Submission to the RG from Germany
12 August 2006

In the briefing of 29 August 2016 Member States were given the opportunity to submit comments to the presented "Preliminary Findings" of the PIP-Review-Group until 12 September 2016. Please find below some first comments to be forwarded to the Review Group. Please note that these comments are not exclusive. Due to the very limited time given, an in-depth analysis could not have been performed. Hence, we do not necessarily agree with findings we have not commented on, as further in-depth analysis and discussion is ongoing.

Using the PIP FW as a model for other pathogens
Finding 1
Germany agrees with the finding that expanding the current framework to pathogens other than influenza might be a very complicated process. Thus it seems to be beneficial that the PIP FW should institutionally be furthermore part of the influenza-program within the structure of WHO.

Genetic Sequence Data
Finding 3
In our point of view publication (at least) IVPP data should be performed preferably in databases having a mechanism to trace the source laboratory as well as the further usage of the GSD (f. e. GISAID offers these possibilities). This procedure should be adequate to the traceability sourcing from end-products (which is not established yet).

The idea of handling GSD in a special section seems to be favorably. The complex of traceability should be clearly straightened in this section.

Standard Material Transfer Agreement 2 (SMTA2)
Finding 3:
"Although SMTA2s were designed to be broad enough to accommodate a range of commitments, no companies to date have agreed to provide technology transfer. This reluctance to enter into technology transfer agreements may be for intellectual property rea-sons or because not all eligible manufacturers have influenza-relevant technologies that could be made available for license through WHO."
Since WHO does not license products, the last sentence could be misleading and therefore should be changed accordingly.

Finding 7:
"Member States with in-country influenza vaccine production capacity need to include the SMTA requirements of the manufacturer(s) into their pandemic influenza response plans. It is essential that Member States ensure that manufacturers can fulfil their SMTA2 commitments to provide WHO with real time access to pandemic vaccines and allow the ex-port of these vaccines to other countries."
Although some Member States might have in-country vaccine production capacity, various manufacturing steps (e.g. antigen production, formulation, filling, packaging) might take place in different Member States, especially during a pandemic due to capacity constraints. In addition, global vaccine manufacturers might have confidential contracts with a number of Member States to provide pandemic vaccine. It seems not to be feasible that Member States can ensure that these manufacturers fulfil their SMTA2 commitments since MS are not contractual partners. It would be of interest how and on which base a possibility for the MS to exert influence to the manufacturers is seen by the WHO.

Partnership Contribution collection
Finding 2:
"….However Member States have signed up to the Framework and can hold their companies to account to fulfil these obligations."
Member States do not have information on which companies have signed a SMTA2 and which of these companies have fulfilled their contribution payments. Moreover, Member States have no legal mechanism to enforce payment by companies.

Nagoya Protocol to the Convention on Biological Diversity
It might be pointed out that the preamble of the Nagoya Protocol neither explicitly includes nor excludes pathogens.

We look forward to receiving the finalized report of the PIP-Review's Group findings and wish to express again our sincere gratitude to the work of the Review Group.

Kind regards,
Christophe Bayer

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Bundesministerium
für Gesundheit

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