Working draft, presented on the basis of progress achieved, for the consideration of the Intergovernmental Negotiating Body at its second meeting

(Document A/INB/2/3)

Specific comments prepared by the European Union and its Member States

Modifications proposed in the text of the Working Draft are indicated in blue, in square brackets and are underlined and italicised. Proposed deletions are indicated in blue and are strikethrough. All the comments are of a preliminary nature and this input should not be regarded as an EU negotiating position.

Working draft, presented on the basis of progress achieved, of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (the "WHO CAII") for the consideration of the Intergovernmental Negotiating Body at its second meeting

Preamble

EU comments:

Preambular paragraphs are important as framing and interpretative tools. The text proposed in the Working draft appears however long with some repetitions (see for example the repetitions between paragraphs 8 and 19 of the Working Draft). It would also be important to avoid duplications between preambular paragraphs and the principles laid down under Part II, Article 4.

More specifically:

- We propose specific drafting suggestions, which could be taken into account in due course, including for the preparation of the Conceptual Zero Draft.
- The language used in some paragraphs, especially in paragraphs 15 and 16, is not fully accurate and would need to be improved. Stable and sound intellectual property systems are one of the most important enablers of public and private investment and transfer technology and know-how, including in low and middle income countries. Flexibilities in the TRIPS Agreement allow countries to adapt the legal framework to their specific needs, but do not necessarily lead to technology transfer. In addition, as a general matter, it should be noted that we understand references to technology transfer to mean voluntary technology transfer.
- We consider that it would be useful to include a few new paragraphs in the the preamble, including one paragraph after paragraphs 15 and 16, to recall the important role of publicly-funded research and development for the development of medical countermeasures for pandemics.
- We also consider that it would be useful to include in the preamble, or in another appropriate

section, a reference to the importance of digitalisation/harnessing digital technologies (e.g. important for surveillance or contact tracing), as well as to the dimension of (risk) communication and tackling dis/misinformation, taking into account national legislation and context.

- Paragraphs 30 and 31 could be moved up in order to underscore their importance.

Specific drafting suggestions:

1. *Reaffirming* the principle of sovereignty*[and the responsability]* of States ~~in international cooperation to~~ *[in]* address*[ing]* public health matters, notably pandemic prevention, preparedness, response and health systems recovery;
2. *Recognizing* that equity should ~~remain as~~*[be]* a principle, an indicator, and an outcome of pandemic prevention, preparedness and response;
3. *Emphasizing* that, in order to make health for all a reality, individuals and communities need access to high quality health services, skilled health workers providing quality, people-centered care, and policy-makers committed to investing in *[strong and resilient health systems with primary health care and]* universal health coverage;
4. *Reiterating* the necessity to work towards achieving *[robust public health capacities,]* strong and resilient health systems and universal health coverage, as an essential foundation for effective pandemic prevention, preparedness and response, and to adopt an equitable approach to prevention, preparedness and response activities, including to mitigate the ~~risk that~~ *[additional negative impacts of]* pandemics ~~exacerbate~~ *[on]* existing inequalities in access to services;
5. *Recalling* the International Health Regulations (2005) of the World Health Organization and *[the role of State Parties and other stakeholders]* ~~their importance~~ 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;
6. *Recognizing* that the international spread of disease is a global threat with serious consequences for public health, human lives*[, animal health, as well as for our societies]* and economies, that calls for the widest possible international cooperation and ~~the~~ participation of all countries in an effective, *[coordinated,]* appropriate and comprehensive international response;
7. *Recognizing* that pandemics have a disproportionately heavy impact on the poor and the most vulnerable, with repercussions on health and development gains, in particular in ~~developing~~ *[low and lower-middle income]* countries, thus hampering the achievement of the Sustainable Development Goals and universal health coverage;
8. *Mindful* that, as the threat of pandemics is a reality that has catastrophic health, social, economic*[, environmental, political]* and *[other cross-cutting]* ~~political~~ consequences, especially for the vulnerable and disadvantaged, pandemic prevention, preparedness and response must be systemically integrated into whole-of-government and whole-of- society approaches to recovery and thereby break the cycle of "panic and neglect";
9. *Reflecting* on the lessons learned from coronavirus disease (COVID-19) and other recent outbreaks, including those of Ebola virus disease, Zika virus disease, Middle East respiratory syndrome, and Monkeypox, with global and regional impact, and with a view to addressing gaps and improving future response;
10. *Acknowledging* that there are significant differences in countries' capacities to prevent, prepare for, respond to, and recover from pandemics;
11. *Deeply concerned* by the gross inequities that prevailed in timely access to medical and other COVID-19 pandemic response *[countermeasures]* ~~products~~, notably vaccines, oxygen supplies, personal protective equipment, diagnostics and therapeutics;
12. *[Recognising the need to enhance]* ~~*Concerned* by the lack of~~ global solidarity, ~~and lack of~~ effective global coordination ~~exhibited during COVID-19 pandemic, and~~ *[as well as accountability and transparency to avoid]* ~~the~~ serious negative impact*[s of public health threats with pandemic potential, especially]* on countries with limited capacities and resources;

13. *Acknowledging* that pandemic prevention, preparedness and response at all levels and *[sectors,]* particularly in ~~developing~~ *[low and lower-middle income]* countries*[,]* require sufficient financial, *[human]* and technical resources;

14. *Emphasizing* that improving pandemic prevention, preparedness and response relies on a commitment to mutual accountability, transparency and shared ~~but differentiated~~ responsibility by all countries and relevant stakeholders;

15. *Recognizing* *[the importance of discussions across several relevant international organisations]* ~~that protection of intellectual property rights is important for the development of new medicines and also recognizing the concerns about its effects on prices, as well as noting discussions in relevant international organizations,~~ on ~~for instance~~ innovative options to enhance the global effort towards the production and timely*[,]* ~~and~~ equitable*[, affordable and sustainable]* access to and distribution of *[efficacious and efficient countermeasures, as well as]* health technologies and know-how, by means that include local production;

16. ~~*Reaffirming* the flexibilities and safeguards contained in the Agreement on Trade-Related Aspects of Intellectual Propoerty Rights and their importance for ensuring appropriate transfer of technology, and know-how for production of pandemic response products, as well as sustainable supply chains for their equitable distribution;~~

    Alternative text proposed, based on UNGA Resolution A/RES/76/257 adopted on 29 March 2022:

    [Recalling the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as amended, as well as the Doha Declaration on the TRIPS Agreement and Public Health, and recognizing that intellectual property protection is an important element for the development of public health emergency response products in the fight against future pandemics; Recognising in addition that the TRIPS agreement should be interpreted and implemented in a manner supportive of the right of Member States to protect public health and, in particular, to promote access to medicines for all, and noting the need for appropriate incentives in the development of new health products, including incentives targeted at low and middle income countries;]

17. *[Recoginsing that publicly-funded research and development plays an important role in the development of medical countermeasures for pandemics;]*

18. *Emphasizing* that policies and interventions on pandemic prevention, preparedness and response should be supported by the best-available scientific evidence and adapted to take into account resources and capacities at subnational and national levels;

19. *Recognizing* the synergies between multisectoral collaboration – through whole-of-government and whole-of-society approaches at the country level – and international*[, regional and cross-regional]* collaboration, coordination and ~~global~~ solidarity, and their importance to achieving sustainable improvements in pandemic prevention, preparedness and effective response;

20. *[Reaffirming the importance of diverse, gender-balanced and equitable representation and expertise in pandemic prevention, preparedness and response decision-making, as well as in the design and implementation of activities;]*

21. *Acknowledging* that the repercussions of pandemics, beyond health and mortality, on socio-economic impacts in a broad array of sectors, including economic growth, employment, trade, transport, gender inequality, food insecurity, education and culture, require a multisectoral whole-of-society approach to pandemic prevention, preparedness and response and recovery;

22. *Reiterating* the determination to achieve health equity through action on social*[, political and economic]* determinants of health and well-being by a comprehensive intersectoral approach;

23. *Acknowledging* the impacts of determinants of health *[across different sectors]* on the vulnerability of communities, especially the vulnerable and *[disadvantaged]*~~marginalized~~, to the spread of pathogens and the evolution of an outbreak *[and reaffirming the importance of a Health in All Policies approach to prevent disease and promote health to resilience and recovery]*;

24. *Reaffirming* the importance of *[the]*~~a~~ One Health approach, and the necessity of synergies between multisectoral collaboration at the national*[, regional]* and international levels to safeguard human*[, animal and ecosystems]* health, detect and prevent health threats at the interface of animal and human ecosystems *[,*

in particular zoonotic spillover and mutations, and sustainably balance and optimise the health of people, animals and ecosystems and, in this respect, acknowledging the creation of the Quadripartite (WHO, the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (WOAH) and the United Nations Environment Programme (UNEP)) to better address any One Health-related issue];

