


India's Cosmetic Revolution: Navigating Growth and Regulatory Transformations

Ravi Goyal¹, Abhay Asthana¹ and Deepinder Singh Malik^{1*} 

¹Chitkara College of Pharmacy, Chitkara University, Punjab, India.

*deepinder.malik88@gmail.com (Corresponding Author)

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ABSTRACT

Background: The Indian cosmetic industry has witnessed rapid expansion due to urbanization, rising disposable incomes, and increasing demand for natural and cruelty-free products. This growth has driven the need for a well-defined regulatory framework. The Drugs and Cosmetics Act, 1940, along with oversight by the Central Drugs Standard Control Organization (CDSCO) and standards set by the Bureau of Indian Standards (BIS), forms the foundation of cosmetic regulation in India. The introduction of the Cosmetics Rules, 2020 has further strengthened the regulatory system by modernizing definitions, licensing procedures, and safety requirements.

Purpose: This review aims to critically analyze the current regulatory framework governing the design, manufacturing, and distribution of cosmetics in India, with emphasis on recent amendments and their practical implications.

Methods: A qualitative narrative review was conducted using secondary data sources, including regulatory documents, CDSCO guidelines, BIS standards, and relevant literature retrieved from PubMed, Scopus, and Google Scholar (2010–2025). Only studies relevant to cosmetic regulation were included.

Results: The review identifies that the Cosmetics Rules, 2020 have significantly streamlined licensing procedures, introduced risk-based regulatory oversight, and improved alignment with international frameworks, particularly in areas of GMP compliance, labeling requirements, and import regulation.

Conclusion: The updated regulatory framework has enhanced transparency, product safety, and quality assurance within the Indian cosmetic sector. Further alignment with global standards and supportive measures for industry stakeholders can strengthen regulatory effectiveness and promote sustainable growth.



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1. Introduction

Over the past few decades, the Indian cosmetics business has experienced strong expansion, fueled by shifting lifestyles, urbanization, and growing disposable incomes. The Indian cosmetic market is projected to reach USD 20 billion by 2025, growing at a CAGR of 25%, and will constitute 5% of the total global cosmetics market. Additionally, the market will continue to rise strongly due to consumers' growing demand for specialty cosmetic products made up of natural, organic, non-toxic, and cruelty-free ingredients (Pal *et al.*, 2020). The market is segmented into a wide range of skin care, hair care, fragrances, oral care, and color cosmetics. The demand for cosmetic products spans across different demographics, with a notable increase in male grooming products. The proliferation of e-commerce

platforms has significantly boosted online sales of cosmetic products (Pathak & Nichter, 2021).

In recent years, the Indian cosmetic industry has transformed significantly due to evolving consumer preferences, rising personal care awareness, and the influx of domestic and international brands. Regulatory frameworks play a crucial role in facilitating product safety, quality, and efficacy, which in turn fosters consumer trust and industry growth. Initially, the cosmetic market in India was predominantly unregulated, with minimal oversight on product standards. However, as the market expanded and consumer safety concerns grew, the Indian government introduced stringent regulations to govern the import, manufacturing, labelling, export, and marketing of cosmetic products. Cosmetic regulatory legislation in India is driven through the Drugs and Cosmetics Act, 1940 and

Rules. The legislative body is the Central Drugs Standard Control Organization (CDSCO), which is headed by the Drugs Controller General of India (DCGI) and is under the Ministry of Health and Family Welfare. The Bureau of Indian Standards (BIS) also plays a crucial role in setting the quality and safety standards for cosmetics. As per the Drugs and Cosmetics Act, the definition of cosmetics under Section 3 (aaa) is “any article intended to be rubbed, poured, sprinkled, or sprayed on, or introduced into, or otherwise applied to, human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and includes any article intended for use as a component of cosmetic” (Singh *et al.*, 2018). This Act was primarily focused on enforcing the safety and efficacy of drugs, with provisions for cosmetics to prevent the sale of substandard and unsafe products. Over the years, regulations have evolved to address new challenges posed by advancements in cosmetic formulations and the growing demand for safe, high-quality products. Amendments have been made to include specific guidelines for labelling, safety testing, and the import and export of cosmetic products.

The Act consists of a number of important provisions related to the safety, quality, and regulation of cosmetics. First of all, it highlights the significance of guaranteeing the safety of cosmetic products through proper safety assessment, labelling of ingredients, and continuous observation for side effects. For example, under the regulations, testing should be done to determine whether there are any hazardous chemicals in the products, such as heavy metals, microbial presence, and other toxins. Besides, the Act provides certain standards to assure the required level of quality without any contaminants and with consistent products following BIS standards, such as IS 4707, which outlines prohibited substances in cosmetics. Moreover, the Act introduces a way of market surveillance in relation to the non-compliance of certain products, and as a result, penalties can be imposed in terms of inspection and possible recall conducted by CDSCO. Another significant aspect is the harmonization with international guidelines regarding exports from the country in order to meet the requirements of the International Organization for Standardization (ISO) and the International Cooperation on Cosmetics Regulations (ICCR), thus promoting growth in the international market. Finally, this Act regulates innovation in the field by controlling nanomaterials and other advanced products (Chawra, 2022).

This article attempts to provide readers with a comprehensive overview of the existing regulatory framework in place in India for the design, manufacture, and commercial distribution of cosmetics, as well as insight into the practical implications of legislative variances. Moreover, this review also provides insights regarding the latest amendments made in Indian cosmetic regulations.

