




# Suggested Improvements to the Current East African Community Medicines Regulatory Harmonization Joint Review Process and a Proposed New Review Model for this Initiative

Nancy Ngum<sup>1,2</sup> · Chimwemwe Chamdimba<sup>2</sup> · Dedith Mbonyingingo<sup>3</sup> · Fred Siyoi<sup>4</sup> · Emile Bienvenu<sup>5</sup> · Mawien Atem<sup>6</sup> · Adam Fimbo<sup>7</sup> · David Nahamya<sup>8</sup> · Burhani Simai<sup>9</sup> · Stuart Walker<sup>1,10</sup> · Sam Salek<sup>1,11</sup> 

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## Abstract

**Background** In 2012, the East African Community Medicines Regulatory Harmonization (EAC-MRH) initiative was established to improve access to safe, effective, and high-quality medical products to patients in the East African region. The East African Community (EAC) Partner States, the Republic of Burundi, Democratic Republic of Congo, Republic of Rwanda, United Republic of Tanzania, Republic of Kenya, Republic of South Sudan, and the Republic of Uganda, have a population of 290 million inhabitants. The timely access to medical products for this population was to be achieved through harmonisation of regulatory requirements, joint assessments, joint inspections of manufacturing sites, and the strengthening of regulatory systems. The aims of this study were (1) to investigate ways in which the regional initiative could be a well-coordinated and functioning regional assessment and inspection process on which national registration decisions can rely; (2) to investigate whether a sustainable semi-autonomous regional agency could provide regulatory guidance and coordination for the entire region; and (3) to propose a new and improved model for the EAC-MRH.

**Methods** Three established questionnaires were used to collect and analyse data on the EAC national regulatory authorities (NRAs) and EAC-MRH initiative 2020–2023: (1) The Optimising Efficiencies in Regulatory Agencies (OpERA) questionnaire was completed by senior officials in the seven authorities that were leading the medicine registration departments about their own respective NRA. The heads of authorities of these NRAs further validated the completed questionnaire, which documented the general organisation of the authorities in terms of their structure, organisation, resources, review process, and timelines. (2) The Process Effectiveness and Efficiency Rating (PEER) questionnaire was completed by the seven authorities to obtain the views of the individual medicines regulatory authorities of the EAC-MRH initiative to identify the strengths and challenges regarding the performance of the joint assessment of the EAC-MRH initiative. (3) The PEER questionnaire, modified for the pharmaceutical industry, was completed by the heads of regulatory units in the pharmaceutical companies that had used the EAC-MRH process for the review and approval of their applications.

**Results** The number of applications received for joint reviews increased from nine applications in 2015 to 44 applications in 2023, and the median review time reduced from 553 calendar days in 2015 to 259 calendar days in 2023. A key benefit for pharmaceutical companies using the work-sharing initiative to apply for marketing authorisation was the reduced burden associated with the need to prepare only one application for submission and eventual access to several markets simultaneously.

**Conclusions** The EAC-MRH initiative can only be effective and efficient if the NRAs in the region are operating at an optimal level. Therefore, proposals were made to address the gaps identified in the regulatory review processes of the EAC NRAs and to improve effectiveness and efficiency. Importantly, a centralised submission and tracking process was proposed as the new and improved model for the EAC-MRH initiative.

## Key Points

Data and recommendations from this study on the East African Community Medicines Regulatory Harmonization (EAC-MRH) initiative informed this proposed new improved model for regulatory review.

A centralised submission and tracking process is a key recommended element for a new and improved model for the initiative.

Ensuring legal mandates and sustainable financing among East African Community (EAC) regulatory authorities will enable needed growth in human resources and infrastructure for this important work-sharing programme.

## 1 Introduction

In 2012, the East African Community Medicines Regulatory Harmonization (EAC-MRH) initiative was established to improve access to safe, effective, and high-quality medical products to patients in the East African region. The East African Community (EAC) Partner States, the Republic of Burundi, Democratic Republic of Congo, Republic of Rwanda, United Republic of Tanzania, Republic of Kenya, Republic of South Sudan, and the Republic of Uganda, have a population of 290 million inhabitants [1]. The timely access to medical products for this population was to be achieved through harmonisation of regulatory requirements, joint assessments, joint inspections of manufacturing sites, and the strengthening of regulatory systems. As part of the implementation of one of the provisions of the EAC Treaty on regional harmonisation in health, the EAC Secretariat, in collaboration with the EAC national regulatory authorities (NRAs), established the EAC-MRH project as the regional coordinating body of the African Medicines Regulatory Harmonisation (AMRH) initiative in 2012 [2]. The initial focus of the project was on the registration of generic medical products and later expanded to other medical products and regulatory functions [3]. There has been a limited achievement of these objectives.

To assess the regulatory review process of the EAC-MRH initiative over the last 10 years, a literature review was conducted to understand the factors that can contribute to or have hindered the successful implementation of this initiative. The history of the initiative, the legal framework, the organisational structure, and the operating procedure as well as the challenges and successes of the initiative were documented.

The impact of this work-sharing initiative depends on the uptake of the regional decisions by the national authorities. The work-sharing aspect entails the seven NRAs sharing activities to accomplish a regulatory task. This includes but is not limited to joint assessment of applications for marketing authorisations, joint inspections of manufacturing sites for good practices, joint development of technical guidelines or regulatory standards, and exchange of information. The reasons for the review of the work-sharing initiative were to evaluate the regulatory review processes of the NRAs of the countries in the EAC region and also to identify strengths and challenges of the EAC-MRH initiative.

Several studies [3–5] have highlighted the lack of a legal framework for the EAC-MRH as a fundamental challenge for this initiative. Limited resources and capacity with a fragmented legal framework at both national and regional level are major challenges, and a lack of financial sustainability for this initiative has negatively affected the successful implementation of its activities [6]. The harmonisation initiative is being hampered further by countries having inconsistent regulatory processes and using different technical standards and guidelines as well as the fact that there is no binding legislation [4]. The payment of fees by the manufacturer at the regional and national level is another major challenge, as this has caused a delay in the registration of the regionally recommended products in the countries [2]. Another challenge faced by this initiative is the lack of a tracking system to monitor and capture clear registration timelines at both the country and regional level [5]. This lack of a centralised system for submission and tracking of applications has also been a critical challenge as it has negatively affected transparency and communication with applicants and even amongst assessors. The lack of clarity about the process for submission, different labelling requirements in participating countries, the lack of a centralised system for payment of the application fees to all EAC NRAs, and unequal workloads among member countries are some other challenges that have been identified [5, 7]. These challenges have negatively affected the progress in implementing the EAC-MRH initiative. The aim of this study was to propose a new and improved model for the EAC-MRH.

The aims of this study were (1) to investigate ways in which the regional initiative could be a well-coordinated and functioning regional assessment and inspection process on which national registration decisions can rely; (2) to investigate whether a sustainable semi-autonomous regional agency could provide regulatory guidance and coordination for the entire region; and (3) to propose a new and improved model for the EAC-MRH.

## 2 Methods

The state of EAC regulatory review at both the regional and national levels was first investigated to underpin the development of a proposed new improved regulatory review model for the EAC regional work-sharing initiative. To this effect, a study was conducted for the period 2020–2023. An established structured questionnaire [8] was used to obtain information from the seven NRAs participating in the EAC-MRH. This questionnaire, Optimising Efficiencies in Regulatory Agencies (OpERA), was completed by senior officials in the seven authorities who are leading the medicine registration departments. The heads of authorities of these NRAs further validated the completed questionnaire, which documented the general organisation of the authorities in terms of their structure, organisation, and resources. Furthermore, activities that contribute to measures that would improve transparency and consistency were also reviewed to understand how quality is built into the regulatory review process to enhance good review practices implemented by these authorities [9]. The questionnaire also captured the main steps in the review and approval process and identified the dates for key milestones in the review process [10].

