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Articles

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China's Life Science and Healthcare-No.3 Amendment of the Regulations on Cosmetics in China

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In China, the basic regulatory mechanism of cosmetics has remained almost unchanged since the enactment of the ***Regulations on Hygiene Supervision of Cosmetics*** in 1989. However, the enactment of the ***Regulations on Supervision and Administration of Cosmetic***s on June 16, 2020 (effective from January 1, 2021) (the **"Regulations"**) marked the first step of the material reform to the regulatory mechanism on cosmetics in China.

Following the Regulations, competent authorities have released or amended a series of other measures and regulations to further implement such reform. Those regulations and rules include the ***Regulations on the Cosmetics Registration*** (effective from May 1, 2021), the ***Measures for the Supervision and Administration of Cosmetics Production and Sales*** Cosmetics(effective from January 1, 2022), and the ***Regulations on the Supervision and Administration of Cosmetics for Children*** (including not only products labeled "for children" but also "for families") (effective from January 1, 2022). And a new ***Cosmetics Production and Quality Management Code*** (Cosmetics GMP) was also enacted and came into effect since July 1, 2022.

One of the major goal of this reform is the strengthening of the responsibilities and obligations of registered owners of cosmetics (Market Authorization Holder, hereinafter referred the "MAHs"), manufacturers and distributors in terms of quality responsibility, traceability, reporting of defective reactions and recalls, following the approaches that have been adopted to regulate pharmaceutical products and medical device. In this newsletter, we will introduce the main points of the amended regulatory mechanism for cosmetics in China.

I. Cosmetics Registration System

First, the framework of the registration system for cosmetics and cosmetic ingredients in China can be summarized as follows.

Definition of Cosmetics	Cosmetics means daily chemical products used on the surface of the human body, such as skin, hair, nails, lips, etc., by applying, spraying, or other similar methods, for cleansing, protecting, beautifying, or modifying them.
Classification of Cosmetics	Cosmetics are classified in two grades. 1. Special Cosmetics: Cosmetics used for hair dyeing, perms, blemish removal and/or whitening effects, UV, hair loss prevention, and cosmetics advertising new efficacy effects are classified as special cosmetics and must be approved before sale or import. The registration certificate is valid for 5 years. 2. Ordinary Cosmetics: Cosmetics other than special cosmetics are classified as ordinary cosmetics and must be registered before sale or import.

Classification of Cosmetic Ingredients	Cosmetics ingredients are classified into three grades. 1. Ingredients banned for use in the production of cosmetics (ingredients listed in the inventory of prohibited cosmetic ingredients) 2. Ingredients have already been used in cosmetics in China(ingredients listed in the inventory of existing cosmetic ingredients (IECI). The current valid IECI is IECI 2021) 3. New cosmetic ingredients (natural or artificial ingredients used for cosmetics for the first time in China) (1) New cosmetic ingredients with antiseptic, UV, coloring, hair dyeing, blemish removal, and whitening effects are subject to approval control (approval is required to obtain after evaluation by a technical assessment organization of China). (2) New cosmetic ingredients other than the above (registration is required and the registration is considered completed upon submission of the prescribed documents). The MAH of new cosmetic ingredients shall submit a safety report three years after the use of the new cosmetic ingredients. New cosmetic ingredients for which no safety problems have occurred for three years will be added to the IECI[1] . The approval/registration of new cosmetic ingredients that posed a safety hazard will be canceled by the NMPA.
Cosmetic MAH	1. Basic requirements for MAH (1) must be a legally established corporation or other organization. (2) have a quality control system appropriate for the product (3) can monitor and evaluate cosmetic failure reactions about the product. 2. The main obligations and responsibilities of MAH are as follows. (1) establish a production quality control system in conformity with Cosmetics GMP. (2) when the cosmetics MAH outsource the manufacturing to other manufacturer, it must supervise the contracting manufacturer. (3) designate a person responsible for quality and safety. (4) establish a system to record receipt inspection and product sales of ingredients and packaging materials that come into direct contact with the product (in the case of outsourced manufacturing, this is to be done jointly with the contractor). (5) establish a factory shipment inspection system (in the case of outsourced manufacturing, to be conducted jointly with the contractor) (6) sample detention and storage (7) ensure truthfulness and legality of advertisement, the indication of efficacy (8) monitoring and reporting of defective reactions (9) obligation to respond to recalls (10) Others 3. Overseas MAHs must designate a domestic corporation as its domestic agent ("domestic responsible person" in the Regulations on the Management of Registration and Filing of Cosmetics), have a domestic agent apply for approval/registration,

