

**Open-Ended Working Group (OEWG) Proposed Co-chairs'  
Non-paper on the Pandemic Influenza Preparedness**

**What this Paper is and is not**

This informal note has been prepared by the Ambassadors of Mexico and Norway. It is intended to reflect their thoughts and views on the remaining issues in the Framework. This is not a negotiating document; it is provided in the interest of transparency and with the aim of facilitating the work of the OEWG.

**Background**

Pandemics of influenza pose a significant and difficult to handle risk to all countries. Global consciousness of the threat of pandemic influenza increased with the emergence and spread of H5N1. Since then WHO Member States have been seeking ways to improve pandemic influenza preparedness. The system was tested with the 2009 H1N1 Pandemic. Initial appraisals of how the system functioned indicate that while viruses were shared in a rapid, systematic and timely manner by all States, benefits such as vaccines were not available in a similar manner.

**Statement of the Problem:**

The Co-chairs have identified a global insufficiency of influenza vaccine and antivirals and unfair access to these.

Three elements are associated with this problem:

- a. Access to vaccine: the issue is not only one of financial resources, but also availability of vaccine.
- b. Insufficient production of vaccine: the global manufacturing capacity today is limited to producing about 900 million doses.
- c. Price: vaccines are not affordable for many developing and least developed countries.

In addition, there is insufficient transparency, equity and effectiveness of the system for the sharing of viruses and benefits

**Key Challenges:**

In the Co-Chairs' opinion, the following areas need to be addressed to assure sharing of viruses and benefits on an equal footing:

1. Increase transparency, certainty and efficiency in the WHO Network for access to and transfer of viruses:
  - o Wild-type viruses
  - o Vaccine viruses (e.g. candidate vaccine viruses)
  - o Information derived from studies and analyses of viruses
2. Ensure transparency, certainty, efficiency, affordability and fairness in the sharing of benefits:
  - o Vaccines
  - o Antivirals
  - o Manufacturing capacity for influenza vaccines and adjuvants
    - Transfer of technology
    - Know-how
  - o Tiered-pricing for purchases of pandemic vaccine, antivirals, etc.
  - o Capacity-building (laboratories, regulatory)

3. Identify the role and impact of intellectual property rights with respect to increasing manufacturing capacity

**Possible avenues for addressing these challenges:**

The Co-Chairs believe that the following are possible avenues to successfully address the key challenges above.

1. Establish a Fund based on predictable sources of funding
  - o Possible uses of the Fund are:
    - Purchase of pandemic supplies (vaccine, antivirals – establish regional stockpiles) using tier-pricing and advanced purchase agreements
    - Finance other key benefits such as know-how and current and future patents, to enable increased vaccine production capacity
  - o Sources of funding for the Fund
    - Charge to be paid by certain recipients of PIP Vaccine viruses, Reference reagents, High-growth reassortant influenza viruses, Influenza reference viruses, WHO recommended influenza viruses for vaccine use
    - The charge will be applied to profit-making manufacturers
    - Voluntary financial contributions from countries
    - Voluntary financial contributions from other actors such as Foundations
    - Other contributions (i.e. in-kind)
  - o Governance and Management of the Fund
    - Establish a transparent governance structure under the auspices of WHO
    - Establish eligibility criteria for the use of the fund (e.g. GNI per capita, variability of pandemic concentration etc)
    - Identify relevant institution to manage the fund according to financial best practice.
2. Strengthen the Global Action Plan to increase supply of pandemic influenza vaccines (GAP) and increase global influenza vaccine production distributed in different regions of the world in 5 years through:
  - o Transfer of technology and know-how to developing countries including through sub-licensing when needed
  - o Provision of predictable and sustainable financial resources to the GAP
  - o Development of domestic and regional health policies to encourage use of seasonal influenza vaccine
  - o Encouraging research and development for new, innovative and more efficient vaccine production technologies
3. Establishment of new CCs with a view to improve regional distribution and based on national policies and priorities
4. Adopt Guiding Principles as a basis for developing an SMTA to be applied within the GISN system and for these institutions relationship with institutions and manufacturers outside the GISN. The Guiding Principles should include:
  - o Reference to the respective WHO Networks Terms of Reference and in particular responsibilities with respect to sharing viruses and information
  - o Compliance with the traceability mechanism

- Provisions regarding onward transfer to institutions outside the GISN
  - reference to payment according to charge structure
  - commitment to tiered pricing in pandemic times and/or in-kind contributions including to preparedness stockpiles of antiviral medicines
  - commitment to provide information about further transfer of materials received
  - reference to granting WHO a non-exclusive, royalty-free sub-licensable license for pandemic preparedness purposes under specific defined terms (e.g.. territory, further IP development, quality standards etc)
  - encouragement to further voluntary benefit sharing on an ad hoc basis

**Summary and Next Steps:**

The Framework continues to be the basis for improving the system. The possible approaches set out above are concepts for reflection and possible inclusion in the Framework to address the outstanding issues. Details in relation to the establishment, governance and management of the fund and the SMTA will need to be defined through a transparent process based on further studies outlining options.