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DISCUSSION PAPER

INDUSTRY OUTLOOK ON POLICY FRAMEWORKS FOR THE COSMETICS SECTOR

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INDUSTRY OUTLOOK ON POLICY FRAMEWORKS FOR THE COSMETICS SECTOR

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Contents

Executive Summary

This discussion paper examines key challenges in India's cosmetics regulatory framework, particularly focusing on three key areas: the combined regulation of drugs and cosmetics, the existing pre-market approval processes, and limited harmonisation between central and state authorities. Despite the sector's promising growth potential, the current regulatory structure may hurt innovation and the sector's growth.

The paper examines current challenges and global best practices to recommend reforms, including enacting separate cosmetics legislation, adopting a notification-based system, and improving coordination between authorities.

1. Introduction

India's cosmetics sector is dynamic and plays a crucial role in the nation's economy.[1] By 2025, the cosmetics market is projected to generate USD 20 billion in revenue,[2] growing at an annual rate of 8-9%.[3] The sector is primarily governed by the Drugs and Cosmetics Act of 1940[4] ('the Act'/'D&C Act'), a pre-independence law, and the Cosmetic Rules, 2020.[5] Additionally, labelling declarations issued by the Bureau of Indian Standards ('BIS') regulate the sector, with cosmetic standards outlined in the Ninth Schedule of the Cosmetic Rules, 2020.[6]

Further, the Cosmetics Rules, 2020 (2020 Rules), introduced a structured framework for registering, importing, manufacturing, selling, labelling, testing, and analysing cosmetics in India, aiming to align the framework with international standards. The Central Drugs Standard Control Organisation[7] (CDSCO) led by the Drugs Controller General of India, serves as the central licensing authority, overseeing registrations and import regulations under the D&C Act and D&C Rules.

The existing cosmetics framework can pose challenges to innovation and growth. Regulatory hurdles, such as *approval* requirements for minor formula modifications or pack size adjustments, lead to delays, increase costs, and limit manufacturers' ability to adapt to consumer trends.[8]

The latest regulatory development is the draft Drugs, Medical Devices, and Cosmetics Bill of 2022[9] ('Draft Bill'), which aims to replace the D&C Act to better address evolving market needs. While the Draft Bill[10] seeks to centralise regulatory oversight and establish uniform standards, concerns persist regarding logistical challenges and its impact on state-level regulatory bodies.

This white paper explores ongoing challenges in the cosmetics sector from the current regulatory framework. Chapter 2 analyses the implications of regulating drugs and cosmetics under a common framework. Chapter 3 examines pre-market approval processes and their impact on stakeholders. Chapter 4 addresses the lack of harmonisation between central and state authorities. Finally, Chapter 5 presents recommendations to support the sector's growth in India.

1. Kajol Paswann, 'The Future of Indian Cosmetics Industry: Recommendations for Newcomers' (Times of India Blog, 6 November 2022) <https://timesofindia.indiatimes.com/blogs/voices/the-future-of-indian-cosmetics-industry-recommendations-for-newcomers/> (last visited Dec. 3, 2024).
2. 'Growth of the cosmetic industry in India' (IBEF) <https://www.ibef.org/research/case-study/growth-of-the-cosmetic-indusry-in-india> accessed on 18 February 2025
3. Indian Beauty & Hygiene Association, https://ibhaindia.com/ (last visited Dec. 3, 2024).
4. Ministry of Health & Family Welfare, News Highlights, Govt. of India, https://main.mohfw.gov.in/newshighlights-97 (last visited Dec. 3, 2024).
5. Drugs and Cosmetics Rules, 1945, G.S.R. 371(E), Acts of Parliament, 1945 (India). / Cosmetic Rules 2020.
6. Ministry of Consumer Affairs, Food & Public Distribution, BIS Standards List, Govt, https://www.services.bis.gov.in/php/BIS_2.0/bisconnect/get_is_list_by_category_id/11 (last visited Dec. 3, 2024).
7. Central Drugs Standard Control Organization, Home, https://cdsco.gov.in/opencms/opencms/en/Home/ (last visited Dec. 3, 2024).
8. Current Law Stifles Innovation, Separate Law Needed for Cosmetics Products: Says HUL,economic times, https://economictimes.indiatimes.com/industry/cons-products/fashion-/-cosmetics-/-jewellery/current-law-stifles-innovation-separate-law-needed-for-cosmetics-products-says-hul/articleshow/103818981.cms?from=mdr (last visited Dec. 3, 2024).
9. Draft New Drugs, Medical Devices and Cosmetics Bill, 2022, Ministry of Health and Family Welfare, 2022 (India), https://prsindia.org/files/parliamentry-announcement/2022-08-21/Drugs,%20Medical%20Devices%20and%20Cosmetics%20Bill.pdf (last visited Dec. 3, 2024).
10. Ministry of Health & Family Welfare, News Highlights, Govt. of India, https://main.mohfw.gov.in/newshighlights-97 (last visited Dec. 3, 2024).

