

**THE UNITED REPUBLIC  
OF TANZANIA  
MINISTRY OF HEALTH  
AND SOCIAL WELFARE**

**TANZANIA FOOD AND  
DRUGS  
AUTHORITY**

**TFDA**

**PROCEDURES FOR  
ESTABLISHING  
A PHARMACEUTICAL  
MANUFACTURING PLANT  
IN TANZANIA**

Tanzania Food and Drugs Authority

Protects Public Health

For further information p/se contact:-

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The Tanzania Food and Drugs Authority is a regulatory body charged with the responsibility of regulating all matters relating to quality, safety and effectiveness of foods, drugs, cosmetics and medical devices. In order to achieve the responsibility, TFDA controls importation, manufacture, storage, promotion, sell and distribution of the products to ensure compliance to prescribed requirements for the purpose of protecting public health.

**PROCEDURE**

Pharmaceutical manufacturers who intend to establish plants in Tanzania are required to comply to the following requirements:

1. Obtain a certificate of incentive from the Tanzania Investment Centre (TIC)

National Environmental Management Council (NEMC) on suitability of a site/plot for pharmaceutical manufacturing activities. NEMC conducts environmental assessment to determine whether presence of an industry in an area can have detrimental effect to surroundings.

3. Submit the above documents to TFDA Officer together with a schematic drawing of a proposed plant. An investor should state clearly in an application form the type(s) of drugs to be manufactured.

4. TFDA will scrutinize the application and grant an approval of the drawings for construction of a pharmaceutical plant if it is satisfied that the drawings have been designed to meet the requirements of Tanzania Good Manufacturing Practice (GMP) guidelines.

will inspect the plant and grant premises registration certificate upon being satisfied that the facility meets the minimum requirements of GMP.

6. The manufacturer will thereafter, be required to apply to TFDA for manufacturing license and registration of drugs so that they can be allowed to circulate the products in the market.

The requirements of registration of drugs demand submission of dossier (s) and samples for evaluation, as provided for in the Guidelines for Registration of Pharmaceutical Products in Tanzania.

The guidelines for Good Manufacturing Practice and guidelines for medicinal products registration are available at TFDA Offices at a nominal price of Tanzania Shillings 5,000/= and 10,000/= respectively.

**INTRODUCTION**

2. Obtain an approval from the

5. On completion of construction,