2. Evolution of Cosmetic Regulations in India

Before the 1940s, the Indian cosmetic market was largely unregulated, with minimal oversight on product safety and quality. In 1940, the Drugs and Cosmetics Act was introduced as a significant step in Indian cosmetic regulation, which aimed to regulate the import, distribution, manufacture, and sale of drugs and cosmetics. Initially, this Act focused more on drugs; however, it laid down the groundwork for future cosmetic regulations in India. During the 1950s–1970s, the regulatory framework for cosmetics remained static. The focus was primarily on product safety for consumer use, but specific guidelines and standards were still lacking. After this period, several specific standards and guidelines were introduced for cosmetics in India (Katkar *et al.*, 2024).

In the 1980s, the BIS began developing and implementing specific guidelines for cosmetics, which covered various aspects such as product safety, labelling, and quality control. In 1982, the BIS introduced the IS 6608:1982 standard for skin powders, which set their quality benchmark. In 1987, BIS introduced IS 4707, which provided a list of substances restricted in cosmetics, aligning Indian regulations more closely with international safety standards (Chauhan *et al.*, 2022).

In the 2000s, globalization prompted India to align its cosmetic regulations with international standards by introducing Good Manufacturing Practices (GMP) to ensure hygienic manufacturing conditions. In 2018, significant amendments were made to the Drugs and Cosmetics Rules, which included the requirement of registration certificates for imported cosmetics and compliance with GMP standards. These amendments enhanced consumer safety and ensured that only high-quality products are available in the market.

In 2020, a draft of the Cosmetic Rules was introduced, which further proposed updates to the regulatory framework, emphasizing transparency, safety, and quality. These rules introduced new guidelines for cosmetic registration, labelling requirements, and the prohibition of certain harmful substances. In 2021, BIS introduced the IS 17516 standard, which aligns with the international ISO 16128 guidelines for natural and organic cosmetic ingredients. This standard promotes the use of safer and environmentally friendly cosmetic products (BIS, 2012).

3. Regulatory Authorities for Cosmetics in India

The CDSCO, under the Ministry of Health and Family Welfare, is the primary regulatory body for cosmetics in India. It ensures the safety, efficacy, and quality of cosmetics via regulation and enforcement. The DCGI heads the

CDSCO and is responsible for the approval of licenses for certain categories of cosmetics. The DCGI ensures that cosmetics manufactured and marketed in India meet the specified quality and safety standards. Moreover, the DCGI functions as the Central Licensing Authority, which grants the import registration certificate and regulates the import of cosmetics into India via Gazette Notification G.S.R. 763(E) under the provisions of the Drugs and Cosmetics Act, 1940. The DCGI also ensures that any article falling within the definition of a cosmetic is required to be registered, along with pack size, variant(s), and manufacturing premises, before its import into the country.

The BIS develops and maintains standards for cosmetics, which are critical for the quality and safety of cosmetic products. The State Drug Control Authorities

operate at the state level, maintaining compliance with the regulations set forth by the CDSCO and BIS. They conduct inspections, monitor manufacturing practices, and ensure that cosmetic products in the market comply with the enforced regulations (Vadia *et al.*, 2026).

4. Cosmetic Regulations and Their Regulatory Procedures in India

The classification of cosmetics in India is broadly segmented into various categories based on the function and type of cosmetic product. The classification is described in Figure 1 below. For understanding cosmetic regulations in India, there are various aspects which are discussed one by one below.

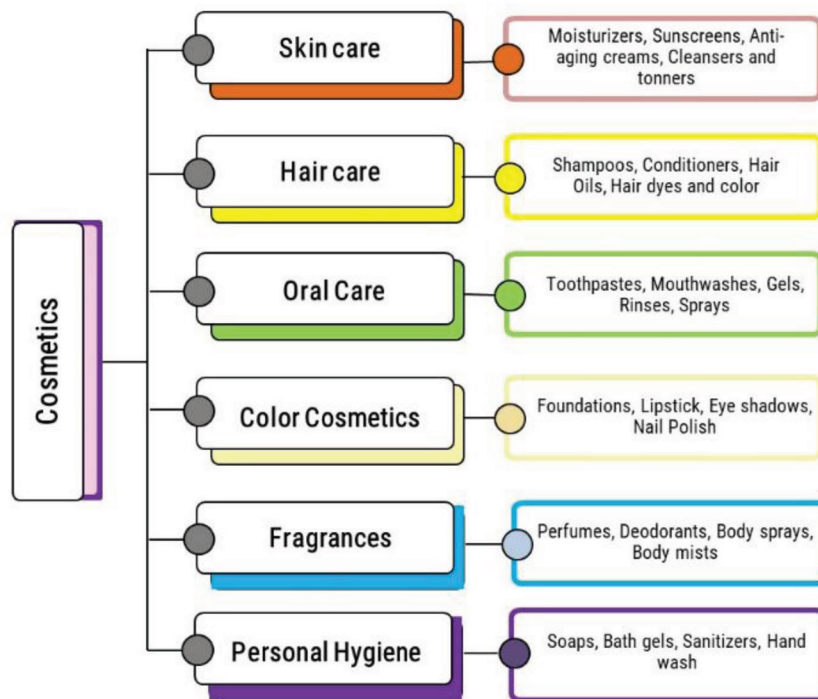


Figure 1: Different Types of Cosmetics

4.1. Licensing and Registration Regulation

The manufacturer must formulate the cosmetics as per the standards prescribed in Schedule S of the Drugs and Cosmetics Act. The dyes, colors, and pigments used in cosmetics must be as per Schedule Q of the Act. The manufacturing of cosmetics is regulated under a system of inspection and licensing by the State Licensing Authorities appointed by the respective state governments. For a manufacturing licence, manufacturers must obtain a license in Form 32, as specified in the Drugs and Cosmetics Rules, and submit the application in Form 31. The license

is obtained from the State Drug Control Authorities. The manufacturing premises must be inspected by the regulatory authorities to ensure compliance with GMP. The manufacturing license is valid for 5 years and must be renewed thereafter.

