



Legislation and Regulation for Import Manufacture Distribution and Sale of Cosmetics in Sri Lanka

Akhilesh Akki¹, P. Subhash Chandra Bose², M. P. Venkatesh^{1*}, K. Divith¹ and Gorthi Nihar¹

¹*Department of Pharmaceutics, JSS College of Pharmacy, JSS Academy of Higher Education and Research, Sri Shivarathreeswara Nagara, Mysuru – 570015, Karnataka, India.*

²*Department of Pharmaceutics, MNR College of Pharmacy, Sangareddy-502294, TS, India.*

Authors' contributions

This work was carried out in collaboration among all authors. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/JPRI/2021/v33i47B33095

Editor(s):

(1) Dr. Koteswara Mudigonda, Propharmex Company, India.

Reviewers:

(1) Azhar Hameed Gatea, University of Thi-Qar, Iraq.

(2) Djoharsjah Meuraxa, Pancasila University, Indonesia.

(3) Vinayendra Mani, Graphic Era Hill University, India.

(4) Audumbar Digambar Mali, Sahyadri College of Pharmacy, India.

Complete Peer review History: <https://www.sdiarticle4.com/review-history/75315>

Review Article

Received 17 August 2021

Accepted 19 October 2021

Published 30 October 2021

ABSTRACT

The goal of cosmetics regulation is to provide Sri Lankans with safe and high-quality cosmetics that are equivalent to those in other nations. To accomplish these regulators and industry should collaborate to achieve common objectives. This category includes skin creams, lotions, perfumes, lipsticks, nail polishes, and eye and lip cosmetics. Face makeup, shampoos, permanent waves, hair colours, teeth pastes, deodorants, and any other cosmetics Ingredient intended for use in cosmetic items and gadgets, soap making Cosmetics that do not state that they are for human use are not considered cosmetics under the law. According to the Sri Lankan government, cosmetics must be registered before they can be manufactured, supplied, distributed, or sold. The regulations' goal is to provide guidance and inform marketing authorization holders and consumers about the regulatory authorities' procedures and criteria for determining aesthetic suitability, as well as the requirements for registration and how applications should be made, and how to import, manufacture, distribute, and sell cosmetics in Sri Lanka [NMRA].

Keywords: NMRA [National Medicines Regulatory Authority]; cosmetics; registration; regulation; DRA [Drug Regulatory Authority].

1. INTRODUCTION

According to Sri Lankan guidelines Cosmetics can be defined as any substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes. All cosmetics, manufactured, imported, sold and distributed and offered for sale in Sri Lanka should be registered under the provisions of the Act. Cosmetic manufacturers and importers within or outside Sri Lanka intending to market their products in Sri Lanka should register their products. The application for registration must be made in Schedule IV Form A of the Cosmetics, Devices and Drugs Regulations together with the appropriate documentation. The registration documentation must be written in English and provided in a hard file cover. Foreign manufacturer's products must be presented through a local representative. [1] Cosmetic items must be registered before they can be manufactured, supplied, distributed, or sold, according to the government guidelines of Sri Lanka. Those wishing to begin importing into Sri Lanka should get a Tax Identification Number (TIN Number) and register as a registered importer with Sri Lanka Customs. After a three-month term has passed, no one should sell any cosmetics other than those that have been registered with the authority. Importers and manufacturers of cosmetics, as well as those who have products imported or made on their behalf, must register their items with the Drug

Regulatory Authority (DRA). The applicant is responsible for the product as well as the information provided in support of his application for product registration. [1,2]

1.1 Classification of Cosmetics According to Sri Lankan Guideline [1,2]

Cosmetic goods will be divided into two groups for registration purposes, based on their level of risk [3].

1.2 Cosmetics

They're cosmetics that can be absorbed via the skin or mucous membrane, include potentially dangerous ingredients, or are marketed at youngsters. This category is subject to a lot of scrutiny.

1.3 Controlled Cosmetics

They are cosmetics that have the potential to be absorbed via the skin or mucous membrane, contain potentially dangerous ingredients, or are marketed to children. This category is subject to a lot of scrutiny [4].

