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Review Article

Pharmaceutical Analysis For Novel Drug Formulation

Comparison of Cosmetics Regulations in India and Singapore: A Regulatory Overview

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Abstract: Cosmetics are the fastest-growing market potential in the world and have a higher interest rate for women than men. Beauty and personal care products have often been used to enhance beauty, appearance and perfection. A blend of synthetic and herbal cosmetics thrives in India's cosmetics sector. A cosmetic product should be a complete package with all outstanding properties, such as adequate safety, efficacy, potency and marketability of the product. These characteristics are only possible with a good regulatory structure, scheme, and organisation in place. Cosmetic products are continuously revised and managed. which is the task of many regulators. The cosmetics industry has grown exponentially across the world, offering a means for a consumer to transform his or her look and make the product easily recognisable and appealing. The protection of cosmetic products is governed by various regulatory authorities around the world, each with their own set of rules and regulations that the product must follow. There are many regulatory bodies doing work efficiently. These bodies provide us with strict regulations which help us in guiding Manufacturing, Importing, Packaging, Labelling and other aspects of trade in the cosmetic industry. Cosmetic description, manufacturing specifications, licences, import regulations, labelling regulations, packaging regulations, and fee details are mentioned and also the legal authority in India (CDSCO) and Singapore (HSA) are addressed in this context and approval process of import of cosmetics has been discussed in this article. There are drugs and cosmetics legislation (D&C) in India and the Bureau of the Indian Standard (BIS), for Singapore Health products (ASEAN Cosmetic Directive) regulations 2007 under HEALTH PRODUCT ACT are discussed.

Keywords: Cosmetics, Regulatory Bodies, Legal Authority, Regulations.

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1. INTRODUCTION

The cosmetics sector uses innovative emerging technology to produce new cosmetics with many characteristics. Many regulators control the production and selling of cosmetic products all over the globe. [1] The cosmetics industry in India is dominated by increasing people's personal disposable income, raising knowledge of the aesthetic of the body, along with rising herbal demand. The adoption of herbal cosmetics is increasing. Products led by the 15% annual increase in the segment people are very conscious of potential adverse skin effects. Indian cosmetics are up about 20% annually, and is growing in India, and responsible for ensuring product quality and safety. The Cosmetics regulations are very complex and time consuming in India that are essential for post-marketing approvals before marketing. They are the following: Essential for cosmetics producers, importers and distributors knowing the Indian regulatory framework. The production of cosmetics is regulated by a State Licensing Authority appointed by the respective State Governments in accordance with drugs and cosmetics Act, 1940 and rules made thereunder, while imports of cosmetics are controlled by the Central Licensing Authority appointed by the Central government in accordance with the registration system.[2]. Under the provisions of the Drugs and Cosmetics Act, 1940, the Drugs Controller General (India) acts as the Central Licensing Authority, granting the Import Registration Certificate and regulating the import of cosmetics into India through Gazette notification G.S.R 763(E). Any article that falls under the 1940 D&C Act and 1945 Rules and the Bureau of Indian Standards provides the labelling statements to control cosmetic products in India (BIS). The BIS specifies cosmetics standards for products included in Schedule "S" of the Drugs and Cosmetics Rules 1945. The Bureau of Indian Standards defines skin creams and lipstick in Indian Standards (IS) 6608:2004 and 9875:1990, respectively (BIS). According to IS 6608:2004, the manufacturer is not allowed to audit the finished cosmetic for heavy metals and arsenic if the raw materials requiring heavy metals inspection have been tested and to follow the standards. Under Rule 134 of the Drugs and Cosmetics Rules, the use of cosmetics containing Dyes, Colours, and Pigments other than those defined by the Bureau of Indian Standards (IS: 4707 Part I as amended) and Schedule Q is prohibited. The CDSCO (CENTRAL DRUG STANDARD CONTROL ORGANIZATION) is the agency that regulates and licences them. [3] In Singapore, cosmetic law is governed by the Health Product Act-2007. They are overseen and licenced by the Health Sciences Authority (HSA), which is part of the Ministry of Health. Companies shall comply with the Cosmetics Products Act (Association of southeast Asian nations Cosmetic Directive) and the Health Products Regulations, which are overseen by the Cosmetics Control Unit. No registration / license shall be requisite or must be evaluated or authorised by HSA for enterprises to sell cosmetic products in the country before sale. Companies, on the other hand, must send a product notification to HSA. This law complies with the Association of Southeast Asian Nations Cosmetic Directive regulation (ACD). Singapore's cosmetical products shall be compliant with the Health Products Act provisions and its 2007 Regulations on Health Products (the Regulations).[4]They Aligns with the ASEAN Cosmetic Directive (ACD), which has enforced regulatory norms and norms similar to those for European Union cosmetic products (EU). New suppliers may need to refer to this documentation for additional details. For more information on regulatory requirements and recommendations on cosmetic products kindly contact the Cosmetic Product Safety Guidelines[5].

