ANNEX 1

PANDEMIC INFLUENZA PREPAREDNESS FRAMEWORK (“PIP FRAMEWORK”)
ADVISORY GROUP ANNUAL REPORT TO THE DIRECTOR-GENERAL
UNDER PIP FRAMEWORK SECTION 7.2.5

2012 Annual Report

TABLE OF CONTENTS

1 Web-only supplementary annex. PIP Framework-related tasks/activities.
EXECUTIVE SUMMARY


Virus sharing

This initial Report provides essential context about the Global Influenza Surveillance and Response System (GISRS) and its key roles and responsibilities in surveillance, preparedness and response. The Advisory Group noted multiple examples of the collaborative work of WHO and Member States to strengthen laboratory and disease surveillance capacity for detection and risk assessment of influenza viruses with human pandemic potential. The continued sharing of viruses enables the development of candidate vaccine viruses with pandemic potential and reference reagents – critically important tools when a pandemic virus emerges. The Influenza Virus Traceability Mechanism (IVTM) has increased the transparency of GISRS activities and the sharing of viruses with human pandemic potential and other PIP biological materials. The Advisory Group noted other areas of work that contribute to pandemic preparedness, including efforts to strengthen regulatory capacity, vaccine deployment capacity, an H5N1 vaccine stockpile, and laboratory and disease surveillance for influenza viruses with human pandemic potential.

Gaps remain, however, as many countries still lack basic capacities for laboratory and disease surveillance, shipping of influenza viruses, and the regulation and deployment of influenza vaccines during a pandemic. Sharing of PIP biological materials is critical for health security and must continue. As provided for in the PIP Framework, any non-GISRS recipient of PIP biological materials must assess what benefits it can contribute based on its nature and capacity and enter into a binding contract, or Standard Material Transfer Agreement 2 (SMTA 2), with WHO. However, work on the SMTA 2s is at an early stage.

Benefit sharing

The PIP Framework aims to ensure that benefits arising from the sharing of PIP biological materials are made more accessible and available to countries based on public health risk and need. In this regard, WHO has initiated discussions with four large influenza vaccine manufacturers to commence the process to sign the first SMTA 2s; the transition to sharing of PIP biological materials with non-GISRS entities that have concluded a SMTA 2 needs to happen as quickly as possible.

The Framework provides for influenza vaccine, diagnostic and pharmaceutical manufacturers that use the WHO GISRS to make an annual contribution to WHO. Pursuant to Section 6.14.3 of the Framework, these payments, termed the “Partnership Contribution”, are to commence in 2012 in the amount of approximately US$ 28 million. The Advisory Group recommended to the Director-General that 70% be used for pandemic preparedness and 30% for pandemic response. Of the approximately US$ 20 million per year for pandemic preparedness activities, the Advisory Group recommended that 70% be used to build and/or strengthen surveillance and laboratory capacity; 10% to conduct disease burden studies; 10% to strengthen regulatory capacity and thereby improve access and effective deployment of pandemic vaccines and antiviral medicines; and 10% to strengthen risk communications. The Advisory Group proposed a general approach, including factors to consider, for selecting countries to receive Partnership Contribution resources in each of these areas and requested that the PIP Secretariat develop a method by which factors will be applied in the selection of countries.
**Governance**

The Director-General appointed 18 members of the PIP Advisory Group in 2011 upon receipt of nominations from Regional Directors. In accordance with the PIP Framework, there are three members from each of WHO’s six regions, representing developed and developing countries, affected countries, and a skill mix of policy-makers, public health experts and influenza experts. The Advisory Group, over the course of its first three meetings, has made recommendations to the Director-General on several key elements of the PIP Framework including: the Partnership Contribution, the urgency to commence SMTA 2 negotiations, and an interim approach for the sharing of PIP biological materials with entities outside GISRS pending the conclusion of SMTA 2s. The Advisory Group anticipates that, as operationalization of the Framework advances, subsequent Annual Reports will focus more on these key elements.
1. INTRODUCTION

The PIP Framework became effective on 24 May 2011 when it was adopted by the Sixty-fourth World Health Assembly. It provides a global framework for the sharing of influenza viruses with human pandemic potential and the sharing of benefits arising from such sharing. Implementation of this Framework is integral to increasing global pandemic influenza preparedness and improving response measures for the next pandemic.

As one of the three components of the Framework’s oversight mechanism, the Advisory Group monitors the implementation of the Framework and provides evidence-based reporting, assessment and recommendations regarding its functioning. Section 7.2.5 of the PIP Framework requires the Advisory Group to present an Annual Report to the Director-General on its evaluation of the implementation of the Framework.

This is the first Annual Report of the Advisory Group since adoption of the PIP Framework. It covers the 12 month period beginning in May 2011 up to May 2012. The 2013 Annual Report will cover the period May 2012 to October 2013. Thereafter, Annual Reports will cover a 12-month period commencing 1 October and ending 30 September of the following year. To ensure that the data are up-to-date, there may be a need for an Addendum prior to the Director-General’s submittal of the Report to the Executive Board in January.

In developing the Report, the Advisory Group was mindful that the Framework specifies the Annual Report should cover 7 areas:

1. necessary technical capacities of the WHO Global Influenza Surveillance and Response System (GISRS);
2. operational functioning of WHO GISRS;
3. WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building);
4. increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential;
5. the Influenza Virus Traceability Mechanism (IVTM);
6. the sharing of influenza viruses and access to vaccines and other benefits;
7. use of financial and non-financial contributions.

Appendix 1 details where information about these areas can be found in the report.

It is important to note that certain key elements of the Framework, e.g. conclusion of Standard Material Transfer Agreement 2s (SMTA 2s) and receipt and use of Partnership Contribution resources, are at an early stage; therefore, few data for these areas are available at this time. The Advisory Group anticipates that, as operationalization of the Framework advances, subsequent Annual Reports will focus more on these key elements.

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1 See PIP Framework Section 7.2 and Annex 3.
2 See PIP Framework Section 7.2.5 and Annex 3, Section 2.6.
This initial Annual Report serves as a “baseline” as it provides essential context about GISRS and its key roles and responsibilities. The Report highlights activities during the 12-month period that have improved and strengthened GISRS in accordance with the Framework’s objective and scope. In this regard, it must be remembered that the Framework applies to influenza A(H5N1) and other influenza viruses with human pandemic potential. It does not apply to seasonal influenza viruses or other non-influenza pathogens.1

Organization and method

The Report is organized into three substantive sections: virus sharing, benefit sharing and governance with supporting appendices. A supplementary annex will be available on the WHO web site that details PIP Framework-related tasks/activities.

