



Council of the
European Union

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NOTE

From: General Secretariat of the Council

To: Council

Subject: ANNEX to the Recommendation for a COUNCIL DECISION authorising the opening of negotiations on behalf of the European Union for the conclusion of an international agreement on pandemic prevention, preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005)

DIRECTIVES FOR THE NEGOTIATION OF AN INTERNATIONAL AGREEMENT ON PANDEMIC PREVENTION, PREPAREDNESS AND RESPONSE AS WELL AS FOR THE NEGOTIATION OF COMPLEMENTARY AMENDMENTS TO THE INTERNATIONAL HEALTH REGULATIONS (2005)

1. Within the framework of the intergovernmental process set out in Decision SSA2(5) adopted by the Special session of the World Health Assembly (WHA) of 1 December 2021, which provides a globally inclusive negotiating forum, the Commission, alongside Member States, will aim at negotiating an international agreement on pandemic prevention, preparedness and response¹ (hereinafter “Pandemic Agreement”).
2. Within the framework set out in Decision EB150(3) adopted by the Executive Board of the World Health Organization (WHO) on 26 January 2022, the Commission, alongside Member States, will aim in addition at negotiating complementary amendments to the International Health Regulations (2005) (IHR).
3. The Commission, on behalf of the European Union for matters falling within Union competence, as defined by the Treaties, shall endeavour to achieve a comprehensive negotiated outcome, which encompasses the objectives and principles outlined below, drawing on the lessons learnt during the COVID-19 pandemic, and in view of preparedness for possible public health emergencies in the future.

¹ This designation denotes an agreement within the meaning of Article 2.1(a) of the Vienna Convention on the Law of Treaties and is without prejudice of the name that the agreement signatories will ultimately chose, e.g. convention, treaty or agreement.

4. As the exact scope of the envisaged international agreement is not yet known, the Council may revise and further develop these directives, as appropriate, in particular to address any issue not specifically covered therein, including, but not limited to, financing or any other envisaged provisions that may have an impact on Union competences other than the protection and improvement of human health, such as environment, trade, free movement, data protection, internal market and development cooperation.
5. The Pandemic Agreement, which should complement the International Health Regulations (2005) (hereafter referred as IHR), will set out substantive, legally-binding obligations for its Parties aimed primarily at:
 - preventing and controlling;
 - detecting and reporting; and
 - preparing for, and responding to public health threats with pandemic potential.
6. The substantive obligations should be framed, including in the Pandemic Agreement's preamble, by a series of general objectives and principles, such as the right to enjoyment of the highest attainable standard of health, international solidarity, equitable access to medical countermeasures (e.g. personal protective equipment, access to vaccination, therapeutics and diagnostics, health and social services as well as medical care), the timely sharing of data and information, including for facilitating research and enabling the public to avail, use and understand verified and timely information, the "One Health" approach, the need to address the close links between human, animal and environmental health, the links between health and human rights, including sexual and reproductive health and rights as per the new European Consensus on Development, and the centrality of WHO and role of multilateral cooperation in the global health governance. The principle of equity should guide the work, including through disability-sensitive and gender-responsive approaches.

7. The Pandemic Agreement should also include provisions setting out:
- the institutional framework;
 - rules on further rule-making, if necessary;
 - monitoring, compliance and accountability mechanisms;
 - country commitment and ownership as well as “whole of government”/cross sectorial 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; and
 - technical assistance and capacity building for implementation, including financial mechanisms that take into account all resources.

8. In particular, an effective Pandemic Agreement will require significant investment in implementation support. This should include:
- Strengthening WHO’s ability to support national and regional core health system capacities for pandemic prevention, preparedness, detection and response;
 - Strong technical assistance and capacity building for low and lower middle income countries aimed at:
 - the effective implementation of Pandemic Agreement 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); and
 - the improvement of the health systems capabilities in the area of pandemic preparedness and response, including to ensure continuity of essential health services during public health emergencies, by increasing health and social services workforce capabilities and to ensure integrated, interdisciplinary surveillance to prevent, detect and respond to public health emergencies with pandemic potential, by developing and deploying digital health and social care tools.
9. The Pandemic Agreement should also address antimicrobial resistance, in a “One health” approach.

10. The Pandemic Agreement 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. Legally binding provisions may be complemented by non-binding provisions (such as guidelines, standards and declarations).
11. All United Nations Member States and regional (economic) integration organisations to which its Member States have transferred competences over matters related to the provisions of the agreement should be allowed to become parties of the Pandemic Agreement or any of its protocols. Specific arrangements for cooperation with relevant international organisations and non-governmental stakeholders should also be set out.
12. Transitional periods for implementation and related implementation support should also be considered, with particular attention to the needs of low and lower-middle income countries.
13. The objectives of pandemic preparedness and response pursued through the Pandemic Agreement may require complementary amendments to the IHR. Any possible complementary amendments to the IHR should aim at clarifying and strengthening existing IHR provisions and increasing their effective implementation, while ensuring complementarity, coherence and compatibility between such amendments and the provisions of the Pandemic Agreement.

14. In particular, complementary amendments to the IHR should seek to: a) achieve a more effective implementation and monitoring of the IHR at national and regional level; b) strengthen compliance mechanisms; c) improve early detection, as well as the sharing of information, analysis and samples in case of outbreaks; d) promote the adoption of more rapid response measures; e) increase the transparency and effectiveness in decision-making of bodies under the IHR, including by complementing or reforming existing bodies; f) promote the use of new digital tools that may improve the implementation of the IHR; and g) facilitate the process of further amending the IHR to address changing needs.
 15. The Commission will represent the Union, for matters falling within Union competences, in the inter-governmental negotiating body in charge of developing a Pandemic Agreement, as set out in the WHA Decision SSA2(5), and any preparatory or related body, as well as in the framework set out in decision EB150(3) to negotiate complementary amendments to strengthen the IHR.
 16. The Commission should endeavour to ensure that the Pandemic Agreement and any possible complementary amendments to the IHR are consistent with relevant Union legislation and policies, as well as the Union's commitments under other relevant multilateral agreements.
 17. The Commission should conduct negotiations in accordance with relevant Union legislation in force, including the EU legal framework on cross-border health threats.
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