

KEY POINTS RELEVANT TO SWISS COMPANIES

Definition & Classification:

Cosmetics refer to daily chemical products intended to be applied to the external part of the human body, such as skin, hair, nails, lips, etc. by spreading, spraying, or other similar ways for the purpose of cleansing, protecting, beautifying and modifying.

The cosmetic products are classified as “special cosmetics” and “general cosmetics”. Special cosmetics refer to hair dye, hair perm, whitening, sunscreen, anti-hair loss products, and products with new efficacy claims. Special cosmetics are subject to registration. General cosmetics are defined as all other cosmetics excluded from special cosmetics and shall conduct filing.

Toothpaste shall be managed in line with general cosmetics. After conducting efficacy evaluation following the national or industrial standards by the filing party of toothpaste, they can claim that toothpaste has the effects of preventing caries, inhibiting plaque, resisting dentin sensitivity, and reducing gum problems.

Soaps are outside the scope of the CSAR, except for those with the efficacy of special use cosmetics.

Ingredient Management:

Cosmetic ingredients are classified into “new ingredients” and “ingredients in use”, i.e. ingredients included in the “Inventory of Existing Cosmetic Ingredients in China” (hereinafter referred to as IECIC, current version 2015).

Cosmetic ingredients will be regulated based on their risks. Ingredients with high risk (e.g., preservatives, sunscreen ingredients, colorants, hair dyes and whitening agents) shall register with the National Medical Products Administration (hereinafter referred to as NMPA) and obtain approval, while the management of ingredients with low risk is shifted to filing management. The filing is deemed to be completed after applicants submit the required documents in a government-designated online system.

The registrant or the filing party of new ingredients shall report the usage and safety information to the NMPA every year for 3 years. Only the new ingredients without safety problems before the expiry of a 3-year observation period will be included in the IECIC.

Pre-Market Approval - Registration & Filing

Conditions for registrant and filing party

- (1) It is an enterprise or other organization established according to law;
- (2) There is a quality management system that is suitable for the products that apply for registration and filing;
- (3) Have the ability to monitor and evaluate the adverse effects of cosmetics

Required registration & filing dossiers

- (1) The name, address and contact information of the registrant and the filing party;
- (2) The name, address and contact information of the manufacturer;
- (3) Product name;
- (4) Product formula or a full list of all ingredients;
- (5) The standards adopted;
- (6) A sample manuscript of the label;
- (7) Testing reports;
- (8) Safety assessment dossiers.

Overseas cosmetics registrants and filing parties shall designate legal entity in China to handle cosmetics registration and filing.

The registrant who applies for special cosmetics registration for the first time or the filing party files for general cosmetics for the first time shall submit proof that they meet the conditions specified for registrant and filing party under CSAR.

When applying for registration of imported special cosmetics or filing of imported general cosmetics, the certification documents that the products have been put into market for sales in the producing countries (regions) and the certification materials that the overseas producers meet the cosmetics production quality management standards shall be submitted at the same time. If the cosmetics are designed for export to China, for which the certification documents that the products have been put into market for sales in the producing country (region) are not available, the applicant shall submit the relevant research and test data targeting at Chinese consumers.

Registration certificate validation

The registration certificate for special cosmetics is valid for 5 years. If the registration needs to be renewed after the expiry of the validity period, the application for renewal shall be submitted 30 working days before the expiring date.

The registration will not be renewed, if

- (1) The registrant fails to apply for renewal of registration within the prescribed time limit;
- (2) The mandatory national standards and technical specifications have been revised and cosmetics applying for renewal of registration cannot meet the requirements of the revised standards and technical specifications.

Labelling Requirements & Efficacy Claim

The CSAR requires that the smallest sales unit of cosmetics shall have a label. The label shall comply with relevant laws, administrative regulations and mandatory national standards, and the content shall be true, complete and accurate.

Imported cosmetics can use Chinese labels directly, or can be attached to the original foreign language package by means of affixing, and the contents of the attached Chinese labels should correspond to those of the original labels.

Information required on the label

- (1) Product name and serial number of special cosmetics registration certificate;
- (2) Name and address of the registrant, the filing party, and the entrusted production enterprise;
- (3) Serial number of cosmetics production license;
- (4) Standard number for product implementation;
- (5) Full ingredients;
- (6) Net content;

- (7) Use period, use method and necessary safety warnings;
- (8) Other contents that should be marked in accordance with laws, administrative regulations and mandatory national standards.

Information not allowed on the label

- (1) Express or imply content with medical effects;
- (2) False or misleading content;
- (3) Contents that violate social order and good customs;
- (4) Other contents prohibited by laws and administrative regulations.

Efficacy Claim

There should be sufficient scientific basis for declaring the efficacy of cosmetics. The registrant and the filing party shall publish the abstracts of documents, research data or product efficacy evaluation data, on which efficacy claims are based, on the special website prescribed by NMPA and accept supervision of the public.

Enhanced Compliance Obligations on Cosmetic License Holders

Overseas cosmetics registrant and filing party should designate a legal entity in China to register or file cosmetics, to undertake specific tasks of administrative licensing, to assist in carrying out adverse reaction monitoring, and to implement product recalls.

