EAST AFRICAN COMMUNITY
MEDICINES REGULATION
HARMONIZATION INITIATIVE

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Venue: Seville, Spain            Date: 8th November 2011
Scope of the Presentation

• Background
  – The Partner States and some key figures
  – EAC Treaty on Regional Cooperation on Health
  – Challenges on access to essential medicines

• African Medicines Regulation Harmonization Initiative

• EAC Medicines Regulation Harmonization Initiative
  – Objectives and critical milestones
  – Envisaged benefits
  – Implementation arrangements
  – Sustainability

• Conclusions
Background - 1

• EAC is a regional grouping of 5 countries
  – Burundi, Kenya, Rwanda, Tanzania and Uganda
    • 6 NMRAs (2 in Tanzania - TFDA and ZFDB)
  – Population of 133.5 million (June 2010)
  – GDP of $74.5 billion and Av. Per Capita $ 558 (2010)

• Communicable and non-communicable diseases are responsible for the high morbidity, mortality and disability in East Africa and globally

• Strong Political commitment by the EAC Council of Ministers by endorsing the EAC proposal for AMRH including proposed incremental staffing
Background (2)

- 4th EAC Council of Ministers of Health
  - Approved drafting of EAC Summary MRH Project Proposal in March 2009
  - Submitted to AU/NEPAD in May 2009
- 18th EAC Council of Ministers
  - Approved preparation of Expanded EAC MRH Project Proposal in September 2009
  - Submitted to AU/NEPAD + BMGF in October 2009
Chapter 21 (Article 118) of the EAC Treaty concerning health issues in the Partner States cover nine (9) priority health activities including harmonization of:

- Medicines policies, registration and regulation
- Medicines registration procedures and standards
- National health policies and regulations and promoting the exchange of information on health issues
Background – (4)

• Access to essential medicines for the treatment of Communicable and non-communicable diseases remains limited because of:
  – Limited public financing
  – Constraints in health service delivery
    • quality of diagnosis, accurate prescribing, selection, distribution, dispensing of medicines, medicines quality, health system capacity and lack of research and development
  – High prices
  – Disparate drug registration requirements
  – Reliance on importation
  – Varied capacity of the six (6) EAC NMRAs
The African Medicines Regulatory Harmonization (AMRH) Initiative

- AMRH launched by a consortium of partners in 2008 (BMGF, WHO, DFID, CHAI, NEPAD, PAP, AU)
- Initial BMGF-funding to NEPAD Agency for proposal development, advocacy
- The AMRH Consultation in February 2009 agreed to actively pursue medicines regulatory harmonization
- The World Bank was approached in April 2010 and asked to be the trust fund holder
- A trust fund has recently been established by the World Bank and EAC proposal is being considered for the first grant.
Also enlisting support from likely in-kind donors
Primarily technical assistance from regulators and manufacturer organizations

**Monetary contributions**
- Bill & Melinda Gates Foundation
- DFID
- gtz
- Norway
- Canada

**In-kind contributions**
- World Health Organization
- Clinton Health Access Initiative
- FDA
- Canada Health Canada
- NEPAD
- SAGMA
- WAPMA
- EMA
- Australia
- World Bank
- IFPMA
- ICH-GCG
- IFPMA
- IPA
- IFPMA
- UPMA
- IEA
- AFSSAPS
- MHRA
- The Global Fund
- USAID
- UNITAID
- Switzerland
- Sweden

In addition RECs and member countries will be contributing to harmonization plans
THE AMRH VISION

THE PRESENT

- Regulators' capacity highly variable, some with almost no capacity at all
- Varied requirements and formats
- Lack of clear guidelines, minimal transparency
- Inadequate collaboration and work sharing
- Reference evaluations\(^1\) underleveraged

THE FUTURE

Reduced hurdles for manufacturers
- Single set of requirements
- Clear guidelines established
- Fewer dossiers to prepare (one per REC)

Faster registration
- Stronger, more consistent capacity
- Streamlined processes and enhanced use of reference evaluations
- Resource pooling and information sharing

SAFER, EFFICACIOUS & QUALITY MEDICES AVAILABLE
EAC MRH Project

• 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]
EAC MRH Project Objectives (1 to 3)

- **Objective 1**: To implement an agreed common technical document for registration of medicines in EAC Partner States

- **Objective 2**: To implement a common information management system for medicines registration in each of the EAC Partner States’ NMRAs which are linked to all Partner States and to EAC Secretariat

- **Objective 3**: To implement a quality management system in each of the EAC Partner States’ NMRAs
EAC MRH Project Objectives (4 to 6)

- **Objective 4:** To build regional and national capacity to implement medicines registration harmonization in the EAC

- **Objective 5:** To create a platform for information sharing on the harmonized medicines registration system to key stakeholders at national and regional level

- **Objective 6:** To develop and implement a framework for mutual recognition based on Chapter 21, Article 118 of the East African Community Treaty
Critical Project Milestones