[1] Before added to the IECI, the cosmetic ingredients shall be managed as new cosmetic ingredients.

	and procure the domestic agent to cooperate with respect to the monitoring of failure reactions, and product recalls. 4. Be responsible for the quality and safety of cosmetic products and the advertising of their efficacy. MAH must publish on a website, designated by NMPA, a summary of the literature, research data, or product efficacy evaluation data on which the product's efficacy claims are based according to the Code of Evaluation of Cosmetic Indications.
Cosmetics Production Company	Obtaining a production license, compliance with cosmetics GMP required, etc.
Cosmetics Sales Company (Wholesale, Retail)	Cosmetics sales license must be required, etc.
Cosmetics Concentrated Trading Market Manager and Exhibition Promotion Association Manager	Examination of real-name registration for market participants and conduct regular inspection, etc.
E-commerce Platform Operator	Obligation to conduce real-name registration of all cosmetic products business operators in its platform and conduct the supervision, etc.

II. Classification and Registration System of Cosmetic Ingredients

The Regulations classify new cosmetic ingredients into high-risk new cosmetic ingredients and other new cosmetic ingredients. The high-risk new cosmetic ingredients can not be used unless such cosmetic ingredients are registered with the NMPA. And in order to complete such registration, a technical evaluation by the administration body is required. For other new cosmetic ingredients, such technical evaluation by the administration body isn't required. Previously, there were cases in which cosmetics manufacturers choose to not import the cosmetics sold overseas to China because the cosmetic ingredients used fall into the category of new cosmetic ingredients and, prior to the enactment of the Regulations, approval for all new cosmetic ingredients was mandatory regardless of whether the new cosmetic ingredients are high-risk or not. The considerable time and effort that was required to secure such approval has been a great challenge to overseas cosmetic manufacturers.

In addition, the three-year safety observation period was also established for new cosmetic ingredients, and the respective procedures for cases where a safety issue arises or does not arise were clarified. The procedures for registration and filing of new cosmetic ingredients are also stipulated in the Regulations.

III.Responsibilities of Cosmetics MAH and Domestic Agent

The cosmetics MAH is responsible for the quality of cosmetic products, the designation of quality and safety managers, the responsibility of shipping products on the market, the product sales records, the monitoring of defective reactions, and the handling of recalls.

Under the former law, when applying for approval or registering of cosmetics and new cosmetic ingredients, if the applicant is in a foreign country, it was required to designate and authorize a domestic agent to represent the applicant in such procedure, but it is not clear whether such agent also bear the responsibility or obligation to deal with any problems that may arise regarding cosmetics after such approval or registration.

In contrast, under the Regulations, overseas cosmetic MAH must designate a domestic agent and have a domestic agent apply for approval or registration, to procure such domestic agent to cooperate on monitoring failure reactions, and product recalls. If the designated domestic agent doesn't cooperate in monitoring defective reactions or conducting recalls, the administrative authority has the power to impose sanctions upon such domestic agent.

As for the distinction between domestic cosmetics and imported cosmetics, "domestic cosmetics" are referred to cosmetics that the last process of manufacturing which contacting the contents of such cosmetics is completed domestically in China. It is worth noting that according to such a definition, in the case of a foreign cosmetics MAH that conducts outsource manufacturing in China and the product whose last process of manufacturing which contacting the contents of the cosmetics is completed, the cosmetics product shall be classified as domestic cosmetics product, but it is still necessary for such overseas cosmetics

MAH to designate a domestic agent. On the other hand, when a domestic cosmetics MAH outsource manufacturing to overseas contractors and the last process of manufacturing contacting the contents of the cosmetics is completed overseas, the product is considered an imported cosmetic product, but if since the MAH is located in China, it is not necessary to designate a domestic agent.

IV. Designate a Quality and Safety Manager

According to the Regulations, MAH and the cosmetics contract manufacturing companies must appoint a quality and safety manager. The quality and safety manager must have expertise in the safety and quality of cosmetics, chemistry, chemical industry, biology, medicine, pharmacy, food, public health, or law, be familiar with relevant laws and regulations, mandatory national standards, and technical codes, and have at least five years of experience in the production or quality control of cosmetics (Article 32, Paragraph 2 of the Regulations and Article 7 of the Cosmetics GMP).

The quality and safety manager should be responsible for the implementation of the following and be able to independently execute the work.

(1) Establishment, organization, and implementation of the quality management system of the company, and regularly reporting to the legal representative on the operation of the quality management system.

