

Pandemic Influenza Preparedness Framework

# Partnership Contribution Implementation Plan 2013 – 2016

ORIGINALLY PUBLISHED 17 JANUARY 2014



World Health  
Organization

Updated 31 January 2015

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**Note to readers**

In 2014, Outcome and Output indicators, along with their associated Measurements of success, Baselines and Targets, were refined following detailed field evaluations. The resulting modifications are reflected in Annex 7.

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# Executive Summary

The *Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits* (PIP Framework) is an international arrangement adopted by the World Health Assembly in May 2011 to improve global pandemic influenza preparedness and response.<sup>1</sup>

The Framework establishes a PIP Benefit Sharing System that includes an annual partnership contribution (PC) to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers using the WHO global Influenza Surveillance and Response System (GISRS). The Framework specifies that the PC resources shall be used to improve pandemic preparedness and response and that the Executive Board will decide on the proportion that should be allocated to each. In May 2012, the Executive Board decided that for the period 2012-2016, 70% of resources should go to preparedness and 30% to response. The annual PC is currently US\$ 28 million. In 2012, US\$ 18,121,000 were received as a voluntary contribution from seven manufacturers. From 2013-2016, it is expected that US\$ 28 million will be received annually so that by the end of 2016 a total of US\$ 130,121,000 will be available. This Implementation Plan is built against that expectation.

The PIP Framework stipulates that the Director-General will decide on the use of the resources based on advice from the PIP Advisory Group, and interaction with industry and other stakeholders.

The process to develop this plan began in early 2012 and was discussed at each Advisory Group meeting and during several consultations with industry and other stakeholders. The development of a global, multi-year

plan of this magnitude has inherent limitations, in part due to the number of countries, regions and technical areas in which work is to be undertaken, and the processes used to ensure fairness, equity and public health needs-based allocations to countries. The Implementation Plan is to be considered a “living document” that will be regularly validated and revised as necessary.

The Implementation Plan relies on and refers to the Gap Analyses, which support the establishment of the outcomes and outputs defined herein. In addition, this Implementation Plan provides key deliverables, with indicators and estimated budgets for use of PC resources. If all assumptions hold, it is expected that by 2016 the following Outcomes should be achieved:

- **Laboratory and Surveillance:** The capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.
- **Burden of Disease:** National policy makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources.
- **Regulatory Capacity Building:** Countries with weak or no regulatory capacity will be able to regulate influenza products, including vaccines, antivirals and diagnostics, and to accelerate registration of these commodities in case of an influenza pandemic.
- **Risk Communications:** Global risk communications capacities are strengthened with a special focus on pandemic influenza communications
- **Planning for Deployment:** Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics, will be developed and regularly updated.

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<sup>1</sup> See <http://www.who.int/influenza/pip/en/>

# Introduction

## 1. Pandemic Influenza Preparedness: A multi-sectoral approach

Strengthening national and global capacities to detect, prepare for, and respond to epidemic and pandemic diseases has been a topic of at least nine World Health Assembly resolutions since the founding of the World Health Organization (WHO)<sup>2</sup>. As a matter of global health security, preparing for the next pandemic influenza remains a high priority for WHO and its Member States.

A foundational concept for any plan to address pandemic influenza preparedness is recognition of the unpredictability and inevitability of influenza pandemics and their potentially devastating impact on all sectors of society. Advance planning coupled with strengthening capacities to mitigate these effects is therefore critical. The *"Pandemic Influenza Preparedness Framework for the sharing of Influenza viruses and access to vaccines and other benefits"* (the "PIP Framework" or "Framework"), adopted by the World Health Assembly in May 2011, aims to do just that through a multi-faceted approach that complements two important priorities at WHO: implementation of the International Health Regulations (2005) and the Global Action Plan for Influenza Vaccines.

### The International Health Regulations (2005)

The International Health Regulations ("IHR") is an international treaty among all WHO Member States. First adopted in 1969, the IHR underwent significant revisions in 2005 to address a range of issues brought to the forefront of international concern by the emergence of severe acute respiratory syndrome ("SARS"), which in 2003, was the first 'public health emergency' of the 21st century. The revised Regulations contain several innovations, including: (a) a scope not limited to any specific disease or manner of transmission, but covering "illness or medical condition, irrespective of origin or source, that presents or could present significant harm to humans"; (b) State Party obligations to develop certain minimum core public health capacities; and (c) obligations on States Parties to notify WHO of events that may constitute a public health emergency of international concern (PHEIC) according to defined criteria.

Pandemic influenza is a global public health emergency. Specific preparations for a robust response by governments necessarily dovetails with overall efforts of governments to implement the IHR and reach the levels of core surveillance and detection capacities articulated in IHR Article 5 and Annex 1.

### Global Action Plan to Increase Influenza vaccine supply ("GAP")

In 2003, following six quiet years, human cases of infection due to A(H5N1) re-emerged. The spread of the virus in several Asian countries' human and poultry sectors prompted the development of vaccines. Concerns quickly grew over the limited capacity to produce sufficient influenza vaccine to cover the world's population. In response, WHO launched the Global Action Plan for Influenza Vaccines (GAP)<sup>3</sup> – a comprehensive strategy to reduce the global shortage of influenza vaccines for seasonal epidemics and pandemic influenza, in all countries of the world, through three major approaches: 1) increase the number of countries that use seasonal influenza vaccine; 2) increase influenza vaccine production capacity, particularly in developing countries; and 3) continue to champion the need for research and development for new influenza vaccines and technologies. The GAP program, which commenced in 2006, was further refined and extended, in 2011.

### The PIP Framework

The Member State-led process that culminated in the adoption of the PIP Framework started in 2007, spurred in large part by growing concern of a possible A(H5N1) pandemic. The process lasted four years. The resulting PIP Framework is a unique tool to promote global action to prepare for pandemic influenza. As such, it fits within the larger context of the two WHO initiatives described above, with preparedness as both the driver and the desired outcome.

## 2. Partnership Contribution

The PIP Framework establishes a PIP Benefit Sharing System,<sup>4</sup> that operates to, *inter alia*, provide all countries with pandemic surveillance and risk assessment, and build capacity in countries where needs are identified.<sup>5</sup>

<sup>2</sup> See: WHA22.47; WHA48.13; WHA56.19; WHA56.29; WHA58.5; WHA59.2; WHA60.28; WHA63.1; WHA64.5

<sup>3</sup> See [http://www.who.int/influenza\\_vaccines\\_plan/en/](http://www.who.int/influenza_vaccines_plan/en/)

<sup>4</sup> See PIP Framework, Section 6.01

<sup>5</sup> See PIP Framework Section 6.0.2

The Partnership Contribution (PC) is one element of the PIP Benefit Sharing System. As an innovative sustainable financing mechanism, it recognizes the desirability of having all users of the WHO Global Influenza Surveillance and Response System (GISRS) contribute to the PIP Benefit Sharing System, financially or in kind, according to their capacity over time.<sup>6</sup>

The PC is an annual payment to WHO from influenza vaccine, diagnostic and pharmaceutical manufacturers using the GISRS.<sup>7</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>8</sup> (See **Fig. 1**) 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>9</sup> Therefore, the annual PC to be received by WHO is US\$ 28 million.

The process to decide on the use of PC resources is addressed in the Framework as follows:

- Based on the advice of the Advisory Group and a proposal from the Director-General, the Executive Board decides on the proportional allocation of resources between preparedness and response;<sup>10</sup>
- Based on advice from the Advisory Group, and interaction with manufacturers and other stakeholders, the Director-General decides on the use of resources.<sup>11</sup>

During its first two meetings (November 2011 and February 2012), the PIP Advisory Group (PIP AG) discussed the PC, noting the priority that should be afforded this unique mechanism to build pandemic influenza readiness

**Fig. 1: Pandemic influenza preparedness process**



<sup>6</sup> See PIP Framework sections 6.14.1 and 6.14.2

<sup>7</sup> See PIP Framework Section 6.14.3

<sup>8</sup> See PIP Framework Section 6.14.4

<sup>9</sup> See PIP Framework Section 6.14.3 and 6.14.4

<sup>10</sup> See Framework Section 6.14.5

<sup>11</sup> See Framework Section 6.14.6



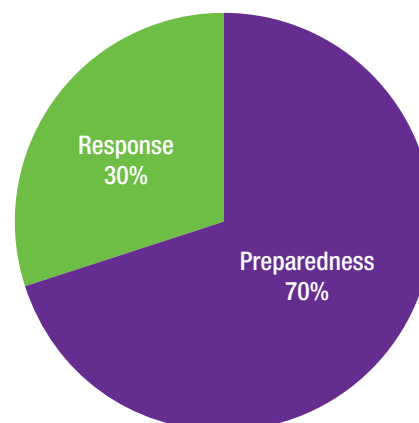
and response capacities. The PIP AG underscored that the PC should complement and build on on-going capacity-building efforts required under the International Health Regulations (2005)<sup>12</sup> and the Global Action Plan for Influenza Vaccines (GAP),<sup>13</sup> observing that, collectively, these efforts would better prepare the world for the next influenza pandemic. In recommending allocations of PC resources to specific technical areas, the PIP AG stated that in a decade's time:<sup>14</sup>

- All countries should have in place well established core capacities for surveillance, risk assessment, and response at the local, intermediate and national level, as required by the IHR.
- All countries should have access to a National Influenza Centre (NIC) laboratory – the backbone of the GISRS.
- A clearer picture of the health burden that influenza imposes on different populations should be established.
- All countries should have access to pandemic influenza vaccines and antiviral medicines to help reduce pandemic-related morbidity and mortality.
- All countries should have improved capacities to carry out effective risk communications at the time of a pandemic.

Recognizing the significant global needs for improved preparedness, detailed notably in the IHR Review Committee Report, the PIP AG provided the following advice to the Director-General on the proportional allocation of resources between preparedness and response:

1. In the early phases of the Framework's implementation, more of the Partnership Contribution should be used for preparedness than response.
2. 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.
3. 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 Partnership Contribution resources as required to respond to said emergencies. The Director-General should report on

**Fig. 2: EB 131 decision on Proportional distribution (May 2012)**



any such modification to Member States.

4. The proportional division should be reviewed again in 2016.

The guidance was accepted by the Director-General and submitted to the 131st Executive Board that likewise accepted it, in accordance with PIP Framework Section 6.14.5. (See **Fig. 2**)

In May 2012, the PIP AG recommended a further breakdown for the use of preparedness resources as follows:<sup>15</sup>

- 70% to build and/or strengthen surveillance and laboratory capacity;
- 10% to conduct disease burden studies;
- 10% to strengthen regulatory capacity to improve access and effective deployment of pandemic vaccines and antiviral medicines; and
- 10% to strengthen risk communications.

The PIP AG also specified that for reasons of feasibility, flexibility and practicality, each of these proportions should be viewed as approximate targets, i.e. +/- 5% for each.

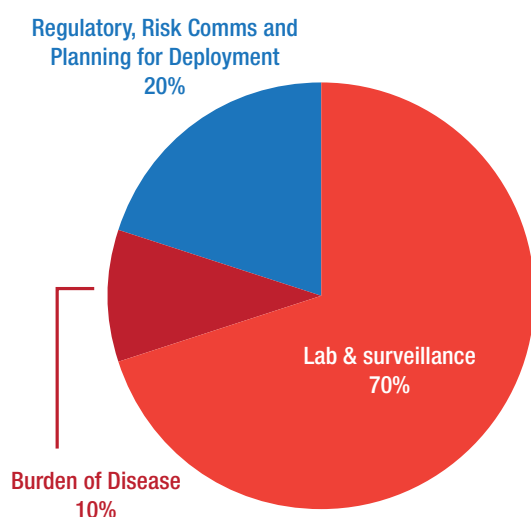
<sup>12</sup> See International Health Regulations (2005). Available at: <http://www.who.int/ihr/9789241596664/en/index.html>

<sup>13</sup> See Global pandemic influenza action plan to increase vaccine supply. Available at: [http://whqlibdoc.who.int/hq/2006/WHO\\_IVB\\_06.13\\_eng.pdf](http://whqlibdoc.who.int/hq/2006/WHO_IVB_06.13_eng.pdf)

<sup>14</sup> See [http://www.who.int/influenza/pip/advisory\\_group/PIP\\_AG\\_Recommendations\\_16May2012.pdf](http://www.who.int/influenza/pip/advisory_group/PIP_AG_Recommendations_16May2012.pdf)

<sup>15</sup> See [http://www.who.int/influenza/pip/advisory\\_group/PIP\\_AG\\_Recommendations\\_16May2012.pdf](http://www.who.int/influenza/pip/advisory_group/PIP_AG_Recommendations_16May2012.pdf) at paragraph 6

**Fig. 3: PIP AG Recommendation - Preparedness (70%)**



In March and October 2013, after further deliberations as well as interaction with industry and other stakeholders, the PIP AG further refined its advice on the Implementation Plan, suggesting that it be revised to create a new section entitled “Preparedness for Pandemic Interventions” under which there would be three sub-chapters as follows: Regulatory Capacity Building, Risk Communications and Planning for Deployment. In addition, the PIP AG recommended:

- That a portion of PC funds, not exceeding 10%, averaged over the next 4 years (2013-2016), be used by the PIP Secretariat to enable work, either on-going but at risk, or not yet undertaken because of lack of funds, to be made possible so as to meet the objectives of the PIP Framework.
- That implementation of activities under the PC begin in January 2014.
- That the PIP PC Implementation Plan should be considered a “living document” that can be revised over time.

