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**NOTE**

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From: General Secretariat of the Council  
To: Council

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Subject: Negotiations for an international agreement on pandemic prevention,  
preparedness and response, as well as complementary amendments to  
the International Health Regulations (2005)  
*- Information from the Presidency and the Commission*

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Delegations will find in [Annex](#) an information note from the Presidency and the Commission on the above mentioned subject to be raised under “Any other business” at the meeting of the EPSCO Council (Health) on 9 December 2022.

**Information from the Presidency and the Commission on the negotiations for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005)**

**Background**

The European Union has been a major actor in the global COVID-19 response from the very beginning, and has cooperated closely with the World Health Organization (WHO), the leading multilateral organisation in the field of health.

The EU and its Member States have led international efforts in setting out the process for the negotiation of an international agreement on pandemic prevention, preparedness and response, which was initiated at the special session of the World Health Assembly (WHA) in November 2021, and for the negotiation of complementary amendments to the International Health Regulations (IHR 2005).

In line with several sets of European Council conclusions calling for a comprehensive global response to the pandemic<sup>1</sup> and Council conclusions on strengthening the European Health Union<sup>2</sup>, the EU and its Member States continue to play an active role in the negotiation process.

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<sup>1</sup> Conclusions adopted by the European Council at its meetings on 24 and 25 June 2021 and on 24 and 25 March 2022.

<sup>2</sup> [EUR-Lex - 52021XG1220\(01\) - EN - EUR-Lex \(europa.eu\)](#)

Bearing in mind the prominent role of the European Union in the global health architecture, the Council authorized on 3 March 2022 the opening of negotiations on behalf of the EU for an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the IHR (2005). In accordance with the text of the Council Decision<sup>3</sup>, the Commission and the Member States should cooperate closely during the negotiation process. To that end, the Working Party on Public Health has been designated the special committee in accordance with Article 218(4) of the Treaty on the Functioning of the European Union (TFEU) and practical arrangements<sup>4</sup> have been agreed.

### **Negotiations for an international agreement on pandemic prevention, preparedness and response**

The first meeting of the Intergovernmental Negotiating Body (INB) was held on 24 February 2022 and two resumed sessions took place on 14 and 15 March 2022 and from 6 to 8 July 2022. Based on the INB outcomes, the WHO Member States were invited to provide suggestions, ideas and thoughts on substantive elements for a convention, agreement or other international instrument on pandemic prevention, preparedness and response. The EU contribution was prepared and duly submitted<sup>5</sup>.

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<sup>3</sup> Council Decision of 3 March 2022 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).

<sup>4</sup> Practical arrangements for the participation of the European Union and its Member States in the negotiation of an international agreement on pandemic prevention, preparedness and response, as well as of complementary amendments to the International Health Regulations (2005).

<sup>5</sup> [https://www.eeas.europa.eu/delegations/un-geneva/european-union-contribution-identification-substantive-elements-convention\\_en?s=62](https://www.eeas.europa.eu/delegations/un-geneva/european-union-contribution-identification-substantive-elements-convention_en?s=62)

At its second meeting, held from 18 to 21 July 2022, the INB made a significant step forward by consensually agreeing that the instrument should be legally binding and that it should contain both legally binding and non-legally-binding elements. In that regard, mindful that the decision will be taken by the WHA, the INB indicated that Article 19 of the WHO Constitution is the comprehensive provision under which the instrument should be adopted, without prejudice to also considering, as work progresses, the suitability of Article 21. The INB also discussed for the first time a working draft prepared by its bureau. Overall, the majority of WHO members welcomed the document as a significant step forward and a good basis for further discussion. In their address to the INB, the EU and its Member States advocated a strong and ambitious universal instrument, which must complement and not overlap with the IHR (2005), and subsequently submitted written comments on the working draft on 15 September 2022.

