

22. März 2016

Entwurf DEU-Sprechpunkte

Third Meeting of the Pandemic Influenza Preparedness Review Group, open session

Geneva, 30 March 2016

Germany welcomes the initiated review process and the work of the PIP-Secretariat.

Undoubtedly, the implementation of the PIP-Framework has contributed to improve global pandemic influenza preparedness.

The PIP-Framework can already be named a success story. However, it is a success story in progress with many challenges ahead.

The PIP-Framework names two key goals. The **first** is to increase the access of developing countries to vaccines and other pandemic related supplies:

- To achieve this, fair sharing and effective and efficient use of benefits is crucial. In this regard, the preparedness work resulting from the PIP-Framework should be linked to the accelerated process of implementing the International Health Regulations' core capacities.
- Just to give another example, in the next years, the production capacity for vaccines will be a key priority. The Global Action Plan to increase vaccine supply, GAP, has at least in some regions resulted in an improved rate of vaccination and availability of vaccines. We are, however, far away from having sufficient production resources. Germany would appreciate it if both activities, namely the PIP process and the GAP, would co-operate with a view to increasing regional vaccine production technology and the development of more efficient vaccines that need a smaller amount of antigens.

Key goal number two named by the PIP-Framework is to improve and strengthen the sharing of influenza viruses with human pandemic potential:

- We agree, for this, the handling and sharing of genetic sequence data (GSD) for influenza viruses with pandemic potential and benefiting from doing so are crucial issue for the future. The technological development, allowing GSD being used to manufacture vaccines and other influenza-related products, underlines the need to address regulatory and intellectual property issues, including benefit sharing, but also monitoring and tracing methods, as well as biosecurity and biosafety issues.
- The Technical Working Group (TWG) on the "sharing of influenza genetic sequence data under the PIP Framework" has provided a well appreciated draft paper on "Optimal Characteristics of an influenza genetic sequence data sharing system under the PIP Framework". Germany considers the GISAID EpiFlu™ Database addressing most if not all characteristics for the optimal sharing of GSDs as described by the

Technical Working Group, in particular allowing the sharing of genetic sequence data in the spirit of PIP Framework, ensuring fair, timely and transparent access to GSD in a sustainable way.

- GISAID has also the potential through its Data Access Agreement to monitor the use of GSDs, and therefore to ensure that benefit sharing obligations are met by the users.
- To foster GSD sharing, Germany will therefore continue its support for the PIP-Framework and in particular continue to host GISAID.
- Germany submitted comments to the TWG paper. In our comments we have applied a “one health” approach, compiling input of our experts from the human and animal health sector. In our comments we have also raised questions on missing justifications for some options and on the rationale why other potential options were not included in the paper. We are convinced and are grateful that the PIP Review Committee will consider Germany’s comments on the paper, as well as the Review Committee will do with the comments received by other member states and entities.

Upfront to this meeting the PIP Framework Secretariat and the Review asked for views on three essential questions on the PIP-Framework:

- 1) What are the Framework’s achievements?
- 2) Has the implementation of the PIP-Framework improved global pandemic influenza preparedness?
- 3) What are the challenges ahead?

As asked for on the PIP-Review Committee website, Germany will submit written comments on this questions in due course. Our comments will be based on thorough consultations with our experts.