RWANDA FDA
Rwanda Food and Drugs Authority

REGULATIONS GOVERNING CONTROL OF MEDICATED COSMETICS

(Rwanda FDA law N° 003/2018 of 09/02/2018, Article 8)

REGULATION DEVELOPMENT HISTORY

DRAFT ZERO BY COUNSULTANTS	19 August 2019
ADOPTION BY RWANDA FDA	18 February 2020
STAKEHOLDERS CONSULTATION	20 February 2020
ADOPTION OF STAKEHOLDERS' COMMENTS	26 February 2020
DATE FOR COMING INTO EFFECT	20 April 2020

ADOPTION AND APPROVAL OF THE REGULATIONS

In EXERCISE of the powers conferred upon Rwanda Food and Drugs Authority by Article N° 9 of the Law N° 003/2018 of 09/02/2018 establishing Rwanda FDA and determining its mission, organization and functioning, hereby ADOPTS and ISSUES these regulations N° CBD/TRG/011 Rev_0 Governing Control of Medicated Cosmetics, made this 20th day of April, 2020.

Dr. Charles KARANGWA
Ag. Director General

ARRANGEMENT OF THE REGULATIONS

CHAPTER 1: GENERAL PROVISIONS

Article 1: Purpose of these Regulations

The purpose of these regulations is to provide a legal framework for the effective and efficient of Control of medicated cosmetics and providing an open transparent and non-discriminatory process and minimum requirements for the registration, manufacture, importation, distribution and use of Medicated Cosmetic products in Rwanda. The implementation of these Regulations will enhance safety and effectiveness of medicated cosmetics on Rwanda markets and protect public health from substandard, counterfeit, mislabelled or unsafe medicated cosmetics.

Article 2: Citation

These regulations may be cited as "*Regulations N^{o} CBD/TRG/011 Rev_0 Governing Control of Medicated Cosmetics*

Article 3: Application

These regulations shall apply to all Medicated Cosmetics and ingredients used to manufacture medicated cosmetics intended to be marketed in Rwanda.

Article 4: Definitions

In these regulations, unless the context otherwise requires:

1. "**Address"** means where the business of manufacture or sale or distribution or storage or display of Medicated cosmetic product is carried out which includes the house number, plot number, street name, Town/City, State, Country, website, email, phone number etc.
2. **"Advertisement"** is a form of communication through the media about products, services or ideas paid for by an identified sponsor. It is used to encourage, persuade or manipulate an audience (viewers, readers or listeners) to continue with or take some new action.
3. **"Advertising"** means the publicity of goods and description of all products (which includes any form of notices in circulars, handouts, labels, wrappers, catalogues and price lists, bill boards, posters, newspapers, magazines, digital and social media, and any other documents) made orally, online or otherwise or by means of projected light and sound recordings;

4. "**applicant**" means the person by, or on whose behalf, an application for, an update or amendment to an existing registration, is made. After the product is registered, the applicant shall be the "Marketing Authorisation Holder".
5. **"Fee"** means the fee prescribed in Regulation CBD/TRG/004 related to regulatory services and charges.
6. **Appropriate fee"** means the fee prescribed in the Ministerial Order
7. **"Approve" or "approval"** means official consent by the Authority as an acceptance of a registration of the Medicated cosmetics or practices related to that in the Rwandan market;
8. **"Authority"** means the Rwanda Food and Drugs Authority or the acronym "Rwanda FDA" established by Law N° 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization, and functioning.
9. **"Batch number or Lot"** means the number or a combination of numbers and letters specifically given to a cosmetics product which is linked to the manufacturing history of the product;
10. **"Colour"** means a substance used as an ingredient of a cosmetic product solely to give tonality to the product;
11. "Container" means any form of packaging of cosmetics for sale as a single item whether by completely or partially enclosing the cosmetics and includes wrappers. A container may enclose several units or types of packages when such is offered to the consumer.
12. "Contract manufacturer" means any person who manufactures any product on the order of another person to whom a manufacturer's licence has been issued under these Regulations;
13. "Cosmetic" means any substance or preparation intended to be placed in contact with the various external parts of the human body (including epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance or correcting body odours, protecting them or keeping them in good conditions.

