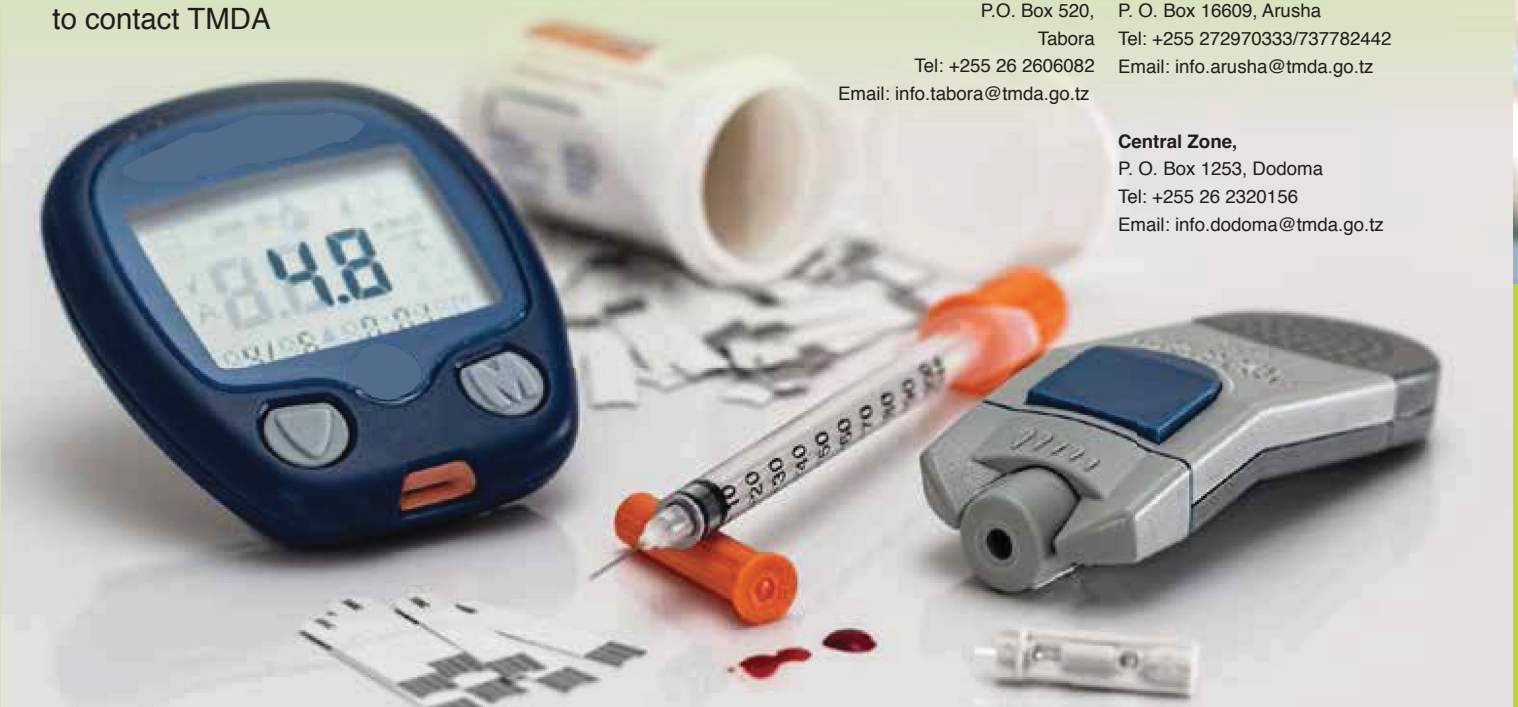
requirements (for pharmaceuticals) and ISO standards (for medical devices), a manufacturing license will be issued.

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

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



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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, Community Development, Gender, Elderly and Children 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 prem ises 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 construc tion/renovation of premises if satisfied that the drawing has been designed to meet the require ments.
4. After completion of construction, TMDA will inspect the plant and upon being satisfied that it meets Good Manufacturing Practice (GMP)