Botswana Medicines Regulatory Authority

BOMRA
MEDICINES REGULATORY AUTHORITY

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Revision Status Sheet

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1. Purpose

This document provides guidance on the regulation of cosmetic products.

2. Scope

Applicable to all cosmetics products manufactured, imported and sold in Botswana.

3. Definitions and Abbreviations

3.1. Definitions

For the purpose of this guideline, the following definitions shall apply:

3.1.1. Act – Medicines and Related Substances Act, 2013 and its amendments

3.1.2. Regulations - Medicines and Related Substances Regulations 2019

3.1.3. Cosmetic – Means (a) any substance or mixture of substances, manufactured, sold or represented for use by rubbing, pouring, spraying, or applying by any other means to the human body, for the purpose of cleansing, beautifying or altering the appearance; or (b) any article intended for use as a component of a cosmetic;

3.1.4. Product Information File – A cosmetic product dossier containing all the information about the finished product, ingredients, packaging, manufacturing process and labelling, confirming the characteristics, safety and efficacy of a product.

3.1.5. Responsible Persons – Entities or person(s) involved in the supply chain of cosmetic products with regard to their eventual sale or manufacture in Botswana. These include importers, retailers, manufacturers, distributors, and exporters or their representatives that are resident in Botswana. (See table in annex III)

3.1.6. Claim – Purported benefits or uses of a cosmetic product as indicated on the product label, inserts, and promotional material on whichever platform it's made available.

3.1.7. Product Variant – Items in a range of cosmetic products which are produced by the same manufacturer, similar in composition and are intended for the same use but are available in different colours, fragrances or flavours.

3.2. Abbreviations

3.2.1. BOBS – Botswana Bureau of Standards

3.2.2. BoMRA – Botswana Medicines Regulatory Authority

3.2.3. BRIMS – BoMRA Regulatory Information Management System

3.2.4. INCI – International Nomenclature of Cosmetic Ingredients

3.2.5. MRSA – Medicines and related substances act 2013

3.2.6. RP – Responsible persons

3.2.7. Cosmetic Notification Holder (CNH) - The CNH refers to a company who is responsible for placing the cosmetic product in the market.

The CNH must be a locally incorporated company or legal entity in the field of cosmetics, with a permanent address and registered with Companies and Intellectual Property Authority (CIPA).

The CNH may or may not be the product owner.

4. Regulatory requirements

Cosmetics are regulated by BoMRA under the Medicines and Related Substances Regulations 2019 which were promulgated under the MRS Act 2013. They have since been exempted from registration per section 23 (3a) of the Act. Therefore, cosmetics do not require authorization or pre-approval before their importation and sale in the Botswana market. However, there are other requirements that stakeholders must comply with as per this guideline.

4.1. What are cosmetics?

Cosmetics are defined on two aspects, the mode of application and the purpose. The mode of application implies and limits them to topical applications and the oral cavity. Therefore, cosmetics are **not** ingested, injected, fed intravenously or inhaled.

They are also defined as substances, mixtures or components of cosmetic products. This clearly separates cosmetics as products and makes a distinction between cosmetics-based procedures and cosmetics. For example, an injectable can be used for cosmetic procedures, however the injectable itself will **not** be a cosmetic.

4.2. Safety of cosmetics

All cosmetics must be safe when used according to instructions. Responsible persons and CNHs must ensure that their products do not pose any safety risks to the end-user when applied under normal or reasonably foreseeable conditions of use.

4.3. Manufacturer of cosmetics

Manufacturers must ensure that all products are manufactured in sanitary conditions. Additionally, manufacturers are encouraged to comply with the provisions of good manufacturing practices. ISO 22716:2007 or its later revisions, GMP for Pharmaceutical Product (WHO), are examples of standards that provide guidelines for the production, control, storage, and shipment of cosmetic products.

