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

NOTICE TO APPLICANTS, AUGUST 2019

INVITATION FOR EXPRESSION OF INTEREST (EOI) – SUBMISSION OF APPLICATIONS FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS IN 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: 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 FDA; Drug and Food Control Authority – Republic of South Sudan; Tanzania Food and Drugs Authority (TFDA) and Zanzibar Food and Drugs Agency (ZFDA) - United Republic of Tanzania. The World Health Organization (WHO) and The Swiss Therapeutic Agency (Swissmedic) provide expert advice to the NMRAs on matters related to regulation of medical products. The final decision on the outcomes is by EAC experts and Heads of National Medicines Regulatory Agencies.

3. The ultimate aim of this 3rd EOI is to further urge applicants to submit medicinal products applications for consideration under the EAC joint evaluation scheme, in availing medicines for the treatment of diseases of importance for the EAC region. We would like applicants to note that following a comprehensive evaluation of the joint assessment process at the end of 2017 by the Boston Consulting Group and identification of areas of improvement, these have been addressed and the process has been streamlined to bring efficiencies (see brochure accompanying this EOI).

4. 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 all NMRAs in the region. The submission procedures, joint assessment and approval procedure are described in the EAC procedure for marketing authorization of medicines available at EAC-NMRAs websites and www.mrh.eac.int.

5. Assessment of applications submitted under this invitation will include:

(i) Evaluation product dossiers, which shall include product data and information as specified in the EAC Guidelines 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);
(iii) Joint inspections of clinical sites (if applicable), which shall adhere to Good Clinical Practices (GCP).

6. Interested applicants are invited to submit applications for all medicinal products, however the priority shall be given to the following:

(i) Medicines for maternal, neonatal and children health
(ii) Proposed paediatric formulations
(iii) Anti-neoplastics and Immunosuppressive for children
(iv) Medicines for neglected diseases: Anti-leishmaniasis, Anti-pneumocystosis and anti-toxoplasmosis, Anti-filariasis, Anti-strongyloidiasis
(v) Anti-cancer medicines
(vi) Anti-diabetic medicines
(vii) Anti-hypertensive medicines
(viii) Prescription Medicines from Domestic Manufacturers within the EAC region
(ix) Anti- retroviral, anti-malarial, anti-tuberculosis medicines and reproductive health medicines
(x) New chemical entities (molecules) entering the EAC market.

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.

7. Submission procedure

For an application to qualify for the EAC Joint Assessment Procedure an applicant should express interest and pay the relevant fees in at least two (2) NMRAs. All applications including product dossiers, samples and site master files are submitted to EAC NMRAs following a procedure laid down in '***EAC Guidelines on Procedural Aspects for Applications for Marketing Authorization of Pharmaceutical Products'***. All applications under the EAC joint Scheme will be submitted to the lead NMRA on Medicines Evaluation and Registration – Tanzania Food and Drug Authority.

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 designated Bank Accounts. Additional information is available at the NMRAs websites as below:

Table I:

S/no	Regulatory Authority	Partner State	Website/Link
I	Department of Medicines and Medical Laboratories	Burundi	*ebamenyekanye@gmail.com*

Ii	Pharmacy and Poisons Board	Kenya	***https://practice.pharmacyboardkenya.org***
Iii	Rwanda FDA	Rwanda	***http://www.moh.gov.rw***
Iv	Drug and Food Control Authority	South Sudan	***http://www.dfcass.org***
V	Tanzania Food and Drug Authority	United Republic of Tanzania (TFDA)	***http://www.tfda.go.tz***
Vi	Zanzibar Food and Drug Agency	United Republic of Tanzania (ZFDA)	***http://www.zfda.go.tz***
Vii	National Drug Authority	Uganda	***https://www.nda.or.ug***
Viii	EAC Secretariat	EAC	***http://www.mrh.eac.int***

9. Contacts for EAC Partner States National Medicines Regulatory Agencies Focal Persons

Contacts Information of EAC Partner States NMRAs

I. **Tanzania Food and Drugs Authority**
Tel: +255 22 2450751/
Mobile: +255 685 701 735
: +255 658 445222
: +255 777 700002
Email: eacmrh@tfda.go.tz

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

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

IV. **Rwanda FDA**
Kigali, Rwanda
Mobile: +250 788634679
: +250 788792286
: +250 788306405
Email : jkabatende@rwandafda.gov.rw

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

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

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

V. Contacts Information of EAC Secretariat

Tel: +255-27-2162100/14
Email: eacmrh@eachq.org