14. Cosmetovigilance: is the on-going and systematic monitoring of the safety of cosmetics in terms of human health. The aim is to detect adverse effects of cosmetic products, and to prevent adverse effects by taking appropriate measures.
15. "Fragrance" means a substance used as an ingredient of a cosmetic product solely to impart odour to the product;
16. "Importer" means any person or body corporate permitted and authorized under the laws and regulation in Rwanda pertaining to cosmetics to import medicated cosmetic products
17. Ingredients means any substance that is one of the components of a cosmetic and includes colouring agents, botanicals, fragrance and flavour, but does not include substances that are used in the preparation of the cosmetic but that are not present in the final product as a result of the chemical process
18. "Inner label" means primary packaging material label;
19. Label" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a package (container) of a Medicated cosmetic product.
20. "Law" means Law No. 003/2018 of 09/02/2018 establishing the Rwanda FDA and determining its mission, organization and functioning
21. "License" means permission from Authority to manufacture, import/export and sell one or more of its products.
22. "Licensed importer" means a person to whom an import licence has been issued under these Regulations;
23. "Licensed manufacturer" means a person to whom a manufacturer's licence has been issued under these Regulations, and includes a contract manufacturer;
24. "Licensed wholesaler" means a person to whom a wholesaler's licence has been issued under these Regulations;
25. "Manufacture of cosmetic" means and includes all operations involved in the production, processing, compounding, formulating, filling, refining, transforming, packing, packaging, repackaging and labelling of the cosmetics;

26. manufacturer' means any natural or legal person who manufactures, assembles cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trademark
27. "Media" means newspaper, magazine, medical/journal, television, radio, the internet; Out of home, vehicle branding, posters, handbills, cinema, point of sale material; online, digital and social media, any form of projected light and sound recordings or any of such means of communication.
28. "Medicated cosmetics "or "cosmeceuticals" are products that have both cosmetic and therapeutic (medical or drug-like) effects, and are intended to have a beneficial effect on skin health and beauty. Like cosmetics, they are applied topically as creams or lotions but contain active ingredients that have an effect on skin cell function. In some cases, their action is limited to the skin surface (such as exfoliants), while others can penetrate to deeper levels, either enhancing or limiting normal skin functions
29. "Registration certificate" means a registration certificate issued under Chapter III of this regulation
30. "Registered product" means a product currently registered in accordance with the provisions of these Regulations;
31. "Outer label" Outer label" means secondary packaging material label;
32. "Package labelling" includes the label on the immediate container plus all other printed matter such as outer wrapper, carton or leaflet associated with the package;
33. "Principal display panel" means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for display for retail sale;
34. "Premises" means any place that includes a vehicle, vessel, railway carriage, aircraft and building;
35. Pharmacovigilance (PV)" means the science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems;
36. "Post-marketing surveillance (PMS)" means surveillance activities that occur following market approval of a regulated product including maintenance of product

authorization and/or registration of variations or renewals; regular inspection of manufacturers, wholesalers, distributors and retailers; quality control testing; pharmacovigilance; promotion control; public reporting of poor quality products; handling of market complaints; and removal and disposal of non-compliant products

37. 'Recall' means any measure aimed at achieving the return of a cosmetic product that has already been made available to the end user;
38. "Rwanda FDA" means the Rwanda Food and Drugs Rwanda FDA or its acronym "Rwanda FDA", established under Article 2 of the Law;
39. Unsanitary conditions: means such conditions or circumstances as might contaminate with dirt or filth, or render injurious to health of cosmetic.
40. withdrawal' means any measure aimed at preventing the making available on the market of a cosmetic product in the supply chain;
41. (PDP)" Principal display panel
42. INCI: International Nomenclature of Cosmetic Ingredients

CHAPTER II: CONTROL OF MEDICATED COSMETICS

SECTION ONE: ASSESSMENT AND REGISTRATION OF MEDICATED COSMETICS

Article 5: Application for registration of medicated cosmetics

a. All medicated cosmetics shall be registered with the authority before they are placed on Rwanda market according to the provisions of these regulations. A person who intends to manufacture, import or export a product shall apply to the Authority for registration of medicated cosmetics.

b. An application for registration of medicated cosmetics shall be made to the Authority in writing by the Marketing authorization holder, the manufacturer or local technical Representative.

