

Kenya Bureau of Standards

Standards for quality life

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FRAMEWORK FOR THE PLACEMENT OF COSMETICS AND RELATED PRODUCTS INTO THE KENYAN MARKET

Acknowledgment

Special acknowledgement goes to the Pharmacy and Poisons Board and Kenya Bureau of Standards team who worked tirelessly on this document.

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1. BACKGROUND

1.1 The Pharmacy and Poisons Board

The Pharmacy and Poisons Board ("the Board") is the Kenya's National Medicines Regulatory Authority established in 1957 under the Pharmacy and Poisons Act, Chapter 244 of the Laws of Kenya. The Board regulates the Practice of Pharmacy and the Manufacture and Trade in medical products and Health Technologies (HPTs).

The mandate of the Board is articulated in the Pharmacy and Poisons Act of 1957 (CAP 244) as well as the Health Act, 2017 as: to protect and promote the health of the public by regulating the profession of pharmacy and ensuring access to quality, safe, efficacious and affordable health products and technologies. The Board also advises government entities and the public on matters of safety, quality and effectiveness of medical products and health technologies.

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The Board regulates;

- Professional practice of pharmacy i.e. the registration and licensing of pharmacies and pharmacy practitioners
- Pharmacy training institutions.
- The quality, safety and efficacy of all medicinal substances i.e. Conventional and/or complementary products, dietary supplements and medical devices/vaccines/Herbal
- Import and export of all medicinal substances
- Advertisement and promotion of all medicinal substances in the country
- Clinical trials

Overtime the mandate of the Board has grown to include the regulation of medical devices, health technologies, nutritional supplements, cosmetics, vaccines, and blood and herbal products.

1.2 Kenya Bureau of Standards

Kenya Bureau of Standards (KEBS) is the National Standards Body in Kenya. It was established through "The Standards Act" Cap. 496 of the Laws of Kenya. Legal Notices (LNs) have expanded its scope. KEBS started its operations on 12th July 1974.

KEBS is mandated under the Standards Act to provide standardization and conformity assessment services through:-

- Promotion of standardization in commerce and industry
- Provision of testing and calibration facilities
- Product and system certification
- Undertaking educational work in standardization and practical application of standards
- Maintenance and dissemination of International System of Units (SI) of measurements

KEBS standardization services include development of standards (company, national, regional & international), maintenance of measurement standards (metrology), and technical support for multilateral and bilateral trade agreements. Conformity assessment services carried out by KEBS include inspection (import and export), quality assurance (product certification), market surveillance, system certification, testing services and calibration services. KEBS also offers training and education through the National Quality Institute. It also operates a Standards Information Centre, and is the WTO TBT National Enquiry Point for Kenya.

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2. INTRODUCTION

This framework was developed for regulation of cosmetics in Kenya.

3. SCOPE

3.1 This framework covers requirements that governs the placement of cosmetics and related products, labelling as well as post market surveillance. It covers both locally manufactured as well as imported cosmetic products.

3.2 This framework does not cover the detailed requirements for different classes of cosmetics and related products recognized in Kenya. Applicants are required to obtain the requirements from respective agencies.

3.3 The framework does not cover implants, injectables, inhalers, enteral and nutricosmetics.

4. DEFINITION OF TERMS

Cosmetic product any substance or mixture intended to be placed in contact with the external parts of the human body (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, protecting them, keeping them in good condition or correcting body odours.

5. CLASSIFICATION

5.1 Criteria

5.1.1 Risk based approach has been adopted in the classification of cosmetics and related products in Kenya. Consideration is given to potential risk on the human body and environment, ingredients, route of administration, label claims, and the target population for which the product is developed.

5.2 Classes

For the purpose of regulation, cosmetics and related products shall be classified as follows:

Class 1: Special cosmetics and related products

5.2.1 Products that, while making no explicit medical claim, are marketed with claims/promises to deliver for preventing or interfering with normal operation of a physiological function whether permanently temporarily or whether by way of terminating, reducing, postponing or increasing or accelerating operation of the functions in human beings fall under this class.

Class 2: General cosmetics

5.2.2 Cosmetics and related products that do not fall under class 1 are classified as general cosmetics. They provide the body with appropriate aesthetics, texture, pH, color and smell. They include but not limited to:

Toilet soaps, shampoos, lotions, creams, gels, nail polish/removers, hair and body oils, powders, sprays and perfumes, baby preparations, preparations for lip care/makeup, eye care/makeup, etc

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6. PRODUCTS WITH MEDICAL/THERAPEUTIC CLAIMS

6.1 These are products or any substances or mixtures intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity containing medical/therapeutic claims or containing pharmaceutical ingredients.

6.2 This includes any product that makes any of the following claims/ promises to deliver on its own or have ingredients known to:

a) Treating (curing, healing etc), preventing or alleviating diseases or symptoms of diseases;
b) diagnosing diseases or ascertain the existence, degree or extent of a physiological conditions; or
c) preventing or interfering with normal operation of a physiological function whether permanently temporarily or whether by way of terminating, reducing, postponing or increasing or accelerating operation of the functions in human beings.

