

MEDICINES AND RELATED SUBSTANCES ACT, 2025

COSMETICS REGULATIONS, 2026

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In exercise of the powers conferred by **sections 88 and 89** of the Medicines and Related Substances Act, 2025, the Minister, after consultation with the Botswana Medicines Regulatory Authority, makes the following Regulations:

PART I

Preliminary

Citation

1. These Regulations may be cited as the Cosmetics Regulations, 2026, and shall come into force on the date of publication in the Government Gazette.

Interpretation

2. In these Regulations, unless the context otherwise requires —

“**Act**” means the Medicines and Related Substances Act, 2025;

“**adverse event**” means any undesirable experience associated with the use of a cosmetic product, including skin irritation, sensitisation, systemic reactions, or any other undesirable effect on human health;

“**Authority**” means the Botswana Medicines Regulatory Authority established under the Act;

“**cannabidiol**” means the non-psychoactive phytocannabinoid derived from *Cannabis sativa* L., commonly referred to as CBD;

“**claim**” means any representation, assertion, or statement about a cosmetic product that describes its function, characteristics, benefits, ingredients, origin, or performance, whether made expressly, by implication, or by way of image, symbol, or digital communication, and includes representations made through social media, online platforms, and digital advertising;

“**cosmetic product**” means any substance or mixture intended to be placed in contact with the external parts of the human body, including the epidermis, hair system, nails, lips, external genital organs, teeth, or mucous membranes of the oral cavity, for the exclusive or principal purpose of cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition, or correcting body odours, but does not include a medicine as defined in the Act;

“cosmetic product safety report” means a safety assessment document prepared by a qualified safety assessor, demonstrating that a cosmetic product is safe for its intended use and conforming to the prescribed safety evaluation framework;

“distributor” means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a cosmetic product available in the Botswana market;

“endocrine-disrupting substance” means a substance or mixture that alters the function of the endocrine system and consequently causes adverse health effects in an intact organism, its progeny, or subpopulations, in accordance with criteria established by the World Health Organization or other internationally recognised scientific bodies, and as may be further specified in guidelines issued by the Authority under regulation 33;

“general use cosmetic” means a cosmetic product that is simple in method of application and presents minimal risk to the health of consumers under normal or reasonably foreseeable conditions of use;

“Good Manufacturing Practice” or **“GMP”** means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use, as prescribed by the Authority or by international standards recognised by the Authority, including the relevant ISO standards and WHO guidelines;

“importer” means any natural or legal person established in Botswana who places a cosmetic product from a third country on the Botswana market;

“manufacturer” means any natural or legal person who manufactures a cosmetic product, or has a cosmetic product designed or manufactured and markets it under that person’s name or trademark;

“market” means to sell, offer for sale, import, export, distribute, promote, advertise, store, or otherwise make available a cosmetic product to persons in Botswana, whether for commercial gain or otherwise;

“microplastic” means a synthetic solid polymer particle, whether of regular or irregular shape and with a size ranging from 0.1 nanometres to 5 millimetres,

that is not biodegradable and is intentionally added to a cosmetic product for a functional purpose;

“**Minister**” means the Minister responsible for health;

“**nanomaterial**” means an insoluble or biopersistent material that is intentionally manufactured and has one or more external dimensions, or an internal structure, on the scale from 1 to 100 nanometres;

“**notification**” means the process by which a responsible person submits prescribed information to the Authority regarding a cosmetic product prior to placing it on the market in Botswana;

“**product information file**” or “**PIF**” means the documented technical dossier maintained by the responsible person in respect of each notified cosmetic product, containing all information required under these Regulations;

“**responsible person**” means an entity or person involved in the supply chain of cosmetic products with regard to their eventual sale or manufacture in Botswana, including importers, retailers, manufacturers, distributors, and exporters, or their representatives, that are resident in Botswana;

“**serious undesirable effect**” means an undesirable effect that results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies, or an immediate vital risk or death;

“**special use cosmetic**” means a cosmetic product that, by reason of its claims, composition, or properties, presents a higher complexity and a heightened risk to human health under normal or reasonably foreseeable conditions of use;

“**tetrahydrocannabinol**” means the primary psychoactive constituent of *Cannabis sativa* L., commonly referred to as THC.

