FICCI FMCG DIVISION: COSMETICS SUBCOMMITTEE

WHITE PAPER ON COSMETICS INDUSTRY

Market Landscape & Ease of Doing Business Challenges

FMCG SECTOR

Fast-moving consumer goods (FMCG) sector is the 4th [1]largest sector in the Indian economy with Household and Personal Care accounting for 50 per cent of FMCG sales in India. Growing awareness, easier access and changing lifestyles have been the key growth drivers for the sector. However, in the last few years, the FMCG market has grown at a faster pace in rural India compared with urban India. Semi-urban and rural segments are growing at a rapid pace and FMCG products account for 50 per cent of total rural spending. FMCG Sector has been expanding at a healthy rate over the years because of rising disposable income, a rising youth population, and rising brand awareness among consumers. In India, the FMCG market is expected to grow at a compound annual growth rate (CAGR) of 27.9% from 2021 to 2027, reaching nearly US$ 615.87 billion. The urban segment contributes significantly to his growth, but rural areas are also seeing increased demand, supported by good harvests and government spending. Over the last decade, India has seen consistent growth in the personal care and cosmetics market with increasing shelf space in boutiques and retail stores across the country. Many multinational brands have entered the Indian market, primarily aided by dedicated support structure and their respective pricing strategies. The Indian cosmetics industry is majorly categorised into skin care, hair care, oral care, fragrances, and colour cosmetics segments. The overall market share is expected to grow to US$ 20 billion by 2025 with a Compound Annual Growth Rate (CAGR) of 25%. On the other hand, the global cosmetics industry is growing at 4.3% CAGR and will reach US$ 450 billion by 2025. By 2025, along with this growth, India will constitute 5% of the total cosmetics market and reach the top five global markets in terms of revenue.

KEY GROWTH SEGMENTS IN THE FMCG SECTOR

Fast Moving Consumer Goods (FMCGs) are those goods that are sold at a quick pace at a relatively low price point. Very often, FMCGs have a short shelf life because of high consumer demand and because they often tend to be perishable. The average consumer buys these products on a regular basis for use in their daily lives. The industry is characterized by low-profit margins and a high volume of sales. Some significant examples of FMCGs include milk, fruits, vegetables, cereals, packaged foods, medicines, and toiletries. To broadly classify the FMCG sector into categories, it consists of food and beverages, healthcare, and other goods including household and personal care.

Figure 1

Food & Beverages	Household care	Personal care
Includes staples such as cereals, pluses, salt and sugar; tea, coffee, bottled water, biscuits, breads, cakes and other snack foods.	Includes laundry soaps, detergents, fabric softeners, dish/utensil cleaners, toilet cleaners, floor cleaners and sir fresheners	Tooth paste, mouth wash, dental floss, hair oils, shampoo, conditioners, personal washes(soaps), facewashes and deodorants.

[1] FICCI FMCG Report

The FMCG Industry in India covers a wide variety of products ranging from toiletries to pre-packaged foods. Each category of products under the broad umbrella of FMCG has its own set of regulatory compliances, apart from the general compliances that most businesses are subjected to.

GROWTH AND TRENDS IN INDIA'S BEAUTY, COSMETICS & PERSONAL CARE MARKET

Over the past decade, India's **Beauty, Cosmetics, and Personal Care (BPC) market** has experienced remarkable growth, with an increasing presence in both boutiques and retail stores across the country. The entry of multinational brands has been supported by a dedicated infrastructure and tailored pricing strategies, further driving the market's expansion. The Indian cosmetics sector is primarily divided into skin care, hair care, oral care, fragrances, and colour cosmetics, with the overall market projected to reach a value of US$ 20 billion by 2025, reflecting a robust Compound Annual Growth Rate (CAGR) of 25%. In contrast, the global cosmetics market is growing at a modest 4.3% CAGR, expected to reach US$ 450 billion by 2025, with India set to contribute 5% of this global share, positioning it among the top five markets worldwide. Furthermore, India's online BPC e-commerce sector is accelerating, fuelled by growing digital adoption and consumer demand for convenience. By 2023, the online BPC market was valued at US$ 3.5 billion, with innovation in categories like coloured cosmetics, driven by emerging online brands, continuing to fuel consumer interest and market expansion.