The Process Effectiveness and Efficiency Rating (PEER) questionnaire was completed by senior officials in the seven authorities, and the completed questionnaires were validated by the heads of authorities. This questionnaire was used to obtain the views of the individual medicines regulatory authorities of the EAC-MRH initiative about the performance of the joint assessment initiative to date. It also identified the challenges experienced by the individual authorities throughout the life cycle of the EAC-MRH initiative and then determined the strengths and weaknesses of the initiative, in order to eventually identify ways of improving the performance of the joint assessment and envisage a strategy for moving forward to improve effectiveness and efficiency [7].

The PEER questionnaire, modified for the pharmaceutical industry, was completed by the heads of regulatory units in the pharmaceutical companies that have used the EAC-MRH process for the review and approval of their applications. This questionnaire was used to obtain the views of the pharmaceutical companies about the performance of the joint assessment initiative to date as well as identify the challenges experienced by the pharmaceutical companies throughout the life cycle of the EAC-MRH initiative. Subsequently, this determined the strengths and weaknesses of the initiative and eventually identified ways of improving the performance of the joint assessment initiative as well as envisaged a strategy for moving forward to improve effectiveness and efficiency [5].

The PEER questionnaire was completed by the senior officials responsible for monitoring and documenting regulatory performance metrics in the seven authorities in the EAC-MRH (Burundi, Kenya, Rwanda, South Sudan, Tanzania, Uganda, and Zanzibar), as well as all nine active members of the ZAZIBONA/Southern Africa Development Community (SADC) MRH (Botswana, Democratic Republic of Congo, Malawi, Mozambique, Namibia, South Africa, Tanzania, Zambia, and Zimbabwe) and all seven members of the Economic Community of West African States (ECOWAS) MRH (Burkina Faso, Cote d'Ivoire, Ghana, Nigeria, Senegal, Sierra Leone, and Togo) that participated in the three initiatives that were used for this comparative study. The completed questionnaires were further validated by all the Heads of Agency in the three regions. The questionnaire provided the elements to compare the operating model, review process, and requirements of the three harmonisation initiatives and to compare the successes and challenges of these initiatives as well as identify opportunities for improvement and alignment of the initiatives and develop recommendations for the way forward [11].

The regulatory review processes of the seven NRAs in the EAC region were evaluated and compared for the first time by this research: Burundi Food and Medicines Regulatory Authority (ABREMA), Kenya Pharmacy and Poisons Board (KPPB), Rwanda Food and Drugs Authority (RFDA), South Sudan Drug and Food Control Authority (DFCA), Tanzania Medicines and Medical Devices Authority (TMDA), Uganda National Drug Authority (NDA), and Zanzibar Medicines and Medical Devices Agency (ZMDA).

The results of this study led to a comparison of the NRAs in these countries in terms of organisation of the regulatory authorities and key milestones in the review processes from when an application is received to when it is granted marketing authorisation. Also analysed were the target timelines and number of applications received and approved from 2020 to 2023 based on the type of application, that is new active substances (NASs) or generics, the kind of review model used (full review, verification, or abridged), and the implementation of good review practices. The measures put in place for quality decision making by these authorities during scientific reviews were also examined.

## 3 Results

The two questionnaires (OpERA and PEER-Regulatory) were completed by the Heads of Registration Department of all seven EAC-MRH member countries. In addition, 25 manufacturers were determined to be eligible for this study. There were 11 non-responders in this group, leading to a

56% response rate (14 responders), all of whom completed the PEER-Industry questionnaire. These study participants were distributed into three categories: generics (foreign), that is applicants who manufacture generic medicines outside the EAC region; generics (local), that is applicants who manufacture generic medicines within the EAC region; and innovators, that is applicants who submitted applications for registration of innovator medicines. During the period of study, there were no local innovators. From the results of this study, it was noted that the regulatory review processes of these authorities vary and require further alignment. A point in case is the clock-stop time, that is, the period during which regulatory review stops while an applicant answers regulatory authority questions regarding an application. Clock-stop times vary from authority to authority, making it difficult to compare the actual review timelines against the target timelines. Other differences in regulatory review processes include those of target timelines for review models as well as disparities in target timeline for start and finish of expert committee reviews. The key recommendations from this study were to invest in regulatory systems strengthening, streamline country processes, and minimise the differences that exist within NRAs as these interventions will improve patients' access to safe, high-quality, and effective medical products, especially during the operationalisation of the African Medicines Agency (AMA).

This study also proposed a very important recommendation, which is the need to review the operating model of the EAC-MRH programme so as to identify areas of improvement regarding the effectiveness and efficiency of the initiative. All seven NRAs in the region and 14 out of the 25 pharmaceutical companies who had submitted applications through the EAC-MRH process from 2015 to 2022 participated in this study. This study resulted in the identification of the successes and challenges of the EAC-MRH after 10 years of implementation regarding regulators, the pharmaceutical industry, and patients and proposed measures that

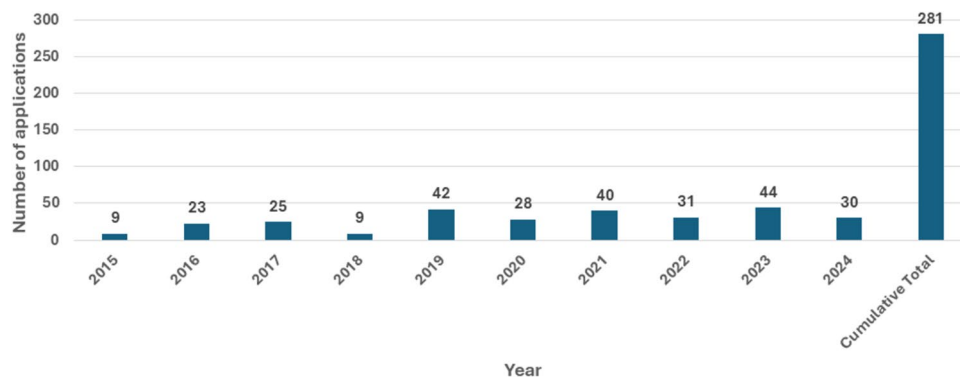
can improve the effectiveness and efficiency of the work-sharing initiative.

### 3.1 Successes of the EAC-MRH

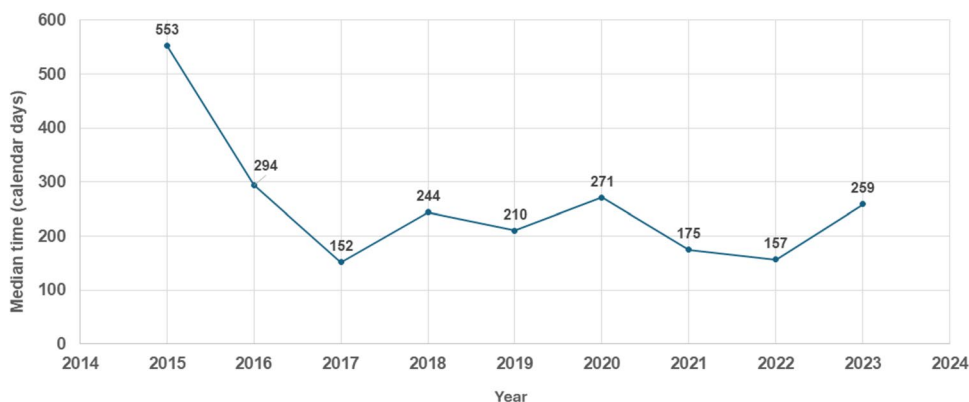
This initiative has developed harmonised technical requirements and guidelines for the regulation of medical products together with a compendium of established common technical documents (CTD) to provide harmonised medicines registration procedures [2]. Median timelines for joint reviews from submission of application to when a decision is made have decreased [3], and the timelines for registration of medical products have also been reduced by almost half [6]. It was affirmed that this initiative has improved regulatory capacity for NRAs in the region, especially as it has provided a platform for information sharing and learning from best practices [5]. A key benefit for pharmaceutical companies using the work-sharing initiative to apply for marketing authorisation was the reduced burden associated with the need to prepare only one application (modules 2–5) for submission to many countries and eventual access to many markets simultaneously [7]. Applicant time and resources are also conserved by the need to prepare only one response package for a consolidated list of queries from many countries. Shorter timelines for approval of applications through the EAC process as compared to some country processes were also identified as a key success factor for the initiative. The benefit of this process for patients is that the harmonised and working efforts have resulted in quicker access to quality-assured medicines and increased availability [7].

