REGIONAL COOPERATION ON MEDICINES REGULATION:

THE EAC MEDICINES REGULATION HARMONIZATION (MRH) PROJECT

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To: the 1st meeting of medicines regulatory authorities of Sudan and neighboring countries

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Presentation outline

- Background
- Vision
- Milestones
- Implementation arrangements
- National level coordination
- Progress report

UGANDA

- Total area – 241,038sq km
- Total population is 36.34 million
- Official language is English
- Capital city –Kampala
- Independence day 9th October 1962

Background About NDA

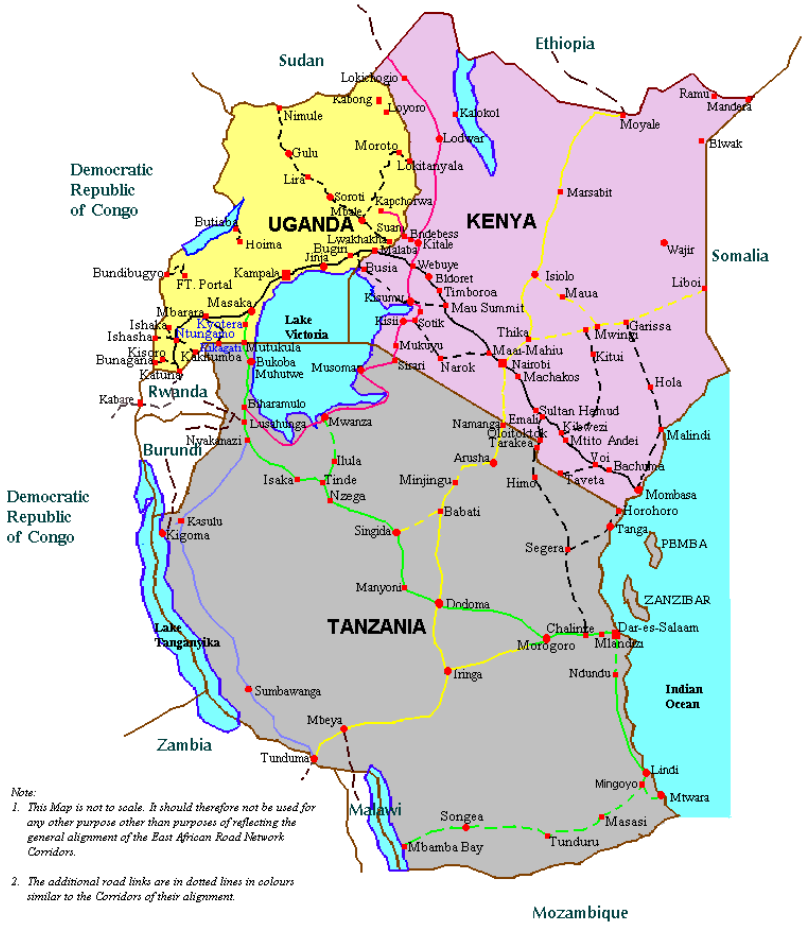
- National Drug Authority (NDA) was established by an Act of Parliament in 1993 currently the National Drug Policy and Authority (NDP/A) Act, Cap. 206 of the Laws of Uganda (2002 Revised edition)
- NDA is a body corporate with perpetual succession and a common seal and may sue or be sued in its corporate name.
- The mandate of NDA is to promote use of safe, efficacious and good quality medicines.

Background About NDA

- Reports to the Minister of Health
- Vision; “a world class drug regulatory agency effectively protecting and promoting public health.”
- Mission “ ;to ensure access to quality, safe and efficacious human and veterinary medicines and other healthcare products through the regulation and control of their production, importation, distribution and use.”

%98of working budget comes from fees collected for services and the rest from development partners

LOCATION MAP OF EAST AFRICA



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
  - Provides for harmonization of drug registration and regulation
    - Harmonize drug 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 .

PROJECT BACKGROUND

- The African Union's NEPAD Agency and development partners (BMGF, UK DFID, CHAI, GIZ) are supporting harmonization of medicines regulation in Africa through the eight regional economic blocks (EAC, ECOWAS, SADC, UEMOA, COMESA, IGAD, CEN-SAD and UMA)
- EAC medicines regulation harmonization project (5 years) was launched on 30th March 2012
  - USD2.4m (regional coordination and capacity building)
  - USD3.1m (institutional development and strengthening of NMRAs)
- Participating authorities: DPML (Burundi), NDA (Uganda), PPB (Kenya), PTF (Rwanda), TFDA (Tanzania Mainland) and ZFDB (Zanzibar)
- The purpose of harmonized medicines regulation is to ensure rapid availability of essential medicines and to promote free movement of medicines in the region

