HARMONIZATION OF DRUG REGULATION IN THE EAST AFRICAN COMMUNITY

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Presentation Outline

- Composition of the EAC
- Rationale for harmonization
- Background
- Harmonization initiatives
- Achievements in EAC harmonization
- Way forward
EAST AFRICAN COMMUNITY

- BURUNDI
- KENYA
- RWANDA
- TANZANIA
- UGANDA
Rationale for Harmonization

♦ Economic block established:
  ♦ Tariff agreement East African Community Customs Union (2 March 04)
  ♦ Similarities of current regulations
  ♦ Proximity of countries
  ♦ Culture
  ♦ Language – English, Swahili
  ♦ Smaller number of countries - easier to harmonise and implement
  ♦ **Possibility of accelerated Political Federation**
  ♦ Good industry - DRA relations
    ♦ Local Manufacturers/Importers Pharmaceutical Associations
Background

• The East African Treaty of 1999 provided for areas of cooperation and gave political impetus to the harmonization process

• Initially the EAC was comprised of Uganda, Kenya and Tanzania later on, in June 2006 Rwanda and Burundi joined the Community

• Following the Directive of the EAC Council of Ministers in 2000, the Health Committee established working Groups in which issues regarding medicines were placed under Research, Policy and Health Systems Working Group. This working group was tasked to draft common drug policy and harmonized drug registration procedures for the partner states.

• Meeting of Technical staff from NMRAs in EAC, Dar es salaam 2001: developed guidelines and application forms for registration of Veterinary Drugs

• Formation of EAC Customs Union in January 2005 established common external tariffs on medicines thus providing need for harmonization of medicines regulatory systems in the three countries

• African Drug Regulators Conference, Addis Ababa 2005: recommendation to promote harmonization using existing Regional blocks. EAC delegates agreed to hold meeting in December 2005 in Kampala
Aim of the harmonization process

Harmonization of medicines regulation in the EAC aims at achieving the following benefits:

a. Efficient regulatory systems for good control of medicines
b. Efficient use of available limited resources within EAC
c. Facilitate movement of pharmaceutical products within the community
d. Improved access to good quality and affordable medicines both for domestic use and for export
Harmonization Initiatives

• Partner States met in December 2005 in Kampala, Uganda to conduct a situational analysis on drug regulation in each of the states using the WHO assessment tool

• Areas of harmonization were identified and a plan of action was developed

• Areas of harmonization include
  – a. Medicines registration
  – b. Control of pharmaceutical manufacturing
  – c. Control of medicines importation and exportation
  – d. Inspection and licensing of pharmaceutical premises
  – e. Quality control
  – f. Control of medicines promotion and advertising
  – g. Control of clinical trials
  – h. Pharmacovigilance
Harmonization Initiatives II

• Partner states met in August 2006 in Nairobi, Kenya to establish technical working groups and their terms of references.

• The technical working groups agreed upon were:
  – Administrative aspects
  – Quality
  – Safety and Efficacy
  – GMP
  – Veterinary

• They also developed strategies to combat counterfeit drugs and substandard medicines in the EAC.
Achievements

• Participation of partner states in harmonization initiatives
• Development of a five year action plan ending 2010.
• Establishment of a website for shared point
• Development of Technical working groups and their terms of reference
• All DRAs have appointed focal persons for Medicine Regulation Harmonization
Achievements II

• Training in drug regulation for partner states
  – GMP Inspection
  – Assessment of Bioequivalence studies
  – Registration of ACTs

• Development of drug regulation curricula for incorporation in the Pharmacy degree course

• The East African Council of Ministers has already endorsed plan for harmonization – centralized DRAs.

• Road map for harmonization drawn and approved.

• Conditions exist for harmonization in the EAC

• Can be used as a building block for harmonization in the African Union
Support to EAC

- Financial support from WHO and EU
- Technical support from WHO
- Technical support from COMESA
- Proposed support from ECSA
Way forward

- **Harmonization of medicine regulation** will facilitate **pooled procurement** hence **should come first** in order to avoid serious compromises during pooled procurement.
- Harmonization guidelines and pooled procurement procedures should **promote growth of the local (EAC) pharmaceutical industries** in order to ensure sustainable access to Essential Medicines and to take advantage of the grace period up to 2016 before enforcement of patents become mandatory to the least developed countries.
- WHO drug regulation assessment for Uganda and Tanzania that had been previously carried out by the partner states.
- The appointment of the **Focal Person for Harmonization of Medicine Regulatory in the EAC** should be **prioritised to facilitate the process**, given the understaffing of all the NMRAs of the EAC Partners States.
- Operationalize the Technical working groups in the partner states
- Proposals for funding the activities of the EAC drug regulation harmonization process
ASANTE SANA!