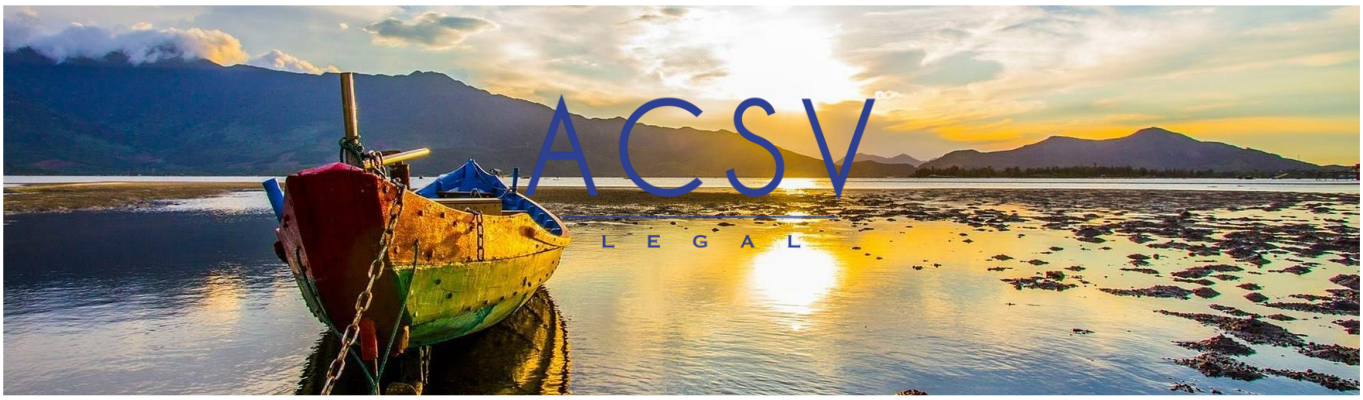

LEGAL UPDATE

UPCOMING CHANGES IN VIETNAM'S COSMETICS REGULATORY FRAMEWORK

The Ministry of Health (**MOH**) has issued a draft decree ("**Draft Decree**") to replace Decree No. 93/2016/ND-CP and a draft circular ("**Draft Circular**") to amend and supplement several provisions of Circular No. 06/2011/TT-BYT, thereby updating the regulatory framework for cosmetics in Vietnam. Below are the key updates outlined in the Draft Decree and Draft Circular.

1. Certificates & GMP Requirements

The Draft Decree introduces stricter requirements for product origin documentation and manufacturing practices:

i. Certificate of Free Sale (**CFS**): For imported cosmetic products, a valid CFS issued by a competent authority in the exporting country must be submitted, confirming that the product is legally sold in the country of origin.
   - Exemptions may apply under certain international trade agreements, such as the CPTPP or ASEAN frameworks.
   - The CFS must be valid at the time of submission and accompanied by a notarized Vietnamese translation.

ii. Good Manufacturing Practices (**GMP**) Compliance: The Draft Decree mandates GMP compliance for all cosmetic manufacturers—both domestic and foreign—according to ASEAN Cosmetic GMP Guidelines or other recognized standards.
   - Cosmetic manufacturers must obtain a GMP Certificate from a competent authority.
   - A transition period is proposed until mid-2028, after which only products from GMP-certified facilities may be legally notified and circulated in Vietnam.

2. Cosmetic Identification Code

The Draft Decree introduces the concept of a "Cosmetic Identification Code", which will be issued to each cosmetic product upon successful completion of the notification process.

The identification code may be presented in the form of a QR code or electronic barcode, linked to the national cosmetic database administered by the MOH.

Although the technical structure has not been finalized, the code is expected to include key data such as the product name, responsible entity, issuance date, circulation status, and relevant legal information.

The adoption of this system is considered a significant step forward in modernising regulatory oversight, enhancing post-market surveillance, and combating counterfeiting in Vietnam's rapidly growing and digitalising cosmetics sector.

3. Cosmetics Advertising

The Draft Decree introduces several important regulations regarding the advertising of cosmetic products. Notably, it sets out a list of prohibited words and phrases that must not be used in advertisements to prevent exaggerated claims, misleading information, or unverified effects. These include, but are not limited to, the following Vietnamese terms:

"điều trị", "tiệt trừ", "chuyên trị", "hàng đầu", "đầu bảng", "đầu tay", "lựa chọn", "chất lượng cao / tuyệt hảo / tuyệt vời / cực kỳ", "bảo đảm / đảm bảo 100%", "an toàn", "dứt", "cắt đứt", "chặn đứng", "giảm ngay", "giảm liền", "giảm tức thì", "khỏi ngay", "khỏi hẳn", "chữa bệnh", "tốt nhất", "duy nhất", "nhất", "trị nám vĩnh viễn trong 7 ngày", "trị mụn, trắng da "thần tốc", "kem trị nám, mỹ phẩm "tự nhiên 100%", "trắng da cấp tốc / siêu tốc", "khỏi", "khỏi hẳn", etc.

This list is illustrative and not exhaustive. Businesses are advised to review the full Draft Decree or seek legal

counsel to ensure full compliance with the advertising restrictions.

4. Proposed Changes to Cosmetic Product Registration Procedures

The Draft Circular introduces flexibility in the submission of cosmetic product registration dossiers, allowing applicants to choose from three methods:

i. online submission via the National Public Service Portal;
ii. direct submission at the relevant authority; or
iii. submission through public postal services.

For online submissions, applicants must provide one copy of the cosmetic product registration form, which must be digitally signed by the legal representative. This method aims to streamline administrative processes and enhance efficiency.

For direct or postal submissions, applicants are required to submit two hard copies of the registration form, each bearing physical signatures and official stamps. This ensures the authenticity of documents and aligns with regulatory requirements.

5. Updates to the Registration Form Content

The Draft Circular also introduces changes to the registration form requirements to align with updated regulatory guidelines. The registration form, as detailed in Appendix No. 01-MP, must be completed in accordance with the instructions provided in Appendix No. 02-MP. These changes aim to standardise the registration process and enhance regulatory oversight.

Additionally, organisations and individuals submitting cosmetic product registrations will bear full responsibility for the accuracy, legality, and truthfulness of the provided information, in compliance with applicable laws and regulations.

6. Changes to Imports for Research and Testing

Under the Draft Circular, companies that import cosmetics for research and testing purposes must submit an import request using the prescribed form (Appendix No. 14-MP) to the Department of Health (**DOH**) in the province where their headquarters are located. This requirement ensures regulatory oversight and compliance with established procedures.

The Draft Circular specifies that the maximum allowable quantity for each cosmetic product imported for research and testing is 10 (ten) samples, with each product permitted for import only once per year. These limitations are intended to prevent unauthorised distribution and ensure that imported samples are used strictly for research and testing.

For online submissions, one copy of the import request form must be submitted via the designated electronic system. In cases of direct or postal submissions, three hard copies are required: one retained by the DOH, one returned to the applicant for customs clearance, and one used for administrative processing. This structured submission method ensures transparency and proper documentation of research-related imports.

7. Conclusion

The Draft Decree and Draft Circular are expected to streamline administrative procedures, enhance regulatory transparency, and create a more supportive environment for cosmetic businesses operating in Vietnam.

With the public consultation phase now complete, both drafts are under final review and are anticipated to be promulgated in 2025. Businesses should begin reviewing their internal processes and preparing for compliance with the upcoming changes to ensure a smooth and timely transition once the new regulations take effect.

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