25. *Underscoring* that multilateral *[and regional]* cooperation and *[good]* governance are essential to prevent, prepare for, and respond to pandemics that by definition know no borders and require collective action *[and solidarity]*;
26. *Considering* the importance and public health impact of other growing threats such as the spread of antimicrobial resistance among animal and human *[microorganisms and into the environement]* ~~pathogens~~, ~~and~~ *[as well as the consequences of]* climate change *[and biodiversity loss]*, ~~in particular~~ ~~its~~ *[including their]* impact on small island developing states; *[Considering further that these impacts are likely to spread on a larger scale in the future;]*
27. *Recognizing* the importance of the need to work synergistically with other relevant areas and mindful of the work being undertaken in those areas, notably *[on animal health,]* climate change*[, biodiversity loss]* and antimicrobial resistance;
28. *[Considering the effects of antibiotic and drug resistance on care and treatment necessary to respond to pandemics and the need for a holistic One Health approach to infection prevention and control];*
29. *Underscoring* the importance to promote early, safe, transparent and rapid sharing of samples and genetic sequence data of pathogens *[and to facilitate access to outbreak areas for investigation, oversight and monitoring]*, taking into account relevant national and international laws, regulations, obligations and frameworks, including, as appropriate, the International Health Regulations (2005), the Convention on Biological Diversity and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity and the Pandemic Influenza Preparedness Framework *[and also mindful of the work being undertaken in other relevant areas and by other United Nations and multilateral organizations or agencies]*;
30. *Recognizing* *[that a large multilateral effort is needed to build an effective global health architecture and that there is also a]*~~the~~ need to foster necessary linkages, promote coherence and enhance synergies among existing, relevant instruments*[, while avoiding duplication of efforts]*;
31. *Recognizing* the central role of WHO on pandemic prevention, preparedness and response as the directing and coordinating authority *[in global health]*~~on international health work~~, *[including in]* convening and generating scientific evidence, and more generally the role of multilateral cooperation in global health governance*[, including cooperation across relevant international organizations]*; and
32. *Recalling* the preamble to the Constitution of the World Health Organization, which states that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition;

[Overall] vision *[and purpose]*

EU comments:

Generally a text of this kind, describing the overall, high level aim of an instrument, may be included in the section setting out the agreement's objectives. Regardless of positioning, the text appears very convoluted. If it is also intended as a comunication tool, the text requires significant streamlining.

In addition, we consider that it would be important not to limit the scope of the WHO CAII to pandemic, but to extend it to public health threats with pandemic potential.

Specific drafting suggestions:

This section would articulate the vision and aspirational goals for the WHO CAII. It would provide a higher-level framing of objective and scope that goes to its core purpose.

[Building upon the One Health approach], ~~T~~*[t]*his WHO CAII aims to protect *[the health and wellbeing of]* present and future generations from the devastating consequences of pandemics *[and of public health theats with pandemic potential]*, on the basis of equity, human rights and solidarity with all people and countries, recognizing the sovereign rights of countries and respect for their national context, as well as the differences in capacities and levels of development among them*[. The WHO CAII aims at]* ~~, for~~ a world where, *[through the shared commitment of all of states and stakeholders, as well as,]* through ~~a~~ whole-of-government and whole-of-society approach*[es]*~~, at the national level~~, *[international]* cooperation *[and solidarity are]* ~~is~~ enhanced and fostered ~~at the international level~~ to prevent, prepare for and respond to future pandemics, with a view to ~~achieving~~ *[supporting]* universal health coverage, ~~in order to protect~~ and advance*[ing]* the enjoyment of the highest attainable standard of health for all peoples, *[including vulnerable populations]*.

Part I. Introduction

Article 1. Definitions and use of terms

***EU comments*:**

The definition of "regional integration organization" should be included under Article 1. Other definitions could also be added, such as the definitions of antimicrobial resistance, medical countermeasures, essential health services or zoonosis.

We would think that the definitions of pandemic and public health threats with pandemic potential should encompass situations where antimicrobial resistance becomes so acute and widespread that it gives rise to epidemics due to resistant pathogens and not allowing to treat patients in many countries in the world.

There is also a need to further consider whether definitions of terms, which are already quite well known, widely used or of common understanding, are really needed. In general, definitions will flow from the actual content of the provisions, depending of what terms are in need of a specific description. For instance, access may not need a definition per se.

> *This article would define or explain, as appropriate, all relevant terms and phrases, for example, technical terms, institutions, organizations and other terms, for the purposes of this WHO CAII[and would help clarify its scope]*. Such terms could include, inter alia: access, affected States, affordability, *[antimicrobial resistance,]* assisting States, biotechnology, community engagement, epidemic, equity, external assistance, gain-of-function, genomic sequence data, global public goods, health systems recovery, health systems resilience, infodemics, One Health, pandemic, pandemic preparedness, pandemic prevention, pandemic recovery, pandemic response, preparedness, prevention, public health threats with pandemic potential, readiness, recovery, *[regional integration organization as Party to the WHO CAII,]* response, *[essential health services,]* universal health coverage, utilization of genetic resources, whole-of-government, whole-of-society*[and, zoonosis]*.

Article 2. Relationship with international agreements and instruments

***EU comments*:**

The approach proposed under Article 2 is acceptable. As already stated in our oral comments presented during the INB meeting, we consider that it is essential to ensure complementarity and coherence of the WHO CAII with the IHR. These aspects require specific attention in the drafting of the provisions of the WHO CAII. It will in particular be important to reflect on how to ensure an integrated approach to the implementation assessment of both the IHR and the WHO CAII. Similarly, we believe that it will be important that the WHO CAII is closely linked with other relevant organisations, such as the Quadripartite organizations and many others. At the same time, we need to be mindful of respective mandates of such organisations and ensure no duplication of initiatives and no overlapping provisions, as these can cause legal uncertainty and lead to waste of limited resources. In that context, it could be helpful to include a list

of internationally (binding) agreements and instruments that bear relevance for or that may be affected by the WHO CAII. It is also important to identify areas or substance matter that address important health priorities under this instrument, but that may require action in other international agreements or instruments accross relevant sectors.

On paragraph 2, we believe that it would be important to clarify, be more specific and clearly state what is meant by "appropriate steps will be taken".

In addition, we would note that the establishment of close cooperation with relevant UN bodies, secretariats and other international and regional institutions, which have an essential role in pandemic prevention, preparedness and response (PPR), should be sought, and an explicit provision to this effect needs to be included in the WHO CAII. As we see reference to this element in Part V.1.b. below, we may also want to consider moving Article 2 under Part V.

Specific drafting suggestions:

This article would define the relationship, complementarity and potential hierarchy between this WHO CAII and other agreements, conventions, or international instruments.

1. The Parties recognize that this WHO CAII and other relevant international instruments should be interpreted so as to be compatible*[, complementary]* and synergistic. The provisions of this WHO CAII shall not affect the rights and obligations of any Party deriving from other existing international instruments *[and shall respect the competencies of other organizations or treaty bodies]*.
2. In the event that any part of this WHO CAII 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, *[especially from the perspective of One Health],* with a common goal of strengthened pandemic preparedness, prevention and response.
3. The provisions of this WHO CAII shall in no way affect the right of Parties to enter into bilateral or multilateral instruments, including regional or subregional instruments, on issues relevant or additional to this WHO CAII, provided that such instruments are compatible with and do not conflict with their obligations under this WHO CAII. The Parties concerned shall communicate such instruments through the governance mechanism for this WHO CAII.
4. For the purpose of this Article, the term "WHO CAII" includes this WHO CAII and any annexes, guidelines, protocols or other sub-arrangements, whether presently existing or established at a later date, established under this WHO CAII.

Part II. Objective(s), principles and scope

Article 3. Objective(s)

EU comments:

The introductory paragraph to this section appears rather convoluted. We would note that transparency and accountability are also important overarching principles that need to guide the objective of the WHO CAII. **The elements listed under 1 to 5 are quite appropriate, concrete and easy to understand. They should remain so.**

To restate: the instrument's objectives are: 1. increase and sustain the capacity to prevent pandemics; 2. increase and sustain pandemic preparedness capacities; and 3., 4. and 5. increase and sustain the capacity to respond to pandemics (including the more detailed elements described in 3. and 4., which could be merged under the same paragraph, and the specific recovery elements noted in 5.). This approach aligns with the title of the instrument set out in the WHASS decision.

Specific drafting suggestions:

This article would define the objective(s) of the WHO CAII.

The objective(s) of the WHO CAII, guided by the overarching principles of equity, *[transparency and accountability,]* shared ~~and differentiated~~ responsibilities, and respective capabilities, in the light of different national circumstances, is to save lives and protect livelihoods, through improving the world's capacities for preventing, preparing for and responding to pandemics. *[In doing so, the WHO CAII aims to contribute to the implementation of the Sustainable Development Goals. Building upon the One Health approach],* ~~T~~*[t]*he WHO CAII aims to address the systemic gaps and challenges that exist in these areas, and across the cross-cutting strategic themes of equity, governance and leadership, systems and tools, and financing, through measures at the national, regional and international levels:

1. to continually and substantially increase and sustain the capacity to prevent pandemics from occurring;
2. to continually and substantially increase and sustain pandemic preparedness capacities;
3. ~~Ensure availability and equitable access to affordable medical and other pandemic response products~~;

   to ensure coordinated, timely, and evidence-based pandemic response*[, including through the timely availability and equitable access to affordable, safe and efficacious medical and other pandemic response products and / or countermeasures]*; and
4. to facilitate speedy and equitable restoration of capacities for prevention, preparedness and response through a whole-of-government and whole-of society approach.

