

4. After completion of construction, TMDA will inspect the plant and upon being satisfied that it meets Good Manufacturing Practice (GMP) requirements (for pharmaceuticals) and ISO standards (for medical devices), a manufacturing license will be issued.

5. Furthermore, applicants will be required to apply for registration of medicinal products and medical devices to be manufactured from registered plant and marketed in the country before the products are allowed to circulate in the market. The Guidelines on Submission of Documentation for Registration of Human Medicinal Products is available at the TMDA offices or through TMDA website: [www.tmda.go.tz](http://www.tmda.go.tz)

Incase of any clarification, please do not hesitate to **contact TMDA**



**Invest in Tanzania**

Health Commodities Manufacturing

### Why TANZANIA?

- Access to Tanzania (61.7M ), East Africa Community (295. 1M) and SADC
- (Over 450M ) market.
- Strategic Location : Bordering 8 countries & Indian Ocean
- Economic Stability
- Peace and Political Stability
- Rich Natural Resource
- Investment Guarantees

### Attractive incentives

- Latex Condoms & Gloves – 59B+
- Injectables – 53B+
- Anticancer Drugs – 10B+
- Vaccines – 43B+
- Lab Reagents (Biochemistry & Hematology) – 170B+
- Medical Devices – 76B+

### Priority Product Demand ( Annual Value -TZS )

- 0% import duty on capital goods, raw materials
- VAT exemptions on pharma inputs and packaging raw materials.
- 50% capital allowance first year
- Right to repatriate 100% of profits
- 10 expatriates allowed automatically
- 10 years Corporate Income Tax exemption
- Duty -free importation
- On site customs services
- Visa, land, and logistics facilitation
- Zero -rated VAT on exports
- The right to transfer out side the country 100% of foregn exchange earned, profits and capital

### Director General,

Tanzania Medicines and Medical Devices Authority (TMDA)  
P. O. Box 1253 Dodoma / 77150, Dar es Salaam,  
Tel: +255 22 2450512/2450751/2452108  
E-mail: [info@tmda.go.tz](mailto:info@tmda.go.tz) Website: [www.tmda.go.tz](http://www.tmda.go.tz)  
Toll free: 0800110084



@tmdatanzania

#### Eastern Zone Offices,

Off Mandela Road, Mabibo  
P.O BOX 31356, Dar es Salaam  
Tel: +255 737226328, 788470312  
Email: [info.easternzone@tmda.go.tz](mailto:info.easternzone@tmda.go.tz)

#### Central Zone Offices,

Uhindini Street,  
Fahmida Complex, Morogoro  
P.O BOX 163, Morogoro  
Tel: +255 26 2320156  
Email: [info.morogoro@tmda.go.tz](mailto:info.morogoro@tmda.go.tz)

#### TMDA Western Zone,

Meremeta Street, Bomani  
P.O BOX 240, Geita  
Email: [info.geita@tmda.go.tz](mailto:info.geita@tmda.go.tz)

#### Northern Zone Offices,

Ngorongoro Tourism Center Building,  
Fourth Floor  
P.O BOX 16609, Arusha  
Tel: +255 272970617/737782442  
Email: [info.arusha@tmda.go.tz](mailto:info.arusha@tmda.go.tz)

#### Southern Zone,

NBC Building, 1st Floor P.O BOX 48,  
Serengeti Road, Ruvuma, Songea  
Tel: +255 766729416  
Email: [info.ruvuma@tmda.go.tz](mailto:info.ruvuma@tmda.go.tz)

## TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

**TMDA**

Tanzania Medicines & Medical Device Authority



**ESTABLISHMENT OF  
PHARMACEUTICAL  
AND MEDICAL DEVICES  
MANUFACTURING PLANTS  
IN TANZANIA**

# ESTABLISHMENT OF PHARMACEUTICAL AND MEDICAL DEVICES MANUFACTURING PLANTS IN TANZANIA

## INTRODUCTION

Tanzania Medicines and Medical Devices Authority (TMDA) is a regulatory body under the Ministry of Health with the responsibility of regulating the quality, safety and effectiveness of medicines, medical devices and diagnostics.

The manufacture of pharmaceutical products and medical devices involves operations of production, quality assurance, release, storage and related controls. Such operations need to be carried out in premises that comply with the Tanzania Good Manufacturing Practices (GMP) requirements. Adherence to minimum GMP requirements ensures that pharmaceutical products meet quality standards for their intended use.

Pharmaceutical and Medical Devices premises must be located, designed and constructed to suit the operations to be carried out. Furthermore, premises should be situated in an environment that, when considered together with measures to protect the manufacturing processes, present minimum risk of causing any contamination of materials or products to be manufactured.



## PROCEDURES FOR ESTABLISHING A PHARMACEUTICAL AND MEDICAL DEVICES MANUFACTURING PLANTS IN TANZANIA

1. In order to establish a pharmaceutical and medical devices manufacturing plants, applicants are required to fill and submit Application forms for registration of premises and business permit. Application forms should be accompanied by the following documents:-
  - i) A copy of Certificate of Registration and Licensing Authority (BRELA)
  - ii) A copy of Certificate of Incentive from the Tanzania Investment Centre (TIC), if available
  - iii) A copy of memorandum and Articles of Association; and
  - iv) An approval from the National Environment Management Council (NEMC), on suitability of the site/plot for manufacturing activities.

2. The above documents should be submitted to TMDA together with a schematic drawing of a proposed manufacturing plant depicting premises layout, air handling system and specific locations of the equipment. Premises layout should among other things indicate ancillary, storage, weighing, and production and quality control areas.
3. Thereafter, TMDA will scrutinize the application and grant approval of the drawings for construction/renovation of premises if satisfied that the drawing has been designed to meet the requirements.

