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REGIONAL COMMITTEE DOCUMENT

Reports of WHO global working/advisory groups:

Pandemic Influenza Preparedness (PIP)

Since 1957, influenza viruses have been shared by Member States through the WHO Global Influenza Surveillance and Response network (GISRS); but in 2007 issues were raised about how this might be linked to access to vaccines and other benefits.

To address these issues, the World Health Assembly resolution WHA60.28 recommended the Director-General to:

- develop a framework and mechanism for benefit sharing;
- establish an international stockpile of influenza A (H5N1) vaccine; and
- prepare guidance on vaccine distribution.

The resulting *Pandemic Influenza Preparedness Framework* (PIP Framework) is expected to enhance the capacity for surveillance, risk assessment and early warning.

The PIPFW also aims to prioritize financial and "in kind" benefits to developing (H5N1 affected) countries that lack capacity to produce/access influenza vaccines, diagnostics and pharmaceuticals according to public health risk and needs (i.e. there will be a structured approach to a proportional allocation of the benefit to Member States).

The financial component of the expected benefit (the Partnership Contribution) is expected to be US$ 28 million per year.

To date, negotiation has been commenced by the WHO Secretariat with only a single "third party" (GSK), although discussions with others may start soon.

In order to implement the PIP Framework at national level, Member States should continue to share influenza viruses with pandemic potential with a WHO reference laboratory of their choice.

Transfer of influenza viruses and products derived from them (also referred to as PIP Biological Materials) is governed by type 1 and type 2 Standard Material Transfer Agreements (SMTAs).

Type 1 SMTAs govern the transfer of viruses from National Influenza Centres to GISRS laboratories, so their adoption is a part of national implementation.

Type 2 SMTAs govern the transfer of viruses to third parties (typically manufacturers of vaccines and pharmaceuticals). Although Member States have no direct role in negotiation of these agreements, they may wish to be aware of how negotiations are proceeding, and how the ensuing benefits are expected to be allocated.

Member States may also consider advocating for a mechanism to allow their needs to be more directly articulated to the Advisory Group/Secretariat in order to inform decisions about the allocation of benefit, and the negotiation of "in kind" benefits/technology transfer.

The High-Level Preparatory (HLP) Meeting held in the Regional Office in New Delhi from 2 to 5 July 2012 reviewed the working paper and made the following recommendations:

Action by Member States

- To ensure that laboratories concerned continue to share influenza viruses in a timely manner, including those with pandemic potential.

Actions by WHO-SEARO

- To accelerate the process of negotiating "type 2" SMTAs.
- To advocate for flexibility in the proportional distribution of funds according to identified needs in order to ensure optimal use of resources from the Partnership Contribution.
- To strengthen national influenza centres and WHO collaborating centres.

The working paper and the HLP Meeting recommendations are submitted to the Sixty-fifth Session of the Regional Committee for its consideration.

Introduction

1. Since 1957, influenza viruses have been shared by Member States through the WHO Global Influenza Surveillance and Response network (GISRS). In 2007 issues were raised about how such virus-sharing might be linked to access to vaccines and other benefits. To resolve these issues, the World Health Assembly resolution WHA60.28 recommended the Director-General to:

- develop a framework and mechanism for benefit sharing;
- establish an international stockpile of influenza A (H5N1) vaccine; and
- prepare guidance on vaccine distribution.

2. The resulting document, the *Pandemic Influenza Preparedness Framework* (PIPFW) was adopted through the World Health Assembly resolution WHA64.5. It is expected that the PIP Benefit Sharing System will provide information and build capacity for pandemic surveillance, risk assessment and early warning purposes. The PIPFW will also ensure prioritization of financial and "in kind" benefits to developing (especially affected) countries, according to public health risk and needs, particularly where these countries lack the capacity to produce or access influenza vaccines, diagnostics and pharmaceuticals.

3. The financial component of the expected benefit (the Partnership Contribution) is expected to be US$ 28 million per year. It is proposed that 30% of this sum is used for pandemic response and 70% for preparedness. It is further proposed that the component for preparedness will be split for surveillance/lab capacity (70%), disease burden studies (10%), risk communication (10%) and support to vaccine deployment (10%). To date, negotiation has been commenced by the WHO Secretariat with only a single "third party" (GSK), although discussions with others may start soon. The recent SEA Regional consultation recommended that the negotiation process be speeded up.

