Session 7: National Regulatory Authority’s Role in product commercialization, licensing & innovation of influenza vaccines

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Key regulatory pre-requisites

• Legal basis and mandate to develop regulatory requirements
• Availability of domestic vaccine manufacturer(s) & and one or more approved seasonal influenza vaccine(s);
• Good Manufacturing Practices (GMP) inspection capacity preferably using the Pharmaceutical Inspection Cooperation Scheme (PIC/S)
• A clearly outlined regulatory pathways for the licensing of pandemic influenza vaccines
• Regulatory provision to request post-marketing surveillance studies if needed;
• A flexible approach to the receipt and review of information as part of pandemic influenza vaccine licensure;
Key regulatory pre-requisites

• Issuance of government contracts to manufacturers to produce investigational vaccines and conduct clinical trials preferably signed at a national level

• Review of information on a vaccine against novel human influenza virus as part of the licensure process

• Utilization of immunogenicity as a likely predictor of efficacy and seek postmarket confirmatory evaluation of effectiveness

• Wherever possible, full evaluation of the manufacturing, safety, quality and immunogenicity of pandemic vaccines before an influenza pandemic

• Identified emergency use options and provisions, including evaluating potential risks and benefits should a pandemic influenza vaccine be needed for use before the licensure process can be completed
Regulatory strengthening programmes in Africa

• Most African countries lack capacity to manufacture and evaluate quality, safety and efficacy of influenza vaccines
  – Legislation and regulatory frameworks; Infrastructure, HR & Financial resources

• Sept 2004 - Developing Country Vaccine Regulators’ Network (DCVRN) established by WHO
  – to contribute to the strengthening NRAs in developing countries where vaccines are manufactured, particularly in the area of authorization and evaluation of vaccine clinical trials

• 2006 - The African Vaccine Regulators Forum (AVAREF) involving 19 countries established by WHO
  – to address gaps in ethical and regulatory oversight of clinical trials in Africa
Regulatory strengthening programmes in Africa...

- 2009 African Medicines Regulatory Harmonization (AMRH) Initiative
  - Contribution to the Pharmaceutical Manufacturing Plan for Africa (PMPA)
  - Initial focus to increase access to quality, safe & efficacious medicines through harmonization of medicines registration as pathfinder to other regulatory functions & products
  - East African Community MRH Project launched in March 2012
  - Focus on efficient, effective & transparent regulatory approval processes: harmonised regulatory requirements, joint assessments and GMP inspections, regulatory capacity building
  - Platform for collaboration with AVAREF
Harmonization of regulatory pathway

**Key factors:**

- Agreement on core data requirements: quality, nonclinical, clinical, and post-marketing specifications
- WHO prequalification of vaccines against novel human influenza viruses, pandemic and seasonal influenza vaccines
- Information sharing between NRAs and vaccine manufacturers

**A harmonized regulatory process would facilitate:**

- the availability of pandemic influenza vaccine in a timely manner on a global scale;
- WHO prequalification of pandemic influenza vaccines; and
- the ability to distribute pandemic influenza vaccine between countries

**NB:** Individual governments have the responsibility for implementing their own national pandemic influenza preparedness plans.