Pandemic Influenza Preparedness Framework: Distribution of Partnership Contribution among companies[1]

Note: This document replaces the version dated 22 November 2012 which has been archived and may be viewed at http://www.who.int/influenza/pip/PC_Distribution_22Nov2012u.pdf

I. INTRODUCTION

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"). In Section 6.14.3, Member States established 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 would be used to strengthen pandemic influenza preparedness and response.

The Director-General will decide on the specific use of the resources, issuing detailed implementation plans that will be regularly developed and/or updated, as appropriate. In accordance with Section 6.14.6 of the Framework, such implementation plans will be based on advice from the PIP Advisory Group, an independent and international group of experts (whose membership is drawn from all six WHO regions) that advises the Director-General on implementation of the Framework, and interaction with manufacturers and other stakeholders. The implementation plans will include transparent oversight and accountability, consistent with WHO financial rules, regulations and practices.

The Framework specifies that the PC is to commence in 2012 and that the sum of the annual PC will be fixed at 50% of the running costs of the WHO GISRS, which is understood to be a reference index. In other words, for purposes of determining the amount of the PC, it was agreed to use the WHO GISRS 2010 running costs, which were estimated to be US$ 56 million. The Framework specifies that such running costs may change over time and that the Partnership Contribution will change accordingly. Reviews of GISRS running costs will be undertaken at intervals of 5 years to avoid undue burdens on GISRS laboratories that will be providing information to the Secretariat, to avoid undue expenses related to data collection and to increase predictability for budget and Partnership Contribution purposes.

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1. A proposal received by WHO on 5 September 2012 from the International Federation of Pharmaceutical Manufacturers and Associations ("IFPMA") was used as reference for the proposals contained herein as further explained in footnote 7 below.

2. The WHO GISRS is defined in Section 4.3 of the Pandemic Influenza Preparedness Framework as "the international network of influenza laboratories, coordinated by WHO, that conduct year-round surveillance of influenza, assessing the risk of pandemic influenza and assisting in preparedness measures. The WHO GISRS comprises National Influenza Centers, WHO Collaborating Centers on Influenza, WHO H5 Reference Laboratories and Essential Regulatory Laboratories."

The total 2013 PC will be US$ 28 million.

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

This document provides a methodology and formula for the distribution of the PC among companies, in accordance with Section 6.14.3 of the PIP Framework. It takes into account collaboration with industry and the recommendations of the PIP Framework Advisory Group. In future years, this distribution may be refined as experience in implementing the Framework is gained.

II. DETERMINING THE LIST OF POTENTIAL CONTRIBUTORS

A) Criteria for inclusion in the list of potential contributors

As a first step, it is useful to review the Framework language which establishes who is to contribute to the annual PC. Framework Section 6.14.3 states:

> "Influenza vaccine, diagnostic and pharmaceutical ***manufacturers, using the WHO GISRS***, will make an annual partnership contribution to WHO for improving global pandemic influenza preparedness and response." (Emphasis added.)

In that phrase, two critical terms identify the entities expected to make an annual partnership contribution:

- "Influenza vaccine, diagnostic and pharmaceutical manufacturers": The Framework does not establish any hierarchy among the manufacturers.

- "Using the WHO GISRS": In the spirit of transparency and equity, and consistent with the plain meaning of the text, any manufacturer within the classes identified (vaccine, diagnostic, pharmaceutical) that accesses the WHO GISRS is considered to be using it. The definition is intended to encompass more entities than those receiving physical PIP biological materials (i.e., those that must conclude Standard Material Transfer Agreement 2s) [3].

B) Concept of "using the WHO GISRS"

GISRS brings together scores of world-class scientists, primarily from public health organizations or academia, who collaborate on a frequent basis to generate data, analyses, and physical materials that are made available, for the most part without charge, to interested parties at large for the benefit of increasing knowledge, surveillance, preparedness and response capacities for influenza. Physical materials developed and provided by or through GISRS labs include candidate vaccine viruses, reference reagents, reference reagents for vaccine potency determination, and influenza reference viruses. Data, information and analyses include virus characterization, sequence information, results of viral sensitivity tests as well as epidemiological

[3] In this connection, the PIP Advisory Group, at its October 2012 meeting, advised the Director-General as follows: "The Advisory Group considers that the use of GISRS has contributed to the development and registration of vaccines, antivirals and diagnostics. Therefore, it is logical that all such manufacturers contribute to the Partnership Contribution."

patterns[4]. Such materials and information have been and/or are currently used by manufacturing entities in many ways, including developing, testing, producing or marketing products. "Use of GISRS" is therefore understood to include receipt of physical materials, or use of data and/or information, some of which may not be routinely provided to the general public; this includes participating in, and/or receiving summaries of information related to, pre- and post-Vaccine Composition Meeting teleconference calls.

