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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Public Health (General)
Subject:	Agreement on pandemic preparedness and response: an initial blueprint - Commission Services Reflection Paper

Delegations will find enclosed a reflection paper on an agreement on pandemic preparedness and response, as prepared by the Commission services.

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COMMISSION SERVICES REFLECTION PAPER

Agreement on pandemic preparedness and response: an initial blueprint

Multilateral cooperation is essential to fighting pandemics that by definition know no borders and require collective action. There is widespread recognition of the need to be better prepared globally for preventing and responding rapidly and effectively to future pandemics. There is, however, a debate about the merits of different possible cooperation instruments and whether they should be binding or not. Such an analysis depends on the subject matter of the cooperative efforts. The European Commission sees an important role for international law to play in improving preparedness for and response to future pandemics and combatting serious cross-border threats to health at national, regional and international level.

The COVID-19 crisis has laid bare several governance failures in the global health system that need to be remedied.[1] Setting stronger objectives for cooperation, behavioural standards and obligations for States, regional and international institutions is a tool that should not be overlooked, while recognising that it is not a complete solution. If undertaken in conjunction with domestic health system strengthening, it can provide a more robust international preparedness and response framework. Voluntary cooperation and political engagement remain necessary, but setting legal standards and

[1] The recent Commission communication on "Drawing the early lessons from the COVID-19 pandemic" (COM(2021) 380 final) provides an initial assessment of shortcomings the current crisis has exposed. This includes the limitations of the current surveillance and information-sharing systems, the uneven level of research and advice in different countries, the need to better combine public and private efforts to incentivise breakthrough research and innovation in the health and pharmaceutical sector, the systemic underfunding in preparedness and the need for surge funding and other mechanisms to allow swift support for the research, development, manufacturing and procurement of essential countermeasures, as well as the need to monitor and shape market priorities and capacities for essential health supplies at every stage, from research and development to production and supply.

compliance incentives and mechanisms is a crucial part of an effective multilateral cooperative response.

The Commission thus considers that it is important to set out an initial, possible outline for an international agreement with realistic prospects of rapid and effective implementation, but also bold in the objectives it seeks to achieve, both in the short and long run. This could facilitate convergence among the WHO membership and the decision to initiate the negotiation process at the November Special Session of the World Health Assembly. *The Commission looks forward to discussing and refining the ideas laid out in this reflection paper.*

The negotiation for an International Agreement on Pandemic Preparedness and Response (hereinafter Pandemic Agreement, PA)[2] should strike a balance between achieving concrete and rapid results in key areas, and charting the course for future work, including, but not limited to, supplementary Protocols in a number of highly complex areas of cooperation, which would require a longer negotiation time. An early harvest of useful and pragmatic commitments set out in the PA will increase the credibility of the initiative and help create momentum for further rule-making.

The need to set in motion a dynamic and flexible process of international cooperation among states and other stakeholders argues against prioritising an overall revision of the 2005 International Health Regulations (IHR), which is likely to require a protracted negotiation effort.[3] The PA should aim at promoting compliance with, but not amending the IHR. It should set out compatible,[4] complementary, clarifying provisions, including, when necessary, compliance incentives, and enhanced obligations that would be enforceable

[2] At this stage of the reflection, the generic term "international agreement" is preferred to refer to an instrument that is binding under international law, and to avoid dwelling on the name that the agreement signatories may ultimately chose.

[3] The IHR are an instrument of international law that is legally-binding on 196 countries, including the 194 WHO Member States. They provide an overarching legal framework that defines countries' rights and obligations in handling public health events and emergencies that have the potential to cross borders. The decade-long process leading to the 2005 IHR started in the 1990s as a result of the return of old epidemics such as cholera in certain parts of South America and the emergence of new infectious agents such as Ebola haemorrhagic fever. In 1995 the World Health Assembly adopted a resolution calling for the revision of the existing 1969 Regulations.

[4] The objective of compatibility is set out in Article 57.1 of the IHR. To the extent that some PA provisions could be deemed to modify the IHR, that would be permissible under IHR Article 57.2, as well as in general Article 41 of the Vienna Convention on the Law of Treaties (VCLT).

only among PA Parties.[5] However, in time the usefulness of such enhanced provisions could become widely accepted and lead to amendments and/or agreed interpretations of the IHR, as appropriate.

