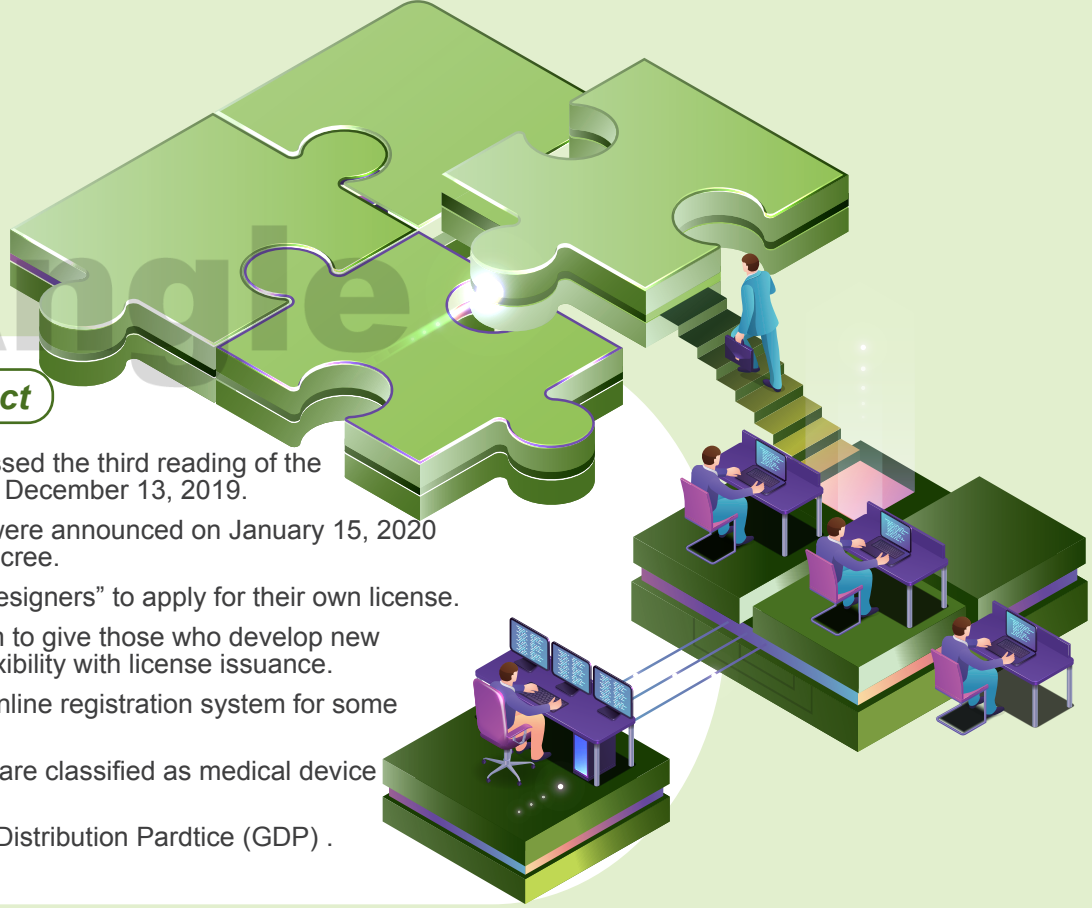
Ch5 Consummated Medical Devices and Cosmetics Management



Medical Device Act

- The Legislative Yuan passed the third reading of the "*Medical Devices Act*" on December 13, 2019.
- The Act with 85 articles were announced on January 15, 2020 under the Presidential Decree.
- Allows medical device "designers" to apply for their own license.
- Establishes a mechanism to give those who develop new medical devises more flexibility with license issuance.
- Adopting the electronic online registration system for some low-risk medical devices.
- Medical device repairers are classified as medical device dealers.
- Implementation of Good Distribution Pardtice (GDP) .

International Cooperation

- Hold the APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop.
- Strive to join the IMDRF Working Group and continue to send staff to participate in the annual meeting.
- Conduct the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation.
- Conduct the Conference on International Medical Device Regulations in South East Asia and Brazil.
- Hosted the Conference on Analytical Techniques for Cosmetics.