6.3 Such products shall be considered as medicinal products and shall be regulated by the Pharmacy and Poisons Board. Applicants intending to market such products are required to comply with the applicable marketing authorization requirements found at www.pharmacyboardkenya.org

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7. GENERAL REQUIREMENTS

7.1 Authority to market cosmetic products in Kenya

7.1.1 Placement of Cosmetic and related products that fall under **Class 1** shall be regulated by both the Pharmacy and Poisons Board and KEBS.

7.1.2 Cosmetics and related products that are listed below shall be regulated by the Pharmacy and Poisons Board. Applicants intending to market this class of products are required to comply with the applicable requirements found at www.pharmacyboardkenya.org

a) Anti-aging products
b) Anti-wrinkle products
c) Anti-dandruff products
d) Anti-inflamatory products
e) Sunscreens and sun protection products
f) Hair growth promoting/restoration
g) Anti-hair loss
h) Aromatherapy substances
i) Hydroxy Acids: Alpha Hydroxy Acids (AHAs), Beta Hydroxy Acids (BHAs), Poly Hydroxy Acids (PHAs)

7.1.3 All other Cosmetics and related products that fall under Class 2 but are not listed above shall be regulated by the Kenya Bureau of Standards. These include the products listed below. Applicants intending to market this class of products are required to comply with the applicable standards and requirements found at www.kebs.org

a) Skin lightening products containing vitamins, acids and other such ingredients. Skin lightening products shall not contain hydroquinone or corticosteroids.

b) Anti-oxidants

c) Fluoride containing tooth paste

d) Hair dyes containing phenylene diamine and derivatives

e) Antiperspirants

f) Depilatories

g) Anti-bacterial products

h) Insect repellants

7.1.4 Cosmetic and related products that fall under **Class 2** shall be regulated by the Kenya Bureau of Standards. Applicants intending to market this class of products are required to comply with the applicable standards and requirements found at www.kebs.org

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7.2 Quality, safety and efficacy of product

7.2.1 The manufacturer and, where applicable importer/distributer, must assume responsibility for the quality, safety and efficacy of the products marketed in Kenya to ensure that they are fit for their intended use, comply with the requirements of the marketing authorization and/or Kenyan Standard and that they do not place consumers at risk due to inadequate safety, quality or efficacy as may be applicable.

7.2.2 Regulatory instruments including, standards, guidelines and where applicable procedures shall be published by the respective agencies. Online catalogue of Kenyan standards is available on www.onlinecatalogue.kebs.org and on www.pharmacyboardkenya.org for instruments published by the Pharmacy and Poisons Board.

7.3 Post market surveillance

In accordance with applicable laws:

7.3.1 Under this framework, a manufacturer is responsible for post market surveillance. He is to collect and evaluate experience gained from products that have been placed on the Kenyan market, and to identify the need to take any action. Any such actions shall be shared with the responsible agency.

7.3.2 In exceptional cases the responsibility for post market surveillance shall lie with the distributer/importer/wholesaler, responsible for the placement of a product in the Kenyan market.

7.3.3 The Pharmacy and Poisons Board shall monitor compliance of cosmetic and related products under classes 1 through surveillance in the market place and at the premises of the company or person responsible for placing the product in the market.

7.3.4 The Kenya Bureau of Standards shall monitor compliance of cosmetic and related products under class 1 products listed under them, and class2 through surveillance in the market place and at the premises of the company or person responsible for placing the product in the market.

7.3.5 The following post market activities shall be performed in compliance with the respective guidance and procedures published by the respective agencies responsible:

7.3.6 Handling of market complaints, Corrective and Preventive Actions (CAPA) follow-up, recalling/withdrawing, reshipment, destruction and seizure.

7.4 Labelling

7.4.1 The labelling on the packaging, on company brand's website, or in an advert/advertisement shall be in compliance with, where applicable, Kenyan Standards and/or applicable product requirements published by the Kenya Bureau of Standards and Pharmacy and Poisons Board.

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8. TRANSITION PERIOD

8.1.1 There will be a one year transition period from the date of signing this framework to comply with the requirements of this framework.

8.1.2 This framework may be amended or supplemented at any time by agreement between the Pharmacy and Poisons Board and the Kenya Bureau of Standards.

9. REFERENCES

(EU Regulation 1223/2009, Article 2.1.a)

IN WITNESS WHEREOF, the undersigned being duly authorized by their respective Organizations have signed this framework.

Done at ..... on this..... day of ..... 2022 in two originals each in the English Language.

Signed for and on behalf of:

THE PHARMACY AND POISONS BOARD	**KENYA BUREAU OF STANDARDS**
Signature:.....	Signature:.....
Name:.....	Name:.....
Title:.....	Title:.....

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