the Charter of the United Nations and the [general IRN] principles of international law, [[including States' obligations under international human rights law ADD CAN, the sovereign[ty ADD AUS] right [DEL AUS] [, in full respect of their territorial integrity, MAR/DEL DZA] to determine and manage [with[in ADD] PAK their jurisdiction ADD ARG, PAK [ for control ADD PAK] their approach to public health, notably pandemic prevention, preparedness, response and recovery of health systems, pursuant to their own policies and legislation, [and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the people of other States or of areas beyond the limits of national jurisdiction ADD ARG] [ and in accordance with relevant international health instruments to which they are parties, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the people of other States or of areas beyond the limits of national jurisdiction. ADD PAK] [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, CAN, SGP] [violate international human rights obligations. ADD CAN][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] **DEL WHOLE**NZL[Sovereignty also covers the rights of States over their biological [and intellectual ADD SAU] 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, CAN/RES SGP, JAM/RETAIN RUS] [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] [This, in accordance with national legislation, based on the principles: precautionary, scientific and proportionality, that is, with a view to preventing a greater evil, according to the best scientific evidence, which ensures an adequate relationship of means finally ADD ARG]

[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 [purpose[s <u>DEL NZL</u>] DEL FJI] [objectives FJI] of [the WHO CA+ NZL] this agreement. USA, CAN, SGP, NZL, GBR, FJI, KOR, ARG, TON, UK]

[[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, provided they shall uphold the purposes and objectives of the WHO CA+. Sovereignty also covers the rights of States over their natural and biological resources AFR GROUP)[[ALT (3) CHI Sovereign Equality – Pursuant to the Charter of the United Nations and the principles of international law, States have the sovereign right to determine and manage its approach to public health, in particular prevention, preparedness, response and recovery of their health systems from pandemics, in accordance with the provisions of their own policies Sovereignty also encompasses the rights of States regarding their biological resources.]

4. Equity – The absence of [unfair, RES AUS/RETAIN HTI, EGY] avoidable or remediable differences, including in their [respective ADD PAK] capacities, [and resources for prevention, preparedness, response and recovery from pandemics ADD ARG, PAK] among and within countries, [or regions ADD JPN] including between groups of people, whether those groups are defined [culturally, based on gender ADD CAN] 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[s ADD CAN] THA, CAN, TUN, HTI, ZAF, AFR GROUP, NGA, EGY, OMN, COL, TON, MOZ, FJI, PER, AUS recovery cannot be achieved without DEL PAK [Achieving equity requires ADD PAK] political will and commitments [of all States ADD ARG] in addressing the structural [challenges DEL ZAF] [determinants such as political, legal, and economic 3 barriers ADD ZAF] 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, UK] safe [effective, quality, affordable essential GBR, USA, AUS, NGA, OMN, NOR, UK] [and efficacious DEL GBR, USA, AUS, NGA, UK] [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] [dignified and respectful treatment, ADD 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. [DEL WHOLE NZL, RUS] [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]

[ALT: Within the present instrument the Parties shall commit to promote, respect, and facilitate equity in all the phases of pandemic prevention, preparedness, response, and recovery, including by ensuring fair, equitable and timely access to quality to health products, technologies and know how as global public goods ADD AFR GROUP]

[ALT (4) Equity shall be at the centre of pandemic prevention, preparedness, response and recovery, both at the national level within States and at the international level between States, with the purpose of achieving equitable health and societal outcomes for all, which requires specific measures to protect the most vulnerable individuals and communities, including depending on the context: elderly, people with disabilities, people with underlying health conditions, women, children, indigenous peoples, LGBTQIA+ communities, migrant and refugee communities, and front line workers. NZL]

[ALT (4) Equity – The absence of unfair, avoidable or remediable differences, including in their respective capacities and resources for prevention, preparedness, response and recovery from pandemics, among and within countries, including between groups of people, whether those groups are defined socially, economically, demographically, geographically or by other dimensions of inequality Achieving equity requires political will and commitments in addressing the structural challenges and ensuring timely access in all States to affordable, safe and efficacious pandemic-related products and services, essential health services, information, and social support, as well as tackling the inequities in terms of technology, health workforce, infrastructure, and financing, among other aspects. ADD PAK

[State Parties shall prevent, prepare for, respond to, and recover from pandemics on the basis of their common but differentiated responsibilities and respective capabilities. States that hold more resources relevant to pandemics, including pandemic-related products and manufacturing capacity, shall bear a commensurate degree of differentiated responsibility with regard to global pandemic prevention, preparedness, response and recovery. 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. **AFR GROUP (move to after Equity)**]

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, RETAIN AUS], preparedness, [ for [RETAIN [AUS]] and DEL NGA] response [to ADD AUS], and [health system THA, EGY, HTI, OMN] recovery from NGA, OMN, AUS] [to DEL NGA, AUS] pandemics requires [national, DEL BGD, NGA, PAK, IRN, CHN, EGY, SAU/ RETAIN HTI, THA] [regional THA, IRN, TON, EGY, HTI, SAU] [international, multilateral, bilateral and [multisectoral DEL IRN/RETAIN PAK] [inclusive ADD PAK] collaboration, coordination and cooperation, [and solidarity through global unity, preventing and removing the causes of asymmetries and inequities among and within States to ADD ARG] [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, RETAIN AUS] [of DEL NGA. RETAIN AUS] [for NGA] a [fairer, DEL SGP] [more DEL NGA, RETAIN AUS] equitable and better prepared world. [To achieve this, Parties, while defining and taking measures for preparedeness, prevention,

response and recovery, should take measures to address the specific needs and special circumstances of developing country and least developed country Parties, so that all Parties can effectively prevent, prepare, respond and recover from pandemics. ADD PAK] DEL WHOLE NZL] [NOTE: IRN – reorder "...bilateral, regional and multilateral"] [MOVE TO PREAMBLE NZL]

[ALT International Cooperation States shall cooperate to ensure fair, equitable and effective prevention of, preparedness for, response and recovery to pandemics, through bilateral, regional, multilateral and multi stakeholder collaboration, coordination, and cooperation. AFR GROUP]

[Transparency – The effective prevention of, preparedness for and response to pandemics [and health system recovery THA] depends [on ADD PAK][the safe CAN] [transparent DEL/rapid USA, CAN], open and timely sharing, [access to and disclosure **DEL CAN**] of accurate [and verified CHN] [and relevant THA] information, data [samples USA] [research, results, terms and conditions in government contracts ADD PAK] [research results, and procurement contracts, production cost, sales revenue and units sold of products relates to the pandemic, and ADD ARG] [and other relevant elements that may come to light DEL USA] (including biological samples, genomic sequence data, [pathogens COL] [antimicrobial susceptibility data SAU] [and DEL AUS] 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 [contexts ADD CAN] [privacy DEL CHN] and data [privacy CHN] protection rules, DEL CAN] regulations and laws. DEL RUS, NZL] [MOVE TO PREAMBLE NZL]

[ALT The Parties, subject to their benefit sharing obligations under this instrument and other relevant international instruments, commit to timely sharing, access to and disclosure of accurate information, data and other relevant elements that may come to light (including biological samples, genomic sequence data, and clinical trial results , regulatory decisions, and procurement and supply chain information, prices, research and development production costs, patent landscapes of medical health products revenue from sale, and units sold of pandemic related products, marketing costs, subsidies, incentives,). AFR GROUP]

[ALT DEF Transparency – [is the practice of being open, honest, and accountable in decision-making and communication. It involves providing timely and accurate information and data to stakeholders, promoting clarity and understanding, and ensuring that individuals, organizations, and institutions are held responsible for their actions and decisions. Transparency is crucial for building trust, fostering collaboration, and preventing corruption and unethical behavior in all areas of life. New definition SAU]

7. [Accountability [AND ACCESS TO JUSTICE ADD ZAF]— States are accountable for strengthening and sustaining their [human, environmental and animal] ADD CAN] health systems' capacities and public health functions [and social determinants of health and ADD CAN] to provide adequate [early warnings and rapid, equitable, and effective responses, including through adequate USA, AUS] health and social measures [to uphold human rights and non-discrimination ADD COSR] by

adopting and implementing legislative, executive, administrative and other measures [that seek to promote USA, AUS [for DEL USA, AUS] fair, equitable, effective and timely pandemic prevention, preparedness, response and recovery of health systems. [States are also directly accountable to their populations and mechanisms need to be established to engage with communities, particularly with persons in vulnerable situations, to ensure transparency through accessible information and communications, and ensure their participation in decisionmaking systems. ADD COSR] [[All Parties shall [endeavour to ADD SGP] cooperate DEL CAN] [Cooperation ADD CAN] with other States [and **DEL CAN**] relevant [international DEL/intergovernmental TUR] organizations, [and other stakeholders is essential ADD CAN] [enhancing public and private sector support at all levels ADD SAU] 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, RUS/RETAIN CRI, UGA] [The Parties shall establish national, regional, and international review procedures, processes, and mechanisms to facilitate accountability through a dynamic review procedure, process and mechanism to facilitate accountability under the Pandemic Treaty ADD ZAF] [NOTE: Discuss accountability in Chapter 7 CHN]

[ALT 7: States Parties in accordance with their capabilities, shall commit to timely and effective prevention, preparedness and response to Pandemics which requires individual and collective accountability. All state parties including WHO, commit to the implementation of the provisions of WHO CA+ in order to collectively strengthen, support and sustain capacities for prevention, preparedness, response and recovery of health systems. State Parties shall design and effectively implement collective accountability mechanisms. State Parties shall hold each other accountable for extra territorial measures that adversely impact the ability of other States to timely and effectively prevent, prepare, respond to and recover from pandemics. AFR GROUP]

[NEW PARA BEFORE (8) Cooperation and coordination: The effective prevention of, preparedness for and response to pandemics requires national, international, multilateral, bilateral and multisectoral coordination and cooperation. All Parties shall cooperate with other States and coordinate through the relevant international organizations, in order to collectively strengthen, support and sustain capacities for global prevent, preparedness, response to pandemics and recovery of health systems ADD PAK]

[Common [but differentiated DEL AUS, NZL, MCO, THA, EU/RETAIN EGY, CHN] responsibilities [and [respective PAK, NAM, PER, IRN, FJI, IND, BGD, SWZ] [RESPECTIVE ADD ZAF] capabilities DEL/RETAIN PAK]but different capacities [and needs for support THA] AUS, NZL, MCO, THA, EU] [in pandemic prevention, preparedness, response and recovery of health systems DEL PAK DEL WHOLE NZL Common responsibilities but different capacities in pandemic prevention, preparedness, response and recovery of health systems ADD NZL] - [All States are responsible for the health of their people, including pandemic prevention, preparedness, response and recovery, and **DEL PAK**] [p **DEL PAK**] [P ADD PAK] revious 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] [Parties ADD PAK]. [States that hold more [capacities and ADD ARG, PAK] resources relevant to pandemics, including pandemic-related products and manufacturing capacity, [should DEL ZAF] [must ADD ZAF] bear, where appropriate, a commensurate degree of differentiated responsibility with regard to global pandemic prevention, preparedness, response and recovery DEL AUS, NZL, MCO/ RETAIN PAK | , including to act in solidarity with other ADD PAK]. 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 [and least developed ADD ARG] Parties, especially those that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate capacities [and resources ADD PAK] to respond to pandemics; and (iii) potentially bear a disproportionately high burden. DEL USA, ISR, JPN, CAN, GBR, NZL, UK, RUS/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, SWZ ] RESERVE JAM]

[ADD In [When ADD ARG] implementing common but differentiated responsibilities, [the ADD ARG] parties shall, [inter alia ADD ARG] 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 [in this document ADD ARG] 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 [deadlines ADD ARG] time periods for the implementation of the obligation of this agreement in accordance with Annex XX. BRA, SYR, BGD, ARG]

[ALT 8: Common but differentiated responsibilities and respective capabilities in pandemic prevention, preparedness, response and recovery of health systems AFR GROUP] [Common responsibilities and differentiated capabilities in pandemic prevention, preparedness, and response [and recovery of health systems] – All States are responsible for the health of their people, including pandemic prevention, preparedness and response [and recovery]. 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+. At the same time the specific needs and special circumstances of Parties, in particular Parties which are low and lower-middle income countries, as well as Parties 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, shall be fully considered and addressed through the provision of technical assistance and capacity building. ADD EU

#### **[NEW PARA 8**]

International Solidarity and Cooperation in Pandemic Prevention, Preparedness and Response

The effective prevention of, preparedness for and response to pandemics requires national, international, multilateral, bilateral and multi sectoral collaboration, coordination and cooperation, through global unity, to achieve the common interest of a fairer, more equitable and better prepared world.

To this end, all Member States, which are responsible for the health of their people, shall aim to fully cooperate among themselves. To achieve objectives of the WHO CA+, all Member States should contribute to countering pandemic threats, and should consider the specific needs of Member States with capacity constraints and particular vulnerabilities. ADD JPN]

9. [Inclusiveness – The active engagement with, [active outreach to ADD COSR] and participation of, all relevant stakeholders and partners across all levels [as applicable ISR], [consistent with relevant and applicable international [and [national DEL CHE] 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. DEL NZL, RUS] [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][Targeted efforts should be made to ensure

the participation of persons in vulnerable situations through inclusive and accessible decision-making processes AD COSR] [MOVE TO PREAMBLE NZL]

- 10. [Community engagement [and participation BWA] Full [effective and meaningful ADD CAN] engagement of [diverse ADD CAN] communities [is essential for better TGO] in [pandemic AUS, CAN, SGP/DEL EGY] prevention, preparedness, [and TGO] response to pandemics, as well as TGO] [and DEL TGO] recovery of health systems [is essential DEL TGO/RETAIN CAN] [support individuals and communities and ADD CAN] to mobilize social capital[, DEL SGP] [and ADD SGP] resources, [promote ADD SGP] adherence to public health and social measures, [for the achievement of universal health coverage BWA] and to [gain DEL SGP] [build ADD SGP] [mutual trust between civil society, public health institutions and governments ADD CAN] [trust in government.[s ADD SGP] DEL CAN] DEL WHOLE NZL, RUS] [as well as to support public health efforts with service delivery, community mobilization, and reducing risks through improved community actions, including at the human, animal, and environment interface ADD CAN][Communities play a critical role in providing essential health services, particularly for vulnerable and marginalized groups. AUS/DEL EGY] RES CHN] [MOVE TO PREAMBLE NZL]]
- 11. [Gender equality Pandemic prevention, preparedness, response and recovery of health systems will be guided by and benefit from the goal of [full AUS, BRA, CAN] equal [and [effective, CAN] meaningful AUS, BRA, CAN] participation, decision-making AUS, BRA] and leadership of [all persons ADD ARG] [persons of [all genders CAN] in all areas and sectors AUS, BRA, UK; DEL NGA, EGY, SAU, MAR] [[men and women DEL CAN] in decision-making DEL AUS, BRA, CAN, ARG, UK; RETAIN NGA, EGY] [and achievement of AUS, BRA, UK] [with a particular focus on DEL AUS, BRA, CAN, UK] [gender equality DEL CAN] [and empowerment of women PHL], taking into account the [impacts on and AUS, UK] [rights ADD COSR] [specific DEL CAN/RETAIN COSR] [differentiated CAN] needs [and rights AUS, BRA] of [all DEL EGY, ZAM] women and girls [the major role of women in the global health workforce PHL], using a country-driven, gender [responsive/transformative DEL EGY, SAU, NGA] [sensitive EGY, SAU, NGA], [intersectional ADD ZAF] participatory [, inclusive, PHL] and fully transparent approach. DEL IRN] DEL AFR GROUP, NZL, OMN, RUS] [MOVE TO PREAMBLE NZL]
  - [ALT Gender equality [Is achieved when women and men have equal rights, opportunities, and responsibilities and are treated equally under the law and by society according to national circumstances, needs, and priorities. This means that women and men have equal access to education, healthcare, employment, and political representation and that they are free from discrimination and violence. Gender equality is not just a matter of women's rights but is essential for sustainable development, economic growth, and social progress. SAU]
  - [ALT Gender equality Pandemic prevention, preparedness, response and recovery of health systems will be guided by and benefit from the goal of achieving gender equality and inclusive participation and equal opportunities for leadership at all levels of 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. USA]
- 12. [Non-discrimination and respect for diversity All individuals should have fair, equitable and timely access to [global public goods, including THA] pandemic-related products, health services and support, [without fear of discrimination or distinction [based on DEL THA] [of any kind as to THA] [sex, [gender DEL NGA, EGY, SAU, SYR, IRN] identity, age, ethnicity, disability AUS, ARG, BRA] race, [gender, PHL] religion, political belief, [sexual orientation AUS, ARG, BRA;

DEL NGA, SAU, EGY, SYR, ZAM, MAR, IRN, IDN] economic or social —[gender or any other ADD CHI] condition DEL NZL, CHE, RUS] [without fear of discrimination or any distinction. ADD CHE] [, or other status THA] [among others ADD ARG] DEL AFR GROUP]. MOVE TO PREAMBLE NZL]

[Non-discrimination and respect for diversity – All individuals should have fair, equitable and timely access to pandemicrelated products, health services and support, without fear of discrimination or distinction based on [age, gender, disability, ADD COSR] race, religion, political belief, economic or social condition.

[ALT Non-discrimination and respect for diversity – [refer to the principles that all individuals should be treated equally and fairly, regardless of their race, ethnicity, sex, age, religion, political beliefs, or socioeconomic status. This includes ensuring equal access to opportunities, services, resources and promoting the full participation and inclusion of all individuals in society. It also involves recognizing and valuing the diversity of cultures, beliefs, and perspectives within and across communities and working towards building a more inclusive and equitable world for all, SAU]

[ALT 12. Non-discrimination and respect for diversity – All individuals should benefit from fair, equitable, and timely pandemic prevention, preparedness, response, and recovery of health systems from pandemic including access to safe and effective pandemic-related products, health services and support, without fear of discrimination or distinction based on gender, race, religion, political belief, economic or social condition and implemented with a focus on equitable outcomes. USA]

13. [[Rights of DEL CAN, UK/RETAIN ARG] [Consideration[s CAN] for CAN, UK] [individuals and groups DEL JPN, RETAIN ARG] [people JPN] [at higher risk DEL CAN, RETAIN ARG] [experiencing inequities CAN] and [DEL ARG] [in vulnerable DEL CHI] [situations DEL JAM/RETAIN CHI [groups ADD JAM] [, places and ecosystems CAN] [and historically discriminated ADD ARG of vulnerability ADD CHI – [Nationally determined and prioritized actions, including support, [will DEL THA] [shall THA] DEL AUS, BRA] [Governments will AUS, BRA] take into account [specific needs of THA] communities [and DEL THA] [those of THA] persons in vulnerable [situations, **DEL JAM**] [groups ADD JAM] places and ecosystems. [Indigenous **DEL** ARG [peoples **DEL** AUS, BRA, ARG] [Peoples AUS, BRA] [women and girls in all their diversity, CAN] [and local communities IDN], persons belonging to national or ethnic, religious or linguistic minorities, refugees, [DEL ARG] [displaced persons AUS, BRA] [migrants, asylum seekers, stateless persons DEL ARG], [people under foreign occupation, prisoners and detainees, PSE, SYR] [persons in humanitarian settings and fragile contexts, marginalized communities, older **DEL ARG**] [people DEL JPN, **ARG**] [persons JPN], persons with [physical or mental CAN disabilities, [persons with [physical and mental ADD AUS] health conditions, PHL] [persons with health conditions **DEL ARG**], [women and girls, including those who are AUS, BRA] pregnant [women DEL AUS, BRA, ARG], [infants, children and adolescents, among others, DEL **ARG**], [people experiencing homelessness, those living in congregate settings, people who use drugs, and people living or working in unsafe or polluted environments CAN] [for example **DEL** ARG], [according to the respective Member States' national context IDN] are DEL SGP] [Such communities and persons may be ADD SGP] 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. DEL THA] DEL IRN, JAM, RUS DEL AFRICA GROUP, NZL][MOVE TO PREAMBLE NZL]

[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. Women, 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, [persons deprived of liberty, ADD COSR] marginalized communities, older people, persons with disabilities, persons with health conditions, [LGBTQI+ persons, ADD COSR] 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

- [ALT 13. Public health needs, including individuals and groups at higher risk and in vulnerable situations Nationally, regionally, and globally determined and prioritized actions should be based on public health needs, including support, taking into account persons in vulnerable situations, during pandemic emergency prevention, preparedness, response, and health system recovery. 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 emergencies, owing to social and economic inequities, as well as legal and regulatory barriers, that may prevent them from accessing health services, their roles in their communities, which might expose them to higher risk, or impacted by health conditions that may cause them to be at higher risk for serious illness and/or death from a pathogen. USA]
- 14. One Health [The WHO CA+ shall be guided by a One Health approach, whereby pandemic prevention, preparedness and response measures are ADD AUS] [Effective pandemic prevention, preparedness and response should reflect the close links and UK [M DEL AUS] [m ADD AUS] ultisectoral and transdisciplinary actions [should DEL AUS] recogniz[e DEL AUS] [ing ADD AUS] DEL PAK] [Given ADD PAK] the DEL UK] [close linkages and interdependence of the health of humans, domestic and wild animals, plants and the wider environment (including ecosystems) ADD SGP] [interconnection between [the health of UK] people, animals, plants and their shared environment **DEL SGP**], [for which **DEL PAK**] a[n ADD SGP] [coherent, DEL SGP] integrated and unifying approach should be strengthened [and applied]. ADD USA [at the global, national, and community level [s ADD AUS] CAN, AUS [at the global, regional and national level, ADD JAM] [with an aim to sustainably balance DEL THA] and optimize the health of people, [animals and ecosystems DEL THA] [, including through, but not limited to, attention to DEL PAK [necessary for ADD PAK] the prevention of DEL ARG/ **RETAIN PAK**] [and response to THA] [epidemics [due to **DEL ARG**] [novel THA] [pathogens **<u>DEL ARG</u>**] [resistant to antimicrobial agents DEL THA, <u>ARG</u>] [and zoonotic diseases <u>DEL ARG</u>, PAK, UK, USA] [and their spillover THA, AUS] [and food safety TUN] DEL BRA].[UPGRADE AS CHAPTER OMN]
- 15. [Universal health coverage The WHO CA+ [will DEL THA, AUS/RETAIN USA] [shall THA, AUS] be [guided DEL USA] [supported ADD USA] by [efforts to ADD USA] [the aim of DEL USA] achiev[ing DEL USA] [e ADD USA] universal health coverage [focusing on primary health care THA][ in all States], for which strong and resilient health systems [based on primary health care AUS, BRA] are of key importance, as a fundamental [supporting ADD USA] aspect of [pandemic prevention, preparedness, response, and health systems recovery, as well as supporting the achievement ADD USA] [achieving DEL USA] [human development including THA] [the Sustainable Development Goals DEL THA] through promoting [good THA] health and well-being for all at all ages. DEL NZL] [MOVE TO PREAMBLE NZL]

16. Science and [evidence-informed DEL UK, USA] [evidence-based UK, USA] [policies and THA] decisions – [Based on scientific criteria, and the best available evidence. ADD ARG] [Science, [the best available ADD SGP] evidence DEL ARG] [from research, as well as other factors such as context, public opinion, equity, feasibility of implementation, affordability, sustainability and acceptability to stakeholders ADD SGP] [and findable, accessible, interoperable and reusable DEL CHI] [high quality UK] data DEL SGP] should inform all public health [policies and THA] decisions and the development and implementation of guidance for pandemic prevention, preparedness, response and recovery of health systems DEL RUS] [shall be based on science, evidence, and findable accessible, interoperable and reusable data THA]. [In the data management process, it should

seek the balance of ethical and legal factors necessary to protect the interests of the parties stakeholders related to each data set, as well as achieve anonymization. ADD CHI

17. [Central role of WHO – DEL AUS] [Coordination in global health governance <u>AUS</u>, <u>PRY</u>]—The implementation of the WHO CA+ is advanced in coordination with the respective roles, mandates, and work of global health actors. AUS] As the directing and coordinating authority on [global health DEL AUS] [international health work AUS], and the leader of multilateral cooperation in global health governance, WHO is fundamental to strengthening pandemic prevention, preparedness, response and recovery of health systems. [NOTE IRN proposes to move to preamble] [WHO is an actor in the

multilateral cooperation, collaborator in strengthening the prevention of pandemics and emergencies, preparedness, response and recovery of health systems ADD PRY DEL WHOLE JAM, NZL MOVE TO ARTICLE 2 NZL

- [17 bis. Coordination across the United Nations system and with other international organizations The WHO CA+ should facilitate coordinated action on pandemic prevention, preparedness, response, and health systems recovery across the UN system, including through the Quadripartite, and with other international organizations CAN, DEL AFR GROUP]
- 18. [Necessity and THA] Proportionality [SUGGESTION BY ARG TO USE IHR DEFN]—Due consideration should be given, including through regular monitoring and policy evaluation, to proportionality so ADD USA] [ensuring DEL USA] that the [impacts of DEL THA, AUS] measures aimed at preventing, preparing for and responding to pandemics are [necessary to protect public health THA] proportionate[, effective and efficient CAN] to their intended objectives and that the benefits arising [therefrom outweigh DEL ARG] [costs DEL AUS, ARG] DEL WHOLE NZL, RUS] [any harms ADD AUS] [justify the design, financing and implementation ADD ARG] [Unintended consequences of measures should be monitored and considered on an ongoing basis. CAN] RESERVE CHN, SWZ, SGP][MOVE TO PREAMBLE NZL]

[ALT 18 Proportionality - State Parties in preventing, preparing and responding to pandemics shall base their decisions, on science and evidence in order to ensure that measures taken are commensurate and proportionate to achieve the intended objectives AFR GROUP]

[Science and evidence-informed [policies and THA] decisions – Science, evidence and findable, accessible, interoperable and reusable data should inform all public health [policies and THA] decisions and the development and implementation of guidance for pandemic prevention, preparedness, response and recovery of health systems [shall be based on science, evidence, and findable accessible, interoperable and reusable data THA]. AFR GROUP].

19. **[Pandemic prevention, preparedness, response and recovery as a global public good NGA, ETH]** 

[ NEW PARA 19. Pandemic prevention, preparedness, response, recovery and universal access to health products as a global public good

Recognising that no one is safe until everyone is safe, State Parties commit to timely and effective multilateral action, through the provision of sustainable and predictable financing and equitable access to health products, technologies and know-how aimed at pandemic prevention, preparedness, response and recovery. AFR GROUP]

[NEW PARA 19. [STRENGTHENING HEALTH SYSTEMS: Parties shall entrench long-term and transformative investments in public health systems of adequate quality, accessibility, acceptability, and availability in all communities using multisectoral approaches. Parties should effectively regulate private and public sector actions that impact public health whilst recognizing the benefits of community and national health systems strengthening beyond global health security priorities. ADD ZAF]

### 20. [International cooperation URY]

[NOTE: NGA proposal to add "in line with national context" next to all references to vulnerable people.]

[NEW PARA 20.[Information, Technology and Data Management: Ensure the accessibility of all public health information necessary in pandemic preparedness and responses, including through public dissemination of disaggregated data. Parties shall put in place adequate and effective human rights safeguards when data and technology are used with the stated aim of responding to or in preparation for pandemics, particularly in the deployment of new technologies and infrastructure, and new sources of data. Obligations to share information, sequences, or samples should be coupled with obligations to equitably share the benefits of the use of information, sequences, and samples, as well as ensure availability and access to technologies. ADD ZAF]

#### [NEW PROPOSED PRINCIPLES BGD

- 1. Pandemic Prevention, Preparedness, Response and Recovery as a Global Public Good: Pandemic prevention, preparedness, response and recovery are recognized as global public good in view of the achievement of any State in the promotion and protection of health is of value to all1 States and their peoples.
- 2. Common but differentiated responsibilities and International Solidarity: The Member States should be prepared to protect humankind from pandemics, on the basis of equity and in accordance with their common but differentiated responsibilities and respective capabilities. In view of the common danger of unequal development in different countries in the promotion of health and control of communicable disease2, different contributions to Climate Change3, which has become a major cause of emergence of novel pathogens, and the negative effect of climate change on human health, especially in developing countries, small island developing States and vulnerable local communities4, and the significant relationship between health equity and global economic and political system5, States have common but differentiated responsibilities. Accordingly, developed country Member States shall take responsibilities to share financial and technological resources with developing countries to establish, develop and maintain pandemic prevention, preparedness, response, and recovery capacities. All States shall

act in a spirit of international solidarity, partnership, and service6, especially during a public health emergency period.

- 3. Equitable Access to Health Products, Technologies and Knowhow: Equitable access to health products, technologies and know how, either for preventing disease outbreaks or from preventing disease outbreaks becoming pandemic for all States and their people is considered as essential pandemic preparedness.
- 4. The establishment of normalcy at the earliest possible time: The enjoyment of the highest attainable standard of health by all peoples? requires ending the pandemic in the shortest span of time and establishment of normalcy across all countries and populations at the same time.
- 5. Respect for Human Rights: The implementation of the provisions of the new instrument including prevention, preparedness, response and recovery activities must comply with human rights, including right to health and right to science. The harmonization of any conflicting human rights in the implementation of the provisions should be based on public health rationale and scientific evidence.
- 6. Science, Evidence and Equity Based Decision Making: Decisions made pursuant to the new instrument should be science, evidence and equity based. Solutions based on science and evidence must be informed by ethical considerations and equity, before adopting the same as policy measures.
- 7. Consistency with UN Charter, the Constitution of WHO and Complementarity with International Health Regulations (IHR) 2005: The implementation of the provisions of the new instrument shall be based on interpretation of its provisions consistent with Charter of United Nations and Constitution of WHO, respectful of national sovereignty, and in a way, ADD BGD]

#### Article 5. [Scope

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

DEL BGD, IDN, RUS, BRN, BGD; AUS DEFER DISCUSSION; COMBINE WITH ARTICLE 3

[NEW EU PROPOSAL: introduce a new Chapter II entitled 'Preventing, detecting and reporting pandemic situations' [DEL NEW PROPOSAL PENDING ELABORATION OF ABS MECHANISM TO ADDRESS BENEFIT SHARING AFR GROUP]

### A. Preventing pandemic situations

## Article A.1. - Preventing pandemic situations

1. The Parties shall undertake actions to strengthen infection prevention and control, at all levels, including, but not limited to, households, communities and healthcare facilities, as well as the veterinary sector, with the aim of preventing pandemic situations. In particular:

- a. Parties shall strengthen efforts to ensure access to safe water, sanitation and hygiene and guarantee access to appropriate health services as a preventive infection control measures for the general public, including hard-to-reach settings in the Parties' territory, as well as animals.
- b. Parties shall ensure the implementation of infection prevention and control measures applying as far as possible the latest WHO, FAO, Codex Alimentarius, International Plant Protection Convention (IPPC), and WOAH standards and guidelines.
- c. Parties shall strengthen efforts to ensure the sound management of healthcare and protective equipment waste, which may be contaminated.
- d. Parties shall require healthcare institutions to have in place an infection prevention and control programme no later than [...] years after the entry into force of the Agreement.
- e. Parties shall strengthen animal disease preventive measures, including, but not limited to, on farms, transport of animals, live animal markets, trade in wild animals and in veterinary practices both for food-producing and companion animals taking into account the relevant WOAH standards. Those measures include water and feed hygiene, infection prevention and control measures, biosecurity and animal welfare support measures.
- 2. Parties shall take actions to prevent pandemic situations due to pathogens resistant to antimicrobial agents in accordance with the provisions set out in Annex 2.
- 3. Parties shall take actions to prevent the inadvertent laboratory release of pathogens in accordance with the provisions set out in Annex 3.

### B. Surveillance

#### Article B.1. - Pathogen surveillance and identification

- 1. Each Party shall within its territory develop, strengthen and maintain the capacity to detect, identify and characterize pathogens presenting significant risks, including pathogens in animal population presenting a zoonotic risks, and vector-borne diseases, and to assess as much as possible their likelihood to cause spread in human and animal populations and serious diseases leading to pandemic situations.
- 2. Without prejudice to existing reporting and notification obligations, each Party shall inform the Secretariat of this Agreement (hereinafter the "Secretariat") in a rapid and effective manner about the pathogens referred to in paragraph 1 that it has detected, and communicate the information and data on their characteristics that it has been able to assemble. The Party shall communicate in a rapid and effective manner to the Secretariat new or updated data or information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international and regional organizations. For purposes hereof, "rapid" shall be understood to mean within [...] hours from the time of identification of a pathogen with pandemic potential or from the time the relevant data or information have become available. "Effective" shall be understood as sufficient information on the specific geaographic localisation, all information already

available on the original infection case or cases, on risks of contamination and on all actions already undertaken for preventing the spread of the outbreak.

3. The Parties shall cooperate with one another and with the support of the Secretariat, in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of Parties which are low and lower middle income countries, especially with respect to the capacity to perform genetic sequencing of detected pathogens and safely handle samples containing pathogens, as well as to use related digital tools. The Parties shall also promote and facilitate the provision of necessary assistance by relevant international and regional organizations.

## Article B.2. - Surveillance at the wildlife-livestock-human interface

- 1. In view of the objective set out in article B.1., each Party shall develop, strengthen and maintain the capacity to carry out integrated surveillance of infectious diseases in humans, of infectious diseases in animals presenting significant risks for zoonotic, including vectorborne, spillover, as well as of relevant environmental indicators, and samples taken from specific environmental settings, for the purpose of preventing and controlling the spillover of potentially dangerous pathogens, including antimicrobial resistant pathogens, between humans and animal populations, as well as between different animal species. For this purpose the Parties shall ensure the cooperation and exchange of information among national and regional authorities responsible for surveillance. Such surveillance shall encompass livestock, companion animals, [high-risk wildlife **DEL PRY]** [wild, autochthonous or native fauna **ADD PRY**] and vectors as defined by the Conference of the Parties. Parties shall promptly communicate to the Secretariat new or updated data, analysis and information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international and regional organizations, especially for the purpose of early warning and detection.
- 2. Parties shall cooperate with one another in bilateral, regional and multilateral settings in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of low and lower middle-income countries which are Parties to the Agreement. In particular, Parties shall cooperate to strengthen public health laboratory and diagnostic capacities, including capacities for genomic sequencing, as well as digital health and data science capacities. Parties shall coordinate surveillance activities as appropriate taking into account the decisions of the Conference of the Parties and the recommendations of relevant international organizations and bodies.
- 3. The Conference of the Parties shall adopt recommendations on the harmonization and standardization of information and data arising out of their surveillance activities to ensure the interoperability of data information systems and the comparability and integration of information and data for the purpose of an effective assessment of national, regional and international risks of zoonotic and vector-borne diseases, while maintaining appropriate standards of data protection.

# C.Preventing and controlling zoonotic spill-overs through the One Health approach

## Article C.1. - Control of wildlife trade

- 1. Subject to their international obligations, Parties shall adopt legislative, administrative and technical measures to ensure safe legal trade and prohibit and prevent the illicit national and international trade of animal and plant species that may pose a higher risk of zoonotic diseases based on the result of their surveillance under Articles B.1. (Pathogen surveillance and identification) and B.2. (Surveillance at the wildlife-livestock-human interface).
- 2. The Parties shall put in place export and import authorisation procedures for specimens of animal and plant species mentioned in paragraph 1 to assess the risk to human and animal health deriving from pathogens generally or likely hosted by the species to which the specimens in question belong, or from laboratory testing of the specimens. They shall not allow or, as the case may be, subject the export or import authorization to specific risk mitigation measures to prevent or reduce the risk of emergence and spread of disease into human or other animal populations. The Parties shall facilitate the rapid export of biological samples of wild animals for purposes of zoonotic disease research and effective response to pandemic situations.

#### Article C.2. - International standards and national measures

- 1. The Conference of the Parties shall, on the basis of the findings and advice of the Panel of Expert provided for in Article P.3 (*Scientific advice*) as well as of the advice of relevant international organizations, in particular the Quadripartite organisations, and other relevant organisations and bodies, adopt guidelines, recommendations, standards and other instruments, as necessary, to guide and support the Parties in the adoption of national measures aimed at the implementation of the provision under Section B, and more generally to the reduction of risks of zoonotic, including vector-borne, spillover in accordance with the One Health approach.
- 2. The Parties shall, in accordance with their international obligations, adopt policies and measures of a legislative, regulatory, administrative and technical nature for the purpose of:
  - a. Identification and mapping of geographical areas, animal and plant species, activities and practices within their jurisdiction which may require particular surveillance:
  - b. Monitoring environmental factors associated with the risk of zoonotic diseases, such as vector- and water-borne pathogens and diseases, water quality, unsustainable land uses or deforestation, predictive climatic, entomology or vegetation indices [the comprehensive management of common and bioinfectious solid waste, considering the waste classification, waste inventory, source separation, storage, labelling, transport, management and final disposal ADD PRY].;

- c. On the basis of their activities under sub-paragraphs a) and b), reducing as much as possible the risk of zoonotic diseases by controlling and adapting relevant activities and practices, such as certain unsustainable land uses and wildlife consumption practices;
- d. Adapting farming practices, including within the context of large-scale animal farming, aimed at preventing the insurgence of antimicrobial resistant pathogens;
- e. Establishing, strengthening, monitoring and enforcing as appropriate hygienic practices and risk management measures in markets selling live animals and live wildlife;
- f. Developing, strengthening and maintaining animal welfare policies and practices to ensure the humane and adequate treatment of wildlife, farm and companion animals at all stages of their trading, rearing, transport and slaughter, as well as to improve hygiene and, where possible, reduce long distance transportation of live animals.
- g. Monitoring the effectiveness of the adopted policies and measures for the purpose of constantly strengthening them and increasing their effectiveness.
- 3. Without prejudice to their existing obligations under international law the Parties shall base the policies and measures provided for under this Article on the recommendations, guidelines and standards adopted by the Panel of Expert provided for in Article P.3 (Scientific advice), as well as by relevant international organizations and bodies, with particular regard to WHO, WOAH and the Codex Alimentarius Commission.
- 4. The Parties shall fully take into account the rights, as set out in the UN Declaration on the Rights of Indigenous Peoples, needs and traditional practices of indigenous and local communities under their jurisdiction in order to avoid any discrimination or depriving such communities of their livelihood and traditional knowledge. The Parties shall consult and involve indigenous and local communities in the elaboration and implementation of the measures referred to in this Article.
- 5. Each Party shall report specifically on the national or regional measures adopted and implemented under this Article to the Conference of the Parties every [...] years after the entry into force of the Agreement for that Party as part of their reporting under article P.2. The Conference of the Parties shall specify the information required from Parties, with particular regard to the challenges encountered and assistance needed. The reports shall also be examined by the Implementation and Compliance Committee for the purpose of identifying general or specific problems requiring action by the Conference of the Parties and by the Parties concerned.

6. Each Party shall promote technical, scientific and research cooperation with other Parties in implementing the provisions of this Article, inter alia, through the development and implementation of national and where possible regional policies and measures. In promoting such cooperation, special attention should be given to the development and strengthening of national, and where possible regional, capabilities, by means of human resources development and institution building, especially in low and lower-middle income countries, as well as other middle income countries in need.

## D. Early detection and reporting of pandemic situations

## Article D.1. - Applicability

This section shall apply between Parties to the Agreement without prejudice to the International Health Regulations (2005), and in particular Part II thereof.

