



Department of Health and Aged Care Department of Foreign Affairs and Trade

Preparing for, and responding to, future pandemics and other international health emergencies

Consultation Paper

Contents

1.	Consultation Overview	3
2.	Context	3
3.	Negotiations to the international legal framework for future pandemics and other internation	al
hea	Ith emergencies	5
4.	What Happens Next?	9

1. Consultation Overview

This consultation paper seeks your views to inform Australia's engagement in two concurrent negotiation processes through the World Health Organization (WHO) to strengthen the international legal framework to prepare for, and respond to, future pandemics and other international health emergencies: This includes the negotiation of:

- 1. a new international legal instrument on pandemic prevention, preparedness and response (pandemic instrument), and
- 2. changes to the *International Health Regulations (2005)*.

The Australian Government is interested in understanding what Australian stakeholders and the community want to see in these reforms. Your views will help inform Australia's engagement in both negotiation processes. We have included three focus questions on the consultation webpage to guide your input into this consultation.

2. Context

Why is the development of a pandemic instrument, and changes to the IHR, important?

Australia supports a world better prepared for future outbreaks, epidemics, and pandemics. The development of a pandemic instrument, and changes to the IHR, present a unique opportunity for the Australian Government to consider whether legal frameworks governing a suite of contemporary global health issues remain fit-for-purpose for future pandemics and other health emergencies.

Australia wants to strengthen international cooperation on pandemic prevention, preparedness and response, and reflect lessons learned from the global response to COVID-19. We need to ensure communities, governments and the global community are better prepared in the future.

What are the International Health Regulations?

The *International Health Regulations* (2005) (IHR) are an overarching international legal framework that is legally-binding on 196 State Parties¹, including all 194 WHO Member States.

The IHR are the existing legal framework defining countries' rights and obligations in handling infectious disease outbreaks, public health events and emergencies that have the potential to cross borders. First adopted in 1969, the IHR have been amended four times (in 1973, 1980, 1995 and 2005) in response to changes in the international spread of diseases with increased international travel and trade. The 2005 revision of the IHR was in response to the SARS epidemic.

The scope and purpose of the IHR is to prevent, control and provide a public health response to the international spread of disease that is proportionate to public health risk, whilst avoiding unnecessary interference with international trade and traffic.

Further information about the International Health Regulations can be found here: <u>International</u> Health Regulations (who.int) and International biosecurity obligations.

¹ State Parties are countries that have ratified or acceded to the *International Health Regulations 2005*.

How did the process for development of a new pandemic instrument come about?

The <u>Independent Panel for Pandemic Preparedness and Response</u> was set up by the WHO, in response to a request from the World Health Assembly (WHA)², to "provide an evidence-based path for the future, grounded in lessons of the present and the past, to ensure countries and global institutions, including specifically WHO, effectively address health threats." The Panel based its work on "insights and lessons learned from the health response to COVID-19 as coordinated by WHO".³

The Panel examined why COVID-19 became a global health and socio-economic crisis. The Panel published its findings in its report, *Covid-19: Make it the last pandemic*, in May 2021.⁴ The report identified a need for stronger leadership and coordination at national, regional and international levels to prevent and respond to pandemics and recommended the development of a new pandemic instrument to address gaps in the international response, clarify responsibilities between States and international organisations, and establish and reinforce legal obligations and norms.

In December 2021, at a Special Session of the WHA, WHO Member States, including Australia, agreed to commence negotiations on a new international instrument for pandemic prevention, preparedness and response (pandemic instrument), under the constitution of the WHO. Member States agreed to establish an Intergovernmental Negotiating Body (INB) to draft and negotiate the instrument for consideration at the 77th WHA in May 2024. The INB comprises all 194 WHO Member States, including Australia, and invited stakeholders and international organisations.

The pandemic instrument is intended to strengthen international cooperation in order to reduce the risk and impact of international health threats, such as that posed by the COVID-19 pandemic. For further information on the INB, please see our <u>frequently asked questions</u> and the <u>WHO INB</u> <u>website</u>

How did the proposed IHR changes come about?