The content of the Report is based on existing data in WHO reports or databases; specific data collections or surveys were not undertaken. Country-specific data and analyses were aggregated for inclusion in the Report.

Information and data for the Report were provided by several clusters at WHO headquarters, WHO regional offices and WHO GISRS laboratories, notably Collaborating Centres. Some information was self-reported by Member States.

2. VIRUS SHARING

2.1 Necessary technical capacities of GISRS

This section of the Annual Report focuses on the structure and function of GISRS and its necessary technical capacities. This descriptive information provides essential context for the subsequent assessment of the operational functioning of GISRS.

The core of WHO GISRS is an international network of influenza laboratories under the coordination of WHO.2 The WHO GISRS laboratories work collectively to: (a) monitor the evolution of influenza viruses and provide risk assessment and recommendations in areas including laboratory diagnostics, vaccines and antivirals; and (b) serve as a global alert mechanism for the emergence of influenza viruses with pandemic potential.3

GISRS is comprised of four complementary categories of laboratories as detailed below. The network regularly expands to include new laboratories, or categories of laboratories, as needed.

- 138 National Influenza Centres (NICs) in 108 countries4
- 6 WHO Collaborating Centres (WHO CCs)

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1 See PIP Framework Section 3.
2 The laboratory network was formerly known as the Global Influenza Surveillance Network (GISN). The new name of the system came into effect following the adoption of the PIP Framework on 24 May 2011.
4 The number of NICs up to 1 May 2012 was 138; from 1 May to 5 October 2012, two additional NICs were recognized: one in Bahrain and one in Mauritius bringing the total to 140 NICs in 110 countries.
• 4 WHO Essential Regulatory Laboratories (WHO ERLs)
• 12 WHO H5 Reference Laboratories (WHO H5 Ref Labs)

Appendix 2 describes the functions and technical capacities for each category of laboratory.

The GISRS is a voluntary network in which member laboratories agree to work under category-specific Terms of Reference (TORs), for their work with influenza viruses with human pandemic potential. The TORs specify that laboratories must comply with the standard conditions under which PIP biological materials may be transferred both within and out of GISRS pursuant to SMTAs; the use of the IVTM, i.e. an electronic, internet-based system to record the movements of PIP biological materials; and other terms and conditions that address, inter alia, laboratory analyses, biosafety and biosecurity, intellectual property rights, research and publications. The TORs for work with seasonal influenza viruses are not a part of the PIP Framework.

2.2 Operational functioning of GISRS

This section of the Annual Report assesses how GISRS operates in practice to carry out some of its key roles, responsibilities and functions as specified under the Framework’s TORs. Whenever possible, findings are limited to influenza viruses with human pandemic potential. However, since the majority of influenza viruses reported to GISRS are seasonal viruses, it is not possible in all instances to report data restricted to influenza viruses with human pandemic potential.

Laboratory capacity

Under their PIP Framework’s TORs, NICs collect specimens from suspected cases of H5N1 or other unusual influenza viral infections, perform laboratory diagnosis, and ship specimens or virus isolates to a WHO CC or WHO H5 Ref lab for advanced virological analysis.

During May 2011–May 2012, WHO CCs performed detailed analyses to characterize a total of 205 isolates of influenza A(H5N1) from 7 different countries.

The Advisory Group notes that analysis of H5N1 or other influenza viruses with human pandemic potential represents only a small portion of the more than 1.1 million total specimens that GISRS laboratories processed during this period of time. Diagnosing influenza requires special reagents that are updated regularly. During the report period, NICs and other influenza laboratories in 130 different countries, areas or territories had access to, without charge, reagents developed by the Atlanta WHO CC to test for seasonal and other influenza viruses, including those with human pandemic potential.

Efficient and timely transport of specimens or virus isolates may be hampered by logistical challenges in some countries that can delay diagnosis, virus characterization and risk assessment. In addition, countries do not always have financial resources necessary to ship virus samples from NICs or other

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1 Annex 4 of the PIP Framework establishes Guiding Principles for the development of TORs for WHO GISRS laboratories that are applicable to H5N1 and other human pandemic influenza viruses. Annex 5 details the TORs for each category of laboratory in GISRS.

2 See PIP Framework Section 4.1 for a definition of PIP biological materials.

3 The PIP Framework contains two types of SMTAs which are binding contracts. SMTA 1 establishes the conditions which apply to transfer of PIP biological materials among members of GISRS. SMTA 2 establishes the conditions which apply to transfer of PIP biological materials from a GISRS laboratory to an entity outside GISRS.
national laboratories to WHO CCs and other reference laboratories for advanced analysis and characterization. During the reporting period, the WHO Shipping Fund Project was used to ship viruses from 78 laboratories in 69 countries at a cost of US$ 210,605. Despite the Project’s significance in facilitating virus sharing in a timely manner, due to reduced donor funding, the Project can now support only half the number of shipments compared to prior years.

Transport of infectious substances requires qualified local staff that undergo formal training and certification in the proper handling and packaging of infectious substances for international shipment; WHO headquarters and regional offices work collaboratively to support such training. Training is done on an ongoing basis as certificates are valid for only 24 months. From May 2011 to May 2012, 53 laboratory staff from 46 countries were trained and certified (14 from the Eastern Mediterranean Region, 29 from the European Region and 10 from the South-East Asia Region).

Assessment of laboratory capacity

Few data were available to assess laboratory capacity specifically for H5N1 and other influenza viruses with human pandemic potential. However, data were available to assess two aspects of overall laboratory-related capacity:

- quality of laboratory testing performance
- good laboratory practice.

NICs use the polymerase chain reaction (PCR) as the principal method for diagnosis and surveillance of seasonal influenza viruses and viruses with human pandemic potential. WHO, working with the H5 Reference Laboratory and NIC in China, Hong Kong Special Administration Region, initiated an external quality assessment project (EQAP) in 2007 to monitor the quality and comparability of the performance of PCR testing among participating laboratories. Participation in the project is voluntary. Of 159 NICs and other laboratories that participated in the June–July 2011 EQAP, 124 (78%) returned correct results for all 12 samples which included a mix of seasonal and A(H5N1) viruses. The majority of laboratories correctly identified 9 or more of the 12 samples (Table 1); 89% of laboratories reported correct results for all samples containing influenza A(H5N1).

