

**United States Feedback to the Preliminary Findings of the  
Pandemic Influenza Preparedness (PIP) Framework Review Group**  
September 14, 2016

The United States thanks the Director-General, the PIP-FW Secretariat and the members of the Pandemic Influenza Preparedness Framework Review Group for the PIP-FW Review preliminary findings report. The United States maintains its commitment to global influenza preparedness and response through implementation of the PIP Framework and encourages WHO's continued prioritization of pandemic influenza. In addition to previous written comments provided throughout the PIP-FW review process, the U.S. is providing technical feedback to specific findings which require further consideration and/or clarification. We look forward to the opportunity to review the Review Group's full findings report.

**General Comments**

The report references evidence relied upon by the Review Group in making several findings but does not include the evidence in this report. We look forward to reviewing in the final report the evidence upon which the Review Group's findings are based, noting in particular our interest in the evidence relied upon for Virus-Sharing Metric Finding 1 regarding a noted steady decline in sharing over the past two years, and Partnership Contribution Implementation Finding 7 noting that virus sharing is not increasing (e.g., shipping concerns, not following protocols, etc.).

**Comments on Specific Findings**

Overarching Finding 3 and Virus Sharing Finding 4

We support the findings' acknowledgment of benefits beyond those facilitated through the Partnership Contribution and STMA2.

Expanding the Framework to Seasonal Influenza

We support continued recognition of the linkage between seasonal and pandemic influenza efforts/programs (see, e.g., Overarching Finding 3). While we note the Review Group's finding regarding expanding the Framework to seasonal influenza, we recommend and encourage that any decision on such an expansion should be done so through a comprehensive consultative and analytical process sooner rather than later. In particular, any expansion of the Framework should not place undue burden on the Global Influenza Surveillance and Response System (GISRS) and its process for timely sharing of seasonal viruses. The potential expansion should also be driven by sound public health policy rather than a perceived need to situate the Framework within separate international regimes (e.g., the Nagoya Protocol as stated in the Overarching Finding).

Improved Communication about the Framework

Regarding the improved communications finding, the process for determining which countries receive PIP Partnership Contribution (PC) support should be clarified for future determinations, including the guidance to regional offices and any processes that may be put in place. Related, specific examples of how the PC has contributed to the GISRS and the development of multi-year plans and capacity building should be included in the final report.

#### Genetic Sequence Data

The United States encourages the Secretariat to organize continued thoughtful discussion of how genetic sequence data (GSD) should be handled under the Framework. We note that future discussions would benefit from robust consideration of the meaningful differences between GSD and biological material. These discussions would also benefit from a more complete understanding of the benefits engendered by the sharing of GSD. Access to GSD may call for different thinking about what type of benefits should be triggered, and a simple mapping of the current benefits tied to biological material may not be appropriate. We encourage Member States to focus on other benefits such as attribution, and inclusion of scientists from GSD-originating countries in research, among others.

#### Benefit Sharing Finding 5

Regarding Finding 5 under the SMTA-2 section, all trainings should be vetted and coordinated through existing groups within the Collaborating Centers (CCs) and WHO Global Influenza Program to ensure consistency and avoid duplicative efforts.

#### Governance Finding 7

We want to highlight Finding 7 and encourage the greater interaction among GISRS members, including the CCs, the Advisory Group, and the PIP Secretariat. This will be particularly important as the PIP PC Implementation Plan II is developed.

#### Linkages with Other Instruments and WHO Programs

We support the findings dedicated to the Global Action Plan for Influenza Vaccines and the International Health Regulations. It is important that the final report fully assess these collective efforts dedicated to capacity building and outline clearly how program and resource efforts are complementary.

We support the finding that notes that awareness of the Nagoya Protocol “in sectors other than the environment is limited, and its potential implications for public health are not widely understood.” This lack of awareness underlines the problems engendered by applying an instrument designed for biodiversity conservation purposes to the public health realm. As implementation of the Nagoya Protocol by its Parties has the potential to impact global public health, we stress the need for health ministries to work closely with environmental ministries on issues related to access to and benefit sharing of genetic resources. The United States maintains that the Nagoya Protocol is not applicable to influenza viruses with pandemic potential and there should be no conflict between the Protocol and issues related to public health.