## Article D.2. - Early Detecting and Reporting

- 1. Notwithstanding Article 6.1 of the IHR, in case of an event which may constitute a pandemic situation in accordance with Article 3 (*Determination of a pandemic situation*), the Party within which such event or occurrence is taking place shall immediately provide the Secretariat with all relevant information and respond promptly to requests for consultation by the WHO and the Parties likely to be affected.
- 2. Notwithstanding Article 10.2 of the IHR, the same Party shall also verify and provide within the shortest possible period and in no case later than 24 hours any other information or report as requested by the WHO with a view to allowing the WHO to assess the public health threat and inform other Parties accordingly.
- 3. The Secretariat, in cooperation with Parties in a position to do so, and in accordance with Article D.4., shall offer its assistance to the Party concerned for the purpose of collecting and analyzing relevant information, making full use of an integrated One Health approach.
- 4. Notwithstanding Article 10.4 and 11 of the IHR, if the Party concerned does not provide or verify the information as provided for in paragraphs 1 and 2, the Secretariat shall be allowed to share with other Parties, relevant international organizations and the public the information available to it, and independently assessed by it, in accordance with established epidemiological principles.
- 5. As part of the provision of information in accordance with paragraph 1, the Party concerned may make a request for emergency health and other support. In accordance with article I.1., all Parties in a position to provide such support, shall cooperate with the requesting Party and the WHO, which shall facilitate and coordinate, together with other relevant international, regional and non-governmental organisations, the provision of emergency medical and other assistance.

#### Article D.3. - Sharing of information and data

In accordance with the provisions of Article E.1. (Sharing of pathogen samples, genetic sequences and equitable sharing of benefits), the Party within which an event or occurrence as referred to in Article D.2. (Early Detecting and Reporting) is taking place shall make available, in accordance with open access and open science principles, relevant international and national practices and data protection rules, any scientific findings, surveillance and diagnostic data, research results and samples, including when stored in relevant data repositories, and agree on access conditions that allow for their reuse for research and development purposes with the aim of informing public health responses, limiting the spread of diseases and enabling the rapid development of safe and efficacious medical and other counter-measures.

## Article D.4. - Field missions for the purpose of verification and support

- 1. Notwithstanding Article 10.3 and 4 of the IHR, WHO should offer to deploy field missions including, as necessary, experts from other relevant international organizations, in particular the Quadripartite organisations, for the purpose of supporting a Party in the verification of an event, investigation about its origins, assessment of the public health risk and evaluation of the effectiveness of the public health measures implemented by that Party.
- 2. Parties shall not unjustifiably refuse an offer by WHO to deploy the field mission referred to in paragraph 1 and shall strive to agree on the timing and terms of reference of the mission within 24 hours from receipt of the offer. Parties and the WHO should to the extent possible make use of the standard terms of reference set out in Annex 4 to this Agreement.
- 3. If a Party rejects the offer, it shall provide WHO within 24 hours with the reasons for its refusal and may at the same time request additional information from WHO about the purpose and objective of the field mission. WHO shall respond to any such request within 12 hours. If the Party rejects the offer or does not respond within 12 hours from the provision by WHO of the required information, WHO shall inform other Parties and report to the Conference of the Parties.
- 4. A Party receiving a WHO field mission shall collaborate in good faith to ensure the effectiveness of the mission, shall make information available and provide access to sites and facilities, shall ensure the security of the visiting team and shall respect the privileges and immunities of WHO and those of other organizations involved. WHO shall inform other States Parties about the outcome of the mission, including any refusal by the Party to collaborate with the visiting team.

## Article D.5. - Support to detection capacities

- 1. WHO should provide, or facilitate the provision of, technical cooperation to assist Parties, with particular regard to Parties which are low and lower middle income countries, in strengthening their capacities for the surveillance, detection, reporting and verification of public health threats which may cause pandemic situations, including the provision of necessary equipment.
- 2. WHO should consult with relevant international organizations and bodies, such as the Quadripartite organizations, as well as the secretariats of relevant multilateral environmental

conventions with a view to securing their participation and collaboration in the activities provided in this section, including field missions. Agreements to this effect with the relevant organizations shall be approved by the Conference of the Parties.

EU]

# [NEW EU PROPOSAL: introduce a new Chapter II entitled 'Preventing, detecting and reporting pandemic situations

## **A. Preventing pandemic situations**

### **Article A.1. - Preventing pandemic situations**

- 1. The Parties shall undertake actions to strengthen infection prevention and control, at all levels, including, but not limited to, households, communities and healthcare facilities, as well as the veterinary sector, with the aim of preventing pandemic situations. In particular:
- a) Parties shall strengthen efforts to ensure access to safe water, sanitation and hygiene and guarantee access to appropriate health services as a preventive infection control measures for the general public, including hard-to-reach settings in the Parties' territory, as well as animals.
- b) Parties shall ensure the implementation of infection prevention and control measures applying as far as possible the latest WHO, FAO, Codex Alimentarius, International Plant Protection Convention (IPPC), and WOAH standards and guidelines.
- c) Parties shall strengthen efforts to ensure the sound management of healthcare and protective equipment waste, which may be contaminated.
- d) Parties shall require healthcare institutions to have in place an infection prevention and control programme no later than [...] years after the entry into force of the Agreement.
- e) Parties shall strengthen animal disease preventive measures, including, but not limited to, on farms, transport of animals, live animal markets, trade in wild animals and in veterinary practices both for food-producing and companion animals taking into account the relevant WOAH standards. Those measures include water and feed hygiene, infection prevention and control measures, biosecurity and animal welfare support measures.
- 2. Parties shall take actions to prevent pandemic situations due to pathogens resistant to antimicrobial agents in accordance with the provisions set out in Annex 2. 3. Parties shall take actions to prevent the inadvertent laboratory release of pathogens in accordance with the provisions set out in Annex 3. B. Surveillance

### Article B.1. - Pathogen surveillance and identification

1. Each Party shall within its territory develop, strengthen and maintain the capacity to detect, identify and characterize pathogens presenting significant risks, including pathogens in animal population presenting a zoonotic risks, and vector-borne diseases, and to assess as much as possible their likelihood to cause spread in human and animal populations and serious diseases leading to pandemic situations.

- 2. Without prejudice to existing reporting and notification obligations, each Party shall inform the Secretariat of this Agreement (hereinafter the "Secretariat") in a rapid and effective manner about the pathogens referred to in paragraph 1 that it has detected, and communicate the information and data on their characteristics that it has been able to assemble. The Party shall communicate in a rapid and effective manner to the Secretariat new or updated data or information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international and regional organizations. For purposes hereof, "rapid" shall be understood to mean within [...] hours from the time of identification of a pathogen with pandemic potential or from the time the relevant data or information have become available. "Effective" shall be understood as sufficient information on the specific geaographic localisation, all information already available on the original infection case or cases, on risks of contamination and on all actions already undertaken for preventing the spread of the outbreak.
- 3. The Parties shall cooperate with one another and with the support of the Secretariat, in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of Parties which are low and lower middle income countries, especially with respect to the capacity to perform genetic sequencing of detected pathogens and safely handle samples containing pathogens, as well as to use related digital tools. The Parties shall also promote and facilitate the provision of necessary assistance by relevant international and regional organizations.

### Article B.2. - Surveillance at the wildlife-livestock-human interface

- 1. In view of the objective set out in article B.1., each Party shall develop, strengthen and maintain the capacity to carry out integrated surveillance of infectious diseases in humans, of infectious diseases in animals presenting significant risks for zoonotic, including vector-borne, spillover, as well as of relevant environmental indicators, and samples taken from specific environmental settings, for the purpose of preventing and controlling the spillover of potentially dangerous pathogens, including antimicrobial resistant pathogens, between humans and animal populations, as well as between different animal species. For this purpose the Parties shall ensure the cooperation and exchange of information among national and regional authorities responsible for surveillance. Such surveillance shall encompass livestock, companion animals, high-risk wildlife and vectors as defined by the Conference of the Parties. Parties shall promptly communicate to the Secretariat new or updated data, analysis and information as soon as they become available. The Secretariat shall make available the information received under this paragraph to the other Parties as well as to relevant international and regional organizations, especially for the purpose of early warning and detection.
- 2. Parties shall cooperate with one another in bilateral, regional and multilateral settings in the development of the capacities mentioned in paragraph 1, with particular regard to the development and strengthening of the capacities of low and lower middle-income countries which are Parties to the Agreement. In particular, Parties shall cooperate to strengthen public health laboratory and diagnostic capacities, including capacities for genomic sequencing, as well as digital health and data science capacities. Parties shall coordinate surveillance activities as appropriate taking into account the decisions of the Conference of the Parties and the recommendations of relevant international organizations and bodies.
- 3. The Conference of the Parties shall adopt recommendations on the harmonization and standardization of information and data arising out of their surveillance activities to ensure the

interoperability of data information systems and the comparability and integration of information and data for the purpose of an effective assessment of national, regional and international risks of zoonotic and vector-borne diseases, while maintaining appropriate standards of data protection.

C. Preventing and controlling zoonotic spill-overs through the One Health approach

#### **Article C.1. - Control of wildlife trade**

- 1. Subject to their international obligations, Parties shall adopt legislative, administrative and technical measures to ensure safe legal trade and prohibit and prevent the illicit national and international trade of animal and plant species that may pose a higher risk of zoonotic diseases based on the result of their surveillance under Articles B.1. (Pathogen surveillance and identification) and B.2. (Surveillance at the wildlife-livestock-human interface).
- 2. The Parties shall put in place export and import authorisation procedures for specimens of animal and plant species mentioned in paragraph 1 to assess the risk to human and animal health deriving from pathogens generally or likely hosted by the species to which the specimens in question belong, or from laboratory testing of the specimens. They shall not allow or, as the case may be, subject the export or import authorization to specific risk mitigation measures to prevent or reduce the risk of emergence and spread of disease into human or other animal populations. The Parties shall facilitate the rapid export of biological samples of wild animals for purposes of zoonotic disease research and effective response to pandemic situations.

#### Article C.2. - International standards and national measures

- 1. The Conference of the Parties shall, on the basis of the findings and advice of the Panel of Expert provided for in Article P.3 (Scientific advice) as well as of the advice of relevant international organizations, in particular the Quadripartite organisations, and other relevant organisations and bodies, adopt guidelines, recommendations, standards and other instruments, as necessary, to guide and support the Parties in the adoption of national measures aimed at the implementation of the provision under Section B, and more generally to the reduction of risks of zoonotic, including vectorborne, spillover in accordance with the One Health approach.
- 2. The Parties shall, in accordance with their international obligations, adopt policies and measures of a legislative, regulatory, administrative and technical nature for the purpose of:
- a) Identification and mapping of geographical areas, animal and plant species, activities and practices within their jurisdiction which may require particular surveillance;
- b) Monitoring environmental factors associated with the risk of zoonotic diseases, such as vectorand water-borne pathogens and diseases, water quality, unsustainable land uses or deforestation, predictive climatic, entomology or vegetation indices;
- c) On the basis of their activities under sub-paragraphs a) and b), reducing as much as possible the risk of zoonotic diseases by controlling and adapting relevant activities and practices, such as certain unsustainable land uses and wildlife consumption practices;
- d) Adapting farming practices, including within the context of large-scale animal farming, aimed at preventing the insurgence of antimicrobial resistant pathogens;

- e) Establishing, strengthening, monitoring and enforcing as appropriate hygienic practices and risk management measures in markets selling live animals and live wildlife;
- f) Developing, strengthening and maintaining animal welfare policies and practices to ensure the humane and adequate treatment of wildlife, farm and companion animals at all stages of their trading, rearing, transport and slaughter, as well as to improve hygiene and, where possible, reduce long distance transportation of live animals.
- g) Monitoring the effectiveness of the adopted policies and measures for the purpose of constantly strengthening them and increasing their effectiveness.
- 3. Without prejudice to their existing obligations under international law the Parties shall base the policies and measures provided for under this Article on the recommendations, guidelines and standards adopted by the Panel of Expert provided for in Article P.3 (Scientific advice), as well as by relevant international organizations and bodies, with particular regard to WHO, WOAH and the Codex Alimentarius Commission.
- 4. The Parties shall fully take into account the rights, as set out in the UN Declaration on the Rights of Indigenous Peoples, needs and traditional practices of indigenous and local communities under their jurisdiction in order to avoid any discrimination or depriving such communities of their livelihood and traditional knowledge. The Parties shall consult and involve indigenous and local communities in the elaboration and implementation of the measures referred to in this Article.
- 5. Each Party shall report specifically on the national or regional measures adopted and implemented under this Article to the Conference of the Parties every [...] years after the entry into force of the Agreement for that Party as part of their reporting under article P.2. The Conference of the Parties shall specify the information required from Parties, with particular regard to the challenges encountered and assistance needed. The reports shall also be examined by the Implementation and Compliance Committee for the purpose of identifying general or specific problems requiring action by the Conference of the Parties and by the Parties concerned.
- 6. Each Party shall promote technical, scientific and research cooperation with other Parties in implementing the provisions of this Article, inter alia, through the development and implementation of national and where possible regional policies and measures. In promoting such cooperation, special attention should be given to the development and strengthening of national, and where possible regional, capabilities, by means of human resources development and institution building, especially in low and lower-middle income countries, as well as other middle income countries in need.
- D. Early detection and reporting of pandemic situations

#### **Article D.1. - Applicability**

This section shall apply between Parties to the Agreement without prejudice to the International Health Regulations (2005), and in particular Part II thereof.

#### Article D.2. - Early Detecting and Reporting

1. Notwithstanding Article 6.1 of the IHR, in case of an event which may constitute a pandemic situation in accordance with Article 3 (Determination of a pandemic situation), the Party within

which such event or occurrence is taking place shall immediately provide the Secretariat with all relevant information and respond promptly to requests for consultation by the WHO and the Parties likely to be affected.

- 2. Notwithstanding Article 10.2 of the IHR, the same Party shall also verify and provide within the shortest possible period and in no case later than 24 hours any other information or report as requested by the WHO with a view to allowing the WHO to assess the public health threat and inform other Parties accordingly.
- 3. The Secretariat, in cooperation with Parties in a position to do so, and in accordance with Article D.4., shall offer its assistance to the Party concerned for the purpose of collecting and analyzing relevant information, making full use of an integrated One Health approach.
- 4. Notwithstanding Article 10.4 and 11 of the IHR, if the Party concerned does not provide or verify the information as provided for in paragraphs 1 and 2, the Secretariat shall be allowed to share with other Parties, relevant international organizations and the public the information available to it, and independently assessed by it, in accordance with established epidemiological principles.
- 5. As part of the provision of information in accordance with paragraph 1, the Party concerned may make a request for emergency health and other support. In accordance with article I.1., all Parties in a position to provide such support, shall cooperate with the requesting Party and the WHO, which shall facilitate and coordinate, together with other relevant international, regional and nongovernmental organisations, the provision of emergency medical and other assistance.

### Article D.3. - Sharing of information and data

In accordance with the provisions of Article E.1. (Sharing of pathogen samples, genetic sequences and equitable sharing of benefits), the Party within which an event or occurrence as referred to in Article D.2. (Early Detecting and Reporting) is taking place shall make available, in accordance with open access and open science principles, relevant international and national practices and data protection rules, any scientific findings, surveillance and diagnostic data, research results and samples, including when stored in relevant data repositories, and agree on access conditions that allow for their reuse for research and development purposes with the aim of informing public health responses, limiting the spread of diseases and enabling the rapid development of safe and efficacious medical and other counter-measures.

## Article D.4. - Field missions for the purpose of verification and support

- 1. Notwithstanding Article 10.3 and 4 of the IHR, WHO should offer to deploy field missions including, as necessary, experts from other relevant international organizations, in particular the Quadripartite organisations, for the purpose of supporting a Party in the verification of an event, investigation about its origins, assessment of the public health risk and evaluation of the effectiveness of the public health measures implemented by that Party.
- 2. Parties shall not unjustifiably refuse an offer by WHO to deploy the field mission referred to in paragraph 1 and shall strive to agree on the timing and terms of reference of the mission within 24 hours from receipt of the offer. Parties and the WHO should to the extent possible make use of the standard terms of reference set out in Annex 4 to this Agreement.

- 3. If a Party rejects the offer, it shall provide WHO within 24 hours with the reasons for its refusal and may at the same time request additional information from WHO about the purpose and objective of the field mission. WHO shall respond to any such request within 12 hours. If the Party rejects the offer or does not respond within 12 hours from the provision by WHO of the required information, WHO shall inform other Parties and report to the Conference of the Parties.
- 4. A Party receiving a WHO field mission shall collaborate in good faith to ensure the effectiveness of the mission, shall make information available and provide access to sites and facilities, shall ensure the security of the visiting team and shall respect the privileges and immunities of WHO and those of other organizations involved. WHO shall inform other States Parties about the outcome of the mission, including any refusal by the Party to collaborate with the visiting team.

### **Article D.5. - Support to detection capacities**

- 1. WHO should provide, or facilitate the provision of, technical cooperation to assist Parties, with particular regard to Parties which are low and lower middle income countries, in strengthening their capacities for the surveillance, detection, reporting and verification of public health threats which may cause pandemic situations, including the provision of necessary equipment.
- 2. WHO should consult with relevant international organizations and bodies, such as the Quadripartite organizations, as well as the secretariats of relevant multilateral environmental conventions with a view to securing their participation and collaboration in the activities provided in this section, including field missions. Agreements to this effect with the relevant organizations shall be approved by the Conference of the Parties. EU
- Chapter III. Achieving equity in, for and through pandemic prevention, preparedness, response and recovery of health systems

[ALT TITLE Strengthening the enabling environment for more rapid, equitable, and effective access for pandemic prevention, preparedness, and response USA]

#### [[ADD EU: DEL NEW CHAPTER 3. AFR GROUP.]

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 **DEL PRY**] [non-lucrative ADD PRY] 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]

## [NEW PARA EU PROPOSAL

[Proposal on access and benefit-sharing

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

- 1. 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.
- 2. 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.

- 3. 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.
- 4. 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 Parties 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.
- N. Scientific and research cooperation

#### Article N.1. Scientific and research cooperation

- 1. 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;
- c) 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]

Article 6. [Predictable [and ADD PAK] [, equitable, AF GROUP, HTI, TUN, PAK, ZAF] [global [production, distribution, SWZ, MYS, NAM, ETH, BGD] supply chain DEL BGD] [(procurement, production and distribution) ADD PAK] and logistics [network DEL AF GROUP, PAK, TUN, PAK, BGD] [mechanism[s DEL AF GROUP, PAK, ZAF] AF GROUP, PAK, BGD, PAK]

[ALT. BRN Article 6 Title: Equitable access to pandemic countermeasures]

[ALT IND Article 6 Title: Medical Countermeasure Coordination Platform.]

## [ALT. AFR GROUP REPLACE ALL REFERENCE TO NETWORK WITH MECHANISM]

[ADD CHAPEAU: 1. The Parties recognize the importance of strengthening the enabling environment for more rapid, equitable, and effective access for pandemic prevention, preparedness, and response, including to support sustainable development of, and equitable access to, pandemic emergency response-related products, including in fragile, humanitarian, and hard-to-reach settings. The Parties recognize the need for this environment to be fully integrated within broader evidence-based approaches to pandemic prevention, preparedness, and response. ADD USA]

[2. The Parties also recognize the importance of working together in a fully inclusive, transparent, and participatory manner with a range of partners at the community, local, national, regional, and global levels, including with governmental actors, the WHO and other international organizations, and other relevant stakeholders in strengthening the enabling environment for more rapid, equitable, and effective access for pandemic prevention, preparedness, and response ADD USA]

#### [RESERVE ARTICLE 6 ARM, CAN, CHE]

1. [The Parties [, recognizing the shortcomings of the preparedness for and response to the COVID-19 pandemic, DEL BRA, IDN, NAM, SWZ, PRY, ARG, JAM RUS/ RETAIN AUS] agree on the need for [an DEL AUS] [adequate DEL BRA, NAM, PAK, DOM, RETAIN AUS], [fair, IDN, BRA, NAM] [resilient ADD AUS] equitable, transparent, [robust, agile, DEL AUS] effective and diverse global supply chain [s ADD AUS] and logistics [network DEL ZAF, AFR GROUP] [networks ADD AUS] [mechanism ZAF, AFR GROUP] [to promote equitable access to pandemic-related products (or MCM: Medical Countermeasures) and reconfirm the importance of coordination mechanisms ADD JPN] for pandemic prevention, preparedness, response and recovery [of health systems IDN, BRA, NAM, SAU, HTI, JAM] [, 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] [to ensure the availability and equitable access to pandemic related products for all. ADD PAK] [and without interfering with the sovereignty of states to manage their own supply and logistics ISR] DEL BGD, MEX]

[[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] [to ensure timely control of pandemics and other public health emergencies. AFR GROUP].

[ALT 6.1. BRN In the event of declaration of a pandemic, the Parties shall ensure that appropriate countermeasures are developed, manufactured, and deployed to provide for an effective and equitable global response.']

[ALT 6.1 The Parties recognize the significant challenges posed by the COVID-19 pandemic and the urgent need for a comprehensive, equitable, transparent, and agile global supply chain for pandemic prevention, preparedness, response, and recovery. This supply chain should be designed to ensure the availability and equitable access to pandemic-related products, including pharmaceuticals, medical equipment, and other essential supplies, as part of a robust pandemic prevention, preparedness, response, and recovery network SAU]

[New para 1 - The Parties agree on the need for a sustainable, scalable, equitable, agile, effective, transparent, robust end-to-end medical countermeasure coordination platform that is augmented with vaccines, therapeutics and diagnostics (VTD), R&D and manufacturing networks for the availability and accessibility of safe, effective, quality, and affordable medical counter measures, particularly in LMICs. IND]

[New para 1 bis. The proposed global medical countermeasure coordination platform shall be designed to be resilient and sustainable and support MCM efforts, particularly in LMICs ensuring the accessibility, availability, and affordability of medical countermeasures by strengthening the regional and country's capacity during inter -pandemic times and shall have the capacity to scale up to provide end-to-end medical countermeasures support during health emergencies. IND]

[New para 1 ter. The platform shall coordinate and monitor the overall functioning of these VTDs, R&D and Manufacturing Networks, provide support in mobilizing resources, facilitate the interoperability of tech transfer & know-how, and also provide support for procurement and logistics of VTDs during health emergencies, distribution and last mile connectivity IND]

- 2. [[The WHO <u>DEL JPN</u>] [A WHO led and <u>Members States co-chaired ADD ZAF</u>] Global Pandemic Supply [Chain and <u>DEL JPN</u>] Logistics [,and <u>Coordination ADD JPN</u>] [Network <u>DEL PAK</u>] (the "Network") DEL ZAF, AFR GROUP, <u>BGD</u>, <u>PAK</u>] [Mechanism ZAF, AFR GROUP, <u>BGD</u>, <u>PAK</u>] [[is hereby <u>DEL BGD</u>] established DEL SWZ, <u>IND</u>, <u>RUS</u> / 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, <u>EGY</u>][pursuant to paragraph 1 shall carry out the following functions: <u>ADD</u> BGD][RESERVE SAU].
- [ALT 6.2. BRN In order to support the equitable distribution of medical countermeasures and other pandemic-related products, the Parties agree to the establishment of the WHO Global Pandemic Countermeasures Network (the "Network"). The operationalization of the Network will be led by WHO, linked with other international organizations and relevant institutions, and leverage on existing regional and international mechanisms.]
- [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' <u>DEL AFR GROUP</u>] [health products ADD AFR GROUP] 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]
- [ALT 2 A WHO led and Members States co-chaired, Global Pandemic Supply Chain and Logistics Supply and Logistic Mechanism is hereby established. This inclusive WHO Global Pandemic Supply Chain and Logistics Supply and Logistic Mechanism, will adopt a Whole-of-Government and whole of society approach including all other relevant stakeholders such as: Member States, UN agencies, pharmaceutical companies, regulatory authorities and civil society. A Binding and Accountable Mechanism shall be based on agreed WHO governance binding instruments and accountable to all interested parties through the WHO mechanism. AFR GROUP]
- 3. The Parties shall [support <u>DEL ARG/RETAIN AUS, BGD, PAK]</u> [cooperate to ADD ARG] the [Network's DEL ZAF, AFR GROUP, AFR GROUP, <u>PAK, BGD/RETAIN AUS</u>] [M <u>DEL PAK</u>] [m <u>ADD PAK</u>] echanism['s <u>DEL PAK</u>] ZAF, AFR GROUP, <u>PAK</u>] [development and operationalization [based on the 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, <u>AFR GROUP</u>] it, as appropriate THA] in inter-pandemic times as well as appropriate [and timely <u>ADD PAK</u>] scale-up in the event of a pandemic [and timely control of other health emergencies [AFR GROUP] 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, <u>AFR GROUP</u>] [In that <u>DEL</u> AUS, AFR GROUP] [in this ADD AUS] regard, the Parties shall:

- (a) [determine the types and size of products [materials, supplies, and trained workforce ADD MEX] needed for robust pandemic prevention, preparedness and response, [and health system recovery, ADD SAU] including costs and logistics for establishing and maintaining strategic stockpiles of such [MCM ADD JPN] products [in an equitable manner, ADD PAK] [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 DEL RUS][, based on regular epidemiological risk and vulnerability assessment MAR];
- [(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, [as well as establishing global, regional, and national stockpiles AFR GROUP], [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, AFRICA 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] AFR GROUP];
- assess anticipated demand for, and map sources of, manufacturers and suppliers, including (b) raw materials and other necessary inputs, for [scalable and ADD AUS] 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 ADD PAK] 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, CHI] [requiring ETH, ZAF, AFR GROUP, NAM] transparency in cost and pricing of **DEL CHI**] all elements along the supply chain **DEL** JPN] [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, AFR GROUP]

- [(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, <u>PAK</u>] a mechanism to ensure the fair [and DEL ZAF, AFR GROUP] equitable [and context specific ZAF] allocation [at suitable cost EGY, NGA] [<u>at affordable cost ADD PAK</u>] of pandemic-related products [(or <u>MCM</u>) <u>ADD JPN</u>] 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 ADD PAK] ETH, AFR GROUP] international consolidation hubs, [with global geographic spread, NGA, AFR GROUP] as well as regional staging areas, [in compliance with transport safety regulations of the States Parties CHN, AFR GROUP] to ensure that transport of supplies is streamlined and uses the most appropriate means for the products concerned; [for specifically listed State Parties; ADD JPN] and AFR GROUP]

# [gather and make openly available information on costs and pricing of all elements along supply chains ADD ARG]

(e) develop [an interoperable PHL] [a DEL PHL] dashboard for pandemic-related [product DEL THA] [or MCM ADD JPN] [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 DEL PAK, ZAF] [mechanism ADD PAK, ZAF].]

#### [[sub-clauses (a) to (e) DEL BGD].

- [(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]

[NEW PARA h) Assist parties in particular developing states parties in implementing the provisions of this part through provision of adequate funding, technological transfer capacity building on pandemic and public health literacy. AFR GROUP]

# [NEW PARA i) Enable inclusive equitable and effective cooperation and participation in the activities undertaken under this part. AFR GROUP]

[NEW PARA (f) Collaborate for global equitable allocation and coordinated global procurement of pandemic-related products ADD PAK]

[ NEW PARA (g)Develop guidelines for advanced purchasing contracts to support equitable and timely access to pandemic-related products including pharmaceutical finished products. ADD PAK]

[ NEW PARA (h)Establish a procurement facility to pool demand for pandemic-related products from developing countries. ADD PAK]

[ NEW PARA (i) Provide timely information to the WHO about any advance purchase agreements under negotiations and notify WHO on conclusion. ADD PAK]

[ NEW PARA (j) Provide WHO timely information on any disruption in production and distribution of Pandemic related products in respective jurisdictions. ADD PAK]

#### [NEW PARA (k)Develop financing modalities for the mechanism. ADD PAK]

- [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 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; **DEL TUR**]
- (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; **DEL TUR**]
- (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]

[ALT 6(3) BRN. The Network will function during the inter-pandemic period with appropriate scale-up during a pandemic, if appropriate. The Parties agree that the functions of the Network during the inter-pandemic period are as follows:

- (a) determine the relevant countermeasures needed for robust pandemic prevention, preparedness, and response;
- (b) assess and map the availability, accessibility, anticipated demand, and possible supply chain vulnerabilities of such countermeasures;
- (c) identify efficient multilateral and regional purchasing mechanisms, including pooled procurement mechanisms and in-kind contributions, collaborating with existing mechanisms as appropriate;
- (d) establish a reserve system of pandemic countermeasures, for sale to buying countries with access challenges.
- 6.3 bis Upon the declaration of a pandemic, in addition to the functions outlined in 6.3 above, the Network shall:
- (a) evaluate possible countermeasures and provide guidance to Parties on the countermeasures needed for an effective response to the pandemic, and where appropriate, if not already established, develop reserve systems for these effective countermeasures;
- (b) determine the equitable allocation of the reserved countermeasure quantities for countries in need;
- (c) assist buying countries with provision of information on market conditions, matters related to the utilization of countermeasures, regulatory and licensing issues, and advanced purchase agreements where appropriate;
- (d) provide pricing guidelines to buying countries and manufacturers for the relevant countermeasures.]
- 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 **DEL MEX**] 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], [medical equipment, reagents and commercial tests ADD MEX] mindful of the need for [equitable and ADD JPN] unhindered access to pandemic-related products **DEL MEX**, RUS, ARG[. DEL SAU] [(or MCM). ADD JPN] [, according to national circumstances, needs, and priorities SAU] DEL BGD]
- [NEW PARA The Parties shall strengthen business continuity measures to ensure the openness and accessibility of airports and seaports to the extent possible, with the necessary public health measures in place to ensure the safety of the general population as well as frontline aviation and maritime workers. ADD SGP]
- [ALT The Parties commit that any emergency trade measures in the event of a pandemic, are targeted, proportionate, transparent, temporary, and do not create unnecessary barriers to trade

or unnecessary disruptions in supply chains of pharmaceutical raw materials and ingredients, mindful of the need for unhindered access to pandemic-related products ARG].

- [ALT 6.4. BRN The Parties shall support the Network's development and operationalization, including financially where appropriate, and participate in the Network, within the framework of WHO by committing to:
- (a) Provision of relevant information to the Network on domestic market conditions, pricing, supply, and demand for countermeasures;
- (b) Where appropriate, and if Parties are able to do so, make available donations to the Network for supply to countries in need;
- (c) Encourage manufacturers to provide countermeasures at an affordable price, including where appropriate, not-for-profit pricing for countries in need or persons in vulnerable situations;
- (d) Cooperate to ensure that international stockpiles of countermeasures are established, or existing ones strengthened;
- (e) During a pandemic, not impose regulations that unduly interfere with the trade in, or of, medical countermeasures as defined by the Network;
- (f) During a pandemic, notwithstanding any travel or trade restrictions, facilitate unimpeded access to countermeasures and other medical supplies.]

[4.a The Mechanism shall ensure Affordability, Equity, Transparency and Fair access to Pandemic related counter-measures. All parties shall ensure predictable funds and sustainable financing for the Mechanism, through equitable contributions by the Parties. AFR GROUP]

- 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] DEL AFR GROUP]. The commitment to facilitate such access is understood to be legally binding and [to apply in all circumstances, DEL TUR] consistent with [.consistent with (national regulation, and principles of international law including the national security of each Party. ADD SAU)] humanitarian principles [. DEL NGA] [, subject to no local objections NGA] DEL BGD, RUS] as well as public health principles.
- [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]

# [ALT 5. The Parties shall ensure the unimpeded access of humanitarian staff and cargo, consistent with international humanitarian law and principles." EU]

6. [The Parties, working through the Governing Body for the WHO CA+, shall [collaborate and ADD PAK] take all appropriate measures to [establish and DEL IDN] start functioning of the [Network DEL PAK, ZAF] [mechanism ADD PAK, ZAF] [immediately, but no later than six months THA] [no later than XX DEL THA, AFR GROUP/RETAIN PAK] [, 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+ **DEL PAK, RUS**]. 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]

[ADD ARTICLE EU "For the purpose of emergency response measures, the Parties recognize the need to enhance coherence and coordination, with the aim to maintain the integrity of supply chains and ensure ininterupted supplies of essential products and countermeasures. To this end, travel and transport restrictions, quarantine obligations and border control measures affecting among others essential and cross-border workers, need to be proportionate, nondiscriminatory, and appropriate to the country-specific health situation."]

## **INEW ARTICLE 6 USA PROPOSAL**

## **Increasing Global Supply Chain Transparency and Coordination**

- 1. The Parties recognize the need for global supply chains supporting pandemic prevention, preparedness, and response that are resilient, equitable, transparent, robust, agile, geographically distributed, and diverse.
- 2. In furtherance of this goal, the Parties intend to work, in coordination with relevant stakeholders on a voluntary basis, and to strengthen global and regional pandemic emergency response-related product supply chains, as appropriate, including for both finished products and the materials necessary for their production, taking into account the need to tailor supply to demand, including surge capacity to respond to sudden increases in demand.
- 3. The Parties intend to take steps, working with relevant stakeholders on a voluntary basis and in accordance with applicable laws, to increase the transparency of supply chains for pandemic emergency response-related products during pandemic emergencies, including, for example, by:
- a. assessing and reporting demand for pandemic emergency response-related products, including potential demand surges;
- b. establishing and maintaining secure systems for stakeholders to voluntarily share information about and report shortages and availability of resource-constrained supplies of finished products, manufacturing components, and raw materials; and
- c. encouraging and considering approaches to incentivize manufacturers of pandemic emergency response-related products to voluntarily publish information on sourcing, manufacturing volume, and capacity.

- 4. The Parties recognize the importance of ensuring that any emergency trade measures designed to tackle a pandemic emergency, if deemed necessary, are targeted, proportionate, transparent, temporary, and do not create unnecessary barriers to trade or unnecessary disruptions in supply chains.
- 5. The Parties intend to safeguard the humanitarian principles of humanity, neutrality, impartiality, and independence, and to facilitate access to pandemic emergency responserelated products, including for vulnerable populations and those in fragile and humanitarian settings.
- 6. Each Party shall consider establishing and maintaining national stockpiles, or participating in regional strategic stockpiles, of various pandemic emergency response-related products, as well as maintaining the relevant logistical capacities for their use and assessing such stockpiles and logistical capacities at regular intervals.
- 7. The Parties shall consider establishing and operationalizing international consolidation hubs for use during pandemic emergencies, as well as regional staging areas, to facilitate streamlined transport of pandemic emergency response-related products during a pandemic emergency. USA]

New Article 6bis USA PROPOSAL- Considerations for creating and strengthening equitable access mechanisms and sharing of pandemic emergency response-related products

- 1. The Parties intend to strengthen or establish regional, global, or other mechanisms to coordinate and facilitate access, allocation, delivery, and administration of pandemic emergency response-related products, including for low-and middle-income countries and fragile, humanitarian, and hard-to-reach settings, during pandemic emergencies.
- 2. In furtherance of this goal, the Parties acknowledge the importance of timely and equitable access to pandemic emergency response-related products. Toward this end, in the development of regional, global, or other access and allocation coordination mechanisms, the Parties emphasize the following considerations for engagement
- a. The mechanisms need to complement the existing global health architecture, leverage the relative strengths and mandates of existing organizations and stakeholders, and be guided by equity and public health needs;
- b. Precautions need to be taken to avoid competition for resources among procuring entities including regional organizations and/or mechanisms;
- c. Pre-defined approaches for surge financing for pandemic emergency response-related products need to be identified, particularly in the earliest stages of a pandemic emergency; d. Relevant partner countries, regional entities, and manufacturers need to be given meaningful opportunities to provide input into the development of the mechanisms and in their governance; f. Mechanisms need to include planning for prompt national regulatory approvals/authorizations and an effective plan for addressing liability issues;

- g. Partner countries may benefit from support on issues such as procurement, country readiness, local and regional manufacturing, delivery, demand, and uptake;
- h. Decisions to activate coordination through the mechanisms need to be based on clearly defined and objective criteria and triggers. Parties acknowledge that the tiered alert system and the declaration of a pandemic emergency by the WHO Director General may be used as one criterion to activate and deactivate a mechanism.1
- i. An approach for convening and timely information sharing to help coordinate relevant stakeholders and strategic communications to advance priority areas of focus.
- 3. Whenever possible, when sharing pandemic emergency response-related products with recipient countries, organizations, or access mechanisms, each Party shall abide by the following:
- a. The selection and shelf life of pandemic emergency response-related products are data driven and in alignment with identified needs and the distribution and administration/dispensing timelines and capabilities of the recipients;
- b. Prospective recipients are made aware of any expiration dates, availability of the products, and required ancillaries as far in advance as possible;
- c. As appropriate, sharing countries coordinate with each other and with other global or regional access mechanisms, to maximize allocation to populations with the highest risk and greatest public health need and to facilitate rapid absorption/administration;
- d. Products shared with global or regional access mechanisms are unearmarked for greatest effectiveness and to support long-term planning;
- e. Sharing countries release products in large volumes and in a predictable manner, in order to reduce transaction costs and facilitate recipient planning; and
- f. Shared products are accompanied with essential ancillaries, and coordinated with the availability of support for distribution and administration, to ensure rapid allocation and absorption.
- 3. The Parties request WHO to convene, in partnership with key ACT-A partners, additional discussions among WHO Member States, as well as other relevant stakeholders, including relevant private sector actors, non-governmental organizations, and international organizations, and consistent with Article 6bis(1-3) and Article [new benefit sharing mechanism], on the development of potential mechanisms to coordinate access and allocation of pandemic emergency response related products during future pandemic emergencies. USA]

#### [ALT ARTICLE 6 NGA: Access to Medical Supplies

(1) The Parties agree on the need for an adequate, equitable, transparent, robust, agile, effective, and diverse global supply chain and logistics network for pandemic prevention, preparedness, response, and recovery.

(3)...

(c) develop, strengthen and implement a mechanism to ensure the fair and equitable allocation of pandemic-related products based on public health risks and needs;

(4)....

- (5) The Parties commit to safeguard the humanitarian principles of humanitp, neutrality, impartiality and independence, and to facilitate the access of humanitarian staff and cargo. The commitment to facilitate such access is understood to be legally binding and to apply in all circumstances, consistent with humanitarian principles. NGA1
  - Article 7. [[Access to technology DEL USA/RETAIN ARG, IDN] [and [to ARG] intellectual property ARG, PAK]: promoting sustainable and equitably distributed production and [voluntary CAN] transfer of technology and know-how [on voluntary and [mutually agreed terms EGY, CAN] USA, , AUS] [retain original text for title AF GROUP, EGY] [RESERVE JAM]
- The Parties [affirm the right to enjoy the benefits of scientific progress and its applications and ADD COSR] recognize that inequitable access to pandemic [emergency response USA]-related products [(including but not limited to vaccines, therapeutics and diagnostics) DEL USA, RETAIN AUS] [during pandemic emergencies USA] [should DEL MEX, AUS] [shall MEX] [can in part be ADD AUS] be [DEL AUS] addressed by [but not limited to GBR, UK] [inter alia, promoting investments to CAN] increased [quality and GBR, UK] [sustainable GBR, CAN, AUS, uk] [pandemic-related ADD SAU] [manufacturing capacity that is more equitably, geographically [at regional and sub-regional levels SLV] and strategically distributed DEL CHI, RUS] PROPOSE PARA BE SHIFTED TO PREAMBLE ESW, RUS for States Parties, in particular, those requiring support for access to [ADD AUS] medical countermeasures JPN] [pandemic-related products ADD AUS [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 products, CHE] [Other factors such as export restrictions, regulatory delays and logistical problems should also be addressed to improve access. ADD AUS] [For this purpose, the parties undertake to strengthen the existing mechanisms to increase technology in health matters in all countries, particularly in developing countries, through initiatives that promote the transfer technology, data, training and specialized knowledge necessary for the possible adoption of essential health technologies ADD CHI]

[1.bis (new) The COVID-19 pandemic has revealed the fallibility of traditional ways of working when it comes to equitable access to essential health technologies. Alternative mechanisms should be explored to promote global public health goods, based on equity, strong science, open collaboration and global solidarity. ADD COSR]

2. The Parties[, working through the Governing Body for the WHO CA+ DEL USA/ RETAIN and collaborating with WTO NGA]], [and with relevant international organisations ADD AUS] shall [consider USA] [strengthen[ing USA] DEL AUS] [existing DEL USA, RETAIN AUS] [or ADD AUS][and [DEL AUS]] develop DEL CHE, RUS] [developing USA, AUS] [innovative DEL USA] multilateral mechanisms that promote [and incentivize DEL RUS] [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 DEL ARG, RETAIN AUS] [voluntary and USA, JPN, AUS] [mutually agreed terms DEL ARG, ESW], [as well as the objectives of this instrument COL] [to capable

[DEL ARG] 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, AUS]

[2 bis (new) Existing mechanisms developed during the COVID-19 pandemic, like the COVID-19 Technology Access Pool (CTAP) should be further developed to call on key stakeholders and the global community to commit to undertaking actions urgently needed to advance the pooling of knowledge, intellectual property and data that will benefit all of humanity ADD COSR]

[NEW PARA 2 bis. The above-mentioned multilateral mechanisms shall work together to create an end-to-end technology pool and database consisting of details of the process and specifications of pandemic related products to facilitate open manufacturing of efficacious and quality products.

