



Regional Mutual Recognition System in Africa- The EAC Experience

Noel M. Aineplan

Ag. Manager, Harmonisation- NDA





Scope of presentation

EAC- Burundi, Kenya, Rwanda, Tanzania, Uganda,
South Sudan(just joined)

- Background
- Progress towards MRP



Background

Workshop for African regulators organised by GALVmed in Cape Town in 2010. Requested for

- Development of a harmonised registration system for immunologicals
- Training for their regulators in registration of veterinary vaccines
- Establishment of a system of Mutual Recognition





Harmonised Documents

EAC Technical Working Group's harmonised documents:

- Dossier structure
- Technical Guideline
- Templates for labelling and Summary of Product Characteristics (SPC)
- Harmonised Application Form for use in National or MRP applications
- 20+ other technical documents harmonised



Training & technical meetings

- Training completed
 - Dossier preparation training (to vaccine manufacturers)
 - Dossier assessment training
 - GMP inspection training
- Numerous technical workshops(12)
- Engagement with policy makers, private sector & other stakeholders through stakeholder meetings in 5 EAC countries





NMRA_s

- Burundi - Ministry
- Kenya - PPB and later VMD
- Rwanda - RAB
- Tanzania - TFDA
- Uganda - NDA
- S. Sudan - Ministry





A system of Mutual Recognition

Two types of MRP:

1. For new product applications
2. For expansion of existing Marketing Authorisations

How it starts:

- Applicants selects RC and CCs
- Pre-submission meeting may be held between RC and Applicant.



Progress towards MRP

1. **Article 108** of the EAC Treaty forms the legal basis for harmonization of regulations for veterinary medicines registration within the EAC Partner States
- 2 The Sectoral Council on Agriculture and Food Security **adopted the Concept of Mutual Recognition Procedures** on the 5th September, 2014, in Kigali, Rwanda
3. These **decisions were adopted by the EAC Council of Ministers** on the 28th of November, 2014 in Nairobi, Kenya resulting in a Decision Number: EAC/CM 30/Decision 34.

4. The 34th meeting of the Council of Ministers on 5th September 2016 Ministers **directed Partner States to implement the Mutual Recognition Procedure (MRP) for IVPs & develop harmonised GMP guidelines for conducting joint assessments:** EAC/CM 34/Decision 35

5. The 10th Meeting of the Sectoral Council on Agriculture and Food Security **directed the EAC Secretariat and Partner States to convene stakeholder sensitisation meetings** on MRP in all Partner States and **directed the Secretariat to set up a coordination office and mobilise resources to finance MRP activities**

Slide



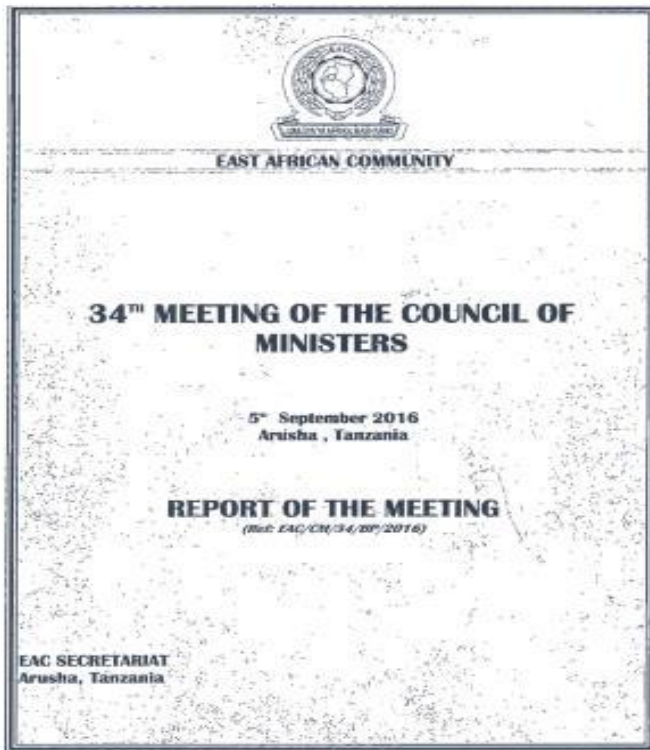
Progress towards MRP

- (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*).