1.4 General Cosmetics

All cosmetics that aren't covered in the controlled cosmetics section [4].

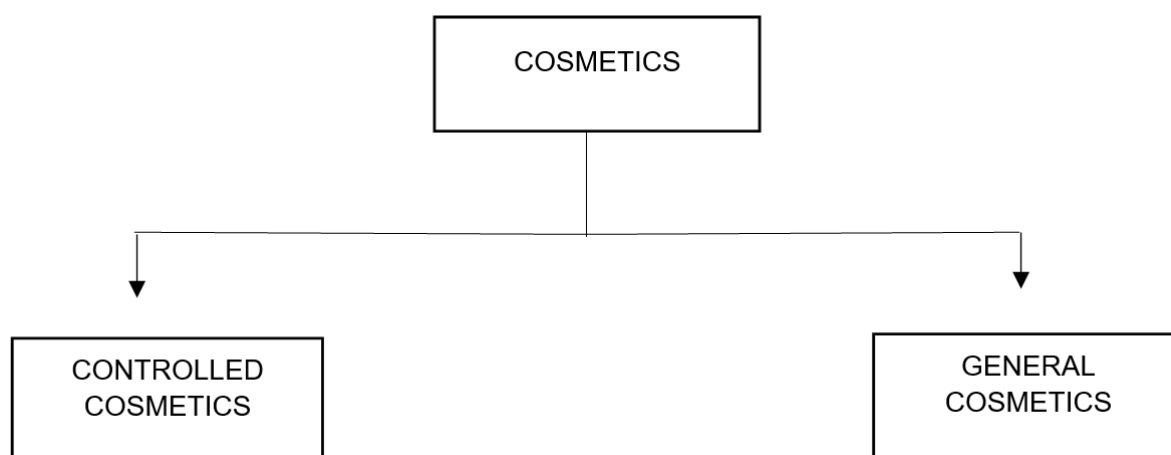


Fig. 1. Classification of Cosmetics According to Sri Lankan Guideline

2. LEGISLATION AND REGULATION

- Regulations promulgated by the Ministry of Health under section 38 of the Cosmetics, Devices, and Drugs Act, No.27 of 1980, as amended by Act No.38 of 1984, and agreed by parliament.
- The Cosmetics Regulations No. 38 of 1984, often known as the Cosmetics Regulations, came into force on January 1, 1986.
- Every cosmetic covered by the Cosmetics, Devices and Drugs Act, No.27 of 1980, as amended by Act No.38 of 1984, is referred to as a "Registered Cosmetic" for the purposes of these regulations.
- Cosmetic items must be registered before they can be manufactured, supplied, distributed, or sold, according to the Sri Lankan government. The registration procedures are described in depth in the following topics. [4]

➤ **Who Should Submit an Application for A Product License?**

- Persons who import or manufacture cosmetic products, or have products imported or made on their behalf, must register their products with the Drug Regulatory Authority (DRA).
- The applicant is responsible for the product and any information provided in support of his product registration application. [5]

➤ **Materials From a Variety of Sources**

- Separate registrations are required for products with the same formulation and name but sourced from various manufacturing facilities. [5]

➤ **Where Should I File and How Should I File It?**

- The DRA has application forms accessible. The duly filled application should be sent to the DRA, 120 Norris Canal Road, Colombo 10, in a hard cover file in duplicate. [5]

2.1 Registration Process of Cosmetics in Sri Lanka [6]

Objective of Registration:

- To ensure that cosmetics sold in Sri Lanka are safe and do not cause harm to people's health.
- To forbid the use of some harmful compounds as ingredients in cosmetics.
- To guarantee that cosmetic goods are properly labelled, including batch numbers and ingredient lists. [9]

▪ **Data required for the registration of a cosmetic application**

- a. A copy of a sample import licence is attached.
- b. Free sale certificate or certificate to foreign government issued by competent health authorities in the country of origin or certified by the Sri Lankan Embassy in the country of origin or foreign affairs.
- c. The manufacturer's letter of authorization designating the Market Authorization Holder.
- d. The final product's certificate of analysis report.
- e. Ingredients are listed by chemical name, CAS number, and function, as well as their exact proportions.
- f. Two fully packed samples of cosmetics in the form meant for marketing (containing Lot no., Man. Date, Exp.date, Manufacturer's & Importers data)
- g. All pages should be numbered from top to bottom and vice versa with an index, and documents should be written in English, in a legible font size, printed on one side A4 and provided in a hard file cover.
- h. Each cosmetic that needs to be registered should have its own application. [i.e., merchandise with a variety of colours, brands, and so forth.] Foreign-made products must be filed through a Marketing Authorization Holder. [8].

