

Advisory Group Recommendations to the Director-General on
Potential uses of PIP Partnership Contribution resources for pandemic preparedness and
response

On behalf of the Advisory Group, its Chair has the honour to transmit to the Director-General the recommendation of the Group on the potential uses of the Partnership Contribution that will be received by WHO in 2012 pursuant to PIP Framework Section 6.14.3. These recommendations are provided under Framework Section 6.14.6, as well as Section 2.4 of the Advisory Group's Terms of Reference.

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

BACKGROUND

On 24 May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (the "PIP Framework").¹ The foundational principle of the PIP Framework places the sharing of influenza viruses with pandemic potential² on an equal footing with access to benefits derived from such sharing. One such benefit is the Partnership Contribution (PC).

The PC is an annual payment to WHO by influenza vaccine, diagnostic and pharmaceutical manufacturers who use the WHO Global Influenza Surveillance and Response System (GISRS).³ Given this criterion - use of GISRS – Member States established the amount of the annual PC at 50% of the annual cost to run GISRS.⁴ These running costs were understood to be the reference index for determining the amount of the PC and it was recognized that this amount would change over time.⁵ It was also understood that the PC would not be used to support the running costs of GISRS laboratories. The running costs of the GISRS for 2010 were estimated to be US \$56.5 million which would make the annual PC approximately US \$28 million. The Advisory Group, therefore, based its considerations on this figure, US \$28 million per year. WHO will receive the first payment in 2012.

The Framework specifies that the PC is to be used for two purposes: 1) inter-pandemic preparedness measures and 2) response activities in the event of a pandemic. It requires the Director-General to consult with the Advisory Group on:

- the proportion of PC funds that should be used for inter-pandemic preparedness measures as opposed to being reserved for pandemic response purposes;⁶ and
- the actual use of the resources which requires interaction with industry and other key stakeholders.⁷

RECOMMENDATIONS

Global pandemic preparedness and response: a 10-year horizon for strengthened capacities

¹ The Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits. Available at: <http://www.who.int/influenza/pip/en/>.

² Hereafter, the term "viruses" will be used in this document in the interest of brevity; however, all such references indicate "influenza viruses with pandemic potential".

³ GISRS is an international network of influenza laboratories, coordinated by WHO, that receives influenza viruses from Member States. These laboratories conduct year-round surveillance of influenza, assess the risk of pandemic influenza and assist in preparedness measures which include the development of "candidate vaccine viruses" that are used by vaccine manufacturers to produce influenza vaccine.

⁴ See Framework Section 6.14.3.

⁵ See Framework Section 6.14.3, footnote 1.

⁶ See Framework Section 6.14.5.

⁷ See Framework Section 6.14.6

The PC is a unique mechanism to build pandemic influenza readiness and response capacities. It complements and builds on on-going capacity-building efforts required under the International Health Regulations (2005)⁸ and the Global Action Plan for Influenza Vaccines (GAP).⁹ Collectively these efforts are working to better prepare the world for the next pandemic of influenza. Within a decade's time:

- 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.

The proposals that follow support activities in these key areas.

Guiding principles

By placing the sharing of benefits on equal footing with the sharing of viruses with human pandemic potential, the PIP Framework embodies the principles of fairness and equity.^{10,11} It follows that use of the PC should be faithful to these same basic principles.

1. The Advisory Group recommends that 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 IHR core capacities, income, health and epidemiology;
- consider the critical foundation of epidemiological and laboratory surveillance;
- take into account the modest amount of PC resources.

⁸ International Health Regulations (2005). Available at:
<http://www.who.int/ihr/9789241596664/en/index.html>.

⁹ Global pandemic influenza action plan to increase vaccine supply. Available at:
http://whqlibdoc.who.int/hq/2006/WHO_IVB_06.13_eng.pdf.

¹⁰ See, *inter alia*, Framework Section 1, paragraph 9 and Section 2.

