
ENHANCING CONSUMER SAFETY IN COSMETICS: A LEGAL LENS ON INDIA'S REGULATORY FRAMEWORK AND REFORM

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INTRODUCTION

Personal care and beauty products are now integral to the daily routines of millions in India. However, this growing reliance on cosmetics, especially cosmetics claiming antiaging impacts particularly skin glow creams & serums, and various others offering therapeutic effects, demands robust legal scrutiny as they possess underline threat to public health. Despite their transformative claims, these products often bypass comprehensive regulatory evaluations as they escape falling under pharmaceuticals.

In *Consumer Education and Research Centre v. Union of India*, the Supreme Court has categorically emphasized that the right to health is a fundamental right under Article 21 of the Constitution. This decision imposes a positive duty upon the State to ensure that commercial industries, including cosmetics, operate in a manner that does not jeopardize public health. While India does have a legislative foundation under the Drugs and Cosmetics Act, 1940, the changing dynamics of the market and proliferation of modern cosmetic industries necessitates a legal institutional response by the state.

LEGAL FRAMEWORK OF COSMETICS IN INDIA

India governs cosmetics primarily under the Drugs and Cosmetics Act, 1940 (DCA) and the associated Rules of 1945. Section 3(aaa) of the Act defines a cosmetic as any article meant to be applied to the human body for beautifying, cleansing, or altering appearance. However, the Act fails to provide a distinct classification for "cosmeceuticals" products with both cosmetic and pharmaceutical properties. Chapter III and IV of the Act deals with imports, manufacture, sale and distribution of drugs and cosmetics.

Regulatory authority lies with the Central Drugs Standard Control Organization (CDSCO),

which functions under the Ministry of Health and Family Welfare. The CDSCO's Cosmetics Division is responsible for issuing, manufacturing and import licenses, ensuring quality compliance, and enforcing labelling regulations of cosmetics. Yet, unlike drugs, cosmetics are largely exempt from pre-market approval under Rules 122A and 122B of Drugs and Cosmetics Rules 1945, except in limited circumstances involving dyes, colors, or imported formulations. This places the entire burden of ensuring product safety on manufacturers, limiting the State's role in proactive oversight.

Cosmetics are also categorically regulated by the The Cosmetics Rules 2020 which were issued under the Act. Specifically, Chapter IV of the rules mentions about the process to be followed by the manufacturer of cosmetics for sale or for distribution. Nevertheless, numerous voids remain which has failed to provide enhanced consumer safety.

GAPS AND CHALLENGES IN THE EXISTING FRAMEWORK

The Indian legal and regulatory framework for cosmetics, rooted in the Drugs and Cosmetics Act of 1940, Drugs and Cosmetics Rules 1945 & The Cosmetics Rules 2020 has failed to keep pace with the evolving risks and market realities of the rapidly evolving cosmetic industry. One of the most significant shortcomings is the absence of a dedicated legal statute on Cosmetics. Unlike jurisdictions such as the United States of America and the European Union, where cosmetics are regulated under distinct statutory frameworks, India continues to subsume cosmetics within the broader pharmaceutical regime which overlooks the health impact by certain class of cosmetics.

Equally troubling is the lack of a statutory requirement for pre-market testing of cosmetics by state. There are no binding obligations for toxicity assessments or clinical trials before products reach consumers. As per Rule no. 40 of the cosmetics Rules 2020, testing of cosmetics only takes place when the purchaser applies for it which clearly marks absence of mandatory premarket clinical test of Cosmo-pharmaceuticals. It is significant because many anti-aging cosmetics contain active pharmaceutical ingredients like retinoids, peptides, and hyaluronic acid that influence physiological functions and can endanger consumer's health. Despite this, they are regulated the same as basic cosmetics, creating a regulatory vacuum.

Although there are certain safety standards outlined by the Bureau of Indian Standards, with respect to cosmetics its compliance is neither mandatory nor consistently enforced. As a

result, the market has witnessed the unchecked proliferation of products containing harmful substances like mercury, hydroquinone etc.

