Evaluation of Good Review Practices in member agencies of the East African Medicines Regulatory Harmonisation Initiative

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Background

The African Medicines Regulatory Harmonisation (AMRH) Initiative came into force in 2009.

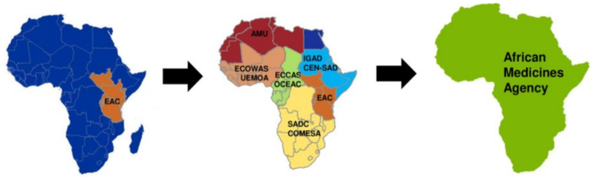
This initiative was established by African Union Development Agency (AUDA-NEPAD) and Partners.

Aim of AMRH to improve access to medical products and technologies in Africa through harmonisation of medicines regulatory in five regions in Africa (SADC, EAC, IGAD, ECCAS and ECOWAS).

To operationalise this initiative, Medicines Regulatory Harmonisation Projects were established in all these regions. These projects are operating at different levels of maturity.

EAC-MRH launched in 2012

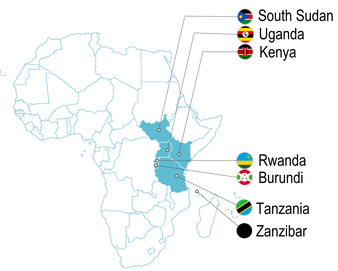
The EAC and other harmonization Initiatives in Africa are the pillars to the AMA



Objectives

To evaluate Good Review Practices (GReVP) in the agencies participating in the East African Medicine Regulatory Harmonisation Initiative and map strategies for moving forward as they are going through the process of alignment for the operationalisation of the African Medicines Agency (AMA).

Study Participants (NRAs)



Methods

MIXED METHOD DESIGN

An exploratory mixed method design using both qualitative (semi-structured Interviews) and quantitative using questionnaire techniques.

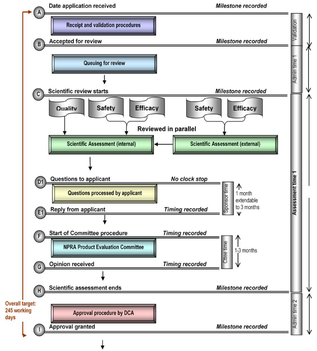
VALIDATED QUESTIONNAIRE

A Validated questionnaire was used to examine the regulatory performance of the countries in the EAC region

STUDY PARTICIPANTS

Study participants : Burundi, Kenya, Rwanda, Tanzania, South Sudan, Zanzibar

The OpERA Tool for Monitoring Regulatory Performance



Optimising Efficiencies in Regulatory Agencies

Part 1 - Organisation of the agency

Information on its structure, organisation and resources.

Part 2 - Types of Review Models

Explores review model(s) for the scientific assessment of medicines in terms of the extent to which data is assessed in detail by the agency, and how the agency might rely on the results of assessments and reviews carried out elsewhere.

Part 3 - Key Milestones in the Review Process

Identify the main steps in the review and approval process and identifies key 'milestone' dates in the process. This allows for the analysis of timelines.

Part 4 - Good Review Practices (GRevP): Building quality into the assessment and registration process

Identity's the activities that contribute to those measures that have been adopted to improve consistency, transparency, timeliness, and competency in the review processes.

Part 5 - Quality Decision-Making Process

Explores the quality of the decision-making process and whether or not the agency has measures in place to ensure that good decisions are made around the data during the registration process.

