International Health Regulations (2005): authorising Member States to accept the amendments contained in the Annex to Resolution WHA77.17 and adopted on 1 June 2024

2024/0299(NLE) - 28/01/2025 - Legislative proposal

PURPOSE: to invite 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.

PROPOSED ACT: Council Decision.

ROLE OF THE EUROPEAN PARLIAMENT: Council may adopt the act only if Parliament has given its consent to the act.

BACKGROUND: on 3 March 2022, with the adoption of Decision (EU) 2022/4512, the Council 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).

On 1 June 2024, at the Seventy-seventh session of the World Health Assembly (WHA), the Members of the World Health Organization (WHO) adopted by consensus the various amendments to the International Health Regulations (2005) contained in the Annex to Resolution WHA77.17 and aimed at strengthening their effectiveness.

Pursuant to Article 22 of the Constitution of the WHO, the amendments are to enter into force for all Members of the WHO except for such Members that have notified the Director-General of rejection or reservations within the period stated in the notice of adoption of those amendments.

A significant number of the amendments concern matters for which the Union has competence to support, coordinate or supplement the actions of the Member States and in relation to which Union rules exist, in particular in the field of serious cross-border threats to health under Regulation (EU) 2022/2371. In addition, some of the amendments correspond to areas covered by Union law in relation to the supply of crisis-relevant medical countermeasures as laid down in Regulation (EU) 2022/2372, to the protection of public health in the event of a public health emergency as laid down in Regulation (EU) 2022/123 of the European Parliament and of the Council, to the free movement of persons as laid down in Directive 2004 /38/EC of the European Parliament and of the Council, to civil protection as set out in Decision No 1313 /2013/EU of the European Parliament and of the Council, or to development cooperation as set out in Regulation (EU) 2021/947 of the European Parliament and of the Council

This Decision does not make use of the possibility for the Union to exercise its external competence with regards to areas in relation to which Union rules do not already exist. The Member States remain competent in respect of the matters covered by the amendments, in so far as the amendments do not affect Union rules or alter the scope thereof, including foreseeable future developments of those rules. In addition, Member States remain solely responsible 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. Furthermore, this Decision does not create additional financial obligations for Member States.

None of the amendments are contrary to Union law, and it is therefore not necessary to make reservations in respect of the amendments falling within the competence of the Union.

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).

In these circumstances, and in accordance with the principle of sincere cooperation, the Union's competence should be exercised externally through the Member States acting as intermediaries.

CONTENT: under this draft Council Decision, Member States are invited 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 2024, 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 Decision.