Article 4. Principles

EU comments:

Principles (together with preambular paragraphs and other intoductory provisions, such as objectives) are important as framing and interpretative tools. Depending on how they are drafted, they may also entail obligations. The text proposed under Article 4 appears long, with some repetitions and some language and can be further improved and streamlined.

For instance we note that the definition of equity is rather constrained. We suggested a broader understanding in our previous contributions (see excerpt from EU comments to the white paper: *"the principle of "equity" will entail setting out, inter alia, provisions aimed at ensuring the timely availability and affordability of, as well as non-discriminatory and transparent access to countermeasures; the support for regionally-based manufacturing facilities; the enhancement and diffusion of scientific knowledge and research relating to the causes and impacts of epidemics; the sharing of burdens and benefits of the cooperation efforts set out in the agreement; as well as the provision of requisite implementation support and capacity building, especially for the low and lower middle income countries, as well as other middle-income countries in need, such as the Small Island Developing States. It will also require adopting disability-sensitive and gender-responsive approaches and addressing the needs of vulnerable groups*").

We also consider that the central role of WHO, as the directing and coordinating authority in global health, and the role of science in guiding approaches and response measures, are important principles that should be recalled under Article 4.

The wording used under principle 9 of the Working Draft seems to refer to the CBDR principle as established in the 1992 Rio Declaration and the subsequent United Nations Framework Convention on Climate Change of Earth Summit (1992). We are not convinced of the application, as such, of the CBDR principle in the context of global health threats. While capabilities are different, we believe that responsibilities should remain shared. In addition, the criteria provided under i), ii) and iii) seem somewhat unclear to us. We would suggest to use more specific language, such as countries in humanitarian crises, armed conflicts and with weakened health systems.

Additional principles, such as the consultation and involvement of stakeholders, potentially affected communities and civil society, the use of integrated partnerships or the precautionary principle, could also be included under Part II, Article 4.

Specific drafting suggestions:

This article would define the principles that will guide the achievement of the vision and objective(s) of this instrument and implement its provisions.

To achieve the objective(s) of this WHO CAII and to implement its provisions, the Parties will be guided, inter alia, by the principles set out below:

1. **The right to health** – The enjoyment of the highest attainable standard of health, defined as a state of complete physical, mental and social well-being, *[which includes access to timely, acceptable, and affordable health care of appropriate quality,]* is one of the fundamental rights of every human being without distinction of *[any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property , birth or status]* ~~age, race, religion, political belief, economic or social condition~~.
2. **Universal health coverage** – The WHO CAII will be guided by the goal of achieving universal health coverage*[, for which strong and resilient health systems are of key importance,]* as an overarching principle to promote health and wellbeing for all at all.
3. **Respect of human rights** – The implementation of the WHO CAII will be with full respect for the dignity, human rights and fundamental freedoms of persons*[, including sexual and reproductive health and rights in the context of the Beijing Platform for Action and the Programme of Action of the International Conference on Population and Development*.
4. **Equity** – A fair, equitable, effective and timely response to pandemics requires ensuring fair access to affordable*[, safe and efficacious]* pandemic response *[countermeasures]*~~products~~, among and within countries, including between groups of people, irrespective of their social or economic status.
5. **One Health** – Multisectoral*[, coordinated and coherent]* actions ~~that recognize~~ *[resulting from]* the *[recognition that the health of humans, domestic and wild animals, plants, and the wider environment (including ecosystems) are closely linked and inter-dependent, and with the aim of]* ~~importance of animal health, human health, and environmental health~~ working together to ~~achieve better public health outcomes,~~ *[sustainably balance and optimize the health of people, animals and ecosystems] (NB: borrowing from the definition of One Health from the One Health High Level Expert Panel endorsed by the Quadripartite)*.
6. **Transparency** – International action to prevent and prepare for pandemics depends on coordinated, timely, and transparent sharing of information, data, and other factors necessary*[, such as access to outbreak areas,]* to ensure countries are able to carry out a robust response, for which Parties are accountable, through a whole-of-government and whole-of-society approach~~, based on and guided by the best available science~~.
7. ***[Responsibility and]*Accountability** – Effective global response to pandemics requires ~~high levels of~~ collective *[efforts]* ~~capacity~~ by all countries*[, including at the highest political level]*. All Parties are *[responsible and]* accountable for strengthening and sustaining their health systems' capacities*[,]* ~~and~~ public health functions*[and one Health structures. All Parties shall cooperate with other States and relevant international organisations]* in order to collectively strengthen, support and sustain global prevention, preparedness and response capacities*[, including through information sharing]*.
8. ***[Science-and evidence-based approach** – Any action undertaken by a Party in the field of pandemic prevention, preparedness and response must be based on and guided by the best available science and evidence].*
9. **Solidarity** – *[Parties undertake to increase to]* ~~I~~*[i]*ntensif*[y]*~~ied~~ international cooperation, ~~based on a set of specific obligations for Member States (especially, but not limited to, obligations from developed to developing countries) is required~~ to prevent, prepare for, respond to and recover from

pandemics*[, with special attention to the needs of low and lower-middle income countries]*.

10. **Shared ~~but differentiated~~ responsibilities and *[different]* capabilities** – Full consideration and prioritization is required of the specific needs and special circumstances of *[countries, in particular low and lower-middle income countries]* ~~developing country Parties~~, especially those that (i) are particularly vulnerable to adverse effects of pandemics; (ii) do not have adequate conditions to respond to pandemics; and (iii) would have to bear a disproportionate or abnormal burden.
11. **Sovereignty** – States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to determine and manage their approach to public health, notably pandemic prevention, preparedness and response pursuant to their own policies *[and legislation]*, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to other States and their peoples.
12. *[**Proportionality** – Due consideration should be given, including through continuous policy evaluation, to ensure that the impacts of measures aimed at preventing, preparing for and responding to pandemics are proportionate to their intended objectives;]*
13. **Community Engagement** – As communities are a cornerstone of health, effective and appropriate pandemic prevention and preparedness require sustained community engagement efforts that make communities more likely to trust governments in times of vulnerability and uncertainty, such as pandemics, and thereby play a central role that is fundamental to pandemic response.
14. **Inclusiveness** – The engagement with and participation of all relevant stakeholders and partners, consistent with relevant and applicable international and national guidelines, rules and regulations (including those relating to conflicts of interest) is fundamental to empowering communities and achieving the objective(s) of this WHO CAII.
15. **Gender equality** – Pandemic prevention, preparedness and response will take into account the specific *[risks faced by women and girls and their specific]* needs ~~of women and girls~~, using a country-driven, gender-responsive, participatory*[, equitable]* and fully transparent approach*[, in particular by ensuring that women are included in decision-making on pandemic prevention, preparedness and response]*.
16. **Non-discrimination and respect for diversity** – The impact of pandemics should not impede the enjoyment of the highest attainable standard of health without distinction of *[any kind as to race, colour, sex, language, religion, political or other opinion, national or social origin, property , birth or status]* ~~race, religion, political belief, economic or social condition.~~
17. **Rights of *[persons in]* vulnerable *[situations]* ~~populations~~** – Nationally determined and prioritized actions will take into account *[persons in]* vulnerable *[situations]* ~~people~~, places and ecosystems. ~~Indigenous populations, refugees, migrants, persons with disabilities, children and adolescents, for example,~~ *[These]* may be particularly impacted by pandemics, owing to social and economic inequities, *[humanitarian crisis situations,]* as well as *[by]* ~~to~~ legal and regulatory barriers that may prevent them from accessing health services.
18. ***[Central role of WHO in pandemic prevention, preparedness and response**– The central role of WHO, as the directing and coordinating authority in global health, and the role of multilateral cooperation in the global health governance, are fundamental for the achievement of the objectives of the WHO CAII.]*

Article 5. Scope

***EU comments*:**

The scope appears in line with the objectives described in Article 3. The issue of recovery may be better described as part of "response" to include, in line with Article 3, support for restoration of capacities for prevention, preparedness and response.

As noted for Article 3, we consider that it would be important not to limit the scope of the WHO CAII to

pandemic per se, but to extend it to public health threats with pandemic potential.

Specific drafting suggestions:

This article would define the scope of the WHO CAII.

This WHO CAII applies to ~~pandemic~~ *[the]* prevention, preparedness *[for]* and response *[to cross-border health threats with pandemic potential]* at the national, regional and international levels. This WHO CAII also applies to ~~pandemic~~ recovery *[following a pandemic]*, to the extent that it supports health systems' resilience and continuity of health care services.

Part III. General *[provisions]* ~~obligations~~

***EU comments*:**

It is unclear whether the suggested approach under Part III is that each point (1 to 12) should be translated into a discrete provision/ article. At the moment the introductory paragraphs reads: "… the following general obligations should be taken into account".

