**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)

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**1. POLICY**

Drugs 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.

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**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.

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**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) Community Pharmacies:

   (a) Form MH 2050 Form 3 completed in triplicate;

   (b) A covering letter summarising the business prospects;

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

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

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

   (f) A sketch/plan of the premises;

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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 brief note on other intended employees;

(h) Private Practice Licence

(i) Information on other related businesses;

(j) A copy of the payment receipt from Block B 3rd Floor, Ministry of Health Headquarters.

(2) Pharmaceutical Manufacturers:

(a) Form MH 2050 Form 3 completed in triplicate;

(b) A covering letter summarising the business prospects;

(c) An organisational structure of the company;

(d) Information about pharmacists at key operations (Production and Quality Assurance);

(e) Registration certificates from Botswana Health Professions Council;

(f) At least two references and a brief C.V. for each pharmacist;

(g) Job descriptions.

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

(i) A brief note on other intended employees;

(j) A list of products to be handled;

(k) A list of equipment to be used in warehouse, production and quality control;

(l) A sketch/plan of the premises;

(m) Information on other related businesses;

(n) A copy of the payment receipt from Block B 3rd Floor, Ministry of Health Headquarters.

Submissions shall be in the following order:

1) Covering letter;

2) Receipt of payment;

3) Form MH 2050 (3 copies);

4) Certificate of Registration of Pharmacist;

5) Brief C.V. Pharmacist and references;

6) Sketch/Plan of premises and other details;

7) Other intended employees;
8) Related businesses;
9) List of drugs to be handled;
10) List of equipment;
11) Letters of appointment.

APPLICANTS SHOULD ALLOW 2 WEEKS FOR APPLICATION PROCESSING.

**4. MINIMUM (PRE-LICENSING) REQUIREMENTS FOR A PHARMACY**

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

(1) Premises:

   (a) The premises of a pharmacy shall be used exclusively for pharmaceutical services.

   (b) The premises shall be well built, dry, well lit, air conditioned and of sufficient dimensions to allow the goods in stock, especially medicines to be kept in a logical appropriate manner.

   (c) The area of the section to be used as dispensary (excluding the shelving space) shall not be less than 6 square metres for one pharmacist working there in, with additional 2 square metres for each additional pharmacist (Sufficient space should be provided in the dispensary to ensure an efficient flow of work and effective communication and supervision).

   (d) The floor of the pharmacy shall be tiled to be rendered smooth and washable.

   (e) The walls shall be plastered and painted with washable paint or tiled so as to maintain smooth and washable surfaces devoid of holes, cracks and crevices.

   (f) A pharmacy shall be supplied with ample supply of good quality water.

   (g) A suitable door shall separate the dispensing area from the other areas. The height of the door shall be the same height as the dispensary counter. The door shall be lockable to render the dispensary inaccessible in the absence of a pharmacist.

   (h) The dispensary shelves should be designed such that they discourage members of the public from reading the labels of prescription drugs.

   (i) A sink with adequate supply of hot and cold running water shall be provided within the dispensing area for washing hands, apparatus, etc. (some detergent and a means of drying hands, except cloths, should be provided)

   (j) Some space for confidential counselling shall be provided. Its dimensions shall be at least three square metres and be able accommodate two chairs and a table. It should be made of solid material and adjacent to the dispensing area.

   (k) A min/max thermometer should be in the dispensary and anywhere where medicines are stored.
(2) Personnel:

(a) The pharmacy shall be operated under the continuous personal supervision of a registered pharmacist.

(b) A training plan for the staff should be in place and be implemented

(3) Furniture and apparatus:

The furniture and apparatus of a pharmacy shall be adapted to the uses for which they are intended and correspond to the size and requirements of the establishment. The finishing of the Pharmacy should be smooth and impervious.

A pharmacy shall be provided with a dispensing bench, the top of which shall be covered with smooth washable and impervious material like stainless steel, laminated material, plastic, melamine, Formica etc.

(a) A pharmacy shall be provided with a lockable steel cabinet fixed on the wall or floor for the storage of habit forming drugs. The key or lock combination thereof shall be on the person of the pharmacist.

(b) A pharmacy shall be provided with the following minimum apparatus and equipment.

(i) A suitable number of tablets and capsules counters and spatulas to minimise contamination of medicines when dispensing

(ii) A suitable range of graduated glass measuring cylinders, mixing slab or tile and any suitable glassware necessary for the proper carrying out of the dispensing duties of a pharmacist.

(iii) A refrigerator unit capable of storing products within a selected temperature range e.g. 2-8°C. The efficiency of this refrigerator should be daily checked with a Min /Max thermometer and a record book of such in place.

(iv) A suitable range of containers for the dispensing of tablets capsules creams, ointments, and liquids.

(v) A suitable range of labels for the above mentioned containers. The labels shall bear the details of the pharmacy, batch number and the expiry date

(vi) A digital scale of minimum 100mg weight.