As a result, the preparedness allocation has been revised to reflect these further refinements, which are consistent with the initial overall recommendation. Each of these proportions should be viewed as approximate targets, i.e. +/- 5% for each. (See **Fig. 3**)

### 3. Assumptions

As a general principle, it is assumed that “collateral” benefits will accrue from improving capacities in the four major areas of work described in the Framework. Thus, while the focus of activities implemented with PC resources may specifically target influenza prevention or control, the capacities developed are more generic or cross sectoral and will necessarily strengthen the overall preparedness and capacity of countries to respond to public health emergencies of all kinds. (See **Fig. 4**)

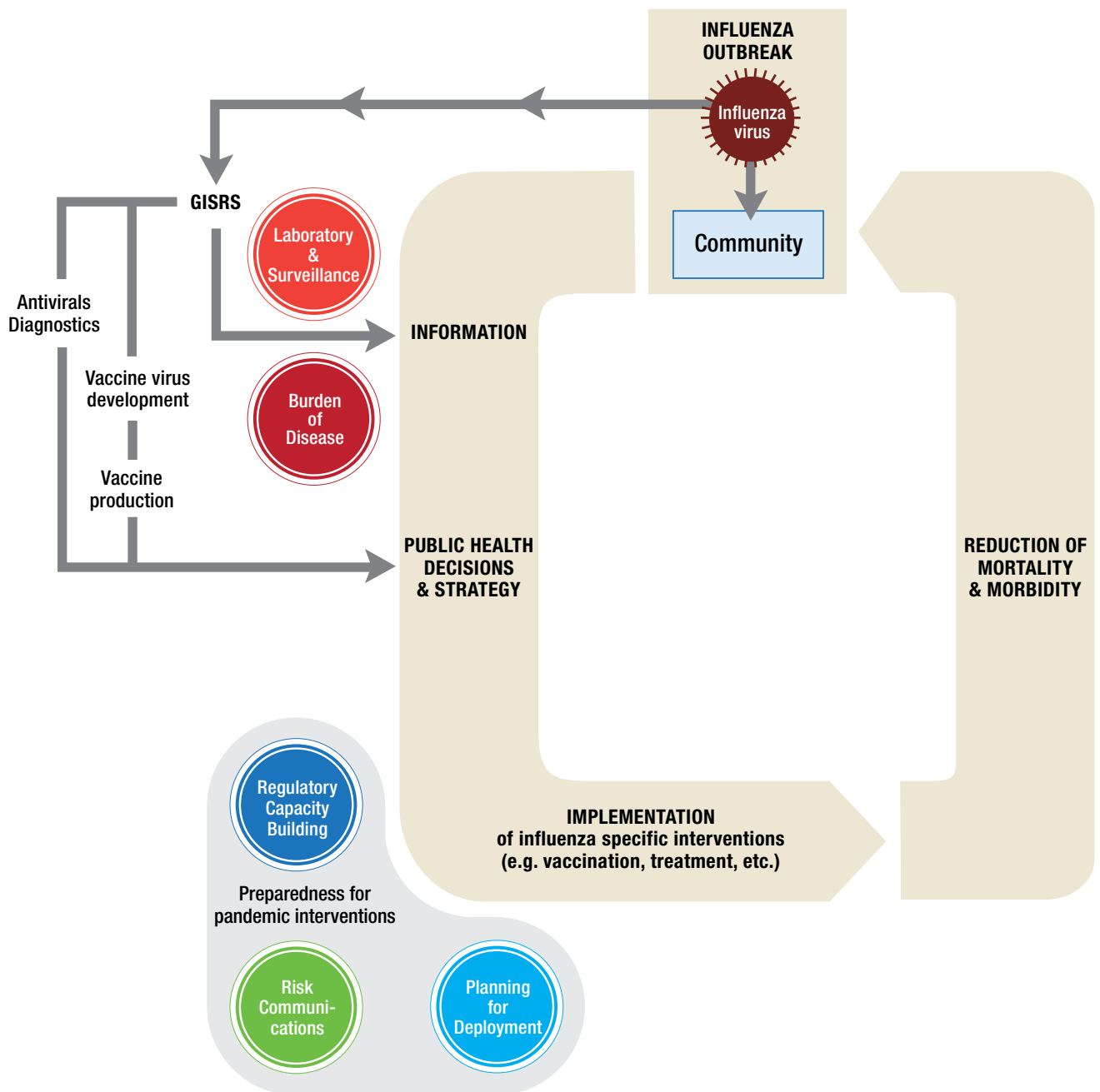
Other assumptions, and where relevant, implications of the same, include the following:

- *WHO will receive US \$28M<sup>16</sup> annually from 2013-2106:* Implementation will be contingent on **actual** receipt of funds. WHO does not have other funds, independent of the PC, to finance the activities proposed herein. Once approved, the Implementation Plan should be considered a commitment against which PC must be provided on a regular and timely basis if the activities are to be implemented.
- *The Advisory Group will provide the Director-General with guidance on the use of the PC that reflects interaction with industry and other stakeholders<sup>17</sup>* The Advisory Group and WHO will regularly interact with industry and other stakeholders, providing regular information on progress to ensure transparency in the implementation of the work plan
- Budgets for activities are based on estimated costs in each Region.

<sup>16</sup> This figure is based on the running costs of GISRS in 2010 which were approximately US \$56.5 million. The running costs of GISRS are understood to be a reference index for the partnership Contribution of 50%. Such running costs may change over time and partnership contribution will change accordingly. (see PIP Framework Section 6.14.3, footnote 1).

<sup>17</sup> See PIP Framework section 6.14.6

**Fig. 4: Pandemic influenza preparedness cycle**



## 4. Planning Principles

Ensuring coherence, complementarity and synergy in the implementation of PC, IHR and GAP activities is fundamental to securing the greatest impact of limited resources. Given the potential overlap of objectives for these three areas, joint planning and coordination has been undertaken to identify additional, complementary activities that can hasten the achievement of outcomes (See **Table 1**). So, for example, the influenza specific laboratory and surveillance capacity building efforts proposed in certain countries will also support achievement of the required IHR core capacities under Article 5 and Annex 1. Likewise, development of burden of disease estimates and strengthening regulatory capacity will support the roll out of the Global Action Plan for influenza vaccines but will not duplicate efforts. A key planning principle has therefore been to coordinate closely with the IHR and GAP programs to ensure a sound, cost efficient and effective use of PC resources.

**Table 1: Synergies for PIP Implementation Framework with IHR and GAP**

PIP	International Health Regulations (IHR)	Global Action Plan for the access to influenza vaccine (GAP)
Laboratory & Surveillance	X	
Burden of Disease		X
Regulatory		X
Risk Communication	X	

Other guiding principles include:

- **Efficiency:** PC funds are provided to WHO to increase/strengthen global pandemic preparedness and response. It is critical that any funds used by WHO to manage use of the funds be reasonable and moderate.
- **Appropriateness:** Each PIP-funded project will deliver specific outputs according to the PC plan structure. Cost composition (staff, procurement, travel, contracting, etc.) will be driven by the nature of the specific activities required to deliver these outputs.

- **Flexibility:** Within the parameters of the planning document, and based on progress against deliverables, funds may be reprogrammed between projects to maximize the achievement of outcomes.
- **Monitoring:** Progress against targets/deliverables will be assessed every six months.
- **Transparency:** Allocation and use of PC funds will be done transparently
- **Accountability:** WHO will be fully accountable for the use of all PC funds used by WHO for WHO.
- **Sustainability:** A plan to address the long-term sustainability of activities proposed for funding with PC must be developed with the recipient and included in the Implementation Plan.
- **'SMART' approach:** Global needs are almost infinite. Defining specific, measurable, attainable, relevant and time-bound objectives is critical if impact is to be achieved and sustained. The outputs defined under each outcome are SMART and will be achieved if all assumptions are satisfied.

## 5. Methodology

### Development of the Implementation Plan

1) This Implementation Plan builds on work started in 2012 when the Advisory Group articulated several principles and factors that should be taken into account:

- PIP Framework principles including fairness, equity, public health risk and need of all countries and the particular vulnerability of H5N1;
- Evidence-based and considered indicators, adapted to the Framework, such as IHR core capacity, income, health and epidemiology;
- The critical foundation of epidemiological and laboratory surveillance;
- The modest amount of PC resources;
- The need to ensure the involvement of at least one country from each WHO region while retaining a primary focus on countries with the highest need.

2) In accordance with section 6.14.6 of the PIP Framework, the Implementation Plan was developed through a process of consultations with the Advisory Group, and interactions with industry and other stakeholders. From February 2012 to October 2013 five consultations were held (Annex 1).

3) The Implementation plan was developed on the bases of the three areas of focus specified in the Framework.<sup>18</sup> In addition, based on the recommendations of the IHR Review Committee<sup>19</sup> and interactions with industry and other stakeholders, the PIP AG added two areas: 1) risk communications and 2) planning for deployment, both of which are integral parts of effective pandemic response.

4) A high level draft outline of the PC Implementation Plan was reviewed by the Advisory Group, industry and other stakeholders in March 2013. The document provided draft “outcomes” and “outputs” for consideration under each of the four activity areas. Upon review, the Advisory Group supported the overall approach and suggested that further refinement and other analyses be provided in the Implementation Plan (A66/17 Add.1, Annex)<sup>20</sup>

5) In close collaboration with Regional Offices, the Secretariat developed the following:

1. Gap analyses (See document entitled “Pandemic Influenza Preparedness Partnership Contribution 2013-2016 – Gap Analyses”)
2. First level implementation plans for each area including key deliverables, activities, key milestones, indicators of success and estimated budgets
3. A list of priority countries by region and area to be approved by the Director-General.

### Identification and prioritization of recommended country recipients

The PIP Framework is a multi-faceted instrument that aims to improve global pandemic influenza preparedness and response. **All countries** are called upon in one capacity or another, to cooperate in, and contribute to, the efficient, effective and sustainable achievement of the objectives of the Framework. The process to recommend countries to the Director-General for approval refers to the

identification of priority, low-resourced countries, that, based on the gap analyses, are in need of direct support to improve their preparedness capacities. The Secretariat will nonetheless work actively with all countries to support and encourage their engagement in improving global pandemic preparedness.

### 1. Laboratory and Surveillance (“L&S”) capacity building

Given the significant proportion of preparedness funds that are to be allocated to L&S capacity building, a specific process was undertaken by Regional Offices to identify and prioritize potential country recipients.

a) The work to develop Regional lists of recommended countries to receive PIP PC funds for L&S began with a technical assessment of capacities to identify global and regional gaps for influenza specific laboratory and surveillance capacity strengthening. The technical assessment was based on the factors identified by the Advisory Group (see Methodology, paragraph 1, above). Data were entered into a global database and used to group countries by level of capacity and need.

b) WHO regional offices further refined their country prioritizations with additional elements including:

- Political situation of countries in the region, notably whether a country is in a complex emergency
- On-going donor funding and investments in a country
- Absorptive capacity of a country
- Country population size
- Geographical location of a country in the region/sub-region (notably for island states)
- Interest of a country/Ministry of Health to work in influenza
- Ability of countries to build on existing capacities to produce influenza surveillance data which could be shared with neighbouring countries.

c) Regional Offices recommended countries in their region, in priority order and with a rationale, that could receive PC resources to:

1. Strengthen capacities to detect influenza outbreaks
2. Strengthen capacities to monitor influenza outbreaks
3. Strengthen capacities to produce and share information on influenza and participate in and contribute to GISRS

<sup>18</sup> See section 6.14.4 of PIP Framework: [http://whqlibdoc.who.int/publications/2011/9789241503082\\_eng.pdf](http://whqlibdoc.who.int/publications/2011/9789241503082_eng.pdf)

<sup>19</sup> See Chapter 3, section I, Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza (H1N1) 2009. [http://www.who.int/ihr/publications/RC\\_report/en/index.html](http://www.who.int/ihr/publications/RC_report/en/index.html)

<sup>20</sup> A66/17 Add.1, [http://www.who.int/influenza/pip/A66\\_17Add1-en.pdf](http://www.who.int/influenza/pip/A66_17Add1-en.pdf), accessed 12 November 2013

- d) The recommended country lists were shared with and reviewed by the Advisory Group that noted the following in its Report to the Director-General:

*To avoid the risk of perceived conflict of interest in selection of countries, the Advisory Group wished to clearly articulate the process to develop the draft Regional Office Recommended Country Recipients document. The following was noted:*

- The role of the Advisory Group was limited to providing criteria for country selection:
  - Country development status;
  - IHR core capacities;
  - Country needs for influenza epidemiological and laboratory surveillance; and
  - H5N1 vulnerability.
- In their review of the list, the Advisory Group:
  - Noted the work of selection which has been made among the numerous possible recipients by the WHO Regional Offices for this first phase of the Implementation Plan and acknowledged the need for supporting rationales.
  - Noted the importance of providing PC resources to countries that need basic capacities as well as to countries that have existing capacities but where additional support can serve as a regional resource to other countries.

