EAST AFRICAN COMMUNITY

MEDICINES REGULATORY HARMONIZATION (EAC-MRH) INITIATIVE

NOTICE TO APPLICANTS, JUNE 2020

INVITATION FOR EXPRESSION OF INTEREST (EOI) – SUBMISSION OF APPLICATIONS FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

1. As part of implementation of provision of EAC Treaty on Regional Cooperation on Health, Chapter 21, Article 118, the EAC Secretariat in collaboration with EAC Partner States National Medicines Regulatory Authorities (NMRAs) initiated the process of harmonizing requirements for the regulation of medicines with the primary goal of improving access to safe, efficacious and good quality medicines in the region.

2. The East African Community Medicines Regulatory Harmonization (EAC-MRH) Initiative is implemented collaboratively by all the seven (7) NMRAs in the region, namely: Department of Pharmacy, Medicines and Laboratories (DPML) - Republic of Burundi; Pharmacy and Poisons Board (PPB) - Republic of Kenya; National Drug Authority (NDA) - Republic of Uganda; Rwanda Food and Drugs Authority (Rwanda FDA) – Republic of Rwanda; Drug and Food Control Authority - Republic of South Sudan; Tanzania Medicines and Medical Devices Authority (TMDA) and Zanzibar Food and Drugs Agency (ZFDA) - United Republic of Tanzania.

3. The following procedures will be undertaken under the EAC Joint Regulatory review;

(i) Evaluation of product dossiers

(ii) Joint inspection of manufacturing sites/desk review, according to the EAC Guidelines on Good Manufacturing Practices (GMP);

(iii) Joint inspections of clinical sites (if applicable), according to the Good Clinical Practices (GCP).

(iv) Joint post-marketing quality surveillance and safety reporting

(v) Enforcement of regulatory decisions

4. Priority list of Products

The EAC has widened the scope of priority list to include common mapped applications already submitted to at least two NMRAs, biotherapeutics and biosimilars. Interested applicants are invited to submit applications for all medicinal products, however the priority shall be given to the following:

i. Priority list medicines for management of the following medical conditions
   a) Medical conditions with regard to maternal, neonatal and children health
   b) HIV, malaria, tuberculosis, reproductive and neurological disorders
   c) Neglected diseases: leishmaniasis, pneumocystosis and toxoplasmosis, filariasis, and strongyloidiasis
   d) Cancer, diabetes, hypertension, kidney, hepatic, and neurological conditions

ii. Prescription Medicines from Domestic Manufacturers within the EAC region

iii. Biotherapeutics Products and Biosimilars

NOTE:

a) Common mapped applications in at least two EAC Partner States NMRAs
b) Applicants are invited to submit EOI for medicinal products, which are not WHO prequalified, and for which they do not intend to submit to WHO's Prequalification Program in the future.
c) Applicant will have a period of two (2) years to introduce the product to all EAC Partner States following a positive outcome by paying applicable fees to the respective country.

5. Submission of applications

An application qualifies for the EAC Joint Assessment Procedure following an expression of interest and payment of the relevant fees in at least two (2) NMRAs. All applications shall be submitted to the lead NMRA on Medicines Evaluation and Registration – Tanzania Medicines and Medical Devices Authority and EAC Partner States NMRAs. while GMP inspections applications shall be submitted in parallel to the Lead NMRA in GMP inspections - The National Drug Authority - Uganda

Following successful assessment, applicants are urged to meet national requirements for marketing authorization in the remaining Partner States within two years of recommendations through EAC Joint Procedure. Please note that the submitted product dossier application shall be as accepted by EAC Joint Assessment. The final regulatory decision on the outcomes of the joint assessment is taken by EAC Partners States NMRAs.

6. Procedures and timelines for the EAC Joint Procedure

The procedures and timelines are described in the EAC procedure for marketing authorization of medicines, and the attached EAC Brochure on Joint regulatory Procedures available at EAC Secretariat and EAC- Partner States NMRAs websites. In an effort to reduce the market authorization timelines, it is expected that the process will take 181 working days of the regulators time and at least 180 calendar days applicant's time with a maximum of three query cycles.

7. **Invitations for Expression of Interest (EOI)**

The EAC Secretariat in collaboration with EAC Partner States NMRAs is now inviting applicants to submit medicinal products applications for consideration under the EAC joint evaluation scheme through medicines@tmda.go.tz.

8. **Fees structures and payment methods**

All chargeable and payable fees towards regulatory services offered by the Partner States NMRAs, will be paid through individual NMRAs. EAC Coordination Fee is as indicated in Table 1 and Table 2 below. For more information, please contact EAC Regional Technical Officers and EAC Secretariat.

Table 1: EAC Coordination Fees for Assessment of Human Medicines Applications & Active Pharmaceutical Ingredient

S/N	**Product/service**	**Imported medicines (USD)**	**Domestic manufactured medicines (USD)**
1	Screening fee	**500**	**250**
2	Joint coordination fee for assessment of new human medicines (conventional and herbal)	**1,500**	**750**
3	Joint coordination fee for assessment of Biologicals	**2,500**	**1250**
4	Joint coordination fee for assessment fee for variations of registered medicines: (a) Major variation (b) Minor	 **900** **350**	 **450** **250**
5	Joint coordination fee Active Pharmaceutical Ingredient Master File Procedure (APIMF) and inspection	**10,000**	**5000**

Table 2: EAC Coordination Fee for Joint GMP Inspections

Fee Structures per site	**EAC**	**Rest of Africa**	**Rest of the World**
Joint GMP Inspection Fee	500	1,000	1,500

9. Contacts for EAC Partner States National Medicines Regulatory Authority Focal Persons & EAC Secretariat

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