(vii) A suitable range of mortars and pestles of glass or earth-ware material

(viii) A computer with dispensing programme and printer

(ix) Access to copying facilities

(x) A landline telephone

(4) Reference material:

A pharmacy should have access to the following minimum reference books:

The latest edition of Martindale (The Extra Pharmacopoeia) (Up to four years old):
(i) The latest addition of MIMS or any other compendium or MDR up to 1 year old;

(ii) A medical dictionary;

(iii) A copy of the Drugs and Related Substance Act and Regulations.

(iv) List of drugs allowed into Botswana and the latest appendix

(v) Pharmacy practice standards

(5) Security and Fire Protection:

(a) The pharmacy shall be equipped with an effective and appropriate security system and a suitable fire protection system which shall be regularly serviced.

4.1. OPERATION REQUIREMENTS FOR RETAIL PHARMACY PRACTICE

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

(1) Original copies of the license of the premises and approval shall be displayed at all times in the premises.

(2) The original Health Professions Council registration certificate and a Blue card of pharmacist shall be displayed at all times in the dispensary.

(3) The name of the pharmacist in-charge shall be printed on a name plaque and shall be displayed conspicuously in the pharmacy.

(4) The pharmacy shall be operated under the continuous personal supervision of the pharmacist-in-charge. When it is compulsory that the pharmacist be absent from the pharmacy e.g. when sick then the following options may be adopted:

   a) The services of a duly registered locum pharmacist may be engaged

   b) The dispensary shall be closed until the services of a registered pharmacist are obtained. All Schedule 3 shall be moved into the dispensary

(5) The Drugs Regulatory Unit shall be informed immediately in writing of any change, resignation or dismissal of the pharmacist-in-charge or additional employment of other pharmacists in the pharmacy.

(6) The job descriptions of the pharmacist shall be drawn up.

(7) Good personal hygiene instructions and procedures shall be written and displayed in the pharmacy.

(8) The Pharmacist should wear formal clothes or a white coat over their street clothes

   All Staff should be provided with uniform

(9) Smoking, eating and chewing should not be allowed in the dispensary area.
"No Smoking", and "No Eating" signs shall be conspicuously displayed in the pharmacy and the dispensary.

The pharmacist shall engage in a suitable continuous education programme offered by any recognised institution. Records of such training shall be kept.

Cleaning procedures and schedules for cleaning of floors, shelves, toilets should be drawn up and displayed.

Drugs shall be segregated from all other materials.

A refrigerator for storage of thermo-labile materials shall be installed in the pharmacy, and shall not be used for any foodstuff. A Min/Max daily record shall be kept.

Schedule 1A, 1B and 1C drugs shall be kept under lock and key and all registers and records of ordering and dispensing of these shall be maintained and be made available for inspection. Schedule 1A, 1B and 1C drugs shall be dispensed only on a written prescription, a record of the transaction entered into a Habit Forming Drugs Register and a prescription record book, and a copy of the prescription retained at least 5 years for the former and 3 years for the later.

In addition:

i). The HFD register should be balanced every month

ii). The key of the HFD cabinet shall be on the person of the pharmacist at all times

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

iv). Copies of the HFD invoices shall be kept separately for at least 3 years

A prescription record book or electronic records shall be kept for all prescription drugs. Copies of prescriptions and invoices shall be kept in the pharmacy.

All schedule 3 drugs shall be sold only with the knowledge of the pharmacist.

Schedules 1 and 2 drugs shall be segregated from Schedule 3 drugs, which in turn shall be segregated from Schedule 4 drugs. Schedule 3 shall be kept within proximity and within view of the pharmacist.

There shall be a written procedure for checking and destroying or returning of expired drugs. Records of expired drugs and their destruction shall be kept.

All expired drugs shall be segregated from other stocks and kept in a place labelled "Expired Drugs". The labels shall be printed on laminated or better material.

All different sections of the pharmacy shall be clearly labelled using laminated paper or material.

Adequate compounding equipment should be purchased when in-house compounding is to be carried out, and substances prepared in-house shall be kept for a period not exceeding 7 days unless stability for that period can be substantiated.
(23) A detailed record of compounding including date of preparation, batch number(s) of ingredients, quantities, calculations, expiration date of the ingredients and product, signature of the pharmacist shall be kept in the pharmacy.

(24) Prescriptions should be dispensed in suitable containers labelled in accordance with the DRSA requirements.
   
   a) No medicines should be sold to any person below the age of sixteen
   
   b) No Schedule 2 medicines should be sold without a prescription

(25) Only registered drugs or listed drugs (List of Drugs Allowed into Botswana) and shall be kept in the pharmacy.

(26) When the operation of a pharmacy is changed, the name and license change should be effected within 6 months.

(27) The bulk breaking records shall be kept and they should include all details of the medicines