In light of the COVID-19 pandemic, Member States agreed at the 75th WHA in May 2022, to establish a Working Group to consider targeted changes to the IHR. These changes would be limited in scope, and address specific issues and gaps, to support the implementation of the IHR and its universal application to protect people from the spread of international diseases.

The reforms currently being negotiated will ensure lessons learned during the COVID-19 pandemic are acted on. It will enable the IHR to remain responsive to evolving global public health threats and strengthen the ability of States Parties to co-operate internationally to prepare for, and respond to, infectious disease outbreaks and health emergencies.

The process to amend the IHR is being led by WHO Member States through the Working Group on Amendments to the International Health Regulations (WGIHR). The process builds on various review panels that examined the functions of the IHR and the global health architecture during the COVID-19 pandemic. This includes the Independent Panel for Pandemic Preparedness and Response mentioned above. All WHO Member States, including Australia, can participate in the negotiations.

² The World Health Assembly is the governance body for the World Health Organization. It is comprised of all 194 WHO Member States and meets annually.

³ Independent Panel for Pandemic Preparedness and Response, <u>About the Independent Panel</u>, accessed 18 May 2022.

⁴ Independent Panel for Pandemic Preparedness and Response, <u>COVID-19: Make it the Last Pandemic</u>, May 2021, p. 45.

For further information on the WGIHR, please see the Department of Health and Aged Care's frequently asked questions and the WGIHR website.

How do changes to the IHR relate to the pandemic instrument?

The process of amending the IHR runs in parallel with the INB. While the two processes are complementary in nature, they are two distinct processes led by Member States. Formal negotiations for both the pandemic instrument and IHR reforms are expected to conclude with agreed instruments for adoption at the 77th World Health Assembly (WHA) in May 2024.

What is the World Health Organization?

The WHO is a United Nations agency "that connects nations, partners and people to promote health, keep the world safe and serve the vulnerable – so everyone, everywhere can attain the highest level of health".⁵

3. Negotiations to the international legal framework for future pandemics and other international health emergencies

The Australian Government considers a new pandemic instrument and IHR reforms provide an important opportunity to strengthen national, regional and global preparedness for future pandemics and other international health emergencies as well as the WHO's ability to respond to future health threats.

What is the role of the WHO in these reform processes?

Both the pandemic instrument and changes to the IHR are being negotiated through intergovernmental mechanisms consisting of all WHO Member States. When requested, the WHO Secretariat provides technical input to guide negotiations. The WHO will continue to oversee the implementation of the IHR as it has done so since its inception. It is anticipated that the WHO will likely oversee the implementation of the pandemic instrument once it is finalised and agreed by WHO Member States, including supporting countries to implement their obligations under the instrument.

Will these instruments affect Australia's sovereignty or ability to decide its own approach to a future pandemic?

Australia's sovereignty to make policy decisions in the best interests of Australian citizens will not be affected.

The pandemic instrument and amended IHR will <u>not</u> grant the WHO powers to override national laws or decisions, or impose public health measures such as lockdowns, mandatory quarantines, or mandatory vaccines.

.

⁵ World Health Organization, <u>About WHO</u>.

Australia will retain its national right to decide its domestic health policies. These include public health and safety measures such as border control measures and the use of masks and vaccines.

For further information on the process for implementing the pandemic instrument and amended IHR, once negotiated, in Australia, please see Section 4.

How do negotiations to develop a pandemic instrument work?

Negotiations to develop a new pandemic instrument are conducted by an Intergovernmental Negotiating Body, comprised of all WHO Member States. The INB is led by a Bureau comprised of representatives drawn from the six WHO regions. Draft versions of the pandemic instrument, agendas, live webcasts, and reports of meeting outcomes are available on the WHO INB website. The latest draft of the pandemic instrument was released on 2 June 2023 and is available on the WHO website.

How do negotiations to amend the IHR work?

Negotiations to amend the IHR are governed by the WGIHR, set up specifically by the WHO to consider Member State proposals for reform. The WGIHR is currently considering more than 300 changes proposed by 96 State Parties to the IHR. Australia did not propose changes through the formal process and is engaging in the WGIHR to consider changes proposed by other States Parties. An article-by-article compilation of changes proposed by States Parties to the IHR is publicly available on the WHO website.