[Handwritten signature]

[Handwritten initials]

[Handwritten initials]

[Handwritten mark]



Progress towards MRP

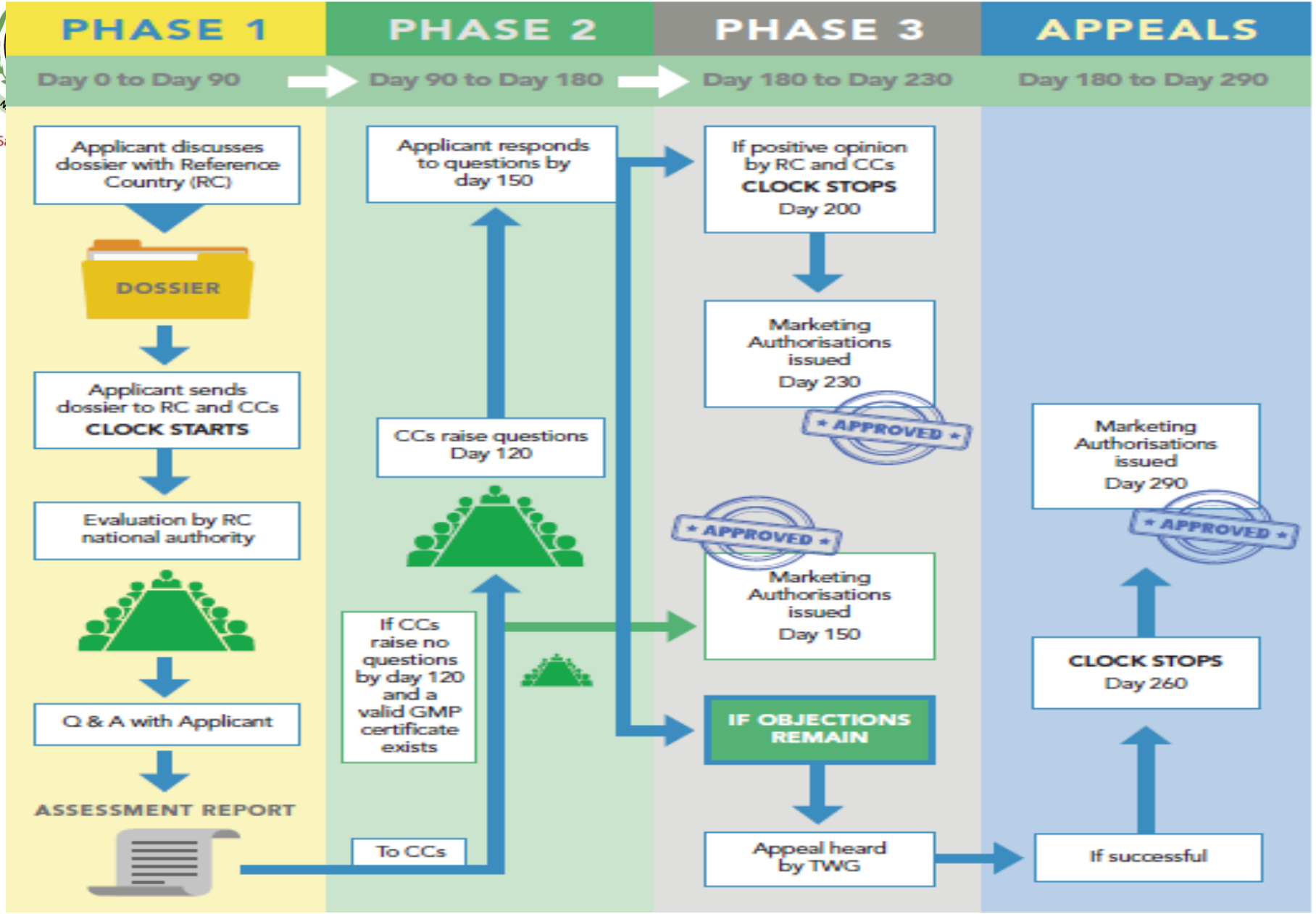
EAC letter to Partner States, 17th February 2017:

“At the 34th meeting of the Council of Ministers on 5th September 2016, Ministers directed Partner States to implement the Mutual Recognition Procedure (MRP) for IVPs (EAC/CM34/Decision 35). EAC calls upon all heads to the medicines regulatory agencies to make arrangements to initiate MRPs upon request by applicants.”

ATPS Report 2017:

“The MRP is legally binding on Partner States as anchored in the Council of Ministers’ decision with reference to the functions and the effects of the Council of Ministers’ decision as spelt out in *Chapter 5* of the EAC Treaty.”





