Botswana Medicines Regulatory Authority

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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

1 Purpose

This document provides guidance to industry and stakeholders on product classification and/or determination for registration, manufacturing, importation, exportation, sale, and advertising for product(s) that are in the food-medicine interface.

2 Scope

This guideline applies to borderline products in the food-medicine interface that have a potential of being regulated under the Botswana Medicines and Related Substances Act (MRSA) 2013 and/or the Food Control Act 1993 through Botswana Medicines Regulatory Authority (BoMRA) or Ministry of Health (MoH) respectively.

This guideline does not apply to traditional medicines.

3 Definitions and abbreviations

3.1 Definitions

The following definitions shall apply;

3.1.1 Attribute

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

3.1.2 Borderline Products

For the purposes of this guideline, these are products for which the regulatory pathway for a medicine or foodstuff is not clear because it possesses both medicine and/or food characteristics.

3.1.3 Claim

A claim is any representation which states, suggests or implies that a product has particular characteristic(s) relating to its origin, nutritional properties, nature, production, processing, composition or any other quality. The claims may be made on the product's labelling, websites, promotional/advertisement materials, etc. Claims are classified as:

3.1.3.1. Health claim: Means claims stating, suggesting, or implying that a relationship exists between a product's constituent(s) and health, and can be divided into two types (functional or disease risk-reduction claims). Health claims are acceptable in food regulations as long as they do not state or imply that the food product has a property to treat or prevent a disease, symptoms, or any other adverse conditions. In addition, the food product must not achieve its intended purpose (functional or disease risk-reduction) by any pharmacological, immunological or metabolic means.

3.1.3.2. Medicinal claim: In the context of a medicine definitions, depending on the overall presentation of the product, uses or claims including words, symbols, pictures, or any other means, to treat, prevent, alleviate or help with a disease and/or a specific symptom will be

considered as a medical claim. Thus, products with such uses or claims will be subject to medicine regulations.

3.1.3.3. Nutrition claim: Means any representation which states, suggests or implies that a food has particular nutritional properties including but not limited to the energy value and to the content of protein, fat and carbohydrates, as well as the content of vitamins and minerals.

3.1.4 Complementary medicine

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

a) the mitigation or prevention of abnormal physical states; or

b) restoring, correcting or modifying physical, mental or organic functions in humans, 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.

3.1.5 Food

Means 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.

3.1.6 Food Supplement

Means a product other than tobacco intended to supplement the diet, and shall include all of the following characteristics:

a) Contains concentrated source of one or more of the following; vitamins, minerals, amino acids, essential oils, natural substances of plant or animal origin, enzymes, substances with nutritional or physiological function or contains any combination of any of these.

b) Is intended to be taken orally in the form of tablet, capsule, powder, soft gel, gelcap, granules or liquid.

c) Is not represented for use as a conventional food or as a sole item of a meal or diet.

d) Is labelled as food supplement.

These may include categories of the following but not limited to:

3.1.6.1. Fortified Food: Means food or condiments in which one or more micro-nutrients (vitamins and minerals) have been deliberately added with the purpose of improving the nutritional quality of that food supply.

3.1.6.2. Functional Food: Food that by virtue of the presence of physiologically active food components provide health benefits beyond basic nutrition when consumed as part of a varied diet on a regular basis and at effective levels.

3.1.6.3. Medical nutrition products/ therapy: Refers to nutritional products used under medical supervision to manage disease-or condition-related dietary needs. They can be administered as orally, enterally or parenterally.

3.1.6.4. Meal Replacement: A meal replacement is a drink, shake, bar, or soup, intended as a substitute for solid food, usually with controlled quantities of calories and other nutrients.

3.1.6.5. Sports Supplement: These are drinks, powders, pills, or effervescent tablets that are primarily intended to be consumed for energy, endurance, performance and recovery from intensive physical activity.

3.1.7 Herbal Tea

Herbal tea is any tea not derived from the Camellia sinensis (i.e. the plant that is used to create black, oolong, green, and white teas). It is not a true tea but instead, is an infusion or blend of various leaves, fruits, bark, roots, or flowers belonging to almost any edible, non-tea plant. This preparation is considered complementary medicines as per the MRSA, 2013.