These changes have not yet been agreed. Proposed changes have been subject to technical review by an IHR Review Committee, comprised of experts from a range of relevant disciplines. The <u>terms of reference</u> for this Review Committee detail the scope of the work and analysis that the Committee was requested to undertake on the changes proposed by State Parties. In February 2023, the IHR Review Committee provided a <u>report</u> to the WHO Director General outlining their technical recommendations on the proposed changes. This report, and the changes as a whole, are now being considered by the WGIHR.

What is the current status of negotiations for these two processes?

The INB held a series of meetings in February, March and June 2022 to discuss proposals for a pandemic instrument. Further meetings have been held in July and December 2022, February – March 2023, April 2023 and June 2023, with more planned through to May 2024. Reports for each meeting are available on the WHO INB website.

The WGIHR has met four times, to establish procedures and engage in substantive discussions on proposed changes. Reports and agendas of each meeting are available on the WHO WGIHR website.

For a prospective timeline of INB and WGIHR meetings, please see Section 4.

The INB and WGIHR are expected to present final outcomes of the negotiations to the 77th WHA (the WHO's decision making body) for consideration in May 2024.

How is Australia involved in negotiations?

Both the INB and WGIHR are Member State-led processes. They have been set up to be open to all WHO Member States and "work in an inclusive manner." Australia was centrally involved in establishing negotiation processes which are inclusive and transparent and enable Member States to draw on technical expertise from relevant experts.

Representatives from the Department of Health and Aged Care and the Department of Foreign Affairs and Trade, informed by consultation across the Australian Government, are engaging actively in the negotiations to promote and protect Australia's interests.

What types of issues are being discussed during negotiations?

Together, both instruments are intended to form a coherent legal framework for preparing for, and responding to, future pandemics and other international health emergencies.

<u>In relation to the pandemic instrument</u>, Member States, including Australia, are actively discussing the following key issues:

- Achieving equity in, for and through pandemic prevention, preparedness, response, and recovery of health systems
- Ensuring predictable global supply chains and logistics networks
- Enabling co-development and transfer of technology
- Timely sharing of information, pathogens and their associated data, and equitable sharing of benefits arising therefrom
- Strengthening regulatory systems
- Increasing research and development capacities
- Pandemic prevention and public health surveillance
- Preparedness monitoring and pandemic simulation exercises
- Ensuring efforts to prevent, prepare for, and respond to, pandemics uphold human rights and protect the most vulnerable
- Applying a multisectoral approach to pandemic, prevention, preparedness and response, engaging stakeholders beyond the health sector
- Incorporating a One Health approach to pandemic prevention, preparedness and response
- Strengthening health system resilience as well as health and care workforce
- International coordination, collaboration, and cooperation on procedures and guidelines for pandemic prevention, preparedness and response
- Communication and public awareness
- Sustainable and predictable financing for pandemic prevention, preparedness, and response, and
- Governance arrangements to support effective implementation of the instrument.

<u>In relation to proposed IHR reforms</u>, IHR States Parties, including Australia, are actively discussing the following key issues:

• Strengthening disease surveillance and timely notification of disease outbreaks

⁶ WHO International Negotiating Body, 'Proposed method of work', 10 March 2021, WHO Doc A/INB/1/3 Rev.1; WHO Working Group on Amendments to the International Health Regulations (2005), 'Proposed method of work', 11 November 2022, WHO Doc A/WGIHR/1/3 Rev. 1.

- Strengthening global coordination, collaboration, and cooperation to respond to future health emergencies
- Strengthening compliance and implementation of IHR obligations
- Procedures for the determination of a public health emergency of international concern, including a regional alert system
- Strengthening public health responses to infectious disease outbreaks
- Strengthening implementation of IHR core capacities
- Financial and technical support to strengthen country implementation of IHR core capacities, and
- Notification, verification and provision of information in relation to disease outbreaks.

What are the Australian Government's priorities for a new pandemic instrument and amended IHR?

The Australian Government is working to ensure that any new pandemic instrument and changes to the IHR support countries to prepare for, and respond to, new public health threats. We want to better position Australia, our region, and the international community to prevent, and respond to future pandemics and other international health emergencies.