C) Concept of "manufacturers"

In considering this term, the Framework (Section 4.3) defined a broad category of entities:

> "public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations or commercial entities that ***develop and/or produce*** human influenza vaccines and other products derived from or using H5N1 or other influenza viruses of human pandemic potential." (Emphasis added.)

It is clear that the intent was to identify a broad group of manufacturing entities that use the WHO GISRS, regardless of corporate structure.

The phrase "develops and/or produces" introduces two additional elements into the process of identifying potential contributors. The terms "develop" and "produce" have been understood to mean the following:

> "Develop" is understood to mean that in the past 15 years, a company has developed or is 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 it has obtained a provisional or final licensure, registration or market authorization for such product, but has 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.
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> "Produce" is understood to mean that in the past 15 years, a company has produced or is 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 the company has 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.

D) Summary: Potential contributors

Based on the foregoing the list of potential contributors should comprise:

- Vaccine, pharmaceutical or diagnostic entities
  - Using GISRS
    - That develop and/or produce
      - Products derived from or using H5N1 or other influenza viruses with human pandemic potential that can be used to prevent, treat or diagnose infections from H5N1 or other influenza viruses with human pandemic potential.

[4]. To see the full complement of GISRS laboratories, activities and products, see: http://www.who.int/influenza/gisrs_laboratory/en/

To be identified as a contributor, an entity must be a manufacturer and use GISRS.

To identify as many potential contributors as possible, the Secretariat will, on an annual basis, post on the PIP webpage and send, a short questionnaire. The list of companies contacted by WHO, as well as all the answers from companies responding to the questionnaire, will be posted by WHO on an annual basis on the PIP webpage. The list of contributors will be identified using questionnaire responses[5].

III. DEFINING THE DISTRIBUTION AMONG COMPANIES

A) Integrating the concepts of nature and capacity, and equity

Any formula to distribute the PC among companies must take into consideration the *nature* and *capacity* of each company, as well as the *equity* of the distribution[6].

The phrase "nature and capacities" introduces qualitative factors to distinguish entities within the broad category of influenza vaccine, diagnostic and pharmaceutical manufacturers, to ensure that differences among companies are taken into consideration. The *nature* of companies is captured in the definition of "influenza vaccine, diagnostic and pharmaceutical manufacturers" found in Section 4.3 of the PIP Framework: "public or private entities including academic institutions, government owned or government subsidized entities, non-profit organizations or commercial entities." The *capacity* of manufacturers is understood to include the capacity of the manufacturer to produce the influenza product and its capacity to make a financial contribution.

By including factors of nature and capacity, the important concept of equity is addressed. Distribution among companies should reflect an equitable apportionment that targets all users but differentiates among them to ensure that those most able to pay do so, while preserving the incentive to develop and innovate.

B) Defining the method & formula for allocating the Partnership Contribution among companies[7]

The data set retained for use in the distribution formula is the average annual influenza product sales per manufacturer, for 3 past years plus 2009 (the pandemic year)[8]. Expressed as a mathematical formula, this is:

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5. In this connection, the Advisory Group, at its October 2012 meeting, recommended to the Director-General that: "Recognizing that certain contributors have been identified through representative associations, the Director-General should make reasonable efforts to identify all other potential contributors to the Partnership Contribution through the use of a questionnaire and other available means."

6. Framework Section 6.14.3 states, in relevant parts: "The distribution between companies is to be based on transparency and equity, based on their nature and capacities."