If the manufacturer intends to manufacture cosmetics in a facility owned by another licensed manufacturer, then they must obtain a loan license in Form 32-A. The application should be made in Form 31-A. The manufacturing or loan license is also subject to approval by the State Drug Control Authorities; however, its grant is conditional upon fulfillment of specific requirements. These include full compliance of

the premises with Good Manufacturing Practices (GMP) as stipulated in Schedule M-II of the Drugs and Cosmetics Rules, the availability of adequate facilities for testing and quality control, and the employment of qualified technical staff, including a competent person who possesses the prescribed qualifications and relevant experience in the field (Bhat & Venkatesh, 2020).

4.2. Good Manufacturing Practices (GMP) Regulations

The GMP requirements or premises for the manufacture of cosmetics should be as per the requirements/regulations mentioned in Schedule M-II of the Drugs and Cosmetics Rules, 1945. The requirements as per the regulations are discussed below (Mishra & Kurmi, 2023), (Amar et al., 2026).

- **General Requirements:** The industry must be situated in a clean location, maintaining hygienic conditions throughout the premises. It should not serve as a residence or be connected to any residential area. Proper ventilation and cleanliness are mandatory. The building design should support hygienic manufacturing conditions, preventing the access of animals and microbes. The walls of the manufacturing area should be smooth, waterproof, and easy to clean up to a height of 6 feet from the floor, while the flooring should be smooth, even, washable, and designed with curved edges to avoid dust accumulation. The water used in manufacturing must be of potable quality, with proper arrangements for wastewater disposal. Workers must be free from infectious diseases and provided with clean uniforms, masks, headgear, and gloves as per the requirements, along with access to washing facilities. Workbenches for operations like filling, labelling, and packaging should have smooth, washable, impervious tops.
- **Requirements for Plant and Equipment:** The requirements for plant and equipment are established in such a way that they ensure that the manufacturing process is conducted in a safe, hygienic, and efficient environment and upholds the safety and quality of cosmetics. Table 1 below discusses the equipment, area, and other requirements as recommended in Schedule M-II for the manufacture of different cosmetics.
- **Raw Materials:** The licensee must maintain an inventory of all raw materials used in cosmetic manufacturing and keep the records. Upon receipt, the material should be quarantined and stored in a manner that allows for batch segregation and stock rotation based on the 'first in/first expiry' principle. Each batch within the delivery must be sampled, tested, and released individually. Raw materials should be clearly labelled with the product name, manufacturing details, internal code, batch number, status, and relevant dates. Only quality-controlled and shelf-life-compliant raw materials should be used, and containers must be placed on raised platforms/racks, not directly on the floor.
- **Documentation:** It is crucial for the Quality Assurance system and is integral to GMP, covering all aspects of manufacturing, material specifications, and control methods. It ensures that personnel have the necessary information to provide an audit trail for investigating any defective batches. Records must be completed on time to ensure product traceability and retained for at least one year after the product expiry. Labels, which are vital for cosmetic identification, must be clear and detailed. All printed materials should be examined by the QC department before release, and records of labelling and packaging materials must be maintained.
- **Quality Assurance (QA):** It encompasses all aspects that influence the quality of cosmetic products, thereby facilitating compliance with the requisite standards for their intended use. A proper QA system guarantees that the cosmetic products are designed and developed as per GMP and Good Laboratory Practices (GLP). This includes the implementation of adequate controls on starting materials, intermediate products, and bulk/finished products with necessary calibrations and validations. Finally, cosmetic products must not be released for sale/supply until authorized personnel certify that each production batch complies with the label claim requirements and all other relevant requirements.
- **Quality Audit and Self-Inspection:** To ensure GMP compliance, manufacturers should implement a self-inspection system supported by quality audits to evaluate and improve production and quality control. An independent team of experienced qualified people, either from within or outside the company, should be appointed to conduct objective audits. The self-inspection process should be well documented, including results, evaluations, conclusions, and recommended corrective actions with effective follow-up. The written instructions for self-inspection should cover various aspects such as premises, personnel, equipment maintenance, material storage, production controls, QC, documentation, sanitation, validation, instrument calibration, recall procedures, complaint management, label control, and results from previous inspections with corrective actions taken.
- **Validation and Process Validation:** It is a crucial component of GMP and must be conducted according to pre-defined protocols, encompassing processing,

testing, and cleaning procedures. Processes and procedures should be based on validation studies and undergo periodic revalidation to ensure their effectiveness. Critical processes must be validated either prospectively or retrospectively. Any significant

changes to the manufacturing process, including changes in equipment or materials that may impact product quality or process reproducibility, must also be validated.

Table 1: Equipment, Area and Other Requirements for Manufacturing Different Cosmetic Products