Australia's engagement in these processes is guided by the following key priorities and principles:

- Enhance global, regional, and national health capacities to better position the international community to respond to pandemics and other international health emergencies
- Enhance sharing of information on diseases with pandemic potential
- Equitable and timely access to health emergency countermeasures, such as vaccines, medicines, and personal protective equipment
- A One Health approach: recognising that the relationship between human, animal and environmental health should guide pandemic prevention
- Enhance the WHO's ability to assess and respond rapidly to outbreaks
- Strengthened national and global investment in health emergency prevention and preparedness
- Promote fairness, advance gender equality, and uphold human rights
- Support engagement with private and civil society stakeholders
- Ensure alignment with other relevant international agreements
- Uphold intellectual property rights in order to promote innovation and research and development, and
- Effective governance, accountability, and compliance mechanisms to support the implementation of the pandemic instrument and IHR.

Feedback and comments received through this consultation will guide the further refinement of Australia's priorities for engagement.

4. What Happens Next?

Will the pandemic instrument and changes to the IHR be legally binding in Australia?

Signing a pandemic instrument and agreeing to IHR changes may create new international legal obligations for Australia. The INB has <u>agreed</u> that the new pandemic instrument should have both legally binding and non-legally binding elements. The IHR is already legally binding on all 196 State Parties and the proposed changes are intended to be legally binding.

However, the pandemic instrument and changes to the IHR will not be legally binding on Australia until the instruments have gone through relevant parliamentary processes. Once negotiations are finalised and the World Health Assembly has adopted the pandemic instrument and changes to the IHR, the Australian Government will undertake <u>several steps</u> to decide whether or not to agree to these instruments. This includes consideration by the <u>Joint Standing Committee on Treaties</u> (JSCOT).

For further information on the treaty making process please see the Department of Foreign Affairs and Trade website.

What are recent developments, and key dates moving forward?

Figure 1 details key dates in the negotiation process to establish a new pandemic instrument and consider changes to the IHR:

Figure 1: INB and WGIHR Meeting Timeline

Date	Meetings
2022	
24 February	First meeting of the INB
14-15 March	First meeting of the INB (resumed session)
12-13 April	First round of INB public hearings
6-8 June	First meeting of the INB (resumed session)
18-22 July	Second meeting of the INB
21 September	INB informal, focused consultation: Legal matters
29-30 September	Second round of INB public hearings
5 October	INB informal, focused consultation: Operationalizing and achieving equity
7 October	INB informal, focused consultation: Intellectual property, production and transfer of technology and know-how
14 October	INB informal, focused consultation: One Health and antimicrobial resistance, climate change, and zoonoses
14-15 November	First meeting of the WGIHR

Date	Meetings	
2022		
1 December	IHR Review Committee - open session with Member States, UN technical agencies and non-state actors in official relations with WHO	
5-7 December	Third meeting of the INB	
2023		
12 January	IHR Review Committee on Amendments - open session with Member States, UN technical agencies and non-state actors in official relations with WHO	
20-24 February	Second meeting of the WGIHR	
27 February - 3 March	Fourth meeting of the INB and meetings of the drafting group	
28-30 March	Third meeting of the WGIHR	
3-6 April	Fifth meeting of the INB and continuation of meetings of the drafting group	
12-16 June	Continuation of the INB drafting group	
17-21 July	Sixth meeting of the INB and continuation of drafting group meetings	
21 and 24 July	Joint INB and WGIHR Plenary meeting	
24-28 July	Fourth meeting of the WGIHR	
4-6 September	Continuation INB drafting group meeting	
2-4 October	Fifth meeting of the WGIHR	
6-10 November	Continuation of the INB drafting group	
29 November - 1 December	Sixth meeting of the WGIHR	
4-6 December	Seventh meeting of the INB	
2024		
19 February - 1 March	Eighth meeting of the INB and continuation of the drafting group	
18-29 March	18–29 March	
27 May - 1 June	Pandemic instrument and targeted IHR changes to be presented to the 77th World Health Assembly for adoption. *	

^{*}If the instruments are adopted, Member States will consider whether to sign on to the pandemic instrument and adopt the changes to the IHR through their respective domestic processes (please refer to Section 4).