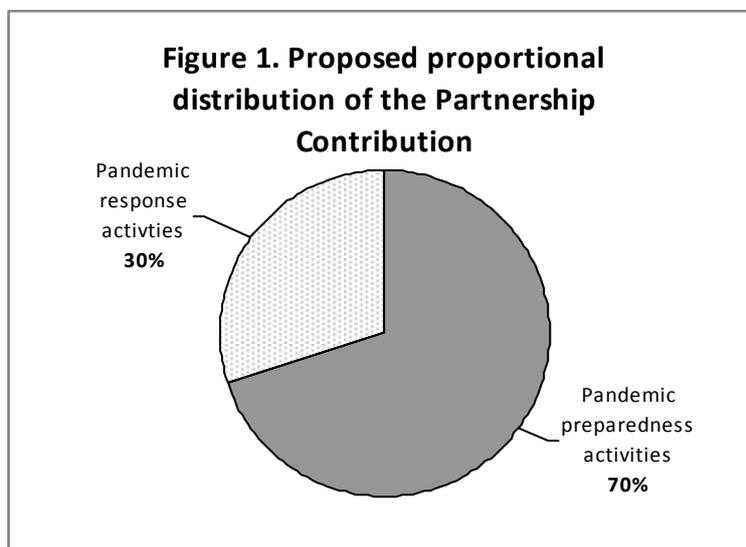
¹¹ Ethical considerations in developing a public health response to pandemic influenza. Available at:
http://www.who.int/csr/resources/publications/WHO_CDS_EPR_GIP_2007_2c.pdf.

Proportional Distribution of the PC

2. The Advisory Group recommends, in a first phase, to direct a greater proportion of the PC resources to pandemic preparedness activities and a lesser proportion to the reserve for pandemic response. This approach is responsive to one of the principal conclusions of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza H1N1 2009, namely that “the world is ill-prepared to respond to a severe influenza pandemic or to any similarly global, sustained and threatening public-health emergency.”¹² The IHR Review Committee noted that nearly half of States had “...neither assessed surveillance and response capacities nor planned for improvements.”

The PIP Advisory Group affirms the value of assigning a

greater proportion of funds to preparedness at the early stages of implementation of the PC to allow time to build and strengthen capacity in various areas. The Group stresses the need to achieve the greatest impact by building capacity in countries where it is lowest and observes that preparedness requires long-term investment, particularly when capacity building requires training and transfer of knowledge. Focusing PC resources on preparedness also takes into account lessons learnt from the H1N1 2009 influenza pandemic which demonstrated that implementation of response measures, such as access to vaccines, is enhanced with advance preparation. The Advisory Group also notes that the full implementation of the Framework will provide access to quantities of pandemic vaccines and antiviral drugs necessary to establish a response.



3. The Advisory Group recommends that 70% (or approximately US \$20 million per year) of the PC be directed toward pandemic preparedness activities and 30% (or approximately US \$8 million per year) be directed toward pandemic response activities (Figure 1). 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 PC resources as required to respond to pandemic influenza emergencies. The Director-General would report on any such modification to Member States.

4. The Advisory Group recommends that this proportional split be fixed for an initial period of 5 years, i.e. from 2012 through 2016. Preparedness activities often entail long-term capacity building and training efforts. A fixed flow of resources over a defined period of time would facilitate the timely achievement of concrete results. The proportional distribution will be reviewed in 2016. The timing of this review would coincide with the review requirements

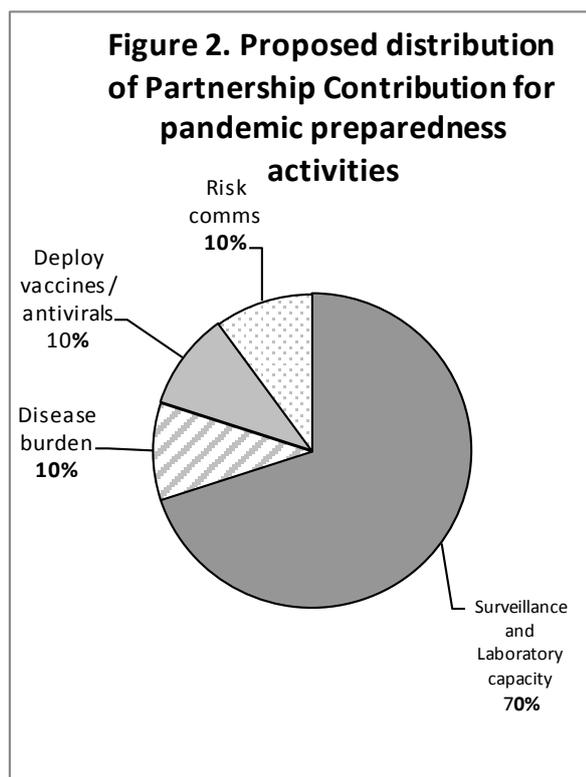
¹²The report is available at: http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf.

