A Proposed Improved Model for the East African Community Medicines Regulatory Harmonisation Joint Review Process

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Nancy Ngum · Chimwemwe Chamdimba
Dedith Mbonyingingo · Fred Siyoi Emile Bienvenu
Mawien Atem · Adam Fimbo · David Nahamya
Burhani Simai · Stuart Walker · Sam Salek.



AUDA-NEPAD
AFRICAN UNION DEVELOPMENT AGENCY

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 regulation 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

Study Aim

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;

To investigate whether a sustainable semi-autonomous regional agency could provide regulatory guidance and coordination for the entire region; and

To propose a new and improved model for the EAC-MRH.

Methods

3 Standardised Questionnaires were completed by;

The Head of the Medicine's Registration Division in each of the Seven National Regulatory Agencies (NRAs)

Pharmaceutical Industry Companies that had used the EAC-MRH process for the review and approval of their applications

Results:

Results: Product Applications & Timelines (2015-2024)

- Over the current period there was a continuous improvent in the number of applications submitted (Fig 1)
- Similarly, there was an overall continuous reduction in the review times during the same period (Fig 2)
- It appears that certain efficiency measures were introduced during the pandemic (2021-2022)
- Fig 3 shows the cycles that were implemented by the Region over this period

Fig 1. Cumulative Trend of Product Applications (2015 to Feb 2024)

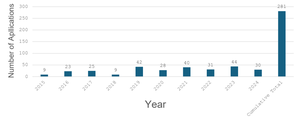
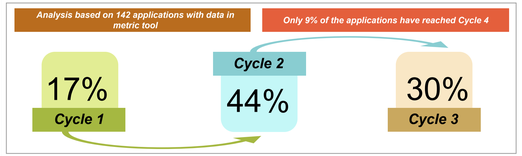


Fig 2. Median timelines for medicines per year (2015 -2023)

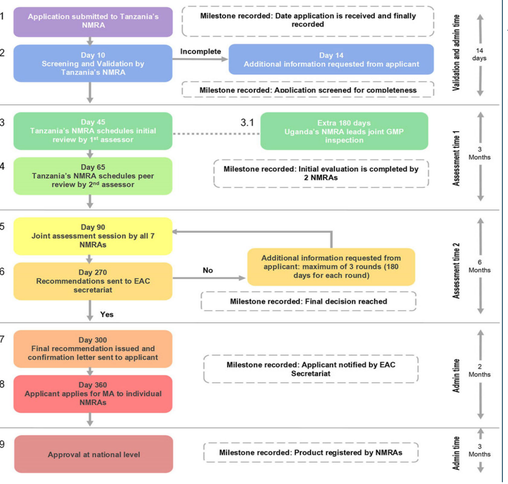
FIG 3. Current Evaluation Process- Cycle



Results- Current Review Process of the EAC.

- The current work-sharing model for the EAC-MRH initiative is shown in Fig. 4.
- A framework should be developed to enable a centralised regional submission and review 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 which would be conforming to the AU Model law for medical products regulation (Fig 5)
- The African Union AU Model law is a legislative framework that addresses these challenges by harmonising requirements and processes (Fig 5)

Fig 4. Current review process map and milestones for East African Community (EAC) joint assessment procedure.



