

GERMANY'S STATEMENT
ON SUBSTANTIVE ISSUES AND CONCERNS REGARDING THE PIP FRAMEWORK AND ITS IMPLEMENTATION
Special Session of the PIP Advisory Group, 13 October 2015

Germany would like to thank the Advisory Group and the PIP-Secretariat for the invitation to this important meeting and the opportunity to express its views on some aspects that should be considered during the review process, especially the importance of capacity building and the sharing of influenza genetic sequence data (GSD)

Germany considers the PIP framework as a very successful instrument for fostering pandemic preparedness and contributing to an equal access to efficient countermeasures. However, there is some room for improvement.

The first years of the PIP process focused on epidemiological preparedness and the establishment of national influenza centers. 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 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.

Another aspect that Germany would like to highlight is the handling of gene sequence data.

The Federal Republic of Germany entered, in 2010, into a public-private partnership with the GISAID Initiative and has since hosted the publicly-accessible EpiFlu™ database, employing a unique sharing mechanism which ensures that inherent rights (e.g. IPR) of contributors of GSD are not forfeit. Access to EpiFlu™ is free and open to anyone who positively identifies himself or herself and agrees to respect the rights of contributors. This ensures fair and transparent sharing of GSD, making certain that all users mutually respect the rights of contributors and other users. Importantly, this mechanism provides contributors with the necessary incentive to rapidly share GSD, in the interests of Global Public Health.

The WHO Collaborating Centers for Influenza (WHO CCs) provide scientific oversight and, as stressed in last year's AG October Report, most GISRS laboratories use GISAID.

In relation to monitoring the use of GSD under the PIP Framework, access to GSD in EpiFlu™ can be traced, permitting lawful audits and providing the basis for an enforceability mechanism, and recourse of MS should the need arise. Like other MS, Germany is concerned about access to GSD of highly pathogenic influenza viruses and believes systems like GISAID make a valuable contribution to Global Health Security. It is of the opinion that GSD have to be part of the sharing and benefit schemes under the PIP Framework. Systems like GISAID contribute in this sense to Global Health Security.

While the PIP-FW does not address a generic term for such a database, we would like to point out that GISAID satisfies all the conditions of the Definition of an Open Access Contribution stated the Berlin Declaration (2003), in particular "to provide a mechanism to enforce proper attribution":

Germany understands that some aspects of the handling of data might need clarification and streamlining with the PIP process. We would be happy to contribute to the further development of the PIP process, in particular by contributing our experience with the data-sharing system.

Thank you for your attention!