



Brussels, 14 November 2024
(OR. en)

15621/24

Interinstitutional File:
2024/0299(NLE)

SAN 652
PHARM 155
COVID-19 20
PROCIV 92

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	13 November 2024
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2024) 541 final
Subject:	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

Delegations will find attached document COM(2024) 541 final.

Encl.: COM(2024) 541 final



EUROPEAN
COMMISSION

Brussels, 13.11.2024
COM(2024) 541 final

2024/0299 (NLE)

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

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **The International Health Regulations (2005) and the process for the negotiations of amendments**

The International Health Regulations (2005) are an instrument of international law, adopted pursuant to Article 21 of the Constitution of the World Health Organization (WHO) in 2005, replacing the Regulations adopted in 1969. They entered into force in 2007. They are legally-binding on 196 countries, including the 194 WHO Member States, as well as the Holy See and Liechtenstein. The Regulations, to which all EU Member States are Parties, provide an overarching legal framework in the field of global health security and define the Parties' rights and obligations in handling public health events and emergencies that have a cross-border potential.

In January 2022, in light of the lessons learned from the COVID-19 pandemic, the Executive Board of WHO, through its decision EB 150(3)¹, urged WHO Member States and, where applicable, regional economic integration organisations (essentially the European Union), to take all appropriate measures to consider potential amendments to the International Health Regulations (2005) to strengthen the global preparedness and response capacity to public health emergencies. The decision of the Executive Board further specified that *“such amendments should be limited in scope and address specific and clearly identified issues, challenges – including equity, technological or other developments – or gaps that could not effectively be addressed otherwise but are critical to supporting effective implementation and compliance of the International Health Regulations (2005) and their universal application for the protection of all people of the world from the international spread of disease in an equitable manner”*.

Following the Executive Board's decision, WHO Member States agreed through a decision adopted at the Seventy-fifth World Health Assembly², to set a process for the negotiations of targeted amendments to the International Health Regulations (2005). To this end, they established the Working Group on Amendments to the International Health Regulations (WGIHR), with the task of working *“exclusively on consideration of proposed targeted amendments to the International Health Regulations (2005), consistent with decision EB150(3) (2022) for consideration by the Seventy-seventh World Health Assembly in 2024”*.

Sixteen WHO Member States, including four on behalf of regional groups³, submitted their proposed amendments by the deadline of 30 September 2022, as set out in the Decision of the World Health Assembly. The submissions included more than 300 amendments – covering 33 of the 66 articles of the International Health Regulations (2005), and five of its nine annexes – and proposed to introduce six new articles and two new annexes⁴.

¹ [EB150\(3\) - Strengthening the International Health Regulations \(2005\): a process for their revision through potential amendment.](#)

² [WHA75\(9\) - Strengthening WHO preparedness for and response to health emergencies.](#)

³ Armenia, Bangladesh, Czech Republic on behalf of the Member States of the European Union, Eswatini on behalf of the Member States of the WHO African Region, India, Indonesia, Japan, Malaysia, Namibia, New Zealand, Republic of Korea, Russian Federation on behalf of the Member States of the Eurasian Economic Union, Switzerland, United States of America, Uruguay on behalf of the Member States of the Southern Common Market (MERCOSUR).

⁴ [Proposed Amendments to the International Health Regulations \(2005\) submitted in accordance with decision WHA75\(9\) \(2022\).](#)

The WGIHR started its work on 14 November 2022 and concluded it on 24 May 2024. The outcome of the WGIHR negotiations⁵ was submitted to the Seventy-seventh World Health Assembly for its consideration. Negotiations on several outstanding issues continued during the week of the World Health Assembly and the Assembly adopted the amendments to the International Health Regulations (2005) by consensus on 1 June 2024 through its Resolution WHA77.17⁶.

