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Regulatory Control of Diagnostics in Tanzania

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Outline of the Presentation

1. Tanzania Food and Drugs Authority
2. Regulatory framework for control of diagnostics in Tanzania
3. WHO Pilot Project in Tanzania
   - Strengthening regulatory capacity of diagnostics control
   - Post-marketing surveillance of diagnostics
4. Expected outcome of the WHO Pilot
5. Recommendations
Tanzania Food and Drugs Authority (TFDA)

• **Executive Agency** under the Ministry of Health and Social Welfare
  – Established under the Tanzania Food, Drugs and Cosmetics Act No.1, 2003
  – National Health Policy, 2007 & Act No.1, 2003 mandates TFDA
    • to regulate quality, safety and effectiveness/performance of food, medicines, cosmetics, medical devices and diagnostics

• **Mission** - protect and promote public health by ensuring quality, safety and effectiveness of food, drugs, cosmetics and medical devices (including diagnostics)

• **Vision** - become the best Regulatory Authority in regulating food, drugs, cosmetics and medical devices (including diagnostics) in Africa by 2015
Regulatory Framework of Diagnostics

• Section 5 of the Tanzania Food, Drugs and Cosmetics Act No.1, 2003
  – Mandates TFDA to regulate all matters relating to safety and performance of medical devices
    • importation, manufacture, labelling, marking and identification, storage, promotion, sell and distribution of medical devices in the country.

• Medical device – legal definition
  – An instrument, apparatus, implement, medical equipment, machine, contrivance, implant, \textit{in vitro reagent}, or other similar or related article, including any component, part or accessory.
Regulatory Framework (2)

• **A medical device ---**
  – intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease, in man or other animals;
  – ........

• *The on-going review of Act. No.1, 2003 intends to adapt the GHTF harmonized definition of medical devices*
Regulatory framework – Where are we today?

• 2008: Department of Medical Devices Assessment and Enforcement established

• 2009: Notification of all devices on the market
  – Over 3,500 devices notified to TFDA by 2010

• 2010: Registration started – Priority list of devices
  – TFDA adopted Classification Rules promulgated by GHTF
    • Classes A, B, C and D
    – 89 applications received and 11 registered by end of Feb, 2011
  – More applications expected in 2011
Where are we today?

• Finalized guidance documents (www.tfda.or.tz)
  – Guidelines on Submission of Documentation for Registration of Medical Devices
    • Diagnostics not covered
  – Guidelines for Application Permit to Deal with Business of Medical Devices
  – Guidelines for Good Distribution Practices of Medical Devices
**WHO Pilot Project on strengthening regulatory capacity of diagnostics and PMS**

- Tanzania is one of 5 countries implementing the WHO pilot project

- **AIM of the Project** – to address gaps identified by WHO assessment
  - November 2009 with regard to regulation of diagnostics in Tanzania.

- **Identified gaps**
  - Overlapping roles in regulation of diagnostics among various departments under the Ministry of Health and Social Welfare
    - Private Health Laboratories Board, TFDA
  - Lack of clear regulations and guidelines on control of diagnostics
  - Limited trained staff for regulatory oversight of diagnostics
  - Inadequate storage and transportation of diagnostics
  - Lack of batch release testing of diagnostics
  - Lack of PMS system for diagnostics

- **Framework Action Plans developed and approved**
WHO Project ...

• Objectives
  – Building and/or strengthening of national regulatory capacity and PMS of diagnostics
  – Strengthening procurement and supply chain management of priority diagnostics
  – Building and/or strengthening of National Health Laboratory Quality Assurance and Training Centre
    • to carry on testing of diagnostics batches

• First disbursement of funds received
  – Implementation of action plans starts April, 2011
WHO pilot project

• Action plan to address the gaps was developed by in-country stakeholders in collaboration with WHO

  – Ministry of Health and Social Welfare (MoHSW)
  – Medical Stores Department (MSD)
  – National Health Laboratory (NHL-QATC)
  – Public Health Laboratories Board (PHLB)
  – Tanzania Food and Drugs Authority (TFDA).
Major activities under the project

• Development of regulations, guidelines and procedures for regulation of diagnostics

• Recruitment and training of project staff

• Introduce procedures for batch testing of priority diagnostics e.g. HIV and malaria

• Develop national capacity to detect, investigate, communicate and contain adverse events linked to poor quality diagnostics
Expected outcome of the WHO pilot

- Established framework for regulation of diagnostics
  - Regulations, guidelines for registration and PMS
- Well trained staff on regulation and PMS
  - Established capacity to conduct post-marketing surveillance of diagnostics
- Ensure availability of quality diagnostics in Tanzania
  - Improved healthcare delivery at all levels
- Experience gained in Tanzania will be rolled over to other countries in the region
Key Recommendations

• Provide platform for exchange of regulatory information on diagnostics
  – e-databases and shared websites

• Involvement of regulatory authorities in WHO PQ
  – Hands on training on assessment of dossiers & inspection of manufacturers

• WHO to expand the scope of diagnostics being prequalified beyond HIV and Malaria

• Expand the pilot to involve other countries in the region
Thank you