On 14 November, the INB bureau released the conceptual zero draft, based on submissions provided by relevant stakeholders, including the EU and its Member States, with the aim of discussing it during the third meeting of the INB. While noting that the conceptual zero draft is a good step forward, the EU and its Member States consider that the document is still not mature enough to be used as a basis for the formal negotiations.

### **Amendments to the International Health Regulations (2005)**

On 21 January 2022, the United States of America proposed a set of amendments to the IHR (2005) in accordance with Article 55, subparagraph 1, of the IHR (2005), with a view to their possible adoption at the seventy-fifth session of the WHA in May 2022<sup>6</sup>. On the basis of that proposal, which was supported by the European Union<sup>7</sup>, the WHA adopted amendments to Article 59 of the IHR on the entry into force and period for rejection or reservations.

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<sup>6</sup> [Strengthening WHO preparedness for and response to health emergencies - Proposal for amendments to the International Health Regulations \(2005\)](#)

<sup>7</sup> Council Decision of 20 May 2022 on the position to be adopted on behalf of the European Union in the seventy-fifth session of the World Health Assembly as regards certain amendments to the International Health Regulations (2005).

In line with decision WHA75(9), adopted at the same WHA session, IHR States Parties were invited to submit their proposed amendments to the IHR (2005) by 30 September 2022, and a Review Committee on the IHR (2005) has been convened by the WHO Director-General to make technical recommendations on the proposed amendments with a view to informing the work of the Working Group on Amendments to the International Health Regulations (2005) (WGIHR). The report of the IHR Review Committee is to be submitted no later than 15 January 2023.

Based on a comprehensive coordination process with technical meetings in Geneva, the EU and its Member States prepared a set of proposals for amendments to Articles 3, 6, 7, 11, 12, 15, 23, 35, 36, 43, 44, 48, 49 and new 54 bis of and Annex 1(4) and Annex 6 to the IHR. On 30 September the Czech Republic, which currently holds the Presidency of the Council of the European Union and is a State Party to the International Health Regulations (2005), submitted the proposed amendments to the WHO on its own behalf, as well as on behalf of the Member States of the European Union and in coordination with the European Union. Explanatory notes on the proposed amendments were sent to the WHO on 26 October.

During the opening session of the IHR Review Committee which took place on 27 October 2022, the EU and its Member States summarised the proposed amendments and explained the rationale behind them. The first procedural meeting of the WGIHR was held on 14 and 15 November 2022. The WGIHR elected its bureau<sup>8</sup> and discussed its proposed methods of work, in particular the necessary coordination of the WGIHR's work with the work of the INB.

### **Special committee meetings under the Czech Presidency**

The Presidency organised four meetings of the Working Party on Public Health in its capacity as special committee within the meaning of Article 218(4) TFEU.

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<sup>8</sup> Dr Abdullah Asiri of Saudi Arabia and Dr Ashley Bloomfield of New Zealand were elected as co-chairs, with the following vice-chairs: Dr Sultani Matendehero of Kenya, Mr Colin McIff of the United States, Ambassador François Rivasseau of France, and Ambassador Grata Endah Werdaningtyas of Indonesia.

The first special committee meeting was held on 7 July 2022 and focused on the preparations for the second INB meeting, including a preliminary consideration of the working draft of the pandemic agreement prepared by the INB bureau and discussion of the provision of the WHO Constitution under which the instrument should be adopted. An exchange of views on the implementation of the practical arrangements was also held.

The second special committee meeting was convened on 6 October 2022 to discuss, amongst other things, the process for submitting IHR (2005) amendments. A first exchange of views on the practical division of tasks in the context of the negotiations was also organised.

The third special committee meeting under the Czech Presidency took place on 27 October 2022 and several issues were discussed, including a proposal to amend Article 64 of the IHR (2005), the practical division of tasks in the context of the negotiations on IHR (2005), and the setting of priorities for the pandemic agreement.

The fourth special committee meeting, on 24 November, focused on the preparations for the third INB meeting.