World Organisation for Animal Health

Training Seminar for National Veterinary Products Focal Points

Veterinary Products: A Vital Tool for Improving Animal Health and Welfare

05 – 07 September 2023 Lilongwe, Malawi

The Fleming Fund

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EAST AFRICAN COMMUNITY

One People, One Destiny

Veterinary Products: a Vital Tool for Improving Animal Health and Welfare

EAC: Summary on technical and regulatory harmonization

05th – 07th September 2023
Lilongwe-Malawi

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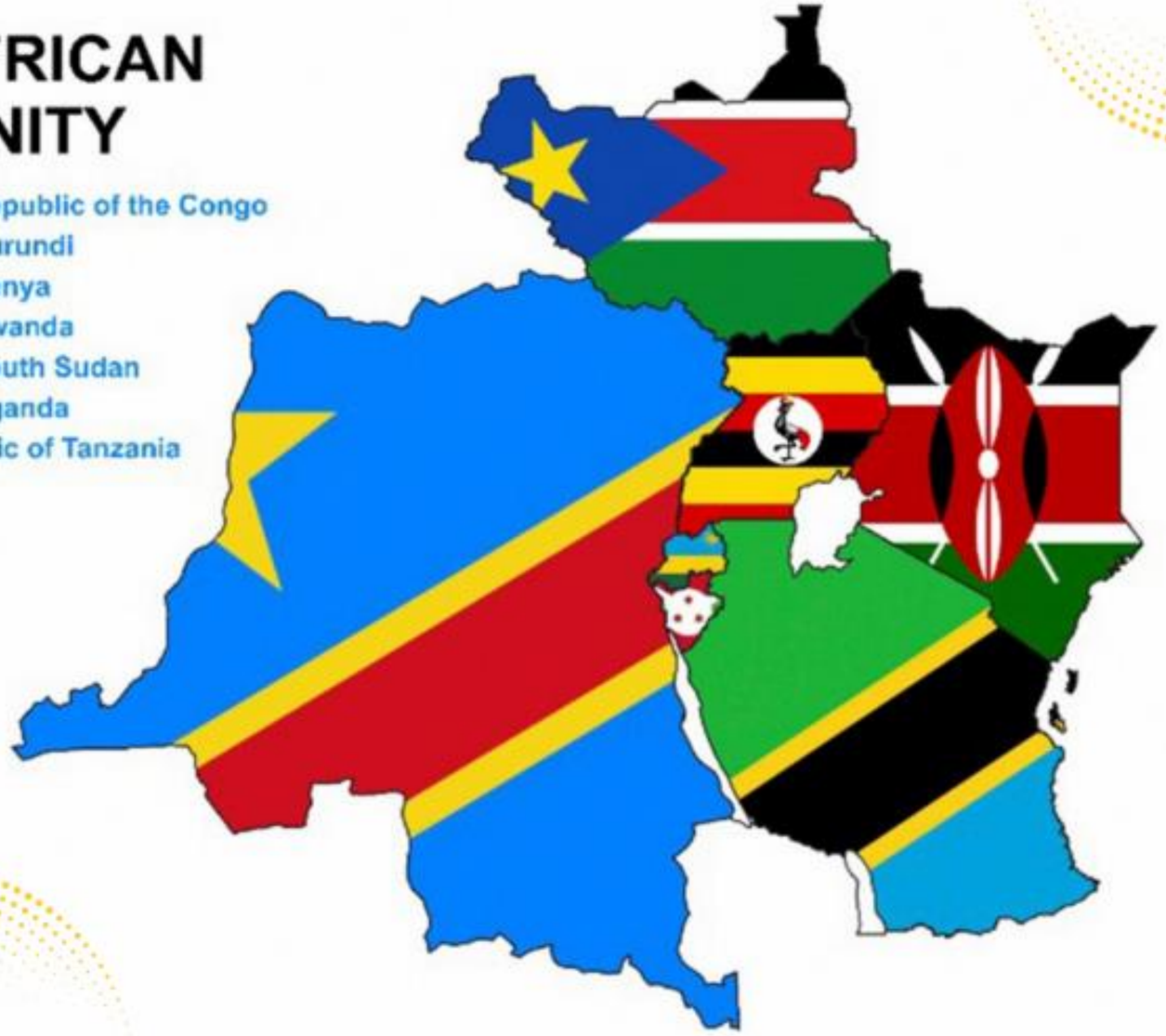
EAC MRP-Coordinator

