White paper: draft annotated outline of a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response (Document A/INB/1/12)

Written comments of the European Union

General comments:

The EU welcomes the White Paper and warmly thanks the Bureau and the Secretariat for their efforts. The paper is an important stepping stone, which will move the discussion forward.

Overall, the structural elements proposed are appropriate. We welcome in particular the articulation of the substantive parts of the future pandemic agreement/instrument (hereinafter PA) around the areas of prevention, preparedness and response. We note that there is however a need to further simplify the annotations under each heading of the PA to avoid duplication and redundancies across the different substantive parts. We also acknowledge that several issues/ elements may straddle the prevention, preparedness and response areas. We trust the Bureau to make the best judgement on allocating each issue/ element under one of the main substantive areas, so as to avoid duplication.

We believe that it is important to have clarity and consistency on the scope of the PA throughout the document. We consider that the PA should apply to public health threats with pandemic potential. Human rights, international solidarity and equity, the centrality of WHO, the One-Health approach, the principle of non-discrimination, the prioritization of the vulnerable, as well as transparency and accountability are of utmost importance. They need to permeate all sections of the PA and should provide key guidance for the interpretation and implementation of its provisions.

For this reason, it would be important to ensure that the proposal to have a separate section on One Health does not lead to a "silo" approach. We believe that it is essential to ensure that the PA builds on a comprehensive One Health approach, which is by definition an integrated, unifying approach to address cross-cutting issues.

In addition, duplications of initiatives and provisions should be avoided with regard to already existing international instruments, such as the IHR and the TRIPS Agreement, including the recently approved package on trade and health at the WTO. As a general matter, we understand references to technology transfer to mean voluntary technology transfer.

We appreciate the importance of the strategic pillars resulting from the discussions in the WGPR. We note that these pillars, especially the principle of equity, are cross-cutting in nature and will without any doubt be of high relevance across the entire text of the PA. Repeating these categories as sub-headings under each substantive section needs to be considered further when we move to the drafting phase as such subsections might lead to an overcomplicated structure and to some unnecessary duplications. Similarly, the division of all substantive themes into sub-themes also leads to redundancy. Thus, we are not convinced by the need to mention them explicitly.

It will anyway be important to keep some flexibility in our approach to adjust the structure as we further build content.

We also note that the substantive elements included in the White Paper are in most cases described in very generic terms. This makes it difficult to offer appropriate comments at this stage.

In order to move towards more specific proposals for each area, we would encourage the INB Bureau to further consider the EU open-ended submission submitted on 29 April, as indicated in the specific comments provided below.

We will provide further and more specific comments on language at the appropriate time.

Specific comments

Preamble

This part would introduce guiding principles, overarching themes, recalling and recognizing the importance of other relevant instruments (e.g. UN, human rights, SDGs, WHA/EB resolutions/decisions, etc.).

EU Comment: See below under Principles.

Part I. Introduction

Section 1. Definitions and use of terms

This section would define all relevant terms (pandemic, equity, etc.) and phrases (technical terms, institutions, organizations, etc.), for the purposes of the instrument.

EU Comment:

The definition of "public health threats with pandemic potential"[1] will be important to establish the scope of the PA. Similarly, it will be important to set out definitions of other key terms, while relying on definitions established or supported by the international organisations, such as the new definition of "One Health" developed by the One Health High Level Expert Panel (OHHLEP).

Section 2. Relationship with international agreements and instruments

This section would define the relationship, complementarity and potential hierarchy between this instrument and other agreements, conventions, or international instruments.

EU Comment:

There should be clarity on the relationship of the PA with existing instruments, in line with the relevant provisions of the Vienna Convention on the Law Treaties. Complementarity and coherence between the PA and other instruments, such as the IHR, the Convention on Biological Diversity and the Nagoya Protocol should be ensured.

The actions related to preventing and dealing with pandemic threats require strengthened coherence and cooperation across multiple policy areas and institutions. In particular, the PA should seek the establishment of close cooperation with relevant UN bodies, secretariats and other international and regional institutions, which have an essential role in PPR.

Part II. Objective, scope, and guiding principles

Section 3. Objective and scope

This section would define the objective(s) and scope of this instrument.
The objective of the instrument could be to *save lives and protect livelihoods* by addressing the gaps and challenges that exist in pandemic prevention, preparedness, response and recovery, across the four cross-cutting strategic themes of equity, governance and leadership, systems and tools, and financing. Substantive elements to address these gaps and challenges may be mapped accordingly and further clustered under five subthemes: access; transfer of technology and know-how; coordination, collaboration and cooperation; multi-sectoral actions; and capacities and systems strengthening.