1.1 Description

1.1.1 Regulations of cosmetics in India

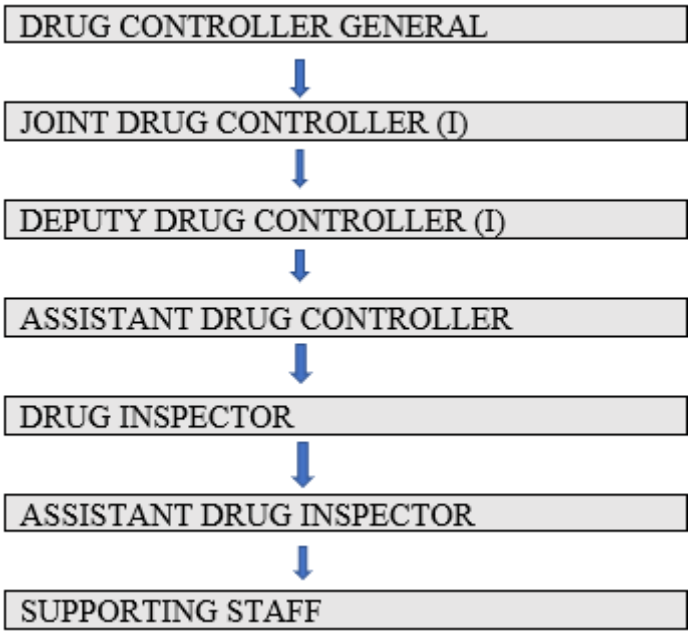
1.1.1.1 Definition

Cosmetic is defined as any article intended to be rubbed, poured, sprinkled, sprayed on, or introduced onto, or otherwise applied to, the human body or any parts thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and includes any article intended for use as a component of cosmetic under section 3(aaa) of the drugs and cosmetics act, 1940.[4,5]

1.1.1.2 Regulatory authority of India (CDSCO)

The cosmetics manufacture is controlled by the authorities appointed by the state government to inspect and provide authorities in need of license and for the Cosmetics supplies into India are strictly controlled by central licensing agencies as per D&C act 1940. The CDSCO in India is the office of drug controller general (DCG). This authority issues the authorisation and also regulates cosmetics supplies into India through Gazette notification G.S.R 426. (E). [5]

1.1.1.3 Organogram of Cosmetics



1.2 Requirements of factory premises for manufacture of cosmetic product

The plant facilities are examined by a state regulatory agency inspector, before granting license (issued in form no 31). The officer finds the following during inspection:

- The applicant has enough space for the production, monitoring, and storage of raw materials, packing products, and finished products.
- The applicant provided the necessary facilities and machinery to produce the cosmetics.
- The applicant is given adequate raw materials testing facilities

Requirements for manufacturing facilities for cosmetics manufacturing protected by Schedule M (II) of the Drugs and Cosmetics Law 1945. The below are the requirements:

- Location and surroundings.
- Buildings
- Water supplies,
- Water disposal,
- Health clothes and hygienic practices of the workers, healthcare facilities
- Working benches for cosmetics operations.

1.3 To obtain license:

The protocol for manufacturing of cosmetics in India is outlined in the Drugs and Cosmetics rules,1945. Here cosmetics are divided into 11 categories by schedule M(II) follows: [5,6]

- Powders
- Creams, lotions, emulsions, cleansing milks, pastes
- Shampoos, hair dyes
- Nail polishes and nail lacquers
- Lipsticks and lip glosses
- Toothpastes, tooth powders
- Eye preparations
- Depilatories
- Toilet soap
- Aerosols
- Alcoholic perfume solutions

