

# DEPARTMENT OF LICENSING & ENFORCEMENT

*Import/Export*

C O N T R O L   U N I T





The department of Inspection and Licensing through the Import/Export control unit (IMPEX) is responsible for establishing and maintaining an effective and efficient import/export control system for Botswana Medicines Regulatory Authority (BoMRA) to ensure compliance with all Botswana import/export control laws and regulations governing medicines and related substances.

The unit ensures that importation of medicines is carried out within a framework of sound import/export controls and to guide inspectors and partner agencies who perform routine evaluation of consignments at Ports of Entry.

The IMPEX unit is mandated to issue permits for the import, export and transit of medicines and related substances.

Permits are currently issued for the following registered/listed products:

- Veterinary medicines
- Human Medicines
- Psychotropics, Narcotics and Precursors (HFD) (as defined in MRSA 2013)

#### **GENERAL REQUIREMENTS FOR CONTROL OF IMPORTS AND EXPORTS**

1. No person(s) shall import or export from Botswana any registered medicine, for the purpose of wholesale dealing, unless he is duly appointed as an authorized importer or exporter by the Authority in respect of the type of medicine as per the (MRSA section 28).
2. Only outlets licensed as wholesalers can import medicines from all schedules. Other authorised importers including traders can import schedule 4 medicines, complementary medicines and cosmetics.
3. Importation of raw materials or packaging materials shall be restricted to pharmaceutical manufacturers.
4. No person(s) shall import any pharmaceutical product unless the product is registered by the Authority or exempted from registration.
5. Application for convectional medicines should be made separately from that of complementary medicines. Permits for the different product classes are also issued separately i.e. veterinary medicines, human medicines or HFDs.
6. All documents submitted for permit application must be completed in English.
7. Importation of medicines for personal use is permitted for one month's supply without a Doctor's prescription and up to three months supply with a Doctor's prescription. Medicines for personal use do not require an import permit.
8. Exempted medical devices issued with a BoMRA registration exemption letter do not require a permit.

## 5.1 IMPORTER CATEGORIES

Importers of Medicines shall fall under the following categories:

- a. Pharmaceutical wholesalers
- b. Pharmaceutical Manufacturers
- c. Authorised Researchers
- d. Other authorized entities the Authority may permit

## APPLICATION FOR IMPORT AUTHORISATION

Upon receiving the application as specified above, BoMRA will verify whether the requirements have been fulfilled.

An application will be rejected if it does not meet any of the importation requirements.

If the application meets the prescribed requirements, the applicant will be required to pay fees as stipulated in the Regulations in force.

An application will be given a rejection form stating clearly reason (s) for rejection.

All applications will be processed within two (2) working days with exception of special requests which may take longer periods.

Authority will issue an import permit as set out in the regulations.

Note: All applications must be submitted at least 10 days before the arrival of the consignment to avoid delays in processing import applications.

| PERMIT TYPE                     | EQUIREMENTS FOR APPLICATION   |
|---------------------------------|---|
| <b>Import-General medicines</b> | Application form<br>Purchase order                                  |
| <b>Import-HFG</b>               | Application form<br>Purchase order                                  |
| <b>Export permit</b>            | Application form<br>Import permits<br>Export permits                |
| <b>Transit permit</b>           | Application form<br>Invoice<br>Import permits                       |
| <b>Registration sample</b>      | Application form<br>Purchase order<br>Registration screening letter |

All exempted applications should be accompanied by a BoMRA exemption letter.



## DESIGNATED PORTS OF ENTRY:

The importation of all consignments of medicines should be done through the designated ports of entry, which are as follows:

For **BOTH** human medicines and Veterinary Medicinal Product

- Sir Seretse Khama International Airport
- Tlokweng Border Post
- Pioneer
- Ramokgwebana Border post
- Mamuno
- Kazungula Ferry border

**NB:** No importations through ordinary or unregistered posts shall be allowed.

More requirements for import and export control see the following guidelines at [www.bomra.co.bw](http://www.bomra.co.bw)








1. Guidelines on import/export control
2. Guidelines on handling pharmaceutical donations
3. Guidelines for importation of medicines for personal consumptions.

For more information contact the IMPEX Unit at 3737162/44/43/3620 903 for emergencies after working hours kindly contact 267 73181144/26773430190.





Promoting access to safe medicines

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