[1] This definition would also determine whether the PA covers pandemic situations or also extends to epidemics events.

EU Comment:

The definition of "public health threats with pandemic potential" will be important to establish the **scope of the agreement**. The PA **object and purpose** should be to set out **substantive obligations** for the Parties and other related provisions aimed at strengthening pandemic prevention, preparedness and response, using a One Health approach, as well as at strengthening the capacity of WHO and of Member States to address public health threats with pandemic potential, including AMR. This could be achieved through three main, interrelated **objectives**:

1. Preventing and controlling,
2. Detecting and reporting, and
3. Preparing for, and responding to, public health threats with pandemic potential (adopting a whole-of-a-society approach).

Section 4. Principles

This section would set out the relevant principles to achieve the objective of the instrument and any related instruments, and to implement its provisions (e.g. human rights, non-discrimination, prioritization of the vulnerable; equity and fairness; effectiveness and timely actions; transparency and accountability; sustainability; inclusivity and solidarity).

EU Comment:

The substantive obligations should be framed by a series of **general goals** and **overarching principles**, in particular:

- the human right to health, including universal health care access and the links between health (both physical and mental health) and human rights (comprising sexual and reproductive health and rights (as per the European Consensus on Development), as well as a gender-responsive approach to health, among other elements)[2],
- international solidarity and equity, with respect inter alia to equitable access to medical and non-medical countermeasures, financing and capacity strengthening,

[2] The EU remains committed to the promotion, protection and fulfilment of all human rights and to the full and effective implementation of the Beijing Platform for Action and the Programme of Action of the International Conference on Population and Development (ICPD) and the outcomes of their review conferences and remains committed to sexual and reproductive health and rights (SRHR), in this context. For further elaboration see New European Consensus on Development, 2017, paragraph 34, available at: European Consensus on Development | International Partnerships (europa.eu)).

- the centrality of WHO, as the directing and coordinating authority in international health cooperation, including for pandemic prevention, preparedness and response, and more generally the role of multilateral cooperation in the global health governance,
- the "One Health" approach, including the need to address the close links between human, animal and environmental health, in line with the definition developed by the One Health High Level Expert Panel (OHHLEP)
- the crosscutting effects of pandemics beyond health, including socio-economic impacts (affecting for instance employment, trade, transport, gender inequality, education and culture) requiring an intersectoral "whole-of-society" approach to pandemic PPR, including through public private partnerships,
- transparency and accountability in decision-making and implementation, informed by scientific evidences and insights, as well as consistent and accurate data,
- The use of digital technology in prevention, preparedness and response, while guaranteeing strong protection for personal data.

These principles could be set out in the **preamble** and/or the introductory part of the PA, and most importantly should permeate the substantive provisions of the agreement. They should also provide key guidance for the interpretation and implementation of such provisions.

In particular, 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.

Section 5. General obligations

This section would set out general obligations, and could include, *inter alia*:

- develop, implement, periodically update and review, comprehensive multisectoral national pandemic prevention, preparedness, response and recovery strategies, *including for One Health and antimicrobial resistance*, and provide regular reporting on pandemic prevention, preparedness and response capacities. (47)
- establish or reinforce and finance a national coordinating multi-sectoral mechanism or focal points for pandemic prevention, preparedness, response and recovery. (57)
- cooperate with other Member States and competent international and regional intergovernmental organizations and other bodies in the formulation of proposed measures, procedures and guidelines for pandemic prevention, preparedness, response and recovery (including those related to infection prevention and control, water, sanitation and hygiene (WASH) and antimicrobial resistance, transfer and treatment of patients, travel and movement of frontline workers). (7, 25, 30, 33, 34, 38, 43, 62, SH)
- 2.2. engage with communities, civil society and non-State actors, including the private sector, as part of a whole-of-society approach. (SH)
- 2.7. commit to long-term development cooperation and investment in pandemic prevention, preparedness and response.
- 2.9. develop and adopt science and evidence-based policy decisions.
- 3.8. provide forecasting, intelligence, and timely information sharing, through appropriate and up-to-date platforms and technologies. (11, 61)
- 4.3. commit to rapid and effective mobilization of adequate human, financial and other necessary resources to affected countries, based on public health need. (12, 20, 56)
- 4.4. commit to sustainable and predictable financing of global systems and tools, and global public goods. (64)
- 51. provide access, upon request, to experts to provide technical assistance to Member States that require strengthening of capacity for system preparedness and response to health emergencies.