Cosmetic Hygiene and Safety Act

- The act was announced by the President on May 2, 2018.
- The date of implementation was also be set on July 1, 2019 by the Executive Yuan, except for the relevant provisions of the information that shall be labeled on outer packaging or containers of cosmetics will be implemented on July 1, 2021.
- Announced 30 sub-regulations and orders in 2019.
- The cosmetics businesses shall establish product information file before the product is introduced on the market.
- Cosmetic manufacturing sites shall comply with GMP for the implementation of quality management.
- The cosmetics manufacturers should employ a pharmacist or a professional cosmetic technical personnel to be stationed in the factory to supervise the production and manufacturing.
- Stipulated the implementation methods of recycling, Establish product source and flow data, and proactive notification system.
- Formulate relevant regulations such as promotional phrases and incentives.

05 Consummated Medical Devices and Cosmetics Management

To improve Taiwan's medical devices and cosmetics management systems and to align domestic laws and regulations with international regulations and standards, the "*Medical Devices Act*" was drafted and the Act has been promulgating according to the Presidential Decree issued on January 15, 2020. Moreover, as the "*Cosmetic Hygiene and Safety Act*" has been promulgate according to the Presidential Decree issued on May 2, 2018, TFDA has completed promulgation of 30 relevant regulations in 2019, marking the beginning of a new era for Taiwan's management of cosmetics. In addition, through active participation in various international organizations, including Asia-Pacific Economic Cooperation (APEC) and the International Medical Device Regulators Forum (IMDRF), TFDA worked to enhance Taiwan's international visibility and influence.

In response to the rapid development of smart medical devices, TFDA announced the "*Guidance for Manufacturers: Cybersecurity for Networked Medical Devices*" with new test and verification methods for smart medical devices to ensure the cybersecurity and quality of smart medical devices. In 2019, several different quality inspection methods on medical devices and cosmetics were revised or added, to comprehensive improve the Taiwan's inspection standards. TFDA also actively conducts the listing and registration management of precision medicine molecular diagnostics laboratories to facilitate the development of precision medicine industry.

Section 1 Improving the Medical Device Act and Relevant Regulations

Introduction of the Policy

With diversifying development of global medical devices and diversified types of products, businesses operation model, and classification management system are different from the pharmaceutical industry; hence, to improve the management of medical devices in Taiwan, it is necessary to stipulate a special medical devices management act to respond to the demands in domestic market and to align with international standards. Moreover, in recent years, with rapid development of smart medical devices with communications technology, it is necessary to establish regulations to govern the management of smart medical devices that suit Taiwan's conditions and help businesses overcome legal obstacles they faced during the product development process and speed up the development process.

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Implementation Strategy

I. Completed the legislation of the "Medical Devices Act"

After years of effort, the Legislative Yuan passed the third reading of the "*Medical Devices Act*" on December 13, 2019 and the Act with 85 articles were announced on January 15, 2020 under the Presidential Decree. The Act allows medical device "designers" to apply for their own license and establishes a mechanism to give those who develop new medical devices more flexibility with license issuance, to encourage all industries to invest in technology research and development. Moreover, the Act has deregulated some low-risk Class I medical devices, so registration and approval of such low-risk medical devices can be complete via online listing, such change enhances classification management of medical devices. In addition, medical device repairers are also classified as medical device dealers. Medical device firms that sell medical devices with certain level of risk are required to provide information regarding the place of origin and flow of products; medical devices firms are also required to manage the storage conditions, transportation and personnel who transport the products, and to follow Guidance for Good Distribution Practice for medical devices. See Figure 5-1 for the key points of the "*Medical Devices Act*."

