



# **EAST AFRICAN COMMUNITY MEDICINES REGULATION HARMONIZATION INITIATIVE**

**Mr. Hiiti Sillo - Director General**  
Tanzania Food and Drugs Authority (TFDA)

and

**Mr. Gordon SEMATIKO – Executive Secretary/Registrar,**  
National Drug Authority (NDA) of Uganda

**Venue: Seville, Spain**

**Date: 8<sup>th</sup> 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)

- 4<sup>th</sup> EAC Council of Ministers of Health
  - Approved drafting of EAC Summary MRH Project Proposal in March 2009
  - Submitted to AU/NEPAD in May 2009
- 18<sup>th</sup> EAC Council of Ministers
  - Approved preparation of Expanded EAC MRH Project Proposal in September 2009
  - Submitted to AU/NEPAD + BMGF in October 2009

# Background (3)

- 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 NMRA's

# 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

Stakeholders likely to provide support

**Monetary contributions**

Logos for monetary contributors: Bill & Melinda Gates Foundation, DFID (Department for International Development), gtz (Partner for the Future Worldwide), France, Norway, and Canada.

**In-kind contributions**

Logos for in-kind contributors: World Health Organization, Clinton Health Access Initiative, NEPAD (The New Partnership for Africa's Development), FDA, Canada Health Canada, SAGMA, WAPMA, Australian Government Department of Health and Ageing Therapeutic Goods Administration, The World Bank, and emeA.

Other stakeholders interested in AMRH

Logos for other stakeholders: The Global Fund (Investing in our future To Fight AIDS, Tuberculosis and Malaria), USAID (FROM THE AMERICAN PEOPLE), UN AID, Switzerland, EU, and Sweden.

Logos for other stakeholders: IFPMA ICH-GCG, MHRA, IPMA, and afssaps (Agence française de sécurité sanitaire des produits de santé).

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<sup>1</sup> 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 NMRA's by end of year 5
- A common integrated IMS established and linked in all NMRA's and EAC Secretariat by end of year 4
- QMS implemented in each NMRA's 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

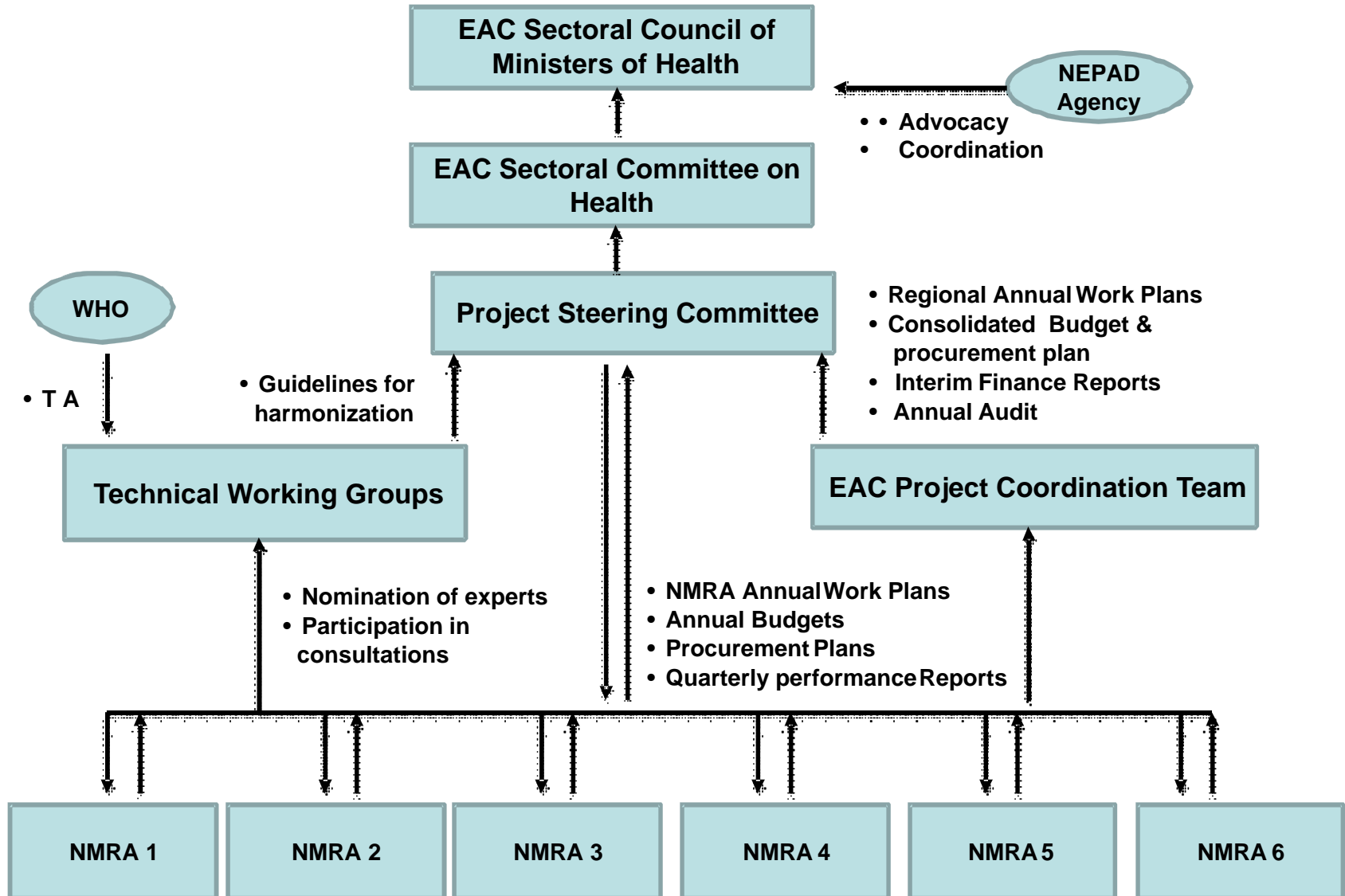
## Envisaged Benefits (2)

- 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 Implementation Arrangements



# Optimizing Existing Regional Capacity

- To optimize already existing capacities and mentoring to effective implementation of the project it was agreed to twin NMRAAs 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 NMRA's 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 NMRA's 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

*CONTACT ADDRESS - EAST AFRICAN COMMUNITY*

**Secretary General**  
East African Community  
EAC HQs, AICC Building  
Kilimanjaro Wing (5th Floor)  
P. O Box 1096, Arusha, Tanzania.

Tel: +255-27-2504253/8,  
Fax: +255-27-2504255/4481

Email: [eac@eachq.org/health@eachq.org](mailto:eac@eachq.org/health@eachq.org)