05

Medical Devices and Cosmetics Management Reforms

The Draft of Medical Device Act

Advancing R&D and Product Innovation in the Medical Device Industry.

Promoting Diversified Management of the Medical Device Industry.

Normalized Product Destination and Distribution Quality Management.

Consolidation of Medical Device Risk Management System.

Medical Device Clinical Trials Management.

Promoting Listed Medical Device Safety Surveillance Management.

Advancement in Management of Medical Device & Consultation

Training 47 Seed Regulators in Medical Device Management.

Successfully Assisted 8 Domestic Innovative Medical Devices into Market.

20 Thousand Times Telephone Counseling.

739 Items of Medical Devices Available for Online Sale.

Successfully Assisted 4 Medical Devices for Clinical Srials.

Guidelines for the 3D Printing of Medical Devices (Draft).

New System for the Management of Cosmetics

Additional Information Requirement for Nail Cosmetics.

Regulations Governing the Application of Animals Testing for Cosmetics or Cosmetic Ingredients.

Regulations Governing 15 Ingredients such as Safrole that are Ingredients Prohibited for Use in Cosmetic Products.

Cosmetic Hygiene and Safety Act

Scope of Management.

Proactive Report.

Product Notification and Product Information File System.

Abolition of Criminal Punishment & Increase of Administration Fines.

05 Medical Devices and Cosmetics Management Reforms

In light of the obvious differences between medical devices and drugs in terms of their characteristics and industrial operation models, and in order for our laws and regulations governing medical devices to comply with their international counterparts, the Administration separated laws and regulations governing medical devices from the *Pharmaceutical Affairs Law* and prepared the *Draft Medical Devices Act*. In addition, in order for the cosmetics management system to comply with the international counterpart and to increase the competitive advantages of Taiwan's cosmetics industry around the globe, proactive efforts have been made to amend the *Cosmetic Hygiene and Safety Act* to maintain the hygiene and safety of cosmetics.

To expedite commencement of the clinical trial phase for innovative medical devices or to shorten the time frame needed for marketing and accordingly boost competitive advantages of Taiwan's medical device industry around the globe, the Administration established the project regulatory consultation and assistance mechanism and prepared the "*Guidelines for Additive Manufacturing (3D Printing) of Medical Devices*."

Section 1 Preparation of the Medical Devices Act

Origin of Policy

The requirements on the management of medical devices that are available in our country can be found in the *Pharmaceutical Affairs Act*. In light of the obvious differences between medical devices and drugs in terms of their characteristics and industrial operation models, and to improve the management of medical devices for compliance with international laws and regulations, the *Medical Devices Act* was planned separately to help normalize the domestic medical device management system.

Implementation Measures

1. The Administration started to separately plan the medical device law framework and legality assessment in 2014 by reference to international management regulations and our own national conditions, and invited the industrial, governmental, academic, and research representatives to attend the negotiation meeting so as to collect opinions. By the end of 2017, 16 rounds of workshops and discussion meetings had been held to help concerned parties understand highlights of the draft. (See Figure 5-1 for the process of promoting the *Draft Medical Devices Act.)*
2. In order to realize an open and transparent government, the draft was announced on December 5, 2016 to facilitate the collection of diversified opinions. The WTO reporting procedure was completed on January 31, 2017. Respective member states had 60 days to provide opinions. During the period, a total of 34 unions, associations, societies, or institutions submitted letters expressing their opinions and all the opinions were included while the draft was under assessment. It was reviewed and approved by the Executive Yuan on December 14, 2017. The draft consisted of 83 articles in total.
3. The Legislative Yuan passed the first reading of the *Draft Medical Devices Act* on December 29, 2017, and submitted it to the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan for review.