Article 6: Application requirement for registration of medicated cosmetics

a) Application for registration of medicated cosmetics shall be made in hard and electronic copies as detailed in *guidelines on submission for documentation for registration of medicated cosmetics* Nº **DHT/GGL/023**.

b) A separate and complete application for registration of products shall be submitted for each medicated cosmetic with different ingredients and formulation, intended use, forms, site of manufacture.

c) A separate and complete application for registration of products shall be submitted for product with the same ingredients and formulation but with different colours and/or fragrance

d) Except as otherwise provided in these Regulations, no person shall manufacture, sell, supply, import, export or administrator any product unless the product is registered and the person holds the appropriate licence required and issued under these Regulations.

e) All medicated cosmetics that are manufactured, imported, exported distributed, sold and used in Rwanda shall be packed and labelled in accordance to this regulation.

f) Products containing substances that are prohibited or suspended from use in Rwanda or listed as banned or suspended in international conventions that Rwanda has signed and ratified shall not be registered.

g) The authority shall publish the list of prohibited, restricted, suspended and banned ingredient to be used in the medicated cosmetics.

Article 7: Data requirement for registration of medicated cosmetics

All applications for registration of medicated cosmetics shall comply with the technical requirements as determined by the Authority in *guidelines on submission for documentation for registration of medicated cosmetics* Nº **DHT/GGL/023**. The application shall be accompanied by data to support quality, safety and efficacy of medicated cosmetic

Article 8: Language

All applications and supporting documents shall be in **English.**

Article 9: Authenticity of document

a. Any document submitted shall be authentic when approved by the applicant or by the authorized person.

b. The Authority shall reject an application for registration of medicated cosmetics if it is satisfied that the submitted documents are not authentic or integrity of data is questionable.

Article 10: Accountability of the applicant and marketing authorization holder

The applicant shall be accountable for all information supplied in support of his application for registration of the product and variations thereof.

The marketing authorization holder shall be accountable for:

a. manufacturing the product in compliance with the specifications approved according to provisions of these Regulations;

b. updating, when necessary, summary of product characteristics and package inserts for the purpose of enabling a correct and safe use of the product;

c. communicating the variations to the Authority within the framework of the relevant provisions of the guidelines;
d. providing responses to the issues raised/requested by the Authority, in relation to a registered product;
e. to carry out post market surveillance to monitor the safety of the product in the market and provide safety update reports to the Authority;
f. ensuring that the product continues to comply with the safety, efficacy and quality requirements prescribed in the Law and Regulations.

Article 11: Safe custody and confidentiality of information

a. The Authority shall ensure safe custody of information related to the registration of medicated cosmetics submitted by applicants.
b. All information submitted shall be treated confidential and shall not be disclosed to any third party without a written consent of the applicant.

Article 12: Assessment process of medicated cosmetics

a. The Authority shall, upon being satisfied by the application, conduct assessment to verify the compliance with safety, quality and efficacy requirements of medicated cosmetics. The authority shall set out guidelines, SOPs, forms, and tools for medicated cosmetics assessment procedures.
b. The Authority may, during the assessment of the product, require the applicant to submit additional samples, documents, information, data or clarification to support the application for registration.

Article 13: Good Manufacturing Practices certification

During the assessment of medicated cosmetics,

a. The applicant is requested to apply for GMP inspection for manufacturing site of the product to be registered and pay the prescribed GMP inspection fees.
b. The Authority shall as it may deem necessary conduct on-site inspection and causal inspection of the non-clinical studies (where applicable), clinical trials (where

applicable), and production site inspection to confirm the authenticity, precision and integrity of information and data submitted.

c. In addition , internationally valid GMP certificates or valid certificate of quality management system(QMS) must be submitted

Article 14: Requirement for registration of medicated cosmetics

The authority shall issue a certificate of registration of medicated cosmetics only if:

1. The medicated cosmetic dossier is assessed and fulfil requirements of Safety, quality and efficacy
2. The manufacturing site of the medicated cosmetics is compliant to the Good Manufacturing Practices or other internationally recognized certification or certificate of quality management system.
3. Medicated cosmetic fulfils the requirements of laboratory quality tests

Article 15: Approval of medicated cosmetics

Upon approval of registration of medicated cosmetic, the Authority shall:

a) enter in the register the prescribed particulars of the medicated cosmetics;
b) allocate a registration number to the medicated cosmetics;
c) issue to the marketing authorization holder a certificate of full registration as per prescribed format.

Article 16: Publication of a registered medicated cosmetics

The Authority shall publish a list of registered medicated cosmetic products on the authority's website specifying the registration number, name under which the product is registered (brand and common name), product form, name and country of the marketing authorization holder, name and country of manufacturer, Local technical representative and expiry date of the registration certificate.