3.1.8 Indication

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

3.1.9 Medicine

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

ii. restoring, correcting or modifying any somatic or psychic 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.

3.1.10 Novel Food

A novel food is a type of food that does not have a significant history of consumption or is produced by a method that has not previously been used for food. Characteristics of novel food may include;

a) New or emerging food or food ingredients that are not yet consumed on a wide basis by any population or by a targeted population.

b) All foods that have been obtained using new innovative food technologies or that are derived from animal, plant, microbes or mineral sources not yet currently used for human consumption.

c) Foods fortified with nutrients which are not typically used for fortification.

3.1.11 Weight Loss Product

Weight-loss product refers to any product designed, used, or marketed to prevent weight gain or produce weight loss/slimming, reduce or eliminate fat, reduce dress/ clothing size, or increase caloric deficit in a user of the product.

3.2 Abbreviations

The following abbreviations shall apply;

3.2.1 BoMRA – Botswana Medicines Regulatory Authority

3.2.2 FCA – Food Control Act No 11 of 1993

3.2.3 MoH – Ministry of Health

3.2.4 MRSA – Medicines and Related Substances Act of 2013

3.2.5 MRSR – Medicines and Related Substances Regulations of 2019

3.2.6 NFCD – Nutrition and Food Control Division

4 Introduction to Registrability and Classifications

4.1. Food-Medicine Interface

Food-medicine 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.

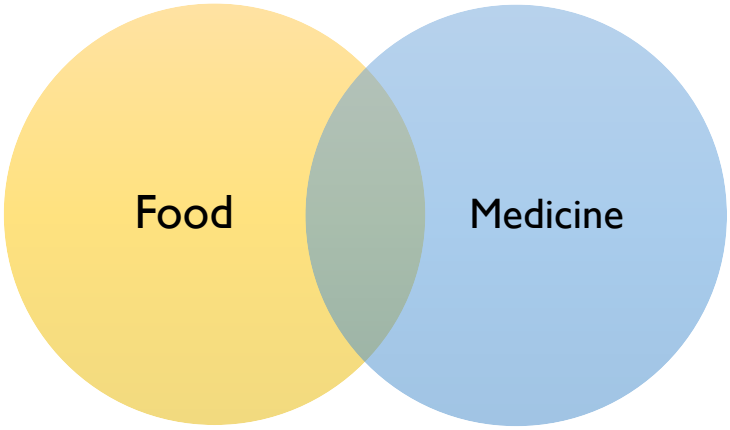

Figure 1: Depiction of food-medicine interface (FMI)

4.2. Competent Authorities

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. Further regulated aspects include manufacturing, importation, exportation, sale, and advertising for product(s)

The Ministry of Health through the Food Control Act ensures the provision of clean, safe and wholesome food to consumers. In carrying out this mandate, NFCD provides for the control of the supply of safe and wholesome food by assessing compliance of food products against the Labelling of Pre-Packaged Foods Regulations (SI, 15, 2003), and verification of safety through certificate of analysis from a competent authority. NFCD assesses compliance of food products in accordance with national standards and other relevant international standards. The current Food Control Act does not make provision for the registration of food products before placing them on the market. Compliance of food supplements is assessed against SADC guidelines for registration of food supplements (2007).

4.3. Classification

Regarding products in the food-medicine interface, it may not be apparent as to what class a particular product is. These products are referred to as borderline products. Borderline products (medicine/food interface) will always exist as new products come into the market. The underlying priority for the regulators 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 or food, one needs to consider the attributes and claims. This is summarized below;

