Implementation of the Pandemic Influenza Preparedness Framework Written Submission to the Review Group AUSTRALIA

Australia welcomes the opportunity to participate in the PIP Framework review and makes the following written submission addressing the eight questions posed to Member States by the Review Group.

1) Has the PIP Framework helped better prepare Member States for a pandemic? How could this capacity be improved?

Broadly, Australia considers that the Framework has been successful in better preparing Member States for a pandemic. Forty-three (43) targeted countries were assisted through the provision of PIP funding and technical assistance, to improve and/or develop local laboratory capacity and surveillance processes. We welcome improved capacity in the PIP target countries in the Western Pacific Region (as detailed in the PIP Framework Annual Report 2015) - particularly risk communication training and support, and capacity for detection, monitoring (for virological data) and sharing in particular increasing towards stated targets.

Australia considers that Partnership Contributions have helped better prepare Member States for pandemics by providing a robust and transparent mechanism, overseen by experts from a representative group of Member States, which mobilises additional funds for pandemic preparedness and response from industries that benefit from the WHO's collective work in this area. 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 the Secretariat undertake further qualitative assessments in consultation with relevant experts to determine what improvements have occurred. Consideration should also be given to whether activities have been undertaken to build research capacity among source countries - for example collaborative research efforts between countries contributing viruses and the Collaborating Centres and Essential Reference Laboratories.

The Influenza Traceability Mechanism has also provided Member States an important pathway to improve transparency on virus sharing. It is concerning however, that as noted in the PIP Advisory Annual Report 2015, improved capacity does not appear to have translated into an increase in virus sharing (virus sharing decreased by 71% in 2015). Australia welcomes the April 2016 Advisory Group recommendation to the Director-General aimed at increasing virus sharing. We encourage the Secretariat to review sample sharing mechanisms and consider whether the system for virus sharing is working optimally; and whether improvements could be made to the Global Influenza Surveillance and Response System. Capacity could be improved by looking at whether the lessons learned from the 2009 pandemic in relation to the mobilisation of vaccines, anti-virals, and diagnostics have been incorporated into forward looking plans. Regional exchange strategies for influenza viruses with pandemic potential could be strengthened. Member States should be strongly encouraged to ensure the systematic and timely sharing of all viruses with pandemic potential through the Global Influenza Surveillance and Response System.

We acknowledge that as compared to 2009 the World Health Organization (WHO) has secured advanced access to three times the amount of pandemic vaccines and antivirals. We recognise the importance of Standard Material Transfer Agreements 2 (SMTA2s) in ensuring Member States have access to pandemic supplies during future health emergencies.

2) What are the key challenges in the implementation of the PIP Framework? What are possible ways to overcome these challenges?

There are a number of challenges inhibiting the full implementation of the PIP Framework.

Australia notes that ongoing funding for the implementation of the PIP Framework will be a key challenge moving forward. There is potential for other health issues to divert attention and resources away from PIP Framework implementation. It is necessary to highlight linkages between the PIP Framework and other emergency programmes and instruments, such as the International Health Regulations (IHRs), the Global Action Plan for Influenza Vaccines, the Joint External Evaluation tool and the Global Health Security Agenda (GHSA), to encourage capacity building and avoid duplication of effort.

Greater transparency is also required in the allocation and implementation of the Partnership Contributions. This would ensure confidence the contributions are being directed to countries most in need, and that they are translating into improved capacity for those countries. One avenue to achieve this could be by analysing and monitoring outcomes of Partnership Contributions to ensure their appropriate and effective use is in line with the April 2016 Advisory Group recommendation to the Director-General. Reporting on funded countries should be made publicly available; performance of activities should be appropriately measured, and: it must be clear that PIP funding is being used for PIP-related activities. Full participation (i.e. complete sharing of viruses) by countries receiving PIP funding with GISRS laboratories is critical - this has not always been the case. It may also be appropriate for the Review Group to consider a mechanism to discontinue funding to 'funded but non-compliant' countries or options to evenly distribute funding to eligible countries. Recipient countries should also focus on building national capacity to ensure laboratory and surveillance activities are sustainable in the long term.

3) Are the principles underpinning the PIP Framework, e.g. transparency, fairness, equity, efficiency, and virus sharing and benefit sharing on an equal footing, being implemented?