Application

3. These Regulations apply to all cosmetic products marketed, manufactured, imported, exported, distributed, stored, advertised, promoted, or otherwise made available in Botswana.

(2) These Regulations shall be read together with the Act and any other written law in force in Botswana that regulates the safety and quality of products intended for human use.

(3) A cosmetic product shall not be presented or labelled as having properties of preventing, treating, or curing a human disease.

PART II

Classification of Cosmetic Products

Classification of cosmetic products

4. For the purposes of notification and regulatory oversight, the Authority shall classify cosmetic products into the following categories —
 - (a) general use cosmetics, which are simple in their method of application and present minimal risk to the health of consumers; and
 - (b) special use cosmetics, which have increasing complexity in their claims, properties, or composition and present a higher risk to human health under normal or reasonably foreseeable conditions of use.
- (2) The Authority shall, by notice in the Government Gazette, publish and maintain a list of product categories assigned to each classification under subregulation (1).
- (3) Where a cosmetic product meets the criteria of both categories under subregulation (1), it shall be classified as a special use cosmetic.
- (4) The Authority may revise the classification of a cosmetic product upon its own initiative or upon application by a responsible person, taking into account new safety data, scientific developments, or international best practice.

PART III

Notification and Responsible Persons

Obligation to notify

5. A person shall not market a cosmetic product in Botswana unless —
- (a) the cosmetic product has been notified to the Authority through the notification portal established under regulation 7; and
 - (b) the responsible person has complied with all conditions prescribed by or under these Regulations.
- (2) Notification shall be effected prior to placing a cosmetic product on the market.
- (3) A responsible person who seeks to notify a cosmetic product shall submit to the Authority, through the notification portal, the following information —
- (a) the category and intended function of the cosmetic product;
 - (b) the complete qualitative and, where required, quantitative composition of the product, including the International Nomenclature of Cosmetic Ingredients (INCI) names of all ingredients;
 - (c) the physicochemical and microbiological specifications of the product;
 - (d) the method of manufacture and a statement of compliance with Good Manufacturing Practice;
 - (e) a summary of the cosmetic product safety report prepared in accordance with regulation 10;
 - (f) the name, contact particulars, and registered address of the responsible person;
 - (g) proof of payment of the prescribed notification fee;
 - (h) a specimen of the proposed label and packaging; and
 - (i) such other information as the Authority may prescribe.
- (4) Where the Authority requires additional information or documentary evidence to complete its assessment, the responsible person shall furnish such information within the period specified by the Authority.

(5) A responsible person shall notify the Authority of any material change to the particulars submitted under subregulation (3), and the Authority may, following its assessment, amend, suspend, or cancel the notification.

(6) A person who markets a cosmetic product in contravention of this regulation commits an offence and is liable to a fine not exceeding P500 000 or to imprisonment for a term not exceeding two years, or to both.

Responsible persons

6. A responsible person shall, in relation to any cosmetic product marketed or intended to be marketed in Botswana —

- (a) ensure that the cosmetic product complies with these Regulations and with all applicable requirements prescribed under the Act;
- (b) maintain and make available to the Authority, upon request, the product information file for such period as the Authority may prescribe;
- (c) cooperate with the Authority in any regulatory action taken in respect of the cosmetic product; and
- (d) ensure that the cosmetic product is manufactured and distributed in compliance with Good Manufacturing Practice.

(2) Where a responsible person has reason to believe that a cosmetic product which has been placed on the market does not comply with these Regulations, that person shall immediately take the corrective measures necessary to ensure compliance, or to withdraw or recall the product, and shall forthwith inform the Authority accordingly.

(3) There shall be only one responsible person per cosmetic product marketed in Botswana.

(4) A responsible person may, by written agreement, authorise another person resident in Botswana to act on its behalf for the purposes of these Regulations, provided that the authorising responsible person remains jointly liable for compliance.