The PA should be able to deploy the cooperation tools that are best suited to achieve the desired results. Typically international agreements are made up of a mix of legally binding rules, hortatory provisions and other commitments. Similarly, the PA should include "hard law" provisions where necessary, but also resort to setting out "soft law" standards accompanied by compliance incentives, "best efforts" commitments backed by a general good faith obligation, as well as "political" commitments subject to reputational considerations. The dichotomy binding/non-binding should be set aside as both approaches can be complementary. The PA design[6] should be *dynamic* and encompass both binding and non-binding provisions (such as guidelines, standards and declarations), with the choice to be made by the negotiating parties with the objective of devising the most effective solution for each individual issue under negotiation.

In addition, a *flexible* and open participation model should be adopted. All States and regional economic organizations should able to become parties to the PA and/or any of the specialised Protocols to be negotiated under its umbrella. In addition, all UN member States should be allowed to participate as observers even if they are not contracting parties of the PA or any of its Protocols. Openness to non-governmental stakeholders' participation and contribution should also be a hallmark of the PA initiative. The possibility of provisional application of the PA and its Protocols should also be envisaged in light of the urgency of the issues at stake. Transitional periods for implementation by low and lower middle income countries should also be provided for.

The PA should be understood as an "international agreement" within the meaning of Article 2.1(a) of the Vienna Convention on the Law of Treaties. It

[5] The relations between the provisions of the PA and those of the IHR (which can also be characterised as an international agreement within the meaning of Article 2.1(a) of the VCLT) should be governed by Article 30.4.b of the VCLT, which states that "as between a State party to both treaties [any of the Parties to the PA, which is also a IHR State Party] and a State party to only one of the treaties [any IHR State Party], the treaty to which both States are parties [the IHR] governs their mutual rights and obligations." Nothing thus changes in the relations between the Parties to the PA and the other IHR State Parties. For them the PA is covered by the rule *pacta tertiis nec nocent nec prosunt*, as also reflected in Article 34 of the VCLT.

[6] The European Union is expected to participate fully as a regional economic integration organization.

could be adopted preferably pursuant to Article 19 of the WHO Constitution, in so far as the requirement to remain within the confines of the "competence of the Organization" is interpreted in a way that would allow for the possibility to make rules and undertake commitments in areas, which are necessary for combatting pandemics, for instance from the One Health perspective, but could be deemed beyond the WHO's remit (e.g. reinforcing the existing provisions related to trade in wild animals).

The PA object and purpose should be to set out substantive obligations for States and other related provisions aimed at three main, interrelated (and sometime overlapping) priorities:

1. Preventing and controlling,
2. Detecting and reporting, and
3. Preparing for and responding to pandemic threats.[7]

The definition of "pandemic threats" would be important to establish the scope of the agreement. A possible definition of threat could rely on guidelines defining events and situations, which can cause or threaten to cause a public health emergency of international concern with serious and lasting impact on the public health of the PA Parties.[8] Several provisions, especially in the areas of detection, reporting and response would become applicable as soon as a "public health emergency of international (transboundary) concern *with pandemic potential*" is declared.[9] The authority to do so could be vested in a group of experts established under the PA (and possibly chaired by the WHO Director General).[10]

The substantive obligations should to be framed by a series of general objectives and principles, such as the human right to health, international solidarity, One Health approach, the need to address the close links between human, animal and environmental health, and the global public good character of pandemic countermeasures (e.g. personal protective equipment, access to vaccination, therapeutics and diagnostics). These principles could be set out in

[7] Under each of these objectives many different obligations, commitments and other cooperative initiatives can be pursued. Many of these are outlined below in a non-exhaustive fashion.

[8] The assessment of such events would build on the experience made under the IHR.

[9] The declaration of a public health emergency of international concern with pandemic potential would not be subject to a prior declaration of a public health emergency of international concern under the IHR.

[10] The body needs to be shielded from political influences. It could be composed of international experts appointed in their independent expert capacity and may include the Heads of relevant UN bodies.

the Preamble of the PA and/or the introductory part of the PA. The PA would also need to include horizontal provisions setting out:

4. Institutional framework,
5. Rules on future rule-making,
6. Monitoring and accountability mechanisms, and
7. Financial support, technical assistance and capacity building.

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1. Preventing and controlling pandemic threats

This objective requires new or enhanced provisions aimed at:

a) Preventing and controlling zoonotic spill-overs through:

Enhanced surveillance/monitoring and notification systems, at the wildlife-livestock-human interface enabling timely flow of information between human health, animal health and environmental authorities.

Regulation of wild and live domestic animal markets and stricter surveillance and control of illicit wildlife traffic and wet markets.

Pathogen surveillance and identification of pathogens with a high zoonotic infection potential (including the setting up of an early warning and response system) in livestock, companion animals and high-risk wildlife populations.