Australia remains committed to the agreed objectives of the PIP Framework. However, we consider that there is scope to improve the implementation of its principles. Australia remains concerned about the significant decline in virus sharing observed in 2015 and notes there are outstanding Partnership Contributions from identified contributors. Australia would welcome greater transparency in the selection of countries for PIP funding, as well as improved reporting on the use of funding (refer to question 2).

4) How should the PIP Framework ensure it remains relevant and effective?

Given the increasingly crowded global health security agenda, it is difficult to maintain focus on one disease. The PIP Framework and the Global Influenza Surveillance and Response System are useful models that could be used for the sharing of other pathogens. Further consideration should be given to identifying the synergies between established models such as the Global Health Security Agenda and the International Health Regulations to assist in reducing duplication of effort for global capacity building. The PIP Framework also needs to be integrated, where possible, with the new WHO Health Emergencies Programme.

It is crucial that the PIP Framework adapts to evolving aspects of technology - particularly genetic sequencing. The implications of the availability and use of genetic sequencing data is a growing concern and should be handled with caution. Genetic sequencing data should be sufficiently managed under the Framework as not to circumvent benefit sharing. Consideration should be given to arrangements for sharing of sequence data and associated benefits in the future. Australia notes the IHR Review Committee recommendation on sharing of genetic sequence data, and is grateful for the work being undertaken by the PIP Advisory Group - which offers a way forward on this issue in the context of the PIP Framework.

5) Have there been any collateral benefits (i.e. benefits beyond the initial intent) arising from implementation of the PIP Framework? If so what are these benefits?

The PIP Framework has provided a novel benefit sharing mechanism with potential for expansion into other areas of WHO's preparedness work - particularly virus and benefit sharing for novel pathogens; coordinating policies and practices that promote fair, equitable and transparent allocation of scarce medical resources during health emergencies, and; training for building emergency response capacity.

The global influenza vaccine production capability appears to have significantly increased. It is less clear what the funds provided through the PIP Framework have achieved in terms of Member State preparedness. It is recognised, however, that it may take a number of years before progress can be accurately captured. In the interim, further transparency around the use of funding would be valuable.

We note that the PIP Framework may have driven other projects or activities in other Member States, for example the designation of National Influenza Centres (NICs). Global pandemic response capacity and capability building may have the collateral benefit for Australia of greater access and information sharing.

6) What views do Member States have on using the PIP Framework as a model for sharing of other pathogens?

The importance of timely information sharing was a key learning from the Ebola outbreak - it is clear that an appropriate sharing agreement is required to ensure there are no delays in sharing viruses during future pandemics. An appropriate mechanism for the sharing of novel pathogens with pandemic potential is required. Thorough consideration needs to be given to whether this could occur under an expanded PIP Framework or if new mechanisms need to be established - potentially using the PIP Framework as a model.

Although the PIP Framework may be a useful model with applicability to sharing other pathogens, an expansion may pose significant challenges. Further consideration should be given to reviewing benefit sharing implications and identifying synergies between established global sharing models. This could assist in decreasing duplication of effort for global capacity building. Any expansion of the Framework would also need to consider the burden on the Global Influenza Surveillance and Response System laboratory network. A preliminary step could involve the sharing of the PIP Framework principles by demonstrating success in enabling virus sample and benefit sharing on equal footing.

7) How well is the work of the PIP Framework communicated to Member States?

Australia notes that the bulk of information that Member States receive is from meeting papers. We would welcome further dialogue outside of formal meetings and debriefs to share information. Of particular use would be regular reviews of implementation and policy, community and Member State surveys, and interaction to ensure stakeholder awareness and engagement with the Framework. These would allow for regular and timely feedback on emerging trends or concerns to be provided to the Advisory Group and Review Group.

The Review presents a timely opportunity to reinvigorate Member States engagement with the work of the PIP Framework.

8) How do Member States view their interaction with the PIP Framework Secretariat? How could this interaction be strengthened?

Australia appreciates the efforts of the PIP Framework Secretariat to improve transparency, through webcasting Advisory Group proceedings, newsletters, meeting face-to-face with missions and producing reports. Further dialogue outside of formal meetings and debriefs to share information would be welcome, as would greater visibility of progress and resources available to keep up to date with proceedings.