# Progress of the East African Community Medicines Registration Harmonization (EAC - MRH) Project

**Adonis Bitegeko**
**Manager–Medicines Inspection and Enforcement,**
**Tanzania Food and Drugs Authority**

# Outline

- Background

- EAC Regional Cooperation on Health

- EAC Medicines Registration Harmonization (EAC-MRH) Project

- Progress made and driving force for the success

- Lessons learnt

- Challenges

- Conclusion

# Background

- EAC is a regional intergovernmental organization of 5 Partner States
  - Republics of 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

# LOCATION MAP OF EAST AFRICA



Note:
1. This Map is not to scale. It should therefore not be used for any other purpose other than purposes of reflecting the general alignment of the East African Road Network Corridors.

2. The additional road links are in dotted lines in colours similar to the Corridors of their alignment.
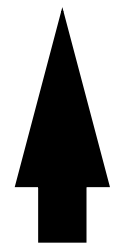
# EAC Regional Cooperation on Health

- ## Chapter 21 (Article 118) of the EAC Treaty
  - Provides for harmonization of drug registration and regulation
    - Harmonize medicines registration procedures

    - Harmonize national health policies and regulation and promote the exchange of information on health issues in order to achieve quality health within the Community.

# 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 and 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 medicines within the region to complement the implementation of the EAC Customs Union operational from 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
2. A common integrated IMS established and linked in all EAC Partner States and EAC Secretariat
3. Quality management system implemented in all Partner States' NMRAs and EAC Secretariat
4. Regional and national capacity built to implement medicines registration harmonization in the EAC
5. A platform for information sharing created
6. A framework for mutual recognition developed and implemented

# Progress Made

- **Project Steering Committee**
  - ◦ Established to oversee project activities
  - ◦ Composed of Chief Pharmacists (MoH), Heads of NMRAs, NMROs & Partners
  - ◦ 3 meetings held in Bujumbura, Burundi from 28-29 May, 2012 and 1-2, Nov, 2012 in Arusha, Tanzania and Bujumbura, Burundi 2-3 September, 2013.

- **4 Technical Working Groups (TWGs)**
  - ◦ Established and operational with lead Partner States' NMRAs
    1. Medicines Evaluation and Registration (MER) – 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 Officers  (NMRO) from each NMRA completed
○ Effective date 1ˢᵗ April 2013
○ Interviews completed for 4 posts at Regional level
  • Senior Medicines Regulation Officer, e-Health and Informatics Officer, Accountant and Pharmaceutical Programme Assistant
○ The above are working with Senior Health Officer (Medicines & Food).
○ Project staff  form Coordination Team at the EAC Secretariat

# Progress made – TWG on Medicines Evaluation and Registration (MER)

- Responsible for development and implementation of an agreed common technical document (CTD) for registration of medicines
- Composed of 2 experts from each NMRA + WHO Technical person

- Meetings held

- 15 video conferences – between July 2012 and May 2013

- 3 face to face meetings- in July, October 2012 and May 2013

# Progress made – TWG on MER (2)

- **Documents completed**
  - Terms of References for the TWG
  - Annual work plans of activities
  - EAC Guidelines on Submission of Application for registration of Medicines – Common Technical Document (CTD) with Annexes
    - Annex I – Covering letter.
    - Annex II – EAC application form for marketing authorization of medicinal product.
    - Annex III – Expert report
    - Annex IV – Letter of access for DMF/CEP
    - Annex V – Quality Overall Summary – Product dossier
    - Annex VI – Quality review requirements

# Progress made – TWG on MER (3)

- EAC guidelines on therapeutic equivalence requirements.

- EAC list of standard terms for pharmaceutical dosage forms and routes of administration.

- EAC guidelines on procedural aspects of application for registration of human medicinal products.

- EAC guidelines on stability requirements.

- EAC guidelines on Summary of Product Characteristics (SPC).

- EAC guidelines on Patient Information Leaflet (PIL).

- EAC guidelines on labeling requirements.

# Progress made – TWG on MER (4)

**Draft guidelines under discussion:–**

- EAC guidelines on biowaiver
- EAC common glossary of terms

**Under development**

- EAC guidelines on variation of a registered medicinal product
- EAC common assessment procedure
- Guidelines on fixed dose combinations

# Progress made – TWG on GMP Inspection

- Responsible for
  - development of harmonized legal framework and guidelines for Good Manufacturing Practice inspections
  - development, updating and review of harmonized procedure for planning, organizing, conducting and monitoring joint GMP inspections

- Composed of
  - 2 experts from each NMRA
  - WHO expert

# Progress made – TWG on GMP Inspection (2)

- Meetings held
  - 11 video conferences – between June 2012 and May 2013
  - One face to face – in August 2012
  - Second planned for June 2013

- Guidelines completed
  - GMP Guidelines with annexes
    - Annex: GMP for API
    - Annex: Qualification and validation
    - Annex: Quality Risk Management
  - Guideline for preparation of a Site Master File

