



Council of the
European Union

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LIMITE

SAN 14
PHARM 4
COVID-19 3
PROCIV 3

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	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)

With a view to the meeting of the Working Party on Public Health that will take place on 18 January, delegations will find attached a draft text as prepared by the Presidency.

Changes compared to document 14710/21 are marked in **bold underline** and deletions in ~~strikethrough~~.

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)]

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty in the Functioning of the European Union, and in particular **Article 168(5), in conjunction,** Article 218(3) and (4) thereof,

Having regard to the recommendation from the European Commission,

Whereas:

- (1) The **Seventy-fourth World Health Assembly called for a** special session of the World Health Assembly of 29 November to 1 December 2021 was called by the World Health Organization (WHO) **in its** Decision WHA74(16) of 31 May 2021 to consider the benefits of developing a WHO convention, agreement or other international instrument on pandemic preparedness and response with a view towards the establishment of an intergovernmental process to draft and negotiate such a convention, agreement or other international instrument on pandemic preparedness and response^{1,2};

¹ **Decision WHA74(16) of 31 May 2021**

- (2) The special session of the World Health Assembly that took place on 29 November to 1 December 2021 decided to establish an intergovernmental negotiating body (the “INB”) open to all Member States and regional economic integration organization, as appropriate, to draft and negotiate a WHO convention, agreement or other international instrument on pandemic preparedness and response²;**
- (23) The Union, should participate in the negotiations on such convention, agreement or other international instrument, [as well as on complementary amendments to the International Health Regulations (2005) (IHR),] for matters falling within Union competence, as defined by the Treaties;**
- (4) In the area of the protection and improvement of human health, including as regards the fight against major global health scourges, Union action shall complement national policies;**
- (5) In accordance with Article 168(7) TFEU, the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care, should be fully respected throughout the negotiating process;**
- (6) This Decision is without prejudice to the division of competences between the Union and its Member States and to the participation of Member States to the negotiations as defined by the Treaties;**
- (7) The negotiating directives annexed to this decision should be revised and further developed as appropriate depending on the evolution of the negotiations;**
- (38) The negotiations will take place in the context of the WHO;**

² **Document SSA2(5) of 1 December 2021**

HAS ADOPTED THIS DECISION:

Article 1

The Commission is hereby authorised to negotiate on behalf of the Union, **for matters falling within Union competence, as defined by the Treaties** an international agreement on pandemic preparedness and response, [as well as complementary amendments to the IHR] within the framework of the decisions taken during the special session of the World Health Assembly of 29 November to 1 December 2021.

Article 2

The negotiating directives are set out in the Annex.

Article 3

The negotiations shall be conducted in **close** consultation with the ~~[name of the special committee to be inserted by the Council]~~ **Working Party on Public Health which is hereby designated as the special committee within the meaning of article 218(4) TFEU. In this view, the Commission shall regularly report back to the special committee and consult it on a regular basis. Whenever requested by the Council, the Commission shall report to the Council on the conduct and the outcome of the negotiations, including in writing.**

Article 4

This Decision is addressed to the Commission.

Done at Brussels, 1.12.2021

*For the Council
The President*
