Overview of Stakeholders’ Workshops on Vaccine Manufacturing Capacity Enhancement

Office of the Secretary
Office of Global Affairs
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HHS funding to the WHO addresses global and country-specific needs for pilot scale influenza vaccine production, with the goal of preparing countries for eventual commercial scale manufacturing of influenza vaccines.
Together with WHO and other relevant stakeholders, HHS is facilitating a series of international stakeholders’ workshops focusing on developing sustainable influenza vaccine production capacity worldwide.
The primary purpose of the workshop series is to generate ideas for a comprehensive framework and strategic plan declaring the present state, future vision, and steps necessary to reach the shared goal of creating regionally-based, independent, sustainable vaccine production capacity in developing and emerging-economy countries.
January 2010 Stakeholders’ Workshop
January 2010 Stakeholders’ Workshop

- Range of stakeholders including ministries of health and of foreign affairs, non-governmental and philanthropic organizations, academia, vaccine manufacturers, and developing and emerging-economy countries
January 2010 Stakeholders’ Workshop

• These workshops are intended to inform the review and refinement of the implementation plan for the WHO Global Pandemic Influenza Action Plan to Increase Vaccine Supply (GAP), as part of the formulation of a GAP-2.
January 2010 Stakeholders’ Workshop

Key Themes

1) Lack of demand for seasonal influenza vaccine
2) Lack of manufacturing surge capacity
3) Need for new partnership models
4) Emphasize old vs. new influenza vaccine technologies?
5) Need for technology transfer
January 2010 Stakeholders’ Workshop

Key Themes

6) Insufficient regulatory infrastructure
7) Gaps in quality control and adverse event reporting
8) Challenges of training and retaining skilled workforce
9) Gaps in public health surveillance infrastructure
10) Challenges of media communications and public education
Hyderabad, India International Workshop Objectives-Technical

- Survey a range of technologies used to develop and manufacture biopharmaceutical products that address public health threats
- Provide decision-makers with knowledge to determine what technologies are best suited to their needs
- Identify models of successful technology transfer for vaccine manufacturing
Hyderabad, India International Workshop Objectives-Strategic

• Identify drivers and obstacles to the building of sustainable vaccine production capacity

• Provide an opportunity to foster partnerships between nations, policy makers, and technology experts and innovators

• Outline policy options for leveraging resources for short, medium, and long-term
SAVE THE DATE

Workshop on International Regulatory Capacity Enhancement for Influenza Vaccines (WIRCEIV)

8-10 June 2011
Sao Paulo, Brazil

Co-Chaired by:
World Health Organization (WHO)
Developing Countries' Vaccine Regulators Network (DCVRN)
U.S. Department of Health and Human Services (HHS)

Hosted by:
The Brazilian National Health Surveillance Agency (ANVISA)

For additional workshop information, please visit:
http://www.globalhealth.gov/topics/vaccineWorkshops/index.html
Regulatory Workshop Topics

• THE ROLE OF WHO IN INFLUENZA VACCINE OVERSIGHT

• THE REGULATORY PATHWAY AND UNIQUE CHALLENGES FOR INFLUENZA VACCINES

• MODELS OF INTERACTIONS BETWEEN NRAS AND DECISION/POLICY MAKING GOVERNMENT BODIES IN INFLUENZA VACCINE PREPAREDNESS

• INVENTORY OF REGULATORY MODELS
Regulatory Workshop Topics

- Capacity Building Models to Address Needs and Gaps
- WHO Supported Regulatory Capacity Building in Vaccine Trials in Developing Countries
- Mentoring Partnerships Between Regulators
Regulatory Workshop Findings

- The capacity for vaccine regulatory oversight, available expertise and resources vary greatly amongst NRAs from developing countries.
- No regulatory model can fit-all and be directly imported into a recipient NRA because of differences in political, cultural, public health, scientific, legal and regulatory contexts.
Regulatory Workshop Considerations

• Technical partners should provide targeted support in methods and approaches to review, prequalification and post-market surveillance.

• Support needs to be based on countries’ thorough assessment of needs and priorities, and commitment to regulatory systems strengthening.
Regulatory Workshop Considerations

- Technical partners should strike a balance between providing expertise and strategies while respecting the autonomy of the recipient NRA.
Regulatory Challenges

• Lack of clear legislative framework,
• Dispersion of regulatory responsibility,
• Lack of resources,
• Lack of qualified staff,
• Lack of political support,
• Lack of understanding and/or appreciation for importance of regulatory capacity
Regulatory Considerations

• Various mechanisms or channels of communication between NRAs and MOH were identified as being effective, including the use of working groups, teleconferences, joint committees, and multi-organizational networks.

• In some cases, these mechanisms were established during the pandemic and have since weakened or dissolved post-pandemic.
Regulatory Considerations

- To coordinate and network NRAs and policy makers need to have proper agreements in place (MOUs, Letters of Exchanges) to provide for information flow between NRAs and policy makers and to assist in clarifying scopes, mandates and the general relationship governing information sharing.
Regulatory Considerations

• In regions where NRAs are less developed, regional approaches should be considered for networking, training, setting regulatory standards, and mutual recognition of approvals/registration
Future Workshops

- November 2011: Workshop on Enhancing International Vaccine Manufacturing Workforce Capacity – Capetown, South Africa
Future Workshops

• International Workshop on Enhancing Media Communications and Public Education for Influenza Vaccine/Vaccination – 2012

• International Workshop on Enhancing Business Planning and Partnership Development for Influenza Vaccine Manufacturers in Developing Countries?
Additional Information

• For additional information on the Stakeholders’ Workshop Series please visit: http://www.globalhealth.gov/topics/vaccineWorkshops/index.html