Notification portal and register

7. The Authority shall establish and maintain a secure electronic cosmetic products notification portal through which all notifications under these Regulations shall be submitted.
- (2) The Authority shall maintain a register of all notified cosmetic products, which shall —
 - (a) be accessible to the public through the Authority’s official website;
 - (b) contain such particulars as the Authority may prescribe; and
 - (c) be updated by the Authority on a regular basis to reflect the current status of all notified products.
 - (3) Upon successful notification, the Authority shall issue a notification reference number to the responsible person, which shall be affixed to the cosmetic product in such manner as the Authority may prescribe.

Notification fees

8. A responsible person who submits a notification under regulation 5 shall pay such fees as may be prescribed in the Schedule to these Regulations or as the Minister may, by notice in the Government Gazette, prescribe from time to time.
- (2) The prescribed fee shall be payable at the time of submission of the notification application and shall be non-refundable, whether or not the notification is accepted.
 - (3) The Authority may prescribe different fees for general use cosmetics and special use cosmetics, taking into account the complexity of the assessment required.

PART IV

Safety and Quality Requirements

General safety requirement

9. A responsible person shall ensure that any cosmetic product placed on the market in Botswana is safe for human health when used under normal or reasonably foreseeable conditions of use, having regard to —
- (a) the presentation, labelling, instructions for use, and any other information provided by the responsible person;
 - (b) the nature, appearance, and packaging of the product, including the type of consumer who may be expected to use it, having particular regard to vulnerable groups including children under the age of three years, pregnant women, and persons with compromised skin integrity;
 - (c) the use of cosmetic ingredients at acceptable concentrations in accordance with current scientific knowledge; and
 - (d) the microbiological and physicochemical stability of the product.
- (2) The Minister shall, in consultation with the Authority, prescribe requirements for acceptable, restricted, and prohibited cosmetic ingredients, with due regard to international standards, including those published by the European Union Cosmetics Regulation, the International Cooperation on Cosmetics Regulation (ICCR), and the WHO.
- (3) A cosmetic product shall be considered unsafe where it —
- (a) contains a prohibited ingredient listed under regulation 13;
 - (b) contains a restricted ingredient in excess of the permitted concentration;
 - (c) is contaminated with pathogenic microorganisms or chemical impurities beyond acceptable limits;
 - (d) is not manufactured in accordance with Good Manufacturing Practice;
- or
- (e) has been found to cause an adverse event upon post-market surveillance.

- (4) Where the Authority determines that a cosmetic product on the market is unsafe, or does not comply with the requirements of these Regulations, it shall order the responsible person —
 - (a) to immediately take any corrective measures necessary for compliance;
or
 - (b) to withdraw or recall the product from the market and to cooperate with the Authority in any regulatory action required to eliminate the risks posed by the product.
- (5) A person who contravenes the provisions of this regulation commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

Cosmetic product safety report

- 10.** A responsible person shall, prior to notification, ensure that a cosmetic product safety report is prepared in respect of each cosmetic product.
 - (2) The cosmetic product safety report shall be prepared by a qualified safety assessor and shall include —
 - (a) Part A: the cosmetic product safety information, covering the quantitative and qualitative composition, physicochemical and microbiological specifications, impurities, packaging material information, normal and reasonably foreseeable use, exposure assessment, ingredient toxicological profiles, and undesirable effects and serious undesirable effects; and
 - (b) Part B: the cosmetic product safety assessment, comprising the safety assessor’s evaluation of the adequacy and accuracy of the Part A information, conclusions on the safety of the product, and any warnings and conditions of use necessary to ensure the product’s safe use.
 - (3) A qualified safety assessor shall hold a degree in pharmacy, toxicology, medicine, dermatology, or a related discipline and shall have relevant post-qualification experience in safety assessment or a related field, as may be further prescribed by the Authority.

- (4) The responsible person shall update the cosmetic product safety report whenever there is a change in the product formulation, manufacturing process, or safety profile.

Product information file

11. A responsible person shall maintain a product information file for each notified cosmetic product and shall make it available to the Authority upon request.