## 2. Burden of Disease Studies

Regions were requested to identify countries where studies could be conducted or scaled up, and to provide a rationale for their recommendations. To support this process, Regions were provided with a map of Member States with burden of disease information on influenza and of Member States in the GAP technology transfer project.

## 3. Preparedness for response

### a) Regulatory Capacity Building

In consultation with Regional Offices, the cluster of Health Systems and Innovations, Department of Essential Medicines and Health Products took the lead to develop the implementation plan for Regulatory Capacity Building. A gap analysis was developed based on findings from a recent global meeting on national regulatory capacity strengthening<sup>21</sup> and countries in need were prioritized

using the following factors:

- Population and economic development status;
- On-going regulatory capacity building efforts in vaccines, antivirals and/or diagnostics;
- Existing National Regulatory Authority (NRA) Institutional Development Plans (IDP) in the databases of the WHO Regulatory Systems Strengthening (RSS) Programme;
- Interest to donors i.e. Global Alliance for Vaccine and Immunization (GAVI) graduating and eligible countries;
- Countries without licensed pre-qualified vaccines, with local production not existing; and with production capacity not existing;
- Countries with existing national control laboratories;
- Countries with newly introduced or with the plan to introduce new vaccines (as of 2012);
- Regulatory history during the 2009 H1N1 pandemic-related WHO Deployment Initiative; and,
- GAP countries.

### b) Risk Communications

The Director-General's Communications Office, in close collaboration with communication focal points in Regional offices, led the development of the implementation plan for this area. Lists of priority countries were identified using data in the 2012 Report by the Director-General on implementation of the International Health Regulations (2005)<sup>22</sup> as well as additional factors which included:

#### Primary factors

- Countries with low capacity or for which there was no information on capacity for IHR implementation
- Commitment and requests from Ministries of Health
- Countries at significant risk of disease outbreaks and other public health emergencies
- Countries where other IHR capacity building work is already being carried out, with the aim of building synergies, cost-effectiveness, and/or achieving stronger results.

#### Secondary factors

- Assessment of the country's ability to sustain capacities
- Regional representation
- Ability to build in-country collaboration – bringing partners together
- Countries with unstable public health/political/social infrastructure, but which are able to absorb risk communications support

<sup>21</sup> Workshop on International Regulatory Capacity Enhancement for Influenza Vaccines (WIRCEIV) [http://www.who.int/influenza\\_vaccines\\_plan/objectives/workshop\\_WIRCEIV\\_8\\_10\\_June\\_2011/en/index.html](http://www.who.int/influenza_vaccines_plan/objectives/workshop_WIRCEIV_8_10_June_2011/en/index.html)

<sup>22</sup> See: [http://apps.who.int/gb/ebwha/pdf\\_files/EB132/B132\\_15-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_15-en.pdf)



- Countries with varying levels of capacity required under the IHR (e.g. surveillance, laboratory, points of entry, etc.)
- Countries with a recent event of poor transparency

### **c) Planning for deployment**

This activity applies to all countries

## **6. Limitations**

The development of a global, multi-year plan of this magnitude has inherent limitations in part due to the number of countries, regions and technical areas in which work is to be undertaken, and the processes used to ensure fairness, equity and public health needs-based allocations to countries. The Implementation Plan will therefore be subject to regular validation in a transparent manner to ensure that stakeholders are duly apprised of progress in its operationalization.

## **7. Overview of next steps**

### ***Approval by the Director-General***

Following its endorsement by the PIP AG, this Plan has been submitted to, and approved by, the Director-General.

### ***Phased roll-out of activities***

Funds will be disbursed for a phased start-up of activities and implementation should start in January 2014, as recommended by the PIP Advisory Group. For all areas, this will involve starting with a subset of planned activities against detailed implementation plans. For instance, for laboratory and surveillance capacity building implementation will start in 1-2 countries per region.

The annual receipt of PC funds necessarily means that the start of activities will be staggered. As new funds become available, they will be distributed to scale up, expand or begin more activities. So, for instance, for laboratory and surveillance capacity building or burden of disease studies, new countries will be added as funds are made available.

An important consequence of this staggered roll-out is that not all activities will be completed at the same time. For instance, most laboratory and surveillance capacity building plans are based on three (3) years of implementation. Countries that begin implementation later will likely have activities run into 2017 (See Annex 4).

### ***Implementation of Activities***

In all countries selected for laboratory and surveillance activities, the first steps will include conducting a country specific analysis to tailor activities to the specific country gaps and needs. The process will include refining indicators, and/or defining new ones if necessary.

### ***Implementation pre-requisite: Dedicated staff***

WHO will assign dedicated staff to PIP PC implementation to ensure there is appropriate and adequate capacity to manage and monitor the technical and financial implementation of activities. PC resources will be used to cover the costs of staff that are dedicated 100% to PIP PC implementation.

### ***Development of Reporting Tools***

To ensure that the reporting obligations set out herein meet expectations, WHO will develop and share with the PIP AG, industry and other stakeholders a draft template within the first six months of 2014.

# 1. Laboratory & Surveillance Capacity Building

## Analysis of gaps and needs: Summary

Effective influenza surveillance is a cornerstone of preparedness. Surveillance of influenza has two components : virological surveillance – the key role played by laboratories – and disease surveillance (also often referred to as “epidemiological surveillance”) based on reporting of influenza cases from the health system. These two components are complementary and many developing countries require capacity building in both.

A timely and effective response to an influenza pandemic relies on the capacity of countries to detect the emergence of a novel influenza virus at an early stage in order to perform initial severity assessments, implement early response measures and inform the composition of a vaccine. On-going monitoring of the situation through routine influenza surveillance will guide the public health response strategy.

Detection and monitoring are thus the two essential **functions** of influenza surveillance. The two are inter-related and complementary but require different strategies.

Detection functions require: a health care workforce which is well-informed and understands the importance of recognizing and reporting unusual events; effective reporting channels known to health care providers; laboratories and staff trained to identify novel viruses; and capacity to fully characterize a novel virus. While it is not necessary or feasible for every country to acquire this capacity, it is essential that it be accessible to every country through the shipping of samples to reference laboratories.

Routine monitoring of influenza provides baseline historical data to assess the importance of a newly emerged virus and its potential impact. In addition, the data gathered through routine monitoring provide the means to define high-risk groups, identify important epidemiologic patterns such as geographic and seasonal variations, and monitor for changes in the behaviour of a novel virus. Effective monitoring requires laboratory capacity for routine diagnostic testing, and surveillance of cases of influenza like illness (ILI) coupled with the surveillance of Severe Acute Respiratory Infections (SARI).

It is important that all countries have the capacity for early event detection and basic monitoring. The 2009 influenza

pandemic demonstrated that the emergence of a novel influenza virus cannot be predicted either in time or place. It was observed through retrospective assessments of influenza deaths during the 2009 pandemic, that the impact and behaviour of the H1N1 virus varied markedly between regions. This was underappreciated during the course of the event because of the lack of diagnostic and monitoring capacity in much of the developing world. The value of pre-existing monitoring systems was also demonstrated. As each country subsequently became affected, only those with baseline data and data collection systems in place were able to evaluate the impact that the event was having relative to previous seasons. Countries that had existing routine monitoring systems in place before the event were able to quickly adapt and expand them to monitor the evolution of the pandemic while those without such systems were only able to do subjective assessments.

Since the (H1N1) 2009 pandemic, global influenza surveillance has improved but there are still many countries with inadequate capacity, particularly in sub-Saharan Africa and southern Asia. The gaps and needs assessment highlighted significant gaps in global monitoring and detection capacities. These gaps, if not corrected, will inevitably lead to delays in detection, reporting, and evaluation of emerging novel influenza viruses and an inability of the country to fully evaluate their importance and guide their public health response to a pandemic.

A detailed gap analysis is contained in the document entitled “*Use of PIP Partnership Contribution 2013-2016 – Gap Analyses.*”

## Outcome

Capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

### Measurement of success:

At least 35 developing countries will have the capacity to detect and/or monitor influenza outbreaks and to participate in regional and global networks for the sharing of information and viruses.

## Output 1

National capacity to **detect** respiratory disease outbreaks, due to a novel virus, is strengthened.





In all selected countries, an assessment of detection capacities will be conducted using standardised criteria and indicators. The results of the assessment will be used to determine the country's capacity level. A scoring system will be used to classify countries by capacity level and will provide the baseline. Periodically a new assessment will be carried out using the same criteria and indicators in order to monitor progress and the final assessment of achievements.

The indicators used for the scoring will refer to following dimensions:

- Health care workforce is well-informed and understands the importance of recognising and reporting unusual events
- Effective reporting channels known to health care providers and community leaders
- Lab capacity to identify novel virus available
- Mechanism to verify and response to an event in place

Indicator	Baseline	Target
Number of countries with an established and functioning event based surveillance system	8	43

### Key Deliverable 1: Develop national capacity to detect and investigate new influenza virus sub-types

*Activities: All examples listed in the "activities" are a compilation of activities that will be undertaken in some regions and some countries. Detailed work plans with relevant indicators will be established at country level*

#### Laboratory Surveillance:

- Assess specific gaps in national laboratory capacity to identify and characterise influenza viruses
- Develop or revise laboratory preparedness plans
  - Develop protocols to detect novel viruses
  - Develop surge capacity protocols
  - Provide training and conduct exercises for laboratory staff to respond to surge situations, e.g. outbreaks of severe respiratory disease

- Provide laboratory training on virus isolation and characterization, use of new technologies such as RT-PCR, biosafety procedures and specimen shipment
- Provide support for start-up costs
  - Reagents, primers, etc.
  - Biosafety cabinets, RT-PCR machine

#### Epidemiological Surveillance:

- Review national respiratory disease early detection systems, including assessment of
  - Level of awareness of health care providers to need for recognizing and reporting unusual events;
  - Existence of a reporting mechanism and its linkage with the laboratory
  - Availability of trained epidemiologists for outbreak investigation and response
- Develop or revise national preparedness plans for early detection of, and response to, influenza events
- Provide training on surveillance methodology, outbreak investigation, and intervention strategies to address gaps found in the assessment of national respiratory disease early detection systems
- Provide support for start-up costs
  - Information technology and data management software and hardware

#### Human animal interface:

- Promote partnership building between human and animal health sectors
  - Conduct planning workshops to improve data sharing and surveillance at the human-animal interface
  - Establish joint surveillance for influenza at the human-animal interface in selected pilot districts/governorates at higher risk of animal-human transmission
  - Provide training on joint field investigation at the human-animal interface for influenza and other epidemic/pandemic prone respiratory viruses

### Key Deliverable 2: Strengthen information and virus sharing at national level

#### Activities

- Build, enhance, and/or maintain a national information management system for surveillance data
  - Provide training on data entry, information management, and virus sharing
- Develop software bridges to share data within the country and with regional and global partners
- Provide support for start-up costs for information systems



## Output 2

National capacities to **monitor** trends in circulating influenza viruses is strengthened

This output will be aimed at developing or increasing the capacities of countries to produce baseline data on influenza patterns for transmission and impact that can be used to make informed policy decision to prevent and control influenza. For instance these decisions could include prioritizing high risk groups to receive antiviral drugs or vaccine, how to minimise the impact on the health care system, and when to vaccinate. These baseline data will also be critical for evaluating the appearance of new events

Indicator	Baseline	Target
Number of countries able to consistently <sup>23</sup> report and analyse virological data	26	35
Number of countries able to consistently <sup>23</sup> report and analyse epidemiological data	5	17

### Key Deliverable 1: Strengthen influenza laboratory surveillance and the link with epidemiological surveillance

#### Activities:

- Evaluate capacity of labs to scale up capabilities to fully characterize novel influenza viruses; this could include genetic sequencing and antiviral susceptibility testing
- Provide training on influenza virus isolation, advanced virus characterization and logistics to increase capacity for advanced characterization of new viruses
- Work with national authorities to ensure the sustainability of these investments; in countries with no National Influenza Centre (NIC)
- Provide support for start-up costs for advanced capacities

### Key Deliverable 2: Strengthen influenza disease surveillance (SARI and /or ILI surveillance)

#### Activities:

- Evaluate existing ILI and/or SARI surveillance systems for completeness and timeliness of data collection, integration with existing system(s) for respiratory diseases, adherence to global standards, use of data in policy development, representativeness and adequacy of coverage.
- Establish or expand sentinel surveillance for SARI and ILI following evaluation
- Conduct training and workshops in data analysis and interpretation, and reporting of surveillance data, including virological information
- Provide training in the development of national influenza bulletins
- Review national influenza data management systems and identify gaps
- Provide technical support to develop regular surveillance data analysis and reporting
- Provide support for start-up costs for information systems

### Key Deliverable 3: Enhance national data sharing capacity to ensure monitoring and assessment of influenza events of international concern

#### Activities:

- Establish / strengthen / expand data management systems to improve external data sharing from national to regional level.
- Conduct training on information sharing and data management systems
- Provide support for start-up costs for information systems

## Output 3

Global collaboration, through the sharing of information and viruses, is strengthened and the quality of the system is improved (PCR detection quality assurance)

<sup>23</sup> Consistently means that a country reports most of the weeks during the influenza season(s)