Positively, the number of applications received for joint reviews increased from nine in 2015 to 44 in 2023 (Fig. 1). Review timelines have significantly reduced from 2015 to 2023, with a 53% decline in the median time at the NRA level (Fig. 2). The median time represents a positive regional joint assessment including manufacturer and regional

**Fig. 1** Cumulative trend of product applications in the EAC-MRH (2015 to Feb 2024). *EAC-MRH* East African Community Medicines Regulatory Harmonization



**Fig. 2** Median timelines for medicines per year recommended for registration by EAC-MRH (2015–2023). *EAC-MRH* East African Community Medicines Regulatory Harmonization



assessment time for the cohort of applications that received a positive regional assessment in that calendar year.

### 3.2 The Proposed New Improved Review Model for EAC-MRH

To ensure clarity, the results will be presented in three parts: part 1—a proposed improved model for the EAC NRAs; part 2—proposed improvements to the current operating model of the EAC-MRH initiative; and part 3—a proposed new improved model for the EAC-MRH initiative.

#### 3.3 Part 1: Proposed Improved Model to the EAC NRAs

The regulatory review systems of the NRAs in the EAC region need to be strengthened so as to improve the effectiveness and efficiency of the EAC-MRH work-sharing initiative and eventually the AMA when it is operational. These are some proposals for implementation by the NRAs to improve their regulatory review systems.

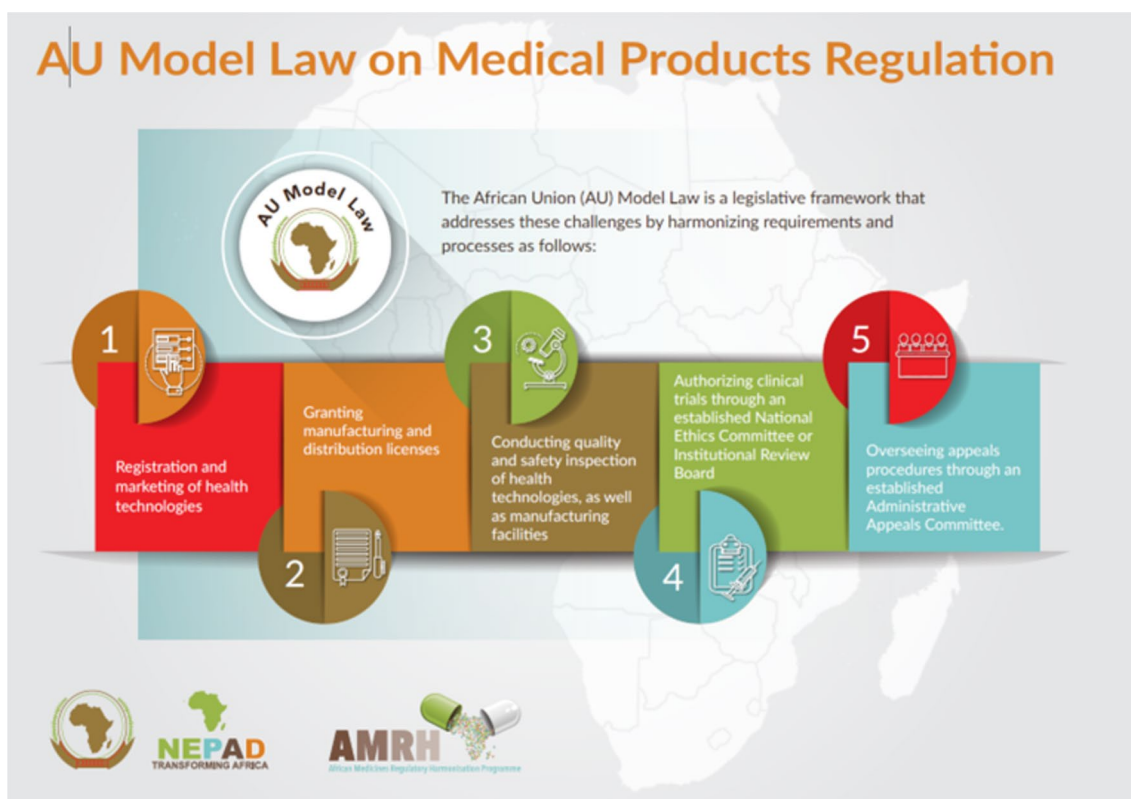
##### 3.3.1 Legal Frameworks

One of the key challenges faced by NRAs that stimulated the establishment of regulatory harmonisation was the fragmented legal frameworks of countries in Africa. The NRAs in the EAC region are called upon to domesticate the African Union (AU) Model Law on Medical Products Regulation [12]. The AU model was endorsed by the AU Heads of State and Governments in 2016. “The purpose of this law is to establish an effective and efficient system of medical products regulation and control and ensure that such products meet required standards of safety, efficacy and quality” [13]. This is a non-prescriptive piece of legislation expected to be domesticated and implemented by all the AU member states and regional economic communities (RECs) with the objectives of increasing NRA partnerships, harmonising regulatory systems, and eventually providing favourable conditions

for increased development of medicines and medical technologies [4] (Fig. 3). It describes the essential features and requirements that must be included in the regulatory system and offers African nations a template for harmonising their regulatory systems [6].

The AU Model Law is also intended to assist countries in incorporating the ability to charge, collect, and utilise fees for services carried out during the examination or enactment of their laws. Collection of fees for the harmonisation initiative has not been implemented yet due to a delay in the development and approval of the sustainability plan for this initiative. The development of the sustainability plan started in 2018 and, due to some political hurdles, was only approved in 2024 by the Sectoral Council. There are ongoing preparatory efforts toward the implementation of fees. Domestication of the law will ensure that the authorities in the region have comprehensive laws for regulation of medical products and eventually facilitate the harmonisation process of the EAC-MRH initiative. Domesticating the AU Model Law will also address the obstacle regarding the delay of national decisions after a regional recommendation due to national laws on reliance. The harmonisation initiative will not have any value if regional recommendations do not translate into countries granting marketing authorisation to the recommended medical products. Legislation that specifically allows for national authorisations based on reliance on documents/recommendations from trusted reference authorities or initiatives (like the EAC-MRH) is key [4].

According to Ncube and colleagues [4], only four NRAs (ABREMA, Burundi; KPPB, Kenya; TMDA, Tanzania Mainland; and ZFDA, Tanzania Zanzibar) out of the seven in the region have domesticated the AU Model Law. Several reasons have been highlighted on why some countries have not domesticated the law: “Lack of human and financial resources, competing priorities at the national level, overlapping roles of government institutions, and the process of amending/repealing laws being slow and lengthy” [4].