- (2) The product information file shall contain —
- (a) a description of the cosmetic product sufficient to clearly attribute the product information file to the cosmetic product;
 - (b) the cosmetic product safety report referred to in regulation 10;
 - (c) a description of the manufacturing method and a declaration of compliance with Good Manufacturing Practice;
 - (d) evidence of the effect claimed for the cosmetic product, where justified by the nature of the claim;
 - (e) a declaration confirming compliance with the prohibition on animal testing under regulation 14, and data on any animal testing performed in relation to the development of the product or its ingredients that was carried out in compliance with legal requirements in third countries prior to the prohibition taking effect; and
 - (f) records of all adverse events reported in respect of the cosmetic product.
- (3) The product information file shall be kept for a minimum period of ten years from the date on which the last batch of the cosmetic product was placed on the market.
- (4) The product information file shall be maintained in English and shall be kept at the registered business address of the responsible person in Botswana, or at such other address as the Authority may approve.

Good Manufacturing Practice

12. A manufacturer of a cosmetic product shall ensure that the product is manufactured in compliance with Good Manufacturing Practice.

- (2) A manufacturer shall be presumed to comply with Good Manufacturing Practice where the manufacturer applies the standards set out in —
- (a) ISO 22716:2007 (Cosmetics — Good Manufacturing Practices — Guidelines on Good Manufacturing Practices); or
 - (b) such other international standard as the Authority may recognise by notice in the Government Gazette.
- (3) The Authority may conduct inspections of manufacturing premises and may require a manufacturer to produce evidence of GMP compliance, including third-party audit reports or certificates.

PART V

Ingredients and Restricted Substances

Prohibited and restricted ingredients

13. A person shall not use in the manufacture of a cosmetic product any ingredient that is listed as a prohibited ingredient in the list published under regulation 19.

(2) The Authority may restrict the use of a cosmetic ingredient by specifying —

- (a) the product types in which the ingredient may be used;
- (b) the maximum permitted concentration;
- (c) any other conditions of use; and
- (d) any labelling requirements relating to warnings or conditions of use.

(3) The Authority may, on the basis of safety and public interest, or following a prior restriction or prohibition by any international regulatory authority recognised by the Authority, restrict or prohibit the use of any cosmetic substance.

(4) In determining whether to restrict or prohibit an ingredient, the Authority shall have regard to —

- (a) available scientific and toxicological evidence;
- (b) the precautionary principle;
- (c) relevant international standards and decisions of recognised bodies, including the European Union's Scientific Committee on Consumer Safety (SCCS), the WHO, and the International Cooperation on Cosmetics Regulation (ICCR); and
- (d) the need to protect human health and safety, including the safety of vulnerable groups.

(5) A person who manufactures or places on the market a cosmetic product containing a prohibited ingredient commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

Prohibition of animal testing

- 14.** No person shall conduct, commission, or cause to be conducted animal testing for the purpose of satisfying the safety requirements under these Regulations in respect of—
- (a) a finished cosmetic product; or
 - (b) any combination of ingredients in a finished cosmetic product.
- (2) No person shall market in Botswana a cosmetic product the formulation of which has involved animal testing of the finished product after the commencement of these Regulations.
- (3) The prohibition under subregulations (1) and (2) shall not apply to —
- (a) animal testing conducted in a third country in compliance with that country’s legal requirements, where such testing was undertaken before the commencement of these Regulations; or
 - (b) the use of historical animal testing data for purposes of safety assessment, provided that such data is disclosed in the product information file in accordance with regulation 11(2)(e).
- (4) The Authority shall, in guidelines issued under regulation 33, provide guidance on alternative safety testing methods that satisfy the safety assessment requirements under these Regulations.
- (5) A person who contravenes subregulation (1) or (2) commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

Endocrine-disrupting substances

- 15.** A person shall not use in the manufacture of a cosmetic product any substance that has been identified as an endocrine-disrupting substance and listed as prohibited under regulation 19, or classified with endocrine-disrupting properties by a scientific or regulatory body recognised by the Authority.
- (2) Where a cosmetic ingredient is under scientific review for endocrine-disrupting properties, the Authority may, in application of the precautionary principle, restrict the use of that ingredient in cosmetic products.

