Disposal Of Unwanted Medicines

Any counterfeit product, substandard, expired, banned medicines or cosmetics in possession of any person shall be disposed of in a manner set out in the Medicines and Related Substances Regulations.

If a person is convicted of an offence under this Act or any regulation made under it, the court may order any medicine or substance in respect of which the offence was committed to be seized and disposed of as the authority may require.

The authority may at the same time withdraw any approval or authorisation previously given by the authority to that person. **Sec 66 (3) M&RS Act.**

Offences and Penalties

common contraventions of the provisions of this act
Prescription/dispensation of any schedule 1 or schedule 2 medicine without being authorised by this Act

Obstruction or failure to comply with any reasonable request by the authority in the exercise of its functions under this Act;

It is an offence to import, exports, manufactures, distributes, sells, dispenses or advertises products or other substances falsely purporting to be, or intended or likely to induce anyone to a mistaken belief that it is a registered medicine.

Sale of Unregistered Cosmetics.

Contravention of this section is an offence and transgressors are liable to a fine of P100 000 or to imprisonment to a term of ten years or both.

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Botswana Medicines Regulatory Authority

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BOMRA
MEDICINES REGULATORY AUTHORITY

MEDICINES & RELATED SUBSTANCES ACT No.8 OF 2013

Integrity · Customer Focus · Efficiency · Team Work

MANDATE

The Botswana Medicines Regulatory Authority (BoMRA) derives its mandate to regulate the supply chain of medicines for human and veterinary use, medical devices and cosmetics from the Medicines and Related Substances (8) Act 2013. The Authority was set up in 2017 in order to:

1. Ensure that all medicines and related substances, cosmetics and medical devices used in Botswana are in conformity with established criteria of quality, safety and efficacy.

2. Ensure conformance to standards and adherence to best practice by all involved in the supply chain of medicines, medical devices and cosmetics.

3. Ensure conformance to good laboratory practice by private-ly-owned medicine quality control laboratories through inspections and conducting tests and analysis of medicines.

4. Ensure the safety and quality of cosmetics and medical devices by ascertaining that companies adhere to best practice standards.

Registration of Medicines, Cosmetics

All human and veterinary medicinces, medical devices and cosmetics must be registered by the Authority before they may be brought into, sold or used in Botswana. Registration is necessary to allow the Authority to determine the safety and efficacy of medicines, by ensuring they meet the quality standards for use in Botswana, so as to protect humans and animals using them in Botswana.

Any person who wishes to sell, distribute, manufacture, import, store, dispense, advertise, promote any medicine or cosmetic must ensure that the medicine or cosmetic has been registered with BOMRA.
In certain special circumstances, the Authority may allow the use of unregistered medicines through the granting of exemption including, amongst others, where medicines are prescribed outside Botswana for personal use.

Any person who fails to comply with registration requirements committs an offence and liable to a fine not exceeding P100, 000.00 or imprisonment to a term not exceeding 10 years, or both. **Refer to section 23 of the M&RS of 2013.**

Import, Export, Distribution and sale of medicines

Any person wishing to import, export, distribute or sell medicines and cosmetics must apply and be issued with a license by BoMRA. Licenced persons are expected to adhere to the M&RS Act, and conditions prescribed by BoMRA. BoMRA may withdraw (cancel) a license in the event that medicines are imported, exported, distributed or sold other than in accordance with the Act and in the event of such withdrawal the premises for which the license was issued will cease to operate. **Section 33 M&RS Act.**

A person who imports, exports, distributes or sells medicine without a licence commits an offence and is liable to a fine not exceeding P100, 000.00 or imprisonment not exceeding 10 years. **Section 28 M&RS Act.**

Manufacturing

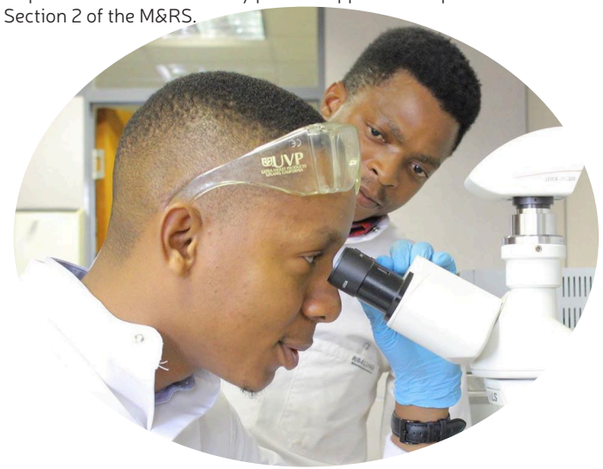
Any person wishing to manufacture medicines and cosmetics must apply and be issued with a license by BoMRA. A person who contra-venes this section commits an offence and is liable to a fine not exceeding P100, 000.00 or imprisonment not exceeding 10 years. **Section 27 M&RS Act.**

Pharmacies and Dispensaries

Any person wishing to operate a pharmacy or dispensary must apply and be issued with a license by BoMRA. The Pharmacy must always be under the continuous supervision of a registered Pharmacist.
A person who contravenes this section commits an offence and is liable to a fine not exceeding P15, 000.00 or imprisonment. **Section 26 M&RS Act.**

Inspections

BoMRA inspects all licenced premises, or premises seeking a licence, and may inspect any 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.
Inspections are carried out by persons appointed inspectors in terms of Section 2 of the M&RS.



Inspections of licenced premises, or premises seeking a licence assess compliance with Good Manufacturing practices (GMP), Good Distribu-tion Practices (GDP), Good Pharmacy Practices (GPP) along the medicines supply chain in line with requirements of the M&RS. BoMRA inspects every facility at least once a year.

Inspectors may further seize medicines found on premises, a vehicle, transshipment, or receptacle where the medicines are held in contraven-tion of the provision of this Act. **Sec 47 M&RS Act.**

Import and Export Authorisations

Import and export of medicines is carried out by licenced wholesalers who must also obtain an authorization from BoMRA for each purchase order. These purchase orders are verified against the medicines register to ensure only registered medicines are imported into the country and persons will not be able import and export medicine without a purchase order except in exceptional circumstances such as importation for personal use.

Advertising

Any person who wishes to advertise or promote medicines or cosmetics must submit promotional materials to BoMRA and be issued with approval. No one is allowed to sell a cosmetic product if any label or advertisement of the cosmetic contains any symbol or statement that implies therapeutic or medicinal claim.
A person who contravenes the provision of the law is liable to a fine not exceeding P100, 000.00 or imprisonment not exceeding 10 years. **Sec 46, Sec 60, Sec 66 of M&RS Act and Reg 53, 65.**