VolkswagenStiftung

MARTIN-LUTHER-UNIVERSITÄT HALLE-WITTENBERG

MUHAS

UFZ

Workshop

Drug lifecycle control in Subsaharan Africa

From production to responsible safe disposal and elimination in wastewater treatment plants

(Med4Africa)

TMDA

Tanzania Medicines & Medical Devices Authority

African Medicines Regulatory Harmonization: Experience from Tanzania

Workshop

"Drug lifecycle control in Sub-saharan Africa: - From production to responsible safe disposal and elimination in wastewater treatment plants"

Adam Mitangu Fimbo
Director General

Background

- **AMRH** - programme of the African Union (**AU**)
- Implemented as part of the **Pharmaceutical Manufacturing Plan for Africa (PMPA)** under the theme **"Strengthening of Health Systems for Equity and Development in Africa"**

- The programme began in **2009** as a response to addressing challenges faced by **National Medicine Regulatory Authorities (NMRAs)** in Africa.

Background

- **Challenges included:**
  - Weak or non-coherent legislative frameworks
  - Redundant or duplicative processes
  - Inefficiency & limited technical capacity
  - Sluggish medicines registration processes incl. delays in decision making

Background

- **Programme collaborators:**
  - African Union Commission (**AUC**)
  - Pan-African Parliament (**PAP**)
  - World Health Organization (**WHO**)
  - Bill and Melinda Gates Foundation (**BMGF**)
  - World Bank (**WB**)
  - UK Department for International Development (**DFID**)
  - U.S. President's Emergency Plan for AIDS Relief **(PEPFAR)**
  - Global Alliance for Vaccines and Immunization (**GAVI**)

EAC – MRH Programme

- Involves all NMRAs of EAC Partner States
- **ABREMA** – Burundi
- **RFDA** – Rwanda
- **KPPB** - Kenya
- **TMDA** – Tanzania Mainland
- **ZFDA** – Tanzania - Zanzibar
- **NDA** – Uganda
- **DFCA** – South Sudan
- Now…(**ACOREP** – DRC)

EAC - MRH Programme Goal and Achievements

EAC Treaty

Chapter 21, Article 118

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

- EAC Common Technical Document (CTD)
- EAC GMP Standards and Guidelines
- Technical Cooperation Framework Agreement for EAC & NMRAs
- 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

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

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

All sites compliant to EAC GMP Standards

190Applications for Joint Scientific Review

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

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

3 Semi-autonomous NMRAs established between 2017 – 2021

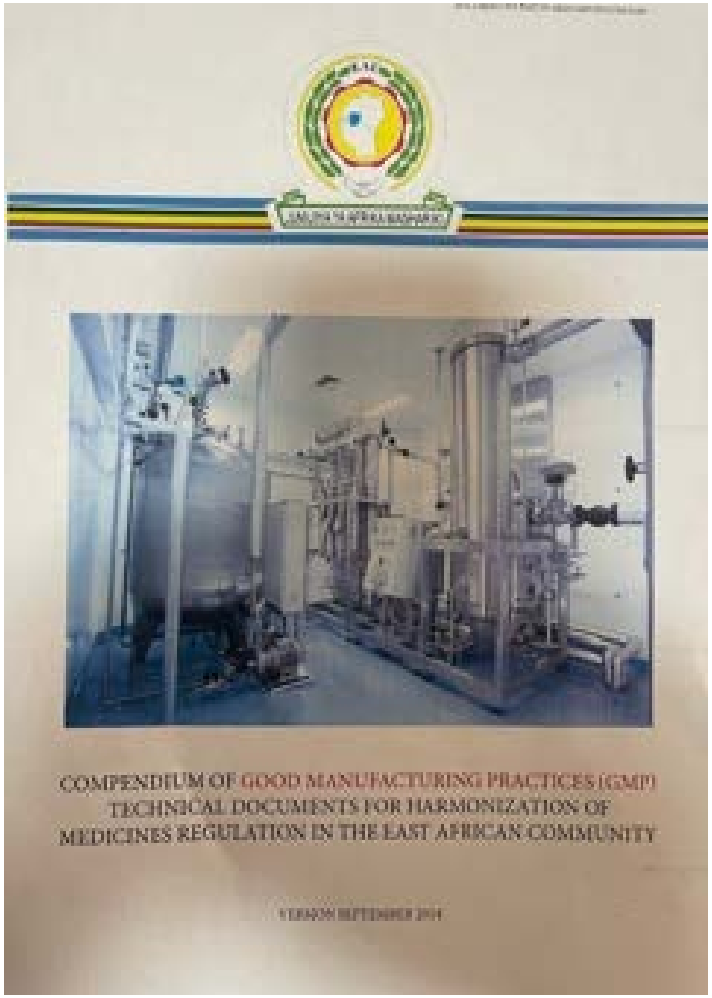
ZFDA, 2017
Rwanda FDA, 2018
ABREMA, Burundi, 2021

