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; **"advertisement"** in relation to a medicinal product, includes any pictorial, visual or otherwise descriptive matter or verbal statement or reference communicated, distributed, or made available to the public or any section thereof through any medium or method to the public or any section thereof, including those

"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 but is not limited to ????representations made through social media, online platforms, and digital advertising;

"Clinical trial" -means a systematic investigation involving human participants undertaken to evaluate the safety, skin compatibility, tolerability, acceptability, performance, or cosmetic efficacy of a cosmetic product under normal or intended conditions of use, including studies conducted to substantiate cosmetic claims, provided that the product is not investigated for the diagnosis, treatment, mitigation, or prevention of disease.

"cosmetic" means (a) any substance or mixture manufactured, sold or represented for use by rubbing, pouring, spraying, or applying any other means to 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, beautifying or changing their appearance, protecting them, keeping them in good condition, or correcting body odours (b) any article intended for use as a component of a cosmetic;

"cosmetic notification holder" means a local person resident in Botswana responsible for maintaining the notification for a product is the register.**"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 who moves cosmetics from (a) the premises of the manufacturer of such products; (b) from another central point to the end user; (c) or to an intermediate point, by means of various transport methods, via various storage or health establishments; **"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;

"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 determined 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 (a)produces finished cosmetic product from raw materials by using various tools, equipment, and proceses, and then sells the cosmetic to the consumers, wholesalers, distributors,

retailers, or to other manufacturers for the production of more complex goods. (b) or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark;

"material change" means any change to a notified cosmetic product or to the particulars submitted in its notification that affects, or may reasonably be expected to affect, the safety, quality, identity, or regulatory status of the product, and includes —

(a) any change to the qualitative or quantitative composition of the product, including the addition, removal, or substitution of an ingredient, or a change in the concentration of an ingredient;

(b) any change to the physicochemical or microbiological specifications of the product;

(c) any change to the method of manufacture or the site of manufacture;

(d) any change to the cosmetic product safety report, including a revised safety assessment or new toxicological information;

(e) any change to the identity, contact particulars, or registered address of the responsible person;

(f) any change to the product name, label, claims, or intended function of the product; and

(g) any change to the warnings, directions for use, or precautions applicable to the product,

but does not include a change of a purely administrative or editorial nature that has no bearing on the safety, quality, identity, or regulatory status of the product;

“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;

"preservatives" means substances which are exclusively or mainly intended to inhibit the development of micro-organisms in the cosmetic product;

"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;

"product variant" means 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.

"recall" means any measure aimed at achieving the return of a cosmetic product that has been made available to the end user.

"responsible person" means any 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;

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

'**undesirable effect**' means an adverse reaction for human health attributable to the normal or reasonably foreseeable use of a cosmetic product;

"UV filters" means substances which are exclusively or mainly intended to protect the skin against certain UV radiation by absorbing, reflecting or scattering UV radiation.

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.

(4) Borderline determination between cosmetics and medicines shall be made by the Authority per the guidelines.

PART II

Cosmetics Authorisation

4. Market Authorisation

(1) A person shall not, in relation to any cosmetic product have in his or her possession or have in his or her control any such cosmetic product for purposes of

(a) importing;

(b) exporting;

(c) manufacturing;

(d) distributing;

(e) sale;

(j) promoting;

(g) advertising;

(h) storing; or

(i) dispensing, unless the person has notified the Authority of the cosmetic product in a manner prescribed by this Act.

(2) A person who wishes to notify or apply to the Authority in accordance with subsection (1), shall pay such a fee as may be prescribed.

(3) The Authority shall maintain a register of notified cosmetic products and such register shall be accessible online to the public.

(4) A cosmetic shall not be presented for sale as having properties of preventing, treating, or curing a human or animal disease.

(5) Subregulation (1) does not apply to cosmetics imported for personal use in accordance with section 64 of the Act or to investigational cosmetics used in approved clinical trials.

(6) The Authority may exempt a cosmetic product from notification or registration as determined by the guidelines.

PART III

Classification of Cosmetic Products

Classification of cosmetic products

5. (1) All cosmetic products regulated under these Regulations shall comply with the safety, notification, and quality requirements prescribed herein, regardless of their intended use, composition, or method of application.