2. Common Frameworks for Drugs and Cosmetics

2.1. Context

The D&C Act governs both drugs and cosmetics under a common regulatory framework, despite their distinct purposes and characteristics. The Act ignores the inherent difference between cosmetics and drugs; the *former* serves the purpose of cleansing, beautifying, or altering appearance,[11] while the *latter* is used to diagnose, treat, mitigate, or prevent diseases and disorders.[12]

Despite these fundamental differences, the Act prescribes the same framework for the manufacturing, importing, and licensing of both categories, despite their different nature and end-use. From a scientific perspective, drugs and cosmetics serve distinct functions. Cosmetics and personal care products, composed of natural or synthetic compounds, enhance appearance or scent[13] and include products such as hair and skin care items, perfumes, and dental care products.[14] In contrast, drugs refer to substances (excluding food) used to prevent, diagnose, treat, or alleviate disease symptoms or abnormal conditions.[15] They can also affect brain function and influence mood, awareness, thoughts, feelings, or behaviour.[16]

2.2. Potential Implications

The current regulatory framework presents four key challenges.

a. **High Compliance Costs and Delays:** Since the approval process for cosmetics follows a regulatory procedure similar to that of drugs, compliance costs can be disproportionately high, despite the fundamental differences between the two categories. Under the D&C Act, products such as soaps, skincare items, and other cosmetics must meet the same regulatory standards as pharmaceuticals. The cosmetics industry is highly trend-driven and requires rapid innovation. However, delays in licensing and pre-market approvals often disrupt product launch timelines.

b. **Restrictions on Cosmetics Processing:** The D&C Act defines "manufacture" for cosmetics similar to that for drugs, leading to unnecessary restrictions on routine cosmetic processing activities such as repacking from bulk, kitting, and banding. As a result, manufacturers must obtain additional permissions for standard industry practices, creating regulatory bottlenecks.

c. **Limitations on Product Claims:** The D&C Act often evaluates cosmetics claims through the same lens as drug claims. As a result, India may disallow claims widely accepted in global markets or require a notification-based system[17] to review minor modifications.[18] However, India's reliance on a pre-market approval process further delays product launches, hindering industry growth.

d. **Lack of Specialised Oversight:** Cosmetics-related governance falls under the purview of the Drug Technical Advisory Board, which primarily comprises drug experts. These experts, while highly knowledgeable in pharmaceuticals, may have limited expertise and experience with cosmetics' unique formulations, safety assessments, and industry-specific requirements. A similar challenge exists with the Drug Consultative Committee, where drug-focussed expertise continues to shape regulatory outcomes, leading to potential misalignment with global best practices for cosmetics.