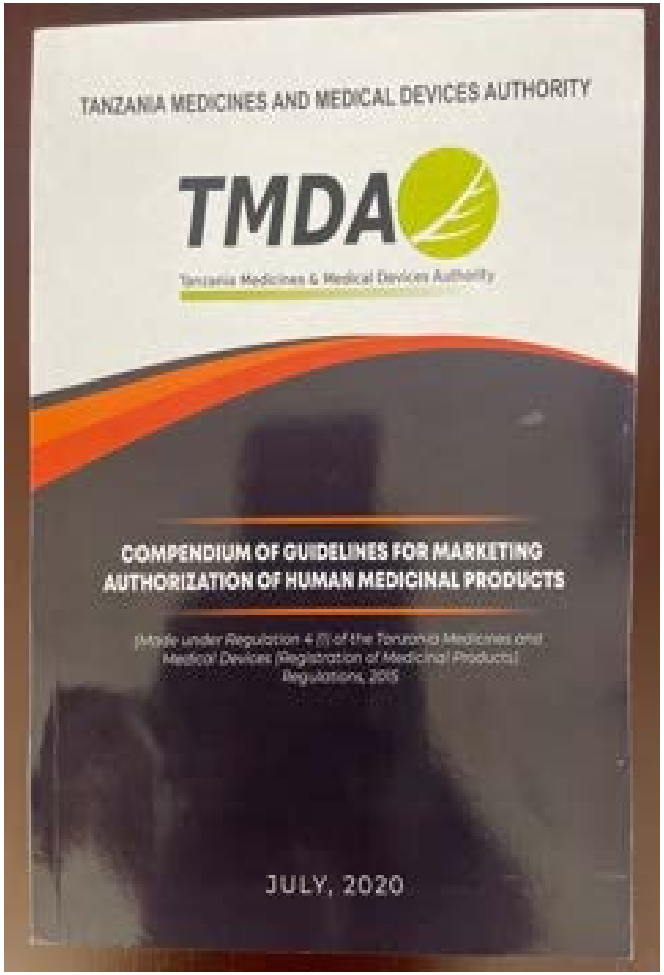
4 EAC NMRA are ISO 9000:2015 Certified

TMDA; ZFDA; PPB & NDA

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

Domesticated guidelines





Status of Marketing Authorization of Medicinal Products

NMRA	Number of Products Submitted by Applicant for MA	Number of Products Granted MA	Timelines for Granting Marketing Authorization (Working Days)
KPPB	39	39	30 - 90
ABREMA	3	1	60-180
Rwanda FDA	21	21	120 - 180
NDA	30	30	30 - 180
TMDA	95	95	30 - 90
ZFDA	2	2	30 - 90
DFCA	0	0	

Programme benefits

- Streamlined regulatory approach
- One submission, one scientific review & one recommendation applicable to all Partner States
- Efficiency
- Reduce time and duplication of efforts
- High level of expertise and competency of assessors and inspectors
- Products authorized for marketing in all EAC Partner States

EAC – Mutual Recognition Procedure (EAC – MRP) for veterinary medicinal products

Main objective:

- To harmonize immunological and pharmaceutical veterinary medicines registration systems within the region

EAC – MRP

- EAC- MRP was adopted by the EAC Council of Ministers on **28th November, 2014**

- TWG and the Coordination Group for Mutual Recognition (CGMR) were created to facilitate the procedure

- On **27th September 2019**, the procedure was officially inaugurated

EAC – MRP - Achievements

- Guidelines on Technical documentation for registration of vet products under EAC-MRP developed

- **18** applications (14 immunologicals & 4 pharmaceuticals) jointly assessed
- **7** products have been approved

- A total of **77** experts have been trained within the region

SADC – MRH Programme

15 NMRAs

- **MCAZ** – Zimbabwe (2013)
- **BOMRA** – Botswana (2013)
- **ZAMRA** – Zambia (2013)
- **NMRC** – Namibia (2013)
- **SAHPRA** – RSA (2016)
- **ACOREP** – DRC (2017)
- **ANARME** - Mozambique (2017)
- **TMDA** – Tanzania (2018)
- **PMRA** – Malawi (2018)
- Ministry of Health Eswatini
- **AGMED** – Madagascar
- Lesotho
- Comoros
- Seychelles

Joint Review

- To reduce timelines for registration of medicines
- To efficiently utilize available regional resources
- To ensure the availability of good quality medicines within the region