PROJECT VISION

THE PRESENT

- *Regulators capacity highly variable*
- *Different requirements and formats*
- *Lack of clear guidelines and transparency*
- *Reference evaluations underused*

THE FUTURE

Reduced hurdles for manufacturers

- *Single set of requirements*
- *Clear guidelines established*
- *Fewer dossiers to prepare (one per REC(*

Faster registration

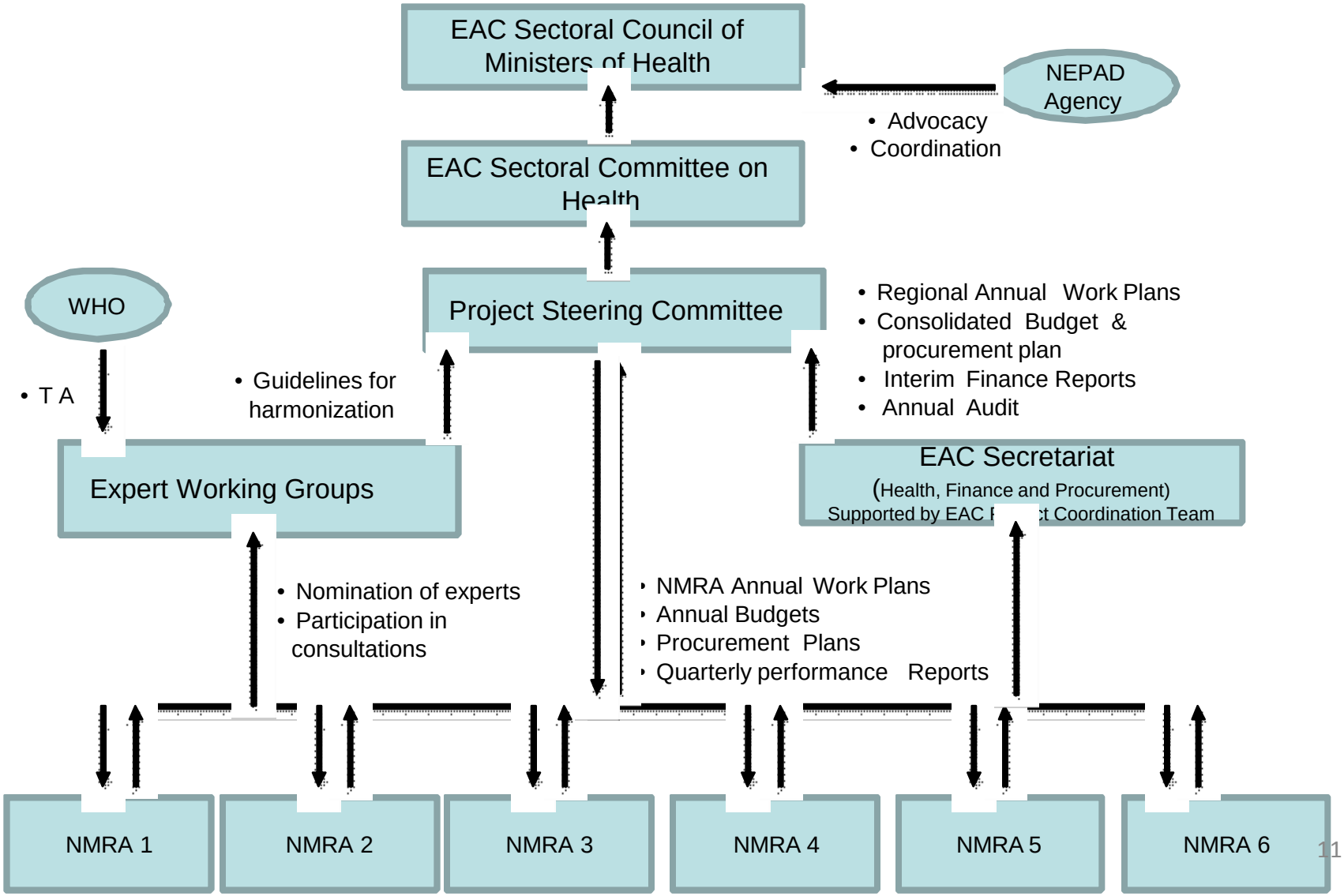
- *Improved capacity of all NMRAs*
- *Streamlined processes and enhanced use of reference evaluations*
- *Resource pooling and information sharing*