The Commission negotiated the amendments to the International Health Regulations (2005) on behalf of the European Union, for matters falling within Union competence, based on an authorisation from the Council of the European Union set out in Council Decision (EU) 2022/451 of 3 March 2022⁷. 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 Group 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) and the Commission has cooperated closely with Member States' experts and representatives through regular coordination meetings in Geneva.

On 31 May 2024, before the adoption of the amendments at the Seventy-seventh World Health Assembly, the Special Committee received a written communication⁸ from the Commission, as the Union Negotiator, whereby the Commission informed Member States that the adoption of the amendments to the International Health Regulations (2005) was foreseen to take place on 1 June 2024, pending finalisation of a few outstanding issues, and that its expectation was that the final outcome of the negotiations would be in line with the negotiating directives. Right before adoption by the World Health Assembly, an on-the-spot meeting was held in Geneva with EU Member States, where the Commission confirmed its assessment on the final outcomes of the negotiations.

In parallel to the negotiations of the amendments to the International Health Regulations (2005), WHO Member States have been negotiating a new international agreement on pandemic prevention, preparedness and response (hereafter “the Pandemic Agreement”). The objective is to establish through the two instruments a coherent international framework dealing with the whole spectrum of public health emergencies. At the Seventy-seventh World Health Assembly, on 1 June 2024, WHO Member States agreed that more time was needed to finalise the negotiations on the Pandemic Agreement. They decided to extend the mandate of the Intergovernmental Negotiating Body, in charge of the negotiations and of the drafting of the agreement, with the goal of concluding its work by the Seventy-eighth World Health Assembly in 2025, or earlier if possible, in which case a special session of the World Health Assembly would be convened in 2024.

- **Reasons and objectives of the proposal**

The amendments to the International Health Regulations (2005) adopted through Resolution WHA77.17 contribute to strengthening global preparedness, surveillance and response to public health emergencies and address lessons learned from the COVID-19 pandemic, two

⁵ [A77/9 – Working Group on Amendments to the International Health Regulations \(2005\) – Report by the Director-General.](#)

⁶ [WHA77.17 - Strengthening preparedness for and response to public health emergencies through targeted amendments to the International Health Regulations \(2005\).](#)

⁷ OJ L 92, 21.3.2022, p. 1.

⁸ Council Document WK 7838/2024 INIT

fundamental priorities of EU action in the field of global health⁹. The implementation of the amendments is therefore clearly in the interest of the Union. The current mpox outbreak, with the declaration on 14 August 2024 by the WHO Director-General of a public health emergency of international concern, is also a clear reminder of the critical and urgent need to reinforce the global framework to prevent, prepare for and respond to public health emergencies. The majority of the amended provisions concern matters that have been regulated at EU level, in particular in the areas of serious cross-border threats to health, cooperation with the competent organisations in the sphere of public health and protection of public health in the event of a public health emergency. None of the amendments are contrary to Union law and no reservation to the amendments is thus required.

The Union is not in a position to accede to the International Health Regulations (2005), as the Regulations do not provide for the possibility of accession by regional economic integration organisations¹⁰. The objective of the present proposal is therefore to suggest to the Council to authorise EU Member States, acting jointly in the interest of the Union, to accept the amendments to the International Health Regulations (2005) adopted through Resolution WHA77.77.

- **Content of the amendments to the International Health Regulations (2005) adopted through Resolution WHA 77.17**

The amendments to the International Health Regulations (2005) adopted through Resolution WHA 77.17 are fully in line with the negotiating directives as adopted by the Council and annexed to Council Decision (EU) 2022/451. The amendments include the following modifications:

