World Health Organization

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

Questions and Answers

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This document is a "living document" and will be updated and expanded periodically as new questions are received by the WHO Secretariat.

The purpose of this document is to familiarize readers with the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits ("PIP Framework"). Any rephrasing of actual PIP Framework text is not intended to, and does not in any manner modify the official text of the PIP Framework. All readers are encouraged to read the PIP Framework which may be found at:
http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf

I. GENERAL

Q1: What is the PIP Framework?
A: The PIP Framework brings together Member States, industry, other key stakeholders and WHO to implement a global approach to pandemic influenza preparedness and response. The PIP Framework aims to improve preparedness and response for pandemic influenza by improving and strengthening the WHO Global Influenza Surveillance and Response System ("GISRS") so it is more fair, transparent, equitable, efficient, and effective in facilitating the sharing of influenza viruses with pandemic potential and increasing the access to pandemic influenza vaccines and other benefits.

For more information see:
PIP Framework: http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf
GISRS http://www.who.int/influenza/gisrs_laboratory/en/

Q2: When did the PIP Framework become effective?
A: The PIP Framework became effective on 24 May 2011 when it was adopted by the Sixty-fourth World Health Assembly. While the PIP Framework is now in effect, some elements will require several months to years to be fully functional.

Q3: Why was the PIP Framework developed?
A: The PIP Framework was developed for two fundamental purposes: (1) To increase access to pandemic influenza vaccines and other pandemic influenza-related benefits for countries in need in the event of an influenza pandemic; and (2) to ensure the continued sharing of viruses necessary for continuous global monitoring and assessment of risks for an influenza pandemic and for the development of safe and effective influenza vaccines.

Q4: What biological materials does the PIP Framework cover?
A: The PIP Framework applies only to influenza viruses with human pandemic potential, and specifically does not cover seasonal influenza viruses. The biological materials covered by the PIP Framework are called “PIP biological materials” and they are defined in Section 4.1.

Q5: How will the PIP Framework be implemented, and by whom?
A: WHO will act as the secretariat for implementing the PIP Framework and will work with private and public partners to facilitate achieving results as efficiently as possible.
For more information see PIP Framework Sections 6.1bis, 6.14, 7.1 (General) and 7.2 (Advisory Group)

Q6: What are some of the responsibilities of Member States?
A: Some major responsibilities of Member States are to: 1) ensure the timely sharing of influenza viruses with human pandemic potential; 2) contribute to the pandemic influenza benefit-sharing system, including by working with relevant public and private institutions, organizations and entities so they make appropriate contributions to this system; and 3) continue to support GISRS.

Q7: What are the responsibilities of industry?
A: For purposes of the PIP Framework, industry includes manufacturers of influenza vaccines, antiviral medicines and diagnostic materials. Such manufacturers who use GISRS, notably because they receive PIP biological materials, will contribute annually to the "Partnership Contribution" and will sign an agreement (or "Standard Material Transfer Agreement 2") with WHO that includes certain benefit sharing commitments.

Q8: How does the PIP Framework affect existing relationships between WHO and its network of laboratories?
A: The PIP Framework affirms the current relationships between WHO and the GISRS laboratories but also standardizes certain significant elements:

1) The four categories of laboratories in GISRS are: (1) National Influenza Centres ("NICs"), (2) Collaborating Centres ("CCs" or "WHO CCs"), (3) Essential Regulatory Laboratories ("ERLs") and (4) H5N1 Reference Laboratories ("H5RLs").All laboratories that are part of GISRS agree to work under WHO Terms of Reference (TORs). The TORS for each category of laboratory in GISRS have been standardized. Other TORs related to non-PIP biological materials remain unchanged.
2) The PIP Framework adopts two kinds of Standard Material Transfer Agreements (SMTAs). The first SMTA covers all GISRS laboratories and establishes conditions for transferring PIP biological materials *within* GISRS and is called "SMTA1". There is a second and different SMTA (called "SMTA2") for transfers of PIP biological materials for a GISRS laboratory to entity *outside* GISRS.

For more information see PIP Framework Annex 1 (SMTA 1,) Annex 2 (SMTA 2) and Annex 5 for Terms of Reference for all categories of laboratories in GISRS.

