EAST AFRICAN COMMUNITY (EAC)

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

NOTICE TO APPLICANTS

2nd 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. The East African Community Medicines Regulatory Harmonization (EAC-MRH) programme is implemented collaboratively by all the six (6) 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, Pharmacy Task Force (PTF), Ministry of Health - Republic of Rwanda and Tanzania Food and Drugs Authority (TFDA) and Zanzibar Food and Drugs Board (ZFDB)- United Republic of Tanzania.

2. The ultimate aim of this 2nd EOI is to increase the scope and list of selected medicinal products and sources available in relation to treatment for health importance diseases.

3. 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.

4. Assessment of applications submitted under this Invitation will include evaluation of:

   a) 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;
   b) Manufacturing sites, which shall adhere to *EAC Guidelines on Good Manufacturing Practices* (GMP);

c) Clinical sites (if applicable), which shall adhere to Good Clinical Practices (GCP).

5. Interested applicants are invited to submit applications for recommended dosage forms and strengths (where specified) of the following medicinal products:

A: Priority Medicines to Mother and Children

1. Amoxicillin dispersible tablets 125mg/250mg/500mg;
2. Artesunate: rectal and injection dosage forms 50–200 mg;
3. Gentamicin injection 10mg in 2ml ampoule;
4. Magnesium sulfate: injection 500 mg/ml in a 2ml ampoule, 500 mg/ml in a 10ml ampoule;
5. Oral Rehydration Salts (ORS) co-packed with Zinc dispersible tablet or equivalent flexible oral solid dosage form;
6. Oxytocin: 10 IU in 1ml ampoule;
7. Sulfamethoxazole + trimethoprim; Injection: 80 mg + 16 mg/ml in 5-ml ampoule; 80 mg + 16 mg/ml in 10-ml ampoule; Oral liquid: 200 mg + 40 mg/5 ml; Tablet: 100 mg + 20 mg; 400 mg + 80 mg.

B: Proposed paediatric formulations

1. Acyclovir; Oral liquid: 200 mg/5 ml; Powder for injection: 250 mg (as sodium salt) in vial;
2. Dexamethasone Oral liquid: 2 mg/5ml;
3. Fluconazole; Oral liquid: 50 mg/5ml;
4. Griseofulvin; Oral liquid: 125 mg/5 ml, Solid oral dosage form: 125 mg;
5. Nitrofurantoin: Oral liquid: 25 mg/5 ml.
6. Praziquantel Tablet 150 mg or oral liquid formulation
7. Prednisolone Oral liquid: 5 mg/ml;
8. Rufinamide 40mg/ml.

C: Anti-neoplastics and Immunosuppressives for children

1. Asparaginase Powder for injection: 10 000 IU in vial;
2. Azathioprine Powder for injection: 100 mg (as sodium salt) in vial &Tablet (scored): 50 mg;
3. Ciclosporin Capsule: 25 mg & Concentrate for injection: 50 mg/ml in 1ml ampoule;
4. Cyclophosphamide Powder for injection: 500 mg in vial;
5. Cytarabine Powder for injection: 100 mg in vial;
6. Dactinomycin Powder for injection: 500 micrograms in vial;
7. Daunorubicin Powder for injection: 50 mg (hydrochloride) in vial;
8. Doxorubicin Powder for injection: 10 mg; 50 mg (hydrochloride) in vial;
9. Mercaptopurine Tablet: 50 mg;
10. Methotrexate, Powder for injection: 50 mg (as sodium salt) in vial, Tablet: 2.5 mg (as sodium salt);
11. Vincristine Powder for injection: 1 mg; 5 mg (sulfate) in vial.

Any other appropriate strength(s) for children is invited.

D: Medicines for neglected diseases

Anti-leishmaniasis

1. Miltefosine Solid oral dosage form: 10 mg; 50 mg.

Anti-pneumocystosis and anti-toxoplasmosis

1. Pyrimethamine Tablet: 25 mg;
2. Sulfadiazine Tablet: 500 mg.

Anti-filariasis

1. Ivermectin.

Anti-strongyloidiasis

1. Thiabendazole.

E: Anti-cancer medicines

F: Anti-diabetic medicines

G: Anti-hypertensive medicines

H: Prescription only Medicines from Domestic Manufacturers within the EAC region

F: Anti- retroviral, anti-malarial, anti-tuberculosis medicines and reproductive health medicines

Applicants shall be invited to submit EOI for medicinal products which are not prequalified and they are not interested to submit the same applications to WHO Prequalification Program in future.

6. Submission procedure

All applications including product dossier, samples and site master file must first be submitted to the lead NMRA in medicines evaluation and registration which is Tanzania Food and Drugs Authority for screening and later to the remaining EAC NMRAs following a procedure laid down in '***EAC Procedure for Marketing Authorization of Medicinal Product Dossiers***'.