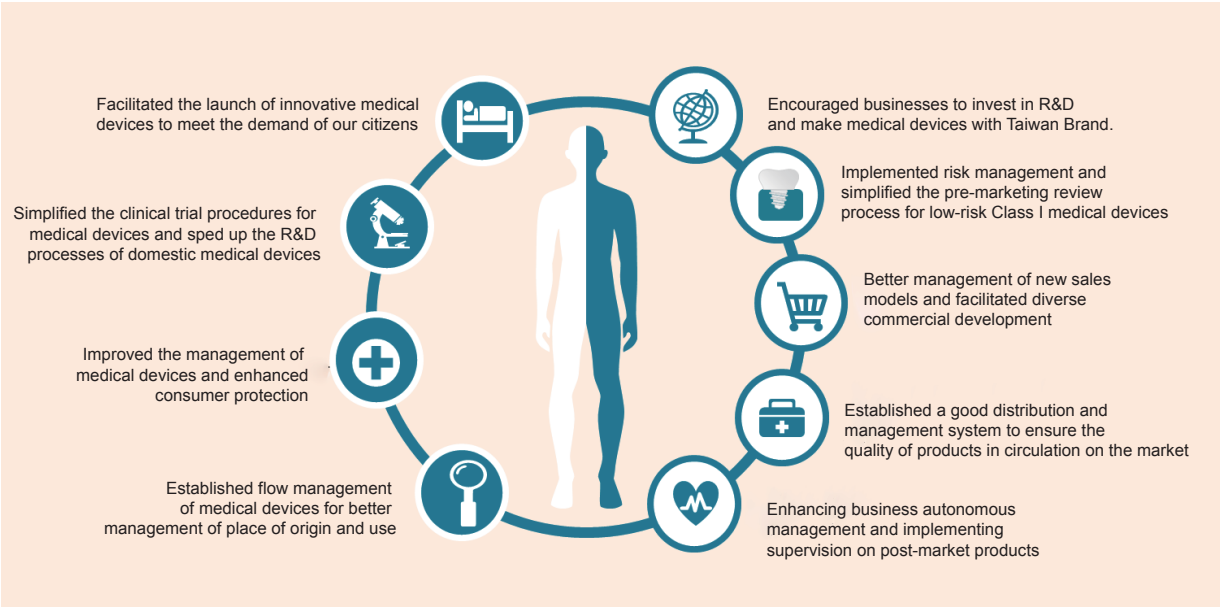

Figure5-1 Key Points of the "*Medical Devices Act*"

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II. Improving the management of smart medical devices to facilitate the development of the industry

"*Guidance for Industry: Cybersecurity for Networked Medical Devices*" was drafted after consolidating guidance and standards of advanced countries and international organizations on cybersecurity of networked medical devices. The Guidance announced on December 15, 2019. For medical device manufacturers, the Guidance provides key points related to cybersecurity for product design, research and development, application of registration and market approval, and post-market considerations. To improve manufacturers' understanding of regulations governing smart medical devices, TFDA invited international experts and organized four information meetings on management regulations governing smart medical devices and pre-market review, with a total about 500 participants(Figure 5-2). TFDA also assisted R&D firms of smart medical devices in Taiwan and provided advice on various issues related to registration and market approval. In total, six firms received such support.

Achievements and Benefits

After the "*Medical Devices Act*" takes effect in Taiwan, it is expected that the Act can help ensure the safety, efficiency, and quality of medical devices used by our citizens. Medical device firms can use the Act as the legal basis for conducting their businesses. The public can have better access to medical devices. In other words, citizens in Taiwan can use medical devices that meet international standards and the Act opens a new chapter for management of medical devices in Taiwan. TFDA announced the "*Guidance for Industry: Cybersecurity for Networked Medical Devices*" to ensure cybersecurity of medical devices. In addition, by improving laws and regulations, speeding up pre-market review, providing consultation and training of talents, at present, two domestically manufactured innovative computer-assisted detection software are now on the market.