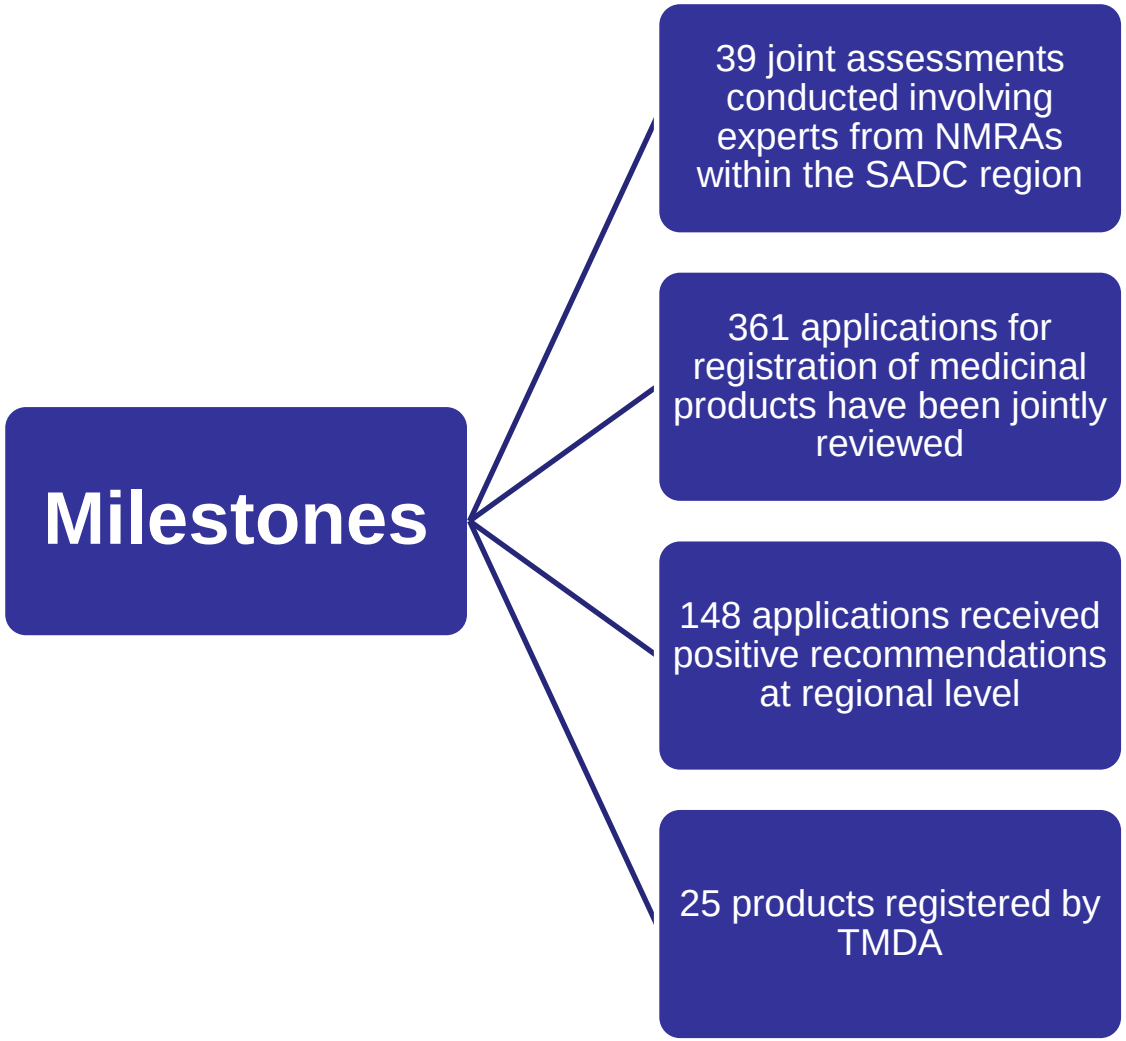
Eligible products

- Essential medicines for treatment of **10 priority diseases** (HIV, TB, Malaria, Acute Respiratory Infections, Diarrhoea, Diabetes, Cardiovascular, Cancer, Obstetrics , Gastroenteritis and Colic
- Reproductive Health Products (MNCH)
- Any other medicines for public health emergency

Eligibility → CTD format application submitted in at-least 2 **ZAZIBONA** participating countries

Timeline → **90 days**

SADC – MRH Programme



Conclusion

- Both programmes - instrumental in streamlining regulatory processes
- We now have a common understanding of regulatory requirements in the region
- Pool of experts has been created
- Information sharing is now quite effective
- Benefits Tanzania as we border 8 other countries – helps to curb entry of SF products