

**Q10: What is the process to sign the SMTA2?**

**A10:** When an entity is contacted by WHO, the negotiation process is expected to take six to nine months. This consists of an informal discussion phase, during which background and information are shared between WHO and the entity, and a formal negotiation phase which ends with the signing of the SMTA2.

**Q11: Can we continue to receive PIP biological Materials while the agreement is being negotiated?**

**A11:** The Framework requires that entities sign an SMTA2 before receiving PIP Biological Materials from GISRS. However, given the large number of SMTA2 that need to be concluded, an interim process has been put in place to allow shipments of PIP Biological Materials to continue while these agreements are being negotiated.

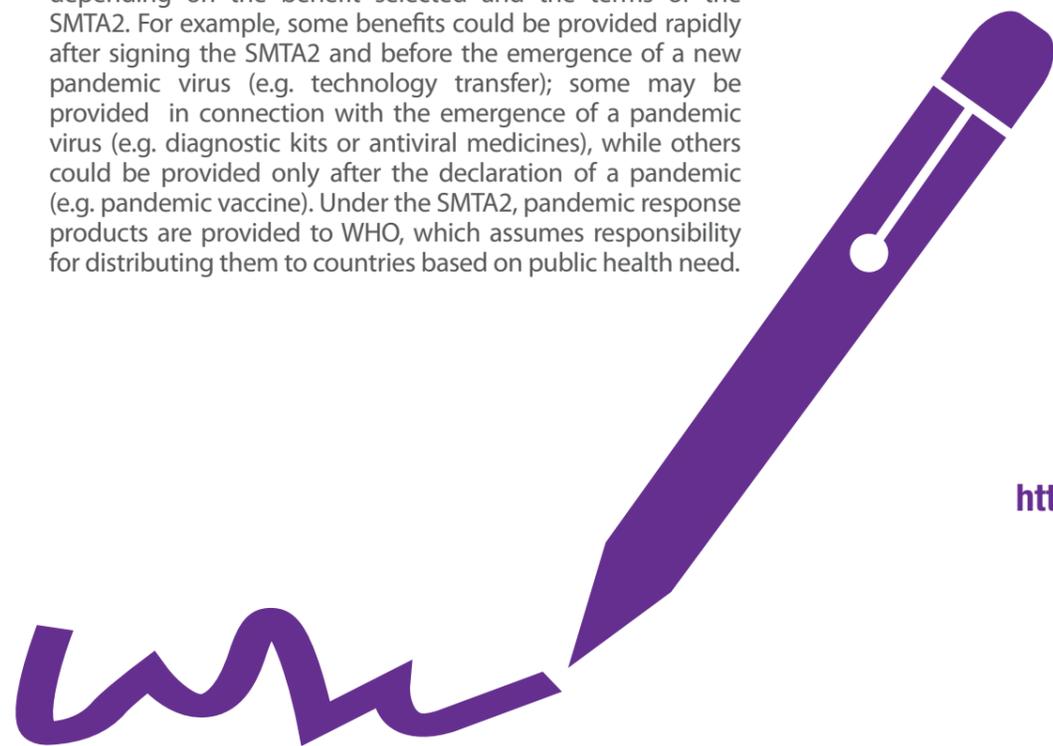
Under this interim process, shipments of PIP Biological Materials include a Shipment Notice that states that by accepting the materials, the recipient agrees to conclude an SMTA2 with WHO at some point in the future. The interim process allows important virus sharing to continue so that critical public health activities that rely on access to these materials are not compromised.

**Q12: Must I sign an SMTA2 every time I access PIP Biological Materials from GISRS?**

**A12:** No, you must sign an SMTA2 only once. After the SMTA2 is signed, you may receive as many PIP Biological Materials as you need.