Systematic exchange of information and data on pathogens, mutations and genetic sequencing at the animal-human interface.

Universally accessible sample collection capacities (repositories) and equitable pathogen sample sharing.

Increased 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.

b) Preventing inadvertent laboratory release of pathogens through:

Enhanced regulation and independent oversight of laboratory conditions and safety protocols to ensure biosecurity and biosafety.

c) Preventing epidemics due to pathogens resistant to antimicrobial agents (AMR) through:

Enhancing the provisions on surveillance and reporting.

Strengthening the knowledge, and evidence base through surveillance and research in both human and livestock populations.

Setting global targets on use of antimicrobials to protect human, animal and plant health, as well as related to indicators of release of antimicrobials in the environment.

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 and the One Health Global Leaders Group on AMR.

Committing to reduce inappropriate use of antimicrobials globally by applying antibiotic stewardship practices (e.g. no antibiotic without prescription, more systematic use of diagnostic tests prior to antibiotic prescription, restriction on the use of antimicrobials for growth promotion or prophylactic use in animal husbandry).

Making available incentives to promote the development of new antimicrobials, rapid diagnostic tests and alternatives to antimicrobials for human and animal use.

2. Detecting and reporting pandemic threats

This objective requires new or enhanced provisions aimed at:

Strengthening the obligations to identify and report health threats and share data and information on outbreaks, including with a view to enabling the rapid development of medical and non-medical countermeasures.

Enlarging the mandate of the WHO and the World Organisation for Animal Health (OIE) to investigate events and outbreaks independently (including the

authority to verify State reports, disseminate outbreak data, conduct in-country assessment and share available scientific data) committing to rapid information sharing.

3. Preparing for and responding to pandemic threats

Achieving this objective would require new or enhanced provisions aimed at:

a) enhancing tools for medical and non-medical countermeasures needed for responding to outbreaks that risk developing into pandemics, as well as

b) coordinating emergency responses.

a) Enhancing preparedness tools

Providing WHO and OIE with the necessary resources to field health emergency teams (and related resources), which can be deployed rapidly at national and regional level to identify and respond to health emergencies and support States parties when information of high-risk events become known to the WHO or the OIE.

Coordination of, and support to, research, development and innovation, including at regional level, including genomic sequencing capacities.

Development of protocols and recommendations for voluntary sharing of scientific findings, surveillance and diagnostic data, research results and samples.

Development of protocols and recommendations for non-pharmaceutical, non-medical interventions.

Considering the transformation of the "Access to COVID-19 Tools Accelerator" (ACT-A), on the basis of an in-depth review and evaluation, into a permanent multi-stakeholder platform for end-to-end emergency procurement and delivery for vaccines, diagnostics, therapeutics and other essential supplies.

Developing mutual recognition and/or equivalence protocols for emergency use and transport of vaccines, diagnostics, therapeutics and other essential medical products.

Enhancing the availability, accessibility and affordability of medical countermeasures, including by stockpiling relevant healthcare resources and providing incentives to increase regional manufacturing capacity for vaccines,

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therapeutics and diagnostics and other essential medical products, as well as personal protective equipment.[11] Identifying geographical gaps in the ability to deliver the above (e.g. manufacturing, distribution capacity) and tailor incentives.

Promoting the reduction of trade barriers, exercising restraint from export restrictions and introducing trade-facilitating measures on critical products to combat pandemic, including inputs used in the manufacturing, distribution and approval of vaccines therapeutics and medical devices, including diagnostics.

b) Coordination of emergency response measures

Enhanced coordination of containment measures, including travel and transport restrictions, quarantine, border controls and specific provisions for transport workers, including seafarers and other essential workers, with a view to also maintaining the integrity of supply chains, ensuring supplies of essential goods such as food and medical products.

Reinforcing WHO's mandate for coordination of emergency response and better equip WHO to discharge this role within the territories of the PA Parties, including through enhanced cooperation with other relevant UN agencies such as the International Labour Organization, International Maritime Organization and International Civil Aviation Organization.

4. Institutional aspects

The PA should establish a Conference of the Parties (COP), as its governing body. All UN Member States should be allowed to participate in the COP as observers even if not parties to the PA. The COP should also serve as the Meeting of the Parties (MOP) to any of the Protocols agreed under its umbrella. All UN Member 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-governmental stakeholders (e.g. NGOs, academia, private sector) should be allowed and encouraged,

[11] An important problem to also consider is the pollution that may result from emissions and waste deriving from the increased production of protective equipment.

especially with a view to promoting and facilitating the implementation of the PA.