stipulated in the Framework, e.g. review of the Framework by 2016 and proposal of any revisions to the World Health Assembly in 2017.

Use of the PC: pandemic preparedness activities

While the Framework does not direct or limit the use of the PC to specific technical areas, section 6.14.4 does identify three concrete areas: strengthening laboratory and surveillance capacity, conducting disease burden studies and improving access and effective deployment of pandemic vaccines and antiviral medicines.

The Framework specifies that the Advisory Group and the Director-General should interact with manufacturers and other stakeholders (See section 6.14.6). Such interaction took place on 23 February 2012 and views were provided to the Advisory Group and the Director-General, *inter alia*:



- PC resources should be directed more to pandemic preparedness than to response.
- A key focus of preparedness should be building influenza surveillance and laboratory capacity in developing countries, including improving the coverage of NICs and WHO Collaborating Centres, with a view to optimal strategic geographical balance among regions, transfer of technology, training of staff, and long-term sustainability.
- The importance of national regulatory activities and the WHO prequalification process was underlined with the view of accelerating access to drugs and vaccines.
- The Secretariat should begin Standard Material Transfer Agreement 2 (SMTA 2) negotiations as soon as possible.
- Implementation of the Framework should be as transparent as possible.
- There was general agreement that such interactions should continue on an annual basis.

5. The Advisory Group recommends starting with activities in support of these three technical areas as well as in one additional area that will strengthen effective pandemic response: risk communications. This approach takes into account the following considerations. First, implementation of the Framework is still in its very early stages. It is, therefore, prudent to focus on a limited and feasible range of activities to start. Lessons learnt from these early activities will facilitate the design and implementation of later activities with improved efficiency. Second, information was developed for three of these technical areas under resolution WHA63.1 to assist the Open Ended Working Group to reach final agreement on the PIP Framework.¹³ This information can be used in formulating a plan for use of the PC. Third, the findings of WHO's

¹³ [A/PIP/OEWG/3/2](http://apps.who.int/gb/pip/pdf_files/OEWG3/A_PIP_OEWG_3_2-en.pdf). Technical studies under resolution WHA63.1. Available at: http://apps.who.int/gb/pip/pdf_files/OEWG3/A_PIP_OEWG_3_2-en.pdf.

Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009 lend support for this approach.¹⁴ Finally, Member States have conveyed to WHO their strong interest in all these areas.

6. 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 (Figure 2). For reasons of feasibility, flexibility and practicality, each of these proportions should be viewed as approximate targets, i.e. +/- 5% for each.

6.1 Strengthening surveillance and laboratory capacity

6.1.1. Background and context

Pandemic preparedness spans a broad spectrum of thematic areas that should be addressed in an integrated way so as to enable the best possible response. A public health surveillance approach that includes epidemiological, laboratory and clinical surveillance, and risk assessment would significantly strengthen preparedness measures.