# Progress made – TWG on GMP Inspection (3)

- SOPs completed
  - EAC Procedure : SOP for **planning** an inspection
  - EAC Procedure : SOP for **preparing** an inspection
  - EAC Procedure : SOP for **conducting** an inspection
  - EAC Procedure : SOP for writing and reviewing the GMP Inspection report and annex on classification of non-compliances
  - EAC Procedure : SOP for **follow-up** and enforcement of non-compliance
  - EAC Procedure : SOP for training and **qualification** of inspectors competencies
  - EAC Procedure : SOP for planning, organizing, conducting and monitoring **Joint GMP** Inspection
  - EAC Procedure : SOP on recall procedures

# Progress made – TWG on GMP Inspection (4)

- Templates completed
  - EAC Template: Inspection **Report** Format
  - EAC Template: GMP **Certificate** Format

- Underdevelopment
  - EAC Procedure : SOP for **sample** collection and handling
  - EAC Procedure : SOP for management of inspection **documentation** and records
  - EAC Procedure : SOP for management of regulatory information on inspections
  - EAC Procedure : SOP for **Information sharing** on regulatory inspection (findings, outcomes)
  - EAC Template: **Aide-Mémoire** / Check-list for GMP Inspection

# Progress made – TWG on Information Management System (IMS)

- Assessment on the existing information management system (IMS), and requirements analysis for design development and implementation of a harmonised system for the six EAC NMRAs and EAC Secretariat concluded in February 2013

- The assessment was conducted by experts from WHO and EAC Secretariat.

- Results and findings from the assessment were presented in the second face to face meeting in May 2013 for comments and way forward.

# Progress made – TWG on IMS (2)

- Nine video conferences - between July 2012 and June, 2013

- Two face to face – in August 2012 and May, 2013

- Process mapping for registration and GMP is under discussions

- Specification for video conference  equipments developed and reviewed for procurement.

# Progress made – TWG on IMS (3)

- Documents completed
  - Terms of References for the TWG
  - Annual work plan of activities
  - Terms of reference for the assessment of the existing IMS in the EAC Partner States NMRAs and EAC Secretariat

- Documents in draft
  - Guidelines for the development of common IMS for medicines regulation
  - Assessment report

# Progress made by TWG on QMS

- The aim is to implement agreed common QMS requirements for regulation of medicines & ISO certification

- Made up of 2 experts from each EAC NMRAs(12)

- WHO & World bank provides technical and administrative assistance

**Meetings held**

- 20 video conferences – from July, 2013 to June, 2013

- Two face to face meetings – in Sep & December 2012

# Progress made by TWG on QMS (2)

**Documents completed**

- The EAC QMS requirements for the regulation of medicines, cosmetics, medical devices & diagnostics
- Guidelines for the implementation of  QMS
- Manual on the implementation of EAC QMS
- Manual for development & control of EAC documents
- Road map for the implementation of QMS

# Progress made by TWG on QMS (3)

- Manual for development and control of EAC documents

- Road map for the implementation of QMS requirements

**SOPs finalized & adopted**;

- Procedure for control of documents

- Procedure for control of records

- Procedure for control non-conforming products

# Progress made by TWG on QMS (4)

**Work scheduled procedure for (drafts):**

- Planning &conducting audits

- Conducting management review meetings

- Handling complaints and appeals

- Corrective & preventive actions

- Confidentiality and conflict of interest

# Progress made by TWG on QMS (5)

**Work Scheduled:**

▸ Training on Lead Auditor course- Planned in July, 2013

▸ Face to face meeting – July, 2013

▸ Customize WHO Assessment Tool- 2013

▸ Coordinate Baseline survey to assess status of implementation of QMS- 2013

▸ Coordinate Development & Implementation of Peer Auditing System -2013

# Timelines for TWGs

- They are required to complete all pending documents by 31$^{st}$ January, 2014.

- The documents to be submitted to the EAC council of ministers for approval by 28$^{th}$ March, 2014.

- The documents to be piloted under joint dossier evaluation and GMP inspection.

# Driving force for the success

- NEPAD's roles in providing advocacy and political support

- Commitment and support provided by the Ministries responsible for EAC Affairs and Health

- Commitment and support of the EAC NMRAs and EAC Secretariat coordination team

- Commitment of the Project Steering Committee which advises the Ministers on various matters related to the project

# Driving force for the success (2)

- Commitment of TWGs and WHO experts in the development of harmonized documents

- Videoconference facility provided by the World Bank have helped TWGs to develop and finalize harmonized documents

- Involvement of EAC NMRAs experts in joint WHO/EAC assessment  sessions have helped to build capacity to the community's experts in developing a Common Technical Document

# Lessons learnt

▸ Harmonization of standards is sometimes hampered when Partner States are not on the same development paths. i.e. Varying capacities in terms of human resources (number and skills), infrastructure e.t.c.

▸ Difficulties have been observed in obtaining agreement on details of harmonization especially when it involves loss of income

# Lessons learnt

- Need to have EAC frameworks for medicine policy and medicine regulation.