OUTLINE OF THE PRESENTATION

1. East Africa Community in Brief
2. Veterinary Medicinal product's Regulatory systems in EAC
3. EAC Veterinary Medicines Harmonization Initiative
4. EAC application assessment timelines
5. Benefits of harmonization

EAST AFRICAN COMMUNITY

- Democratic Republic of the Congo
- Republic of Burundi
- Republic of Kenya
- Republic of Rwanda
- Republic of South Sudan
- Republic of Uganda
- United Republic of Tanzania



The East African Community

now spans from the Indian Ocean to the Atlantic Ocean

JUMUIYA YA AFRIKA MASHARIKI

THE EAST AFRICAN COMMUNITY

In Brief

The East African Community (EAC) is a regional inter-governmental organization of the Republic of **Burundi**, the Democratic Republic of **Congo**, the Republic of **Kenya**, the Republic of **Rwanda**, the Republic of **South Sudan**, the Republic of **Uganda** and the United Republic of **Tanzania**, with its headquarters in Arusha, Tanzania.

Vision

A prosperous, competitive, secure, stable and politically united East Africa.

Mission

To widen and deepen economic, political, social and cultural integration in order to improve the quality of life of the people of East Africa through increased competitiveness, value added production and investment.

Quick Figures

Total Surface Area
4.8 million sq. km

Population
280 million *(2020)*

GDP Nominal
US$ 278.1 billion *(2020)*

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EAC REGIONAL INTEGRATION PILLARS

A HIGHLIGHT

CUSTOMS UNION

2005

Enabling the EAC Partner States to enjoy economies of scale, with a view to supporting the process of economic development through the establishment of a Single Customs Territory.

COMMON MARKET

2010

Accelerating economic growth and development while maintaining a liberal stance towards the 5 Freedoms of movement for all factors of production in the region.

MONETARY UNION

2013

Laying the groundwork within a 10-year span, while allowing the EAC Partner States to progressively converge their currencies into a single currency in the Community.

POLITICAL FEDERATION

ONGOING

Putting in place initiatives to fast-track political integration. In May 2017 EAC Heads of State adopted the Political Confederation as a transitional model of the East African Political Federation.

Veterinary Medicinal product's Regulatory systems in EAC

Sound regulatory systems are critical for protecting public health and environment.

Regulation ensures international standards of quality, safety and efficacy are complied to in a country or A region

Status National authorities in EAC

ABREVPA

VMD

Rwanda FDA

No functional system

TMDA

NDA

DRC ???

Mutual Recognition procedure (MRP)

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Regulatory activities

- Marketing authorization
- Good Manufacturing Practice (GMP)

} Key area of harmonization

- Post-marketing surveillance
- Pharmacovigilance activities
- Clinical trials oversight activities

Every country needs an assured supply of safe, efficacious, good quality and affordable medicinal products.

Functional regulatory authority with Sound and effective regulatory systems.

A constant supply of quality veterinary products promote trade and improves economic status of citizens

EAC Veterinary Medicines Harmonization Initiative

Legal provision

MRP initiative is anchored in the Article 108 (e) of the EAC Treaty that provides for adoption of a common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines.

Harmonization of requirements, procedures and standards represents the strongest assurance that the same products receives similar regulatory consideration and decisions across different countries and regions

Provides a clear advantage for both industry and regulatory bodies that work towards the same objective and limit biasness.