- Introduction of a definition of “pandemic emergency”, as well as a related declaration mechanism, to trigger more effective international collaboration in response to events that are at risk of becoming, or have become, a pandemic (Articles 1 and 12, with conforming amendments in Articles 11, 12, 13, 15, 48 and 49).
- Creation of National IHR Authorities to coordinate national IHR implementation, besides the pre-existing National IHR Focal Point, while leaving flexibility to States Parties to establish the National IHR Authority and the National IHR Focal Point as one or two entities (Articles 1 and 4).
- Introduction of an explicit reference to “preparedness” within the scope of the International Health Regulations (2005), to recall the importance, under the Regulations, of functions related to the building of core capacities in an on-going manner, in the absence of public health emergencies (Article 2).
- Provisions aimed at enhancing the commitment to solidarity and equity. This includes the introduction of an explicit reference to these principles under Article 3, as well as the introduction of substantive provisions strengthening access to medical products (Article 1 with the new definition of “relevant health products” and Articles 13, 15, 16, 17 and 44) and financing (Articles 44 and 44 bis). Under Article 44 bis, a Coordinating Financial Mechanism is established to promote and support

⁹ Council conclusions of 29 January 2024 on the ‘EU Global Health Strategy: Better health for all in a changing world’, document ST 5908/24 and related Commission Communication COM(2022)675 of 30 November 2022.

¹⁰ It should be noted that the Commission had put forward a proposal to amend Article 64 to the International Health Regulations (2005) to allow regional economic integration organisation to become parties. Such proposal did not meet the agreement of some EU Member States and could not be finalised by the deadline of 30 September 2022. The proposal was therefore not included in the package of proposed amendments submitted by the Czech Republic on behalf of the EU and its Member States.

identification of, and access to, financing required to “*equitably address the needs and priorities of developing countries, including for developing, strengthening and maintaining core capacities*”, comprising those relevant for pandemic emergencies.

- Provisions aimed at improving the timely sharing of information in case of public emergencies, between WHO and relevant intergovernmental organizations (Article 6) and between WHO and States Parties (Articles 8 and 10).
- Introduction of a requirement for WHO, when issuing recommendations, to take into account the need to facilitate international travel and maintain international supply chains (Article 18).
- Provisions aimed at improving coordination between conveyance operators and port authorities, with a requirement for conveyances operators to prepare, as appropriate, for the application of health measures on board, as well as during embarkation and disembarkation (Annex 4), as well as through clarifications provided in Articles 24 and 27.
- New provisions enabling the use of digital health certificates under the Regulations (Article 35 and Annex 6) and requiring WHO to develop and update, as necessary technical guidance for health documents.
- Provisions aimed at facilitating consultations requested by a State Party impacted by a health measure taken by another State Party in order to clarify its scientific basis and to find a mutually acceptable solution (Article 43).
- Clarification on the composition and way of working of the Emergency Committee (Articles 48 and 49).
- Establishment of the States Parties Committee to facilitate the effective implementation of the amended Regulations. The objective of the Committee is in particular to promote and support cooperation among States Parties for the purpose of effective implementation of the Regulations, upon technical advice from a Subcommittee, which remains to be established (Article 54 bis).
- Provisions aimed at strengthening core capacities of State Parties (Articles 5(1) and 13(1) and Annex 1), by introducing in particular in Annex 1, more detailed core capacities requirements for prevention and preparedness, as well as a requirement to engage stakeholders and communities in the context of preparedness and response, and a requirement for the national response level to ensure coordination with, and provide support to, the local and intermediate response levels.
- The revision of the Decision instrument (Annex 2) for the assessment and notification of events that may constitute a public health emergency of international concern, including the clarification that clusters of cases of severe acute respiratory disease of unknown or novel cause shall lead to the utilization of the algorithm set out in the Annex.
- Additional editorial amendments in Articles 5, 12, 13, 15, 19, 20, 21, 23, 28, 37, 44, 45, 49, 50, 53 and Annexes 1, 3, 4 and 8.

- **Consistency with existing policy provisions in the policy area and competences**

The purpose and scope of the International Health Regulations (2005), as amended through Resolution WHA77.17, are “*to prevent, prepare for, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate and restricted to public health risks, and which avoid unnecessary interference with*

international traffic and trade.” The main policy area covered by the International Health Regulations (2005) and by the amendments adopted through Resolution WHA77.17, is thus related to the fight against serious cross-border health threats, which is an area where the Union has competence, in accordance with Article 168(5) TFEU.