Article 17: Validity of registration

A certificate of full registration issued under Article 16 shall, unless earlier suspended or revoked, and subject to payment of prescribed annual retention fees, be valid for a period of five (5) years from the date of issuance and may thereafter be renewed.

Article 18: Application for variation of a registered medicated cosmetics

a. Any variation to a registered medicated cosmetic, information shall be notified in writing to the Authority through an application in the approved format.
b. An application for variation shall be submitted as per the requirements set out in the Guidelines for Variation of Registered medicated cosmetics in force at the time of submission.

Article 19: Retention of medicated cosmetics on the register

a. The registered medicated cosmetics is retained on the register annually after payment of fees.
b. Application for retention on the register shall be submitted one (1) month before the due date.
c. The medicated cosmetics shall be removed from the register if application and payment of fees is not effected as stated in article 19 a and 19 b.

Article 20: Application for renewal of registration certificate

a. Application for renewal of registration shall be made to the Authority at least ninety (90) calendar days before its expiry.
b. A grace period for renewal shall extend to ninety (90) days after the specified expiry date.
c. Failure of renewal within the grace period, the application shall be considered as new.
d. The application shall be in the prescribed format as per Rwanda FDA guidance for renewal of medicated cosmetics.

Article 21. Timelines for medicated cosmetics Registration

a) A new application shall be processed within six (6) months of receipt of the application if application is complete.
b) An application for renewal of a medicated cosmetics products shall be made to the Authority at least ninety (90) calendar days before expiration of the last registration
c) If the applicant is required to provide any requested additional data within ninety (90) calendar days. This additional data or query responses shall be processed within thirty (30) calendar days.
d) Approval Variation of registration; Complete applications will be processed within three (3) months of receiving the application including evaluation of documentation and consideration by a committee on product registration.
e) Approval Renewal of registration: Complete applications will be processed within four (4) months of receiving the application including evaluation of documentation and consideration by a committee on product registration.
f) Failure to comply with these conditions or if the queries have been reissued for a fourth time and the applicant provides unsatisfactory responses, the application will be rejected.

Article 22: Suspension of registered medicated cosmetics

The Authority may suspend registered medicated cosmetics if it is satisfied that:

a) A registered medicated cosmetic has been advertised in manner which is false or misleading or does not comply with the Regulations currently enforced by the Authority;
b) The marketing authorization holder has contravened these Regulations;
c) The marketing authorisation holder made a false or misleading statement or misrepresentation in the application;
d) The marketing authorisation holder has failed to comply with the terms and conditions of the registration as provided in certificate of registration;

e) The marketing authorisation holder has failed to pay the prescribed retention fees within the prescribed time;
f) The marketing authorisation holder has failed to submit periodic post-marketing surveillance reports;
g) The marketing authorisation holder, intentionally and without justifiable reasons has failed to submit reports on adverse effects; and
h) Renewal of registration has been defaulted beyond the specified grace period.

Article 23: Notice of suspension

Any suspension shall be effected upon a written notice thereof.

The notice for suspension of registered medicated cosmetics shall:

a) Set out the reason for the proposed suspension, any corrective action required to be taken and the time within which it must be taken;
b) Require the marketing authorisation holder to show reasons as to why the suspension should not be effected.

Article 24: Suspension or cancellation of registration without notice

a) The Authority may cancel or suspend the registration of a medicated cosmetic without prior notice to prevent harm to the health of users.

   The Authority shall cancel, suspend, or withdraw the registration of a product if:

   i. The ground on which it was registered is later found to be false.
   ii. The circumstances under which it was registered no longer exist.
   iii. Any of the provisions under which it was registered has been contravened.
   iv. The standard of quality, safety and efficacy, as prescribed in the Documentation for registration is not being complied with.
   v. The premises, in which the product or part thereof is manufactured, labelled, Packaged or stored by or on behalf of the holder of the certificate of registration is unsuitable for the manufacture, packaging or storage of the cosmetic.

b) The marketing authorization holder may apply to the Authority, in writing, requesting that the cancelation or suspension be uplifted.

c) The Authority may, within thirty (30) days after the date of receiving the application review its decision.

