



Council of the
European Union

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PROCIV 11

LEGISLATIVE ACTS AND OTHER INSTRUMENTS

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

COUNCIL DECISION (EU) 2022/...

of ...

**authorising the opening of negotiations on behalf of the European Union for
an international agreement on pandemic prevention, preparedness and response,
as well as complementary amendments to the International Health Regulations (2005)**

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the recommendation from the European Commission,

Whereas:

- (1) On 31 May 2021, by means of its decision WHA74(16), the 74th World Health Assembly (WHA) called for a special session to be convened in order to consider the benefits of developing a World Health Organization (WHO) convention, agreement or other international instrument on pandemic preparedness and response, with a view to establishing an intergovernmental process to draft and negotiate such a convention, agreement or instrument.
- (2) On 1 December 2021, by means of its decision SSA2(5), the second special session of the WHA decided to establish an intergovernmental negotiating body, open to all WHO Member States, Associate Members and regional economic integration organisations, to draft and negotiate a WHO convention, agreement or other international instrument on pandemic prevention, preparedness and response, with a view to adoption under Article 19, or under other provisions of the WHO Constitution as may be deemed appropriate by the intergovernmental negotiating body.
- (3) On 20 January 2022 the Director-General of the WHO communicated to the State Parties the text of a proposal for the amendment of the International Health Regulations (2005) (IHR) proposed by the United States of America pursuant to Article 55(1) of the IHR.
- (4) The 150th session of the Executive Board of the WHA, which took place from 24 to 29 January 2022, decided to urge WHO Member States and, where applicable, regional economic integration organisations to take all appropriate measures to consider potential amendments to the IHR.

- (5) The Union, for matters falling within its competence, should participate, alongside its Member States, for matters falling within their competence, in the negotiations for a convention, agreement or other international instrument on pandemic prevention, preparedness and response, as well as complementary amendments to the IHR, as provided for by the Treaty on European Union and the Treaty on the Functioning of the European Union (TFEU).
- (6) In accordance with Article 6 and Article 168(5) TFEU, in the area of the protection and improvement of human health, including as regards the fight against major cross-border health scourges as well as monitoring, early warning of and combating serious cross-border threats to health, Union action should support, coordinate or supplement the actions of the Member States.
- (7) 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, including the management of health services and medical care and the allocation of the resources assigned to them, should be fully respected throughout the negotiating process.
- (8) This Decision is without prejudice to the division of competences between the Union and its Member States or to the participation of Member States in the negotiations in accordance with the Treaties.
- (9) In accordance with the principle of sincere cooperation, the Commission and the Member States should cooperate closely during the negotiation process, including through regular contacts with the Member States' technical experts and representatives in Geneva.

- (10) To this effect, practical arrangements which will apply in the conduct of the negotiations should be defined as soon as possible, in particular with a view to ensuring effective cooperation between the Union negotiator and the Member States, without prejudice to the role of the special committee within the meaning of Article 218(4) TFEU.
- (11) The Council should revise and further develop the negotiating directives laid down in the addendum to this Decision as appropriate depending on the evolution of the negotiations.
- (12) The negotiations will take place in the context of the WHO,

HAS ADOPTED THIS DECISION:

Article 1

1. The Commission is hereby authorised to negotiate on behalf of the Union, for matters falling within Union competence, in accordance with the Treaties, an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the IHR, within the framework of WHA decision SSA2(5) of 1 December 2021 and of WHO Executive Board decision EB150(3) of 26 January 2022 respectively.
2. The negotiations shall be conducted on the basis of the negotiating directives set out in the addendum⁺ to this Decision. Those directives shall be revised and further developed as appropriate depending on the evolution of the negotiations.

Article 2

1. The negotiations shall be conducted in close consultation with the Working Party on Public Health, which is hereby designated as the special committee within the meaning of Article 218(4) TFEU.
2. The Commission shall report to and consult the special committee 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.

⁺ See document ST 6133/22 ADD 1 at <http://register.consilium.europa.eu>

Article 3

This Decision is addressed to the Commission.

Done at ...

For the Council

The President