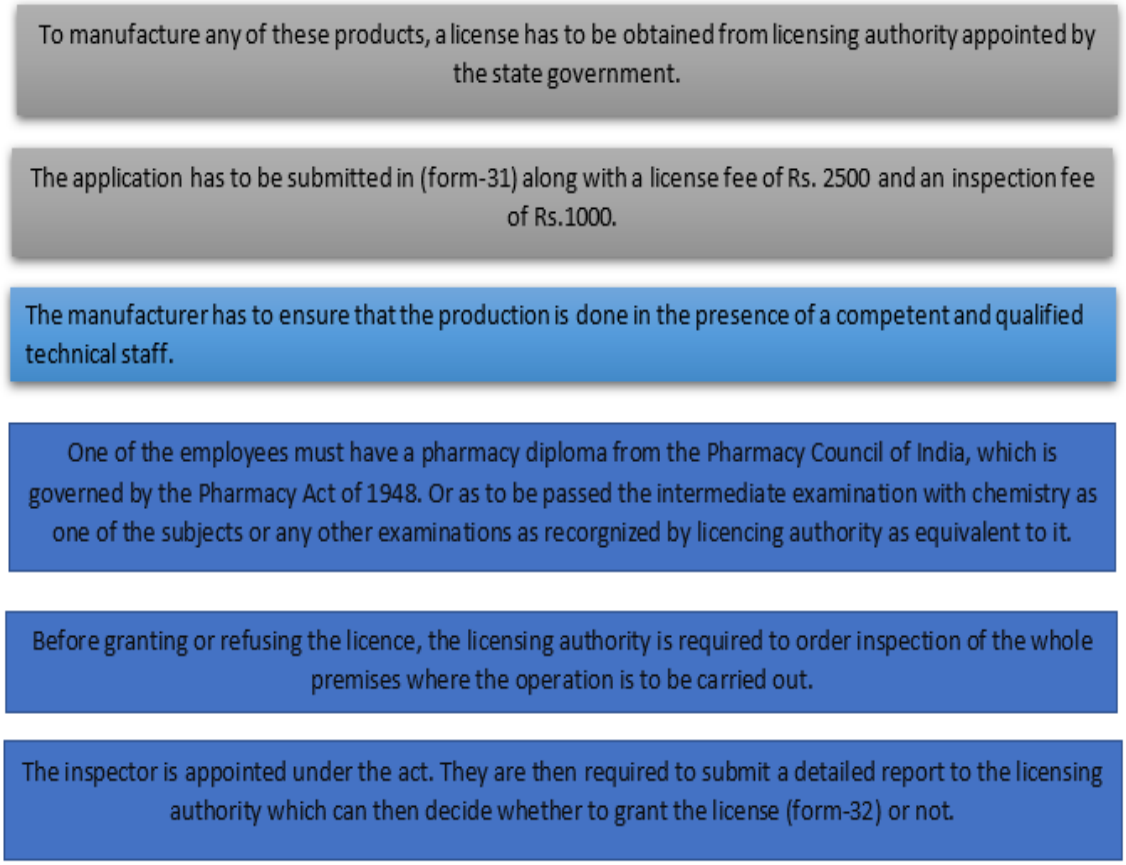


Fig 1: Procedure to obtain license

1.4 Registration for import of cosmetics

The SUGAM Portal is used to submit an online application for cosmetics registration. [6,8] Purpose: To provide stakeholders with guidance on submitting a Form COS-1 application to CDSCO for providing a license to import cosmetics into India in Form COS-2. Guidance: Request for issuance of certificates for cosmetic imports in India must be available in online form COS-1 on CDSCO's SUGAM Portal, either by the supplier himself, or by importer, or approved by the manufacturer's company.

1.5 Process for registration of cosmetics

Step 1: Determine if your product requires registration.
Step 2: Appoint an Indian agent who is approved to represent you.
Step 3**:** Request a regulatory dossier under COS-1.
- Document requirements
- Based on animal testing on imported cosmetics

Step 4**:** to obtain registration certificate in form COS- 2
Step 5: Marketing it in India.

1.6 Importer registration

The manufacturer's registered office is located in India.
- The manufacturer's approved representative.
- The manufacturer's subsidiary.
- Other importers.

1.7 Procedure for registration for import

- To begin, the imported cosmetic substance must be registered in the website CDSCO by submitting an application in form COS-02 with a cover letter.
- The registration certificate will be obtained within 6 months of the submission of the application form.
- Then, the registration would be accepted till 3 years after which renewal would be required for the further continuation.

- The covering letter – purpose should be clearly mentioned
- Fee: Treasury challan (in original)
- Power of attorney
- Schedule D(III)
- Original or a copy of the label
- Free sale certificate (FSC) / marketing authorization letter/ manufacturing license, if any
- Product specification and testing protocol should be submitted.
- List of countries that have market authorization or import permission.
- Pack inserts, if any
- Declaration form for nonanimal testing
- Heavy metals and hexachlorophene content declaration
- If any other specified documents
- Label for registered imported cosmetics
- Application in Form COS-1
- Soft copies of the information about the brands, products and manufactures.
- Fee: (Bharatkosh Online Payment)

Fig 2: Document required for the import of cosmetics in India

Timeline for application processing[7]

The registration certificate will be released within ninety days of the date on which the application form and all relevant documents are received (especially the specifics required with Schedule D III).

1.8 Time for issuance and validity

The registration certificate will be issued six months after the application form and supporting documentation are received. The certificate of registration for the import of cosmetics is valid for three years from the date of issue.