Article 25: Restoration of a cancelled or suspended registered medicated cosmetics

Pursuant to the provision of Articles 21, 22, and 23, the Authority may, upon satisfaction that the reasons of the suspension or cancellation of registered medicated cosmetics has been corrected or if such reason for suspension or cancelation was unfounded, reinstate the registered medicated cosmetics.

Article 26: Refusal to register a Medicated Cosmetics

The Authority shall refuse to grant marketing authorisation of a medicated cosmetic if it is satisfied that:

a) The application for registration does not comply with these regulations;
b) The information the applicant provides to the Authority is not sufficient to enable the Medicated cosmetics to be assessed;
c) Product was manufactured, prepared, preserved, packaged or stored under unsanitary condition;
d) The information on product label does not comply with these regulations;
e) Contain any substance that may cause harm to the health when the cosmetic is used;
f) Consists in whole or in part of any filthy or decomposed substance or of any foreign matter;
g) The Medicated cosmetics contains prohibited substances or don't comply with prescribed concentrations in cosmetic products as stated in the Ministerial Order N°20/38 du 26/02/2016 determining the list of cosmetics whose use is prohibited in Rwanda

Article 27: Cancellation or revocation of marketing authorisation

a. The Authority may cancel or revoke the marketing authorization of a registered medicated cosmetic if:

1. It is not in the public interest that the registered medicated cosmetic should be made or continue to be made available;
2. The medicated cosmetic has been banned in Rwanda;
3. The medicated cosmetic no longer meets the quality, safety and effectiveness requirements; and
4. The marketing authorisation has been suspended for a period of more than 12 months.

b. A written notice of cancellation shall then be issued to the marketing authorisation holder, stating the reasons for cancellation.

Article 28: Packaging and labeling information

1. The packaging material shall be made of substances/materials which, safe and suitable for its intended use and the product shall be packed in container which will maintain its safety and quality
2. The information on the label of a cosmetic shall be informative, accurate, prominent, distinct, and legible and remain so throughout the useful life under normal conditions of sale and use of the cosmetic.
3. The labeling shall be at least in one of the Official language used in Rwanda and complies with INCI name in ingredient listing.
4. The cosmetic products shall not be described or presented in any manner that is deceptive, false, misleading or is likely to create an erroneous impression regarding its character in any respect, quality, quantity and origin
5. The following information must appear on the outer packaging or immediate container or leaflet of the all medicated cosmetic products:
    a. The brand name (where applicable)
    b. Name of the product
    c. Manufacturer's name and physical address
    d. Marketing authorization holder (Where applicable)
    e. Lot or batch number
    f. Manufacturing date

g. Expiry date
h. Net content (weight/volume)
i. List of ingredients used (INCI name)
j. Function of the cosmetic product
k. Instructions for use
l. Country of origin
m. Storage conditions
n. Warnings and cautions

SECTION TWO: CONTROL OF MANUFACTURE

Article 29: Inspection and premises licensing

a. No person shall conduct the business of manufacturing, wholesale or retail or offer for sale any Medicated Cosmetics, except in premises inspected and licensed by the Authority for the manufacture, importation, storage, packaging, distribution and sale of Cosmetics.
b. Any person who wishes to manufacture, import, store, package, distribute or offer for sale any registered Cosmetics, regulated under the Law shall before doing so, obtain a license for his/her premises and shall ensure that such premises comply with the minimum requirements.
c. A separate application and fee is required for each premises at a separate physical location operated by the same applicant.
d. The Authority shall, prior to issuing a premises license, inspect the premises to determine that the premises are suitable for the purpose for which the license is to be issued.
e. Inspection fees for new premises shall be part of the application fee and re-inspections carried out due to unsuccessful initial inspections will attract an inspection fee in addition to the application fee paid.

Article 30: Application for new operational license

a. Any person who is required to and wishes to make an application for the licensing of premises dealing in Medicated Cosmetics shall complete the appropriate application through an online system accessible to the Authority's website.
b. All application shall be completed in English and be accompanied by the appropriate fee.
c. New application license requirements for medicated cosmetics are:
    1. Business registration certificate;
    2. Lease contract of the location;
    3. Evidence of payment of prescribed fees;
    4. Copy of the identity card or passport of the owner

5. Two recent passport-size photograph of the owner.

Article 31: Application for Renewal of Operational license

An application for the renewal of Cosmetics premise license shall be made annually, one month before the due date after completing all requirements.