4.4. Labelling of cosmetics

4.4.1 Cosmetics shall be labelled in English, legible,

comprehensible and indelible with the following information provided on the product container –

(a) Name of the product and its function, unless it is clear from the presentation of the product

(b) Instructions on the use of the cosmetic product, unless it is clear from the product name or presentation

(c) List of ingredients (using INCI names)

i. The ingredients must be declared in descending order of weight at the time they are added.

ii. Perfume and aromatic compositions and their raw materials may be referred to by the word "perfume", "fragrance", "aroma" or "flavour".

iii. Ingredients in concentrations of less than 1% may be listed in any order after those of concentration of more than 1%.

iv. Colouring agents may be listed in any order after the other ingredients in accordance with the colour index number or denomination adopted in Annex IV.

v. For decorative cosmetic products marketed in several colour shades, all colouring agents used in the range may be listed, provided that the terms "may contain" or "+/-" be added.

vi. The ingredients shall be specified using the nomenclature from the latest edition of standard references. Botanicals and extract of botanicals should be identified by its genus and species. The genus may be abbreviated.

vii. The following shall not, however, be regarded as ingredients:

• Impurities in the raw materials used

• Subsidiary technical materials used in the preparation but not present in the final products

• Materials used in strictly necessary quantities as solvents, or as carriers, for perfume and aromatic compositions which are in turn added as ingredients in the final formulation

(d) Name and address of the Responsible Person

(e) Shelf life, expiry date and/or period of use after opening (PAO)

The manufacturing or the expiry date of the product in clear terms (e.g.

month/year). The date shall be clearly expressed and shall consist either of the month and year or the day, month and year in that order. The date of minimum durability shall be the date until which this product, stored under appropriate conditions, continues to fulfil its initial function and, in particular, remains in conformity with safety requirements. It should be preceded by the words "expiry date" or "best before". If necessary, this information shall be supplemented by an indication of the conditions which must be satisfied to guarantee the stated durability.

Indication of the expiry date shall be mandatory for cosmetic products with minimum durability of less than 30 months.

(f) Batch number

(g) Storage conditions

(h) Directions for use; and

(i) Any warnings and precautions

4.4.2 In cases where the size, shape or nature of the container or package does not permit the particulars laid down in paragraphs 4.4.1 (a) – (i) to be displayed, the use of leaflets, pamphlets, hang tags, display panel, shrink wrap, or digital platform in the vicinity of the product etc. shall be allowed. However, the following particulars at least shall appear on small immediate packaging:

a) The name of the cosmetic product.

b) The manufacturing batch number

c) Durability

d) Ingredients

e) Warning/precautions

4.4.3 In cases where the cosmetic product is imported in bulk container, the following particulars at least shall appear on the container:

a) The name of the cosmetic product.

b) The name of manufacturer and manufacturing batch number

Stakeholders can also refer to the BOS ISO 22715:2006, a standard on Cosmetics — Packaging and labelling,

4.5. Cosmetic ingredients

BoMRA has adopted the following Botswana Standards on Cosmetics:

- Classification of cosmetics raw materials and adjuncts – Part 1 – Dyes, colours and pigments **BOS688 – 1b**
- Classification of cosmetics raw materials and adjuncts – Part 2 – List of raw materials generally not recognized as safe for use in cosmetics **BOS 688 – 2b**

4.5.1. Prohibited ingredients (Annex A of 2b)

These are ingredients that should not be used in cosmetic products. Any product containing a prohibited substance is considered an illicit product and should not be imported or sold in the Botswana market.

4.5.2. Restricted ingredients (Annex B of 2b)

These are ingredients that can be used, however with certain restrictions. These restrictions may be with regards to maximum allowed concentration, area of application, and/or mandatory warning on the label

4.5.3. Allowed ingredients (Annexes C and D of 2b)

This is a list of colourants, preservatives, and UV filters that are allowed in cosmetic products. For ingredients outside the criteria previously listed here, check against the list of prohibited and restricted ingredients.

4.6. Therapeutic indications

Cosmetics shall not carry any therapeutic or medical claims. Cosmetics are intended for beautifying, cleansing or superficial alteration of appearance. Any product that carries therapeutic claims is considered a medicine. So, cosmetic do not treat, cure, heal, mitigate, or alleviate diseases or any medical condition including skin diseases. Products with these claims are considered medicines and require registration before importation. If unsure about the classification of your product, a registrability process exists to help clients with classification.