11. D&C Act, section 2 (aaa).
12. D&C Act, section 2 (b).
13. ScienceDirect, Cosmetics, https://www.sciencedirect.com/topics/materials-science/cosmetics (last visited Dec. 3, 2024).
14. ScienceDirect, Cosmetics, https://www.sciencedirect.com/topics/materials-science/cosmetics (last visited Dec. 3, 2024).
15. National Cancer Institute, Drug Definition, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/drug (last visited Dec. 3, 2024).
16. National Cancer Institute, Drug Definition, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/drug (last visited Dec. 3, 2024).
17. Freyr Solutions, Cosmetic Regulatory Landscape in the UK: An Overview, https://www.freyrsolutions.com/blog/cosmetic-regulatory-landscape-in-the-uk-an-overview (last visited Dec. 3, 2024).
18. Current Law Stifles Innovation, Separate Law Needed for Cosmetics Products: Says HUL,economic times, https://economictimes.indiatimes.com/industry/cons-products/fashion-/-cosmetics-/-jewellery/current-law-stifles-innovation-separate-law-needed-for-cosmetics-products-says-hul/articleshow/103818981.cms?from=mdr (last visited Dec. 3, 2024).

2.3. Potential Solutions

a. A Separate Cosmetics Framework

The current regulatory framework poses challenges for the modern cosmetics sector. Non-uniform enforcement mechanisms and overlapping jurisdictions between central and state authorities create inefficiencies and inconsistencies. Frequent regulatory changes and a fragmented approach make it difficult for industry players to navigate the complex web of laws, rules, and guidelines. The lack of clarity and harmonisation increases uncertainty, requiring substantial investment in research, compliance, and testing. These time-consuming processes not only burden existing businesses but they also discourage new entrants from entering the sector.

While the government's recent efforts have separated the Cosmetics Rules, establishing a standalone cosmetics Act is necessary. A dedicated regulatory framework could enhance industry efficiency and consumers safety while aligning with global best practices, where cosmetics are governed separately from drugs.

b. Establish a Cosmetics Expert Advisory Council (Cosmetic Technical Advisory Board - CTAB / Cosmetics Consultative Committee - CCC):

A dedicated council should be formed, comprising domain experts from various fields within the cosmetics industry. This council can include representatives from regulatory authorities, cosmetologists, toxicologists, dermatologists, industry experts, clinical research organisations, academic institutions, and raw material manufacturers. The committee should be responsible for making informed decisions on cosmetics regulation, ensuring that safety, efficacy, and innovation are prioritised.

c. Revise the Definitions of "Manufacturer" and "Cosmetics"

The definition of "manufacturer"[19] and "cosmetics"[20] should be updated to align with international standards, particularly those followed by the Association of Southeast Asian Nations (ASEAN) and EU. Harmonising these definitions with global best practices can enhance regulatory clarity, improve global competitiveness, and expand market access for Indian cosmetics manufacturers.

d. Consider International Precedents

i. European Union: Globally, several jurisdictions have dedicated regulatory frameworks for cosmetics. The European Union Regulation (EC) No 1223/2009[21] streamlines procedures, reduces administrative burdens, and strengthens in-market control to ensure better protection of human health. This regulation applies exclusively to cosmetic products, distinguishing them from medicinal products, medical devices, and biocidal products.

The distinction is based on a precise definition of cosmetic products, detailing both their intended applications and purposes.[22] Additionally, the regulation simplifies market access by requiring a single, centralised notification through the EU Cosmetic Products Notification Portal[23], eliminating redundant approvals and enhancing regulatory efficiency.[24]

ii. South Korea: Before 2000, cosmetics in South Korea were regulated under the Pharmaceutical Affairs Act,[25] which restricted industry growth. Recognising this, the South Korean government introduced a dedicated Cosmetics Act[26] on July 1, 2000. This legislation established a separate regulatory framework for cosmetics, covering manufacturing, importing, production, advertising, labelling, and safety evaluations. The reforms allowed the sector to develop independently, fostering innovation and boosting market expansion.