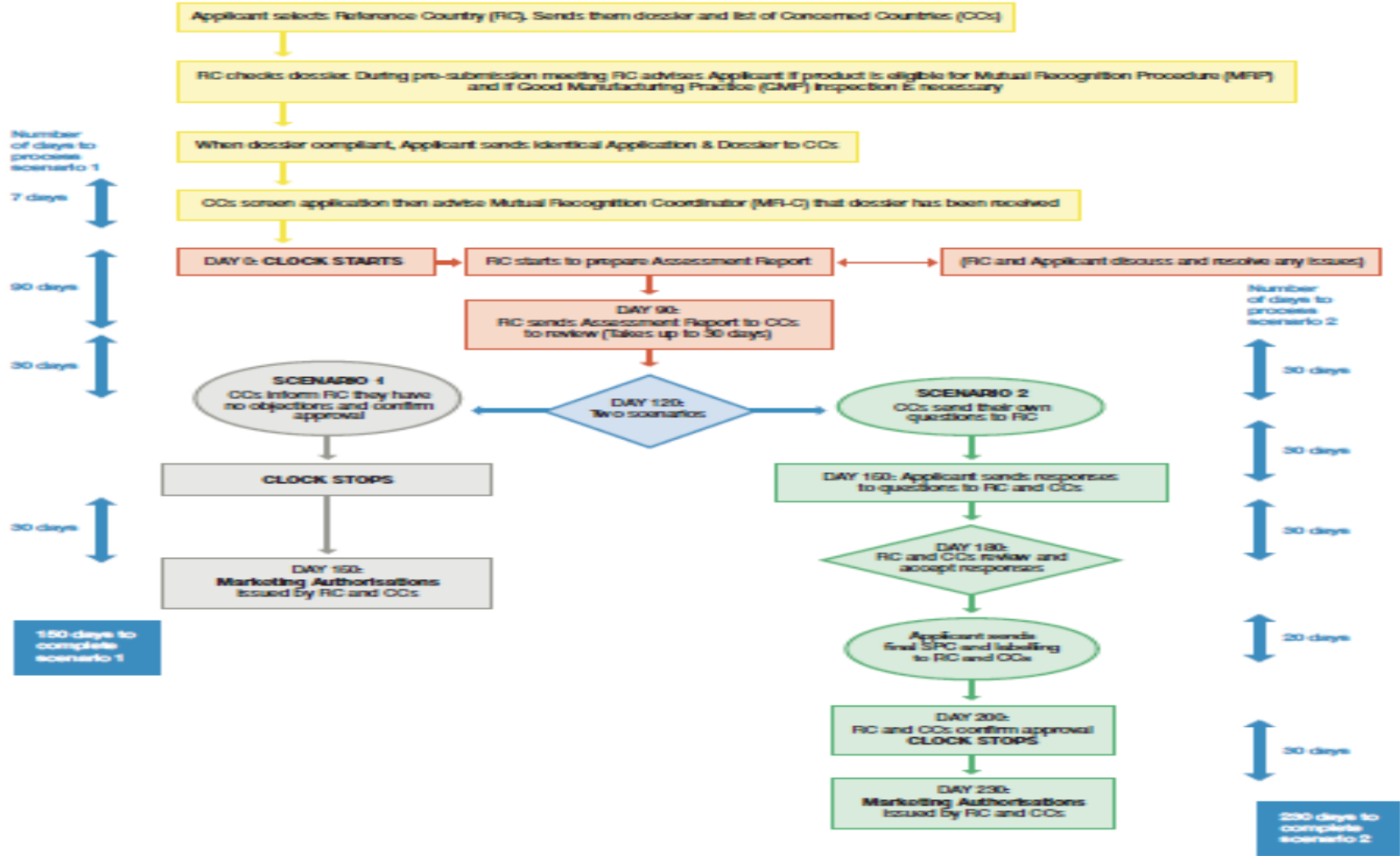


Mutual Recognition Procedure for Veterinary Vaccines in the EAC

Short and Medium Processing Times (150 – 230 days)



Application process begins here





Progress towards MRP

Effective implementation of MRP requires:

1. The commitment of Partner States' NRAs.
2. Sensitisation of stakeholders & their buy in
3. Willingness of applicants to use new MRP system



Progress towards MRP

The system is now open for business

- ❖ 1st MRP application completed in June 2018- Uganda and Rwanda; other countries were observers
- ❖ EAC MRP Coordinator office is being established
- ❖ 2 applications to be evaluated in July and Sept.
- ❖ There are plans to expand MRP to cover pharmaceuticals- Draft guidelines ready
- ❖ Interests by other RECs – SADC & ECCAS/CEMAC





Special Thanks

- EAC Secretariat
- Lois Muraguri and Team – GALVmed
- EAC TWG Members



THANK YOU

