2013 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

Purpose and background

The purpose of this questionnaire is to determine if your company/institution is an "Influenza vaccine, diagnostic and pharmaceutical manufacturers using the Global Influenza Surveillance and Response System (GISRS)." Your national government, along with 193 other countries, established this class of manufacturers as part of the Pandemic Influenza Preparedness Framework (the "PIP Framework"), a 2011 internationally-agreed policy on global public health.

The PIP Framework brings together many stakeholders, including industry, that are to work together to ensure that the world is better prepared to respond to the next pandemic influenza. A specific element of the PIP Framework is an annual "Partnership Contribution" that is to be made to WHO by "Influenza vaccine, diagnostic and pharmaceutical manufacturers using the WHO Global Influenza Surveillance and Response System (GISRS)" (see Framework Section 6.14.3). The Framework defines "influenza vaccine, diagnostic and pharmaceutical manufacturers" as follows:

"Influenza vaccine, diagnostic and pharmaceutical manufacturers" means public or private entities including academic institutions, government owned or government subsidized entities, nonprofit organizations or commercial entities that 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).

To be identified as a contributor to the annual Partnership Contribution, an entity must be a manufacturer and use GISRS [1]. This questionnaire explains what is understood by the terms "manufacturer" and "use GISRS".

You are requested to complete this Questionnaire by 18 April 2013 after which the Questionnaire will be closed. In due course, the Secretariat will publish the following on the WHO PIP Framework internet page: the list of companies contacted; the responses provided by each company; and the list of companies that did not respond.

[1] Entities that are manufacturers under the PIP Framework but do not "use GISRS" are not expected to make a Partnership Contribution. Entities that "use GISRS" but are not manufacturers are not expected to make an annual Partnership Contribution.
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 *

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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.
Do you *use* GISRS? “*Use GISRS*” is understood to mean that in your product development, testing, production or marketing you have used or received from GISRS, materials, services, or information not routinely provided to the general public (such as analyses of viruses, viral sensitivity or epidemiological analyses).

Please answer *Yes*  No