The WHO should provide Secretariat support to the PA and its Protocols (different arrangement involving joint secretariat functions bringing together different international organisations could be envisaged in specific policy areas). Appropriate assessed financial means should be made available to cover Secretariat costs.

The scope of preventing and dealing with pandemic threats goes beyond the WHO's remit and requires strengthened cooperation across multiple policy areas and institutions. In particular, the PA should provide for the establishment of close cooperation with other relevant UN bodies and international institutions, which have an essential role in preventing pandemic risks, including, but not limited to:

- the Food and Agriculture Organization (FAO) and the OIE as the regards the risk of zoonoses potentially originating from livestock;
- the United Nations Environment Programme (UNEP) for human interaction with wildlife habitats
- UNESCO for the education role in pandemic prevention;
- IMO, ICAO and ILO for transport and labour;
- the OIE for a focus on animal welfare and health;
- the UN Framework Convention on Climate Change/Intergovernmental Panel on Climate Change for climate induced diseases;
- environmental treaties, such as the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and the Convention on Biological Diversity (CBD), which have a vital role in reducing the risk of zoonosis.

The PA should aim to rationalise the role and when necessary enhance the mandates of several relevant, existing expert and advisory bodies, such as the "One Health High-Level Expert Panel", including by subsuming them under the institutional structure of the PA or establishing institutional links with them. It should also establish new bodies only where a clear need exists and no duplication is created. This may be the case for the proposed Global Health Threats Council at Heads of State/Government level, which may be instrumental to provide the necessary leadership and implementation momentum.

5. Future rule-making

The PA design should strike a balance between negotiating and agreeing a set of provisions, which can be rapidly implemented and setting out a built-in negotiation agenda for the conclusion of specialised Protocols. These should be open also to 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. Specialised Protocols could also take the form of agreements under IHR Article 57.2.

The PA should set out provisions facilitating the negotiation of specialised Protocols, including in terms of secretariat and financial assistance. Protocols could 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, standards and indicators.

6. Monitoring and accountability mechanisms

Monitoring and accountability mechanisms have a key role to play in promoting implementation and compliance. These should include:

Expanding the mandate of national and regional focal points on preparedness and response to cover PA commitments (e.g. the national focal points for the IHR).

Establishing a periodic peer review, based on independent evaluation (and country visit) of State parties compliance with relevant international obligations (including the IHR and the PA) and other commitments,[12] aimed at:

a. assessing pandemic readiness and remediation needs,
b. designing improvement pathways based on objective and verifiable benchmarks and best practice (to be prepared by WHO

[12] This should include international obligations binding on the PA Parties, as well as other commitments against which the PA Parties would agree to be reviewed (examples could be the AMR Global Action Plan and the One-Health National Action Plans).

and other relevant organisations, including non-governmental stakeholders),

c. backed by assistance (including financial) and capacity building support.

Establishing an oversight authority, comprised of independent experts, to which national and regional authorities would report on regulatory actions and policy improvements and mandated to carry out verification and inspection missions.

As noted the PA should include both binding and non-binding 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 should be provided for. Infringement of an identified set of key obligations by a PA Party could be sanctioned with the denial of benefits by the other PA Parties.

7. Provision of financial support, technical assistance and capacity building

An ambitious PA design requires a significant investment in implementation support. This should include:

Strengthening WHO's mandate and ability to support national and regional core health system capacities for pandemic prevention, preparedness, detection and response.

Committing to financial support, technical assistance and capacity building for low and lower middle income countries 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 preparedness and response, including by increasing health workforce capabilities to prevent, detect and respond to public health emergencies with pandemic potential, as well as developing and deploying digital health tools.

Committing to specific assistance initiatives for upper middle income countries in need.

Streamlining the existing mechanisms created to finance and implement outbreak preparedness, such as the WHO's Contingency Funds for Emergencies, the World Bank's Pandemic Emergency Facility and relevant public/private initiatives like CEPI, GAVI Alliance, etc.

Seeking to build a (non-binding) cooperative framework across major donors (e.g. international financial institutions and multilateral development banks, G20 initiatives, bilateral donors, philanthropies) and the private sector, and possibly establish an international pandemic financing facility to support both long-term (e.g. local research, development and production of medical and non-medical countermeasures) and emergency interventions.

Determine the provisions, which low and lower middle income countries can implement after a transition period stipulated in the PA and requiring the acquisition of implementation capacity through the provision and assistance of capacity building.

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