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China's State Council Modernizes Cosmetic Regulation

China's State Council released the new Cosmetic Regulation (the "**New Regulation**") on June 16, 2020, which is a major overhaul of the current 30-year-old Cosmetic Regulation (the "**Current Regulation**"). The New Regulation, effective January 1, 2021, reflects the Chinese government's latest regulatory philosophy. It introduces a risk-based approach to regulate cosmetic products, emphasizes compliance throughout the entire product life cycle, and increases responsibilities of cosmetic license holders to ensure product safety and quality.

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Enhanced Compliance Obligations on Cosmetic License Holders

Similar to the marketing authorization holder initiative in the pharmaceutical and medical device industry, the New Regulation introduces the concept of a cosmetic product "registrant" or "notifying entity" as the cosmetic license holders. The New Regulation holds cosmetic license holders responsible for compliance obligations related to cosmetic products marketed in their names. Among others, cosmetic license holders should establish a quality assurance system and an adverse event monitoring and evaluation system to ensure quality and safety of their cosmetic products throughout the product lifecycle.¹ They should designate quality and safety responsible persons to manage quality control and product release matters.² Last but not least, cosmetic license holders must publish the summary of evidence and reference documents on a government-designated website to substantiate and support functional claims of cosmetic products.³

Foreign cosmetic license holders shall designate a Chinese legal entity to handle the regulatory matters in China for them in relation to product registration or notification, adverse event monitoring and reporting as well as product recall.⁴ The New Regulation does not explicitly require such legal entities to be jointly liable with foreign cosmetic license holders for any violations of the New Regulation. Instead, the New Regulation imposes penalties separately on foreign cosmetic license holders and their Chinese designees. If foreign cosmetic license holders refuse to accept penalties, their products could be banned from importation for up to 10 years.⁵ If the Chinese designees fail to assist foreign cosmetic license holders in adverse event monitoring/reporting and product recalls, they may be subject to penalties such as corrective actions, fines up to RMB 0.5 million, or five-year debarment of responsible persons from engaging in cosmetic businesses.⁶ The New Regulation is silent on the consequences if a Chinese designee fails to perform other regulatory matters, such as product registration or notification matters for foreign cosmetic license holders. The New Regulation seems to leave such matters to negotiations between foreign cosmetic license holders and their Chinese designees.

The New Regulation significantly increases administrative penalties for a variety of violations. For example, the New Regulation imposes penalties up to 15-30 times the illegal gains, a sharp uptick from 3-5 times the illegal gains under the Current Regulation.⁷ The New Regulation also imposes personal liability on responsible corporate officers of an entity that violates the New Regulation. Such officers would be subject to fines up to five times his or her annual income from the non-compliant entity and lifetime debarment in serious cases.⁸

Stimulation of Innovation for New Ingredients

¹ See Articles 18 and 29 of the New Regulation.

² See Article 32 of the New Regulation.

³ See Article 22 of the New Regulation.

⁴ See Article 23 of the New Regulation.

⁵ See Article 70 of the New Regulation.

⁶ See Article 70 of the New Regulation.

⁷ See Article 59 of the New Regulation.

⁸ See Article 59 of the New Regulation.

Under the Current Regulation, all new cosmetic ingredients are subject to a lengthy approval process. On the contrary, the New Regulation requires only certain high-risk new ingredients (e.g., preservatives, sunscreen ingredients, colorants, hair dyes and whitening agents) to be approved by the regulatory authority.⁹ Applicants of other unlisted new ingredients only need to go through a simplified notification process. Through this process, they can complete notification right after they submit all the required notification documents in a government-designated online system.¹⁰

The New Regulation implements a three-year monitoring period to newly approved or notified ingredients. After the expiration of the three-year monitoring period, the relevant new ingredient can be listed in the Catalogue for Ingredients in Use, provided that no safety concern arises during this period. This implies that if any company would like to use newly approved or notified ingredients without going through the same approval or notification process separately, they have to wait for three years until the relevant new ingredient is listed as “ingredients in use”. However, if a new ingredient creates any safety concern within its three-year monitoring period, the regulatory authority can revoke the approval or notification of such new cosmetic ingredient.¹¹

New Rules for E-commerce Platforms

Online sales of cosmetic products are booming in recent years, but the Current Regulation does not address issues associated with this topic. The New Regulation mandates e-commerce platform operators to oversee online sales activities that are conducted through their e-platforms. Specifically, they should (i) record and verify the identity of cosmetic distributors or retailers that trade on their e-platforms, (ii) procure these distributors or retailers to refrain from conducting any acts that would violate the New Regulation, (iii) report misconduct to the supervising authority, and (iv) suspend provision of e-platform services to these non-compliant distributors or retailers in serious cases. The New Regulation also requires cosmetic distributors or retailers to truthfully, accurately and timely disclose all the required information of cosmetic products that they trade on e-platforms.¹²

Outstanding Questions under the New Regulation

The New Regulation re-defines “special cosmetics” as cosmetics used for hair dye, perm, freckle elimination and skin whitening, sunscreen, anti-hair loss and cosmetics with new functional claims.¹³ However, the scope of “cosmetics with new functional claims” awaits further interpretation by the regulatory authority. Moreover, “products used for hair growth, hair removal, breast beauty, body building, and deodorization” are no longer defined as “special cosmetics” under the New Regulation. It is unclear how these products will be regulated, for example, whether they will be regulated as regular non-functional cosmetics or will be subject to any other special regulation.

Impacts of the New Regulation

The New Regulation’s emphasis on innovation and compliance may reshape the landscape of cosmetics industry. The shortened time to market of new ingredients brings opportunities to innovative cosmetic market players. The increased responsibilities of cosmetic license holders and severe consequences for non-compliance will likely force cosmetic companies to improve their quality management system and perform their obligations more diligently through the product lifecycle.

⁹ See Article 11 of the New Regulation.

¹⁰ See Article 13 of the New Regulation.

¹¹ See Article 14 of the New Regulation.

¹² See Article 41 of the New Regulation.

¹³ See Article 16 of the New Regulation.