

Partnership Contribution Standard Operating Procedures

June 2015

This document replaces the version dated May 2013

In May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the “Framework” or “PIP Framework”)¹.

Section 6.14.3 of the Framework establishes an annual Partnership Contribution (PC) to be paid by influenza vaccine, diagnostic and pharmaceutical manufacturers using the WHO global influenza surveillance and response system (GISRS)². Resources contributed are to be used to strengthen pandemic influenza preparedness and response (see PIP Framework section 6.14.4).

The distribution of PC among companies is to be based on transparency and equity, and the nature and capacities of the relevant manufacturer (see PIP Framework section 6.14.3). The World Health Assembly tasked the Director-General, in consultation with the Advisory Group, to collaborate with industry to further define the specific amounts to be contributed by each manufacturer (see PIP Framework section 6.14.3).

These standard operating procedures (SOPs) are used by the WHO PIP Secretariat (the “Secretariat”) to identify manufacturers using GISRS and distribute the PC among companies, in accordance with section 6.14.3 of the Framework. The SOPs may be updated and/or revised as necessary.

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Identify Manufacturers using GISRS

1. Develop, review and/or revise a Questionnaire to identify manufacturers using GISRS (see model at Annex 1)
 - Questionnaire to be reviewed and finalized each January
2. Develop Manufacturer List. This may include the following:
 - Liaise with manufacturers’ associations³ to identify relevant member companies
 - Conduct internet searches to identify manufacturers not affiliated with associations
 - Collate information from WHO databases, GISRS, regulatory authorities, Member States
 - Collate information from civil society organizations and other stakeholders
3. Publish questionnaire on PIP Framework website (<http://www.who.int/influenza/pip/en/>)
 - Publish Questionnaire on PIP Framework internet webpage on or about 1 February each year

¹ For more information about the PIP Framework, see <http://www.who.int/influenza/pip/en/>

² For more information about GISRS, see http://www.who.int/influenza/gisrs_laboratory/en/

³ The Secretariat is currently collaborating with the following manufacturers’ associations: AdvaMedDx, BIO, DCVMN and IFPMA

- Send Questionnaire link via email to all prior year Contributors and companies previously identified
 - Send Questionnaire link to additional companies identified through Step 2
 - Send Questionnaire link to all associations for information
4. Review responses from manufacturers upon receipt
- Check responses against publicly available information, including annual reports, press releases, IVTM records and consult with stakeholders, as necessary, subject to availability of resources.
5. Follow-up
- As needed the PIP Secretariat follows up with the company and works with it to ensure that the final answers of the company are accurate
 - The PIP Secretariat makes three attempts to contact manufacturers to request a response to the questionnaire or clarification of responses provided
 - The Secretariat maintains a list of companies that do not respond to requests to complete the Questionnaire or provide clarifications when asked, and regularly informs the Advisory Group thereof
 - In the event of a high non-response rate the Secretariat may bring this issue to the attention to the Advisory Group who may then advise the Director-General to inform Member States.
6. Close the Questionnaire
- On or about 15 March, the Questionnaire closes for the current calendar year

Analyse Questionnaire & Establish List of Contributors

7. Answers to the Questionnaire determines whether a company is or is not a Contributor:
- *If a manufacturer responds:*
 - **YES to either question 1 or 2; and**
 - **YES to sub-questions 3a or 3b or 3d***It is included as a Contributor*
 - *If a manufacturer responds:*
 - **NO to Questions 1 and 2; or**
 - **NO to sub-questions 3a or 3b or 3d***It is not included as a Contributor*

Publish Questionnaire Results

8. Following the closing of the Questionnaire, the Secretariat publishes:
- The list of all manufacturers contacted
 - Responses provided by each manufacturer
 - The list of contributors to the Partnership Contribution for the current calendar year.
9. Questionnaire results from previous years are archived on the PIP Framework website.

Apply the Partnership Contribution Formula

10. On or about 1 April each year, the Secretariat sends all Contributors identified through the Questionnaire, a “Band Selection and Certification Form” (BSF) to be completed (see model in Annex 2).
11. Recipients complete the BSF and return it to the Secretariat no later than 1 May each year. No sales or other data are to be submitted to the Secretariat.
12. The PIP Secretariat, using the information contained in the duly completed BSFs applies the formula and calculates the amount due from each Contributor.

Request Payment from Contributors

13. On or about 1 June each year, the Secretariat issues to each Contributor a ‘Request for Payment’ (see model at Annex 3).
14. Unpaid amounts from previous year(s) will be reflected in invoices until full payment is received.