- (3) The Authority shall, in guidelines issued under regulation 33, specify —
 - (a) the criteria and methodology to be used in identifying and evaluating endocrine-disrupting substances for regulatory action;
 - (b) the scientific bodies and regulatory frameworks whose determinations the Authority recognises for the purposes of this regulation; and
 - (c) requirements for safety data demonstrating the absence of endocrine-disrupting properties, where the Authority requires such evidence in respect of a specific ingredient.
- (4) A person who manufactures or places on the market a cosmetic product containing a prohibited endocrine-disrupting substance commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

Microplastics in cosmetic products

16. A person shall not use intentionally added microplastics in the manufacture of a cosmetic product, except as may be permitted by the Authority in guidelines issued under regulation 33.

- (2) Where any microplastic ingredient is present in a cosmetic product, whether as a constituent of the formulation or arising from the degradation of other ingredients, the responsible person shall —
 - (a) declare the presence of such microplastic ingredient in the notification submitted under regulation 5;
 - (b) include in the product information file a technical assessment of the source, function, concentration, and environmental persistence of the microplastic ingredient; and
 - (c) include on the label of the cosmetic product a statement, in such form as the Authority may prescribe, indicating the presence of microplastic ingredients.
- (3) The Authority shall, in guidelines issued under regulation 33, specify —
 - (a) the categories of microplastic ingredients that are prohibited, restricted, or permitted for use in cosmetic products;

- (b) the threshold concentrations and conditions applicable to permitted microplastic ingredients; and
- (c) labelling and disclosure requirements specific to microplastic ingredients.
- (4) A person who contravenes subregulation (1) or (2) commits an offence and is liable to a fine not exceeding P500 000 or to imprisonment for a term not exceeding two years, or to both.

Nanomaterials in cosmetic products

17. A responsible person who seeks to use a nanomaterial as an ingredient in a cosmetic product shall comply with the requirements of this regulation in addition to all other applicable requirements under these Regulations.

- (2) Where a nanomaterial is used as an ingredient in a cosmetic product, the responsible person shall —
 - (a) declare the nanomaterial in the notification submitted under regulation 5, indicating the name, particle size range, physicochemical characteristics, and function of the nanomaterial;
 - (b) include in the product information file a safety assessment specific to the nanomaterial in its nano-form, addressing exposure, toxicological profile, and environmental considerations; and
 - (c) indicate the nanomaterial on the ingredient list on the label of the cosmetic product by following the name of the ingredient with the word “nano” in brackets.
- (3) The Authority shall issue guidelines under regulation 33 governing the safety requirements, notification procedures, and labelling obligations applicable to nanomaterials in cosmetic products, with reference to internationally recognised frameworks including those of the Scientific Committee on Consumer Safety (SCCS) of the European Union and the International Cooperation on Cosmetics Regulation (ICCR).
- (4) A person who contravenes this regulation commits an offence and is liable to a fine not exceeding P500 000 or to imprisonment for a term not exceeding two years, or to both.

Cannabidiol-containing cosmetics

18. Cosmetic products containing cannabidiol (CBD) may be regulated as cosmetics under these Regulations, subject to compliance with cannabis control standards as may be prescribed.

(2) A cosmetic product containing CBD shall comply with the tetrahydrocannabinol (THC) content limits as may be prescribed by the Authority in consultation with the relevant competent authority.

(3) The responsible person for a CBD-containing cosmetic product shall, in addition to the requirements under these Regulations, comply with any applicable requirements under the laws of Botswana governing cannabis and cannabis products.

Published lists

19. The Authority shall publish and maintain, in the Government Gazette and on its official website, lists of —

- (a) substances prohibited for use in cosmetic products;
- (b) substances permitted for use in cosmetic products subject to restrictions;
- (c) colorants, preservatives, and ultraviolet filters that are permitted for use in cosmetic products; and
- (d) substances identified as endocrine-disrupting substances for the purposes of regulation 15.

(2) The lists referred to in subregulation (1) shall be reviewed and updated by the Authority at regular intervals, taking into account developments in scientific knowledge and international regulatory standards.

