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REGULATORY

Cosmetics (Amendment) Rules, 2025: Enhancing Labelling, Licensing, and Oversight

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Introduction

The Cosmetics (Amendment) Rules, 2025, notified in the Gazette of India on 29 July 2025, mark a measured yet meaningful shift in India's regulatory approach to cosmetics. Introduced under the Drugs and Cosmetics Act, 1940, these amendments do not overhaul the existing framework but instead fine-tune critical aspects of compliance bringing greater clarity to labelling norms, enhancing documentation standards, refining licensing processes, and reinforcing the institutional responsibilities of regulatory authorities. In doing so, they reflect the Indian regulator's evolving priorities: procedural adherence, and sustained accountability, traceability, and alignment with international best practices.

1. **Rewriting Definitions: A Matter of Shelf Life and Safety**

In a move that eliminates longstanding ambiguity, the amendment clarifies the meaning of "**use before**" and "**expiry date**" under Rule 3(w). Going forward:

- "Use before" implies the first day of the mentioned month.
- "Date of expiry" implies the last day of that month.

This clarification is not cosmetic. In a sector where consumer safety hinges on accurate shelf-life information, clear labelling ensures consistency in interpretation by both consumers and regulatory authorities.

2. **From "Officer" to "Authority": Language That Aligns with Responsibility**

What may appear to be minor adjustments in terminology are, in fact, critical to ensuring legal clarity and consistency. The amendment replaces the term "Controlling Officer" with "Controlling Authority" at various places in Rules 6, 9, 31. This revision brings the terminology in line with other regulatory statutes and reinforces that decision-making powers rest with competent licensing bodies, not merely designated individuals.

3. **Recordkeeping and Batch Traceability: Beyond Paper Compliance**

A notable revision of Rule 26 demands licensees maintains batch-wise records of both raw materials and final products for a period of three years or six months beyond expiry, whichever is longer. Records may be in hardcopy or electronic format. Notably, the amendment carves out an exemption for soap manufacturers, who may follow separate procedures approved by the licensing authority.

This change reflects a shift in the regulatory posture: documentation is no longer a procedural formality but a core tool for traceability, quality assurance, and post-market surveillance.

4. **Laboratory Architecture: Centralisation with Defined Roles**

Under the substituted Rule 11, the Central Drugs Laboratory is officially designated to act as the Central Cosmetics Laboratory, empowered to:

- Analyse and test samples under the Act,
- Function as an appellate testing authority, and
- Perform any specific function assigned by the Central Government.

The formal attribution of appellate functions introduces a two-tiered testing structure, reinforcing the credibility of enforcement actions that rely on sample analysis.

5. **Licensing as a Tool of Enforcement, Not Mere Permission**

The newly inserted Rule 31A empowers the State Licensing Authority to suspend or cancel a cosmetic licence for non-compliance with licence conditions or the Act, following due process. A show-cause notice and an opportunity to be heard are mandatory.

The order must be reasoned and issued in writing. Licensees may appeal such decisions to the State Government within 90 days from the date of the order.

This provision redefines licensing not as a static authorisation but as a conditional right, subject to ongoing compliance and regulatory scrutiny.

6. **Enabling Export, Without Sacrificing Accountability**

Rule 34(10) is amended to allow cosmetic products meant for export to carry labelling that complies with the law of the importing country. Where the consignee requires omission of the manufacturer's name and address, the container may bear a state-approved code number instead.

This change reflects India's responsiveness to international supply chain norms while ensuring that domestic authorities retain traceability via controlled coding mechanisms.

7. **Other Notable Changes**

Rule 53, which deals with the disposal of confiscated cosmetics, has been amended to specifically include references to spurious cosmetics as defined under Section 17D of the Drugs and Cosmetics Act, 1940. This ensures that enforcement authorities have a clear statutory basis to seize and destroy counterfeit cosmetic products in addition to adulterated ones, thereby strengthening regulatory action against fraudulent goods.

Separately, Rule 49 has been amended to remove references to sample dispatch via courier services. While the rule does not state a reason, the omission appears intended to encourage the use of more secure and traceable methods for transporting official cosmetic samples, such as hand delivery by authorised personnel or regulated logistics providers, to preserve chain of custody and evidentiary integrity.

The amendment updates the terminology in Rules 60 to 62, which govern the recognition and oversight of testing institutions for cosmetics. By replacing the term "licence" with "approval," the amendment clarifies that such entities are not subject to the same licensing regime as cosmetic manufacturers. This change brings greater administrative precision and avoids confusion between manufacturing licences and regulatory approvals granted to testing laboratories.

A System in Transition

What emerges from the *2025 amendment* is not just a rulebook tweak, but a glimpse into the regulatory philosophy shaping India's cosmetic sector:

- Precision in language and definitions replaces interpretive gaps.
- Decentralisation strengthens state-level oversight.
- Digital and durable records raise compliance from formality to forensic readiness.
- Licensing processes become dynamic, not static.

Taken together, these reforms represent the architecture of a regulatory system increasingly designed to monitor, and to anticipate and prevent non-compliance. With clearer standards, stronger oversight, and an emphasis on accountability, the Cosmetics (Amendment) Rules, 2025 lay the groundwork for a more resilient and internationally aligned regulatory environment, one that demands adherence to rules, and continuous, demonstrable commitment to consumer safety and product integrity.

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