The issues outlined in this section are important. Whether they should be characterised as "general" will however need to take into account the content of the provisions that will be set out in other parts of the WHO CAII and in particular in the substantive parts. Many of the issues covered in this section appear quite specific, such as for instance points 2, 7 and 8 of the Working Draft. Also many of these issues to be actionable would require a further set of specific provisions, somewhere else in the agreement.

Re point 1 of the Working Draft, we welcome the proposed element on the development, implementation, periodically update and review of comprehensive multisectoral national pandemic prevention, preparedness, response and recovery strategies. We would however suggest to stress that these strategies should be conceived using the One Health approach. The regional, sub-national and local levels also need to be addressed, as well as the level of details and frequency of the reporting requirements.

Re point 2 of the Working Draft, we would propose to put this point lower in the list.

Re point 10 of the Working Draft, we would suggest clarifying what would be covered under the commitment to sustainable and predictable financing of "global systems and tools", and "global public goods". In addition, we would like to note that there might be a role for the WHO Contingency Fund for Emergencies.

We would also suggest to include a few additional general provisions as indicated below, while in due course considering the relationship between general and specific provisions.

Specific drafting suggestions:

This Part would set out general obligations. Potential text could be along the following lines:

To strengthen pandemic prevention, preparedness and response, using a whole-of-society and whole-of-government approach, consistent with the right to health and respect of human rights, and in accordance with each Party's capabilities and respectful of each Party's sovereign rights and their national *[and regional]* context, the following general *[provisions]* ~~obligations~~ should be taken into account:

1. *[take responsiblity to develop, maintain and strenghten prevention, preparedness and response measures and capacities, including through the implementation of the International Health Regulations (2005)]*;
2. develop, implement, periodically update and review, *[at the local, national, regional and global level,]* comprehensive, *[sustainable,]* inclusive, *[and]* multisectoral ~~national~~ pandemic prevention, preparedness, and response strategies, *[based on the One Health approach,]* and provide regular *[information and]* reporting on pandemic prevention, preparedness and response capacities *[and actions, while avoiding duplications]*;

3. engage with communities, civil society and non-State actors, including the private sector, as part of a whole-of-society approach to pandemic prevention, preparedness and response*[, while ensuring that no conflicts of interests arise]*;
4. adopt and implement legislative, executive, administrative and/or other measures for fair, equitable, effective and timely pandemic prevention, preparedness and response;
5. cooperate, in the spirit of solidarity, with other Parties and competent international and regional intergovernmental organizations and other bodies in the formulation of measures, procedures and guidelines for pandemic prevention, preparedness, and response*[, ensuring that national measures are tailored to avoid unnecessary, unintended and/or undesirable consequences affecting other Parties and/ or vulnerable populations]*;
6. ~~Develop and apply~~*[use]* science and evidence*[, in an integrative, holistic, and multidisciplinary approach,]* to inform policy and measures for effective pandemic prevention, preparedness and response;
7. provide forecasting, intelligence, and timely information sharing and alert mechanisms, through appropriate and up-to-date platforms and technologies*[, while safeguarding the protection of personal data]*;
8. provide access, upon request, to *[WHO and other]* experts to provide technical assistance to Parties that require strengthening of capacity for system prevention, preparedness, and response to pandemics;
9. mobilize, adequate human, financial and other necessary resources*[, including medical and non-medical countermeasures,]* to affected countries in containing outbreaks ranging from small scale to large scale global spread, based on public health need*[s]*;
10. ensure long-term, sustainable and predictable financing and mobilization of human resources, including necessary surge capacity, for pandemic prevention, preparedness and response at the national level;
11. ensure sustainable and predictable *[resources to strengthen pandemic prevention, preparedness and response, including]* ~~financing of global systems and tools, and global public goods~~ through relevant international organizations, institutions, and partners;
12. *[protect health workforce, health facilities and the delivery of health services, products and goods, in all contexts, especially in conflict zones, in line with the principles of humanitarian and international human rights law;]*
13. *[commit to gender equality in policy development to mitigate unintended effects of measures for pandemic preparedness, response and recovery, including by gathering and analysing relevant data, promoting diverse and equitable representation in decision-making, and using gender-relevant expertise in design and implementation of activities, as appropriate;]*
14. cooperate to mobilize sustainable financial resources for ~~sustainable financing of~~ ~~*WHO*~~ *[the implementation of the WHO CAII and]* to support countries for effective implementation of pandemic prevention, preparedness and response measures;
15. support, through national legislative or executive processes ~~or procedures, measures that promote~~*[, as necessary, the]* effective and transparent implementation and monitoring of this WHO CAII.

Part IV. Specific provisions/areas/elements/obligations

This Part would build on the general obligations set out above and would introduce, by theme, specific obligations/provisions/areas/elements/obligations, as appropriate, to implement the WHO CAII.

To strengthen pandemic prevention, preparedness and response, using a whole-of-society and whole-of-government approach, consistent with the right to health and respect of human rights, and in accordance with the capabilities of each Party and respectful of its sovereign rights and their national context, the following should be taken into account:

EU general comments on Part IV:

Part IV is composed of a long list of sections, each devoted to a specific issue and presented in 'an

inventory-mode', mixing horizontal issues, together with issues that are more technical in nature. In some cases, the link or connection from one section to the following one is difficult to grasp.

We would think that a logical thread should be recognisable in how issues are presented under Part IV. One possibility would be to structure Part IV along the objectives of prevention, preparedness and response, as such structure has in our view the advantage of being easily understandable by the general public. Alongside, there could be one or more thematic parts, devoted to entirely horizontal issues, such as scientific cooperation. This would also be in line with the mandate provided in the decision of the special session of the WHA. In any event the subject matter covered by Part IV should be easily understandable, by setting out clear and coherent headings/titles of the sections contained in the Part.

In this regard, some additional efforts should be made to merge some sections for clarity and to avoid duplication. We would suggest to merge in particular:

- sections 1 and 2;
- sections 4 and 11, and
- sections 5, 8 and 9, with the following possible subheadings: general, regional, national and subnational/community.

We also see some overlaps and repetitions between section 12 under Part IV and section 2 under Part V. We would therefore suggest to move section 12 to Part V and merge both sections.

We consider that more emphasis could also be given under Part IV to the prevention related aspects, in particular:

- Specific attention should be given in Part IV to Epidemiological surveillance/Epidemic intelligence/ Early detection of health threats in order to organise consistent and robust surveillance, as well as early detection, of emergent or reemergent pathogens with pandemic potential (based on the experience of the WHO Hub on Pandemic and Epidemic Intelligence);
- Issues related to the prevention of the emergence of zoonotic diseases, particularly in animals, and of their spill over, should be better reflected under Part IV;
- Specific provisions aimed at preventing epidemics due to pathogens resistant to antimicrobial agents should be included in Part IV. Global standards aimed at preventing the emergence and spread of AMR have already been developed for some sectors, e.g. for animals and the food chain by WOAH and Codex Alimentarius Commission. There needs to be coherence with and references to those existing standards;
- The aspects for raising awareness among the general public about the risks of the spread of pandemics could also be further developed.

In terms of preparedness and response, more attention could be paid to:

- Institution-building and capacity building for sustainable PPR;
- Strategies not only to transfer know-how, but also to retain that knowledge in countries with weak PPR;
- Local production and knowledge-transfer now seems to be the only measure to ensure availability of medical countermeasures. But attention should also be paid on how to:
    - ensure the long-term viability of local production once it has been set up;
    - retain newly trained staff in the targeted countries;
    - improve understanding of supply chain vulnerabilities.

In addition, more emphasis should be given to the One Health approach that needs to be applied horizontally to the whole WHO CAII, as well as to the role of PPR in achieving the SDGs.

We also suggest including a new section on human rights related issues to highlight the importance of ensuring the full respect of the principles of non-discrimination and proportionality in relation to pandemic response (see proposal for a new section 15). This is in our view an important element for securing public support for the implementation of response measures.

We also note that it would be important, when developing specific provisions for the WHO CAII, to take into account national, and as applicable regional, legislation and context.

1. Achieving Equity

EU comments:

We would propose to move point b under Section 3 on "Strengthening and sustaining health systems' resilience and capacities".

Specific drafting suggestions:

Equity is central to achieving and sustaining the objective(s) of WHO CAII. In developing international, regional or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to ensure availability and *[timely]* accessibility to *[efficacious]* ~~quality~~, safe, ~~and~~ effective *[and]* affordable health~~care~~ services (including clinical and mental health care), and pandemic response *[countermeasures]* ~~products~~ through primary health care and universal health coverage;

b. measures to ensure strengthening of national*[, and where appropriate regional,]* regulatory authorities that have the capacities to *[prepare for and]* accelerate emergency approval procedures *[to allow for the timely]* ~~ensure~~ availability of key pandemic response *[countermeasures]* ~~products in the countries~~ *[, while ensuring, including through post-marketing surveillance, that they are safe and efficacious]*;

c. measures to ensure access and benefit sharing, which would include, but not be limited to: rapid, regular and timely pathogen and genomic sequence sharing through ~~a~~ *[one or more]* standardized real time ~~global~~ platform*[s]*; and timely access to affordable, safe, *[efficacious]* and effective pandemic response products, including diagnostics, vaccines, personal protective equipment and therapeutics*[, through the active assistance of WHO]*;

d. Measures to ensure priority of access to pandemic response *[countermeasures]* ~~products~~ by healthcare workers, other frontline workers, and *[other target groups as appropriate, depending on the specific health threat and the pandemic circumstances, with specific attention given to the]* ~~vulnerable~~ persons *[in vulnerable situations]*;

e. Measures to ensure equitable and affordable access to *[efficacious]* ~~quality~~, safe and effective pandemic response products, including those drawn from strategic stockpiles, and their equitable distribution;

f. Measures to address social determinants of health, economic development, and environmental *[or zoonotic]* determinants.

