



Protecting Livestock – Improving Human Lives

## Legal framework and policies affecting the Mutual Recognition Procedure (MRP) in the EAC

GALVmed-OIE-SADC meeting on regulatory harmonisation

Johannesburg, May 2017



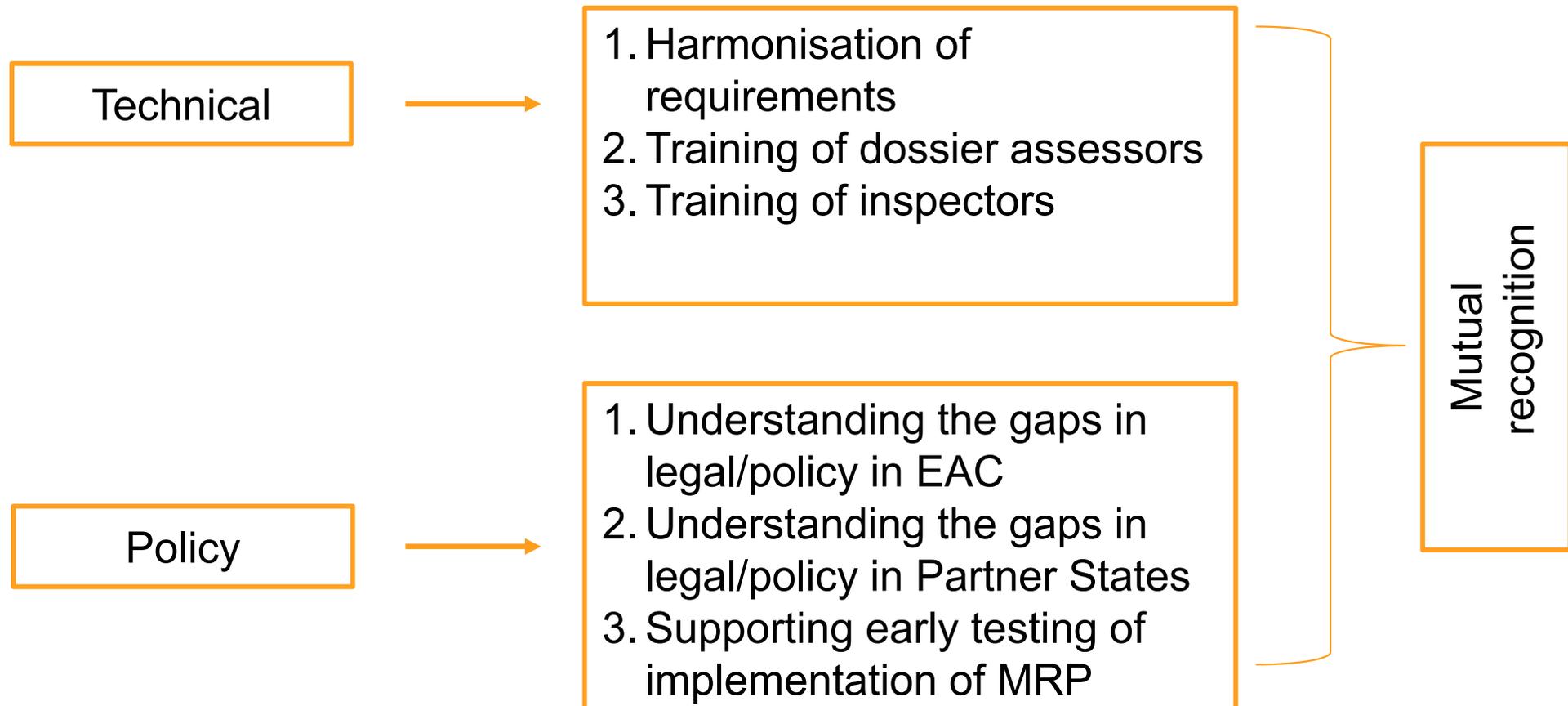
**Problem:** inefficient, unpredictable system for registering veterinary medicines resulting in insufficient supply of quality veterinary medicines

GALVmed believes it can contribute to developing an efficient, predictable system for registration of veterinary medicines

**Expected outcome:** quality veterinary medicines are registered and made available in African markets in an efficient, timely and predictable manner

**Expected impact:** livestock morbidity and mortality reduced

Technically driven but conscious of policy/legal aspects



Needs driven, attentive, inclusive, “bottom-up”