At EU level, Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU¹¹ provides the framework and mechanisms for coordinating and strengthening prevention, preparedness and response to serious cross-border threats to health of biological, chemical, environmental or unknown origin. The Regulation lays down rules on a wide range of issues, including prevention, preparedness and response planning, joint procurement of medical countermeasures, epidemiological surveillance and monitoring, early warning and risk assessment, coordination of response and recognition of public health emergency at Union level.

Commission Implementing Decision (EU) 2018/945 of 22 June 2018 on the communicable diseases and related health issues to be covered by epidemiological surveillance and case definition¹² establishes a list of communicable diseases and their case definitions, which are covered by epidemiological surveillance at EU level.

Commission Implementing Decision (EU) 2017/253 of 13 February 2017 on the procedures for the notification of alerts as part of the early warning and response system (EWRS) and for the information exchange, consultation and coordination of responses¹³ lays down the procedures under which EU Member States can alert, share information and coordinate national responses to serious cross-border threats in a secure manner, while Commission Implementing Regulation (EU) 2023/1808 of 21 September 2023¹⁴ sets out the template for the provision of information on prevention, preparedness and response planning in relation to serious cross-border threats to health in accordance with Regulation (EU) 2022/2371 of the European Parliament and of the Council.

The majority of the amendments of the International Health Regulations (2005) adopted through Resolution WHA77.17, in particular the amendments to Articles 1, 2, 4, 5, 6, 8, 10, 11, 12, 13, 15, 16, 43, 48, 49, as well as Annexes 1 and 2, involve areas covered by the above-mentioned acts and all these amendments are fully consistent and aligned with the objective of EU law on prevention, preparedness and response to serious cross-border threats to health.

In addition, in accordance with Article 168(7) TFEU, the Member States are responsible 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. The amendments to Article 4, for the part leaving to IHR States Parties the flexibility to establish the national IHR authority as a separate or joint entity with the national IHR focal point; the amendments to Article 43, which leave the possibility to IHR States Parties to decide whether to engage or not in the consultation mechanism; as well as the amendment to Article 44(2) bis on domestic funding concern matters falling within the sole Member State competence.

- **Consistency with other Union policies**

Several other policy areas for which the Union is competent are also covered by the International Health Regulations (2005), as amended through Resolution WHA77.17.

¹¹ OJ L 314, 6.12.2022, p. 26.

¹² OJ L 170, 6.7.2018, p. 1.

¹³ OJ L 37, 14.2.2017, p. 23.

¹⁴ OJ L 234, 22.9.2023, p. 105.

The amendments to Article 13 of the International Health Regulations (2005) are in line with the Union policy aimed at ensuring a sufficient and timely availability and supply of crisis-relevant medical countermeasures, including through emergency measures. In particular, Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices¹⁵ includes provisions related to the monitoring of medicine shortages that might lead to a crisis situation and Council Regulation (EU) 2022/2372 of 24 October 2022¹⁶ establishes a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level. The amendments to Article 13 of the International Health Regulations (2005) are fully consistent with the objective of EU law in this field.

The amendments to Article 18 of the International Health Regulations (2005) are in line with the Union policy adopted in the context of the COVID-19 pandemic, including with the objective to preserve the operation of supply chains and free movement of transport workers, particularly as set out in the Communication from the Commission¹⁷ on the implementation of the Green Lanes under the Guidelines for border management measures to protect health and ensure the availability of goods and essential services of 24 March 2020.

