



Joint Plenary Meeting of the Intergovernmental Negotiating Body (INB) and the Working Group on Amendments to the International Health Regulations (WGIHR) (2005): Agenda item 3

24 July 2023, Geneva – The innovative pharmaceutical industry appreciates the opportunity to provide our view on moving toward coherence and complementarity.

On the joint issue discussed at IHR and INB related to access to pathogens and equitable access to pandemic countermeasures, we are concerned to see the Pandemic Influenza Preparedness (PIP) model used as a reference for developing solutions as we consider it unfit to ensure better pandemic preparedness and response, and not practically replicable beyond influenza for the following reasons:

1. There is a well-established, centralized tracking and sharing of influenza pathogens. For all other pathogens, sharing occurs through various networks, as well as bilaterally. Bringing all under the umbrella of WHO would be technically and legally challenging and would undermine the efforts of already established networks.
2. There are only a handful of influenza manufacturers, making it possible to sign Standard Material Transfer Agreements (SMTA2s) in inter-pandemic periods. Identifying who will be the successful innovators in the next pandemic is not possible. Applying the PIP model would imply signing SMTA2s with hundreds, possibly thousands of entities involved in vaccine, therapeutic, and diagnostic R&D related to pathogens of pandemic potential. You have to bear in mind that, over the last decade, only 14 SMTA2s were successfully signed.
3. The PIP model does not provide an obligation to share pathogens and does not solve the issue of burdensome national access- and benefit-sharing laws being applied to influenza samples, where we have already seen cases of national ABS rules negatively impacting supplies of seasonal influenza vaccines.
4. An SMTA does not address export restrictions, which were a key barrier to equitable access during COVID-19, and hence might prevent companies' ability to comply with supply obligations.
5. Finally, PIP has fortunately never been used and tested since its creation and remains a theoretical model.