East African Community

One People, One Destiny

EAST AFRICAN COMMUNITY MEDICINES REGULATORY HARMONIZATION (EAC MRH) PROGRAMME

East African Community Pharma Stakeholder's Consultation Workshop, Nairobi- Kenya, November 2017

JOINT REGULATORY PROCEDURES

Improving access to safe, efficacious and quality medicines

The East African Community Medicines Regulatory Harmonization (EAC-MRH) Program is promoting a streamlined and standardized approach in assessment of safety, quality and efficacy of medical products and health technologies. before all EAC Partner States NMRA grants market authorization. The EAC Joint Assessment Procedure is an efficient way to introduce innovative medical products for treatment of conditions of public health importance, reduce duplication of efforts and is less costly to both Pharmaceutical Manufacturers and Governments. The program employs scientific based assessment, inspections and principles of work and information sharing, convergence and reliance on regulatory decisions

Scope of Joint Regulatory Activities:

The program seeks to harmonize key regulatory functions/activities to include; Medicines Evaluation and Registration, GMP assessments (Inspections and Desk reviews), Pharmacovigilance, Post Market Surveillance and Clinical Trials Oversight.

This brochure focuses on the EAC joint assessment and joint GMP procedure for Marketing Authorization.

Why the Joint Process

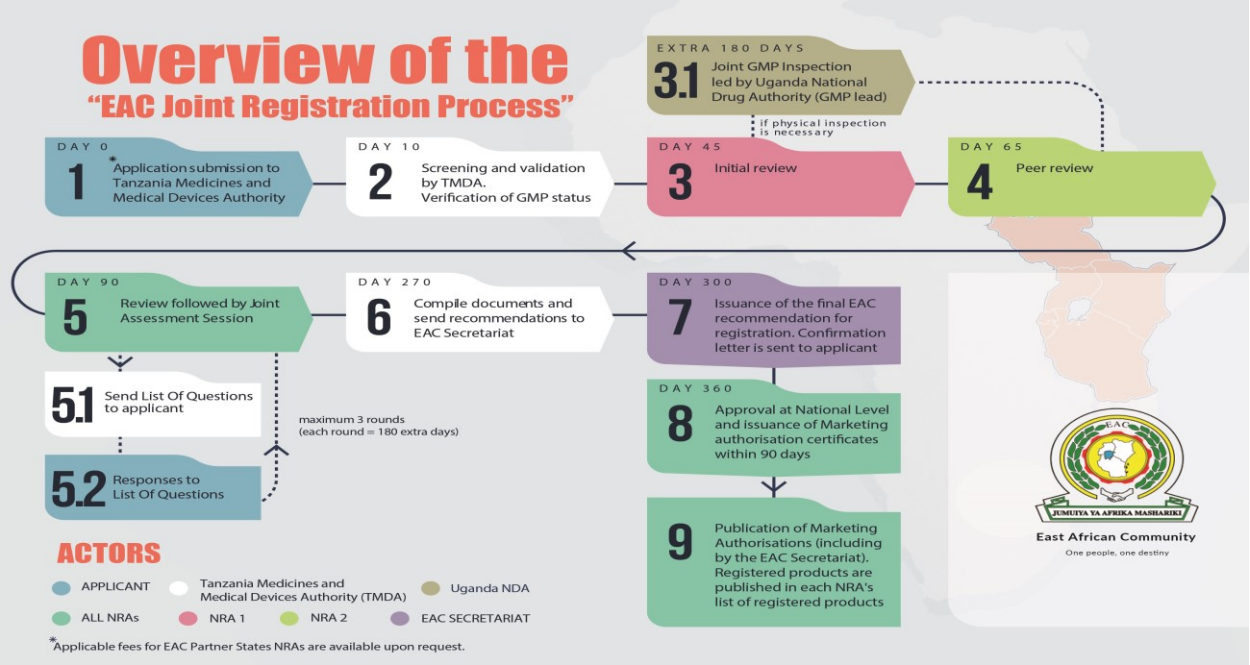
- Single point of contact in submission of dossiers
- Efficient and predictable process
- Provide access to larger market
- Final decision is valid in all EAC Partner States NMRAs
- Cost reduction to all parties

How to Participate

i. Applicant responds to Expression of Interest issued by the East African Community Secretariat; or,
ii. Marketing Authorizations and GMP Applications filed in more than one NMRA (common applications) are eligible upon consenting to the joint procedure by the applicant

N.B: Participation to the above process is voluntary

13th EAC MRH Programme Steering Committee meeting, Dar es Salaam, July 2018



- Submit an application to the lead NMRA -Tanzania Food and Drug Authority (TFDA);
- Screening will be conducted and applicant notified within 14 days
- If the dossier is complete, the application will be scheduled for joint assessment
- Dossier assessment will be conducted within three months following successful screening
- Evaluation of additional data conducted within two months of receipt (Maximum of *three rounds of queries is permitted)*
- Following successful dossier evaluation and compliance with Good Manufacturing Practices, the experts will make recommendation to EAC Secretariat
- The EAC Secretariat issue a confirmation letter to the applicant/manufacturer
- National approval granted within three months from the date of joint acceptance.
- The respective EAC Partner States NMRAs will issue certificates, which confirms the final registration outcome.
- Registered products shall be maintained in each NMRA's list of registered products.
- The EAC Partner States NMRAs will monitor safety and quality of the products in line with the national policies and regulations.

EAC Joint Good Manufacturing Practice Inspections

Initiation of EAC joint GMP is through three mechanisms;

- An official request from a manufacturer;
- A joint interest of at least two EAC Partner States NMRAs
- A joint procedure in the framework of a multiple application for marketing authorization to more than one NMRAs.