The amendments to Article 35 and Annex 6 of the International Health Regulations (2005) relate to areas covered by Union law on the free movement of persons, including the conditions for the exercise of the right to free movement laid down in Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States¹⁸. These amendments also relate to areas covered under Regulation (EU) 2016/399 of the European Parliament and of the Council of 9 March 2016 on a Union Code on the rules governing the movement of persons across borders (Schengen Borders Code)¹⁹. The amendments to Article 35 and Annex 6 of the International Health Regulations (2005) are fully consistent and aligned with these fields of Union law.

The amendments to Articles 44 and 44 bis involve areas covered by Union law related to civil protection, as set out under Decision No 1313/2013/EU of the European Parliament and of the Council of 17 December 2013 on a Union Civil Protection Mechanism²⁰ and to the Union multiannual financial framework to pursue the objectives and principles of the Union's external action, as set out under Regulations (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 on Neighbourhood, Development and International Cooperation Instrument (NDICI) – Global Europe²¹. The amendments to these articles are fully consistent and aligned with EU law in those fields.

- **Acceptance of amendments to the International Health Regulations (2005)**

Consent to be bound by WHO regulations (as provided for in Article 21 of the WHO Constitution) is subject to a simplified procedure based on tacit acceptance. The matter is regulated by Article 22 of the Constitution, which provides for a simplified entry into force regime whereby any State that intends to become party to a regulation will do so, provided that it does not notify to the Director General of the WHO a rejection or reservation to the

¹⁵ OJ L 20, 31.1.2022, p. 1.

¹⁶ OJ L 314, 6.12.2022, p. 64.

¹⁷ OJ C 96 I, 24.3.2020, p. 1.

¹⁸ OJ L 158, 30.4.2004, p. 77.

¹⁹ OJ L 77, 23.3.2016, p. 1.

²⁰ OJ L 347, 20.12.2013, p. 924.

²¹ OJ L 209, 14.6.2021, p. 1.

said regulation, or amendment thereto, within the time frame notified by the Director General for that purpose.

In the case of the Amendments to the International Health Regulations (2005) adopted through Resolution WHA77.17, the time frame for their entry into force, as well as the period for rejections or reservations, is stipulated in Article 59 of the International Health Regulations (2005). Article 59 was itself subject to several amendments adopted at the Seventy-fifth World Health Assembly in 2022²², which shorten the period for rejection of, or reservation to a new amendment from 18 to 10 months from the date of the Director-General's notification of adoption of the amendment and reduce the entry into force date from 24 to 12 months from the same date. The amendments in question entered into force on 31 May 2024, thus the new amendments covered by this proposal and adopted through Resolution WHA77.17 on 1 June 2024 by the Seventy-seventh World Health Assembly fall under the new provisions.

However, four States Parties, including two EU Member States (the Netherlands and Slovakia) have rejected the amendments to Article 59 adopted in 2022. Unless they withdraw their rejection, they will remain subject, with respect to the new amendments covered by this proposal, to the original text of Article 59 as set out in the International Health Regulations (2005), with a period of 18 months for rejection or reservation of these amendments from the date of their notification and a period of 24 months from the same date for their entry into force.

The amendments to the International Health Regulations (2005) as adopted through Resolution WHA77.17 were notified by the WHO Director-General to all States Parties on 19 September 2024. Consequently, the amendments shall enter into force on 19 September 2025 for all States Parties to the International Health Regulations (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.

2. LEGAL BASIS

• Procedural legal basis

The procedural legal basis for this proposal for a Council Decision is Article 218(6)(a)(iii) and (v) of the TFEU, which applies regardless of whether the Union is a member of the organisation, which adopted the international agreement²³.

• Substantive legal basis

The substantive legal basis for a decision under Article 218(6) TFEU depends primarily on the objective and content of the international agreement for which conclusion is sought in the Union's interest. If the agreement pursues two aims or has two components and if one of those components is identifiable as the main one, whereas the other is merely incidental, the decision under Article 218(6) TFEU must be founded on a single substantive legal basis, namely that associated with the main or predominant aim or component. With regard to an agreement that simultaneously pursue a number of objectives, or that has several components, which are inseparably linked without one being incidental to the other, the substantive legal

²² [WHA75.12 - Amendments to the International Health Regulations \(2005\)](#).

