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TANZANIA FOOD AND DRUGS AUTHORITY

GUIDELINES ON PROCEDURAL ASPECTS FOR APPLICATIONS FOR MARKETING AUTHORIZATION OF MEDICINAL PRODUCTS

(Made under Section 52 (1) of the Tanzania Food, Drugs and Cosmetics Act, 2003)

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ABBREVIATIONS AND ACRONYMS

BMR	-	Batch Manufacturing Record
GCP	-	Good Clinical Practice
GMP	-	Good Manufacturing Practice
ICH	-	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
MA	-	Marketing Authorization
MAH	-	Marketing Authorization Holder
WHO	-	World Health Organization

1. INTRODUCTION

All medicinal products in the country are regulated by Tanzania Food and Drugs Authority (TFDA). As a preliminary step, TFDA issues marketing authorization of all medicinal products for human use prior to their use. The objective of medicinal product marketing authorization is to ensure that medicinal products marketed in the region are safe, efficacious and of good quality and are manufactured in facilities that complies with the requirements prescribed in the TFDA Good Manufacturing Practice guidelines. All local manufacturers, wholesalers, distributors and importers of medicinal products must be licensed before they can conduct their businesses.

The guideline covers the steps that are followed from the submission of a dossier to the final outcome, the timeframe and procedure for the Authority to amend, where necessary the conditions of marketing authorization of a particular product.

2. SCOPE

The guideline is applicable for all types of application submitted to TFDA, that include new application, renewal of application and application for variation of a registered medicinal product.

3. TYPES OF APPLICATIONS

3.1 For purposes of submission to the Authority, applications are classified into new application, Application for Variation of a registered medicinal product and renewal application.

3.2 A new application is an application for registration of a medicinal product that is intended to be placed on the market for the first time. A new application may only be made by the applicant and he shall be the person who signs the application form.

3.3 A new application for registration shall include submission of relevant documentation as provided in the main guidelines for registration of medicinal products in use.

4. GENERAL REQUIREMENTS AND APPLICATION PROCEDURES FOR MEDICINAL PRODUCT REGISTRATION

4.1 All applications and supporting documents shall be in English. All submitted documents which are in any language other than English must be accompanied by a certified or notarized English translation.

4.2 The responsibility of applying for product marketing authorization rests with the company responsible for the introduction of the product into the Tanzanian market, i.e.: the Marketing Authorization Holder (MAH).

4.3 Applications must be duly completed and supported by all of the required documents i.e. Module I to Module V in accordance with the Guidelines on Submission of Documentation for Registration of Pharmaceutical Products.

4.4 The submitted application dossiers shall be screened for completeness within fourteen (14) working days. Dossiers which are incomplete will not be accepted for evaluation.

4.5 A dossier is a file that contains detailed scientific information on the chemistry, formulation, manufacturing, quality control and non-clinical and clinical studies that demonstrates quality, safety and efficacy of active pharmaceutical ingredient(s) and the corresponding finished pharmaceutical product.

Different sections of the dossier shall be distinctly marked and page numbered in the style: **page x of y** and have a table of contents indicating the sections and page numbers. Where information is required in the application forms its location shall be cross referenced in dossier. Information for each section shall be printed on both sides of an A-4 paper which will be arranged sequentially on a 1.00 mm or more diameter stainless spring and clamped with a stainless steel binder of not less than 1.0 mm thick in an A4 expandable spring file. The file shall be of cardboard or paper material of not less than 600gsm.

4.6 The covering letter shall be submitted in hard copy and the entire dossier on a CD-ROM or the entire application be electronically submitted to the Authority.

4.7 Data shall be presented on A4 and 80g/m^2 paper with readily readable letters of at least 12 font sizes. Every page shall be numbered sequentially. Extension sheets, tables, diagrams and other supporting documents shall as far as possible be of the same size, well annotated, numbered and appropriately cross-referenced.

4.8 Application must be accompanied by adequate number of samples to enable full specifications analysis plus one repeat.

4.9 The processing fee as prescribed in the fees and charges regulation must be paid to the Authority at the point of submission of the application.

5. PROCESSING OF APPLICATIONS (MANAGEMENT OF APPLICATIONS)

5.1 Upon acceptance of an application, an acknowledgement for the receipt of the application will be issued within and a reference number will be generated. The reference number shown in this acknowledgement should be used in all subsequent correspondences relating to the application.

5.2 The authority shall complete screening of the dossier for completeness within fourteen (14) working days from receiving such application.

5.3 In the event that the dossier is incomplete, it will be rejected. The applicant will be notified of the rejection and asked to come and collect the dossier.

5.4 In case of a positive outcome during screening, the Authority shall notify the MAH in writing that the screening has been successfully completed and place the dossier in the evaluation queue.

