The Status of Labelling Harmonization - EAC

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OUTLINE

- **Program Goal and Achievements**
- **Program Benefits: The benefits of harmonizing labelling across EAC Region**
- **Challenges that regulators face to arrive at a harmonized label**
- **Progress being made in EAC region with respect to harmonizing labelling**

Program Goal and Achievements

EAC Treaty
Chapter 21, Article 118

Harmonization of regulatory requirements, guidelines, standards and tools for medical products

- **ABREMA, Burundi**
- **PPB, Kenya**
- **Rwanda FDA, Rwanda**
- **DFCA, South Sudan**
- **NDA, Uganda**
- **TMDA & ZFDA, Tanzania**

- **EAC Common Technical Document (CTD)**
- **EAC harmonized compendium of Guidelines for Medicines Registration**
- **EAC GMP Standards and Guidelines**
- **Harmonized Guidelines for Vaccines, Biotherapeutics, Biosimilars, IVD's, Pharmacovigilance, Post-Marketing Surveillance , Clinical Trials & APIMF Procedure**

- **WHO & SwissMedic – Technical Assistance**
- **AU AUDA-NEPAD – Policy & Advocacy**
- **BMGF- Financial Resources & Partnership since 2012**
- **WB, SDC, DFID, USAID, GIZ, - Financial Resources**

Access to Safe, Efficacious & Quality Medicines by Patients

26 Joint GMP Inspections (Africa, Asia, Europe and USA)

All site compliant to EAC GMP Standards

187 Application for Joint Scientific Review

184 Applications Jointly Assessed
95 Medical Products Approved for MA
89 Applications under different level of review process

3 Semi-autonomous NMRAs established between 2017 – 2021

ZFDA, 2017
Rwanda FDA, 2018
ABREMA, Burundi, 2021

4 EAC NMRA are ISO 9000:2015 Certified

TMDA; ZFDA; PPB & NDA

Median Time for Joint Scientific Review

- Submission to end of assessment for all products: 53 to 221 working days
- Regulator's time: 44- 391 working days
- Manufacturers' time to answer queries: 5- 927 working days

Development of Integrated Information Management System and Programme Website – www.eac.int/mrh

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Program Benefits: Harmonizing labelling across EAC Region

Streamlined Regulatory Approach

One Submission ,
One Scientific Review &
One Recommendation applicable to all Partner States

Less Cost to Pharmaceutical Industry and Regulatory Authorities

Efficiency

Reduce Time and Duplication Efforts

High Level of Expertise and Competency of Assessors and Inspectors

Program Benefits: The benefits of harmonizing labelling across EAC Region

- Accelerated and expanded access to quality essential medicines
- Facilitate regulatory convergence and reliance
- Increase overall value of the regional harmonization
- Reduces costs to industry which in turn lead to increased cost effective medicines

Challenges that regulators face to arrive at a harmonized label

- **Located within different climatic zones (Storage statement on the label)**
- **Country specific requirements e.g. Reg. No. , the word “sterile”**
- Differences in legal frameworks
- Being a member of more than one Regional Economic Communities (RECS), e.g. Tanzania is within EAC and SADC

Progress being made in EAC region with respect to harmonizing labelling

- Harmonized Guidelines on format and content of the label, SmPC and PIL – Part of the EAC Compendium of Guidelines on Medicines Registration
- All NMRAs in EAC have domesticated EAC Harmonized Guidelines
- Agreement reached to have all EAC Member states domesticate the harmonized guidelines developed under EAC MRH

Thank you for your Attention!

Do you have any Questions?