ADD ESW]

#### [NEW PARAS BGD

A WHO Technology Access Pool is hereby established as a part of the Mechanism mentioned in Article 6 for performing the following functions:

- (a) to assist the designated facilities:
- (i) by transferring the technologies related to pandemic related products obtained under Article 6(3), to designated production facilities;
- (ii) by developing a database that shall provide details of pandemic related products for all known pandemic potential diseases including technological specifications and manufacturing process documents for each product, explaining end to end product development, which will be accessible to designated production facilities for the production during pandemics;
- (b) to make available the technologies and database mentioned above to manufacturers other than designated production facilities on the recommendation of the Mechanism under paragraph 2(i) of Article 6.
- (c) to develop standard terms and conditions for the licenses to be used with manufacturers who have signed SMTA contained in PARTB of ANNEX-X with WHO established pursuant to Article 10;
- (d) to develop standard terms and conditions for licenses, sublicenses or any other contractual instruments for transfer of technology for purposes of this chapter.
- (e) to obtain permission from the technology holders or developers which could be transferred outside the designated production facilities that would help promote efficiency of the pandemic PPRR and to transfer the same to potential developing country manufacturers on fair and equitable terms;

- (f) to develop and maintain a database of all the pandemic related products and technologies, including product specification, manufacturing process documents, designs etc. that are openly available in the public domain;
- (g) to perform any other activities that are necessary for ensuring equitable access to pandemic related products as well as those recommended by the governing body of WHO CA+ or the Mechanism under Article 6, if any ADD BGD].
- 3. [During inter-pandemic times DEL USA] [Between pandemic emergencies USA], [all DEL USA, CAN, <u>ESW</u>] [the USA] [the CAN] Parties [shall CHE] [[commit to establish these mechanisms and DEL CHE, CAN, **BGD**, **ESW**, **RUS**] shall DEL USA] [take measures [ADD ARG] to BRA]:
- (a) -[[[coordinate, <u>DEL RUS]</u> collaborate, facilitate and incentivize <u>DEL BRA</u>, <u>ESW/RETAIN IDN</u>] [ensure that BRA, <u>ESW</u>] manufacturers [/developers ADD RUS] of pandemic-related products [especially those [that receive ADD ESW] [ing BRA] public funding for research and development BRA, <u>ESW</u>] [of pandemic-related products ADD ESW] to [securely CAN] transfer [where appropriate and feasible, CAN] relevant technology and know-how [on a voluntary basis, CAN, <u>AUS</u>] [to [capable DEL BRA, <u>ESW</u>] [other BRA] manufacturer(s) [[(as defined below) DEL IDN, <u>ESW, RUS</u>] on mutually agreed terms DEL BRA, <u>ESW</u>], including <u>DEL BGD</u>] through [technology transfer
- Hubs[, ADD SGP] [and DEL SGP] product development partnerships DEL BGD] [Technology Access Pool ADD BGD], [[and enabling access to equipment and reagents, ADD SGP] and [to address the needs to develop DEL BRA, ESW] new pandemic-related products [for public health purposes ADD SGP] in a short time frame, [to increase geographically distributed manufacturing capacity of [new ADD ESW] pandemic-related products in a short time frame BRA, ESW] [and provide incentives to manufacturers that do not receive public funding to transfer relevant technology and know-how.ADD ESW]DEL JPN, ARG, ESW]
- [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]
- [ALT 3(a) ensure that manufacturers that receive public funding for research and development of pandemic related products to transfer relevant technology and know-how to other capable manufacturer(s) (as defined below) on mutually agreed terms, including through technology transfer hubs and product development partnerships, and to address the needs to increase geographically distributed manufacturing capacity of new pandemic-related products during a pandemic in a short time frame; and provide incentives to manufacturers that do not receive public funding to transfer relevant technology and know-how ARG].
- [ALT 3(a) coordinate, collaborate, facilitate and incentivize entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, on mutually agreed terms, licences to capable manufacturers, notably from developing countries, to use their intellectual property and other protected substances, products, technology, knowhow, information and knowledge used in the process of pandemic response

product research, development and production, in particular for pre-pandemic and pandemicrelated products; IDN

[ALT 3(a) Take appropriate steps including enacting laws and through relevant provisions in respective contracts, to ensure that manufacturers, including those that receive public funding for research and development of pandemic-related products transfer relevant technology and knowhow to other manufacturer(s) on mutually agreed terms, including through technology transfer hubs and product development partnerships, and to and provide incentives to manufacturers that do not receive public funding to transfer relevant technology and know-how. ADD PAK]

[3.a bis: (new) Promote that all publicly-funded and donor-funded research outcomes are affordable, available, and accessible to all on a global scale through appropriate provisions in funding agreements, and include specific provisions regarding accessibility to and affordability of resulting health products through global, non-exclusive and transparent voluntary licensing, of intellectual property rights, know-how and data; ADD COSR

(b) [intend to USA] strengthen [coordination DEL USA/RETAIN CAN, AUS] [among the Secretariats of CAN] [cooperation USA], [with DEL CAN/retain AUS] relevant [regional and ADD AFR GROUP] international organizations [as appropriate USA, AUS], [including United Nations agencies, DEL USA/RETAIN AUS] on issues related to public health [(including as impacted by animal health and environmental health under the One Health principle), biosafety and security CAN, AUS], 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 [relevant ADD AUS] organizations, CAN, AUS] [timely matching of supply to demand and DEL EU/RETAIN AUS] mapping manufacturing capacities and demand DEL BGD] DEL ESW [as well as ensuring transparency that will support and facilitate effective and timely notification of measures and coordination of rules and policies PHL] [including the establishment of regional manufacturing capacities through mRNA hubs in all the regions which should include the diversification of production both raw material and complete products ADD ZAF].;

[ALT (b) PARA strengthen coordination, with relevant international organizations, including United Nations agencies, on issues related to public health, intellectual property and trade, including timely matching of supply to demand and mapping manufacturing capacities and demand; ADD ESW]

[ensure that international collaborations on research and development of pandemic-related (c) 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] [promote ADD ARG] [encourage DEL PAK, EGY, IDN, BGD, ESW, MEX/RET USA, CAN, ARG, AUS, EU, UK [and incentivize ADD ARG] [require PAK, EGY] [where they deem appropriate CAN] [facilitate ADD BGD] [Guarantee that ADDD MEX] entities, [where they deem appropriate ADD AUS] [as appropriate UK] [including manufacturers [within their respective jurisdictions DEL PAK] DEL EU, USA, AUS], [that DEL PAK, RETAIN AUS] [to PAK] conduct research and development of [relevant countermeasures EU] [[[pre-pandemic and DEL USA, AUS] 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 DEL ARG][DEL voluntary and USA, AUS] [mutually agreed terms DEL PAK, ARG. BGD, ESW / RETAIN USA, AUS, ], licences to [capable DEL PAK, ARG. BGD] [geographically distributed USA, AUS] [capable [DEL ARG/RETAIN AUS] manufacturers RESERVE USA], [notably DEL USA, AUS] [including USA, AUS] from [low and lower-middle income EU] [developing DEL EU, ARG] [high income countries and middle and low income ADD ARG] countries, [with the aim to increase the affordability and availability of relevant countermeasures EU] [that operates in a manner that is consistent with their national guidelines and regulations, ADD BGD] [to use their intellectual property [and other protected substances, products, technology, know-how, information DEL RUS] and knowledge used in the process of [[development DEL RUS] and production of USA, AUS] [pandemic ADD AUS, RUS] [emergency response-related USA] [related ADD AUS] [response DEL AUS/RETAIN RUS] product[s USA, AUS] DEL PAK, ARG] [research, development and production, [in particular DEL UK] for DEL PAK] [of PAK] pre-pandemic and pandemic-related products DEL USA, AUS, MEX]; and DEL EU, JPN, RUS] [Manufacturers that receive public funding for research and development of pandemic related products shall transfer the relevant technology and know-how to other manufacturers, and Parties to grant non-exclusive licenses to manufacturers from developing and least developed countries ADD ZAF].

[ALT ESW (c) require entities, including manufacturers within their respective jurisdictions, that conduct research and development of pre-pandemic and pandemic-related products, in particular those that receive significant public financing for that purpose, to grant, licenses to capable manufacturers, notably from developing and least developed countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of pandemic response product research, development and production, in particular for prepandemic and pandemic-related products; and]

- [(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]
- [ALT 3 (C) States Parties shall provide, in their intellectual property laws and related laws and regulations, exemptions and limitations to the exclusive rights of intellectual property holders to facilitate the manufacture, export and import of the required health products, including their materials and components. AFR GROUP]
- [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 ADD SAU Collaborate [DEL ARG/RETAIN AUS] [with other Parties and relevant entities IDN] [to DEL ARG/RETAIN AUS] [ensure DEL CAN, AUS] [support CAN, AUS] equitable [global pricing CAN] [timely ADD ESW] and affordable [pandemic response funds DEL RUS][access to health technologies [through ADD JPN] [in particularly in developing countries ADD CHI] [that DEL JPN] promot[e DEL JPN] [ing ADD JPN] the strengthening of national [health DEL CHI] systems [, including at primary health care level, CAN] [and [to ADD COSR] [of innovation and health ADD CHI] mitigate social inequalities DEL IDN RUS][ and ensure that all people have equal access to the applications of scientific progress without discrimination. ADD COSR]

[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]

- [ALT 3(e) During inter-pandemic times, States Parties especially those housing manufacturers shall strengthen their domestic legislation to include legislation that support technology transfer while providing incentives such as tax breaks to manufacturers implementing these laws. AFR GROUP].
- [ALT (3) (d) (d) ensure that international collaborations on research and development of pandemic-related products, especially with regard to vaccine, therapeutics and diagnostics development, including representation from developing countries and entities, including manufacturers to conduct research and development of Pandemic related products to grant nonexclusive, licenses to manufacturers, notably from developing countries, to use their intellectual property and other protected substances, products, technology, know-how, information and knowledge used in the process of research, development and manufacturing of pandemic related products ADD PAK]

[MOVED FROM PARA 4 Apply the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement ARG];

- [NEW PARA (e) During inter-pandemic times, States Parties especially those housing manufacturers shall strengthen their domestic legislation to include legislation that support technology transfer while providing incentives such as tax breaks to manufacturers implementing these laws ADD ZAF]
- 4. [In the event of a pandemic [emergency USA], DEL BRA] the Parties [shall ADD BGD] [: DEL BRA/RETAIN AUS] [should make ADD BRA, PAK] 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 [DEL WHOLE SAU] [4 ALT The Parties acknowledge 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]
- [4 ALT In the event of a pandemic, the Parties shall take measures including suspending the enforcement of IPRs that may create barriers to manufacture and supply of products during the pandemic. ADD PAK]
  - (a) [[[will DEL NGA, IDN, ARM, EGY, <u>BGD</u>] [shall NGA, IDN, ARM, EGY, <u>ESW</u>] [take <u>DEL SGP</u>] [[consider taking ADD SGP] appropriate measures to [support <u>DEL BGD</u>] [implement <u>ADD BGD, ESW</u>] [an internationally-agreed ADD SGP] time-bound waiver[s <u>DEL SGP</u>] of intellectual property rights [in their jurisdiction ADD BGD] [that can accelerate DEL CHE/<u>RETAIN ESW</u>] [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/<u>RETAIN ESW</u>] up manufacturing of <u>DEL SGP</u>] pandemic-related products during a pandemic, to the extent [that such a waiver is ADD SGP]necessary to [facilitate the manufacturing PHI] [increase the availability and adequacy of affordable <u>DEL SGP</u>] [meet the need for ADD SGP] [pandemic-related products [to complement existing relevant flexibilities under the TRIPS Agreement PHI]; DEL USA, GBR, ARG, AUS, JPN, SAU, UK, RUS]
  - [(a) [[[will DEL NGA, IDN, ARM, EGY/ RETIN <u>SGP</u>] [shall NGA, IDN, ARM, EGY] [take <u>DEL SGP</u>] [[consider taking ADD SGP] appropriate measures to support [[an internationally-

agreed ADD SGP] time-bound waiver[s DEL SGP] of intellectual property rights [over ADD SGP] [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 DEL SGP] of pandemic-related products during a pandemic, to the extent that [it ensures the AFR GROUP] [facilitate the manufacturing PHI] [such a waiver is SGP] necessary to [meet the need for SGP] [increase availability and adequacy of affordable DEL SGP] pandemic-related products [which should include the diversification of production both raw material and complete products. AFR GROUP] [to complement existing relevant flexibilities under the TRIPS Agreement PHI]; DEL USA, GBR, JPN]

[NEW PARA In the event of a pandemic, the Parties will suspend the application of intellectual property rights that may create barriers to the manufacture and supply of products during the pandemic. Neither Party shall challenge these measures based on any international obligations that the Party suspending the obligation may have. ARG]

(b) [Affirm the right to use GBR, UK] [[will DEL CHE, NGA, IDN, ARM, AUS, BGD, ESW/RETAIN SGP] [shall NGA, IDN, ARM] [are entitled to CHE][endeavour to ADD SGP] [apply the DEL ESW] full use of DEL GBR, AUS, UK/RETAIN ESW] [are entitled to use ADD AUS] 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, UK] the research exception and "Bolar" provision), DEL UK] 31 and 31bis of the TRIPS Agreement DEL CHE, AUS]; RESERVE USA] [and not exercise any direct or indirect pressure or coercion on the parties using the flexibilities in the TRIPS Agreement. Further, state parties shall take measures to restrain the Non-State Actors including business associations from lobbying or advocating against the use of TRIPS flexibilities on the pandemic related products ADD BGD] [Parties should make use of the full flexibilities provided in the TRIPS agreement, without interferences that translate to the failure of granting non-exclusive licenses and transfer of relevant technology and know-how to manufactures ADD ZAF] [NOTE: Delink from chapeau 7.4 ARG, BRA] DEL JPN, SAU]

[ALT ESW (b) Shall make full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and in Articles 27, 30 (including the research exception and "Bolar" provision), 31 and 31bis of the TRIPS Agreement; and not exercise any direct or indirect pressure or coercion on the parties using the flexibilities in the TRIPS Agreement. Further, state parties shall take measures to ensure that Non-State Actors including business associations are prevented from lobbying or advocating against the use of TRIPS flexibilities on the pandemic related products.]

(c) [[shall DEL USA, <u>AUS</u>] [intend to USA, <u>AUS</u>] encourage [all DEL USA/<u>RETAIN AUS</u>, <u>SGP</u>] holders of patents [intellectual property ADD ARG] related to the production of pandemic [emergency response USA]-related products [to take steps to promote equitable access via voluntary licensing arrangements <u>ADD AUS</u>, <u>USA</u>] [to [consider waiving ADD SGP] [waive, DEL SGP] or [manage <u>DEL SGP</u>] [managing ADD SGP] as appropriate [and taking into account the humanitarian purpose ADD ARG], payment of royalties DEL USA, <u>AUS/RETAIN AUS</u>] [including with USA] [by DEL USA/<u>RETAIN AUS</u>] 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 [encourage ADD SGP]] [require <u>DEL SGP] DEL AUS</u>] [to ADD ARG] [may encourage ADD <u>AUS</u>] [, as appropriate, DEL IDN, <u>ARG</u>] those that have received public financing for the development of pandemic-related products to do so; DEL CHE, USA] and [at end of paragraph:

Parties shall suspend the enforcement of IPRs that may create barriers to manufacture and supply of products during a pandemic, to achieve and to promote sustainable and equitably distribution of production and transfer of technology and know-how ADD ZAF] DEL WHOLE BGD, ESW, JPN, SAU, RUS]

- [(c) ALT 4 (B) Shall apply the full use of the flexibilities provided in the TRIPS Agreement, without interferences that translate to the failure of granting non-exclusive licenses and transfer of relevant technology and know-how to manufactures, including those recognised in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and in Article 27, 30 (including the research exception and Bolar provisions), 31 and 31bis of the TRIPS Agreement AFR GROUP] [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]
- 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, PAK]. Encourage all holders of patents related to the production of pandemic related products to waive, or manage as appropriate, payment of royalties by developing country manufactures on the use, during the pandemic, of their technology for production of pandemic related products, and shall require, as appropriate, those that have received public financing for the development of pandemic related products to do so; and
- (d) [shall <u>DEL AUS</u>] [ensure IDN] [may ADD AUS] [encourage DEL IDN] all research and development institutes, including manufacturers, in particular those receiving significant public financing, to [waive <u>DEL SGP</u>] [consider waiving <u>ADD SGP</u>], or [manage <u>DEL SGP</u>] [managing ADD SGP] as appropriate, royalties on the continued use of their technology for production of pandemic-related products. RESERVE EU/DEL JPN, BGD, ESW, SAU, RUS]
  - [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 **[has been NGA]** 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, PAK, AFR GROUP] [Encourage all holders of patents related to the production of pandemic related products to waive, or manage as appropriate, payment of royalties by developing country manufactures on the use, during the pandemic, of their technology for production of pandemic related products, and shall require, as appropriate, those that have received public financing for the development of pandemic related products to do so; and BRA, PAK] [NEW PARA ) shall encourage transparency of prices and economic data along the value chain of pandemic-related products in particular on those that have received public financing ARG]

5. [[For purposes of this Article, "capable [DEL ARG] manufacturer" refers to an entity that operates in a manner [that is DEL ARG] consistent with national and [/or IDN] international guidelines and regulations, including biosafety and biosecurity standards. DEL RUS] MOVE under Article 1 SWZ, ARG, IDN, CAN, ROK, AFR GROUP RESERVE PARA 5 USA] RESERVE Article 7 AUS] [MOVE TO ARTICLE 1 ESW, MEX, RUS] [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] DEL AFR GROUP] [NEW PARA 6 The parties shall ensure, when engaged in bilatareal or regional trade or investment treaty negotiations to not include provisions that interfere with the full use of the flexibilities provided in the TRIPS Agreement, including those recognized in the Doha Declaration on the TRIPS Agreement and Public Health of 2001 ARG]

Article 8. [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] <u>DEL AFR GROUP</u>[Regulatory strengthening

1. [[For the purposes of regulating pandemic-related products, AUS, JAM] [T DEL AUS, JAM] [t ADD AUS, JAM] he Parties shall [endeavor to ADD CAN] strengthen the capacity [and performance DEL JAM] of [relevant AUS] national [and regional ETH, AUS] regulatory authorities [and endeavour to AUS] [and DEL PAK, ARG/RETAIN CAN] [aim to ADD CAN] [. [W DEL JAM] [w ADD JAM] here [as ADD PAK] appropriate, [the Parties shall PAK, AFR GROUP, ARG] [increase DEL RUS] [as appropriate, ADD SGP] [strive to ensure ADD RUS] the [harmonization DEL AUS] [convergence AUS, PRY] of regulatory requirements [to support reliance-based decision making AUS, NZL] at the international [and DEL AUS] regional [and bilateral AUS] level[s AUS][where appropriate ADD CAN] [, including, as applicable, through [capacity building cooperation between regulatory [authorities DEL PRY] and IDN] [facilitated THA] mutual recognition agreements DEL BGD] DEL AUS, NZL, UK]. 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 AFR GROUP] [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. BGD1

2. [Each Party [encourage to ADD SAU] shall build and strengthen its country ['s ADD JAM] [and/or regional ETH, AUS regulatory capacities [, reliance practices AUS] [and performance DEL JAM, PAK] [including but not limited to the capacities of regulators, assessors and inspectors in the areas of registration, clinical trial approvals, pharmacovigilance, good manufacturing practices as well as quality management systems, UK] for DEL CHN/ RETAIN AUS] [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 ADD SAU] [where applicable, AUS] the sharing of [[regulatory [dossiers DEL AUS, RUS]] DEL THA, BRN, UK] 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, AFR GROUP] [regulatory ETH] institutions DEL UK] [information and data, in accordance with national laws, with other national regulatory authorities UK] [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 is fundamental. ZAF AFR GROUP]

#### [To this end, parties shall:

- (a) provide appropriate exceptions to any exclusive rights in test data used to establish the safety and efficacy of products, and
- (b) ensure that information regarding the design of tests for bioequivalence or bio-similarity be shared with generic producers.
- (c) require that pandemic products be registered in all countries and regions in which the product is needed or requested. AFR GROUP]

[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 **work program ARG**], including a [schedule ARG] timeline, for the alignment of the key regulatory requirements and practices for multi-regional

and multi-country [multinational ARG] clinical trials so that, in the face of new public health emergencies, countries are ready to offer an immediate regulatory response. BRA, ARG]

[NEW PARA 2 bis: 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 authorising or approving use of pandemic emergency response-related products during a pandemic;
- (b) any additional relevant regulatory flexibilities or programs that may be activated during pandemics; and
- (c) a contact point within each relevant national and/or regional regulatory authority for inquiries concerning its pandemic processes and procedures.

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

[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, [endeavour ADD CAN] as appropriate, [to ADD CAN] monitor and regulate against substandard and falsified pandemic-related products, [including AUS] through existing [Member State DEL CHN] mechanisms on substandard and falsified medical [and laboratory ADD MEX] 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, <u>AUS</u>]

[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 Ensure and promote, including via conditions in funding agreements, wide and rapid registration of health tools, including where clinical trials have been conducted ADD SAU]

[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]

[4. [New para] The Parties shall promote responsible and sustainable use of pandemic products across sector, particularly antimicrobial use and consumption in human and animal sectors, through the adoption of appropriate regulation. ADD SGP]

[NEW PARA 4. [Each Party shall take steps to ensure that it has legal, administrative, and financial frameworks in place to support emergency regulatory approvals for the effective and timely regulatory approval and procurement of pandemic response products during a pandemic. UK]

[NEW PARA 5. [Each party should consider putting in place for emergency use during a pandemic, a framework to enable the use of a reliance or recognition process, in accordance with national laws, if it lacks the systems and capacity to undertake its own national regulatory approval for pandemic response products in an effective and timely manner.UK]

[ALT ARTICLE 8 TEXT:

## [RESERVE ALT ARTICLE 8 TEXT AFR GROUP]

- 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.

# 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 response-related products.
- 7. The Parties, as appropriate, intend[s <u>DEL USA</u>] 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<sub>1</sub>

[New USA Proposal: Liability Risk Management

- 1. Each Party shall develop national strategies for managing liability risks in its territory regarding the manufacture, distribution, administration, and use of pandemic emergency response-related products. Strategies could include, for example, the development of model contract provisions, no-fault compensation mechanisms, insurance mechanisms, policy frameworks and principles for negotiation of procurement agreements and/or donation of pandemic emergency response-related products, and building expertise for contract negotiations in this matter.
- 2. Each Party shall implement or participate in no-fault compensation mechanisms for pandemic emergency response-related products that are transparent and complement any liability protections

and/or other liability risk management mechanisms, and shall consider developing strategies for sufficiently funding such mechanisms.

- 3. The Parties request that WHO and other relevant entities, as well as its regional offices, coordinate to expand country eligibility for existing no-fault compensation mechanisms for pandemic emergency response-related products or to create new mechanisms.
- 4. In accordance with national laws, each Party shall make publicly available online information regarding any global, regional, or country-level liability frameworks and no fault compensation mechanisms that apply to the manufacture, distribution, administration, or use of pandemic emergency response-related products during pandemic emergencies in its jurisdiction. WHO shall compile links to such information on its website.
- 5. The Parties shall work with WHO and other relevant organizations, as appropriate, to develop recommendations for and capacity building tools on liability risk management during pandemic emergencies, regarding the manufacture, distribution, administration, or use of pandemic emergency response-related 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, AFR GROUP]Increasing research and development capacities [RESERVE JAM][ [in support of equitable access to pandemic-related products ROK]

# [ALT ARTICLE 9 TITLE Strengthening research and development (R&D) processes and capacities is an essential component of regulatory strengthening. ADD SAU]

1. The Parties recognize the need to build and strengthen [cross-sectoral UK] capacities and institutions for [innovative DEL ETH, USA, PAK, RUS] [well-designed and well-implemented USA] [scientific ADD RUS] research and development for pandemic [emergency response USA] -related products, and research regarding the impact of pandemic and of public health measures implemented (including social, epidemiological and communication research) ADD ARG [in non-pandemic periods, including those which may be needed in the animal health sector UK] [particularly in DEL USA, **RETAIN ARG**] [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] [, taking into account the vast diversity of the laws, regulations and customs which, in different countries, determine the pattern and organisation of science technology and innovation ADD SGP [ taking into account

applicable, including local rules regarding legal protection created results of intellectual activity ADD RUS]

[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]

# [NEW PARA 1. bis: [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 (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]

[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] SHOULD BE MOVED FOR DISCUSSION UNDER ARTICLE 20 AFR GROUP]

# [NEW PARA Art 9.1(bis) 1. The Parties will develop national approaches to support the transparent, public sharing of clinical trial results conducted within their territories AUS]

- 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 AFR GROUP], DEL THA] [efficiency of R&D, and equitable access to health tools MYS] [facilitating equitable access to pandemic-related medical products ADD MEX] 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 DEL AFR GROUP] [received DEL THA, AFR GROUP, MEX, RUS] [provided THA] [include terms and conditions on recipients for, inter alia: ADD MEX] DEL BGD]:
  - (a) [promote DEL ETH, AFR GROUP/ RETAIN AUS] [require ETH] [ensure AFR GROUP] [guarantee ADD ARG] the [open innovation ensuring freedom of operation to all BGD] [free, DEL JPN, RUS/RETAIN ARG, AUS] public DEL RUS] dissemination of the results of [publicly and DEL USA, AFR GROUP, AUS/RETAIN ARG] government-funded research [and promote the same for research that is not publicly funded ETH, AFR GROUP] 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]; [in accessible languages and formats; ADD COSR]
  - (b) [[endeavour to DEL ETH, IDN, BGD, <u>ARG, JAM</u>] [consider ADD JAM] [ensure IDN] includ[e <u>DEL JAM</u>] [ing <u>ADD JAM</u>] terms and conditions on prices of products, [<u>pricing policies, ADD SAU</u>] allocation, data sharing and transfer of technology, [<u>as well to exclude confidentiality provisions ADD ARG</u>] as appropriate, [<u>taking into account the current, including local rules in regarding the legal protection of the created results of intellectual property activities <u>ADD RUS</u>] [and publication of contract terms <u>DEL SAU</u>] [in accordance with national laws <u>ADD JAM</u>]; <u>DEL JPN, AUS</u></u>

[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 <u>USA/ DEL AUS</u>]-related products, at the earliest reasonable opportunity and to the fullest extent possible in accordance with national laws. USA, AUS]

- (b) [ensure that promoters of research for pandemic-related products assume an appropriate level of the associated risk DEL USA, <u>RETAIN ARG</u>][; and that they are obliged to maintain affordable prices for products throughout the entire stage of the pandemic, including during the recovery stage, until coverage of XXX of the exposed population is achieved ADD ARG][, as well as comply with relevant safeguard guidelines established in national legislation and/or relevant international agreements, in force or derived from the health emergency; ADD MEX];
- (c) [[consider USA, <u>JAM</u>] promot[e DEL USA, JAM] [ing USA, <u>JAM</u>] [, facilitate IDN] and incentiviz[e DEL USA, JAM] [ing USA, <u>JAM</u>] technology co-creation and joint venture initiatives [with developing State Parties THA] [as needed and create public research and development initiatives ETH]; and **DEL RUS**]
- (d) [[consider including [through effective regulations and policies IDN] provisions promoting global access in USA] [establish[ing ADD JAM] [and enact ETH] [appropriate DEL BGD] [conditions DEL JAM] [in the grant agreement BGD] [mechanisms to facilitate ADD JAM] [for publicly DEL USA] [government USA] funded research DEL BGD] and development DEL BGD] [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] [with taking into account the existing, including local rules regarding the legal protection of the created results of intellectual activity ADD RUS] and pricing [through effective regulations and ADD IDN] [policies DEL IDN/RETAIN IDN] [during pandemic emergencies USA]. DEL JPN]
- [NEW f) [consider promoting USA/<u>DEL AUS</u>] [<u>promote ADD AUS</u>] and [prioritizing USA/<u>DEL AUS</u>] [<u>prioritize ADD AUS</u>] investment in research and development of pandemic [emergency response USA/<u>DEL AUS</u>]-related products that can expand accessibility across diverse settings and among diverse populations. USA, <u>AUS</u>]

[NEW f) affordable pricing of end products, including on a no-profit or no-loss basis upon PHEIC determination

[(NEW PARA 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].

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 MYS1

[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 AFR GROUP]

[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 AFR GROUP]

[NEW h) States Parties shall strengthen their domestic legislation to include laws that support technology transfer while providing incentives such as tax breaks to manufacturers implementing these laws. AFR GROUP]

[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]

[NEW g) provide for regulatory frameworks that progressively force private producers to comply with similar commitments to those stated in this section, in the event of pandemics 1 ADD ARG]

#### [ALT 9(2) SUB-ARTICLES MEX

- a) Providing public access to research outputs;
- (b) Performing technology transfer for the manufacture of resulting pandemic-related medical products to capable manufacturers in geographically diversified regions;
- (c) Adopting affordable and economically sustainable pricing policies, including on a no profit/no loss basis upon PHEIC determination;
- (d) Granting of non-exclusive licenses, including provisions for data sharing, technology transfer and waiving or managing as appropriate royalties;
- (d) Agreeing commitments to timely supply of dedicated volumes of medical countermeasures to developing countries and/or delegated global or regional procurement entities;
- (e) Providing licenses and rights to assume or sublicense the development and/or commercialization of funded products in the event of actual or anticipated failure or shortcoming by a product developer to perform its obligations under funding agreements;
- (f) 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 ADD MEX]

[Article 9.2 bis: With a view to promoting greater sharing of knowledge, transparency, [ADD efficiency of R&D, and equitable access to health tools], each Party, when providing public funding for research and development for pandemic prevention, preparedness, response and recovery of health systems, shall, [ADD include binding terms and conditions on recipients of publicly funded research and development, which include: public dissemination and transparency of research inputs (including specimens, samples, compound libraires, and datasets with appropriate data protections), processes (including protocols, clinical trial design, and R&D costs), and outputs (including clinical trial results, open access publications, and data sharing); b) affordable pricing of end products, including

on a no-profit/no-loss basis upon PHEIC determination; c) 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; d) adherence to allocation frameworks as determined by WHO when PHEIC is declared; and e) 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 AFR GROUP]

[2bis:States Parties shall encourage the public dissemination of the results of privately funded research for the development of pandemic related products AFR GROUP]

- 3. [Each USA] The [ADD ARG] Part[y USA] [ies shall DEL USA, RETAIN ARG] [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 DEL RUS] [while balancing transparency with security CAN] by: DEL SAU]
  - (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, <u>SAU</u>, <u>RUS</u>] [licensing and funding agreements ETH, <u>AFR GROUP</u>];

### [ALT EU disclosing disaggregated information, for instance by sex and age..."]

- (b) [making it compulsory for manufacturers [that receive public funding for the production DEL ETH, <u>AFR GROUP</u>] of pandemic-related products to disclose prices and contractual terms [where appropriate ADD AUS] for public procurement in times of pandemics[, taking into account the extent of the public funding received DEL ETH, <u>AFR GROUP</u>]; and DEL CAN, JPN, SAU, USA, SAU, RUS]
- (c) [[encouraging DEL BRA, <u>AFR GROUP</u>, <u>ARG</u>] [ensuring BRA, <u>AFR GROUP</u>, <u>ARG</u>] 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 , <u>RUS</u>/RETAIN BRA, <u>AFR GROUP</u>]
- [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, <u>AUS</u>]
- [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, <u>AFR GROUP</u>] 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. [New para] The parties shall facilitate a One Health, needs-driven model of research and development for anti-infective agents, including new antimicrobials (particularly antibiotics), while also ensuring equitable and sustainable access to these products. ADD SGP] [The Parties shall establish, no later than [XX 12 months following the treatz entrz into force NGA, with reference to existing models, [and taking into consideration each States Parties' needs and context, ADD SGP] a [global DEL SGP] [national ADD SGP] compensation mechanism for injuries resulting from pandemic [response products AFR GROUP] [vaccines DEL AFR GROUP/RETAIN NGA] [or other therapeutics ADD NGA] [to which Parties shall contribute based on the principle of Common but Differentiated Responsibilities BGD]. DEL CAN, RUS, USA, SAU, CHN, AUS, RUS] [Reserve to be discussed along with finance and benefit sharing AFR GROUP]

[(5 bis) The Parties shall ensure no-fault compensation funds are available to compensate individuals for serious adverse events from pandemic response products that are in research phase or under emergency use approval AFR GROUP].

# [DEL 9(5)-9(7) BRN]

- 6. [Pending establishment of such [global <u>DEL SGP</u>] [national <u>ADD SGP</u>] compensation mechanism, each Party shall, in contracts for the supply or purchase of pandemic-related products, [endeavour [BGD]] to DEL IDN] exclude [buyer/recipient <u>DEL JAM</u>] indemnity clauses [in favour of the producer or seller <u>ADD JAM</u>] 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 [or for risks derived from the gross or willful negligent conduct of the manufacturers, especially regarding aspects related to the ethics of the investigation ARG] [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 in supply contracts with other parties. BGD] DEL CAN, RUS, USA, JPN, SAU, CHN, AUS] Reserve to be discussed along with finance and benefit sharing AFR GROUP]
  - 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, <u>AFR GROUP, ARG</u>] exclude confidentiality provisions that serve to limit disclosure of terms and conditions. DEL USA, JPN, SAU, CHN, <u>AUS, JAM, RUS</u>] RETAIN AFR GROUP Delete all references to endeavour and replace with shall AFR GROUP]
  - **8.** [Each Party shall [, as applicable, DEL BGD] [and in accordance with national laws ADD JAM] implement and apply [relevant USA] [the minimum ADD CHI] international [biosafety and biosecurity CAN] standards for [Biorisk management, including USA], oversight of and reporting on laboratories [and <u>DEL MEX</u>] research [and diagnostic ADD MEX] facilities that carry out [pandemic prevention, preparedness, and response-related research and development, USA] [work to genetically alter organisms [,including research ADD AUS] to [increase <u>DEL MEX</u>] [modify ADD MEX] their pathogenicity and transmissibility, DEL USA] [strictly for the advancement of science and medicine... ADD ZAF] in order to prevent [[accidental DEL CAN] release DEL USA] [unintended or deliberate misuse USA] [or misuse DEL CAN] 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] [and this must be monitored and reported to the WHO ADD ZAF].

[NEW PARA 8 bis: The parties [are encouraged to **DEL AFR GROUP**] [shall AFR GROUP] 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, <u>AUS</u>]

[NEW (8) SUB-PARA ii. [Each party shall notify WHO of any such work to genetically alter organisms to increase their pathogenicity and transmissibility with the name and address of such laboratories and research facilities ADD ZAF].

[NEW (8) SUB-PARA ii. [Each party shall immediately inform WHO of any incidents whare there was accidental release of these pathogens regardless of the measures put in place to contain them, indicating the name and address of the laboratories and research facilities that had such incident as well as measures being put in place to mitigate the effects of the incidence ADD ZAF]

- 9. The Parties [are encouraged to **DEL MEX**] [shall ADD MEX] promote [, cooperate IDN] and strengthen knowledge translation and [science and ADD AUS] evidence-based communication tools [, USA] [and DEL USA] strategies[, and partnerships USA] relating to pandemic prevention, preparedness, response and [health systems ADD JAM] 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/RETAIN BRN] [public health, and health policy ADD BRN] research ecosystems, [including national and global clinical research networks USA] [and ensure international standards for ethical research and procedures PHL] [focused on pandemic prevention, preparedness, and response ADD BRN]. In that regard, the Parties[, as appropriate DEL BGD/RETAIN BRN] [, commit to DEL USA/RETAIN BRN]: [NEW (a) bis) 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, AUS]

[NEW (a) ter 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, AUS]

[NEW PARA (a): 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, AUS]

[NEW PARA (b): 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, <u>AUS</u>]

[NEW PARA (c): 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, AUS]

[NEW PARA (d): 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]

(a) [foster[ing DEL USA] **DEL JAM]** [encouraging ADD JAM] and [or ADD JAM] 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, AFR GROUP] [and guidelines PHL];

[NEW PARA (a bis) Promote the establishment of national, regional and global clinical research networks that are coordinated and work collaboratively in order to conduct timely research on new treatments and vaccines to tackle pandemics in the shortest possible time while avoiding the duplication; BRA]

[NEW PARA (a ter) Invest in infrastructure and training of clinical research networks in developing countries in order to be prepared to provide timely and appropriate responses to pandemics; BRA]

[NEW PARA (a quart) Ensure that clinical trials conducted during health emergencies are equitable, address geographic, socioeconomic and health disparities and promote racial, ethnic and gender diversity for better understanding of the safety and efficacy of new vaccines and treatments in subgroups of the population. BRA]

[NEW PARA (b bis) Ensure that resources are directed to well-designed projects that can produce robust and reliable evidence. BRA]

[ALT 9(10)(A) BRN (a) fostering and coordinating PPR-related research including appropriate multi-center studies, leveraging on where appropriate;]

(b) [ensuring equitable access to resources (funding or in-kind), clinical research and clinical trials [and sufficient quantities of tested products ETH, <u>AFR GROUP</u>], so that resources are deployed optimally[, equitably ETH, <u>AFR GROUP</u>] [and DEL IDN] efficiently [as well as geographically and strategically distributed IDN] DEL JPN, SAU, USA, <u>RUS</u>];

[ALT 9.10. (b) BRN ensure support for capacity building programmes, projects, partnerships, and resources for the conduct of PPR-related research, at the national level and the international level with preferential access for researchers from countries with more limited research capacity;]

- (c) [supporting DEL USA] [intend to promote, in accordance with national laws, USA] transparent [ethical ADD BRA] 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] [as appropriate ADD AUS] [including negative, nul and unexpected results,BRA] 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, <u>AUS</u>] disclos[e USA] [ing DEL USA, <u>AUS</u>] disaggregated information, for instance by <u>[ sex ADD AUS]</u> gender [and <u>DEL AUS</u>] age, [and health condition ADD AUS] to the extent possible and as appropriate, on the results of clinical research and clinical trials relating to pandemic prevention, preparedness, response and <u>[health systems ADD JAM]</u> recovery [of health systems THA, AUS][ while ensuring the protection of personal data.. BRA]

[NEW PARA E ensure trials are designed in a manner that address needs of patients globally, particularly those in developing countries; and AFR GROUP]

[NEW (e) [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 multi-center research and mechanisms to support emergency governance approaches during a pandemic to support expedited review where necessary; UK, AUS]

[NEW PARA (f): guarantee rapid and ongoing availability of products tested in trials to the populations making up the trial population AFR GROUP]

[NEW PARA(f) 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, AUS]

[NEW PARA (g): 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, AUS]

- [11. Foster information sharing through open science approaches for rapid sharing of scientific findings and research results, irrespective of the outcome AFR GROUP]
- [12. Strengthen research and development processes and capacities and increase resources, human and financial, for rapid and timely development and production, at national, regional and global levels, of pandemic response products, particularly in developing countries. AFR GROUP]

[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, <u>AUS</u>] [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

# [RESERVE NEW ARTICLE 9. Scientific and research cooperation AFR GROUP]

- 1. 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;
- c. 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.

