Progress of EAC Medicines Registration Harmonization (MRH) Project

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Outline

• Background
• EAC Medicines Registration Harmonization Project
• Progress made
• Conclusion
Background

- EAC is a regional intergovernmental organisation of 5 Partner States
  - Burundi, Kenya, Rwanda, Uganda and the United Republic of Tanzania
  - 6 NMRAs including the Zanzibar Food and Drugs Board
- Population: 133.1 million (2010)
- GDP (current market prices): $79.2 billion (2010)
- EAC Headquarters: Arusha, Tanzania
EAC Regional Cooperation on Health

• **Chapter 21 (Article 118) of the EAC Treaty**
  – With respect to cooperation in Health, the Partner States undertake to;
    • Harmonize drug registration procedures so as to achieve good control of pharmaceutical Standards

• Develop common drug policy which would include establishing quality control capacities and good procurement practices
EAC MRH Project

• EAC is the first Regional Economic Community in Africa to launch the medicine regulatory harmonization project under the African Medicines Registration Harmonization Initiative (AMRHI).

• The East African Community MRH Project was launched on 30th March, 2012 in Arusha, Tanzania.

• The launch marked the beginning of implementation of the Project by the EAC Partner States NMRAs in coordination by the EAC Secretariat and in collaboration with the Partners – NEPAD Agency, WHO, the World Bank, others.
EAC MRH Project (2)

• **Purpose:** To harmonize medicines registration in the EAC Partner States in order to
  – increase the rapid availability of safe, efficacious and good quality essential medicines in the region
  – enable free movement of pharmaceuticals within the region to complement the implementation of the EAC Common Market Protocol which came into effect in July 2010

• **Goal:** To have a harmonized and functioning medicines registration system within the East Africa Community in accordance with national and internationally recognized policies and standards

[WHO & ICH]
Major Milestones of the EAC MRH project

1. An agreed **common technical document for registration** of medicines implemented in at least three EAC Partner States by end of 2014

2. A **common integrated IMS** established and linked in all EAC Partner States and EAC Secretariat by end of 2016

3. **Quality management system** implemented in each of the EAC Partner States' NMRAs

4. Regional and national **capacity built** to implement medicines registration harmonization in the EAC

5. Platform for **information sharing** on the harmonised medicines registration system to key stakeholders at national and regional level created

6. A framework for **mutual recognition** of regulatory decisions made by other EAC Partner States NMRAs developed and implemented
Progress Made

- **Project Steering Committee**
  - Established and composed of Chief Pharmacists (MoH), Heads of NMRAs, NMROs & Partners
  - Two meetings already held in May and November, 2012 respectively

- **4 Technical Working Groups (TWGs)**
  - Established and operational with *lead* Partner States’ NMRAs
    1. Medicines Evaluation and Registration *(Tanzania)*
    2. Good Manufacturing Practice (GMP) Inspection *(Uganda)*
    3. Quality Management System (QMS) *(Kenya)*
    4. Information Management System (IMS) *(Rwanda)*
Progress made (2)

• Recruitment of project staff
  – National Medicines Regulation Officer (NMRO) from each NMRA
    • process completed for 6 NMRAs pending approval by EAC Council of Ministers
  – Regional level – process ongoing for 4 posts
    • Senior Medicines Regulation Officer, e-Health and Informatics Officer, Accountant and Pharmaceutical Programme Assistant
  – Project staff will strengthen coordination at the EAC Secretariat
Progress made – TWG for Medicines Evaluation and Registration

• Responsible for development and implementation of an agreed common technical document (CTD) for registration of medicines
• Composed of 2 experts from each NMRA + WHO
• Meetings held
  • 5 video conferences - between June and November 2012
  • 2 face to face meetings - in July and October 2012
Progress made – TWG for Medicines Evaluation and Registration (2)

• Documents developed
  – Terms of References for the TWG – finalized
  – Annual work plan of activities – finalized
  – Harmonized application form for registration of human medicines and four guidelines;
    1. Structure and format of Common Technical Document (CTD)
    2. Summary of product characteristics
    3. Labeling
    4. Patient information leaflet
    5. Stability studies
Progress made – TWG for GMP

• Responsible for
  – development of harmonized guidelines and manual for Good Manufacturing Practice

• Composed of
  – 2 experts from each NMRA
  – WHO expert

• Meetings held
  • 4 video conferences - between June and October 2012
  • One face to face - in July-August 2012
Progress made – TWG for GMP Inspection (2)

• Documents developed
  – Terms of References for the TWG – finalized
  – Annual work plan of activities – finalized

– Drafts
  • EAC Guidelines on GMP
  • EAC Manual for GMP inspection
Progress made by TWG for QMS

• Responsible for
  – development and implementation of quality management system in each Partner States’ NMRAs
  – Composed of 2 experts from each NMRA + WHO

• Meetings held
  – 5 video conferences - between June and November 2012
  – One face to face - in August 2012
Progress made by TWG for QMS (2)

• Documents developed
  – Terms of References for the TWG - finalized
  – Annual work plan of activities - finalized

• Draft documents;
  • EAC QMS Requirements
  • EAC Guidelines for implementation of QMS Requirements for EAC NMRAs
  • EAC QMS Manual
Progress made – TWG for IMS

• Responsible for
  – development and implementation of common IMS for medicines registration in each of the NMRAs which is linked in all Partner States and EAC Secretariat
  – Composed of 2 experts from each NMRA + WHO

• Meetings held
  – 5 video conferences - between July and October 2012
  – One face to face - in August 2012
Progress made – TWG for IMS (2)

• Documents developed;
  – Terms of References for the TWG – finalized
  – Annual work plan of activities – finalized
  – Terms of reference for the Consultancy to assess existing IMS in the EAC Partner States NMRAs and EAC Secretariat-finalized
  – Draft guidelines for the development of common IMS for medicines regulation
Conclusion

• EAC MRH Project is a model for the African Medicines Regulatory Harmonization (AMRH) Initiative
  – sets an example for other regional economic communities in Africa

• Success requires commitment of
  – Partner States NMRAs, Programme and Development Partners
    • NEPAD Agency - advocacy & coordination at continental level
    • WHO – technical support
    • The World Bank - mobilization of additional resources
  – Continued participation of regional experts in WHO activities and ICH GCG Meetings & Regulators Forum
Thank you very much

Asanteni sana

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