EU Comment:

The issues outlined in this Section are important. Whether they should be characterised as "general obligations" may need to take into account the content of the provisions that will be set out in other parts of the agreement/instrument and in particular in the substantive parts (i.e. Part III, IV, V and possibly VI).

More specifically on the proposed elements included in the White Paper under Section 5:

- 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 rephrase the proposed element as follows (proposed additional text in bold, and proposed deletion in strikethrough): "develop, implement, periodically update and review, comprehensive multisectoral national pandemic prevention, preparedness, response and recovery strategies, ~~*including for*~~ **based on the One Health approach and including, inter alia,** *antimicrobial resistance*, and provide regular reporting on pandemic prevention, preparedness and response capacities", to stress that these strategies should be conceived using a One Health approach (and not only include One Health as a separate element). 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

- the establishment or reinforcement of a national coordinating multi-sectoral mechanism or focal points for pandemic prevention, preparedness, response and recovery should be done in close collaboration with national IHR focal points.
- in relation to the proposed substantive element "4.4. *commit* to sustainable and predictable financing of global systems and tools, and global public goods", 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.

Part III. Measures relating to prevention

EU Comment:

As indicated in the EU open-ended submission, we believe that addressing pandemic prevention requires new or enhanced provisions aimed at:

a) Enhancing the global early warning capacity;
b) Preventing and controlling zoonotic spill-overs;
c) Preventing inadvertent laboratory release of pathogens
d) Preventing epidemics due to pathogens resistant to antimicrobial agents through a One Health approach
e) Capacity building.

Tackling these challenges (especially b, c, d, e) should be underpinned by national and regional One Health action plans. These One Health action plans

should consider the main drivers of disease emergence, including climate change and biodiversity loss, and set out concrete actions to avoid or mitigate the potential emergence and re-emergence of pathogens, from both natural and man-made ecosystems.

More specifically, we note that the items set out in the White Paper under Part III do not cover the following points of the EU open-ended submission:

a) Enhancing the global early warning capacity;

Point 14 of the EU submission, i.e. an early warning and alert system for modelling and forecasting, has been integrated under Section 5 – General obligations, under the substantive element "*3.8. provide forecasting,* intelligence, and timely information sharing, *through appropriate and up-to-date platforms and technologies."*

One element is however missing: the suggestion that the information should be collected from multi-sectoral sources, including those focused on environmental, climate, human and animal health data.

Point 15 of the EU submission (on modalities for the sharing of relevant data) appears entirely missing and should be reflected under Part III:

- Establish harmonised modalities for the sharing of relevant data and information collected at national and regional level, as well as for cooperation in the improvement of the quality of data and analytical capacities.

b) Preventing and controlling zoonotic spill-overs;

Issues related to emerging zoonoses are only mentioned in one of the substantive elements resulting from the online tool, i.e.: element "3.2. Early warning, rapid investigation, risk assessment and rapid response for emerging zoonoses", which is included under Part IV related to preparedness and Part V related to response, but not under Part III related to prevention.

Reducing the risk of zoonotic spillover in line with the One-Health approach should be a key objective of the PA. This objective is currently not sufficiently reflected in the proposed outline and is not addressed under Part III. Points 16 to 24 of the EU submission should be better reflected in the proposed outline, and in particular under Part III:

- Enhance and harmonise surveillance and notification systems, where necessary, at the wildlife-livestock-human interface (in line with the One

Health approach) and enable the timely flow of information through interoperable surveillance and risk assessment systems between human health, animal health and environmental authorities at local, regional and international levels (including by supporting the WHO Hub for Pandemic and Epidemic Intelligence). The PA provisions should be complementary to existing IHR and World Organisation of Animal Health (WOAH) provisions.