Receive Partnership Contribution funds

15. Partnership Contribution payments are due 30 days from issuance of the ‘Request for Payment’ (see paragraph 13).
 - Payment is made in US dollars.
 - Payment is made to a designated WHO bank account and administered in accordance with WHO financial rules and regulations.
 - If a Contributor’s annual sales are in a currency other than US dollars, the Contributor is responsible for converting its sales’ currency to US dollars using the exchange rate for December for each applicable year using the rates published by the United Nations Treasury - Operational Rates of Exchange:
<http://treasury.un.org/operationalrates/OperationalRates.aspx>
16. On request and in consultation with the Secretariat, a Contributor may pay its contribution in installments.

Maintain, revise, and/or update Contributor list

17. Manufacturers leaving the influenza vaccine, antiviral or diagnostic industry inform the PIP Secretariat in writing indicating the date at which the company will cease development and/or production of influenza-related products *and use of GISRS*. The company is removed from the Contributor list. Should such a manufacturer re-enter the influenza industry, it should so inform the PIP Secretariat.

Develop implementation plan

18. The Secretariat develops a draft implementation plan for use of the PC funds.

19. The draft implementation plan is discussed with and revised based on advice from the Advisory Group and interaction with industry and other stakeholders.

Decide on Use of PC Funds

20. The Executive Board decides on the allocation of Partnership Contribution resources between preparedness and response, based on a proposal submitted by the Director-General following the advice of the Advisory Group, as required under the Pandemic Influenza Preparedness Framework, Section 6.14.5.
21. The Advisory Group interacts with industry and other stakeholders and provides advice to the Director-General on the use of the Partnership Contribution.
22. The Secretariat submits to the Director-General, for her consideration and approval, the draft implementation plan developed with advice from the Advisory Group and interaction with industry and other stakeholders.
23. The Director-General decides on the use of the Partnership Contribution.

Report

24. A table identifying contributing manufacturers in the bands they have selected using the BSF, is published yearly on the PIP Framework website; tables for previous years are archived on the PIP Framework website.
 - Any queries regarding a contributor's band are forwarded to the Contributor for action, with copy to the Advisory Group.
25. The PIP Advisory Group evaluates the implementation of the Framework, *inter alia*, use of financial and non-financial contributions (See section 7.2.5 of the Framework) and reports thereon annually to the Director-General.
26. The Director-General reports annually to the Executive Board on the distribution of the Partnership Contribution between companies based on transparency and equity, and their nature and capacities (See section 6.14.3 of the Framework).
27. The Director-General reports biennially to the World Health Assembly on the status of, and progress on, *inter alia*, use of the Partnership Contribution (See section 7.4.1 of the Framework).

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Model: Partnership Contribution Questionnaire

Question 1

Definition

For purposes of this question:

"Develop" is understood to mean that:

- a. you have developed or are currently developing a product (including human influenza vaccine, antiviral, diagnostic or other product) to prevent, treat or diagnose infections from H5N1 or other influenza viruses with human pandemic potential,
- and**
- b. you have obtained a provisional or final licensure, registration or market authorization for such product, but have not implemented production, distribution or sales.

1. In the past 15 years have you developed, or are you currently developing, human influenza vaccines or other products derived from or using H5N1 or other influenza viruses of human pandemic potential? (The phrase "using H5N1 or other influenza viruses of human pandemic potential" is understood to include use of viruses for product development, testing, production or marketing purposes.)

ANSWER YES or NO

Question 2

Definition

For purposes of this question:

"Produce" is understood to mean that:

- a. you have produced or are currently producing a product (including human influenza vaccine, antiviral, diagnostic or other product) to prevent, treat or diagnose infections from H5N1 or other influenza viruses with human pandemic potential,
- and**
- b. such product has obtained national licensure, registration or market authorization, and you have implemented production, distribution or sales of such product. This would include, for example, producing vaccine from procured bulk material.

2. In the past 15 years have you produced, or are you currently producing, human influenza vaccines or other products derived from or using H5N1 or other influenza viruses of human pandemic potential? (The phrase "using H5N1 or other influenza viruses of human pandemic potential" is understood to include use of viruses for product development, testing, production or marketing purposes.)

ANSWER YES or NO

Question 3

Definition

For purposes of this question:

- i) "product" means human influenza vaccine, antiviral, diagnostic, or other product to prevent, treat or diagnose infections from H5N1 or other influenza viruses with human pandemic potential.