Indicator	Baseline	Target
Number of countries that participate in EQAP and score 100%	109	120
The number of countries sharing virus with WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years	90	108
Number of countries consistently reporting epidemiological data to regional or global platforms	55	71
Number of countries which consistently report virological data to a global platform	108	124

### Key Deliverable 1: Share representative viruses in a timely manner

#### Activities:

- At the Global level:
  - Enhance the WHO Shipping Fund Project
  - Update training materials for shipment of infectious substances
- At the Regional level:
  - Develop capacities to select, package and ship quality influenza viruses
  - Train staff to select and ship quality viruses/specimens
  - Train laboratory staff in logistics, specimen collection, packaging and shipment of influenza and other pandemic-prone respiratory viruses as per IATA regulations.
  - Establish regional fund for shipment of viruses
  - Purchase specimen collection kits and other necessary consumables

### Key Deliverable 2: Enhance networking to maximise use of limited resources

#### Activities:

- Support to GISRS network
  - Coordinate laboratory capacity building activities
  - Update reporting tools and standards related to the functions of the WHO GISRS
  - Strengthen regional networks through the improvement of data sharing between countries with similar transmission patterns.
  - Improve regional databases
  - Support regular reporting of laboratory confirmed cases into regional data bases
  - Develop software bridges to share data within Regions and with global partners

### Key Deliverable 3: Maintain high quality influenza virus detection capacity

#### Activities:

- At the Global level:
  - Continue the WHO External Quality Assessment Programme (EQAP)
  - Update diagnostic reagents and protocols
- At the Regional level:
  - Train NIC staff in good laboratory practices and quality management, advanced virus genetic characterization and virus isolation
  - Organize academic exchange programme/study tours on good lab practices
  - Organize intercountry workshops on EQAP
  - Purchase lab equipment and reagents to support laboratory training

## 2. Burden of Disease

### Analysis of gaps and needs: Summary

A clear understanding of influenza burden at the national level is necessary to enable policy makers and planners to plan appropriate intervention strategies. Burden of disease data that includes estimates of influenza-associated mortality and hospital admissions, and the economic impact on health care systems will allow influenza to be placed in the context of other public health demands and facilitate appropriate resource allocation. In addition, understanding the relative burden as it affects different risk groups allows interventions to be targeted to those with highest risk of severe disease.

The global burden of influenza is poorly defined largely due to an absence of burden data from low- income countries. Most information available globally derives from a few countries located in temperate climates. Such information is not representative of the epidemiology of influenza in much of the developing and tropical world. The lack of knowledge makes it difficult – at both national and global levels – to understand the relative importance of influenza as a public health priority, and how to balance influenza interventions with other competing health issues. The global burden of disease estimates will provide a benchmark to assess future pandemic severity and impact.

It is impractical to develop disease burden estimates for all countries of the world in the short term. Meaningful estimates require at least 5 years of surveillance data. However, representative countries from limited geographical areas where influenza transmission and socio-economic conditions are similar will provide usable data to neighbouring countries until such time that surveillance in those countries can be developed. Further, country expertise in developing influenza burden estimates can be applied to other diseases.

A detailed gap analysis is contained in the document entitled *"Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016 Gap Analyses."*

### Outcome

National policy makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources.

### Measurement of success

All 6 WHO regions develop regional representative burden of disease data to guide developing countries' policy making

### Output 1

Derive regionally representative influenza disease burden estimates from selected countries

Indicator	Baseline	Target
Number of countries with burden of disease estimates	0	14

### Key Deliverable 1: Development of standardized tools for economic burden estimates

#### Activities:

- Establish an expert group to define costing inputs and relevant methods for analysis
- Develop a simple tool to provide national estimates of economic impact due to influenza
- Pilot the tool in 2 countries

### Key Deliverable 2: Production of national estimates for hospital and economic burdens, and mortality

#### Activities:

- Establish a technical steering group to advise WHO on disease burden activities
- Establish a pool of experts to provide technical support to countries
- Train national health professionals to use the *WHO Manual on Burden of Diseases Studies*<sup>24</sup> and the economic

<sup>24</sup> Publication under final revision



burden manual to be developed

- Identify countries with sufficient data and interest to develop estimates and provide technical support to national teams through the international pool of experts
- Produce national mortality estimates related to influenza in countries where data are available with the support from a pool of international experts

## Output 2

Develop a global estimate of influenza disease burden derived from national estimates

Indicator	Baseline	Target
Global estimate of influenza disease burden derived from national estimates published	N/A	Estimate published by Dec 2016

### Key Deliverable: Development of a methodology to estimate the global influenza burden

#### Activities:

- Define a strategy to combine national estimates of burden of disease into a global estimate
- Develop and work with an international network of burden of disease collaborators to produce credible global estimates of influenza mortality, hospitalization, and economic burden that will include information on high risk groups and areas

## 3. Preparedness for pandemic interventions

The 2009 H1N1 pandemic offered a number of lessons to improve preparedness in a broad range of areas including legal, regulatory, logistics and communications.<sup>25</sup> If an efficient and effective response is to be possible in the next influenza pandemic, actions to address as many of these issues as possible should be undertaken now. Some of these may be addressed using PC funds – others are slated for action under either the IHR or GAP.

Given the critical importance of vaccines and antiviral medicines in reducing pandemic influenza morbidity

and mortality, preparing countries to receive these products is vital. Three specific areas have been identified for strengthening preparedness for future pandemic interventions: the capacity of countries to efficiently license pandemic vaccines for use; the capacity of countries to communicate effectively during a public health emergency; and the capacity of WHO to effectively, efficiently, safely and equitably deploy vaccines and antivirals to countries in need. Each area is addressed below.

### 3A. Regulatory Capacity Building

#### Analysis of gaps and needs: Summary

Experts at the 'Workshop on international regulatory capacity enhancement for influenza vaccines', 8-10 June 2011, São Paulo, Brazil,<sup>26</sup> indicated that robust regulatory capacity is unquestionably essential to achieve the WHO global health agenda, the millennium development goals (MDG), the Decade of Vaccines goals and a number of vaccine-specific initiatives. Regulators and policymakers from across the world met to discuss ways to build regulatory capacity in developing countries. The workshop served as a catalyst to initiate and strengthen partnerships and coordination between governments, Ministries of Health, National Regulatory Authorities (NRAs), regulatory networks, and international organizations.

In order to address regulatory gaps for influenza vaccines, the experts advised that:

- A percentage of the grants countries receive to build manufacturing capacity should be allocated for National Regulatory Authority (NRA) capacity building<sup>27</sup>;
- Support should be provided to strengthen regional regulatory partnerships, approaches, and networks, and particularly models that address the specific regulatory needs of developing countries;

- Enhancing pharmaco-vigilance and monitoring of adverse events following immunization in countries with and without influenza vaccine manufacturing capacity should be undertaken;
- Support should be provided to strengthen the evaluation of clinical trial data for regulatory registration; and,
- Support should be provided to implement WHO regulatory capacity building initiatives and recommendations, including the Regulatory Systems Strengthening (RSS) Programme, the medicines and health products prequalification programme, the NRA Strategic Forum of Regulatory Agencies for Vaccines, the Global Learning Opportunities for Vaccine Quality, and the Global Action Plan (GAP) for Influenza Vaccines.

These recommendations informed the review and refinement of the second WHO consultation on the GAP for Influenza Vaccines (GAP II) in July 2011.

The 'Main operational lessons learnt from the WHO pandemic influenza A(H1N1) vaccine deployment initiative'<sup>28</sup> were discussed at a WHO consultation of more than 50 representatives from donor and recipient governments, international organizations and vaccine manufacturers on 13-15 December 2010 in Geneva. Experiences and

<sup>25</sup> Main operational lessons learnt from the WHO pandemic influenza A(H1N1) vaccine deployment initiative, Meeting report, [http://whqlibdoc.who.int/publications/2012/9789241564342\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241564342_eng.pdf), accessed 18 June 2013

<sup>26</sup> Workshop on International Regulatory Capacity Enhancement for Influenza Vaccines (WIRCEIV) [http://www.who.int/influenza\\_vaccines\\_plan/objectives/workshop\\_WIRCEIV\\_8\\_10\\_June\\_2011/en/index.html](http://www.who.int/influenza_vaccines_plan/objectives/workshop_WIRCEIV_8_10_June_2011/en/index.html), accessed 20 November 2013

<sup>27</sup> Funding grants for regulatory capacity building should be similar to grants provided to manufacturers through the WHO technology transfer initiative. This measure would ensure balanced capacity building for both manufacturing and regulation.

<sup>28</sup> Main operational lessons learnt from the WHO pandemic influenza A(H1N1) vaccine deployment initiative, Meeting report, [http://whqlibdoc.who.int/publications/2012/9789241564342\\_eng.pdf](http://whqlibdoc.who.int/publications/2012/9789241564342_eng.pdf), accessed 18 June 2013



challenges with crucial aspects of the process to deploy 78 million doses of pandemic H1N1 vaccine<sup>29</sup> to 77 of the poorest countries in the world were shared and recommendations on improving the process were formulated.

Review of the deployment process showed that national regulatory requirements constituted a significant limiting factor in the optimal deployment of pandemic vaccines. Although it was recognized that countries have unique regulatory requirements, it was suggested that a harmonized approach to importing, distributing and registering vaccines during pandemic events could ease deployment. Seeking early engagement with, and approval by, NRAs would ease the process of legally releasing imported vaccines or other medicines for prompt shipment. For the most part, WHO prequalification of influenza vaccines aided in reducing or eliminating country-specific regulatory delays in many countries. Having established legal agreements between donors and beneficiary countries ahead of a pandemic would have significantly reduced deployment time as well. Finally, it was recognized that keeping national deployment plans (NDP) up to date would reduce time for country planning.

For influenza antivirals, the medicines and other health technologies prequalification programme has developed a collaborative procedure to fast track the national registration of prequalified medicines. Early engagement of Member States in this procedure would achieve rapid registration of key antivirals, such as oseltamivir and zanamivir during pandemics. The presence of an internationally accepted pharmacopeial standard for a medicinal product also facilitates the entry of additional manufacturers into the supply chain, which increases availability and reduces cost of the medicine.

Very few jurisdictions regulate diagnostics. Thus there is a need for quality assessment mechanisms such as WHO Prequalification of influenza diagnostics to provide guidance to countries and procurers regarding the quality, safety and performance of such priority diagnostics. There is also a need to support countries

with developing regulatory systems for diagnostics and other medical devices used in a response to an influenza outbreak, ensuring that any regulations are appropriate and can be implemented effectively. Such support can include development of mechanisms to recognize WHO Prequalified diagnostics, and to assess any outstanding risks associated with the diagnostics when used in a particular jurisdiction.

Additionally there is a need to ensure sufficient laboratory capacity, ensuring a comprehensive and appropriate outbreak/pandemic response via institutional development plans (IDPs) in priority countries, with follow up on agreed training, guidance and technical support.

In short, the evidence, experience and consensus of international experts from Member States indicate that national regulatory preparedness for influenza products including vaccines, antivirals and diagnostics in response to a pandemic should be a priority area for investment of PIP contributions. The recommendations of the PIP Advisory Group are fully consistent with the findings and priorities identified through the international consultations mentioned.

A detailed gap analysis is contained in the document entitled *"Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016 Gap Analyses."*

## Outcome

Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic.

### Measurement of success

At least 16 countries will have improved their regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics and to accelerate national approval registration of these commodities in case of an influenza pandemic.

<sup>29</sup> Securing donor commitments, prequalifying vaccines, helping countries to satisfy the prerequisites for supply and managing global deployment.