<table>
<thead>
<tr>
<th>Number of correct results (N=12 samples tested)</th>
<th>Number of laboratories (N=159 participating laboratories)</th>
</tr>
</thead>
<tbody>
<tr>
<td>12 (100%) samples correct</td>
<td>124 (78%)</td>
</tr>
<tr>
<td>11 (92%) samples correct</td>
<td>12 (8%)</td>
</tr>
<tr>
<td>10 (83%) samples correct</td>
<td>11 (7%)</td>
</tr>
<tr>
<td>9 (75%) samples correct</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>&lt;9 (&lt;75%) samples correct</td>
<td>8 (5%)</td>
</tr>
</tbody>
</table>

A good laboratory practice (GLP) survey was undertaken in 2012 among laboratories enrolled in the WHO EQAP. The survey consisted of 38 questions that examined organization and personnel; facility design, specimen handling, equipment and consumables; pre-examination procedures; examination procedures; post-examination procedures and result reporting; quality assurance; and safety. When compared to the GLP survey of 2010, improvements were seen in a number of areas (Table 2).

<table>
<thead>
<tr>
<th>Survey item</th>
<th>2010 results (% of 142 laboratories)</th>
<th>2012 results (% of 148 laboratories)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training for new staff</td>
<td>92%</td>
<td>97%</td>
</tr>
<tr>
<td>On-job training</td>
<td>63%</td>
<td>70%</td>
</tr>
<tr>
<td>Validation of reagents for molecular diagnosis</td>
<td>67%</td>
<td>61%</td>
</tr>
<tr>
<td>Evaluation of test and primers/probes for molecular diagnosis</td>
<td>59%</td>
<td>78%</td>
</tr>
<tr>
<td>Conduct internal audits</td>
<td>54%</td>
<td>62%</td>
</tr>
<tr>
<td>Unidirectional workflow for molecular diagnosis</td>
<td>45%</td>
<td>86%</td>
</tr>
<tr>
<td>Regular equipment maintenance</td>
<td>87%</td>
<td>100%</td>
</tr>
<tr>
<td>Standard operating procedures (SOPs) for molecular diagnosis</td>
<td>94%</td>
<td>97%</td>
</tr>
<tr>
<td>Staff safety guidelines</td>
<td>92%</td>
<td>97%</td>
</tr>
<tr>
<td>Staff health programme</td>
<td>78%</td>
<td>85%</td>
</tr>
</tbody>
</table>

2.3 WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)

This section of the Annual Report provides information about other pandemic preparedness activities that GISRS conducted during the reporting period. Pandemic preparedness activities led by groups other than GISRS are also described.

GISRS: laboratory pandemic preparedness

Influenza vaccines are the most effective measure to mitigate the potential impact of an influenza pandemic as most people will be susceptible to infection with the newly emerged virus. The development of candidate vaccine viruses and associated reference reagents is an important part of pandemic preparedness. During May 2011–May 2012, GISRS developed and made available the following candidate vaccine viruses and reference reagents for pandemic preparedness:

- A(H5N1): 4 new candidate vaccine viruses and 3 new reference reagents
- A(H9N2): 1 new candidate vaccine virus

1 During May 2011–May 2012, there were 8 summaries published on the status of development and the availability of candidate vaccine viruses and potency testing reagents for A(H5N1) (available at: http://www.who.int/influenza/vaccines/virus/candidates_reagents/a_h5n1/en/index.html); 2 for A(H9N2) (available at: http://www.who.int/influenza/vaccines/virus/candidates_reagents/a_h9n2/en/index.html); and 2 for A(H3N2)v (available at: http://www.who.int/influenza/vaccines/virus/candidates_reagents/variant_a_h3n2/en/index.html).
• A(H3N2)v: 3 new candidate vaccine viruses.

Summary reviews of the antigenic and genetic characteristics of A(H5N1) and A(H9N2) and the current status of the development of new candidate vaccine viruses for potential use for human vaccine development are available following the vaccine composition meetings for northern and southern hemispheres in February and September of each year.¹

GISRS regularly works to develop or update existing laboratory guidelines and best practices. These activities are often applicable to both seasonal influenza viruses and viruses with human pandemic potential. A brief synopsis of relevant activities during May 2011–May 2012 follows.

• **Improving influenza vaccine virus selection:** To explore ways to improve the influenza vaccine virus selection process for both seasonal influenza viruses and viruses with human pandemic potential, WHO held an informal consultation in December 2011. Participants included WHO CCs and ERLs, NICs, national regulatory authorities, research, academic and veterinary laboratories, institutions and organizations, and human influenza vaccine manufacturers. The major areas of focus were the extent, timeliness and quality of virological and epidemiological surveillance data; the development and application of new assays and new modeling approaches; the relationship between virus characteristics and vaccine efficacy; and regulatory considerations.

• **Standardization of terminology for the variant A(H3N2) virus recently infecting humans:** Since July 2011, increasing numbers of human cases of infection with a variant influenza A(H3N2) virus have been detected in the United States of America (USA). No reports have been received from other Member States. This virus has different virological characteristics from current circulating seasonal influenza viruses in humans. In order to improve communications and avoid confusion, the Food and Agriculture Organization of the United Nations (FAO), the World Organisation for Animal Health (OIE) and WHO established a working group of experts to standardize the terminology for variant influenza viruses. The joint recommendation was A(H3N2)v, where “v” stands for “variant”.

• **Updated unified nomenclature system for the highly pathogenic H5N1 avian influenza viruses:** In October 2011 the WHO/OIE/FAO H5N1 Evolution Working Group published an updated unified nomenclature system for highly pathogenic avian influenza A(H5N1) viruses. A unified system facilitates the interpretation of sequence/surveillance data from different laboratories. Since the previous update in 2009, H5N1 viruses have continued to evolve and diversify as they spread and infect animals and humans. The 2011 recommendations were based on detailed analyses and comparisons for nearly 3000 H5N1 virus gene sequences.²

• **Recommendations on laboratory methods for antiviral susceptibility surveillance:** Over the last ten years antiviral drugs have become an important intervention for the treatment and prophylaxis of influenza virus infection. In countries where antiviral drugs are licensed, national guidance on their use in clinical management is developed and updated. Use and stockpiling of antiviral drugs is a key component of the pandemic preparedness plans of many countries. For these reasons, monitoring of antiviral susceptibility of influenza viruses through laboratory surveillance is an increasingly important need. An Expert Working Group

on Antiviral Susceptibility for WHO GISRS, therefore, was established to develop practical
guidance for NICs setting up surveillance of antiviral susceptibility; to provide
recommendations on the appropriate antiviral surveillance strategy; and to develop guidance
on interpretation of laboratory antiviral susceptibility surveillance data. At their first meeting
in November 2011, the expert Working Group reviewed and developed practical guidance for
NICs on current laboratory methodologies for testing the antiviral susceptibility of influenza
viruses to current antivirals.