- Regulation of wild and live domestic animal markets and stricter surveillance and control of illicit wildlife traffic and traditional food markets, both domestically and internationally.
- Pathogen surveillance and identification of emerging and re-emerging pathogens with a high zoonotic infection potential (including through the early warning and alert system described in section 1.a. of the EU submission and the improvement and interconnection of databases) in livestock, companion animals and high risk wildlife populations and vectors. This should build on the work of the Scientific Advisory Group for the Origins of Novel Pathogens (SAGO), while mindful of remaining consistent and avoiding duplications with the WOAH mandate.
- Systematic exchange of information and data on pathogens, variants and genetic sequencing at the animal-human interface with standardized and harmonized data.
- Universally accessible sample collection capacities (repositories) and equitable pathogen sample sharing, also by connecting and standardizing existing sharing platforms, while respecting biosecurity and biosafety requirements.
- Develop protocols and recommendations for voluntary sharing of scientific findings, surveillance and diagnostic data, research results and samples, including through the contributions of the WHO Hub for Pandemic and Epidemic Intelligence. Set incentives for low and lower-middle income countries to share their data.
- Increase knowledge and capacity to prevent and address risks from zoonoses and other public health threats at the human-animal-ecosystem interface, notably due to the loss of natural habitats and decreasing biodiversity or other factors, in line with the “One Health” approach and taking into account the work of the OHHLEP.

- Promote environmental protection actions aimed at significantly reducing the risk of zoonotic spill-overs.
- Enhance joint trainings between, and continuing education of, human and animal health professionals and the inclusion of the One Health approach in health studies.

c) Preventing inadvertent laboratory release of pathogens

Point 25 of the EU submission is reflected under the following element "3.19. Standards and protocols for public health laboratory biosafety and biosecurity". In the White Paper, there is however no explicit mention of issues related to inspection and training.

Point 26 of the EU submission on the independent oversight of laboratory conditions and safety protocols is also not mentioned and should be better reflected under Part III:

- Enhance the independent oversight of laboratory conditions and safety protocols to ensure biosecurity and biosafety.

d) Preventing epidemics due to pathogens resistant to antimicrobial agents through a One Health approach

AMR is mentioned under Part II, Section 5 on the General principles. The White Paper refers to: i) the development, implementation, periodically update and review of comprehensive multisectoral national pandemic prevention, preparedness, response and recovery strategies, including for One Health and AMR, and ii) the cooperation with other MS and competent international and regional intergovernmental organizations and other bodies in the formulation of proposed measures, procedures and guidelines for pandemic prevention, preparedness, response and recovery, including those related to AMR.

Points 27 to 33 of the EU submission, which set out more specific proposals on AMR, including the establishment of specific Actions Plans on One Health, should be included in the White Paper, preferably under Part III.

The following elements should therefore be better reflected under Part III (making use of the expertise of the Quadripartite):

- Enhance the provisions on surveillance and reporting of antimicrobial use (AMU) and antimicrobial resistance (AMR) in human, plant/crops and

livestock populations, mindful of the need to strengthen data-sharing platforms, streamline processes and avoid duplication.

- Strengthen the knowledge and evidence base through surveillance and research in both human and animal populations and plants.
- Together with One Health/Quadripartite (WHO, Food and Agriculture Organization (FAO), WOAH and United Nations Environment Programme (UNEP)), set 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.
- Require 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.
- Commit 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).
- Promote 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.
- Committing to provide a specific support to low and middle income countries, where the burden of AMR is disproportionately higher.

e) Capacity building

Point 35 of the EU submission is reflected under the substantive element "3.20. Sustainable support for national capacity, including to ensure an adequate number of health workforce with public health competency". We believe that the focus under the PA should be on the Health Emergency Workforce. This workforce should preferably be trained through a network of

centres of excellences and national or regional facilities, with the WHO Academy playing a supporting role.

While the White Paper includes a substantive element on "Global, regional and national simulation and tabletop exercises", the establishment of coordinated plans and multidisciplinary training tools for health professionals as proposed in **point 36 of the EU submission** is not mentioned and should be better reflected under Part III:

- Consider the establishment of coordinated plans and multidisciplinary training tools for health professionals (including shared protocols on common skills, use of distance-learning, periodic coordinated exercises and the development of equivalent job profiles), tailored and adapted to the different needs and contexts, and by making use of a network of facilities and initiatives (such as the WHO Academy and the Laboratorium initiative launched under the Italian G20 Presidency).