## Output 1

Develop guidelines on regulatory preparedness for non-vaccine producing countries that enables them to expedite approval of influenza vaccines used in national immunization programs and/or deployed by United Nations agencies in response to a pandemic emergency

Indicator	Baseline	Target
Regulatory preparedness guidelines endorsed by the WHO Expert Committee on Biologicals Standardization (ECBS)	0	1

### Key Deliverable 1: Develop scope and purpose of guidance document

#### Activities:

- Develop inventory of existing, applicable and relevant regulatory guidance on pandemic influenza preparedness
- Plan, organize and conduct an informal consultation to develop outline, refine the scope and purpose of the guidelines

### Key Deliverable 2: Production of guidance document

#### Activities:

- Plan, organize and conduct an informal consultation to review draft
- Submit advance draft for public comment on-line
- Refine advanced draft and submit to ECBS for endorsement

### Key Deliverable 3: Effective dissemination of the guidance document

#### Activities:

- Subject to endorsement by ECBS:
  - publish guidelines in the WHO Technical Report Series and WHO website
  - conduct regional implementation workshops in English, French and Spanish
  - translate document from English into all UN official languages

## Output 2

NRA capacity to regulate influenza products including vaccines, antivirals and diagnostics is strengthened

Indicator	Baseline	Target
Number of countries which developed regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics in case of a pandemic as per the WHO NRA assessment and IDP elaboration and implementation	0	16

### Key Deliverable 1: Completion of NRA assessment

#### Activities:

- Refine the WHO Regulatory Systems Strengthening (RSS) tools to assess regulatory needs for influenza products including vaccines, antivirals and diagnostics
- Use of the WHO RSS tools in-country to develop NRA Institutional Development Plans (IDPs)<sup>30</sup> that address regulatory gaps for influenza products including vaccines, antivirals and diagnostics

### Key Deliverable 2: Regulatory gaps addressing

#### Activities:

- Address regulatory capacity building needs and provide technical support as per the IDP for prioritized countries in each WHO region
- Provide partial support to existing inter-regional and regional regulatory networks to develop capacity in each WHO region<sup>31</sup>
- Conduct regional workshops on expedited review for licensure/registration of WHO prequalified influenza products including vaccines, antivirals, and diagnostics
- Support regulators in target countries to participate in review of prequalification applications for influenza products including vaccines, antivirals and diagnostics

<sup>30</sup> [http://www.who.int/immunization\\_standards/vaccine\\_regulation/nra\\_rp\\_info/en/index.html](http://www.who.int/immunization_standards/vaccine_regulation/nra_rp_info/en/index.html), accessed 11 Sep 2013

<sup>31</sup> For example, the Developing Country Vaccine Regulatory Network (DCVRN), the African Vaccine Regulatory Forum (AVAREF), the Western Pacific Regional Alliance for National Regulatory Authorities for vaccines (WPRO Alliance), the Eastern Mediterranean Regional Office (EMRO) approach, Pan American Network for Drug Harmonization (PANDRH), the East African Community (EAC)





- Support regulators in target countries to participate in the prequalification rotation programme in WHO headquarters
- Support capacity building activities for NRAs to assess the safety of influenza vaccines and antivirals as per IDPs

### **Key Deliverable 3: Develop tools for progress monitoring and evaluation**

#### *Activities:*

- Use existing WHO NRA database management and planning systems that link work plans, IDPs, and expected outcomes/output/deliverables while updating relevant information for reporting and impact assessment

## **Output 3**

Regulatory processes to accelerate approval of influenza vaccines, antivirals and diagnostics during a public health emergency are incorporated into deployment plans for pandemic influenza products

Indicator	Baseline	Target
Number of countries with a common approach for accelerated regulatory approval of influenza products in a public health emergency	0	45

### **Key Deliverable 1: A Common regulatory approach for accelerated approval of influenza vaccines, antivirals and diagnostics during a public health emergency is developed and adopted**

#### *Activities*

- Develop a common regulatory approach for expedited review of influenza product dossiers;
- Solicit feedback from regulators and industry
- Seek endorsement of the common approach from NRAs

## 3B. Risk Communications

### Analysis of gaps and needs: Summary

Effective risk communications is a critical and complex part of the management of any public health emergency, especially one as widespread and complex as a pandemic. The explosion of real-time information sources, especially social media, has created enormous demands for effective, coherent and credible communications during emergencies.

Preparation for communicating during pandemics – communicating risk to health, communicating about actions the public can take to protect their and their families' health (including to support the uptake of vaccines), and dealing with rumours and perceptions – requires developing or strengthening capacities and maintaining those capacities during the relatively long periods between pandemics. A pandemic is a public health emergency of international concern (PHEIC) and is detected, defined and responded to under the International Health Regulations (2005). Therefore the IHR form the legal and operational basis for pandemic communications and risk communications. As all States Parties are obliged to develop capacities for IHR, there is also a practical opportunity for their engagement in building up capacities for pandemic communications preparedness using IHR as the framework.

Using the nine requirements of national risk communications capacities strengthening as defined by the *IHR Monitoring Framework: Checklist and Indicators for monitoring progress on the implementation of the IHR Core capacities in States Parties, WHO, 2011*, is an efficient and effective way to strengthen and monitor risk communications capacities for a pandemic response.

Many countries, however, are still lacking in this essential capacity. In the 2012 report by the Director-General on the Implementation of the International Health Regulations (IHR), countries reported on their capacities in risk communications. According to the latest data, Member States provided self-assessments on their risk communications capacities. Analysis of the data reveals that:

- 55 Member States did not report on their risk communications capacity
- 56 reported less than 60% of required risk communications capacity
- 41 others reported less than 50% of the required risk communications capacity

This means that 28% did not report on their risk communications capacities. Of those who reported, 29% reported less than 50% of required capacity.

Risk communications capacity building related to pandemic preparedness is aimed at ensuring that countries have policies, procedures, skills and other core elements in place for communicating to national and international audiences during public health emergencies of international concern. The work outlined in this plan will take forward activities to (a) support all countries, and (b) provide intense support for at least 30 priority countries to ensure that the baseline communication needs are met during an influenza pandemic or other public health crisis and can be sustained beyond the three-year scope of this project.

The implementation plan for risk communications capacity building is anchored in the recommendations in the 2012 report by the Director-General on the Implementation of the IHR and in the review of the Organization's response to the 2009 H1N1 Influenza pandemic. It builds upon extensive work already carried out by the WHO Secretariat, including its newly established Emergency Communications Network (ECN). The ECN is a pre-selected, pre-trained and assessed group of communications experts from within and outside WHO who are ready to be deployed to countries to provide support in the area of risk, pandemic and crisis communications. The plan will also strengthen collaboration with partner institutions already working to strengthen global communications capacity, including the US Centers for Disease Control and Prevention (CDC), the Public Health Agency of Canada, Public Health England, and the European Centre for Disease Control (ECDC).

A detailed gap analysis is contained in the document entitled "*Pandemic Influenza Preparedness Framework Partnership Contribution 2013-2016 Gap Analyses*."



## Outcome

Global risk communications capacities are strengthened with a special focus on pandemic influenza communications

### Measurement of success:

The number of countries that self-report at least 50% of the IHR risk communications milestones increases from 100 to 120 countries.

## Output 1

Access to risk communications training and platforms is increased enabling all countries to respond more effectively to a potential influenza pandemic or other Public Health Emergencies of International Concern (PHEIC)

Indicator	Baseline	Target
Tools and web-based risk communications training material accessible to Member States in all language versions and Portuguese	0	194
Number of registered users of online material	0	500
Number of trainings completed on risk communications IHR learning platform	0	200

### Key Deliverable 1: Update existing guidance and tools and develop new ones based on lessons learnt during the H1N1 pandemic

#### Activities

- Develop guidance document and tools for risk communications strategy development, review and evaluation of strategies, including case studies specific to influenza (i.e. vaccine safety and adverse events etc.),
- Translate guidance document into all official UN languages, Portuguese, and national languages as required

- Develop an online training programme for risk communication in UN languages and Portuguese
- Develop an online toolkit of communications product templates that can be adapted during an influenza pandemic or emergency event, including fact sheets, Q&As, press releases, action checklists etc.

### Key Deliverable 2: Conduct training workshops and ensure sustainable collaboration between stakeholders

#### Activities:

- Evaluate risk communication capacities of all Member States without current assessment or very low self-assessment to identify groups of countries with similar needs and develop phased training approach
- Conduct six regional risk communications trainings
- Develop and pilot vaccine safety and adverse events training
- Establish information sharing systems between IHR focal points and other technical partners
- Facilitate exchange of expertise and lessons learnt between Member States and other key stakeholders

## Output 2

Risk communications capacity is established in priority countries with little or no capacity.

Indicator	Baseline	Target
Targeted Member States will have benefited from IHR risk communications capacity strengthening	0	30



### Key deliverable 1: Enhance national capacity for risk communication

#### Activities:

- Conduct 30 country-level training workshops (including skills and tools, simulation exercises with a focus on influenza and vaccines, national strategy development, communications coordination, review and evaluation)
- Provide mentoring and in-country support when needed
- Develop a network of regional risk communication peers for mutual country-level support

### Key Deliverable 2: Conduct media training at subregional levels to provide local media with an understanding of complex scientific information to enable accurate reporting in emergencies.

#### Activities:

- Develop training module and materials for print, online, radio and television journalists and editors
- Conduct workshops for local, national and regional media

## Output 3

Global Emergency Communications Network (ECN) operationalized to provide support to countries before, during and after public health emergencies

### Key deliverable 1: Strengthen development of the

Indicator	Baseline	Target
Proportion of requests for risk communications surge support responded to within 72h by WHO	0	80%

### Emergency Communications Network

#### Activities:

- Identify skilled communicators for the ECN
- Establish SOPs and ToRS for providing communications surge capacity to countries
- Train identified communicators and establish a deployment roster

### Key deliverable 2: Deploy network support to countries in emergencies

#### Activities:

- Establish protocols, equipment and tools for deployment
- Manage country deployments
- Review deployments and adjust protocols



## 3C. Planning for Deployment

### Analysis of gaps and needs

Review of the A(H1N1) pandemic provided the opportunity for WHO to glean many lessons to improve preparedness for future pandemics. The Report of the WHO Pandemic A(H1N1) Vaccine Deployment Initiative and the MOLL report<sup>32</sup> both noted that stakeholders<sup>33</sup> felt insufficiently prepared to respond to several of the key areas of deployment of pandemic supplies. The reports highlighted that almost 50% of recipient countries took 4 months or more to achieve readiness to receive vaccines and other products. Feedback from the WHO deployment team underscored the importance of developing a common approach and better coordination among deployment stakeholders, as well as across the technical areas that impact on deployment operations, notably regulatory and legal affairs. In addition to these lessons learned, the reports and deployment specialists uniformly recommended that preparedness be improved and maintained with regular updates.

A critical feature of preparedness is the capacity to manage change. A strong preparedness plan will factor in the broad number of variables that affect preparedness. For vaccine deployment this would include the rate of vaccine production, the physical volume of ancillary products, and/or the need to manage hubs with temporary stockpiles. The best technical plans, however, are only effective if the stakeholders understand them, are able to operationalize them, and have the skill and training to manage changes that will inevitably occur.

To address this necessary element of preparedness, activities will focus on:

- development of simulation tools to enable rapid development of scenarios that address global distribution, capacity to cover eligible recipient countries, and costs;
- developing and securing endorsement of a common approach to deployment across stakeholders;
- updating agreements to reflect regulatory and other changes; and
- developing tools to support improved country preparedness.

### Simulation to support a common approach

Simulation tools will be developed that account for the numerous variables that impact deployment. Examples of

variables for pandemic vaccines include the rate at which vaccine can be produced, the physical location of vaccine production plants, the capacity to manage cold chain during shipment, and the physical volume of different vaccines. The simulation tools will be kept up to date with real time information (such as expansion or reduction of vaccine production capacity) as it becomes available. They will also be used to support change management in an actual deployment.

Deployment brings together numerous stakeholders and requires effective coordination in a significant number of technical areas, such as vaccine management, regulatory status of medicines, and sufficient availability of ancillary products. Using information from the simulation tool, a series of workshops will be held to update stakeholders and solicit feedback on deployment issues. In addition, model terms of reference (TORs) for a core team of staff at WHO, as well as recommended TORs for staff within deployment partner institutions will be developed and used to maintain a clear and common approach to deployment. This is intended to address the finding that during the deployment of H1N1 vaccines, managing both a significant number of stakeholders and their individual expectations, created challenges that impacted on the efficiency of deployment operations.

### Updating country preparedness

Lessons learned from the deployment of WHO (A)H1N1 vaccines stressed that gaps in country preparedness often were difficult to resolve or took significant time, delaying delivery of necessary products. It was recommended that deployment planning tools and workshops be updated on a regular basis, especially with a view of providing additional deployment support to countries that are less advanced in their planning and readiness to deploy. In an emergency, it is likely that supplies will be limited and it will be important to move supplies only when each country has capacity to deploy.

### Outcome

Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics, will be developed and regularly updated.

**Measurement of success:** National plans for 16 countries are developed and updated through simulation exercises every 2 years.

<sup>32</sup> [http://www.who.int/influenza\\_vaccines\\_plan/resources/h1n1\\_vaccine\\_deployment\\_initiative\\_moll.pdf](http://www.who.int/influenza_vaccines_plan/resources/h1n1_vaccine_deployment_initiative_moll.pdf)

<sup>33</sup> For purposes of this section, "stakeholders" include deployment partners, donor governments, UN partners, countries, Ministries of Health, NGOs and service providers that support deployment activities. Stakeholders may be involved in both the complex legal agreements that affect implementation as well as actual implementation activities.



## Output 1

A common approach to manage deployment operations is developed and shared with stakeholders and deployment partners

Indicator	Baseline	Target
A common deployment approach is developed with multiple deployment stakeholder endorsement	0	1
Number of training and simulation exercises with deployment stakeholders	0 training sessions held post-H1N1	Up to 8 training sessions held with stakeholders

### Key Deliverable 1: Generic simulation exercises are developed and effectively disseminated to stakeholders

#### Activities:

- Develop a logistics tool to simulate potential distribution options based on known variables, including costs.
- Document the variables and assumptions used in the tool e.g., "first-in-first-out" approach to distribution versus assignment of specific product.
- Identify product related variables for scenarios specific to H7N9, such as rates of vaccine production, logistics details for specialty products and presentations, e.g., nasal spray administration devices, vaccines in pre-filled presentations, etc.
- Identify typical cold chain capacities and bottle necks at global, regional hubs, and national levels through desk reviews, surveys, or interviews.
- Develop scenarios for estimated weekly capacity to transport and uptake vaccines and medicines.
- Identify hubs within free trade zone jurisdictions where vaccines and medicines can be staged and repackaged as needed.
- Refine scenarios for discussion and training purposes.