2. Fair, equitable and timely access and benefit sharing

EU comments:

Ensuring fair, equitable and timely access and benefit sharing is a key factor in achieveing equity. It is therefore unclear what separates section 1 from section 2, especially as there are some clear overlaps between the two sections (see point 1.c.).

In addition, it would be important to clearly spell out what is meant by "Fair, equitable and timely access": in our view it applies to both data (including data with direct relevance to the emergency response) and biosamples.

While the WHO CAII should be considered as a specialized international access and benefit-sharing instrument (ABS instrument) in line with the Convention on Biodiversity and its Nagoya Protocol, it is also important to note that establishing a fair and equitable access and benefit sharing for the purpose of pandemic prevention, preparedness and response under WHO provides an opportunity for a mechanism where derived benefits (such as access to countermeasures, vaccines, etc…) should be equally shared with all countries in needs, with special attention to the needs of low and lower-middle income countries. Benefits cannot be returned to or shared only with the country of access of the pathogens.

In general, we stress that it would be crucial not to create unnecessary administrative hurdles for research.

On point b), the proposed wording cannot be supported, as this could imply that the WHO CAII could be considered by some State Parties as a specialised ABS instrument and not by others, thus causing significant legal uncertainty.

On point d), reference should also be made to other relevant data types beyond pathogens and genomic sequences. All data should be FAIR (i.e.: meeting the principles of findability, accessibility, interoperability and reusability) and made available for research and development of medical countermeasures either immediately or after a short embargo period. Clearly, research relying on sequence data should continue to be possible without access barriers within the framework of existing good scientific practice.

Specific drafting suggestions:

Establishing a *[specific]* ~~comprehensive~~ system for access and benefit sharing is a cornerstone to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to establish a *[specific]* ~~comprehensive~~ system for access and benefit sharing, ~~including but not limited to, consistency with~~ *[taking into account]* relevant elements of the Convention on Biodiversity and its Nagoya Protocol, ~~by building upon or adapting mechanisms and/or principles contained in existing or previous instruments~~;

b. ~~measures to promote and facilitate recognition of the system as a specialized comprehensive access and benefit sharing system, at the national level.~~

c. measures to engage with all relevant actors in the design, development and implementation of the comprehensive system for access and benefit sharing;

d. measures to ensure timely sharing of pathogens *[with pandemic potential,]* ~~and~~ genomic sequence data *[and any other relevant data, according to open science principles,]* through one or more standardized *[and secured]* real-time platforms ~~available to all Parties~~ *[with transparent and multi-stakeholder governance]*.

3. Strengthening and sustaining health systems' resilience and capacities

Specific drafting suggestions:

[Strengthening human and veterinary h]~~H~~ealth systems and capacity ~~strengthening~~ are core to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national ~~legislative, administrative, technical and/or other~~ measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to strengthen ~~public health~~ *[human and veterinary health]* functions and robust surveillance, *[access to outbreak areas and]* outbreak investigation and control, early warning, information sharing, *[including by linking existing databases]* ~~and~~ *[as well as human and veterinary laboratory]* capacities *[included but not limited to]* ~~for~~ genomic sequencing, in order to inform risk assessment of and trigger rapid response to *[public health threats with pandemic potential, including]* emerging and re-emerging zoonoses, and develop *[multisectorial]* prevention strategies for epidemic-prone diseases, notably at

the human-animal-environment interface;

b. measures to ensure preparedness capacity assessment is undertaken, and *[local,]* national *[and regional]* action plans are developed and periodically tested through *[regular]* global, regional and national simulation and tabletop exercises, that include risk and vulnerability mapping;

c. measures to ensure *[universal health coverage through]* recovery and restoration of resilient health systems ~~through universal health coverage~~, including systems for a rapid and scalable response;

d. *[measures to prevent disruption of health services and to support the continued provision of health care, especially primary health services, including routine immunization, the provision of oral and mental health services, the prevention of non-communicable diseases risk factors, as well as sexual and reproductive health and rights in the context of the Beijing Platform for Action and the Programme of Action of the International Conference on Population and Development, with specific attention to the situation of the most vulnerable populations;]*

e. measures to strengthen ~~public~~ *[human and veterinary]* health laboratory and diagnostic capacities and networks, including standards and protocols for *[human and veterinary]* ~~public~~ health laboratory biosafety and biosecurity*[, including with the support of the WHO Academy]*;

f. measures to provide oversight of and report on laboratories that do work to genetically alter organisms in order to increase pathogenicity and transmissibility in order to prevent accidental release of these pathogens, *[while ensuring that these measures do not create any unnecessary administrative hurdles for research]*.

4. *[Promoting sustainable l]*~~L~~ocal production and *[voluntary]* transfer of technology and know-how

EU comments:

We would suggest an alternative text in relation to Section 4 point d, as we believe that the correct implementation and effective use of the flexibilities provided under the TRIPS Agreement should be a shared objective. However, we consider the WTO as the most appropriate forum for these discussions. IP waivers per se are not able to ensure a more equitable access to pandemic response products. Access to COVID vaccines during the first part of the COVID-19 pandemic was limited by insufficient global production capacities (infrastructure, raw materials, personnel, etc).

We would also suggest to move point c. under the previsous section on "Strengthening and sustaining health systems' resilience and capacities".

Specific drafting suggestions:

Broadening and diversifying access to relevant technology and know-how for the production of pandemic response *[countermeasures]* ~~products~~ such as vaccines, is fundamental to achieving and sustaining the objective(s) of this WHO CAII *[and requires a sustainable approach, including functioning production in normal times, good manufacturing practices, licensing, regulatory capacity and qualified human resources]*. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to support initiatives and multilateral mechanisms that promote and provide relevant *[and voluntary]* technology transfer and know-how, while being respectful of intellectual property rights, to potential manufacturers in ~~developing countries~~ *[all regions]*, which *[enable and]* increase global manufacturing capacity and supplies of ~~affordable,~~ essential pandemic response *[countermeasures]* ~~products~~ that match the global demand resulting from pandemics*[, while ensuring the affordability, safety and quality of these countermeasures]*;

b. measures to encourage and facilitate participation of private sector entities in *[voluntary]* technology and know-how transfer through initiatives and multilateral mechanisms;

c. measures to ensure equitable and affordable access to health technologies, promoting the strengthening of national health systems and mitigating social inequalities;

d. *[technical assistance and capacity-building m]*~~M~~easures to *[ensure that efficient legislative frameworks are in place enabling Parties to make use of the existing flexibilities as provided for under the TRIPS Agreement]* ~~support time-bound waivers of protection of intellectual property rights during pandemics where there is inequitable, delayed or no access by developing countries to pandemic response products that can minimize mortality~~;

e. measures to strengthen *[and maintain regionally based]* ~~developing countries'~~ capacity to manufacture pandemic response *[countermeasures]* ~~products~~ through *[research and development, and voluntary]* technology transfer and know-how*[, based on a sound framework for intellectual property rights,]* to ensure adequate global supplies, which meet surge demand.

5. Governance and coordination, collaboration, and cooperation

EU comments:

On point f., we see the need to ensure coherence with the IHR, and avoid duplications.

Specific drafting suggestions:

Governance, coordination, collaboration and cooperation, based on the principles of accountability, *[inclusivity]* and transparency, at all levels are essential to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, executive, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to promote global, regional and national political commitment, coordination and leadership for pandemic prevention, preparedness and response, by means that include establishing ~~appropriate~~ *[good]* governance ~~arrangements~~ *[principles]* rooted in the Constitution of the World Health Organization *[and based on the One Health approach]*;

b. measures to support mechanisms that ensure global, regional and national policy decisions are science- and evidence-based, through enhanced coordination, collaboration and sharing of information among experts, scientific bodies, and networks *[making full use of the One Health approach]*;

c. measures to strengthen and sustain long-term development cooperation in pandemic prevention, preparedness and response, by enhancing WHO's central role as the directing and coordinating authority on international health work, and ~~mindful of the need for coordination~~ *[to coordinate]* with entities in the United Nations system and other intergovernmental organizations;

d. measures to recognize the specific needs of vulnerable populations, *[including in conflict zones,]* indigenous populations, fragile areas such as small island developing States, *[as]* well as those promoting equitable gender, geographical and socioeconomic status representation and participation in global*[,]* ~~and~~ regional *[and national]* decision-making processes, global networks and technical advisory groups;

e. *[measures that enhance mutual trust (governments-communities-people);]*

f. measures to facilitate mobility and international travel during pandemics*[, while acknowledging that travel restrictions necessary to safeguard public health should remain a possibility and while guaranteeing strong protection of personal data]*.

