

SEVENTY-FIFTH WORLD HEALTH ASSEMBLY Agenda item 16.2

WHA75.12 28 May 2022

Amendments to the International Health Regulations (2005)

The Seventy-fifth World Health Assembly,

Having considered the Proposal for amendments to the International Health Regulations (2005),¹ which includes in its Annex proposed amendments submitted by the United States of America in accordance with paragraph 1 of Article 55 of the International Health Regulations (2005);

Recalling decision EB150(3) (2022) on Strengthening the International Health Regulations (2005): a process for their revision through potential amendment, which noted the discussions of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies related to strengthening the International Health Regulations (2005), including through implementation, compliance and potential amendments, and urged Member States to take all appropriate measures to consider potential amendments to the International Health Regulations (2005), with the understanding that this would not lead to reopening the entire instrument for renegotiation;

Expressing appreciation for the work of the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies in developing an inclusive Member State-led process for considering amendments to the International Health Regulations (2005);

Welcoming decision WHA75(9) (2022) on Strengthening WHO preparedness for and response to health emergencies, in which Member States decided to commence a Member State-led process to consider proposed amendments² to the International Health Regulations (2005) beyond those adopted below;

Recalling that Member States decided to establish the Working Group on Amendments to the International Health Regulations (2005) (WGIHR), through the Working Group on Strengthening WHO Preparedness and Response to Health Emergencies, to discuss targeted amendments to 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 of and compliance with 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;

Noting States Parties' right to notify the Director-General of rejections or reservations, pursuant to Articles 61 and 62, of the below amendments of the International Health Regulations (2005),

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¹ Document A75/18.

² Including the other proposed amendments set out in the Annex to document A75/18, as well as other amendments which have or may be submitted by other States Parties to the International Health Regulations (2005) or the Director-General, including through the above-mentioned Member State-led process.

- 1. ADOPTS, in accordance with paragraph 3 of Article 55 of the International Health Regulations (2005), the amendments to Article 59, and the consequent necessary updates to Articles 55, 61, 62, and 63 of the International Health Regulations (2005) set out in the Annex below;
- 2. URGES States Parties, consistent with Article 44 of the International Health Regulations (2005), to collaborate with each other in the provision or facilitation of technical cooperation and logistical support, particularly in the development, strengthening and maintenance of the public health capacities required under the International Health Regulations (2005).

CERTIFIED TRUE COPY

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ANNEX

Article 59: Entry into force; period for rejection or reservations

1. The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, these Regulations shall be 18 months from the date of the notification by the Director-General of the adoption of these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

1bis The period provided in execution of Article 22 of the Constitution of WHO for rejection of, or reservation to, an amendment to these Regulations shall be 10 months from the date of the notification by the Director-General of the adoption of an amendment to these Regulations by the Health Assembly. Any rejection or reservation received by the Director-General after the expiry of that period shall have no effect.

- 2. These Regulations shall enter into force 24 months after the date of notification referred to in paragraph 1 of this Article, and amendments to these Regulations shall enter into force 12 months after the date of notification referred to in paragraph 1 bis of this Article, except for:
 - (a) a State that has rejected these Regulations or an amendment thereto in accordance with Article 61:
 - (b) a State that has made a reservation, for which these Regulations or an amendment thereto shall enter into force as provided in Article 62;
 - (c) a State that becomes a Member of WHO after the date of the notification by the Director-General referred to in paragraph 1 of this Article, and which is not already a party to these Regulations, for which these Regulations shall enter into force as provided in Article 60; and
 - (d) a State not a Member of WHO that accepts these Regulations, for which they shall enter into force in accordance with paragraph 1 of Article 64.
- 3. If a State is not able to adjust its domestic legislative and administrative arrangements fully with these Regulations or an amendment thereto within the period set out in paragraph 2 of this Article, as applicable, that State shall submit within the applicable period specified in paragraph 1 or 1 bis of this Article a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than 12 months after the entry into force of these Regulations or an amendment thereto for that State Party.

Article 55: Amendments

- 1. Amendments to these Regulations may be proposed by any State Party or by the Director-General. Such proposals for amendments shall be submitted to the Health Assembly for its consideration.
- 2. The text of any proposed amendment shall be communicated to all States Parties by the Director-General at least four months before the Health Assembly at which it is proposed for consideration.

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3. Amendments to these Regulations adopted by the Health Assembly pursuant to this Article shall come into force for all States Parties on the same terms, and subject to the same rights and obligations, as provided for in Article 22 of the Constitution of WHO and Articles 59 to 64 of these Regulations, subject to the periods provided for in those Articles with respect to amendments to these Regulations.