**Fig. 3** The AU Model Law on Medical Products Regulation. Source: AUDA-NEPAD website. AU African Union, AUDA-NEPAD African Union Development Agency – New Partnership for Africa’s Development

### 3.3.2 Benefit-Risk Assessment

For NRAs to rely on each other or harmonise medicine regulation, there is a need for them to use standardised templates that will enable quality decision-making processes and transparency. Although regulatory authorities may receive applications that have the same information from manufacturing authorities, they may make different decisions, as most of them use checklists for their review. There is now a growing interest from regulatory authorities to use a more structured approach for decision making and transparency. A consistent and transparent benefit-risk assessment decision is based on a structured flow of information and the systematic approach to assessing the benefits and risks, which is well documented and communicated to relevant stakeholders for accountability purposes [14, 15]. It is important that the key players such as patients, medical practitioners, and regulators identify with the regulatory decisions being made. Nowadays, to improve transparency and accountability and to be in line with good review practices, regulatory authorities are facing a great deal of pressure to implement a systematic and structured approach in making regulatory decisions on the benefit-risk assessments of medical products

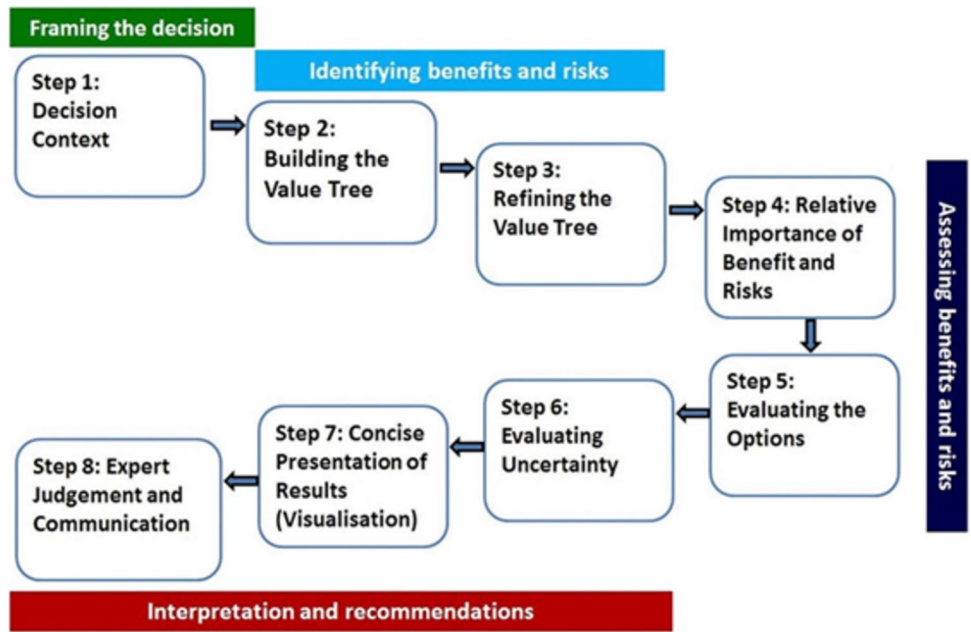
[16]. Regulators are expected to make a balanced judgement regarding the benefits and risks of a new medical product that is being brought to the market and communicate this judgement to the public as one of the measures to enhance regulatory effectiveness [15].

How do authorities in the EAC region document and communicate the benefits and risks of a medical product? The benefit-risk assessment process is not yet implemented in this region. The Centre for Innovation in Regulatory Science (CIRS) has developed an eight-step (Fig. 4) Universal Methodology for Benefit-Risk Assessment (UMBRA) that can be used by NRAs in the EAC region to document benefit-risk assessments in a structured and systematic way [17].

### 3.3.3 Building NRA Capacity

Only one NRA in this study reviews applications on NASs; however, it is important to empower the NRAs to be able to review applications for novel medicines, a capacity that may become increasingly relevant during emergency situations. NRAs should also invest more in human resources to be able to respond in a timely manner to high demands for their services.

**Fig. 4** UMBRA benefit-risk framework. Reprinted [15]. UMBRA Universal Methodology for Benefit-Risk Assessment



**3.3.4 Develop and implement a robust regulatory information management system**

The AMRH programme has recommended a model regulatory information management system (RIMS) for countries that do not have information management systems for use by the NRA. A robust RIMS should be developed by each NRA in the region to provide online and real-time medicine regulation information and support workflow management in the authority, as this will assist in the management of data during the review process. The RIMS should contain metric tools that countries can use to track applications and capture data on key milestones throughout the registration process. NRAs should also implement the electronic common technical document (e-CTD), which is the digitalised way to accelerate assessment reviews. The RIMS should be interoperable and can be integrated with the RIMS of other NRAs in the region and also linked to the regional EAC-MRH system and eventually the continental RIMS when AMA becomes operational (Fig. 5). The Regulatory Information Sharing

Portal (RISP) being developed by the AMRH Programme in African Union Development Agency – New Partnership for Africa’s Development (AUDA-NEPAD) should be able to extract key regulatory information from national RIMS and the regional EAC-MRH system to share at the continental level (Fig. 5). Countries are called upon to develop their websites and make publicly available all products recommended through the MRH process and which are granted marketing authorisation in the country. To ensure effective implementation of RIMS by NRAs, the AMRH Information Management System Technical Committee (IMS TC) has developed a digitalisation strategy for RIMS in Africa to guide countries as they develop their robust information management systems (Fig. 6). It is important for all the EAC NRAs to customize this strategy and use it to develop their systems to enable interoperability of systems in the region.

**Fig. 5** Regulatory information sharing portal (RISP) links to national regulatory authorities (NRAs), regional economic communities (RECs), and African Medicines Regulatory Harmonisation (AMRH)/African Medicines Agency (AMA)

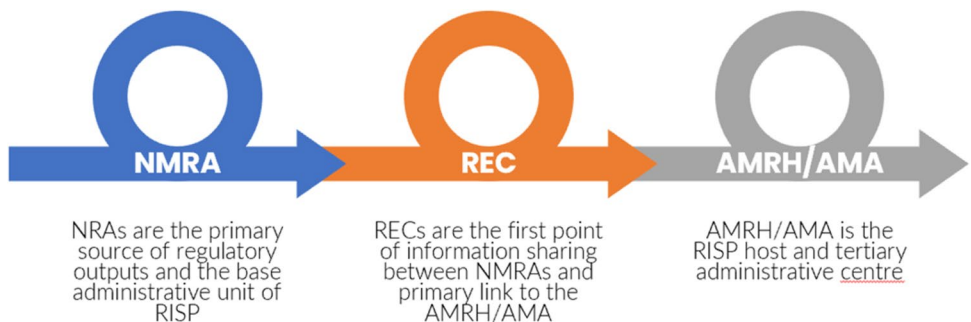




Fig. 6 Six strategic priorities for implementing regulatory information management systems (RIMS) in Africa

### 3.3.5 Implementation of Target Timelines by NRAs

All member states should use 90 calendar days as the target timeline to register products after an application has been received by the NRA after the regional recommendation. A joint recommendation should be made for the application and a joint good manufacturing practice (GMP) inspection conducted or GMP decision made (GMP compliance) before the clock starts. Currently, a great deal of time is often lost when an applicant delays submitting their application to the NRA of interest after the regional recommendation is made, and applicants should be given a target timeline for submitting these applications. Such target timelines have been implemented in the West Africa and Southern Africa work-sharing programme, where a maximum of 2 years and 1 year, respectively, is given to applicants to submit their application to the country of interest after the regional recommendation, after which the application must be re-submitted for review again at the regional level. Part of the reasons for this delay in granting marketing authorisation is that some countries may start their review process again after they receive a regional recommendation. Some countries have different timelines when the scientific committees, meet which might not align with the time when the regional recommendations are made. Using the SADC model, 1 year is being proposed to the EAC-MRH. Countries should track the progress of each application from receipt of application to marketing authorisation.