• Protocols for A(H5N1) testing: The continuous evolution of A(H5N1) genetic clades makes
it critical to regularly review, update and validate H5 primers and protocols. The WHO PCR
working group meets annually to make recommendations for the GISRS network on the use
of PCR in the surveillance and diagnosis of influenza.¹ Currently, the most commonly used
protocol in the network is the H5 assays provided by the WHO CC in Atlanta, USA;
18 countries use protocols provided by other WHO CCs and reference laboratories.

• Updated seasonal influenza TORs for NICs: The NIC TORs are in the process of being
updated for seasonal influenza viruses.

Regulatory capacity

During the reporting period WHO organized 20 country-level training programmes and workshops for
national regulatory authorities and held a global training on lot release procedures for national control
laboratory staff new to influenza vaccine manufacturing.

Representatives from 34 countries attended the WHO cosponsored Workshop on International
Regulatory Capacity Enhancement for Influenza Vaccines, 8–10 June 2011, São Paulo, Brazil and
proposed a number of priorities and next steps for enhancing regulatory capacity for influenza
vaccines including support to:²

• designate a percentage of grants provided to countries for developing vaccine manufacturing
capacity be set aside for national regulatory authority (NRA) capacity building;

• strengthen regional regulatory partnerships, approaches and networks, particularly models
that address the regulatory needs of developing countries;

• enhance post-marketing surveillance and monitoring of adverse events following
immunization in countries with and without influenza vaccine manufacturing capacity;

• strengthen the evaluation of clinical trial data for regulatory registration;

• support WHO regulatory capacity building initiatives and recommendations including the
NRA Strengthening Programme, the Vaccine Prequalification Programme, the NRA Strategic
Forum of Regulatory Agencies for Vaccines, the Global Learning Opportunities for Vaccine

¹ The report of the 4th meeting of the WHO working group on polymerase chain reaction protocols for detecting
subtype influenza A viruses is available at:

² Workshop report available at: http://www.who.int/immunization_standards/national_regulatory_authorities
These and other proposals from the Workshop helped to inform the Second WHO Consultation on the Global Action Plan for Influenza Vaccines (GAP), 12–14 July 2011 Geneva. The consultation report noted that “strengthening of national and other regulatory agencies to promote the timely and efficient assessment and approval of locally manufactured or imported influenza vaccines will require a long-term strategy and strong political commitment”.

**Vaccine deployment capacity**

WHO finalized in 2012 its *Guidance on Development and Implementation of a National Deployment and Vaccination Plan for Pandemic Influenza Vaccines*. It is designed for public and private sector officials at all levels with responsibility for planning and managing deployment and vaccination operations. The initial draft was completed and field-tested shortly before the start of the 2009 (H1N1) pandemic. Countries used the Guidance to develop their pandemic national deployment and vaccination plans (NDVPs). It was revised in 2010–2011, incorporating experience and lessons learned from the pandemic at global, regional and country levels, as well as key recommendations from global and regional workshops on NDVP implementation.

The guidance and accompanying planning tools can assist countries to develop, assess and update their NDVPs. The guidance covers all the processes and structures that need to be functional for vaccine deployment, and operations before and during a pandemic. A sample template for drafting an NDVP is included. In addition, a checklist to assist in the assessment of NDVPs has been developed and included in a supplementary document.

**H5N1 vaccine stockpile**

An international stockpile of 150 million doses of H5N1 vaccine was established in 2008 through pledges from two manufacturers. In response to the 2009 H1N1 pandemic, these two manufacturers agreed to convert their H5N1 pledges into H1N1 pandemic vaccine. They also increased their pledges to a total of 160 million doses. Of the 78 million doses of pandemic H1N1 vaccine that WHO deployed to low- and middle-income countries, 40 million doses came from the H5N1 vaccine stockpile. This reduced the remaining number of pledged pandemic vaccine doses to 120 million. Manufacturers subsequently agreed to reconvert the 120 million doses of pledged pandemic vaccine back to H5N1 vaccine, or other pandemic influenza vaccine, if needed.

The Strategic Advisory Group of Experts (SAGE) Working Group on Influenza Vaccines and Immunizations was tasked in February 2011 to reconsider options for the nature, deployment and storage of the 120 million doses of pledged pandemic H5N1 vaccine. The Working Group proposed three options and considered that a virtual stockpile with a small physical stockpile of filled doses of H5N1 vaccine for outbreak control may provide flexibility, minimum costs and simplify the logistics of storage. Discussions are ongoing to explore other options and technical aspects of implementing the various options for the final recommendations to SAGE.

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Revision of pandemic preparedness guidelines

The revision of the pandemic preparedness and response guidance has commenced, with various background documents being produced. WHO is developing a multisectoral, all-hazards, generic approach to preparedness, which is expected to form the basis for the influenza guidance document. A discussion paper on revision of the pandemic phases has been circulated for engagement with internal and external stakeholders.

In addition, the WHO European Regional Office (EURO) has gathered experiences of the pandemic to contribute to the drafting of a EURO-ECDC (European Centre for Disease Control and Prevention) planning guide. These and lessons from other WHO regions and Member States worldwide will be incorporated into the revised global guidance. It is intended that the new guidance will be largely completed over a one-year period.

2.4 Increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential

Maintaining and improving the GISRS network for surveillance of seasonal influenza is critical for response capacity during a pandemic. This section of the Annual Report provides information about activities undertaken during May 2011–May 2012 to enhance both laboratory and disease surveillance for H5N1 and other influenza viruses with human pandemic potential.

Laboratory surveillance

Strengthening GISRS, through efforts to build capacity at country level, is integral to robust pandemic preparedness and response. Efforts are ongoing to increase the number of NICs. During May 2011–May 2012, 2 new NICs were recognized: one in Doha, Qatar in March 2012 and one in Amman, Jordan in April 2012. However, gaps in the network remain as many countries, particularly in the African Region, do not have a NIC. Oftentimes, lack of a NIC correlates with lack of overall capacity for surveillance and response to influenza. The network regularly expands to include new laboratories or categories of laboratories, as needed. For instance, a new category of Collaborating Centres working at the human-animal interface is under development.