7. In this connection, the Advisory Group, at its October 2012 meeting, made the following recommendations to the Director-General: "In accordance with Section 6.14.3 of the Framework, the Director-General should consider the IFPMA proposal as reference for joint negotiation with industry with a view to presenting (through electronic means) an agreed formula to the Advisory Group for its consideration by 12 November 2012 and its finalization by the Director-General by 16 November 2012. The formula should explicitly include Partnership Contributions from antiviral manufacturers. This is because the Advisory Group considers that the sales of influenza antivirals by manufacturers benefit directly or indirectly from the use of GISRS, considering its role in monitoring the susceptibility of the circulating virus to antivirals. Further work should be conducted to explore the possibility of contributions from entities that fall into the Research and Development category." Accordingly, the IFPMA proposal is used as a reference herein. For example, the bands and weights proposed are based on the IFPMA Proposal at Alternative #3found in the 5 September 2012 IFPMA submission. Likewise, the formula for calculating the individual PC payments by companies, is the formula proposed by IFPMA.

8 The inclusion of the year 2009 may be reassessed at the time of the review of the Framework and its Annexes pursuant to PIP Framework Section 7.4.2.

(3 Prior year influenza product sales + 2009 influenza product sales)/4

Options considered for developing the distribution formula

Two options were considered but not retained.[9]

The first option considered was a *proportional* formula with 7 bands[10]. The proposal was not retained because it was not seen as sufficiently equitable due to fact that two companies in the same "band" could make the same contribution while having significantly different levels of sales.

The second option considered was a *progressive* formula in which companies with high sales would pay a higher rate of contribution than companies with lower sales. The proposal was not retained for following reasons:

a) Sales averages inherently reflect global variations in marketing, pricing and competitive dynamics that are specific to country marketplaces.
b) A progressive approach could have disproportionately affected companies.
c) One of the tenets for establishing the methodology for contributions is simplicity. Establishing a progressive methodology required creation, on an arbitrary basis, of a "progressivity factor".

The Approach

For the foregoing reasons, the formula is based on *proportional* distribution of PC and use of more bands which are narrower than those considered in the first option.

The bands and weights are based on those proposed by the IFPMA in its paper of 5 September 2012 "Alternative 3". To create more bands, the same weightings were applied to extend the bands upwards and refine the bands into narrower ranges. The results are set forth below in Table 1 below.

Table 1: Sales Bands & Weights

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

[9] A written proposal was received on 5 September 2012 from IFPMA. In accordance with PIP Framework Section 6.14.3 the Director-General and the Advisory Group collaborated with industry on 4 & 31 October 2012, 8 November 2012, and 13 February 2013.
[10] The proposal was based on "Alternative #3" found in the 5 September 2012 IFPMA submission.

Band Number	Average annual influenza product sales (in USD millions)	Weight
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

Based on their average annual influenza product sales, each manufacturer will be placed into one of the sales bands on the left, which corresponds to a band weight, shown on the right. Each entity within a given band will make an identical contribution to the PC.

The formula for calculating an individual company's payments into the PC is based on three elements[11]:

- Total amount of the PC to be paid in a given year;
- The "band weight" of each individual manufacturer in the list of contributors; and
- The sum of the "band weights" of all contributing entities.

The formula is as follows:

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

IV. PROCESS TO PLACE COMPANIES WITHIN CONTRIBUTION BANDS

The approach is based upon sales data. In some cases, such data are public information but in other cases, data on sales is privileged information covered under local laws, rules or regulations. The process outlined below is based on, and recognizes, the following critical factors:

- That the foundational principle of the PIP Framework is trust among stakeholders;
- There is need to ensure that the full amount of contributions is received annually; and
- It is difficult to establish a single, uniform system applicable to all contributors, in all countries.

Taking these 3 factors into account, the approach to establish the sales of contributing companies is as follows:

[11] The elements and formula are those contained in the IFPMA proposal of 5 September 2012.

a) Each Company required to make a contribution under the Partnership Contribution will itself determine which band it fits into in Table 1 above, according to its average influenza product sales for the appropriate years;
b) The Company will inform WHO of its band selection using a pre-defined form. In light of the differences between local laws, rules and regulations, no actual sales data will be provided to WHO;
c) The form will be signed and certified by at least 2 of the three following Company officials: CEO, CFO, certified accountant/auditor;
d) Any questions related to the band selected will be referred to the Company;
e) A yearly table showing the bands in which all contributing have been placed will be published by WHO;
f) In accordance with PIP Framework Section 6.14.3, the Director-General will report to the Executive Board, on an annual basis, any questions received in relation to the foregoing, notably under d) above.