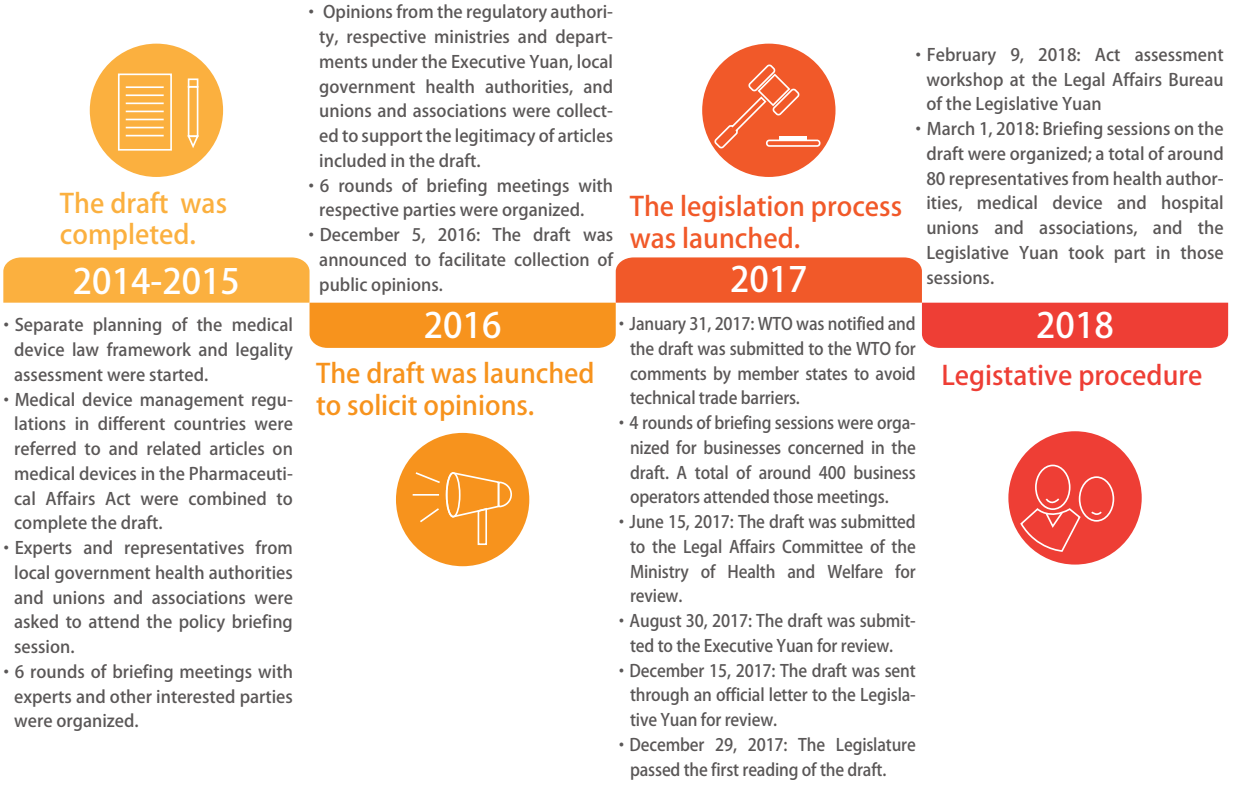

Figure 5-1 The process of promoting the Draft Medical Devices Act

Outcomes and Benefits

1. Advancing R&D and product innovation in the medical device industry

The term of "Medical Device Manufacturer" is defined according to the key process in medical device manufacturing. Medical device designers can also be the permit holders to provide incentives for the industry, academia, and research institutions to research and develop high-end medical devices. The conditional approval mechanism is introduced along with post-approval study or safety surveillance to expedite the entry of innovative medical devices into the market.

2. Promoting diversified management of the medical device industry

Medical device rental or repair businesses are considered as Medical Device Dealers. It is required that technicians be hired for the different sectors in the medical device industry to enhance professional management and ensure product safety.