GALVmed
Protecting Livestock – Improving Human Lives

Initially WOAH tasked GALVmed to build capacity of assessors and GMP inspectors. Harmonise technical guidelines. (2011)

1 TRAINING

- Dossier assessment training (Immunological, Pharmaceutical and FMD)
- GMP inspection training
- Numerous technical workshops

2 HARMONISING TECHNICAL DOCUMENTS

- Dossier structure
- Technical Guidelines
- Templates for labelling and SPC
- Application forms for use in National or MRP applications
- >30 technical documents and have been reviewed

3 DEVELOPING & IMPLEMENTING MRP

- MRP in use for immunologicals since early 2017
- In use for pharmaceuticals from mid 2020
- 34 applications received from 11 companies
- MRP currently being expanded to include registration of veterinary pesticides

Harmonised documents for technical guidance to applicants on MRP are available on EAC website: http://www.eac.int/documents/category/livestock

- Guideline on the Technical Documentation required to be included in a Registration Dossier For an Immunological Veterinary Product - GL. 2 and annotated for FMD vaccine
- Guideline for marketing authorizations of vet pharma products – GL. 13
- Best Practice Guide - GL. 5
- Pre-Submission Meeting guide - GL. 6
- Repeat-Use MRP (RU-MRP) - GL. 10
- Variation GLs - 9 & 15
- GMP and Veterinary Pesticides guidelines

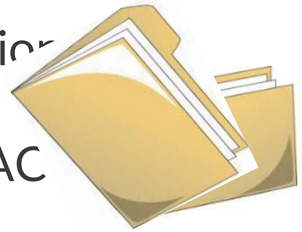
Internal documents for regulators

- Guideline for preparation of dossier assessment report
- Dossier assessment template
- Responses to queries evaluation template
- Product Calendar
- GMP inspection manual
- Template for Evaluation of Corrective and Preventive Actions

MRP of initiative & EAC MRP submission process

Coordination

The procedure is Coordinated at both nation and regional levels through Coordination Group Mutual Recognition(CGMR) and EAC Mutual Recognition Coordinator(MR-C).



The applicant submits identical dossiers to a minimum of 2 countries the RC and CCs.

Then the EAC Mutual Recognition Coordinator (MR-C) starts the clock.