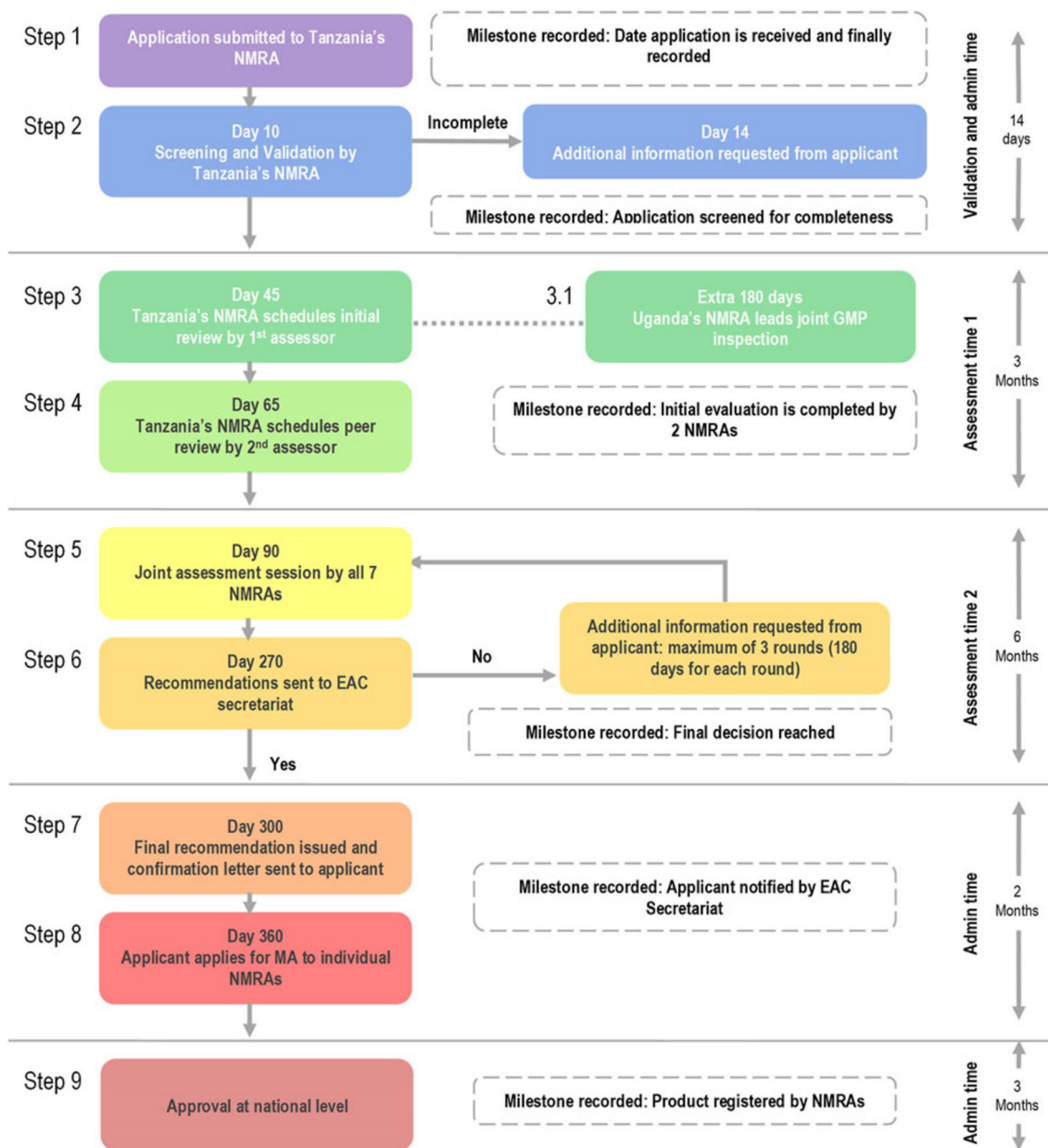
### 3.3.6 Implementation of Reliance

In the EAC region, Tanzania and Rwanda have attained World Health Organization (WHO) Global Benchmarking Tool maturity level 3 (WHO GBT ML3). It is clear that not all countries can attain the ML3 status in the near future, and it is therefore imperative for the NRAs to rely on the more resourced WHO-listed regulatory authorities and the EAC-MRH work-sharing initiative. In a study to evaluate the impact of reliance in an NRA and how it improves patient access to medical products, Danks et al. [18] demonstrated how, through the use of an abridged review for NASs and generics, it reduced regulatory review times from 179 days for a full review to 91 days for an abridged review [19]. Countries in the region are therefore called on to domesticate continental guidelines developed by the AUDA-NEPAD Technical Committees to enhance the harmonisation process.

### 3.4 Part 2: Proposed Improvement to the Current Work-Sharing Operating Model of the EAC-MRH Initiative

The current work-sharing model for the EAC-MRH initiative is shown in Fig. 7. Initially, the EAC-MRH lead authority receives applications for joint review only when the applicant has paid the application fees to two or more countries in the region. A framework should be developed to enable a centralised regional submission and review

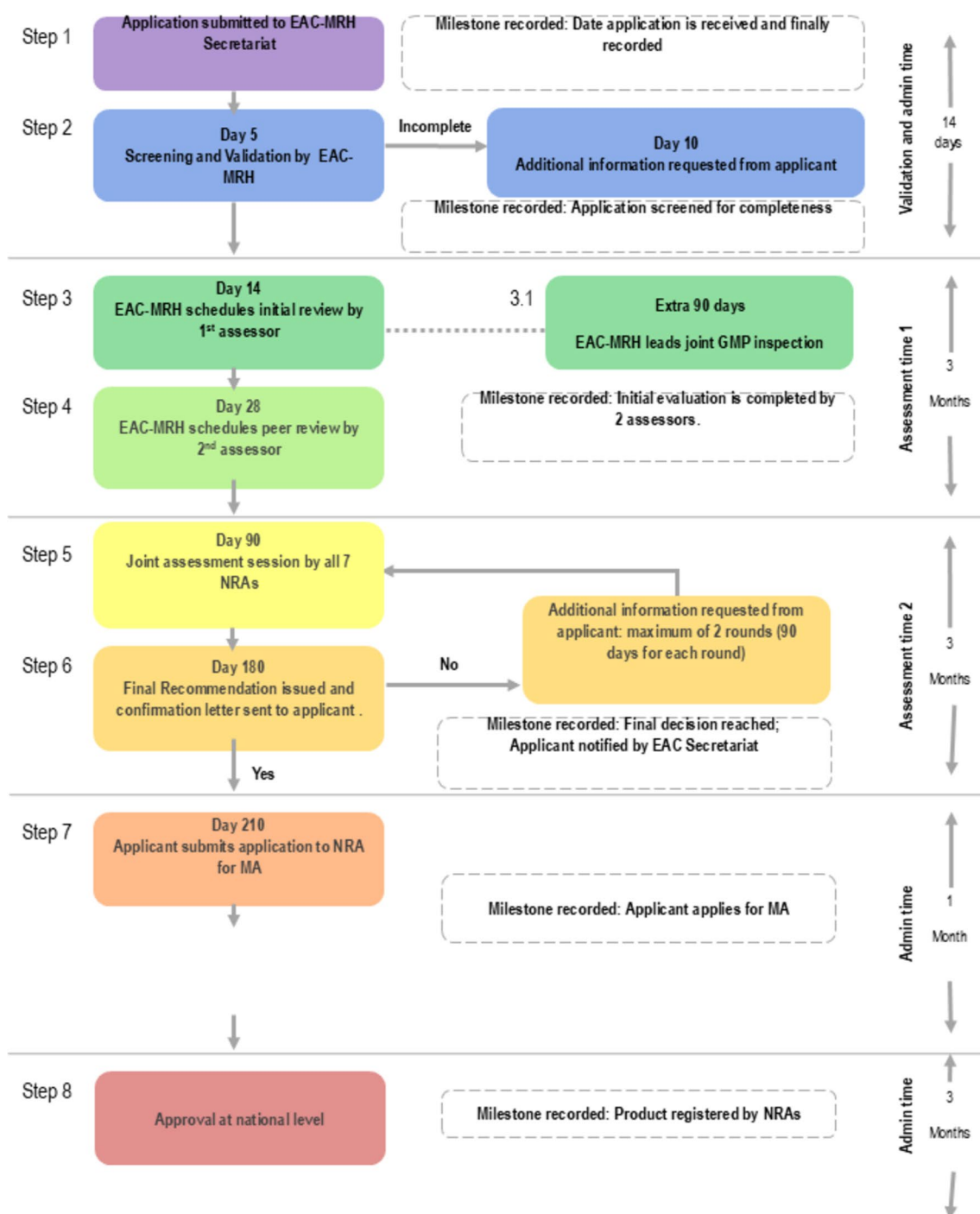




**Fig. 7** Current review process map and milestones for East African Community (EAC) joint assessment procedure. Reprinted [7]. *GMP* good manufacturing practice, *MA* marketing authorisation, *NMRA* national medicines regulatory authority

prior to submission to the individual countries of interest for registration. Consideration should be given to using three routes/procedures for the approval of medical products in the region; that is, a fully centralised procedure, a decentralised procedure, and a national procedure. In each of these approaches, full, abridged, or verification procedures will still be conducted in the revised model. These new procedures will not replace the full, abridged, and verification procedures, but will rather be new legal frameworks under which these three approaches to an assessment can be conducted. In order to enable the creation of

a completely centralised approach similar to that which is implemented in the European Union (EU), it would be necessary for the region to pursue the creation of a regional legally enforceable framework (Fig. 8). Regardless of legislative maturity or capacity, the adoption of the centralised procedure might be made mandatory for some essential medical products to provide appropriate access in all member states. Another advantage of a centralised process is the use of local specialists in central safety monitoring and the assessment of complex items (Fig. 8).