S.no	Cosmetic Category	Equipment	Area Specified	Other Specifications
1	Powders – cake make-up, face powder, face packs, compacts, masks, rouges, etc.	Powder mixer with dust collector, ball mill/grinder, sifters with sieves of suitable mesh size, trays and scoops (stainless steel), perfume and color blender, filling and sealing equipment along with dust extractor. In case of compacts – a separate mixer and compact pressing machine, weighing and measuring devices, storage tanks	Advised having an area of 15 sq. meters and sufficient exhaust fans	-
2	Lotions, emulsions, creams, pastes, shampoos, cleansing milks, shaving creams, hair oils, etc.	Mixing and storage tanks, agitator, heating kettle, colloidal mill/homogenizer, filling and sealing equipment, weighing and measuring devices	Advised having an area of 25 sq. meters along with flameproof exhaust systems	-
3	Nail polishes and nail lacquers	Mixer, storage tanks, filling machine, weighing and measuring devices	Advised having an area of 15 sq. meters	Premises – should be located in an industrial area and partitioned from other cosmetic manufacturing areas via metal or brick. Fireproof floors, walls, ceilings, doors, and electrical wires. Prohibition of smoking, cooking, and dwelling. Availability of fire extinguishers. Storage – All explosive ingredients and solvents must be kept in metal cupboards. No Objection Certificate – from the local Fire Brigade authorities to be furnished.
4	Lipsticks and Lip Gloss	Jacketed kettle, vertical mixer, mixing vessel, ball mill, moulds with refrigeration facility, weighing and measuring devices	An area of 15 sq. meters is recommended	-
5	Depilatories	Mixing tanks, mixer, weighing and measuring devices, moulds	An area of 10 sq. meters is recommended	-
6	Eyebrows, eyelashes, eyeliners, kajal, surma	Mixing tanks, mixer and homogeniser, filling and sealing equipment, weighing and measuring devices, powder sterilizer, mortar and pestle	Advised having an area of 10 sq. meters with a separate area of 5 sq. meters for base sterilization	-

7	Aerosol	Mixing tanks, air compressor, propellant filling and crimping machine, filling machine, leak testing machine, filtration equipment, weighing and measuring devices	Advised having an area of 15 sq. meters	No Objection Certificate – from the local Fire Brigade authorities to be furnished.
8	Alcoholic fragrance solution	Mixing tank with stirrer, filtering, filling, and sealing machine, weighing and measuring devices	Advised having an area of 15 sq. meters	-
9	Tooth powder and pastes	Mixer, powder and tube filling equipment, planetary mixer with de-aerator system, stainless steel sieves, crimping machine	Advised having an area of 15 sq. meters	Manufacturing facilities for white and black tooth powder must be located separately.
10	Toilet Soaps	Kettles or pans for saponification, boiler and stirrer, storage tanks, driers, mixer and roller machine, granulator, chipping machine, cutter, plodder, stamping, pressing, and embossing machine, weighing machine	A minimum area of 100 sq. meters is recommended	-

4.3. Safety and Efficacy Regulations

According to BIS regulations, the manufacturer must possess adequate proof of safety, documentation, data, or any relevant information demonstrating that the product is safe for use. In cases where the product necessitates specific usage instructions and warnings, these must be clearly communicated to consumers. If any efficacy claim is made, the manufacturer must provide scientific evidence such as clinical trials, scientific literature, or other relevant data to support the claims. Misleading and unsubstantiated claims on labels are prohibited (Mishra & Kurmi, 2023).

4.4. Packaging and Labelling Regulations

Cosmetic regulations ensure that cosmetics are packaged in a manner that guarantees safety, quality, and compliance with the regulatory standards. For packaging, two major laws are considered, i.e., the Drugs and Cosmetics Act and BIS standards. Cosmetic packaging involves three levels: primary, secondary, and tertiary. The primary packaging directly encloses the product and must protect it from contamination and deterioration to maintain product safety and effectiveness throughout its shelf-life. Secondary packaging provides additional protection and often includes branding and information for the consumer, while tertiary packaging is used for bulk handling, transportation, and storage, safeguarding the product during distribution. All levels of packaging are designed to maintain the integrity of the cosmetic product until it reaches the consumer.

For products that could be harmful if ingested by children, the cosmetic regulations recommend the use of child-resistant packaging. For certain cosmetics, tamper-evident packaging is required to ensure product integrity and consumer safety. BIS provides detailed guidelines for various packaging materials and their suitability for different types of cosmetic products.

The Act and Rules stipulate specific guidelines for the labelling of cosmetic products. The name of the cosmetic product and the manufacturer's address must be clearly indicated on both the inner and outer labels. For small containers, it is sufficient to mention only the principal place of manufacturing along with its pin code, thereby omitting the full manufacturing address. The outer label must provide detailed information regarding the quantities of ingredients used in the product. In addition, the inner label should include a dedicated section titled 'Directions for Proper Use', which details the important instructions, advice, and warnings necessary for the safe use of the product. Furthermore, every label must include the batch number and the manufacturing license number (Beg, 2020).

4.5. Import Regulations

According to the Drugs and Cosmetics Act, 1940 and Rules, 1945, to import cosmetics, importers have to obtain a separate registration certificate in Form 43 for each category of cosmetic products. The application for the registration certificate must be submitted in Form 42. The registration certificate is then

approved and issued by CDSCO if the information provided is as specified under Schedule D III, which provides the format for information and undertaking requirements to be submitted by the manufacturer or the authorized importer.

Documents required for approval include: a) a copy of the manufacturing license and free sale certificate from the country of origin; b) details of the product, including ingredients, specifications, and testing protocols; c) labelling information and product samples; d) information about the manufacturing site; e) Schedule D III annexure duly filled; f) treasury challan; and g) power of attorney. The registration certificate is valid for 3 years, and the manufacturing site is inspected by CDSCO officials as per Rule 21 or 22 of the regulations.

The imported cosmetics must comply with labelling and packaging requirements as specified in Part XV of the Drugs and Cosmetics Rules, 1945. Moreover, the label of imported cosmetics must bear the registration certificate number of the item and the name and address of the registration certificate holder for marketing of the said product in India. The labels must include all essential information:

- a) name and address of the manufacturer;
- b) list of ingredients in decreasing order of concentration;
- c) net content by weight or volume;
- d) manufacturing date and expiry date;
- e) batch number; and
- f) directions for use and any necessary warnings and precautions.

The labelling information must be in English or Hindi.