2.2 The Registration's Validity Duration is

- For the first time registration, a Provisional Registration for a term of one year (or two) will be issued, as mentioned in the certificate.
- The Full Registration of a product is mentioned in the certificate and is valid for a term of five years.
- If the authority requests more information, the applicant must provide it within three months to allow for a more thorough review.
- If the product is refused, the holder of the market authorisation can file a registration appeal.

2.3 Registration Validity

2.3.1 Full product registration

- A cosmetic's full registration will be valid for five years. Registration must be renewed every five years.

2.3.2 Provisional registration

- Provisional registration for a duration of one year may be given under specific circumstances. Provisional Registration will be allowed for a period of one year.

2.4 In Support of their Request to Register a Cosmetic Product, the Application should Include all of the Facts Listed Below

- Applicants' name and address
- Applicants' status: manufacturer / importer applicants'
- Name and address of person in charge of cosmetic marketing
- The cosmetic's name is: official or approved name / brand name
- Cosmetics are divided into two categories: controlled and general
- Cosmetics product category:
- Formulation and substance of the package:
- DRA Sri Lanka accepts a certificate of analysis from a laboratory.
- Certificate of free sales (CFS) - a certificate from the country's health authority or a recognised entity

confirming that the cosmetic is in use there and for how long, if applicable.

- For various reasons, the state is not available.
- A complete sample of the cosmetic in the form in which it will be sold
- A sample of the label that was used on the containers
- An illustration of the package inserts
- All supporting documents must be translated into English if they are written in a language other than English.
- In addition, the corporation must submit the goods in the shortest possible pack size.
- If the label contents and presentations differ, submit labels, package inserts, and outer cartons for each pack size.
- Additional information about the application must be submitted if and when the Licensing Authority requests it. [2]

2.5 Fees for Registration

The charge for cosmetics registration is set forth in Schedule II of the regulations, with the most recent update being Gazette Notification No. 1601/15 dated May 2009, and will be subject to revision as needed.

2.6 Fee for Processing

The registration charge for cosmetics is Rs.500 [Sri Lankan Rupees]. Cosmetic Evaluation Sub Committee

2.7 Renewal of Registration [9]

- A renewal application must be submitted within six months of the registration's validity date.
- Flow Chart of Registration Process of Cosmetics [9]

2.8 Data Requirements for Preparation of Cosmetics Application for Registration

Form A **Schedule I**

Information Required for Registration of a Cosmetic

- 1 Name of applicant.....
- 2 Address.....

- 3 Status of applicant:
 Manufacturer
 Importer.....
- 4 Name and Address of Manufacture.
- 5 Name of the cosmetics:
 (1) Brand name (if any):
 (2) Official or approved name:.....
- 6 Type of Cosmetics:
 (e.g.: Hair Lotion, Face Powder, Toilet Soap)
- 7 Formulation and Package size: -
 (e.g. : Powder, Cream, Lotion etc.,)
- 8 Composition:
 The ingredients should be listed by their chemical name and should include their exact quantities.
- 9 A certificate from the health authorities of the country in which the cosmetics is produced, confirming that the Cosmetics is in use there and the period of use and if not, reasons for not marketing it in the country of manufacturer:
10. Certificate of Analysis and full information concerning analytical assessment and other control methods to ensure strength, quality and stability. :
11. List of countries in which the cosmetics is approved or registered for sale.
12. Fully packed sample of the cosmetics in the form that will be offered for sale should also be sent.
13. A sample of the label (s) used in the containers and package insert (if any) should be supplied.
14. All data should be submitted English, in a hard file cover, duplicate.

Applications made without these requirements will not be accepted.