3. Normalizing product destination and distribution quality management

It is specified that Medical Device Dealers and medical institutions shall create and preserve data of direct supply sources and destinations of products. Medical device distribution quality of medical devices is promoted to ensure that the quality of products is not compromised during transportation.

4. Consolidating medical device risk management system

For certain low-risk medical devices, the electronic online register system is adopted in order to streamline the pre-marketing application process. In addition, annual declaration applied to extend the validity of registration and urge timely update to the information of listed medical devices.

5. Constructing medical device clinical trial management

Applicable regulations on clinical trials of medical devices are separated to improve the management system, ensure the safety and rights of trial subjects, and fulfill the requirements on management of clinical trials on medical devices.

6. Promoting listed medical device safety surveillance management

It is specified that medical institutions shall cooperate to implement the medical device safety surveillance system and urge manufacturers to conduct spontaneous monitoring and management of listed product risks and adopt corrective and preventive measures to protect the safety of consumers. (See Figure 5-2 for Highlights of the Medical Devices Act and Its Benefits.)

Figure 5-2 Highlights of the Medical Devices Act and Its Benefits

Section 2 Review and Consultation for Innovative Medical Devices

Origin of Policy

The development of medical devices based on innovative technologies has been significantly accelerated in the past few years. Such medical devices usually employ novel technical principles or claim new intended uses, however, researchers and developers are faced with the challenge that there are no similar products or pre-clinical test standards available for reference. In order to support the R&D teams to develop innovative medical devices, the Administration established and updated respective standards applicable to medical devices, created a regulatory consultation network covering the entire product life cycle, and set up a Medical Device Advisory Board formed by members strong in biomedical engineering and experienced with clinical practice (Figure 5-3). When it is considered necessary, external experts will also be invited to take part in the consultation services to provide advice and jointly resolve the regulatory issues confronted by developers during their development of innovative medical devices.

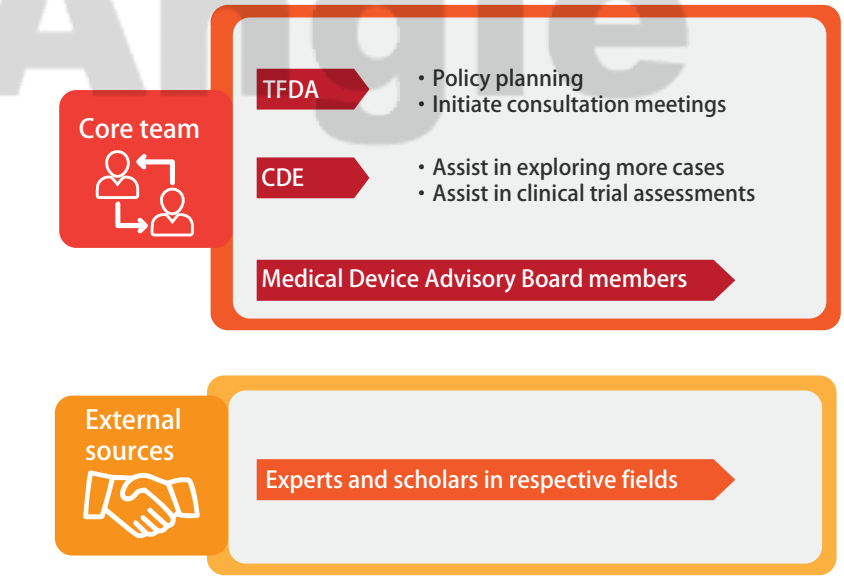

Figure 5-3 Operational framework of the medical device project counseling and assistance team