[RESERVE: UK on all paragraphs in this Article 9 for which they did not provide textual amendments. RESERVE ON NEW ARTICLE 9 AFR GROUP]

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

[ RESERVE Article 10 [[[WHO Pathogen Access and Benefit-Sharing System AFR GROUP, JAM, CHE]

### [ALT: AMENABLE TO FURTHER NEGOTIATIONS AFR GROUP]

[NEW CHAPEAU The need for a transparent multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with human pandemic potential and including genomic sequence data, and fair and equitable benefits arising therefrom, that applies and operates in both interpandemic and pandemic times, is hereby recognized. In pursuit thereof, it is hereby agreed to establish the WHO Pathogen Access and Benefit-Sharing System (the "PABS System"). WHO shall ensure the full application of the WHO PABS System to all WHO Members with respect to access to pathogens with human pandemic potential including genomic sequence data and fair and equitable benefit sharing arising therefrom ADD ZAF].

1. The [Parties [recognize [the ADD ARG]] that global pandemic preparedness and response BRA, PAK, DOM, HTI, CHN] [the DEL BRA, PAK] [need for a DEL BRA, PAK, DOM, CHN] [requires BRA, PAK DOM, HTI, CHN] [a DEL BRA, PAK] multilateral, fair, equitable and timely [system for DEL BRA, PAK, DOM, CHN] sharing of, on an equal footing, [of data on the genomic sequences of pathogenic microorganisms ADD RUS] pathogens with pandemic potential [[and DEL BRA, ARG, BGD] [including their BRA, PAK, DOM, CHN] [genomic DEL BGD, RETAIN ARG, BGD] [genetic COL] sequences DEL BGD, JPN, RUS] [genomic sequence data or parts thereof ADD BGD] [and digital sequence information BRA, PAK, DOM, CHN, ARG] 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, ARG] [their DEL BRA, PAK] from DEL BGD] from [their utilization BRA, PAK, DOM, CHN, ARG, BGD], [that applies and operates in both inter-pandemic and pandemic times, [is hereby recognized DEL BRA, PAK, DOM, CHN, ARG] [including access to pandemic-related

products BRA, PAK, DOM, CHN]. In accordance with the provisions included in the Convention of Biological Diversity and Nagoya Protocol on access and benefit sharing ADD ARG] In pursuit thereof, [the Parties agree BRA, PAK, DOM, CHN] [it is agreed DEL BRA, PAK, DOM, CHN, BGD] [to DEL BGD] [Parties hereby ADD BGD] 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 DEL BGD]. The [terms of the DEL BGD] PABS System shall be [developed BGD] [operational ADD BGD] [no later than XX with a view to their provisional application consistent with Article 35 hereof DEL BGD] DEL BRA, PAK, DOM, TUN, CHN, IRN, IDN] [vears of the adoption of WHO CA+, and in cases where WHO CA+ has not entered into force by virtue of Article 35. ADD BGD].

[ALT (1) SAU [The need for a multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with pandemic potential and genomic sequences, and benefits arising therefrom, that applies and operates in both inter-pandemic and pandemic times, is hereby recognized. In pursuit thereof, it is agreed 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]

[ALT (10(1) In the exercise of their sovereign rights, the Parties agree to establish a multilateral system, which efficient, effective, and transparent, to facilitate access to pathogens with pandemic potential, their genetic sequence data and other forms of digital sequence information on genetic resources, and to share, on an equal footing and in a fair and equitable way, the monetary and non-monetary benefits arising from the utilization of such resources, data and sequence information]. ADD ZAF]

# [NEW PARA 1Bis. The WHO Pathogen Access and Benefit Sharing System (the "PABS System") is hereby established. IDN]

[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]

- 1. The [Parties recognize that global pandemic preparedeness and response BRA, PAK] [the need for DEL BRA, PAK] require[s DEL BRA, PAK] a multilateral, fair, equitable and timely [system for DEL BRA, PAK] sharing of, on an equal footing, pathogens with pandemic potential [and DEL BRA, PAK], [including BRA, PAK] their genomic sequences [and digital sequence information BRA, PAK] and benefits [that BRA, PAK] aris[ing DEL BRA, PAK]e [there DEL BRA, PAK] [from their utilization BRA, PAK], [that applies and operates in both inter-pandemic and pandemic times, is hereby recognized DEL BRA, PAK].[including access to pandemic-related products BRA, PAK]. In pursuit thereof, [the Parties agree BRA, PAK] 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].
  - 2. [The PABS System shall [cover all <u>[genomic sequence data ADD RUS]</u> [pathogenic microorganisms pathogens with pandemic [and <u>PHEIC ADD BGD</u>] potential, [<u>their genomic sequence data and parts thereof ADD BGD</u>] [including their genomic sequences, <u>DEL BGD, RUS</u>] [and digital sequence information ADD ARG] as well as access to benefits arising [<u>from their</u>]

utilization. ADD BGD] [therefrom, and ensure that it DEL BRA, PAK, BGD] 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] [operates [synergistically DEL IDN, SGP] [consistently ADD IDN] [in a manner compatible ADD SGP] with [the Convention on Biological Diversity and the Nagoya Protocol ADD IDN] on Access and Benefit Sharing, or any ADD ARG] other relevant DEL BRA, PAK, BGD] [international access and benefit-sharing instruments BRA, PAK, DEL BGD].[The health assembly or the governing body of WHO CA+ may at any point of time, after 5 years of successful functioning, may include other pathogens, their genomic sequence data or any other genetic resources related to public health ensuring benefits arising from their utilization are also shared fairly and equitably through PABS System ADD BGD].[The PABS System shall also apply to pathogens that have the potential to cause a public health emergency of international concern within the scope of the IHR. ADD IDN] DEL ZAF]

[ALT 10 (2)(a): [The PABS System shall cover all pathogens with human pandemic potential, including their genomic sequence data, as well as fair and equitable benefit-sharing arising therefrom and ensure that the PIP Framework operates synergistically with the PABS System. The PABS System in its entirety shall also apply to pathogens that have the potential to cause a public health emergency of international concern within the scope of the IHR. ADD ZAF]

[ALT 10 (2)(b)[The scope of the PABS System may be extended to include other pathogens and their genomic sequence data currently being shared by Members, with additional fair and equitable benefit sharing commitments including appropriate amendments to the SMTAs, upon the decision by the World Health Assembly ADD ZAF]

[ALT 10 (2) (c) [ADD The production of vaccines, diagnostics, therapeutics and other medical products for public health emergency of international concern and pandemic, irrespective of the technology, information or material used, implies use of pathogens with human pandemic potential including genomic sequence data. ADD ZAF]

[NEW PARA 2. The PABS system aims to ensure public and timely access to pathogens with pandemic potential and the corresponding benefit sharing ARG] DEL JPN

3. [The PABS System shall include the following elements and shall be regulated as follows: **DEL ZAF**, **RUS**] [For the purposes of PABS, the following definitions shall apply ADD ZAF]

[Access to pathogens with pandemic [and pheic ADD BGD] potential DEL RUS]

(a) [Each Party <u>DEL BGD</u>] [PABS System shall ADD BGD], [through its relevant [public health authorities ADD PHL] and authorized laboratories, shall <u>DEL BGD</u>] [provide access to ADD BGD], in a [rapid <u>DEL BGD</u>], systematic and timely manner: (i) [provide <u>DEL BGD</u>] pathogens with pandemic [and PHEIC ADD BGD] potential from early infections due to pathogens [with pandemic potential <u>DEL BGD</u>] or subsequent variants [to a laboratory <u>DEL BGD</u>] [through laboratories ADD BGD] [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 <u>DEL BGD</u>] the genomic sequence [data ADD BGD] of such pathogens [with pandemic potential <u>DEL BGD</u>] [or parts thereof ADD BGD] [to <u>DEL BGD</u>] [one or more publicly accessible <u>DEL BGD</u>] database [established by WHO ADD BGD] [of its choice DEL BRA, PAK, DOM, CHN, <u>BGD</u>] [a designated database(s) BRA, PAK, DOM, CHN, <u>ARG</u>] DEL JPN]. [ to entities,10 that agree to terms and conditions of PABS system

including the applicable standard agreements as provided in Annex [X]. ADD BGD] [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, BGD, ZAF, RUS]

(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 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 databases of its choice DEL BRA, PAK] [a designated database(s) BRA, PAK]. [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, PAK]

[ALT PARA 3(a) Any Party, providing through its authorized laboratories,: (i) pathogens with pandemic potential from early infections due to pathogens with pandemic potential or subsequent variants to a laboratory recognized or designated as part of an established WHO coordinated laboratory network,; and (ii) genomic sequence of such pathogens with pandemic potential, does so on the understanding that the Terms of Reference of the WHO Coordinated laboratory Network and Standard Material Transfer Agreements are applicable, Sharing of genomic sequences shall be through a WHO managed database that is transparent and accountable to WHO Members and that facilitates user access through a click-wrap data user agreement that inter alia operationalizes fair and equitable benefit sharing and allows monitoring of medical research or any other research that genetically alters an organism to enhance its biological characteristics or functions, ADD IDN]

[ALT PARA 3(a) [PABS Materials: means pathogens with human pandemic potential, whether wild-type or modified, including their biological materials and parts thereof, clinical specimens, genomic sequence data including associated data (meta and clinical data), within the scope of PABS System] ADD ZAF]

[NEW 3 (a) bis In the event of a pandemic, the Parties may develop the activities referred in subparagraphs (i) and (ii) of paragraph (a), through any laboratories, regardless of its relevance or authorization" ADD MEX]

### [NEW TITLE WHO Coordinated Laboratory Network ADD BGD]

(b) [[The PABS System will be consistent with international [, regional and national SAU] legal frameworks, notably those for collection of patient specimens, [and about the confidentiality of ADD ARG] [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] DEL WHOLE BGD, IDN, RUS]

[ALT. A WHO Database for sharing of genomic sequence data and other associated information as well as fair and equitable sharing of benefits arising from their use is hereby established. Any sharing of genomic sequence data of pathogens covered under PABS system or parts thereof shall be through the database established by WHO, subject to the

# national laws and regulations regarding the data collection, storage, sharing and processing ADD BGD

[ALT 10(3) (b) Genomic Sequence Data: "genomic sequences" means the order or sequence of the nucleotides in DNA and RNA, or amino acids in proteins. They contain genetic information that determines the biological characteristics of an organism or a virus. In the case of viruses, this includes characteristics such as pathogenicity, transmissibility and antiviral susceptibility. Laboratories can determine the genetic sequence of a particular organism, using sequencing technologies. The data generated through this process is called "genomic sequence data (GSD)" or "genetic sequence data (GSD)" ADD ZAF].

(c) Access shall be accorded [expeditiously <u>DEL IDN</u>] by <u>I and among ADD IDN</u>] the laboratory recognized or designated as part of an established WHO coordinated laboratory network, subject to [conclusion <u>DEL IDN</u>] [the application ADD IDN] of [a <u>DEL IDN</u>] [the annexed ADD IDN] Standard Material Transfer Agreement, <u>II ADD IDN</u>] [which will be agreed upon by the Parties BRA, PAK] [developed for the purposes of the PABS System, with the recipient in accordance with subsection (i) below. <u>DEL IDN</u>] 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 <u>DEL IDN</u>, <u>RUS</u>] [which shall not include operational costs of the PABS System JPN]; <u>Any onward transfer and use of pathogens of pandemic potential including genomic sequences outside the WHO Coordinated Laboratory Network shall only be to specified entities that have signed SMTA2. ADD IDN]</u>

[ALT 10(3)(c) Authorized national laboratories: means laboratories authorized and designated by a Member State to provide PABS Materials to the PABS System and recognized as part of the WHO Coordinated Laboratory Network. ADD ZAF]

#### [NEW TITLE Standard Agreements ADD BGD]

(d) [Recipients of materials [and data ADD PHL] shall not claim any intellectual property or other rights [that limit the facilitated access DEL BRA, PAK, DOM, CHN, ARG, IDN] [to DEL IDN] [on the ADD IDN] pathogens with pandemic potential, or their genomic sequences or [their BRA, PAK, DOM, CHN] [any ADD IDN] components, [or digital sequence information BRA, IDN, PAK, DOM, CHN, ARG] [thereof ADD IDN] [in the form received DEL BRA, PAK, DOM, CHN]; and DEL JPN, BGD, RUS [or on any other form or for any use. ADD IDN]

[ALT. PABS system shall ensure entities having access to pathogens, genomic sequence data or parts thereof have entered into applicable relevant standard agreements with WHO as provided in Annex [X] before their access. BGD]

[ADD DEFN 10 (3) (d) [Qualified Entities: Manufacturers of diagnostics, vaccines, therapeutics and other medical products means public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations, commercial entities, that develop and/or produce diagnostics, vaccines, therapeutics and other medical products including personal protective equipment (PPE), ancillary medical supplies and other supplies required for administration of diagnostics, vaccines and therapeutics as well as any other products required for prevention, control and response in relation to spread of infection and disease ADD ZAF].

[NEW TITLE Non-Applicability of Intellectual Property Rights BGD]

- (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, <u>ARG</u>] RESERVE ON SECTION, IRN] **DEL WHOLE BGD, IDN, RUS**]
- [ALT. Parties shall not grant Intellectual Property Rights over Pathogens, genomic sequence data or parts thereof covered under PABS system, their modified forms, their use in natural or modified form in any specific health product or technology. BGD]

[ ADD DEFN 10 (3) (e) [ADD WHO Coordinated Laboratory Network means an international network of authorized national laboratories coordinated by WHO and governed by the PABS System. To be a part of the WHO Coordinated Laboratory Network, an authorized national laboratory must meet the criteria for designation and agree to comply with provisions of SMTA 1 and annexed Terms of Reference ADD ZAF].

# [Fair and equitable benefit-sharing [RESERVE ZAF] DEL RUS]

- [The Parties agree that benefits [monetary and non monetary COL] arising from facilitating (f) access to [ and use of ADD BGD] pathogens [and information on pathogens ADD PHL] [with pandemic potential DEL BGD] [and to the relevant traditional knowledge COL] [genomic sequence data and parts thereof under PABS AD BGD] [their genetic sequence data and other forms of digital sequence information ADD ZAF [shall DEL ZAF] [must ADD ZAF] be shared fairly and equitably in accordance with the provisions of the PABS System [and its standard agreements ADD BGD]. [and shall be consistent with and not run counter to the Convention on Biological Diversity and the Nagova Protocol. ADD IDN [Accordingly, it is understood that DEL BGD, ZAF [Development, Innovation or ADD BGD] [The Parties further agree that ADD ZAF [p DEL BGD] [P ADD BGD] roduction [of pandemic vaccines or other DEL BGD] [any ADD BGD] pandemic-related products, [or of any products used for **PHEIC response ADD BGD** irrespective of the technology, information or material used, implies [use DEL BRA, PAK, DOM, CHN] [utilization BRA, PAK, DOM, CHN, ARG] of pathogens [with pandemic potential, [[including the DEL BRA, PAK, DOM, CHN] [their BRA, PAK, DOM, CHN] genomic DEL ZAF] [genetic ADD ZAF] sequence DEL BGD, RUS] [, components and digital sequence information BRA, PAK, DOM, CHN, ARG] DEL JPN] [genomic sequence data or parts thereof accessed under PABS.ADD BGD] [data and other forms of digital sequence information ADD ZAF];
- [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 ADD ROK]
- (g) [Facilitated access <u>DEL IDN</u>] [Access to specified entities outside the WHO Coordinated Laboratory Network ADD IDN] shall be provided [pursuant to <u>DEL IDN</u>] [if such entities have signed the annexed <u>ADD IDN</u>] a Standard Material Transfer Agreement [2 ADD IDN] [as set out in Annex XX, to registered Users that have accepted to make the requisite partnership contribution and have paid any monies due from them ADD ZAF], [the form of which shall be [agreed upon by the Parties and ADD BRA, PAK] set out in the PABS System and <u>DEL IDN</u>] that [inter alia ADD IDN] shall contain the benefit-sharing [options available <u>DEL BRA, PAK, IDN</u>] [to <u>DEL IDN</u>] [access the ADD ARG] [of ADD IDN] [entities accessing DEL BRA, PAK, DOM, CHN, <u>ARG</u>] [obligations that the access to BRA, PAK, DOM, CHN] pathogens with pandemic potential [is subject to BRA, PAK, DOM, CHN]; and <u>DEL ZAF, RUS</u>]

[he partnership contribution should be 1% of all income from sales, royalties and licences ADD ZAF] [including genomic sequences. SMTA 2 shall require specified entities to agree to provide the following benefits during a PHEIC or a pandemic: ADD IDN] DEL WHOLE BGD]

[NEW PARA (g bis). In addition, any entity outside the WHO Coordinated Laboratory Network using the PABS system agrees to make a monetary contribution to the PABS system. The Executive Board will determine which proportion of monetary contributions should be used for inter-PHEIC/pandemic preparedness measures, and which proportion should be reserved for response in the event of a public health emergency of international concern or a pandemic. IDN]

(h) [[Such options shall include, but not be limited to DEL BRA, PAK, DOM, CHN, RUS] [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) [(a) ADD BRA, PAK] [real- DEL BRA, PAK] time[ly ADD BRA, PAK] 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, [antimicrobials, ADD **SGP** personal protective equipment and therapeutics, DEL BRA, PAK, DOM, CHN] [pandemicrelated products BRA, PAK, DOM, CHN] to [enable DEL BRA, PAK] [support their ADD BRA, PAK] equitable [global ADD BRA, PAK] distribution [through the WHO Allocation Mechanism, ADD BRA, PAK 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, IDN; (ii) [commitments by the [countries DEL] SGP] [States Parties ADD SGP] 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. IDN, ARG, BGD, JPN, RUS [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]RESERVE ZAF]

[SUB-PARA (a) DEL BRA, PAK] 1. [real DEL BRA, PAK] -Timely [access by DEL BRA, PAK] [Reserve for BRA, PAK] WHO [to DEL BRA, PAK] a minimum of 20% of the production of [safe, efficacious and effective pandemic-related products, including diagnostics, vaccines, personal protective equipment and therapeutics DEL BRA, PAK] p[andemic-related products 1 BRA, PAK], to enable[support their BRA, PAK] equitable [global distribution through the WHO Allocation Mechanism BRA, PAK] [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]

[SUB-PARA ALT Such options shall include, but not be limited to: (i) [real-time access by WHO to 20% of the production of safe, efficacious sand effective pandemic-related products, including diagnostics, vaccines, personal protective equipment and therapeutics, 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; (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 SAU]

[NEW PARA : The benefit-sharing obligations of manufacturers of products related to the pandemic developed from the use of pathogens with pandemic potential will include: i) reserving for the WHO 20% of the production of products related to the pandemic to support to global equitable distribution or a WHO allocation mechanism. Products related to the pandemic will be provided to WHO and ii) . (ii) Collaborate with manufacturers in developing countries and WHO initiatives to transfer technology and know-how and strengthen capacities for timely scale-up of production of pandemic-related products. ARG]

[NEW PARA [The <u>DEL ARG</u>] benefit-sharing options for any entity accessing covered pathogen[<u>ic ADD ARG</u>- material or digital sequence information access may include, [<u>but are not limited to ADD ARG</u>] among other:

- access fees/fee per sample collected or otherwise acquired
- sharing of research and development results [DEL ARG; ALT the exchange 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]

[NEW PARA b) Collaborate with manufacturers from developing countries and Least Developed 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]

[ NEW PARA (c) by the countries where manufacturing facilities are located that they facilitate the shipment to WHO of these medical countermeasurespandemic-related products by the manufacturers within their jurisdiction, according to schedules to be agreed between WHO and manufacturers. BRA, PAK]

**INEW PARA** The benefit-sharing options for any entity accessing covered pathogen material or digital sequence information access may include, among others:

- 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]

[Recognition of the PABS System as a specialized international instrument [RESERVE ZAF]
DEL RUS]

(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 [paragraph 4 of Article 4 of ADD SGP] the Nagoya Protocol [and CBD ADD ARG]; RESERVE TUR, IRN] DEL SAU, IRN] DEL WHOLE BGD, IDN, RUS][ The recognition of the PABS System as a specialized international access and benefit sharing instrument shall be considered at an appropriate time after PABS becomes fully operational

and consistently provides fair and equitable benefit sharing, taking into account discussions and outcomes of the Convention on Biological Diversity and the Nagoya Protocol. ADD IDN RESERVE ZAF] (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, ARG, BGD, IDN, RUS] RESERVE ZAF]

(k) [The Parties shall support the further development and operationalization of the PABS System, including [bv implementing ADD SGP] 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, ARG, BGD, IDN, RUS] RESERVE ZAF]

[NEW PARA Parties to this agreement, acting thorough the governing body of CA+, shall review the operations and functioning of the PABS Systems every five years and may take steps as appropriate to recognize the PABS system as a specialized international ABS instrument within the meaning of the Nagoya Protocol, if necessary. BGD]

[New section: Access and benefit-sharing committee

- [(X) An access and benefit-sharing committee is hereby established. It shall serve, [inter alia <u>DEL</u> <u>DEL</u>][among others <u>ADD ARG</u>], as a means for establishing guidelines [for <u>DEL ARG</u>] [of <u>ADD ARG</u>] benefit-sharing, providing transparency and ensuring a fair and equitable sharing of benefits <u>BRA</u>, <u>PAK</u>].
- [(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 <u>DEL ARG</u>] members shall be nominated by <u>[the ADD ARG]</u> 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 <u>DEL ARG</u>] [will ADD ARG] be determined by the Conference of the Parties <u>BRA, PAK</u>].
- (X) The committee may make recommendations to the Conference of the Parties on matters relating to the PABS. BRA, PAK, DOM, CHN, ARG] 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, ARG], [working through the Governing Body for the WHO CA+, shall DEL ARG] [and will ADD ARG] develop and finalize [the ADD ARG] additional elements and tools necessary to fully implement, operationalize and sustain the PABS System, no later than XX. RESERVE CHE, PHL, UK] DEL IDN, RUS] RESERVE ZAF]
- [ ALT (10) (4) The Director-General shall apply the PABS System including the Standard Material Transfer Agreements (SMTAs) with respect to any sharing of PABS Materials by any WHO Member through its authorized national laboratories. The Operations of PABS System shall be governed according to paragraphs 5 to 14 in Annexure 1 and the elements identified therein]. ADD ZAF]

[All parts of the PABS should come into force simultaneously. BRA, PAK, DOM, CHN, <u>ARG</u>] RESERVE ARTICLE 10 AUS] RETAIN NGA]

[NEW PARA 5. Any WHO activities or initiatives involving pathogens covered under PABS system, the genomic sequence data, or parts their of, including those of WHO Biohub, and WHO Hub for Pandemic and Epidemic Intelligence shall be through and governed by the PABS system.ADD BGD]

[RESERVE ON ENTIRE ARTICLE 10 AFRICA GROUP: SUBMITS GENERAL OBSERVATIONS]

### INEW PARAS IDN

#### Governance of PABS System:

[(k bis) The World Health Assembly with advice from the Director General shall oversee implementation of the PABS system. The Director-General shall on a biennial basis inform the World Health Assembly, through the Executive Board, on the status of, and progress on implementation of the PABS system IDN]

[(k ter) A PABS Advisory Group is hereby established to guide implementation of the PABS system in accordance with its terms of reference including ensure the effective functioning of fair and equitable benefit sharing of the PABS system. The Advisory Group shall be independent and free of conflict of interests and based on equitable representation of the WHO regions, taking into account the importance of balanced representation between developed and developing countries. The PABS Advisory Group will comprise 18 members drawn from three Member States in each WHO Region, with a skill mix of internationally recognized policy makers, public health experts and technical experts. IDN]

[(k quarter) The Director General, in consultation with the Advisory Group shall put in place in a timely manner a transparent traceability mechanism that uses an electronic system in order to track in real time the movement of materials including genomic sequences shared into, within and out of the WHO Coordinated Laboratory Network. IDN]

[(k quint) To ensure that rapid, systematic and timely feedback is provided to Originating laboratories and Member States, the Director-General will also include in the traceability mechanism and associated electronic reporting systems a request that the receiving laboratory provide a summary report of laboratory analyses and on request any other available information required by the originating laboratory regarding the shared Materials including genomic sequences. IDN]

### **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.

- The Parties shall also promote the voluntary transfer of technology, knowhow 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] RESERVE AFR GROUP]

## [NEW ANNEXTURE TO ARTICLE 10 ADD BGD]

## [Part A: AGREEMENT BETWEEN NATIONALLY AUTHORIZED LABORATORIES (NAL) AND WHO

## {Chapeau to agreement specifying parties to the agreement}

#### **Article 1: Subject Matter and Scope**

#### Article 2: Peaceful Use Clause:

NAL agrees that handling of the pathogens, genomic sequence data and parts thereof, including its storage and processing shall be in accordance with applicable biosafety and biosecurity rules and standards, including any national legislations or international agreements or decisions of any relevant international organization that may be applicable.

## Article 3: Sharing of Access to Pathogens, Genomic sequence data or Parts Thereof:

- 1. NAL agrees to provide access to Pathogens, Genomic sequence data or Parts Thereof covered under Article 1 to only to entities who has entered into relevant agreement with WHO.
- 2. NAL shall be responsible for complying with any relevant national legal, administrative or policy regulations with respect to providing such access.

## Article 4: PABS Tracking Mechanism

The NAL shall inform the WHO of shipments or transfer of Pathogens or Parts thereof to entities inside the WHO coordinated laboratory network or outside, by recording in the PABS Tracking Mechanism.

## Article 5: Acknowledgement of contributors

NAL undertakes to appropriately acknowledge the contributions of collaborators, including laboratories/countries providing access to Pathogens, Genomic sequence data or Parts thereof, in their research outcomes, including in the presentations and publications they make.

#### **Article 6: Capacity Building Measure for Developing Countries**

NAL shall actively seek the participation of scientists to the fullest extent possible from developing countries, especially those providing initial access to pathogens in scientific projects associated

with research and development based on such pathogens, genomic sequence data or their parts thereof.

#### **Article 7: Outcomes of Utilization by NAL**

All outcomes of research and development or other projects utilizing shared pathogens, genomic sequence data or parts thereof shall be made available to WHO. WHO is hereby authorized to use such outcomes for the purposes of pandemic and PHEIC response.

[Other provisions could be on: (1) Dispute Settlement (2) Warranty (3) Indemnity (4) Termination/Duration of Agreement]

## PART B: STANDARD MATERIAL TRANSFER AGREEMENT

#### **Article 1. Parties to the Agreement**

#### **Article 2: Subject matter of the Agreement**

- 1. PABS Materials as defined in paragraph (x) of Article 3 transferred to the Recipient are subject to the provisions of this Agreement.
- 2. Purpose of Access: {to be filled by recipient}

### **Article 3: Definitions [place holder]**

#### **Article 4: Intellectual Property**

The Recipient shall not seek or assert any intellectual property rights over any PABS Materials or parts thereof, in any form including any modified forms or for any use.

## Article 5: Benefit Sharing Obligations of the Recipient

1. The Recipient commits to keep WHO informed of all uses PABS Materials and to share been benefits as provided below including the required monetary contributions in a timely manner, for using the PABS System.

[OPTION A\* – Paragraphs (2) to (5) are applicable to Recipients who are manufacturers of Health Products required for responding to PHEIC or Pandemics]

- \*Note: When the recipient is a manufacturer of diagnostics, vaccines, therapeutics and other medical products required for prevention, control and response in relation to spread of infection and disease including academic institutions, government owned or government subsidized entities, non-profit organizations, commercial entities, that develop and/or produce such products, OPTION A applies.
- 2. The Recipient shall comply with WHO's allocation plan, and ensure supply each of their produce including vaccines, therapeutics, diagnostics or any other medical products at affordable prices to developing countries during a public health emergency of international concern or a pandemic.
- 3. The Recipient shall deposit biological materials, which they derive using PABS system at the WHO cell bank to facilitate the availability of biological materials used for the production of vaccines, therapeutics, diagnostics or any other medical products during public health emergency of international concern or pandemic which WHO is free to share with designated manufacturers in developing countries during a public health emergency of international concern or a pandemic.

- 4. In addition, the Recipient shall commit the recipient shall commit to at least:
- (i) Donate at least 20% of real time of their production to WHO of all the applicable products.
- (ii) Grant to WHO royalty-free, non-exclusive licenses on standard terms and conditions to use its intellectual property, and other protected technology, know-how used in the process of development and production, for the production and supply of such products needed in a public health emergency of international concern or a pandemic in developing countries. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions and in accordance with sound public health principles to facilitate production and supply in developing countries.
- 5. X% of total annual revenue for each product or service developed and commercialized using the PABS System shall be paid to the PABS System as annual contribution. Applicable Annual Income shall be reported to WHO in a manner prescribed by WHO.

For the purposes of this paragraph, product or service includes any technology, outcome, diagnostics, vaccines, therapeutics and any service provided supporting the development of products for commercialization.

[Note: Right to modify or expand the benefit sharing commitments is hereby reserved, as soon as there is clarity on the scope of WHO CA+ including commitments with respect to access.]

[OPTION B – Below provided paragraphs (2) and (3) are applicable to all other Recipients who are not covered under OPTION A.]

- 2. The Recipient commits to comply with WHO's Recommendations during a public health emergency of international concern or a pandemic, especially when the products or other outcomes of the use of the PABS Materials that the recipient derived are covered by such recommendations.
- 3. X% of total annual revenue for each product or service developed and commercialized using the PABS System shall be paid to the PABS System as annual contribution. Applicable Annual Income shall be reported to WHO in a manner prescribed by WHO.

[Note: Right to modify or expand the benefit sharing commitments is hereby reserved, as soon as there is clarity on the scope of WHO CA+ including commitments with respect to access.]

## **Article 6: Genomic Sequence Data**

The Recipient agrees to comply with the terms and conditions applicable to the users of the WHO Database contained in the Part C of Annex X.

#### **Article 7: Third Parties**

- 1. The Recipient shall only further transfer the PABS Materials if the prospective recipient has concluded an SMTA with WHO. Any such transfer shall be reported to the WHO.
- 2. The Recipient shall remain fully responsible for the compliance of all obligations with respect to PABS Material in the event of transfer of PABS Materials to any third parties under contract with the Recipient. The Recipient shall ensure that PABS Materials shall not be utilized by such third parties for research, development or production other than as directed by the Recipient and

that the PABS Materials are returned to the Recipient or destroyed, in accordance with appropriate bio-safety standards, at the end of utilization.

[Other provisions could be on: (1) Dispute Settlement (2) Warranty (3) Indemnity (4) Termination/Duration of Agreement]

## PART C: DATA PROCESSING AGREEMENT TO BE USED AS CLICK WRAP AGREEMENT WHO DATABASE

By registering as a user having a verified institutional account, users agree their access to genomic sequence data subject to the following terms and conditions:

#### (i) User shall not

a. distribute or share data accessed hereby with any third party who is not a registered user of the WHO Database;

b. use data accessed hereby in any activity that may lead to development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;

c. seek or assert intellectual property rights over any genomic sequence data accessed or parts thereof, in any form including any modified forms or for any use;

#### (ii) The user further agrees that

a. Outcomes of non-commercial use of data shall be made freely available and accessible in the public domain and the same shall be reported to the PABS System in the format as prescribed by the WHO;

b. In the event, the User is a Qualified Institutional Entity or becomes a Qualified Institutional Entity as defined by the PABS System, the User becomes bound by terms and conditions contained in SMTA contained in Part B;

c. monetary contributions as set out in SMTA under PART B of this ANNEX shall be paid in a timely manner;

d. any research that genetically alters an organism in a way that is potentially dangerous to human life and environment including any forms of gain of function research using PABS resources, including genomic sequence data shall be conducted after taking prior consent from WHO and in accordance with any conditions WHO may prescribe.

(iii) The User shall further take demonstrable efforts in making the participation of scientists from originating laboratory, especially those from developing countries, feasible in their scientific projects associated with research on the genomic sequence data.

(iv) The User shall appropriately acknowledge in presentations and publications, the contributors or collaborators, in particular those who made available the genomic sequence data thorough WHO Database.

[Note: Right is hereby reserved to alter the Data use conditions above based on a later stage, when there is clarity about the scope of WHO CA+ and PABS BGD]

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

[NEW Article BRN 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.]

## [NEW Article 10. AFR PROPOSAL WHO Pathogen Access and Benefit-Sharing System

- 1. The need for a transparent multilateral, fair, equitable and timely system for sharing of, on an equal footing, pathogens with human pandemic potential and including genomic sequence data, and fair and equitable benefits arising therefrom, that applies and operates in both interpandemic and pandemic times, is hereby recognized. In pursuit thereof, it is hereby agreed to establish the WHO Pathogen Access and Benefit-Sharing System (the "PABS System"). WHO shall ensure the full application of the WHO PABS System to all WHO Members with respect to access to pathogens with human pandemic potential including genomic sequence data and fair and equitable benefit sharing arising therefrom.
- 2. The Scope of the PABS System shall be as follows:
- (a) The PABS System shall cover all pathogens with human pandemic potential, including their genomic sequence data, as well as fair and equitable benefit-sharing arising therefrom and

ensure that the PIP Framework operates synergistically with the PABS System. The PABS System in its entirety shall also apply to pathogens that have the potential to cause a public health emergency of international concern within the scope of the IHR.

- (b) The scope of the PABS System may be extended to include other pathogens and their genomic sequence data currently being shared by Members, with additional fair and equitable benefit sharing commitments including appropriate amendments to the SMTAs, upon the decision by the World Health Assembly.
- (c) It is understood that production of vaccines, diagnostics, therapeutics and other medical products for public health emergency of international concern and pandemic, irrespective of the technology, information or material used, implies use of pathogens with human pandemic potential including genomic sequence data.
- 3. For the purposes of PABS, the following definitions shall apply:
- (a) PABS Materials: means pathogens with human pandemic potential, whether wild-type or modified, including their biological materials and parts thereof, clinical specimens, genomic sequence data including associated data (meta and clinical data), within the scope of PABS System.

[Placeholder: This definition is proposed without prejudice to further textual suggestions to improve the definition, once there is clarity on the scope and functioning of the PABS System]

- (b) Genomic Sequence Data: "genomic sequences" means the order or sequence of the nucleotides in DNA and RNA, or amino acids in proteins. They contain genetic information that determines the biological characteristics of an organism or a virus. In the case of viruses, this includes characteristics such as pathogenicity, transmissibility and antiviral susceptibility. Laboratories can determine the genetic sequence of a particular organism, using sequencing technologies. The data generated through this process is called "genomic sequence data (GSD)" or "genetic sequence data (GSD)".
- (c) Authorized national laboratories: means laboratories authorized and designated by a Member State to provide PABS Materials to the PABS System and recognized as part of the WHO Coordinated Laboratory Network.
- (d) Qualified Entities: Manufacturers of diagnostics, vaccines, therapeutics and other medical products means public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations, commercial entities, that develop and/or produce diagnostics, vaccines, therapeutics and other medical products including personal protective equipment (PPE), ancillary medical supplies and other supplies required for administration of diagnostics, vaccines and therapeutics as well as any other products required for prevention, control and response in relation to spread of infection and disease.
- (e) WHO Coordinated Laboratory Network means an international network of authorized national laboratories coordinated by WHO and governed by the PABS System. To be a part of the WHO Coordinated Laboratory Network, an authorized national laboratory must meet the criteria for designation and agree to comply with provisions of SMTA 1 and annexed Terms of Reference.

#### [Placeholder: Terms of Reference are to be developed]

4. The Director-General shall apply the PABS System including the Standard Material Transfer Agreements (SMTAs) with respect to any sharing of PABS Materials by any WHO Member through its authorized national laboratories. The Operations of PABS System shall be governed according to paragraphs 5 to 14 and the elements identified therein.

#### 5. WHO Coordinated Laboratory Network

- (a) The Director-General shall establish a WHO Coordinated Laboratory Network linking authorized national laboratories to achieve the objectives of PABS System. The Director-General may designate certain authorized national laboratories as WHO Collaborating Centres for purposes of PABS System, provided it reflects adequate regional and sub-regional representation, as appropriate and balanced representation between developed countries and developing countries. The Director-General has the responsibility to ensure that each region and sub-region has sufficient capacity and facilities to undertake thorough risk assessment and response activities as set out in the Terms of Reference of the WHO Coordinated Laboratory Network including interlaboratory sharing of outcomes arising from utilization of PABS Materials.
- (b) By providing PABS Materials to other laboratories within the WHO Coordinated Laboratory Network, the provider Member State provide their consent for the onward transfer and use of PABS Materials to Qualified Entities that have signed SMTA2 with WHO.
- (c) WHO shall be responsible to facilitate the funds required to cover the costs related to shipment of PABS Materials to and within the WHO Coordinated Laboratory Network.

#### 6. Standard Material Transfer Agreements

- (a) All transfers of PABS Materials by an authorized national laboratory to another authorized national laboratory of its choice, and further transfers within the WHO Coordinated Laboratory Network shall be subject to agreement with the provisions of Standard Material Transfer Agreement 1 (SMTA1) in Annex 1.
- (b) The Director-General shall using the Standard Material Transfer Agreement 2(SMTA2) in Annex 2, enter into agreements with Qualified Entities outside the WHO Coordinated Laboratory Network.
- (c) WHO Secretariat shall take all measures necessary to apply, implement and operationalize SMTA 1 and SMTA 2 and the monetary contribution for pandemic preparedness and response.

#### 7. Monetary Contribution for Pandemic Preparedness and Response

(a) Any entity including manufacturers of diagnostics, vaccines, therapeutics and other medical products using or benefitting from the PABS System, shall make an annual monetary contribution to WHO for improving preparedness and response of public health emergency of international concern and pandemic. It is decided that the sum of annual contribution shall be x% of total annual revenue for each product or service developed and commercialized using the PABS System. Annual revenue includes all financial benefit such as income from sales and royalties.

For the purposes of this paragraph, product or service includes any technology, outcome, diagnostics, vaccines, therapeutics and any service provided supporting the development of products for commercialization.

[Placeholder: The percentage has to be determined. It is currently being examined, further proposals on this will be made in the upcoming meetings.]

(b) The Director-General will propose to the Executive Board which proportion of contributions should be used for inter-PHEIC/pandemic preparedness measures, and which proportion should be reserved for response in the event of a public health emergency of international concern or a pandemic, based on the advice of the "PABS Advisory Group".

### 8. Traceability and reporting mechanisms

(a) The Director-General, shall put in place in a timely manner a transparent traceability mechanism that uses an electronic system in order to track in real time the movement of PABS Materials into, within and out of the WHO Coordinated Laboratory Network.

#### 9. Genomic Sequence Data

- (a) The Director General shall hereby establish a WHO PABS Sequence Database. Members shall take necessary measures to ensure that genomic sequence data within the scope of the PABS System are shared through the WHO PABS Sequence Database and consistently with its requirements.
- (b) Any sharing of genomic sequence data by laboratories within WHO Coordinated Laboratory Network shall be through the WHO PABS Sequence Database. WHO PABS Sequence Database shall accept submissions of functional genomic sequence data, including virological, clinical, epidemiological and demographic information and metadata, including source of specimen, its geographical origin, spatial and temporal isolation data as well as the raw data files. The uploading entities, at the time of the uploading, will ensure that such data are provided therewith in a format as prescribed by the WHO PABS Sequence Database.
- (c) Laboratories within the WHO Coordinated Laboratory Network shall not transfer genomic sequence data to entities outside the WHO Coordinated Laboratory Network unless the entity is a Qualified Entity and has signed SMTA2.
- (d) Laboratories within the WHO Coordinated Laboratory Network shall not upload the genomic sequence data to any other databases.

