

**Pandemic Influenza Preparedness Framework
Written Submission to the Review Group**

**AUSTRALIA
September 2016**

Australia welcomes the opportunity to provide written comments on the Pandemic Influenza Preparedness Framework Review Group's preliminary findings.

Overarching Findings

Australia welcomes the preliminary findings in relation to the Framework providing an innovative approach to improving pandemic preparedness. We acknowledge the Framework's success in enabling virus and benefit sharing on an equal footing and establishing an innovative relationship between the public and private sectors. The Framework has also provided a critical tool to support WHO in securing access to vaccines and antivirals, funding capacity building and establishing a reserve fund for emergency responses.

Australia welcomes the findings in relation to ensuring the relevance of the Framework in the face of competing public health emergencies. Maintaining the currency of the Framework and promoting its continued relevance to all stakeholders is essential for its ongoing success. Australia supports improving communication about the Framework's achievements and decisions, as well as its collateral benefits to ensure ongoing commitment from stakeholders.

Australia supports additional monitoring to assess the implementation of the Framework as a whole, and would welcome a more robust performance measurement system to ensure that key outcomes are measured and standardised. We would also welcome a regular review of the scope and functioning of the Framework to continue to ensure its optimal use. A quinquennial (five-yearly) review could provide an appropriate timeframe to ensure continued relevance and mitigate against unnecessary administrative burdens.

Expanding the Framework to seasonal influenza and other infectious diseases

Australia remains committed to the agreed objectives of the Framework to improve pandemic influenza preparedness and response. We consider it is important to continue to build on the Framework's success and secure its place in the broader context of efforts to strengthen global health security, however note any decisions to expand the Framework's scope require thorough consideration.

Further detail of the Review Group's deliberations regarding expanding the Framework to include seasonal influenza would be welcomed, noting the associated complexities with this proposal. While this option presents a solution to the implications associated with the Nagoya Protocol (if the Framework is recognised as a 'specialized international access and benefit-sharing instrument for all human influenza viruses'), the increased workload and associated burden on the Framework's infrastructure, including the Global Influenza Surveillance and Response System (GISRS) and the Influenza Virus Traceability Mechanism (IVTM) is concerning. It is expected that the inclusion of seasonal influenza viruses under the Framework would be resource intensive and has the potential to overwhelm GISRS and impact the timeliness and effectiveness of GISRS members' essential 'business as usual' work.

Australia recommends the feasibility of this proposal be carefully examined in consultation with Member States and relevant stakeholders.

It's acknowledged that the Framework has provided a novel benefit sharing mechanism with potential to be used as a model for other infectious diseases. The importance of timely information sharing was a key learning from the Ebola outbreak, and expanding the Framework to include novel pathogens has been recommended by the UNSG High Level Panel on Global Health Crises. Australia considers appropriate sharing agreements are required to ensure there are no delays in sharing pathogens during future pandemics.

We acknowledge the Review Group's findings that expanding the Framework may be a very complicated process and potentially threaten its viability. While the sustainability of the Framework should remain a key priority, we would welcome further insight into the Review Group's deliberations on this issue, as well as the viability of encouraging broader interpretation of IHR Article 6 on sharing information to address this.

Virus Sharing

Early detection of viruses with pandemic potential and the rapid sharing of both information and viruses are critical for timely pandemic response. Australia remains concerned about the decline in virus sharing and welcomes the Review Group's findings to urgently address this.

Australia acknowledges the IVTM as a crucial component of the Framework in supporting the systematic and timely sharing of all viruses with pandemic potential and ensuring the principles of the Framework are appropriately upheld. We strongly support improving communication with WHO Collaborating Centres and National Influenza Centres (NICs) and providing further guidance on the interpretation of, and obligations under, the Framework, as well as the use of the IVTM, noting the limited exposure of some NICs to the IVTM and the risks this presents to operation of the Framework.

We urge the Secretariat to address the barriers to virus sharing as matter of priority, in line with the Advisory Group's recent recommendations (April 2016). We would also welcome further analysis by the Review Group regarding the reasons for the decrease and concrete recommendations regarding how to adequately address these.

Genetic Sequence Data

Australia supports further clarity around the handling of genetic sequencing data (GSD) to ensure consistency with the principles of sharing other PIP materials, and considers benefit sharing arrangements should be addressed as a matter of priority. We note the Review Group's finding that monitoring all access to GSD is unlikely to be feasible due to the many public and private ways of sharing and accessing GSD and associated workload implications, however monitoring GSD use in commercial end products and tracking commercial products would be achievable. It's acknowledged that WHO's leverage in this space will centre on the unwillingness for companies to buy products unless WHO can guarantee their structure and composition.

Australia shares concerns that changing the definition of PIP biological materials would require significant amendments and likely complex and timely negotiations. Further detail on the viability of developing an Annex for Article 6 to include GSD is warranted, while this approach appears reasonable in principle, it's acknowledged it may be very difficult to cover all possible sequence variations that could be produced.

It's acknowledged that the storage and sharing of digital information, including the uploading online of genetic sequences, is being considered in a number of international contexts, including for example, synthetic biology discussions through the Convention on Biological Diversity. Any approach should be informed by, and align with, developments in other international fora.

Benefit Sharing

Australia acknowledges the importance of Partnership Contributions in mobilising additional funds for pandemic preparedness and assisting target countries to develop capacities to detect and monitor novel influenza. While the Review Group's findings on Partnership Contributions implementation are noted, we would like to continue to see greater transparency in 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 and sustainable capacity in those countries. In this respect, Australia would welcome further engagement of Member States and regional and country offices in the planning, implementing and monitoring of Partnership Contributions, as well as improved communication regarding priority country selection for Partnership Contribution implementation.

We also note with concern that virus sharing is not increasing in four H5 affected countries despite an increase in resources and welcome the Review Group's recommendations to appropriately address this.

Governance

Australia broadly supports the findings in relation to the Framework's governance structure. Australia commends the work of the PIP Advisory Group in overseeing the implementation of the Framework and considers regular stakeholder engagement with Member States and the private sector an important component of the Framework's successful operation. We also support encouraging regional office participation in Advisory Group meetings, noting regional and country offices important role in promoting and supporting the Framework.

As per the findings, opportunities to increase stakeholder engagement with civil society, GSIRS members and WHO Collaborating Centres should be explored, noting these centres hold a repository of knowledge which can be drawn on to strengthen the Framework, informed by the parties directly affected. Further outreach will also assist to clarify the relevance and importance of the Framework amongst all stakeholders.

Australia supports the necessary human and financial resources being provided to support the work of the Advisory Group and the PIP Secretariat to enhance capability, particularly in the context of implementing the recommendations of the Review Group.

Linkages with other instruments and WHO programmes

Ensuring alignment and synergies between activities under the Framework and other preparedness programmes and instruments is important, particularly in the context of capacity building. It's acknowledged that there may be collateral benefits of Partnership Contributions being spent on improving IHR capacities and Australia would support further analysis being undertaken during the next review.

Australia welcomes the preliminary findings in respect to the Nagoya Protocol. Australia considers that the PIP Framework is a 'specialised international access and benefit-sharing instrument' under Article 4(4) of the Nagoya Protocol for pandemic influenza viruses and would welcome formal acknowledgement by the World Health Assembly to provide clarity and facilitate global understanding. We welcome the work being undertaken by the Secretariat to consider the public health implications of the Nagoya Protocol, particularly on the production of seasonal influenza vaccines, noting that uncertainty over legal obligations under the Nagoya Protocol may lead to delays in sharing materials and look forward to considering the outcomes of the Secretariat's work.