**Fig. 8** Proposed new East African Community Medicines Regulatory Harmonization (EAC-MRH) programme centralised procedure. *EAC* East African Community, *GMP* good manufacturing practice, *MA* marketing authorisation, *NRA* national regulatory authority

### 3.4.1 GMP Inspections

The two routes for applicants for EAC GMP inspection are the country process or the joint inspection process. Joint inspections entail inspectors from the participating countries inspecting a manufacturing site together. Some

delays with GMP are caused when applicants have not paid joint GMP inspection fees but pay the country fees, after which the country initiates the GMP process. Ideally, however, products that are jointly reviewed should be jointly inspected. There are cases where manufacturers or applicants do not submit an application for GMP because

a previous GMP audit is still valid or compliant and they have been inspected by two or three well-resourced NRAs such as the TMDA, KPPB, or NDA. In such cases, the GMP Technical Working Group (TWG) will review the reports of these NRAs that have inspected the site and consolidate the report and then make a recommendation. The GMP lead NRA for EAC-MRH is the NDA and should continue to be pragmatic in combining joint GMP and country processes. It is important to combine regional GMP and national decisions. A document review should be encouraged, especially as the resources are minimal and the standard operating procedures (SOPs) need to be drafted by the technical team.

### 3.4.2 Reliance and Review Model

Reliance mechanisms should be implemented both at the regional and national levels. “The RECs should continue to support and advocate the strengthening of the capacity of their member states using the WHO GBT assessments and other tools such as Optimising Efficiencies in Regulatory Agencies (OpERA) and the Quality of Decision-Making Orientation Scheme (QoDoS) to facilitate inter-country and inter-REC reliance including unilateral and mutual recognition.” Inter-REC reliance should be promoted among the RECs, and if one REC has recommended a product for registration, the other RECs implementing the MRH programme should also rely on this decision, using an abridged or verification review process [19, 20].

A WHO Technical Report in 2021, suggests the use of a standard pathway for marketing authorisation “which entails independent decision making and complete review of the application by NRAs”. This might involve using the CTD format of dossier that has a long registration timeline. The work-sharing pathway allows for possible concurrent or parallel decision making such as REC joint assessments. In addition, it would then be possible to observe and rely on the review in EU-Medicines for all (EU-M4all) or Swissmedic Marketing Authorisation for Global Health Products [21].

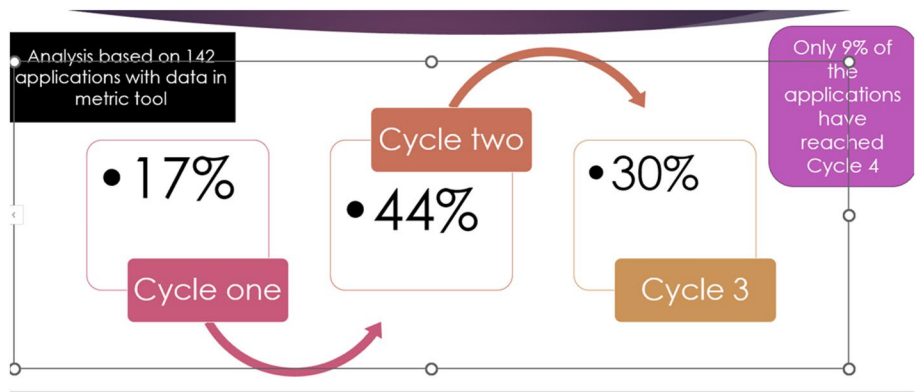
Reliance pathways entail the NRA decision being dependent on those made by trusted regulators, a unilateral or mutual recognition pathway, risk-based pathways, abridged review, verification of sameness review, WHO collaborative registration procedure (CRP), or regional reliance pathways (ZAZIBONA, EAC, ECOWAS).

It is critical to ensure that the MRH initiative has a legal mandate. Moreover, the EAC Compendium, developed in 2014 by the EAC-MRH TWG to provide guidance to the NRAs in managing applications, needs to be revised, as it is now 10 years since these guidelines were developed [22].

### 3.4.3 Set Number of Cycles for the Review Process

Applicants may be slow in responding to queries, thereby delaying the review process, and there is a need to review the query response cycles (round of queries). Currently, four cycles are permitted; however, it is important to reduce the maximum to two query cycles, after which the application should be removed from the process and resubmitted as a new application (Fig. 9). A guideline on time points should be developed and implemented. The NRA time points should be evaluated when all requirements for registration are available, and it is important for metrics to include only regulators’ time at this point so that it is clear on how long regulators take to review a product. The time points for manufacturers to respond to queries should be 60 calendar days for the first queries and 30 calendar days for the second as per the example from the SADC-MRH pilot on a centralised procedure. Furthermore, the manufacturers’ response to the queries from the region review should be sent to all member NRAs. Subsequently, the individual NRAs should market the products that have been jointly reviewed on receiving the regional recommendation. However, if the manufacturer only wishes to market in one or two member estates, they should submit individually to the respective NRAs and not use the regional process.

Fig. 9 Current evaluation process. East African Community report cycle



### 3.4.4 Conduct Stakeholder Consultations for the EAC Work Sharing

It is important to conduct stakeholder consultations in order to attract more applications. It would be helpful to perform online webinars to attract new applicants and to create an awareness of the joint review sessions as well as prepare and share expressions of interest for applicants to submit applications for the joint review. In addition, a coordinating point for country-level engagements should be established and validating exercises conducted to ensure clean and accurate data for each application that is approved available in that country.

### 3.4.5 Capacity Building and Training of Assessors

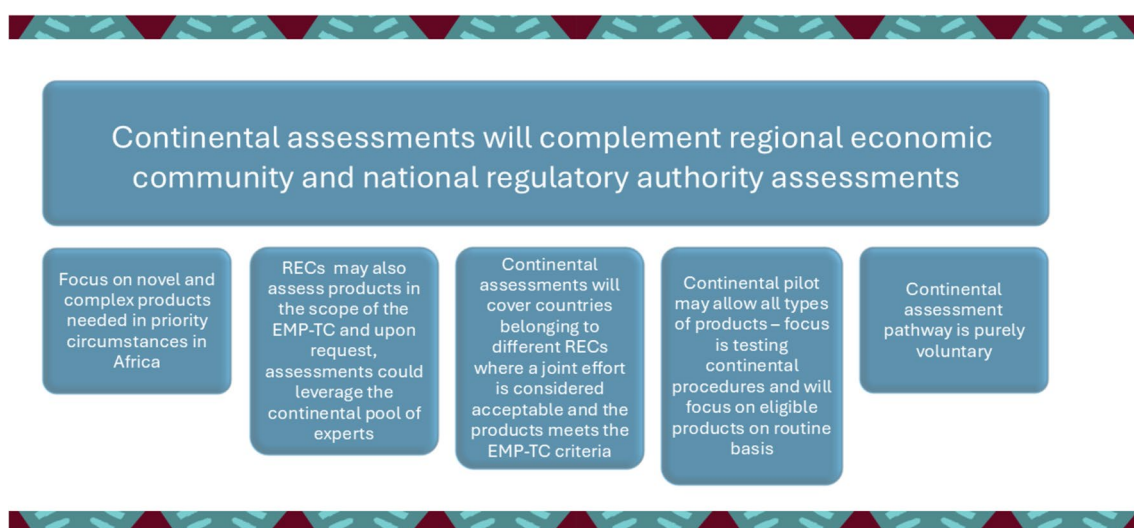
One recommendation is to use the WHO Competency Framework to evaluate the ability of the assessors and identify training needs. It is difficult to track the impact of the training offered to assessors over the years as this has not been monitored and assessors attend training on an ad hoc basis. Each REC MRH should develop a list of training needs for the year, which will be handed to the Regulatory Capacity Development Technical Committee of the AMRH/AMA, who will then coordinate this training, using existing Regional Centres of Regulatory Excellence (RCORE), as well as other training opportunities that are available. It should be noted that a certification scheme for assessors has been established by the University of Witwatersrand, and it is currently sponsored by the Gates Foundation [23].