#### 10. Access to WHO PABS Sequence Database

- (a) WHO PABS Sequence Database shall provide access to registered users with verifiable institutional accounts. For the purpose of WHO PABS Sequence Database, registered users with verifiable institutional account are users supported by an institution that has registered with WHO, whose credentials are verified by WHO.
- (b) Registered users with a verified institutional account shall have access to genomic sequence data from WHO PABS Sequence Database, subject to agreement inter alia to the following terms

and conditions that will be contained in a click-wrap Data Access Agreement annexed as Annex 3:

- (i) Data shall be used solely for individual purpose;
- (ii) Data shall not be distributed to any third party who is not a registered user of the WHO PABS Sequence Database;
- (iii) Data shall not be used in any activity that may lead to development, or production of biological agents, toxins, weapons, equipment, or means of delivery specified in Biological Weapons Convention;
- (iv) User shall not seek or assert intellectual property rights over any genomic sequence data accessed or parts thereof, in any form including any modified forms or for any use;
- (v) Any outcomes of non-commercial use of data should be made freely available and accessible in the public domain and the same shall be reported to the PABS System in the format as prescribed by the WHO PABS Sequence Database such that it shall be linked to the respective genomic sequence data accessed;
- (vi) User is aware of the requirements of the PABS System including the WHO PABS Sequence Database, its benefit sharing requirements: monetary contribution and other benefit sharing contained in SMTA2;
- (vii) The User agrees to pay the required monetary contributions in a timely manner, as set out in paragraph 7, for using or benefitting from the PABS System;
- (viii) The User is aware that a Qualified Entity as defined by the PABS System has to commit to terms and conditions contained in SMTA2. In the event, the User is a Qualified Entity or becomes a Qualified Entity as defined by the PABS System, the User agrees to be bound by terms and conditions contained in SMTA2.
- (ix) The User shall actively seek the participation of scientists to the fullest extent possible from originating laboratory, especially those from developing countries, in their scientific projects associated with research on the genomic sequence data and actively engage them in preparation of manuscripts for presentation and publication.
- (x) The User shall appropriately acknowledge in presentations and publications, the contributions of collaborators, in particular the laboratories/countries providing PABS Materials, using existing scientific guidelines.
- (xi) Any User engaged in "Gain-of-function" research, or in any other research that genetically alters an organism in a way that may enhance its biological characteristics or functions, shall inform and regularly update WHO on the outcomes of the research. The User also agrees to comply with any conditions that may be imposed by WHO, to safeguard public health.
- (c) Other Databases may link with WHO PABS Sequence Database subject to agreement inter alia to the following terms and conditions that will be contained in a Database Access Agreement between WHO and other database:
- (i) Access shall only be provided to registered users with verifiable institutional accounts. Registered users with verifiable institutional account means users supported by an institution that has registered with the database, whose credentials are verified by the database.
- (ii) Agrees to regularly provide WHO the list of registered users and their contact details.
- (iii) Agrees to inform its users that access to genomic sequence data obtained from the WHO PABS Sequence Database is subject to inter alia to terms and conditions mentioned in paragraph (b) and by accessing the genomic sequence data the user agrees to the terms and conditions contained in the Data Access Agreement of WHO.

- (iv) Agrees to monetary contribution as required by the WHO PABS System for any commercialization of genomic sequence data obtained from the WHO PABS Sequence Database.
  (d) Laboratories within the WHO Coordinated Laboratory Network may have access to the WHO PABS Sequence Database as a registered user, subject to the terms and conditions contained in SMTA1.
- (e) Qualified Entities may have access to the WHO PABS Sequence Database as a registered user, but shall be deemed to be bound by the terms and conditions contained in SMTA2.

#### 11. Governance of the PABS system

- (a) The implementation of the PABS system will be overseen by the World Health Assembly with advice from the Director General. An independent, free of conflict of interests, oversight "PABS Advisory Group" is established to monitor and provide guidance on the functioning of the PABS system and to undertake assessments of the trust-based system needed to protect public health.
- (b) The Director-General, in consultation with Member States, will continue to ensure that the PABS Advisory Group is based on equitable representation of the WHO regions, taking into account the importance of balanced representation between developed and developing countries. The PABS Advisory Group will comprise 18 members drawn from three Member States in each WHO Region, with a skill mix of internationally recognized policy makers, public health experts and technical experts.
- (c) The PABS Advisory Group will function to assist the Director-General in monitoring the implementation of the PABS system, in accordance with the terms of reference for the Advisory Group of this system. The PABS Advisory Group will present an annual report to the Director-General on its evaluation of the implementation of this system.
- (d) The Director-General shall on a biennial basis inform the World Health Assembly, through the Executive Board, on the status of, and progress on implementation of the PABS system in particular monetary contributions and implementation of SMTA 1 and SMTA2.

#### 12. Responsibilities of WHO Secretariat

(a) WHO shall take all measures necessary to ensure the fair, transparent, equitable, effective and efficient implementation of the PABS System.

## (b) WHO shall make publicly available:

- (i) the list of registered users of the WHO PABS Sequence Database;
- (ii) monetary contributions received under paragraph 7; (iii) the signed SMTA2s with Qualified Entities;
- (c) IPPST shall monitor the use of PABS Materials especially use for "Gain-of-function" research, or in any other research that genetically alters an organism in a way that may enhance its biological characteristics or functions and report annually to Members. In the event of research that has the potential to adversely impact public health, IPPST shall take necessary measures to supervise that research to safeguard public health.

- (d) WHO activities including WHO Hub for Pandemic and Epidemic Intelligence, WHO BioHub System involving sharing of pathogens with human pandemic potential and its genomic sequence data shall be through and governed by the PABS System.
- 13. Recognition of the PABS System as a specialized international instrument
- (a) Members shall consider measures for recognition of the PABS System as a specialized international instrument within the meaning of the Nagoya Protocol, five years after the PABS System including its WHO PABS Sequence Database and benefit sharing becomes operational.
- 14. Responsibilities of Member States
- (a) Members are committed to ensure the fair, transparent, equitable, effective and efficient operationalization and functioning of the PABS System including its various components and Members shall cooperate with WHO in good faith.
- (b) Members shall support and take measures to ensure the compliance of non-state actors with the components of the PABS System such as the WHO PABS Sequence Database, monetary contributions, standard material transfer agreements.
- (c) Members agree to urgently facilitate the immediate shipment to WHO of products that Qualified Entities have committed to supply under SMTA2 during a public health emergency of international concern or a pandemic. AFR GROUP
  - Article 11. Strengthening and sustaining [core USA] preparedness and health systems' resilience
- [Each ADD JPN] [The DEL JPN] Part[ies DEL JPN] [y shall take the necessary measures to strengthen their own health systems in order to strengthen and sustain the pandemic prevention, preparedness, and response, in taking into account ADD JPN] [recognize DEL JPN] the need [for **DEL AUS]** [to develop and sustain ADD AUS] [equitable and ADD JPN] [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, BGD] [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] [with a view to achieving and sustaining ADD JPN] universal health coverage, [and with a focus on primary health care and community-level interventions ADD AUS [able ADD EU] to [prevent and EU] mitigate the shocks caused by pandemics and DEL BGD, PAK] to [support CAN] [ensure DEL CAN] continuity of [quality CHN] health services [and creating resiliency USA] [s and prevent health systems from being overwhelmed, ADD AUS, DEL JPN] [and general access thereto also in a situation of crisis ADD EU] [[, thus preventing health systems from becoming DEL BGD, PAK] [without being BGD, PAK] overwhelmed DEL EU, AUS] [in the times of pandemic outbreaks and spread BGD, PAK] [during pandemic emergencies USA] [during a pandemic ADD AUS]. [Parties shall take all necessary steps to organize, strengthen and sustain their health systems at national level to reach and maintain the aforementioned standard.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. NOR1

[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]

[[The [developed country BGD, AFR GROUP] Parties [[shall ADD AUS] provide BGD, PAK, THA, HTI, IRN, AFR GROUP] [are encouraged DEL IDN, PAK] [shall take necessary measures IDN, EGY [to DEL PAK] enhance DEL BGD, IDN, PAK, THA, HTI, NGA, EGY, TUN, COSR] [WHO's six pillars of health systems strengthening [through ADD ZAF] AF Group, ZAF] [commit NGA] [shall take necessary measures IDN, EGY] [[shall continue to cooperate on and ADD AUS, UK] are encouraged [shall enhance ADD COSR] 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 **DEL** ARG] [to MLIC ADD ARG] [countries DEL ARG], to strengthen [health systems and ADD AUS] [capacities for health UK, AUS] capacity and resilience, including MYS] [primary health care and hospital care facilities and to achieve BGD, PAK] [[health emergency DEL THA, HTI/ RETAIN AUS] [pandemic THA, HTI] prevention [and DEL THA, HTI, AUS] preparedness[, [response CHN, UK, AUS] [[and ADD AUS] health system [recovery ADD AUS] THA, HTI, UK] [particularly of primary and secondary health care facilities, ADD PAK] [consistent with the goal of DEL BGD, AFR GROUP/ RETAIN 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, RUS]

NOTE: UK Will propose 11.2. alt.

[NEW 2.bis [Each Party shall: maintain and progressively strengthen primary health care and community services that are able to reach all individuals and communities, including, without limitation, by developing capacities of those working at the forefront on pandemic prevention, preparedness and response activities, such as contact tracing and data collection; enable effective patient referral systems; and integrate use of primary health care capacity into the planning and implementation of public health responses and into the maintaining of essential health service delivery during health emergencies and crises UK]

[[ALT (2) JPN Each Party shall, in accordance with national law, adopt policies and strategies, supported by implementation plans, across the public and private sectors and relevant agencies, consistent with relevant tools, including, but not limited to, the International Health Regulations, and strengthen and reinforce health systems, primary health care and public health functions for the following 6 building blocks.

(a) Service delivery

- continued provision of quality routine and essential health services during pandemics, including clinical and preventive care such as mental health care and immunization, with a focus on primary health care and community-level interventions;
- (b) Health workforce
- strengthening and sustaining a skilled and competent health and care workforce (as stipulated in Article 12.);
- strengthening human resource capacities during inter-pandemic times and during pandemics;
- (c) Health information systems
- surveillance (including using a One Health approach), outbreak investigation and control, through interoperable early warning and alert systems (as stipulated in part B and D of EU proposal);
- sustained laboratory capacity for genomic sequencing, as well as for analysing and sharing such information;
- prevention of epidemic-prone diseases, and emerging, growing or evolving public health threats with pandemic potential, notably at the human-animal-environment interface;
- 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;
- post-emergency health system recovery strategies;
- (d) 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);
  - strengthening public health laboratory and diagnostic capacities, and national, regional and global networks, including standards and protocols for infection prevention and control, and public health laboratory biosafety and biosecurity;
  - creating and maintaining up-to-date, universal platforms and technologies for forecasting and timely information sharing, through appropriate capacities, including building digital health and data science capacities;
  - (e) 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);
  - (f) 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);
- [[[The Parties [are encouraged DEL IDN, THA, HTI, AFR GROUP,] [shall explore IDN, NGA, 3. AFR GROUP [commit NGA, AFR GROUP] [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/RETAIN CAN] [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 accordance with article 10. ADD ARG][, 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 CANI, DEL BGD, CHN, ARM, PAK, AFR GROUP, RUS MOVE RUS DEL EU DEL JPN [including emerging and re-emerging zoonoses UK] RESERVE ZAF]

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

#### [ALT ((2) and (3) NGA

- (2) The Parties commit to enhance 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. NGA]
- (3) The Parties commit to establish glòbal, regional, and national collaborative genomics networks that are dedicated to epidemiological genomic surveillance and the global sharing ofemerging pathogens with pandemic potential. NGA]
- [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. [Developed State Parties will support, through financial, technical and technological support, assistance, and cooperation, in particular to developing countries, AFR GROUP] [Each Party DEL AFR GROUP, PAK/RETAIN AUS, CAN] [The Parties ADD PAK] shall[, in accordance with [each parties AFR GROUP] [national DEL USA, AUS/RETAIN AFR GROUP] [applicable USA, AUS] law[s ADD PAK] DEL EU, RETAIN AFR GROUP, PAK] [and supported by implementation plans USA], [and through mutual collaboration develop and ADD PAK] adopt [measures ADD SGP] [policies and strategies, [as appropriate USA] [supported by implementation

plans **DEL SGP**], 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 **[other international agreements SGP]** [relevant tools **DEL SGP**], including, but not limited to, the International Health Regulations **DEL EU**] [, [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, **AUS**] [such as BGD, PAK] [the following 6 building blocks JPN]:

[[11.4.a.bis equal access to hospital treatment by eliminating protocols, frameworks and systems of prioritisation and pre-emptive triage that deny access based on assumptions linked to life expectancy or quality of life, and actual or perceived age, disability or health condition. ADD COSR]

## [NEW PARA: "create and strengthen public health institutions at national, regional and international levels" AFR GROUP].

[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 DEL AUS] [minimal disruption to ADD AUS] quality routine and essential health services [including home care BRA] during pandemics [emergencies USA], including[, for example, USA] [home care, ADD ARG] clinical [sexual and reproductive health services CAN] [and DEL MEX] [preventive care such as JPN] mental health [care and DEL MEX] [prevention, ADD MEX] immunization, [sexual and reproductive health services ADD ARG] [sexual and reproductive health care AUS] [and maternal, neonatal and child health services FJI, AUS, NZL] [palliative and rehabilitation, sexual and reproductive health services and maternal, neonatal and child health services ADD MEX] [with a focus on primary health care [and DEL AUS, IDN] [referral health services IDN] community-level interventions, [[and particular attention to people [persons] in vulnerable situations ADD AUS] EU] [[expansion of the access to health systems, ensuring the reception and control of suspected cases during the pandemics BRA] [prevention of infections, ADD SGP] 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 DEL AUS]; DELINK as SEPARATE point under Article 11.4 ARM] DEL JPN] DEL EU, BGD] RESERVE UK]
- (b) [(a) bis Health Workforce: strengthening and sustaining a skilled and competent health and care workforce (as stipulated in Article 12.) JPN]; [strengthening [human resource DEL USA, UK/ RETAIN ARG, AUS] [human 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, AUS] [of the multidisciplinary workforce needed USA] [and competencies ADD MEX] [during inter-pandemic times [and DEL AUS] [preparing for and [to ensur[e] ADD]

<u>AUS</u>]ing surge capacity BRN] during pandemics [<u>DEL BGD</u>] [, including capacities to protect human resources from health risks PHL] [emergencies, including, for example, protection from the impact of pandemic emergencies USA]; <u>DEL RUS</u>] MOVE RUS/ALT MOVE to Art 12 CHN] [including the establishment of mechanisms or arrangements for [the <u>ADD ARG</u>] emergency [recruitment <u>ADD ARG</u>] hiring of health professionals at [the <u>ADD ARG</u>] 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] [Collaborative IND] surveillance [[including <u>DEL AUS</u>] using a One Health approach[, when appropriate USA]) DEL CHN], [horizon scanning, BRN] [that covers surveillance of drivers of spill-over and disease <u>emergence</u>, including at the <u>human-animal-environmental interface ADD AUS</u>] outbreak [detection CAN] investigation and control, through [interoperable DEL USA, <u>AUS</u>] early warning and alert systems [DEL RUS, BGD] [, [with the goal of interoperable <u>ADD AUS</u>] [ility, as well as with other sectors, as appropriate for national priorities and needs USA] [and timely notification BRA, <u>ARG</u>] [JPN: text as stipulated in Parts B and D of EU proposal] [systems ADD AUS] [as well as strengthening early warning, surveillance, and response capacity for emerging zoonoses at the community level CAN, <u>AUS</u>];

[(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 alt.) strengthening and supporting harmonised, multisectoral One Health approaches to surveillance, data-sharing and communication across sectors, and include surveillance of antimicrobial consumption and use; ADD SGP]

- [(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/ RETAIN AUS, IDN] [national and/or regional ADD AUS] laboratory [and its CHN] [capacity DEL CHN/ RETAIN AUS] [capacities, including capacities CHN] for [testing BRN] genomic sequencing [and [collecting pathogens and clinical samples AUS] USA], [including through national, regional and international networks, ADD EU] [antimicrobial susceptibility testing, ADD SGP] [as well as for DEL AUS] [establishing new technologies ISR] [and ADD AUS] analysing [and DEL IDN] sharing [and safeguarding IDN] such information [DEL BGD] [in real time ISR] [through a good data governance IDN] [for samples USA][or samples in a safe and secure manner ADD AUS];

## [ALT (d) JPN 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;

- <u>strengthening public health laboratory and diagnostic capacities, and national, regional and global networks, including standards and protocols for infection prevention and control, and public health laboratory biosafety and biosecurity;</u>
- creating and maintaining up-to-date, universal platforms and technologies for forecasting and timely information sharing, through appropriate capacities, including building digital health and data science capacities ADD JPN]
- (e) [cross sectoral UK, <u>AUS</u>] prevention of [zoonoses BRN, <u>AUS</u>] and 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 [<u>DEL BGD</u>] [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, <u>AUS</u>] [including through community-based One Health approaches CAN]; **DEL RUS, AFR GROUP, REFER TO RATIONALE IN ARTICLE 18**]
  - [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, <u>AUS/RETAIN CAN]</u> [pandemic THA, HTI, <u>AUS</u>] health system recovery strategies [<u>DEL BGD</u>] [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 DEL CAN][and animal health USA, BRN, AUS] [One Health CAN] laboratory [and diagnostic DEL BRN] [, diagnostic, and reporting BRN] capacities, [retention of laboratory staff THA, HTI] and DEL CHN][including pathogen genetic sequencing, and where appropriate, the use of point of care and self-administered testing ADD BRN] 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 DEL SGP] [DEL BGD] MERGE with 4.(d) CHN] [during inter-pandemic times, during and after pandemics THA, HTI] [MERGE 4(g) with 4(d) TUN] [RESERVE AFRICA GROUP]
- (h) [creating and maintaining up-to-date, [networked USA] [universal DEL USA, <u>AUS</u>] [<u>networked ADD AUS</u>] platforms and technologies for forecasting[, where possible, USA] and timely information sharing, [including [<u>for ADD AUS</u>] human, animal, and environmental data, pathogens and clinical

samples, USA, <u>AUS</u>] [through appropriate capacities including <u>DEL AUS</u>], [open data infrastructures, CAN] [and <u>ADD AUS</u>] building [on existing systems and <u>ADD AUS</u>] digital health [including telemedicine services IDN] and [open BRA] data science capacities [<u>DEL BGD</u>] [(open science) BRA] [to modernize data management CAN] RESERVE UK].

#### [DEL SUB-PARA (a)-(h) BGD]

[NEW para 4.(i) Strengthen existing hospital systems and plan for : (a) attending surge of patients requiring beds with oxygen support and other logistics (b) Provisions for intensive care and ventilators IND]

[(i) [Strengthening sustainable systems for human, animal, plant and environmental health through a strong focus on infection prevention and control to prevent and mitigate infectious disease and antimicrobial resistance risk across sectors (including key interventions such as water, sanitation and hygiene, biosecurity, vaccination and waste minimisation and management). ADD SGP]

[NEW para 4(i) create and strengthen public health institutions at national, regional and international levels ADD ZAF, AFR GROUP].

[NEW PARA (4) (j) strengthening public health emergency operational centres capacities during inter-pandemic times and during pandemics; ADD ZAF]

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]

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

[NEW PARA (j) 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]

[NEW PARA (k) 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]

[NEW PARA (l) strengthening research and development capacities for evidence-based decision-making CAN]

[NEW PARA (m) systematically evaluating, exchanging and utilizing scientific evidence to inform decision-making CAN]

[DEL BGD original listed ítems under 3]

[NEW SUBPARAS / listed ítems 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]

(d) [[NEW PARA (i) Strengthening field training for healthcare workers that are involved in pandemic response ARG]

[NEW PARA 5. The Parties agree to establish a health data governance framework with strong and secure data infrastructure that facilitates leveraging digital technology for an end-to-end pandemic management IT platform which would include collaborative surveillance, laboratory networks including that for genomic sequencing, epidemiological intelligence, forecasting, health emergency response, end-to end counter measures platform and risk communication including countering misinformation and disinformation. ADD IND]

NEW PROPOSED ARTICLE 11 PARAS, (FOLLOWING 4):

## [NEW PROPOSED ARTICLE 11 PARAS, (FOLLOWING 4): DEL ALL REFERENCES IN THE DOCUMENT TO LOW AND MIDDLE INCOME COUNTRIES, AFR GROUP].

#### [RESERVE NEW PROPOSED ARTICLE 11 PARAS, (FOLLOWING 4): AFR GROUP.]

- [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 [ADD AUS].
  - 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, AUS] DEL AFR GROUP][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]

[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] DELETE, AFR GROUP].

#### **INEW PROPOSED PARAS EU**

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.

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 nongovernmental entities shall provide capacity building, training and support, relying as much as possible on existing training and capacity building facilities.

The Conference of the Parties may adopt as appropriate protocols, annexes and guidelines for the implementation of the provisions of this Article.

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.]

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

## [[NEW PROPOSED ARTICLE 11 BIS, PROPOSED TO PRECEDE CURRENT PARAGRAPH 1 AFR GROUP]

#### 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]

#### [NEW Article 11 bis BRN

#### Pandemic prevention using a One Health Approach

- 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-animalenvironment 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.
- 2. In this regard, the Parties shall promote and implement a One Health approach at national, regional, and global levels that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing international instruments.
- 3. Each Party shall develop and implement appropriate multisectoral coordination mechanisms that address pandemic prevention at the humananimal-environment interface including through risk assessment procedures based on the drivers of emerging and re-emerging infectious diseases within their territories.
- 4. 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]

Article 12. Strengthening and sustaining a skilled [and <u>DEL ZAF</u>] competent [and motivated AF GROUP, SWZ, ETH, <u>ZAF</u>] health and care workforce

ADD motivated at each paragraph wherever there is a reference to skilled trained and competent work force AFR GROUP][REPLACE "HEALTH AND CARE WORKFORCE" WITH "HEALTH WORKFORCE" THROUGHOUT THE ARTICLE IND]

- [Each Party [in line with their respective capacities PAK, IRN] [in keeping with respective national capacities and laws ADD JAM] shall [, subject to national laws NGA, EGY, AFR GROUP] [take the [necessary DEL SAU] steps DEL THA, SAU] [to DEL USA] [with respect to regional and country-specific workforce [emergency medical teams MEX, URY, TUN, DOM, HTI] approaches, [pursuit ADD SAU] to USA] safeguard, protect, invest in[scale up recruitment of THA] and sustain a skilled, trained, [and ADD JAM] competent [and committed DEL JAM] [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 gender-responsive [and inclusive ADD AUS] manner DEL RUS, IRN, NGA / RETAIN CAN] [in a gender sensitive manner NGA, EGY], with due protection of [its DEL BGD, AUS, IDN] [their IDN] [employment, [safety, IDN] [civil DEL USA, SGP, CHI] [and human rights DEL SGP] 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 [applicable ADD SGP] 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], [including protection from violence and stigma, ADD MEX] with the aim of [ensuring SGP] [increasing and sustaining DEL SGP capacities for pandemic prevention, preparedness [and DEL IDN] response [and recovery of health system IDN, THA], [while DEL UK] [including UK] maintaining [quality ADD MEX] essential health services [during pandemics UK, AUS] [in both, source and destinations countries PHL, ISR]. [and all other essential public health functions. ADD MEX] [This DEL USA] [These steps may USA] includes, subject to [national DEL USA, AUS] [applicable USA, AUS] law [and policies SGP]:
  - (a) strengthening [prevention and MEX, URY, TUN, DOM, HTI] [in- and post-service DEL UK, <u>AUS</u>] [pre- and in- service competency-based education and UK, <u>AUS</u>] [education and ADD MEX] training, [supportive supervision, UK, <u>AUS</u>] [including on human rights, non-discrimination and elimination of stereotypes and biases, ADD COSR] [deployment, <u>DEL MEX</u>] [employment, ADD MEX] [remuneration, <u>DEL JAM</u>] 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 <u>DEL RUS</u>] [and vouth <u>ADD MEX</u>] [sex <u>ADD RUS</u>] disparities[, USA, <u>AUS</u>] [and DEL USA, <u>AUS</u>] inequalities[, and security concerns USA, <u>AUS</u>] within the health and care workforce, to [ensure <u>DEL CAN</u>] [support <u>ADD CAN</u>] meaningful representation, engagement, participation[, USA] [and DEL USA, <u>AUS</u>] empowerment[, and safety USA, <u>AUS</u>] of all health [emergency USA] [and care DEL USA] workers, while addressing [violence, harassment CAN] discrimination, [violence and harassment <u>ADD MEX</u>] stigma [from chat BRA] and inequality and eliminating bias, including unequal remuneration, and noting that women [and people with disability <u>AFRICA GROUP</u>] still often face significant barriers to [taking <u>DEL AUS</u>] [reaching <u>ADD AUS</u>] 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, <u>AUS</u>]
- [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 <u>ARG</u>] territories and respond also the need to retain health professionals in these areas. BRA, <u>ARG</u>]
- [NEW PARA 12(1)(c) (c) building a cross sectoral and multi-disciplinary workforce, whereby Parties shall promote or establish One Health joint training and continuing education programmes for human, animal and environmental health workforces, particularly for veterinary and environmental services needed to prevent spillover events, to build complementary skills, capacities and capabilities to prevent, detect, control, and respond to pandemic health threats ADD PARA
- [NEW (c) [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 adequate environmental services, including water, sanitation and hygiene, disinfection, and ventilation in relevant settings UK]
- [1 bis 1BIS The Parties shall, as appropriate, monitor and regulate labor [DEL ARG] [the working ADD ARG] conditions of health and care workers in order to protect this workforce, especially from [the ADD ARG] risk of contagion, exhausting working hours and participation in experimental procedures unapproved by government agencies. BRA, ARG] 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, <u>AFR GROUP</u>] Parties [in line with their respective capacities PAK] [[are encouraged DEL NGA, PHL, IDN, THA, AF GROUP, <u>ZAF/RETAIN AUS</u>] [shall AF GROUP, <u>ZAF</u>] [commit NGA] [shall PHL, THA]] [shall take necessary measures IDN] to enhance DEL BGD, IRN, <u>PAK/RETAIN AUS</u>] [shall provide BGD, IRN, <u>PAK</u>] financial and technical support, assistance and cooperation, [on voluntary and mutually agreed terms, <u>ADD JPN</u>] in particular to developing countries, [subject to availability of resources, <u>ADD SGP</u>] to strengthen [, retain PHL] and sustain [through relevant incentives <u>ADD MEX</u>] a skilled and competent health and care workforce [as well as other relevant sectors for the response and recovery phases MEX, <u>URY</u>, TUN, DOM] [with public health emergency competence THA] at the [subnational, USA, <u>AUS</u>] national[, and regional USA, <u>AUS</u>] level[ <u>s ADD AUS</u>]. [During pandemics and in case of shortages, WHO and Mechanism under Article 6 shall prioritize the need of frontline health workers. <u>ADD PAK</u>] 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]

# [NEW PARA 2BIS] Developed State Parties shall take necessary measures to reduce brain drain of healthcare workers from developing countries and to offer compensation to developing countries for the economic cost of brain drain. AFR GROUP]

[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]

#### [ADD EU ARTICLE EXPANDING ON ARTICLE 12(2):

#### Article I.1 - Enhancing and coordinating emergency preparedness and response measures

- 1. Parties shall endeavor to establish or designate emergency health teams at national and where appropriate regional level. Emergency health teams should be multi-disciplinary, based on a One Health approach, and ensure the essential functions and capacities for responding to a pandemic situation. Emergency health teams should include public health expertise and logistics support. The role of emergency health teams shall be to improve the timeliness, quality and coordination of health and emergency services.
- 2. Parties in a position to do so shall support and assist other Parties in need, at their request, in particular Parties which are low or lower middle income countries, in training and capacity building for their local or regional emergency health teams. The Secretariat in cooperation with relevant organisations and bodies shall also provide regular training and assist local and regional emergency medical teams of Parties in maintaining the capacity for immediate deployment at national and regional level.

- 3. Parties having established emergency health teams shall make best efforts to respond to requests for deployment by Parties affected by pandemic situations to which they are not able to fully respond with their national resources. The Secretariat shall coordinate the deployment of emergency health teams in close coordination with the requesting Parties and the WHO, including by selecting teams with the required expertise and appropriate equipment, and advising on the modalities, location and duration of their deployment.EU ]
- 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 Collaboration Centres IDN] [where reasonably possible ADD SGP] to support [pandemic affected IDN] Parties upon request, [and is accountable for preventing and responding to sexual abuse and harassment CAN] [and is trained in and accountable for their actions in preventing and responding to sexual exploitation, abuse and harassment ADD 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] [also ADD IDN] [will extend ADD PAK] [support DEL NGA, SAU, USA] [commit to NGA] [shall encourage USA] [for ADD PAK] [propose ADD SAU] 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] [that are equitably distributed, including in developing countries DEL PAK] 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 [multidisciplinary AF GROUP, AUS] public health emergency [multi-disciplinary ADD ZAF] 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]

#### [ADD NEW PARA 5 (AFR GROUP):

The Parties shall develop and implement comprehensive strategies and plans to protect health workers and public health officials from violence and intimidation in the course of carrying out pandemic prevention, response, and recovery. These plans should:

- (a) Be based on the best available evidence of effective strategies to prevent threats, violence, and intimidation of health workers and public health officials in pandemic response through education of the public, security measures, training, and support.
- (b) Provide for ongoing monitoring of incidents involving threats or acts of violence or intimidation of health workers and public health officials in connection with pandemic response

and systematically collect data on such incidents to develop and evaluate measures taken to avoid them.

- (c) Provide psychosocial support for health workers and public health officials in situations of exposure to threats, violence, or intimidation.
- (d) Ensure accountability for threats and acts of violence and intimidation against health workers and public health officials, including effective penalties and remedies.
- (e) Engage health workers and communities to understand their concerns about pandemic response and consult them in developing measures to protect health workers and public health officials engaged in the response from threats, violence, and intimidation.
- (f) Support health facility administrators, health workers, and public health officials in developing security strategies and communicate regularly with them to share measures that have proven effective.

ADD NEW PARA 6: The Parties shall protect health workers by ensuring adequate tools and safe environments by:

- (a) developing and implementing comprehensive strategies to ensure all health workers, including community health workers, have timely access to high quality and properly fitting personal protective equipment to protect from infection, as well as training in its use.
- (b) Implementing effective strategies to ensure adequate water, sanitation, and hygiene services and infection prevention and control in all care delivery settings, including administrative procedures, sterilisation of equipment and ventilation.
- (c) Developing and implementing comprehensive policies and procedures to ensure all health workers, including community health workers, have priority access to health products, including vaccines.
- ADD NEW PARA 7: State Parties shall establish and maintain effective workforce planning systems to effectively and efficiently deploy trained health workers during pandemics, or to address outbreaks that threaten to become pandemics, as well as communication systems that permit rapid and efficient communication with all health workers, including community health worker. AFRICA GROUP)

[FN: ADD on Gender SAU]

- Article 13. [[Preparedness monitoring, simulation exercises and [universal [peer DEL ARM, USA] [health and emergency preparedness (UHPR ADD USA] review DEL CHN, IRN, RUS] DEL IND, HTI, PAK, RETAIN ARM] [and assessment ADD ARG] [Mechanism ADD ZAF] [Health systems performance assessment IND, HTI, FJI, PAK] [Preparedness monitoring, evaluation and review TUN] RESERVE JAM]
- 1. [[In the event of a pandemic, THA] Each Party shall [in keeping with national capacities, ADD JAM] undertake regular [and systematic DEL THA] [national IDN] [capacity DEL USA] assessments in order to identify capacity gaps [[and enhance response readiness, [by USA] USA, AUS] [including]

in the human, animal and environmental sectors, ADD AUS] [across sectors UK] [and DEL USA] develop[ing USA] [update ADD IND] and implement [comprehensive, inclusive, multisectoral DEL RUS] national [regional and international ADD ZAF] 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 [and supported ADD ZAF] by WHO DEL RUS] [, where appropriate ADD JAM] [FAO, WOAH, and UNEP AUS], including but not limited to those established by the International Health Regulations Monitoring and Evaluation Framework, in partnership with relevant organizations USA] [and the other Quadripartite members UK] DEL RUS].

[NEW PARA 1 BIS. Based on the multi-sectoral national plans and strategies of Member States, WHO Regional Offices shall develop multi-sectoral regional plans pandemic prevention, preparedness and response and health system recovery, in consultation with its Member States. [ND]

[NEW PARA 1 BIS. The Health Assembly (or the governing body of the WHO CA+ - for example, Conference of the Parties) shall periodically review the functioning of this WHO CA+ ADD RUS]

- 2. [Each Party shall [, in collaboration with an independent review and advisory committee, ADD **ARM**] 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 [among others ADD IDN] appropriate [multi-sectoral UK] simulation [or tabletop DEL CHN] exercises, [and intra-and after-action reviews. These efforts are for the purposes of helping to USA] [as defined by the WHO and its regional offices ADD ZAF] [[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, JAM] [will DEL USA, JAM, THA, RETAIN ARM] [shall THA] conven[e DEL USA, RETAIN ARM] [ing USA, JAM] [or participate CHN] [regular ADD JAM] multi-country or regional [multi-sectoral UK] [, and when appropriate, border COL] [simulation ADD ZAF] [tabletop DEL CHN, RETAIN ARM] [simulation CHN] exercises [every two years, DEL USA, THA, JAM/ RETAIN ARM] [no later than XX after the declaration of a public health emergency with pandemic potential THA] [in leadership and coordinating role ADD RUS] [and at no less than every five years, ADD JAM] with [technical support DEL RUS] from the WHO Secretariat [and its regional offices COL] [, as appropriate CHN] [and an independent review and advisory committee ADD ARM], [including contact with the executive bodies of the other Quadripartite organisations with a view to establishing appropriate forms of cooperation with them UK] with an aim to identify gaps in multi-country [preparedness COL] response capacity[. DEL AFR GROUP][,as well as technical and financial needs AFR GROUP] [Participation in such events carried out by the parties to the extent possible ADD RUS]

- 4. [Each Party shall provide [annual (or DEL THA, <u>JAM</u>] 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 [<u>utilising the reporting template at Annex XXX AD JAM</u>] DEL USA, <u>AFR GROUP, RUS</u>]. RESERVE RUS, ETH, IRN][ including documentation of best practices in pandemic prevention, preparedness, response and health system recovery ADD IND]
- 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/RETAIN IDN, ZAF] [capacity building and ADD IDN] funding[, both external and domestic, USA] [predictable and adequate funding ADD ZAF] for developing countries DEL THA] for this purpose DEL THA, RUS].
- 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] [that leverages the use of existing monitoring and evaluation tools ADD SGP] to [review USA] [assess DEL USA] national, regional and [global DEL ZAF] [public health THA] [preparedness DEL THA] [international ADD ZAF] 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, AFR GROUP, RUS] DEL THA] RESERVE PAK, ETH, IRN]
- 7. [The Parties shall [consider USA] [endeavour to implement [ing ADD THA] DEL USA, THA] [work towards ADD THA] the recommendations generated from [the ADD THA] review [and assessments ADD THA] mechanisms, including prioritization of activities for immediate action [, as appropriate to their nationally determined public health priorities BGD, EGY] [in accordance with their nationally determined health priorities. ADD PAK] RESERVE PAK, ETH, IRN] [DEL AFR GROUP, RUS]

RESERVE ARTICLE 13: CHN, NAM, EGY.

[NEW PARA 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.