Moreover, the absence of a cosmetovigilance mechanism makes it nearly impossible to track adverse reactions, allergic responses, or cumulative health effects arising from prolonged use of cosmetics. In the pharmaceutical sector, post-market surveillance is a well-established practice, but the cosmetic sector remains unmonitored in this regard. This gap has led to a serious accountability loophole.

STRENGTHENING THE REGULATORY FRAMEWORK: SUGGESTIVE REFORMS

To address these deficiencies, India must undertake a comprehensive overhaul of its cosmetic legal and regulatory framework. At the heart of this reform should be the enactment of a dedicated Cosmetics Safety Act. Such a statute must clearly define and categorize various types of cosmetic products, including cosmeceuticals, herbal, and medicated cosmetics, and impose a risk-based classification system. This is the urgent need considering the diverse proliferation of cosmetics. The products containing active pharmaceutical ingredients or posing higher health risks should be subject to mandatory clinical trial.

Additionally, a specialized regulatory authority tentatively termed the National Cosmetics Regulatory Authority (NCRA) should be established under the existing umbrella of the CDSCO. This body should be vested with the authority to oversee licensing, quality control, inspections, laboratory testing, and enforcement of regulatory norms across the cosmetics industry.

Parallel to this, India must institute a National Cosmetovigilance Programme modeled after the pharmacovigilance systems used in the pharmaceutical industry. Such a programme should make it mandatory for manufacturers, healthcare professionals, and consumers to report adverse effects. A centralized database should be created for logging complaints and triggering timely product recalls. This will not only ensure consumer safety but also instill greater industry accountability.

COMPARATIVE JURISPRUDENCE: GLOBAL BEST PRACTICES

International best practices offer valuable lessons for reforming India's cosmetic laws. They

can be adopted well ensuring untainted health of consumers. Mentioned below are have formulated a dedicated statute for dealing with cosmetics and their impact on public health:

Europe

The European Union's Cosmetics Regulation (EC) No. 1223/2009 requires pre-market registration, a responsible legal entity for each product, and a Product Information File (PIF) detailing safety assessments. The EU also maintains a list of banned substances. India should emulate this approach by introducing centralized safety documentation and ingredient blacklists.

United States of America

The Modernization of Cosmetics Regulation Act (MoCRA) 2022 of United States of America, requires facility registration, adverse event reporting, and empowers the FDA with recall authority. India could adopt similar post-market controls and recall frameworks within the CDSCO.

South Korea

South Korea regulates cosmetics under both the Cosmetic Act 2000 and the Pharmaceutical Affairs Act 1953. "Functional cosmetics," including anti-aging creams, require efficacy data and pre-approval. India could replicate this dual-layered model by introducing performance-based regulatory categories.

Japan

Japan's Pharmaceutical and Medical Device Act 2014 categorizes certain cosmetics as "quasi-drugs," subjecting them to rigorous safety and efficacy validation. This hybrid model allows regulatory flexibility while ensuring health safeguards. India could adopt a similar category for therapeutic cosmetics.

CONCLUSION

India's cosmetic and skin care industry is projected to expand even more rapidly. Yet, its regulation continues to rely on a legacy legal system ill-suited for today's complex and chemically advanced products. With respect to cosmetics, the absence of structured safety

evaluations, no pre-market approval and weak post-market surveillance, and misleading advertising norms compromise public health and consumer rights.

To safeguard the health and dignity of consumers which is paramount for good public health, India must at least amend the Cosmetic Rules 2020 or enact a separate Cosmetics Safety Act, establish a dedicated regulatory authority, and ensure scientific oversight at every stage from product development to retail. These reforms will not only protect public health but also strengthen consumer confidence and align Indian laws with global benchmarks, fulfilling the constitutional promise of right to health under Article 21 of the Indian Constitution.