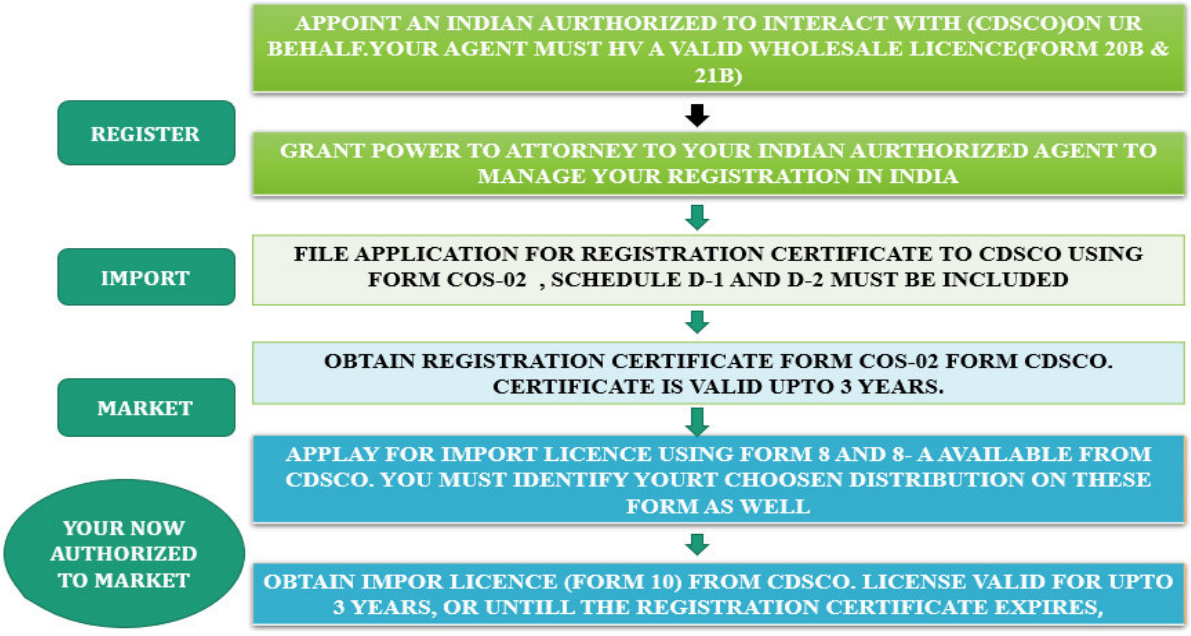


Fig 3: Cosmetic registration in India flow chart

1.9 General label requirements[8,9]

The labelling standards established by the drugs and cosmetics legislation of 1945.

- The product name, manufacturing address mentioned in the inner and outer labels
- if the container is small in size, the principal place of manufacture and the pin code are sufficient.
- The external label specifies the net content of the products used in the product's manufacture, usage of the product and any warnings and also include names and amount of harmful ingredients should be mentioned in inner label
- Batch number is denoted as letter "B" and manufacturing license number is denoted as M mark.
- In the case of the above product categories, quality requirements shall conform to India standards developed and revised by BIS.
- According to D and C Rules, 1945, the original label for proposed products must contain the following: - the original label proposed must contain

• Cosmetic's name

- The name and address of the manufacturer and the country of production. The name and address of the originating firm if the component was not manufactured in a manufacturer's plant. (i.e., the label said "Made in..... (Name of Country)" specified.
- In addition, the name of the manufacturer and its principal manufacturing location as well as the pin code should be issued for exceptionally small containers where the address of the manufacturer could not be given.
- Before Use
- Proper Usage and directions
- Number of lot/ batches
- The number of the manufacturing licence.
- Certificate Number of Registration and, in accordance with Part XV of the D&C rules, 1945. Name and address of the RC Holder — Information if any

Both labels on packaged products must provide the following information:

- The importer's name and address.
- The packaged product contains generic or standard names.
- Net volume specified in the normal weight and measurement unit
- The period and year of the product is manufactured, packaged, or transported.
- The packaged goods' maximum retail purchase price (MRP) at which the item will be delivered to the end customer.

1.10 Outer label contains

Solids and semi-solids are declared by net weight, while liquids are measured by fluid volume. The names of the ingredients are listed in descending order of their percentage of the total product. This declaration is not needed for a package of perfume, toilet water, or solid or semi-solid cosmetic with a net content of less than 60 mL or any package of solid or semi-solid cosmetic with a net content of less than 30 grams.