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

[NEW PARA 8. Based on the results of the implementation mechanisms established by the WHO CA+, every X years the COP will establish updated targets for Parties' to meet. The targets will create concrete goals for increasing capacities to comply with the provisions of WHO CA+. Cost estimates will be created for each Party to meet the targets under their existing costed National plans. The Secretariat will compile the costs at the national, regional, and global level to inform the amount of financing that needs to be supported under Article 19 to meet the goals of the WHO CA+. AFR GROUP]

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

### [[ALT Article 13. Universal Health and Preparedness Review (UHPR) DEL AFR GROUP.]

- 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. CHE1

## PROPOSAL BY ARG TO INCLUDE ART. 13 (2-5) TO INCLUDE IN THE EVALUATION FRAMEWORK THAT WILL BE DEVELOPED (UHPR OR OTHER)

ARTICLE 14. [[Prioritization and AF GROUP] [Protection DEL AF GROUP/RETAIN AUS, ZAF] [and [prioritization and ADD ZAF] promotion AUS, NZL, AF GROUP, UK] of [human rights DEL AF GROUP] DEL WHOLE RUS] [right to health AF GROUP, ZAF][MOVE TO CHAPTER 1 ADD EU]

## [DEL WHOLE Article 14 BRN, RESERVE JAM]

- The Parties shall [ensure that all EU] [[, in accordance with their [national laws DEL CAN, ARG, UK, CHI/RETAIN SGP, TUR] DEL AUS, NZL, PHI] [and international obligations AFR GROUP] incorporate non-discriminatory measures to protect human rights as part of their [national laws **DEL CAN**[[obligations under international human rights law[s ADD PAK], CAN, ARG, PAK, UK] [and international obligations AF GROUP, ZAF] [and having regard for public health concerns ADD SGP [incorporate DEL THA/RETAIN SGP] [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] [, as appropriate, ADD SGP] [[to [promote and ADD COSR] [guarantee, respect AD CHI] [protect DEL THA/RETAIN COSR, SGP] [and promote AUS, NZL, UK, CHI] human rights DEL AF GROUP/RETAIN ZAF] [[and to ADD ZAF] promote the right to health AF GROUP, ZAF] [and fundamental freedoms USA, UK] [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] [of health system ADD IDN] [[with a particular emphasis **DEL USA**] on the [rights of DEL THA] DEL USA, **UK**] [taking into account the [the needs of people at high risk, people living in humanitarian settings, the protection of health and other essential workers, and the rights of ADD USA] challenges faced by USA, UK] [and participation ADD COSR] persons in vulnerable [situations DEL JAM] [groups ADD JAM] DEL **RUS**] [and by health and other essential workers USA, UK].
- 2. [Towards this end, each Party [in accordance with their national circumstances, needs, and priorities ADD SAU] shall: DEL RUS]
- (a) [endeavour to IDN] incorporate into its laws and policies [and practices NZL, <u>AUS</u>] [related to <u>promotion and protection of ADD PAK</u>] human rights [protections <u>DEL PAK</u>] [and the right to health AF GROUP] [and preserving the right of every person to quality, accessible and affordable healthcare PHI] [, as appropriate, <u>ADD SGP</u>] during [[a pandemic <u>ADD AUS</u>] [s THA, BGD, AF GROUP] [[public health emergencies DEL BGD, AF GROUP][pandemics <u>ADD BGD</u>], including, but not limited to, requirements that DEL THA] any limitations on human rights [, the rights to health <u>AFR GROUP</u>] [pandemic <u>AFR GROUP</u>] 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 and carried out in accordance with the principles of legality, necessity and proportionality, ADD CHI][are non-discriminatory, [necessary DEL CHI] [, proportionate and the least restrictive THA] to achieve the public health goal [and [the least restrictive **DEL SGP, CHI**] necessary to protect the health of people **DEL CHI**] DEL THA, **AUS**] [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 **DEL AUS**] and take into account the needs [and lived experiences ADD COSR] [of people at high risk and persons in vulnerable [situations **DEL JAM**] **DEL CHI**] [groups **ADD JAM**]; [and DEL PHI] (iii) people living under any restrictions on the freedom of movement, such as quarantines and isolations, have [sufficient **DEL COSR** [equal ADD COSR] access to [pandemic-related products THA] [medication DEL THA], [hospital treatment and other ADD COSR] health services and other necessities [and rights DEL IDN, AUS, THA, SGP]; and DEL UK, RUS [(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, COL1; and (iv) ensuring that migrants, including the sea-based workers, are not left behind in multi-level and multi-disciplinary approaches; | [iv) the criteria and mechanisms to declare the beginning and end of the emergency and for the exercise of the guarantees of rights of patients in contexts of health emergencies are established, (v) when addressing prevention, preparedness, response and recovery, respect the special needs of Indigenous Peoples and vulnerable populations, including access to health services, and ADD ARG

- [[[endeavour to [develop DEL IDN, CHI / RETAIN AUS] [engage with communities, civil societies, and other relevant stakeholders, to support a whole-of-government and whole-of-society approach IDN] [, as appropriate, ADD SGP] [create ADD CHI] [an independent and inclusive advisory committee to [give relevant advice to THA] advise the government DEL IDN/RETAIN AUS, PAK] [engage with communities, civil societies, and other relevant stakeholders THA, IDN] [to support of whole-of-government and whole-of-society approach, in developing legal and policy framework IDN] [in fulfilling its human rights obligations ADD PAK] on human rights [promotion and THA] protections during [public health emergencies DEL THA, AUS] [pandemics THA], [a pandemic and monitor human rights protections ADD AUS] [[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, UK, RUS [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 TUR**] DEL 2(b) AF GROUP, **ZAF**][ The advisory committee should include representation from groups of people at high risk and persons in vulnerable situations, including women, Indigenous peoples, older persons, persons with disabilities, people deprived of their liberty, and others who are disproportionately impacted; and ADD COSR
  - [(b) endeavour to develop an independent and inclusive advisory committee to advise the government on human rights protections during public health emergencies, including on the development and implementation of its legal and policy framework, and any other measures that may be needed to protect human rights **DEL AFR GROUP**, **ZAF**]

[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] **DEL TUR**]

[ALT 2(b) (To ADD AFR GROUP) Ensure that 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. ZAF, AFR Group]

[NEW PARA (b)bis ensure transparency and accountability for public health and emergency measures by carrying out ex-ante and post-facto human rights impact assessments and adopting safeguards to mitigate disproportionate effects on persons in vulnerable situations, that are based on the best available evidence including by eliminating stereotypes and assumptions of the value or quality of life of any groups. Mechanisms should be established to engage with communities, particularly persons in vulnerable situations, and promote their participation in decision-making systems, including by ensuring that all information and communications about emergency measures are disseminated in accessible formats and languages to uphold the right to information of all people. ADD COSR]

(c) [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] [in accordance with national laws of respective Parties ADD TUR]

[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]

[NEW (c) Take measures such that the actions of Non-governmental organizations within their territory shall not impede the enjoyment of human rights in other countries and territories ADD PAK]

[NEW (d) Take measures to protect economic, social, and cultural rights and create conditions that would assure to all medical services and medical attention without discrimination and stigmatization of any individual, community or society in vulnerable situation ADD PAK]

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 3. 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. ADD PAK]

[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 4. 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 to ensure full realization of right to enjoy benefits of the scientific progress and its applications, in particular equitable access to pandemic related products ADD PAK]

[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 [solidarity, peace, ADD ARM] coordination, collaboration and cooperation

- 1. The Parties [subject to Member States national laws [and practice <u>DEL</u> NGA] <u>NGA</u>, MAR] [recognize the need to DEL AF GROUP, <u>ZAF</u>] [shall AF GROUP, <u>ZAF</u>] coordinate, collaborate and cooperate, [in accordance with the International Health Regulation, ADD ARG] in the spirit of international solidarity [and full respect for national sovereignty CHN, IRN, MAR] [and territorial dignity of states ETH]], [amongst themselves ADD RUS] with competent international and regional intergovernmental organizations and [other bodies <u>DEL RUS</u>] [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 <u>DEL USA</u>] [intend to ADD USA]:
- (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 [including across sectors as appropriate ADD USA] [by means that include [establishing appropriate governance arrangements DEL THA, USA, RUS] [as well as mechanisms to monitor bilateral, and multilateral international cooperation and assistance BGD, BRA, HTI, PAK, EGY];
- (b) support [mechanisms that ensure <u>DEL USA</u>] global, regional and national policy decisions [that ADD USA] [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]

## [ALT Para 1(b): [ensure global ceasefire during pandemics to promote global cooperation against common global threats; ADD ARM]

- (c) [develop, as necessary, and implement [global DEL ARG, AUS] policies [drawing on international guidance AUS] that recognize the [rights and ADD COSR] specific needs, [of, and strive to protect ADD USA] [and ensure the protection of [all people, in particular ADD ARG], [women and girls, in all their diversity ADD CAN] persons in vulnerable [situations DEL JAM] [groups ADD JAM] [places and ecosystems ADD CAN], [indigenous peoples DEL AUS, CAN] [Indigenous Peoples AUS, CAN], [people living in congregate settings such as persons with disabilities, older persons and prisoners, ADD COSR] [and DEL AUS] [those living in fragile environments or areas, [such as DEL AUS] [and ADD AUS] Small Island Developing States, DEL ARG, IDN, JAM, SGP] [and landlocked developing countries PRY] IDN DEL ARG] who face multiple threats simultaneously, DEL USA] [and ADD USA] by gather[ing DEL USA] and analys[ing DEL USA] [e ADD USA] data, including data disaggregated by [gender, DEL EU] [sex ADD EU] [age, disability ADD COSR] [age, and disability ADD AUS] [geography, socioeconomic status, and other relevant population subcategories ADD CAN] [and age ADD USA] to show the impact of policies on different groups; DEL RUS]
- (d) promote [all human SAU] [equitable [representation on the basis of ADD CAN] [gender DEL RUS, IRN/RETAIN CAN], [race, color, ethnic, BRA] [geographical and socioeconomic status, DEL RUS, IRN] DEL SAU] [representation and participation, DEL CAN] [as well as [equal and meaningful ADD CAN] the participation of youth [older persons ADD AUS] [and DEL COSR] women, DEL RUS, SAU, IRN, ARG, USA] [of all women, adolescents, and girls, and gender diverse persons, ADD ARG] [people with disabilities and Indigenous Peoples ADD AUS] [Indigenous Peoples ADD CAN] [older persons, Indigenous peoples and persons with disabilities, ADD COSR] [older persons, Indigenous peoples and persons with disabilities, ADD COSR] in global [and DEL FJI, USA] regional [and national FJI, USA] 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 <u>DEL USA</u>] [work together to incentivize ADD USA] countries [that <u>DEL USA</u>] [to ADD USA] report [public <u>DEL USA</u>] health emergencies [with pandemic potential THA], [, and collectively develop collaboration mechanisms ADD MEX] [as an incentive <u>DEL USA</u>] to facilitate transparency and timely reporting and sharing of [verified CHN] information; [aligned to International Health Regulations on travel and trade and with strict monitoring and imposition of penalties for defaulting Parties ADD ZAF] [in accordance with responsibilities under the International Health Regulations ADD USA] [and <u>DEL USA</u>] [for which purpose, measures based on scientific criteria must be adopted, proportionate to the risk, which recognize support to those countries when they request it for containment at the Source and seek to prevent unjustified damage ADD ARG]

[(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) [Where appropriate and with due to regard to the principle of sovereignt ADD JAM] facilitate [at the request of the state party ADD AFRICA GROUP] [at the invitation of the party RUS, CHN, IRN] WHO['s BGD, BRA, HTI, PAK, CHN, EGY, IRN, MAR, JAM] [with rapid DEL BGD, BRA, HTI, PAK, CHN, EGY, IRN, MAR, JAM/DEL AUS] access [as soon as practicable ADD AUS] 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, JAM] to assess and support the response to emerging outbreaks [for outbreaks of pandemic potential) ADD OMN] [, 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][when requested by the state in which the emergency occurs ADD ARG] DEL WHOLE USA, RUS].

[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, ZAF]

[NEW PARA (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. ADD AUS]

- [[Recognizing the central role of WHO as the [directing and **DEL SAU**] coordinating authority 2. on international health work, [as established in Article 2 of the WHO Constitution MEX] and mindful of the need for coordination with [the other agencies of the Quadripartite, ADD AUS] regional organizations, entities in the United Nations system [under the strategic coordination leadership of the UN Resident Coordinator System, ADD CAN [and DEL CAN] other intergovernmental organizations, [and other stakeholders engaged in pandemic prevention, preparedness and response, ADD CAN the WHO Director-General [After meetingthe criteria of a pandemic, reviewingtheIHR amendments, and consulting with concern parties in a regional leveland Governing Bodyfor theWHO CA+ ADD SAU] shall, in accordance with terms set out herein, declare [public health emergencies with pandemic potential and THA] pandemics. DEL USA] 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] MOVE TO PREAMBULAR SECTION MEX]
- 2. Recognizing the central role of WHO as the directing and coordinating authority on international health work, and mindful of the need for coordination with regional organizations, entities in the United Nations system and other intergovernmental organizations, the WHO Director-General shall, in

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<sup>&</sup>lt;sup>1</sup> 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.

accordance with terms set out herein, declare pandemics. [The Health Assembly may consider and 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 BRA, PAK]

- [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 Parties to the CA+, in accordance with the principle of "common but differentiated responsibilities and respective capabilities"; and
- (c) Voluntary contribution by 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, PAK]
- [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 3- [In accordance with the guidelines and recommendations of the WHO to ensure a coordinated and effective response to a pandemic, before declaring the end of the pandemic, the state should conduct a comprehensive review of the epidemiological situation and based on the consultation with concerned parties on a regional level, expert advice, and Governing Body for the WHO CA. Each sovereign state shall declare the end of the pandemic within its respective jurisdiction. The criteria for declaring the end of the pandemic may vary depending on local circumstances but should generally include sustained declines in new cases, hospitalizations, and deaths, as well as effective testing, tracing, and vaccination programs. The state should also ensure that it has the necessary infrastructure and resources in place to prevent a resurgence of the pandemic. ADD SAU

[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]

# 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 **DEL USA**] [leadership **ADD USA**] of, and contribution to, community readiness and resilience for pandemic prevention, preparedness, response and recovery of health systems [including both the Border Management Authorities and communities living along the borderlines ADD **ZAF**].

- 2. [[Each Party [shall <u>DEL ARG, USA/RETAIN AUS] [are encouraged to ADD ARG] [in keeping with national capacities, ADD JAM] [is urged to ADD USA] establish, [and ADD JAM] implement [a national ADD JAM] [and adequately finance <u>DEL USA] [or otherwise support ADD USA]</u> an effective [national <u>DEL JAM]</u> [and/or sub-national AUS, CAN] coordinating <u>DEL CAN]</u> multisectoral [mechanism <u>DEL USA] [led by the appropriate levels of government ADD CAN] [committee or other means of coordination ADD USA] with meaningful representation, engagement and participation of [local authorities and TUR] [by ADD USA] communities [civil society, and the private sector. ADD USA] [, in accordance with Alma Ata and Astana Declarations BGD, PAK] [, as appropriate IDN]. [including Indigenous communities ADD CAN] [key actors of the community or civil society ADD PRY] DEL SAU] RESERVE UK]</u></u>
- 3. [[Each Party [should DEL IDN, TUN, <u>AUS, USA]</u> [shall IDN, TUN, <u>AUS]</u> [intends to ADD <u>USA]</u> promote [,in accordance with its national context, ADD AUS] effective and meaningful engagement of [local authorities, TUR] communities, [including those comprised of persons in vulnerable situations ADD USA] 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], [thought institutionalising participatory governance and community engagement mechanisms UK] [and representative organisations ADD AUS] [subject to national laws and avoiding conflicts of interest ADD ZAF] as part of a [whole-of-government TUR] whole-of-society response DEL EU/RETAIN AUS] in decision-making [when deciding on [measures to prevent, prepare for and respond to a pandemic, and in ADD AUS] as well as when EU], [in ADD USA] implement[ation DEL EU/RETAIN AUS] [ing EU], monitoring and evaluati[on DEL EU/RETAIN AUS] [ing of these measures EU], [as well as DEL EU/RETAIN AUS] [provide ADD USA] effective [and accessible ADD AUS] feedback [mechanisms DEL USA] [opportunities. ADD USA] [should also be provided EU]. [, avoiding conflicts of interests BGD] MOVE to General Provisions EU] DEL RUS]
- Each Party [is encouraged to/intends ADD USA] [shall DEL USA] develop, [in accordance with its national context, DEL COSR] [in consultation with organizations representing persons in vulnerable situations ADD COSR] comprehensive[, multisectoral AUS] national pandemic prevention, preparedness, response and [health system[s ADD JAM] THA, JAM] 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/**RETAIN** AUS [vulnerable JPN] populations [who would most benefit from earliest access to medical countermeasures while ensuring equity JPN] [for [ex-ante and post-facto human rights impact assessments to prevent discrimination, including in ADD COSR access to pandemic-related [information ADD COSR] products[, social protection PHL] and [health DEL COSR] 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 [and routine health services UK] 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. [Subject to member states' national law ADD NGA] [E DEL NGA] [e ADD NGA] ach Party [based on national capacities ADD JAM] [will DEL THA, IDN, JAM, USA] [shall THA, IDN] [is encouraged to ADD USA] take [necessary ADD IDN] steps [in consultation with organizations representing persons in vulnerable situations ADD COSR] to address [the social, environmental and economic DEL THA] [relevant THA] determinants of health, [intersectional inequalities AUS]

[structures and systems that render people vulnerable ADD COSR] [and vulnerability conditions DEL THA, COSR] that contribute to the emergence and spread of pandemics [and ensure strong social protection measures PHL], [exacerbate inequalities ADD COSR] and [prevent or DEL THA] mitigate the socioeconomic impacts of pandemics [which may ADD USA] [arising from pandemic prevention, preparedness, response and health system recovery. THA] [, include[ing but not limited to, DEL USA] 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 DEL JAM] [groups ADD JAM][in line with national context NGA]. DEL THA] [ADD definition of person in vulnerable situations in Article 1 NGA] RESERVE UK]

6. [Subject to member states' national law ADD NGA] [E DEL NGA] [e ADD NGA] ach Party [should DEL IDN, <u>USA</u>] [shall endeavour IDN] [intends to ADD USA] 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 <u>DEL JAM</u>] [groups ADD JAM] [in line with national context NGA], [including [through ensuring their participation in decision-making processes and <u>ADD COSR</u>] mobilizing [social capital <u>DEL JAM</u>] in communities for mutual support. <u>DEL USA</u>] 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 [intend ADD USA] [[commit DEL USA] to DEL THA, ETH, AFR GROUP, AUS] [shall THA, ETH, AFR GROUP] [increase DEL USA] [strengthen ADD USA] 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, AFR GROUP] [including where relevant in relation to zoonotic disease spillover risks and the impacts of human behaviours on risk UK], [of zoonotic disease spillover risks and the impacts of human behaviours on risk ADD AUS] as well as [timely THA, ETH] access to [and dissemination of THA] information on pandemics [, their causes AUS] and their effects, [combat the infodemic, ADD USA] [and DEL USA] [including ADD USA] tackl[e DEL USA] [ing ADD USA] [[false, misleading, DEL AUS] misinformation [and AUS] or DEL PHL] disinformation [taking into account social gradient of health literacy ADD RUS] [or false and misleading information PHL], [including through [engagement with communities, civil societies, and private sectors, as well as IDN] promotion of international cooperation. DEL USA] [at the national, regional, and international levels ADD USA]. 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 international human rights law UK], [and in cooperation with diverse groups, the CAN] development and implementation of [risk communication, community engagement, infodemic management, and ADD USA] educational and public awareness programmes [co-created with communities on outbreaks and ETH, AFR GROUP] [on DEL ETH] pandemics [[, their causes AUS] and their [drivers and CAN], in particular the

interconnections between human, animal and environmental health ADD AUS] and their effects, by informing the public, [communicating risk [translating science, CAN, AUS] and managing infodemics DEL USA] [without delay THA] through effective [bidirectional ETH, AFR GROUP] [meaningful engagement and accessible CAN, AUS] channels [and communication infrastructure THA], including [but not limited to, ADD USA] social media[,in a way that is broadly accessible, including to persons in vulnerable situations AUS];[ and through making available information and communications in accessible and alternative languages and formats including sign language, Braille, captioning, plain language, easy to read and plain language, as well as child friendly information and communications; ADD COSR] [trusted community messengers, community-based health workers, leaders, influencers, and organizations, and by promoting capacity development across all relevant sectors in infodemic management ADD USA]

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

- Declaration of Human Rights, ADD USA] conduct regular [community outreach, IDN] [social listening DEL AUS, UK] [research AUS] [monitoring UK] and analysis to identify the prevalence and [profiles DEL UK] [nature UK] of [misinformation DEL PHL/RETAIN AUS, USA] [disinformation including false news PHL], [and the public's questions, concerns, and frustrations, AD USA] [[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 [the infodemic, including ADD USA] misinformation [, DEL UK] [and UK] disinformation [and false news DEL UK], 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]. DEL WHOLE USA]

## [Building a resilient information ecosystem as a part of strengthening pandemic prevention, preparedness and response; and ADD USA]

[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 PARA (d) adequate allocation of resources including financial shall be used by the governing body to promote public awareness literacy across all levels in particular across platforms where there is high level of misinformation, disinformation and infodemics ADD ZAF]

[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, <u>USA</u>] [shall conduct THA] <u>[are encouraged ADD USA]</u> to research <u>[including conducting of routine monitoring of health literacy level, ADD RUS]</u>

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, [in a pandemic emergency, including ADD USA] confidence [and DEL USA] uptake, [and demand ADD USA] of vaccines, use of appropriate therapeutics [(including antimicrobials) ADD SGP] [use of non-pharmaceutical interventions, ADD USA] and trust in science and government institutions [while strengthening digital health operations and infrastructure THA].

- 3. The Parties [shall <u>DEL USA</u>] [are strongly encouraged to ADD USA] promote science and evidence-[informed <u>DEL USA</u>] [based ADD USA] effective and timely risk assessment, [taking into account SGP] [including <u>DEL SGP</u>] [the <u>DEL USA</u>] [any ADD USA] uncertainty [and the evolving nature ADD USA] of data and evidence, [during a pandemic emergency, and including use of social and behavioral science, ADD USA] 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 literacy across all levels in particular across platforms where there is high level of misinformation, disinformation and infodemics 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]

### **INEW EU PROPOSAL**

### Article M.1 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
- (d) promote effective and accessible communication specifically aimed at informing persons in vulnerable situations and people living in humanitarian settings;

(e)

- 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]

# Article 18. [One Health [DEF SHOULD BE ADDED TO ARTICLE 1 ADD ZAF] RESERVE WHOLE ZAF]

[DEL Article 18 AFR GROUP] [RESERVE ARTICLE JAM]

### [UPGRADE AS CHAPTER AND NOT JUST ARTICLE OMN]

The Parties, [[recognizing that the majority of emerging and re-emerging BRA, ARG, AUS] 1. 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] [[shall ADD AUS] [to DEL AUS] engage and coordinate between all relevant actors and across sectors, particularly across the human health, animal health and environment sectors, for pandemic prevention, preparedness and response under a One Health approach. GBR] [and in line with the guidance of the Quadripartite ADD AUS], [[in the context of pandemic prevention, [detection, SGP] 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 **DEL AUS**[[, with clear access and benefit sharing rules NAM, BRA, IDN] [in a way ADD AUS] that is coherent, integrated, [transparent ADD ARG] coordinated[, equitable BGD, NAM, IDN] and collaborative [among DEL SGP] [across ADD SGP] all relevant [actors, DEL SGP] [sectors and all levels ADD SGP] [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] DEL GBR, UK 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] **DEL AFR GROUP.**]

[ALT The Parties shall make efforts to utilise a One Health approach when addressing public health threats that is coherent, integrated, coordinated and collaborative among all relevant actors, with the application of existing instruments and initiatives. ADD ZAF]

[ALT Recognizing that the majority of emerging infectious diseases and pandemics have been caused by zoonotic pathogens, and in the context of pandemic prevention, preparedness, and response and recovery of health systems, the Parties intend to promote and implement a One Health approach which recognizes the interconnectedness and interdependence of human, animal (wildlife and domestic), and environmental health systems. This approach needs to be a coherent, integrated, coordinated and collaborative effort among all relevant actors and stakeholders, including the Quadripartite, respecting their individual authorities and mandates and with the application of existing instruments and initiatives such as the International Health Regulations Monitoring and Evaluation Framework. ADD USA]

- The Parties, with [an **DEL AUS**] [the **ADD AUS**] aim of safeguarding human [, animal, plant and environmental ADD SGP] health and detecting[, ADD SGP] [and DEL SGP] preventing [and responding to public SGP] health threats, shall promote [and enhance synergies between DEL GBR, AUS, CAN, UK] multisectoral and transdisciplinary collaboration [and cooperation JPN, GBR, UK] [and coordination ADD AUS] at the [subnational, GBR, AUS, UK] [and ADD AUS] national [, regional GBR, AUS, CAN, UK [[level DEL JPN] and [cooperation at DEL JPN] DEL GBR, UK] [and GBR] the **DEL AUS**] international level[s GBR, AUS, UK] [, in order to [detect, GBR, AUS, <u>UK</u>] identify, [and GBR, <u>UK</u>] conduct [multi-sectoral GBR, <u>AUS, UK</u>] risk assessment of [and share DEL GBR, UK] [information on ADD SGP] [pathogens with pandemic potential DEL BGD/RETAIN AUS] [while sharing benefits derived from and improving equity related access to medical counter measurement and R&D, CHN] [information about the unusual events BGD] [in accordance with article 10 ADD ARG [ and their genetic sequences, ADD AUS ] [, and associated risk drivers ADD SGP] at the interface between human[s GBR, AUS], animal[s GBR, AUS, UK] and [the GBR, AUS, UK] environment [[ecosystems DEL AUS]], [that may cause a pandemic or that may be early sign of imminent pandemic outbreak BGD] [while recognizing their interdependence DEL BGD] DEL GBR, UK]. DEL BRA] DEL AFR GROUP]
- [ ALT. The Parties, collaboration at the national regional, international level, in order to identify, conduct risk assessment of and share pathogens with pandemic potential at the interface between human, animal and environment ecosystems, while recognizing their interdependence. [RESERVE ZAF]
- [ALT With an aim of safeguarding human health from future pandemic emergencies and detecting and preventing health emergency threats, the Parties shall promote and enhance synergies between sectors and promote multisectoral and transdisciplinary One Health collaboration at the local, subnational, and national level and cooperation at the regional and global levels, in order to effectively identify, conduct risk assessments, share samples and relevant genetic sequence data, in accordance to national law, and implement data-driven, locally relevant interventions to address pathogens with pandemic potential, especially at the interface between human, animal and environment ecosystems, while recognizing their interdependence. ADD USA]
- 3. The Parties[, within their national capacities, BGD, IRN] [informed by surveillance activities and studies on pathogen infection dynamics and existing relevant guidelines and norms and alert systems, shall ADD AUS] [recognizing that improving the health and welfare of animals and the environment has positive downstream benefits for human health, ADD CAN|[will DEL AUS/RETAIN CAN identify [mitigate against ADD ZAF] and [integrate into relevant pandemic prevention and preparedness plans interventions that **DEL ZAF**] [address GBR/**DEL UK**] [reduce or mitigate the disease emergence/re-emergence or spillover risks associated with GBR, AUS, UK the drivers of the emergence and re-emergence of disease at the human-animal-[plant-ADD SGP] environment [interface, including [conducting in-depth trade off analysis to support interventions in intersectoral issues related to ADD ZAF] but not limited to [pollution ADD CAN] climate change, [animal welfare, ADD CAN] land use change, wildlife [harvest and ADD CAN] trade, [desertification <u>DEL CAN</u>] [, biodiversity loss ISR, <u>AUS</u> / ALT pressure on biodiversity COL] [natural habitat degradation ADD CAN] and antimicrobial resistance DEL CHN/RETAIN AUS] 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] DEL AFR GROUP] acknowledging that Indigenous Peoples have long had an understanding of the interconnectedness of humans, animals and ecosystems ADD AUS]

- [ALT 3. The Parties intend to identify and integrate into relevant pandemic prevention and preparedness plans, data-driven research to improve the understanding of the drivers for the emergence and re-emergence of disease at the human—animal—environment interface, such as climate change, land use change, wildlife trade, ecosystem degradation, and antimicrobial resistance. Further research can help identify locally appropriate, effective, risk-proportionate mitigation strategies for which costs and benefits can be assessed, and needs for food security and equity considered and balanced. ADD USA]
- 3. [[The Parties [commit to <u>DEL AUS] [shall ADD AUS]</u> regularly assess [their RUS] One Health capacities [according to national needs RUS][, insofar as they relate to pandemic prevention, [detection, ADD SGP] preparedness, response and recovery of health systems DEL BGD] [as specified in Annex XX BGD], and to identify gaps, policies and the [funding <u>DEL AUS] [financing and resources ADD AUS]</u> 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, <u>ZAF</u>] RESERVE 18.4 GBR] **DEL AFR GROUP**]
- [ALT 4. The Parties intend to develop effective monitoring and regulating practices, considering the International Health Regulations Monitoring and Evaluation Framework, in accordance to national law, to regularly assess One Health capacities, insofar as they relate to pandemic prevention, preparedness, and response and recovery of human health systems, recognizing the interface between human, animal and environment ecosystems, and to identify gaps, duplication of efforts, synergies, and policies, as well as the funding needed to strengthen those capacities, in alignment with existing obligations and agreements. ADD USA]

[NEW PARA (4) Establish a dedicated One Health Fund to strengthen capacities for One Health especially in developing countries in line with the principles of the CBDR (once they have been defined ADD ZAF].

- 5. [[The Parties [in accordance with their respective obligations ADD ZAF] [commit to DEL MEX, AUS, ZAF, USA] [[shall MEX, AUS] align implementation of their obligations ADD AUS] [shall ADD MEX] [will ADD ZAF] [strengthen synergies DEL AUS/RETAIN MEX] with other existing relevant [international legal BGD] instruments that address the drivers of pandemics[, such as climate change, biodiversity loss, [wildlife trade COL] [weak animal health systems ADD USA] [ecosystem degradation DEL SAU] and increased [health ADD USA] risks at the human-animal-[plant-] 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] RESERVE 18.5 GBR] DEL AFR GROUP]
- 6. [The Parties [shall GBR, AUS, UK] [commit DEL USA] [intend ADD USA] to [strengthen DEL GBR, AUS, UK] [work towards strong GBR, UK] multisectoral, coordinated, interoperable [and DEL GBR, UK] integrated [and pathogen agonistic GBR] [risk-based ADD USA] [One Health DEL USA] surveillance systems DEL AUS] [develop interdisciplinary epidemiological surveillance with comparable and consistent metrics, based on existing systems ADD AUS] [with a One Health focus ADD USA] and [related capacity, including the monitoring of drug-resistant pathogens, at all levels, across human, animal, plant and broader environment health, GBR] [strengthen laboratory capacity to identify and assess the risks and emergence [and re-emergence ADD USA] of pathogens and variants with pandemic potential, in order to [minimize DEL AUS] [reduce the risk of ADD AUS] spill-over [and spillback ADD USA] events, [identify ADD USA] [and DEL USA] [mutations

**DEL CAN**] [and variants of concern, ADD USA] and [assess ADD USA] the risks associated with [pandemic potential diseases IDN][ infectious diseases, including ADD USA] [[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 DEL CAN, USA] outbreaks in wildlife or domesticated animals [and ADD USA] [as well as release of pathogens from laboratory facilities ADD CAN] [and livestock, including in both rural and remote areas, ADD USA] from [spilling over to humans and growing to ADD USA] becoming a pandemic [in humans ADD USA] DEL GBR, AUS, UK] DEL IDN]. [to facilitate rapid detection of health threats, sharing of intelligence between sectors and robust multi-sectoral risk assessment. GBR, AUS, UK] DELETE PARA 6 BGD, CHN] DEL AFR GROUP]

[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] **DEL AFR GROUP**]

[[New para (6)] The Parties commit to build and strengthen intersectoral One Health workforces (including human, animal, plant and environmental services) that have the skills, capacities and capabilities to prevent, detect, control, and respond to health threats in a timely and effective manner. ADD SGP]

[NEW Paragraph 18 (6). The Parties will, in accordance with national priorities and public health needs, strengthen surveillance systems to be able to identify [the risks and emergence of disease ADD ZAF]

[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] **DEL AFR GROUP**]

[NEW 6 bis The Parties shall cooperate with global or regional initiatives and develop or strengthen national initiatives, working towards pandemic prediction, identification of emergence hot-spots and cold-spots, and multi-hazard early warning and risk communication systems which incorporate disease surveillance, including drug-resistant pathogens, alongside monitoring of environmental, climatic and anthropogenic drivers of disease, including through the sharing of data and intelligence within a trust architecture and the linkage of early warning mechanisms to decision making processes in order to support early action. GBR, UK DEL AFR GROUP]

[NEW 6.bis The Parties commit to enhance financial and technical support, assistance and cooperation, in particular to developing countries, to strengthen surveillance systems and laboratory capacity in promoting and implementing One Health approach at the national level. [IDN]

[NEW PARA "The parties will maintain close contact with international organizations Aimed at guaranteeing the transparency of the zoosanitary, phytosanitary and quality and safety situation in food Through collecting, analyzing and disseminating information and scientific evidence, with

the purpose of guaranteeing zoo and phytosanitary status and avoiding unnecessary duplication of efforts and resources ARG]

[NEW PARA (6)(b) share surveillance information data through relevant networks and with Quadripartite partners where relevant to support access to timely information and the rapid identification of emerging threats AUS].

[Article 18.6 bis: [ADD: The Parties commit to strengthen One Health leadership and governance through clear mechanism for coordination and accountability to better equip us to anticipate, prevent and respond to complex challenges such global pandemics CAN].

[Article 18.6 ter: [ADD: The Parties commit to strengthen One Health research capacity to bring human, animal and environmental scientists to take One Health approach for pandemic prevention, preparedness, response and health system recovery CAN].

- 7. [Each Party[, within its national capacity and condition, CHN, IRN] [[in accordance with their national circumstances, needs ,and priorities ADD SAU] [shall DEL IRN/ RETAIN SAU, ZAF] [within their national capacities ADD ZAF] [will commit to IRN]: [DEL WHOLE PARAGRAPH BGD]
  - (a) [Develop and ADD USA] [implement [science-based ARG, BRA] actions [including but not limited to improving infection prevention measures, antimicrobial research and development, access to and stewardship of antimicrobial, harmonisation of surveillance and management of environmental antimicrobial run-off, GBR, UK] [National Action Plans on antimicrobial resistance, as described by the WHO Global Action Plan on Antimicrobial Resistance, including through enhanced surveillance, detection, response, and prevention in human health, especially at the interface between human, animal and environment ecosystems, while recognizing their interdependence, to help minimize complexities that AMR can introduce during ADD USA] to [prevent DEL USA] [and prepare for GBR, UK] [reduce the risk of and prepare for ADD AUS] pandemics from [zoonotic pathogens and ADD AUS] 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. [IND] DEL CHN]; DEL AFR GROUP]

[(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] **DEL AFR GROUP**]

[[ADD: a bis) raise awareness and increase understanding (knowledge) of zoonotic and emerging disease risks and prevention (where appropriate), at all levels of society to build widespread support for risk-reduction strategies CAN];

(b) foster [science-based ARG, BRA] [and implement ADD AUS] [One Health ADD USA] actions at national [subnational ADD USA] [and community DEL CHN] levels that encompass whole-of-government and whole-of-society approaches [that align with existing commitments and obligations ADD USA] to [prevent, detect and ADD AUS, USA] control [zoonotic DEL SGP] [or potentially zoonotic GBR, AUS, UK] outbreaks [of zoonotic diseases ADD SGP] [(in wildlife [,livestock, ADD USA] and domesticated animals) DEL ZAF], [their spillover to humans, taking into account relevant tools and guidelines, and including engagement of communities, those affected by outbreaks and those in surveillance that identify zoonotic

outbreaks and conducts research to investigate the source; ADD USA] including [the training and ADD CAN] [strengthening ADD SGP] engagement of communities [with strong interactions with animal populations ADD SGP] [in surveillance [that identifies zoonotic outbreaks DEL SGP] [for such diseases, ADD SGP] [and antimicrobial resistance at source DEL USA] DEL CHN, IND, ZAF]; DEL AFR GROUP]

(c) [develop and <u>DEL ZAF</u>] implement a national [One Health action <u>DEL ZAF</u>] strategies, policies and plan[s] <u>ADD ZAF</u>] [[on antimicrobial resistance <u>DEL ZAF</u>] [that considers the environment, and <u>ADD CAN</u>] that strengthens antimicrobial stewardship [and infection prevention control <u>ADD ZAF</u>] in the human [and <u>DEL CAN</u>] [, <u>ADD CAN</u>] animal [and environmental <u>ADD CAN</u>] 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] <u>DEL ZAF</u>] and provides [technical DEL CHN] support [of affordable access to, medicines, diagnostic tools, vaccines and other interventions, CHN] to developing countries DEL BRA, MEX, <u>AUS</u>, <u>USA</u>]; <u>DEL AFR</u> GROUP]

# [ALT 18.7 (c ) regularly assess One Health capacities related to pandemic prevention, preparedness, and response and address areas for improvement. ADD USA]

[ ALT 18.7(c) Embed a cross-sectoral One Health approach across relevant national action plans and strategies (inter alia national One Health Action Plan on AMR, National Action Plan on Health Security) through active collaboration between the Ministries of Health, Environment, Agriculture, Finance and others as required. GBR, AUS, UK] DEL AFR GROUP]

- (d) [in line with their national priorities and context, ADD ZAF] [enhance surveillance to identify and report on pathogens resistant to antimicrobial agents in humans, [livestock <u>DEL CAN</u>] [animals, including domestic animals and wildlife, the environment ADD CAN] and aquaculture that have pandemic potential, building on the existing global reporting systems; and [promote food quality and safety; and SAU] [Need to clarify first on who will determine the pandemic potential of resistant pathogens in humans livestock and aquaculture ADD ZAF] DEL sub-para (d) BRA, CHN, IRN / RETAIN SWE, FRA, NOR, ITA, SAU] <u>DEL AFR GROUP</u>]
- [ALT (d) enhance surveillance and detection in human health, especially at the interface between human, animal and environment ecosystems, while recognizing their interdependence, to identify and report emerging pathogens with pandemic potential, and ensure safe and secure sharing of genetic sequence data concerning such pathogens among sectors so as to inform timely decision-making at appropriate national and regional levels, and global levels, building on the IHR and other existing global reporting systems; and ADD USA]
- (e) take the One Health approach into account at national, subnational and [facility DEL GBR, AUS, SGP, UK] [community GBR, AUS, UK] [local ADD SGP] levels [(including within health facilities, agricultural settings, markets and livestock transit points) GBR, AUS, UK] in order to produce science-based evidence, and [support, facilitate and[/or DEL NGA] oversee ADD NGA] the correct, evidence-based and risk-informed implementation of infection prevention and control[, including via strengthening the implementation of water, sanitation and hygiene and the management of wastewater GBR, AUS, UK]. DELETE PARA 7 BGD] RESERVE CHN, URY, PRY / MOVE to Article 4 RUS] [PROPOSE MERGING WITH (1) ZAF] DEL AFR GROUP]

[ALT (e.) taking the One Health approach into account at national, subnational, regional, and facility levels, in order to produce science-based evidence – including related to the social and behavioral sciences and risk communication and community engagement, and support, facilitate and/or oversee the science-based, data-driven and risk-based interventions to address zoonotic disease threats at their source including implementation of infection prevention and control, ADD USA]

[NEW PARA [ (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. ADD SAU]

# [NEW e bis) Strengthen regulatory authorities overseeing containment facilities to ensure pathogen security. CAN]

- [(f) Support other States Parties, in particular developing countries parties in establishing and maintaining One Health surveillance systems and laboratory capacities BRA, IDN, IRN] <u>DEL AFR GROUP</u>]
- [(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] **DEL AFR GROUP**]

[NEW (f) Share with all the Parties in real time knowledge and troubleshooting in order to build and sustain 6 &7 ISR] DEL AFR GROUP]

[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, <u>AUS</u>] <u>DEL AFR GROUP</u>]

[NEW PARA These measures have to be based on scientific principles, applied only to the extent necessary to protect human, animal or plant life or health, and not be maintained without sufficient scientific evidence, including through an assessment of risk ARG]

### [NEW PARA (8) USA PROPOSAL

#### 8. The WHO Director General shall:

a. work closely with the UN Food and Animal Organization, UN Environment Program, World Organization for Animal Health, and other relevant international organizations with responsibilities outside public health (including those that address biodiversity, climate change, and trade), to ensure policies, guidances, and other tools related to One Health and pandemic prevention, preparedness and response are informed by and consistent with their expertise, policies, guidances, tools, and practices as developed and agreed to by their members.

b. ensure coordination within WHO among divisions that work on One Health related issues such as biodiversity and climate change on One Health and PPR.

c. Ensure that WHO member countries are at forefront of any work on One Health related issues, including the development and implementation of new or updated obligations, policies, or frameworks. ADD USA]

#### [ADD ARTICLE EU PROPOSAL

#### **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]
- Chapter VI. Financing for pandemic prevention, preparedness, response and recovery of health systems
  - Article 19. [Sustainable [flexible ADD AFR GROUP] and predictable financing [ADD FLEXIBLE throughout the article AFR GROUP][RESERVE JAM]
- 1. The Parties recognize the important role that [sustainable ADD AUS] 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 well as the greater responsibility of the developed country Parties to finance the implementation of WHO CA+ considering the pandemic PPRR as a global public good BGD, AFR GROUP] [in collaboration with regional mechanisms ADD ZAF]. In that regard, each Party [shall DEL USA] [intends to USA] [in collaboration with regional mechanisms AFR REGION] [[Funding models to take into account all party's capacity and capabilities Country ownership shall be central to determine priorities, present funding application, and tailor responses, considering their political, trade, cultural and epidemiological context and aligning with new needs, learning and realities. ADD ZAF]:
  - (a) [cooperate **DEL SGP**] [**Consider cooperating SGP**] with other Parties, within the means and resources at its disposal, to raise [sustainable PAK, AUS] financial resources [, in a sustainable manner which includes but are not limited to grants and low risks and costs of funds, BGD] for effective implementation of the WHO CA+ through [domestic, USA, <u>AUS</u>] bilateral and multilateral [a new or existing SAU] [regional [and <u>DEL AUS</u>] [or ADD AUS] sub-regional NZL] funding mechanisms [including the Pandemic Fund IDN] [This must take into account the financing proposal under consideration of the international Health Regulation (2005) support the activities of the WHO CA+. AFR REGION, <u>ZAF</u>]; RESERVE 1.a USA]
  - (b) plan and provide [domestic USA] [adequate DEL USA/RETAIN AUS] financial support [to other parties, especially [DEL AFR GROUP] to developing countries BGD, AFR GROUP] [in line with its national fiscal capacities [and as appropriate USA] [and programs SAU] DEL AFR GROUP] for: [NEW sub(x) Health Systems Strengthening and Upgrading to the resilience levels as determined under Article 11 BGD, AFR GROUP] (i) strengthening [and sustaining core capacities for USA] pandemic prevention, preparedness, response [and recovery of health systems RESERVE USA] [in alignment with the IHR Monitoring and Evaluation Framework and associated metrics USA, AUS]; (ii) implementing its national plans, programmes and priorities; [including social support when necessary; ADD MEX] [- including multisectoral national action plans on antimicrobial resistance SGP] [and DEL CHN, BGD] [(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] DEL sub(iii) BGD] [and; (iv) increasing concerted financial support for health care workforce CHN]; [;iv)

### <u>support and assist other states parties at their or WHO's request in emergencies to facilitate</u> containment at the source ADD ARG]

(c) [[intend to USA] [[commit DEL PHL, AUS] [endeavour PHL, AUS] [to [finance necessary amount domestically, JPN] [prioritize and increase or DEL US] maintain DEL JPN, SGP] [and, where possible to increase USA], including through greater collaboration between the health, finance [and DEL USA, AUS] private[, and other USA, AUS] sectors, and other USA] as appropriate, [domestic funding [[by [a significant allocation USA] [an allocation ADD 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, BGD, SGP, ZAF, PRY DEL USA DEL PAK AF GROUP DEL ROK [within the means and resources at its disposal BGD] [in accordance with its respective capacities PAK] [funding appropriate to its current health expenditure ADD ZAF to DEL AUS/RETAIN ZAF [for ADD AUS] [for ADD SGP] pandemic prevention, preparedness, response [and health systems recovery, RESERVE USA] notably for improving and sustaining relevant capacities [reinforcing social protection systems and services that contribute to fulfilling key determinants of health ADD COSR] and working to achieve [resilient health systems that contribute to ADD USA] universal health coverage [and to develop debt swap mechanisms for offsetting investments made in the governmental health sector against the debts payable by developing countries to the international financial institutions or developed countries BGD]; and RESERVE 19.1.c AUS, DEL AFR GROUP, BRN

[ALT C BIS] to provide financial support for pandemic prevention, preparedness, response and health systems recovery, notably for improving and sustaining relevant capacities in developing countries and working to achieve universal health coverage. AFR GROUP]

[ALT C ter to establish programmes that convert debt re-payment into pandemic prevention, preparedness, response, and recovery investments in health to be attained under individually negotiated "debt swap" agreements. An implementing country should invest in programs to strengthen health systems through the established mechanism with a creditor country canceling debt owed by the implementing country. AFR GROUP]

[ALT C QUART) Commit to expanding partnerships with development finance institutions in providing additional financing to developing countries, through prioritized debt relief, debt restructuring, provision of grants rather than loans that will guarantee that programs protect essential health and related spending from encroachment and to take advantage of economic benefits of frontloading finance for prevention and preparedness or support investments. AFRICA GROUP]

[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][allocate ADD JPN], in accordance with its respective capacities, and [based on the principle of solidarity, ADD MEX] [funding USA] [XX% of its gross domestic product DEL USA, JPN, CHN, NZL, UK, NOR, TUN, MEX, EU, SGP] [provide financial support CHN] [funding ADD SGP] 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 CHE] DEL AUS]

[particularly for developed countries to commit XX% of its gross domestic product to support developing countries in this regard CHN]. [This commitment shall create new funds and shall not dilute nor detract from current commitments of ODA at 0.7% of donors' Gross National Income BGD] DEL ROK, **BRN**, **SAU**]

\_[(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]

[NEW (e) be unfettered in its ability to prioritize the protection and promotion of the health of their populations by suspending its debt servicing and other capital outflows, in order to ensure adequate financial resources to deal effectively with the pandemic prevention, preparedness, response and recovery of health systems. BGD]

## [New Paragraph 19 (1)(e): Governance structure to be inclusive of all State Parties to ensure representation and inclusivity ADD ZAF]

2. The Parties [recognize the importance of coordination of USA] [[shall DEL JPN] [endeavour to SGP] ensure, through [innovative DEL SAU, NZL, BGD] DEL USA] [existing [and/or new DEL CHE, AUS] DEL BGD] [financial BGD] mechanism[s DEL BGD, CHE] [established under the framework of International Health Regulations 2005 BGD], 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 DEL BGD], to support strengthening [health systems and progressive realization of universal health coverage such that BGD] pandemic prevention, preparedness, response and recovery of health systems [are enhanced BGD], [based on public health risk and need, DEL BGD] particularly in developing countries. [Parties shall agree to the establishment of programmes that convert debt re-payment into pandemic prevention, preparedness, response, and recovery investments in health to be attained under individually negotiated "debt swap" agreements. An implementing country should invest in programs to strengthen health systems through the established mechanism with a creditor country canceling debt owed by the implementing country. AFR GROUP, ZAF]

[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: **DEL AFR GROUP, RETAIN ARG**].

