FACT SHEET
Process for amending the PIP Framework

Background
During the outbreaks of H5N1 influenza in 2006, it became clear to WHO Member States that a formal arrangement was needed to increase equitable access to vaccines during influenza pandemics, particularly for countries in need. At the same time, Member States recognized that ongoing, systematic virus sharing was critical to ensuring continuous global monitoring and risk assessment and to aid in developing safe and effective pandemic influenza vaccines.

In 2007, Member States came together to start negotiating the PIP Framework. In doing so, WHO facilitated a landmark step forward in public health, when the PIP Framework, including its annexes, was adopted by consensus at the Sixty-fourth World Health Assembly (WHA) on 24 May 2011 in resolution WHA64.5. Resolution WHA64.5 was adopted in accordance with Article 23 of the WHO Constitution, which gives authority to the WHA “to make recommendations to Members with respect to any matter within the competence of the Organization”. The text of the PIP Framework is annexed to resolution WHA64.5.

Any amendment to a recommendation of the WHA requires that the WHA express its will to revise such recommendation and articulate clearly what changes are agreed with reference to the original recommendation. This typically occurs through the adoption, by the Assembly, of a subsequent resolution or decision on the same subject.

Approaches to amending the PIP Framework
In decision WHA70(10) on the Review of the PIP Framework, the WHA requested the Director-General to, inter alia, conduct a thorough and deliberative analysis (“the Analysis”) of the issues raised by the Review Group’s recommendations on seasonal influenza and genetic sequence data (GSD), including the implications of pursuing or not pursuing possible approaches.

If, further to the consideration of that Analysis, Member States decide to amend the PIP Framework to include seasonal influenza viruses and/or GSD, a number of possible approaches could be taken:

- Adding a new definition to section 4 or modifying an existing definition — such changes would then apply to every appearance of the term throughout the text;
- Adding a new provision or modifying an existing one;
- Adding or modifying a footnote; for example, the Operational Exemption footnote regarding the definition of “PIP biological materials” under section 4.1 could be amended to accommodate the handling of PIP biological materials under certain circumstances;
- Adding one or more new annexes;
- Any combination of the above approaches.

1 The PIP Framework has five annexes: 1) Standard Material Transfer Agreement 1; 2) Standard Material Transfer Agreement 2; 3) Advisory Group Terms of Reference; 4) Guiding Principles for the development of terms of reference for current and potential future WHO Global Influenza Surveillance and Response System (GISRS) laboratories for H5N1 and other human pandemic influenza viruses; and 5) Terms of Reference related to work with pandemic influenza preparedness biological materials.