6. Health workforce*[, including veterinary services]*

EU comments:

We consider that it is important to include a clear reference to veterinary services in Section 6, in line with the One Health approach.

The strengthening of the emergency health workforce is also a very important element for sustainable pandemic prevention, preparedness and response and should be addressed.

Specific drafting suggestions:

An adequate, skilled, trained, competent and committed *[emergency]* health workforce, at the frontlines of pandemic prevention, preparedness and response, *[embedded in national health systems and including veterinary services, if needed]* is central to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, executive, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to strengthen pre-, in- and post-service training of adequate numbers of health workers, *[and other sector workers such as veterinarians,]* at the national and local levels, equipped with public health competences *[and up to date, interdisciplinary curricula]* and to ensure laboratory capacity for conducting genomic sequencing through sustainable funding support, deployment and retention for health workforce resilience that can be mobilized for pandemic response;

b. measures to ensure recovery and restoration of resilient health systems *[in response to a pandemic]* through sustaining universal health coverage and primary health care capacity, including systems for a rapid and scalable response, notably through sustainable support and adequate deployment of health workforce with public health competences;

c. measures to *[support]* ~~ensure~~ an available, skilled and trained ~~global~~ public health emergency workforce ~~that is deployable to support affected countries,~~ through scaling up of ~~training and~~ *[the]* capacity of *[existing]* training institutes~~, upon request~~. *[These training institutes should form a network of national and regional facilities and centres of expertise, and foster common protocols to make response missions and deployments of surge staff more predictable and standardised, with the WHO Academy playing a supporting role;]*

d. *[Measures to support the establishment and maintenance of professional, multisectoral and well-trained readiness groups, as well as to strengthen WHO-led ability to offer assistance to support domestic teams investigating outbreaks when alarming epidemiological signs are detected;]*

e. *[Measures that ensure a gender based and equitable approach and protect the rights and well-being of all health workers, including their mental health.]*

7. One Health

EU comments:

The One Health approach seems to be confined in section 7. We reiterate our comment raised in our previous written submissions that the One Health approach is by definition an integrated, unifying approach to address cross-cutting issues that needs to permeate all other sections of the WHO CAII. The application of this principle in the different chapters of the WHOCAII should be strengthened.

In relation to AMR, the general reference included in section 7, without specifying any further measures aimed at preventing epidemics due to pathogens resistant to antimicrobial agents, is insufficient. We consider that the WHO CAII should include specific provisions on AMR, framed within the broader One Health approach. This could be achieved by inserting the specific provisions in the One Health section, or by including a separate section on AMR as indicated in the EU contribution on the identification of the substantive elements (and as further indicated below).

Specific drafting suggestions:

The whole-of-government and whole-of-society One Health approach is fundamental to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical*[, scientific]* and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to promote *[and implement]* a comprehensive One Health approach, *[at national, regional and international level,]*~~promoting~~ *[aiming at]* coherence *[and collaboration]* among all relevant

actors, *[sectors,]* instruments, initiatives and issues, *[with a view to reducing pandemic risks, including the ones resulting from]*~~such as climate change and~~ antimicrobial resistance~~, insofar as they relate to pandemic prevention, preparedness and response~~;

b. measures to strengthen multisectoral coordinated, integrated One Health surveillance systems *[to detect early zoonotic spillover events and mutations, in order]* to minimize *[and reduce the threat from zoonotic]* spill-over events and mutation, and prevent small-scale outbreaks *[in wildlife or domesticated livestock]* from becoming a pandemic.

c. measures to strengthen regular monitoring and *[timely]* sharing of *[biological material or organisms]* ~~pathogens~~ with pandemic potential*[, as well as any pathogen]* from ~~wildlife and domesticated livestock~~ *[wild, production and companion animals that causes emerging and re-emerging zoonotic diseases, while establishing effective communication mechanisms at international level in case of outbreaks]*;

d. measures to ensure that actions at *[regional,]* national and community levels encompass whole-of-government and whole-of-society perspectives;

e. measures to regularly assess One Health capacities, as well as gaps in, policies for and funding support needed to strengthen One Health capacities;

f. measures to strengthen the synergy *[and avoid duplication]* with other existing relevant instruments which address the drivers of pandemics*[, such as climate change, biodiversity loss, ecosystem degradation or increased risks at the animal-human-ecosystems interface due to human activities]*;

g. measures to promote and enhance synergies between multi-sectoral collaboration at *[regional, and]* national level, and cooperation at the international level, to safeguard human *[animal and ecosystems]* health, and to detect and prevent health threats at interface between animal and human ecosystems.

7 *Bis (Based on the EU contribution on the identification of substantive elements)*
[Preventing epidemics due to pathogens resistant to antimicrobial agents through the One Health approach

Antimicrobial Resistance (AMR) is often described as a slow tsunami or silent pandemic. In addition, AMR could be an aggravating factor during a pandemic. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. *Measures to enhance the provisions on surveillance and reporting of antimicrobial use (AMU) and AMR in human, plant/ crops and livestock populations, mindful of the need to strengthen data-sharing platforms, streamline processes and avoid duplication.*

b. *Measures to strengthen the knowledge and evidence base through surveillance and research in both human and animal populations and plants.*

c. *Measures setting global AMR targets, inter alia on reductions in current levels of resistance, on the use of antimicrobials in human, animal and plant health, on infection prevention and control measures, as well as related indicators on the release of antimicrobials in the environment, defined together with One Health/Quadripartite (WHO, Food and Agriculture Organization (FAO), World Organisation for Animal Health (WOAH) and United Nations Environment Programme (UNEP)).*

d. *Measures requiring the establishment and effective implementation of One-Health National Action Plans, in line with the WHO Global AMR Action Plan, and the recommendations of the Interagency Coordination Group on Antimicrobial Resistance, as well as the future independent panel on evidence for action against AMR.*

e. *Measures to reduce the unnecessary use of antimicrobials globally by applying antibiotic stewardship practices (e.g. no antibiotic without prescription, increased use of diagnostic tests prior to antibiotic prescription when relevant, phasing out of the use of antimicrobials for growth promotion in animals, restriction in the prophylactic use in animal husbandry) and by implementing effective infection*

prevention and control programs in healthcare institutions.

f. *Measures to promoting the development and availability of preventative, diagnostic and therapeutic medical countermeasures relevant to combat AMR, notably old and new antimicrobials and rapid diagnostic tests for human and animal use.*

g. *Measures to provide a specific support to low and middle income countries, where the burden of AMR is disproportionately higher.]*

8. Governance, whole-of-government and other multisectoral actions at national level

EU comments:

We consider that additional clarifications would be needed on what is meant by "public financial management" in point c.

Specific drafting suggestions:

Governance, whole-of-government and other multisectoral actions are prerequisites to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to collaborate through an all-encompassing whole-of-government, multistakeholder, whole-of-society approach*[, including by strengthening health literacy,]* to tackle the social determinants of health that contribute to the emergence and spread of pandemics as well as to prevent or mitigate the socioeconomic impacts of pandemics, including but not limited to those affecting economic growth, employment, trade, transport, gender inequality, education, food insecurity, nutrition and culture;

b. measures to proactively develop~~, through a whole-of-government and multi-sectoral collaboration,~~ plans that facilitate speedy and equitable restoration of *[health]* capacities following a pandemic *[through a whole-of-government, multi-sectoral collaboration and based on the One Health approach]*;

c. measures to support timely mobilization of surge capacity of human and financial resources, and public financial management to facilitate timely allocation of resources to the frontline response;

d. measures to delegate authority during pandemics to local government *[where needed]*, in accordance with the country context *[and national legal system]* in order to better respond to the pandemic, with strong involvement by relevant stakeholders.

9. Governance, community engagement and whole-of-society actions at national and subnational levels

EU comments:

We consider that additional clarifications would be needed on what is meant by "Social capital" in point c.

Specific drafting suggestions:

Governance, community engagement and whole-of-society actions at national and subnational levels are prerequisites to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to promote *[science and evidence-based]* effective and timely risk communications to the public;

b. measures to promote and strengthen the engagement/participation of communities in all elements of pandemic prevention, preparedness and response to ensure their ownership of and contribution to national readiness and resilience, including public health and social measures;

c. measures to mobilize social capital in the community for mutual support especially to ~~vulnerable~~

~~populations~~ *[persons in vulnerable situations]*.

d. measures to ensure engagement of civil society, communities and non-State actors, including the private sector, as part of the whole-of-society response*[,while ensuring that no conflict of interests arise]*.

10. Global supply chain and logistics network

EU comments:

We consider that additional clarifications should be provided on the following points:

- point a.: in relation to the second part of the paragraph, i. e. "that both leverages well-established and proven systems, processes, and mechanisms that are in place, mindful of the need to build on respective strengths and promote transparency in cost and pricing";
- point d.: in relation to the establishment and operationalisation of "international consolidation hubs, as well as regional staging areas to ensure that transport of supplies is streamlined" and the definition of "priority countries".