- (a) Annual [share ADD ARG] [participation DEL ARG] contribution [by pandemic vaccine, diagnostic and therapeutic DEL ARG] manufacturers [of pandemic, diagnostic and therapeutic vaccines] [which use DEL ARG] [using ADD ARG] 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 **DEL ARG]** [from ADD ARG] 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, <u>PAK</u>]

- 3. The [developed country BGD] Parties shall promote, as appropriate, the use of [domestic USA, <u>AUS</u>] bilateral, regional, subregional and other appropriate and relevant channels to provide funding [at all levels USA, <u>AUS</u>] [including but not limited to grants and other low risk and cost of funds BGD] for the development and strengthening of [national health systems in order to enhance the efficacy of BGD] pandemic prevention, preparedness, response and health system [capacity building and USA, <u>AUS</u>] recovery programmes of developing country Parties[, and shall ensure the financial mechanism mentioned in paragraph 2 receive not less than XX% of their total funds earmarked for international health work. BGD]
- 4. [The Parties [intend to encourage USA] [will facilitate DEL USA] [will endeayour to AUS] rapid and effective mobilization of [adequate DEL USA] [additional AFR GROUP] financial resources [via transparent domestic financing mechanisms for responding to **public** 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 DEL ARG] [countries DEL CHN, ARG] [developing Parties CHN], [through financial mechanism established under IHR 2005, BGD] [the country where the event occurs. ADD ARG] based on public health [risk and PHL, CAN] need, [and their nationally determined priorities PAK] [to maintain and restore routine public health [and other essential health services ADD CAN] [functions **DEL CAN**] during and in the aftermath of a pandemic response RESERVE USA]. DEL PARA 4 SAU] [Such financial resources shall be mainly composed of grants and other low risk and cost of funds. BGD] [Parties must commit to expanding partnerships with development finance institutions in providing additional financing to developing countries, through prioritized debt relief, debt restructuring, provision of grants rather than loans that will guarantee that programs protect essential health and related spending from encroachment and to take advantage of economic benefits of frontloading finance for prevention and preparedness or support investments. ZAF [The mobilisation of financial resources shall be supported by High level Champions ADD ZAF1

[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]

[New Paragraph 19 (4) (a) - Parties must commit to expanding partnerships with development finance institutions in providing additional financing to developing countries, through prioritized debt relief, debt restructuring, provision of grants rather than loans that will guarantee that programs protect essential health and related spending from encroachment and to take advantage of economic benefits of frontloading finance for prevention and preparedness or support investments ADD ZAF.]

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 [additional AFRICA GROUP] financial assistance for [developing country DEL ARG] [LMIC countries ADD ARG] 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] [in accordance with their nationally determined public health priorities, BGD] [, without limiting their participation in or membership of these organizations DEL USA]. [Parties shall cooperate in these relevant IFIs and regional development banks to ensure that their financing conditionalities do not impede the ability of the receiving states to implement the obligations under WHO CA+ in accordance with their national circumstance and policies. BGD] [Parties shall report their efforts in this regard to the governing body of WHO CA+. BGD]

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

[NEW 6. The Parties shall promote and facilitate the use of bilateral, regional, multilateral and other appropriate and relevant channels to provide greater collaboration between the health, finance and private sectors and put in place mechanisms for the automatic suspension of debt servicing of developing countries facing unsustainable debt burdens, so that financing for the promotion and protection of the health of their populations can be effectively prioritized. BGD, TUN]

### [NEW CHAPTER VI BIS: COMMON BUT DIFFERENTIATED RESPONSIBILITIES AFR GROUP, BGD]

**Common But Differentiated Responsibilities** 

ARTICLE 19A: Common Obligations During Pandemics and in Other Public Health Emergencies of International Concern

- 1. This provision shall apply only when a declaration of Pandemic or PHEIC is declared by WHO and is not terminated by WHO.
- 2. Parties that have the expertise or experience on responding to the disease that is causing pandemic or PHEIC shall share the information with WHO, especially on any effective patient treatment protocol, proven ways of sanitizing contaminated places or environment, measures that were successful in containing the spread of infection, or any specific medical or health product found to be useful. WHO shall assess veracity or adaptability of such information and make it available to all.
- 3. Parties that have additional healthcare workforce shall offer WHO a probable deployment of such health workforce in affected countries that are in need for health workforce, subject to rules and regulations developed by WHO in this regard.
- 4. Parties that have availability of the health products such as vaccines, diagnostics and therapeutics required for responding to pandemic and PHEIC more than the requirement mentioned in the WHO allocation plan, if any, shall immediately share with WHO the excess doses for early distribution in countries that lack access to such health products. Parties that have strategic stockpiles and in the opinion of the WHO will not be affected by the spread of disease in reasonable circumstances shall immediately share stockpiles with WHO to assist the affected countries facing immediate shortage.
- 5. Parties that have technologies and know-how within their jurisdiction that can be used in response to pandemics or PHIEC, shall immediately share the technology and know-how with WHO, including technologies relating to the manufacturing of pandemic related products. WHO shall assess such technologies and shall deploy them suitably for use in order to establish normalcy at the earliest possible time.
- 6. Parties having logistics capacities within their jurisdiction shall promptly extend to WHO or other UN agencies its abilities to support vulnerable countries and populations by sending medical personnel and supplies.

- 7. Parties within their financial capacities shall aid all WHO coordinated activities in Pandemic or PHEIC response to the fullest of their abilities with an aim to re-establish normalcy at the earliest possible time.
- 8. Parties shall monitor the prices of the pandemic related products and services, including export prices, and if required intervene and take measures, including implementing price caps to facilitate availability and affordability to the Parties in need during pandemics or PHEIC AFR GROUP.

[ARTICLE 19B: Provision of Financial Support, Technology Transfer, Technical Assistance and Support for Capacity Building for Developing Countries

- 1. The developed country Parties shall provide new and additional financial resources, including for the transfer of technology and provision of technical assistance and support for capacity building, to meet the costs incurred by developing country Parties in complying with their obligations under the WHO CA+. The implementation of this commitment shall take into account the need for adequacy and predictability in the flow of funds and the importance of appropriate burden sharing among the developed country Parties.
- 2. The developed country Parties shall take all practicable steps to promote, facilitate and finance, as appropriate, the transfer of, or access to, health technologies and know-how to developing country Parties, to enable them to implement the provisions of the WHO CA+. In this process, the developed country Parties shall support the development and enhancement of endogenous capacities and technologies of developing country Parties, including for strengthening cooperative action on technology development and transfer at different stages of the technology cycle. Other Parties and organizations in a position to do so may also assist in facilitating the transfer of such technologies.
- 3. Developed country Parties shall upon request facilitate the provision of technical assistance and support for capacity building to developing country Parties either bilaterally or through the appropriate international organizations to help them build sustainable capacity. Other Parties are encouraged to provide or continue to provide such support voluntarily.
- 4. Developed country Parties and other Parties that provide technical assistance and support for capacity building in this area should do so in a way that does not compromise existing development priorities of developing country Parties.
- 5. Developed country Parties shall annually provide to the MOP of the WHO CA+ transparent and consistent information on the financial support, technology transfer, technical assistance, and support for capacity building for developing country Parties provided and mobilized in accordance with the modalities, procedures and guidelines to be adopted by the MOP at its first session. Other Parties are encouraged to do so. ]

[ARTICLE 19C: Special Treatment for Developing Countries

- 1. The provisions contained in the WHO CA+ shall be implemented by developing country Parties in accordance with this Chapter.
- 2. The specific needs and special circumstances of developing country Parties, especially those that are particularly vulnerable to the adverse effects of pandemics and other public health

emergencies of international concern and of those that would have to bear a disproportionate or abnormal burden under the Convention, should be given full consideration.

- 3. Financial assistance, technology transfer, technical assistance, and support for capacity building shall be provided by developed country Parties to help developing country Parties to implement the provisions of the WHO CA+. The extent and the timing of implementation of the provisions of the WHO CA+ shall be related to the implementation capacities of developing country Parties, recognizing that enhanced support for developing country Parties will allow for higher ambition in their actions. Other Parties are encouraged to provide or continue to provide such support voluntarily.
- 4. Where a developing country Party continues to lack the necessary capacity, implementation of the provision(s) concerned will not be required until implementation capacity has been acquired. Where a developing country Party continues to lack the necessary primary health care and hospital care capacities to the resilience levels as determined under Article 11, implementation of other capacity building shall not be required in such a manner that investments will be diverted away from primary health care or hospital care capacities.
- 5. The extent to which developing country Parties will implement their commitments under the WHO CA+ will depend on the effective implementation by developed country Parties of their commitments under this Chapter related to financial resources, transfer of technology, technical assistance, and support for capacity building for developing country Parties and will fully take into account administrative and institutional capabilities as well as that economic and social development and poverty eradication are the first and overriding priorities of the developing country Parties.
- 6. Developing country Parties shall have full flexibility in the implementation of the WHO CA+ in [light of their capacities, avoiding undue burden and respectful of their national sovereignty. AFR GROUP][accordance with their national capacities and priorities premised upon sovereign prerogatives BGD]

**NEW ARTICLE 0.1. Provision of implementation support** 

[[NEW ARTICLE O.1. Provision of implementation support DEL AFR GROUP]

- 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[RESERVE JAM]

# [Article 20. Governing Body for the WHO CA+ <u>RESERVE WHOLE</u> ARTICLE RUS]

- 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: [DEL USA]
  - (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 **DEL WHOLE USA**]

- (b) [the [Officers DEL IDN] [Bureau of the Conference of the Parties (Bureau) IDN] of the Parties, which shall be the administrative organ of the Governing Body. DEL USA] [delegates representing Parties; and include observers from 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 non-governmental, 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 governing body, renewable every three years, unless at least one third of the Parties object. For the avoidance of doubt, it is understood that only delegates representing Parties will participate in any decision-making, whether by consensus, voting, or otherwise, of the Governing Body. ADD USA]
- 3. The [COP <u>DEL USA][Governing body USA]</u>, 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 <u>DEL USA][Governing body USA]</u> may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO CA+. The [COP <u>DEL USA][Governing body USA]</u> shall:
  - (a) [be composed of delegates representing Parties; **DEL USA**]
  - (b) convene regular sessions [of the Governing Body <u>DEL USA</u>]; the first of which shall take place not later than one year after the date of entry into force of the [Convention <u>DEL USA][WHO CA+ USA]</u>, at a time and place to be determined by the WHO Secretariat, with the time and place of subsequent [ordinary <u>DEL IDN</u>] [regular IDN] sessions to be determined by the [COP <u>DEL USA][Governing Body USA]</u> upon a proposal of the [Officers of the Parties DEL IDN] [Bureau IDN] [, with consideration being given to hosting by WHO's Regional Office <u>USA</u>];
  - (c) convene special sessions [of the Governing Body **DEL USA**] at such other times as may be deemed necessary by the [COP <u>DEL USA</u>][Governing Body <u>USA</u>], 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
  - (d) [at the first meeting of the Governing Body, USA] adopt [by consensus at its first regular session IDN] its [r DEL IDN] [R ADD IDN] ules of procedure, as well as those of the [any ADD USA] [other bodies of the Governing Body DEL IDN] [Bureau IDN] [by consensus at its first session CHN], which shall include decision-making procedures. [Such procedures may include specified majorities required for the adoption of particular decisions DEL CHN, USA].
- 4. [The [Officers of the Parties DEL IDN] [Bureau IDN], as the administrative organ of the Governing Body, shall: **DEL USA**]
  - (a) [be composed of [two DEL IDN] [one IDN] President[s **DEL IDN]**, [four DEL IDN] [five IDN] Vice-Presidents and two rapporteurs, serving in their individual capacity and elected by the COP [as representatives from each of the six WHO regions IDN] for XX years; and <u>DEL USA</u>]
- 5. [endeavour to make [administrative IDN] 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[s IDN] and Vice-Presidents. **DEL USA** [In the event of equal votes, the resolute decision

will be the one that includes the vote of the president. ADD SAU [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+. RESERVE CHN, USA/DEL WHOLE AUS

### [ALT Article 20. Governing Body for WHO CA+

- 1. The Implementation Committee established under the Framework of IHR 2005 shall serve as the Meeting of Parties to WHO CA+, which shall be the governing body of WHO CA+ that shall look after effective and coherent implementation of WHO CA+ complimentary to IHR 2005 implementation. Parties to IHR 2005 who are not Parties to WHO CA+ shall only participate as observers in the proceedings of the Implementation Committee serving as Meeting of Parties to WHO CA+ and shall have no vote in any of the matters under consideration of Meeting of Parties.
- 2. The MOP shall keep under review every three years the implementation and outcome of the WHO CA+ and any related legal instruments that the MOP may adopt, and shall make the decisions necessary to promote the effective implementation of the WHO CA+. The MOP shall further:
  - (a) monitor the progress of the implementation of Articles 6 to 10/Chapter III, under continuous assessment programme, and provide guidance on addressing the gaps and enhancing the implementation.
  - (b) consider reports from financial mechanism acting pursuant Article 19, IPPST established under Article 21bis, Global Production, Distribution and Logistics Mechanism established under Article 6, and Technology Access Pool established under Article 7 and provide guidance to such mechanisms, WHO Secretariat and Parties.
  - (c) shall review the developing countries' report on their contribution to financial mechanism, technology access pool or transfer of technology otherwise, technical assistance, capacity building or any other assistance offered towards the developing countries submitted pursuant to Article 19B(6) and provide specific recommendations to such parties on enhancing such assistance provided.
- 3. The first MOP 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 annual sessions to be determined by the MOP.
- 4. Special sessions of MOP may be convened at such other times as may be deemed necessary by the MOP, or at the written request of any Party or Director General, 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
- 5. MOP shall elect its office bearers or bureau based on applicable practice of WHO and it shall adopt its rules of procedure, as well as those of the other bodies under WHO CA+, which shall include decision-making procedures. Such procedures may include specified majorities required for the adoption of particular decisions.
- 6. The Director General shall cause the work of the MOP be submitted to the WHA, including any decisions, guidance or recommendations issued thereof. ALT ARTICLE 20 BGD, NAM, <u>AFR</u> <u>GROUP</u>]

# Article 21. [Consultative Body for the WHO CA+ [RESERVE USA, RUS] DEL AFR GROUP, AUS]

- 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 [on request basis and IDN], without participating in any decision-making. **RESERVE USA**]
- 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. **RESERVE USA**]
- 3. [The Consultative Body shall be composed of (i) [delegates representing Parties; and (ii) DEL IDN] 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+ [each of which shall be chosen in such a manner as to ensure equitable representation of the regions NGA]. Further, DEL IDN][ and (ii) ADD IDN] representatives of any body or organization, whether national[, regional IDN] or international, governmental or nongovernmental, private sector or public sector, which is qualified in matters covered by the WHO CA+, [which IDN] may be admitted upon formal application, in accordance with terms and conditions to be adopted by the COP [by consensus CHN], [taking into account the equitable representation of the WHO regions IDN] renewable every three years, [unless at least one third of the Parties object DEL CHN]. RESERVE USA]
- 4. [The Consultative Body shall be subject to the oversight of the COP, including rules of procedure adopted by the COP. **RESERVE USA**]

**RESERVE ART 21 CHN**]

### [ALT Article 21. Global Production, Distribution and Logistics Mechanism <u>RESERVE AFR</u> GROUP]

- 1. Global Production, Distribution and Logistics Mechanism (Mechanism) established under Article 6 shall function as an independent organ of the secretariat to carry out the functions stated in Article 6, with necessary staff as determined by Director General. The Mechanism may establish expert groups or committee of experts with equitable geographical representation free of conflict of interest to carry out its tasks.
- 2. The Director General shall take all necessary measures to operationalise the functioning of the mechanism within 2 years of adoption of WHO CA+ take into account the possibility of provisional application of the Article 6. In this regard, Director General shall provide financial resources mobilize funds from the Parties for the
- 3. The mechanism shall
  - (a) Work in close coordination with IPPST and PABS system to carry out the recommendations of IPPST for pandemic preparedness and response
  - (b) Coordinate and assist the activities of Technology Access Pool

- (c) Report to the IPPST and to governing bodies of WHO CA+ through the WHO Director General
- (d) Maintain transparency in activities and publish an annual report of activities ALT ARTICLE 21 BGD]

[Africa Group in principle supports the establishment of an intergovernmental panel on Pandemic Science. There should be linkages between the intergovernmental panel envisaged under article 6 and the governing body. The details of the text are to be reviewed and discussed further AFR GROUP!

### [21 bis Intergovernmental Panel on Pandemic Science and Technology

1. Parties hereby establish an Intergovernmental Panel on Pandemic Science and Technology (IPPST) as subsidiary body of WHO CA+ governing body consisting of experts free from the conflict of interest nominated by governments from various disciplines related to pandemics and appointed by the Director General for assessing the science related to pandemic prevention, preparedness, response and recovery whose reports could be reviewed by the WHO CA+ governing body/IHR 2005 implementation committee.

#### 2. IPPST shall:

- (a) assess the status of available scientific knowledge and evidence relating to Pandemics it causes, predictability, prevention measures, preparedness and response requirements.
- (b) assess global, and regional situations and may forecast the emerging pandemic threats, level of risk they possess, need for any specific preparedness programme or response options including the availability or need for new research on the health products and technologies;
- (c) assess the threats and prepare a R&D blueprint for pandemics
- (d) prepare strategies and guidelines for preparedness and response for various known pandemics
- (e) conduct health technology assessment of pandemic related products and share with results with Parties and WHO Mechanisms:
- (f) act in coordination with R&D observatory mechanism as well as R&D Blueprint in development of prioritisation of R&D objectives and targets;
- (g) stock-take and monitor of all types of genetic research and big data analysis associated with highly transmissible pathogens, and alert scientific community about any potential biosecurity concern and develop standards and operating procedures to avoid such concerns;
- (h) develop guidelines on research involving pandemic potential pathogens including genetic engineering with a view to avoid biosafety and biosecurity concerns including accidental laboratory leakages of disease-causing agents.
- (i) Any other tasks entrusted by the governing body or World Health Assembly
- 3. Towards the purposes of para 2 IPPST shall

- (a) carry out the systematic review of the published scientific and public health literature and develop recommendations ensuring highest levels of scientific quality, independence and credibility at all stages of the its functioning;
- (b) provide recommendations to the various mechanisms established under new instrument and IHR 2005 on scientific aspects relating to Pandemic Prevention, Preparedness, Response and Recovery;
- (c) provide advice on scientific communication on related subject matters and specifically with respect to any ongoing pandemics and its response;
- (d) engage the scientific community and other knowledge holders within their work programme, taking into account the need for different disciplines and types of knowledge, gender balance, and effective contribution and participation by experts from developing countries;
- (e) explore different knowledge systems and take into account any lessons or scientific inputs including from indigenous knowledge systems
- (f) perform any other revenant activities to fulfil its mandate, as appropriate.
- 4. IPPST shall meet at least once in year and also free to set up experts' committees or panels to carry out its functions. IPPST shall carry out its functions in a transparent way and meetings shall be open to WHO Member States m, NSAs in official relation with WHA. IPPST may conduct closed meetings while it discusses information on the projects involving implications for paragraph 2(g) and (h).
- 5. WHO shall host its secretariat and provide for all necessary support including its technical expertise for the functioning of IPPST. Parties shall also provide necessary information to the IPPST for the efficient discharge of duties of IPPST, and in particular information regarding the research projects involving implications for paragraph 2(g) and (h). BGD, <u>AFR GROUP</u>]

# Article 22. [Oversight mechanisms for the WHO CA+ <u>DEL COL</u>, <u>USA/RESERVE WHOLE ARTICLE RUS, AFR GROUP</u>]

### [ALT Title Article 22Implementation and Compliance Committee ADD COL, USA]

- 1. [The [Governing Body <u>DEL SGP</u>] [COP ADD SGP], at its first [regular session IDN] meeting, shall consider and approve cooperative [and effective IDN] procedures and institutional mechanisms to promote [<u>implementation and, ADD AFR GROUP</u>] compliance with the provisions of the WHO CA+ [and also address cases of non-compliance <u>DEL AFR GROUP, AUS, USA, COL</u>].
- 2. [These [measures, DEL IDN] procedures and mechanisms shall include monitoring provisions and [accountability <u>DEL RUS</u>] 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[, capacity building or technical IDN] or assistance, where appropriate. These measures shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under the WHO CA+. DEL RUS] RESERVE ART 22 CHN, AFR GROUP/ DEL AUS, USA, COL]

#### [ALT. PARAS USA, COL

- 1. A committee to facilitate and consider the implementation of and promote compliance with the provisions of the WHO CA+ is hereby established. The committee shall be facilitative in nature and function in a manner that is transparent, non-adversarial and non-punitive.
- 2. The committee shall consist of members possessing appropriate qualifications and experience, nominated by Parties and elected by the Governing Body, with due consideration to gender balance and equitable geographical representation.
- 3. The committee shall operate under the modalities and rules of procedure adopted by the Governing Body at its first meeting, consider issues of implementation and compliance at the individual and systemic levels, inter alia, and report periodically and make recommendations, as appropriate while cognizant of respective national circumstances, to the Governing Body.
- 4. In the course of its work, the committee may draw on appropriate information from any bodies established under the WHO CA+ or the WHO, as well as from any information submitted to the WHO by States Parties through other mechanisms.
- 5. The Committee shall meet jointly, as appropriate with any Committee that may be established to review IHR implementation and compliance. USA, COL

# Article 23. [Assessment and review <u>RESERVE WHOLE ARTICLE AFR GROUP</u>]

The [Governing Body <u>DEL SGP</u>] [COP ADD SGP] shall [develop a Monitoring and Evaluation Framework PHI] establish a mechanism to undertake, [three <u>DEL AUS, RUS</u>] [five ADD AUS, RUS] years after the entry into force of the WHO CA+, and thereafter [every three years <u>DEL AUS, RUS</u>] [at intervals ADD AUS] [five years ADD RUS] 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+. RESERVE ART 22 CHN]

[[The Governing Body shall [develop a Monitoring and Evaluation Framework PHI] 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+. RESERVE ART 22 CHN] [RESERVE AFR GROUP, THE THREE YEAR PERIOD INDICATED IS TOO SHORT, AND SHOULD BE SUBJECTED TO FURTHER DISCUSSIONS]

#### [Article 24. Secretariat RESERVE WHOLE ARTICLE]

- 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 provide administrative and logistical support to the Governing Body for the purpose of the implementation of this agreement and USA] to make arrangements for sessions

of the Governing Body [and any subsidiary bodies DEL IDN] and to provide them with services as required;

- (b) to transmit reports [and other relevant information regarding implementation of this agreement USA] received by it pursuant to the WHO CA+;
- (c) to provide support to the Parties, [on <u>DEL USA</u>] [<u>lin response to USA</u>] request, <u>[s made by the Governing Body USA]</u>, [in the compilation and communication of information required <u>DEL USA</u>] 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 <u>DEL WHOLE AUS</u>].

RESERVE CHAPTER VII RUS]

### [ALT Proposal on institutional arrangements

#### Article P.1. Conference of the Parties

[RESERVE Article P.1. Conference of the Parties AFR GROUP]

- 1. A Conference of the Parties is hereby established as the main body responsible for promoting and supporting the implementation of this Agreement.
- 2. The first session of the Conference of the Parties shall be convened by the Director General of the World Health Organization not later than six months after the entry into force of the Agreement. Thereafter, ordinary sessions of the Conference of the Parties shall be held every year or as otherwise decided by the Conference.
- 3. [As requested by at least one fourth of the Parties or by the Director-General of the WHO, the Conference of the Parties may be convened at the level of Heads of State and Government with the aim to provide political support for the implementation of the Agreement and for the effective and equitable improvement of pandemic prevention, preparedness and response **DEL AUS**].

- 4. [Extraordinary sessions of the Conference of the Parties, including at the level of Heads of States and Government, shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party or of the Director General of the WHO, provided that, within four weeks of the request being communicated to them by the Secretariat, it is supported by at least one fourth of the Parties **DEL AUS**].
- 5. At its first session, the Conference of the Parties shall adopt by consensus:
  - a) its Rules of Procedure;
  - b) its financial rules, which shall also apply to the funding of its subsidiary bodies, as well as financial provisions governing the functioning of the Secretariat.
- 6. At each ordinary session, the Conference of the Parties shall adopt a budget for the financial period until the next ordinary session.
- 7. The Conference of the Parties shall review and assess the implementation of the Agreement and take any decisions necessary to achieve its objective. To that end, it shall:
  - a) perform the functions assigned to it by the Agreement,
  - b) consider ways to facilitate the effective implementation of the Agreement, with particular attention to the needs of Parties which are low and lower middle income countries:
    - c) promote, at national, regional and international levels, the development, implementation and evaluation of multisectoral strategies, plans and programmes, as well as policies, legislation and other measures to ensure the implementation of the Agreement, following the "One Health" approach;
    - d) consider the periodic reports submitted by the Parties in accordance with Article P.2;
    - e) consider the recommendations and advice transmitted to it by the panel of Experts and the Implementation and Compliance Committee;
    - f) promote and facilitate the mobilization of financial resources for the implementation of the Agreement;
    - g) establish such subsidiary bodies as are necessary to achieve the objective of the Agreement;
    - h) consider and adopt, as appropriate, protocols and annexes in accordance with Article...;

- i) consider ways to enhance the coordination in the implementation of the IHR and the implementation of the Agreement;
- j) cooperate with relevant international organizations and intergovernmental and non-governmental bodies, including those operating at the regional level; and
- f) consider and take any other action or decision required for the achievement of the objective of the Agreement.
- 8. Organizations, institutions, programmes, funds and entities of the United Nations system, the World Trade Organization, the World Organization for Animal Health, any other relevant international organisations, as well as any State not a Party to the Agreement, may be represented at sessions of the Conference of the Parties as observers. Any other body or agency, whether national or international, governmental or non-governmental, including civil society and the private sector, that is qualified in areas covered by the Agreement and has requested the Secretariat to participate in the sessions of the Conference of the Parties as an observer, is admitted unless one third of the Parties present object. This provision shall also apply to the admission and participation of observers to the subsidiary bodies of the Conference of the Parties.
- 9. In order to ensure the best possible cooperation and coordination of actions to achieve the objective of the Agreement, the Conference of the Parties shall establish and strengthen regular cooperation with relevant international and regional intergovernmental organizations, including, but not limited to the World Health Organization, the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health, the United Nations Environment Programme, the World Intellectual Property Organization, the World Trade Organization, the International Monetary Fund and the World Bank.

### Article P.2. Periodic reports to the Conference of the Parties

[RESERVE Article P.2. Periodic reports to the Conference of the Parties AFR GROUP]

- 1. Each Party shall submit to the Conference of the Parties periodic reports on its implementation of the Agreement, which shall include the following:
  - a) information on legislative, executive and administrative measures, good practices or other measures taken to implement the Agreement;
  - b) information on any constraints or difficulties encountered in the implementation of the Agreement and on the measures taken or under consideration to overcome them;
  - c) information on implementation support received under the Agreement; and
  - d) other information as required by specific provisions of the Agreement.
- 2. The frequency, conditions and format of the periodic reports submitted by the Parties shall be determined by the Conference of the Parties at its first session, with the aim to facilitate

reporting by the Parties and avoid duplications. These reports shall be drawn up in a clear, transparent and exhaustive manner, without prejudice to respect for applicable rules on confidentiality, privacy and data protection.

- 3. The Conference of the Parties shall adopt appropriate measures to assist Parties, upon request, in meeting their obligations under this Article, with particular attention to the needs of Parties which are low and lower middle income countries.
- 4. The periodic reports submitted by the Parties shall be made publicly available online by the Secretariat.

# Article P.3. Scientific advice

[RESERVE Article P.3. Scientific advice AFR GROUP]

- 1. An expert body to provide scientific advice is hereby established as a subsidiary body of the Conference of the Parties to provide the Conference of the Parties with information, science-based and other technical advice on matters relating to the Agreement. This Panel of Experts shall comprise independent experts competent in the relevant fields of expertise and sitting in their individual expert capacity. It shall be multidisciplinary in line with the One Health approach. It shall report regularly to the Conference of the Parties on all aspects of its work. The body shall:
  - a. Collect, consider and evaluate the most advanced and recent information and scientific knowledge available on the origins, prevention, surveillance, control and impacts of pandemics;
  - b. Provide or compile assessments of the state of scientific knowledge relating to zoonotic and other risks in accordance with the One Health approach;
    - c. Prepare scientific and evidence-based assessments on the effects of measures taken in the implementation of the Agreement and make recommendations as appropriate;
    - d. Provide advice as appropriate on scientific programmes, international cooperation in research and development related to matters covered by the Agreement, as well as on ways and means of supporting endogenous capacity building in low and lower-middle income countries, as well as other middle income countries in need:
    - e. Respond to scientific, technological and methodological questions that the Conference of the Parties or other subsidiary body may put forward, and
    - f. Provide advice and recommendations on any matter as requested by the Conference of the Parties.

- 2. The Panel of Experts shall take due account of relevant work by, and allow for the participation in its proceedings of, relevant international and regional intergovernmental organizations, governmental and non-governmental organizations and bodies, as well as academic experts.
- 3. The Panel of Experts shall consist of [...] independent experts selected by common accord by the Heads of the Quadripartite Organisations on the basis of criteria of competence, independence, multidisciplinarity, gender equality and equitable geographic representation. Its composition may be modified by the Conference of the Parties.
- 4. The Panel of Experts shall elaborate its rules of procedure, which shall be approved by the Conference of the Parties at its second session.
- 5. The Conference of the Parties shall ensure the availability of the resources necessary to enable the Panel of Experts to achieve its objectives and perform its tasks. **AUS**]

# Article P.4. Implementation and Compliance Committee

[RESERVE Article P.4. Implementation and Compliance Committee AFR GROUP]

- [1. An Implementation and Compliance Committee is hereby established as a subsidiary body of the Conference of the Parties.
- 2. The Committee is mandated to promote implementation of, and review compliance with, the provisions of the Agreement, including by addressing matters related to possible non-compliance. It shall be facilitative in nature and shall pay particular attention to the respective national and regional capabilities and circumstances of Parties, in particular the needs of Parties which are low and lower middle income countries;
- 3. For that purpose, the Committee shall make recommendations to the Conference of the Parties. Such recommendation may include proposals for consideration of the Conference of the Parties aimed at facilitating and providing support for the implementation of the Agreement, with particular attention to the needs of Parties which are low and lower middle income countries;
- 4. The Committee shall consist of [...] members, which are independent experts, nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality and equitable geographical representation. The first members of the Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 6. The members of the Committee shall have recognized competence in fields relevant to the Convention and reflect an appropriate balance of expertise.

- 5. The Committee shall consider:
  - a) written submissions from any Party with respect to compliance with the provisions of the Agreement;
  - b) periodic reports by the Parties submitted in accordance with Article P.2.;
  - c) any issue submitted to it by the Conference of the Parties; and
  - d) other relevant information SUPPORTED BY AUS].
- 6. The Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Committee.
- 7. The committee shall collaborate with relevant monitoring and review bodies and mechanisms that may be established by the World Health Assembly or by the Parties of the IHR including by providing for joint sessions.
- 8. The Committee shall make every effort to adopt its recommendations by consensus. In the absence of consensus, the recommendations shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two-thirds of the members.

# Article P.5. Countermeasures Expert Committee

[RESERVE Article P.5. Countermeasures Expert Committee AFR GROUP]

- 1. A Countermeasures Expert Committee is hereby established as a subsidiary body of the Conference of the Parties.
- 2. The Committee is mandated pursuant to Article G.1. to monitor and analyse issues related to the availability, affordability and quality of countermeasures and report to the Conference of the Parties, discharge all functions set out in the Agreement and respond to requests from the Conference of the Parties. It shall pay particular attention to the needs of Parties which are low and lower middle income countries;
- 3. The Committee shall consist of [...] members, which are independent experts, nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality, multidiciplinarity, including legal, economic and industrial organisation expertise, and equitable geographical representation. The initial members of the Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 4. The members of the Committee shall have recognized competence in fields relevant to the Agreement, and in particular section G thereof, and reflect an appropriate balance of expertise.

- 4. The Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Committee.
- 5. The Committee shall make every effort to deliberate by consensus. In the absence of consensus, its recommendations or decision shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two-thirds of the members.

# Article P.6. Secretariat [RESERVE Article P.6. Secretariat AFR GROUP]

- 1. A Secretariat is hereby established.
- 2. Secretariat functions under the Agreement shall be provided by the World Health Organization in cooperation with the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health and the United Nations Environment Programme. The Heads of the respective organizations will determine the modalities of their cooperation in discharging the Secretariat functions under the Agreement. Such modalities shall be approved by the Conference of the Parties at its first session.
- 3. Secretariat functions shall be:
  - a) to make arrangements for sessions of the Conference of the Parties and its subsidiary bodies and to provide them with services as required;
  - b) to assist the Parties, particularly Parties which are low and lower middle income countries, in implementing the Agreement;
  - c) to ensure coordination and cooperation with the secretariats of relevant international and regional organizations and with other relevant bodies;
  - d) to enter into such administrative or contractual arrangements as may be required for the effective discharge of its functions;
  - e) to perform other secretariat functions specified by the Agreement and any additional functions entrusted to it by the Conference of the Parties.

EU1

## [ALT EU PROPOSAL ON INSTITUTIONAL ARRANGEMENTS

## **Article P.1. Conference of the Parties**

1. A Conference of the Parties is hereby established as the main body responsible for promoting and supporting the implementation of this Agreement.

- 2. The first session of the Conference of the Parties shall be convened by the Director General of the World Health Organization not later than six months after the entry into force of the Agreement. Thereafter, ordinary sessions of the Conference of the Parties shall be held every year or as otherwise decided by the Conference.
- 3. As requested by at least one fourth of the Parties or by the Director-General of the WHO, the Conference of the Parties may be convened at the level of Heads of State and Government with the aim to provide political support for the implementation of the Agreement and for the effective and equitable improvement of pandemic prevention, preparedness and response.
- 4. Extraordinary sessions of the Conference of the Parties, including at the level of Heads of States and Government, shall be held at such other times as may be deemed necessary by the Conference, or at the written request of any Party or of the Director General of the WHO, provided that, within four weeks of the request being communicated to them by the Secretariat, it is supported by at least one fourth of the Parties.
- 5. At its first session, the Conference of the Parties shall adopt by consensus: a) its Rules of Procedure; b) its financial rules, which shall also apply to the funding of its subsidiary bodies, as well as financial provisions governing the functioning of the Secretariat.
- 6. At each ordinary session, the Conference of the Parties shall adopt a budget for the financial period until the next ordinary session.
- 7. The Conference of the Parties shall review and assess the implementation of the Agreement and take any decisions necessary to achieve its objective. To that end, it shall:
- a) perform the functions assigned to it by the Agreement,
- b) consider ways to facilitate the effective implementation of the Agreement, with particular attention to the needs of Parties which are low and lower middle income countries;
- c) promote, at national, regional and international levels, the development, implementation and evaluation of multisectoral strategies, plans and programmes, as well as policies, legislation and other measures to ensure the implementation of the Agreement, following the "One Health" approach;
- d) consider the periodic reports submitted by the Parties in accordance with Article P.2;
- e) consider the recommendations and advice transmitted to it by the panel of Experts and the Implementation and Compliance Committee;
- f) promote and facilitate the mobilization of financial resources for the implementation of the Agreement;
- g) establish such subsidiary bodies as are necessary to achieve the objective of the Agreement;
- h) consider and adopt, as appropriate, protocols and annexes in accordance with Article...;

- i) consider ways to enhance the coordination in the implementation of the IHR and the implementation of the Agreement;
- j) cooperate with relevant international organizations and intergovernmental and nongovernmental bodies, including those operating at the regional level; and

f) consider and take any other action or decision required for the achievement of the objective of the Agreement.

- 8. Organizations, institutions, programmes, funds and entities of the United Nations system, the World Trade Organization, the World Organization for Animal Health, any other relevant international organisations, as well as any State not a Party to the Agreement, may be represented at sessions of the Conference of the Parties as observers. Any other body or agency, whether national or international, governmental or non-governmental, including civil society and the private sector, that is qualified in areas covered by the Agreement and has requested the Secretariat to participate in the sessions of the Conference of the Parties as an observer, is admitted unless one third of the Parties present object. This provision shall also apply to the admission and participation of observers to the subsidiary bodies of the Conference of the Parties.
- 9. In order to ensure the best possible cooperation and coordination of actions to achieve the objective of the Agreement, the Conference of the Parties shall establish and strengthen regular cooperation with relevant international and regional intergovernmental organizations, including, but not limited to the World Health Organization, the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health, the United Nations Environment Programme, the World Intellectual Property Organization, the World Trade Organization, the International Monetary Fund and the World Bank.