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19. The Drugs and Cosmetics Act 1940; The Drugs and Cosmetics Rules 1945.
20. The Drugs and Cosmetics Act 1940; The Drugs and Cosmetics Rules 1945.
21. EU Monitor, Regulation (EC) No 1223/2009 of the European Parliament and of the Council on Cosmetic Products, https://www.eumonitor.eu/9353000/1/j9vvik7m1c3gyxp/vibn2mp7slr0 (last visited Dec. 3, 2024).
22. European Commission, Regulation (EC) No 1223/2009 of the European Parliament and of the Council on Cosmetic Products <https://health.ec.europa.eu/system/-files/2016-11/cosmetic_1223_2009_regulation_en_0.pdf> (last visited Dec. 3, 2024)
23. European Commission, Cosmetic Product Notification Portal, https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-product-notification-portal_en (last visited Dec. 3, 2024).
24. European Commission, Legislation on Cosmetics, https://single-market-economy.ec.europa.eu/sectors/cosmetics/legislation_en#:~:text=Main%20 legislation,all%20 operators%20in%20the%20 sector. (last visited Dec. 3, 2024).
25. Korea Legislation Research Institute, Cosmetics Act, https://elaw.klri.re.kr/eng_service/lawView.do?hseq=40196&lang=ENG (last visited Dec. 3, 2024).
26. Ministry of Food and Drug Safety, Guidelines on Cosmetics, https://www.mfds.go.kr/eng/brd/m_60/view.do?seq=69876 (last visited Dec. 3, 2024).

This dedicated Cosmetics Act aimed to enhance safety standards, facilitate international trade, and boost the global competitiveness of South Korea's cosmetics sector.[27] Between 2000 and 2020, South Korea's cosmetics industry experienced remarkable growth,[28] with an average annual growth rate of 13.4%.[29] The tremendous growth is largely attributed to the separate regulatory framework established by the Cosmetics Act of 2000.

iii. ASEAN Cosmetic Directive (ACD): The ASEAN Cosmetic Directive (ACD) provides a unified regulatory framework for cosmetics across the 10 ASEAN member states. Since 1998, ASEAN cosmetic regulators and industry stakeholders have collaborated through the Cosmetic Product Working Group (CPWG) under the ASEAN Consultative Committee for Standards and Quality (ACCSQ) to address regulatory barriers in this sector. The collaboration led to the signing of the Agreement on the ASEAN Harmonised Cosmetic Regulatory Scheme[30] by ASEAN Ministers during the 35th ASEAN Economic Ministers Meeting on 2 September 2003. This directive aims to harmonise regulations, reduce trade barriers, and enhance regulatory efficiency within the region, facilitating seamless market access for cosmetic products

The ASEAN Harmonised Cosmetic Regulatory Scheme covers (i) the ASEAN Mutual Recognition Arrangement of Product Registration Approvals for Cosmetics and (ii) the ASEAN Cosmetic Directive.[31] To facilitate smooth implementation, seven technical documents were developed, including an illustrative list of cosmetic products by category, product registration requirements and procedures, common labelling requirements, a handbook on ingredient listings, common claims guidelines, common import and export requirements, and good manufacturing practices.[32]

Given these international precedents, India can benefit from establishing a dedicated regulatory framework for cosmetics, tailored to the sector's current demands while aligning with global best practices.

