



Essential Medicines, Vaccines, and Health Technologies Unit  
*Technology and Health Services Delivery Area*

Immunization Unit  
*Family and Community Health Area*

Communicable Diseases Unit  
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# **PREPAREDNESS PLANNING FOR INFLUENZA PANDEMIC (VACCINE SUPPLIERS)**

**Strengthening public/private partnership  
for pandemic vaccine supply to the Americas**

## **FINAL REPORT**

**Washington, D.C., 21 November 2005**

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## PREPAREDNESS PLANNING FOR INFLUENZA PANDEMIC

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### Introduction

The session was opened by Dr. Carissa Etienne, Assistant Director of the Pan American Health Organization (PAHO), on behalf of PAHO Director Dr. Mirta Roses Periago. Dr. Etienne welcomed the participants and acknowledged that vaccine suppliers have been partners in the Region's success in reducing and eliminating vaccine-preventable diseases. She put the influenza pandemic into context and highlighted the challenge that this pandemic represents for all. PAHO recognizes that vaccines are the first line of response against an influenza pandemic, but also understands that a gap between the recognition of the pandemic and vaccine production and effective supply and distribution can be anticipated. The challenge is to reduce that gap. Dr. Etienne made a call for action and labeled it a moral responsibility. In the face of a potential public health disaster, she encouraged all stakeholders to coordinate efforts for ensuring vaccine availability and access to vaccine for everyone in the Americas.

Dr. Jon K. Andrus, Chief, Immunization Unit, and Dr. Jorge Bermudez, Chief, Essential Medicines, Vaccines, and Health Technologies Unit, stated the meeting objectives, the primary one being to strengthen public/private partnership for influenza pandemic vaccine supply for the Americas. Drs. Andrus and Bermudez served as co-chairs of the meeting.

### Regional Preparedness Plan for Influenza Pandemic

Dr. Otavio Oliva, PAHO's focal point for influenza pandemic, presented PAHO's strategic and operational plan. He gave an update on the global situation regarding avian influenza with the A/H5N1 and the human cases that have occurred in five Asian countries. He emphasized that the risk assessment provides a window of opportunity to strengthen national public health systems and capacity, to improve diagnosis, therapies, and vaccines, and to coordinate alert and response activities. The 56<sup>th</sup> World Health Assembly and the 44<sup>th</sup> PAHO Directing Council called for developing and implementing national pandemic preparedness plans. As of today, most countries in the Americas are working on these drafts. PAHO's pandemic task force has developed a Regional Operational Preparedness Plan. The objectives of this regional plan are to direct PAHO's technical cooperation efforts and support countries with their national plans, ensuring that they include effective activities.

### Global Perspectives

Dr. Alejandro Costa, from the Global Influenza Program at the World Health Organization (WHO), covered three main topics: increasing uptake of seasonal influenza vaccine, developing new and innovative influenza vaccines, and streamlining licensure and regulatory issues. As a way to promote increased production capacity for influenza vaccines, WHO is promoting the introduction and increased uptake of seasonal influenza vaccine in the world. Also, research and development (R&D) for new and improved seasonal and pandemic vaccines is key to increase the potential availability of both

vaccines. For rapid response to potential pandemic, it would be necessary to start vaccine production as early as possible, considering regulatory and licensing issues.

## **Uptake of Seasonal Influenza Vaccine in the Americas**

Dr. Andrus presented an update on the use of seasonal influenza vaccine in the Americas in the context of the regional policy framework for addressing the unfinished immunization agenda. Dr. Andrus highlighted that seasonal influenza vaccine remains the most underutilized vaccine in the Region. In 2004, PAHO's Technical Advisory Group (TAG) on Vaccine-preventable Diseases recommended annual vaccination for high-risk groups. PAHO also encourages countries to introduce this vaccine for children aged 6-23 months. As of 2005, 15 countries in Latin America and the Caribbean have included influenza vaccine for high-risk groups in their immunization schedules; five of these countries vaccinate children aged 6-23 months. The uptake of influenza vaccine has rapidly increased in the last few years, from only 5 countries purchasing vaccines through the PAHO Revolving Fund in 2003 to 19 countries placing orders for 2006. However, an important gap between demand and supply exists, with limited vaccine supply to meet this increased demand.

Additionally, the Vaccination Week in the Americas has proven a valuable opportunity to put vaccines like influenza on the political agenda and target high-risk groups, with three countries in the Southern Hemisphere using this initiative to mass vaccinate against influenza in 2006. PAHO's regional immunization program will continue to promote the introduction and use of seasonal influenza vaccine for groups at risk in all countries and will continue working with the industry to increase supply for seasonal influenza vaccine.

## **Regulatory Issues Regarding Influenza Vaccine Licensing**

In her presentation, Dr. Maria de los Angeles Cortes, PAHO's Regional Advisor on Vaccines Development, emphasized the importance of addressing regulatory issues in the pandemic preparedness plans. PAHO recommends that National Regulatory Authorities of countries that have a licensed vaccine for seasonal influenza implement a "fast-track" process for licensing the pandemic influenza vaccine. For countries without any licensed seasonal influenza vaccine, PAHO recommends acceptance of vaccines licensed by other National Regulatory Authorities (common licensing). In order to harmonize processes and reference material for licensing and lot release, PAHO is working to strengthen the established regional networks.

## **Proposal for Transfer of Technology**

Dr. Jorge Bermudez discussed the current opportunities to ensure proper access to vaccines and enhance regional production capacity. PAHO supports scaling up vaccine production and technology transfer to countries such as Argentina, Brazil, Cuba, and Mexico. PAHO's role in the technology transfer process should be to facilitate communications between developed and emerging country suppliers. Dr. Bermudez noted that technology transfer will take time and that some intellectual property issues need to be addressed.

