

Germany's responses to the questions to Member States posed by Review Group of the PIP-Framework

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

- The PIP Framework has improved virus and benefit sharing, which is essential to prepare for appropriate and timely response (e.g. vaccine production) to any potential pandemic threat.
- Global seasonal influenza vaccine production capacity has been increased over the last 10 years from 500 Mio to 1700 Mio doses.
- However, the current global capacity is still not sufficient to appropriately cover global vaccine demand in case of a severe influenza pandemic. Further sustained regional vaccine production capacity is needed specifically in low and middle income countries.

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

- Procedures for timely deployment and import of medical countermeasures (MCM) are crucial to respond efficiently in case of an outbreak.
- Switch of vaccine production from seasonal to pandemic production need to be globally triggered by WHO following a clear and transparent process and should be based on a thorough risk assessment when initiating a pandemic vaccine production.

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?

- In general, the principles are implemented including signing of a SMTA-2 along with an Influenza Virus Traceability Mechanism (IVTM) to record the transfer of PIP biological material. Regarding benefit sharing, industry responsibilities include partnership contributions to support capacity building. Capacity for influenza surveillance is strengthened in developing countries and some activities will extend into 2017.
- Implementation of the PIP Framework is a continuous but varying process. While sharing of PIP biological materials initially increased after adoption of the PIP Framework, recent data point to a decreasing trend in IVPP virus sharing. The PIP Advisory Group discussed several approaches to improve virus sharing and agreed also on the need for operational guidance on the PIP Framework.
- Moreover, genetic sequence data (GSD) are of great importance with regard to pandemic preparedness and has to be included in the PIP sharing and benefit systems. Most GISRS laboratories are providing GSD via GISAID, a database that addresses the principles underpinning the PIP framework. Thus, fair and transparent sharing of GSD is basically ensured and contributors are provided with the necessary incentive to rapidly share GSD.

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

- Maintaining of virus and benefit sharing is the most important pre-requisite.
- Balancing the preparedness and response activities, e.g. more efforts on response activities should be considered.
- Ensuring the sharing of GSD in a timely, fair and transparent manner, thus maintaining the choice of the kind of database (with or without data access regulation) contributors may use when sharing the GSDs as it is stated in the PIP-Framework (see No. 5.2.2); in addition please consider our comments to the draft paper "Options to monitor the use of genetic sequence data from influenza viruses with human pandemic potential (IVPP GSD) in end-products".

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.

- Strengthening of international cooperation by technology transfer and capacity building (e.g. laboratory and regulatory capacity, training).
- Possibility to use established systems and networks for surveillance and detection beyond pandemic influenza.

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

- Although the PIP framework is, in principle, implemented, with regard to Genetic Sequence Data (GSD) a number of mechanisms have to be established for handling of GSD derived from influenza virus with pandemic potential (IVPP) under the PIP framework. Especially monitoring of the use of IVPP GSD in end products (i.e. specific vaccines or diagnostics) is a key issue.
- At present, PIP focuses only on global threats having the potential of causing a pandemic as new influenza viruses emerging in animals may have. However, the general requirement of Access and Benefit Sharing (ABS) under the Nagoya Protocol has to be urgently addressed for other pathogens as well. Thus, recommendation 15 of the Report of the UN-High Level Panel on the Global Response to Health Crises released in January 2016 suggest to re-negotiate the PIP-Framework to include novel pathogens. However, it needs to be further discussed whether the PIP-Framework might be extended to other pathogens or remain limited to pandemic influenza and at the same time a separate framework could be developed, following the core principles of the PIP-Framework while addressing additional important pathogens.

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

- In the recent past there was intensive and fruitful exchange between the PIP framework and Germany concerning the meaning, key points and aspects of sharing and benefit systems in general as well as the role of database structure and content for improvement of the cooperation of all participating countries/ institutions. From a German perspective, it would be useful and important to learn more about the opinion and strategies and key points of other Member States. Thus we would welcome a broader discussion about the different aspects as for example the most suitable modi

for exchange of genetic sequence data, respect of inherent right, i.e. copyrights, on virus/ sequence data while ensuring a high level of transparency at the same time.

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

- Germany welcomes the intensive and timely exchange of information in the cooperation with the PIP framework Secretariat. We believe it could be helpful in some circumstances to even intensify the exchange and consultation with all Member States in order to reflect all views of Member States when documents and protocols are being prepared. In the case when there are different opinions among Member States, it would be of merit to have these differences in views reflected in the relevant documents so as to inform all Member States in the most transparent manner.