27. Doris Peters & Jae-Seong Choi, Status of Cosmetics Regulations in Korea, 2 INT'L CHEM. REGULATORY L. REV. 73 (2020), DOI: 10.21552/icrl/2020/2/8.
28. Young Won Park, Paul Hong & Geon-Cheol Shin, Rising and Thriving in the Post COVID-19 Era: A Case Study of COSMAX, a Leader of the Korean Cosmetic Industry, 29 ASIA PAC. BUS. REV. 1105 (2023), DOI: 10.1080/13602381.2022.2059955.
29. Young Won Park, Paul Hong & Geon-Cheol Shin, Rising and Thriving in the Post COVID-19 Era: A Case Study of COSMAX, a Leader of the Korean Cosmetic Industry, 29 ASIA PAC. BUS. REV. 1105 (2023), DOI: 10.1080/13602381.2022.2059955.
30. 'Agreement on the ASEAN harmonized cosmetic regulatory scheme' (ASEAN) <https://www.asean.org/wp-content/uploads/2012/10/20707.pdf> accessed on 18 February 2025.
31. ASEAN Cosmetic Directive <https://aseancosmetics.org/asean-cosmetics-directive/> accessed 18 February 2025.
32. Ong Keng Yong, 'ASEAN Cosmetic Documents: Agreement on the ASEAN Harmonized Cosmetic Regulatory Scheme' ASEAN <https://aseancosmetics.org/doc-docs/agreement.pdf> accessed 18 February 2025.

3. Product Approval Procedure

3.1. Context

The current product approval procedure for cosmetics mirrors that for drugs, requiring pre-market approvals and product permissions from multiple state licensing authorities.[33] Under the D&C Act, Section 18(c)[34] prohibits the manufacture of any cosmetic for sale or distribution without a valid license.[35]

The corresponding rules outline comprehensive licensing requirements that must be met to obtain the requisite license. It includes, inter alia, the submission of necessary documentation to verify the qualifications of both the manufacturer and the premises and the provision and maintenance of sufficient personnel, facilities, and laboratory equipment for testing both the manufactured cosmetics and the raw materials used in production, or the establishment of arrangements for these provisions.[36]

Additionally, the regulations mandate the necessary arrangements for inspectors and the maintenance of appropriate documentation concerning each batch of manufactured cosmetics, along with other essential information.[37] While these requirements aim to ensure safety and quality, they also create administrative bottlenecks. The lengthy approval process, from applying for a license to gathering the necessary documentation and awaiting approval, often leads to unnecessary delays. These inefficiencies hinder the cosmetics industry's ability to quickly respond to market trends, impacting innovation and competitiveness.

3.2. Potential Implications

While the pre-market approval process may be valuable for 'new cosmetics'[38]—those incorporating novel substances to promote safe innovation—it also presents significant challenges. The extensive regulatory requirements can impact innovation, increase operational costs, requiring businesses to heavily invest in documentation, testing, and certification. These compliance hurdles can be particularly burdensome for small businesses with limited financial and human resources, acting as a barrier to entry or slowing down their ability to introduce new products.

Moreover, since the cosmetics sector is highly dynamic, driven by rapidly evolving consumer trends, a lengthy and complex approval process can delay the launch of innovative products in the Indian market. This hampers industry competitiveness, restricting companies' ability to respond to emerging trends and ultimately limiting product diversity for consumers.

3.3. Potential Solutions

a. A shift to post-market surveillance

A possible avenue for reform is the adoption of a notification-based system, which shifts the regulatory focus toward *post-market surveillance*. Under this approach, the organisation responsible for introducing the cosmetic product to the Indian market would file a notification and maintain a Product Information File (PIF) at the manufacturers/marketers' end. The PIF would act as a repository of essential product information, ensuring safety and quality. Regulators should have the authority to request detailed information from manufacturers/marketers at any time, ensuring accountability.

Adopting global best practices, such as a *notification-based system,* could streamline regulatory processes and enhance ease of doing business in the cosmetics sector. Unlike the current time-consuming approval framework, this approach can allow

[33] U.S. Food & Drug Administration, Premarket Approval (PMA),U.S. Food & Drug Admin. <https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-approval-pma#:~:text=A%20Premarket%20Approval%20(PMA)%20application%20is%20a%20scientific%2C%20regulatory,of%20scientific%20and%20clinical%20data>
(last visited Dec. 3, 2024)
[34] The Drugs and Cosmetics Act 1940, s 18(c)
[35] The Drugs and Cosmetics Act 1940, s 27 (b)(ii); 31; 58(2)
[36] Cosmetics Rules 2020, Ch IV
[37] Cosmetics Rules 2020, Ch IV
[38] Cosmetics Rules 2020, r 3(r)

manufacturers to bring products to market more efficiently while maintaining compliance with safety and quality standards. Given the fast-evolving, trend-driven nature of the cosmetics industry, reducing approval delays is essential to fostering innovation and competitiveness.