SAFER, EFFICACIOUS & QUALITY MEDICINES

PROJECT MILESTONES

1. An agreed common technical document for evaluation and registration of medicines domesticated in EAC Partner States by end of year three (3) of the programme
2. A common integrated IMS established and linked in all EAC Partner States and EAC Secretariat by the end of year four (4) of the programme
3. Quality management system implemented in regional and national capacity built to implement medicines:- Three (3) NMRA's ISO certified by the end of year three (3) of the programme
4. Two regional centres of excellence in training assessors and GMP inspectors established in the EAC region by the end of year five (5) of the programme
5. Rwanda and Burundi semi-autonomous NMRA's established by the end of year three (3) of the programme
6. EAC Regional Platform for Information Sharing on regulatory matters established by the end of year three (3) of the programme
7. EAC Legal Framework for mutual recognition of regulatory decisions developed by the end of year five (5) of the programme

Implementation Arrangements



National level coordination

- Executive Secretary NDA and Principal Pharmacist MOH are members of the Project Steering Committee
- EAC Secretariat has deployed a liaison officer, National Medicines Regulation Officer (NMRO), to each NMRA
- NMRO is hosted at the NMRA offices (ref. MOU(
- NMRO is responsible for liaising between EAC and NMRA/MOH on matters pertaining to MRH
- NMRO is responsible for supporting the development and implementation of a Common Technical Document (CTD) for registration, common GMP guidelines, common EAC regional Information Management System (IMS) and Quality Management System (QMS(

MRH PROGRESS

(1)The formation of **5 Expert Working Groups**)EWGs) on specialized areas:

- EWG on Policy, Legal and Regulatory Review
- EWG on Medicines Evaluation and Registration
- EWG on Good Manufacturing Practices
- EWG on Quality Management System

- EWG on Information Management System
- **Project Steering Committee**
  - Composed of Chief Pharmacists (MoH), Heads of NMRAs, NMROs & Development Partners

MRH PROGRESS

((2) **Standards developed**, adopted by EAC organs and by Partner States

- Compendium on Medicines Evaluation and Registration
- Compendium on Good Manufacturing Practices
- Compendium on Quality Management System

(3) **Capacity building** for regulatory work through:

- Trainings: MER (24px) GMP (25px), QMS (35px), project management (24px)
- **NMRA twinning**
  - Uganda / Rwanda;
  - Kenya / Zanzibar &
  - Tanzania (Mainland) / Burundi

MRH PROGRESS

(4)**Technical collaboration**:

- Pilot joint assessment of registration applications with **WHO** (**7 products jointly assessed and registered** (
- Joint inspection of pharmaceutical manufacturing sites with **WHO** (**10 facilities jointly inspected**(
- **10**assessors from EAC are members of the WHO Prequalification of Medicines Program – valuable regional expertise!
- Swiss Medic to support EAC through technical exchange visits

MRH PROGRESS

(5)**Collaboration with training institutions** (in Regulatory Affairs:(

- Kilimanjaro School of Pharmacy/Purdue University
- Makerere University

(6)**Infrastructure development**:

- Support in establishing NMRA office in Burundi
- Procurement of office equipment for all NMROs
- Procurement & installation of video conference facilities for all NMRAs

MRH PROGRESS

(7)**Additional funding** :

Commitment has been made by donors following completion of the first phase (BMG, DFID, GIZ(…

(8)**Phase 2Activities**: Procedures have been finalized for:

- Joint dossier assessment
- Joint inspections
- Abridged regulatory processes by collaborating with stringent regulatory authorities
- A for a for EAC heads of MRAs

MRH PROGRESS

(9)Initial progress of EAC MRH has attracted interest to support harmonization of regulation of medical diagnostics in EAC

- London School of Hygiene and Tropical Medicine/ Pan African Harmonization Working Party on Medical Diagnostics

CHALLENGES

- Slow process in **recruitment of project staff** [world Bank /EAC disparity in policy]
- **Disbursment of funds** for implementation of project activities at national and regional levels [world bank/EAC]
- Participation in the **many face to face TWGs meetings & Video conferences** by all NMRA's experts
- Fear of **loss of income** (fees for registration) and **National Sovereignity**
- **Language** to some experts (french or English?)

CONCLUSION

- EAC MRH Project is a showcase for medicines registration harmonization ; sets an example for other regional economic communities in Africa **[its advisable]**
- Success requires commitment of Partner States NMRAs and supporting Partners
- The roles of **NEPAD** Agency (advocacy + political support) and **WHO**)technical) are very critical
- Continued participation of EAC NMRAs experts in WHO PICs ICH GCG Meetings activities & Regulators Forum
- Regional collaboration and co-operation is the ONLY way forward for effective medicines regulation in Africa

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- WHO for tech assistance and guidance
- EAC heads of NMRAs & MoH
- EAC Secretariat staff & Ministry of EAC
- **National Drug Authority staff and NMRO Uganda**

THANK YOU!!!

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