## **Forecasting for Pandemic Vaccine Supply**

Mr. John Fitzsimmons, Immunization Unit, PAHO, provided an overview of the Revolving Fund as a model partnership between member countries and vaccine suppliers, along with both the challenges and opportunities posed by the increasing uptake of seasonal influenza vaccine in the Region. Meeting demand requirements is the immediate challenge, as less than 70% of the supply is projected to be available in 2005. The expanding market for seasonal influenza in the Americas presents an opportunity for suppliers to expand production, particularly with the Revolving Fund's emphasis on accurate forecasting. An improved supply situation in turn creates new opportunities for countries to optimize coverage levels during inter-pandemic periods.

Mr. Fitzsimmons emphasized the win-win relationships for countries and suppliers working together through the Revolving Fund. Initial estimates of vaccine requirements in the event of a pandemic are being developed by countries within the context of their preparedness plans. Many questions remain, beginning with the potential characteristics of the pandemic vaccine, production capacities, and, ultimately, availability. The Revolving Fund will continue to work with countries and suppliers to articulate arrangements in the event of a pandemic, such as bidding process, formula for allocation of limited vaccine supply to the Americas, and balancing supply with country requests.

## **Presentation by Suppliers**

The representatives of Fiocruz/Bio-Manguinhos (Brazil), Butantan Institute (Brazil), BIRMEX (Mexico), and Pergamino Institute (Argentina) presented on the current activities and future plans with regards to vaccine production, for both regular vaccines and pandemic influenza vaccine. Vaccine production capacity varies between these Institutes at this stage, but there are concrete plans to increase capacity for vaccine production. Butantan Institute is conducting work on adjuvants for influenza vaccine antigen sparing. Also, Butantan Institute should be in a position to produce 20 million doses of influenza vaccine for 2008. BIRMEX indicated that their capacity to produce seasonal vaccine should be available in 2009.

Production of influenza vaccines is divided between seasonal vaccine production, production of a "mock-up" vaccine, and, finally, production of a pandemic vaccine when its formulation becomes known. The timeframe for vaccine production was discussed. It was emphasized that plans to increase production capacity should be divided between short-, medium-, and long-term.

The representative of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), speaking on behalf of sixteen member companies that produce influenza vaccine, presented on the progress of the task force for influenza vaccine. This task force was created in 2002 with the aim to ensure adequate capacity to produce and distribute influenza vaccines, both seasonal (or inter-pandemic) and pandemic. Currently, 90% of influenza vaccine production is concentrated in Australia, Europe, North America, and Japan. IFPMA discussed the importance of increasing production capacity worldwide, including in countries outside the usual producers. The representative mentioned the current strategies for antigen sparing, such as decreasing

antigen content, use of adjuvants, intradermal route, and other novel R&D strategies. Also, the need to comply with WHO recommendation regarding the use of seasonal vaccines, including expanding the target age groups for influenza vaccination, was emphasized. Regarding the regulatory approaches, further harmonization in regulatory pathways needs to be achieved. Regulatory guidelines and processes for pandemic vaccine development and registration, as well as incentives to industry, were discussed. The industry recognizes the critical role of PAHO for increasing influenza vaccine supply.

## **Discussion and Main Conclusions**

The discussion focused on key issues and highlighted the need for collaboration and commitment between international bodies and national authorities and suppliers. One theme was the need to coordinate between WHO, its Regional Offices, and manufacturers regarding the availability of seasonal influenza vaccine in order to guide the countries on a realistic vaccine introduction timeframe. The Region of the Americas could serve as an example by taking advantage of the Revolving Fund platform.

Another theme was the pandemic influenza vaccine production in the short-/medium-term and in the long-term. For the short-term, a mock-up vaccine can be produced with the available technology and using smart composition. Production, Good Manufacturing Practices, and regulatory issues need to continue to be addressed. The R&D agenda should continue to prioritize influenza pandemic vaccine.

Alliances for pandemic vaccine production and distribution are critical to face the pandemic threat and to protect the population of the Americas in an equitable manner. This is not only a corporate responsibility, but a moral and ethical one.

Besides pandemic influenza vaccine, countries are working on their national preparedness plan for influenza vaccine. Worse case-scenarios, i.e., non-availability of pandemic vaccines, are being considered.

This meeting accomplished its goal of bringing together manufacturers and PAHO on the issue of a vaccine for an influenza pandemic. PAHO emphasized that the strategic use of the pandemic vaccine will be critical, taking into consideration sound principles of outbreak control and best public health practices.

Issues to be resolved in future meetings and activities are as follows:

- Seasonal vaccine shortage.
- Need to increase vaccine production capacity (scale-up).
- Enhancing the use of seasonal influenza vaccine.
- Antigen-sparing strategies.
- Novel influenza vaccines (R&D).
- Regulatory issues (liability issues).
- Progress in technology transfer to the Region: Argentina, Brazil, Cuba, and Mexico. Planning needs to be done in advance due to existing time limitations.
- Continue to promote dialogue and collaboration with industry by exchanging updated information, ensuring access to vaccines, maintaining a network of stakeholders, and building consensus on key strategies.

- Global effort – Local capacity.
- Questions to be answered:
  - Need to switch all vaccine production to pandemic vaccine vs. keeping production of other vaccines,
  - Distribution mechanisms,
  - Cold chain issues,
  - Mass vaccination campaigns,
  - Prices, and
  - Most efficient strategies to use pandemic vaccines (outbreak control).