EAST AFRICAN COMMUNITY

NOTICE TO APPLICANTS

EAST AFRICAN COMMUNITY'S PROCEDURE FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

1. INTRODUCTION

Marketing Authorization (MA) is the process of assessing and accepting the dossier to support a medicinal product in view of its marketing, finalized by granting of a document also called marketing authorization. This process is performed within a legislative framework which defines the requirements necessary for application to the concerned medicine regulatory authority, details on the assessment procedure (based on quality, efficacy and safety criteria) and the grounds for approval or rejection of the application, and also the circumstances where a marketing authorization already granted may be withdrawn, suspended or revoked.

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 through the legal mandate of the existing National Medicines Regulatory Authorities (NMRAs) in each of the EAC Partner States 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 Poison 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.

The EAC Medicines Regulation Harmonized guidelines, requirements and standards for Medicines Evaluation and Registration (MER), Good Manufacturing Practice (GMP) and Quality Management System (QMS) as approved by the EAC Council of Ministers **(EAC/CM29/DECISION 36/09/20/2014)** on 20th September 2014 will become effective, January 2015.

2. Procedures for marketing authorization in the EAC

Currently, the East African Community has no Regional Medicines Regulatory Agency, which has legal mandate for marketing authorization of medicinal products. In view of this, and within the framework of the East African Community Medicines Regulatory Harmonization (EAC MRH) project, medicines will be authorized through the national authorization procedure, joint assessment procedure and WHO collaborative procedure.

2.1 National authorization procedure

2.1.1 Each EAC Partner State has its own procedures for the authorization of medicines, within their own territory, that fall outside the scope of the joint assessment procedure and WHO Collaborative procedure. Information about

these national procedures can be found on the website of the National Medicine Regulatory Authority (NMRA) in the country concerned.

2.1.2 This procedure will give marketing authorization in EAC Partner State(s) where application was submitted.

2.2 Joint assessment procedure

2.2.1 This is a procedure for joint assessment by the National Medicines Regulatory Authorities (NMRAs) of the EAC Partner States in the assessment of selected medicinal products, inspection of their respective manufacturing site(s) followed by national approval of jointly accepted medicinal products.

2.2.2 Once the assessment of medicinal products dossiers is complete and jointly accepted, the EAC NMRAs will grant marketing authorization within three (3) months from the date of final assessment and joint acceptance.

2.2.3 The Marketing Authorization Holder (MAH) can begin to make the medicine available to patients and healthcare professionals in EAC countries where marketing authorization has been granted.

2.3 WHO Collaborative procedure

2.3.1 This is a procedure for collaboration between the WHO Prequalification of Medicines Programme (WHO/PQP) and interested National Medicines Regulatory Authorities (NMRAs) in the assessment and accelerated national registration of WHO prequalified pharmaceutical products.

2.3.2 In this procedure, participating authorities are those NMRAs that voluntarily agree to implement this collaborative procedure and accept the task of processing applications for registration of WHO-prequalified pharmaceutical products in accordance with the terms of the Procedure. A list of participating authorities including EAC Partner States' NMRAs is posted on the WHO/PQP web site (http://www.who.int/prequal/).

3. Scope of products under the EAC Joint Assessment Procedure

The scope of medicinal products covered in joint assessment procedure includes the following:-

(a) Priority medicines as defined in the Essential Medicine List of individual Partner States;
(b) Medicines termed as Life Serving Commodities (LSC) by the UN Commission on Life Serving Medicines for Women and Children;
(c) Officially designated 'orphan medicines' (medicines used for rare human diseases)/ medicines for treatment of neglected tropical diseases;
(d) Anti-cancer medicines;

(e) Paediatric preparations;
(f) Medicines not invited for assessment within the scope of WHO Prequalification Programme.

4. Mode of application in the EAC Joint assessment procedure

4.1 Invitation of Expression of Interest (EOI)

4.1.1 At regular intervals and in consultations with EAC NMRAs, the EAC Secretariat will publish an invitation for expression of interest, requesting the interested parties to participate in this procedure in respect of the products mentioned in the invitation.

4.1.2 By submitting an expression of interest, the applicant undertakes to share same information with all EAC-Partner States NMRAs on all relevant aspects of quality, safety and efficacy of the specified medicinal products along with changes carried out and/or planned. The invitations will be published on the EAC Secretariat and NMRAs websites and other media as may be required.

4.1.3 In situations of high public health concern as determined by EAC NMRAs, the EAC Secretariat in consultation with EAC Partner States' NMRAs may directly invite relevant parties to submit specified products for assessment under this procedure without publication of an invitation for expressions of interest.

