FACT SHEET

Purpose of the Analysis requested by Member States in decision WHA70(10)8(b)

Background

The Pandemic Influenza Preparedness (PIP) Framework, adopted in 2011, aims to improve pandemic influenza preparedness and response and strengthen the protection against pandemic influenza, with the objective of fair, transparent, equitable, efficient and effective benefit sharing. In accordance with section 7.4.2 of the Framework, WHO established the PIP Framework Review Group (PIP Review Group) in 2016, mandated to review the Framework with a view to proposing revisions reflecting developments, as appropriate, to the World Health Assembly in 2017.¹

The PIP Review Group found that the principles of the PIP Framework, especially that of placing virus sharing and benefit sharing on an equal footing, remain as relevant today as they were in 2011, given the unique threat that the ever-changing influenza virus presents for public health and the increasing number of health emergencies, such as the Ebola virus disease and Zika virus outbreaks.²

Further, maintaining the contribution of the PIP Framework and demonstrating the benefits of pandemic influenza preparedness are especially important, as countries with several competing health priorities usually focus their attention on current local disease threats and therefore may be unprepared for an influenza pandemic.³ The PIP Framework must continue to demonstrate its contribution towards increasing global health security in the context of a wider landscape of public health interventions in order to remain relevant to policymakers, government, industry and intergovernmental organizations.⁴

However, the PIP Review Group also noted that “there are key issues that must urgently be addressed for the PIP Framework to remain relevant, including the issue of how GSD [genetic sequence data] should be handled under the PIP Framework, and whether or not the PIP Framework could be expanded to include seasonal influenza”.⁵ The Review Group received wide-ranging views from key informants, including Member States, industry and civil society, on both of these complex and challenging issues.⁶

Mandate received through decision WHA70(10)

After considering the PIP Review Group’s report in May 2017, the Seventieth World Health Assembly, in decision WHA70(10), commended the PIP Review Group’s recommendations and requested the Director-General to take them forward expeditiously. Furthermore, the Assembly requested the Director-General “to conduct a thorough and deliberative analysis of the issues raised” by the Review Group’s recommendations on seasonal influenza and GSD, including the implications of pursuing or not pursuing possible approaches, relying on the 2016 PIP Framework Review and the expertise of the PIP Advisory Group, along with transparent consultation of Member States and relevant stakeholders, including the Global Influenza Surveillance and Response System (GISRS).⁷

Seasonal influenza and the PIP Framework

In defining its scope, the PIP Framework states that it “does not apply to seasonal influenza viruses”.⁸ It should be noted, however, that seasonal viruses and those with pandemic potential exist as a continuum, involving humans, birds and other animals. Influenza viruses with pandemic potential (IVPP) result from the continuously evolving nature of influenza viruses, which can re-assort with other influenza viruses. This is known as “antigenic shift” and can lead to new viruses with pandemic potential.

The distinction between seasonal and pandemic viruses can present challenges. This becomes particularly evident when a virus – such as the influenza A(H1N1) – causes a severe epidemic in a country well after the original pandemic has been declared over. This happened in May 2016 in Fiji, when influenza A(H1N1) caused several deaths in pregnant women, well after the pandemic had been declared over.⁹

Additionally, the overwhelming majority of viruses shared through the GISRS are seasonal viruses. The bulk of GISRS work is based on seasonal risk assessment; virus characterization; the development of candidate vaccine viruses (CVVs), reagents and diagnostic kits; and vaccine virus recommendations for the seasonal vaccine. This is of critical importance.
to manufacturers and countries. Moreover, robust seasonal vaccine production is vital for pandemic vaccine production, since the same facilities are used for both.

Notwithstanding the strong linkages between seasonal and pandemic influenza, the PIP Review Group highlighted the need to carefully examine the implications of expanding the PIP Framework to include seasonal influenza, including potential workload implications for GISRS laboratories, and how to address benefit sharing.

Genetic sequence data and the PIP Framework

The PIP Review Group also considered GSD, which is not included in the definition of PIP Biological Materials (BM). GSD is important for surveillance and risk assessment because sequences from circulating influenza viruses can reveal specific genetic changes that have been associated with pathogenicity and human-to-human transmission. GSD is also used to study influenza virus evolution, and segments of GSD can be used to design primers and probes for diagnostics. While GSD generally cannot fully substitute for physical virus samples in areas such as product development (mostly due to regulatory requirements), GSD is increasingly being used to develop new types of vaccines.

On the matter of how GSD should be handled under the PIP Framework, some good progress has already been made by the PIP Framework Advisory Group. In accordance with PIP Framework section 5.2.4, the Director-General has been consulting with the Advisory Group “on the best process for further discussion and resolution of issues relating to the handling of genetic sequence data” from influenza viruses with pandemic potential, as part of the PIP Framework. There are diverse views among the numerous stakeholders involved in the discussions around the handling of GSD under the PIP Framework. Some favour strict traceability and monitoring of access and use, while others see advantages to more flexibility. It was clear from the PIP Review Group’s interviews and wider discussions that there remains some confusion as to potential options for future data sharing and operating procedures. A key challenge has been the lack of agreement on what should be traced or monitored and how benefit sharing should be structured. Options could include tracking access to GSD or tracing commercial products developed using GSD. Transparency in both the sharing and traceability of GSD would be crucial in identifying any resulting benefit that should be shared.

Many IVPP sequences are already being shared; what is not currently clear under the PIP Framework is how GSD sharing should trigger benefit sharing and what the trigger should be. Therefore, the PIP Review Group concluded that clarity is urgently required on the handling of GSD under the PIP Framework to ensure that it is guided by the same principles as those used in the sharing of PIP BM.17

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4. Ibid.
8. See PIP Framework section 3.2.
10. See PIP Framework section 4.1.
13. Ibid.
14. Ibid.
16. Ibid.