### Key Deliverable 2: Prepare implementing partners on using the common approach to deployment of pandemic products

#### Activities:

- Develop an engagement strategy for implementing partners, including definitions and TORs, and share with stakeholders for feedback.

- Develop an engagement strategy for recipient countries, including SOPs, definitions and share with countries through a limited consultation for feedback.
- Host 1 training meeting for implementing partners to establish an understanding and commitment to a common approach based on the above SOPs, TORs and deployment scenarios
- Host 5-6 training meetings for country representatives and regional managers to establish understanding and commitment to a common approach based on the SOPs, TORs and deployment scenarios
- Finalize a manual of SOPs, TORs and establish a regular update schedule.

## Output 2

Country deployment readiness systems are simplified and updated

Indicator	Baseline	Target
Model country recipient agreement is revised and updated	0	1
Countries and partners accessing web-based planning tools	0	16

### Key Deliverable 1: Model agreement between WHO and country recipients of pandemic supplies such as vaccines and antiviral medicines, are updated and simplified

#### Activities:

- Revise model country recipient agreements to receive donated vaccines and medicines to reflect:
- Seek feedback from country representatives
- Finalize revised model

### Key Deliverable 2: National Deployment Planning process is revised and updated

#### Activities:

- Revise national deployment planning templates to align with existing emergency request tools
- Review and revise the process to accelerate response time
- Develop a web based option for submission of plans, order request, and country information tracking

## 4. Monitoring and Reporting

Performance monitoring and assessment will be regularly conducted in order to alert managers to problems and impediments, assess achievements and identify successes, and inform decision-making and adjustment of policies, strategies and programmes. It will also assist WHO in meeting its reporting requirements, as outlined below. WHO will monitor implementation in order to regularly review progress towards achieving the planned results, at office level (country, regional, headquarters) and Organization-wide. This will allow WHO to identify areas requiring improvement or adjustment.

Monitoring and assessment will involve review by the responsible officers of the status of each project, updating indicator values, reviewing and analysing financial implementation, and submitting performance reports.

For the PIP PC, monitoring will comprise of a systematic review of technical and financial implementation based on progress against indicators at the Outcome, Output and activity level (ref. Annex 5, Logframe). Monitoring assessments will be performed quarterly.

### Reporting

WHO will provide the following documents, reports and/or progress updates as indicated below. The documents will be provided throughout the entire implementation period (See Figure X below).

- **Semi-annual:** PIP PC Implementation progress updates
  - Formal updates on technical and financial implementation
  - Includes achievement against indicators
  - Transmitted to PIP AG, and shared with all stakeholders

- **Annual:** Report from the PIP AG to Director-General on its evaluation of implementation of the PIP Framework (See Framework Section 7.2.5) Such annual reports will cover all the elements outlined in Section 7.2.5 including the use of financial and non-financial resources
- **Biennial:** Report from the Director-General to the World Health Assembly through the Executive Board (PIP Framework section 7.4.1)
  - In particular, the Director-General will provide the governing bodies with a financial report on the use of the partnership contribution (See Framework section 7.4.1(iv))
- **Ad hoc:** In addition, and as needed, WHO will provide written statements of technical and financial progress to be shared with Senior Management and the Advisory Group to provide the bases for strategic assessment and decision-making.

See **Table 2**.

In 2016 there will be a review of PIP Framework and its annexes, proposing revisions reflecting developments as appropriate, to the World Health Assembly in 2017, thorough the Executive Board.

The technical and financial reports will present information aggregated according to the Outcomes and Outputs described in this implementation plan at the Country, Regional and Headquarters levels. Financial reporting will be broken down by component – staff or activity – and further details on activity costs will be provided according to the expenditure codes in WHO's financial administration system. Reports will include statements of total PC funds received, committed, and remaining (balances) as of the reporting date.

**Table 2: Partnership Contribution Reporting Cycle**

Partnership Contribution Reporting Cycle	Q1			Q2			Q3			Q4		
	J	F	M	A	M	J	J	A	S	O	N	D
<b>Products</b>												
PIP PC Implementation progress updates to AG, and shared with I/OS (Semi-annual)			X						X			
Report from the AG to DG on PIP Framework (annual)											X	
Biennial Report of the Director-General on implementation of the PIP Framework*											X	
<b>Meetings</b>												
PIP Advisory Group meetings			X						X			
WHO Executive Board	X				X							
World Health Assembly					X							

\*Note: The next Biennial Report of the Director-General is due to the EB and WHA in 2015



## 5. Management of Funds

The Partnership Contribution shall be used for the purposes indicated in this workplan and shall be administered in accordance with the Financial Regulations and Rules, and financial and administrative rules and practices of WHO. The PC funds will be maintained in separate project accounts (preparedness and response).

In accordance with World Health Assembly resolution WHA34.17, Program Support Costs (PSC), a standard 13% charge in partial reimbursement for the cost of related technical and non-technical support and services, will be deducted by WHO. In accordance with WHO's established financial Policies and Guidelines regarding the use of funds during emergencies, PSC on the Response component will be calculated at 7%.

Income and expenditure recorded in respect of the contribution shall be identified and kept separately by WHO in the relevant account.

While the PIP Framework calls for annual contributions totalling USD 28M, at the time of this writing, WHO has received USD 18,121,000 in PIP Partnership Contributions. As future PC amounts and timing are uncertain, the Organization will plan and implement on the basis of cash received. Detailed annual work plans will be established each year, taking into consideration available fund balances.

The US\$ 18,121,000 currently held by WHO according to the allocation methodology described herein as set forth in Annex 1, are allocated approximately as follows:

- Preparedness: US\$ 10,102,000
- Response: US\$ 4,573,000
- PIP Secretariat: US\$ 1,604,000
- PSC: US\$ 1,842,000

At the time of this writing, WHO has implemented Secretariat funds only. Because PSC is charged as a function of expenditure, only a portion of the PSC amount has been expended. Pending acceptance of the PC Implementation Plan, no Preparedness or Response funds have been expended.



## 6. Roles and responsibilities

WHO plays a critical role as the world's leading technical authority on health. The Organization has 194 Member States, with offices in over 150 countries.

At WHO, Implementation of Partnership Contribution funds will be managed by senior staff including the Assistant Director-General, Health Security and Environment. All projects under the areas of work (Laboratory and Surveillance Capacity Building, Burden of Disease, Regulatory Enhancement, Risk Communications, Planning for Deployment) will have designated project managers accountable for the management of resources and delivery of the results. Each Regional Office will have one designated project manager for PIP PC implementation.

In accordance with its mandate and its Terms of Reference<sup>34</sup> the Advisory Group will advise the Director-General on the

use of the PC. It will monitor, assess and provide an annual report on its assessment of the implementation of the PC. The information to conduct these tasks will be provided by the Secretariat. Monitoring by the Advisory Group will enable on-going assessment of the PC, supporting its overall assessment of the functioning of the Framework.

The Secretariat will operate with as much transparency as possible in the planning, implementation and use of PC resources. It will ensure that the semi-annual updates contain sufficient quantitative and qualitative information to assist stakeholders in understanding progress achieved and/or challenges encountered.

### **WHO – A global organization and structure**

The three levels of the organization – country offices, regional offices and headquarters – carry out the following functions as shown in **Table 3** and **Fig. 4**.

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<sup>34</sup> See PIP Framework sections 6.14, 7.2 and Annex 3

**Table 3: Roles and responsibility at the three levels of the organization**

Function	Country Offices (COs)	Regional Offices (ROs)	Headquarters
<b>Planning</b>	<ul style="list-style-type: none"> <li>Develop country level PC plans</li> </ul>	<ul style="list-style-type: none"> <li>Contribute to the development of country level plans</li> <li>Develop Regional level plans</li> </ul>	<ul style="list-style-type: none"> <li>Develop global level plans</li> <li>Compile the Implementation Plan (all three levels)</li> <li>Engage with AG and I/OS throughout planning process</li> <li>Provide templates</li> <li>Provide policy guidance to COs and ROs (e.g. process to propose countries, staffing, etc.)</li> </ul>
<b>Implementation</b>	<ul style="list-style-type: none"> <li>Support implementation of country level activities</li> </ul>	<ul style="list-style-type: none"> <li>Coordinate Regional activities</li> <li>Support country offices and Countries, e.g. training, technical advice or know-how</li> <li>Convene regional meetings and working groups, when required</li> </ul>	<ul style="list-style-type: none"> <li>Disburse funds</li> <li>Implement HQ led activities (shipping funds project, etc.)</li> <li>Coordinate implementation at all levels</li> <li>Develop guidance documents (e.g. Regulatory Capacity Building)</li> <li>Support regional offices by providing specialized technical assistance</li> <li>Convene global meetings, when required</li> </ul>
<b>Monitoring/ Reporting</b>	<p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>Monitor and assess PIP PC implementation at the country level</li> <li>Make course corrections in coordination with RO and HQ, as necessary</li> </ul> <p><b>Reporting</b></p> <ul style="list-style-type: none"> <li>Submit country level input for report to the Regional Office</li> </ul>	<p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>Monitor and report on regional implementation</li> <li>Support country level monitoring and reporting</li> <li>Make course corrections in coordination with CO and HQ, as necessary</li> </ul> <p><b>Reporting</b></p> <ul style="list-style-type: none"> <li>Compile country reports</li> </ul>	<p><b>Monitoring</b></p> <ul style="list-style-type: none"> <li>Provide monitoring /reporting templates</li> <li>Aggregate, validate, analyze finding from HQ, regions and countries</li> <li>Make, or proposed course corrections, in coordination with RO and CO, as necessary</li> </ul> <p><b>Reporting</b></p> <ul style="list-style-type: none"> <li>Provide consolidated reports and information updates to AG, Member States and other stakeholders.</li> </ul>
<b>Governance</b>			<ul style="list-style-type: none"> <li>Convene Advisory Group meetings</li> </ul>

**Fig. 4: Implementation of PIP PC at 3 WHO levels**

## COUNTRY OFFICES (Selected countries)



Laboratory  
& Surveillance



Burden of  
Disease



Regulatory  
Capacity Building

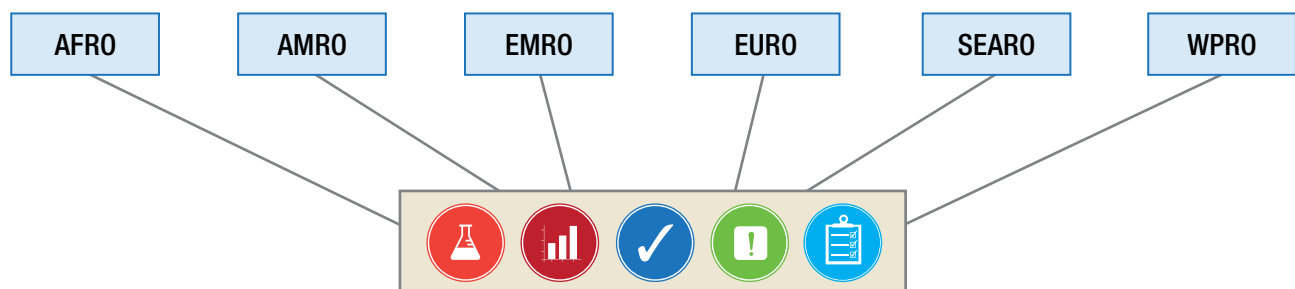


Risk  
Communications

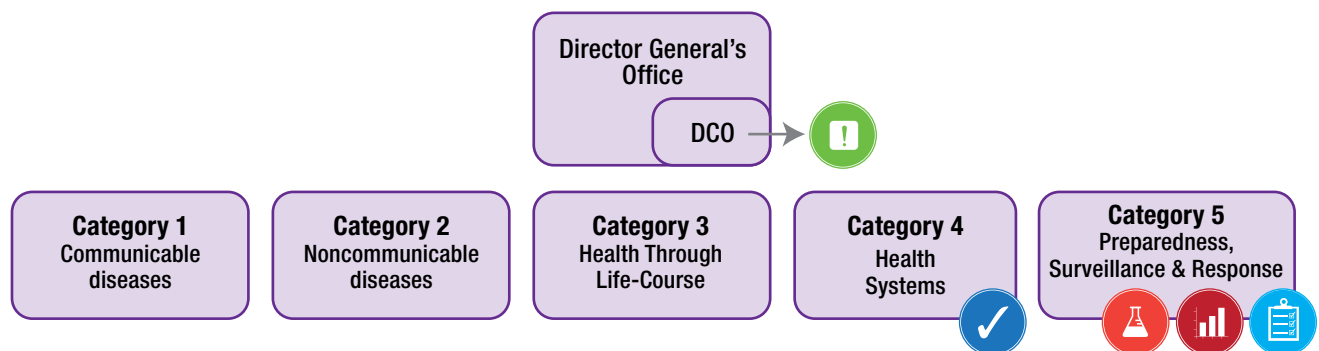


Planning for  
Deployment

## REGIONS



## HEADQUARTERS




# Annexes

# Annex 1

## PIP PC Implementation Plan Development Consultation Process



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 Consultations with industry and other stakeholders were undertaken.