2.9 Procedure for Importing Cosmetics to Sri Lanka [10]

- Those who intend to begin importing into Sri Lanka should get a Tax Identification Number (TIN/VAT Number) and register as an importer with Sri Lanka Customs.
 - Sri Lanka Customs is part of the Ministry of Finance and Mass Media, and is responsible for facilitating lawful trade, international trade, revenue collection, and export-import data gathering, among other things.
 - The CUSDEC, or Customs Goods Declaration, is the name given to the good declaration in Sri Lanka.
 - Import Cargo requires the importer to submit a Customs Declaration via DTI (Direct Trader Input).
 - Any delay in filing or lack of documentation might cause the clearance procedure to be delayed, causing the importer to be charged demurrage on the imported cargo.
 - The effectiveness of the Customs Clearance process is determined by the presence of legitimate documents, the correctness of the information presented in the documents, and the timeliness with which the documents are submitted and the requisite Customs Clearance applications are filed.
- Obtaining a licence to import samples [9]

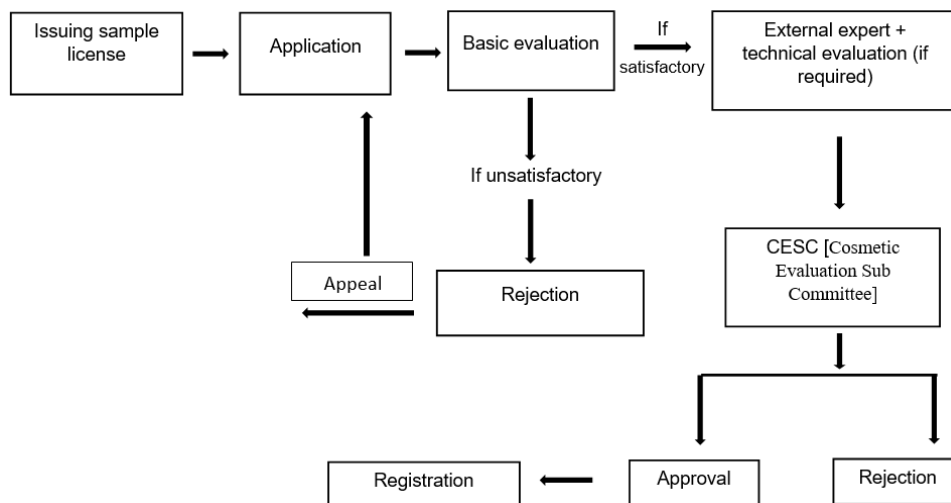


Fig. 2. Registration Process of Cosmetics

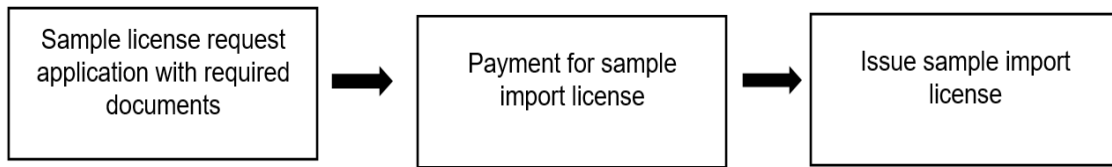


Figure no:3 Obtaining a licence to import samples

2.10 Submission of an Application for Registration [9]

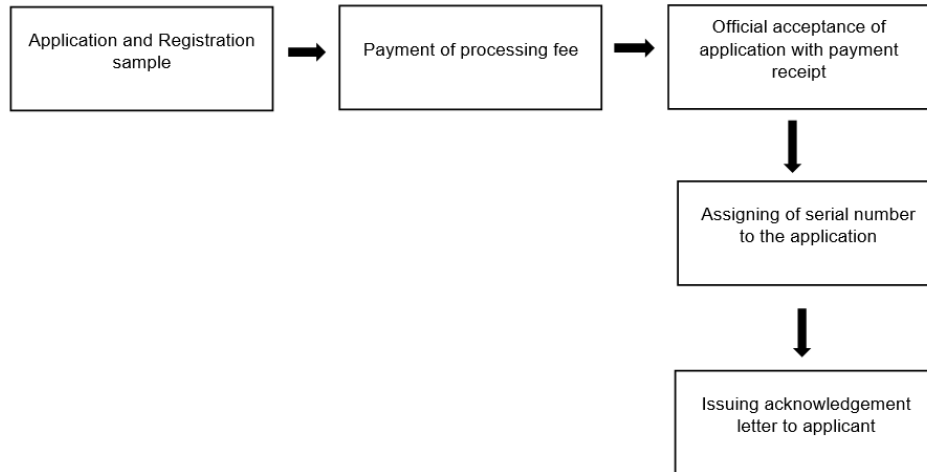


Fig. 4. Submission of an application for registration

2.11 Manufacturing Sites Approval process [11]

- Foreign Manufacturing Facility Approval
- Local Manufacturing Facility Licensing

2.12 Foreign Manufacturing Facility Approval

- The procedure applies to foreign manufacturing facilities seeking marketing approval for their products in Sri Lanka. A desk examination of important documents, including the site master file, is part of the procedure. Before the location may be approved, a GMP inspection may be required.
- A foreign manufacturer must appoint a Sri Lankan business organisation as its local authorised representative in order to register items in Sri Lanka.
- The local agent will submit applications on behalf of the foreign manufacturer's parent firm. Each manufacturing site from which the manufacturer intends to export items to Sri Lanka requires its own application.

- To facilitate a desk review, the application must be submitted online via NMRA's web site eNMRA, which entails the uploading of important information and documents. If all documentation show that the facility meets NMRA regulations, the next step is to conduct a GMP inspection. The legal requirements are stated in the NMRA Act, No. 5 of 2015 (section 51) and regulations 2 to 10 of Part I of the Medicines Regulations.
