



Brussels, 15 May 2025  
(OR. en)

8781/25

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**Interinstitutional File:**  
**2024/0299 (NLE)**

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**SAN 204**  
**PHARM 63**  
**COVID-19 10**  
**PROCIV 48**

#### 'I/A' ITEM NOTE

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From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Council Decision inviting Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024 - Adoption

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1. WHO Members agreed through a decision adopted at the Seventy-fifth World Health Assembly<sup>1</sup>, to set a process for the negotiations of targeted amendments to the International Health Regulations (2005).
2. Based on an authorisation from the Council set out in Council Decision (EU) 2022/451 of 3 March 2022<sup>2</sup>, the Commission negotiated the amendments to the International Health Regulations (2005) on behalf of the European Union, for matters falling within Union competence. The Commission, as the Union negotiator, was guided by the negotiating directives annexed to the Decision, laying down the main objectives and principles to be achieved. Pursuant to Decision (EU) 2022/451, the Working Party on Public Health of the Council has served as the special committee within the meaning of Article 218(4) of the Treaty on the Functioning of the European Union (TFEU).

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<sup>1</sup> [WHA75\(9\) - Strengthening WHO preparedness for and response to health emergencies.](#)

<sup>2</sup> OJ L 92, 21.3.2022, p. 1.

3. The World Health Assembly adopted the amendments to the International Health Regulations (2005) by consensus on 1 June 2024 through its Resolution WHA77.17<sup>3</sup>. The amendments contribute to strengthening global preparedness, surveillance and response to public health emergencies and address lessons learned from the COVID-19 pandemic, two fundamental priorities of EU action in the field of global health.
4. Consent to be bound by WHO regulations is subject to a simplified procedure based on tacit acceptance<sup>4</sup>. Any WHO Member is to be bound by a WHO regulation, provided that it does not notify to the Director General of the WHO a rejection or reservation to the said regulation, or amendment thereto, within the time frame notified by the Director General for that purpose.
5. The amendments to the International Health Regulations (2005) were notified by the WHO Director-General to all States Parties on 19 September 2024. Consequently, and in accordance with the Article 59 of the IHR (2005), the amendments shall enter into force on 19 September 2025 for all States Parties to the IHR (2005) to which the 2022 amendments apply and on 19 September 2026 for the four States Parties to which the 2022 amendments do not apply<sup>5</sup>.
6. While the International Health Regulations (2005) do not allow the Union to become a party, all EU Member States are State Parties to the International Health Regulations (2005).
7. On 13 November 2024, the Commission submitted to the Council a proposal for a Council Decision authorising Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024 (15621/24+ADD 1).
8. Members of the Working Party on Public Health examined the proposal at the informal videoconference on 22 November 2024 and at the Working Party on Public Health meeting on 11 December 2024. The Presidency compromise resulting from this meeting is set out in document 16880/24.

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<sup>3</sup> [WHA77.17 - Strengthening preparedness for and response to public health emergencies through targeted amendments to the International Health Regulations \(2005\).](#)

<sup>4</sup> Article 22 of the Constitution of the WHO.

<sup>5</sup> Slovakia, the Netherlands, Iran and New Zealand.

9. On 27 January 2025, the Council reached an agreement in principle on the draft decision, as set out in document 17046/24 + ADD1.
10. Pursuant to Article 218(6)(a) TFEU, the proposed Council Decision requires for its adoption the consent of the European Parliament.
11. The consent of the European parliament is a precondition for the adoption of the Decision. The European Parliament gave its consent on 6 May 2025 (P10\_TA(2025)0073).
12. In view of the above, and subject to confirmation by the Permanent Representatives' Committee, the Council is invited to:
  - adopt the decision inviting Member States to accept, in the interest of the European Union, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024, as set out in document 17046/24 + ADD1 + ADD1 COR1, which constitutes the version of the draft Council Decision as finalised by the legal/linguistic experts.