Botswana Medicines Regulatory Authority

Approved By: _____ _____

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12	Addition of provision for Release of customer information	1.0	Director, Licensing & Enforcement	13/12/2021

1. Preamble

1.1 The Medicines Regulatory Authority (BoMRA) was established through an Act of parliament; the Medicines and Related Substances Act of 2013. The act provides for the regulation of medicines, medical devices, and cosmetics in Botswana in order to promote human and animal health by providing guarantees for quality, safety and efficacy of medicines and medicinal products throughout the supply chain. To achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the import and export of medicines.

1.2 This document provides guidance on what is required to acquire a license for operating a pharmaceutical retailer or wholesaler by BoMRA. It is a requirement to comply with the set guidelines in accordance with the Medicines and Related Substances Act. All stakeholders involved in the supply chain shall ensure the safe handling of medicines so that their quality is maintained until the end user.

2. Laws, Regulations, Policies and Guidelines Applied

2.1 These guidelines were developed using principles from the following;

a) Medicines and Related Substances Act, 2013,

b) Medicines and Related Substances Regulations, 2019

3. Definitions and Abbreviations

3.1 Definitions

3.1.1 Community Pharmacy – A pharmacy which provides general healthcare services compound and dispense prescription and non-prescription medication to the public in a retail setting rather than a hospital or clinic.

3.1.2 Dispensary - An area where medicines are stored, prepared, and dispensed to the public.

3.1.3 Inspection – An assessment or evaluation of something, in this case a pharmaceutical facility, to ensure that it meets certain standards or specifications prescribed by the governing body.

3.1.4 Pre-licensing inspection – An inspection which focuses on a new establishment that has applied as such or existing establishment that wishes to change premises or to extend their scope. This type of inspection shall be announced by the regulator.

3.1.5 Routine inspection - An inspection which focuses on an existing operation that has applied for renewal of their approval license. This type of inspection may be announced.

3.1.6 Responsible Pharmacist - An individual registered as a pharmacist with Botswana Health Professions Council and duly assigned the responsibilities for ensuring compliance with the minimum requirements for operating a licensed pharmaceutical business.

3.1.7 License variation- includes change in the premises name, responsible person, and change in the postal address for the premises

3.2 Abbreviations

3.2.1 BHPC– Botswana Health Practitioners Council

3.2.2 DVS- Department of Veterinary Services

3.2.3 GDP- Good Distribution Practice

3.2.5 HFD- Habit Forming Drugs

3.2.6 PPL- Private Practice License

4. Personnel

4.1 Responsible Pharmacist

4.1.1 An individual registered as a pharmacist with Botswana Health Professions Council.

4.1.2 Should ensure that there is continuous supervision of the community pharmacy.

4.1.3 Shall notify the authority immediately upon resignation or termination of employment where appointed.

4.1.4 Ensures that any deficiencies that may be identified during an inspection are addressed within the stipulated time**.**

4.2 Pharmacy Technician

4.2.1 An individual registered as a Pharmacy Technician with the Botswana Health Professions Council. Shall work under direct supervision of a Pharmacist

4.3 Pharmacy Assistant

4.3.1 Responsible for any other duties as assigned by the pharmacist except dispensing of medication. Shall work under direct supervision of responsible pharmacist.

5. Guidelines for Operating a Community Pharmacy

Inspection is required for granting or re-granting a license or approval of a substantial modification.

5.1 Submission requirements- Pre-licensing

5.1.1 The responsible pharmacist shall submit application documents on behalf of the premises to be licensed. Following submission, the application documents shall be processed within 10 working days where an inspection will be triggered.

5.1.2 The applicant should submit proposed sketch plan of the premises to the authority for approval before any physical partitioning is done

5.1.3 All applications shall be submitted to BOMRA, Plot 112, International Finance Park, posted via mail to Private Bag 2, Gaborone Station, Gaborone, or scanned copy of application via email to **inspections@bomra.co.bw**

5.1.4 The applicant shall submit the following application materials for licensing of new operations

a) Completed Application Form 8; Application for premises licence BOMRA/IL/IL/P01/F02

b) A certified copy of the pharmacist's registration certificate issued by BHPC.

c) A certified copy of BHPC blue card.

d) Completed declaration of continuous personal supervision by the pharmacist; BOMRA/IL/IL/P01/F03

e) A detailed sketch plan of the premises approved by the Authority;

f) Proof of installation of a dispensing system

g) A certified copy of a valid private practise license for the pharmacist.

h) Proof of payment.

i) Certified copy of identity card or passport

j) Two references.

k) Completed application checklist; BOMRA/IL/IL/P01/F04

5.1.5 An application with missing supporting documents shall not be accepted.

5.2 Submission Requirements- Routine Inspection

5.2.1 The applicant for an existing and licensed pharmacy shall submit the following application materials at least 3 months before license expires;

a) Completed Application Form 8; BOMRA/IL/IL/P01/F02

b) A certified copy of the pharmacist's registration certificate issued by BHPC

c) A certified copy of BHPC blue card.

d) Completed declaration of continuous personal supervision by the pharmacist; BOMRA/IL/IL/P01/F03

e) A certified copy of a valid private practise license for the pharmacist.

f) Proof of payment.

g) Completed application Checklist; BOMRA/IL/IL/P01/F04

5.2.2 An application with missing supporting documents shall not be accepted.

5.3 Variation of License

5.3.1 Application for variation of license shall be submitted to BOMRA in the following cases;

a) Change in the name of the premises

b) Change of responsible person

c) Change of postal address

5.3.2 Where variation includes change in the physical address of the premises, and or ownership, an application for pre-licensing shall be required with payment of the applicable fee.

5.4 Organisation and Management

5.4.1 The premises shall be under continuous supervision of a registered pharmacist

5.4.2 The name of the pharmacist shall be displayed clearly at the entrance.

5.4.3 The trade license and the BOMRA licence shall be displayed in the dispensary in such a way that is visible to the public

5.4.4 A copy of BHPC registration certificate and valid private practice license of the pharmacist shall be displayed at all times in the dispensary in a way that is visible to the public.

5.4.5 Any change with the Responsible Pharmacist shall be communicated to the Authority within 30 days. The pharmacy may not be under continuous supervision of locum pharmacists or pharmacist without PPL for a period exceeding 30 days.

5.4.6 Where there is any variation of a license, the license holder shall apply to BOMRA using Form 8 accompanied by application fee.

5.5 Personnel, Training and Health

5.5.1 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.

OR

b) The dispensary shall be closed and locked until the services of a registered pharmacist are obtained.

5.5.2 The Botswana Medicines Regulatory Authority shall be informed immediately in writing of any change in the organisational structure, or additional employment of other pharmacists in the pharmacy.

5.5.3 There shall be written job descriptions for all employees which clearly define their roles and responsibilities.

5.5.4 Training of personnel involved in retailing activities shall be based on written standard operating procedures (SOPs). A training record should be maintained.

5.5.5 The pharmacy shall inform the Authority about the intent to change premises location by application for pre-licensing inspection using Form 8 accompanied by application fee. When the operation of a pharmacy is changed, the name and license change should be effected within 6 months.

5.6 Premises

5.6.1 The premises of a dispensary shall be used exclusively for pharmaceutical services and activities.

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

5.6.3 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, 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)

5.6.4 The floor of the pharmacy shall be tiled to be rendered smooth and washable.

5.6.5 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.

5.6.6 A suitable door with minimum height of 900mm shall be used to separate the dispensing area from the other areas. The door shall be lockable to render the dispensary inaccessible in the absence of a pharmacist.

5.6.7 There shall be no unauthorised entry into the dispensary.

5.6.8 The dispensary shelves should be designed such that they discourage members of the public from reading the labels of prescription drugs. A barrier shall be made of wood, tinted or frosted glass.

5.6.9 A waiting area shall be provided. The area shall be at least 2 meters away from the dispensing space/ dispensary.

5.6.10 A room for confidential counselling shall be provided. Its dimensions shall be at least three-square metres and be able to accommodate two chairs and a table. It should be made of solid material, adjacent to the dispensing area and covered at the top.

5.6.11 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).

5.6.12 A continuous temperature monitoring device shall be provided in the dispensary and anywhere where medicines are stored. The temperature of the pharmacy should range between (+15 °C and +25°C) ±3°C.

5.6.13 A pharmacy shall be equipped 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.

5.6.14 A pharmacy shall be equipped with a lockable steel cabinet fixed on the wall or floor for the storage of habit-forming drugs.

5.6.15 There should be sufficient security measures in place in the pharmacy.

5.6.16 A fire extinguisher which is regularly serviced should be mounted in the pharmacy.

5.6.17 "No Smoking", and "No Eating" signs shall be conspicuously displayed in the pharmacy and the dispensary.

5.6.18 Dustbins shall be covered.

5.7 General Medicine Storage

5.7.1 All different sections of the pharmacy shall be clearly labelled using waterproof and durable material. No A4 paper should be used for labelling.

5.7.2 Drugs shall be segregated from all other products.

5.7.3 All surfaces shall be finished with an impervious washable material, be in good state of repair and be free of dust and pests.

5.7.4 There shall be sufficient space to allow for storage and efficient workflow and no drug cartons shall be kept directly on the floor surface.

5.7.5 Traditional or crude herbal products or products of animal origin shall not be kept in the pharmacy.

5.7.6 A refrigerator for storage of thermo-labile medicines shall be installed in the pharmacy and shall not be used to store any foodstuff. The refrigerator shall be equipped with a continuous temperature monitoring device.

5.7.7 Schedule1, 2 and 3 drugs shall always be stored in the dispensary, whereas schedule 4 can be stored in the front shop (if any).

5.7.8 Schedule 2 drugs shall be stored in a way that patients cannot read their labels.

5.7.9 Schedule 1A, 1B and 1C drugs shall be kept in a lockable HFD cabinet. The key shall always be with a pharmacist.

5.7.10 No smoking and no eating signs shall be displayed in the pharmacy and dispensary.

5.7.11 All different sections of the pharmacy shall be clearly labelled using a waterproof and durable material.

5.7.12 All expired drugs shall be segregated from other stocks and kept in a place labelled "Expired Drugs".

5.7.13 The pharmacy and its surroundings shall be kept clean at all times.

5.7.14 The premises shall be free from pests.

5.8 Documentation and Procedures

5.8.1 The following Standard Operating Procedures shall be available:

a) Good personal hygiene;
b) Cleaning of premises (floors, shelves, etc.);

c) Receipt, storage and pre-packaging (bulk breaking),
d) Dispensing
e) Goods requiring special handling (e.g. thermo-labile; cold chain management)
f) Returned, rejected and expired drugs;
g) Product complaints;
h) Handling customer complaints
i) Recalled medicines;
j) Follow up of patients
k) Ensuring supplier's authenticity
l) Elimination of pest, insects, rodents and others.
m) Extemporaneous preparations
n) Adverse drug reaction reporting
o) Handling of HFDs
p) Procedure for identifying counterfeit products

5.8.2 A training plan for in-house trainings for personnel

5.8.3 A risk management plan to prevent the circulation of counterfeit medications and medical products. It shall highlight the measures in place to prevent the sale and use of counterfeit products and how to address the counterfeit products once detected.

5.8.4 All documented procedures and plans shall be reviewed at least once every 2 years.

5.8.5 A pharmacy shall be equipped with the following minimum apparatus and equipment:

i. A suitable number of tablets counters and spatulas
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 suitable range of containers for the dispensing of tablets, capsules, creams, ointments, and liquids
iv. A suitable range of labels for the above-mentioned containers (in iv), The labels shall bear the details of the pharmacy, strength, batch number, expiry date, provision for patient name, directions for use and name of the drug. (the details as per the regulation 8)
v. A digital scale.
vi. A suitable range of mortars and pestles of glass or earth-ware material
vii. A computer with dispensing programme and printer
viii. Access to copying facilities
ix. A telephonic; fax or email contact.

