# Botswana Medicines Regulatory Authority

MEDICINES REGULATORY AUTHORITY

**Approved By:** _____

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**Director - Product Evaluation and Registration**

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**Date of approval (DD/MM/YY)**

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## Revision status sheet

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## 1. Purpose

The guideline provides content and how to apply for classification of products if the applicant is not certain of the classification of their product or whether it is indeed registrable with BoMRA.

## 2. Scope

This guidance applies to all borderline products that have a potential of being regulated by BoMRA. The guideline does not apply to medical devices at the moment. Traditional medicines are also not in the scope of this guidance.

## 3. Definitions and Abbreviations

### 3.1 Definitions

The following definitions shall apply:

### 3.1.1 Medicine (MRSR, 2019):

a. any substance, mixture combination of substances manufactured, sold, or presented for use in –
   i. the diagnosis treatment, alleviation, modification or prevention of disease, illness, abnormal physical or mental condition or the symptoms thereof, or
   ii. restoring, correcting or modifying any somatic or physic or organic condition; or
b. any controlled substance, to the extent that it complies with paragraph (a);
c. a substance or mixture of substances that is used to manufacture medicine or is sold as a raw material, a pre-cursor chemical or intermediate;
d. any labelled preparation in pharmaceutical dosage form that contains as active ingredients, one or more substances of natural origin that are derived from plants or animals;
e. herbal tea, or homeopathic, ayurvedic, or other, medicine that contains as active ingredients, substances of natural origin, and may be derived from any part of plants or animals in a pharmaceutical dosage form;
f. vitamins and minerals prepared in a pharmaceutical dosage form
g. any medical device; or
h. any premix

### 3.1.2 Complementary medicine (MRSR, 2019):

means a labelled substance or mixture of substances manufactured, sold or represented for use as adjuvants to conventional therapy in:

i. the mitigation or prevention of or abnormal physical states;
ii. restoring, correcting or modifying physical, mental or organic functions in human and animals as determined by the Authority;

and originate from plant, mineral, animal (including microorganisms), homeopathic preparations, nutritional substances in accepted pharmaceutical dosage forms, a combination of the above or any other such preparations as may be approved by the Authority

### 3.1.3 Cosmetic (MRSR, 2019):

Any substance or mixture of substances manufactured, sold or represented for use by rubbing, pouring, spraying or applying by any means to the human body for the purpose of cleansing, beautifying, altering their appearance;

### 3.1.4 Food

Any animal product, fish, fruit, vegetable, condiment, beverage and any other substance whatever, in any form, state or stage of preparation which is intended or ordinarily used for human consumption, and includes any article produced, manufactured, sold or presented for use as food or drink for human consumption, including chewing gum, and any ingredient of such food, drink or chewing gum (Food Control Act of Botswana)

### 3.1.5 Attribute:

A quality or feature regarded as a characteristic or inherent part of someone or something

### 3.1.6 Claim:

Refers to the properties that the substance purportedly possesses. Claims can be in form of labelling, in the form of advertisements, "testimonies". Claims (in part with attributes) indicate to the customer the intended use of the product.

### 3.1.7 Indication:

A medical condition that a medicine is used for. This can include the treatment, prevention and diagnosis of a disease.

## 3.2 Abbreviations

3.2.1 **BoMRA** – Botswana Medicines Regulatory Authority
3.2.2 **MRSR** – Medicines and Related Substances Regulations, 2019

## 4. Introduction to registrability/classification

## 4.1. Borderline products

BoMRA regulates medicines, medical devices and cosmetics, to promote human and animal health. In carrying out this mandate, a person or company marketing a product has a responsibility to ensure that they do so in accordance with the applicable law. Medicines

(including Human, Veterinary and Complementary medicine), medical devices and cosmetics require marketing authorization or exemption before being placed on the Botswana market. In some instances, it may not be apparent as to what class a particular product lies. These products are referred to as borderline products.