The Guiding Principles that underpin the TORs for GISRS laboratories call for sharing of experience and provision of capacity strengthening to Member States; WHO CCs in particular provide training and laboratory support to NICs, especially in developing countries, on laboratory techniques and skills. During May 2011–May 2012, more than 50 training courses and onsite capacity building activities were organized and/or supported by WHO regions, WHO CCs and ERLs for countries in all six WHO regions. Training included laboratory management; strengthening capacity for detection, diagnosis, and monitoring; serology; data management and basic epidemiological analysis; bioinformatics on molecular evolution; sequencing; antiviral susceptibility testing; and licensing for transport of infectious substances.

Disease surveillance

During the reporting period a total of 51 confirmed human cases of H5N1 were reported to WHO from six countries.]

1 See http://www.who.int/influenza/human_animal_interface/H5N1_cumulative_table_archives/en/ for the number of confirmed human cases for avian influenza A(H5N1) reported to WHO.
Surveillance for human infections with influenza A(H5N1) and emerging viruses with human pandemic potential requires systematic, good quality routine surveillance for influenza-related disease. The 2009 pandemic revealed multiple gaps in global influenza surveillance capacity. To address these gaps, WHO embarked on a multistep process to revise global influenza surveillance guidelines; this process formally commenced with the Global Consultation on Influenza Surveillance Standards held in Geneva in March 2011. An interim document, *WHO Interim Global Epidemiological Surveillance Standards for Influenza (July 2012)*, has been posted for review.1

### 2.5 Sharing of influenza viruses with pandemic potential

**Influenza Virus Traceability Mechanism (IVTM)**

In November 2007, the Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of influenza viruses and access to vaccines and other benefits requested that WHO develop a system to track all influenza viruses with human pandemic potential contributed by Member States to the WHO GISRS. In response to this request, an Interim Virus Tracking System (IVTS) was implemented in January 2008. The IVTS was replaced by the IVTM which was initially launched in December 2010; its use became obligatory upon adoption of the PIP Framework on 24 May 2011.2

The IVTM is an electronic, internet-based system for tracking the transfer and movement of PIP biological materials into, within and out of the WHO GISRS. It documents the sharing of influenza viruses with pandemic potential in a transparent manner; users can trace the geographic transfer of such influenza viruses and view the Derivation Tree for the same.

Review of IVTM records indicates that during May 2011 to May 2012 a total of 120 shipments of PIP biological materials were sent and recorded in the IVTM; 72 (60%) of these 120 shipments were sent to 38 non-GISRS laboratories.3 During this same period, a total of 82 human or animal viruses with pandemic potential (i.e. A(H5N1), A(H3N2)v, and A(H9N2) viruses) were recorded in the IVTM by eight different countries.

The IVTM, while an important tool for recording virus sharing, is a relatively new tool for both GISRS users and public users, alike. WHO has developed and pilot-tested training modules to familiarize users with the IVTM: one is for public users to assist them in “how to” search the IVTM database; a second training module assists registered GISRS laboratory users in “how to” use the IVTM system to record receipt and transfers of PIP biological materials. Future plans include increasing awareness among registered users and WHO Regional and IHR National Focal Points about reporting to IVTM; and providing hands-on support to complement the “how to” tutorial series to enhance the timely sharing of PIP biological materials via the IVTM. Improvements in the information technology (IT) platform are also planned; they will take into account feedback and lessons learned from registered and public users.

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3 Some shipments included more than one PIP biological material.
Public-access databases

During the reporting period, genetic sequence data for 46 influenza A(H5N1) isolates from five different countries and five A(H3N2)v isolates from a single country were shared through public-access databases. No genetic sequence data for H7 or H9 influenza viruses were deposited in a public-access database during this period.

Interim process for sharing PIP biological materials

Since adoption of the PIP Framework in May 2011, GISRS laboratories have received requests for PIP biological materials from entities outside GISRS. Direct application of Article 4.3 of SMTA 1 would have resulted in complete cessation of sharing PIP biological materials until WHO and recipients concluded SMTA 2 agreements. In view of this, WHO shared with the Advisory Group during its February 2012 meeting an interim approach for transferring PIP biological materials that had been developed and implemented. The Advisory Group, noted that sharing of PIP biological materials is critical for health security and must continue. However, for the sake of benefit sharing, the incentive to conclude SMTA 2s cannot be lost. The Advisory Group recommended:

- the Secretariat should elaborate a practical, balanced and uniform approach for the transitional period to obtain recognition from recipients of PIP biological materials outside GISRS that they will enter into discussions with WHO on a SMTA 2;

- if a SMTA 2 is not concluded with the recipient within six months after the beginning of negotiations, no further PIP biological materials will be transferred to that recipient.1

The Director-General acknowledged the advice provided by the Advisory Group in the matter of the “Interim Approach” and communicated to the Advisory Group in May 2012 her proposed way forward to address their concerns as follows:

- The Director-General recognizes the urgency to efficiently conclude SMTA 2s with non-GISRS recipients of PIP biological materials (PIPBM).

- As such, the recommendation to define a time limit to complete individual negotiations on SMTA 2s is reasonable.

- The Interim Approach, however, needs to take into consideration the reality that there are still significantly different levels of understanding of the PIP Framework among recipients of PIPBM that are outside GISRS.

- The Director-General therefore believes that an interim, stepwise approach, consistent with the Advisory Group’s advice, will best enable WHO to conclude SMTA 2s and thereby achieve the public health objectives of the PIP Framework.

- To this end, the Director-General proposes the following Interim Approach:

  - Step 1 – Discussions: An informal period of time to allow WHO and individual non-GISRS recipients of PIPBM to exchange information with each other and gain knowledge about the PIP Framework, as appropriate;

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Step 2 – Negotiations: The formal period of negotiations that will start with the exchange of negotiating documents. The Secretariat will send the party a “Notice of Commencement of SMTA 2 Negotiations” to record the date of commencement and the anticipated date of conclusion which should be no longer than 6 months. The Secretariat will regularly update the Advisory Group on the progress in negotiations.

If an SMTA 2 is not concluded within six months after the beginning of negotiations the recipient should expect no further transfers of PIPBM. The Director-General will bring the matter to the attention of the PIP Advisory Group and request advice on when and under what conditions transfers of PIPBM might resume for that recipient.

This Interim Approach may be reviewed as necessary to take into account the experience arising from its application, notably the need for time-bound discussions under Step 1.

An Information Note with this Interim Approach was dispatched to all GISRS laboratories for their information and action on 23 May 2012.