REGULATIONS GOVERNING COSMETICS IN INDIA

The regulation of cosmetics in India is governed by a comprehensive framework comprising the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945, the Medical Devices Rules, 2017, the New Drugs and Clinical Trials Rules, 2019, and the Cosmetics Rules, 2020. The central authority responsible for regulating cosmetics is the Central Drugs Standard Control Organisation (CDSCO).

KEY ASPECTS OF THE COSMETICS RULES, 2020:

- **Classification and Licensing:** Cosmetics are categorized for licensing purposes, with specific regulations governing the manufacture, import, sale, and distribution. Manufacturers must meet detailed premises, storage, and equipment specifications.
- **Manufacturing and Labelling:** The rules outline mandatory information that must appear in manufacturing records, including product names, ingredients, and batch sizes, while ensuring that Bureau of Indian Standards (BIS) are adhered to.
- **New Cosmetic Definition:** Introduces the concept of "new cosmetics," defined as products containing novel ingredients not previously used globally or not recognized in cosmetic literature, along with the associated importation requirements.
- **Import and Compliance Streamlining:** Simplifies the import process with a single license application and registration certificate for multiple cosmetics produced by the same manufacturer, along with regulations outlining cases where imports may be prohibited.
- **Voluntary Recall Mechanism:** Introduces a voluntary recall system allowing manufacturers to withdraw products from the market if deemed harmful to consumers.

- **Cosmetic Licenses:** Defines different types of cosmetic licenses, specifying the licensing and inspection process, as well as requirements for factory premises, labelling, and testing of cosmetic samples.
- **Decriminalization:** Two sections of the Drugs and Cosmetics Act, 1940, have been decriminalized:

1. **Section 29:** Replaced the original fine with an increased fine for misuse of Central Drugs Authority reports in advertising.
2. **Section 30:** Replaced imprisonment with a higher fine for subsequent offences.

LATEST CONCERN IN COSMETICS SECTOR IN INDIA

The cosmetics industry in India is rapidly evolving, yet regulatory frameworks continue to present challenges that impede growth, innovation, and ease of doing business. To foster a more conducive environment, industry stakeholders have identified several key areas for improvement. These include **aligning regulatory definitions**, **implementing streamlined post-market surveillance, addressing inconsistencies in state-level regulations, revisiting QCO mandates, modernizing enforcement mechanisms,** and **enabling digital advancements** for efficiency.

While these issues are critical, it is equally important to approach them with a balanced perspective that prioritizes immediate actionable requests alongside the industry's long-term vision for a globally competitive and innovative ecosystem. This white paper highlights the sector's **immediate concerns** requiring urgent attention and lays out a **broader roadmap** for achieving a modernized, globally aligned regulatory framework. By addressing pressing challenges and envisioning future reforms, the cosmetics industry looks forward for conducive environment that supports sustainable growth and global competitiveness.

AGENDA ITEMS FOR IMMEDIATE ACTIONABLE REQUESTS IN COSMETICS INDUSTRY

1. CHALLENGES OF REGULATORY COMPLEXITY AND DELAYS Below are few issues highlighting the regulatory complexities:

1.1 REGISTRATION DELAYS In the last industry meeting with the Secretary, MoHFW, in July 2024, the esteemed office of CDSCO proposed an **electronic product registration system** aimed at significantly reducing timelines for regulatory approvals. Under this system, the endorsement of additional pack sizes could be completed within one week, and the addition of product variants within one month. This represents a substantial improvement compared to the current 90-day timeline prescribed under existing rules for cosmetic product registration. To further bridge the gap and facilitate quicker market access, the industry requests the implementation of an **electronic notification system**, enabling importers and producers to upload self-declarations that act as in-principal approvals. This streamlined, digitized process would ensure timely access to seasonal and festive products, enhancing market responsiveness, boosting sales, and contributing positively to economic growth.

