

Pandemic Influenza Preparedness Framework Review

Australia's submission April 2016

Australia welcomes the opportunity to participate in the PIP Framework review and makes the following written submission addressing the review questions.

Implementation of the PIP Framework is vital to global pandemic preparedness. Australia remains committed to the agreed objective of the PIP Framework to improve pandemic influenza preparedness and response, and strengthen the protection against pandemic influenza by improving and strengthening the WHO global influenza surveillance and response system, with the objective of a fair, transparent, equitable, efficient, effective system for, on an equal footing:

- (i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and
- (ii) access to vaccines and sharing of other benefits.

Australia considers the review provides a timely opportunity to reflect on progress to date, look at priority areas for improvement; and also consider how emerging challenges might be best addressed, particularly in relation to the advent of synthetic biology and the continuing emergence of novel pathogens with pandemic potential.

1. What are the achievements since the PIP Framework was adopted?

Overall, Australia considers the Framework has been a success. The highlight has been the Partnership Contributions, which have provided a robust and transparent mechanism, overseen by experts from a representative group of Member States, to mobilise additional funds for pandemic preparedness and response from the industries that benefit from the WHO's collective work – the work of the Secretariat and Member States – in this area.

The Influenza Virus Traceability Mechanism has provided an important mechanism for improving transparency on virus sharing and there has also been some progress in agreeing and implementing SMTA2s.

The Framework has also provided a novel benefit sharing mechanism with potential for expansion into other areas of WHO's preparedness work, for example virus and benefit sharing for novel pathogens and managing the implications of the Nagoya Protocol.

2. Has implementation of the PIP Framework improved global pandemic influenza preparedness, including inter-pandemic surveillance, and capacity to respond?

Virus sharing and use of Partnership Contributions

To the extent that Partnership Contributions have been implemented to improve surveillance and laboratory diagnostic capacity in low and middle income countries, Australia considers pandemic preparedness is likely to have improved. It is important however, that further qualitative assessment is undertaken by the Secretariat in consultation with relevant experts. It is concerning that any improved capacity does not appear to have been translated into an increase in virus sharing (noting the PIP Advisory Group Annual Report 2015 reports a 71% decrease in virus sharing in 2015).

Further, we consider that Secretariat's views should be sought on whether the system for virus sharing working optimally and what improvements could be made from the Global Influenza Surveillance and Response System perspective.

Australia would also like to see greater transparency on the allocation and implementation of the Partnership Contributions to have confidence that they are being directed to countries most in need, and that they are translating into improved capacity in those countries.

Additionally, an issue long unresolved from Australia's perspective was when a virus ceases to have pandemic potential and therefore no longer meets the definition of PIP Biological Materials. Any lessons learnt from the H1N1 experience in this regard are of particular interest.

Standard Material Transfer Agreement 2s

While recent progress has been made in the negotiation of SMTA2s with research or academic institutions, it is concerning that the slow progress in negotiating SMTA2s with manufacturers has the potential to undermine the equity of the benefit sharing arrangements – including for those manufacturers who have already signed SMTA2s. Australia and others have previously provided additional funding to WHO specifically for this purpose.

We encourage WHO to investigate measures to further accelerate finalisation of SMTAs with other manufacturers of vaccines, diagnostics and medicines and would support the use of a certain portion of the partnership contributions by the Secretariat to accelerate progress in negotiating SMTA2s.

In assessing whether implementation of PIP Framework has improved global pandemic influenza preparedness and capacity to respond, consideration should also be given to:

- Whether activities have been undertaken to build research capacity including among source countries (for example collaborative research efforts between countries contributing viruses, the Collaborating Centres and Essential Reference Laboratories).
- How capacity building efforts for influenza vaccine manufacturing have progressed in lower income countries, including an assessment of their effectiveness.
- How lessons learned from the 2009 pandemic in relation to the mobilisation of vaccines, anti-virals, and diagnostics have been incorporated into forward looking plans.

3. What are the challenges, and possible ways of addressing them?

Impact of genetic sequencing data

The implications of the availability and use of genetic sequencing data is a growing concern. Handling genetic sequencing data in the context of the PIP Framework has the potential to undermine the Framework's operation through circumventing benefit sharing. This review provides a good opportunity to ensure genetic sequencing data can be sufficiently managed under the Framework. Australia welcomes further consideration of arrangements for sharing of gene sequence data, as well as managing sharing of associated benefits into the future.

Novel pathogens

The importance of timely information sharing was a key learning from the Ebola outbreak in West Africa. It is apparent that an appropriate sharing agreement is required to ensure there are no delays in sharing viruses during future pandemics. In this regard, Australia considers that the Framework's successes need to be built upon in order to secure its place in the broader context of efforts to strengthen global health security.

The United Nations Secretary General's High Level Panel on Global Health Crises recommended addressing this issue through extending the PIP Framework to include novel pathogens (refer to recommendation 15). Australia would welcome further consideration of the appropriateness of including novel pathogens with pandemic potential under the Framework.

Nagoya Protocol

The potential public health implications of the Nagoya Protocol, including the sharing of influenza viruses by countries which have signed and ratified the Protocol, have been recognised but require more detailed consideration.

Australia acknowledges the work being undertaken by the Secretariat to analyse the implications and looks forward to considering its report at the 140th session of the Executive Board and in the interim, encourages Member States to continue to share viruses with pandemic potential.