### 3.4.6 Develop Website and Implement a Regulatory Information Sharing Portal

The MRH programme should publish all recommended products on their websites and implement the AMRH regulatory information sharing portal (RISP) project that will enable them to share regulatory information and knowledge exchange on the continent. An electronic document management system (EDMS) is being developed through RISP that will also assist the RECs MRH to manage applications received and the distribution of the application to the assessors for preliminary review before the joint review meetings are organised.

As indicated in Fig. 10, the RECs information management system will be the interphase between national and continental RIMS. It is important that the EAC-MRH develop a robust information management system that will implement the continental digitalisation strategy at the REC level. The activation and updating of the EAC website to advocate joint activities should also be implemented.

The additional weaknesses and challenges found in the current operating model of the initiative, such as the lack of detailed information for applicants on procedures and the inadequate tracking and monitoring of timelines for products in the participating countries once the joint review is completed, should be addressed by an investment in robust information management systems. By giving the region the authority to disclose this information for interested parties, this investment will increase process openness and confidence. Additional research should be carried out in these areas, which will promote increased transparency and the use of metrics to increase efficiency. It is important to have a centralised online system to make it easier for the applicants



**Fig. 10** The guiding principles of the continental (African Medicines Regulatory Harmonisation/African Medicines Agency) review process. *EMP-TC* Evaluation of Medical Products Technical Committee, *REC* regional economic community

to track their applications and indicate whether they wish to follow a joint or country process. In addition, the AUDA-NEPAD, Trademark Africa, and TMDA IT experts should align efforts to link the metrics used for the EAC-MRH process to the RISP, which is currently under development.

The EAC-MRH should improve the metrics currently being collected. Also, the EAC Secretariat should recruit a biostatistician who can continue to improve the processes for capturing timelines and ensuring understanding.

### 3.4.7 Communication with Applicants

As an initiative that implements a decentralised procedure, EAC-MRH should inform both current and potential applicants at time of submission of the target timelines for the joint review process and emphasise that, similar to other decentralised procedures like those of the European Medicines Agency (EMA) or Australia-Canada-Singapore-Switzerland Consortium (ACCESS), approval timelines in different countries will vary and depend on the national process. Also, the EAC-MRH should implement the practice of publishing an expression of interest as is the situation with the ECOWAS MRH.

### 3.4.8 Define Roles and Responsibilities of the EAC-MRH in the AMA Era

According to the AMA Treaty, RECs have a fundamental role to play in the regulatory ecosystem in Africa. There are three levels of this ecosystem (national—NRA; regional—REC; continental—AMA), each of which will need defined roles and responsibilities to avoid duplication. The roles

of the RECs in the three-tier medicine regulatory system as recommended would include promoting collaboration; coordinating on-going AMRH activities within the region; including regulatory responsibilities for selected activities and supporting NRAs lacking capacity in identified activities; vigilance of products, especially against the movement of substandard and falsified products; providing guidance; providing links between AMA and NRAs; organising joint evaluations, inspections, and other such activities; designation, promotion, strengthening, coordination, and monitoring of RCOEs; and coordinating the collection, management, storage, and sharing of information on medical products, including substandard and falsified medical products.

From the roles and responsibilities highlighted above, a key recommendation from this study is to define a minimum functional package of structure, infrastructure, human resources, policies, and communication that would enable the EAC-MRH to be the gateway for AMA implementation. The suggested priority categories by the AMRH TC on Evaluation of Medicinal Products (EMP TC) for medical products for the continental review is illustrated in Fig. 11.

## 3.5 Part 3: A Proposed New Improved Model for the EAC-MRH Initiative

Based on the outcomes of this research, the key challenge identified that has negatively affected the effectiveness and efficiency of this initiative is the lack of a centralised process for the submission and tracking of dossiers. It is therefore recommended that a centralised submission process be implemented for the EAC-MRH as a new improved model for this initiative (Fig. 8). This will eliminate most



Fig. 11 Priority categories for continental review of medicinal products in Africa (EMP TC)

of the challenges identified in this research and give the EAC-MRH Secretariat a legal mandate to receive and review applications. This will entail the establishment of a Regional Medicines Authority for the EAC. The review process should be simplified and predictable, with proposed timelines that will make the process more attractive over the standard pathway. The guidance on using this centralised process should be a “SMART” initiative especially with the introduction of an electronic process (e-CTD). A centralised process for the payment of fees for joint reviews should be established alongside this process. Instead of having too many entry points, applicants interested to have their applications reviewed through the EAC-MRH should apply directly to the EAC-MRH, after which the review process as per Fig. 8 can start. Health is for all, and this study proposes that manufacturers who choose to use the regional joint review process should submit their applications to all NRAs in the community. This will increase access to medical products, which is the goal of the initiative rather than manufacturers selecting only certain member states and not others. If a manufacturer only wants to market in one of two member states, they should submit individually to those NRAs and not use the regional process.

Milestone one will then be the recording of the date at which the application and screening fees are received (step 1). The centralised submission will eliminate the 7-day deadline given to the countries to submit the applications they have received by the Lead Authority. Instead, screening of the application should be carried out within 5 days after receipt of the application. Screening fees should also be paid during the time of submission of the application. In step 2, the EAC-MRH Secretariat would screen and validate the application. If there is missing information, the applicant would be notified and additional information submitted within 5 days. The EAC-MRH would then assign the application for an initial review by the first assessor by day 14 (step 3).

The centralised process should have a pool of assessors with varied skills who can be called on to conduct the first and the second review of the applications for a fee (step 4). After the application is peer reviewed by the second assessor, a joint assessment can then be planned by day 90 (step 5) for all assessors in the seven NRAs. If the application is an NAS or complex molecule that is not eligible for the continental process (Fig. 11), the Evaluation of Medicinal Products technical committee can be invited to assist with the review. As clearly stated earlier [12], AMA (the continental review) will not replace but only complement the work of the RECs and NRAs. Once operationalised, the AMA will depend on the regions to contribute to its review process. Therefore, the focus of the AMA, for the foreseeable future, will be strengthening its position as a continental agency as well as placing more emphasis on the regional infrastructure,

which would give the regions more jurisdictional power as well as autonomy.

Other reliance mechanisms/review models should be implemented during the joint assessment of dossiers to fast track the review time. Another 90 days should be taken to complete the assessment process after the joint review to obtain additional information from the applicant. Only two rounds should be accepted for query responses. By day 180, a final recommendation should be issued by the EAC-MRH Secretariat and a confirmation letter sent to the applicant (step 6: Fig. 8). Within 30 days after the confirmation letter is sent to the applicant, the applicant can submit the application to the NRA(s) of interest, which will be day 210 of the cycle (step 7). The NRA would be expected to register or grant marketing authorisation within 90 days after receipt of the application, which will be by day 300 of the cycle (step 8).

If we compare the review process map and milestones for the current EAC joint assessment procedure (Fig. 7) and the new proposed EAC-MRH centralised procedure (Fig. 8), a significant reduction in the review timeline would be observed from when the final recommendation is issued and the confirmation letter sent to the applicant by day 180 (Fig. 8) instead of the initial day 300 (Fig. 7). It is only at this stage that the EAC-MRH still has control over the application, after which it is out of the EAC-MRH process and they will not have control over what the applicant does with the letter issued. The applicant could delay the submission of the application for marketing authorisation to the NRA(s) or work within the given time frame of 30 days as compared to the initial 60 days allocated. A comparison of the current and proposed operating models is given in Table 1.