**Q13: When do I provide the benefits I selected?**

**A13:** Benefits are provided either before or during a pandemic, depending on the benefit selected and the terms of the SMTA2. For example, some benefits could be provided rapidly after signing the SMTA2 and before the emergence of a new pandemic virus (e.g. technology transfer); some may be provided in connection with the emergence of a pandemic virus (e.g. diagnostic kits or antiviral medicines), while others could be provided only after the declaration of a pandemic (e.g. pandemic vaccine). Under the SMTA2, pandemic response products are provided to WHO, which assumes responsibility for distributing them to countries based on public health need.



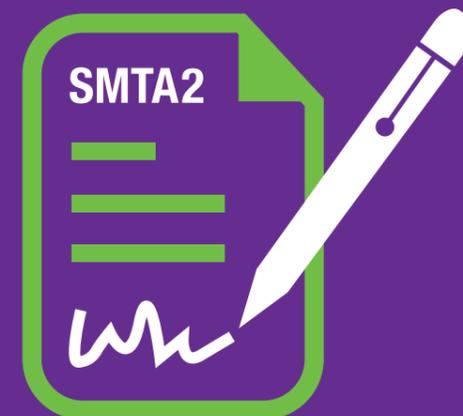
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# FAQs

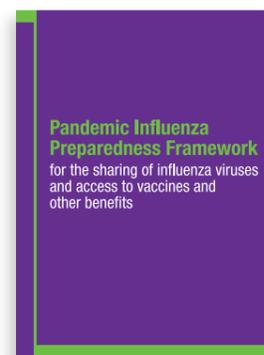
Frequently Asked Questions About Standard Material Transfer Agreements 2



## Q1: What is the PIP Framework?

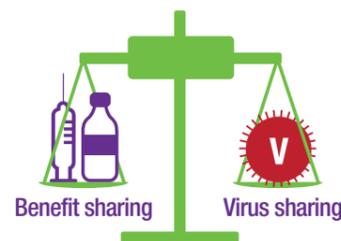
**A1:** The Pandemic Influenza Preparedness (PIP) Framework<sup>1</sup> is an innovative public health instrument that has one key goal: **to increase public health security so that when the next influenza pandemic strikes, countries are better prepared to address it.** That goal is attained through two ways:

- 1) improving the pandemic preparedness of countries by assessing where capacities are weakest and helping countries strengthen them; and
- 2) putting in place advance donation or purchase agreements that guarantee access by WHO to life-saving products such as vaccines and antiviral medicines. Those agreements are called Standard Material Transfer Agreements 2 or "SMTA2". By addressing public health security in this manner, WHO and its partners are ensuring that at the time of the next pandemic, there is greater equity in the world.



## Q2: What is an SMTA2?

**A2:** A **Standard Material Transfer Agreement 2 (SMTA2)** is a contract between WHO and a non-GISRS<sup>2</sup> entity (a company, lab, or other type of institution) that has received PIP Biological Materials<sup>3</sup> from GISRS. Through this contract, the entity commits to provide to WHO specific items that may be used to prepare for (e.g. training, technology licenses) or respond to (e.g. vaccines, antivirals, diagnostic kits) pandemic influenza. The SMTA2 ensures that users of PIP Biological Materials share, in some manner, some benefits with WHO. Depending on the nature and capacity of the entity, the entity will have different benefit sharing options available to it (**see Q5 for more information**).



<sup>1</sup> Developed by WHO Member States and unanimously adopted by the Sixty-fourth World Health Assembly on 24 May 2011.

<sup>2</sup> WHO coordinates the sharing of influenza viruses with pandemic potential through an international network of public health laboratories called the 'Global Influenza Surveillance and Response System' (GISRS). Under the Framework, Member States are expected to share their influenza viruses on a regular and timely basis with GISRS. GISRS laboratories use the viruses for risk assessment, and to develop candidate vaccine viruses and other products that are provided on request to influenza product manufacturers and institutions.

<sup>3</sup> PIP Biological Materials are influenza viruses or virus materials with human pandemic potential, such as H5N1, and include human clinical specimens, influenza virus isolates, extracted RNA, cDNA and influenza candidate vaccine viruses developed by GISRS laboratories.