1.11 Inner label contains

- Adequate safety directions including an alert, caution, or specific guideline to be followed by the customer in its use of the device.
- The names and amounts of toxic or toxic ingredients must be noted. Excipient names according to the content percentage.
- The number of the batch is followed by "B" Number of the production licence followed by "M" letter.
- In the order of their concentrations decreasing to 1 percent, in each order less than 1 percent, the ingredients must be declared (Provided that this statement need not appear for packs of less than 60 ml of liquids and 30 gm of solid and semi solids).
- Using prior to date rather than better before the previous day declared to be xx months/year from the date of packing. Any alert, warning or path to be followed by the user, naming and quantity of the dangerous or toxic ingredients.
- No one may change or default any manufacturer's inscription or trademark on any bottle, sticker or cover.
- The following is prohibited: no cosmetic should be used to conceive or pretend to convey or communicate to the intended audience some incorrect or deceptive idea.
- The hair teeth which include colour, colours or pigment must be marked with both the internal and the external labels in English and local languages: hair teeth which include Para-Phenylenediamine or other teeth, colours or pigments.
- "Caution: This substance contains additives that, in certain circumstances, can induce skin irritation; thus, a preliminary test should be performed according to the following instructions. This substance must not be used to stain the eyelashes or brows; doing so can result in blindness."
- Preparation will cause extreme skin inflammation; thus, a preliminary test should be done to determine the sensitivity, use soap and water or alcohol to clean a small area of skin behind the ear or on the inner surface of the forearm. Apply a little amount of hair dye in the infected area and wash the area with soap and water after twenty-four hours. It is fair to assume that there is no hypersensitivity if there is no pain or discomfort.
- To perform a preliminary examination to assess sensitivity, clean a small area of skin behind the ear or on the inner surface of the forearm with soap and water or alcohol. After twenty-four hours, apply a small amount of hair dye to the affected region and wash it with soap and water. It is safe to say that since there is no pain or irritation, no hypersensitivity exists.
- Special provisions for fluoride toothpaste: The fluoride content of toothpaste shall not exceed 1000 ppm (0.22 percent), and the fluoride content in ppm, as well as the expiry date, shall be stated on the tube and carton.

1.12 Packaging guidelines

For the packaging of products three major laws are considered i.e., Legal Metrology Law, Drugs And Cosmetics Law And Bureau Of Indian Standards (Bis).

1.13 Cosmetics prohibited/restricted

- Rules 134, 135 A and 135 of the D&C Act note that no cosmetic containing the colour of coal tar other than those provided for in the 'Q' and Indian Standards is manufactured (IS:4707 part 1).
- Any cosmetic that is mislabelled or counterfeit, as well as of poor quality.
- Cosmetics with not more than lead (20 ppm) arsenic compounds (2ppm), mercury compounds are restricted from the usage in coal tar colour.
- Any cosmetic product that contains any component that could make it unhealthy or dangerous for use under the instructions specified or prescribed.
- Some hexachlorophene-containing cosmetics.
- Importation of animal-tested cosmetics is prohibited.[10]

1.14 Guidelines on misbranded and spurious cosmetics for misbranded cosmetics[11]

According to D&C, act cosmetics is said to misbranded when:

- It holds any dye, colour, pigment which is not advised.
- It is not directed or labelled in a proper advised way.
- If the label, or whole of the container provides any deceptive or false information.

According to D&C act, a cosmetic is said to spurious when:

- It is imported with any name that refers to some other cosmetics

- It creates emulation, replacement, of any cosmetics or has a similar name as that of any cosmetic product.
- Either a person or company is the manufacturer of the cosmetic which is specified on the label, but that person or company is not that person or company. If it gives the impression that it is a result of a manufacturer or retailer that it is not.

Table 1: ***Contraventions and fee details***

Contravention in brief	Penalty
Importation of spurious cosmetics	3-year imprisonment with a fine of five thousand rupees which can last beyond 5-years.
Importation of cosmetics that are restricted by section 10-A	3-year imprisonment with a fine of five thousand rupees which can last beyond 5-years.
Repeated offence of spurious cosmetics and cosmetics which are restricted by section 10-A	5-years imprisonment and fine of up to 10 thousand rupees
Misbranded cosmetics not of standard quality are not used for manufacturing and sale	3-year imprisonment with a fine of five thousand rupees which can last beyond 5-years.

1.15 Regulations of cosmetics in Singapore

1.15.1 Definition

A cosmetic product in Singapore is defined as any substance or preparation that is intended to be placed in contact with the external parts of the body, such as skin, nails, lips, or mouth (including gum, teeth, and tongue), for the purpose of: Cleaning them cleaning them, perfuming them Changing their appearance, correcting body odours, protecting them, Keeping them in good condition. Furthermore, cosmetic products are divided into two types:

- High Risk: Hair dyes containing phenylenediamine as well as dental and oral care drugs are deemed to be more dangerous additives for use around the eyes and mouth.
- Low risk: all other cosmetic products not listed above are considered lower risk, such as skin whitening products, hydrating agents, and so on.[12]

1.16 Introduction

Companies responsible for introducing cosmetic products into Singapore must contact the Health Sciences Authority (HSA) and obtain acknowledgement approval before introducing the products into the local market. The product notification is sent via the HSA's PRISM online framework (Pharmaceutical Regulatory Information System). Register for CRIS (Client Registration and Information System) in order to gain access to PRISM.