KEY DAYS

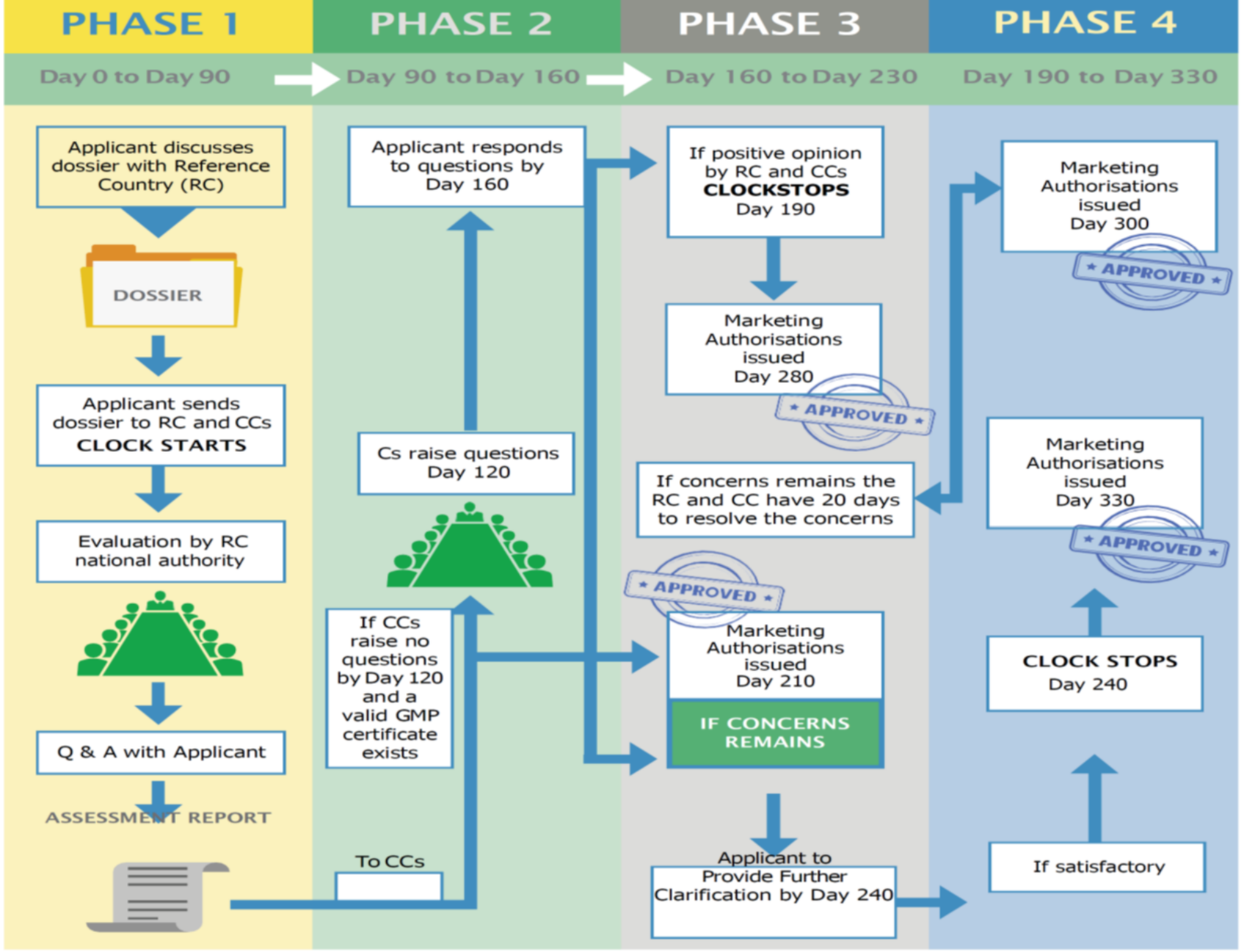
The MR-C then prepares a product calendar for the MRP applications and set a timetable. Key MRP calendar days

0, 90,120,130.

One assessment report is generated by RC and shared with CC for review and in put

Most of the functional regulatory authorities in EAC have migrated from manual to online system. Therefore, MRP initiative is working towards developing an online submission portal that will be linked other systems

EAC MRP – The procedural overview of MRP



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Regulatory harmonization represents a process where regulatory authorities align technical requirements for the registration and marketing of Medicinal products.

Benefits of harmonization

1. Ensuring favorable marketing conditions to support early access to medicinal products.
2. Promoting competition and efficiency.
3. Reducing unnecessary duplication of efforts (Dossier evaluation, clinical and efficacy testing).
4. Work sharing and regulatory reliance enhancement
5. Increase collaboration across countries and development of trust among regulators.
6. Strengthen regulatory capacity of partner states.
7. Ensure the efficient evaluation.
8. Enables both regulatory authorities and industry to pursue a shared commitment to protect the public.
9. More time is made available to regulators to handle other activities.

Challenges of harmonization

1. The National Medicines Regulatory Authorities (NMRAs) have different legal frameworks and at different levels of regulatory maturity
2. Establishing and sustaining a mature regulatory system.
3. Lack of adherence to Good Regulatory Practices principals which affects public's confidence in the regulator.

ACKNOWLEDGEMENT

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USAID
FROM THE AMERICAN PEOPLE

Pan African Veterinary Vaccine Centre
AU-PANVAC

Thank you
Asante
Merci