# Annex 2

## PIP Framework Partnership Contribution

### Budget (2013-2016)

Outcomes & Outputs	USD
<b>PREPAREDNESS</b>	
<b>1. Laboratory &amp; Surveillance</b>	
Detection capacity	19'430'500
Monitoring capacity	17'494'000
Strengthening networks	12'234'000
<b>Subtotal</b>	<b>49'158'500</b>
<b>2. Burden of Disease</b>	
Regionally representative estimates	5'055'000
Global estimates	960'000
<b>Subtotal</b>	<b>6'015'000</b>
<b>3. Preparedness for Interventions</b>	
<b>A. Regulatory Capacity</b>	
Guidelines	735'000
Targeted training	5,815,000
Common approach for accelerated approval	500,000
<b>Subtotal</b>	<b>7'050'000</b>
<b>B. Risk Communications</b>	
Training on risk communication	2'530'000
Support to priority countries	1'802'000
Emergency communications network	1'500'000
<b>Subtotal</b>	<b>5'832'000</b>
<b>C. Planning for Deployment</b>	
Deployment operations	1,276,000
Country readiness	343,000
<b>Subtotal</b>	<b>1'619'000</b>
<b>Subtotal</b>	<b>14,501,000</b>
Preparedness: +/-70%	69,674,500
Planning Contingency (3.2%) (1)	2,870,836
Response: +/-30%	32,834,271
<b>Total for Preparedness and Response</b>	<b>105'379'607</b>
Secretariat (2)	11'515'133
PSC (3)	13'226'260
<b>TOTAL (4)</b>	<b>130'121'000</b>

(1) The Planning Contingency will be assigned to Preparedness or Response components, as warranted by achievement of deliverables and circumstances.

(2) Secretariat costs cover management and implementation of various elements of the PIP Framework, including preparation and convening of meetings of the Advisory Group, SMTA-2 negotiations, and reporting. As recommended by the Advisory Group and accepted by the Director-General, (see A66/17 Add.1), these costs will not exceed 10%, averaged over the next four years (2013-2016) of the overall PC.

(3) WHO Program Support Cost (PSC) is calculated at 13% of direct costs for the Preparedness and Secretariat components, and 7% of direct costs for the Response component.

(4) The total income projection for 2012-2016 is subject to change, in accordance with with PIP Framework Section 6.14.3, footnote 1, which provides, in relevant parts, that GISRS running costs may change over time and the Partnership Contribution will change accordingly.

# Annex 3

## by WHO Major Office

### Budget for Outcome 1 (2013-2016)

### Laboratory & Surveillance

Outcomes & Outputs	Africa	The Americas	South-East Asia	Europe	Eastern Mediter-anean	Western Pacific	Global	TOTAL USD
<b>PREPAREDNESS</b>								
<b>1. Laboratory &amp; Surveillance (1)</b>								
Detection capacity	3'500'000	3'000'000	3'152'000	3'124'500	3'404'000	3'250'000	-	19'430'500
Monitoring capacity	5'000'000	3'000'000	3'010'000	2'234'000	1'150'000	3'100'000	-	17'494'000
Strengthening networks	2'150'000	1'350'000	1'544'000	1'740'000	1'500'000	2'050'000	1'900'000	12'234'000
<b>Subtotal</b>	<b>10'650'000</b>	<b>7'350'000</b>	<b>7'706'000</b>	<b>7'098'500</b>	<b>6'054'000</b>	<b>8'400'000</b>	<b>1'900'000</b>	<b>49'158'500</b>

(1) Budget totals for each WHO region represent implementation of activities in the following number of countries:

- Africa: **6 countries**
- The Americas: **8 countries**
- Eastern Mediterranean: **7 countries**
- Europe: **6 countries**
- South-East Asia: **6 countries**
- Western Pacific: **6 countries**

# Annex 4

## Risk Analysis

This high level risk analysis identifies risks in different areas and assesses their potential effects on project implementation. Mitigation measures are proposed and will be preventively implemented.

RISK	POTENTIAL EFFECTS	MITIGATION STRATEGY
<b>PLANNING</b>		
Industry/other stakeholders ("I/OS") do not endorse the detailed implementation plan	<ul style="list-style-type: none"> <li>Delayed start of implementation</li> </ul>	<ul style="list-style-type: none"> <li>Communicate implementation plan approval process</li> <li>Engage with I/OS throughout planning process</li> <li>Share draft plans</li> </ul>
Lack of coherence with, or duplication of, GAP & IHR, activities	<ul style="list-style-type: none"> <li>Inefficient use of PC funds</li> </ul>	<ul style="list-style-type: none"> <li>Include IHR and GAP in implementation plan development</li> </ul>
Real or perceived conflict of interest in the development of recommended country recipients	<ul style="list-style-type: none"> <li>Member States and stakeholders raise concerns</li> </ul>	<ul style="list-style-type: none"> <li>Limit the role of the PIP AG to providing criteria for country selection</li> </ul>
<b>IMPLEMENTATION</b>		
Delayed implementation of projects	<ul style="list-style-type: none"> <li>Stakeholder impatience/dissatisfaction</li> <li>MS raise concerns with DG</li> </ul>	<ul style="list-style-type: none"> <li>Develop realistic timeframes and funding estimates</li> <li>Provide regular implementation updates to DG, AG, I/OS, MS</li> <li>Determine cause of delays &amp; address ASAP</li> <li>Ensure appropriate disbursement mechanism to facilitate access to funds for implementation</li> </ul>
Industry withholds or delays PC payments	<ul style="list-style-type: none"> <li>Project implementation delayed/stopped/truncated</li> </ul>	<ul style="list-style-type: none"> <li>Adhere to PC SOPs to identify contributors and collect PC funds on time</li> <li>Develop scalable and modular plans to accommodate available resources</li> <li>Review and monitor implementation on a regular basis, adjust plans and reprogramme resources, as necessary</li> </ul>
Lack of country recipient commitment	<ul style="list-style-type: none"> <li>Outputs not achieved; outcomes compromised</li> </ul>	<ul style="list-style-type: none"> <li>Develop clear criteria for country selection</li> <li>Develop strong monitoring programme</li> </ul>
Projects are not sustainable	<ul style="list-style-type: none"> <li>Key elements of PIP Framework benefit sharing system questioned</li> </ul>	<ul style="list-style-type: none"> <li>Ensure sustainability is integral to project development and a criterion for country selection</li> </ul>
Outbreak of pandemic influenza	<ul style="list-style-type: none"> <li>Implementation slowed or halted</li> </ul>	[ Pandemic response begins ]
<b>MANAGEMENT</b>		
Mistimed or disproportionate input by I/OS	<ul style="list-style-type: none"> <li>Inefficient implementation</li> </ul>	<ul style="list-style-type: none"> <li>Regularly interact with I/OS, to provide opportunities for timely provision of high level guidance</li> </ul>
Insufficient staff (HQ, RO, CO) to properly monitor implementation	<ul style="list-style-type: none"> <li>Projects poorly managed, outputs not delivered, timeframes not met</li> </ul>	<ul style="list-style-type: none"> <li>Develop realistic staffing plan for all levels of project implementation</li> </ul>
<b>ACCOUNTABILITY / REPORTING</b>		
PC Funds not sufficiently distinguishable from other Organization resources	<ul style="list-style-type: none"> <li>Member States and stakeholders raise concerns about implementation</li> </ul>	<ul style="list-style-type: none"> <li>Establish separate financial accounts, work plans and budgets, in accordance with WHO financial rules and regulations</li> <li>Provide AG/EB/WHA regular updates on project implementation</li> </ul>
Insufficient or inadequate implementation reporting	<ul style="list-style-type: none"> <li>Member States and stakeholders raise concerns about implementation reporting</li> </ul>	<ul style="list-style-type: none"> <li>Establish detailed financial and narrative reporting templates for use in all projects funded through PC</li> <li>Preview reporting templates with Advisory Group</li> </ul>



# Annex 5

## Implementation Calendar:

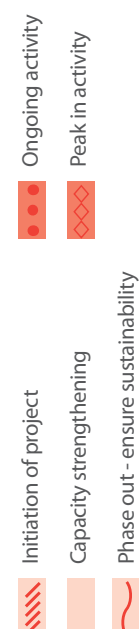
## Laboratory & Surveillance Capacity Building\*



**Outcome:** Capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

	2014				2015				2016				2017			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Output 1</b>																
<b>Key deliverables</b>																
• Develop national capacity to detect and investigate new influenza virus sub-types																
• Strengthen information and virus sharing																
First cohort of countries (2 countries per Region Jan 2014)																
Second cohort of countries																
Third cohort of countries																
<b>Output 2</b>																
<b>Key deliverables</b>																
• Strengthen influenza laboratory surveillance and the link with epidemiological surveillance																
• Strengthen influenza disease surveillance (SARI and /or ILI surveillance)																
• Enhance capacity for sub-regional, regional and global data sharing to ensure monitoring and assessment of influenza events of international concern																
First cohort of countries (2 countries per Region Jan 2014)																
Second cohort of countries																
Third cohort of countries																
<b>Output 3</b>																
Maintain high quality influenza virus detection capacity (External Quality Assessment Project)																
Share representative viruses shared in a timely manner (Use of WHO Shipping fund)																
Enhance networking to maximize use of limited resources																

\* The implementation of activities will be phased, depending on available resources. Countries will be grouped into cohorts. The number of countries in each cohort will be defined (i) according to the funds available and (ii) the readiness to implement activities at country level. Activities in this area have been designed for 3-year implementation periods. Given the receipt of funds in annual tranches, and the staggered start-up of activities in some countries, it is anticipated that implementation of some activities will extend into 2017.



# Implementation Calendar: Burden of Disease



**Outcome:** National policy makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources.

	2014				2015				2016			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Output 1</b>												
Development of standardized tools for economic burden estimates												
Production of national estimates for hospital and economic burden and mortality												
<b>Output 2</b>												
Development of a methodology to estimate the global influenza burden												

# Implementation Calendar: Regulatory Capacity Building



**Outcome:** Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic.

	2014				2015				2016			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Output 1</b>												
Develop scope and purpose of guidance document												
Production of guidance document												
Effective dissemination of the guidance document (Dependent on endorsement by ECBS)												
<b>Output 2</b>												
Completion of NRA assessment												
Regulatory gaps addressing												
Progress monitoring and evaluation												
<b>Output 3</b>												
Common regulatory approach for accelerated approval of influenza vaccines, antivirals and diagnostics during a public health emergency is adopted												

# Implementation Calendar: Risk Communications



**Outcome:** Global risk communications capacities are strengthened with a special focus on pandemic influenza communications

	2014				2015				2016			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Output 1</b>												
Update existing guidance and tools and develop new ones based on lessons learnt during the H1N1 pandemic												
Conduct training workshops and ensure sustainable collaboration between stakeholders												
<b>Output 2</b>												
Enhance national capacity for risk communication (Provide package of services for national risk and pandemic communications capacity strengthening)												
Conduct a media training programme at subregional levels to provide local media with an understanding of complex scientific information to enable accurate reporting in emergencies.												
<b>Output 3</b>												
Strengthen development of the Emergency Communications Network												
Deploy network support to countries in emergencies												

# Implementation Calendar: Planning for deployment



**Outcome:** Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics, will be developed and regularly updated

	2014				2015				2016			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<b>Output 1</b>												
Generic simulation exercises are developed and effectively disseminated to major stakeholders												
Prepare implementing partners on using the common approach to deployment of pandemic products												
<b>Output 2</b>												
Model agreement between WHO and country recipients of pandemic supplies such as vaccines and antiviral medicines, are updated and simplified												
National Deployment Planning process is revised and updated												

# Annex 6

## Global level indicators of success

### Logical Framework:

### Laboratory & Surveillance



Note: Activity level indicators have been developed and are contained in detailed work plans which are part of the working documents of the Secretariat. They will be used to monitor implementation progress and will be reflected in the semi-annual progress updates.

#### Laboratory & Surveillance Capacity Building

**Outcome:** Capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

**Measurement of success:** At least 35 developing countries will have the capacity to detect and/or monitor influenza outbreaks and to participate in regional and global networks for the sharing of information and viruses.