Disease surveillance: The capacity for routine surveillance of influenza-related disease is generally low in low- and lower-middle income countries and smaller countries (i.e. countries with populations less than 1 million).¹⁵ In these countries, surveillance systems do not meet minimal WHO requirements or guidance recommendations.¹⁶ Similarly, capacity to quickly detect unusual events, such as outbreaks of influenza, through various channels, particularly health-care workers, animal health professionals, schools, employers and the media, is estimated to be low in 84% of Member States.¹⁷

Laboratory surveillance and virus sample shipping: Capacity to perform detailed virological analyses of influenza viruses (e.g. determine the subtype, genetic sequence, and antigenic and other viral properties) is low in over 100 countries, primarily in low- and lower-middle-income countries, and particularly in the WHO African and Eastern Mediterranean Regions.¹⁸ Shipping of virus samples from national to regional and global facilities (e.g. to WHO H5 Reference Laboratories and WHO Collaborating Centres) is needed when countries do not have capacity to do detailed analyses. Shipping capacity is low mostly in small-island countries of the WHO

¹⁴ Specifically, the Review Committee recommended that: i) implementation of plans to strengthen core national and local capacities called for in the IHR be accelerated; ii) measures to expand global influenza vaccine production capacity should be pursued; continued support for GAP was cited along with the need to reduce the burden of influenza disease through increased seasonal vaccine use; and iii) WHO establish advance agreements that facilitate approval and delivery of pandemic vaccine to low-resource countries. The Review Committee noted that Member States identified strengthening of risk communication at the local, national and regional level as an important need.

¹⁵ See Country classification lists (a companion paper developed for the Advisory Group) for definitions of country indicators.

¹⁶ See Technical studies, Section III. "Laboratory and surveillance capacity-building"

¹⁷ See Technical studies, Section III. "Laboratory and surveillance capacity-building; percentage extrapolated from two surveys of Member States.

¹⁸ See Technical Studies, Section III. "Laboratory and surveillance capacity-building"

Western Pacific Region (more generally in those countries that have populations of less than 1 million) and in the WHO Eastern Mediterranean Region.

6.1.2 Recommended approach to define potential recipient countries

The WHO GISRS laboratories work collectively to broaden knowledge about circulating influenza viruses and improve detection and risk assessment of viruses with pandemic potential at country and global levels. The critical work of GISRS underpins global pandemic preparedness and response.

It is recommended, therefore, that, in order to strengthen GISRS and thereby improve pandemic influenza preparedness and response, the principal criterion to select countries for receipt of PC resources should be their capacity to participate in GISRS.

For the 88 countries that do not currently have a NIC, PC resources can be used to strengthen influenza surveillance and laboratory capacities. PC resources can also support the development and/or enhancement of capacity to successfully ship virus samples from local laboratories to regional or global GISRS facilities through training of laboratory staff in proper packaging techniques and international shipping regulations, as well as the cost of shipping samples to a WHO Collaborating Centre. Improvement of capacities in these areas strengthens GISRS and improves pandemic preparedness, while not requiring that every country establish a NIC.

For countries that have a NIC or are working to establish a facility as a NIC, it is the responsibility of national governments to support the establishment and on-going maintenance of qualified laboratory facilities. However, PC resources can be used to facilitate some support, such as training and shipment of samples from low- and lower-middle income countries to WHO Collaborating Centres.

Selection of countries to receive funds to strengthen surveillance for influenza, will take into account several factors:¹⁹

- a country's commitment to develop respiratory disease or influenza surveillance including epidemiological, laboratory and clinical surveillance;
- a country's capacity to monitor outbreaks or trends of respiratory diseases including influenza;
- a country's capacity to detect and assess unusual events including shipment of samples when needed;
- gross national income (such as the World Bank gross national income [GNI] index),²⁰ e.g. high income countries will not be eligible;
- geographical balance;
- epidemiological considerations, such as laboratory confirmed cases of H5N1 or other influenza viruses with human pandemic potential.

¹⁹ The method by which factors will be applied in the selection of countries to receive PC funds will be developed by WHO and shared with the Advisory Group at its next meeting in October 2012.

²⁰ See paper entitled "Country classification lists" (developed for the Advisory Group in February 2012).