1.2 PRODUCT LABEL CLAIMS Frequent queries regarding product label claims such as "**Clinically tested/proven**" or "**Dermatologically tested/proven**" create unnecessary delays in product approvals, despite these claims not implying pharmacological action or falling under the scope of drugs. Similarly, claims like "**Anti-Dandruff**" and "**Anti-Acne**" are often subjected to overly stringent, drug-like regulatory scrutiny, which complicates compliance and slows down market launches. Inconsistencies in claim assessments between central and state authorities further exacerbate these challenges, leading to ambiguity and additional regulatory burdens. To address these issues, there is a critical need for clear, standardized guidelines on product label claims, developed in consultation with industry stakeholders. Such guidelines would ensure consistency, fairness, and efficiency in the regulatory process, enabling timely product launches while upholding compliance standards. In the last industry meeting with the Secretary, MoHFW, in July 2024 the industry has suggested the need for a workshop to harmonize efforts between CDSCO and SLAs focusing on claims and registration best practices which was agreed upon by the Secretary MoHFW and the industry is looking forward to expediting of the request.

1.3 DECRIMINALIZATION However, the industry is advocating for the **decriminalization of Section 27 A(ii) of the Drugs and Cosmetics Act, 1940**. The proposed change involves replacing the imprisonment with a higher fine. This adjustment aims to reduce the criminal burden on businesses while still ensuring compliance through significant financial penalties. Such a move would align with broader regulatory trends aimed at decriminalizing minor offenses to foster a more business-friendly environment without compromising public safety.

1.4 HARMONIZED IMPLEMENTATION OF COSMETICS RULES State Licensing Authorities (SLAs) in India are increasingly requiring **re-registration of cosmetic products** for even **minor formulation adjustments**, despite the provisions of the Cosmetics Rules, 2020. According to these rules, manufacturers are only required to inform the Licensing Authority in writing about changes in labelling or composition, along with an undertaking that the products comply with the standards outlined in the Ninth Schedule under the Bureau of Indian Standards. However, SLAs are mandating a revised license for slight variations in ingredient quantities, which adds an unwarranted administrative burden and complicates compliance for manufacturers. This inconsistency is particularly concerning as the same rules allow minor changes in composition for imported cosmetics without necessitating re-registration. In contrast, domestic manufacturers are compelled to seek re-issuance of licenses for similar changes, creating a regulatory disparity. The cosmetics industry emphasizes the need for a uniform approach to streamline the process and align the treatment of locally manufactured products with that of imports, ensuring equitable and efficient regulatory practices.

1.5 CLARIFICATION AND FLEXIBILITY IN DUAL USE LICENSE GUIDELINES Current guidelines for Dual Use Licenses create compliance challenges due to the lack of clear definitions and specific criteria for license validity. The **existing consignment-based issuance is time-consuming** and disrupts supply chains due to potential delays in shipment processing. The industry recommends revising the guidelines to allow **licenses on a tenure (e.g., annual) or volume basis**, which would reduce administrative

burdens and improve compliance. Additionally, providing an **exemption for samples imported for R&D** purposes would further ease compliance pressures and support industry innovation.

1.6. AVAILABILITY OF FREE SALE CERTIFICATES FOR EXPORTERS WITH P2P MANUFACTURING AGREEMENTS Under current regulations, **Free Sale Certificates are issued exclusively to manufacturers**, which **excludes exporters using third-party manufacturing** arrangements from obtaining these certificates required for certain international markets. The industry suggests **extending Free Sale Certificates to these exporters**, which would enable compliance with international trade requirements, facilitating smoother export processes, and reducing market access issues

1.7 SIMPLIFICATION OF EXPORTS OF 'MAKE IN INDIA' PRODUCTS The latest notification of the **Cosmetic Amendment Rules May 2023** introduces several provisions to facilitate the export of 'Make in India' products, significantly **easing the labelling burden for export packs**. This initiative, which **should be enforced immediately to boost exports**, includes simplified labelling requirements that reduce the need for multiple labels to comply with different international standards. Additionally, the certification process for obtaining **Free Sale Certificates (FSCs)** has been streamlined, making it easier for manufacturers to certify their products for export. Furthermore, the Central Drugs Standard Control Organisation (CDSCO) provides enhanced regulatory support to manufacturers, helping them meet international regulatory requirements more efficiently. This is why this notification, which should be enforced immediately, is crucial to boosting exports.