b. Consider International Precedents

i. United Kingdom (UK): The UK Cosmetic Regulations[39] follow a similar approach, requiring businesses to maintain a PIF for each product. The PIF includes essential documentation such as safety assessments, claim substantiation, and manufacturing details, ensuring product safety and accountability. This regulatory model upholds high standards in the UK cosmetics sector.[40] Adopting a similar framework would align India with global best practices.[41]

ii. United States (US): The U.S. Food and Drug Administration (FDA) regulates the cosmetics sector under the Federal Food, Drug, and Cosmetic Act (FD&C Act),[42] which does not *mandate pre-market approval* for cosmetic products.[43] Instead, it holds cosmetic manufacturers responsible for ensuring product safety. The regulatory framework focuses on post-market surveillance, equipping authorities with robust powers to monitor and address safety concerns effectively. The Modernization of Cosmetics Regulation Act (MoCRA), enacted on December 29, 2022,[44] strengthens FDA oversight by mandating stringent safety measures, product registration, and transparency. It, inter alia, empowers the FDA to initiate recalls and suspend operations of facilities linked to significant health risks, thereby enhancing consumer protection.[45]

iii. European Union (EU): The EU enforces a post-market surveillance system that assigns Member States the responsibility of monitoring their cosmetics markets.[46] To ensure a coordinated approach to consumer product issues, the market surveillance authorities of all EU countries have established the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC). This network facilitates cooperation by coordinating activities, exchanging information, developing and executing joint projects, and sharing expertise and best practices in cosmetics market surveillance.[47]

This transition to a notification system-based post-market surveillance system would be a progressive step, aligning regulatory requirements with the unique characteristics of the cosmetics sector while maintaining consumer protection. It would necessitate more stringent and proactive market monitoring, ensuring that relevant authorities have the necessary authority, resources, and expertise to enforce regulations effectively.

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39. The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, Schedule 34 (UK), https://www.legislation.gov.uk/ukdsi/2019/9780111176368/scahedule/34 (last visited Dec. 3, 2024).
40. Freyr Solutions, Cosmetic Regulatory Landscape in the UK: An Overview, https://www.freyrsolutions.com/blog/cosmetic-regulatory-landscape-in-the-uk-an-overview (last visited Dec. 3, 2024).
41. Mariana Ferreira, Ana Matos, Ana Couras, Joana Marto, Helena Rebeiro, 'Overview of Cosmetic Regulatory Frameworks around the world' 9(4), 17 (2022) ARTAC <https://www.mdpi.com/2079-9284/9/4/72> accessed 18 February 2025.
42. Personal Care Products Council, U.S. and EU Cosmetics Regulation, https://www.personalcarecouncil.org/u-s-and-eu-cosmetics-regulation/ (last visited Dec. 3, 2024)
43. Cosmereg, Post-Market Surveillance: Cosmetics in Europe and USA, <https://cosmereg.com/post-market-surveillance-cosmetics-in-europe-and-usa/#:~:text=The%20purpose%20of%20post%2d Marketing,regulations%20that%20govern%20this%20process> (last visited Dec. 3, 2024).
44. U.S. Food & Drug Administration, Modernization of Cosmetics Regulation Act of 2022 (MoCRA), https://www.fda.gov/cosmetics/cosmetics-laws-regulations/modernization-cosmetics-regulation-act-2022-mocra (last visited Dec. 3, 2024).
45. Taobe Consulting, Global Cosmetic Regulations, https://taobe.consulting/global-cosmetic-regulations/ (last visited Dec. 3, 2024).
46. REGULATION (EC) No 1223/2009 of the European Parliament and of the council of 30 November 2009 on cosmetic products Art. 22.
47. European Commission, 'Market Surveillance' (EC) <https://single-market-economy.ec.europa.eu/sectors/cosmetics/market-surveillance_en> accessed 18 February 2025.