6.2 Disease burden studies

6.2.1. Background and context

Influenza disease burden studies provide national health authorities with the evidentiary base for national seasonal influenza vaccination policy and programme development. The 2006 GAP²¹ identified collecting disease burden data as a key element in its strategy to increase demand for seasonal vaccines and thereby sustainably increase global pandemic influenza production capacity. The GAP-II consultation in July 2011 reinforced that the lack of disease-burden and associated cost-effectiveness data remain barriers to evidence-based decision-making on the introduction of seasonal influenza vaccines. GAP has been the catalyst for a significant expansion in influenza vaccine manufacturing, with global annual production capacity increasing from less than 500 million doses per year in 2006 to close to 1 billion doses per year at the end of 2010.²² However, if these gains in global vaccine production are to be sustainable, further disease burden and cost-effectiveness data collection, with the aim to increase seasonal vaccine use, must continue. They remain a priority for the GAP programme.

Globally, disease burden data for influenza are limited, particularly for low- and lower-middle-income countries, where influenza vaccine is not widely used. A disease burden study will require, for a limited period of time, significant epidemiological and laboratory work. However, the findings could provide baseline data that could be applied to regions or sub-regions.

6.2.2 Recommended approach to define potential recipient countries

It is recommended that the principal criterion to select countries where disease burden studies should be conducted is the availability of data on influenza disease burden. Data obtained through completed or on-going studies will be mapped according to WHO transmission zones, i.e. geographical groups of countries, areas or territories with similar influenza transmission patterns.²³

Currently, burden of disease data are not available for a large number of developing countries. Selection of a subset of these countries will take into account several factors:²⁴

- a country's commitment to provide the necessary support needed to conduct a study;
- geographical balance, noting that certain regions of the world are particularly underrepresented and that it may be possible to extrapolate data from one country to others in the same transmission zone;
- gross national income (such as the World Bank GNI index),²⁵ e.g. high income countries will not be eligible;
- epidemiological considerations, such as laboratory confirmed cases of H5N1 or other influenza viruses with human pandemic potential.

²¹Global pandemic influenza action plan to increase vaccine supply. Available at: http://whqlibdoc.who.int/hq/2006/WHO_IVB_06.13_eng.pdf.

²² See http://www.who.int/influenza_vaccines_plan/objectives/objective2/en/index.html.

²³ See http://www.who.int/csr/disease/swineflu/Influenza_transmission_zones.pdf.

²⁴ The method by which factors will be applied in the selection of countries to receive PC funds will be developed by WHO and shared with the Advisory Group at its next meeting in October 2012.

²⁵ See Country classification lists (a companion paper developed for the Advisory Group) for definitions of country indicators.

6.3 Effective deployment of pandemic vaccines and antiviral medicines: Enhancing regulatory capacity

6.3.1. Background and context

During the influenza A (H1N1) 2009 pandemic, WHO secured donations of nearly 78 million doses of vaccine. The donations were targeted to developing countries that satisfied certain conditions, principally lack of access to pandemic vaccine. Delays were encountered in deploying vaccine to potential recipient countries due to several factors, notably, limited national regulatory capacity to authorize vaccines for use.^{26,27}

A review of the experience of pandemic H1N1 vaccine deployment underscored, *inter alia*, the challenges of complex regulatory requirements. Some of the key findings included:

- Available vaccine could not be delivered due to delays in national regulatory approval for importation and use of pandemic vaccine in some countries.
- The need for full registration (and in some cases clinical trials) by the national regulatory agencies in some countries hindered deliveries of vaccines.
- Allocation decisions were delayed due to some recipient countries' limited legal capacity to assess rapidly the acceptability of terms in legal donation agreements, such as exceptional liability and indemnification clauses.

The rapid and efficient deployment of pandemic vaccines and antiviral medicines requires functional regulatory authorities. Regulatory authorities are assessed as functional against specific criteria in the areas of: marketing and licensing capacity; post-marketing surveillance for adverse events following immunization; laboratory capacity; manufacturing plant inspections; and clinical trial authorization. Strengthening regulatory authority capacities requires, *inter alia*, targeted technical support and training for regulators as well as the development of WHO guidelines.

6.3.2. Recommended approach to define potential recipient countries

It is recommended that resources be allocated to two activities:

- the development of WHO guidelines on *Regulatory preparedness for seasonal and pandemic influenza vaccines in non-vaccine producing countries*; and
- targeted technical support and training for regulators.