Figure5- 2 Workshop on the pre-market review system of smart medical devices from different countries

Section 2 Expand the International Cooperation on Medical Devices

Introduction of the Policy

TFDA has been committed to promoting international cooperation on medical devices over the years and actively participating in international organizations to strive for hosting international conferences and activities, to enhance Taiwan's international participation and influence, as well as to create an internationalized regulatory environment for medical devices. In 2019, the implementation priorities include applying for conducting a pilot workshop of the Regulatory Science Training Center of Excellence (CoE) for medical devices, participating in IMDRF regulatory affairs, promoting the fulfillment of the cooperation framework between Taiwan and Japan on medical products regulation, and strengthening the regulatory communication on medical products with ASEAN countries.

Implementation Strategy

I. Hold the APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop

At the end of 2018, TFDA applied to APEC Life Sciences Innovation Forum's Regulatory Harmonization Steering Committee (APEC LSIF-RHSC) for conducting a pilot workshop of the Regulatory Science Training Center of Excellence (CoE) for medical devices and the application was approved by the RHSC on March 21, 2019. The "2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop" was held from October 22 through 24, 2019 (Figure 5-3), to share principles and experience for evaluating medical device safety and effectiveness with international standards. TFDA also conducted activities such as keynote speeches, group discussions, case studies, and factory visit.

II. Strive to join the IMDRF Working Group and continue to send staff to participate in the annual meeting

The International Medical Device Regulators Forum (IMDRF) is a voluntary international organization consisted of global medical device regulatory agencies. With the approval of IMDRF Management Committee in June 2019 and as a representative of Asian Harmonization Working Party (AHWP), TFDA became a member of the Principles of IVD Medical Devices Classification Working Group to participate in the development of relevant guidance. In addition, TFDA also represented APEC to join IMDRF Management Committee meetings in March and September of 2019 and reported the work progress of APEC during open forum.

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Figure5-3 2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop

III. Conduct the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation

In order to implement the Taiwan and Japan medical products regulation cooperation framework arrangement, the Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Taipei on October 1, 2019. For medical devices, the industry and government representatives of both sides shared regulations on in vitro diagnostic medical devices and priority review mechanism. Several topics were discussed extensively, including guidance on medical device cybersecurity, review focus of in vitro diagnostic medical devices and development trend of products, post-market supervision and regulatory mechanism for high-risk medical devices, and simplified submission for medical device registration.

IV. Conduct the Conference on International Medical Device Regulations in South East Asia and Brazil

The "Conference on International Medical Device Regulations in South East Asia and Brazil" was held at the International Convention Center of National Taiwan University Hospital on August 12, 2019. Representatives from Singapore, Thailand, and Brazil were invited to share their medical device regulations.

Achievements and Benefits

For the APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop, overall satisfaction rate of trainees was 4.7 points (out of 5 points). A total of 41 trainees from the industry and academic sectors of 8 different APEC member economies participated. After the completion of training, trainees are able to assist in promoting the concept of medical device standards to APEC member economies and help achieve the harmonization of regulations. This event also fully demonstrates the regulatory capacity and capability of Taiwan while facilitating the establishment of cooperative agreement and mutual recognition. In addition, TFDA actively participates in annual meetings and working group meetings of IMDRF to help expand Taiwan's global visibility and participation level in important international organizations. And by conducting annual Joint Conference of Taiwan and Japan on Medical Products Regulation, TFDA continues to promote interaction and understanding of regulatory information between both sides, strengthen the collaboration between industry and government, align with international standards, assist the industry to deploy into international markets, and protect the public health and welfare. Years of case review and regulatory communication also enhance the mutual trust between both sides. It is hoped that the product registration process may be accelerated in the future to benefit medical device manufacturers of both sides.

Section 3 Implementation of Cosmetic Hygiene and Safety Act

Introduction of the Policy

In response to the marketing globalization and enhancement of cosmetics management, the "*Cosmetic Hygiene and Safety Act*" was announced by the President on May 2, 2018. The date of implementation was also be set on July 1, 2019 by the Executive Yuan, except for the relevant provisions of the information that shall be labeled on outer packaging or containers of cosmetics will be implemented on July 1, 2021. This new law was stipulated in accordance with the international regulations. It enables to strengthen the management of manufacturing facilities and product full lifecycle as well as to build up a safe environment for high-quality cosmetics and more comprehensively regulate and protect the rights of consumers.