Borderline products (medicine/cosmetic/food interface) will always exist as new agents come into the market. The underlying priority for the Authority is to answer the question, "What is the Public Health Risk". Other tenets considered include whether the product may be misused or abused and the perceived use of the product by the public. In determining whether a particular product is a medicine, food or cosmetic, one needs to consider the attributes and claim. This is summarized below:

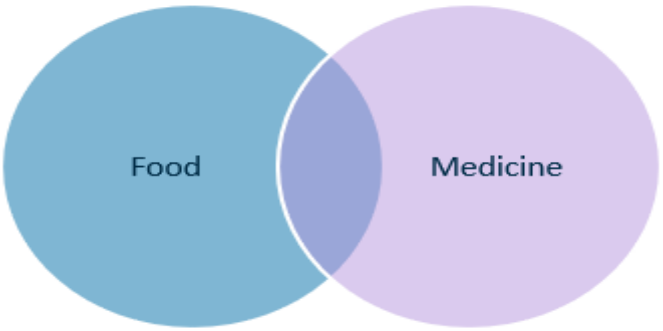

### 4.2 Determination of classification

An attribute of the product may include its presentation, pharmaceutical form, ingredients with known medicinal properties amongst other facets. A claim is when the product is presented as having properties for treating or preventing a disease. It may also include modifying or restoring a physiological function of the body. Claims may be explicit such as on the product information, advertising, testimonials or may be implicit such as the product name.[i]

Determination of classification is important as it determines how the product will be regulated. BoMRA regulates medicines and cosmetics whilst the National Food Control Board regulates food. This is important as there will ensure the legality of inspection and seizure of products; recall of unsafe products; and enforcement action taken against individuals and companies. However, regulation (including determination of registrability (and classification) is not an exact science. All determinations are to be done case by case.

Legislation pertaining to medicines/foods/cosmetics are not globally harmonized. Therefore, a product may be classified as a food in one jurisdiction and as a medicine in Botswana.

### 4.3 Food-medicine interface




**4.3.1.** Interface is the crossover area between food and medicine. The interface represents products that may not be immediately classified as food or medicine. Products in this category include imported dietary supplements marketed as foods but resemble medicines. A large part within the crossover for these two categories is that the products are for oral consumption. If the product is not taken orally, then the product is not a food. Some foods may contain herbal ingredients to be used primarily for culinary purposes. These normally would not be treated as complementary medicine (herbal medicines fall under this classification) unless the herbal product has a traditional and well-established use as a medicinal ingredient. In general:

**4.3.1.1.** Products are considered medicines if:

**4.3.1.1.a**. They are in pharmaceutical dosage forms – foods are not ordinarily taken in capsule or tablet form.

**4.3.1.1.b**. Foods with sublingual/buccal absorption – foods do not ordinarily require sublingual or buccal absorption.
**4.3.1.1.c.** Foods with a stated posology (dose and duration) – foods (except functional foods such as those used as meal replacements) are not ordinarily consumed as a dosage.
**4.3.1.1.d.** Foods with medicinal claims on the product information (label, advertising, package insert etc.).

### 4.3.2 Sports supplements

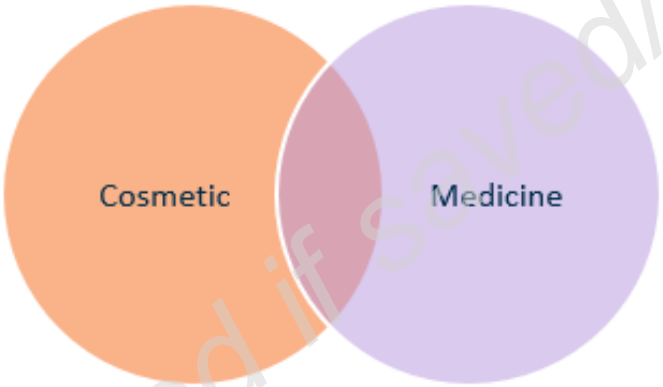
These products bring about certain complexities due to the following:

**4.3.2.a.** The shear vastness in the number of products available on the market.
**4.3.2.b.** The different types of supplements e.g.; shredders, fat burners, weight loss, testosterone boosters, pre-workout, amino acids etc. Some of these do not have a nutritional role e.g. testosterone boosters, pre-workout (contain stimulants) and shredders that have herbal ingredients that reduce fat.
**4.3.2.c.** Confusion around jurisdictional responsibilities between BoMRA, National Food Control Board

**4.3.2.d**. Novel substances – the sports industry is releasing new products containing ingredients that have not been classified before. Some are derivates of existing foods or medicines. Furthermore, the use of branded names for ingredients with more common names.
**4.3.2.e**. Risk & behaviors of consumers- elevated risk to consumers, in part because the subset of consumers obtaining and using sport supplements actively seek a performance 'edge' and are more likely to buy novel products

**4.3.2.f.** BoMRA will monitor these products through the Post Marketing Surveillance to ensure that they are not adulterated i.e., do not contain anabolic steroids.