It is further recommended that the selection of countries for targeted training for regulators take into account several factors:²⁸

- a country's commitment to achieving a functional regulatory authority;
- whether the country produces influenza vaccine or antiviral medicine;
- geographical balance, focusing on regions and sub-regions of the world where regulatory capacities are weakest;

²⁶ See also section on Risk communications.

²⁷ See Technical Studies, *Obstacles in access and effective deployment* in Section V. "Access, affordability and effective deployment."

²⁸ The method by which factors will be applied in the selection of countries to receive PC funds will be developed by WHO and shared with the Advisory Group at its next meeting in October 2012.

- gross national income (such as the World Bank GNI index),²⁹ e.g. high income countries will not be eligible;
- epidemiological considerations, such as laboratory confirmed cases of H5N1 or other influenza viruses with human pandemic potential.

6.4. Risk communications

6.4.1. Background and context

Country and regional reviews of the 2009 pandemic response identified strengthening of risk communications as one of the most critical needs.^{30,31} The pandemic highlighted the difficulty Ministries of Health experienced in communicating information about complex scientific principles, uncertainty, risk and transparency in decision-making.^{32,33} These challenges adversely impacted key response measures, most notably deployment and uptake of pandemic (H1N1) 2009 vaccine. A WHO survey of Member States that evaluated the WHO pandemic (H1N1) 2009 vaccine deployment initiative found that the lack of clarity about vaccination campaigns and concerns about the safety, efficacy and benefits of the vaccine, significantly hampered vaccine uptake in recipient countries.³⁴

Regional workshops that reviewed country experiences in pandemic vaccine activities reached similar conclusions.^{35,36} Pandemic communications planning in many instances had not anticipated the power of social media (e.g. Facebook, Twitter and other fora) to spread erroneous information and rumours. Rumours about the dangers of vaccination and the vaccine's safety profile led, in some instances, to low uptake of vaccine by risk groups such as health-care workers and pregnant women.³⁷ Effectively countering such rumours proved very difficult for many countries.

Strengthening risk communication capacity requires specific training to understand, plan for, and implement the principles of risk communications, and manage media and public risk perception.

²⁹ See Country classification lists (a companion paper developed for the Advisory Group) for definitions of country indicators.

³⁰ Main operational lessons learnt from the WHO Pandemic Influenza A(H1N1) Vaccine Deployment Initiative. Report of a WHO Meeting held in Geneva, Switzerland, 13–15 December 2010. ISBN 978 92 4 156434 2. Available at:

http://www.who.int/influenza_vaccines_plan/resources/h1n1_vaccine_deployment_initiative_moll.pdf.

³¹ Report of the Review Committee on the functioning of the International Health Regulations (2005) and on pandemic influenza A (H1N1) 2009. Available at:

http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_10-en.pdf. See Section I (Communications).

³² *Ibid.*

³³ Evaluation of the implementation of national H1N1 pandemic influenza vaccine deployment and vaccination plans. Publication in preparation.

³⁴ *Ibid.*

³⁵ WHO Regional Office for the Eastern Mediterranean. Report on the Regional workshop on reviewing country experiences in pandemic (H1N1) 2009 vaccine deployment and vaccination activities, Beirut, Lebanon 10–12 May 2011. Document WHO-EM/EPI/299/E/10.11/126.

³⁶ WHO Regional Office for the Western Pacific Workshop on lessons learnt from pandemic Influenza A (H1N1) 2009 vaccine deployment and vaccination and training on forecasting and procurement for all vaccines, Manila, Philippines 4 to 8 July 2011.

³⁷ Evaluation of the implementation of national H1N1 pandemic influenza vaccine deployment and vaccination plans. Publication in preparation.

Training programmes can be directed to dedicated media and communications staff, Ministry of Health officials and staff who interact directly with the public (e.g. staff who work on vaccine delivery or training on hand-washing). Risk communication training, including table-top exercises, during the inter-pandemic period will benefit from the lessons learnt during the H1N1 pandemic. In particular, communication training to effectively manage real and perceived vaccine-related adverse events should be a critical area of focus. Although use of PC resources is necessarily focused on pandemic influenza preparedness and response activities, improved risk communications skills at the local, national and regional level will have broad application to public health emergencies in general.