II. ADVISORY GROUP

Q 9: What is the Advisory Group (AG)?
A: The AG is one of the three pillars of the PIP Framework's "Governance and Review" oversight mechanism[1]. The PIP Framework established the AG to monitor the implementation of the PIP Framework and provide evidence-based reporting, assessment and recommendations regarding the functioning of the PIP Framework. The AG will provide guidance and input to the Director-General, presenting an annual report on its evaluation of implementation of the PIP Framework. The PIP Framework identifies 7 specific areas that should be covered in the annual report of the AG:

1) necessary technical capacities of WHO GISRS
2) operational functioning of WHO GISRS
3) WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)
4) increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential
5) the Influenza Virus Tracking Mechanism (IVTM)

[1] The three pillars of the oversight mechanism are: the World Health Assembly which oversees implementation of the Framework; the Director-General who advises the World Health Assembly, promotes implementation of the Framework, and performs specific functions set out in the Framework; and the Advisory Group.

6) the sharing of influenza viruses and access to vaccines and other benefits
7) use of financial and non-financial contributions.

For more information see PIP Framework Section 7, Governance and Review and Annex 3, Terms of Reference Advisory Group.

Q10: What is the structure and composition of the AG?
A: The AG has 18 members - three from each of WHO's six regions, representing developed and developing countries, affected countries.[2] The members provide a skill mix of expertise in policy making, public health and influenza. The Director-General, in consultation with Member States, will continue to ensure that AG members are selected to ensure an equitable and balanced representation.

For more information see PIP Framework section 7.2.2. and Annex 3, section 3

Q11: Does the AG have officers?
A: The AG members will select from among themselves a Chairperson and a Vice-Chairperson. The Chairperson and Vice-Chairperson will serve for two years, after which another Chairperson and Vice-Chairperson will be selected by the AG members.

Q12: How long do members serve on the AG?
A: The Terms of Reference for the AG provide that each member will serve for three years. Further, it provides that the duration of appointment of each member will be three years with a renewal of one third of the members every year and that replacements must maintain the equitable representation of the six WHO regions and affected countries. All members are eligible for two appointments.

Q13: Who appoints members of the AG?
A: The Director-General appoints members of the AG. The Director-General will regularly accept nominations of representatives and will draw from this list to replace outgoing members with a view to maintaining equitable representation of the six WHO regions and affected countries.

Q14: Do AG members represent a government or serve in their personal capacity?
A: Members of the AG act as international experts serving WHO exclusively.

Q15: What happens if an AG Member resigns or is incapacitated?
A: The Director-General will appoint a replacement member with a view to maintaining the equitable representation of the six WHO regions and affected countries. The replacement will complete the term of the previous member.

Q16: What are the AG working procedures?
A: The AG will work under procedures that are consistent with WHO's practices and procedures. As an expert advisory group to the Director General, the Regulations for Expert Advisory Panels and Committees[3] will apply to the AG, including the private nature of

[2] "Affected country" means countries with laboratory confirmed cases of H5N1, or other influenza viruses with human pandemic potential. See Framework section 4.4
[3] See WHO Basic Documents, or http://apps.who.int/gb/bd/PDF/bd47/EN/regu-for-expert-en.pdf

meetings and the provision that members of the AG will not make public statements, individually or on behalf of the AG, on the work of the AG, except as authorized in connection with reporting requirements or by the Director-General.

For more information see PIP Framework Section 7 and Annex 3

Q17: Will AG members be required to complete the WHO Declaration of Interests?
A: Yes, prior to being appointed, each nominee will complete a WHO Declaration of Interests which will be reviewed and assessed using WHO standard procedures. Each member will be asked to update their Declaration of Interests prior to each meeting and disclosures shall be made to the full AG as appropriate.

III. Global Influenza Surveillance & Response System (GISRS)

Q18: Do GISRS labs have terms of reference (TORs) under the PIP Framework?
A: Yes, all GISRS labs have TORs specific to their work with influenza viruses with human pandemic potential. They can be found in Annex 5 of the PIP Framework. TORs for work with seasonal influenza viruses remain unchanged.

Q19: Are GISRS laboratories permitted to conduct research with PIP biological materials?
A: Yes, GISRS laboratories are permitted to conduct research with PIP biological materials under the following conditions:

1) Scientists in the GISRS laboratory must actively seek the participation of scientists from originating laboratories and Other authorized laboratories[4] when conducting scientific research projects using clinical specimens and/or influenza viruses from those countries and actively engage them in preparation of manuscripts for presentation and publication;
2) Scientists in the GISRS laboratory must appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza viruses with pandemic potential or reagents, using guidelines such as those outlined by the International Committee of Medical Journal Editors.