(2) For the purposes of regulatory oversight and proportionate application of requirements, the Authority may, by notice published in the *Government Gazette* and on its official website, designate categories of cosmetic products subject to enhanced regulatory requirements, having regard to —

(a) the nature and concentration of active ingredients;

(b) the intended consumer group, including vulnerable groups such as children under the age of three years, pregnant women, and persons with compromised skin integrity;

(c) the type and specificity of claims made in relation to the product;

(d) the route or method of application; and

(e) available scientific evidence on the safety profile of the product or its ingredients.

(3) Where the Authority designates a category of cosmetic products under sub regulation (2), it shall —

(a) publish the criteria and thresholds applicable to that designation;

(b) specify the additional requirements that apply to products falling within that category; and

(c) afford responsible persons a reasonable transitional period to comply with any enhanced requirements.

(4) The Authority may, upon application by a responsible person or on its own initiative, review and revise the designation of a cosmetic product, taking into account new safety data, scientific developments, or changes in international regulatory standards.

(5) Where there is doubt as to whether a cosmetic product falls within a designated category, the Authority shall determine the matter and notify the responsible person in writing of its decision and the reasons therefor.

PART IV

Safety and Quality Requirements

General safety requirement

6. (1) 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, exposure patterns; and ingredient safety profiles 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 Authority shall determine and publish 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), WHO or any recognised standards

(3) A cosmetic product shall be considered unsafe where it —

(4) (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 undesirable effect upon post-market surveillance.

(5) 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.

(6) 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

7. (1) 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 biological sciences, chemistry, dermatology, medicine, pharmacy, toxicology, or a related discipline and shall have relevant post qualification experience in safety assessment or a related field, as may be further determined 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

8. (1) The Manufacturer and owner of the product 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.

Responsible persons

9. (1) 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.

Good Manufacturing Practice

10. (1) 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 or its later revisions (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 shall conduct inspections of manufacturing premises at such intervals as it may determine, having regard to the risk profile of the products manufactured and the compliance history of the manufacturer.

(4) For the purposes of demonstrating GMP compliance, a manufacturer may produce —

(a) a valid third-party audit certificate issued by a recognised certification body confirming compliance with ISO 22716 or an equivalent standard recognised by the Authority;

(b) a GMP inspection report issued by a recognised national or international regulatory authority within the preceding three years; or

(c) where subparagraphs (a) and (b) are not available, a self-declaration of compliance supported by documented internal audit records, standard operating procedures, and quality management system documentation, in such form as the Authority may prescribe.

5) The Authority shall, in guidelines issued under regulation 37, specify —

(a) a phased implementation schedule for GMP compliance, which shall take into account the capacity constraints of small and medium-sized local manufacturers;

(b) the minimum standards applicable during each phase of implementation; and

(c) the technical assistance and capacity-building measures available to manufacturers to support compliance.

PART V

Notification and Registration

Obligation to notify

(11) (1)A person shall not market a general cosmetic product in Botswana unless the cosmetic product has been notified to the Authority through the notification portal established under regulation 15, and the responsible person has complied with all requirements prescribed under these Regulations in respect of such notification.

(2) Notification shall be submitted to the Authority prior to placing a cosmetic product on the market. Subject to subregulation (3), a responsible person may place the cosmetic product on the market upon submission of a complete notification, without waiting for a response from the Authority.

(3) A notification shall be considered complete upon submission of all information required under subregulation (4) and proof of payment of the prescribed notification fee. The Authority shall acknowledge receipt of a complete notification within the period specified in the guidelines.

(4) Where the Authority determines, following its review of a notification or in the course of market surveillance, that a notified cosmetic product does not comply with these Regulations or presents a risk to the safety of consumers, it may suspend or cancel the notification in accordance with regulation 12, notwithstanding that the product has been placed on the market.

(5) Submission of a notification and placement of a cosmetic product on the market does not relieve the responsible person of liability for the safety, quality, and regulatory compliance of the cosmetic product. The responsible person remains solely accountable for ensuring that the product always complies with these Regulations.

(6) -A responsible person who seeks to notify a cosmetic product shall submit to the Authority, through the notification portal or alternate as determined by the Authority, 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 including CAS numbers where applicable;

(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 (manufacturer and product owner);

(g) proof of payment notification fee as per the fee regulations ;

a specimen of the proposed label and packaging; and(i) such other information as the Authority may prescribe.

