Botswana Medicines Regulatory Authority

Approved By:

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Director – Licensing and Enforcement

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Date of Approval (DD/MM//YY)

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7	Inserted, "subtitle 5.3 Inspection"	1	Director Licensing and Enforcement	31/03/2021
7	Inserted, "5.3.1 The inspection shall be carried out by BoMRA inspectors who shall identify themselves by show of BoMRA inspector identity cards."	1	Director Licensing and Enforcement	31/03/2021
7	Inserted, "5.3.2 The aim of the inspection is to assess premises compliance to these BoMRA Good distribution practises guidelines, Act, Regulations and any other applicable legislation.	1	Director Licensing and Enforcement	31/03/2021
7	Inserted, "5.3.3 The inspection report shall be shared with the inspected facility within 10 working days from the date of inspection.	1	Director Licensing and Enforcement	31/03/2021
7	Inserted, "5.3.4 The inspection report shall categorise the deficiency findings as minor, major and critical based on potential negative effect to quality, safety and efficacy, patient, and the reoccurrence of the deficiency	1	Director Licensing and Enforcement	31/03/2021
7	Inserted, "5.3.5 The inspected premises shall upon receipt of the Inspection report be required to do a Root Cause Analysis and carry out corrective action and preventive action (CAPA) within 10 working days. The implemented actions shall be recorded in the	1	Director Licensing and Enforcement	31/03/2021

	recommended template for Addressing Deficiencies and submitted to BoMRA.			
7	Inserted, "5.3.6 Failure to address the deficiencies shall result in license withdrawal and in case of new application shall result in termination of licensing process after 30 working days from the date of inspection.	I	Director Licensing and Enforcement	31/03/2021
8	Inserted "5.4 A license can only be varied if it is left with more than three month of validity."		Director Licensing and Enforcement	17/11/2021
8	Inserted, clause 5.4.1 and 5.4.2 to explain License variation that require prior inspection and those that do not. Inserted,	I	Director Licensing and Enforcement	17/11/2021
11	Inserted, "8.1.13. All different sections of the Distributor shall be clearly labelled using waterproof and durable material."	I	Director Licensing and Enforcement	31/03/2021
11	Inserted, "8.6.2 Medicines requiring cold storage temperature shall be kept between 2-8˚C."	I	Director Licensing and Enforcement	31/03/2021
11	Inserted, "8.7 and records maintained"	I	Director Licensing and Enforcement	31/03/2021
14	Inserted, "9.2.8 There shall be a referencing system in place that promptly provides link of the dispatched medicines to the original suppliers to enable traceability of pharmaceutical products in the supply chain."	I	Director Licensing and Enforcement	31/03/2021
15	"8.5.2 The storage temperature shall range between 15-25˚C ±3 or according to the	I	Director Licensing and Enforcement	17/11/2021

	manufacturer's recommendation."			
19	Insert Sec 15. Release of client information	1	Director Licensing and Enforcement	14/12/2021

1. Preamble

The Medicine 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. In order to achieve this goal, the Authority has undertaken to develop a set of guidelines and procedures to guide the distributions of pharmaceutical products.

The purpose of this wholesale guidelines is to ensure that the quality and integrity of pharmaceutical products is maintained during the different stages of the distribution cycle. This covers all parties involved in the trade and distribution of pharmaceutical products, wholesale pharmacies as well as other parties such as brokers, suppliers, distributors, logistics providers, traders, transport companies and forwarding agents and their employees.

2. Laws, Regulations, Policies and Guidelines Applied

These guidelines were developed using principles from the following;

i. Medicines and Related Substances Act, 2013, (MRSA)
ii. Medicines and Related Substances Regulations, 2019
iii. WHO Technical Report Series, No. 957, 2010 Annex 5

2.1 Legal Consideration

The importation and importation of Medicines in Botswana shall be through a licensed wholesaler authorised by BOMRA.

1. No person shall import, export, distribute or sell medicines except in accordance with a license issued for the import, export, distribution or sale of medicines. *(Sec 28 (1) of the MRSA, 2013).*
2. A person who wishes to import, export, distribute or sell medicines shall apply to the authority, in the prescribed form accompanied by such fee as may be prescribed and such information as the authority may require *(Sec 28 (2) of the MRSA, 2013).I*
3. The person referred to in subsection (2) shall be resident in Botswana *(Sec 28 (3) of the MRSA, 2013).*
4. The import, export, distribution or sale of medicines in terms of this section shall be under the continuous supervisory control of a pharmacist, or veterinary surgeon *(Sec 28 (4) of the MRSA, 2013).*
5. A person authorised in terms of this act to import, export, distribute, or sell medicines shall not import, export, distribute, sell, or keep in storage contrary to

such conditions as may be prescribed, any medicine after the date of expiry indicated on the package of the medicine *(Sec 28 (4) of the MRSA, 2013)*.

6. The authority shall ensure that all premises are inspected to asses compliance to set guidelines

3. Definitions

3.1 Definitions

For the purpose of these guidelines the following terms shall be defined as follows:

3.1.1 BOMRA - means Botswana Medicines Regulatory Authority

3.1.2 Authority - means Botswana Medicines Regulatory Authority established under section 3 of MRSA 2013.

3.1.3 Authorised importer - means an individual or company or similar legal entity granted permission to import a medicine into Botswana by BoMRA.

3.1.4 Authorised exporter - means an individual or company or similar legal entity granted permission to export a medicine out of Botswana by BoMRA.

3.1.5 Counterfeit product - means a medicine, cosmetic, related substance or a Veterinary Medicinal Products product that is fraudulently mislabelled with respect to identity and/or source. Both branded and generic products can be counterfeited, and counterfeit products may include products with correct ingredients, with the wrong ingredients, without active ingredients, with insufficient quantity of active ingredients or with fake packaging.

3.1.6 Distributor - means any practice whose activities involve the handling, storing or supplying of medicines for wholesale to pharmacies or dispensary.

3.1.7 Export - means sending out a medicine, medical device or scheduled substance from the Botswana or cause a medicine, medical device or scheduled substance to be sent out of the country for purposes other than personal use.

3.1.8 Import - means to bring a medicine, medical device or scheduled substance into the Botswana or cause a medicine, medical device or scheduled substance to be brought into the country for purposes other than personal use.

3.1.9 Manufacture - means all operations involved in the preparation, processing, compounding, formulating, filling, refining, transformation, packaging, repackaging and labelling of controlled drugs;

3.1.10 Medicine: - as defined by the MRSA; including any substance, mixture combination of substances manufactured, sold or presented as suitable for use, in:

a. the diagnosis, treatment, alleviation, modification, prevention of diseases, illness, abnormal physical or mental condition or symptoms thereof or

b. restoring, correcting or modifying any somatic or psychic or organic condition or

c. any controlled substance, to the extent that it complies with (a) or

d. any substance or mixture of substances used to manufacture medicine or is sold as a raw material, precursor chemical or intermediate

e. a complementary medicine; or a substance or mixture of substances declared by the Minister of Health, in consultation with the relevant Authority, by notice in the Gazette to be a complementary medicine or medicine;

3.1.11 Pharmaceutical Operation: means any premises or activities which deal in research, manufacturing, marketing, advertising, dispensing, distribution, storage or handling of medicines, or prohibited substances

3.1.12 Pharmacist: means a person registered as a pharmacist under the Botswana Health Professional Act

3.1.13 Veterinary Surgeon: means a person registered as a veterinary surgeon under the Veterinary Surgeon's act

3.2 Abbreviations

3.2.1 TRS means Technical Report Series

3.2.2 WHO means World Health Organization

4. Scope

These guidelines are meant to:

a. Outline the responsibilities of the stakeholders involved in the distribution or sale of pharmaceutical products

b. Outline the requirements for successful application and licensing of a pharmaceutical wholesale.

c. Outline the documentation necessary to maintain in the operation of a pharmaceutical wholesale.

5. Requirements for operating a Pharmaceutical Operation

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

5.1. Application requirements and procedure

5.1.1 Applications for prospective pharmaceutical operations licence and license renewal shall be by Pharmacist or Veterinary Surgeon and be addressed to the Chief Executive Officer, BoMRA.

5.2.1 The applicant shall submit filled form 8 (annexure 1), Checklist, (Annexure 2) which shall be checked by the officer in charge, stamped and applicant given a copy, declaration form (Annexure 3)

5.2.2 The applicant shall also submit the following;

a) A certified copy of the pharmacist's registration certificate issued by a professional body. In the case of a veterinary surgeon, written proof of registration by the Botswana Veterinary Council.

b) A certified copy of a valid Blue card

c) A detailed sketch plan of the premises to be approved by the Authority (New Operations)

d) Proof of payment (use facility name as reference)

e) Certified copy of identity card or passport

f) Two references (New Operation)

g) Completed application checklist

5.2.3 The applicant is advised to submit sketch plan of premises to BoMRA for approval, before making structural changes to the warehouse.

5.2.4 All applications must be submitted to BoMRA at plot 112, International Finance Park or emailed to **inspections@bomra.co.bw**

5.2. Processing of application

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

5.2.2 If the application meets the prescribed requirements, the authority will proceed to carry out an inspection of the pharmaceutical operations.

5.2.3 An application will be rejected if it does not meet the minimum requirements for pharmaceutical operations. The applicant shall receive an inspection report outlining reasons for not awarding a license.

5.2.4 New operations shall be inspected within ten (10) working days after the submission of an application, the applicant shall be notified of date and time prior to inspection.

5.2.5 License renewal shall be inspected within twenty-one (21) working days after date of application.

5.2.6 Application for renewal of existing license shall be submitted three (3) months prior to license expiry.

5.3 Inspection

5.3.1 The inspection shall be carried out by BoMRA inspectors who shall identify themselves by show of BoMRA inspector identity cards.

5.3.2 The aim of the inspection is to assess premises compliance to these BoMRA Good distribution practises guidelines, Act, Regulations and any other applicable legislation.

5.3.3 The inspection report shall be shared with the inspected facility within 10 working days from the date of inspection.

5.3.4 The inspection report shall categorise the deficiency findings as minor, major and critical based on potential negative effect to quality, safety and efficacy, patient, and the reoccurrence of the deficiency.

5.3.5 The inspected premises shall upon receipt of the Inspection report be required to do a Root Cause Analysis and carry out corrective action and preventive action (CAPA) within 10 working days. The implemented actions shall be recorded in the recommended template for Addressing Deficiencies and submitted to BoMRA.

5.3.6 Failure to address the deficiencies shall result in license withdrawal and in case of new application shall result in termination of licensing process after 30 working days from the date of inspection.

5.4 License Variation

An application shall be made by the responsible pharmacist or veterinary surgeon to the authority requesting the authority to make changes to the license issued. A license can only be varied if it is left with more than three month of validity.

5.4.1 The following components of the license may be varied without the need for inspection:

a) Forwarding address

b) Description of premises

c) Business name

d) Responsible person

5.4.2 The following components of variation shall require prior inspection:

a) Structural modification

b) Physical address (relocation)-a relocation shall not be applied for as a variation of license but rather as pre-licensing. c) Licensee

d) Modification of any substantial nature

5.5 Post- licensure notifications

An application shall be made by the responsible pharmacist or veterinary surgeon to inform the authority of any post licensure notifications.

6. Organization and management

6.1 The facility shall have an organogram or organizational chart clearly indicating authority, responsibility, and interrelations with the company structure

6.2 There must be written job descriptions for all employees which clearly define responsibilities accompanied with each individual role

6.3 All employees must be informed or trained on their Job descriptions. Employees must sign their job descriptions as way of affirming understanding of their roles and responsibilities

6.4 There should be a quality management system in place

6.5 There should be an appointed person with defined authority and responsibility for implementation and maintenance of a quality system

6.6 The operation must have a code of conduct to which all employees adhere to, failing which management must have policies and procedures to address breach of code.

7. Personnel

7.1. Operations shall be done under continuous supervision of a Pharmacist or veterinary surgeon in line with their scope of practise

7.2. All personnel involved in distribution activities must be trained and qualified on the requirements of the WHO Good Distribution Practices for Pharmaceutical products (WHO TRS No. 957,2010, Annex 5) by way of SOP's

7.3. All personnel in the operations must have employment contracts or job descriptions specific to their role/ activities/responsibilities

7.4. All personnel involved in the distribution activities must receive initial and continuing training on SOP'S relevant to their tasks, role, or responsibilities.

7.5. Initial and continuing training of SOP's for all personnel involved in the distribution activities must be included in a written training programme or plan

7.6. All training, either initial or continuing must be assessable and a record or documented evidence of assessment be kept for all personnel

7.7. All personnel involved in the distribution activities must be trained on pharmaceutical product security, product identification, detection of counterfeit pharmaceutical products

7.8. There should be suitably trained and adequate personnel at all stages of the distribution activities

7.9. Where there are more than one pharmacist or veterinary surgeon working for the distributor the Responsible person shall Notify BOMRA and submit their registration cards or certificates

7.10. The responsible pharmacist shall notify BoMRA when they engage a locum, the name and blue card of pharmacist shall be submitted to the authority.

7.11. Change of the responsible person in charge shall be communicated to the Authority within 30 working days.

8. Premises, Warehousing and Storage

8.1. General

8.1.1. The premises shall be under continuous supervision of a pharmacist or veterinary surgeon (resident in Botswana) in line with their scope of practise

8.1.2. The trade licences, BOMRA license and the registration certificates shall be conspicuously displayed at the reception or service point

8.1.3. The name of the responsible pharmacist or veterinary surgeon shall be conspicuously displayed at the entrance

8.1.4. The area of the premises dedicated to the storage of medicines shall not be less than 100m^2

8.1.5. Good storage practices should be applicable where pharmaceutical products are stored throughout the distribution process. Storage areas should be of sufficient capacity

8.1.6. Surfaces should be kept clean, dry and maintained within acceptable temperature limit

8.1.7. Materials and pharmaceutical products should be kept off the floor and suitably spaced to allow cleaning and inspection

8.1.8. Pharmaceutical products should be stored and handled in a manner that prevents contamination, mix-ups and cross-contamination.

8.1.9. Written procedures for cleaning should be available and shall indicate the frequency of cleaning. All cleaning agents shall be approved by management.

8.1.10. HFDs should be stored in a lockable steel cabinet fixed to the wall and the key shall be kept by the responsible pharmacist

8.1.11. Balancing of habit-forming register(s) shall be done within 7 days of sale

8.1.12. There should be a pest control procedure to keep all areas free from pests. This includes the receiving and loading areas. Records shall be maintained to demonstrate the pest control program

8.1.13. All different sections of the Distributor shall be clearly labelled using waterproof and durable material.

8.2. Layout

8.2.1 Premises shall be secured to prevent or provide evidence of unauthorised entry.

8.2.2 Receiving and dispatch areas shall be segregated and clearly labelled. Measures should be taken to protect products from direct sunlight, rain and extreme weather conditions.

8.2.3 Sufficient space should be provided for receiving and dispatch of goods and Temperature monitoring shall be maintained at each area point.

8.2.4 Separate areas for quarantine, recalled, expired medicines should be provided and clearly labelled

8.2.5 There shall be labels in the warehouse prohibiting unauthorised entry, drinking and eating

8.2.6 There shall be no medicines kept on the floor, non-wooden pellets may be temporarily used to hold medicines at receiving and dispatch areas

8.3. Fire Safety

8.3.1 Fire detection and protection equipment shall be kept inside the warehouse and should be regularly serviced.

8.3.2 A procedure for fire prevention, detection and control should be available. Staff should be trained to carry out regular fire drills. Training records shall be maintained.

8.3.3 Smoking shall be prohibited in all areas

8.4. Power supply

8.4.1 The premises shall have access to uninterrupted power supply

8.4.2 An automatic backup generator shall be installed and should be equipped with automatic mains failure start-up and automatic shutdown when power is restored.

8.4.3 The generator should be regularly serviced, and record should be maintained to demonstrate compliance.

8.5. Temperature monitoring

8.5.1 All areas were pharmaceutical products are stored shall be equipped with continuous temperature monitoring systems. Records shall be maintained to demonstrate temperature control.

8.5.2 The storage temperature shall range between 15-25˚C ±3 or according to the manufacturer's recommendation.

8.5.3 Calibration of temperature monitoring devices should be done against a certified, traceable reference standard at least once a year or according to the recommendation of the device manufacturer.

8.5.4 Temperature Mapping shall be carried out in all medicine storage areas.

8.6. Refrigeration

8.6.1 Fridges, cold room and freezers should be capable of maintaining the required temperature range

8.6.2 Medicines requiring cold storage temperature shall be kept between 2-8˚C.

8.6.3 All cold chain keeping equipment should be fitted with lockable doors or lids, or access control system, to prevent unauthorized access

8.6.4 Refrigeration equipment should be equipped with calibrated continuous temperature monitoring device

8.6.5 Refrigerators should have an alarm to indicate when temperatures are out of range.

8.7. Transport Vehicles

8.7.1 Medicines shall be transported in vehicles with Temperature-controlled storage

8.7.2 Temperature monitoring systems or devices shall be used to continuously monitor temperature during medicines transit and records maintained.

8.7.3 The temperature monitoring device shall make temperature records with a minimum recording frequency of six times per hour for each sensor.

8.7.4 Monitoring devices should be calibrated and accurate to ± 0.5 °C

8.7.5 Storage area of the transporting vehicle should be mapped

8.7.6 If third party vehicles are used for transport of medicines, distributors shall have in place written agreements with the carriers who shall comply to 8.7.1- 8.7.6

9 Documentation

9.1. General

9.1.1 Written instructions and records which document all activities relating to the distribution of pharmaceutical products, including all applicable receipts and issues (invoices) should be available.

9.1.2 Records shall be kept in the facility for 3 years after which they can be maintained in a document bank for 5 years.

9.1.3 The documented information, whether paper or electronic, should be secure, attributable, legible, traceable, permanent, original and accurate

9.1.4 For paper documents or records,

i. The ink used shall

a) Be indelible

b) Not be temperature-sensitive or photo sensitive

c) Not be erasable

ii. the Paper used shall not be temperature-sensitive, photosensitive or easily oxidizable.

9.1.5 There should be permanent records, written or electronic, for each stored product indicating recommended storage conditions and any precautions to be observed.

9.1.6 Import and export of medicines shall be done according the BoMRA guidelines on import and export of human pharmaceutical products….

9.2. Documentation Systems

9.2.1 Procedures should be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution processes.

9.2.2 There should be procedures in place for both internally generated documents and those from external sources.

9.2.3 The title and purpose of each document should be clearly stated. The contents of documents should be clear and unambiguous.

9.2.4 All documents should be completed, approved, signed (as required) and dated by an appropriate authorized person(s) and should not be changed without the necessary authorization.

9.2.5 The distributor must establish and maintain procedures for the identification, collection, indexing, retrieval, storage, maintenance, disposal of and access to all applicable documentation.

9.2.6 Documents or Records that are kept in electronic form shall have backups to prevent accidental data loss. Data and record media should be durable

9.2.7 Systems, procedures and methodology used to record and store data should be periodically reviewed for effectiveness and updated as necessary.

9.2.8 There shall be a referencing system in place that promptly provides link of the dispatched medicines to the original suppliers to enable traceability of pharmaceutical products in the supply chain.

9.2.9 There should be a system, which includes a written procedure, to effectively and promptly recall pharmaceutical products known or suspected to be defective or counterfeit, with a designated person(s) responsible for recalls

9.2.10 The wholesaler shall keep records of purchase and sales of pharmaceutical products in the form of invoices that will reflect;

a) The date and transaction of every sale;

b) The name of the medicine;

c) The name and address of every purchaser or supplier;

d) The quantities sold or bought;

e) The batch number;

9.3. Customer verification

The wholesaler must have a process in place that verifies the following:

a) The name of the entity ordering

b) The entity licence/authorisation number from BOMRA

c) Any other relevant documentation

d) That the delivery address on the account and invoice matches the physical delivery address displayed on the licence

9.4 Standard Operating Procedures

9.4.1 The Responsible Pharmacist is responsible for the compilation, review, updating and authorisation of Standard Operating Procedures (SOPs).

9.4.2 For easy retrieval, copies of all SOPs must be present at the point of use.

9.4.3 The following SOPs should (as a minimum requirement) be in place in a wholesale pharmacy:

1. Procedure for creating and reviewing SOP's (SOP for SOP's)
2. procedure for temperature control and monitoring
3. Procedures for temperature mapping
4. Procedure for security of stored pharmaceuticals
5. Procedure for destruction of unsaleable or unusable stocks
6. Procedure for retention of the records.
7. Procedure for recall of pharmaceutical products
8. Procedure for cleaning of premises
9. Procedure for packaging and dispatch of goods
10. Procedure for Handling and Storage of Goods
11. Returned, rejected and expired medicines;
12. Procedure for product complaints
13. Procedure for recalled medicines
14. Procedure for health, personal hygiene, safety and environmental protection
15. Procedure for elimination of pest, insects, rodents and others.
16. Procedure for handling spilled substances.
17. Procedure for handling of Habit-Forming Drugs
18. Procedure for checking of supplier and client authenticity
19. Procedure for receiving stock.
20. Procedure for training of staff.
21. Procedure for segregation of pharmaceutical products
22. Procedure for operation and maintenance of vehicles and equipment
23. Procedure for identification and handling of counterfeit products
24. Procedure for vendor qualification

10 Complaints

There shall be a system in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.

11 Returned and Rejected products

11.1 The Responsible pharmacist and recipients shall be accountable for the return of medicines and shall ensure that counterfeit products are not introduced during this process

11.2 Where any doubt arises over the quality of a pharmaceutical product, it should not be considered suitable for reissue or reuse

11.3 Provision should be made for the appropriate and safe transport of returned products in accordance with the relevant storage and other requirements.

11.4 Returned should be appropriately identified and handled in accordance with a procedure which involves at least the physical segregation of such pharmaceutical products in quarantine in a dedicated area; or other equivalent (e.g. electronic) segregation.

11.5 The storage conditions of returned products should be maintained during storage and transit until such time as a decision has been made regarding the product in question.

11.6 Provision should be made for the appropriate and safe transport of rejected pharmaceutical products prior to their disposal.

11.7 Destruction of pharmaceutical products should be done in accordance with the prescribed national regulations

11.8 Records of all returned, rejected and/or destroyed pharmaceutical products should be kept for a predetermined period.

12 Counterfeit

12.1 No person shall import, export, manufacture, distribute, sell, promote, advertise, store or dispense, any counterfeit products.

12.2 Counterfeit pharmaceutical products found in the distribution chain should be kept apart from other pharmaceutical products.

12.3 Counterfeit pharmaceutical products should be clearly labelled as not for sale and marketing authorization holder should be notified.

12.4 Sale and distribution of a suspected counterfeit pharmaceutical products should be suspended, and the national regulatory authority notified immediately

12.5 Confirmed of the product being counterfeit, a formal decision should be taken on its disposal, ensuring that it does not re-enter the market and the decision recorded.

13 Contract Activities

13.1 Activities relating to distribution of pharmaceutical product which is delegated to another entity should be performed by authorised personnel and in terms of the written contract.

13.2 Compliance to the contract should be mandatory.

13.3 Subcontracting should be acceptable only under stipulated conditions, and the subcontractors should be authorised for that function.

13.4 Auditing of contract acceptor should be done periodically.

14 Self-Inspection

14.1 Self-inspection should be carried out to monitor implementation and compliance with principles of GDP and this should trigger corrective and preventive actions

14.2 Self-inspection should be conducted in an independent, detailed way by a competent person.

14.3 The results of all self-inspection should be recorded. Reports should contain all observations made during inspection and proposals for corrective measures. There should be an effective follow up programme on non-conformities.

15 Release of Customer Information

15.1 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

15.2 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

15.3 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

15.4 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

15.5 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

16 References

The distributor shall be in possession of the following references

i. Medicines and Related Substance Act 2013

ii. Medicines and Related Substances Regulations, 2019

iii. WHO Good Distribution Practices (Technical Report Series. No 961, 2011 Annex 9)

iv. List of medicines and related substances registered in Botswana (Bluebook)

v. List of allowed Veterinary medicinal products (Veterinary Medicinal Products distributor)

vi. Index of Veterinary Specialities – IVS (Veterinary Medicinal Products distributor