REPUBLIC OF BOTSWANA

DRUGS REGULATORY UNIT
Ministry of Health

Ministry of Health Headquarters
Floor 3, Block D
Government Enclave
P/Bag 0038
Gaborone, Botswana
Tel. 267 3632376/80/81/82/83
Email: DUNIT@GOV.BW

MINIMUM REQUIREMENTS TO OPERATE A PHARMACEUTICALWHOLESALE

(To be communicated to the prospective applicant at the time of enquiring on any pharmaceutical operation and referred to when receiving applications for licensing)

1. POLICY

Medicines shall be imported into or exported from Botswana or manufactured, distributed or sold only on a written approval from the Ministry of Health Drugs Regulatory Unit.

2. PURPOSE

The purpose of this guideline is to ensure that potential business operators are well equipped with information on what should be presented to the DRU to facilitate the approval process.

3. SUBMISSION REQUIREMENTS

To import/export, distribute and sell the following items shall be submitted to the Drugs Regulatory Unit:

Pharmaceutical Wholesalers:

1) MH 2050 Form 3 completed in duplicate;
2) A covering letter summarising the business prospects;
3) Registration certificate of the pharmacist from Botswana Health Profession Council;
4) At least two references(letters) and a brief C.V. of the pharmacist;
5) A declaration letter for continuous supervision by a pharmacist;
6) A sketch/floor plan of the premises.
7) A copy of a valid Blue card
8) Proof of payment

APPLICANTS SHOULD ALLOW 2 WEEKS FOR APPLICATION PROCESSING

4. MINIMUM (PRE-LICENSING) REQUIREMENTS FOR A PHARMACEUTICAL WHOLESALER

(To be communicated to applicant prior to the 1st inspection and issuance of Approval for Licensing)

4.1. PRE-OPERATIONAL REQUIREMENTS FOR A PHARMACEUTICAL WHOLESALER

A. Corporate Structure :

The responsible pharmacist of the intended wholesaler shall be a registered pharmacist with the Botswana Health Profession Council. The operation shall be done under supervision of a Registered Pharmacist. The responsibility, authority and interrelationships of all personnel should be clearly defined

B. Premises :

1) The premises shall be located in an easily accessible area.

2) The premises shall have a separate(barrier/distance/non movable and solid) receiving bay/area and Despatch area..There shall be a separate door for receiving and dispatch

3) The entrance of receiving and dispatch areas should protect products from the weather.

4) The receiving area should allow cleaning of the containers of incoming materials, if necessary before storage.

5) Personnel/People should not use Dispatch/Receiving area to access the warehouse

6) Premises shall be clean tidy and in a good state of repair.

7) The storage areas should have adequate lighting and ventilation.

8) The warehouse shall be of an area of NOT less than 100 square meters and shall be separate from offices and rooms of private use.

9) (The premises in which medicinal products are stored shall be made secure with access restricted to authorised personnel only.

10) There should be a lockable steel cabinet fixed on the wall or equivalent for the storage of habit forming drugs. The key or lock combination thereof shall be on the possession of the registered pharmacist

11) Special and segregated areas shall be available for storage of flammable and explosive substances, highly toxic substances, radioactive substances(where applicable).

12) Floors shall be made of a washable material, with coved ends to prevent accumulation of dirt and durable finish which can withstand movement of heavy loads.

13) Walls shall be made with a washable finish e.g. oil paint.

14) There shall be no open drain channels within or close to the premises.

15) A space for storage of cleaning materials shall be provided for.

16) There should be designated areas for expired, damaged, recalled and returned goods. These areas should be clearly marked and labelled as such.

C. Sanitation :

1) Premises shall be constructed and maintained to protect against weather, ground seepage and entrance and harbouring of vermin, birds and pets. Appropriate Pest control measures should be in place.

2) "No Smoking" and "No Eating" signs shall be conspicuously displayed in the warehouse areas.

3) Covered dustbins shall be provided at suitable positions for collection of waste material to be removed later to dedicated collection points.