2.6 Virus sharing: summary and recommendations

The work of WHO GISRS laboratories underpins global influenza surveillance, prevention, preparedness and response. The Advisory Group has noted multiple examples of the collaborative work of WHO and Member States to strengthen laboratory and disease surveillance capacity for detection and risk assessment of influenza viruses with human pandemic potential. The continued sharing of viruses enables the development of candidate vaccine viruses with pandemic potential and reference reagents – critically important tools when a pandemic virus emerges. The IVTM has increased the transparency of GISRS activities and increased the transparency of the sharing of viruses with human pandemic potential. The Advisory Group has additionally noted other areas of work that contribute to pandemic preparedness, including efforts to strengthen regulatory capacity, vaccine deployment capacity, an H5N1 vaccine stockpile, and laboratory and disease surveillance for influenza viruses with human pandemic potential.

Many gaps remain, however. The Advisory Group is aware that many countries still lack basic capacities for laboratory and disease surveillance, shipping of influenza viruses, and the regulation and deployment of influenza vaccines during a pandemic. Sharing of PIP biological materials is critical for health security and must continue. However, the transition to sharing these materials with outside entities that have concluded a SMTA 2 needs to happen as quickly as possible.

Recommendations

(1) Information supplied for this Report continues to support the Advisory Group’s prior recommendation that Partnership Contribution resources focus initially on pandemic preparedness.1

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1 See Annex 3 of this report for a synopsis of recommendations from the Advisory Group to the Director-General on potential uses of PIP Partnership Contribution resources for pandemic preparedness and response.
(2) The Advisory Group has recommended previously that a self-assessment of GISRS with respect to its role, function and capacities in connection with the Framework be undertaken. The Advisory Group notes that this will be undertaken in 2013 subject to the availability of funds. \(^1\)

(3) The Advisory Group recommends that WHO seek support from Member States and other stakeholders to supplement resources for the WHO Shipping Fund Project and the conduct of training programmes to certify staff in the shipping of infectious substances. The 2009 pandemic demonstrated the key role that shipping of virus samples played in the global response.

3. BENEFIT SHARING

The PIP Framework aims to ensure that benefits arising from the sharing of PIP biological materials are made more accessible and available to countries based on public health risk and need. Benefits include vaccines and other pandemic supplies, as well as technical assistance, and transfer of technology, skills and knowledge needed by developing countries to build pandemic influenza preparedness and response capacity.\(^2\) The Framework further provides for influenza vaccine, diagnostic and pharmaceutical manufacturers who use the WHO GISRS to make an annual contribution to WHO. This annual payment, termed the Partnership Contribution, was created to help safeguard the financial sustainability of the PIP benefit sharing system.

This section of the Annual Report reviews how sharing of various benefits has progressed in the first 12 months of the Framework’s implementation.

3.1 Access to vaccines and other benefits

As provided for in Annex 2 of the PIP Framework, any non-GISRS recipient of PIP biological materials must assess what benefits it can contribute based on its nature and capacity and enter into a binding contract, or SMTA 2, with WHO. During May 2011–May 2012, the Director-General initiated discussions with four large influenza vaccine manufacturers to commence the process to sign SMTA 2s. The PIP Secretariat has also provided information on the SMTA 2 and the process to conclude it to over 30 prospective recipients of PIP biological materials.

3.2 Use of financial contributions: the Partnership Contribution

Pursuant to Section 6.14.3 of the Framework, Partnership Contribution payments to WHO are to commence in 2012 in the amount of approximately US$ 28 million.\(^3\) In anticipation of this, and as provided by the Framework,\(^4\) the Advisory Group first presented a series of recommendations to the Director-General on how the Partnership Contribution should be allocated between pandemic preparedness and pandemic response. In developing these recommendations, the Advisory Group, in accordance with Framework Section 6.14.6, interacted with industry and other stakeholders on 23 February 2012 at which time important information and considerations were provided to the Advisory Group and the Director-General relevant to the Partnership Contribution.

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\(^2\) See PIP Framework Section 6 for more information about benefit sharing.

\(^3\) The annual amount of the Partnership Contribution was established by the Member States at 50% of the annual cost to run GISRS. For more information see Framework Section 6.14.3, footnote 1.

These initial recommendations were contained in the Advisory Group’s February 2012 meeting report which the Director-General subsequently transmitted to the Sixty-fifth World Health Assembly for its consideration. In May 2012 the Advisory Group transmitted to the Director-General its fully developed recommendations on the potential uses of the Partnership Contribution.

3.3 Benefit sharing: summary and recommendations

The Framework places virus sharing on an equal footing with benefit sharing; sharing of viruses and benefits is to be is fair, transparent, equitable and efficient. In the year since the PIP Framework was adopted, essential groundwork has been laid to facilitate benefit sharing as envisioned in the Framework. WHO has initiated discussions with influenza vaccine manufacturers to commence the process to sign the first SMTA 2s. The Executive Board at its 131st session on 28–29 May 2012 considered and accepted the Director-General’s proposals, based on the Advisory Group’s recommendations, on the proportional distribution of the Partnership Contribution between pandemic preparedness and response. The Advisory Group also provided the Director-General with recommendations about potential uses of the Partnership Contribution.

Substantial work remains, nonetheless, to advance this initial work into concrete benefits.

Recommendations

(1) WHO should conclude one or more SMTA 2s as soon as possible.

(2) With respect to the Partnership Contribution, the Director-General and the Advisory Group should continue to collaborate with industry in further defining the specific amounts to be contributed by each company as well as the mechanism for implementation and interact with industry and other stakeholders on the use of the resources.

(3) WHO should develop and share with the Advisory Group a method by which factors will be applied in the selection of countries to receive Partnership Contribution funds.

4. GOVERNANCE

4.1 Appointment and composition of the first PIP Advisory Group

The Director-General appointed 18 members of the PIP Advisory Group in 2011 upon receipt of nominations from Regional Directors. In accordance with Sections 7.2.2 and 7.2.3 and Annex 4 of the PIP Framework, there are three members from each of WHO’s six regions, representing developed and developing countries, affected countries, and a skill mix of policy-makers, public health experts and influenza experts. A list of members may be found in Appendix 4 of this Report. At its first meeting, the Advisory Group elected Professor Didier Houssin (France) as Chair and Professor Tjandra Y. Aditama (Indonesia) as Vice-Chair.

