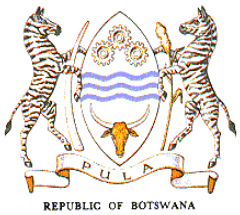

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MINIMUM REQUIREMENTS FOR APPLICATION FOR APPROVAL TO OPERATE A PHARMACEUTICAL BUSINESS

(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

Drugs[1] 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 FOR APPLICATION FOR APPROVAL TO OPERATE A PHARMACEUTICAL BUSINESS

For the purpose of approval for licensing to import/export, manufacture, distribute and sell drugs in Botswana as a pharmaceutical manufacturer, pharmaceutical wholesaler, community pharmacy, a pharmaceutical representative, the following items shall be submitted to the Drugs Regulatory Unit:

(1) Pharmaceutical Wholesalers

(a) MH 2050 Form 3 completed in triplicate;

(b) A covering letter summarising the business prospects;

(c) Registration certificate of the pharmacist from Botswana Health Profession Council;

(d) At least two references and a brief C.V. of the pharmacist;

(e) A declaration letter for personal supervision of a pharmacist;

(f) A sketch/plan of the premises.

[1] According to the Drugs and Related Substances Act devices like condoms are classified as drugs although they are not mentioned in any of the schedules. Potential manufacturers of condoms, sterile gloves, and other sterile disposable products are required to meet the requirements for a pharmaceutical manufacturer except the need for pharmacists.

(g) A copy of the payment receipt from Ministry of Health.

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. An application for wholesale licensing shall be made only when there are intentions of running the business under supervision of a Registered Pharmacist. There should be adequate organisational structure defined with the aid of an organisational chart. The responsibility, authority and interrelationships of all personnel should be clearly defined

B. Premises :

(1) The premises intended to be used for the wholesale business shall be located such that contamination of commodities from the exterior is avoided.

(2)There shall be a receiving area and a dispatch area both protected from the weather. Receiving areas should be designed and equipped to allow packaging containers of incoming pharmaceutical products to be cleaned, if necessary, before storage.

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

(4)The storage areas should have adequate lighting and ventilation.

(5)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.

(6)There shall be a cloakroom and toilet facilities (equipped with adequate hand washing facilities) apart from the storage areas.

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

(8)There should be a secure designated area for the storage of habit forming drugs. The key or lock combination thereof shall be on the possession of the responsible pharmacist.

(9)Special and segregated areas shall be available for storage of flammable and explosive substances, highly toxic substances.

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

(11)Floors shall be made of a washable and durable finish, which can withstand movement of heavy loads.

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

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

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

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.

D. Equipment :

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

(2) There should be a designated area for expired, damaged, recalled and returned goods. This area should be clearly marked and labelled as such.

(3). The storage area should be equipped with temperature recorders or devices that will continuously monitor the storage conditions and record the relevant readings such as maximum and minimum temperature. Appropriate actions on the premises, equipment and/or products should be taken when the storage conditions are not met and these actions taken should be recorded. .

(4) 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. The manual temperature records can be used as a backup.

E. Procedures :

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:

(a) Good personal hygiene;

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

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

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

(e) Returned, rejected and expired drugs;

(f) Product complaints;

(g) Recalled medicines;

(h) Elimination of pest, insects, rodents and others.

(i) Safety procedures relating to all relevant aspects including, for example, the safety of personnel and environmental protection should be in place.

(j) Handling spilled substances.

(k) 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:

a) Good Distribution Practice(WHO)

b) DRSA

c) 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 affected.

a. In the eventuality that a pharmacist resigns dies or 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. A similar approach shall be taken in the case of pharmaceutical representatives.

(2) The license of the business shall be displayed at all times in the premises.

(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 original 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 immediately 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 approval.

(2)All personnel shall undergo medical examinations prior to employment. Personnel who handle drugs shall undergo periodic health checks.

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

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

b) Personnel dealing with special categories of product such as cytotoxic, infectious or sensitizing should be given specific training. Record of all training programme should be kept.

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

(5) Only authorised personnel shall be attired to protect themselves and their products.

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.

(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 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

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

(10) An effective system to control stock rotation shall be devised e.g. FEFO (First Expiry/First Out) and FIFO (First In/First Out). All stocks shall be checked regularly in order to preclude issue of outdated drugs.

(11) 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.

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(13) Transportation of drugs shall only be carried out in vehicles designed to retain product integrity. Only quantities to be delivered are to be carried at any one time. Door to door sale or hawking of drugs is strictly prohibited.

(14)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.

(15)Any suspected counterfeit products found in the distribution network should be physically segregated from other materials to avoid any confusion. They should be clearly labeled as "Not for Sale" or with other similar phrases/words. The DRU should be informed immediately.

(16) All purchase orders for medicines shall be approved by DRU.

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

(18)Import and export permits shall be obtained from D.R.U for all controlled substances and estimates on these submitted to D.R.U.

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.

E. Documentation

A register shall be kept for schedules 1A, 1B and 1C drugs.

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 7 years.