According to this Act, no cosmetic products can be imported unless it complies with the specifications prescribed under Schedule S and Schedule Q, as well as other applicable standards of safety and quality. Importers are required to submit a signed declaration confirming that the cosmetics complies with the provisions outlined in Chapter III of the Act and Rules, which must be presented to customs authorities prior to import. Furthermore, cosmetics may only be imported through designated points of entry as specified under Rule 43A.

The regulations strictly prohibit the use of dyes, colors, and pigments other than those permitted under Bureau of Indian Standards specification IS 4707 (Part 1) and Schedule Q. Additionally, the import of cosmetics containing hexachlorophene is not permitted. Certain categories of cosmetics listed under Schedule D are exempt from the provisions of Chapter III, subject to the conditions specified therein. In the case of personal use, limited quantities of cosmetics that are otherwise restricted under Section 10 of the Act may be allowed, provided they form part of a passenger's baggage, are intended solely for personal use, and are duly declared to customs authorities for prior clearance (Budhwar *et al.*, 2019), (Abdullah & Hamdard, 2012).

4.6. Export Regulations

Exporting cosmetics from India involves compliance with several regulatory requirements to ensure that products meet the standards (i.e., formulation, labelling, and packaging) and regulations of importing countries. Cosmetic products intended for export must be registered with CDSCO, which involves obtaining an Export Registration Certificate. For this, the exporter needs to complete application Form 42, along with all required documents, which include: a) product specifications; b) certificate of analysis; c) safety data sheets; d) ingredient details along with their concentration; and e) shipping documents like invoices, packing lists, and bills of lading.

The application can be submitted online through the SUGAM portal or manually at the CDSCO office. Once the inspection and review are completed, the CDSCO grants the Export Registration Certificate under Form 43, which contains the details of the registered products along with their validity. Further, the exporter is required to obtain the Certificate of Free Sale from the CDSCO, which certifies that the cosmetic product is freely sold in India and meets the necessary Indian standards. This certificate is often required by importing countries as part of their importation process. In some cases, exporters need to obtain a No Objection Certificate (NOC) from the CDSCO for products that have specific regulatory requirements/restrictions (Rai *et al.*, 2015).

5. Recent Amendments and Updates

The Drugs and Cosmetics Act, 1940 and Rules, 1945 have undergone several changes, especially related to cosmetics. Below are the key amendments that have impacted the regulation of cosmetics in India.

5.1. The Drugs and Cosmetics (5th Amendment) Rules, 2014

It introduced significant provisions aimed at promoting ethical standards against animal cruelty in cosmetic testing and ensuring that cosmetics tested on animals elsewhere are not brought into the Indian market. It encourages the adoption of alternative testing methods, i.e., in-vitro methods, computer modelling, etc., for testing cosmetics. Moreover, it opened the doors for Indian cosmetic industries to compete easily in global markets where cruelty-free standards are mandatory.

According to Rule 135-B of this amendment, no person shall use any animal for testing cosmetics within India. There is an explicit ban on this practice, and persons are required to adhere to cruelty-free practices. According to Rule 148-C of

this amendment, the import of non-cruelty-free cosmetics is banned in India after the date of commencement of this amendment, encouraging global manufacturers to adopt humane testing methods. Rule 148-B of this amendment mandates the introduction of a declaration on cosmetic product labels stating that the cosmetic product has not been tested on animals. This ensures transparency and addresses the increasing demand for cruelty-free products by customers (Sahai & Parveen, 2020).

5.2. The Drugs and Cosmetics (8th Amendment) Rules, 2018

This amendment was made with immediate effect to increase application fees for the grant of various import licences and registration certificates for cosmetics due to the need for compliance with stringent manufacturing, labelling, and testing requirements. As per the labelling requirements, cosmetic products must have clear identification on their labels, including the product name, manufacturer's name and address, disclosure of the list of ingredients, manufacturing and expiry dates, and any special precautions/warnings for safe usage. Cosmetic manufacturers must adhere to GMP and hygienic production conditions and must maintain proper documents related to the manufacturing process. The amendment also reinforced the prohibition of animal testing for cosmetics, aligning with global standards (Sharma et al., 2024).

5.3. The Cosmetics Rules, 2020

The Cosmetics Rules, 2020 were introduced to update and streamline the regulatory framework; to provide detailed definitions, clear processes for licensing; to outline proper import guidelines; and to provide clear packaging regulations for cosmetics separate from those for drugs in India. The Rules were made by the Central Government after consultation with the Drugs Technical Advisory Board, in exercise of the powers conferred by Section 12 and Section 33 of the Drugs and Cosmetics Act, 1940. The aim of this amendment was to provide detailed definitions, clear processes for licensing and import, and stringent compliance measures over the previous regulations under the Drugs and Cosmetics Act, 1940 and Rules, 1945.

The new Cosmetic Rules provide clear and updated definitions for terms such as 'actual manufacturer', 'authorized agent', 'import registration certificate', and 'new cosmetic', which were either undefined or vaguely defined in the previous Rules. The DCGI is designated as the Central Licensing Authority for matters related to the import of cosmetics, and the State Drug Controllers are designated as the authorities for manufacturing, sale, and distribution within their respective states. No cosmetic

can be imported into India without obtaining an import registration certificate from the Central Licensing Authority, and the application for registration must be made through an online portal. Regular inspections are mandated to ensure compliance with licensing conditions and safety standards. Government Analysts and the Central Cosmetics Laboratory are designated to test and analyse cosmetic samples for regulatory compliance. Any new cosmetic containing novel ingredients not used or recognized globally must obtain prior permission before being registered for import. A detailed fee structure for various categories of cosmetics and related regulatory activities is specified. Clear labelling requirements, including the 'use before' or 'date of expiry', are mandated to ensure consumer safety. Packaging of cosmetics must comply with the Legal Metrology Rules, 2011, which include accurate declarations of net quantity, manufacturing date, and manufacturer details. Different forms are introduced for licensing, registration, import, and reporting of cosmetics, which are mentioned in Tables 2, 3, 4, and 5 below (Srivastava et al., 2021), (Mishra & Kurmi, 2023).