The registrant and the filing party of new ingredients and new cosmetics should carry out safety assessment either by themselves or entrust a professional institution to perform the assessment prior to registration and filing. Personnel engaged in safety assessment should have professional knowledge related to cosmetics quality and safety, and have more than 5 years of relevant professional experience. Additionally, the cosmetics registrant, filing party and the commissioned production enterprise shall set up quality and safety control persons with professional knowledge of cosmetics quality and safety and at least 5 years of experience in cosmetics production or quality and safety management.

The CSAR 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.

Increased Responsibility of Third Party

The operator of the E-Commerce platform shall ensure real-name registration and bear the management responsibility of the cosmetics operators on the platform. The cosmetics operators on the platform shall fully, truthfully, accurately and timely disclose the information of the cosmetics they operate.

The organizer of the centralized cosmetics trading market and the organizer of the trade fair are required to review the registration certificate and to assume the management responsibilities of the participating cosmetics operators. Furthermore, they shall inspect the participating cosmetics operators on a regular basis and promptly stop and report to the competent authority any activities that violate the CSAR.

In addition, beauty salons, hairdressers and hotels that use or provide cosmetics in their services shall also adhere to the rules required of operators.

IMPACTS ON SWISS COMPANIES

- Under the CSAR, cosmetics categorized as general cosmetics, either manufactured domestically or imported, only require filing with NMPA. This new policy will allow a larger number of foreign cosmetics to enter the Chinese market without complicated pre-market registration and approval.
- The CSAR re-defines “special cosmetics” as cosmetics used for hair dye, hair perm, whitening, sunscreen, anti-hair loss products, and products with new efficacy claims. However, the scope of “cosmetics with new efficacy claims” awaits further interpretation by the regulatory authority.
- Cosmetics used for hair growth, hair removal, breast beauty, body building, and deodorization, that have been registered before the implementation of the CSAR, will have a five-year transition period during which they can still be produced, imported, and sold. After that grace period, such products will be prohibited to produce, import and sell. It is unclear, if these products will be subject to any other special regulations.
- New ingredients except the high risk ones (e.g., preservatives, sunscreen ingredients, colorants, hair dyes and whitening agents) are not required to be registered to launch in the market as long as it is filed with the NMPA. The classification is conducive to innovation, and China authorities encourage and support the production innovation in the market.
- Regarding current mandatory animal testing in China, the CSAR does not provide any clear answer. However, it is expected that the clarification on this issue will come in the near future. According to the previously published consultation draft - “*Administrative Measures on the Filing of Non-Special Use Cosmetics*”, besides few exceptions, such as:
 - *Products claiming for baby or children care;*
 - *Products containing new approved or recorded ingredient, which has not been included in the IECIC;*
 - *According to the quantitative grading results, the applicant, domestic responsible person or actual manufacturer is listed as a key regulatory object;*
 - *The applicant, domestic responsible person or actual manufacturer has been investigated or punished due to the quality and safety issues of the products in the past three years.*the toxicological test can be waived as long as the manufacturer has obtained the relevant qualification certification to the production quality management system issued by the authority and a risk assessment has been passed to ensure the safety of product. Although it still needs to wait for the finalization of the draft and other subsidiary regulations, it is already a good sign that China moves towards the ending animal testing for general cosmetics.
- The CSAR requires efforts to strengthen the quality-control of cosmetic products and establish reassessment to ensure safety and quality. Though the quality control will be more stringent, the new regulations as a whole are a positive development for foreign businesses as they offer more clarity and certainty in the Chinese market than ever before.
- China is speeding up the revision of implementing measures to continuously improve the regulatory system of cosmetics. Recently, two subsidiary regulations to CSAR are published for public consultation. The first, “*Administrative Measures on Cosmetics Registration-Draft*” clarifies requirements for registration and filing management of cosmetics and new cosmetic ingredients. The latter, “*Supervision and Administration Measures on Cosmetics Manufacture and Operation-Draft*” details the obligations of the registrants and filing parties, optimizes the production license management system, strengthens production quality management, refines operation management, clarifies multiple regulatory measures and specifies penalties. Once released, the new regulations of cosmetics will be far more comprehensive to meet the needs of nowadays China’s blooming cosmetics market.

Sources:

- The New Cosmetics Supervision and Administration Regulation (CSAR):
http://www.gov.cn/zhengce/content/2020-06/29/content_5522593.htm (in Chinese)
- Inventory of Existing Cosmetic Ingredients in China (IECIC):
<http://www.nmpa.gov.cn/WS04/CL2193/300096.html> (in Chinese)
- On May 27, 2019, the comprehensive division of NMPA released the draft “Administrative Measures on the Filing of Non-Special Use Cosmetics” for public consultation:
<http://www.nmpa.gov.cn/WS04/CL2103/338025.html> (in Chinese)
- On July 21, 2020, China published the draft “Administrative Measures on Cosmetics Registration” for public consultation
http://www.moj.gov.cn/news/content/2020-07/21/zlk_3252815.html (in Chinese)
- On July 21, 2020, China published the draft “Supervision and Administration Measures on Cosmetics Manufacture and Operation” for public consultation:
http://www.moj.gov.cn/news/content/2020-07/21/zlk_3252791.html (in Chinese)