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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	6 December 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 766 final/2 - ANNEX
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 preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005)

Delegations will find attached document COM(2021) 766 final/2 - ANNEX.

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ANNEX

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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 preparedness and response as well as for the negotiations of complementary amendments to the International Health Regulations (2005)

ANNEX

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

Within the framework of the intergovernmental process set out in the Decision SSA2/CONF./1Rev.1 of the Special session of the World Health Assembly (WHA) of 29 November to 1 December 2021, which provides a globally inclusive negotiating forum, the Commission will aim at negotiating an international agreement on pandemic preparedness and response[1] (hereinafter "Pandemic Agreement"). The Commission, on behalf of the European Union, 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.

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 pandemic threats.

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 pandemic countermeasures (e.g. personal protective equipment, access to vaccination, therapeutics and diagnostics, medical and social care services), "One Health" approach, the need to address the close links between human, animal and environmental health, and the centrality of multilateral cooperation and the WHO in the global health governance.

The Pandemic Agreement should also include provisions setting out:

– the institutional framework;

– rules on further rule-making;

– monitoring and accountability mechanisms;

– "whole of government"/cross sectorial preparedness approaches leading to better mobilisation of all competencies and resources and coherence in pandemic prevention and response; and

– technical assistance and capacity building for implementation.

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:

[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.

- 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 by increasing health and social care workforce capabilities to prevent, detect and respond to public health emergencies with pandemic potential, as well as developing and deploying digital health and social care tools.

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).

All United Nations Member States and regional (economic) integration organisations 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.

In the light of the urgency of the subject matter of the Pandemic Agreement, the possibility of its provisional application, pending ratifications, should be envisaged so as to initiate implementation of the Pandemic Agreement's provisions as early as possible.

Transitional periods for implementation by low and lower middle-income countries and related implementation support should also be provided for.

The objectives of pandemic preparedness and response pursued thorough the Pandemic Agreement may require complementary amendments to the IHR. Such amendments should aim at clarifying and strengthening existing IHR provisions and increasing their effective implementation, while ensuring complementarity and compatibility between such amendments and the provisions of the Pandemic Agreement.

The Commission will represent the Union in the inter-governmental negotiating body in charge of developing a Pandemic Agreement, as set out in the WHA Decision SSA2/CONF./1Rev.1, and any preparatory or related body, as well as in the work of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies related to the development of IHR complementary amendments to strengthen the IHR, and their subsequent negotiation.

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.

The Commission should conduct negotiations in accordance with relevant Union legislation in force.