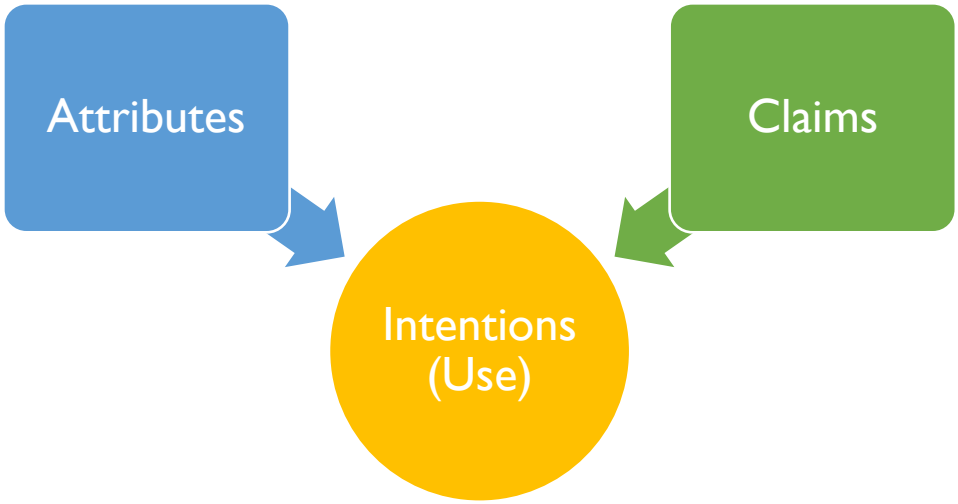

Figure 2: Constitution of intention or use of a product

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.

Product classification is important as it determines how the product will be regulated. BoMRA regulates medicines whilst the NFCD regulates food products. Determination of classification of borderline products is done on a case by case basis. Legislation pertaining to medicines/foods are not globally harmonized. Therefore, a product may be classified as a food in one jurisdiction and as a medicine in Botswana or vice versa.

4.4. Key considerations in classification

The combination of the below factors will be applied when classifying a product.

4.4.1. Form

4.4.1.1. Ordinarily foods are not taken in pharmaceutical dosage forms such as capsules or tablets which are typical forms for medicines.

4.4.1.2. Foods can be presented in their natural and unprocessed or processed form. They can be presented as liquids, solids, semi-solids including powders. Powders are also a common dosage forms for medicines.

4.4.2. Route of absorption

Foods do not ordinarily require sublingual or buccal absorption. Normally foods are expected to be absorbed in the gastrointestinal (GI) tract.

4.4.3. Posology

Foods do not normally have a stated dose and duration except functional foods such as those used as meal replacements.

4.4.4. Claims

4.4.4.1. Foods should not have medicinal claims on the label, advertising (physical or digital), package insert, or name. All other claims should be aligned with Codex Guideline for use of Nutrition and Health Claims (CXG 23-1997).

4.4.4.2. The following claims are prohibited on food:

(i) Claims stating that any given food will provide an adequate source of all essential nutrients, except in the case of well-defined products for which a Codex standard guides such claims as admissible or where appropriate authorities have accepted the product to be an adequate source of all essential nutrients.

(ii) Claims implying that a balanced diet or ordinary foods cannot supply adequate amounts of all nutrients.

(iii) Claims which cannot be substantiated.

(iv) Claims as to the suitability of a food for use in the prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition unless they are:

a) in accordance with the provisions of Codex standards or guidelines for foods as developed by the Committee on Nutrition and Foods for Special Dietary Uses and follow the principles set forth in these guidelines. or,

b) in the absence of an applicable Codex standard or guideline, permitted under the laws of Botswana in which the food is distributed.

(v) Claims which could give rise to doubt about the safety of similar food or which could arouse or exploit fear in the consumer.

4.4.5. Product composition and ingredients

4.4.5.1. Food products should not have ingredients in compositions above those stated in Annex A.

4.4.5.2. Any food or medicine that contains Cannabis and its derivatives regardless of levels of tetrahydrocannabinol (THC), cannabidiol (CBD) and any other psycho-active substance(s) shall make reference to the relevant legislation (Illicit traffic in Narcotic Drugs and psychotropic substances Act of 2018) in Botswana.

4.4.5.3. Anabolic steroids, human growth hormone, synthetic stimulants or diuretics are medicines, therefore foods should not be adulterated with these substances.