Article 32: Refusal of licenses

Where the Authority refuses to grant a license in respect of an application submitted in terms of Article 30, the applicant shall be informed in writing the reasons of refusal and requested to comply with the requirements.

Article 33: Variation, amendment, suspension and cancellation of license

a. The Authority may suspend or cancel a license issued under these Regulations where the person to whom the licence is granted ceases to be fit to carry on the business for which the license is granted.
b. Whenever the Authority varies, amends or imposes any new conditions on any license, the Authority shall communicate the return of such license duly endorsed to the holder thereof within a reasonable time.
c. Any person who fails to comply with a request in terms of Article 32.b shall be guilty of an offence.

Article 34: Good Manufacturing Practices and Good distribution practices

a. The Authority shall, for the purposes of assessing the manufacturing practices of the manufacturer, adopt with the necessary modifications, internationally accepted Good Manufacturing Practices Guidelines.
b. Local or foreign manufacture of medicated cosmetics shall comply with the Good Manufacturing Practices (GMP) Guidelines adopted by the Authority.
c. The manufacturer shall, prior to manufacturing or importation of Medicated cosmetics, as the case may be, make an application to the Authority for assessment of the facility to be used for.

d. The cosmetic wholesaler shall have systems, facilities and operations, that comply with the Good Distribution Practice Guidelines, as adopted by the Authority.

SECTION THREE: IMPORT AND EXPORT LICENSING

Article 35: Eligible Importers/Exporters of medicated cosmetics

Any licensed company or any other person/organization for the justified reasons.

Article 36: Obligation to obtain a Visa and license for import or export of medicated cosmetics

a. No person shall import or export any medicated cosmetics without a Visa and license issued by the Authority.
b. All the required documentation for application shall be made as described in the relevant guidelines.

Article 37: Prohibited operations in import and export

1. No person or association of persons shall import and export medicated cosmetics unless they are granted a license to do so.
2. No person or association of persons shall import medicated cosmetics with shelf life less than two thirds (2/3) of their total shelf life.
3. No person shall obstruct or hinder the Authority inspector in the exercise of their powers or performance of their duties as provided for in the Law.
4. Any person who with fraudulent intent, tampers with any sample taken in terms of the provisions of the Law.
5. Importation of Substandard or non-registered medicated cosmetics.
6. Any product containing a banned substance shall be confiscated and destroyed at cost to the importer and attract a penalty.
7. No person shall make a false or misleading action in connection with any medicated cosmetics.

Article 38: Application and issuance of an import or export Visa and License

The application and issuance of a visa and a license shall be made through an online system for consideration

Article 39: Refusal of a visa and a license

The Authority may refuse to grant a visa or a license to any person who does not comply with the provision of articles 35, 36 and 37 of this regulation.

Where the Authority refuses to issue a visa and a license, the applicant shall be informed in writing the decision and the reasons thereof and the applicant shall be requested to submit to the authority within four (4) days the missing requirement for compliance.

Article 40: Duration of license

Any license, which is issued for the import or export of medicated cosmetics, shall be valid for a period of three (3) months from the date of issue and it is only for single use. In special cases a license may be extended for a further period of not more than three months.

Article 41: Variation, amendment and cancellation of a visa and a license

The Authority may at any time amend or vary the conditions of; or revoke; any visa and license issued in terms of article 36 as it deems fit. The authority shall notify such action in writing to the license holder/importer.

SECTION FOUR: POST MARKETING SURVEILLANCE SYSTEM

Article 42: Post-marketing surveillance

a. The Authority shall establish and maintain a national post-marketing surveillance system and is the only entity mandated to carry out PMS activities in the country.
b. The post-marketing surveillance system shall monitor the overall quality and safety of regulated products and respond to public health risks.
c. The stakeholders may develop protocols and submit to the authority for review and approval for studies/surveys on medicated cosmetics quality while conducting PMS and research institutions have the responsibility to submit research protocols related to post-marketing survey or study to the Authority for approval and their results before publication.
d. All manufacturers and Marketing Authorisation Holders shall jointly be responsible for carrying out post-marketing surveillance activities and shall cooperate with all national post-marketing surveillance programmes.