Comparison of the quality measures implemented by the seven regulatory authorities

Quality Measure	Regulatory Authority						
	BURUNDI	KENYA	RWANDA	SOUTH SUDAN	TANZANIA	UGANDA	ZANZIBAR
Good review practice system	✓	✓	✓	x	✓	✓	✓
Internal quality policy	✓	✓	✓	x	✓	✓	✓
Standard operating procedures for guidance of assessors	✓	✓	✓	x	✓	✓	✓
Assessment templates	✓	✓	✓	x	✓	✓	✓
Peer review (internal)	✓	✓	✓	x	✓	✓	
Dedicated quality department	✓	✓	✓	x	✓	✓	✓
Scientific Committee	✓	✓	✓	x	✓	✓	✓
Shared and joint reviews	✓	✓	✓	x	✓	✓	✓

Comparison of the transparency and communication parameters in the six agencies

Quality Measure	Regulatory Authority						
	BURUNDI	KENYA	RWANDA	SOUTH SUDAN	TANZANIA	UGANDA	ZANZIBAR
Post-approval feedback to applicant on quality of submitted dossiers	✓	✓	x	x	x	✓	✓
Details of technical staff to contact	✓	x	✓	x	x	✓	x
Pre-submission scientific advice to industry	✓	✓	✓	x	x	✓	x
Official guidelines to assist industry	✓	✓	✓	x	✓	✓	✓
Industry can track progress of applications	✓	✓	✓	x	✓	✓	✓
Publication of summary of grounds on which approval was granted	x	✓	x	x	x	✓	✓
Approval times	✓	✓	✓	x	✓	✓	✓
Advisory committee meeting dates	x	x	x	x	x	✓	x
Approval of products	✓	✓	✓	x	✓	✓	✓

Review models employed and target timelines (calendar days - 2022

Type of review model	BURUNDI	KENYA	RWANDA	TANZANIA	UGANDA	ZANZIBAR
Verifications review (type 1)	x	✓c	✓c	x	✓a	x
Target	N/A	90	90	N/A	90	N/A
Abridged review (type 2)	✓b	✓c	✓c	✓c	✓e	✓c
Target	N/A	105	90	126	105	126
Full review (type 3)	✓3A	✓	✓3A	✓3B	✓3A	✓3A
Target	N/A	262	270	252	261	365
Fast Track/Priority Review	✓	✓	✓	✓	✓	✓
Target	N/A	N/A	N/A	126	N/A	126

Comparison of targets for key milestones in the full (type 3) review process - (calendar days).

Target	BURUNDI	KENYA	RWANDA	TANZANIA	UGANDA	ZANZIBAR
Receipt and validation	90	3	30	20	No target time	90
Queuing	60 -180	<365	60-180	60	365	60-180
Primary scientific Assessment	90	No target time	No target time	14	180	180
Questions to applicant (Clock stop)	90	180	90	180	180	180
Review by Expert Committee	90	No target time	No target time	1	30	N/A
Approval procedure (Admin)	30-90	<30	<30	<30	30-90	<30
Overall approval time	90	730	270	252 (exc. Applicant time	547	365

Comparison of continuous improvement initiatives in the six regulatory authorities

Quality Measure	Regulatory Authority						
	BURUNDI	KENYA	RWANDA	SOUTH SUDAN	TANZANIA	UGANDA	ZANZIBAR
External quality Audits	x	x	x	x	✓	x	x
Internal quality Audits	✓	✓	✓	x	✓	✓	✓
Internal tracking Systems	✓	✓	x	x	✓	✓	✓
Reviews of assessors' feedback	✓	✓	✓	x	✓	✓	✓
Reviews of stakeholders' feedback	✓	✓	✓	x	✓	✓	✓

RECOMMENDATIONS

Measuring & Monitoring Timelines

Agencies in the EAC-MRH initiative should implement systems that will enhance the measurement and monitoring of timelines for the key milestones of the registration process such as dates of submission, validation, start of scientific assessment, completion of scientific assessment and registration.

Applicants Communication

Clear registration processes should be documented and shared with the applicants as well as publishing timelines, assessment reports, and the summary basis of approval which will facilitate transparency and accountability.

Work-Sharing

The EAC-MRH should develop measures to mandate the registration of products at a national level following regional recommendation. This approach would ultimately lead to faster availability of medicines to patients as well as reducing demand on capacity.

Quality Decision-Making Practices

Although all the agencies indicated they are implementing the quality decision making practices, there is still a need for training and education in this area.