(2) Making decision on quality and safety issues and issuing relevant documents.

(3) Audit and control of product safety evaluation reports, formulations, manufacturing processes, raw material and material suppliers, product labeling, etc., and review and confirmation of cosmetics registration documents.

(4) Control of shipping of the products to the market.

(5) Monitoring and management of cosmetics defective reactions.

With the consent of the legal representative, the quality and safety manager can entrust the duties other than (1) and (2) to other person within the company. The quality and safety manager shall supervise the performance of duties by these personnel and such an entrustment will not release the quality and safety manager from his or her responsibilities.

In the "Answers to the Common Problems of Cosmetics Production and Management (I)" published by the NMPA on November 8, 2021, the question "Can a quality and safety manager be in charge of different MAHs and contract manufacturers at the same time? ", and the NMPA answers as follows..

"To protect the quality and safety of cosmetics and to ensure that the quality and safety manager fulfills his or her quality and safety management and product release responsibilities under the law, according to the principle of "one certificate, one person", when applying for two or more (including two) licenses to produce cosmetics, the same natural person may not be in charge of the quality and safety management of the above companies. In addition, different MAH and contract manufacturers may not designate the same natural person to be in charge of a quality and safety management. In cases where the MAH and contract manufacturer belong to the same corporate group and implement the same quality control system, and the contract manufacturer produces cosmetics under contract from the MAH, the MAH and contract manufacturer may designate the same natural person to be in charge of the quality and safety management."

It is also worth noting that cosmetics MAH must assign a quality and safety manager who meets the statutory requirements after July 1, 2022.

V. Sanctions for Non-compliance

In the case of not designating a quality and safety manager, the following sanctions will be imposed: confiscation of cosmetics that fall under illegal income and illegal production and management, confiscation of goods such as cosmetic ingredients, packaging materials, tools, and equipment used in illegal production and management, and a fine of RMB 10,000-30,000. If the sales amount exceeds RMB10,000, the fine shall be 3 to 10 times the amount of the sales amount, and if the circumstances are serious, an order to suspend production, cancellation of the cosmetics license document, a fine of 1 to 2 times the amount of remuneration obtained from the company in the previous year for the legal representative or main person in charge, the main person directly responsible for the company, and other personnel directly responsible for the company, and a five-year ban on working in cosmetics production and management activities. In addition, if the overseas MAH does not implement the administrative penalty decision based on the Regulations, the import of the cosmetics in question may be banned for 10 years.

(end)

(Major Revisions to Laws, Regulations, and Guidelines

in the Cosmetics Sector of China)

Field	Name of Law or Code	Date of Amendment	Date of Entry into Force
Basic Laws and Regulations	Regulations on Supervision and Administration of Cosmetics	2020/06/29	2021/01/01
	Regulations on the Supervision and Administration of Cosmetics for Children	2021/09/30	2022/01/01
Approval/Registration of cosmetics and raw materials	Regulations for the Administration of Cosmetics Registration	2021/01/07	2021/05/01
	Rules for Management of Cosmetics Registration Notification Materials	2021/02/26	2021/05/01
	Rules for Management of Materials for Registration of New Cosmetic Ingredients	2021/02/26	2021/05/01
	Cosmetics Classification Regulations and Classification Inventory	2021/04/08	2021/05/01
Production and sales of cosmetics	Measures for the Supervision and Administration of Cosmetics Production and Sales	2021/08/02	2022/01/01
	Cosmetics Production and Quality Management Code (Cosmetics GMP)	2022/01/07	2022/07/01
	Monitoring Defective Reactions to Cosmetics Code	2022/02/15	2022/10/1
Cosmetics advertising, label, expression of efficacy, etc.	Regulations on Supervision and Administration of Cosmetics	same as above	same as above
	Cosmetic labeling management function	2021/05/31	2022/05/01
	Public Notice on the promulgation of the Children's Cosmetics Marker	2021/11/29	2021/11/29
	Code of Evaluation of Cosmetic Indications	2021/04/08	2021/05/01

Legal Updates

Release of the Rules on Security Certification of Overseas Processing of Personal Information Ver. 2.0

On 26 December 2022, the National Information Security Standardization Technical Committee (TC260) released the Rules on Security Certification of Overseas Processing of Personal Information Ver. 2.0 (the "Rules on Certification") as one applicable standard mentioned by the Notice of the Implementation of Protection Certification of Personal Information (the "Notice") which is issued on 18 November 2022.