Article 43: Post Marketing Surveillance roles and responsibilities

a. Manufacturers and holders of marketing authorisations shall support all national post-marketing surveillance programmes including availing samples for pre-distribution quality control testing and continued monitoring of the quality of regulated products through routine sampling and quality control testing from the supply chain.
b. The marketing authorisation holder shall be responsible for the following tasks and responsibilities –
   i. Notifying the Authority of any changes to the registered product and submitting applications for approval of variations to the marketing authorisation.
   ii. Ensuring that only the approved product is available on the market, and that amended products will only be marketed with Authority approval;
   iii. ensuring that there is access to approved premises at all reasonable times and at the request of the Authority for the purposes of inspection;

iv. Instituting a Quality Assurance plan for all registered products that includes voluntary quality control testing, including bearing the costs of such testing;

v. ensuring that Responsible Persons have sufficient authority to influence the post-marketing surveillance activities of the marketing authorisation holder;

vi. conducting cosmetovigilance activities in accordance with the relevant Regulations and Guidelines;

vii. Ensuring appropriate and accurate promotion of approved products;

viii. reporting quality issues and concerns in relation to approved products;

ix. ensuring appropriate complaints handling procedures are in place;

x. immediate notification of and authorisation of the removal and disposal of non-compliant products.

Article 44: Post-marketing surveillance activities

The PMS activities for medicated cosmetics consist of:

a. Screening of product formulation and information to ensure that cosmetics do not contain any prohibited or harmful substances and all restricted ingredients are used within the allowable limits and conditions of use. Screening criteria also includes product name and its claimed benefits

b. Sample collection and testing

c. Monitoring of label compliance

d. Audit of premises for compliance to the Cosmetic GMP

e. Handling of product complaints Guidelines for Control of Cosmetic Products

f. Monitoring of advertisements

g. Monitoring of adverse reactions

h. Risk communication

i. Information sharing through circular and Authority website

Article 45. Promotion and Advertisement of registered medicated cosmetics

a. . Advertising and promotional material that are subject to the regulations include but not limited to Internet materials, including press releases intended for internet publication, Print advertisements, Promotional aids including those used for direct

selling activities, Sales promotions, Telephone help lines, Television and radio commercials, sports, art and other sponsorships.

b. An application for the approval of promotional material and advertisement shall be made by a manufacturer or distributor to the Authority. Promotional materials including scripts, story-boards, art work, radio scripts and any other advertisement material as may be required by the Authority shall be submitted along with an application, to the Authority.

c. All promotional materials submitted under these Regulations shall be authenticated by the authorized technical person of the medicated cosmetics manufacturing company.

CHAPTER III: RESTRICTION FOR SALE OF UNREGISTERED MEDICATED COSMETICS

Article 46: Prohibitions

No person shall manufacture, import, export, distribute, sell, display for sale, offer for sale or use and advertise any medicated cosmetic

a) Either manufacturer, wholesale or retail unless it is in accordance with the provisions of these Regulations, and that person holds the appropriate registration certificate issued by the Authority;
b) Which are adulterated or which contains any substance which when used according to the direction on the label accompanying the medicated cosmetic product is likely to cause harm to the health of the user.
c) Whenever contain prohibited substance or contain substance exceeding the prescribed concentrations as stated in the Ministerial Order N°20/38 du 26/02/2016 determining the list of cosmetics whose use is prohibited in Rwanda
d) Whose label has not been affixed to container with the information required by these Regulations appearing on both the inner and packaging/outer container (as applicable).

CHAPTER IV: MISCELLENIOUS PROVISIONS

Article 47: Appeals and review

a. Any person aggrieved by a decision of the Authority may apply to the Authority for review of the decision showing grounds for dissatisfaction within thirty (30) and fifteen (15) days for import or export permit from the date of notice
b. The Authority shall, within fifteen (15) days from the date of receiving the application, review, reject or vary its own decision.
c. Notwithstanding the provision of Article 30a the applicant shall not be barred from appealing to the supervising Authority without applying to the Authority for review.
d. If a person is dissatisfied with the decision after review, he may appeal to the supervising Authority.

Article 48: Power to issue guidelines

The authority shall issue guidelines, SOPs, forms necessary for the implementation of these Regulations

Article 49: Offences and penalties

A person contravening a provision of these regulations shall be guilty of an offence and the Rwanda FDA may impose a fine as stipulated in the regulation related to regulatory service tariff/ fees and charges or cause the prosecution of offending parties as the case may be.

Article 50: Commencement and repealing

a. This regulation shall enter into force on date of its signature and publication.
b. All prior contrary provisions to these regulations are hereby repealed.

End of Document