1.8 ADOPTION OF QR CODES ON PRODUCTS & REPLACING PAPER LEAFLETS WITH QR CODES Current paper leaflets in household products often contribute to environmental concerns and are challenging for semi-urban and rural consumers to comprehend. Transitioning to **voluntary QR codes on packaging**, supported by a regulatory framework, would reduce paper consumption, enhance consumer accessibility, and offer a more sustainable solution for product information dissemination.

1.9 DIGITAL MODERNISATION Digital advancements such as ONDLS Portal have been instrumental in improving transparency and efficiency in online licensing applications. Expanding digital tools like ONDLS portal for cosmetics across centre and states into a unified portal would harmonize regulatory practices, creating more consistent experience for the cosmetics industry.

AGENDA ITEMS FOR LONG-TERM VISION OF COSMETICS INDUSTRY

2. DEFINITION AND SCOPE OF COSMETICS The current definition of cosmetics in India, as outlined in Section 3 (aaa) of the Drugs and Cosmetics Act, 1940, does not align with international standards such as those of ASEAN and the European Union. It describes cosmetics as "*any article intended to be rubbed, poured, sprinkled or sprayed on, or introduced into, or otherwise applied to, the 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*." To better align with global standards and meet modern consumer needs, it is crucial to expand this definition to include health and hygiene products. Allowing the registration of cosmetics with existing claims would streamline regulatory

processes, ensure consumer safety, and foster innovation within the industry. A broadened definition, developed with industry input, would help clarify the distinct nature of cosmetic products compared to drugs. Stakeholders are advocating **for either a standalone Cosmetics Bill** or a dedicated chapter within existing legislation to reflect the unique nature of cosmetics. This approach would prevent the imposition of stringent drug-like requirements on cosmetics, which could lead to excessive penalties for manufacturing failures. Differentiating drugs from cosmetics in regulatory definitions is essential to avoid overlap, as drugs are intended for treatment or prevention, while cosmetics focus on beautification and cleansing.

3. TRANSITION TO POST-MARKET SURVEILLANCE Globally, cosmetics are regulated through post-market surveillance rather than pre-market approval. **Transitioning India's framework to a similar system, which includes the practice of notifying authorities (both central and state) instead of obtaining prior approvals, would significantly ease operational burdens**. This shift would accelerate market access and harmonize India's processes with global standards. Additionally, the inclusion of "**Cosmetovigilance**" — a systematic monitoring of adverse effects in cosmetics — within Indian regulations would further enhance consumer safety and market transparency.

Transitioning to a **Notification-based post-market surveillance system for cosmetics**, similar to those used in other countries, would indeed streamline processes and enhance consumer safety. Examples from various countries that illustrate how this system works:

1. **European Union**:
    - **Regulation**: Regulation (EC) No 1223/2009 on Cosmetic Products.
    - **System**: In the EU, cosmetics are regulated through post-market surveillance. Manufacturers must ensure product safety before placing them on the market, but there is no pre-market approval. Instead, they notify the authorities via the Cosmetic Products Notification Portal (CPNP). Cosmetovigilance is a key component, where adverse effects are monitored and reported to ensure ongoing safety.
2. **United States**:
    - **Regulation**: Federal Food, Drug, and Cosmetic Act (FD&C Act).
    - **System**: The U.S. Food and Drug Administration (FDA) oversees cosmetics through post-market surveillance. Manufacturers are responsible for ensuring product safety and must report adverse events.
3. **Canada**:
    - **Regulation**: Cosmetic Regulations under the Food and Drugs Act.
    - **System**: Health Canada requires manufacturers to notify them of all cosmetic products before they are sold. This notification includes product details and ingredients. Post-market surveillance is conducted to monitor adverse effects and ensure compliance with safety standards.

4. **Japan**:
    - **Regulation**: Pharmaceutical and Medical Device Act (PMD Act).
    - **System**: In Japan, cosmetics are regulated through a notification system where manufacturers must notify the Ministry of Health, Labour and Welfare (MHLW) before marketing their products. Post-market surveillance is conducted to monitor safety and adverse effects.