Conscious that system needs to include both vaccines & pharma

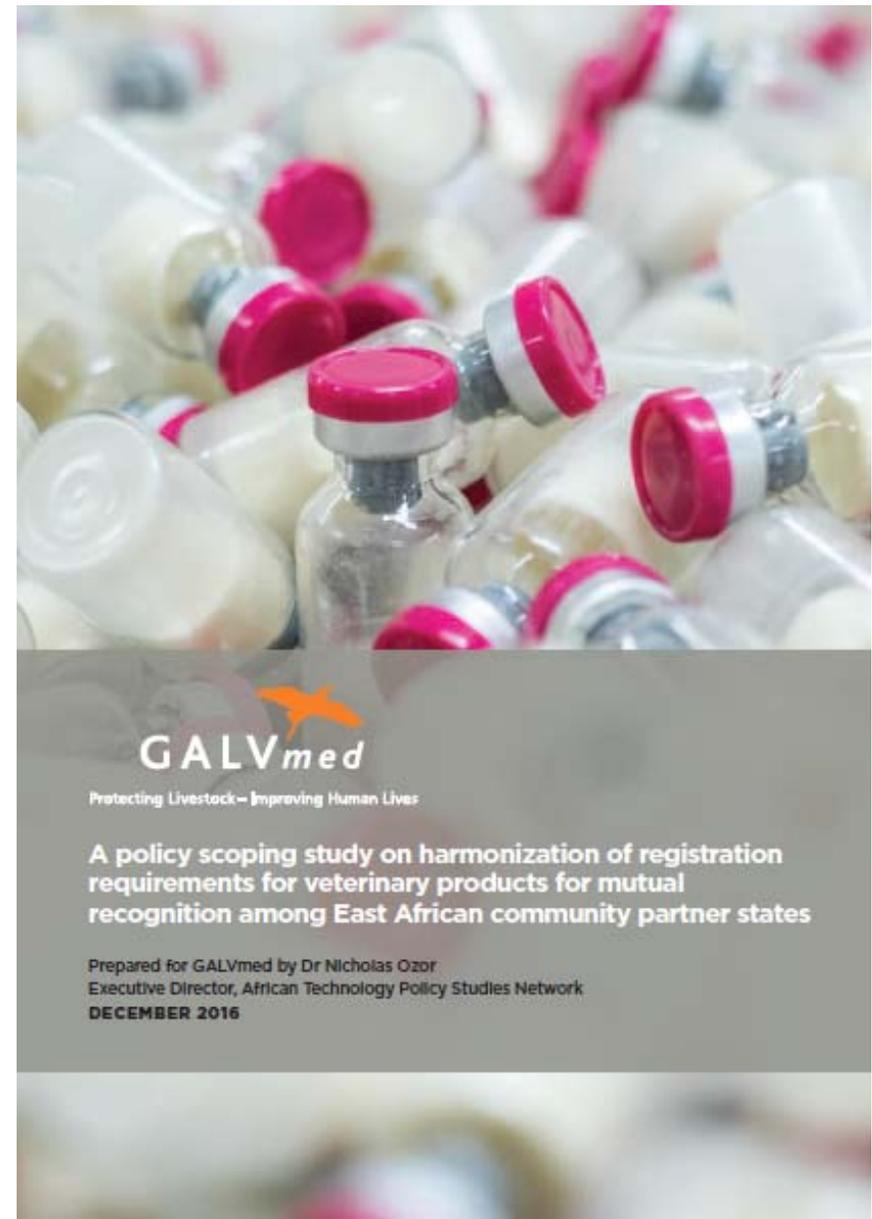


- 2014-2015
- Study looking at policy & practice relating to registration of veterinary products in 30 countries