Moreover, the Cosmetics Rules, 2020 have practical implications for stakeholders. These effects can vary depending on how businesses operate or where they are located. For example, simplifying licensing procedures and establishing a clear set of regulatory guidelines will help reduce uncertainty but will also create additional financial pressures on businesses, especially small businesses, because of the new stringent regulations. Companies now need to invest extra money in better facilities and trained staff to meet the new chemical-related GMP rules and handle the increased paperwork. Further, the requirement for pre-approval of all new cosmetics could add to the timeline for developing and bringing new products to market. Importers also face challenges and costs associated with compliance with documentation requirements, registration requirements, and Indian labelling requirements.

Table 2: Different Forms under Cosmetic Rules, 2020

Type of Form	Purpose
COS-1	Application for Registration Certificate for import of cosmetics
COS-2	Import Registration Certificate to be issued for import of cosmetics (Validity: 5 Years)
COS-3	Permission to import or manufacture new cosmetics
COS-4	Application for issue of Import Registration Number for import of already registered cosmetics

COS-4A	Import Registration Number to be issued for import of already registered cosmetics	COS-15	Form of receipts for seized cosmetics, record register, documents, or any other material object
COS-5	Application for grant of a license to manufacture cosmetics for sale or distribution	COS-16	Where the fair price tendered is refused by the person from whom the sample is taken, the inspector shall record the fact in the receipt in this form
COS-6	Application for grant of loan licence to manufacture cosmetics for sale or distribution	COS-17	Memorandum for dispatch of sample to Government Analyst by the Inspector
COS-7	Self-certification of GMP for manufacture of cosmetics	COS-18	Form of order not to dispose of stock
COS-8	License to manufacture cosmetics for sale or distribution, including licence number and date of issue	COS-19	Report submitted to the Inspector by the Government Analyst after testing the sample
COS-9	Loan license to manufacture cosmetics for sale or distribution	COS-20	Memorandum to Director, Central Cosmetic Laboratory
COS-10	Intimation to the person from whom the sample is taken	COS-21	Report submitted to the sender by the analyst after testing samples
COS-11	Form in which the inspection book shall be maintained	COS-22	Application for grant of approval of laboratory for testing cosmetics/raw materials
COS-12	Import registration certificate/manufacturing license for new cosmetic	COS-23	Approval for carrying out tests on cosmetics in laboratories on behalf of licensees
COS-13	Application from a purchaser for testing/analysis of cosmetic	COS-24	Report submission of testing/analysis by approved laboratories
COS-14	Report of test/analysis of cosmetic from purchaser		

Table 3: Different BIS Standards in India (Kaple & Patil, 2019), (Rampal & Kanti, 2020)

BIS Standard	Type of Cosmetic	Safety Specifications	Packaging Specification
IS 3959	Skin powders	Talc – should be free from asbestos and other impurities. pH – between 5.0 and 8.0. Loss on drying – should not exceed 1.0% w/w. Arsenic content – should not exceed 2 ppm. Lead content – should not exceed 20 ppm. Total heavy metal – should not exceed 100 ppm. Total viable count – should not exceed 1000 cfu/g.	Non-reactive and safe material to be used. Proper sealing to prevent contamination.
IS 7679	Hair creams	Parabens – up to 0.8% of product. Phenoxyethanol – up to 1% of product. pH – between 4.0 and 8.0. Arsenic content – should not exceed 2 ppm. Lead content – should not exceed 20 ppm. Mercury content – should not exceed 1 ppm. Loss on drying – should not exceed 1.0% w/w. Total viable count – should not exceed 1000 cfu/g.	-
IS 7123	Hair oil	Parabens – up to 0.8% of product. Acid value – 4.0 mg KOH/g. Saponification value – 175 to 250 mg KOH/g. Iodine value – between 5 and 150. Arsenic content – should not exceed 2 ppm. Lead content – should not exceed 20 ppm. Mercury content – should not exceed 1 ppm. Total viable count – should not exceed 1000 cfu/g.	Material must be compatible with oil to avoid reactions. Sealing should be leak-proof.

IS 7884	Shampoo	Surfactants such as SLS and SLES should not exceed 15% w/w. Conditioning agents – should not exceed 2% w/w. Thickeners – should not exceed 5% w/w. Parabens – up to 0.8%. Formaldehyde donors – should not exceed 0.1% w/w. pH adjusters – should not exceed 1% w/w. pH – 4.5 to 7.5. Total Active Matter (TAM) – between 10% and 20%. Arsenic content – should not exceed 2 ppm. Lead content – should not exceed 20 ppm. Mercury content – should not exceed 1 ppm.	Material must be suitable for holding liquid and should not react with the product. Sealing should be leak-proof and tamper evident.
IS 17117	Shampoos for babies	Surfactants such as SLS and SLES should be avoided. If used, their concentration should not exceed 1% w/w. Gentler surfactants such as sodium cocoyl isethionate or sodium lauroyl sarcosinate are preferred. Conditioning agents – safe and mild conditioners like cationic polymers or silicones are preferred and should not exceed 2% w/w. Preservatives – safe preservatives such as phenoxyethanol, benzyl alcohol, etc. are preferred and should not exceed 1% w/w. pH adjusters – ingredients like NaOH and citric acid are recommended to maintain pH between 4.5–7. Citric acid should not exceed 0.5% w/w. Formaldehyde donors are to be avoided. Arsenic content – should not exceed 2 ppm. Lead content – should not exceed 10 ppm. Mercury content – should not exceed 1 ppm. Total viable count – should not exceed 1000 cfu/g.	-
IS 6356	Toothpaste	Fluoride content – between 0.1–0.15% w/w. Abrasives – 10–50% w/w. Humectants – between 20–50% w/w. Binders – 0.5–2% w/w. Surfactants – 1–2% w/w. Preservatives – 0.1–0.2% w/w. pH – 6 to 8. Arsenic content – should not exceed 2 ppm. Lead content – should not exceed 20 ppm. Mercury content – should not exceed 1 ppm. Total viable count – should not exceed 1000 cfu/g.	-