## 4.4. Cosmetic-medicine interface




Interface is a crossover area where products could be a cosmetic or a medicine depending on the specific presentation and claims. Like the food-medicine interface, the cosmetic-medicine interface represents products that are externally applied (including for the local oral mucosal area) that and are not immediately clear as to whether they are a cosmetic or a medicine. Unlike the food-medicine interface, both cosmetic and medicine regulation fall under the purview of BoMRA and thus this process will result in a final decision being made without consultation with other authorities.

### 4.4.1 Ingredients

The ingredients used in the product are also used to determine whether a product is a cosmetic or a medicine. If a product contains an ingredient that is scheduled in the MRSA and MRS(R) then the product is a medicine regardless of claims made.

### 4.4.2 Method of application

Cosmetics are ordinarily administered by 'rubbing, pouring, spraying or applying by any means to the human body' and therefore by inference topical application to external parts of the body. Therefore, cosmetics intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product.

### 4.4.3 Claims (Unacceptable vs acceptable claims)

A claim may be made on the label, promotion material and in package inserts. Any product that is labelled and presented in such a way that the product name makes reference to a disease or might be used as a medicine as per definition of medicine above, may be classified as a medicine. However, certain claims might preclude a cosmetic from being a medicine but conversely may not be acceptable as a medicine as well. These typically fall in the interface region.

Example of claims that are acceptable and unacceptable for a cosmetic[ii]

| Area/ Subject | Acceptable | Unacceptable |
|---|---|---|
| Ageing, anti-wrinkle | Cover up age wrinkles, helps prevent the signs of ageing | Eliminates (prevents, stops, reduces, slows, reverses) ageing |
| Acne, pimples, comedones | Removes oil on acne skin, cover (hide) acne | Prevents and treats acne, pimples |
| Teeth | Cleans, whitens, removes stains, plaque removal | Antiseptic action, gingivitis, inflammation of the mouth |
| External Body organs (e.g. feet, hands, breasts, vagina, penis) | Cleans, moisturizes, perfumes | Enlarges, renews |
| Hair | Washes, cleanses loosen dandruff from hair, colour (tint) hair, restores, revitalizes, | Eliminate dandruff, alopecia, prevent hair loss, thinning, stimulate hair growth |

## 5. Requesting for registrability/classification of a product

**5.1** The client submits a fully completed Form BOMRA/ER/CM/P06/F02 including all product information (labels, package insert, fliers, brochures, proposed advertising and promotional material) to email address registrability@bomra.co.bw.

**5.2.** BOMRA evaluates the submitted information.

**5.3.** The applicant is notified of the Authority's decision and any applicable conditions or request for more information.

**5.4.** A product that has been deemed to be not a medicine nor cosmetic and as such not registrable with the Authority is not an endorsement of the product nor does it allow the product automatic entry into the market as it may fall under a different jurisdiction/authority. The applicant will be informed that compliance with other product regulations should be checked with the appropriate authority

The Authority reserves the right to revise their decision on a product deemed not registrable according to any new information on the product including any prohibited advertising claims.

## 6. Records

6.1 Application form/ Evaluation report BOMRA/ER/CM/P06/F02
6.2 Letter/email
6.3 Registrability log book BOMRA/ER/CM/P06/F01

[i] [i]Neil Gower: Regulation of herbal, complementary and traditional medicines in South Africa. Presented at the University of Bonn, Germany. 14-15 Sep 2017.
[ii] Medicines and Healthcare products Regulatory Agency A guide to what is a medicinal product MHRA Guidance Note 8 March 2020.
[iii] THE INTERNATIONAL COSMETIC REGULATORY FRAMEWORK Nicholas Shaw Nunez. University of Barcelona
[i]https://www.tga.gov.au/publication/cosmetic-claims-guidelines accessed 05.10.2020