4) There shall be separate toilets for male and female (equipped with adequate hand washing facilities). The toilets shall not open directly in to the warehouse.

D. Equipment :

1) A fridge/freezer for the storage of thermo-labile material shall be provided.

2) The storage area and the fridge/ freezer should be equipped with temperature recorders or devices that will continuously monitor the storage conditions and record the relevant readings(below 25^0C but exceeding 28^0C) for storage area and (5 ± 3^0C) for fridge

3) The recorders and devices for monitoring the storage conditions should be located in areas that are most likely to show fluctuations and/or the hottest and coldest locations where appropriate. This measuring equipment should be calibrated for the required operating range at defined intervals. Such calibration records should be maintained.

4) Appropriate alarm systems should be in place to provide alerts when there are deviations from pre-defined storage conditions.

5) Alarm levels should be appropriately set and alarms should be regularly tested to ensure adequate functionality.

6) Temperature records of five (5) days must be taken and recorded prior to inspection. Temperature mapping shall be done every 3 years.

7) There shall be an automatic backup generator to be used in times of power failure.

8) There shall be a list of equipment and its maintenance schedules and records will be kept.

9) There shall be a system for recording and monitoring temperature during transportation for cold chain products (validation system).

10) Repair, maintenance, and calibration operations of equipment should be carried out in such a way that the integrity of the medicinal products is not compromised.

E.Procedure:

The following Standard Operating Procedures and/or work instructions concerning the various types of operations within the business shall be written, dated, signed by an authorised person, endorsed or approved by the management and displayed in appropriate positions about the premises:

1) Good personal hygiene;

2) Cleaning of premises (floors, shelves, etc.);

3) Receipt(state type and nature of check), packaging and dispatch of goods;

4) Storage of Goods

5) Goods requiring special handling (e.g. cold chain) include backup support

6) Returned, rejected and expired drugs;

7) Product complaints;

8) Recalled medicines;

9) Safety procedures relating to all relevant aspects including, for example, the safety of personnel and environmental protection

10) Elimination of pest, insects, rodents and others..

11) Handling spilled substances.

12) Handling of Habit Forming Drugs

13) Supplier and Client authenticity

14) A system to validate transportation of goods

15) Training plan for the staff.

F.Security and Fire Protection :

1) There should be additional safety and security measures for combustible liquids, solid and pressured gases (If applicable).

2) Fire warning, escape and extinguishing facilities shall be provided in the building.

G. References :

The company shall also be in possession of some references, minimum requirement being:

1) Good Distribution Practice(WHO)

2) MRSA

3) Bluebook(Drugs allowed in Botswana)

4.2. OPERATION REQUIREMENTS FOR A PHARMACEUTICAL WHOLESALER

(To be discussed at time of issuing of the Approval for Licensing).

A pharmaceutical wholesaler Approval for Licensing is issued on the following conditions. In the event that any of these conditions is neglected, the Approval may be suspended or cancelled.

A. Corporate Structure

1) The Approval for Licensing is issued based on the organisational structure, which gives the pharmacist the necessary autonomy. Any modification to the structure should be communicated to the Drugs Regulatory Unit prior to being effected.

2) In the eventuality that a pharmacist leaves a post for whatever reason, such a change should be reported to the Drugs Regulatory immediately. All pharmaceutical operations shall cease immediately until a suitable and approved replacement or a locum pharmacist been employed.

3) The business shall be conducted under the continuous personal supervision of a registered pharmacist with an up to date registration (Blue Card). A copy of the BHPC certificate shall be displayed in the premises.

4) Copies of all relevant licenses and certificates shall be displayed. All originals shall be made available to inspectors when requested. The supervising pharmacist's name and qualifications shall be displayed conspicuously over the main entrance.

B.Personnel, Training and Health

1) In the absence of the supervising pharmacist, locum pharmacist shall be appointed and their particulars submitted to D.R.U. for filing.

2) All job descriptions of personnel shall be readily available.

3) All personnel shall undergo medical examinations prior to employment.