An exception will be made for important advisory statements on the suitability of a cosmetic product for use by consumers undergoing active treatment for a specific skin condition such as acne, eczema, psoriasis, atopy etc. For example: "Suitable for acne prone skin".

4.7. Claims

A claim attached to a product must be within the confines of the definition of a cosmetic and must exclude any medicinal claim. So, there are acceptable claims which a cosmetic product can carry.

Table 1: Examples of claims that are acceptable and unacceptable for a cosmetic product

Area/Subject	Acceptable	Unacceptable
Ageing, wrinkles	Covers up wrinkles, helps prevent signs of ageing	Eliminates, prevents, stops, reduces, slows or reverses ageing
Acne, pimples, comedones	Removes oil on acne skin, covers or hides acne	Prevents or treats acne, or pimples

Teeth	Cleans, whitens, removes stains, plaque removal	Antiseptic action, gingivitis, inflammation of the mouth
External body organs	Cleans, moisturizes, perfumes	Enlarges, renews
Hair	Washes, cleanses, loosens dandruff, colours or tints, restores or revitalizes	Eliminates dandruff, prevents hair loss or thinning, stimulates hair growth

4.8. Responsibilities of the Cosmetic Notification Holders

CNHs are required to maintain documentation and information that establishes the safety of their cosmetic products when used according to instructions. It is encouraged that this information be compiled into a cosmetic safety report.

5. Cosmetic Listing

5.1. History

The Authority in order to survey the market instituted a cosmetic listing process. This process was conducted first in 2022 where products were listed by RPs.

5.2. Listing of Products by RPs

The listing process has since been resumed via BRIMS, and is envisaged to be a on-going exercise as new products enter into the market. Products listed prior will be migrated. Stakeholders can list new products they are bringing into the market.

New products must be listed prior to being placed in the market.

5.3. Information required

i. Name, address and contacts of the responsible person
ii. Brand name
iii. Product name
iv. List of ingredients (using INCI)
v. Product type
vi. Site of application
vii. Product form
viii. Pack sizes
ix. Storage conditions and shelf-life/expiry date/PAO
x. Colourant variations (where applicable)
xi. Name, address and contacts of the Responsible Person

Where a product has variants, it may be listed as one product, and different colours, fragrances or flavours be added under colourant section of the form.

5.4. Recommended and Required Documentation

Only the mock-up labels of the primary and secondary container where applicable are required. ISO/GMP certification and product information file are not mandatory, however these should be kept by the Responsible Person and made available on the Authority's request.

i. Mock-up label of the primary container

This should be a full representation of the label as it appears on the actual product. Where some of the information is embossed on the container, it should be clearly stated in the mock-up label document (Placeholders can be used where relevant).

ii. ISO/GMP Certification

Valid ISO/GMP Certification from a reputable organization. Certification should always be maintained at all times.

iii. Product Information File

The PIF must also contain the Cosmetic Product Safety Report.

iv. PMS Plan (See section 8)

v. Cosmetic Product Safety Report

This report is in two parts

(a) Cosmetic Product Safety Information

This must at a minimum contain;

- Quantitative (which can be provided as a range) and qualitative formula of the cosmetic product
- Physicochemical characteristics and stability of the cosmetic product
- Microbiological quality
- Impurities, traces, information about the packaging material
- Normal and reasonably foreseeable use

(b) Cosmetic Product Safety Assessment

- Conclusion of the evaluation
- Warning and instructions for use on the label
- Reasoning for the conclusion of the evaluation
- Reference of the assessor and approval of Part B

5.5. Fees

There are currently no applicable fees for listing of cosmetic products.

5.6. Listing Validity Period

There is no applicable renewal period for listing. The listing is valid as long as the product is available on the market and no changes have been made to the product that affects the listing information.

6. Listing withdrawal

For any cosmetic products that are no longer being manufactured or sold for the Botswana market the product may be withdrawn.