1.17 Regulatory agency in Singapore

The Health Science Authority (HSA) of the Ministry of Health in Singapore is the regulatory authority responsible for monitoring and licencing cosmetic products for human use. As HSA division for the supervision of cosmetics regulatory oversight, the Cosmetics Control Unit was established in November 1995.[13]

1.18 Criteria for manufacturing of cosmetic products

The guidance on the production of cosmetics in terms of staff, houses, equipment, sanitation and hygiene, and so on are laid down in Good practice in ASEAN Manufacturing (GMP). Producer of cosmetic components in Singapore does not need the licence of a manufacturer. In order to promote exports of the commodity, the producer can apply for a voluntary GMP certificate.

1.19 Notification

If in Singapore an enterprise is planning to sell or deliver a cosmetic substance, the HSA must be informed. They must make sure that the ingredients used in the cosmetic product comply with the ASEAN Cosmetic Directive (ACD) requirements and the labelling provisions, and that they register with the account for Client Registration and Identification Service (CRIS) before they send a notification. The notice must be sent to the Pharmaceutical Regulatory Information System, which is available online (PRISM). If notice is successfully sent, an acknowledgment of an email notification will be produced and sent to the e mail of the claimant automatically. The material is supplied only after the recognition is achieved. Per year after that, the beauty product will be re-notified if it is still available on the market. The Client Registration and Identification Service (CRIS) is an e-service that enables businesses to authorise staff or service providers to use HSA e-services in MEDICS or PRISM on their behalf.[13]

1.20 Who should submit notification

- And if another company in Singapore has already notified the product and you are buying from the same manufacturer.
- For each particular version of the same beauty product, such as different colours of lipstick and different scents of shampoo.
- However, the organisation must also adhere to such standards, such as labelling, ingredients, and adverse event reporting:
- A large number of items related to advertisement, endorsement, or promotional events
- Products used for tests or trials in connection with some product study or production.
- Products made by or according to the standards of a medical practitioner and provided exclusively for the use of patients under his supervision by that medical practitioner.
- The same product in various pack sizes.[14]

1.21 What responsibilities companies shall take?

- Cosmetic product sellers are accountable for the protection and durability of their goods. Cosmetics must not include adulterants or banned ingredients, and they must not exceed defined content limits.
- The supply of cosmetic products is maintained for about 2 years.

- The safety information and technical information is submitted with request of HSA.
- HSA should be kept informed of any adverse accidents or recalls.
- If a substance is found to be unsafe, it should be recalled.[14]

1.22 The submission of notifications not necessary if,

- A cosmetic substance manufactured or supplied specifically by a medical practitioner in relation to the publicity, approval, or promotion operation by that practitioner or a cosmetic substance supplied solely for use or research in connection with the research or production of such material. Cosmetic materials are not tested by HSA. The consistency and durability of their products are the responsibility of cosmetics sellers. No adulterant and forbidden ingredients used in cosmetic products and must adhere to stringent content standards. Products informed with HSA that do not follow the cosmetic quality specifications.[14]

1.23 Cosmetic products list

- Crems, emulsions, lotions, gels and oils for the skin (hands, face, feet, etc)
- Face masks
- Tinted bases (liquids, pastes, powders)
- Make- up powders, after- bath powders, hygiene powders etc
- Toilet soaps, deodorant soaps, etc
- Perfumes, toilet waters and eau de cologne
- Bath and shower preparations (salts, foams, oils, gels, etc)
- Depilatories
- Deodorants and antiperspirants
- Hair care products
- Hair tints and bleaches,
- Products for waving, straightening or fixing, setting products,
- Cleansing products (lotions, powders, shampoos),
- Conditioning products (lotions, creams, oils),
- Hairdressing products (lotions, lacquers, brilliantines)
- Shaving products (creams, foams, creams, oils)
- Products for making- up and removing make- up from the face and the eyes
- Products intended for application to the lips and around the eyes
- Products for care of the teeth and the mouth
- Products for nail care and make- up (manicure and pedicure products)
- Products for external intimate hygiene
- Sunbathing products
- Products for tanning without sun
- Skin whitening products[14]

Table 2: Process to supply cosmetic products in Singapore overview

Cosmetic products supplying stages	Details
Prior to sending product notification	• The cosmetic product's components must comply with the ACD's specifications. • The product should be compiled with labelling regulations specified.
Product notification to be submitted	• Make Client Registration and Identification Service (CRIS) account application. • Use PRISM to notify the FDA of a new cosmetic product. • Refer the guidance on how to find out and submit notification of cosmetic product.
After submitting product notification	• Comply with the company's obligations. • Submit an amendment to correct claimant records, business information, or manufacturer information. • Re-notification is supposed to take place for one year. • You can delete it if you no longer sell the commodity.