#### Article P.2. Periodic reports to the Conference of the Parties

- 1. Each Party shall submit to the Conference of the Parties periodic reports on its implementation of the Agreement, which shall include the following:
- a) information on legislative, executive and administrative measures, good practices or other measures taken to implement the Agreement;
- b) information on any constraints or difficulties encountered in the implementation of the Agreement and on the measures taken or under consideration to overcome them;
- c) information on implementation support received under the Agreement; and
- d) other information as required by specific provisions of the Agreement.
- 2. The frequency, conditions and format of the periodic reports submitted by the Parties shall be determined by the Conference of the Parties at its first session, with the aim to facilitate reporting by the Parties and avoid duplications. These reports shall be drawn up in a clear, transparent and exhaustive manner, without prejudice to respect for applicable rules on confidentiality, privacy and data protection.

- 3. The Conference of the Parties shall adopt appropriate measures to assist Parties, upon request, in meeting their obligations under this Article, with particular attention to the needs of Parties which are low and lower middle income countries.
- 4. The periodic reports submitted by the Parties shall be made publicly available online by the Secretariat.

#### Article P.3. Scientific advice

- 1. An expert body to provide scientific advice is hereby established as a subsidiary body of the Conference of the Parties to provide the Conference of the Parties with information, science-based and other technical advice on matters relating to the Agreement. This Panel of Experts shall comprise independent experts competent in the relevant fields of expertise and sitting in their individual expert capacity. It shall be multidisciplinary in line with the One Health approach. It shall report regularly to the Conference of the Parties on all aspects of its work. The body shall:
- a) Collect, consider and evaluate the most advanced and recent information and scientific knowledge available on the origins, prevention, surveillance, control and impacts of pandemics;
- b) Provide or compile assessments of the state of scientific knowledge relating to zoonotic and other risks in accordance with the One Health approach;
- c) Prepare scientific and evidence-based assessments on the effects of measures taken in the implementation of the Agreement and make recommendations as appropriate;
- d) Provide advice as appropriate on scientific programmes, international cooperation in research and development related to matters covered by the Agreement, as well as on ways and means of supporting endogenous capacity building in low and lower-middle income countries, as well as other middle income countries in need;
- e) Respond to scientific, technological and methodological questions that the Conference of the Parties or other subsidiary body may put forward, and
- f) Provide advice and recommendations on any matter as requested by the Conference of the Parties.
- 2. The Panel of Experts shall take due account of relevant work by, and allow for the participation in its proceedings of, relevant international and regional intergovernmental organizations, governmental and non-governmental organisations and bodies, as well as academic experts.
- 3. The Panel of Experts shall consist of [...] independent experts selected by common accord by the Heads of the Quadripartite Organisations on the basis of criteria of competence, independence, multidisciplinarity, gender equality and equitable geographic representation. Its composition may be modified by the Conference of the Parties.
- 4. The Panel of Experts shall elaborate its rules of procedure, which shall be approved by the Conference of the Parties at its second session.

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

#### Article P.4. Implementation and Compliance Committee

- 1. An Implementation and Compliance Committee is hereby established as a subsidiary body of the Conference of the Parties.
- 2. The Committee is mandated to promote implementation of, and review compliance with, the provisions of the Agreement, including by addressing matters related to possible non-compliance. It shall be facilitative in nature and shall pay particular attention to the respective national and regional capabilities and circumstances of Parties, in particular the needs of Parties which are low and lower middle income countries;
- 3. For that purpose, the Committee shall make recommendations to the Conference of the Parties. Such recommendation may include proposals for consideration of the Conference of the Parties aimed at facilitating and providing support for the implementation of the Agreement, with particular attention to the needs of Parties which are low and lower middle income countries;
- 4. The Committee shall consist of [...] members, which are independent experts, nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality and equitable geographical representation. The first members of the Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 6. The members of the Committee shall have recognized competence in fields relevant to the Convention and reflect an appropriate balance of expertise.
- 5. The Committee shall consider:
- a) written submissions from any Party with respect to compliance with the provisions of the Agreement;
- b) periodic reports by the Parties submitted in accordance with Article P.2.;
- c) any issue submitted to it by the Conference of the Parties; and
- d) other relevant information.
- 6. The Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Committee.
- 7. The Committee shall collaborate with relevant monitoring and review bodies and mechanisms that may be established by the World Health Assembly or by the Parties of the IHR including by providing for joint sessions.
- 8. The Committee shall make every effort to adopt its recommendations by consensus. In the absence of consensus, the recommendations shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two-thirds of the members.

## **Article P.5. Countermeasures Expert Committee**

- 1. A Countermeasures Expert Committee is hereby established as a subsidiary body of the Conference of the Parties.
- 2. The Committee is mandated pursuant to Article G.1. to monitor and analyse issues related to the availability, affordability and quality of countermeasures and report to the Conference of the Parties, discharge all functions set out in the Agreement and respond to requests from the Conference of the Parties. It shall pay particular attention to the needs of Parties which are low and lower middle income countries;
- 3. The Committee shall consist of [...] members, which are independent experts, nominated by Parties and elected by the Conference of the Parties, with due consideration to gender equality, multidiciplinarity, including legal, economic and industrial organisation expertise, and equitable geographical representation. The initial members of the Committee shall be elected at the first session of the Conference of the Parties. Thereafter, the members shall be elected in accordance with the rules of procedure approved by the Conference of the Parties pursuant to paragraph 4. The members of the Committee shall have recognized competence in fields relevant to the Agreement, and in particular section G thereof, and reflect an appropriate balance of expertise.
- 4. The Committee shall elaborate its rules of procedure, which shall be subject to approval by the second session of the Conference of the Parties. The Conference of the Parties may supplement or clarify the mandate of the Committee.
- 5. The Committee shall make every effort to deliberate by consensus. In the absence of consensus, its recommendations or decision shall be adopted by a three-fourths majority vote of the members present and voting, based on a quorum of two-thirds of the members.

# Article P.6. Secretariat

- 1. A Secretariat is hereby established.
- 2. Secretariat functions under the Agreement shall be provided by the World Health Organization in cooperation with the Food and Agriculture Organization of the United Nations, the World Organization for Animal Health and the United Nations Environment Programme. The Heads of the respective organizations will determine the modalities of their cooperation in discharging the Secretariat functions under the Agreement. Such modalities shall be approved by the Conference of the Parties at its first session.
- 3. Secretariat functions shall be:
- a) to make arrangements for sessions of the Conference of the Parties and its subsidiary bodies and to provide them with services as required;
- b) to assist the Parties, particularly Parties which are low and lower middle income countries, in implementing the Agreement;
- c) to ensure coordination and cooperation with the secretariats of relevant international and regional organizations and with other relevant bodies;

d) to enter into such administrative or contractual arrangements as may be required for the effective discharge of its functions; e) to perform other secretariat functions specified by the Agreement and any additional functions entrusted to it by the Conference of the Parties. ADD EU]

[RESERVE CHAPTER VIII RUS

# Chapter VIII. Final provisions [RESERVE JAM]

## **Article 25. Reservations**

[SUGGESTION: Secretariat to include a paragraph in case a Member State does not ratify the WHO CA+, and how would reservations be considered in such case ARG]

1. [No reservations [or exceptions <u>DEL SGP</u>] may be made to this WHO CA+ [<u>Pandemic Treaty ADD IDN</u>] [unless expressly permitted by other articles of this WHO CA+. DEL IRN, CHN, USA, TUR] DEL IDN] [RETAIN NAM, NGA]

[[No reservations or exceptions may be made to this WHO CA+ [unless expressly permitted by other articles of this WHO CA+. DEL CHN, IRN, USA, TUR] DEL IDN] [RETAIN NAM, NGA, AFR GROUP]

[1bis. The Parties may make reservations to this WHO CA+. Such reservations shall not be incompatible with the object and purpose of this WHO CA+ IRN, CHN]

- 2. [[A reservation **[shall not be ADD USA]** incompatible with the object and purpose of the WHO CA+ [shall not be permitted. DEL IRN, USA] DEL IDN]
- 3. [Reservations that are [receivable <u>DEL CAN]</u> [permitted <u>ADD CAN]</u> 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. DEL IDN][by the Depositary ADD CAN]

# 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 <u>DEL CAN]</u> [confidentiality <u>ADD CAN]</u>, [including as such right is established under international law, <u>DEL CAN]</u> and [will DEL CAN, <u>SAU</u>, <u>UK</u>] <u>DEL SGP</u> [shall CAN, <u>SAU</u>] be consistent with each Party's national law, [and international obligations <u>UK</u>] [as applicable, <u>DEL UK</u>] regarding confidentiality[, <u>UK</u>] [ and <u>DEL UK</u>] privacy [and data protection, as applicable <u>UK</u>].

[ALT 26 Any exchange of data or information by the Parties pursuant to the WHO CA+ shall be consistent with each Party's national law, as applicable, regarding confidentiality and privacy. ADD USA]

# 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 Deposit[a <u>DEL USA</u>] ry.

- 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 DEL IDN, SGP] be considered as having also withdrawn from any [implementing ADD USA] 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 DEL IDN] **DEL SGP**].

# 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+ [, duly accredited and present during the voting ADD USA]. 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 <u>DEL USA</u>] [shall <u>ADD USA</u>] be considered by the COP, [which may invite views of the Consultative Body. <u>DEL USA</u>] [Amendments to the WHO CA+ shall be adopted by the [Governing Body] ADD USA].
- 2. [Amendments to the WHO CA+ shall be adopted by the COP. DEL USA] 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 Deposit[a **DEL USA]** [o ADD USA]ry.
- 3. The Parties shall make every effort to [adopt ADD USA] [reach agreement by consensus on DEL USA] any proposed amendment to the WHO CA+ [by consensus ADD USA]. 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 DEL IDN] [three-quarters IDN] 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 Deposit[a DEL USA] [o ADD USA]ry, 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 **DEL USA**] [two-thirds DEL IDN] [three-quarters IDN] 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.

**RESERVE ART 29 TUR]** 

# Article 30. Adoption [and amendment DEL IDN] of annexes to the WHO CA+

- 1. [The COP may [adopt annexes **DEL SGP**] [**Annexes SGP**] to **DEL USA**] [**amend the ADD USA**] the WHO CA+ [**with Annexes**] and amendments thereto **ADD USA**] [which shall be proposed, adopted and enter into force in accordance with the procedures set forth in Article 29 IDN] [**shall be proposed, adopted and shall enter into force in accordance with the procedure set out in Article 29 SGP].**
- 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. **DEL USA**]
- 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. **DEL USA**]
- 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. DEL IDN, **USA**]
- 4. [States that are [not DEL IDN] [Only IDN] Parties <u>DEL SGP</u>] [States that are signatories <u>SGP</u>] to the WHO CA+ may be Parties to a protocol [thereof, provided the protocol so provides DEL IDN, <u>USA</u>].
- 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[: (a) ROK] ratification, acceptance, [or ROK] approval [or accession DEL ROK] by States, [and to DEL ROK] formal confirmation [or accession DEL ROK] by regional economic integration organizations[, following signature; or (b) accession by States or regional economic integration organizations ROK] [It DEL ROK] [The WHO CA+ ROK] 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. [NOTE: ROK PROPOSAL to place text from "It shall be open" onwards in a new para.]

- 2. Any regional economic integration organization that becomes a Party to the WHO CA+ without any of its Member States being a Party shall be bound by all the obligations under the WHO CA+. In the case of those [regional economic integration ADD CAN] organizations, [where DEL CAN] [for which ADD CAN] one or more of its Member States is a Party to the WHO CA+, the [regional economic integration ADD CAN] organization and its Member States shall decide on their respective responsibilities for the performance of their obligations under the WHO CA+. In such cases, the [regional economic integration ADD CAN] organization and [the DEL CAN] [its ADD CAN] 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 <u>DEL USA]</u> 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 <u>DEL CAN</u>] [deposit <u>ADD CAN</u>] of [the <u>DEL CAN</u>] [its <u>ADD CAN</u>] 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. DEL CAN] [that regional economic integration organization. ADD CAN]

# Article 35. [Provisional application [by the Parties <u>DEL CAN</u>] [, and actions to give effect to the provisions of the WHO CA+ by the World Health Assembly DEL IDN]

1. [Before its entry into force, ADD USA] The WHO CA+ may be applied provisionally, in whole or in part, [by a signatory and/or [Party DEL CAN, USA] [a State or regional economic integration organization ADD CAN, USA] that consents to its provisional application by so notifying the Depositary in writing at the time of signature of the [instrument DEL CAN] [WHO CA+ ADD CAN], or [signature or DEL CAN] 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. DEL CAN] [Depositary ADD CAN]

- 2. Provisional application by a [signatory and/or Party <u>DEL CAN, USA]</u> [State or regional economic integration organization ADD CAN] shall terminate upon the entry into force of the WHO CA+ for [that <u>DEL USA]</u> [a ADD <u>USA]</u> [Party <u>DEL CAN]</u> [State or organization ADD CAN] or upon [written ADD USA] notification [by that [signatory and/or Party <u>DEL CAN, USA]</u> [State or organization ADD CAN, USA] to the Depositary in writing of its intention to terminate its provisional application.
- 3. [Provisions of the WHO CA+ may be [given effect as **DEL CAN**] [reflected in **ADD CAN**] recommendations for all Member States of the World Health Organization under Article 23 of the WHO Constitution, and [given effect as **DEL CAN**] [reflected in **ADD CAN**] 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. DEL IDN, **USA**]

RESERVE ART 35 CHN, TUR]

# 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 <u>DEL CAN</u>] [a solution ADD CAN] by good offices, mediation or conciliation shall not absolve Parties to the dispute from the responsibility of continuing to seek to resolve it. DEL CHN]
- 2. ]When ratifying, accepting, approving, formally confirming or acceding to the WHO CA+, or at any time thereafter, a [Party **DEL CAN**] [State or regional economic integration organization ADD CAN] [may **DEL CHI**] [shall ADD CHI] 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 **DEL SGP**] [COP ADD SGP] **RESERVE USA**].
- 3. [The provisions of this Article shall apply with respect to any protocol as between the Parties to the protocol, unless otherwise provided therein. **RESERVE USA**]

## **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+. **DEL USA**]

# 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. DEL USA]

[ALT ARTICLE 38 The Arabic, Chinese, English, French, Russian, and Spanish texts of the WHO CA+ shall be regarded as equally authentic. ADD USA]

RESERVE CHAPTER VIII RUS]

## [NEW Article 39. ADD Penalties for Contravening the Articles in this Agreement]

Any Parties that contravene or do not adhere to the provisions of this agreement shall be notified in writing by the governing body and be advised on what they should do to ensure adherence thereto. Should the Party not take action to correct the contravention or non-adherence within the given period., such member state shall be liable to XXX ADD ZAF

## [EU ANNEX PROPOSALS [RESERVES ZAF]

ANNEX 1 – Decision instrument for the assessment of events that may constitute a pandemic situation

To be developed under the PA [However, in case option 2 is chosen, it will likely need to be developed as a further amendment/addition to the IHR]

<u>ANNEX 2 – Preventing pandemic situations related to pathogens resistant to antimicrobial agents through the One Health approach</u>

#### **Article 1 - Action plans**

- 1. Each Party shall develop and implement an AMR One Health national, and where possible regional, strategy or action plan, as part of, or complement to, the plan referred to in Article (...) on Plans and measures, taking into account relevant international plans, guidance documents and recommendations.
- 2. The Secretariat shall support the Parties in the preparation of the AMR One Health action plans. The Parties shall pay particular attention to the needs of Parties which are low and lower middle-income countries, in particular through the relevant Quadripartite organisations mechanisms.

# Article 2 - Surveillance of AMR and of antimicrobials consumption/use (AMC/AMU)

- 1. Parties shall collect and report relevant AMR surveillance data in humans, animals, plants and the environment in an integrated manner according to the standards and guidance established by the Quadripartite organisations, as well as data on infections and antimicrobial consumption in human and veterinary medicine. They shall enroll in and report to the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS), and apply other relevant surveillance systems developed by intergovernmental bodies such as the Codex Alimentarius Commission and the Quadripartite organisations.
- 2. Starting no later than [...] years after the entry into force of this Agreement, the Parties shall monitor, and regularly report to the relevant Quadripartite organisations AMR surveillance data in the environment, such as in urban wastewater, surface and groundwater bodies, sewage sludge and soil and make such surveillance data available through the Quadripartite Organisations Secretariats.
- 3. The Secretariats of the Quadripartite Organisations are encouraged to further develop the WHO Global Antimicrobial Resistance and Use Surveillance System (GLASS) standards, Codex Alimentarius, WOAH and other protocols and databases to cover AMR surveillance in animals, plants, the environment, as well as AMC in animals, and enable integrated One Health

surveillance. Where applicable, this should be done either by integrating or establishing links with other existing AMR and AMU data collection mechanisms.

- 4. The Quadripartite organisations Secretariats should provide, every 2 years, an analysis of the data provided under paragraphs 1 and 2. Parties should take this evidence into consideration, in addition to any analysis of data performed at national or regional level, as a basis for improving existing AMR measures and developing and implementing new measures against AMR.
- 5. Parties that are not low and lower middle income countries should undertake to support the design and implementation of infection and AMR and AMC surveillance activities in low and lower middle-income countries through relevant Quadripartite Organisations mechanisms and by facilitating national and regional capacity strengthening activities throughout the relevant parts of the health, environment, food and medicines safety system and by developing national and regional laboratory infrastructure.

#### **Article 3 - AMR targets**

- 1. Parties commit to working towards the following global AMR outcome targets:
- a. For high income countries:
- i. Reduce by [...%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for E. coli resistant to 3rd generation cephalosporin, as calculated and reported by WHO for the year [...], within a period of [... years] after entry into force of this Agreement;
- ii. Reduce by [...%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for methicillin-resistant S. aureus (MRSA), as calculated and reported by WHO for the year [...], within a period of [... years] after entry into force of this Agreement.
  - b. For upper middle income countries:
- i. Reduce by [...%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for E. coli resistant to 3rd generation cephalosporin, as calculated and reported by WHO for the year [...], within a period of [... years] after entry into force of this Agreement;
- ii. Reduce by [...%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for methicillin-resistant S. aureus (MRSA), as calculated and reported by WHO for the year [...], within a period of [... years] after entry into force of this Agreement.
  - c. For low and lower middle-income countries:
- i. Reduce by [...%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for E. coli resistant to 3rd generation cephalosporin, as calculated and reported by WHO for the year [...], within a period of [... years] after entry into force of this Agreement;
- ii. Reduce by [...%] the median resistance rate for the SDG AMR indicator monitoring the proportion of AMR in bloodstream infections (BSIs) for methicillin-resistant S. aureus (MRSA), as calculated and reported by WHO for the year [...], within a period of [... years] after entry into force of this Agreement.]

- 3. The targets set out in paragraphs 1 shall be reviewed by the Conference of the Parties at least every [...] years and adapted if necessary.
- 4. In order to contribute to the attainment of targets referred to in paragraph 1, Parties shall set out their national targets within their AMR One Health plans, including on antimicrobial consumption/use in human, animal and plant health, based on their specific national situation. The targets shall be based on relevant data, including national antimicrobial consumption/use, obtained through the nationally implemented One Health or sector specific AMR surveillance systems as specified in Article 2. The national targets may differ from the global target defined under point 1 for the relevant group of countries. It should however be developed in a spirit consistent with the global targets.
- 5. The Panel of Experts referred to in Article P.5. should monitor progress made towards achieving the global targets. Based on this evidence, and in collaboration with relevant scientific bodies, the Panel should formulate recommendations for action. The analysis and recommendations of the Panel shall be made public. Parties should revise their targets and AMR strategies as necessary, taking into account the recommendations of the Panel.
  - <u>Article 4 Enhanced efforts to the implementation of infection prevention and treatment</u> measures
  - 1. Parties shall improve their infection prevention and control (IPC) capacities by IPC dedicated personnel and basic hygiene measures in health care settings at all levels.
  - 2. Parties shall promote access to effective treatment of infections by the prudent use of antimicrobials as appropriate.
  - 3. Parties shall ensure that their husbandry systems provide for a high level of animal health and welfare allowing a reduce need for the antimicrobial treatment of animals.
  - 4. Parties shall make use of standards and guidance of the Quadripartite organisations, including the WHO Access, Watch, Reserve (AWaRe) classification of antibiotics, to ensure effective treatments of infections as well as prudent distribution and use of quality-assured antimicrobial medicines.
  - 5. Parties shall promote training on IPC/biosecurity and appropriate management of infections, including antimicrobial stewardship, at all settings, including medical, long-term care, nursing, pharmacy, dentistry, midwifery, veterinary, phytosanitary and agricultural schools. This trainingwhich may be supported by the WHO Academy, should include a strong practical component, use a One Health approach and be interprofessional whenever possible.
  - 4. Parties shall undertake to raise public awareness on infection prevention and control, antimicrobial resistance and the prudent use of antimicrobials in human, animal and plant health, as well as the consequences of self-medication with antimicrobials.
- 6. Parties shall take steps to introduce appropriate disposal systems in health care facilities, pharmacies and the community setting, and inform the general public on the correct disposal methods for antimicrobial drugs.

- <u>Article 5 Development and availability of medical countermeasures relevant to address AMR</u>
- 1. Parties should support the development and availability of preventive, diagnostic, and therapeutic medical countermeasures relevant to combat AMR in humans and animals.
- 2. Parties should enhance R&D, production and distribution of vaccines, improving effective vaccines coverage and fostering awareness and acceptance in the population since vaccination is one of the tools to combat AMR.
- 3. Parties should support global initiatives for the establishment of regional and global priority lists of resistant pathogens, such as the WHO Bacterial Priority Pathogens List (WHO BPPL), and medical countermeasures, pipeline analyses, and the establishment of target product profiles.
- 4. Parties should take into account the priorities established in accordance with point 3 in their national research priority setting, funding and policy efforts.
- 5. Parties should coordinate, where possible, their research efforts with each other, and with global research initiatives, notably on the development of medical countermeasures relevant to address AMR.
- 6. Parties should cooperate to foster the resilience of international supply chains, and expand global, regional and local production capacity to ensure availability and accessibility of qualityassured antimicrobials and other medical countermeasures relevant to addressing AMR.
- 7. Parties should support basic research on the mechanisms and spread of AMR to identify innovative approaches for preventing and controlling AMR.
- 8. Parties should coordinate their initiatives and partnerships, including with the private sector, to incentivize research on AMR, and as appropriate, the development, manufacturing and distribution of antimicrobials and medical countermeasures to address AMR. Wherever possible, incentives should be linked to conditions that promote antimicrobial stewardship.

## Article 6 - Prudent use of antimicrobials in human medicine

- 1. Each Party shall, within a period of [... years] after entry into force of this Agreement, adopt and implement measures to prohibit the sale of or free acces to antimicrobials for human use without prescription by authorized healthcare professionals. Parties should ensure appropriate guidance on the use of prescribed antimicrobials at the point of dispension, including on the risks that may promote the development of AMR. Exemptions may be considered for antimicrobials in emergencies and exceptional circumstances. Parties that are not low and lower-middle income countries undertake to support the low and lower middle-income countries to implement this measure.
- 2. Each Party shall, within a period of [... years] after entry into force of this Agreement, adopt and implement national clinical guidelines for the treatment of common infections, taking into account antimicrobial stewardship principles, in particular in first line/primary health care settings, hospitals and long-term care facilities.

3. Parties shall promote, monitor and incentivize the use of diagnostic or susceptibility testing before antibiotics are prescribed or used in human medicine.

# Article 7 - Prudent use of antimicrobials in the veterinary field

- 1. Within a period of [2 years] after the entry into force of this Agreement, each Party shall implement measures to apply standards of the WOAH and Codex Alimentarius on the use of antimicrobial in animals, in particular the Codex Code of Practice to Minimise and Contain Foodborne Antimicrobial Resistance" (CXC 61-2005).
- 2. Each Party shall adopt measures to phase out the use of antimicrobials for growth promotion, starting with medically important antimicrobials.
- 3. Each Party shall adopt measures to ensure that all antimicrobials are administered only based on a prescription by a veterinarian, starting with medically important antimicrobials.
- 4. Parties shall report on the use of antimicrobials in veterinary medicines under the **Quadripartite organisations monitoring systems.**
- 5. Parties shall promote, monitor and incentivize the use of rapid diagnostic or susceptibility tests before antimicrobials are used in veterinary medicine.
- 6. Parties shall take measures to ensure that antimicrobials are used for prophylaxis only under strictly limited circumstances, which shall be clearly defined in applicable legislation.
- Article 8 Responsible and prudent use of antimicrobials in the plant protection/health fields
- 1. Within a period of [2 years] after the entry into force of this Agreement, each Party shall implement measures to apply the Codex Code of Practice to Minimise and Contain Foodborne Antimicrobial Resistance (CXC 61-2005) on the use of antimicrobials in plant protection.
- 2. Antimicrobials shall not be applied routinely, nor used to prevent plant diseases or to compensate for poor agricultural or plant protection practices, inadequate or lack of care, or for poor management. They shall only be applied based on a recommendation of a plant protection/health professional.
- 3. Each Party shall, within a period of [... years] after entry into force of this agreement, ensure that the use of antimicrobials in plants for the purpose of prevention or yield increase has been phased out.
- 4. Parties shall take measures to ensure that antimicrobials are used for prophylaxis only under specific and strictly limited circumstances, which shall be clearly defined in applicable legislation.
- 5. Parties shall promote, monitor and incentivize the use of rapid diagnostic or susceptibility tests before antibiotics are used for plant protection/health purposes.

# ANNEX 3 – Preventing inadvertent laboratory release of pathogens Article 1 - Biosecurity and Biosafety Standards

#### 1. The Conference of the Parties shall:

- a) Decide the information to be submitted by each Party with regard to the laboratories or other similar institutions to which the provisions of this Annex apply, including the biosafety and biosecurity measures applied at each laboratory and the security level attributed to it; the list of laboratories or other similar institutions submitted by each Party should be periodically revised;
- b) Specify the groups of pathogens and biological agents and the type of laboratories requiring the application of the biosafety and biosecurity standards adopted pursuant to this Annex;
- c) Adopt and revise, as appropriate and while taking into account relevant international regulations, guidelines and standards, necessary minimum biosafety and biosecurity standards to be applied by each Party to the pathogens specified in this Article related to acquisition, storage, handling, experimentation, transfer, transport, both within the jurisdiction of the Party as well as to another Party, and destruction.
- 2. The standards referred to in subparagraph c) above shall be elaborated drawing upon best practices developed by Parties as well as relevant international and scientific organizations, having particular regard to their resource implications and the limitations they may impose on the activities carried out in the laboratories concerned.

# **Article 2 - Reporting by Parties**

- 1. Each Party shall report to the Secretariat at intervals to be decided by the Conference of the Parties on its application of the standards referred in Article 1 (Biosecurity and Biosafety Standards), paragraph 2, the reasons for any significant deviation, from them as well as challenges and problems encountered in their application.
- 2. The Secretariat shall submit a summary report to the Conference of the Parties, reflecting in particular progress and challenges encountered by Parties in securing increasingly higher levels of biosafety and biosecurity.
- 3. Each Party shall report immediately to the Secretariat accidents within the laboratories listed under Article 1 (Biosecurity and Biosafety Standards), paragraph 1 with regard to the pathogens referred to in Article 1.2. that have resulted or may result in the release of those pathogens in the environment and may pose a risk to health. The Secretariat shall immediately inform the other Parties and offer or facilitate the provision of technical assistance to the Party or Parties concerned. The Secretariat shall report to the Conference of the Parties about any such accident.

## <u>Article 3 - Implementation support</u>

The Secretariat shall periodically visit the laboratories listed under Article 1.1. for the purpose of supporting the Parties in the effective implementation of the biosafety and biosecurity standards adopted by the Conference of the Parties and of recommending possible improvements in the application of such standards. The conditions and modalities for carrying out visits under this Article shall be decided by the Conference of the Parties.

The specific timing of such visits and the composition of the visiting team will be agreed upon with the Party concerned in accordance with such conditions and modalities.

#### **Article 4 - Technical Assistance**

The Secretariat shall provide, or facilitate the provision of, technical assistance upon the request of any Party in order to assess and improve the biosafety and biosecurity features of any laboratory and other similar institutions. Parties shall collaborate with each other for the same purpose.

#### **Article 5 – National laws**

The provisions of this Annex are without prejudice to the application of relevant national laws.

<u>ANNEX 4 - Field missions for the purpose of verification and support: Standard terms of reference</u>

To be developed

# **ANNEX 5 - Model agreements**

- 5.1 Model transfer agreements (for pathogen samples)
- 5.2 Framework agreement (for pathogen data)

To be developed

ANNEX 6 – Equitable access to countermeasures: Partnership modalities and guidelines

To be developed

## [AFR GROUP ANNEX PROPOSALS

Annex 1: Standard Material Transfer Agreement 1 (within the WHO coordinated laboratory network)

# **Article 1: Parties to the Agreement**

1.1 Parties to SMTA 1 are limited to laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO terms of reference hereby annexed. In this Agreement:

The Provider is the laboratory sending PABS Materials, as herein defined, (name and address of the provider or providing institution, designation of the laboratory, name of authorized official, contact information for authorized official) (hereinafter referred to as "the Provider")

#### and

The Recipient is the laboratory receiving PABS Materials, as herein defined, (name and address of the recipient or recipient institution, designation of the laboratory, name of authorized official, contact information for authorized official) (hereinafter referred to as "the Recipient")

1.2 Provider and Recipient are hereafter collectively referred to as "Parties".

**Article 2: Subject Matter of the Agreement** 

[Placeholder for definition of PABS Materials]

**Article 3: Right and Obligations of the Provider** 

- 3.1 The Provider undertakes to comply with the terms of reference of WHO Coordinated Laboratory Network.
- 3.2. The Provider agrees to the onward transfer and use of the PABS Materials, to all members of the WHO Coordinated Laboratory Network, on the same terms and conditions as those provided in Standard Material Transfer Agreement within the WHO Coordinated Laboratory Network (SMTA 1).
- 3.3 The Provider consents to the onward transfer and use of the PABS Materials to Qualified Entities outside the WHO coordinated laboratory network on the condition that the Qualified Entity has concluded and signed a Standard Material Transfer Agreement outside the WHO coordinated laboratory network (SMTA 2) with the WHO.
- 3.4 The Provider shall inform the WHO of shipments or transfer of PABS Materials to entities inside/outside the WHO coordinated laboratory network by recording in the PABS Tracking Mechanism.

**Article 4: Rights and Obligation of the Recipient** 

- 4.1 The Recipient undertakes the following with respect to the Materials:
- (a) To comply with the terms of reference of WHO coordinated laboratory network and to use the PABS Material solely for purposes listed in the Terms of Reference.
- (b) To inform WHO of shipments of PABS Materials to entities inside/outside the WHO coordinated laboratory network by recording in the PABS Tracking Mechanism.
- (d) In the event of further transfers within the WHO coordinated laboratory network, to do so in accordance with SMTA 1.

- 4.2 The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories, especially those from developing countries, in scientific projects associated with research on clinical specimens or PABS Material from their countries and actively engage them in preparation of manuscripts for presentation and publication.
- 4.3 The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or PABS Material, using existing scientific guidelines.
- 4.4 The Recipient shall share the outcomes of their utilization of PABS Materials with other authorized national laboratories.

# **Article 5: Intellectual property rights**

5.1 Neither the Provider nor the Recipient shall seek or assert any intellectual property rights over any PABS Materials or parts thereof, in any form including any modified form or for any use.

# **Article 6: Genomic Sequence Data**

6.1 With respect to genomic sequence data, the Recipient agrees to comply with the terms and conditions as applicable to the users of the WHO PABS Sequence Database.

# **Article 7: Dispute Resolution**

- 7.1 In the event of a dispute under SMTA 1, Parties concerned shall seek in the first instance to settle the dispute through negotiation or any other amicable means of their own choice. Failure to reach agreement shall not absolve the parties to the dispute from the responsibility of continuing to seek to resolve it.
- 7.2 In the event that the dispute is not settled by the means described under paragraph 1 of this Article, one of the Parties concerned may refer the dispute to the Director-General, who may seek advice of the PABS Advisory Group with a view to settling it. The Director-General may make recommendations to the Parties regarding its resolution and shall report to the World Health Assembly on any such matters.
- 7.3 The Parties also acknowledge the role of the Director-General under the PABS system, in particular paragraph (xxx).

#### **Article 8: Warranty**

The Provider makes no warranties as to the safety of the PABS Materials, or as to the accuracy or correctness of any data provided with them. Likewise, the provider does not make any warranties as to the quality, viability, or purity (genetic or mechanical) of the PABS Materials being furnished.

# **Article 9: Duration of Agreement**

This contractual agreement shall remain in force unless the World Health Assembly decides otherwise.

**Article 10: Acceptance and Applicability** 

10.1 Parties agree that acceptance of designation by WHO to become a part of the WHO coordinated laboratory network including the terms of reference of WHO coordinated laboratory network, constitutes acceptance of SMTA 1.

10.2 Parties agree that SMTA 1 shall cease to be applicable only upon suspension or revocation of designation or recognition by WHO or upon formal withdrawal by the laboratory of its participation in the WHO coordinated laboratories network. Such a suspension, revocation or withdrawal shall not relieve a laboratory of pre-existing obligations under SMTA 1.

# Article 11. Signature

11.1. Further to Article 8 above entitled "Acceptance and Applicability", unless either party requires this Agreement to be executed by signature of a printed document, no further evidence of acceptance is required.

ANNEX 2: STANDARD MATERIAL TRANSFER AGREEMENT 2(SMTA 2)

**Article 1. Parties to the Agreement** 

WHO and Qualified Entity Recipient

**Article 2: Subject matter of the Agreement** 

PABS Materials as defined in paragraph (X) transferred to the Recipient are subject to the provisions of this Agreement.

**Article 3: Definitions** 

[Placeholder: To be added once the definitions are agreed]

**Article 4: Intellectual Property** 

The Recipient shall not seek or assert any intellectual property rights over any PABS Materials or parts thereof, in any form including any modified forms or for any use.

**Article 5: Benefit Sharing Obligations of the Qualified Entity Recipient** 

5.1. The Recipient commits to keep WHO informed of all uses PABS Materials and to make the required monetary contributions in a timely manner, for using the PABS System.

# **5.2.** The Recipient commits to:

5.2.1 Comply with WHO's allocation mechanism, and ensure supply of vaccines, therapeutics and diagnostics at affordable prices to developing countries during a public health emergency of international concern or a pandemic.

For the purpose of this paragraph "Affordable pricing" for developing countries means a price no higher than marginal cost per unit +10% profit margin, while for developing countries categorised by the United Nations as least developed countries at "no profit no loss".

5.2.2. Deposit biological materials at the WHO cell bank to facilitate the availability of biological materials used for the production of vaccines, diagnostics or therapeutics during public health emergency of international concern or pandemic. Biological materials for the purpose of deposition shall include materials that are capable of self-replicating either directly or indirectly including cell lines, hybridomas, plasmids, yeast or mammalian cells among others.

The Recipient agrees that WHO shall allow sharing of biological materials with manufacturers in developing countries for the production and supply of vaccines, diagnostics and therapeutics during a public health emergency of international concern or pandemic

5.3 In addition, the Recipient shall commit to sub-paragraphs A, B, C or D as applicable, to be operational on the WHO declaring a public health emergency of international concern or a pandemic. Where the recipient is a manufacturer of multiple products, the Recipient shall be required to commit to multiple sub-paragraphs A, B, C or D, as applicable, for each product.

A. For manufacturers of vaccines, the recipient shall commit to at least:

A.1 Donate at least 20% of real time vaccine production to WHO for each vaccine manufactured.

A.2 Grant to WHO royalty-free, non-exclusive licenses on standard terms and conditions to use its intellectual property, and other protected technology, know-how used in the process of vaccine development and production, for the production and supply of vaccines needed in a public health emergency of international concern or a pandemic in developing countries. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions and in accordance with sound public health principles to facilitate production and supply in developing countries.

For the purposes of this paragraph, the manufacturer shall on request by WHO share the complete regulatory dossier including the full technical know-how, with the sublicensees of WHO.

- B. For manufacturers of therapeutics, the recipient shall commit to at least:
- **B.1 Donate at least 20% of real time therapeutic production to WHO for each therapeutic manufactured.**
- B.2 Grant to WHO royalty-free, non-exclusive licenses on standard terms and conditions to use its intellectual property, and other protected technology, know-how used in the process of therapeutic development and production, for the production and supply of therapeutics needed in a public health emergency of international concern or a pandemic in developing countries. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions and in accordance with sound public health principles to facilitate production and supply in developing countries.

For the purposes of this paragraph, the manufacturer shall on request by WHO share the complete regulatory dossier including the full technical know-how, with the sublicensees of WHO.

- C. For manufacturers of diagnostics, the recipient shall commit to at least:
- C.1 Donate at least 20% of real time diagnostics production to WHO for each diagnostic manufactured.
- C.2 Grant to WHO royalty-free, non-exclusive licenses on standard terms and conditions to use its intellectual property, and other protected technology, know-how used in the process of vaccine development and production, for the production and supply of diagnostics needed in a public health emergency of international concern or a pandemic in developing countries. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions and in accordance with sound public health principles to facilitate production and supply in developing countries.

For the purposes of this paragraph, the manufacturer shall on request by WHO share the complete regulatory dossier including the full technical know-how, with the sublicensees of WHO.

- **D.** For manufacturers of other medical products shall commit to at least:
- <u>D.1 Donate at least 20% of real time production to WHO of the medical product they manufacture.</u>
- D.2 Grant to WHO royalty-free, non-exclusive licenses on standard terms and conditions to use its intellectual property, and other protected technology, know-how used in the process of medical product development and production, for the production and supply

of medical product needed in a public health emergency of international concern or a pandemic. WHO shall sublicense these licenses to manufacturers especially in developing countries, on standard terms and conditions and in accordance with sound public health principles to facilitate production and supply in developing countries.

For the purposes of this paragraph, the manufacturer shall on request by WHO share the complete regulatory dossier including the full technical know-how, with the sublicensees of WHO.

- 5.4: For A2, B2, C2, D2, WHO shall develop standard license agreements in consultation with PABS Advisory Group and relevant stakeholders taking into account the importance of diversified production in developing countries to facilitate prompt and equitable affordable access in developing countries.
- 5.5 The Recipient shall comply with its respective commitments on the products and timetable determined by the WHO in consultation with the PABS Advisory Group, based on the need to promptly respond to the needs of developing countries.

[Placeholder: Reserve our right to modify or expand the benefit sharing commitments, as soon as there is clarity on the scope of CA+ including commitments with respect to access.]

# **Article 6: Genomic Sequence Data**

6.1 With respect to genomic sequence data, the Recipient agrees to comply with the terms and conditions applicable to the users of the WHO PABS Sequence Database.

## **Article 7: Third Parties and Service Providers**

- 7.1 The Recipient shall only further transfer the PABS Materials if the prospective recipient has concluded an SMTA with WHO. Any such transfer shall be reported to the WHO.
- 7.2 The Recipient shall remain fully responsible for the compliance of all obligations with respect to PABS Material in the event of transfer of PABS Materials to any third parties under contract with the Recipient. The Recipient shall ensure that PABS Materials shall not be utilized by such third parties for research, development or production other than as directed by the Recipient and that the PABS Materials are returned to the Recipient or destroyed, in accordance with appropriate bio-safety standards, at the end of utilization.

Privileges and Immunity, Name and Emblem, Warranties, Duration of Agreement Termination, Governing Law, Signature and Acceptance.]

[Placeholder: Annex 3 Click Wrap Agreement to be developed reflecting terms and conditions as provided in paragraph (X)]