7. Cosmetic Advertisement

Advertisement should not refer to any medicinal or therapeutic claims, as they are beyond the scope of a cosmetic product. Therefore advertisements should;

(a) Not give the impression that it has received professional recommendation or endorsement e.g., depicting doctors, dentists or pharmacists or statements implying the same

(b) Refer to endorsements only in the instances where the endorsement is from a recognized bodies such as Authorities, professional bodies and associations and the endorsement should be public and in a format that is accessible.

(c) Contain statements based on empirical scientific evidence, evidence of which should be readily available on request

(d) Not directly disparage competitors' products. Where comparisons are made, all visuals and audio used should not clear identify or be associated with a competitive brand.

(e) Not reference studies, trials or research, which has not been vetted by an independent third party.

(f) Not have exaggerated or misleading 'before' and 'after' situations.

(g) Include statements 'the effects of the product may vary among individuals' where testimonials are used. These testimonials should be applicable and genuine.

8. Post Market Surveillance

The Authority shall monitor compliance with through a Cosmeto-vigilance programme. The activities shall include but are not limited to;

(a) Screening of product formulation to ensure they do not contain prohibited ingredients, and that restricted ingredients are used within set restrictions.

(b) Monitoring of label and claims compliance

(c) Handling of product complaints

(d) Monitoring of advertisements

(e) Monitoring of adverse reactions

Responsible Persons should have a PMS plan that covers at least c and e above.

9. Licensing requirements

The Inspections & Licensing unit is responsible for the licensing of cosmetic traders, importers, distributors, and manufacturers to ensure quality, efficacy and safety of cosmetic products is maintained throughout the supply chain of the product.

All players within the cosmetics supply chain shall be required to complete the products listing process as per section 5 of this guide prior to submitting an application to acquire a Cosmetics importers license. Applicable fees will be charged for licensing of these facilities.

9.1. Application for Approval to Operate as Cosmetics Importers

For approval of license to import, distribute or sell cosmetic products in Botswana, the following documents shall be submitted.

a. Completed Application form (Licensing of Cosmetics Operations) - (BOMRA/IL/IL/P01/F02)
b. Copy of expiring license (for renewals)
c. Copy of trade license
d. Confirmation of enterprise level i.e., small, medium or large scale
e. Proof of payment (prescribed fee as per MRSR 2019 or its revisions).
f. Certified copy of identity card or passport of the Responsible person

Renewal applications shall be submitted at least three (3) months before expiry of the license.

9.2. Processing of the Applications

a. Applications shall be completed by responsible persons who reside in Botswana
b. Applications should be scanned and emailed to inspections@bomra.co.bw
c. Applications are to be accompanied by a valid proof of payment.
d. . The applicant should verify proof of payment with the BoMRA Accounts office before submitting the application documents.
e. An application not accompanied by supporting documents shall be rejected. The applicant shall receive a rejection highlighting reasons for rejection.

9.3. Variation of License

1. A license holder shall apply to the Authority for variation of his or her license (MRSR 2019, sec 22(1))

2. The application shall be in the form- Application for Licensing of Cosmetic business accompanied by a fee as set out in schedule 5 of the MRSR, 2019 or its revisions.

3. Variation may include but not limited to:

a. Change in business name/ownership of Licensee
b. Change of address of Licensee (where applicable)
c. Change of authorized person

4. The Authority may approve the amendments and where the Authority does not approve, it shall inform the unsuccessful in writing, stating the reasons for the decision. (MRSR 2019, sec 22(3))

9.4. Suspension or Withdrawal of a License

1. Where the license holder does not meet the required standards and guidelines, the authority may suspend or withdraw a license. (MRSR 2019, sec 23(1)).

2. The Authority shall notify the license holder of the decision and may indicate the actions to be taken by the license holder and give the license holder seven days to respond (MRSR 2019, sec 23(2)).
3. The facility shall cease to operate for the suspension duration of 30 days while action is being taken to address non-conformances.
4. Where a license is withdrawn, the facility shall cease to operate. (MRSR 2019, sec 23(4)).
5. The license holder shall re-apply for a license and pay the prescribed fees

9.5. Importation fees

All cosmetics importers shall be subjected to importation fees as prescribed in the MRSR 2019.

