2016 PIP Partnership Contribution Questionnaire

Update Alert: The 2016 Partnership Questionnaire has a new feature whereby companies that have submitted their final answers to a previous year's questionnaire can simply check the box "Check here if there are no changes from last year in your answers" and the PIP Secretariat will use your previous Questionnaire answers. There is no need to complete questions 1-3 if you check this option. Note that final and complete answers from a previous year must be available to the PIP Framework Secretariat to choose this option.

Purpose

This questionnaire allows WHO to identify whether your company/institution is a contributor under the Partnership Contribution. For a short video in English on the PIP Partnership Contribution, please click here. To see the video in other languages, please click here.

Contributor identification

Under the PIP Framework a contributor is considered to be a company/institution that:

- Is an influenza vaccine, diagnostic and pharmaceutical manufacturer (currently or in the past 15 years); and
- Uses (or has used in the past 15 years) the WHO Global Influenza Surveillance and Response System (GISRS)

"Use of GISRS" means your company/institution used or received:

- materials (e.g. virus materials, such as candidate vaccine viruses, wild-type viruses, cDNA, plasmids, or reagents); and/or
- services (e.g. antigenic and genetic characterization of candidate vaccine viruses/seed material, antiviral susceptibility assays); and/or
- 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.

PC Collection Process & Invoicing

If your answers to this questionnaire identify your company/institution as a contributor to the PIP Partnership Contribution:

1. You will receive a “Band Selection and Certification Form” (BSF) that you will need fill out and send back to WHO: The BSF form requests companies/institutions to calculate their 4-year average annual influenza product sales and to use that figure to place themselves into one of 23 “sales bands” (tranches of sales in USD millions). For confidentiality reasons, companies do not provide their sales figures to WHO.

2. WHO will use Band numbers to calculate the amount of Partnership Contribution due from each Contributor. To do this, WHO will enter each company’s sales band in a weighted formula to determine how much each contributor will pay. The formula – developed in close collaboration with industry associations – takes into account fairness and equity, as well as the nature and capacities of manufacturers: companies with higher influenza product sales pay more than those with lower influenza product sales. For further detail on the PC distribution please read: Distribution of Partnership Contribution among companies, May 2013 (link below).

3. Once the formula is applied, each contributor is sent an invoice for its share of the Partnership Contribution. The invoice is payable within 30 days.

Distribution of Partnership Contribution among companies, May 2013
pdf, 495kb
Instructions

The questionnaire consists of 3 questions, one of which has several sub-questions.

The sub-questions of Question 3 are aimed at assisting WHO to better understand the range of entities that use GISRS and that are involved in the development of influenza products. These sub-questions are also meant to sensitize influenza manufacturers to the fact that they may be using GISRS indirectly through subcontractors or by using components developed or produced by another laboratory or company that itself uses GISRS.

Please note the following: Sub-questions 3c), 3e) and 3g) are optional. The Questionnaire may be submitted without filling in those fields or by answering “Do not know” or “Confidential information”. That said, WHO will greatly appreciate any information that may be shared by you in relation to these sub-questions. Please further note that any information provided in these sub-questions 3c), 3e) or 3g) will not be released or shared by WHO with any company, institution, establishment or other entity.

You are requested to complete the questions online no later than 31 March 2016.

In due course, WHO will publish the following results of the 2016 Questionnaire on the WHO PIP Framework webpage:

- the list of institutions contacted;
- the responses provided by each institution (but not answers to sub-questions 3c), 3e) and 3g));
- the list of institutions that did not respond.

*** Begin 2016 Questionnaire ***

Fields marked with an asterisk (*) are mandatory.

Contact details

Company name *

Address *

Country *

Name and title of contact person *

Email *

The e-mail format is "xxxx@yyyy.zzz"

Telephone

Questions

You are requested to answer the nine (9) questions below. In all questions, “you” designates your
Check here if there are no changes from last year in your answers

Note: if you check this option the questions below do not need to be completed

Question 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.)

"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.

Please answer Yes No

Question 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.)

“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.

Please answer Yes 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.

a) In your product development, testing, production or marketing do you use GISRS?
Yes No

b) 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.
Yes No

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

d) 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.
Yes No

e) 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.
f) Have you used GISRS to develop, test or produce another company’s or laboratory’s product?  
Yes  No

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

Name of company or laboratory: