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| | Document type: Policy |
| | Title: Licensing of Public Facilities |
| Function: Inspections and Licensing | Document No: BOMRA/IL/IL/Policy No.3 |
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Botswana Medicines Regulatory Authority



Approved
By:



**Dr Kegomoditswe B.
Maphane**
 Board Chairperson

 10/04/2025
Date of Approval
(DD/MM/YY)



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Revision status sheet

| Page | Changes made | Issue No | Process Owner (Title) | Reviewer's name | Date |
|------|---|----------|-----------------------|-----------------|------------|
| All | Name change from "Licensing of Government Owned Facilities" to "Licensing of Public facilities". | I | MIL | T. Chilume | 17/02/2015 |
| 4 | Change clause 5.1 to include referral, primary and secondary hospitals in the initial phase of implementation of the policy. | I | MIL | T. Chilume | 17/02/2025 |
| 5 | Change Clause 5.3 to indicate that upon complying with regulatory requirements, Government owned facilities shall be issued with a license. | I | MIL | T. Chilume | 17/02/2025 |
| 6 | Delete clause 5.5 and 5.6 | I | MIL | T. Chilume | 17/02/2025 |
| All | Change the accounting ministry from Ministry of Health to relevant ministry | I | MIL | T. Chilume | 17/02/2025 |
| | Added to clause 5.2: However, high-volume clinics (e.g., Nkoyaphiri, Lesirane, Phase 2 Clinic) that function as satellite warehouses for | I | MIL | T. Chilume | 08/05/2025 |

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| | <p>smaller clinics or health posts within a cluster or catchment area, or those that procure directly from suppliers through micro-procurement (e.g., in DHMTs without dedicated district warehouses like Gaborone), may require a differentiated regulatory approach. These facilities pose higher risks due to their larger patient volumes and supply chain roles. The Authority will consider alternative licensing terms, such as extended validity periods or reduced inspection frequencies, to ensure regulatory oversight without overburdening these critical facilities.</p> | | | | |
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1 Purpose

The purpose of this policy is to provide guidance on the regulation of premises owned by Botswana Government.

2 Scope

This policy is applicable to all hospitals solely owned by the Botswana Government that import, export, sell, distribute, dispense and store medicines. These include amongst others Central Medical Stores (CMS), District Health Management Teams (DHMTs) warehouses, Referral, Secondary and Primary Hospital Pharmacies, high volume clinics as well as those under Botswana Defense Force, Botswana Police Services and Botswana Prisons Service.

3 Definitions and Abbreviations

3.1 Definitions

The following definitions shall apply:

- 3.1.1 **The Authority:** - refers to Botswana Medicines regulatory Authority.
- 3.1.2 **Public facility:** Public facilities are those pharmaceutical operations or premises owned and used by the government to provide medicines to its citizens.

3.2 Abbreviations


The following abbreviations shall apply:

- 3.2.1 **BDF** - Botswana Defence Force
- 3.2.2 **BoMRA** - Botswana Medicines Regulatory Authority
- 3.2.3 **BPS** – Botswana Police Services
- 3.2.4 **CAPA** - Corrective and Preventative Actions
- 3.2.4 **CMS** - Central Medical Stores
- 3.2.5 **DHMT** - District Health Management Teams
- 3.2.6 **MRSA**-Medicines and Related Substances Act
- 3.2.7 **WHO** – World Health Organization

4 General

4.1 Background

- 4.1.1 The Authority is mandated with the implementation of the MRSA Act of 2013 and currently strives to achieve WHO Maturity Level 4 – a regulatory system operating at an advanced level of performance and continuous improvement. In this regard, BoMRA is expected to have regulatory oversight on all facilities that store, distribute and

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dispense medicines and this includes government owned facilities. This is prescribed in MRSA as per the legal provisions noted in section 4.2 of this document.

- 4.1.2 Since its inception, the Authority has not been regulating government facilities, and this was a gap in the Authority's regulatory scope contrary to the mandate prescribed by the MRSA.


4.2 Legal requirements

The following are provisions from the MRSA of 2013

- 4.2.1 Section **26.** (1) No person shall practise as a pharmacist or operate a pharmacy or a dispensary on any premises unless —
- (a) the person has applied for and been issued with a licence in respect of the said premises for operating the pharmacy or dispensary;
 - (b) the premises, in the case of a pharmacy, are under the continuous supervision of a pharmacist;
 - (c) in the case of a dispensary, the person is authorised in writing by the Director of Health Services or the Director of Veterinary Services as the case may be, to dispense.
- (2) An application for a licence under subsection (1) shall be made by a pharmacist who is resident in Botswana and shall be made in the prescribed form and accompanied by the prescribed fee.
- (3) The retailing of Schedule 3 medicines shall be through a pharmacy duly licensed as such under this Act.
- (4) A person who contravenes the provisions of this section commits an offence and is liable to a fine not exceeding P15 000, or to imprisonment for a term not exceeding three years, or to both
- 4.2.2 **47.** (1) All premises where medicines or medicated feeds are stored, used, handled, dispensed, manufactured or sold, and any vehicle, transshipment, or receptacle in which medicines are transported, shall be subject to inspection with or without prior arrangement with the person in control of the premises, vehicle, transshipment or receptacle by an inspector authorised by the Authority, in writing, and such inspector shall be given unhindered access to such premises with the right to take samples of any medicines on the premises, without payment, and to carry out any investigation that the inspector considers necessary.

5 Approach

- 5.1 The Authority will implement the regulation of government owned facilities in a phased manner. The initial phase will be to have oversight on the distribution points which include Central Medical Stores, all DHMT distribution warehouse, hospitals and high-volume clinics which serve as satellite warehouses for smaller clinics and health posts


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within a cluster. These facilities distribute to a lot of facilities in the country are therefore high-risk facilities.

- 5.2 Clinics (including mobile stops and health posts) shall be exempted from licensing as these are deemed low risk facilities that cover and store very low quantities to sometimes no stock of medicines. However, high-volume clinics that function as satellite warehouses for smaller clinics or health posts within a cluster or catchment area, or those that procure directly from suppliers through micro-procurement shall be subjected to licensing. High volume clinics pose higher risks due to their large patient volumes and supply chain roles.
- 5.3.1 All eligible public facilities shall be subjected to all regulatory requirements applicable to facility of a similar nature in the private sector. Furthermore, all applicable inspection and licensing processes in place such as procedures and checklists used for private facilities shall be applicable to public facilities. For example, all government distribution warehouses shall be licensed in accordance with BoMRA Good Distribution Practices Guideline – [BOMRA/IL/IL/P01/G03](#) while hospital pharmacies shall be licensed in accordance with BoMRA Guideline for Operating within Group Pharmacies- [BOMRA/IL/IL/P01/G02](#).
- 5.3.2 Upon complying with regulatory requirements, Government owned facilities shall be issued with a license. For facilities found to be non-compliant, BoMRA shall maintain oversight by subjecting the applicable facility to submission of corrective and preventative actions (CAPA's) for the identified deficiencies. These facilities will be given an agreed timeline to have rectified the deficiency and to submit evidence of such CAPA. Where ministry facilitation through provision of resources is required, an agreed timeline taking that into consideration will be considered by the Authority and the relevant Ministry. An implementation plan focused on closing of all identified deficiencies with timelines will be expected from the facilities and /or relevant ministry.

6 Justification for exemption of low-risk facilities from licensing

- 6.1 As government is currently providing for 68.1% of the health care services in the country (Ogunseye O, 2020), low volume clinics and health posts are considered low risk due to their type of facility, the scope of medicines kept by these facilities as well as the quantities of medicines stored and dispensed by these facilities. Furthermore, these facilities get their medicines supply from the CMS, DHMT warehouses, hospitals and high volume clinics which are subjected to licensing therefore reducing the risk associated with these types of premises. Implementing this regulatory approach will ensure we do not overregulate and hinder access to medicines for the general public while at the same time facilitating safe medicines.

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7 Monitoring

- 7.1 A Monitoring Oversight Committee comprising representatives from BoMRA, Ministry representatives, BDF, BPS and Botswana Prison Service shall be formed. The committee shall be responsible for monitoring compliance improvement plans. The committee will meet quarterly where findings for all premises inspected in that quarter shall be presented. This will ensure that Ministry management is aware of the inspection findings and can be in a better position to adequately allocate resources for closing the deficiencies.
- 7.2 The committee will also be responsible for monitoring of the implementation of corrective action of the premises. Overall monitoring shall also include reports on compliance improvement processes and level of industry compliance for the applicable facilities.

8 Responsibility and Authority

- 8.1 The implementation of this policy is the responsibility of the Manager, Inspection and Licensing.

9 Review of the Policy

- 9.1 The policy will be reviewed periodically every two (2) years.