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2 See Appendix 3 of this Report for a synopsis of these recommendations.
4 See PIP Framework Section 6.14.3.
In accordance with the provisions of the PIP Framework, all members will serve for three years. A three-year appointment period was deemed particularly important for the Advisory Group in the early stages of its work as this would allow for continuity of discussions and facilitate implementation of critical and time-sensitive tasks under the PIP Framework. Subsequently, renewal of one third of the members will be initiated every year per the PIP Framework. The Director-General will regularly accept nominations of representatives for the Advisory Group.

4.2 Meetings and recommendations of the Advisory Group

The Advisory Group held two meetings in Geneva (21–22 November 2011 and 22–24 February 2012) and one meeting by teleconference (3–4 May 2012). Special attention was paid at the beginning of each meeting to update the declaration of interests of each member of the Advisory Group; all declarations of interest were detailed in the report of each meeting. Following its first two meetings, the Chair of the Advisory Group led Information Sessions in Geneva for the Permanent Missions on 1 December 2011 and 5 March 2012.

The Advisory Group has made recommendations to the Director-General in several key areas as follows.

The Partnership Contribution

The Advisory Group had extensive discussions during its February and May 2012 meetings on the Partnership Contribution. The Advisory Group presented recommendations with supporting documentation to the Director-General on the proportional distribution of the Partnership Contribution between pandemic preparedness and pandemic response and actual uses of the Partnership Contribution. A synopsis of these recommendations can be found in Appendix 3 of this Report.

Urgency to commence SMTA 2 negotiations

The Advisory Group advised that discussions on the SMTA 2 commence no later than the Sixty-fifth World Health Assembly. To aid in the process, they agreed that the Director-General should encourage Member States to provide legal support.

Interim approach for the sharing of PIP biological materials with entities outside GISRS pending the conclusion of SMTA 2s

While understanding the reasons for an interim approach, the Group recommended that if an SMTA 2 is not concluded with the recipient within six months after the beginning of negotiations, no further PIP biological materials will be transferred to the recipient. The Director-General acknowledged the advice provided by the Advisory Group in the matter of the “Interim Approach” and communicated to them in May 2012 her proposed way forward to address this. This Interim Approach is detailed in Section 2.5 of this Report.

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2 PIP Framework Annex 3, section 3.2.
3 PIP Framework, Annex 3, Section 3.3.
4.3 Governance: summary and recommendations

The Advisory Group has a broad range of expertise and experience which has been an asset in addressing its TORs under the PIP Framework. The Advisory Group is aware of the keen interest in the Framework and its operationalization. The Advisory Group has endeavored to keep Member States updated through Information Sessions and reports to the World Health Assembly and Executive Board and to interact with industry and other stakeholders.

Recommendations

(1) The Advisory Group expressed a view that any decision on the future mandate of the Advisory Group (per PIP Framework Section 7.2.6) should be deferred until the Group had completed a reasonable amount of work.¹

(2) The Advisory Group recommends maintaining the Information Sessions, led by the Chair, for Permanent Missions that follow Advisory Group meetings.

## APPENDIX 1

### INDEX OF TOPICS COVERED IN THE ANNUAL REPORT

<table>
<thead>
<tr>
<th>Topic area (PIP Framework Section 7.2.5)</th>
<th>Location in the Annual Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Necessary technical capacities of the WHO Global Influenza Surveillance and Response System (GISRS)</td>
<td>Section 2.1 Appendix 2</td>
</tr>
<tr>
<td>2. Operational functioning of WHO GISRS</td>
<td>Section 2.2</td>
</tr>
<tr>
<td>3. WHO GISRS influenza pandemic preparedness priorities, guidelines and best practices (e.g. vaccine stockpiles, capacity building)</td>
<td>Section 2.3</td>
</tr>
<tr>
<td>4. Increasing and enhancing surveillance for H5N1 and other influenza viruses with human pandemic potential</td>
<td>Section 2.4</td>
</tr>
<tr>
<td>5. Influenza Virus Traceability Mechanism (IVTM)</td>
<td>Section 2.5</td>
</tr>
<tr>
<td>6. Sharing of influenza viruses and access to vaccines and other benefits</td>
<td>Section 2.3 (H5N1 vaccine stockpile Section 2.5 Section 3.1)</td>
</tr>
<tr>
<td>7. Use of financial and non-financial contributions</td>
<td>Section 3.2</td>
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</tbody>
</table>
APPENDIX 2

FUNCTIONS AND TECHNICAL CAPACITIES OF GISRS LABORATORIES

National Influenza Centres

National Influenza Centres (NICs) typically are the principal resource for influenza-related virological and epidemiological expertise in their country. They serve as the key point of contact between WHO and their country for influenza-related technical issues. NICs analyze specimens obtained from patients and make an initial identification of the influenza virus type and subtype, principally using the polymerase chain reaction (PCR) test. Representative viruses, as well as influenza viruses with potential public health significance, and any available clinical and epidemiological information, are sent to a WHO Collaborating Centre for further virus characterization.

WHO Collaborating Centres

WHO Collaborating Centres for Influenza (WHO CCs) are internationally-recognized centres of excellence for influenza that perform critical and highly technical services. WHO CCs employ sophisticated testing methods such as haemagglutination inhibition, microneutralization and also perform viral gene sequencing. These analyses form the basis for WHO recommendations on influenza vaccines (both seasonal vaccines and vaccines for influenza viruses with pandemic potential) and the development and characterization of candidate vaccine viruses. In collaboration with scientists from Cambridge University, antigenic cartography has been used in recent years as an adjunct to standard methods to improve influenza vaccine virus selection. WHO CCs also monitor antiviral susceptibility using genotypic and phenotypic methods; update and produce the standardized reagents which are distributed to NICs and used to identify circulating influenza viruses; provide advice and training on the most up-to-date laboratory methods; and assess the risk of, and respond to, outbreaks of influenza, especially if there is concern about a new virus with pandemic potential.

WHO Essential Regulatory Laboratories

WHO Essential Regulatory Laboratories (WHO ERLs) are formally associated with national regulatory agencies. The WHO ERLs, together with WHO CCs, conduct human serology studies to assess if the previous season’s vaccine will offer suitable protection against more recent circulating influenza viruses. The WHO ERLs and CCs, in collaboration with vaccine manufacturers, evaluate the growth of candidate vaccine viruses to help manufacturers select the optimal virus for vaccine development and production. The WHO ERLs, with support from vaccine manufacturers, develop, update and calibrate reference agents that are used to test the “potency” of influenza vaccines, including seasonal vaccines and those for pandemic preparedness, before vaccines can be released for marketing or clinical trials.