Implementation Measures

1. In May 2011, the Administration started a program based on the document "Principles for Medical Device Consultation." The program aims to support R&D teams through one-on-one consultation and provide the R&D teams with advice on pre-clinical and clinical validations during their product development. The targeted medical devices of this program are Class II or III medical devices still under development and not available in the domestic market or medical devices seeking for multicenter international clinical trials, in which the medical devices must meet any of the following criteria: first domestic case (FDC), best in class (BIC), new indication in health (NIH), milestone for TFDA (MFT), and multicenter clinical trial (MCT).
2. Through the above program, an R&D team can establish a close correspondence with the regulatory and technical teams within and outside of the Administration since the early R&D phase. The Administration will hold consultation meetings depending on the circumstances, where members of the Medical Device Advisory Board, experts, and scholars will also be invited to help the R&D team to address issues in the consultation meetings.
3. In order to provide manufacturers and the public with quick assistance on medical devices, the Administration has authorized the Center for Drug Evaluation (CDE) to set up a hotline at (02)8170-6008 for basic consultation regarding the regulations of medical devices. The manufacturers and the public can ask questions about laws and regulations on the registration and clinical trials of medical devices on this hotline. In addition, the CDE also trained seeds from local communities to address basic regulatory inquiries, and allows manufacturers from biomedical science parks to reserve in-park regulatory consultation services.

Outcomes and Benefits

1. In 2017, 8 innovative medical devices had been approved and 4 clinical trials of medical devices had been activated with the assistance from the program of "Principles for Medical Device Consultation." The highlighted outcomes includes a Hepatitis B viral load test kit, a Hepatitis D total antibody reagent, a dengue fever NS1 antigen quick test reagent, and an implanted spinal stimulator. The results are considered impressive.
2. In 2017, up to 20,017 regulatory consultations had been provided through CDE's hotline. In addition, several consultation services had been reserved and provided to manufactures in the biomedical science parks to promote innovation of medical devices.
3. With the joint efforts from the Administration, CDE, and 47 seeds trained in 2017 (the completed list of seeds has been published on our website), the scope of regulatory consultation service has been successfully expanded to cover local communities. This regulatory consultation network aims to help businesses to establish regulatory compliance as early as possible.

Section 3 Preparation of Guidelines for 3D-Printing of Medical Devices

Origin of Policy

Many manufacturers, the academic research institutes, and the medical community in our country have devoted to the R&D and manufacturing of 3D-printed medical devices. In order to define related device management scope and regulatory requirements and to also ensure that such products are safe and effective, the Administration referred to management regulations in other countries around the globe and the development status of related industries in our country in 2016 and 2017 to stipulate the "*Guidelines for Additive Manufacturing (3D Printing) of Medical Devices (Draft)*" and officially promulgate it accordingly on January 12, 2018.

Implementation Measures

1. 3D-printing is a new technology applied in the manufacturing of medical devices, and it has a wide scope of application. Thus, regulatory data available for reference in the international realm is quite limited. As such, while the draft was being prepared, one international symposium, three expert meetings (where experts from the industry, government, research institutes, and medical community and related units of the Administration were invited), five visits to domestic and international medical device manufacturing/3D-printing facilities, three internal meetings, and one external and internal briefing session, were respectively organized to extensively collect opinions from all parties, and eventually, the "*Guidelines for Additive Manufacturing (3D Printing) of Medical Devices*" were successfully completed.

2. The Guidelines stipulates its scope of application and includes a list of product attributes in respective parts of the 3D printing technology for management. In addition, special considerations and related verifications and assessments are also covered with regard to the 3D printing software work flow, product quality and manufacturing control, and finished product testing, among others, for industrial reference.

Outcomes and Benefits

Management advice and principles are provided in the Guidelines to expedite review and approval of the 3D-printed medical devices and introduction to the market as early as possible, to create a high-quality industrial development environment, and to push Taiwan's medical device industry onto the world stage. This policy was highly recognized in various respects. So far, a total of 3 permits have been issued for 3D-printed medical devices approved to enter the market, including the dental implant surgical guide and the preformed tooth positioner, among others.