9.6. Manufacturers

Manufacturers who intend to manufacture, register and distribute their cosmetic products or have registered their products with Botswana Medicines Regulatory Authority must comply with Good Manufacturing Practice and would be subject to be will be inspected for compliance to ISO 22716:2007 Cosmetics Good Manufacturing Practices (GMP) or equivalent — Guidelines on Good Manufacturing Practices. Please refer to the BoMRA Guidelines for Good Manufacturing Practices BOMRA/IL/IL/P08/G01, available on the BoMRA website www.bomra.co.bw.

10. Reporting and Enquiries

Website	: https://bomra.co.bw
For Listing and General Enquiries	: cosmetics.services@bomra.co.bw
For Licensing	: inspections@bomra.co.bw
Listing of Product	: https://brims.bomra.co.bw

11. Reference documentation

11.1. Medicines and Related Substances Act 2013

11.2. Medicines and Related Substances Regulations 2019

11.3. Guideline on Application for Registration of Complementary Medicines in Botswana BOMRA/ER/CM/P02/G01

11.4. Guideline on the submission of documentation for registrability/classification of a product BOMRA/ER/CM/P06/G01

11.5. ISO 22716:2007 Cosmetics Good Manufacturing Practices (GMP)

11.6. WHO Good Storage and Distribution Practices (Technical Report Series 1025, Annex 7)

11.7. BoMRA Guidelines for Good Distribution Practices of Pharmaceutical Products BOMRA/IL/IL/P01/G03

11.8. BoMRA Guidelines for Good Manufacturing Practices BOMRA/IL/IL/P08/G01

Annex I: Categories of Products generally regarded as cosmetics

NB: Exclusion criteria still apply, i.e., not all of the products that fall under these category will be cosmetics. E.g., Creams with medicinal claims are not cosmetics. Claims must be compliant (see section 4.7). Products with scheduled ingredients are excluded.

I. Creams, emulsions, lotions, gels, and oils for the skin
II. Face masks
III. Toothpaste
IV. Tinted bases
V. Make-up powders, after-bath powders, hygienic powders
VI. Toilet soaps, deodorant soaps
VII. Perfumes, fragrances, cologne
VIII. Bath and shower preparations
IX. Depilatories
X. Deodorants and anti-perspirants

XI. Hair care products for tinting, waving, straightening, setting, cleansing, conditioning, and hairdressing
XII. Shaving products
XIII. Make-up and make-up removal products
XIV. Lips balms, glosses,
XV. Nail care
XVI. External intimate hygiene
XVII. Sunbathing products
XVIII. Products for tanning without sun
XIX. Skin-whitening products
XX. Anti-wrinkle, anti-aging products (see claims 4.7)
XXI. Hand sanitizers
XXII. Essential oil for skin/hair/nails, they should not have a therapeutic or medicinal claims

This list is not exhaustive.

Annex II: Categories of products that are not cosmetics.

I. Slimming products
II. Eye droppers, containers or sprays
III. Sexual enhancement products
IV. Injections and micro needling
V. Orally ingested products
VI. Products for treatment of diseases
VII. Pain relief products
VIII. Sleep aid products
IX. Surface disinfectants
X. Body disinfectants/sanitizers
XI. Animal or pet care products

XII. Massage or essential oils for therapeutic purposes including inhalation

XIII. Products for systemic detoxification

Annex III: Obligations of the importer, distributor and manufacturer

	Brand Owner/RP/ Manufacturer	**Distributor**	**Importer**
Keep Product Information File	Yes	No	No
Compliance to Labelling, Ingredient Selection	Yes	Yes	Yes
Inform the Authority on safety and quality issues	Yes	Yes	Yes
Provide information on market distribution of product	No	Yes	Yes
Provide safety report	Yes	No	No
Ensure good manufacturing standards	Yes	No	No
Cooperate with Authority in Regulatory Actions (e.g., recall)	Yes	Yes	Yes