In addition to the above-mentioned comments based on the EU open-ended submission, we would suggest to rephrase some of the proposed elements included in the White Paper under Part III, as follows (proposed additional text in bold, and proposed deletion in strikethrough). As identical elements are included in Parts III, IV, V and VI, the modifications proposed below should also be taken into consideration for the proposed elements repeated under Parts IV, V and VI of the White Paper.

- 1.1. **Promote the a**~~A~~ccess to lifesaving, scalable and safe clinical care, including mental health care*, continuity of health services and palliative care,* **as well as to social care, with special attention to the needs of low and lower-middle income countries.**
- 1.14. Rapid, regular**,** ~~and~~ timely **and systematic** pathogen and genomic sequence sharing and related **equitable** benefit sharing, **as appropriate**, including for the development and use of **safe and effective** diagnostics, vaccines and therapeutics.
- *3.8. provide forecasting,* intelligence, and timely information sharing, *through appropriate,* **harmonised** *and up-to-date platforms and technologies,* ***under the leadership of WHO and on the basis on information collected from multi-sectoral sources, including those focused on environmental, climate, human and animal health data.***
- 3.19. Standards and protocols for public health laboratory biosafety and biosecurity, **including for the provision of inspection and training**.

- 1.10. **Promote regional, n~~N~~**National, **sub-national, and local** capacity strengthening, **including in the area of research and development**, to prevent, prepare for and respond to epidemics and pandemics.~~, including for research and development.~~
- 1.16. Strengthened national regulatory authority capacity ~~on licensing~~ for **market approval of** medical countermeasures, **with special attention to the quality control of such medical countermeasures**.
- 3.3. Establishing a skilled and trained global ~~public~~ health emergency workforce, ~~*including GOARN and WHO Emergency Medical Teams,*~~ deployable to support affected countries, **as well as readiness groups, which are centred around local public health and health care resources, familiar with and trusted by the communities that they serve**. **Provide necessary resources to WHO,** *including **for** GOARN and WHO Emergency Medical Teams,* **as well to FAO, UNEP and WOAH to field health emergency teams. Also support PA Parties in need in establishing and strengthening the national health emergency workforce**.
- 3.17. **Promote r~~R~~**esilient health systems for universal health coverage and health security **including strengthened primary care systems with special attention to the need of low and lower-middle income countries**.
- 3.20. **Promote** ~~Sustainable support for~~ national capacity **building**, including to ensure an adequate number of **community** health workforce with public health competency, **in accordance with WHO normative and technical guidelines and with special attention to the needs of low and lower-middle income countries**.

Additional comments:

In relation to our proposed modifications on the substantive element 1.14, we believe that it is important to note that benefits deriving from rapid pathogen and genomic sequence sharing should be available to all in an equitable fashion, and not accrue only to the country of origin of the pathogen and genomic sequence.

In relation to the proposed substantive element "3.6. Global, regional and national simulation and tabletop exercises", we would suggest to consider this in an integrated manner with the part on monitoring and review.

Part IV. Measures relating to preparedness

EU Comment:

We note that the items set out in the White Paper under Part IV do not cover the following points of the EU open-ended submission:

- **Point 38**: provide, in addition to obligations, strong positive incentives to report health threats and share data, to avoid the risk of countries withholding information due to concerns that doing so might produce negative responses.
- **Point 39**: interconnection of digital tools to enhance human, animal and environmental health threats detection capacities and cooperation among PA Parties, while taking into account coherence with IHR.
- **Point 40**: taking the One Health approach as well as the IHR into account, consider enlarging the mandate of WHO, FAO, WOAH and other relevant organisations to investigate rapidly, in a coordinated manner and in close cooperation with national authorities concerned, events and outbreaks which may pose public health threats with pandemic potential (including the authority to verify State reports, disseminate outbreak data, conduct in-country assessment and share available scientific data) and commit to swift information sharing.
- **Point 45**: Develop protocols and recommendations for non-pharmaceutical, non-medical interventions.
- **Point 46**: Consider setting up a dedicated multi-stakeholder platform to facilitate research as well as demand-driven, emergency procurement and delivery of vaccines, diagnostics, therapeutics and other essential supplies, building upon the experience and lessons learned of the "Access to COVID-19 Tools Accelerator" ACT-A and other relevant WHO initiatives.
- **Point 50**: Establish a harmonised and secure system for the issuance, verification and acceptance of digital certificates for vaccination, test and recovery, as well as for contact tracing activities (e.g. the electronic passenger locator form), to facilitate travel of persons during a pandemic, while guaranteeing strong protection for personal data (the EU Digital Covid Certificates may provide some inspiration for such a system, given its widespread use). This objective should be pursued consistently with the possible inclusion of digital tools within the IHR.

