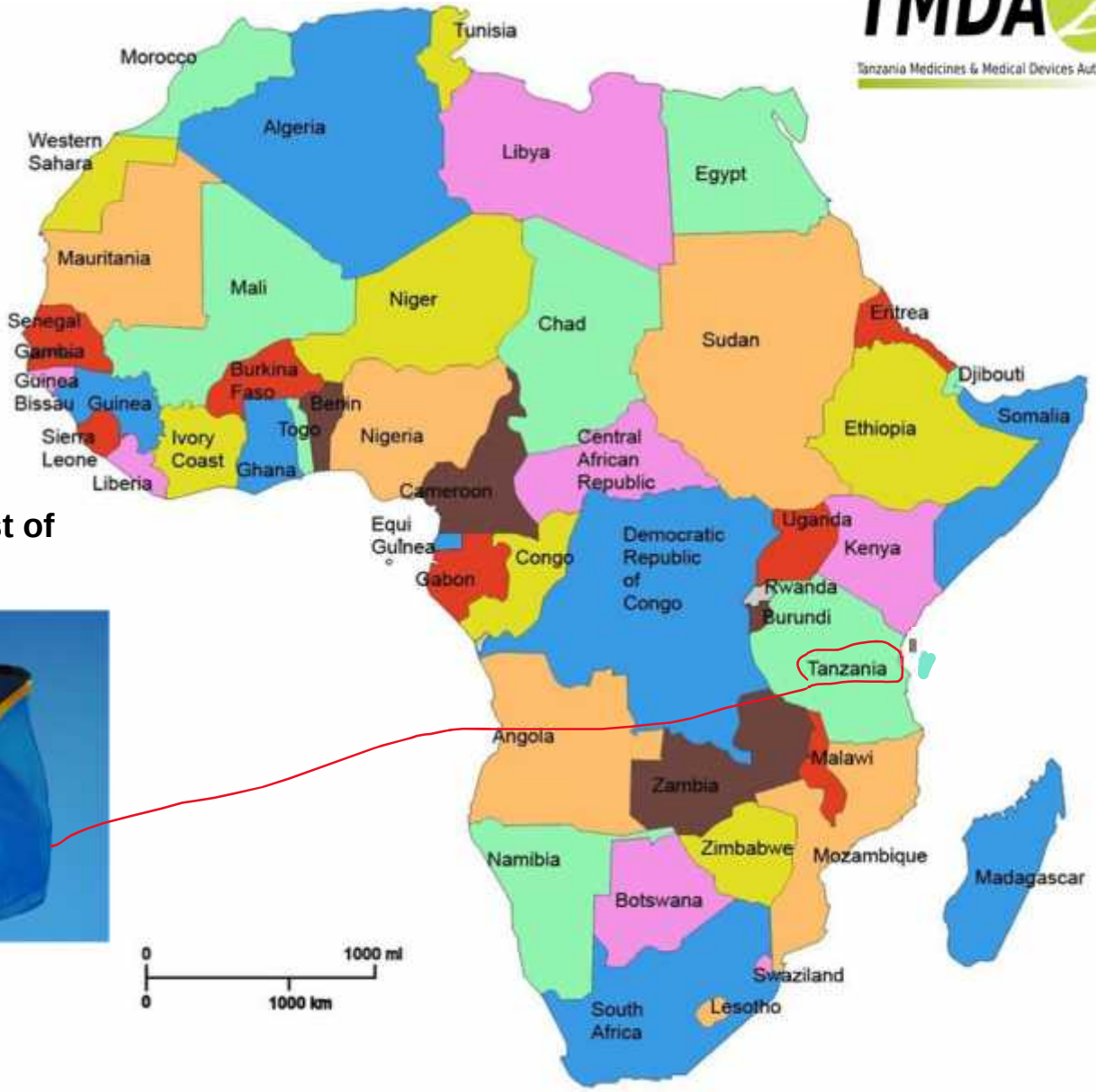
Migrating from routine to risk based Inspection: Optimizing Human resource Post Pandemic:

A case of Tanzania

Dr. Furaha Godfrey Nyunza
TMDA Senior Drug Inspector TMDA

Location of United Republic of Tanzania in Africa

Located on the East Coast of Indian Ocean



Presentation Outline

- TMDA Introduction
- Background
- Risk Based Inspection:
  - GMP Inspection
  - GSDP Inspection
- Achievements
- Challenges

TMDA Introduction

- Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health (MOH).

- Formerly known as Tanzania Food and Drugs Authority (TFDA) – July, 2003 under the Tanzania Food, Drugs and Cosmetics Act, Cap 219.

TMDA Introduction …..

- TFDA Act was amended in 2019 to TMDA Act, Cap 219 after shifting regulation of food and cosmetics to Tanzania Bureau of Standard (TBS).

