The Status of Labelling Harmonization - EAC

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<u>OUTLINE</u>



- 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



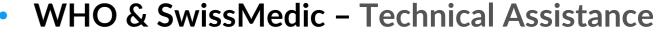
- ABREMA, Burundi
- PPB, Kenya
- Rwanda FDA, Rwanda
- **DFCA**, South Sudan
- NDA, Uganda
- TMDA & ZFDA, Tanzania







 Harmonized Guidelines for Vaccines, Biotherapeutics, Biosimilars, IVD's, Pharmacovigilance, Post-Marketing Surveillance, Clinical Trials & APIMF Procedure



- 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



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?