1.24 Reporting of adverse events

All adverse effects should be reported to HSA by the responsible party. The cosmetic product which causes death and life-threatening effects. Within seven days the company/ organization should report to HSA of being aware of the event. Over the next eight days, the company must file an adverse incident disclosure form. [15,16]

1.25 Product information file (PIF)

Purpose**:** It is a document which gives guidance to new importers on the basis of assessing product safety and quality of cosmetic products. Product Information File that is PIF Guideline key purpose offers guidance to companies in Singapore is to offer companies launching cosmetic products and how PIF is organised and compiled using the format defined. The PIF must be organised and readily consulted by companies putting products on the market in a manner to fulfil the requirements as per ACD. The PIF should be described in four sections, according to the experts. They are in the following

• Part 1: Management documents and quality of products
• Part 2: Quality data on raw material
• Part 3: Quality data for the finished product
• Part 4: Safety and Effectiveness Data

*It is not a legal document; compliance is not a requirement.[17]

1.26 Responsibility of importer's

The responsibility of importers is to ensure that manufactured cosmetic products which are locally supplied are safe and also have appropriate quality and the person importing the product into the local market must meet all regulatory requirements before supplying it.[17]

1.27 Product formulation

Cosmetic products have established safety standards for cosmetic ingredients. Certain ingredients are only used under certain restricted conditions. The importers make certain that the materials used in the products meet the HSA requirements, which include:

- List of contaminants that must not be used in the formulation
- According to those standards and conditions, a listing of chemicals that cosmetic products must not contain.
- listing of colourants permitted in cosmetic products that are used.
- Preservatives list that are used in cosmetics.
- Listing of UV filters that can be used in cosmetic products.

Importers can examine the products for heavy metals and microbiological material, as well as common adulterants, to ensure the absence of any of the more commonly found adulterants in cosmetic products.[18]

1.28 Product testing

For a list of local laboratories approved to perform cosmetic product testing, access the Singapore Accreditation Council (SAC) website. Cosmetics are not intended to treat or cure any medical conditions, so importers should be aware of this. If your manufacturer makes those claims about the materials, be aware that they could contain banned additives.
some of the cosmetics which are having some adulterants. If you deal with these kinds of products, you may want to look at the following tests

- Toothpastes**:** to determine the presence of diethylene glycol which is a toxic substance used in impurity in glycerol and polyethylene glycols, used as an important ingredient in oral care items.
- Teeth whitening products: to check the amount of Hydrogen peroxide in cosmetic products. the presence of a high amount of hydrogen peroxide which is corrosive that causes eye and mucous membranes and skin irritation. The concentration of 0.1 % hydrogen peroxide is recommended.
- Lipsticks: To check the presence of Rhodamine- B which is carcinogenic pigment that is not used in cosmetics
- Skin whitening creams: to check the presence of hydroquinone, tretinoin and mercury. Inappropriate use of hydroquinone causes skin colour change and hypersensitivity reactions (rashes, redness, tingling, and burning).
- Whereas tretinoin causes redness and peeling of skin. It should be used under medical supervision.
- Mercury cannot be used as an ingredient in cosmetic products due to the harmful effect on the kidney, digestive system, nervous system, and can also lead to organ injury, when it is used in high level.[13,19,20,21]

1.29 Requirements for labelling of cosmetics

Labelling of cosmetic products must have reliable and truthful information, and how to use the cosmetic product is also mentioned. Before they are distributed in the Singapore market, they must be labelled under the regulations. Labels or labelling declarations must be written and read in English.

The following detail is printed on the cosmetic product's exterior packaging.

- Name of the cosmetic product
- Cosmetic product feature
- Usage of cosmetic product
- All ingredients list
- Country of production
- Product content (weight/volume)
- Batch number mentioned
- Dates of manufacture and expiry (the shelf life / expiration is only expected for products with a lifespan of less than 30 months.)
- The name and address of the firm in charge of marketing the product in Singapore.
- If special precautions exist, they should be taken as specified.
- The mark's symbol or code must be specified (e.g., colour).[20,21,22]

1.30 Label display

- The sign must be readable, permanent, indelible, and easily and clearly stamped on the package at the time of purchase. Labels or labelling statements for beauty ingredients must be visible on the exterior or intermediate packaging.
- Where the packaging or package size, type, or style does not allow for all of the necessary information to be specified on the label, packets, brochures, hang labels, display panels, and other similar items can be used alongside the product. The name of the cosmetic substance as well as the batch number must be displayed on the immediate packaging or bottle.[23]

1.31 Listing of ingredients

- Cosmetic ingredients must be mentioned on the packaging. A quantity of each and every ingredient, except those ingredients which are specified in descending order of weight, shall not be needed on the packaging of a cosmetic product.
- Ingredients with much less than one percent (by weight) concentrations should be rated in any order after one percent or more is listed as specified.
- Colouring agents are specified in order.
- Fragrances, aromas and their raw products, "perfume," "perfumes" or some other term relevant to them. Also, flavouring can be known as "flavour" or any similar term.