5. **Australia**:
    - **Regulation**: Industrial Chemicals Act 2019.
    - **System**: The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) oversees cosmetics. Manufacturers must notify NICNAS of new cosmetic ingredients, and post-market surveillance ensures ongoing safety and compliance.
6. **Brazil**:
    - **Regulation**: ANVISA Resolution RDC No. 7/2015.
    - **System**: The Brazilian Health Regulatory Agency (ANVISA) requires manufacturers to register or notify cosmetic products depending on their risk category. Post-market surveillance is used to monitor adverse effects and ensure product safety.

By adopting a similar post-market surveillance system, India could streamline the regulatory process, reduce operational burdens, and align with global standards. This Notification-based model would involve **notifying** authorities about new products rather than prior approval and implementing a robust **cosmetovigilance** system to monitor and address adverse effects, thereby enhancing consumer safety and market transparency.

3. ESTABLISHMENT OF A COSMETICS TECHNICAL ADVISORY BOARD (CTAB) Industry recommends **establishing a Cosmetic Technical Advisory Board (CTAB[2]) or establishing a committee of cosmetics experts within DTAB** to address industry concerns and the adoption of a more flexible enforcement approach and to streamline approvals and align Indian Regulations with International Standards.

4. EXEMPTION FOR CERTAIN PRODUCTS NOT EXPLICITLY CATEGORIZED AS CLASS A MEDICAL DEVICES A key example of regulatory ambiguity is the classification of **dental floss** as a **Class A medical device**, which applies to non-sterile and non-measuring medical devices. The current regulatory framework under the **Medical Devices Rules, 2017**, issued under the **Drugs and Cosmetics Act, 1940**, lacks a clear definition of the scope of Class A medical devices. Rule 4 of Chapter II outlines the classification criteria but fails to explicitly list products like dental floss, leaving companies grappling with unnecessary registration requirements. The industry urges that products not explicitly categorized as Class A medical devices be exempt from registration. Such an exemption would reduce administrative burdens and streamline compliance while maintaining safety and efficacy standards.

[2] Panel Discussion at **FICCI Massmerize 2024**: Modernizing India's Regulatory Framework on Cosmetics and beyond

Clarifying the scope of Class A medical devices and aligning the regulatory framework with practical industry needs will enhance efficiency and ensure regulatory practices remain fair and transparent.

5. CHANGE IN THE DEFINITION OF "MANUFACTURE" UNDER THE ACT The **definition of "manufacture"** in the Drugs and Cosmetics Act, 1940 should distinctly separate cosmetics from drugs, ensuring that a license is not required for activities such as further packing, re-packing, kitting and bundling, labelling, ornamenting, etc., of finished products for trade purposes. Specifically, in Section 3(zb), the definition of manufacture should be amended to state: "*In relation to cosmetics, includes any process or part of a process for making, altering, finishing, and packing with a view to its sale or distribution but **does not include** further packing, re-packing, kitting and bundling, labelling, ornamenting, etc., of finished products for the purpose of trade*." This distinction is crucial as gift packing and limited-edition packaging, often driven by celebrative or festive seasons, should not require a license, as it undermines the purpose of these activities. Implementing this change will pave the way for innovative approaches such as combination kitting of products, enhancing consumer convenience, and supporting initiatives to reduce plastic usage and promote sustainability. Additionally, aligning these definitions with the Cosmetic Rules 2020 will provide clearer guidelines for cosmetics, particularly concerning imports.

Modernizing India's cosmetics regulatory framework is essential for encouraging innovation, expanding market access, and enhancing consumer safety. Industry recommendations include establishing the **Cosmetic Technical Advisory Board (CTAB)** to integrate sector-specific expertise, transitioning to a **self-notification model** supported by robust **post-market surveillance**, **simplification of exports** and adopting digital tools to **streamline licensing & regulatory processes**. Addressing these challenges through a focused, streamlined regulatory framework will enable the Indian cosmetics sector to compete globally while safeguarding consumer interests and driving sustainable growth.

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