(7) Notification is valid for 5 years, and is renewable at the prescribed fee

(8) Retention of general cosmetics may be paid at the prescribed fee

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

Registration

(12) (1) A person shall not market a special cosmetic product in Botswana unless

(a) the cosmetic has been registered as determined by the Authority and

(b) the responsible person (product owner) has complied with all conditions prescribed by or under these Regulations.

(2) Registration shall be effected prior to placing a cosmetic product on the market.

(3) A responsible person who seeks to register a special cosmetic shall submit to the Authority, at the prescribed fee the following information through the notification portal or alternate as determined by the Authority;

(a) safety assessment report;

(b) efficacy data supporting claims where applicable;

(c) stability data;

(d) GMP certificate; and

(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) Registered cosmetics shall be retained annually

(6) Registration shall be valid for 5 years and is renewable as per the fee regulations

(7) 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.

(8) 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.

Application procedures

13. Applications shall be submitted through the cosmetics notification portal or using Form in schedule 4.

Assessment and decision

14. (1) Registrations are assessed within a timeline specified in the guidelines.

(2) The Authority may—

(a) accept the notification/registration;

(b) request additional information;

(c) impose conditions; or

(d) refuse, suspend or cancel with reasons.

Cosmetics Register

15. (1) 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 and registered cosmetic products, which shall —

(a) be accessible to the public through the Authority's official website;

(b) contain such particulars as the Authority may determine; and

(c) be updated by the Authority on a regular basis to reflect the current status of all notified and registered products.

(3) Upon successful notification or registration, the Authority shall issue a reference number to the cosmetic notification holder, which may be affixed to the cosmetic product label or container.

Variations, Withdrawals, Suspensions and Cancellations

16.(1) A responsible person, may vary a notification or registration of a cosmetic product where there are changes to the formulation, label, manufacture, and other details of the product, its manufacturer, or as may be required in the guidelines

(2) A person must receive an approval from the Authority before making any changes to a registered cosmetic

(3) A variation must be submitted within 6 months after a change is made to a general sale cosmetic

(4) . A person may withdraw a notification or registration of a cosmetic product.

(5) The Authority may suspend or cancel a notification or registration for various reasons including –

(a) failure to report adverse events to the Authority

(b) failure to meet safety and quality requirements; or

(c) implementing variations without approval of the Authority for registered products

(d) failure to submit a variation within 6 months of implementation for general sale product

(e) A product shall be removed from the register when withdrawn, cancelled or suspended

(f) The market authorization holder shall be provided with reason for cancellation or suspension

(g) A product may be reinstated if the reasons for suspension are addressed

PART VI

Licensing requirements

(17) Requirements for a license

(1) Responsible person shall be required to complete the products market authorisation as per part II of these regulations of this guide prior to submitting an application to acquire a Cosmetics importers license.

(2) Applicable fees will be charged for licensing of these facilities.

(18) Application for Approval to Operate as Cosmetics Importers

(1)For approval of license to import, distribute or sell cosmetic products in Botswana, the following documents shall be submited;

(a) Completed Application form (Licensing of Cosmetics Operations)
(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 .
(f) Certified copy of identity card or passport of the Responsible person

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

license

(19) Processing of the Applications

(1) Applications shall be completed by responsible persons who reside in Botswana as per the guidelines

(2) An application not accompanied by supporting documents shall be rejected. The applicant shall receive a rejection highlighting reasons for rejection.

(20) Variation of License

(1) A license holder shall apply to the Authority for variation of his or her license
(2) The application shall be in the form- Application for Licensing of Cosmetic business accompanied by a fee as set out in schedule 5 .
    (a) Variation may include but not limited to:
    (b) Change in business name/ownership of Licensee
    (c) Change of address of Licensee (where applicable)
    (d) Change of authorized person
(3) 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.

(21) 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.
(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
(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. The license holder shall re-apply for a license and pay the prescribed fees

(22) Import Permit

(1) All cosmetics importers shall be subjected to importation fees as prescribed fee regulations.

(2) The importation requirements shall be detailed in the guideline and published on the website.