6.4.2 Recommended approach to define potential recipient countries

Given the global need for enhancing risk communications in the time of a pandemic, it is proposed as a first step to conduct regional and sub-regional workshops on risk communication strategies. Workshops should be structured in a way that draws on the experience of countries. Such training can help ensure that all countries have access and opportunity to strengthen their national risk communication strategies in the time of a pandemic.

Use of the PC: pandemic response

The Framework requires that manufacturers who request PIP biological materials sign a benefit sharing agreement, i.e. a SMTA 2.³⁸ As part of this contract, influenza vaccine and antiviral medicine manufacturers must select two of six pre-defined benefit sharing options.³⁹ Two of these options, (Options A2 and A4) will require WHO to have funds available at the time of a pandemic to purchase reserves of pandemic vaccines and/or antiviral medicines.

7. It is recommended that the approximately US \$8 million per year available through the PC for pandemic response be reserved to purchase vaccine and antiviral medicines at the time of a pandemic for countries without access.

Once SMTA 2 negotiations, particularly those with the larger manufacturers are completed, more information will be at hand regarding the quantities and associated costs of pandemic vaccine and antiviral medicines available to WHO.

Funds available for pandemic response would be expected to increase over time for three reasons: first, as global preparedness capacity increases, the need for funds to pay for capacity building activities should decline; second, with a conservative investment policy, the funds in the response reserve account should grow over time; finally, through the use of coordinated and timely solidarity campaigns, such as matching fund drives, the response fund could increase significantly.

³⁸ Annex 2 of the Framework contains a model agreement for SMTA 2 to be used by WHO in its negotiations with manufacturers.

³⁹ Two of the six options are for donations to WHO, i.e. a manufacturer agrees to donate at least 10% of its real time pandemic vaccine production (option A1), or donate an amount (to be specified at the time the contract is negotiated) of treatment courses of needed antiviral medicine (option A3). Two of the six options are agreements to reserve pandemic vaccine (option A2) or antiviral medicine (option A4) for purchase by WHO, at affordable prices, at the time of a pandemic. See Framework section 5.4.2 and Annex 2.

Implementation of activities and anticipated outcomes at 5 years

Implementation of PC activities will depend on a flexible and a coordinated approach between WHO headquarters, regional offices and country offices, and will require collaboration and agreement with host countries.

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 PC resources. Country offices, in particular, have knowledge of Member States with low level capacity in the areas identified above and where needs are greatest. Such knowledge is critical to facilitate effective and efficient use of PC resources. The Advisory Group notes that, in some instances, e.g. strengthening laboratory capacity, a regional or sub-regional approach may offer advantages. 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 PC resources over time. Accountability of PC funds is a critical responsibility of WHO. Tracking systems will be helpful to monitor the progress of individual PC activities and overall outcomes.

The Advisory Group anticipates that, in 5 years:

- Gaps in disease surveillance and laboratory capacity will be reduced in key regions, with a concomitant increase in the capacity of countries to conduct risk assessment. This will improve the ability of countries to respond during a pandemic.
- New evidence on the burden of influenza will be gained in geographical areas that currently lack such information.
- Regulatory capacity will be strengthened in countries and across regions.
- The capacity to effectively distribute vaccines and antivirals to and within countries during a pandemic will be increased
- Risk communication strategies and plans will be developed and capacities to implement them will be strengthened

The Advisory Group underscores that, while the PC resources represent a significant contribution, they fall short of what is realistically needed to prepare and respond to the next pandemic. It is hoped that the plans for use of the PC resources will provide leverage for WHO to encourage Member States and other stakeholders to contribute additional financial support and in-kind contributions as noted in the Framework.⁴⁰

Conclusion

The Advisory Group invites the Director-General to consider the advice and recommendations in this document in the process of deciding on the use of the PC resources.

⁴⁰ See Framework Section 6.14.3.1.