(3) The Authority shall, before making any amendment to the lists, give notice of the proposed amendment and afford interested parties a reasonable opportunity to make representations.

PART VI

Labelling and Claims

General labelling requirements

- 20.** A cosmetic product shall not be placed on the market in Botswana unless its container and packaging bear legible, indelible, and clearly visible information in English, including —
- (a) the name and address of the responsible person;
 - (b) the country of manufacture;
 - (c) the nominal content by weight or by volume at the time of packaging, except for small-sized packaging as prescribed;
 - (d) the date of minimum durability, indicated by the words “best used before the end of” followed by either the date itself or a reference to where the date appears on the packaging;
 - (e) where the date of minimum durability would be less than 30 months, the period after opening for which the product can be used without harm to the consumer, expressed in months or years, and indicated by the symbol of an open jar;
 - (f) special precautions to be observed in use, including those required under regulations 13 and 19;
 - (g) the batch number or reference for identification of the manufacturing batch;
 - (h) the function of the cosmetic product, unless clear from the presentation;
 - (i) the list of ingredients, using INCI nomenclature, preceded by the word “Ingredients” in descending order of weight at the time of incorporation, provided that ingredients in concentrations of less than one percent may be listed in any order after those at concentrations of one percent or more; and
 - (j) the notification reference number issued by the Authority under regulation 7(3).

(2) The Authority may prescribe additional labelling requirements for special use cosmetics, including specific warnings, directions for use, age restrictions, and contraindications.

(3) Where it is impracticable, due to the size or shape of the container, for certain labelling information to appear on the container or packaging, such information shall be included on an enclosed leaflet, label, tape, or card attached to or accompanying the product, and a reference or symbol indicating the information shall appear on the container.

(4) A person who markets a cosmetic product bearing a label that does not comply with this regulation commits an offence and is liable to a fine not exceeding P200 000 or to imprisonment for a term not exceeding one year, or to both.

Claims and representations

21. A person shall not, in relation to a cosmetic product, make or cause to be made any claim or representation, whether in print, broadcast media, social media, digital advertising, online platforms, or any other form of communication, that —

(a) is false, misleading, or deceptive, or is likely to create a false impression regarding the product's characteristics, function, or safety;

(b) attributes to the product properties of preventing, treating, or curing a human disease, which would classify the product as a medicine under the Act;

(c) is not substantiated by appropriate evidence maintained in the product information file;

(d) suggests, directly or indirectly, that the product has been evaluated or endorsed by the Authority, unless such endorsement has been expressly given in writing; or

(e) denigrates competitors' products in a manner that is false or misleading.

(2) The prohibition under subregulation (1) extends to claims made through social media influencers, sponsored content, digital endorsements, and any other form of online communication that is made on behalf of or for the benefit

of the responsible person, whether or not such communication is made directly by the responsible person.

(3) Claims shall be assessed in accordance with the common criteria for claims justification, including the criteria of legal compliance, truthfulness, evidential support, honesty, fairness, and informed decision-making, as may be further detailed in guidelines issued by the Authority under regulation 33.

(4) A person who contravenes this regulation commits an offence and is liable to a fine not exceeding P500 000 or to imprisonment for a term not exceeding two years, or to both.

Language of labelling

22. All labelling information required under regulation 20 shall be in the English language.

(2) A responsible person may, in addition to English, include labelling information in any other language.

(3) Where a label contains information in more than one language, the English text shall not be rendered less prominent than the text in any other language.

PART VII

Adverse Event Reporting and Vigilance

Duty to report safety risks

23. Where a cosmetic product presents or may present a risk to the safety of humans, the responsible person shall immediately —
- (a) inform the manufacturer or product owner and submit a report to the Authority setting out details of the non-compliance and any corrective measures to be taken;
 - (b) inform the Authority of the premises at which the cosmetic product is being made available on the market; and
 - (c) inform the Authority of all adverse events related to the product, including the name of the product, the nature of the adverse event, and corrective measures to be implemented.
- (2) The provisions of the Act relating to reporting of unsafe products shall apply, with the necessary modifications, to cosmetic products.
- (3) A report submitted to the Authority under subregulation (1) shall be treated as confidential, except where disclosure is required in the interests of public health.

