



# Benefits of Mutual Recognition Procedure (MRP) in East African Community (EAC) for regulators – Tanzania experience.

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**TANZANIA FOOD AND DRUGS AUTHORITY**

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# Outline of presentation

- Introduction of TFDA
- Mutual Recognition process in East Africa
- **Expected benefit of MRP in EAC**
- **Benefit of Mutual Recognition Procedure in EAC for TFDA as a regulator**

# Introduction

## Tanzania Food and Drug Authority (TFDA)

- Is a regulatory body, established under the food , Drugs and Cosmetic Act 2003,
- The Authority is under the ministry of HCGEC
- TFDA is responsible with protecting the public health by ensuring various standards of Food, Drug, Cosmetics and Medical devices are met and adhered to.

# Introduction Cont...

- Therefore the authority is responsible for controlling the quality, safety and effectiveness of :-
  - Food,
  - Drugs,
  - Herbal drugs,
  - Cosmetics,
  - Medical devices and Diagnostics.

# Mutual Recognition process in East Africa & The benefit of the process in Tanzania

## Background of Mutual Recognition process in East Africa

- 23<sup>rd</sup> – 26<sup>th</sup> November 2010, Gathered the National Focal Points for Veterinary Products from the OIE Member countries of Africa, working under their respective OIE Delegates
  - Regulators under the sponsorship of GALVmed were also invited to this OIE gathering
- Outcome of OIE/GALVmed Conference in Johannesburg, 2010
  - ❖ Request from African Countries :
    - Training for Regulators in Registration of Veterinary Vaccines
    - Harmonised Registration system
    - Mutual Recognition Procedure

## Mutual Recognition Process in East Africa

- Sectoral Council of Agriculture and Food Security adopted the Concept of Mutual Recognition Procedures and the Terms of Reference for the Technical Working Group (TWG) and the Coordination Group on Mutual Recognition (CGMR) on the **5<sup>th</sup> September, 2014**, in Kigali, Rwanda.
- EAC Council of Ministers adopted TORs and concept of MRP on the **28<sup>th</sup> of November, 2014** in Nairobi, Kenya resulting in a Decision Number: **EAC/CM 30/Decision 34**.

# Expected benefit of MRP in EAC

- Accelerates availability of good quality, safe and efficacious of veterinary medicines.
- Avoids duplication of assessment.
- Improves predictability.
- Builds trust between Regulators.
- Allows rapid introduction of new vaccines against new diseases

# The Benefit of Mutual Recognition Procedure in EAC for TFDA as a regulator

- TFDA involved in number of initiative for East Africa MRP of immunological veterinary products.
- The activities in which TFDA was fully involved toward the MRP in East Africa were:
  - I. Development of the MRP guideline for registration of immunological veterinary product (IVP) which is now published in the EAC website and adopted by the EAC member state.
  - II. Development of Standard Operating Procedures (SOPs) for MRP in EAC
  - III. Development of Screening Checklist as well as the application form for registration of IVP under MRP in EAC



# The Benefit of the Mutual Recognition Procedure to TFDA

The involvement of TFDA in the Mutual recognition for registration process of IVP in EAC, the Authority gain a number of benefit, some of them are:

## i. Training of GMP

Capacity building conducted by EAC under the sponsorship of GALVmed to the EAC member state Vaccine regulatory bodies, it increased TFDA inspectors knowledge and confidence toward GMP inspection for veterinary immunological production facilities

## ii. Training on Dossier assessment

Capacity building on the dossier assessment conducted also by EAC under GALVmed sponsor, it assist much to increase knowledge of veterinary biological assessment and hence approval process

# Benefit of the Mutual Recognition Procedure to TFDA .....

iii. Specific guideline for registration of immunological veterinary product.

TFDA is using the MRP guideline for submission of documentation for registration of veterinary biological product.

iv: Speed up the process of registration of immunological veterinary product.

# Thank you

