**2014 Questionnaire to identify influenza vaccine, diagnostic and pharmaceutical manufacturers using WHO Global Influenza Surveillance and Response System (GISRS) under Section 6.14.3 of the PIP Framework**

**PIP Framework**

The Pandemic Influenza Preparedness (PIP) Framework is an international framework that was approved in May 2011 by the 194 countries of the World Health Organization (WHO). The PIP Framework brings together many stakeholders that work together to ensure that the world is better prepared to respond to the next influenza pandemic. To that end, the Framework establishes a PIP Benefit Sharing System, that operates to, inter alia, provide to all countries pandemic influenza surveillance and risk assessment and early warning information, and build relevant capacities in countries where needs are identified.

**Global Influenza Surveillance and Response System (GISRS)**

For more than 60 years, WHO has coordinated the Global Influenza Surveillance and Response System (GISRS), an international network of public health laboratories that conduct global, year-round virological surveillance to assess epidemic and pandemic risks posed by influenza viruses. GISRS currently comprises six WHO Collaborating Centres (CCs), four WHO Essential Regulatory Laboratories (ERLs), twelve H5 Reference Laboratories and 141 National Influenza Centres (NICs) covering 111 countries in the world. GISRS contributes to the bi-annual Influenza Vaccine Composition recommendations made by WHO. GISRS laboratories produce significant influenza risk assessment information (virological and epidemiological), genetic sequence data, virus susceptibility analyses, and physical materials such as candidate vaccine viruses and potency testing reagents – all of which are provided and distributed to laboratories and interested parties around the world, for the most part free of charge.

**Partnership Contribution**

The Partnership Contribution (PC) is one element of the PIP Benefit Sharing System. It is an annual payment, made to WHO by "Influenza vaccine, diagnostic and pharmaceutical manufacturers using the WHO Global Influenza Surveillance and Response System (GISRS)". Amounts to be paid by individual manufacturers are to be based on principles of transparency and equity, and on their nature and capacities (see PIP Framework, section 6.14.3). The Framework defines "influenza vaccine, diagnostic and pharmaceutical manufacturers" as:

- public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations or commercial entities;
- which develop and/or produce human influenza vaccines or other products derived from or using H5N1 or other influenza viruses of human pandemic potential" (see Framework, section 4.3).

Consistent with the Framework, WHO uses the funds provided under the PC to strengthen influenza pandemic preparedness and response capacities in countries that require such support.

**Note**

In 2012 and 2013 a similar Questionnaire was published by WHO. Following receipt of several comments, WHO has modified and/or expanded some of the questions to address concerns
regarding the meaning of the terms “manufacturer” and “use of GISRS”.

The 194 countries that constitute the Member States of WHO, established the Partnership Contribution “with a view to ensuring the sustainable financing of the PIP Benefit Sharing System […]” (see PIP Framework, section 6.14.1). In directing that payment of the annual Partnership Contribution be made by “…manufacturers using GISRS”, WHO Member States intentionally sought to capture the broadest group of manufacturers possible, irrespective of corporate structures or their level of use of GISRS. The objective was to ensure that all manufacturers (as defined in PIP Framework Section 4.3) who use GISRS, participate in some manner in the Partnership Contribution. The PIP Framework therefore contains a broad definition of “manufacturers” which covers public or privates entities, and includes academic institutions, government owned or subsidized entities, non-profit organizations or commercial entities.

With the aim of identifying as many contributors as possible, the following changes are being made to the questions in this year’s Questionnaire:

- The term “manufacturer” has been revised to clarify that it covers entities controlled by a manufacturer, e.g. subsidiaries, affiliates, associates, ventures, concerns, corporations, partners, divisions, branches, holdings, departments, etc.
- The concept of “use of GISRS” has been clarified by providing examples.

Additionally, to increase the potential group of contributors, and assist WHO in better understanding the range of entities that use GISRS, all non-GISRS recipients of PIP Biological Material (PIP BM) recorded in the Influenza Virus Traceability Mechanism (IVTM) will be sent the Questionnaire to complete.

Purpose

The purpose of this questionnaire is to determine if your company/institution/establishment is an "influenza vaccine, diagnostic [or] pharmaceutical manufacturer using the Global Influenza Surveillance and Response System (GISRS)." Under the PIP Framework, to be identified as a contributor to the annual Partnership Contribution, an entity must be an influenza manufacturer and use GISRS. Entities that are ‘manufacturers’ under the PIP Framework but do not ‘use GISRS’ will not be identified as contributors. Likewise, entities that ‘use GISRS’ but are not ‘manufacturers’ will not be identified as contributors.

Instructions

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

Question 3 contains several sub-questions which 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 26 May 2014.

In due course, WHO will publish the following results of the 2014 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 2014 Questionnaire ***

Fields marked with an asterisk (*) are mandatory.

Contact details

Company name *

Address *

Country *

Name and title of contact person *

E-mail *

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 company/institution/establishment, as well as any entities controlled by you, e.g. subsidiaries, affiliates, associates, ventures, concerns, corporations, partners, divisions, branches, holdings, departments, etc.

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?

"Develop" is understood to mean that 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 you have obtained a provisional or final licensure, registration or market authorization for such product, but have not implemented production, distribution or sales. 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.

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?

“Produce” is understood to mean that 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 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. 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.

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:

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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.

Name/description of component:

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Name of company or laboratory:

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

Yes  No
☐  ☐

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

Name of company or laboratory:

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