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REGIONAL COMMITTEE DOCUMENT

Reports of WHO global working/advisory groups:

Pandemic Influenza Preparedness Framework

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, 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
- prepare guidance on vaccine distribution.

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

The PIP Framework 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 the 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. Approximately US$ 18 million of the Partnership Contribution was received by WHO in 2012.

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 for influenza 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.

To date, negotiation of type 2 SMTAs has been concluded by the WHO Secretariat with only two "third parties" (GSK and the University of Florida), although discussions are underway with an additional five entities.

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 1 to 3 July 2013 reviewed the attached document and made the following recommendations:

Action by Member States

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

Actions by WHO-SEARO

(1) To further accelerate the process of negotiating type 2 SMTAs.

(2) To continue to update Member States on the implementation of the PIP Framework, including anticipated benefits.

(3) To ensure the timely involvement of Member States in the process of planning for the use of Partnership Contribution funds.

(4) To support the strengthening of national influenza centres and WHO collaborating centres.

The working paper and the HLP recommendations are submitted to the Sixty-sixth 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, 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
- prepare guidance on vaccine distribution.

2. The resulting document, the Pandemic Influenza Preparedness Framework (PIP Framework) was adopted through 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 PIP Framework 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 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 will be for pandemic response, in the form of a contingency fund, and 70% will be for preparedness. It is further proposed that the component for preparedness will be split for surveillance/laboratory capacity (70%), disease burden studies (10%), risk communication (10%) and support to vaccine deployment (10%). To date, negotiation has been concluded by the WHO Secretariat with only two "third parties" (GSK and the University of Florida), although discussions are underway with an additional five entities.

Situation analysis

4. It had previously been understood that the proportional distribution of benefit between Member States would 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) which is accessible through a public website.

Policy implications

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

- Member States should continue to share influenza viruses with pandemic potential to 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.

7. 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 Regional Office for South-East Asia should be expected to regularly update Member States on Advisory Group recommendations and virus-sharing.

Conclusions and recommendations

Conclusions

- The outbreak of influenza A/H7N9 is a reminder of the changing nature of influenza viruses and the need to maintain vigilance, strengthen surveillance and review pandemic preparedness in the South-East Asia Region.
  - Regional preparedness is enhanced by the ongoing willingness of Member States to share influenza viruses, including those with pandemic potential.
  - The capacity-building expected to result from the Partnership Contribution will be greatly appreciated. Member States would also appreciate being involved in the process of planning for use of these funds, would therefore also welcome a tentative indication of the amount of benefit that might be anticipated.
  - Efforts should be made to accelerate the negotiation of type 2 SMTAs.