Adverse event reporting

24. The Authority shall establish and maintain a cosmetic product vigilance system for the systematic collection and analysis of information on adverse events associated with cosmetic products.
- (2) A responsible person shall, in respect of each cosmetic product placed on the market —
- (a) maintain a record of all adverse events and serious undesirable effects reported to or identified by the responsible person;
 - (b) report all serious undesirable effects to the Authority within the period specified by the Authority; and

- (c) provide the Authority with a periodic summary report of all adverse events recorded in respect of the cosmetic product, in such format and at such intervals as the Authority may prescribe.
- (3) Healthcare professionals and consumers may report adverse events associated with cosmetic products to the Authority through the cosmetic products notification portal or such other channel as the Authority may prescribe.
- (4) The Authority shall analyse the reports received under this regulation and take such regulatory action as may be appropriate in the circumstances.

Withdrawal and recall

- 25.** The Authority may, where it determines that a cosmetic product poses or is likely to pose a risk to public health or safety, direct the responsible person, by written notice, to —
- (a) withdraw the product from the market with immediate effect;
 - (b) recall the product from consumers; or
 - (c) take such other corrective action as the Authority may specify.
- (2) A responsible person who receives a notice under subregulation (1) shall comply with such notice and shall submit a written recall plan to the Authority within the period specified by the Authority.
- (3) A responsible person shall bear the cost of any recall or withdrawal carried out under this regulation.
- (4) A person who fails to comply with a direction to withdraw or recall a product under this regulation commits an offence and is liable to a fine not exceeding P1 000 000 or to imprisonment for a term not exceeding three years, or to both.

PART VIII

Obligations of Manufacturers and Responsible Persons

Obligations of manufacturers

26. A manufacturer of a cosmetic product shall —
- (a) comply with Good Manufacturing Practice in the manufacture of cosmetic products;
 - (b) keep such technical documentation on manufacturing standards, quality control procedures, and product specifications as may be prescribed by the Authority;
 - (c) ensure that manufacturing processes do not introduce contamination or compromise the safety or quality of the cosmetic product;
 - (d) designate a qualified person responsible for technical compliance and quality assurance;
 - (e) cooperate fully with the Authority during inspections, audits, or any other regulatory activity; and
 - (f) retain manufacturing records for a minimum period of ten years from the date on which the last batch of the product was produced.
- (2) A manufacturer who produces a cosmetic product intended solely for export shall notify the Authority in accordance with regulation 5 and shall comply with the safety and manufacturing requirements under these Regulations unless the importing country's requirements provide otherwise and the Authority has granted an exemption in writing.

Record-keeping

27. A responsible person shall maintain accurate and complete records of —
- (a) the notification status and notification reference number of each cosmetic product;
 - (b) the product information file for each notified cosmetic product;

- (c) all transactions relating to the importation, distribution, sale, or export of cosmetic products;
 - (d) all adverse events and serious undesirable effects reported; and
 - (e) all corrective actions, recalls, or withdrawals undertaken.
- (2) Records under subregulation (1) shall be retained for a minimum period of ten years and shall be made available to the Authority upon request.

Importers

- 28.** An importer of a cosmetic product shall, prior to importation, ensure that —
- (a) the cosmetic product has been notified in accordance with regulation 5;
 - (b) the manufacturer of the cosmetic product has complied with the applicable manufacturing standards; and
 - (c) the product bears the labelling required under regulation 20.
- (2) An importer shall cooperate with the Authority and provide it with access to all documentation relating to the cosmetic products imported into Botswana.
- (3) An importer shall indicate on the cosmetic product or its packaging the name, registered business name, and address of the importer, in addition to any information required from the manufacturer.