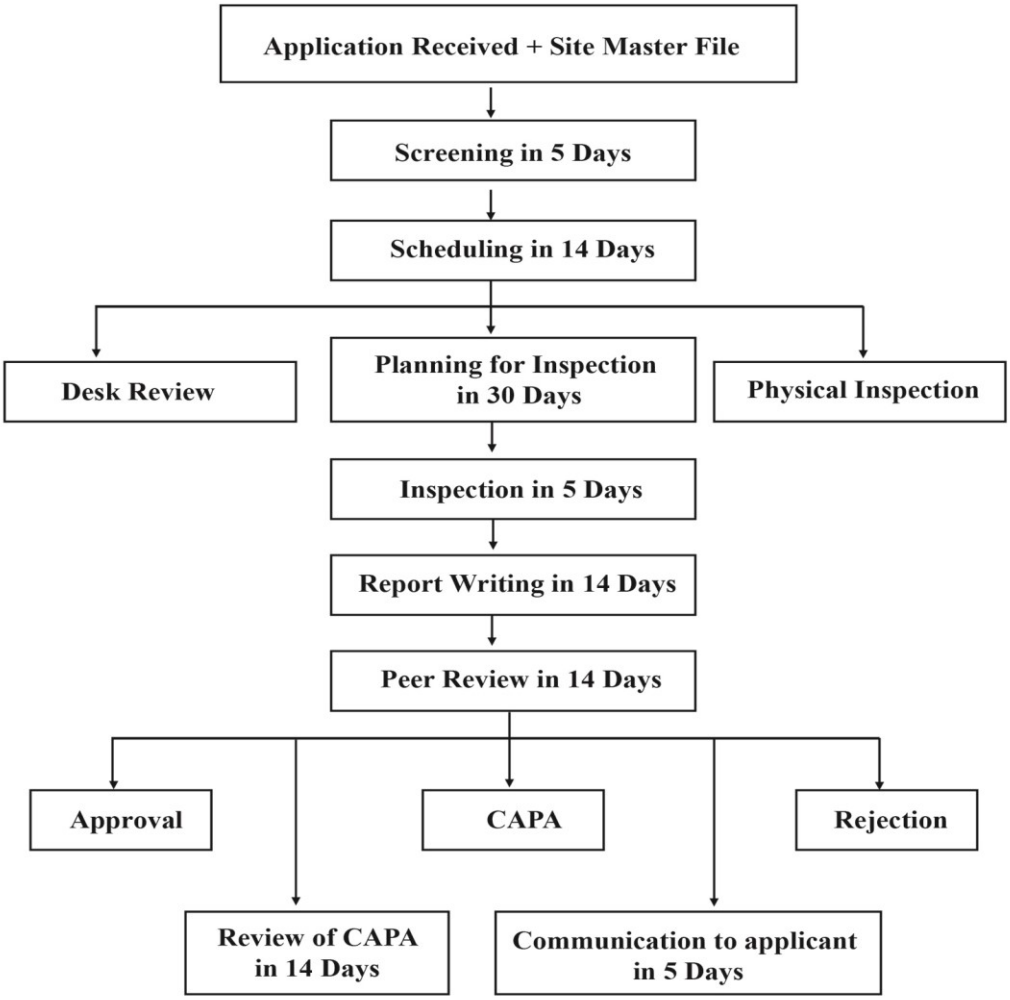
What to do

i. Submit an application including the Site Master File and the applicable fees to the lead NMRA National Drug Authority, Uganda
ii. Communication of the Inspection dates will be done within 14 days by the lead NMRA
iii. Site visit and inspection will be done within 30 days from the day of scheduling
iv. Communication of the outcome of inspection will be within 42 working days from the dates of inspection
v. Review of CAPA and responses by the applicant will be done within 90 days
vi. The letter, which confirms the final Inspection outcome will be communicated by the EAC Secretariat
vii. National approval granted within three months from the date of joint acceptance.

viii. The respective EAC NMRAs will issue the certificate, which confirms the final inspection outcome.

ix. EAC NMRAs will maintain the list of inspected sites and continue to monitor compliance to EAC GMP Standards

EAC JOINT GMP INSPECTIONS FLOW CHART



Applicable fees for joint assessment

Applicable fees for the Republic of Uganda (NDA) and United Republic of Tanzania (TFDA) can be accessed through the link;

https://www.nda.or.ug/ndpa-act-regulations/

https://www.tfda.go.tz/index/sites/default/files/Fees.pdf

Applicable fees for other EAC Partner States NMRAs are available at their offices upon request.

Contacts Information of EAC Partner States NMRAs & EAC Secretariat

Tanzania Food and Drugs Authority
Tel: +255 22 2450751/+255 685 701 735

Email: eacmrh@tfda.go.tz

National Drug Authority
Kampala, Uganda
Tel: +256414255665
Email: eacmrh@nda.or.ug

Zanzibar Food and Drugs Board
Zanzibar, Tanzania
Email: eac.mrh@zfda.go.tz

Kenya Pharmacy and Poisons Board
Tel: +254-720 608 811
Email: eac.mrh@pharmacyboardkenya.org

Department of Pharmacy Medicines and Laboratories
Bujumbura, Burundi
Mobile: +257-71 436 847
Email: dpml.eacmrh@gmail.com

South Sudan Drug and Food Control Authority
Juba, South Sudan
Email: baak211@gmail.com

IV. **Rwanda FDA**
Kigali, Rwanda
Email : cirasabwa@rwandafda.gov.rw

East African Community Secretariat

Tel: +255-27-2162100/ +255 754 775 335
Email : jmashingia@eachq.org