- ii) “use GISRS” means to use or receive:
1. materials (e.g. virus materials, such as candidate vaccine viruses, wild-type viruses, cDNA, plasmids, or reagents); and/or
 2. services (e.g. antigenic and genetic characterization of candidate vaccine viruses/seed material, antiviral susceptibility assays); and/or
 3. information (e.g. sequence information, epidemiological data, antiviral susceptibility data, pre- and post-vaccine composition meeting reports); developed and/or provided by or through GISRS.

Questions

3a) In your product development, testing, production or marketing do you use GISRS?

ANSWER YES or NO

3b) Has another company or laboratory used GISRS to develop, test, produce or market your product on your behalf? That would be the case if, for example, you outsourced testing of your product to another company or laboratory that used GISRS.

ANSWER YES or NO

3c) If you answered “YES” to 3b) above, please provide the name of the company or laboratory.

Name of company or laboratory: _____

3d) Has the development, testing or production of your product, required a component developed or produced by another company or laboratory that used GISRS. For example:

- a component (e.g. primer, probe, protein, antibody, etc.) of your product is developed or produced by another laboratory or company that uses GISRS; or,
- the testing, validation, or quality control of your product requires the use of another laboratory or company’s material or product (e.g. a reagent) which was developed or produced using GISRS.

ANSWER YES or NO

3e) If you answered “YES” to 3d) above, please provide the name of, or describe the component, material or product, and provide the name of the company or laboratory that developed or produced it.

Name/description of component: _____

Name of company or laboratory: _____

3f) Have you used GISRS to develop, test or produce another company’s or laboratory’s product?

ANSWER YES or NO

3g) If you answered “YES” to 3f) above, please provide the name of the company or laboratory.

Name of company or laboratory: _____

Model: Band Selection and Certification Form

Pandemic Influenza Preparedness Framework⁴ ("PIP Framework") Annual Partnership Contribution *Band Selection and Certification Form 'year XXXX'*

Background

Your company has been identified as an influenza vaccine, diagnostic or pharmaceutical manufacturer that uses the WHO Global Influenza Surveillance and Response System (GISRS).

The PIP Framework was unanimously adopted by the 194 countries of the World Health Organization in May 2011. Pursuant to section 6.14.3 of the PIP Framework, and your responses to the recent Questionnaire, your company will be in the annual Partnership Contribution ("PC") arrangement. For 2012, the total PC is set at US \$28 million.⁵ Your company's contribution will be calculated using a formula that has been collaboratively developed with a group of international experts appointed by the WHO Director-General, and with industry, and approved by the WHO Director-General. This formula is based on your company's **average annual influenza product sales (vaccines, diagnostics or pharmaceuticals)**.

Process for your company to follow

1. Determine your company's **average annual influenza product⁶ sales in US\$** for the years [2009, X, Y, and Z]. To determine this number, follow the Steps below⁷.

Step 1

- | | |
|--|-------|
| a) 2009 Annual influenza product sales in US\$ | _____ |
| b) X Annual influenza product sales in US\$ | _____ |
| c) Y Annual influenza product sales in US\$ | _____ |
| d) Z Annual influenza product sales in US\$ | _____ |
| TOTAL (2009+X+Y+Z) | _____ |

Step 2

TOTAL (2009+X+Y+Z) = Average annual influenza product sales in US\$ _____
4

2. Take the figure from Step 2 above, and, using Table 1 below, identify the Band (numbered row) that corresponds to your company's **average annual influenza product sales in US\$**.
3. In accordance with WHO Financial Rules and Regulations, all contributions must be submitted in US dollars, using the UN rate of exchange valid on the day the transfer from the contributing entity is executed. If your annual sales are in a currency other than US dollars, you must convert these sales to US dollars using the exchange rate for December of the applicable year using the rates published by the United Nations Treasury - Operational Rates of Exchange: <http://treasury.un.org/operationalrates/OperationalRates.aspx>

⁴ More information on the PIP Framework may be found at <http://www.who.int/influenza/pip/en/>

⁵ See Framework section 6.14.3 footnote 1

⁶ Influenza vaccines, diagnostics or pharmaceutical products

⁷ The figures used in the Steps below should not be sent to WHO

4. Fill in the attached Form A as indicated and have it signed and certified by 2 of the following persons in your company: Chief Executive Officer, Chief Financial Officer, Certified Auditor or Accountant.
5. Return the Form to WHO either electronically or in hard copy by **[Day/Month/Year]**:
Email: pipframework@who.int
Address: PIP Framework Secretariat, L426
World Health Organization
Avenue Appia 20
1211 Geneva 27, Switzerland
6. Using the information provided by you and all other companies identified by WHO to contribute to the annual PC, the World Health Organization will apply the formula below to determine the amount to be paid by your company.