On point e., we see the need to ensure coherence with the IHR, and avoid duplications. A reference should also be added to the fair treatment of transport personnel, which was severely undermined during the COVID-19 pandemic (e.g. seafarers).

Specific drafting suggestions:

A global, effective and affordable supply chain and logistics network is crucial to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to ensure a concerted and coordinated approach to availability and equitable access to and distribution of *[affordable, safe and efficacious]* pandemic response *[countermeasures]* ~~products~~, that both leverages well-established and proven systems, processes, and mechanisms that are in place, mindful of the need to build on respective strengths and ~~promote~~ *[encourage]* transparency in cost and pricing;

b. measures to prioritize and coordinate requests for essential supplies at national level based on national action plans for pandemic prevention, preparedness and response;

c. measures to facilitate, coordinate, and equitably allocate procurement of supplies, *[including for stockpiling purposes,]* through *[the most efficient multilateral and/ or regional]* ~~pooled~~purchasing mechanisms, based on public health needs*[, with due consideration given to the shelf life of the products and the Parties' storage capacities, and following a demand-driven approach, as well as a best-placed partner approach]*;

d. measures to establish and operationalize international consolidation hubs as well as regional staging areas to ensure that transport of supplies is streamlined, uses the most appropriate means for the products concerned, and promotes equitable, timely and efficient delivery to priority countries;

e. *[in line with the IHR,]* measures to avoid ~~the imposition of~~ unnecessary ~~disturbances~~ *[interference with]* ~~to~~ international ~~travel~~ *[traffic]* and trade, ~~as well as discriminatory travel and trade restrictions, facilitating the flow of people~~ *[as well as to protect the health and alleviate barriers to the work of transport personnel,]* and *[to]* ensur*[e]*~~ing~~ that supply chains remain intact and connected.

11. Research and development

EU comments:

We support Section 11 on research and cooperation and we would propose a more encompassing title, such as "Scientific and technological cooperation".

In line with the previous EU written submissions, we consider that the following elements are important and should be included or better reflected in Section 11:

- set out the notion of scientific and technological cooperation, which does not extend to the inclusion of detailed specifications for national research and development activities;
- the promotion of rapid sharing of scientific findings, surveillance and diagnostic data, research results and samples.

Similarly, we regret that the reference in the white paper to "establish and/or link to existing mechanisms (e.g. a science-policy body) to ensure Member States are advised on science and technology advancements relevant to the development and implementation of international rules and guidelines under the instrument" has gone missing.

Re point c, we consider that additional clarifications would be needed on what is meant by "scalable financing".

Re point d, the second part of the sentence related to the strengthening of the capacities of regulatory authorities is to a large extend a repetition of the element provided under point b in Section 1 (and that we propose to move under Section 3 on "Strengthening and sustaining health systems' resilience and capacities").

Specific drafting suggestions:

Research and development, *[and scientific and technological cooperation],* ~~in an open and secure manner~~ that fosters active participation and engagement of scientists and institutions*[, including]* from developing countries, are a key component to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. *[measures to make research and development integral part of pandemic prevention, preparedness and response, and to foster open science approaches for rapid sharing of scientific findings, surveillance and diagnostic data, research results and samples;]*

b. measures to promote and align international, regional and national action and scientific cooperation, to accelerate innovative research for novel pathogens, *[neglected]* and (re)emerging diseases *[with pandemic potential]*;

c. measures to build and strengthen national capacities and institutions for innovative research and development, by means that include scalable financing and scientific and technical cooperation, collaboration, and communication;

d. measures to strengthen research and development processes for national, regional and global development and production of diagnostics, medicines, and vaccines, *[based on public health needs,]* particularly in ~~developing~~ *[low and lower-middle income]* countries, and regulatory authority capacities to accelerate the process ~~of licensing and~~ *[of]* approving *[safe and efficacious]* pandemic response *[countermeasures]* ~~products~~ for emergency use in a timely manner *[and in line with the One Health approach,]*;

e. *[measures to promote cooperation, taking into account national capacities, in trans-disciplinary fields' research, recognizing in particular all the benefits social sciences can bring to health sciences;]*

f. *[measures to promote the dissemination of the results of publicly funded research for the development of pandemic response products/ medical and non-medical countermeasures].*

12. Preparedness monitoring, simulation exercises and peer review

Specific drafting suggestions:

Effective and efficient monitoring of pandemic prevention and preparedness, through among others means,

exercises ~~and~~ peer review~~,~~ *[and country-led processes,]* are critical to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to develop global and national indicators for monitoring prevention and preparedness, and to *[support Parties, in particular the low and lower-middle income countries in]* regularly conduct*[ing]* simulation exercises *[embracing the One Health approach]* to assess readiness and gaps*[, as well as to plan and implement measures]* for sustaining preparedness capacity;

b. measures to establish, regularly update and broaden implementation of a global *[WHO led]* peer review mechanism to assess national, regional and global preparedness capacities and gaps, by bringing nations together to support a whole-of-government approach, strengthening national capacities for pandemic prevention, preparedness, and response ~~mindful of the need to integrate available data,~~ and engag*[ing]*~~e~~ national leadership at the highest level*[, while taking into account the need to protect potentially sensitive data]*.

13. Pandemic and public health literacy

Specific drafting suggestions:

Addressing science, public health, and pandemic literacy and tackling false, misleading or disinformation are key components of achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to manage public information, risk communication and infodemics through effective channels *[with recognized and trusted scientific experts]*, including social media *[and active engagement of civil society and specific organs according to the national context]*;

b. measures to conduct regular social listening in order to identify and verify misinformation and so to design communications and messaging to the public *[by the relevant, competent authorities]* and counteract misinformation, disinformation and false news;

c. measures to foster health*[, including the One Health approach,]* and science literacy, and promote communications on scientific and technological advances relevant to the development and implementation of international rules and guidelines for pandemic prevention, preparedness and response;

d. measures to promote and facilitate at all appropriate levels, in accordance with national laws and regulations, development and implementation of educational and public awareness programmes on pandemics and their effects, and public access to information on pandemics and their effects;

e. measures to provide timely and effective global communication, *[with accurate, transparent information that are]* based on science and evidence, ~~which~~ *[to]* counter misinformation, disinformation and false news.

14. Financing

EU comments:

We consider the issues covered by this section to be important. Nonetheless, they need to be treated in a coherent fashion with the elements contained under Part V, section 4. Please see specific comments included in the section therein.

Discussion on funding approaches and mechanisms must be based on an in-depth analysis of existing and emerging instruments (especially but not only with regard to the new FIF for pandemic prevention, preparedness and response). Duplication of existing structures and funding mechanisms should be avoided.

Re point a, we would suggest to consider the support that could be provided to Member States by WHO in assessing their financing needs for pandemic prevention, preparedness and response.

Re point b, we would suggest clarifying what would be covered under "sustainable and predictable financing of global systems and tools, and global public goods".

Re point c, we would sugest to move this point under Part IV Section 9 on "Governance, Whole-of-government and other multi-sectoral actions at national level".

Specific drafting suggestions:

Ensuring sustained and predictable financing is essential to achieving and sustaining the objective(s) of this WHO CAII. In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. measures to strengthen domestic financing for pandemic prevention, preparedness and response, including through greater collaboration between health and finance sectors in support of primary health care and universal health coverage;

b. measures to ensure sustainable and predictable financing of global systems and tools, and global public goods, through existing or new mechanisms*[, while avoiding duplication,]* in order to guarantee equitable access to emergency financial mechanisms and to facilitate rapid and effective mobilization of adequate financial resources to affected countries, based on public health need;

c. measures to establish or reinforce*[, including through appropriate training and continuous education,]* and adequately finance an effective national coordinating multi-sectoral mechanism or focal points for pandemic prevention, preparedness, response and recovery*[, in collaboration with the national IHR focal point]*;

d. measures to facilitate and ensure cooperation ~~to~~ *[for the planning and]*mobiliz*[ation]*~~e~~ *[of]* sustainable financial resources for effective implementation of the WHO CAII.

15. *New proposed section on: [**Human rights***

In developing international, regional, or national legislative, administrative, technical and/or other measures for pandemic prevention, preparedness, and response, the following should be taken into account, among others:

a. *ensure that any national measures adopted for designing the response to a pandemic should be necessary, proportionate and applied in a non-discriminatory way, in accordance with applicable international human rights law and should take into account the impact on health as a whole, including on mental health;*

a. *ensure than when public health and social measures are adopted in response to a pandemic threat, preference should be given to the one that has the least negative impact on human rights.]*

Part V. Institutional arrangements

This Part would define the institutional arrangements for the implementation and application of the WHO CAII, which could include its governance, support, and deliberative processes, as well as financial and other resources to support those activities. The specific text of these institutional arrangements will depend on the provision of the WHO Constitution under which the instrument is adopted. Potential text could include without limitation the following components:

1. Governance mechanism for this WHO CAII

EU comments:

The fuctions oulined in this section are useful, but will need to be complemented and described more precisely, including with respect to decision making procedures. We would also reiterate some elements contained in our previous submission on the White Paper on the draft annotated outline. It should be considered to allow all States and relevant international and regional organisations to participate in the

Conferences of the Parties (COP) as observers, even if not Parties to the WHO CAII, with a view to promoting their eventual accession to the instrument. The COP should also serve as the Meeting of the Parties (MOP) to any of the Protocols which may be agreed under its umbrella. Similarly, all States should be allowed to participate as observers in the MOP of any specific Protocol. The COP and the MOPs should oversee and take decisions to promote the effective implementation of the respective instruments. The participation and input of non-state actors (e.g. NGOs, academia, private sector entities) should be allowed and encouraged, especially with a view to informing, promoting and facilitating the implementation of the WHO CAII.

