

**MINISTRY OF HEALTH AND SOCIAL WELFARE**



**REGISTRATION OF MEDICINAL PRODUCTS  
IN TANZANIA**

**JANUARY, 2006**

## **Introduction:**

Section 22 of the Tanzania Food, Drugs and Cosmetics Act, 2003 prohibits manufacturing or import for sale, sell, offer or supply any medicine unless the medicine is registered and the persons holds an appropriate licence or permit issued by the Tanzania Food and Drugs Authority (TFDA). This brochure explains the procedures to be followed in obtaining registration of medicinal products in Tanzania.

**Question:** *What does it mean by drugs registration and what is its importance?*

**Answer:** Drug registration is the process that involves pre-marketing evaluation of medicinal products to confirm their compliance to acceptable standards of safety, quality and efficacy.

**Question:** *What should I do if I want to market a medicinal product in Tanzania?*

**Answer:** Appoint a local responsible person and then apply and obtain registration of the medicine from TFDA.

**Question:** *How do I apply for registration of a medicinal product?*

**Answer:** Visit the Tanzania Food and Drug Authority's (TFDA) Website <http://www.tfda.or.tz> or write TFDA Head Office, P. O. Box 77150, Dar es Salaam to obtain copies of the relevant application guidelines depending on the medicine you want to register i.e. human, veterinary, biologicals or herbal drugs. Each copy is sold at 10,000/= Tshs ex-stock or 65,000/= Tshs, cost and freight.

1. Study carefully the appropriate guideline and compile all data, documents, samples and payments as prescribed in the guidelines.
2. Send by courier or by hand your application to the Director General, Tanzania Food and Drugs Authority at the address on this leaflet. The application should include drug dossier, duly filled in application form, payment or evidence of payment of fees, samples, two copies motivation letter, checklist of fulfillment of application requirements.

After obtaining the appropriate guidelines, study them carefully and compile all data and documentation as prescribed in the guidelines in terms of content and format. Then, file all documents in spring file (arch lever and box files are strictly prohibited), made of biodegradable materials and send the application to the TFDA offices either by hand or courier using the address shown in this brochure.

**Question:** *What should application consist of?*

**Answer:** An application must include:

- a) A complete drug dossier with a motivation letter, an application form and scientific data concerning the medicine.
- b) At least 5 samples of the finished medicinal product

- c) Application fee of US \$ 500 per product and other fees as detailed in the Application for registration guidelines and Fees and Charges regulations.

**Question:** *How long should I wait before getting a response on my application?*

Answer: It takes about 12 months to evaluate an application. Immediately after completion of evaluation, the applicant is informed of the outcome. If for some reasons a query is raised, the applicant shall be required to address the issues raised within 6 months. If no response or a request for extension of time is received within the six months, it will be considered that the application has been withdrawn by the applicant and that will be the end of the application.

**Question:** *Who may apply for registration?*

Answer: Application for registration of a drug can be made by owner of the product (individual, body corporate, partnerships or registered business) responsible for their manufacture or to whose order the product is manufactured for sell in Tanzania.

**Question:** *How long is the validity of the registration before requiring renewal?*

Answer: Registration is valid for five years unless earlier revoked or suspended. After the expiry of this period, you are required to apply for renewal of the products; the guidelines provide requirements and procedures for renewal.

**Question:** *What should I do to ensure that my product remains on the register?*

Answer: You have to pay annual retention fees of US \$ 100 per year per product before the end of every next December from the last payment.

For further information contact us through the following address:

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Tanzania Food and Drugs Authority (TFDA)  
EPI – Mabibo External  
P. O. Box 77150  
Dar es Salaam  
Tel: 255 22 2450751, 255 22 2450512, 255 22 2452108  
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