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 cosmetic notification holder 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 sub regulation (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 undesirable effects and serious undesirable effects s 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 undesirable effects 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 of becoming aware of the effect; and

(c) provide the Authority with a periodic summary report of all undesirable effects 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 undesirable effects 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.

(5) The submission of a repojrt under this regulation shall not, of itself be construed as an admission of liability by the responsible person in respect of the effect reported.

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.

Obligations of other responsible persons

27. Product owners, exporters, retailers, distributors shall ensure that the product they market and export are;

(a) Compliant with the labelling requirements as specified in regulation x

(b) Notified or registered and are listed in the register

(c) Retain product information per regulation 21.

(d) Ensure by applicable means that their product are compliant with these Regulations

Record-keeping

28. 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

29. 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 ensure that on the cosmetic product or its packaging is indicated the business name, and address of the product owner, manufacturer or importer, in addition to any information required from the manufacturer.

PART IX

Ingredients and Restricted Substances

Prohibited and restricted ingredients

30. (1) 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.

(e) the age for which a product containing the ingredient may be used

(f) or any combination of the above

(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) relevant local and 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);

(c) the need to protect human health and safety, including the safety of vulnerable groups; and

(d) the conditions and concentrations under which the ingredient is used in cosmetic products, and whether safe use can be assured through restriction rather than prohibition.

(5) The Authority may, in application of the precautionary principle, restrict or prohibit an ingredient notwithstanding that scientific evidence of harm is incomplete, provided that —

(a) there are reasonable scientific grounds indicating a potential risk to human health;

(b) the measure taken is proportionate to the potential risk identified, and no less restrictive measure would adequately protect human health;

(c) the measure is reviewed within a reasonable period, and in any event within twenty-four months, against the scientific evidence then available; and

(d) the responsible persons affected are afforded an opportunity to make representations in accordance with regulation 29(3) before the measure takes effect, except where immediate action is necessary to prevent serious harm to human health.

(6) A restriction or prohibition imposed under sub regulation (5) shall be lifted or varied where the scientific review under sub regulation (5)(c) does not substantiate the potential risk that justified the measure.

(7) 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

31. 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 sub regulations (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 sub regulation (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

32. (1) 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

33. (1) 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 sub regulation (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

34. (1) 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 to provide guidance the safety requirements, notification & registration 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) or local standards.

(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

35. (1) 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 determined 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

36. (1) 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 sub regulation (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 X

Labelling and Claims

General labelling requirements

37. (1) 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

(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

38. (1) 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 sub regulation (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.

Clinical trials

39. (1) Where scientific literature and available data cannot be used to substantiate a claim, the manufacturer of the product shall be required to conduct clinical trials.

(2) Clinical testing shall be conducted to ensure safety, efficacy and claim substantiation.

(3) Testing shall be conducted with aspects of good clinical practice as appropriate to cosmetic products.

Language of labelling

40. **(1)** 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 XI

Market Surveillance and Enforcement

Market surveillance

41. **(1)** 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, provided that the report shall;

(a) be prepared in a manner that does not disclose confidential business information, trade secrets, quantitative product formulations, or other proprietary information obtained by the Authority in the course of market surveillance or through notifications, registrations, or the product information file; and

(b) where reference to a specific product or responsible person is necessary in the interests of public health or consumer protection, be limited to the information reasonably required for that purpose.

Corrective actions and regulatory measures

42. (1) 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 or registration of a cosmetic product where it determines that —

(a) the notification or registration 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

`43. (1) 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 XII

Miscellaneous

Transitional provisions

44.(1) 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 and registration 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 in consultation with the stakeholders.

(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

45. (1) 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.

(f) obligations of responsible persons

(g) good manufacturing practices

(h) post-marketing surveillance and enforcement

(i) classification of cosmetic products

(j) Licensing of importers and Importation permits

Revocation

46. 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

SCHEDULES

SCHEDULE 1– Application for market authorisation

SCHEDULE 2 – Variation application form

SCHEDULE 3 – Withdrawals application form

SCHEDULE 4 – Renewal application form

SCHEDULE 5 – Licensing application

SCHEDULE 6 – Variation of license

SCHEDULE 7 – Import permit application form

SCHEDULE 8 – Adverse event reporting form

— END OF REGULATIONS —