²³ Opinion 2/91 of the Court of Justice of 19 March 1993, ECLI:EU:C:1993:106, page 1061 on the ILO Chemicals Convention No. 170 and Judgment of the Court of Justice of 7 October 2014, *Germany v Council*, C-399/12, ECLI:EU:C:2014:2258, paragraph 64.

basis of a decision under Article 218(6) TFEU will have to include, exceptionally, the various corresponding legal bases.

The purpose and scope of the International Health Regulations (2005), as amended through Resolution WHA77.17, are *“to prevent, prepare for, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.”* The amendments to the International Health Regulations (2005) adopted through Resolution WHA77.17 aim at strengthening further global preparedness, surveillance and response to public health emergencies.

The Union has competence in health matters as per Articles 4(2)(k) and 6(a) TFEU. Article 168(1) TFEU provides that the Union is competent to adopt measures, which complement the national policies of its Member States, directed towards improving public health, preventing human illness and diseases and obviating sources of danger to human health. Article 168(1) TFEU further lays down that Union *“action shall cover the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as [...], early warning of and combating serious cross-border threats to health.”* To that effect, according to Article 168(5) TFEU, *“the European Parliament and the Council, acting in accordance with the ordinary legislative procedure, may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health”*. In addition, Article 168(3) calls on the Union and the Member States to *“foster cooperation with third countries and the competent international organisations in the sphere of public health”*.

Most amendments to the International Health Regulations (2005) adopted through Resolution WHA77.17 concern matters for which the Union is competent on the basis of Article 168(5) TFEU and that have been regulated in particular through Regulation (EU) 2022/2371, Commission Implementing Decision (EU) 2018/945 of 22 June 2018, Commission Implementing Decision (EU) 2017/253 and Commission Implementing Regulation (EU) 2023/1808.

In addition, some amendments correspond to areas covered by Union law in relation to the supply of crisis-relevant medical countermeasures, protection of public health in the event of a public health emergency, free movement of persons, civil protection or development cooperation. These areas are however incidental to the main policy area and therefore, the decision must be founded on a single substantive legal basis.

Therefore, the substantive legal basis of the proposed decision is Article 168(5) TFEU.

- **Proportionality**

The amendments to the International Health Regulations (2005) as adopted through Resolution WHA77.17 do not go beyond what is necessary to achieve the overall policy objective, which is to strengthen global preparedness, surveillance and response to public health emergencies.

- **Choice of the instrument**

The instrument is a proposal for a Council Decision pursuant to Article 218(6) TFEU.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/ fitness checks of existing legislation**

Non applicable

- **Stakeholder consultations**

Non applicable

- **Collection and use of expertise**

From October 2022 to February 2023, the amendments proposed by States Parties to the International Health Regulations (2005) were examined by a Review Committee convened by the WHO Director-General pursuant to Articles 47 and 50 paragraph 1(a) of the International Health Regulations (2005), as well as Decision WHA75(9). The Committee functioned in accordance with the WHO Regulations for Expert Advisory Panels and Committees²⁴. It was composed of 20 members, selected and nominated by the Director-General from the International Health Regulations (2005) Roster of Experts, covering a wide range of expertise and reflecting gender and geographical representation.

The Review Committee, in accordance with its mandate, issued technical recommendations on the proposed amendments, which informed the work of the WGIHR²⁵. According to the Review Committee experts, the 'extreme diversity of the proposed amendments' ranged from limited technical changes to substantial additions and revisions, reflecting overall the willingness to strengthen the instrument.