# Supportive policy study

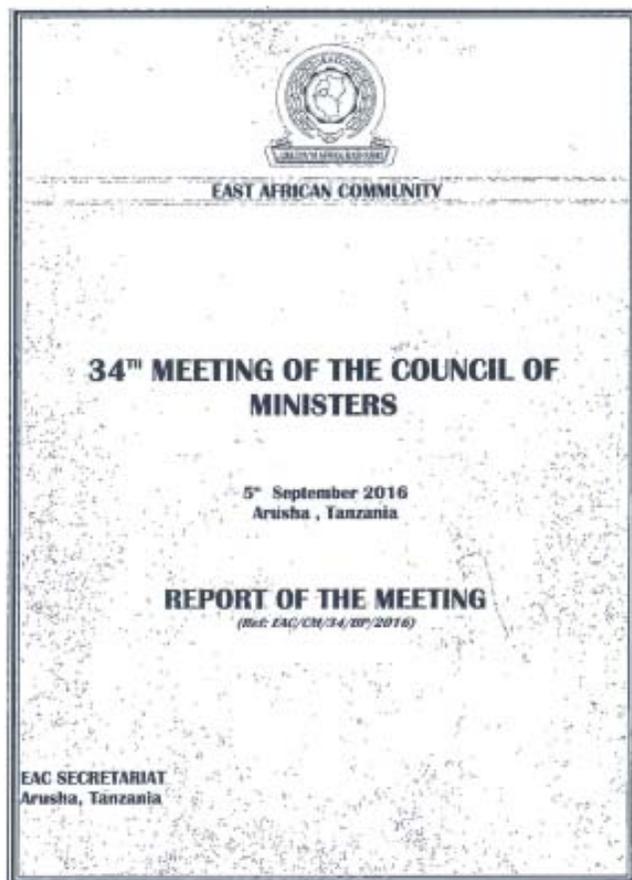
## Objectives

1. To review EAC laws/regulations on regulatory harmonisation insofar as they are applicable to the implementation of MRPs.
2. To review the laws and regulations in EAC Partner States to determine gaps and where alignment is needed in order to implement MRPs at the national level.
3. To identify mechanisms and strategies that will facilitate and enhance national level ratification, domestication and actual implementation of MRPs.



1. Nov 2014 Council of Ministers adopted concept of MRP, TORs for TWG, TORs for Coordination Group for Mutual Recognition (CGMR): **EAC/CM 30/Decision 34**
2. September 2016, Council of Ministers directed Partner States to implement MRP for Immunological Veterinary Products (IVPs): **EAC/CM34/Decision 35**

# Key legal/policy milestone - EAC



## (4) Harmonisation of Registration of Immunological Veterinary Products in the East African Community through Mutual Recognition Procedures

The Session was informed that pursuant to the 30<sup>th</sup> Meeting of the Council of Ministers decision to adopt the Mutual Recognition Procedures (MRP) for harmonisation of the registration procedures of Immunological Veterinary Products (IVP) in the Community, a technical working group meeting was held in March 2015 to formally constitute the Technical Working Group (TWG) and the Coordination Group for Mutual Recognition (CGMR) in accordance with the TORs. The objective of the meeting was to prepare documentation and lay foundation for implementation of the Mutual Recognition Procedures (MRP) in regard to harmonization of registration of Immunological veterinary Products.

To operationalize the MRP system, it was agreed that a number of Standard Operating Procedures (SOPs) be developed to facilitate the implementation of the initiative. To this end, the following SOPs are being developed: SOP for writing SOP; SOP for controlling of documents to cover change control of Technical Documents; SOP for receiving applications for registration of IVP under MRP; SOP for evaluation of applications for registration of IVP -dossier evaluation Form to be attached; SOP for conducting GMP inspection of manufacturing facilities of IVPs; SOP for screening of IVP Applications for Registration; SOP for declaration of interest during arbitration phase of MRP; and Form for declaration of interest during arbitration phase of MRP.

The meeting agreed on the modalities of drafting and finalizing the SOPs and observed that the coding of the SOPs will be consistent with the EAC Quality Management system (QMS).

The meeting identified and discussed the following critical issues in implementation of MRP:

- (a) Applications from facilities not yet inspected for GMP;
- (b) Applications from Non-EAC countries for MRP;
- (c) Joint assessments;
- (d) Joint inspections;
- (e) Harmonization of Variations.
- (f) Harmonization of Renewals and /or Retentions;
- (g) Pharmacovigilance; and
- (h) Fees for MRPs.

The TWG developed a draft Road Map for implementation of the Mutual Recognition Procedures (MRP) on harmonization of Immunological Veterinary Products. The Road Map is attached as Annex V.