- There are now emerging needs to expand to other regulatory functions which were not included in the initial proposal of the EAC-MRH project
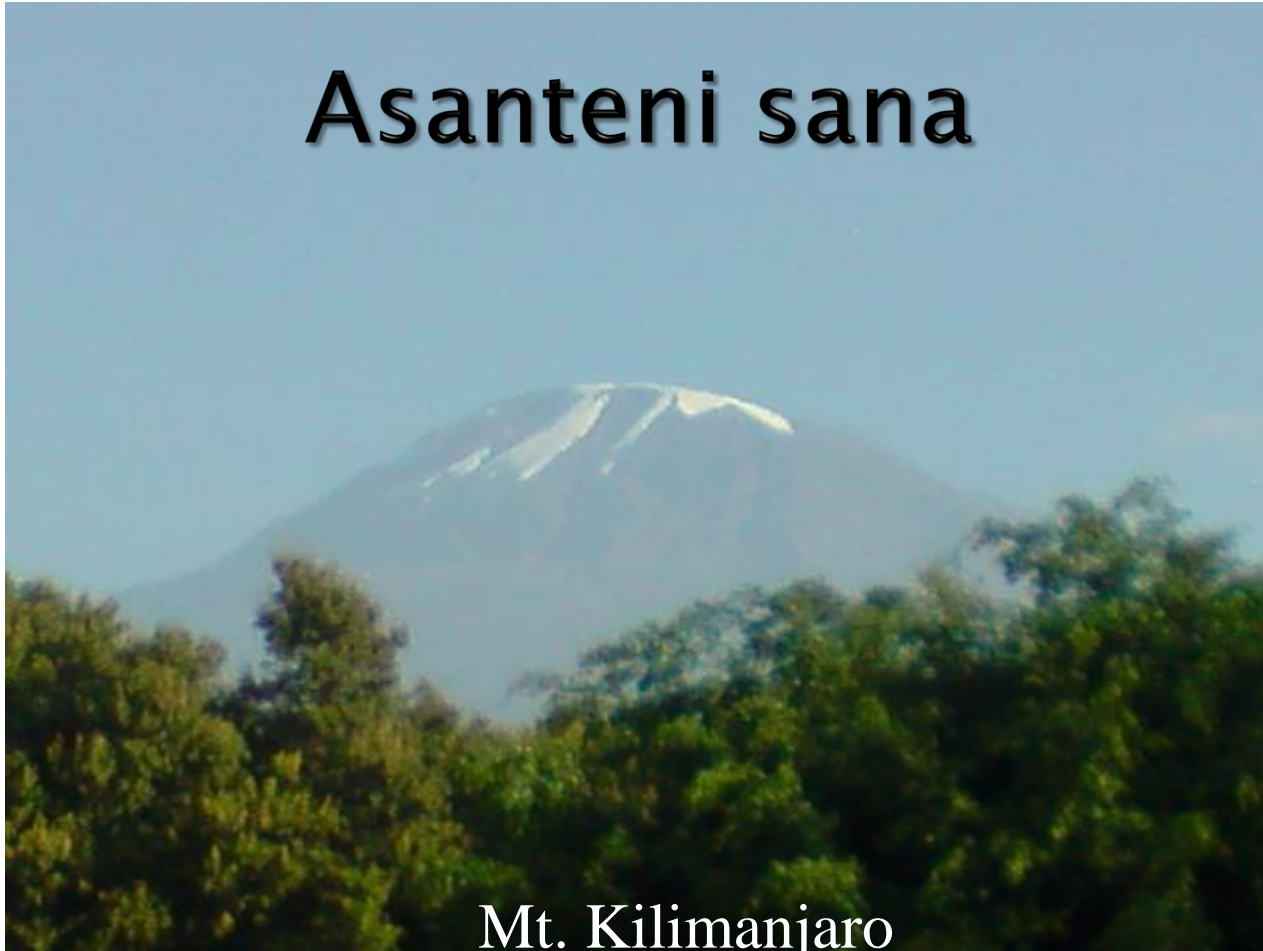
# Challenges

▸ Delays in disbursment of funds to implement project activities at national and regional levels

▸ Lack of technical expertise by NMRAs with limited number of staff

▸ Interoperability of the existing information management system (IMS) in the NMRAs with a new system to be procured.

▸ Choice of the IMS to be procured

▸ Cost of the system and maintanace fee

# Conclusion

- EAC MRH Project is a <u>showcase</u> for medicines registration harmonization
  - ◦ sets an <u>example</u> for other regional economic communities in Africa
- Success requires commitment of Partner States NMRAs and Partners
  - ◦ The roles of <u>NEPAD Agency (advocacy + political support)</u> and <u>WHO (technical)</u> are critical
  - ◦ Continued participation of EAC NMRAs experts in WHO activities and ICH GCG Meetings and Regulators Forum
- Regional collaboration and co-operation is the <u>ONLY way forward</u> for effective medicines regulation especially in Africa

# Thank you very much

Asanteni sana

Mt. Kilimanjaro