Article 61 Rejection

If a State notifies the Director-General of its rejection of these Regulations or of an amendment thereto within the applicable period provided in paragraph 1 or 1bis of Article 59, these Regulations or the amendment concerned shall not enter into force with respect to that State. Any international sanitary agreement or regulations listed in Article 58 to which such State is already a party shall remain in force as far as such State is concerned.

Article 62 Reservations

- 1. States may make reservations to these Regulations or an amendment thereto in accordance with this Article. Such reservations shall not be incompatible with the object and purpose of these Regulations.
- 2. Reservations to these Regulations or an amendment thereto shall be notified to the Director-General in accordance with paragraphs 1 and 1 bis of Article 59 and Article 60, paragraph 1 of Article 63 or paragraph 1 of Article 64, as the case may be. A State not a Member of WHO shall notify the Director-General of any reservation with its notification of acceptance of these Regulations. States formulating reservations should provide the Director-General with reasons for the reservations.
- 3. A rejection in part of these Regulations or an amendment thereto shall be considered as a reservation.
- 4. The Director-General shall, in accordance with paragraph 2 of Article 65, issue notification of each reservation received pursuant to paragraph 2 of this Article. The Director-General shall:
 - (a) if the reservation was made before the entry into force of these Regulations, request those Member States that have not rejected these Regulations to notify him or her within six months of any objection to the reservation, or
 - (b) if the reservation was made after the entry into force of these Regulations, request States Parties to notify him or her within six months of any objection to the reservation, or
 - (c) if the reservation was made to an amendment to these Regulations, request States Parties to notify him or her within three months of any objection to the reservation.

States Parties objecting to a reservation to an amendment to these Regulations should provide the Director-General with reasons for the objection.

5. After this period, the Director-General shall notify all States Parties of the objections he or she has received with regard to reservations. In the case of a reservation made to these Regulations, unless by the end of six months from the date of the notification referred to in paragraph 4 of this Article a reservation has been objected to by one third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and these Regulations shall enter into force for the reserving State, subject to the reservation. In the case of a reservation made to an amendment to these Regulations, unless by the end of three months from the date of the notification referred to in paragraph 4 of this Article, a

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reservation has been objected to by one third of the States referred to in paragraph 4 of this Article, it shall be deemed to be accepted and the amendment shall enter into force for the reserving State, subject to the reservation.

- 6. If at least one third of the States referred to in paragraph 4 of this Article object to the reservation to these Regulations by the end of six months from the date of the notification referred to in paragraph 4 of this Article or, in the case of a reservation to an amendment to these Regulations, by the end of three months from the date of the notification referred to in paragraph 4 of this Article, the Director-General shall notify the reserving State with a view to its considering withdrawing the reservation within three months from the date of the notification by the Director-General.
- 7. The reserving State shall continue to fulfil any obligations corresponding to the subject matter of the reservation, which the State has accepted under any of the international sanitary agreements or regulations listed in Article 58.
- 8. If the reserving State does not withdraw the reservation within three months from the date of the notification by the Director-General referred to in paragraph 6 of this Article, the Director-General shall seek the view of the Review Committee if the reserving State so requests. The Review Committee shall advise the Director-General as soon as possible and in accordance with Article 50 on the practical impact of the reservation on the operation of these Regulations.
- 9. The Director-General shall submit the reservation, and the views of the Review Committee if applicable, to the Health Assembly for its consideration. If the Health Assembly, by a majority vote, objects to the reservation on the ground that it is incompatible with the object and purpose of these Regulations, the reservation shall not be accepted and these Regulations or an amendment thereto shall enter into force for the reserving State only after it withdraws its reservation pursuant to Article 63. If the Health Assembly accepts the reservation, these Regulations or an amendment thereto shall enter into force for the reserving State, subject to its reservation.

Article 63 Withdrawal of rejection and reservation

- 1. A rejection made under Article 61 may at any time be withdrawn by a State by notifying the Director-General. In such cases, these Regulations or an amendment thereto, as applicable, shall enter into force with regard to that State upon receipt by the Director-General of the notification, except where the State makes a reservation when withdrawing its rejection, in which case these Regulations or an amendment thereto, as applicable, shall enter into force as provided in Article 62. In no case shall these Regulations enter into force in respect to that State earlier than 24 months after the date of notification referred to in paragraph 1 of Article 59 and in no case shall an amendment to these Regulations enter into force in respect to that State earlier than 12 months after the date of notification referred to in paragraph 1 bis of Article 59.
- 2. The whole or part of any reservation may at any time be withdrawn by the State Party concerned by notifying the Director-General. In such cases, the withdrawal will be effective from the date of receipt by the Director-General of the notification.

Eighth plenary meeting, 28 May 2022 A75/VR/8

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