

**Pandemic Influenza Preparedness:
Framework for the sharing of Influenza viruses and
access to vaccines and other benefits
("PIP Framework")**

Overview

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Objectives of PIP Framework

- Brings together Member States, industry, other key stakeholders and WHO to **implement a global approach** to pandemic influenza preparedness and response
- Two main objectives to be pursued **on an equal footing**:
 - To **improve sharing of influenza viruses** with potential to cause a pandemic among humans (called "**PIP biological materials**" or "**PIPB**")
 - To achieve more predictable, **efficient and equitable access** to benefits arising from the sharing of viruses, notably vaccines and antiviral medicines

Framework Principles

Intensity of negotiations and broad aspirations of WHO Member States are reflected in the many Principles (excerpts below) adopted in the Framework

- **Focus on countries most at risk** for impacts of future pandemics
- Need for **rapid, systematic and timely sharing** of viruses
- Implementation **consistent with national/international laws**

Scope of PIP Framework

- Applies only to sharing of H5N1 and influenza viruses with human pandemic potential and the sharing of benefits from them
- **Does not apply to seasonal influenza viruses** or other non-influenza pathogens or biological substances that may be contained in clinical specimens shared under Framework

Main Elements of PIP Framework

- Virus sharing
- Benefit sharing
- Governance and review

Virus sharing

- Member States share “influenza viruses with potential to cause human pandemic”
- Virus sharing facilitates global preparation for the next pandemic particularly through
 - Assessment of pandemic risk
 - Development of pandemic vaccines

Framework Tools

The Framework has many tools to facilitate achievement objectives:

- Influenza Virus Traceability Mechanism
- Guiding principles for development of Terms of Reference (“TOR”) for laboratories in the Global Influenza Surveillance and Response System (“GISRS”)
- Terms of reference for all GISRS labs
- Standard Material Transfer Agreements (“SMTA”) 1 & 2
- Partnership Contribution

Tools ...

- **Influenza Virus Traceability Mechanism**
 - Internet-based tool to track movements of PIP Biological Materials (PIPBM)
 - Publicly available at <https://extranet.who.int/ivtm/>
- **Guiding Principles for development of Terms of Reference**
 - For current and future GISRS labs working with PIPBM
- **Terms of Reference for all GISRS labs**
 - Currently, 4 categories of labs with different TORs

Tools... SMTA 1

- Incorporated into all GISRS laboratory TORs
- Establishes rights and obligations of GISRS laboratories when transferring PIPBM both within GISRS and to parties outside GISRS

Tools... SMTA 2

- Signed between WHO and all recipients outside of GISRS that receive PIPBM
- **Creates 3 categories of recipients** (The term “Recipient” is defined in SMTA 2, Article 1 Footnote 1)
 - Cat. 1: Manufacturers of influenza vaccines & antivirals
 - Cat. 2: Manufacturers of other products relevant to pandemic influenza preparedness and response (such as diagnostic kits); and
 - Cat. 3: Others including biotech firms, research and academic institutions
- All recipients must assess benefits they can contribute based on their nature and capacity – Category 1 and 2 recipients must contribute by choosing among pre-defined options; under Category 3, recipients must consider contributing

Partnership Contribution

- Unique tool for public health
- Provides a predictable annual cash contribution to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers using GISRS
 - Combined contributions are equivalent to 50% of GISRS running costs
 - To commence in 2012
 - Contribution resources are to be used to strengthen pandemic preparedness & response, not to support GISRS itself
- Director-General decides on use
 - Based on advice of the Advisory Group and interaction with industry and other stakeholders

Governance and Review of Framework

- 3-pillared oversight mechanism
 - World Health Assembly: oversees implementation
 - Director-General: promotes implementation
 - Advisory Group: Advises Director-General on the use of the Partnership Contribution; monitors & assesses implementation of Framework

Further Information....

- PIP Framework website:
<http://www.who.int/influenza/pip/en/>