• An agreed common CTD implemented in all 6 NMRAs by end of year 5
• A common integrated IMS established and linked in all NMRAs and EAC Secretariat by end of year 4
• QMS implemented in each NMRAs by end of year 3
• Institutional, human and infrastructural capacity built by end of year 5 & capacity building programmes institutionalized into the existing structures
• Governments commitment, industry buy-in & commitment and public awareness created
• A framework for mutual recognition of regulatory decisions developed and implemented by end of year 5
Envisaged Benefits

• Launch an EAC Medicines Regulation **website** to make national and regional legislation and guidelines and national lists of registered products publicly and centrally available by December 2012

• Develop and implement a Common Technical Document (**CTD**) based on WHO/ICH format for application and registration of medicines in all EAC Partner States (requirements, procedures, guidelines) by December 2012
Envisaged Benefits (2)

• Fast track regional registration of medicines for priority diseases
  – Implementation of a joint regional factory inspections policy and a registration approval pathways policy (using risk-based approaches) by December 2012

• Establish systems for joint EAC evaluations and inspections
  – to build capacity and trust within and across Partner States NMRAs by December 2012
  – Integrate the established systems into both regional and national decision making processes to expedite the registration of essential medicines for priority diseases by December 2013
Envisaged Benefits (3)

• Contribute to the establishment of the East African Community Medicines and Food Safety Commission
  – Recruitment of EAC MRH National Focal Points, the EAC Senior Health Officer (Medicines Regulation) and EAC e-Health and Informatics Officer

• Contribute to sharing of best practices on MRH among RECs/NMRAs through facilitation by WHO & NEPAD
  – Increase availability & movement of medicines in RECs
EAC Sectoral Council of Ministers of Health

EAC Sectoral Committee on Health

Project Steering Committee

Technical Working Groups

EAC Project Coordination Team

NEPAD Agency

WHO

• Regional Annual Work Plans
• Consolidated Budget & procurement plan
• Interim Finance Reports
• Annual Audit

• Advocacy
• Coordination

• TA

• Guidelines for harmonization

• Nomination of experts
• Participation in consultations

• NMRA Annual Work Plans
• Annual Budgets
• Procurement Plans
• Quarterly performance Reports

NMRA 1  NMRA 2  NMRA 3  NMRA 4  NMRA 5  NMRA 6
Optimizing Existing Regional Capacity

- To optimize already existing capacities and mentoring to effective implementation of the project it was agreed to twin NMRAs as follows:

  - **Kenya** Pharmacy and Poisons Board (PPB) with **Zanzibar** Food and Drug Board (ZFDB);

  - **Tanzania** Food and Drugs Authority (TFDA) with **Burundi** Department of Pharmacy (DPML);

  - **Uganda** National Drug Authority (NDA) with **Rwanda** Pharmacy Task force
Technical Working Groups

- Four TWGs to be established by November 2011 with lead Partner State NMRA
  - Medicines Registration - Tanzania
  - Good Manufacturing Practices Inspection - Uganda
  - Information Management System - Rwanda
  - Quality Management - Kenya
EAC MRHI Collaboration with WHO

• WHO responsible for
  – providing technical assistance to EAC and NMRAs when required
  – facilitating preparation of technical documents and harmonized guidelines for medicines registration and GMP inspection based on internationally recognized norms and standards and supporting the implementation
  – facilitating capacity building of NMRAs through participation of EAC regulators in regional and international events
    • ICDRA, ICH-GCG, WHO PQ, etc
EAC MRH Collaboration with AU-NEPAD – (1)

- The African Union NEPAD Agency will support
  - engaging with African Regional Economic Communities (RECs) and other arms of African Union

- to enhance political commitment and enactment of relevant policies and regulatory frameworks
  - e.g: the AU Commission, Conference of Health Ministers & Pan African Parliament (PAP) & others
EAC MRH Collaboration with AU-NEPAD – (2)

• The AU - NEPAD Agency will engage with the governance bodies
  – ensure prompt troubleshooting for any institutional and implementation bottlenecks requiring higher level political intervention
    • both at country and regional levels

• NEPAD will facilitate coordination among partners and regional stakeholders and the private sector
Sustainability of the EAC MRH Initiative

• Recent establishment of the EAC Medicines & Food Safety Unit within EAC organization structure
• Recruitment of project staff in accordance with EAC and national recruitment requirements e.g. Scheme of service and salary structures
• Institutionalizing medicines regulatory training programmes in the existing national and regional structures
• Outreach strategy to obtain government commitment, industry buy-in and commitment both at national and regional levels
• Update national medicines policies to incorporate the changes that will occur as a result of the project
• Proposed establishment of the EAC Medicines and Food Safety Commission for long term coordination
Conclusion

- EAC is the first to implement AMRH Initiative
  - Implementation to start Nov/Dec 2011
  - Official launch Jan, 2012

- EAC a showcase - can set an example for other regional economic communities in Africa

- Participation in WHO activities (joint assessments and inspections),
  - ICH (Regulators Forum and GCG) will facilitate and expedite the process
Acknowledgement

• ICH Steering Committee
  – Accepting EAC RHI to join ICH-GCG

• WHO
  – Facilitating the process of joining ICH-GCG
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