## Q3: What is the purpose of an SMTA2?

**A3:** Its main purpose is to establish a structured process for a **fairer, more efficient and more equitable access to critical pandemic supplies** by all countries at the time of a pandemic. In the past, donations of influenza vaccines and antivirals were negotiated during a pandemic, resulting in late access to critical supplies by countries in need. With SMTA2s, WHO and its partners ensure that countries without access to life-saving vaccines, antivirals and other products, will have access to some of the supplies they need **at the same time** as other countries.

## Q4: Who should sign the SMTA2?

**A4:** Any recipient of PIP Biological Materials that is not a GISRS laboratory. Recipients include influenza vaccine, diagnostic and pharmaceutical manufacturers as well as biotechnology firms, research and academic institutions.

## Q5: What do we commit to under the SMTA2?

**A5:** Under the SMTA2, the contracting entity makes specific commitments to WHO based on its nature and capacity. A model SMTA2 is found at Annex 2 of the PIP Framework. That model sets out options that entities must choose from. For example, influenza vaccine manufacturers must select 2 of 6 benefit sharing options which are spelled out in the model<sup>4</sup>; those options include donation or reserve of vaccine for WHO. The different benefit-sharing options are summarized in **Table 1**.

## Q6: If I am a manufacturer of vaccines or antivirals, what benefits will I have to provide?

**A6:** You will need to **select 2 of the 6 benefit sharing options** listed in the column for **Category A of Table 1**.

## Q7: If I am a manufacturer of diagnostics and other products, what benefits will I have to provide?

**A7:** You will need to **select 1 of the 6 benefit sharing options** listed in the column for **Category B of Table 1**.

## Q8: If I am not a manufacturer, what benefits will I have to provide?

**A8:** You will need to **sign an SMTA2** and consider contributing a benefit listed in column for **Category C of Table 1**, and inform WHO of your decision.

## Q9: How do I know if I have to sign an SMTA2?

**A9:** You will have to **sign an SMTA2 if you received a notice** accompanying PIP Biological Materials you requested from GISRS. The notice will inform you that by accepting the materials, your company/institution agrees to sign an SMTA2 with WHO (**see also Q11**).

<sup>4</sup> See PIP Framework Annex 2, Article 4.

**Note:** The benefit sharing options below are described in more detail in **Article 4.1 of the model SMTA2 agreement** found in **Annex 2** of the Framework.

### Table 1: Summary of benefit sharing options

		
<b>Category A</b> (Vaccine & antivirals)	<b>Category B</b> (Diagnostics & other products)	<b>Category C</b> (Academic & research institutions)
Donate % of real-time vaccine production to WHO	Donate diagnostic kits to WHO	Consider contributing to the measures listed below, as appropriate:
Reserve % of real-time vaccine production at affordable pricing to WHO	Reserve diagnostic kits at affordable pricing to WHO	<ul style="list-style-type: none"> <li>• Donations of vaccines;</li> <li>• Donations of pre-pandemic vaccines;</li> </ul>
Donate antivirals to WHO	Support laboratory and surveillance capacity strengthening	<ul style="list-style-type: none"> <li>• Donations of antivirals;</li> <li>• Donations of medical devices;</li> </ul>
Reserve antivirals at affordable pricing to WHO	Support transfer of technology, know-how and/or processes	<ul style="list-style-type: none"> <li>• Donations of diagnostic kits;</li> </ul>
License on technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants to developing country manufacturers, on mutually-agreed fair terms	License on technology, know-how, processes or products needed for the production of influenza vaccines, antivirals or adjuvants to developing country manufacturers, on mutually-agreed fair terms	<ul style="list-style-type: none"> <li>• Affordable pricing of pandemic products;</li> <li>• Transfer of technology and processes;</li> </ul>
Royalty-free license to developing country manufacturers or WHO for production of influenza vaccines, antivirals or adjuvants	Royalty free license to developing country manufacturers or WHO for production of influenza vaccines, antivirals or adjuvants	<ul style="list-style-type: none"> <li>• Granting of sublicenses to WHO;</li> <li>• Laboratory and surveillance capacity building.</li> </ul>