4.2 Data and Information to be submitted

4.2.1 Applicant should submit soft copies of the product dossier(s) with the required information to all EAC NMRAs.

4.2.2 In submitting an EOI for medicinal product evaluation, the applicant should send to all EAC NMRAs the following:-

a) A covering letter, expressing interest in participating in the EAC MRH programme and confirming that the information submitted in the product dossier is complete and correct;

b) A product dossier, in the format specified in the EAC Guidelines on Submission of Documentation for Registration of Human Medicinal Products;

c) Product samples, to enable visual examination and laboratory analysis;

d) A site master file for each manufacturing site listed in the product dossier, in the required format specified in the EAC harmonized guidance documents for submitting a site master file;

e) Evidence of payment to all EAC Partner States' NMRAs where the product is not registered;

4.2.3 Fees to be paid by the applicants to the EAC NMRAs will continue to follow national fees regulations.

4.3 Screening of Dossiers submitted

4.3.1 Each product dossier submitted by an applicant will be screened within two weeks by the lead country in medicines evaluation and registration for completeness.

4.3.2 In the event the dossier is incomplete, the applicant will be informed and requested to complete the dossier.

4.3.3 Dossiers that are considered complete as the result of the administrative screening will be retained by the lead country for evaluation process.

4.4 Dossier Assessment

4.4.1 The product information submitted in the dossiers will be sent to two selected lead EAC Partner States NMRAs for first and second assessment.

4.4.2 The allocation of the application for assessment will be done by a coordination committee established.

4.4.3 First assessment by the selected lead country will be done within a period of one month from the date of acceptance of the application after screening and second assessment will be done after conclusion of first assessment within a period of one week.

4.4.4 Selection of the assessors will follow the EAC Standard Operating Procedure (SOP) for selection of medicines assessors to participate in joint assessment of medicinal product dossiers.

4.4.5 Dossier assessment shall be done prior to GMP and if applicable, GLP and GCP inspections.

4.4.6 The assessment report shall be circulated to team of assessors appointed by the EAC Partner States NMRAs for comments prior to convening of the joint meeting.

4.4.7 There shall be a joint assessment session to compile comments from all assessors and finalize the assessment report.

4.4.8 Queries/ Communications arising from the meeting will be compiled by the lead country Medicines Evaluation and Registration and sent to the applicants/manufacturers within two weeks.

4.4.9 If any additional information is required, applicant will be required to provide such additional information to the lead country within 60 days. EWG on MER will

postpone its decision of the acceptability of the respective product dossier, until such information has been evaluated and found satisfactory in light of the specified standards.

4.4.10 Upon receipt, the responses to the queries shall be assessed immediately by the Partner State, which did first assessment and circulated for comments by all NMRAs.

4.4.11 The assessment reports will be shared to the departments responsible for registration in the NMRAs.

4.4.12 The EAC Partner States NMRAs, during the process of execution of the mandate has the right to bring on board technical support and expertise from WHO or any other stringent MRA, for the purpose of support and capacity building.

4.5 Site Inspection

Site(s) inspection shall be conducted in accordance with the EAC procedure for conducting GMP inspections

4.6 Reporting and communication of the results of assessment

4.6.1 The team of assessors will finalize its report from the joint assessment session according to the established EAC SOP and format, describing the findings and including recommendations and issues to communicate to applicant, manufacturer(s) and/or testing unit(s) or organization(s), where relevant.

4.6.2 The EAC NMRAs reserve the right to terminate the procedure of assessment of a specific product if the applicant is not able to provide the required information within six months and no written request for extension of time has been submitted.

4.6.3 In the event of any disagreement between an applicant and EAC NMRAs, an SOP established by the EAC NMRAs for the handling of appeals and complaints will be followed to discuss and resolve the issues.

4.6.4 The EAC NMRAs shall be entitled to use and publish public assessment reports, subject to the protection of any commercially confidential information of the applicant, manufacturer(s) and/or testing organization(s) [5].

4.7 Outcome of Joint Assessment Procedure

4.7.1 Once the EAC NMRAs are satisfied that the assessment process is complete for the relevant product, and that the EAC harmonized requirements and standards are met, the product, as produced at the specified manufacturing site(s), a notification letter on completion of assessment of the dossier will be issued by the EAC Secretariat to the applicant/manufacturer.

4.7.2 The letter shall state that the final registration outcome will be communicated by the respective NMRAs.

4.8 Maintenance of registration status

The registered products shall be maintained in each NMRA's list of registered products subject to:-

4.8.1 Continued compliance with requirements of quality, safety and efficacy.

4.8.2 Payment of retention fees in accordance with respective NMRA's Fees Regulations in force.

4.8.3 The MAH communicates details to EAC NMRAs of any changes (variations) made to the registered product following the EAC harmonized guidelines on variations to a registered product.

4.8.4 The MAH applies for renewal of their products in accordance with EAC Guidelines on Procedural Aspects for registration of medicinal products.

4.8.5 Continued GMP compliance of the manufacturing site(s).

4.8.6 Continued compliance with National Health Policies and any other directives.