Description	Indicators	Baseline	Target	Means of Verification	Assumptions
<b>Output 1</b> National capacity to detect respiratory disease outbreaks, due to a novel virus, is strengthened.	Number of countries with an established and functioning event based surveillance system	8	43	L&S country capacity survey	1. Necessary staff in place to conduct survey 2. Survey is conducted at yearly/6mthly intervals
<b>Output 2</b> National capacities to monitor trends in circulating viruses is strengthened.	Number of countries able to consistently <sup>36</sup> report and analyse virological data Number of countries able to consistently <sup>37</sup> report and analyse epidemiological data	26 5	35 17	Global and regional databases (FluNet, FLUID)	Country who is monitoring also is willing to share data
<b>Output 3</b> Global collaboration, through the sharing of information and viruses, is strengthened and the quality of the system is improved (PCR detection quality assurance)	Number of countries that participate in EQAP and score 100% The number of countries sharing virus with WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years Number of countries consistently <sup>38</sup> reporting epidemiological data to regional or global platforms Number of countries which consistently <sup>39</sup> report virological data to a global platform	109 90 55 108	120 108 71 124	EQAP database SFP database WHO collaborating centres FluID and regional data base FluNet database	GISRS network manufactures, distributes and analyses EQAP panels All countries have access to shipping materials and couriers

<sup>36</sup> Consistently means that a country reports most of the weeks during the influenza season(s)

<sup>37</sup> Ibid

<sup>38</sup> Ibid

<sup>39</sup> Ibid

# Logical Framework: Burden of Disease



## Burden of Disease

**Outcome:** National policy makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources.

**Measurement of success:** All 6 WHO regions develop regional representative burden of disease data to guide developing countries' policy making

Description	Indicators	Baseline	Target	Means of Verification	Assumptions
<b>Output 1</b> Derive regionally representative influenza disease burden estimates from selected countries	Number of countries with burden of disease estimates	0	14	Published reports or reports submitted to WHO	<ol style="list-style-type: none"> <li>1. Full support from the MoH to conduct BoD studies</li> <li>2. Studies get reported to WHO</li> <li>3. Regular reviews will need to be conducted in order to find new studies.</li> <li>4. Sufficient data is available to conduct the studies</li> <li>5. Experts are available to work with local counterparts on the project</li> <li>6. Additional necessary staff will be hired</li> </ol>
<b>Output 2</b> Develop a global estimate of influenza disease burden derived from national estimates	Global estimate of influenza disease burden derived from national estimates published	N/A	Estimate published by December 2016	WHO publish report	<ol style="list-style-type: none"> <li>1. There is enough data to produce global estimates</li> </ol>

# Logical Framework: Regulatory Capacity Building



## Regulatory Capacity Building

**Outcome:** Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic.

**Measurement of success:** At least 16 countries will have improved their regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics and to accelerate national approval registration of these commodities in case of an influenza pandemic.

Description	Indicators	Baseline	Target	Means of Verification	Assumptions
<b>Output 1</b> Develop guidelines on regulatory preparedness for non-vaccine producing countries that enables them to expedite approval of influenza vaccines used in national immunization programs and/or deployed by United Nations agencies in response to a pandemic emergency	Regulatory preparedness guidelines endorsed by the WHO Expert Committee on Biological Standardization (ECBS)	0	1	Published document in the WHO Technical Report Series (TRS)	Guidelines will be developed using already existing WHO mechanisms for consultation, development, review, endorsement and implementation
<b>Output 2</b> NRA capacity to regulate influenza products including vaccines, antivirals and diagnostics is strengthened	Number of countries which developed regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics in case of a pandemic as per the WHO NRA assessment and IDP elaboration and implementation	0	16	Institutional Development Plans (IDP)	Member States commit to implementation of regulatory capacity effort
<b>Output 3</b> Regulatory processes to accelerate approval of influenza vaccine antivirals and diagnostics during a public health emergency are incorporated into deployment plans for pandemic influenza products	Number of countries with a common approach for accelerated regulatory approval of influenza products in a public health emergency	0	45	List of countries with common approach	Countries and manufacturers agree on approach developed by WHO.



# Logical Framework: Risk Communications



## Risk Communications

**Outcome:** Global risk communications capacities are strengthened with a special focus on pandemic influenza communications.

**Measurement of success:** The number of countries that self-report at least 50% of the IHR risk communications milestones increases from 100 to 120 countries.

Description	Indicators	Baseline	Target	Means of Verification	Assumptions
<b>Output 1</b> Access to risk communications training and platforms is increased enabling all countries to respond more effectively to a potential influenza pandemic or other Public Health Emergencies of International Concern (PHEIC)	Tools and web-based risk communications training material accessible to Member States in all language versions and Portuguese	0	194	Availability of training material on IHR training platform	Member States make use of online-training and related support
	Number of registered users of online material	0	500	Register of trainings completed on IHR risk communications training website	
	Number of trainings completed on risk communications IHR learning platform	0	200		
<b>Output 2</b> Risk communications capacity is established in priority countries with little or no capacity.	Targeted Member States will have benefited from IHR risk communications capacity strengthening	0	30	Programmatic and technical reporting by WHO	Work in targeted Member States will be possible and not undermined by conflict, crisis, instability, high staff turn-over, etc.
<b>Output 3</b> Global Emergency Communications Network (ECN) operationalized to provide support to countries before, during and after public health emergencies	Proportion of requests for risk communications surge support responded to within 72h by WHO	0%	80%	Monitoring of requests & deployment reports	Member States facilitate deployment of ECN members into emergencies (visa, etc.); Deployment not made impossible by meteorological conditions or UN security phase

# Logical Framework: Planning for Deployment



## Planning for deployment

**Outcome:** Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics, will be developed and regularly updated.

**Measurement of success:** National plans for 16 countries are developed and updated through simulation exercises every 2 years.

Description	Indicators	Baseline	Target	Means of Verification	Assumptions
<b>Output 1</b> A common approach to manage deployment operations is developed and shared with stakeholders and deployment partners	A common deployment approach is developed with multiple deployment stakeholder endorsement	0	1	Published common deployment approach	Stakeholders will be available and prepared to participate.
	Number of training and simulation exercises with deployment stakeholders	0 training sessions held post-HTN1	Up to 8 training sessions held with stakeholders	Meeting reports from workshops are available.	
<b>Output 2</b> Country deployment readiness systems are simplified and updated	Model country recipient agreement is revised and updated	0	1	Published model agreement	Countries have capacity to respond to surveys and preliminary planning activities.
	Countries and partners accessing web-based planning tools	0	16	Register of those who have accessed online tools	

# Annex 7

## Details of substantive revisions to outcome and output indicators: Laboratory & surveillance capacity building



### ORIGINAL

**Outcome:** Capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

**Measurement of success:** At least 37 developing countries will have the capacity to detect and/or monitor influenza outbreaks and to participate in regional and global networks for the sharing of information and viruses.

Description	Indicators	Baseline	Target
<b>Output 1</b> National capacity to detect respiratory disease outbreaks, due to a novel virus, is strengthened	Number of countries with an established and functioning event based surveillance system	Standardised score by country developed during the initial assessment	All countries have significantly improved their score, as defined during the initial assessment
<b>Output 2</b> National capacities to monitor trends in circulating viruses is strengthened	Number of countries able to report and analyse consistently virological data by 2016	11	20 of the countries targeted by PC funds
	Number of countries able to report and analyse consistently epidemiological data by 2016	1	Half of the countries targeted by PC funds
<b>Output 3</b> Global collaboration, through the sharing of information and viruses, is strengthened and the quality of the system is improved (PCR detection quality assurance)	Number of countries that participate in EQAP and score 100% by 2016	137	150
	The number of shipments, per country, supported by the Shipment Fund Project each year	2 for developing countries and 1 for developed countries	4 for all countries
	Number of countries reporting consistently 22 epidemiological data to regional or global platforms	57	67 countries
	Number of countries reporting consistently 22 virological data to a global platform by 2016	124	140 countries

### UPDATED — revisions highlighted in bold red

**Outcome:** Capacity to detect and monitor influenza epidemics is strengthened in developing countries that have weak or no capacity.

**Measurement of success:** At least **35** developing countries will have the capacity to detect and/or monitor influenza outbreaks and to participate in regional and global networks for the sharing of information and viruses.

Description	Indicators	Baseline	Target
<b>Output 1</b> National capacity to detect respiratory disease outbreaks, due to a novel virus, is strengthened	Number of countries with an established and functioning event based surveillance system	<b>8</b>	<b>43</b>
<b>Output 2</b> National capacities to monitor trends in circulating viruses is strengthened	Number of countries able to consistently report and analyse virological data	<b>26</b>	<b>35</b>
	Number of countries able to consistently report and analyse epidemiological data	<b>5</b>	<b>17</b>
<b>Output 3</b> Global collaboration, through the sharing of information and viruses, is strengthened and the quality of the system is improved (PCR detection quality assurance)	Number of countries that participate in EQAP and score 100%	<b>109</b>	<b>120</b>
	<b>The number of countries sharing virus with WHO Collaborating Centres, H5 Reference Laboratories and Essential Regulatory Laboratories at least once a year in the past two years</b>	<b>90</b>	<b>108</b>
	Number of countries consistently reporting epidemiological data to regional or global platforms	<b>55</b>	<b>71</b>
	Number of countries which consistently report virological data to a global platform	<b>108</b>	<b>124</b>

# Details of substantive revisions to outcome and output indicators: Burden of Disease



## ORIGINAL

**Outcome:** National policy makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources.

**Measurement of success:** At least 2 developing countries per region can access relevant BOD data to guide their policy on influenza.

## UPDATED — revisions highlighted in bold dark red

**Outcome:** National policy makers will have influenza disease burden data needed for informed decision-making and prioritization of health resources.

**Measurement of success:** **All 6 WHO regions develop regional representative burden of disease data to guide developing countries' policy making**

*No substantive changes to Output indicators*



## ORIGINAL

**Outcome:** Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic.

**Measurement of success:** By 2016 at least 15 countries will have improved their regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics and to accelerate national approval and registration of these commodities in case of an influenza pandemic.

Description	Indicators	Baseline	Target
<b>Output 1</b> Develop guidelines on regulatory preparedness for non-vaccine producing countries that enables them to expedite approval of influenza vaccines used in national immunization programs and/or deployed by United Nations agencies in response to a pandemic emergency	Regulatory preparedness guidelines endorsed by the WHO Expert Committee on Biologicals Standardization (ECBS)	0	1
<b>Output 2</b> NRA capacity to regulate influenza products including vaccines, antivirals and diagnostics is strengthened	Number of countries which developed regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics in case of a pandemic as per the WHO NRA assessment tools by 2016	Limited to no regulatory capacity for the oversight of influenza related products including vaccines, antivirals, and diagnostics in case of pandemic	15
<b>Output 3</b> Regulatory processes to accelerate approval of influenza vaccine antivirals and diagnostics during a public health emergency are incorporated into deployment plans for pandemic influenza products	Number of countries endorsing a common approach for accelerated regulatory approval of influenza vaccines, antivirals and diagnostics during a public health emergency	0	By 2016, 45 countries endorse the common approach

## UPDATED — revisions highlighted in bold blue

**Outcome:** Countries with weak or no regulatory capacity will be able to regulate influenza products including vaccines, antivirals and diagnostics, and to accelerate national approval of these commodities in case of an influenza pandemic.

**Measurement of success:** By 2016 at least 15 countries will have improved their regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics and to accelerate national approval and registration of these commodities in case of an influenza pandemic.

Description	Indicators	Baseline	Target
<b>Output 1</b> Develop guidelines on regulatory preparedness for non-vaccine producing countries that enables them to expedite approval of influenza vaccines used in national immunization programs and/or deployed by United Nations agencies in response to a pandemic emergency	Regulatory preparedness guidelines endorsed by the WHO Expert Committee on Biologicals Standardization (ECBS)	0	1
<b>Output 2</b> NRA capacity to regulate influenza products including vaccines, antivirals and diagnostics is strengthened	Number of countries which developed regulatory capacity to oversee influenza products including vaccines, antivirals and diagnostics in case of a pandemic as per the WHO NRA assessment <b>and IDP elaboration and implementation</b>	<b>0</b>	16
<b>Output 3</b> Regulatory processes to accelerate approval of influenza vaccine antivirals and diagnostics during a public health emergency are incorporated into deployment plans for pandemic influenza products	Number of countries <b>with a common approach</b> for accelerated regulatory approval of <b>influenza products</b> in a public health emergency	0	<b>45</b>

*No substantive change to the Outcome measurement of success or Output 1 indicator*

# Details of substantive revisions to outcome and output indicators: Risk Communications



*No substantive changes to the Outcome measurement of success or Output indicators*

## Planning for Deployment



### ORIGINAL

**Outcome:** Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics, will be developed and regularly updated.

**Measurement of success:** The plan is developed and updated through simulation exercises every 2 years.

Description	Indicators	Baseline	Target
<b>Output 1</b> A common approach to manage deployment operations is developed and shared with stakeholders and deployment partners	The plan is developed through engagement of multiple stakeholders  Number of training and engagement of stakeholders where the tools to support a robust approach are used	0 training sessions held post-H1N1	Up to 8 training sessions held with stakeholders
<b>Output 2</b> Country deployment readiness systems are simplified and updated	Country recipient agreements are revised and updated  Country planning tools are developed and available	H1N1 country plans and country recipient agreements  0	Model country recipient agreement revised by Year 2, Quarter 3  Country planning tools are developed and available by Year 2, Quarter 4

### UPDATED — revisions highlighted in bold cyan

**Outcome:** Plans for deployment of pandemic supplies including vaccines, antivirals and diagnostics, will be developed and regularly updated.

**Measurement of success:** **National plans for 16 countries** are developed and updated through simulation exercises every 2 years.

Description	Indicators	Baseline	Target
<b>Output 1</b> A common approach to manage deployment operations is developed and shared with stakeholders and deployment partners	<b>A common deployment approach is developed with multiple deployment stakeholder endorsement</b>  Number of training and <b>simulation exercises with deployment stakeholders</b>	0	<b>1</b>
<b>Output 2</b> Country readiness systems are simplified and updated	<b>Model</b> country recipient agreement is revised and updated  <b>Countries and partners accessing web-based planning tools</b>	<b>0</b>  0	<b>1</b>  <b>16</b>





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