4.4.6. Public perception and history of use

Products that have been traditionally used as medicines or perceived to be a medicinal product will generally be considered medicines likewise for foods.

5 Requesting for Registrability/Classification of a Product

Self-assessment for registrability of the product should be done by clients using the decision tool as per Annex B. The process for registrability is outlined below:

5.1. The client submits a fully completed Registrability application form – ***BOMRA/ER/CM/P06/F02*** including all product information (labels, package insert, fliers, brochures, proposed advertising and promotional material) to the 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 additional information.

5.3.1. A product that has been deemed to be a medicine is registrable with BOMRA

5.3.2. A product which is deemed to be a food is assessed for compliance to relevant food regulations and standards by the NFCD at MoH.

5.3.3. The relevant competent authorities reserve the right to re-classify a product and such classification shall be final.

5.4. A product that is not classified as food or medicine as per the guidelines may fall under the jurisdiction of a different authority. This guidance note must not be construed to be an authorization to import or place such a product into the market.

6 Records

6.1 Registrability Application Form – BOMRA/ER/CM/P06/F02

7 References

7.1 Commission, E., n.d. *EU Novel food catalogue.* [Online]
Available at: https://webgate.ec.europa.eu/fip/novel_food_catalogue/ [Accessed 07/08/2023 August 2023].

7.2 FAO, 1997. *CAC/GL 23-1997.* [Online] Available at: https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&cad=rja&uact=8&ved=2ahUKEwiX09rZj8qAAxUXTkEAHSshBaQQFnoECA4QAw&url=https%3A%2F%2Fwww.fao.org%2Fag%2Fhumannutrition%2F32444-09f5545b8abe9a0c3baf01a4502ac36e4.pdf&usg=AOvVaw0VVXSTnwr7W0R2o4OSX5L [Accessed 7 August 2023].

7.3 Gazette, G., 1993. *Food Control Act.* s.l.:s.n.

7.4 Gazette, G., 2019. *Medicines and Related Substances Regulations.* s.l.:s.n.

7.5 SADC, 1991. *CODEX GENERAL GUIDELINES ON CLAIMS.* [Online]
Available at: https://www.fao.org/3/Y2770E/y2770e05.htm
[Accessed 07 August 2023].

7.6 SADC, 2007. *SADC Guideline for Registration of Food Supplements,* s.l.: SADC.

Annex A

Table 1: Nutrient or substance limits that preclude product from being classified a food

Nutrient/Substance	Recommended Dietary Allowance (19 years and older) (milligrams)
Vitamin A	700–900 mcg
Vitamin D	200–600 IU (5 – 15 mcg)
Vitamin E	15 mg
Vitamin K	90–120 mcg
Vitamin B1 (thiamine)	1.1–1.2 mg
Vitamin B2 (riboflavin)	1.1–1.3 mg
Vitamin B3 (niacin)	14–16 mg
Vitamin B5 (pantothenic acid)	5 mg
Vitamin B6 (pyridoxine)	1.3 mg
Vitamin B7 (biotin)	30 mcg
Vitamin B9 (folate)	400 mcg
Vitamin B12 (cobalamin)	2.4 mcg
Vitamin C (ascorbic acid)	75–90 mg
Calcium	2,000–2,500 mg
Phosphorus	700 mg
Magnesium	310–420 mg
Sodium	2,300 mg
Chloride	1,800–2,300 mg
Potassium	4,700 mg
Sulfur	None established
Iron	8–18 mg
Manganese	1.8–2.3 mg
Copper	900 mcg
Zinc	8–11 mg
Iodine	150 mcg
Fluoride	3–4 mg
Selenium	55 mcg

Refer to RDA for nutrient requirements and levels for healthy individuals. Foods should not exceed the tolerable upper intake level (UL): Maximum daily intake is unlikely to cause adverse health effects.

Annex B: Self-Assessment Tool

This tool is intended to help the client determine the most likely classification of their product, but the final regulatory decision will be taken by the relevant Authority.

Figure 3: Flow-diagram for a preliminary classification of a product by the client