In the event that substantial questions arise as to the validity of sales figures provided to and used by the Director-General to determine the contribution due by each company, the Secretariat will explore the establishment of a verification system with a 3rd party auditor[12] but such an approach would be subject to the availability of funds unless the services were provided "*pro bono*" by a recognized 3rd party auditor.

V. ADDITIONAL CONSIDERATIONS

A) Distinguishing the three sectors: vaccine, diagnostic and pharmaceutical manufacturers

In developing this document, consideration was given to differentiating the three manufacturing sectors according to their share of a "global influenza market" prior to applying the formula to distribute the PC among companies. This approach was not retained for the following reasons:

(i) The metric for differentiating among the sectors is not immediately obvious. For example, "global influenza market share" can be calculated in a number of ways, using data that is not always without dispute. Similarly, calculating shares of pandemic influenza-related profits would require extrapolating data from multiple sources, estimating both total and individual profits and would likely require data that many companies would consider privileged; and

(ii) The PIP Framework does not differentiate these three sectors. Without an appropriate and transparent metric and without any guidance from the Framework, using this approach would have lacked transparency and equity. It was therefore not retained.

B) Determining the value of "using the WHO GISRS"

[12] Under such a system, the process could be as follows:
a) Each Company identified to make a contribution under the Partnership Contribution will provide its sales figures for each of the years concerned to an independent 3rd party auditor that shall verify the data;
b) The independent third party auditor will hold all such data in confidence;
c) The independent 3rd party auditor will provide to the Director-General a certified table identifying in which band each contributing Company is to be placed;
d) Any questions related to the band assigned to a Company will be referred to the 3rd party auditor;
e) The table showing the bands in which Contributing entity is placed will be published by WHO on its website;
f) The Director-General will report to the Executive Board, on an annual basis, any questions received in relation to the foregoing.

There are other options to determine the contribution to be paid by each manufacturer using GISRS. Sales of products over a period of time, including a pandemic year, were chosen for their simplicity, transparency and fairness. Other possible approaches could be to use units of product produced over a period of time. A third approach could be a combination of sales and production. While any method will have strengths and challenges associated with establishing the data points used, the goal should be to achieve a reasonable and simple formula based on easily verifiable data.

C) Annual review of List of Contributors

In order to ensure that the list of contributors is accurate and current, the Secretariat will issue a questionnaire annually to ensure that all entities that should contribute do so and that contributors that have left the influenza antiviral, diagnostic or vaccine industry are no longer included in the list of Contributors. In this manner, the Secretariat will make best reasonable efforts, on the one hand, to reduce to a minimum the possibility of "free-riders" in the system and, on the other hand, ensure that companies that no longer fall into the category of "manufacturers using GISRS" are no longer solicited to contribute.

D) Currency for contributions

In accordance with WHO Financial Rules and Regulations, all contributions will be submitted in US dollars, using the UN rate of exchange valid on the day the transfer from the contributing entity is executed. If a Contributor's annual sales are in a currency other than US dollars, the Contributor will be responsible for converting its sales to US dollars using the exchange rate for December for the applicable year using the rates published by the United Nations Treasury - Operational Rates of Exchange:
http://treasury.un.org/operationalrates/OperationalRates.aspx

E) Note regarding the Use of PC resources

As highlighted in the Introduction above, this paper solely addresses matters related to determining the distribution of PC among companies. This issue of use of PC resources has been addressed by the Advisory Group and the Director-General in several meetings and the Executive Board, in its 131st session adopted the Director-General's proposal on the proportional division of funds between pandemic preparedness and response (See EB131/4). Consultations with industry and other stakeholders will continue on this matter, and issues related to use of the funds contributed will be addressed in future papers. An implementation plan for use of the resources will be developed and issued by the Director-General in early 2013. The plan will take into account the advice of the Advisory Group as well as input received through interactions with manufacturers and other stakeholders.