Table 4: Other BIS Standards

Category	BIS Standard
Skin powder for infants	IS 5339
Tooth-powder	IS 5383
Skin creams	IS 6608
Shampoo – soap based	IS 7669
Oxidation Hair Dyes, Liquid	IS 8481
Cologne	IS 8482

Nail Polish	IS 9245
Aftershave Lotion	IS 9255
Pomades and Brilliants	IS 9339
Depilatory Chemicals	IS 9636
Shaving Creams	IS 9740
Cosmetic Pencils	IS 9832
Lipstick	IS 9875
Toilet Soap	IS 2888

Liquid Toilet Soap	IS 4199
Baby Toilet Soap	IS 10523
Shaving Soap	IS 5784
Transparent Toilet Soap	IS 11303
Bathing Bars	IS 13498
Cream Bleach	IS 15608
Cold-wax Hair Remover	IS 15152
Powder Hair-dye	IS 10350
Lip Salve	IS 10284
Henna Powder	IS 11142
Kumkum Powder	IS 10999
Sindoor	IS 14649
Face Pack	IS 15153
Oxidation Hair Dyes (Emulsion Type)	IS 15205

Table 5: All Schedules under Cosmetic Rules, 2020

Schedule	Purpose
First Schedule	Authorization from manufacturer to accompany an application for issuance of import registration certificate
Second Schedule, Part 1	Information and undertaking required to be furnished by the manufacturer or authorized importer/distributor with the application form for import registration certificate
Second Schedule, Part 2	Information and undertaking required to be furnished by the manufacturer with the application form for grant of manufacturing licence/loan licence

Third Schedule	Fee payable for licence, permission, and registration certificate
Fourth Schedule	List of categories of cosmetics for import
Fifth Schedule	Fee for test or analysis by the Central Cosmetic Laboratories or State Laboratories
Sixth Schedule	Undertaking for the import of cosmetics to be submitted by the importer with the application form for Import Registration Number
Seventh Schedule	Good Manufacturing Practices and requirements of premises, plants, and equipment for manufacture of cosmetics
Eighth Schedule	Particulars to be shown in manufacturing records
Ninth Schedule	Standards for cosmetics
Tenth Schedule, Part 1	List of colorants allowed for use in cosmetic products as per IS 4707 as amended by BIS
Tenth Schedule, Part 2	List of colorants permitted to be used in soaps
Eleventh Schedule	GLP and requirements of premises and equipment
Twelfth Schedule	Cosmetic classes and extent and conditions of exemption

6. International Regulations for Cosmetics and Comparison

International cosmetic regulations have comprehensive systems that ensure pre-market safety and quality, influenced by public health concerns, scientific progress, and globalization of trade.

In Europe (EU), Regulation (EC) No. 1223/2009 outlines the rules for cosmetics, creating a high standard for these products. All cosmetic products sold in the EU have to be assessed for safety by a qualified assessor before they can be sold. Each cosmetic product also has to be covered by a Product Information File (PIF). The PIF includes information about the product formulation, how it was manufactured, reports regarding its safety, and any other evidence related to claims about the product's effects on a person. Each cosmetic product must also be notified by the manufacturer via the Cosmetic Product Notification Portal (CPNP) before it is sold. There is a total ban on testing

cosmetics and/or ingredients for cosmetic purposes using animals. To help ensure that alternative testing methods are being used, the EU has also established very strict provisions regarding restrictions on ingredients used in cosmetics, labelling of cosmetics sold in the EU, and post-marketing surveillance of cosmetics sold in the EU. This helps provide significant consumer protection (Gautam *et al.*, 2022).

In the United States of America (USA), under the FD&CA, cosmetic products are not subject to pre-market approvals like in the EU (except for color additives); however, it is the responsibility of manufacturers selling these products to ensure that they are safe and properly labelled. The regulatory landscape for cosmetics is changing with the introduction of the Modernization of Cosmetics Regulation Act of 2022 (MoCRA), which provides the FDA with more robust oversight powers, including the requirement for facilities to register with the FDA, products to be listed or submitted to the FDA, and adverse event reporting. Also, while GMPs are not strictly enforced through a binding regulation, the FDA has created guidance for manufacturers to comply with in order to ensure that their products meet quality standards. There is no explicit prohibition against performing animal testing; however, there is discouragement and encouragement for the use of alternative methods. As a result, the US system for regulating cosmetics is more

industry-driven and tends to focus on post-market compliance, with manufacturers being an integral part of compliance (Katz *et al.*, 2022).