WHO H5 Reference Laboratories

The WHO H5 Reference Laboratory group (WHO H5 Ref Labs) perform diagnostic testing and analyses of A(H5N1) and novel influenza subtypes from humans and animals worldwide. The WHO H5 Ref Labs also contribute to the updating of the candidate vaccine viruses for H5 and H9 influenza viruses and assess the pandemic potential of new influenza viruses, i.e. virological risk assessment.

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1 Antigenic cartography is a novel computational methodology that is used to analyze and visualize large volumes of laboratory data generated by GISRS laboratories. See http://www.antigenic-cartography.org/ac.html for more information.
APPENDIX 3

SYNOPSIS OF RECOMMENDATIONS FROM THE ADVISORY GROUP TO THE DIRECTOR-GENERAL ON POTENTIAL USES OF PIP PARTNERSHIP CONTRIBUTION RESOURCES FOR PANDEMIC PREPAREDNESS AND RESPONSE

Guiding principles

- The Advisory Group recommends that the allocations should:
  - take into account Framework principles including fairness, equity, public health risk and need of all Member States, and the particular vulnerability of countries affected by influenza viruses with pandemic potential, especially H5N1;
  - be evidence-based and consider indicators adapted to the Framework such as the International Health Regulations’ (IHR) core capacities, income, health and epidemiology;
  - consider the critical foundation of epidemiological and laboratory surveillance;
  - take into account the modest amount of Partnership Contribution resources.

Proportional distribution of the Partnership Contribution (see Box)

- The Advisory Group recommends, in a first phase, to direct a greater proportion of the Partnership Contribution resources to pandemic preparedness activities and a lesser proportion to the reserve for pandemic response.

- The Advisory Group recommends that 70% (or approximately US$ 20 million per year) of the Partnership Contribution be directed toward pandemic preparedness activities and 30% (or approximately US$ 8 million per year) be directed toward pandemic response activities. For reasons of flexibility and practicality, 70% and 30% should be considered as approximate targets, e.g. in the range of 65% to 75% and 25% to 35%, respectively. The Director-General should be able to temporarily modify the allocation of Partnership Contribution resources as required to respond to pandemic influenza emergencies. The Director-General would report on any such modification to Member States.

- The Advisory Group recommends that this proportional split be fixed for an initial period of 5 years, i.e. from 2012 through 2016.

Use of the Partnership Contribution: pandemic preparedness activities (see Box)

- The Advisory Group recommends starting with activities in support of the three technical areas identified in Section 6.14.4 of the Framework, i.e. strengthening laboratory and surveillance capacity, conducting disease burden studies, and improving access and effective deployment of pandemic vaccines and antiviral medicines, as well as in one additional area that will strengthen effective pandemic response: risk communications.
• The Advisory Group recommends that of the approximately US$ 20 million per year for pandemic preparedness activities, (1) 70% be used to build and/or strengthen surveillance and laboratory capacity; (2) 10% to conduct disease burden studies; (3) 10% to strengthen regulatory capacity and thereby improve access and effective deployment of pandemic vaccines and antiviral medicines; and (4) 10% to strengthen risk communications. For reasons of feasibility, flexibility and practicality, each of these proportions should be viewed as an approximate target, i.e. +/- 5% for each.

Use of the Partnership Contribution: pandemic response

• The Advisory Group recommends that the approximately US$ 8 million per year available through the Partnership Contribution for pandemic response be reserved to purchase vaccine and antiviral medicines at the time of a pandemic for countries without access.

Implementation of activities

• The Advisory Group recommends that WHO headquarters work with and through its regional and country offices to seek their assistance in the implementation of activities supported by Partnership Contribution resources.

• The Advisory Group recommends that WHO (headquarters, regional offices, and country offices) also provide technical guidance, as needed, to develop protocols/methodology and implementation plans for each activity, and that the reporting of measurable results be carried out within defined periods of time.

• The Advisory Group recommends that WHO establish and maintain ways to track the distribution and use of Partnership Contribution resources over time.

Box. Recommendations of the PIP Framework Advisory Group on the distribution and uses of the Partnership Contribution

<table>
<thead>
<tr>
<th>70% directed to pandemic preparedness activities</th>
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<tbody>
<tr>
<td>• 70%  disease and laboratory surveillance capacity</td>
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<tr>
<td>• 10%  disease burden studies</td>
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<tr>
<td>• 10%  regulatory capacity</td>
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<tr>
<td>• 10%  risk communications</td>
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<table>
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<tr>
<th>30% directed to pandemic response activities</th>
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<tbody>
<tr>
<td>• reserved for purchase of vaccine and antiviral medicines at the time of a pandemic for countries without access</td>
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</table>

1 The Advisory Group proposed a general approach, including factors to consider, for selecting countries to receive Partnership Contribution resources in each of these areas. The Advisory Group requested that WHO develop a method by which factors will be applied in the selection of countries and share this with the Advisory Group at its meeting in October 2012.
APPENDIX 4

ADVISORY GROUP MEMBERS

Professor Tjandra Y. Aditama, Director General of Disease Control and Environmental Health, Ministry of Health, Indonesia

Dr William Kwabena Ampofo, Senior Research Fellow & Head – Virology, Noguchi Memorial Institute for Medical Research, University of Ghana, Ghana

Dr Jarbas Barbosa da Silva Jr, Secretary (Vice Minister) of Health Surveillance, Ministry of Health, Brazil

Dr Silvia Bino, Associate Professor of Infectious Diseases, Head, Control of Infectious Diseases Department, Institute of Public Health, Albania

Professor Rajae El Aouad, Director, National Institute of Hygiene, Morocco

Dr Rainer Engelhardt, Assistant Deputy Minister, Infectious Disease Prevention and Control Branch, Public Health Agency of Canada, Canada

Mr David E. Hohman, Former Deputy Director, Office of Global Affairs, Department of Health and Human Services, United States of America

Professor Didier Houssin, President, French Evaluation Agency for Research and Higher Education (AERES), France

Dr Mark Jacobs, Director of Public Health, Ministry of Health, New Zealand

Professor Ziad Memish, Assistant Deputy Minister of Health for Preventive Medicine, Ministry of Health, Saudi Arabia

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Dr Amr Mohamed Kandeel, Chief of Preventative Affairs and Endemic Diseases Sector, First Undersecretary, Ministry of Health and Population, Egypt

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Professor Yu Wang, Director-General, Chinese Center for Disease Control and Prevention, China