1.32 Misleading labelling

No individual shall supply any cosmetics with a label that contain any statement, trademark, image, or other sign that

- Promotes the use of cosmetic product directly or indirectly, or
- Gives an erroneous perception regarding the formulation, structure, consistency, or protection of cosmetic products.[23,24]

Fig 4: Importers should use a checklist to ensure that imported cosmetics are in compliance[25]

1.33 Fees and contraventions details

For both notification fee and renotification fee[25,26]

Table 3: Fee Details

Variants	Yearly Payment/Fee
A single product with a higher probability	26 US dollars

The first three types/variants of a more dangerous product	26 US dollars per variant
Fourth and following variants of drugs of higher risk	6 US dollars per variant
Single product with lower risk	11 US dollars
Lower risk substance in three variants	11 US dollars per variant

Penalty

When considered essential, the Health Sciences Authority may order the suspension of a cosmetic product's sale and supply, as well as its withdrawal from the market.

- It is an offence under Regulation 4(3) of the Health Products (Cosmetic Products – ASEAN Cosmetic Directive) Regulations for the person responsible to supply a cosmetic product for which no previous notification has been submitted. On conviction, the individual responsible faces a fine of up to $20,000 and/or a sentence of imprisonment of up to 12 months.
- A cosmetic product may not contain forbidden substances or undeclared western medicinal compounds, according to the same standards. Please keep in mind that it is a violation of Section 16(1) of the Health Products Act, Cap 122D. Individuals or corporations found guilty face a fine of up to $100,000 and/or imprisonment for up to three years if convicted. [27,28]

Table 4: Comparison of Indian & Singapore Regulations[10,12,13,14,26,28]

Parameters	India	Singapore
Authority	CDSCO	The health sciences authority (HSA)
Regulations and Rules	Drugs and Cosmetics act 1940 rules they're under 1945.	Health products (ASEAN Cosmetic Directive) regulations 2007 under HEALTH PRODUCT ACT.
Labelling regulations	It complies with part XV of D&C act 1940 and rules their under 1945	should comply with health products (cosmetic directive) regulations 2007 under HEALTH PRODUCT ACT.
Notification	-------	Inform the HSA. The submission was made into the online pharmaceutical regulatory information system (prism)
Submission	CDSCO – Submitted through online SUGAM PORTAL	Submitted by PRISM
Dossier	-------	Product information file
License	Required	Not required
Premarket approval	State government is required	-------
Expiry date	Indicates as "use before date"	The lifespan of the product is much less than thirty months, the "minimum durability date" is indicated, and if the durability is more than thirty months "period after opening is indicated.
Post marketing report system	----	YES
Color additive safety	Applicable	Applicable
Label language	English	National/ member state
Labelling declaration	BIS and PCRO	section 18(1) of the Act (HEALTH PRODUCT ACT)
Safety warnings	On inner label only	On inner and outer packages
Safety	Manufacturer must Maintain records.	Manufacturer maintains Product information File (PIF).

2. CONCLUSION

The main goal of this article is to demonstrate differences in cosmetic regulations between India and Singapore, indicating the need to harmonise regulations concerning safety, stability, and labelling issues. The authority for cosmetic regulation in India is CDSCO, which is governed by the Drug and Cosmetics Act and Rules, while the authority for cosmetic regulation in Singapore is the HSA. Currently, there is an urgent need to harmonise the laws governing stability, labelling, and protection. Most critically, cosmetic standards for protection and efficiency must be harmonised so that society can profit. Most notably, cosmetic standards for protection and efficacy must be harmonised so that society is not vulnerable to hormone disruptors, carcinogens, and other toxins. However, when safety aspects are concerned, the regulators have made strict rules and mandates to maintain the safety of the product, like in Singapore there is a Product Information File which provides authority with complete information regarding the product, still some more investigation is needed when safety is a chapter for a product. We need to have more transparency, rigid, tough, inelastic and uniform regulations in order to make them perfect for consumers' consumption and usage.

3. AUTHOR CONTRIBUTION STATEMENT

This work was carried out in collaboration between the three authors. The authors Kavitha N, Balamuralidhara V, Meghana M carried out the literature search, performed statistical analysis, carried out the work and wrote the article and first draft. Author Balamuralidhara V designed the study,

gave the protocol and reviewed and approved the final article. All together read and approved the final manuscript.

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4. CONFLICT OF INTEREST

Conflict of interest declared none.

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