Q20: Some GISRS members are very large institutions. Can a GISRS member be a particular laboratory, group, division, department or branch within that institution, or is it always the whole institution?
A: A group, division, department, branch or specific laboratory within an institution may be designated or recognized by WHO as the GISRS institution. Only the designated group, division, department, branch or laboratory is subject to the relevant WHO Terms of Reference and Standard Material Transfer Agreement 1.

[4] The term "Other authorized laboratory" is defined in Section 4.3 of the Framework.

IV. PANDEMIC INFLUENZA BENEFIT SHARING

Q21: What are the aims of the PIP Framework in terms of benefit-sharing?
A: The aim of the PIP Framework is to ensure that benefits arising from the sharing of PIP biological materials are made more accessible and available to countries based on public health risk and need. The PIP Framework includes provisions concerning:

- pandemic influenza related surveillance and risk assessment, and early warning information;
- benefits such as vaccines and other pandemic supplies to countries lacking such access;
- prioritization of important benefits based on assessment of public health risk and need;
- technical assistance, and transfer of technology, skills and knowledge needed by developing countries to build pandemic influenza preparedness and response capacity.

For more information see PIP Framework Section 6

V. PARTNERSHIP CONTRIBUTION

Q22: What is the Partnership Contribution? Who contributes to it and when will it begin?
A: The Partnership Contribution is an annual contribution to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers who use the WHO GISRS. WHO will receive the first Partnership Contribution in 2012.

Q23: How much is the Partnership Contribution?
A: The PIP Framework establishes the annual Partnership Contribution among all manufacturers to be 50% of the annual estimated cost to run GISRS. In 2010, that cost was an estimated US $56.5 million, so based on that figure, the Partnership Contribution will be approximately US $28 million for 2012. The PIP Framework also encourages Member States and other stakeholders to consider making additional donations and in-kind contributions to WHO for improving global pandemic influenza preparedness and response.

For more information see PIP Framework Section 6.14.3 and 6.14.3.1

Q24: Who will decide how much each company must contribute?
A: The PIP Framework states that the amount to be contributed by each influenza vaccine, antiviral and diagnostic manufacturer using GISRS is to be based on transparency and equity, and on the nature and capacity of each user. It will be up to the companies to decide among themselves how much should be contributed by each individual company. However, the PIP Framework also specifies that the Director-General, in consultation with the Advisory Group, will further define the specific amounts to be contributed by each company. In so doing, the Director-General and the Advisory Group will collaborate with industry.

For more information see PIP Framework Section 6.14.3

Q 25: What will the Partnership Contribution be used for?
A: The Partnership Contribution is to be used for improving pandemic preparedness and response. The PIP Framework provides some examples of possible uses of the Partnership Contribution: conducting disease burden studies, strengthening laboratory and surveillance capacity, access and effective deployment of pandemic vaccines and antiviral medicines. The PIP Framework states that the Director-General, based on advice of the Advisory Group, must propose to the Executive Board the proportion of the Partnership Contribution to be used for inter-pandemic preparedness measures and the proportion to be reserved for response activities in the event of a pandemic.

For more information see PIP Framework section 6.14.4 and 6.14.4

Q26: Who will decide on the use of Partnership Contribution and on what basis?
A: The Director-General will decide on the use of the Partnership Contribution based on advice from the Advisory Group. The Director-General and the Advisory Group will interact with manufacturers and other stakeholders.

Q27: Must GISRS laboratories ensure that a third party recipient of PIP biological materials (that is, an entity outside GISRS) has contributed its Partnership Contribution before they can ship PIP biological materials to that entity?
A: No. The PIP Framework does not place such a responsibility on GISRS laboratories. WHO will be responsible for ensuring that the Partnership Contribution is contributed by the entities that are required to do so.

VI. STANDARD MATERIAL TRANSFER AGREEMENTS

Q28: What are the PIP Framework Standard Material Transfer Agreements?
A: The PIP Framework contains two types of Standard Material Transfer Agreements ("SMTAs") which are binding contracts that provide the conditions under which PIP biological materials may be transferred from one party to the other. "SMTA 1" establishes the conditions which apply to transfers of PIP biological materials among members of GISRS. "SMTA 2" establishes the conditions which apply to transfer of PIP biological materials from a GISRS laboratory to a party outside GISRS.