Section 4 Expansion of Medical Devices Available for Online Sale

Origin of Policy

In order to take care of both the demand for and safety of medical devices suitable for use at home, the Administration announced medical devices that may be sold over the Internet shall follow the four major principles of "home use, non-invasion, non-implantation, and no need for instructions from professionals." Medical device companies and drug stores may apply for and obtain approval from the local health authority, in order to sell medical devices through distance sales channels.

Implementation Measures

1. As of November 1, 2012, according to the characteristics of medical devices, the Administration has gradually lifted the ban on items that may be purchased online. Medical Device Dealers with physical operating sites may apply to local health authorities for a permit and once it is approved, they may sell low-risk medical devices in Class 1 through distance sales channels.
2. The ban on five items were lifted on January 2, 2014, including body fat monitors, condoms, and sanitary pads as Class 2 medical devices that were suitable for use at home as they were non-invasive, non-implanted, and did not require instructions from professionals.
3. The ban on 8 items were lifted on October 15, 2015, including surgical masks, alcohol prep pads, alcohol cotton balls, iodine prep pads, iodine swabs, iodine gauze, Vaseline gauze, suture-free tape, contact lens cleaning and care products, medical image recording and transmission

software, and magnetic resonance imaging software as Class 2 medical devices.

4. On March 16, 2017, the ban on five Class 2 medical devices was further lifted, including blood pressure tourniquets, the motorized vehicle for medical purposes, powered wheelchairs, and otolaryngology drug application devices.

Outcomes and Benefits

1. So far, the Administration has lifted the ban on sale of 739 items in total, including 721 low-risk Class 1 medical devices and 18 medium-risk Class 2 medical devices, to make it convenient for consumers to purchase medical devices on the Internet.
2. When medical devices are purchased online, frauds and the impossibility to return and replace products, failure to operate a product, or health hazards caused by improper use, and issues with after-sale maintenance of products are likely to happen. The Administration has conducted classification on the overall risk of medical devices into consideration. For the time being, medical devices having fulfilled the four principles indicated above have all been allowed to be sold online. (Table 5-1) (Figure 5-4)

Table 5-1 Medical device items that can be sold by pharmaceutical companies (pharmacies) through distance sales channels

Start Date	Medical Device Items	Product Demo
November 1, 2012	Class I medical devices (721 items)	knee braces, Band-Aid, mechanical wheelchairs
January 2, 2014	E.2770 Impedance plethysmography (impedance peripheral blood flow recorder)	Body fat monitor
	L.5300 Condoms	Condoms
	1.5310 Condoms containing spermicide	
	L.5460 Scented or deodorizing sanitary pads	Tampon
	L.5470 Unscented sanitary pads	
October 15, 2015	I.4040 Medical clothing	Surgical masks
	I.0004 Alcohol prep pads	Alcohol prep pads, alcohol cotton balls
	I.0005 Iodine pep pads	Iodine prep pads, iodine swabs, iodine gauze
	I.4014 External non-absorbent gauze or sponge balls	Vaseline gauze
	J.5240 Medical sticky tape and sticky bandage	Suture-free tape
	M.5918 Rigid gas permeable contact lens preserving products	Contact lens cleansing solution, contact lens care solution
	M.5918 Flexible contact lens preserving products	
	Medical device software	Medical image digitizer, communication and storage device
March 16, 2017	E.1120 Blood pressure tourniquets	Blood pressure tourniquets, blood pressure cuffs, blood pressure measuring armbands
	L.5400 Menstrual cups	Menstrual cups
	O.3800 Motorized vehicle for medical purposes	Motorized vehicle for medical purposes
	O.3860 Powered wheelchairs	Powered wheelchairs, powered walking aids installed on wheelchairs
	G.5220 otolaryngology drug application devices	Nasal irrigation devices, nasal sprays

Figure 5-4 Medical devices that pharmaceutical companies (drug stores) may sell through distance sales channels in 2017

Section 5 Stipulation of Cosmetic Hygiene and Safety Act

Origin of Policy

The *Statute for Control of Cosmetic Hygiene* has been enforced since December 28, 1972, and was amended five times. Given trade liberalization and frequent international correspondence in recent years, current management requirements are becoming more and more insufficient to meet practical demand.