In Japan, regulation of cosmetics is done under the Pharmaceuticals and Medical Devices Act (PMD Act) through the Ministry of Health, Labour and Welfare (MHLW). Cosmetics are classified as one of several types of products (quasi-drugs), which means that cosmetics differ from each other based on how they are defined by their characteristics, including efficacy claims such as skin whitening, anti-aging, etc. In contrast to quasi-drugs, which require pre-market approval before they can be sold, cosmetics are not subject to pre-market approvals because they comply with GQP (Good Quality Practice) and GVP (Good Vigilance Practice). The labelling requirements for cosmetics are strict and require all cosmetics to have a “positive” (i.e., not prohibited) ingredient list that is defined under Japanese law, as well as an emphasis on the use of non-animal testing methods for cosmetics (even though animal testing is not prohibited). Due to the mixed regulatory system used by Japan to regulate functional cosmetic safety, Japan has the potential to be an innovative market in relation to regulating functional cosmetics for safety.

Below is the comparative table of basic cosmetic regulations among India, the EU, the USA, and Japan (Kislalioglu, 1996).

Table 6: Comparative Analysis of International Cosmetic Regulations

Parameter	India	EU	USA	Japan
Pre-market approval	Limited	Yes, through notification via CPNP	No	Partial
GMP	Mandatory, but not strictly enforced	Strictly mandatory	Recommended/voluntary	Mandatory
Animal Testing	Banned	Banned	Allowed	Restricted
Notification System	No centralized notification system	CPNP	FDA voluntary system	Centralized MHLW notification system

7. Conclusion

The implementation of the Cosmetics Rules, 2020 in India has brought significant changes and new challenges to the cosmetic industry and regulators. The emerging trends highlighting the impact of these new regulations are shown in Figure 2. The 2020 Rules introduced the concept of “new cosmetics”, which require prior approval from the Central Licensing Authority, ensuring rigorous safety and

efficacy testing before market entry. The Rules simplified the application process for cosmetic licences, updated the fee structure, and extended the validity of licences, thereby reducing the administrative burden on manufacturers and importers. Increased scrutiny and compliance measures, including mandatory testing as per IS 4011:2018, have been implemented to ensure the safety and quality of cosmetics, which has ultimately raised the standards for product safety evaluation and post-market surveillance.

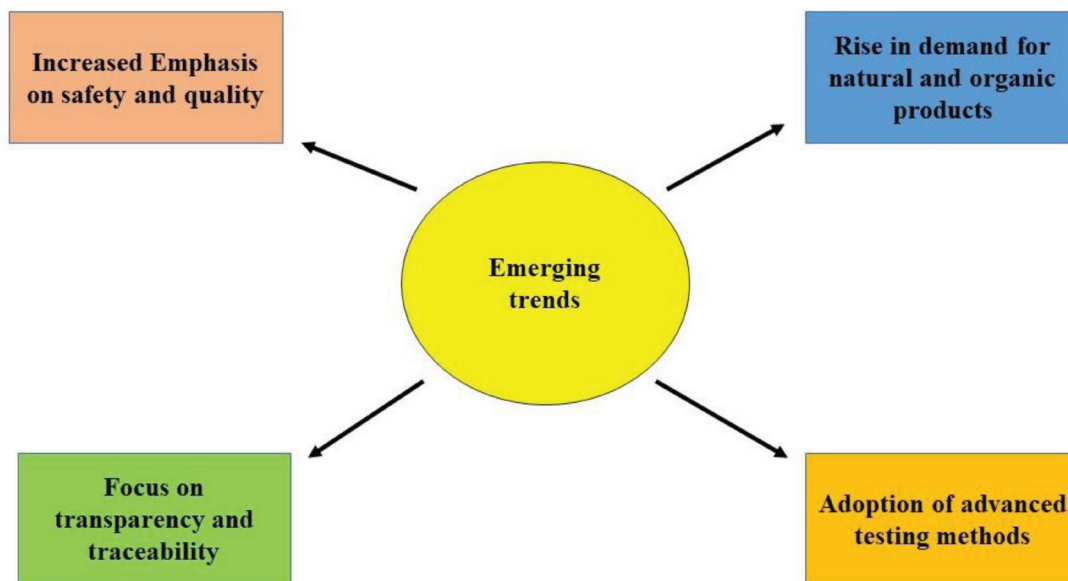


Figure 2: Impact of Cosmetic Rules 2020

Despite these trends, there are several challenges associated with these new rules. Small and medium-sized enterprises (SMEs) in the cosmetic industry face challenges in complying with and adapting to these new regulations due to the costs and resources required for compliance. Ensuring adherence to stringent safety and quality standards can be resource intensive. Moreover, the shift to non-animal testing methods creates challenges in identifying reliable and validated in-vitro testing approaches for a wide range of cosmetic products. The increased regulatory requirements for documentation, labelling, and safety assessments add to the regulatory burden on manufacturers, which slows down the product development and launch process, ultimately impacting time-to-market. The new rules have influenced market dynamics by guaranteeing that only compliant and safe products reach consumers, which has necessitated significant adjustments by manufacturers to meet the new standards. Effective enforcement and monitoring of the new rules pose challenges for regulators, as they require robust surveillance and inspection mechanisms to ensure that all cosmetic products in the market comply with these new regulations.

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Authorship Contribution

Ravi Goyal contributed to the methodology of the study and was actively involved in writing the original draft as well as reviewing and editing the manuscript. Abhay Asthana contributed to the investigation and performed the formal analysis of the study. Deepinder Singh Malik contributed to the conceptualization and methodology of the research, validated the findings, and also participated in the review and editing of the manuscript.

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Declarations

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Conflict of Interest

The authors declare that there is no conflict of interest regarding this manuscript.

Data Availability Statement

The authors declare that the data supporting the conclusions of this study are included within the article.

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AI- based tools were used only for language refinement, grammar correction, paraphrasing, and improving the readability of the manuscript. The scientific interpretation, analysis, conclusions, and overall content of the study were developed and verified solely by the authors.

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