$$\text{Individual payment} = \frac{(\text{Total PC} \times \text{entity's band weight})}{\text{Sum of band weights for all entities}}$$

7. WHO will issue an invoice to your company for this amount. It will be payable within 30 days.

Form A: Band Selection & Certification⁸

**Table 1: Annual Partnership Contribution Band Selection and Certification Form
'Year XXXX'**

Band Number	Average annual influenza product sales (in USD millions)	Weight
1	> 3500 – 4000	750
2	> 3000 – 3500	650
3	> 2500-3000	550
4	> 2100 – 2500	460
5	> 1800 – 2100	390
6	> 1500 – 1800	330
7	> 1200 – 1500	270
8	> 1000 – 1200	220
9	> 800 – 1000	180
10	> 600 – 800	140
11	> 400 – 600	100
12	> 300 – 400	70
13	> 200 – 300	50
14	> 150 – 200	35
15	> 100 – 150	25
16	> 70 – 100	17
17	> 50 – 70	12
18	> 40 – 50	9
19	> 30 – 40	7
20	> 20 – 30	5
21	> 10 – 20	3
22	> 1 – 10	1.1
23	0 – 1	0.1

Key: The symbol ">" means "more than"

CERTIFICATION

_____ certifies that its average annual influenza
(**Company Name**)
product sales (vaccines, diagnostics or pharmaceuticals) for years XX, XX, XX, XX fall within
Band Number _____ (see Table 1 above).

Certified by:

Print Name:

Print Name:

Title:

Title:

Signature:

Signature:

Date:

Date:

⁸ Only Form A, duly completed and signed, should be returned to WHO.

Model: Request for Payment

WORLD HEALTH
ORGANIZATIONORGANISATION
MONDIALE DE LA SANTE

Invoice number:

Invoice date:

Date due:

Pandemic Influenza Preparedness Framework

To: [Name of manufacturer]

Request for payment of
Annual Partnership Contribution [Year]
(PIP Framework section 6.14.3)

	US\$
Total due for [Year]	XXXXX

Payment is due within 30 days of the invoice date to the following bank account:

In US dollars to :

World Health Organization
 Account no. 240-C0169920.3
 IBAN CH31 0024 0240 C016 9920 3
 UBS AG, 1211 Geneva, Switzerland
 SWIFT UBSWCHZH80A

Direct all inquiries to:

PIP Framework Secretariat, L426
 World Health Organization
 Avenue Appia 20
 1211 Geneva 27
 Switzerland
 Email: pipframework@who.int

Terms and conditions

- a. Pursuant to the PIP Framework, adopted by the 64th World Health Assembly, an annual Partnership Contribution is a due from all influenza vaccine, diagnostic and pharmaceutical manufacturers using the WHO Global influenza surveillance and response system (“GISRS”)⁹ (see: PIP Framework Section 6.14.3)
- b. The Partnership Contribution shall be used for improving pandemic preparedness and response, inter alia, for conducting disease burden studies, strengthening laboratory and surveillance capacity, access and effective deployment of pandemic vaccines and antiviral medicines, as decided by the Director-General, based on advice from the Advisory Group (see: PIP Framework Sections 6.14.4 and 6.14.6)
- c. The Partnership Contribution shall be administered in accordance with the WHO Financial Regulations and Rules.
- d. WHO will report annually on the use of the Partnership Contribution resources through the WHO Executive Board and the World Health Assembly. The income and expenditures recorded in respect of the contribution shall be included in the WHO Financial Reports submitted to the World Health Assembly on an annual basis.
- e. All contributions to WHO are subject exclusively to its internal and external auditing procedures. The External Auditors’ certification of accounts and audit report is made available to the World Health Assembly on an annual basis. You may request a copy.
- f. WHO will make an appropriate acknowledgement of the Partnership Contribution in relevant publications or reports habitually made available to its Member States. In the absence of the consent of WHO, Contributors may not use or refer to their Partnership Contributions in any material of a promotional nature. However, Contributors may make reference to their Partnership Contribution in their internal documents and in their annual reports. You may not use the WHO logo/ emblem and name without the prior written consent of WHO.
- g. Nothing contained in these Terms and Conditions shall be construed as a waiver of any of the privileges and immunities enjoyed by WHO under national and international law, and/or as submitting WHO to any national court jurisdiction.

⁹ For more information on the PIP Framework see: <http://www.who.int/influenza/pip/en/>