The Council –

- (a) took note of the progress made in Implementation of MRP on Immunological Veterinary Products (EAC/CM 34/Decision 34);
- (b) directed Partner States' to implement the Mutual Recognition Procedures (MRP) on IVPs (EAC/CM 34/Decision 35);
- (c) directed Partner States to always undertake joint assessment of Dossiers (EAC/CM 34/Directive 42); and
- (d) directed the Secretariat to develop EAC Harmonized Goods Manufacturing Practices guidelines for conducting joint assessment (EAC/CM 34/Directive 43).

1. The EAC Treaty of 2000 – which established the EAC – is a legally binding document among the EAC Partner States, with the mandate to foster integration and cooperation in the EAC region.
2. Article 108 of the EAC Treaty forms the basis for harmonisation of regulations for veterinary medicines registration and sets out the nature of cooperation in plant and animal diseases control within the EAC Partner States.
3. The MRP is legally binding on Partner States as anchored on the Council of Ministers' decision according to Chapter 5 of the EAC Treaty.

1. All the Partner States have laws that regulate registration of veterinary medicines
2. The NRAs are mandated under the line Ministries of Health dealing with human and not animal health, while the veterinary sector is largely governed by the Ministries of Agriculture
3. The NRAs execute their mandates as laid out in the Acts of Parliament, subsidiary legislation, regulations, guidelines and procedures and other internal processes.
4. MRP is aligned with the Partner States' laws

# Mechanisms for enhancing MRP implementation

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1. Majority of stakeholders are not conversant with EAC legal provisions that support the implementation of the Council of Ministers' decision.
2. MRP implementation is moderately integrated in some of the NRAs. The proposed actions by the TWG on implementing MRPs have not been fully actualized
3. More intensive sensitization required among key stakeholders

5. Financial and technical capacities as well as stakeholder engagement were listed as major barriers to implementation of MRPs
6. The respondents highlighted the need for stronger involvement of the EAC Secretariat in the initiative to support and accelerate the adoption of MRPs.

1. The EAC Secretariat should strengthen policy advocacy and stakeholder sensitisation on the legal provisions that give mandate to the harmonization process and MRPs.
2. Need for more targeted efforts, driven by the EAC Secretariat and the TWG, aimed at including key players in using and testing MRP.
3. Need for active dissemination of information on MRP through the EAC website and other relevant EAC stakeholder forums by the EAC Secretariat and the TWG.

1. NRAs to publish the harmonised technical documents
2. TWG members should lead efforts in advocacy and sensitization on MRP as an EAC-led initiative to get buy-in and ownership within their NRAs and among other stakeholders
3. Clarification and transitional arrangements needed in Kenya: being mindful of implications for implementation of MRP
4. Capacity building on MRPs is needed across the EAC NRAs, which can be done by the respective TWG members
5. Need to test the practicality of MRP in the EAC Partner States and allow for review of the process based on experience of NRAs and applicants

1. Intense sensitisation and involvement of the private sector in testing MRP to ensure buy in and constructive feedback on how to make the process more efficient
2. Policy sensitization and advocacy required at both national and regional levels
3. Need to strengthen linkages between NRAs and veterinary sector players e.g. CVOs and other officers
4. Realistic road map and implementation plan required for the roll-out of MRP in EAC
5. Effective communication from EAC Secretariat to NRAs so that info relating to MRP is relayed to relevant parties in NRAs with decision making capacity in a timely manner

6. Champions required among Partner States reps involved in MRP efforts to push the agenda within their respective departments in their home countries to create buy-in and ownership. This would help to promote trust and confidence in adoption of MRP
7. There is a need to strengthen the collaboration between private sector and NRAs to ensure effective implementation of MRPs
8. Sensitisation of the private sector and NRAs to ensure the MRP is piloted properly, NRAs learn from each other, build trust and are comfortable with accepting the assessments made by their counterparts

- Sensitisation activities – (OIE/AU-IBAR EAC Regional Seminar) NRAs, private sector, vet stakeholders, policy players; national and regional
- Testing MRP through use – actual assessment of dossiers and inspections to accelerate building trust among assessors and inspectors
- Capacity building and support for NRAs as they undertake the initial stages of testing MRP
- Increasing our understanding on what else needs to be done so that system includes pharma

- Baseline questionnaire on the status of and processes for registration of veterinary medicines in SADC
- GALVmed/OIE stakeholder workshop on the harmonization of the registration of veterinary medicinal products
- Legal/policy study on registration of veterinary medicines at SADC regional and country level and to identify opportunities for regulatory harmonisation (FANRPAN)

**Thank you!**