The Rules on Certification will the basic standards for the certifying authority to conduct the security certifications on the overseas processing of personal information. The Rules on Certification expressly set out the principles that the processors have to follow when conducting an overseas processing of personal information, the requirement for the protection of personal information to be provided by the overseas receiver of the personal information and the interests and rights of the information subjects.

For more information about the Rules on Certification, please check TC260's official homepage (https://www.tc260.org.cn/front/postDetail.html?id=20221216161852).

The Second Review Draft of the Amendment to the Company Law

The Standing Committee of the National People's Congress released the Second Review Draft of the Amendment to the Company Law (the "Second Review Draft") on 30 December 2022 to further collect public comments.

The Second Review Draft has remained the main body of the First Review Draft but also made some alterations to it. For example, limited liability company is allowed to choose not to establish a board of supervisors or supervisor at all even such company does not establish an audit committee (in the First Review Draft, only limited liability company establishing an audit committee can choose to completely omit the supervisor). In the First Review Draft, it granted very broad powers to the board of directors by saying that the board of directors can exercise the powers except for those have been reserved to the shareholders' meeting. However, the Second Review Draft abandoned such an open-end style approach by resuming the non-exhausting list of powers like the current Company Law.

In addition to the foregoing, the Second Review Draft also hardened the requirements for setting up an audit committee in company limited by shares. In the First Review Draft, company limited by shares is allowed to set up an audit committee to monitor the accounting matters of the company and more than half of the members of such audit committee shall be non-executive directors. The Second Review Draft requires that more than half of the members of the audit committee shall be "independent director" and at least one independent director shall be accounting professional. With respect to the condition of "independent director", the Second Review Draft requires that in order to be eligible to be an independent director, such a director shall not take other position in the company other than the director and shall not hold any relationship with the company that may "possible affect the directors' independent and fair judgement".

In China, amendment to important laws like Company Law requires three-time review before its enactment (the

final amendment will be adopted after the third time review). Therefore, the Second Review Draft is generally believed to be very close to the final amendment.

The Amendment to the Civil Procedure Law

The Standing Committee of the National People's Congress released the Draft of Amendment to the Civil Procedure Law on 30 December 2022 to collect public comments.

Major points of this amendment include further clarification on the application of "collusive lawsuit", enlargement of the applicable scope of disqualification to judge assistant and judicial technical staff, clarification of the rules on judicial technical staff's engagement to the litigation procedure, adjustment to the submission of appeal and further clarification of rules on the recognition and enforcement of foreign judgement.

The Amendment to the Unfair Competition Law

The State Administration of Market Regulation (SAMR) released the amendment to the Unfair Competition Law on 22 November 2022.

The Unfair Competition Law has been relatively frequently amended in recent years (amended in 2017 and 2019) to catch up with the fast changing market conditions. Major points of this amendment include the establishment of unfair competition behaviors with respect to the area of digital economy, further clarification of the scope of the "confusion behaviors", set more detailed provisions regarding the "false propaganda", new mechanism on the protection of business secrets and new prohibition on the abuse of advantage market position.

Guideline on the Use of Absolute Terms in Commercial Advertisement

In China, according to the Advertisement Law, advertiser is not allowed to use absolute terms like "the best", "national level" and "No.1" in its commercial advertisement. Although the principle itself is clear but many problems that frequently arise during the enforcement of such regulation such like how to determines whether a term amounts to an absolute term and if there could be any exception to such regulation remain unclear.

On 7 December 2022, the State Administration of Market Regulation (SAMR) released the draft of the Guideline on the Legal Enforcement of Absolute Terms in Commercial Advertisement (the "Guideline") to collect public comments. The Guideline is aimed to further clarify problems regarding the enforcement of the regulation on absolute terms.

According to the Guideline, absolute terms that are not referred to particular product or service may not be deemed as unlawful. Advertisers are allowed to use absolute terms if such terms are used to simply express the advertiser's business philosophy or the goal that the advertiser is pursuing. And even absolute terms are referred to particular product or service, under certain circumstance, such use of absolute terms could also be allowed. For example, if such a term is used in the comparison between the products and services of same advertiser, or if such a term is used to express the "best method of application", "best timing" or "best duration", or if the trademark contains absolute terms.

Also, the Guideline states that administrative sanctions shall not be imposed if the violation was minor considering the elements like method of publication, duration, numbers of readers and results. However, such an "minor violation exemption" is not applicable if such absolute terms are used to state the curability, validity or effect in advertising products like drugs, medical devices and healthy foods or state the return rate in advertising financial and investment products.

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