- In accordance with regulation 24 of the pharmaceutical's legislation, the NMRA would waive onsite GMP inspection if the particular location had been inspected by a strict NRA or WHO. Following these steps, an approved foreign manufacturer can submit an application to the local agent for marketing authorisation of its products.

2.13 Local Manufacturing Facility Licensing

- The procedure applies to local manufacturing facilities seeking marketing approval for their products in

Sri Lanka. A desk examination of important papers, such as the site master file and many GMP inspections, is part of the procedure.

- A local manufacturer must submit applications for his manufacturing facilities in order to register items in Sri Lanka. To each production location, a separate application must be submitted.
- To enable a desk review and GMP inspections, applications must be submitted online using NMRA's web site eNMRA, which entails uploading of key information and documentation.
- The legal requirements are stated in the NMRA Act, No. 5 of 2015 (section 51) and regulations 26 to 30 of Part II of the Medicines Regulations.
- Local manufacturers can apply for product registration after receiving formulation approval and GMP approval for commercial manufacturing of the facility. Local manufacturers can then apply for a manufacturing licence.
- Despite increased demand for cosmetics, imports of cosmetics are slightly behind the demand supply ratio due to delayed progress of government health care programmes and local currency devaluation. [12]

2.14 Distribution and Sale of Cosmetics

- The capital city is the hub of international trade, with the Port of Colombo handling more than 90% of all imports and exports.
- While there are numerous small and medium-sized importers, the bulk of international trade is handled by 20 to 30 rather large companies.
- Only a few importers have control over distribution networks in other parts of the country; most wholesale to regional distributors or retailers directly. The role of the government in trade and distribution has shrunk. [13]
- Many multinational companies choose local agents based on their financial stability and technical skills. Medium-sized and smaller enterprises are becoming more appealing as the larger trading houses represent several (often competing) foreign ideals. [14]
- Large enterprises, on the other hand, are frequently the preferable choice when products require stocking, service, or nationwide distribution.