For reinforced quality and safety of cosmetic products that are available on the market and to reflect international management trends, the Administration prepared the amended draft of the *Statute for Control of Cosmetic Hygiene* that highlights replacement of the medicated cosmetics registration system with the product notification and product information file system and addition of the requirement for cosmetic businesses to comply with the Good Manufacturing Practice, among others, in order to strengthen the hygiene and safety management mechanism for cosmetic products and to meet the requirements of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

Implementation Measures

1. The Administration began revising the *Statute for Control of Cosmetic Hygiene* in 2011 and has been proactively communicating with external representatives. The public hearing on highlights

of the revision, industrial impacts forum, external briefing sessions, cross-ministerial/cross-departmental meetings, and notice to the WTO for comments from its member states were completed and opinions from all parties concerned were extensively collected to render the amended draft of the Statute for Control of Cosmetic Hygiene. It was reviewed and approved by the Executive Yuan on September 8, 2016, and the title was changed to *Cosmetic Hygiene and Safety Act*. There are a total of 32 articles.

2. This amended draft was reviewed and approved by the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan on December 20, 2017, and it was decided by the Legislative Yuan on December 29 of the same year to be submitted for negotiation among party caucuses. (Note: The amended draft passed the third reading in the 7th meeting of the Legislative Yuan on April 10, 2018. The President promulgated it through the Hua-Zong(I)-Yi-Zi No. 10700045851 order on May 2, 2018, with the date of enforcement to be determined separately by the Executive Yuan.)
3. The Administration has also called for more than a hundred rounds of training and briefing sessions since 2013 and planned the implementation of GMP and product information file systems in phases according to the risk associated with respective products in order to minimize the impacts of the new system on the industry.

Outcomes and Benefits

1. The current amendment takes international regulations into consideration by including non-pharmaceutical toothpaste and mouthwashes in the management of cosmetics. Once the new Act is enforced, for cosmetics categories specified by the central competent authority, businesses must complete product notification and establish the product information file (PIF) before their products are introduced to the market and their manufacturing site must fulfill the Good Manufacturing Practice (GMP). This measure helps not only shorten the time to market and provide consumers with more diversified options and the possibility of searching for product information online but also reinforce the safety management of cosmetics and ensure steady production of qualified cosmetics to maintain the hygiene and safety of cosmetics.
2. In addition, data on the sources and flows of products and systems such as spontaneous reporting obligations of businesses were added this time. The value of the fine involved was significantly increased, too. Penalties for non-compliant cosmetic advertisements were also increased. For violations involving falsified or exaggerated claims, the fine increased from current NTD 50,000 to NTD 40,000-NTD 200,000. For those involving medical efficacy, the fine is reinforced to NTD 600,000-NTD 5 million. The competent authority may demand posting of correction advertisements and products be removed from shelves when violations in advertising are severe. The even more normalized regulations are meant to protect the rights of consumers.
3. The current amendment is a major systematic reform that helps streamline the administrative efficiency of the government and reinforce source and circulation management to protect the

rights of general consumers. Meanwhile, in light of the relatively extensive scope involved in the current amendment, cosmetics businesses are given adequate and reasonable buffer and preparation periods in order to reduce the impacts on the industry. The Administration will also embark on the stipulation of sub-regulations and package measures according to the post-amended *Cosmetic Hygiene and Safety Act* so that the cosmetic hygiene and safety management system in our country is even sounder and complete.

