

Explanatory Statement 5 of 2023

Amendments, adopted by the 75th World Health Assembly, to the *International Health Regulations (2005)* (Geneva, 28 May 2022)

Practical and legal effect

1. The proposed treaty action is tacit acceptance of amendments, adopted by the 75th World Health Assembly (WHA75) on 28 May 2022, to Article 59 (entry into force; period for rejection or reservations) of the *International Health Regulations (2005)* (IHR).
2. The Article 59 amendments reduce the entry into force period for amendments to the IHR from 24 months to 12 months from the date of notification by the Director-General of the adoption of the amendments. The amendments also reduce the period for rejection of, or reservation to, amendments to the IHR from 18 months to 10 months from the date of notification by the Director-General. Amendments to Articles 55, 61, 62 and 63 are necessary technical conforming adjustments for the Article 59 amendments, including to reduce the time period for State Parties to object to another State's reservation from six months to three months.
3. The amendments to Article 59 also state that if State Parties are unable to adjust their domestic legislative and administrative arrangements fully with an amendment to the IHR within 12 months, Parties are granted an additional 12 months for implementation after the entry into force of an amendment. To do this, Parties must submit a declaration to the Director-General regarding the outstanding adjustments and achieve them no later than the additional 12 months period.
4. The amendments do not affect the rights or obligations of existing State Parties to the IHR and do not introduce any further domestic obligations to implement.¹ The amendments only reduce the periods of time for entry into force, rejections of and reservations to amendments to the IHR, and provide State Parties with additional time to implement amendments after their entry into force where required. The amendments are expected to have a negligible legal, financial, or practical impact on Australia.

Nature and timing of the treaty action

5. The IHR entered into force 15 June 2007. The IHR are an international legal instrument, legally binding on 196 State Parties, including Australia. The IHR are designed to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with, and restricted to, public health risks, and which avoid unnecessary interference with international traffic and trade.
6. The IHR establishes a minimum standard for public health prevention, preparedness and response and provides an overarching legal framework that

¹ There are no additional resources required for the implementation of these amendments identified in the World Health Assembly document A75/A/CONF./7 Add.1.

defines the rights and obligations of State Parties to report public health events that have the potential to cross international borders. Australia has incorporated key IHR standards into domestic law, including through the *Biosecurity Act 2015* and the *National Health Security Act 2007*.

7. In January 2022, in accordance with paragraph 1 of Article 55 of the IHR, the United States formally submitted a number of proposed amendments to the IHR. These amendments were negotiated through informal meetings led by the United States.² The amendments to Article 59 were the only amendments agreed upon. On 28 May 2022, WHA75 adopted the resolution WHA75.12 to adopt the amendments to Article 59, as well as the necessary consequential amendments.³ Australia co-sponsored the resolution proposing the adoption of the amendments. On 31 May 2022, the Director-General notified State Parties of the amendments as per paragraph 3 of Article 55 and paragraph 1 of Article 59 of the IHR.
8. Pursuant to paragraph 3 of Article 55 and paragraph 2 of Article 59 of the IHR, the amendments shall enter into force on 31 May 2024. State Parties may reject or make a reservation to any of the amendments in accordance with paragraphs 1 and 2 of Article 59, Article 61, and paragraphs 1, 2 and 3 of Article 62 of the IHR by 1 December 2023. As per paragraph 3 of Article 59 of the IHR, any State Party that intends to make a declaration concerning its inability to adjust its domestic legislative and administrative arrangements to fully adopt the amendments must submit a declaration to the Director-General by 1 December 2023 and must achieve those adjustments no more than 12 months after the date of entry into force of the amendments.
9. If Australia does not lodge a rejection or reservation within the specified timeframe, Australia will be bound to the amendments in accordance with Article 22 of the World Health Organization Constitution and paragraph 3 of Article 55 and Articles 59 to 64 of the IHR.

Reasons for Australia to take the proposed action relating to the treaty matter

10. Australia supports revising the IHR to be more adaptive to evolving global health threats by reducing the time period for entry into force of amendments. Australia's acceptance of this amendment is in line with the international efforts to reform the global health architecture following the COVID-19 pandemic. Support for this amendment is consistent with Australia's current policy to be a leader in global health reform and foreign policy priorities to support key allies, including the United States of America.

Implementing Legislation

11. No change to Australian legislation is required to give effect to the amendments.

International Strategies Branch
Department of Health and Aged Care

Submitted to JSCOT
June 2023

² Member States in attendance at these informal meetings included the United Kingdom, Russia, Japan, Republic of Korea, Chile, Paraguay, Monaco, Brazil, Nigeria, Kenya, South Africa, the European Union, Norway, Turkey, China, Argentina, Switzerland, Mexico, Guatemala, Colombia.

³ I.e. amendments to Articles 55, 61, 62 and 63.



Ref.: C.L.26.2022

Amendments to the International Health Regulations (2005)

The Director-General of the World Health Organization presents his compliments to States Parties to the International Health Regulations (2005) and has the honour to refer to resolution WHA75.12 of 28 May 2022 (copy enclosed), by which the Seventy-fifth World Health Assembly adopted amendments to Articles 55, 59, 61, 62 and 63 of the International Health Regulations (2005).

In accordance with paragraph 3 of Article 55 and paragraph 1 of Article 59 of the International Health Regulations (2005), this circular letter constitutes the notification of the above-mentioned amendments, a certified true copy of which is enclosed.

Pursuant to paragraph 3 of Article 55 and paragraph 2 of Article 59 of the International Health Regulations (2005), the above-mentioned amendments shall enter into force 24 months after the date of the present notification, i.e. on 31 May 2024.

Any State Party intending to reject or to make reservations to any of the amendments, as provided in paragraphs 1 and 2 of Article 59, Articles 61, and paragraphs 1, 2, and 3 of Article 62 of the International Health Regulations (2005), may notify the Director-General accordingly within a period of 18 months from the date of the present notification, expiring on 1 December 2023. Any rejection or reservation received thereafter shall have no effect.

Any State Party that, pursuant to paragraph 3 of Article 59 of the International Health Regulations (2005), intends to make a declaration concerning its inability to adjust its domestic legislative and administrative arrangements fully, may similarly submit such a declaration to the Director-General within a period of 18 months from the date of the present notification, expiring on 1 December 2023.

The Director-General of the World Health Organization takes this opportunity to renew to States Parties to the International Health Regulations (2005) the assurance of his highest consideration.

GENEVA, 31 May 2022

ENCL.: (1)

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),

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



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 1bis 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 1bis 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.

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 1bis 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 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 1bis 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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