## 4 Discussion

For an effective and efficient work-sharing initiative, it is imperative for the EAC-MRH programme to be institutionalised so that it can have a legal mandate to govern its activities. One of the provisions of the EAC Treaty, Chapter 21, Article 118 has already called for regional harmonisation in health [18]. The Memorandum of Understanding that was drafted at the beginning of this project should be finalised and signed, and then it can be used to develop a cooperation framework amongst the countries. The sustainability plan 2023–2030, which has been discussed in depth by the EAC-MRH countries, should be approved by the Sectoral Council (Ministers of Health of the EAC countries). This plan was tabled in the April 2024 sectorial council meeting for endorsement and approval. If this sustainability plan is implemented, the EAC-MRH initiative will be self-sustainable by 2030 and will not be dependent on donor funds as has been the case to date.

**Table 1** Comparison of the current and proposed operating model

	EAC-MRH current decentralised registration initiative	EAC-MRH proposed centralised registration procedure
Timelines	About 360 days from receipt of application to recommendation for Marketing Authorisation	About 180 days from receipt of application to recommendation for Marketing Authorisation
Governing body	EAC Heads of Agencies EAC Heads of Pharmacy Boards EAC Health Ministers	EAC Heads of Agencies EAC Heads of Pharmacy Boards EAC Health Ministers
Secretariat	EAC-MRH Secretariat with TMDA as Lead Authority for registration and Uganda as lead for GMP inspection	Regional Medicines Authority whose structure will be defined or Regional Medicines Regulatory Unit within the EAC Secretariat
Process	Applications are submitted simultaneously to countries of interest leading to multiple registrations	One central submission leading to one registration
Coordination fees	Multiple fees paid to the countries of interest	Single fee paid for screening and joint reviews and inspections. After recommendation, applicants will then pay fees to NRAs
Assessors	Depend on assessors from 7 NRAs only	Will have a pool of assessors to consult with when the need arises
Technical working groups/expert committees	Human medicines	Human medicines Veterinary medicines Herbal/complementary medicines Others as necessary
Scope	Priority list medicines for managing certain medical conditions. Medical conditions with regard to maternal, neonatal, and children health: HIV, malaria, tuberculosis, reproductive and neurological disorders Neglected diseases: leishmaniasis, pneumocystosis and toxoplasmosis, filariasis, and strongyloidiasis Cancer, diabetes, hypertension, kidney, hepatic, and neurological conditions Prescription medicines from domestic manufacturers within the EAC region Biotherapeutic products and biosimilars	All medicinal products with priority Vaccines, biotherapeutics products, and biosimilars Medicinal products for use during emergencies, epidemics, and pandemics Medicines for management of the following medical conditions: Related to maternal, neonatal, and children health Human Immunodeficiency Virus, malaria, tuberculosis, reproductive and neurological disorders Neglected diseases, leishmaniasis, pneumocystosis and toxoplasmosis, filariasis, and strongyloidiasis Cancer, diabetes, hypertension, kidney, hepatic and neurological conditions Locally manufactured medicinal products within EAC region

*EAC* East African Community, *EAC-MRH* East African Community Medicines Regulatory Harmonization, *GMP* good manufacturing practice, *NRA* national regulatory authority, *TMDA* Tanzania Medicines and Medical Devices Authority

Some articles have been published on the strengths and weaknesses of the EAC-MRH initiative [3, 24] after 8 years of implementation. Another study by Arik and colleagues, (2020), proposed a 2-year (2020–2022) roadmap for the EAC-MRH initiative [25]. There has not been a comprehensive study conducted to examine the performance of the 10 years (2012–2022) existence of this initiative. This is therefore the first time that a study has been conducted to evaluate the effectiveness and efficiency of the current operating model of the EAC-MRH initiative, including the challenges faced, and to identify opportunities for improvement [5, 7]. Considerations should be made for implementation of the centralised model.

## 4.1 Recommendations

The following incentives are recommended:

1. Implement an e-CTD, which will enable transparency and improve trust among stakeholders.
2. Encourage governments to provide incentives such as tax reduction for local manufacturers for raw materials, with a regulation to indicate that products produced locally, needing raw materials, should require zero tariffs.
3. Heads of agencies should provide product marketing authorisation, within a maximum of 90 calendar days following the regional recommendation.

4. Data from the region should be provided to the NRAs together with their recommendation for registration, so the countries can expedite marketing authorisation.
5. Establish a pool procurement mechanism for quality-assured products recommended at the regional level.

## 5 Conclusions

In this study a revised scope has been proposed with detailed indicators defined as to how to measure performance. With sustainable financing, the EAC Secretariat will then be able to recruit the needed human resources and acquire the infrastructure necessary for a centralised process with a regional administrative unit hosted in the EAC Secretariat. The EAC-MRH centralised process will act as an interphase between the national and continental (AMA) review processes. Furthermore, it is hoped that this proposed improved model, if implemented, will assist in addressing some of the gaps and eventually lead to a successful implementation of the EAC-MRH work-sharing programme with minimal challenges.

## Declarations

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**Ethics approval** The study was approved by the Health Science Engineering and Technology ECDA, University of Hertfordshire, United Kingdom [Reference Protocol Number: LMS/PGR/UH/04988].

**Consent to participate** The study participants provided implicit consent for taking part in the study.

**Consent for publication** Not applicable.

**Availability of data and material** The data supporting the results reported in the manuscript can be obtained from the authors.

**Code availability** The software application or custom code can be obtained from the authors, if applicable.

**Author contributions** NN designed the study, collected, and interpreted the results and wrote the draft of the manuscript. CC provided data and reviewed the draft of the manuscript. DM provided data and reviewed the draft of the manuscript. FS provided data and reviewed the draft of the manuscript. EB provided data and reviewed the draft of the manuscript. MA provided data and reviewed the draft of the manuscript. AF provided data and reviewed the draft of the manuscript. DN provided data and reviewed the draft of the manuscript. BS provided data and reviewed the draft of the manuscript. SW designed the study, interpreted the results, and reviewed the draft of the manuscript. SS

designed the study, interpreted the results, and reviewed the draft of the manuscript.

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## Authors and Affiliations

Nancy Ngum<sup>1,2</sup> · Chimwemwe Chamdimba<sup>2</sup> · Dedith Mbonyingingo<sup>3</sup> · Fred Siyoi<sup>4</sup> · Emile Bienvenu<sup>5</sup> · Mawien Atem<sup>6</sup> · Adam Fimbo<sup>7</sup> · David Nahamya<sup>8</sup> · Burhani Simai<sup>9</sup> · Stuart Walker<sup>1,10</sup> · Sam Salek<sup>1,10</sup> 

✉ Sam Salek  
m.s.salek@herts.ac.uk

<sup>1</sup> Department of Clinical and Pharmaceutical Sciences, School of Life and Medical Sciences, University of Hertfordshire, Hatfield, United Kingdom

<sup>2</sup> African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), Johannesburg, South Africa

<sup>3</sup> Burundi Food and Medicines Regulatory Authority (ABREMA), Bujumbura, Burundi

<sup>4</sup> Pharmacy and Poisons Board-PPB, Nairobi, Kenya

<sup>5</sup> Rwanda Food and Drugs Authority, Kigali, Rwanda

<sup>6</sup> Drug and Food Control Authority-DFCA, Juba, South Sudan

<sup>7</sup> The Tanzania Medical Devices Authority (TMDA), Dar Es Salaam, Tanzania

<sup>8</sup> National Drug Authority-NDA, Kampala, Uganda

<sup>9</sup> Zanzibar Food and Drugs Authority (ZFDA), Zanzibar, Tanzania

<sup>10</sup> Centre for Innovation in Regulatory Science, London, United Kingdom

<sup>11</sup> Institute of Medicines Development, London, United Kingdom