Section 6 New System for the Management of Cosmetics

Origin of Policy

The use safety of cosmetics is closely related to the general public. Related management laws and regulations shall be constantly updated with time. On November 9, 2016, it was announced through Presidential Order that some articles of the *Statute for Control of Cosmetic Hygiene* were revised: cosmetic businesses shall not subject animals to testing when conducting safety evaluation of cosmetics or cosmetic ingredients in our country. If the ingredient is widely used and its function cannot be replaced by other ingredients or there are evaluation data demonstrating the potential for harming human health, cosmetic businesses must apply for approval with the central competent authority prior to conducting animal tests and the new requirement would take effect on November 9, 2019.

In order to protect the health of consumers, to ensure that natural botanical ingredients in cosmetics came from safe sources, and to promote comparable management systems in our country to international ones, on the other hand, current requirements are revised to prohibit the use of 15 ingredients such as Safrole in cosmetics.

As for commercial nail cosmetics, although it is used on the surface of the nail and contact with skin or inhalation should not occur when used correctly, in light of the fact that it mostly contains organic solvents and that there have been prior events of skin or nail lesions, as a result, improper use and that there is the concern of inhalation of excessive organic solvents during storage and use, in order to protect the safety of users of such products, additional information requirement on such products is included with reference to the requirement for nail cosmetics in the United States and the European Union.

Implementation Measures

1. To go with the amended *Statute for Control of Cosmetic Hygiene* announced on November 9, 2016, the Administration stipulated the Information on Applying for Animal Studies of Cosmetics or Cosmetic Ingredients (Draft). The draft was discussed in the meeting on December 26, 2016, and pre-announced on February 2, 2017. The "*Regulations Governing the Application of Animals*

Testing for Cosmetics or Cosmetic Ingredients" was promulgated on September 14, 2017.

2. In order to protect the safety of consumers while using cosmetics and to promote comparable management systems in our countries to international ones, the Administration pre-announced the stipulation of the "*Regulations governing 17 ingredients such as Safrole that are ingredients forbidden for use in cosmetic products*" on February 2, 2017 and again pre-announced the "*Regulations governing 15 ingredients such as Safrole that are ingredients prohibited for use in cosmetic products*" on August 15, 2017 and announced it on December 8, 2017.
3. Nail cosmetics tend to cause accidents due to improper use. In order to protect the safety of people using nail cosmetics added with organic solvents, the Administration called for the cosmetic industry communication meeting and discussed the issue on November 8, 2016, and announced the stipulated "*Requirements for Additional Information on Nail Cosmetics Added with Organic Solvents*" on May 26, 2017.

Outcomes and Benefits

1. The new cosmetics management systems such as the Regulations Governing the Application of Animals Testing for Cosmetics or Cosmetic Ingredients, Regulations governing 15 ingredients such as Safrole that are ingredients prohibited for use in cosmetic products, and the Requirements for Adding Information on Cosmetics for Nails Added with Organic Solvents were established in 2017.
2. The Administration announced the prohibited importation, manufacturing, distribution, supply, or display of cosmetics containing specific ingredients such as Safrole, Verbena Oil, Woody Root Oil, Fig Leaf Extract, Alocasia Cucullata, Konjac, Alocasia Macrorrhizos, Rose Pericuinkle, Common Cerberustree Seed, Ranunculaceae Ranunculus, Wild Lily, Dioscorea Hispida, Graceful Jesamine, Stellera Chamaejasme, and Hubei Wind flower for intended purposes of distribution or supply on December 8, 2017. The said ingredients were announced to be prohibited for use in cosmetics and the announcement took effect on July 1, 2018.
3. The Administration announced on May 26, 2017, the stipulated "*Requirements for Additional Information on Nail Cosmetics Added with Organic Solvents.*" For nail cosmetics added with organic solvents, it is advised to add information such as "pay attention to ventilation; stay away from fire and heat; avoid use in pregnant women and children under the age of 12; avoid getting on skin, in the eyes, and inhalation; the product is for external use and if swallowed by accident, please seek medical attention" on the label, package insert, or package for enhanced protection of the safety of people using such products.