PART IX

Market Surveillance and Enforcement

Market surveillance

- 29.** The Authority shall conduct post-market surveillance of cosmetic products placed on the market in Botswana to verify that —
- (a) cosmetic products comply with the requirements of these Regulations;
 - (b) responsible persons are fulfilling their obligations; and
 - (c) cosmetic products do not present a risk to the health or safety of users.
- (2) For the purposes of market surveillance, the Authority may —
- (a) inspect premises where cosmetic products are manufactured, stored, distributed, or sold;
 - (b) take samples of cosmetic products for laboratory analysis;
 - (c) require responsible persons to provide information, documents, or records; and
 - (d) carry out such other activities as the Authority considers necessary for effective market surveillance.
- (3) The Authority shall prepare and publish an annual market surveillance report summarising its findings, actions taken, and recommendations.

Corrective actions and regulatory measures

- 30.** Where, following market surveillance or any other investigation, the Authority finds that a cosmetic product does not comply with these Regulations, it may direct the responsible person, by written notice, to take one or more of the following corrective measures —
- (a) reformulate the product;
 - (b) amend the labelling;
 - (c) restrict the distribution of the product;
 - (d) withdraw the product from the market; or
 - (e) recall the product from consumers.

- (2) The Authority may suspend or cancel the notification of a cosmetic product where it determines that —
- (a) the notification was obtained on the basis of false or misleading information;
 - (b) the cosmetic product no longer meets the safety requirements under these Regulations; or
 - (c) the responsible person has failed to comply with a corrective measure directed by the Authority.
- (3) Before taking a regulatory measure under subregulation (2), the Authority shall give the responsible person written notice of its intention and afford that person a reasonable opportunity to make representations.

Offences and penalties

31. Subject to the specific penalty provisions in these Regulations, a person who contravenes any provision of these Regulations commits an offence and is liable to a fine not exceeding P200 000 or to imprisonment for a term not exceeding one year, or to both.

(2) The court may, in addition to any fine or term of imprisonment, order the forfeiture and destruction of any cosmetic product that is the subject of a conviction under these Regulations.

(3) Where a person is convicted of an offence under these Regulations, the court may, in addition to any other penalty, make an order prohibiting that person from marketing cosmetic products in Botswana for such period as the court may determine.

PART X

Miscellaneous

Transitional provisions

32. A person who, at the commencement of these Regulations, is marketing a cosmetic product in Botswana that has not been notified in accordance with these Regulations shall comply with the notification requirements under regulation 5 within the period specified by the Authority in guidelines issued under regulation 33.

(2) During the transitional period, the Authority may, in its discretion, permit the continued marketing of a cosmetic product that does not fully comply with these Regulations, subject to such conditions as the Authority may impose.

(3) A cosmetic product that was lawfully marketed in Botswana prior to the commencement of these Regulations and that fully complies with the requirements of these Regulations may continue to be marketed without further action.

Guidelines

33. The Authority may issue guidelines for the purpose of providing guidance on the application of these Regulations and on good regulatory practice in the cosmetics sector, including guidelines on —

- (a) notification procedures and timelines;
- (b) animal testing alternatives and safety assessment methodologies;
- (c) endocrine-disrupting substance identification and evaluation criteria;
- (d) the use of microplastics and nanomaterials in cosmetic products; and
- (e) claims substantiation requirements, including those applicable to social media and digital advertising.

(2) Guidelines issued under subregulation (1) shall not have the force of law but shall be taken into account by the Authority in exercising its functions under these Regulations.

Revocation

34. Any regulations relating to cosmetics made under any enactment that was in force immediately before the commencement of these Regulations are hereby revoked.

Made this _____ day of _____, 2026.

MINISTER OF HEALTH

SCHEDULE

(Regulation 8)

NOTIFICATION FEES

The following fees shall be payable in respect of notifications under these Regulations:

Item	Description	Fee (Pula)
1.	Notification — General Use Cosmetic	[To be prescribed]
2.	Notification — Special Use Cosmetic	[To be prescribed]
3.	Amendment of a notification	[To be prescribed]
4.	Renewal of a notification	[To be prescribed]
5.	Re-notification following recall or reformulation	[To be prescribed]

Note: Fees shall be reviewed periodically and updated by the Minister by notice in the Government Gazette.

— END OF REGULATIONS —