



A Comparison of the Regional Medicines Regulatory Harmonisation Projects in East, West and Southern Africa.

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BACKGROUND

The African Medicines Regulatory Harmonisation Initiative (AMRH) was established in 2009 to strengthen and harmonise the different regulatory systems in Africa.
This was initiated through the already existing regional economic blocks in Africa.
The first medicines regulatory harmonisation (MRH) project to be established as a pilot was the East African Community MRH in 2012 (Figure 1).
This was followed by the Southern African Development Community MRH in 2015 which included the ZaZiBoNa joint review procedure that had been established in 2013 (Figure 2).
Following this, the Economic Community of West African States MRH was set up in 2017 (Figure 3)
The work of the AMRH over the last 14 years serves as a foundation for the African Medicines Agency (AMA).

Aims & Objectives

The aim of this study was to compare the operating models, successes and challenges of three of the medicines regulatory harmonisation (MRH) projects being implemented in Africa through the African Medicines Regulatory Harmonisation initiative (AMRH)

Methods

Data were collected in 2021-2022 using the Process, Effectiveness and Efficiency Rating questionnaire (PEER) developed by the authors and from existing literature. The national regulatory authorities (NRAs) of 23 countries from the three regions participated in the study (100% response rate)

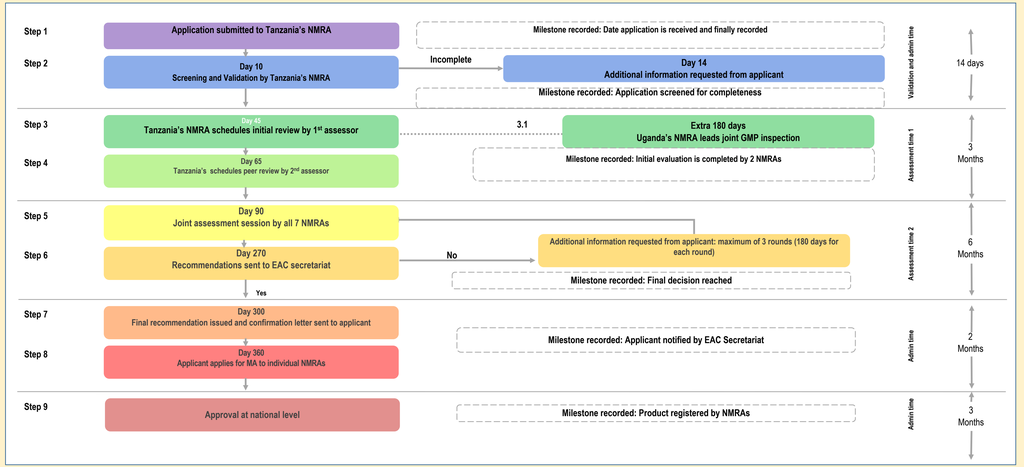
Results

One of the findings was that although the MRH projects were established at different times and at the discretion of each region, the operating models are largely similar with a few differences noted the key being the process for submission of applications for joint review (Table 1)

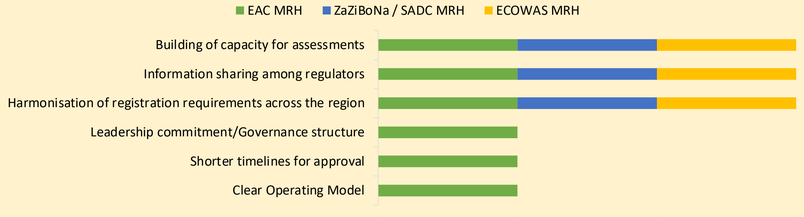
Table 1: Comparison of key milestones in the joint review of an application by region

	EAC MRH	ZaZiBoNa / SADC MRH	ECOWAS MRH
Submission of applications for regional review	Decentralised	Decentralised	Centralised
Technical Review	Decentralised	Centralised	Centralised
Regional recommendation	Centralised	Centralised	Centralised
Marketing authorisation decision	Decentralised	Decentralised	Decentralised

Figure1 Joint Review Process of the EAC MRH



Results: Strengths of MRH initiatives



Results: Challenges faced by applicants

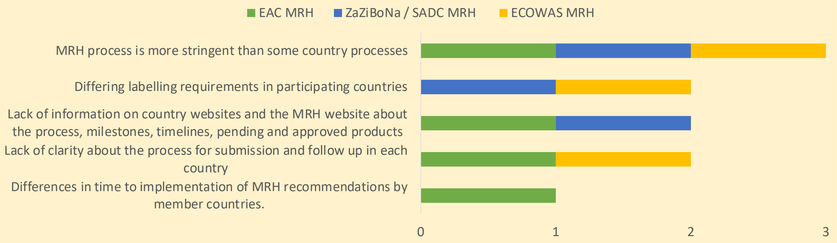
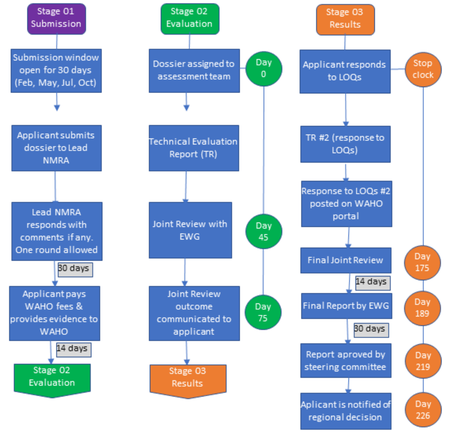


Figure2 Joint Review Process of the ZaZiBoNa

Figure3 Joint Review Process of the ECOWAS



Recommendations

- The operating models of the MRH projects should be fully aligned to improve efficiency in supporting the African Medicines Agency.
- All three Regional Economic Communities (RECs) should develop regional legally binding framework, if possible, to allow for the establishment of a centralised procedure
- The RECs should invest in robust information management systems to rectify the challenges identified in this study
- The RECs should support the strengthening of the capacity of their member states using the WHO Global Benchmarking Tool (GBT) assessments to facilitate inter-country and inter-REC reliance
- The Centre for Innovation in Regulatory Science tools, linked to the WHO GBT indicators, are of value to agencies who wish to assess their regulatory performance.

Conclusions

The results of this comparison allow for the three regional harmonisation initiatives to learn from each other. The implementation of the recommendations from this study will bring about a greater alignment and efficiency in the regional operating models, thereby strengthening the foundation of the soon to be operationalised African Medicines Agency.

Disclosure: None of the authors of this presentation has any disclosures to make concerning possible financial or personal relationships with commercial entities that may have a direct/indirect interest in the subject matter of this presentation.