Situation analysis

4. It is expected that the distribution of benefit will be based on levels of development, current capacity for pandemic influenza preparedness and response and the degree to which Member States are affected by avian influenza A/H5N1. With respect to the latter, it is noteworthy that the following Member States have reported human cases of avian influenza A/H5N1: Bangladesh (6); Indonesia (129); Myanmar (1); and Thailand (25). Several countries are also developing capacity to produce influenza vaccine and might therefore anticipate being the beneficiaries of technology transfer.

5. In order to provide information and transparency over the movement of viruses within GISRS and to third parties, WHO has developed an Influenza Virus Traceability Mechanism (IVTM) that is accessible through a public web site.

Policy implications

6. Implementing the PIP Framework – policy implications for Member States:

- Member States should continue to share influenza viruses with pandemic potential with a WHO reference laboratory of their choice. In doing so, Member States effectively give consent for the onward transfer and use of viruses to third party institutions, subject to Standard Material Transfer Agreements (type 1 and type 2 SMTAs).
- Type 1 SMTAs govern the transfer of viruses from national influenza centres to GISRS laboratories, so their adoption is a part of national implementation.
- Although Member States have no direct role in negotiation of type 2 SMTAs (and third parties are typically located in other regions), they may wish to be aware of how negotiations are proceeding, and how the ensuing benefits are expected to be allocated, including both the relative allocations to Member States and the allocation to different technical/policy areas.
- Member States may also consider advocating for a mechanism to allow their needs to be more directly articulated to the Advisory Group/Secretariat in order to inform decisions about the allocation of benefit, and the negotiation of "in kind" benefits/technology transfer.

Implementing the PIP Framework: the role of WHO and the Advisory Group

- The WHO Secretariat, as supported and directed by the Advisory Group is responsible for guiding the negotiation of type 2 SMTAs and for advising the Director-General on the use/proportional distribution of benefit (as described above).
- WHO-SEARO should be expected to regularly update Member States on Advisory Group recommendations and virus-sharing.

Conclusions and recommendations

Conclusions

7. A regional informal consultation on implementation of the PIP Framework was held from 5 to 6 March 2012 in the Regional Office. The nominated participants of this meeting supported the contents and approach of the PIP Framework. They also stated their belief that implementation of the framework would constitute a global, regional and national "public health good", and would be expected to promote equity in the sharing of influenza viruses and associated benefits. The proposed approach to prioritizing the distribution of benefit to countries according to levels of economic development, current capacity and burden of avian influenza (AI) was also supported. Although the actual benefit that will be forthcoming to the SEA Region Member States is not yet clear, it may be expected to provide an opportunity to strengthen national capacities in the defined technical areas.

Recommendations for Member States

- Advocacy with policy/decision-makers on the contents of the PIP Framework may be needed to harmonize the requirements of the framework with national arrangements and national regulatory frameworks.
- Laboratories concerned should continue to share influenza viruses in a timely manner, including those with pandemic potential.
- Consideration should be given by Member States to harmonizing any plans to strengthen the capacity for influenza pandemic preparedness and response in relation to the PIP Framework with plans to implement IHR core capacities.
- Consideration should be given by Member States to undertake formal or informal national consultations to consolidate and refine PIP Framework implementation priorities (which may then be presented through SEARO to the WHO Secretariat and Advisory Group).

Recommendations for WHO

- WHO, including the regional offices should work with national laboratories and other concerned parties to provide sensitization and orientation on the process and use of the IVTM.
- The process for negotiation of SMTA type 2 should be accelerated.
- Consideration should be given to convening a Regional meeting with manufacturers of vaccines and antiviral drugs.
- Adequate consideration should be given to the issue of liability of all concerned parties with regard to SMTA type 2.
- In order to reflect national/regional priorities, consideration should be given to clarifying and possibly reviewing the process for prioritization of benefits for different technical areas through the partnership contribution to allow input from Member States.
- Consideration should be given to developing a mechanism to allow Member States to provide input into the areas of potential benefit to be negotiated through SMTA type 2 arrangements for non-financial contributions, e.g. “in kind” benefits/technology transfer.
- Consideration should be given in advance to the mechanism for distribution of funds from the partnership contribution and for monitoring the implementation of associated activities.