The WHO should provide Secretariat support to the WHO CAII and its possible Protocols (different arrangements involving joint secretariat functions bringing together different international organisations could be envisaged in specific policy areas, especially when linked to One Health). Appropriate assessed financial means should be made available to cover Secretariat costs.

Specific drafting suggestions:

The WHO CAII shall include a governance mechanism to support its operation and implementation. Depending on the provision of the WHO Constitution under which the instrument is adopted, this governance mechanism could be established as a Conference of the Parties or a Member State Mechanism. It would be expected that the governance mechanism would be based in WHO, and supported by the WHO Secretariat*[, as well as the Secretariat of FAO, WOAH and UNEP, as appropriate, or based on the model of the secretariat of the WHO framework Convention for Tobacco Control]*. The functions of the governance mechanism could include, without limitation:

a. to ~~promote and~~ facilitate the mobilization of financial resources for the implementation of the WHO CAII*[, based on needs assessment]*;

b. to enable collaboration and cooperation across the United Nations system and other international and regional intergovernmental organizations and non-State actors and bodies as a means of strengthening the implementation of the WHO CAII;

c. to establish such subsidiary bodies as are necessary to achieve the objective(s) of the WHO CAII;

d. to assist in addressing the cycle of panic and neglect that burdens existing global pandemic prevention, preparedness and response efforts, and to govern the implementation, functioning, sustainable building and progressive development of capacities, norms and obligations after adoption of the WHO CAII;

e. to promote and facilitate the exchange of information between Parties to the WHO CAII;

f. to promote and guide the development and periodic refinement of comparable methodologies for research and the collection of data relevant to the implementation of the WHO CAII, *[following an integrative, holistic, and multidisciplinary approach]*;

g. to promote, as appropriate, the development, implementation and evaluation of strategies, plans, and programmes for the WHO CAII;

h. to consider reports submitted by the Parties in accordance with the WHO CAII, and adopt regular reports *[and recommendations]* on the implementation of the WHO CAII*[, while taking into account the need to avoid duplication of reporting responsibilities]*;

i. to consider other action(s), as appropriate, for the achievement of the objective of the WHO CAII in the light of experience gained in its implementation.

2. Oversight mechanisms for this WHO CAII

EU comments:

As indicated in the EU open-ended submission to the INB, monitoring and accountability mechanisms have a key role to play in promoting implementation of and compliance with the provisions of the WHO CAII. These mechanisms should allow for an integrated approach across the WHO CAII and the IHR,

while preventing duplications, inconsistencies and double burden. Care should be taken not to create undue administrative hurdles for WHO CAII Parties. Complementarity with possible amendments to the IHR in this area should also be considered.

For instance, we would encourage consideration of the establishment of a periodic peer review, or of the use, when appropriate, of the tools under discussion and development, such as the Universal Health and Preparedness Review (UHPR)[1].

Care should be taken to ensure that the participation in monitoring, compliance and accountability mechanisms is accompanied by appropriate support, especially for low and lower middle income countries, to assist them in these processes.

The WHO CAII will include both compulsory and voluntary provisions. As a result, not all provisions of the agreement will be enforceable and preference should be given to incentivise voluntary compliance. Conciliation and mediation mechanisms alongside dispute settlement should be provided for.

Specific drafting suggestions:

a. The Parties shall consider and approve incentive measures, cooperative procedures and institutional mechanisms to promote oversight of, and compliance with, the provisions of this WHO CAII.

b. These measures, procedures and mechanisms shall include monitoring provisions and accountability measures to systematically address the *[preparedness and response to, and]* impact of pandemics, by means that include submission of periodic reports, reviews, remedies and action, and to offer advice or assistance, where appropriate. These measures shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under this WHO CAII.

3. Assessment and Review

Specific drafting suggestions:

A *[review]* mechanism shall be established to undertake, four years after the commencement of this WHO CAII and thereafter at intervals *[and upon modalities]* determined by the *[Conference of the]* Parties, an evaluation of the relevance and effectiveness of this WHO CAII, and recommend corrective measures*[, including by way of amendments to the text of the agreement]*, as necessary.

4. Financial mechanisms and resources

EU comments:

It would be advisable to establish a separate Part or a Section to address the provision of **implementation support,** as an ambitious WHO CAII design aimed at equitable outcomes requires significant investment in implementation support. This should be linked to gaps identified through a monitoring and accountability mechanism, and integrate both IHR and WHO CAII implementation support, including through:

- Strengthening WHO's role and ability to support national and regional core health system capacities for pandemic prevention, detection, preparedness and response, as well as its coordination role at global level.
- Strengthening country commitment and ownership, as well as "whole of government"/cross-sectoral preparedness approaches leading to better mobilisation of all competencies and resources, and coherence in pandemic prevention and response at global, regional, national and community/local levels.

[1] Consultations on the concept note on the UHPR are currently underway. This process will need to be taken into consideration when developing the monitoring mechanism of the WHO CAII.

- Committing to support, technical assistance and capacity building for low and lower middle income countries[2] aimed at:
    - the effective implementation of the WHO CAII and related IHR commitments,
    - the improvement of national and regional mechanisms for pandemic prevention, detection, preparedness, and response (including inter-agency and inter-sectoral coordination mechanisms),
    - the strengthening of health systems in the area of pandemic prevention, preparedness and response, including by:
        a) increasing health and social services workforce capabilities, including through their appropriate education and training (for continuity of essential health services during public health emergencies, and for integrated interdisciplinary surveillance to prevent, detect and respond to public health threats with pandemic potential),
        b) developing and deploying digital health and social care tools and infrastructure, as well as
        c) improving technical and structural capacity to detect and contain public health threats (e.g. diagnostic equipment, personal protective equipment, isolation facilities and general water, sanitation and hygiene (WASH) infrastructure in health facilities).
- Considering specific assistance initiatives for upper middle-income countries in need.
- Seeking to build a (non-binding) cooperative framework across major donors (e.g. international financial institutions and multilateral development banks, bilateral donors, philanthropies) and the private sector. Consider how best to support implementation-related capacity building, as well as both long-term (e.g. local and regional research, development and production of medical and non-medical countermeasures) and emergency interventions for pandemic PPR.[3] This work should align closely with other global health architecture reforms initiatives, including with a view to sustainably financing the WHO.
- Determining the provisions that low and lower middle income countries can implement after one or more transition periods stipulated in the WHO CAII and requiring the prior acquisition of implementation capabilities through the provision of technical assistance and capacity building.

Specific drafting suggestions:

a. The Parties recognize the important role that financial resources play in achieving the objective(s) of this WHO CAII.

b. Each Party ~~shall~~ *[should make resources available in accordance with its national fiscal capacities to]*~~provide financial~~ support ~~in respect of its~~ national activities intended to achieve the objective(s) of the WHO CAII, in accordance with its national plans, priorities and programmes.

c. Each Party ~~shall~~ *[should plan and]* provide financial support in line with its *[national]* fiscal capacities for the effective implementation of this WHO CAII.

d. The Parties ~~shall~~ *[should]* promote, as appropriate, the use of bilateral, regional, subregional and other appropriate and relevant multilateral channels to provide funding for the development and strengthening of pandemic prevention, preparedness and response programmes of ~~developing country~~ *[low and lower-middle income countries']* Parties.

e. The Parties represented in relevant regional and international intergovernmental organizations, and financial and development institutions shall encourage these entities to provide financial assistance for ~~developing country~~ *[low and lower-middle income countries']*Parties and for Parties with economies in transition to support them in meeting their obligations under the WHO CAII, without

[2] As defined by the World Bank.
[3] This may provide an opportunity to streamline the participation of WHO CAII parties in existing mechanisms aimed to finance and implement PPR, such as the WHO's Contingency Funds for Emergencies and relevant public/private initiatives such as CEPI, GAVI Alliance, etc.

limiting the rights of participation within these organizations.

Part VI. Final provisions

This Part would define the final provisions for the WHO CAII, as appropriate. The specific text, to be determined, will depend on the provision of the WHO Constitution under which the instrument is adopted. The following is a non-exhaustive list of certain topics that could be included.

- Protocols and annexes
- Amendments
- Reservations
- Settlement of disputes
- Withdrawal
- Right to vote
- Signature
- Ratification
- Entry into force
- Depositary
- Authentic texts