4. Harmonisation between Central and State Authorities

4.1. Context

India's cosmetics regulatory framework suffers from non-uniform enforcement mechanisms, resulting in overlapping jurisdictions and responsibilities between central and state authorities. While the D&C Act is a central legislation, inconsistencies persist in how regulations are interpreted and implemented across states. Authorities often are unable to harmonise critical procedures, including document requirements, claims review processes, registration protocols, timelines for manufacturing and import licenses, and online versus offline approval processes.

4.2. Potential Implications

Inconsistent regulatory practices and requirements across states create administrative inefficiencies, leading to unnecessary delays and increased operational costs, particularly for SMEs. These businesses struggle to navigate varying rules and procedures, hindering timely market entry and diverting resources from innovation and growth to regulatory compliance. The lack of uniformity raises compliance costs as SMEs expand across multiple markets, exacerbating financial and operational burdens and making it harder to compete effectively in markets.

4.3. Potential Solutions

a. Implement a uniform set of regulatory requirements across all States, supported by clear guidelines and FAQs for pre-market approvals (under the current system) or the proposed notification-based system. Establishing a single-window online portal for all submissions and approvals could streamline processes and ensure consistency across states.
b. Harmonise the Cosmetic Act & Rules for domestically manufactured and imported products, with respect to documentation requirements, including claims review processes, to ensure regulatory alignment and ease of compliance.

c. Consider International Precedents

i. European Union: EU countries have established the Platform of European Market Surveillance Authorities for Cosmetics (PEMSAC) to enhance cooperation across Member States. This network facilitates collaboration by coordinating activities, exchanging information, developing joint projects, and sharing expertise in cosmetics market surveillance. Comprising representatives from national regulatory authorities, PEMSAC promotes regulatory alignment, advises the European Commission on potential areas for further regulation under the Cosmetics Directive, and addresses enforcement challenges and monitors its provisions.[49]

ii. ASEAN: ASEAN has successfully harmonised cosmetic regulations to improve efficiency and facilitate trade. ASEAN[50] is a significant market for cosmetic products, with a combined population of over 650 million people.[51] In 1998, driven in part by inputs from major cosmetics exporters, ASEAN regulators began collaborating with industry associations to address trade barriers affecting the sector.[52]

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[48] Kempaiah Suresh, Balamuralidhara V, 'Implementation Drugs and Cosmetics Act, 1940 and Rules, 1945 Among the Southern States of India' (2018) IJP <https://www.pharmascholars.com/articles/implementation-drugs-and-cosmetics-act-1940-and-rules-1945-among-the-southern-states-of-india.pdf> accessed 18 February 2025
[49] European Commission, 'Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products' (2009) <https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&do=groupDetail.groupDetail&groupID=1465; https://single-market-economy.ec.europa.eu/sectors/cosmetics/market-surveillance_en > accessed on 18 February 2025
[50] ASEAN includes Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, the Philippines, Singapore, Thailand, and Vietnam.
[51] Freyr Solutions, Understanding Regional Regulations of ASEAN and Their Impact on Cosmetic Products, https://www.freyrsolutions.com/blog/understanding-regional-regulations-of-asean-and-their-impact-on-cosmetic-products#:~:text=The%20ASEAN%20Cosmetic%20Mutual%20Recognition,reducing%20Regulatory%20burdens%20on%20manufacturers. (last visited Dec. 3, 2024).
[52] Freyr Solutions, Understanding Regional Regulations of ASEAN and Their Impact on Cosmetic Products, https://www.freyrsolutions.com/blog/understanding-regional-regulations-of-asean-and-their-impact-on-cosmetic-products#:~:text=The%20ASEAN%20Cosmetic%20Mutual%20Recognition,reducing%20Regulatory%20burdens%20on%20manufacturers. (last visited Dec. 3, 2024).