- Depending on sales volume and product price, sales fees paid to agents range from 3 to 15%. For inefficiency, theft, or failure to meet other conditions mentioned in the agency agreement, agency ties can be terminated. Prior to entering the local market, it is critical to conduct investigation on the suitability of a possible agent/distributor. [15]
- No one may bring into the advertising material of any cosmetic product that has not been registered with the Authority.
- The Cosmetics, Devices & Drugs (CDD) Act 1980 is the legislative framework which provides the legal authority to regulate Cosmetics, Devices & Drugs in Sri Lanka.
- The Cosmetics, Devices, and Drugs (CDD) Act of 1980 establishes the legal framework for regulating Cosmetics, Devices, and Drugs in Sri Lanka. [16]
- Self-inspections should be carried out to check GDP principles' implementation and compliance, as well as to offer appropriate remedial measures. [17]
- The Sri Lanka Distribution Code (hereinafter referred to as "Distribution Code") was drafted in accordance with the provisions of Clauses 18 (c) and 3.1 (c) of the Sri Lanka Electricity Act, No 20 of 2009 (SLEA 2009), which require licensees to develop, implement, and maintain technical or operational codes; and the Public Utilities Commission of Sri Lanka (PUCSL) to approve and regulate the impounded electricity [18].
- No one may sell, offer for sale, or distribute any cosmetic unless the premises where the cosmetic was manufactured, as well as the process and conditions of manufacture, have been approved in the prescribed form and manner as being suitable to ensure that the cosmetic will be safe to use. [19]

3. CONCLUSION

Cosmetics must be registered before they can be manufactured, supplied, distributed, or sold in Sri Lanka, according to the government. To attain these goals, regulators and industry should work together to achieve common goals. Skin creams, lotions, perfumes, lipsticks, nail polishes, and eye and lip cosmetics all fall within this category. Face makeup, shampoos, permanent waves, hair colours, tooth pastes, deodorants, and any other cosmetics ingredient used in cosmetics and gadgets, as well as soap manufacturing Under

the law, cosmetics that do not specify that they are for human use are not considered cosmetics. Cosmetic advertising material that has not been registered with the Authority is prohibited from entering the country. Cosmetic makers and importers from Sri Lanka and elsewhere who want to sell their products in Sri Lanka need register them. The registration application must be submitted in Schedule IV Form A of the Cosmetics, Devices, and Drugs Regulations, together with the required documentation. The registration paperwork must be written in English and kept in a hard file folder. The products of a foreign company must be presented through a local representative.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

REFERENCES

1. National Medicines Regulatory Authority SL. Guidelines for Registration of Cosmetics in Sri Lanka; 2020.
2. Sri Lanka Customs . [cited 2021 Sep 27].
3. National Medicines Regulatory Authority (NMRA) . [cited 2021 Sep 27].
4. Cdd_Regulations_05.Pdf.
5. How to register Your Product . [cited 2021 Sep 27].
6. Regulation For Registration Of Cosmetics In Sri Lanka | LinkedIn . [cited 2021 Sep 27].
7. Public Utilities Commission SL. Distribution Code of Sri Lanka. 2012;(July).
8. National Medicines Regulatory Authority (NMRA) . [cited 2021 Sep 27].
9. How to register Your Product . [cited 2021 Sep 27].
10. How to import to Sri Lanka, step by step process . [cited 2021 Sep 27].
11. Approval of Manufacturing Sites . [cited 2021 Sep 27].
12. (PDF) Drug Registration Process in Sri Lanka . [cited 2021 Sep 27].
13. South Asia's logistical hub: Challenges and opportunities for Sri Lanka's transshipment future | South Asia@LSE [Internet]. [cited 2021 Sep 27].
14. Strategies That Fit Emerging Markets . [cited 2021 Sep 27].
15. DISTRIBUTION AGREEMENT . [cited 2021 Sep 27].
16. How to register your product . [cited 2021 Sep 27].
17. Ministry of Commerce & Industry G of I. Regulatory & Market Profile of Sri Lanka. 2018;1–21.
18. Medicines N, Authority R, Lanka S. National Medicines Regulatory Authority , GOOD DISTRIBUTION PRACTICE (GDP) GUIDELINES. :1–29.
19. Cosmetics, Devices And Drugs Amended By Act No.38 OF 1984, – LawNet . [cited 2021 Sep 27].
20. Ninla Elmawati Falabiba; 2019.

© 2021 Akki et al.; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

Peer-review history:

The peer review history for this paper can be accessed here:
<https://www.sdiarticle4.com/review-history/75315>