



# IMPORTATION OF MEDICINE IN TANZANIA

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The process of importation of medicine in Tanzania is governed and regulated by Tanzania Medicines and medical devices Authority (TMDA), which is the Authority established under section 4 of The Tanzania Medicines and Medical Devices Act, [CAP. 219 R.E. 2021]. The authority has a mandate of checking and inspecting the safety, efficacy and quality standards of the medical devices which are imported in Tanzania. TMDA regulates both human and veterinary medicines which includes both herbal and biocidal products, medical devices and diagnostics.

## **WHO CAN IMPORT MEDICINES IN TANZANIA?**

TMDA through its guidelines on importation and exportation pharmaceutical products and raw materials, has classified groups which can import medicines which are

- Government and Non- Governmental Institutions
- Pharmaceutical Manufacturers
- Clinical Trial Sponsors and Principal Investigators
- Pharmaceutical Importing Wholesalers
- Recipients of Donations.

## **LEGAL REQUIREMENT FOR IMPORTATION OF MEDICINE IN TANZANIA**

- The importer who wishes to import medicines, must register his premises to the TMDA.
- The importer must make an application to the TMDA for the importation permit of the medicines.
- The Medicines to be imported must be fit for human consumption, good quality, safe and not prohibited in the country of origin.
- All the medicines or medical devices in which the importer wishes to import must be registered by TMDA unless given special approval by the Authority to import unregistered medicines.
- The importer should make the importation of the medicines through the authorized Ports of Entry and comply with the laws of Tanzania.
- A person shall not import any medicine with shelf life of more than twenty four months



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whose remaining shelf life is less than 60% or any medicine with shelf life of less or equal to twenty four months whose remaining shelf life is less than 80%.

- The medicine to be imported must comply with the labeling requirements of TMDA.

### **PROCEDURES FOR FILLING AN IMPORTATION PERMIT APPLICATION IN TANZANIA.**

Application for import permit of medicines and medical devices in Tanzania is done online through the TMDA website, where by the applicant need to adhere to the following

- Create a Trader portal account on the TMDA website by filling in his important information. This account will enable the applicant to make the application form importation permit.
- Lodge an application through the application form available at TMDA Website. The applicant will also upload a scanned copies of the proforma Invoice and valid TMDA business permit.

Upon receiving the applications for importation of medicines in Tanzania, TMDA will scrutinize to verify whether the requirements have been fulfilled. If the application meets the prescribed requirements, the applicant will be required to pay import fee as stipulated in the Fees and Charges Regulations and after that the applicant will issued with import permit ready to proceed with importation process.

In case of application not complying with the prescribed requirements, the Authority shall issue online query(s) to the applicant for rectification before further processing or reject right away. Upon receiving query response, the Authority shall reprocess application and if satisfied issue import permit online.

In case of dissatisfaction the Authority shall reject the application and communicate with applicant by letter or online clearly stating reason(s) for rejection. this process usually take 6 to 7 days but it advised that the applicant should make the application earlier before importation so as to save cost and time in case the Authority delay to issue the import permit.

### **SPECIAL IMPORTATION PERMISSION OF MEDICINE**

A special importation permit is an importation permit issued by TMDA to allow the importation of an unregistered medicines for special purpose. It is termed as special since it



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is the general rule that all medicines which are to be imported need to be registered.

The same procedures application for importation medicine will be used, although in an application of the permit an applicant must provide enough reasons as to why he should be issued with the special permit to import unregistered medicines in the country. The groups which can apply for the special permit are; Hospitals,

- Healthcare providers and Clinical trial personnel.
- Government Institutions.
- Hospitals.