5.8.6 Temperature records of 7 days prior to pre-licensing inspection shall be made available at inspection time.

5.8.7 Pest control measures shall be in place and implemented.

5.8.8 All records and transactions and all registers shall be maintained and be made available for inspection. These drugs shall be dispensed only on written prescription, record of the transaction entered into a Habit-Forming Drug register and a prescription record book.

5.8.9 The pharmacy shall keep a register for codeine containing products.

5.8.10 The HFD register should be balanced every month.

5.8.11 The key for the HFD cabinet shall be in the possession of the pharmacist at all times

5.8.12 All entries HFD dispensed shall be made within 7 days.

5.8.13 Copies of the HFD invoices and prescriptions shall be kept separately for at least 5 years.

5.8.14 Containers of every medicine dispensed to a patient shall have a label with information listed below where applicable:

a) Name of the Patient;

b) Name of the medicine and strength

c) Dosage instructions

d) Date of dispensing

e) Name or signature of dispenser

f) Name of pharmacy

5.8.15 Containers of pre-packed medicines shall have a label bearing the following information:

a) Name, strength, and quantity of the medicine

b) Batch number

c) Expiry date

d) Name of manufacturer

5.8.16 No medicines should be sold to any person below the age of sixteen without a legal guardian present.

5.8.17 No Schedule 1 and 2 medicines should be sold without a prescription.

5.8.18 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

5.8.19 A prescription record book or electronic records shall be kept for all prescription drugs. Copies of prescriptions and invoices whether partially or wholly dispensed shall be kept in the pharmacy for at least 3 years.

5.8.20 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.

5.8.21 Up to date Temperature records shall be maintained in the pharmacy demonstrating continuous temperature monitoring.

5.8.22 Expiry record and disposal certificates shall be kept up to date.

5.8.23 The bulk breaking records shall be kept and they should include all details of the medicines.

5.8.24 Invoices from approved distributors shall be kept for at least 3 years.

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

5.9 Reference Materials

5.9.1 A pharmacy shall have access to the following minimum reference books:

a) Medscape on-line
b) The latest addition of MIMS or BNF, any other compendium or MDR up to 2 years old;
c) A medical dictionary;
d) A copy of the Medicines and Related Substance Act 2013 and Regulations 2019;
e) electronic copy of the List of drugs allowed into Botswana and the latest appendix.

5.10 Post licensure Notification

5.10.1 An application shall be made by the responsible pharmacist to inform the authority of any post licensure notifications

6. Release of Customer Information

6.1 BOMRA Inspections and licensing department holds the information relating to customers in strict confidence as the terms and conditions of services provided. Except for information that the customer places in the public domain or when agreed between the Inspectorate and the customer, all other information is considered proprietary information and shall be regarded as confidential.

6.2 The inspection body shall seek authorization and clearance from the Chief Executive Officer, before any customer information is placed in the public domain or shared with a third party.

6.3 The inspection body shall notify the customer in advance, unless prohibited by law, when the inspection body is required, by law or authorized by contractual arrangements, to release confidential customer information.

6.4 Information about the customer obtained from other sources other than the customer (e.g. complainant), shall remain confidential between the inspection body and the

customer. Identity of the source can only be shared with the customer if the source has agreed to it in writing.

6.5 The following information about the customer shall be shared through BoMRA public domains

1. Company Name (licensee and business name)
2. License number
3. Business address (physical address)
4. Type of business (authorized activity)
5. Premises contact details (email, telephone line)
6. RP Name
7. License validity

7. Related Documents

7.1 Declaration form for continuous supervision by a pharmacist; *BOMRA/IL/IL/F03*

7.2 Application Form 8; *BOMRA/IL/IL/F02*

7.3 Application submission checklist; *BOMRA/IL/IL/F04*