EAST AFRICAN COMMUNITY
MEDICINES REGULATORY HARMONIZATION PROGRAMME (EAC-MRH)

EOI No: **001** Date: **July 2021**

INVITATION FOR EXPRESSION OF INTEREST (EOI) – SUBMISSION OF ACTIVE PHARMACEUTICAL INGREDIENT MASTER FILE (APIMF) TO THE EAC.

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 increasing access to and affordability of safe, efficacious and good quality medicines in the region.

2. The East African Community Medicines Regulatory Harmonization (EAC-MRH) programme is implemented collaboratively by all the seven (7) NMRAs in the region, namely: National Medicines Regulatory Authority (ABREMA) - 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 (DFCA) – Republic of South Sudan; Tanzania Medicines and Medical Devices Authority (TMDA) and Zanzibar Food and Drugs Agency (ZFDA) - United Republic of Tanzania.

3. In a bid to facilitate product evaluation by NMRAs and thereby shorten the time for marketing authorization of finished pharmaceutical products across the EAC region, the EAC-MRH programme has introduced a scheme that enables certification of APIs following APIMF assessment and acceptance to avoid duplication of work and minimize different outcomes of evaluation in EAC. Once the submitted APIMF is considered adequate and acceptable after assessment, the API will be included in the EAC approved APIMF data base. Upon API certification, an EAC Certificate of Approval (EACCA) will be issued to the applicant and the API will be included on the EAC list of certified APIs.

4. The accepted EAC-APIMF or the EAC Certificate of Approval (EACCA) will be acceptable in supporting marketing authorization of the finished product consisting of the same API within the EAC partner states. The APIMF holder should provide a letter of access along with the open part of the APIMF to the relevant finished product

applicant applying for marketing authorization of finished product in the EAC Partner States. The Holder of EAC Certificate of Approval (EACCA) should provide the certificate along with its annexures to the relevant finished product applicant applying for marketing authorization of finished product in the EAC Partner States.

5. The EAC Secretariat in collaboration with EAC Partner States NMRAs is now inviting applicants to submit Expression of Interest (EOI) for applications that will be jointly assessed by NMRAs in the region. The submission procedure, joint assessment and approval procedure are described in the EAC procedure for APIMF submission and API certification available at EAC-NMRAs and EAC websites.

6. Assessment of applications submitted under this invitation will include;
   (i) Evaluation of APIMFs, which shall cover drug substance data and information as specified in the EAC Guideline on submission of EAC – Active Pharmaceutical Ingredient Master File (EAC-APIMF) for API certification and the EAC Guideline on Submission of Documentation for Registration of Human Medicinal Products for preparation of marketing authorization application in the technical common document (CTD) format;
   (ii) Joint inspection of manufacturing sites/desk review, which shall adhere to EAC Guidelines on Good Manufacturing Practices (GMP)

7. Interested applicants are invited to submit applications for all drug substances (APIs), however the priority shall be given to the following:
   (i) Drug substances for manufacture of medicines for maternal, neonatal and children health
   (ii) Drug substances for manufacture of medicines for neglected diseases such as leishmaniasis, pneumocystosis, toxoplasmosis, filariasis and strongyloidiasis
   (iii) Drug substances for manufacture of anticancer medicines
   (iv) Drug substances for manufacture of antidiabetic medicines
   (v) Drug substances for manufacture of antihypertensive medicines
   (vi) Drug substances for manufacture of Prescription only Medicines (POM) from domestic manufacturers within the EAC region
   (vii) Drug substances for manufacture of antiretroviral, antimalarial, antituberculosis medicines and reproductive health medicines
   (viii) Drug substances for manufacture of medicines for renal and hepatic disorders.

8. Submission procedure

   The application package consisting of application form for the APIMF procedure and the APIMF will be submitted to the lead NMRA on medicines evaluation and registration – Tanzania Medicines and Medical Devices Authority (medicines@tmda.go.tz) while the application package consisting of filled GMP inspection application form and necessary documentation to facilitate GMP inspection will be submitted to the lead NMRA on GMP – Uganda National Drug Authority with evidence of payment. For an application to qualify for the EAC assessment, an applicant should have expressed interest and paid the relevant fees (covering assessment and GMP inspection) to the EAC secretariat.

9. Fees structure and payment methods:

All chargeable and payable fees will be paid to the EAC secretariat. EAC Coordination Fees for Active Pharmaceutical Ingredient:

S/N	**Product/service**	**Imported medicines (USD)**	**Domestic manufactured medicines (USD)**
1	Joint coordination fee Active Pharmaceutical Ingredient Master File Procedure (APIMF) and inspection	**10,000**	**5000**

More information on payment should be obtained from eacmrh@eachq.org, mashingiaj@eachq.org and amsuya@eachq.org.

10. Contact Information for EAC Partner States NMRAs and EAC secretariat;

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