



Pan American Health Organization

*Regional Office of the
World Health Organization*

<http://www.paho.org>

**Regulatory issues regarding the
license of influenza vaccine**

**Ma. de los Angeles Cortes Dr.Sc.
Regional Advisor on Vaccines and Biologicals
Essential Medicines, Vaccines and Health
Technologies Unit
Washington, DC, 21 November 2005**

Public Health International Organizations

recognize the need :

- To harmonize regulatory pathways for licensure of pandemic influenza vaccines
- To develop global standards to ensure the quality, safety and efficacy of influenza vaccines
- To resolve outstanding laboratory and safety issues
- To address safety issues associated with vaccine use



Harmonization of regulatory pathways

- International consistency in licensing requirements for a pandemic vaccine
- Required studies for marketing authorization
- Acceptance of a common licensure?



International measures

The World Health Organization focuses its efforts to:

- Support National Regulatory Authorities producing norms for ensuring quality, safety and efficacy of vaccines
- International norms governing biosafety requirements for vaccine production (For example, the WHO/CDS/CSR/GIP/2005.8.Doc. Responding to the avian influenza pandemic threat)
- To support the release of vaccine lots worldwide, supplying international reference reagents for the calibration of regional, national and manufacturing standards.



International measures

- **FDA regulatory perspectives:**

FDA would regard pandemic vaccine in the same way that yearly strains variations are treated, provided the pandemic vaccine was manufactured by a company with a licensed product on the US market, with specific consideration to new manufacturing technologies or different formulations (such as use of adjuvants).



International measures

- EMEA Regulatory perspectives:

As pandemic vaccines will differ in their formulation (antigen contents, adjuvants, number of doses), use of data extrapolated from clinical testing of seasonal vaccines is not considered acceptable by EMEA. Clinical trials with a “mock-up vaccine” are therefore required to demonstrate safety and immunogenicity and to establish dose and dosing schedule



International measures

A “mock-up” pandemic vaccine or “pandemic-like” vaccine:

- It is a vaccine that anticipates and mimics the characteristics of a pandemic virus and is designed to confer protection against it.
- It contains viral antigens which humans are immunologically naive
- It differs from antigens used in seasonal vaccines.

A dossier for this pandemic-like vaccine (antigen content, immunogenicity, safety and efficacy) is submitted for provisional regulatory approval prior to the start of a pandemic. When the pandemic occurs, a variation of the dossier with technical data specific to the pandemic virus, is then submitted for final marketing authorization



International measures

- Health Canada is planning an international consultation entitled "Pandemic Influenza vaccines: International Regulatory Preparedness" to be held next March, looking for the participation of key regulatory agencies including WHO, FDA, PAHO, etc., in order to harmonize regulatory pathways, agreement on quality control issues and to cooperation and coordination in regulatory preparedness planning to making available as rapidly as possible all the reagents needed by national control laboratories and manufacturers.



PAHO's proposals to NRA

In the event of pandemic influenza, regarding regulatory issues, PAHO recommend:

- Implementation of a "fast track procedure" for licensing of vaccines produced by manufacturers that already have licensed the seasonal influenza vaccine (as assurance of GMPs compliance) and review of clinical data on efficacy of the pandemic vaccine
- For countries who have not obtained the license for any influenza vaccine, the proposal is the acceptance of products licensed by other NRA
- To strength the established regional networks (PANDRH, RRLNCCV) in order to share information about the strategies for the vaccine's lot release and reagents used for their quality control



Conclusions

International organizations responsible for public health are aware of the need to optimize the knowledge and expertise in order to guarantee that the benefit of using a pandemic vaccine with opportunity overcomes the risk of offering unsafe or inefficient vaccines