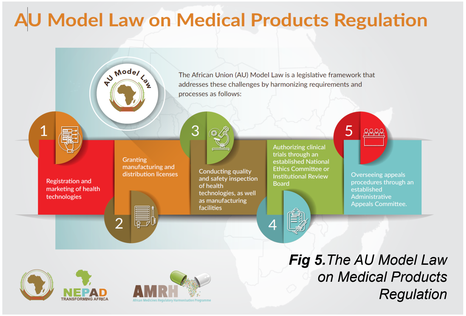


Fig 5. The AU Model Law on Medical Products Regulation

Fig 6. UMBRA Benefit-Risk Framework

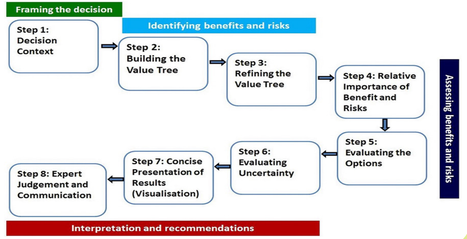


Fig 7. Six Strategic Priorities For Regional Information Management Systems

1. **GOVERNANCE AND STRATEGY** — Ensure digital governance structure that will facilitate digitalisation process is in place
2. **DIGITALISE BUSINESS PROCESS** — Conduct a business process analysis and re-engineering for efficient and maximum optimisation
3. **IMPLEMENT DIGITAL SOLUTION** — Implement RIMS that is efficient, scalable, and interoperable
4. **INTEROPERABILITY STANDARD** — Implement common standard with security and compliance standard
5. **INFRASTRUCTURE & CONNECTIVITY** — Ensure the right infrastructure to drive the digital system is in place with good network connectivity
6. **COMPETENCY DEVELOPMENT** — Ensure a competence framework is established for sustainability and adoption

Results- Additional Considerations for the Proposed Model

- In order to move towards a progressive regulatory process, consideration should be given to implementing a framework and documentation system for the benefit risk assessment for New Active Substances. (Fig 6)
- The foundation of a progressive regulatory process is underpinned by a robust Information Management System. Therefore, six strategic priorities were taken into consideration for the development of the new proposed model (Fig 7)

Results-Proposed new model for EAC

- 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 approach be implemented for the EAC-MRH as a new improved model for this initiative. This will eliminate most of the challenges identified in this research and give the EAC-MRH Secretariat a legal mandate to receive and review applications. (Fig 8)
- The differences between the current and proposed model for the EAC regional EAC process are encapsulated in Tables 1 & 2.

Fig 8. Proposed new East African Community Medicines Regulatory Harmonization (EAC-MRH) Model.

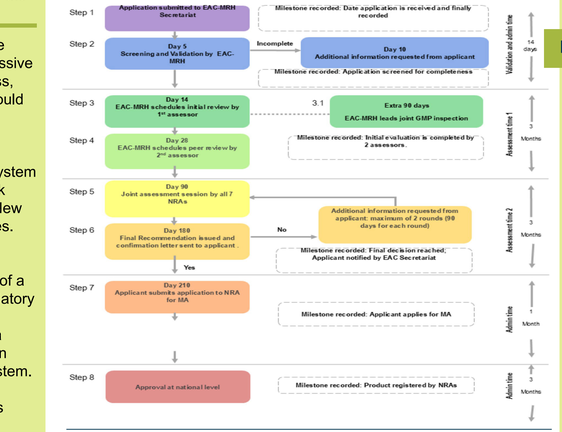


Table 1: Comparing of the Current and Proposed Operating Model

	EAC-MRH current decentralized registration Initiative	EAC-MRH proposed Centralised registration procedure
TIMELINES	About 360 days from receipt of application to recommendation for MA	About 180 days from receipt of application to recommendation for MA
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 Agency for registration and Uganda as lead for GMP inspection	Regional Medicines Agency whose structure will be defined.
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
ASSESSORS	Depend on Assessors from 7 NRAs only	Will have a pool of assessors to consult with when the need arise
TECHNICAL WORKING GROUPS/EXPERT COMMITTEES	Human Medicines	• Human medicines • Veterinary medicines • Herbal/Complementary medicines • Other as necessary

Table 2. Comparing of the Current and Proposed Operating Model

	EAC-MRH current decentralized registration Initiative	EAC-MRH proposed Centralised registration procedure
SCOPE	Priority list medicines for managing certain medical conditions. • Medical conditions with regards to maternal, neonatal and children health o HIV, malaria, tuberculosis, reproductive and neurological disorders o Neglected diseases: leishmaniasis, pneumocystosis and toxoplasmosis, filariasis, and strongyloidiasis o Cancer, diabetes, hypertension, kidney, hepatic, and neurological conditions • Prescription Medicines from Domestic Manufacturers within the EAC region • Biotherapeutics Products and Biosimilars	All medicinal products with priority to; • Vaccines, Biotherapeutics products and Biosimilars • Medicinal products for use during emergencies, epidemics and pandemics • Medicines for management of the following medical conditions; o Relatated to maternal, neonatal and children health; o HIV, malaria, tuberculosis, reproductive and neurological disorders; o Neglected diseases, leishmaniasis, pneumocystosis and toxoplasmosis, filariasis, and strongloidiasis o Cancer, diabetes, hypertension, Kidney, hepatic and neurological conditions o Locally Manufactured medicinal products within the EAC region.

Recommendations

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.