The following points of the EU open-ended submission are only partly reflected in the White Paper:

- **Point 42 of the EU submission** is reflected under the substantive element "3.3. Establishing a skilled and trained global public health emergency workforce, including GOARN and WHO Emergency Medical Teams, deployable to support affected countries". The involvement of other UN organisations, such as FAO and UNEP, and of WOAH is however not explicitly mentioned in the White Paper. The wording of the proposed substantive element we believe should be improved as suggested in our comments included under Part III. In addition, the benefits of a network approach could be mentioned, with the WHO Academy playing a supporting role.
- **Point 47 of the EU submission** is reflected under the substantive element "1.16. Strengthened national regulatory authority capacity on licensing medical countermeasures, *as well as WHO Emergency Use Authorization processes for key medical countermeasures*". Aspects related to transport are however not explicitly mentioned in the White Paper. As previously mentioned, we would also suggest to refer to market approval, instead of licensing.

In addition to the above-mentioned comments based on the EU open-ended submission, we would suggest to rephrase some of the proposed elements included in the White Paper under Part IV, as follows (proposed additional text in bold, and proposed deletion in strikethrough). As identical elements contained in Part IV are also included in Part III, kindly refer for these elements to our comments under Part III:

- 1.5. Availability of and timely access to pandemic response products, including medical countermeasures **and non-medical countermeasures**.
- 1.3. Access to technology and know-how, in connection with epidemic and pandemic countermeasures **on a voluntary basis** ~~*without imposing legal or financial obligations, including time-bound waivers of intellectual property*~~.
- 2.3. Establishing appropriate governance arrangements to address and support pandemic **and epidemic** prevention, preparedness and response, rooted in the WHO Constitution.
- 3.13. Preparedness assessment and **regional,** national**, sub-national and local** action plans.

- 10. Create a multidisciplinary and multisectoral platform of public health emergency operations centres at global, regional and national level**, operating in collaboration with WHO Regional Offices**".
- 1.2. Access to quality, agile, ~~and~~ sustainable **and affordable** health services for universal health coverage.
- 1.16. Strengthened national regulatory authority capacity ~~on licensing~~ for **market approval of** medical countermeasures, *as well as WHO Emergency Use Authorization processes for key medical countermeasures***, with special attention to the quality control of such medical countermeasures**.
- 3.15. Public health laboratory, including mobile laboratories, ~~and~~ diagnostic networks **and strengthening of the laboratory workforce capacities**".
- 4.1. Enhanced collaboration between health and finance sectors in support of universal health coverage, and as a means to support pandemic **and epidemic** prevention, preparedness and response.

Additional remarks:

- The voluntary nature of technology transfer needs to be clearly mentioned in the substantive element 1.3.
- We would suggest to include a new element to reinforce WHO mandate for the publication and dissemination of information and data related to public health threats with pandemic potential, on the basis of reliable epidemiological principles, in case the state concerned would not cooperate within a prescribed period. This would need to be coherent with the WHO mandate and IHR obligations.
- **Point 44 of the EU submission** on the development and strengthening of genomic sequencing capacities at national and regional level is well reflected in the White Paper, through the following elements: "1.14 Rapid, regular and timely pathogen and genomic sequence sharing and related benefit sharing, including for the development and use of diagnostics, vaccines and therapeutics" (for which we have suggested revised wording) and "3.12. Enhancing national capacity for pathogen and genomic sequencing and its sharing for rapid pandemic risk assessment and global alert". In the current outline, both elements are repeated under the three Parts dealing with prevention, preparedness and response (Parts III, IV and V). Thus, to avoid redundancy, we could place the point 1.14 under the "response" chapter and the point 3.12 under the "preparedness" chapter.

- We would suggest to include a new substantive element in line with C-TAP practice, namely: "Consider ways to ensure the dissemination of the results of publicly funded research and development of medical countermeasures".
- In relation to the substantive element "53. *Establish an international social, economic, and health fund to support injured communities and societies as a result of a pandemic*", we note that the establishment of such a fund under the PA may be an important incentive. Clarifications and in-depth analysis are however needed on the proposed mandate and mission, and its articulation with other initiatives, including the proposal for a financial intermediation fund on pandemics hosted by the World Bank. It would also be important to ensure that any duplication is avoided.