- **Impact assessment**

Non applicable

- **Regulatory fitness and simplification**

Non applicable

- **Fundamental rights**

Article 3(1) of the International Health Regulations (2005) lays down that the implementation of the Regulations shall be with full respect for the dignity, human rights and fundamental freedoms of persons. None of the amendments to the International Health Regulations (2005) adopted through Resolution WHA77.17 is altering or undermining this provision.

4. BUDGETARY IMPLICATIONS

The proposed Council Decision is not expected to have any budgetary implications for the Union, as the Union is not Party to the International Health Regulations (2005).

In addition, the amendments, adopted at the Seventy-seventh World Health Assembly, do not create specific financial obligations for the States Parties. Instead, the amendments provide for the establishment of a new Coordinating Financial Mechanism, to ensure a more effective use of existing financing instruments for the implementation of the International Health Regulations (2005).

²⁴ https://apps.who.int/gb/bd/pdf_files/BD_49th-en.pdf#page=160.

²⁵ [A/WGIHR/2/5 – Report of the Review Committee regarding amendments to the International Health Regulations \(2005\)](#).

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

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(6) (a) (iii) and (v) thereof,

Having regard to the proposal from the European Commission,

Having regard to the consent of the European Parliament,

Whereas:

- (1) On 1 June 2024, at the Seventy-seventh session of the World Health Assembly (WHA), the Member States of the World Health Organization (WHO) adopted by consensus the various amendments to the International Health Regulations of 2005 (hereinafter “amendments”) contained in the Annex to Resolution WHA77.17 and aimed at strengthening their effectiveness.
- (2) The Union promotes the strengthening of the International Health Regulations (2005) and their effective implementation.
- (3) Over recent years, the Union significantly strengthened its health security framework through the adoption of several legal acts, in particular Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU¹, and Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at Union level².
- (4) On 3 March 2022, with the adoption of Council Decision (EU) 2022/451³, the Council of the European Union authorised the Commission to negotiate on behalf of the Union, for matters falling within Union competence, an international agreement on pandemic prevention, preparedness and response, as well as complementary amendments to the International Health Regulations (2005).
- (5) The majority of amendments adopted on 1 June 2024 concern matters for which the Union is competent on the basis of Article 168(5) TFEU and in relation to which Union rules exist, in particular in the field of serious cross-border threats to health. In addition, some amendments correspond to areas covered by Union law in relation to the supply of crisis-relevant medical countermeasures, protection of public health in

¹ OJ L 314, 6.12.2022, p. 26.

² OJ L 314, 6.12.2022, p. 64.

³ OJ L 92, 21.3.2022, p. 1.

the event of a public health emergency, free movement of persons, civil protection, or development cooperation.

- (6) The Member States remain competent for the definition of their health policy and for the organisation and delivery of health services and medical care in accordance with Article 168(7) TFEU.
- (7) In accordance with the principle of sincere cooperation, Member States, acting in the interest of the Union, should accept the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA 77.17.
- (8) None of the amendments are contrary to Union law and no reservation to the amendments falling within the competence of the Union is thus required.
- (9) The Union is not party to the International Health Regulations (2005), as only States can be Parties thereto. All Member States are parties to the International Health Regulations (2005).
- (10) In these circumstances, the Union's external competence may be exercised through the Member States acting as intermediaries.

HAS ADOPTED THIS DECISION:

Article 1

Member States are authorised to accept, without reservations, the amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA 77.17 adopted on 1 June 2024⁴, in the interest of the Union, for the parts falling within the competence of the Union.

The text of the amendments to the International Health Regulations (2005) is attached to this Decision⁵.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

*For the Council
The President*

⁴ [WHA77.17 - Strengthening preparedness for and response to public health emergencies through targeted amendments to the International Health Regulations \(2005\)](#).

⁵ The text of the amendments to the International Health Regulations (2005), with several editorial corrections, was circulated to the States Parties to the International Health Regulations (2005) through WHO circular letter C.L.40.2024 of 19 September 2024. These editorial corrections are also reflected in the text of the amendments attached to this Decision.