The process of registering drugs in Tanzania is regulated by the Tanzania Food and Drugs Authority (TFDA) that was established under the Tanzania Food, Drugs and Cosmetics Act of 2003.

As provided for under section 22 of the Act, all drugs to be manufactured for sale, imported or supplied must be registered. The person registering it must hold an appropriate licence or permit required and issued by the Authority.

PRE-REGISTRATION OF DRUGS STAGES

- **REGISTRATION OF PREMISES**

Section 18 of the Act provides that no person shall manufacture for sale, sell and supply or store Registration of products regulated under this Act except in premises registered under this section.

- **APPLICATION FOR LICENCE AND PERMIT**

Under section 20, an application for a licence and permit should be made to the Authority in the prescribed form and shall be accompanied by such fee as may be prescribed in the regulations.

Application for Manufacturing Drugs

Before issuing such licence or permit, the Authority shall consider the following:

- The premises have been inspected by the Authority
- That the substances he intends to use are of satisfactory quality
- The applicant has sufficient financial resources to enable him to manufacture the products and maintain the standard of quality
- That the applicant has not, within twelve months immediately preceding his present application, been convicted of an offence under the Act or any other written law relating to quality standards of products.

Application for Selling Drugs

Before issuing such licence or permit, the Authority shall consider the following:

- The premises under which the drugs will be stored
- The equipment available under the premises
- Suitability of the equipment and facilities which are used for distributing the products

regulated under the Act
- The arrangements made or to be made for securing the safekeeping and maintenance of adequate records in respect of products regulated under this Act stored in or distributed from those premises.

THE STEPS OF REGISTERING A DRUG

CRITERIA FOR REGISTRATION

Criteria for registering drugs are provided for under section 51 of the Act as to include:

- Availability of the drug is in the public interest
- It is safe, efficacious and of acceptable quality
- The site and manufacturing operations comply with current Good Manufacturing Practices
- In the case of a veterinary drug in relation to its effect on the health of animals, consumers of food of animal origin, the environment and users

APPLICATION FOR REGISTRATION

As per section 52, a person who is in the process of registering drugs in Tanzania shall submit their application to the Director General in the prescribed manner and shall be accompanied by application fees, samples and such other particulars as are prescribed in the application guidelines issued by the Authority, and any other information as the Authority may require from time to time.

REGISTRATION OF DRUGS

Section 53 provides that after the Authority receives the application and having conducted investigation, is satisfied that the drug in question is suitable for the purpose for which it is intended, and if it complies with the prescribed requirements it shall approve the registration of that drug to such conditions as it may impose.

After the Authority approves the registration of any such drug, the Director General shall:

- Enter in the register the prescribed particulars of the drugs and any condition or particulars as it may deem fit.
- Allocate a registration number to the drug.
- Issue to the applicant a certificate of registration in the prescribed form showing the registration number of that drug and any conditions subject to which it is registered.

Lastly, where the Authority approves, refuses to approve or cancels the registration of a drug, the Director General shall publish in the Gazette a notification of such approval or refusal and shall in such notice specify, the name under which such drug is registered, the qualitative and quantitative content of its active components, the name of the registrant and the registration number.