Part V. Measures relating to response

EU Comment:

We note that the items set out in the White Paper do not cover the following point of the EU open-ended submission:

- **Point 51**: Mindful of the legal framework set out in the IHR related, *inter alia*, to travel and transport restrictions, quarantine, border controls, consider enhancing coherence and coordination of containment measures at international and regional level, while taking into account national rules and the need for control measures to be appropriate to the country-specific pandemic situation. Such enhanced coordination, including specific provisions for essential workers, especially health professionals and transport workers, should also aim at maintaining the integrity of supply chains and ensuring supplies of essential goods, such as food and medical products.

While **point 54 of the EU submission** is to some extent reflected under the substantive element "1.12. Policy to safeguard vulnerable populations most affected by pandemics", we would like to stress the importance of paying special consideration to humanitarian and fragile contexts, including conflict zones.

Point 55 of the EU submission is only partially reflected in the White Paper, through the substantive elements "3.17. Resilient health systems for universal health coverage and health security", "3.20. Sustainable support for national capacity, including to ensure an adequate number of health workforce with

public health competency". The importance of strengthening primary and community health care especially in low and lower middle income countries is not explicitly mentioned.

In addition to the above-mentioned comments based on the EU open-ended contribution, we would suggest to rephrase the following proposed element included in the White Paper under Part V (proposed additional text in bold, and proposed deletion in strikethrough):

- 71., 72. **Promote t**~~T~~ransparency in prices of countermeasures, **in accordance with guidance from national authorities.**

As identical elements contained in Part V are also included in Parts III and IV, kindly refer for these elements to our comments under previous parts.

Additional comment:

- The principle according to which any response measures undertaken should always be proportionate and non-discriminatory should be an underlying principle of Part V.

Part VI. Measures relating to recovery

This part would cover specific substantive elements that address pandemic recovery, including of the health system, and could include, but would not be limited to, the following.

EU Comment:

A more informed view on the possible need for a separate Part devoted to recovery can be taken once the content of Parts III, IV and V has been clarified and duplication removed.

Part VII. One Health

This part could address a comprehensive approach to One Health, promoting coherence among all relevant actors, instruments and initiatives. (2.8, 3.11)

EU Comment:

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 PA. We need to make sure that the proposal to have a separate section on One Health does not lead to a "silo" approach that needs on the contrary to be overcome. Such separate section, if kept, would need to reinforce the application of the principle in the different chapters of the PA as necessary.

Part VIII. Access and benefit sharing

This part could address pandemic-related access and benefit sharing (ABS), such as proposals to build upon existing mechanisms in the global health ABS arena, i.e., proposals aimed at addressing all emerging and novel pathogens of human pandemic potential by adopting the mechanisms and/or principles contained in existing (GISRS and PIP) or previous (Global Action Plan for Influenza vaccine manufacturing capacity) influenza related systems. (15)

EU Comment:

A more informed view on the possible need for a separate Part devoted to access and benefit sharing can be taken once the content of Parts IV, V and XI in particular has been clarified. It is however clear that the objective to achieve equitable outcomes – namely to ensure that prevention, preparedness and responses to pandemic are equally strengthened worldwide - as a result of the implementation of the agreement/ instrument should permeate all its provisions.

Part IX. Scientific and technical cooperation and communication

This part could 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 (e.g. guidelines for laboratories handling pathogens and other samples of pandemic potential; a mechanism for the accreditation and audit of laboratories).

EU Comment:

As noted in the EU open-ended submission, promoting the voluntary and rapid sharing of scientific findings, surveillance and diagnostic data, research results and samples should be a main goal of the PA. Similarly, the PA should encourage the coordination of and support for research, development and innovation, including at regional level, related to diagnostic, therapeutic and preventative medical and non-medical countermeasures with the objective of accelerating their development and production.

The proposal to include in the PA a part dedicated to enhancing scientific and technical cooperation is to be supported. Technological cooperation also needs to be included and this should be reflected in the proposed heading (i.e.: to be changed to “Scientific, technological and technical cooperation and communication”). This part can also aim at strengthening the role of WHO as a convening and facilitating body in the area of scientific, technical and technological cooperation.