4) All personnel involved in distribution activities should be trained in the requirements of GDP (Good Distribution Practise) and be capable of meeting these requirements.

5) Personnel should receive initial and continued training relevant to their tasks in accordance with training schedule.

6) Personnel dealing with special categories of product such as cytotoxic, infectious or sensitizing should be given specific training.

7) Records of all training programme should be kept.

8) Personnel handling drugs shall be suitably dressed in clean uniform.

C. Procedures

1) The company shall purchase stocks only from approved suppliers and shall devise a system of tracing products back to the supplier/manufacturer

2) Drugs shall be distributed to appropriate licence holders only.

3) A system for ensuring that medicines are sold only to duly licensed persons shall be devised.

4) The receiving person shall be provided with a list and handling instructions for materials requiring special storage.

5) All drugs shall be stored according to the manufacturer's recommended storage condition

6) Special attention shall be paid to drugs requiring special storage conditions e.g. vaccines and other drugs requiring cold storage for cold chain maintenance. Appropriate actions on the premises, equipment and/or products shall be taken when the storage conditions are not met and these actions taken shall be recorded.

7) Goods shall be placed above the floor level either on shelves or pallets. Pallets should be well maintained and kept in a good state of cleanliness.

8) All products should be stored away from the wall and the lights to allow for air circulation. At least one (1) metre away from the lights and ceiling.

9) All returned goods shall be placed in quarantine and returned to other stocks only after the approval of a pharmacist following a satisfactory quality re-evaluation

10) All the drugs in stock shall be registered or exempted. An exemption letter should be available to inspectors on request.

11) An effective system to control stock rotation shall be devised e.g. FEFO (First Expiry/First Out)and FIFO (First In/First Out).Periodic stock reconciliation should be performed comparing the actual and recorded product quantity. All significant stock discrepancies should be investigated to check for inadvertent mix-ups and wrong issuance of stocks.

12) Expired drugs shall be removed from the shelf and stored at designated areas awaiting destruction by incineration or other suitable method (in conjunction with Environmental Health Officers) or returned to the supplier. Record of all disposed products should be kept. The destruction of schedule 1 drugs should be witnessed by a pharmacist and the police.

13) Any system (e.g. computerized and bar coding system) replacing the physical separation should give equivalent assurance in segregation and restriction in accessibility.

14) Transportation of drugs shall only be carried out in vehicles designed to retain product integrity.

15) The vehicle shall be adequately equipped with proper storage facilities, with special consideration for the maintenance of the cold chain. Companies may make use of temperature data loggers or other temperature recording instruments to verify that the desire temperature has been maintained during delivery for each consignment
16) Any suspected counterfeit products found in the distribution network should be physically segregated from other materials to avoid any mix up. They should be clearly labeled as "Not for Sale" or with other similar phrases/words. The DRU should be informed immediately.
17) All purchase orders for medicines shall be approved by DRU.

18) Batch no and expiry date of the products shall be included in the invoices.

19) Import and export permits shall be obtained from D.R.U for all controlled substances and estimates on these submitted to D.R.U.
20) The wholesale shall notify the authority within seven (7) days of any import/ export transactions.

D. Sanitation

1) The storage areas and toilets shall be cleaned every day. The shelves shall be cleaned regularly depending on the environment.

2) Waste material shall not be allowed to accumulate. Waste bins with cover shall be provided.

3) Toilet facilities shall never be used for storing stock.

4) Smoking and eating shall be prohibited inside the storage area.

5) The storage area shall be free from pests.

E. Documentation

1) A register shall be kept for schedules 1A, 1B,1C and Codeine containing medicines.

2) In addition:

   a) The HFD register should be balanced every month.

   b) The key of the HFD cabinet shall be in the possession of the responsible pharmacist at all times.

   c) Entries of the HFD dispensed shall be made within 24 hours.

   d) Copies of the HFD invoices shall be kept separately for at least 5 years.

3) Temperature records shall be maintained

4) Copies of Invoices shall be kept for 5 years

5) Destruction certificate shall be maintained.

6) Recalled and rejected product register shall be maintained.