- TMDA regulates quality, safety and effectiveness: *medicines, medical devices, diagnostics, biocidals and tobacco products.*

Routine GMP Inspection

- Routine GMP inspection is conducted as part of evaluation process for marketing authorization of medicinal products.

- It takes up to 12 months before inspecting a facility after receiving an application.

Routine GMP Inspection

- Longer time frame to conduct GMP inspection is due to:
  - Overwhelming number of application for sites to be inspected annually.
  - Scarce resources – funds and staff as compared to the need.
  - Presence of other competing priorities within the Authority.

Types of GMP inspections by TMDA

- On site GMP Inspections
- Desk Assessment Inspections

On site GMP Inspections

- Is a traditional method of inspecting facilities that intend to seek marketing authorization of their products in Tanzania.

- However in circumstances of emergency like COVID-19 pandemic is not feasible then Desk assessment could be the preferred alternative for establishing to applicable standards

Risk Based Inspection – Desk Assessment

Desk Assessment Inspection

- Desk assessment process involves submission of current, accurate and authentic documentary evidence by applicant/manufacturer to the Authority to demonstrate the conformity of all processes involved in manufacturing of pharmaceutical products.

Advantage of desk assessment

- To make optimal use of inspection resources by conducting off - site assessment of documents thereby reducing duplication and frequency of inspection while relying and accepting approvals of other regulatory authorities or organizations.

Advantage of desk assessment

- It also reduces the inspection resources needed by the manufacturing site(s) hence result in increased availability and affordability of medicinal products to the public.

Criteria for Desk Assessment

- Located in countries with Stringent Regulatory Authority (SRA) or inspected and approved by WHO Listed Authorities (WLA).

- Inspected and approved by WHO under Medicines Prequalification Program.

- Inspected and approved by Regional Harmonization Initiatives namely EAC and SADC.

Collaborative procedures:

- In order to *utilize properly scarce resources available* TMDA has taken measures to collaborate with other regulatory authorities such as:

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

❑ 18 applications (14 immunological & 4 pharmaceuticals) received & jointly assessed, 7 products have been approved

➢ A total of 77 experts have been trained within the region

EAC - MRH Programme 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 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

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

All sites compliant to EAC GMP Standards

187 Applications for Joint Scientific Review

184 Applications Jointly Assessed
89 Medical Products Approved for MA
95 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

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 disease (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 least two (2) **ZAZIBONA** participating countries

Timeline → **90 days**

Types of reliance

- African Vaccine Regulatory Forum (AVAREF) e.g Covid Vaccines have been granted market authorisation by abridged review

- WHO collaborative registration procedures TMDA collaborate with WHO PQ and Based on WHO abridged review is conducted and registration granted in within 90 days
- Swiss medics coordinated registration procedure this is on new chemical entities and line extension applications where registration is granted within 90 days.

Types of Reliance

- Mutual Recognition procedure for veterinary medicines in the EAC TMDA in collaboration with other EAC Patner States NRA's recognises veterinary medicinal products registered in partner states.

- Work sharing or bilateral cooperation (Rwanda FDA and BoMRA) there is MoU for joint activities and work sharing including evaluation and inspection reports

- Reginal Reliance mechanism /joint activities EAC and SADC (ZAZIBONA), TMDA collaborate in harmonization of reqirements and joint regulatory activities to stream line processes and shorten approval timelines.

Risk based inspection - Good Storage and Distribution Practice (GSDP)

Good Storage and Distribution Practice (GSDP) Inspection

- Product types: infusions
- versus topical applications
- CBD (City Business Districts) – Huge numbers consumers, wholesalers and importer
- Hospital (in Tanzania) – there is Government as supplier and Private vendors (through tenders)
- Product price – high priced products are likely to be subjected to counterfeiting/illegal imports
- Recalled products substandard or counterfeit as reported from lab results or informed from WHO

Achievements (TMDA)

- WHO Maturity Level III – 2018 (Re - bench marking to be November, 2022)
- TMDA Certified to ISO, UKAS, ACM
- WHO Prequalified Laboratory

Achievement –TMDA

Collaborative achievement:

Zambia Delegates to TMDA

Designated as the Centre of Excellence for Registration of Medicines in Africa

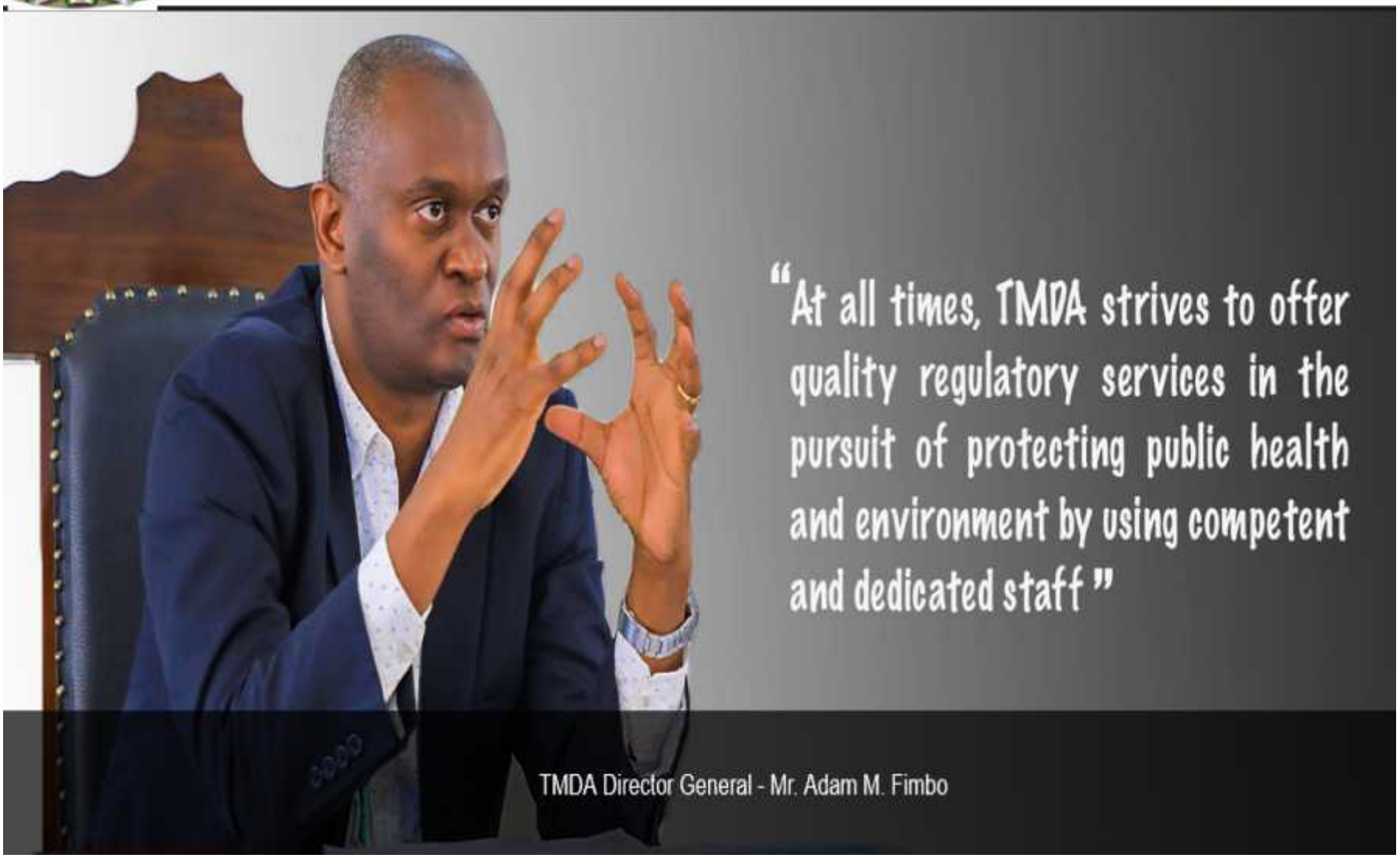
- This is part of the African Medicines Regulatory Harmonization (AMRH) initiative.

A Delegation from Zambia Medicines Regulatory (ZAMRA), Visited TMDA Eastern Zone Offices on 8th September 2022 for Benchmarking Regulatory function

Achievement– PMS and Min Lab

- Min Lab Kit demonstration at TMDA Northern Zone Arusha to participants of Drug Life Cycle Workshop held in Arusha, Tanzania

- Conducting PMS that ensures existence of good quality, efficacious and safe products.
- Presence of functional Min Lab in all active border post and selected hospitals.


"At all times, TMDA strives to offer quality regulatory services in the pursuit of protecting public health and environment by using competent and dedicated staff"
TMDA Director General - Mr. Adam M. Fimbo

Challenges

- Manufacturers – reluctance to provide access of information to inspectors for desk assessment or virtual inspections.
- Differences on legal framework between countries.
- Difference in regulatory issues.

Reference

1. TMDA Guidelines on Submission of Documentation for Establishment Compliance to Good Manufacturing Practices through Desk Assessment; Temporary Waiver & Virtual Inspection of Good Manufacturing Practices of Medicines and Quality Audit of Medical Devices During Emergencies – First Edition, March 2021

2. The Tanzania Medicines and Medical Devices (Good Storage and Distribution Practices) Regulations, 2021

3. www.tmda.go.tz

Thank you (Asante)

Mt. Kilimanjaro