Part X. Health and pandemic literacy

This part could provide measures to foster health and science literacy, including addressing mis-information, dis-information and false or misleading information (infodemics).

EU Comments:

Preparing for, and responding to, public health threats with pandemic potential requires new or enhanced provisions aimed at addressing misinformation and disinformation. Health and science literacy is an important tool in this respect. More specifically, it will be important to:

- Commit to exchanging information and promoting good practices to increase the accuracy and reliability of crisis communication, based on robust and independent evaluation of public health risks. This should be done with a view to providing the public, public health decision makers and health care professionals with accurate, transparent and evidence-based information.
- Encourage meaningful and inclusive dialogue with civil society, frontline workers, vulnerable groups and other relevant stakeholders, to promote community involvement and engagement. This should incentivise and sustain positive behaviours and health practices aimed at reducing the impact of health emergencies and the spread of pathogens, leveraging community structures as appropriate.
- Commit to increasing health education and health literacy for pandemic preparedness and response, including through behavioural change communication, with a view to increasing the population understanding and the effectiveness of risk communication in public health.
- Develop effective tools to promptly identify and counteract misinformation and disinformation.

A more informed view on whether this should be kept as a separate Part can be taken once the content of Part V in particular has been clarified.

Part XI. Governance and review

This part could address: clarity on how to monitor and track Member State commitments, and accountability measures (6); establish a Member State mechanism to oversee implementation, review, compliance and dispute settlement (19); Member States must be obliged to present WHO with routine reports outlining their level of commitment to the proposed agreement.

EU Comments:

1) On the heading:

We consider that the notion of compliance is essential and we would therefore suggest to add it to the title of part XI.

2) Additional comments, based on the elements included in the EU open - ended submission:

When it comes to the institutional provisions of the PA, consideration should be given to establish a Conference of the Parties (COP) as the PA's governing body. In this perspective all States and relevant international and regional organisations should be allowed to participate in the COP as observers, even if not Parties to the PA, with a view to promoting their eventual accession to the PA. 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 PA.

The WHO should provide Secretariat support to the PA 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). Secretariat arrangements should be decided by the time of the adoption of the PA by the WHA to facilitate an early start of the implementation phase. Appropriate assessed financial means should be made available to cover Secretariat costs.

It would be advisable to establish a separate Part or a Section under Part XI to address the provision of **implementation support** as an ambitious PA 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 PA implementation support, including through:

- Strengthening WHO's mandate 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.
- Committing to support, technical assistance and capacity building for low and lower middle income countries[3] aimed at:
    - the effective implementation of PA 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 (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.[4] This

[3] As defined by the World Bank.

[4] This may provide an opportunity to streamline the participation of PA 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.

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 PA and requiring the prior acquisition of implementation capabilities through the provision of technical assistance and capacity building.

As indicated in the EU open-ended submission to the INB, monitoring and accountability mechanisms have a key role to play in promoting implementation and compliance of PA's provisions. These mechanisms should allow for an integrated approach across the PA and the IHR, while preventing duplications, inconsistencies and double burden. Care should be taken not to create undue administrative burden for PA Parties.

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)[5].

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.

As noted, the PA will include both compulsory and, most likely, also 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.

Part XII. Development of the instrument

This part could address matters such as amendments, guidelines, annexes, protocols.

EU Comments:

The PA should aim at laying down substantive provisions and commitments especially in the key areas indicated above, while also charting the course for future negotiations, including by means of supplementary protocols in areas which would likely require a preparation and negotiation period to achieve agreement beyond the 2024 deadline set for the PA. These could be open to

[5] 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 PA.

the participation of States that may not be party to the PA. While negotiated under the umbrella of the PA, each Protocol should be concluded as a self-standing international agreement. Each Protocol may incorporate by reference provisions of the PA to be applicable to Protocol Parties.

The PA should set out provisions facilitating the negotiation of specialised Protocols, including in terms of Secretariat assistance. Protocols may also be negotiated with the support of sector specific international organisations.

In keeping with the dynamic and flexible nature of the PA design, the PA Parties (or some among them) may decide to address additional issues through the setting out of non-binding instruments, such as guidelines, best practices, standards and indicators.

Part XIII. Final provisions

EU Comment:

The PA will need to include several procedural provisions related among others to: signature; ratification, acceptance, approval and accession; reservations; entry into force; amendments; withdrawal; depositary or authentic texts.