

# Guiding Principles for use of PIP Partnership Contribution “Response” Funds

23 October 2014

## I. Background

1. The Partnership Contribution (PC) is an annual payment to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers using the Global Influenza Surveillance and Response system (GISRS).<sup>1</sup> The Framework specifies that PC resources are to be used for improving pandemic preparedness and response, *inter alia*, for conducting disease burden studies, strengthening laboratory and surveillance capacities, and access and effective deployment of pandemic vaccines and antiviral medicines.<sup>2</sup> The Framework states that the annual amount to be received by WHO is equivalent to 50% of the running costs of GISRS, which, in 2010, were approximately US\$ 56.5 million.<sup>3</sup> Therefore, the annual PC to be received by WHO is US\$ 28 million.
2. Recognizing the significant global need for improved preparedness, detailed notably in the IHR Review Committee Report, the PIP Advisory Group (PIPAG) provided the following advice to the Director-General on the proportional allocation of resources between preparedness and response:
  - a) In the early phases of the Framework's implementation, more of the PC should be used for preparedness than response.
  - b) Specifically, over the next 5 years (2012 through 2016) approximately 70% of contributions should be used for pandemic preparedness measures and approximately 30% should be reserved for response activities, recognizing the need and usefulness of flexibility in allocating funds.
  - c) In order to ensure that the proportional division does not hinder necessary response measures during pandemic influenza emergencies, the Director-General should be able to temporarily modify the allocation of PC resources as required to respond to said emergencies. The Director-General should report on any such modification to Member States.
  - d) The proportional division should be reviewed again in 2016.
3. The guidance was accepted by the Director-General and submitted to the 131<sup>st</sup> Executive Board that likewise accepted it, in accordance with PIP Framework Section 6.14.5.
4. Annual contributions received have been divided according to the decision of the Executive Board.
5. This document outlines the Guiding Principles for use of PIP PC Response funds. Use of “Preparedness” funds is covered in the *PIP PC Implementation Plan 2013-2016* approved by the Director-General on 17 January 2014.

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<sup>1</sup> See PIP Framework Section 6.14.3

<sup>2</sup> See PIP Framework Section 6.14.4

<sup>3</sup> See PIP Framework Section 6.14.3 and 6.14.4

6. PIP Framework Section 6.14.6 states that “the Director-General, based on advice from the ‘Advisory Group’, will decide on the use of [Partnership Contribution] resources. The Director-General and the ‘Advisory Group’ will interact with manufacturers and other stakeholders.”
7. The decision on the use of “Preparedness” resources was taken by the Director-General following several significant consultations with the PIP Advisory Group, and interaction with industry and other stakeholders. These took place over several months and meetings, from February 2012 to October 2013.
8. At the time of a pandemic, time will be of the essence and there will be limited or no opportunities to convene the Advisory Group or hold interactions with industry and other stakeholders to discuss the use of “Response” resources.
9. The Guiding Principles will provide the basis for the Director-General to decide on the use of the PC for response purposes without further advice from the Advisory Group, or interaction with industry and other stakeholders.

## II. Guiding Principles governing use of PIP PC Response funds

- 1) **Authority:** Using the Guiding Principles outlined herein, the Director-General shall decide on the allocation and use of PC “Response” funds.
- 2) **Release of PC Response funds:** The release of PC Response funds will be based on the following:
  - Determination of a Public Health Emergency of International Concern (PHEIC) under the International Health Regulations (2005)(IHR): The responsibility of determining a PHEIC lies with the WHO Director-General under IHR Article 12.<sup>4</sup> This requires the convening of an Emergency Committee of experts under IHR Article 48. In accordance with the IHR, the Director-General shall consider the following when determining whether an event constitutes a PHEIC:
    - information provided by the State Party;
    - the decision instrument contained in IHR Annex 2;
    - the advice of the Emergency Committee;
    - scientific principles as well as the available scientific evidence and other relevant information; and
    - an assessment of the risk to human health, of the risk of international spread of disease and of the risk of interference with international traffic.
  - Declaration of a pandemic: During the spread of human influenza caused by a new subtype, and appropriate to the situation, the Director-General may make a declaration of a pandemic.
  - In some instances, the Director-General may allocate some funds to pandemic response activities that would take place in advance of a pandemic declaration, such as for instance, to secure access to antiviral medicines or other essential supplies and equipment.

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<sup>4</sup> See <http://www.who.int/ihr/publications/9789241596664/en/>.

- 3) **Priority setting:** In accordance with PIP Framework section 6.0.2 (iii) WHO will prioritize and provide access to “important benefits, such as and including antiviral medicines and vaccines [...] as high priorities, to developing countries, particularly affected countries, according to public health risk and needs and particularly where those countries do not have their own capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals. Prioritization will be based on assessment of public health risk and need, by experts with transparent guidelines.”<sup>5</sup>
- Criteria to allocate benefits: Development of criteria will be based on assessment of public health risk and need, by experts with transparent guidelines, provided in the Framework (see above). This will require information about, *inter alia*, the level and extent of disease transmission, clinical and virological characteristics of the pandemic virus, its spread, and the development status of countries. Additionally, at the time of the pandemic event, updated information on the production capacities of manufacturers of pandemic products will be necessary. Allocation of benefits will also take into account national pandemic preparedness plans, e.g. regulatory capabilities and plans for deployment of vaccines, antivirals, diagnostics and other pandemic-related products.
  - Coordination with Standard Material Transfer Agreements 2 (SMTAs 2): SMTAs 2 will provide WHO with real-time access to critical pandemic response products (e.g. pandemic vaccines, antivirals, diagnostics and other pandemic-related products). PC Response funds will be used to ensure that WHO can access all such products secured under SMTAs 2 on a donation or reserve basis. While many products will be accessed on a donation basis, funds will be necessary to ship many of these goods to recipient countries. Additionally, funds will be necessary to access goods reserved for purchase at an affordable price.
- 4) **Fairness and Equity:** WHO shall ensure that fairness and equity, as well as public health risk and need, govern access to pandemic response products and services provided by WHO.
- 5) **Transparency:** Information on the allocation and use of PC response funds will be shared in a timely manner with Member States, the PIP Advisory Group, industry and other stakeholders.
- 6) **Accountability:** WHO will be fully accountable for the use of all PC funds used by WHO for response activities.
- 7) **Leverage through the Director-General’s Good Offices:** The Director-General will leverage the positive impact of the use of PC funds and encourage further contributions for pandemic response activities. No PC Response funds will be used to achieve this end.

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<sup>5</sup> See PIP Framework Section 6.02 (iii).