

Botswana scheduling differs from the South African scheduling; the South African scheduling is as follows:

- Schedule 6 & 5 - These are controlled drugs, also known as Habit Forming Drugs (HFD)
- Schedule 4 & 3 - These are prescription only medicines (POM)
- Schedule 2 & 1 - These are known as Pharmacy medicines (PM)
- Schedule 0 - These are General sales list medicines (GSL)

Botswana receives most of the medicines from South Africa. Botswana and South Africa also share the labels and product information such as Package Inserts and Patient Information Leaflets for many products, therefore, more than one schedule may appear on the labels or product information leaflets. It is important for consumers to pay attention to the schedule appearing in their medicines may be for Botswana, South Africa or for both countries, or even another country in or outside the region. Due to differences in the scheduling between Botswana.

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 Botswana Medicines Regulatory Authority



**KNOW YOUR  
MEDICINES**





## INTRODUCTION

Botswana Medicines Regulatory Authority (BoMRA) is a new body established by the Medicines and Regulatory Act (MRSA 2013) under the Ministry of Health and Wellness. BoMRA is responsible for regulating the supply chain of Human and Veterinary medicines, medical devices and cosmetics to ensure their safety, quality and efficacy.

## MISSION

To regulate medicines, medical devices and cosmetics, to promote human and animal health.

## VISION

To be the trusted Authority for excellence in medical products and cosmetics regulation.

**VALUES** are the qualities on which we pride ourselves. They drive us to passionately meet our objectives and targets and mould us into what we want to be known for. The following is a consolidated list of values and value statements that drive the Botswana Medicines Regulatory Authority corporate culture:

- Integrity
- Customer Focus
- Efficiency
- Team Work

## DEFINITION OF MEDICINE

Medicine is defined as any substance suitable for use in the diagnosis, treatment and/or prevention of diseases or illness.

## CLASSIFICATIONS OF HUMAN MEDICINES

| Level of Control            |                                                                                                                           |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------|
| Prescription Medicines:     | They are dispensed by a pharmacist only on the order of a healthcare practitioner                                         |
| General Sales Medicine:     | These medicines are not controlled and are accessible without a prescription or order and may be bought over the counter. |
| Origin                      |                                                                                                                           |
| Chemical Medicine:          | Small molecular weight medicines derived from chemical synthesis e.g., paracetamol                                        |
| Biopharmaceutical Medicine: | High molecular weight medicines derived from biological origins e.g., vaccines, blood products and recombinant proteins.  |
| Class                       |                                                                                                                           |
| Therapeutic Medicines:      | Commonly referred to as allopathic, conventional, scheduled medicines specifically for treatment of disease.              |
| Complementary Medicines:    | Commonly referred to as homeopathic, herbals, vitamins, minerals, unscheduled etc.                                        |

Human medicines may further be classified by **Method of Administration** i.e., oral or injectable, **Sterility** e.g., sterile or non-sterile, **Dosage Form** e.g., table, capsule, ointment, **Mode of Action** e.g., antibiotic, antiretroviral, painkiller etc.

Depending on the use and maximum daily doses, vitamins and minerals products may as well fall under therapeutic medicines group, e.g., Vitamin A, Vitamin K, Vitamin D, Iron, Zinc etc. These products may also be classified as food supplements depending on their form and quantities. In Botswana, therapeutic medicines are classified based on likelihood of abuse, dependence, seriousness of condition to treat, pack size, strength of the medicine etc. Therefore, there are four classes of therapeutic medicines and these are also known as four schedules:

- Schedule 1 (S1) - These are controlled drugs, also known as Habit Forming Drugs (HFD)
- Schedule 2 (S2) - These are prescription only medicines (POM)
- Schedule 3 (S3) - These are known as Pharmacy medicines (PM)
- Schedule 4 (S4) - These are General sales list medicines (GSL)

Any other medicine that does not fall into any of the schedules may be classified as unscheduled, or complementary medicines. Ideally, scheduling of medicines or active substances must be done timely to accommodate new medicines introduced into the market.

All the Scheduled medicines (S1, S2, S3 and S4) medicines are available in pharmacies while only Schedule 4 (S4) medicines are available in supermarkets and other authorized premises. By law, supermarkets and authorized premises should not keep any other scheduled medicines except Schedule 4 medicines.