5.5 Review of application for marketing authorization of a product will follow the appropriate evaluation queue. Priority review may be granted where the product is intended for treatment of a serious or life-threatening disease. Evaluation of priority product shall be carried out within 6 months from receiving the application.

5.6 Evaluation of the application shall be carried out within 12 months from receiving the application.

5.7 Abridged evaluation will be carried out to medicinal products that are registered in any of the agreed benchmark regulatory agencies.

5.8 During product evaluation, the Authority may request for further information and additional supporting documents from the applicant. Applicant should make available such information or documentation required for each correspondence within 60 days from the date of the request.

5.9 If no response is received from applicant after 180 days and there is no request for extension of time, the clock stops and the application will be rejected/closed. A new application will have to be submitted if the MAH wishes to pursue marketing authorization of the product.

5.10 Evaluation of the additional information shall be carried out within 3 months from receiving such information.

5.11 The MAH will be informed of the decision of the Authority in writing as to whether the application has been approved or rejected.

5.12 A registration number will be given when a product is registered. The registration number is specific for the product registered as specified in the registration documents. A certificate of registration shall be issued for the registered product.

5.13 For a product to be issued MA, it must be manufactured in a GMP compliant facility and studies conducted following GCP.

6. MAINTENANCE OF MARKETING AUTHORIZATION

6.1 The conditions for marketing authorization of medicinal products are as follows:-

6.1.1 The product registered with the marketing authorization number as stated in the marketing authorization certificate shall have the name, composition,

characteristics, specifications and origin as specified in the marketing authorization documents.

6.1.2 The holder of the marketing authorization certificate must supply such documents, items, samples, particulars or information as the Authority may require in relation to the registered product.

6.1.3 No change in name, composition, characteristics, origin, specifications, manufacturer, packaging, indications, labelling, package insert, product literature or any other Particulars of the registered product shall be made without prior approval from the Authority.

6.1.4 The marketing authorization number must be:

- printed on the immediate and secondary container / packaging and immediate outer container/packaging and on the leaflet;
- printed in an indelible manner;
- NOT handwritten;

6.1.5 The labels for the registered product must comply with all of the labelling requirements as specified by the guidelines for labelling.

6.1.6 The registered product must only be indicated for use as approved by the Authority.

6.1.7 The holder of the marketing authorization certificate must inform the Authority of any adverse reactions or complaints on quality, safety and efficacy of the registered product immediately after he/she becomes aware of such adverse reactions or complaints.

6.1.8 The holder of the registration certificate must notify in writing to the Authority of any decision to withdraw the marketing authorization of the product and shall state the reasons for the decision.

6.2 MAH shall be required to pay retention fees as specified in the fees and charges regulation.

6.3 The registration of a product shall be valid for 5 years or such period as specified in the registration certificate (unless sooner suspended or cancelled by the Authority).

6.4 The renewal of product registration should be done not later than three months prior to expiry. Applications for renewal of registration shall be made by submitting the following:

i. Duly filled in application form for registration.

ii. Batch Manufacturing Record (BMR) of a real batch manufactured within at most six months before the submission of the application.

iii. Details of all changes during validity of the registration.

iv. Adequate number of samples to enable full specifications analysis plus one repeat.

v. A site master file that describes the manufacturing facilities.

vi. Non-refundable evaluation fee for registration of medicinal product and GMP and GCP inspection fees for facilities not inspected and approved by the Authority within a period specified by the Authority.

7. CANCELLATION OR SUSPENSION OF MARKETING AUTHORIZATION

7.1 The Authority may cancel or suspend the marketing authorization of any product if there are deficiencies in safety, quality or efficacy of the product or failure to comply with the marketing authorization requirements or due to changes in national policies.

7.2 Such products may not be imported and marketed in the country. The holder of the registration certificate shall immediately surrender to the Authority the marketing authorization certificate upon cancellation or suspension of marketing authorization of the product.

8. APPEALS AGAINST AUTHORITY'S DECISIONS ON MEDICINAL PRODUCT MARKETING AUTHORIZATION

8.1 All notice of appeals must be made within thirty (30) calendar days from the date of the Authority's notification.

8.2 MAH shall make appeal by giving grounds for review for each reason given for the rejection of his product. The grounds for the request shall be based on the information that was submitted in the product's dossier. Any additional or new information that was not earlier submitted will not be accepted. The Authority may review or uphold its earlier decision.

9. VARIATIONS IN PARTICULARS OF REGISTERED MEDICINAL PRODUCTS

All variations to a registered product shall be made according to requirements stipulated in the Application Guidelines for Variation of Registered Medicinal Products.