Just four years after ASEAN countries committed to forming the ASEAN Economic Community (AEC) in 1999, the ASEAN Cosmetics Directive (ACD)[53] was introduced as the first Mutual Recognition Agreement (MRA) within ASEAN.[54] This agreement established a fully harmonised regulatory framework, creating unified technical standards and strengthening national regulators' roles within the cosmetics sector.

Implemented in 2008,[55] the ACD standardises cosmetic regulations across ASEAN nations,[56] ensuring product safety while streamlining registration, notification, and post-market surveillance.[57] The framework requires manufacturers to notify authorities of any changes to product formulations or packaging and mandate *post-market surveillance* to maintain safety standards.[58]

India should work towards updating and harmonising its regulatory standards to reflect global scientific advancements and ensuring alignment with international frameworks. This would help eliminate ambiguities, enhance compliance, and support sector growth.

Manufacturing cosmetics in India is governed by a stringent inspection and licensing system managed by state licensing authorities. However, inconsistencies in regulations across states create challenges. Establishing a distinct legislative framework with corresponding rules or streamlining processes under the CDSCO could enhance coherence. Promoting inter-state collaboration would enable states to harmonise their approaches, while issuing clear guidelines could resolve ambiguities and standardise implementation. Additionally, periodic reviews of state laws and enforcement practices would ensure consistency, facilitate necessary corrective measures, and create a uniform, efficient regulatory framework for the cosmetics industry.

[53] ASEAN Cosmetics Association, ASEAN Cosmetic Directive, https://aseancosmetics.org/docdocs/directive.pdf (last visited Dec. 3, 2024).
[54] Freyr Solutions, Understanding Regional Regulations of ASEAN and Their Impact on Cosmetic Products, https://www.freyrsolutions.com/blog/understanding-regional-regulations-of-asean-and-their-impact-on-cosmetic-products#:~:text=The%20ASEAN%20Cosmetic%20Mutual%20Recognition,reducing%20Regulatory%20burdens%20on%20manufacturers. (last visited Dec. 3, 2024).
[55] Freyr Solutions, What Is ASEAN Cosmetic Directive (ACD)?, https://www.freyrsolutions.com/what-is-asean-cosmetic-directive-acd (last visited Dec. 3, 2024).
[56] Freyr Solutions, What Is ASEAN Cosmetic Directive (ACD)?, https://www.freyrsolutions.com/what-is-asean-cosmetic-directive-acd (last visited Dec. 3, 2024).
[57] ASEAN Cosmetics Association, ASEAN Cosmetic Directive, https://aseancosmetics.org/docdocs/directive.pdf (last visited Dec. 3, 2024).
[58] ASEAN Cosmetics Association, ASEAN Cosmetic Directive, <https://aseancosmetics.org/docdocs/directive.pdf> (last visited Dec. 3, 2024).

5. Recommendations and Way Forward

To modernise India's cosmetics regulatory framework, the following key recommendations should be considered:

a. **Regulatory framework:** Establish an independent legislation specifically for the cosmetics sector, replace the current combined approach that regulates both drugs and cosmetics.

b. **Product approval procedure:** Shift from a pre-market approval system to a notification-based framework, supported by robust post-market surveillance. Implementing a standardised Product Information File (PIF) system, aligned with international best practices, will enhance documentation, traceability, and regulatory efficiency.

c. **Harmonisation:** Strengthen coordination between state and central authorities by creating a centralised regulatory platform to ensure uniform implementation of cosmetics regulations nationwide.

d. **Implementation:** Develop streamlined regulatory processes with improved infrastructure and transparent compliance procedures. To support inclusive sector growth while maintaining high-quality standards, capacity-building initiatives, SME-friendly compliance pathways and guidance programs should be introduced.

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