Q29: What is SMTA 1?
A: SMTA 1 provides the conditions under which laboratories in GISRS exchange PIP biological materials among themselves. This SMTA is incorporated into the Terms of Reference of the GISRS laboratories. SMTA 1 covers many matters including:

- handling of PIP biological materials in accordance with applicable WHO guidelines and national bio-safety standards
- transfers of PIP biological materials to entities outside GISRS
- use of the IVTM
- research & publications
- intellectual property rights
- dispute resolution

Q30: What is SMTA 2?
A: SMTA 2 is an agreement between WHO and any non-GISRS recipient[5] of PIP biological materials which contains provisions on benefit sharing. Any entity outside of the GISRS system wishing to receive PIP biological materials must enter into negotiations with WHO using the SMTA 2 draft agreement (See PIP Framework, Annex 2) and assess what benefits it can contribute based on its nature and capacity. The SMTA 2 in PIP Framework Annex 2, has several categories of benefit sharing commitments:

1) by influenza vaccine and antiviral medicine manufacturers, who must select 2 of 6 pre-defined benefit sharing options;
2) by manufacturers of other products relevant to pandemic influenza preparedness and response (e.g. diagnostic manufacturers), who must choose 1 of 6 pre-defined benefit sharing options;
3) by all other recipients who do not fall into categories 1 or 2 above, who must consider contributing to the PIP Benefit Sharing system

For more information see PIP Framework Annex 1 and Annex 2 (SMTA 1 and 2).

Q31: When will SMTA 2s be signed?
A: The process to negotiate and sign SMTA 2 with individual manufacturers and entities will start in 2012 and is anticipated to be a multi-year process taking place in several phases. WHO will start by developing template agreements for the different types of benefit sharing foreseen under the PIP Framework (donations; pre-purchase of vaccine or antiviral medicines; licenses for intellectual property rights). Following this, WHO will contact influenza vaccine manufacturers first, in order to begin negotiation of individual agreements. Later, WHO will work with other recipients so that in time, all non-GISRS recipients of PIP biological materials have signed an SMTA2 with WHO.

Q32: Is there a process to ensure that PIP biological materials can continue to be shared before SMTA 2 s are signed?
A: Yes. WHO is putting in place transitional measures to ensure that the sharing of PIP biological materials is unimpeded. When a GISRS laboratory ships PIP biological materials to recipients outside GISRS, a notice will be included indicating the existence of the PIP Framework and the expectation of WHO that it will initiate SMTA 2 negotiations with the recipient in the future. Acceptance of the PIP biological materials by the recipient means that it agrees to this condition.

Q33: Will the sharing of PIP biological materials with universities, colleges or other educational facilities require an SMTA to be signed?
A: Yes, the sharing of PIP biological materials with any entity outside GISRS will ultimately require the signing of SMTA 2 with WHO. (See also responses to Questions 30 and 31).

VII. INTELLECTUAL PROPERTY RIGHTS

Q34: Will Intellectual Property Rights (IPR) obtained before the entry into force of the PIP Framework be affected by implementation of the PIP Framework?

[5] The term "Recipient" is defined in SMTA2, Article 1, Footnote 1.

A: SMTA 1 makes it clear that any IPR on PIP biological materials obtained before the PIP Framework was adopted on 24 May 2011 are not affected. Additionally, it is possible that GISRS laboratories providing PIP biological materials under SMTA 1 may have used technology protected by IPRs for the generation and/or modification of PIP biological materials. Such IPRs will be respected.

For more information see PIP Framework Annex 1(SMTA 1), Article 6

Q35: Can GISRS laboratories seek intellectual property rights on PIP biological materials?
A: SMTA 1 provides that GISRS laboratories should not seek to obtain any intellectual property rights on PIP biological materials.

For more information see PIP Framework Annex 1, Article 6.1

VIII. INFLUENZA VIRUS TRACEABILITY MECHANISM (IVTM)

Q36: What is the Influenza Virus Traceability Mechanism (IVTM) and what does it do?
A: The IVTM is an electronic, internet-based system that GISRS laboratories are asked to use to record the transfer and movement of PIP biological materials into, within, and to parties outside the WHO GISRS. The IVTM will increase the transparency of GISRS activities and the distribution of PIP biological materials[6]. The IVTM will also enable users to see the results and analyses and tests carried out on the PIP biological materials.

Q37: Is the IVTM limited to PIP biological materials?
A: Yes.

[6] The term "PIP biological materials" is defined in Section 4.1 of the Framework.