Implementation Strategy

I. With the authorization of the parent law, TFDA announced 30 sub-regulations and orders in 2019. TFDA has conducted about 162 education and training sessions and explanation

sessions for the draft of sub-regulations since 2013 and will continue to conduct more related sessions in the future, to assist the businesses to understand the new laws.

II. TFDA has stipulated the "*Regulations Governing Notification of Cosmetic Products*" with reference to the regulations of the European Union and the ASEAN. Starting from July 1, 2021, the registration and management system for general cosmetics and specific-purpose cosmetics will be implemented in two stages. The "*Regulations for Cosmetic Product Information File Management*" was also stipulated. As it is a new management system, we plan a five-year period to bridge the transformation between the old and new system.

III. The GMP will be implemented by three phases starting from July 1, 2024 to facilitate the implementation of quality management for cosmetic manufacturers, and based on the different cosmetic categories the cosmetic manufacturing sites should follow the relevant GMP regulations including newcomers. In addition, we stipulated the "*Regulations for Qualifications and Training of Cosmetics Professional Technicians,*" to enhance the professional knowledge of cosmetics supervisors to ensure that the product manufacturing processes are under professional supervision and management.

IV. We stipulated the "*Regulations for Cosmetics Recall*" and the "*Regulations Governing the Source and the Flow Data of Cosmetic Products*" to establish the recall management system of cosmetics in Taiwan; we also regulated the cosmetics businesses to establish and maintain data on direct supply sources and destinations of products.

V. To enhance the safety of the cosmetics, we stipulated the "*Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety.*" It is clearly specified and requested that the cosmetics businesses should report to TFDA via the system of the post-market quality management for medicinal products, food, and cosmetics when serious adverse effects of consumers happen under the regular use of cosmetics, or the products may pose hygiene and safety hazard or risks of harm, to provide the accurate information to the health agency to investigate immediately.

VI. To regulate cosmetics advertisements and the declaration of false products, TFDA worked with relevant departments, health bureaus of counties and cities, public associations, and consumer protection associations to stipulate the "*Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products*" with the certification guidelines based on general certification standards supplemented by positive and negative examples; in order to encourage the public and internal employees to report illegal cosmetics circumstances, TFDA has discussed with the health bureaus of counties and cities to stipulated the "*Regulations on Cosmetic Hygiene and Safety Violation Report and Reward.*"

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Achievements and Benefits

I. The implementation of the "*Regulations Governing Notification of Cosmetic Products*" enabled the government and businesses to better control the products on the market and its condition of the distribution. Moreover, since 2024, cosmetic categories that are specified by the central competent authority as per public announcement, the cosmetics businesses shall establish product information file before the product is introduced on the market. After that, it would ascertain hygiene and safety management, strengthen the professional capabilities of the business, facilitate the export of our local products and develop Taiwan's cosmetics industry in the world.

II. Cosmetic manufacturing sites shall comply with GMP for the implementation of quality management, to enable the inspection standards aligning with international standards, to enhance the quality image and competitiveness of Taiwan's cosmetics on the international markets and to facilitate the development of the industry. Other than the announced "Cosmetic Manufacturing Sites that can Be Exempted from Factory Registration," we specify that the cosmetics manufacturers should employ a pharmacist or a professional cosmetic technical personnel to be stationed in the factory to supervise the production and manufacturing; and the professional cosmetic technical personnel should have the relevant professional knowledge to ensure the implementation and in-house supervision of cosmetic preparation and manufacturing meet the cosmetics good manufacturing practices, as well as inspection and guidance of maintenance for cosmetic manufacturing sites, facilities and equipment, to further enhance the safety and hygiene of the cosmetics manufacturing process.

III. If the competent authority finds that the cosmetic businesses violate the regulations or the cosmetics have hygiene and safety hazard, relevant necessary measures may be taken such as ordering the illegal products to be withdrawn from the market, recalling or destroying the products, etc. Furthermore, after the data base of the source and the flow of those products are established, the businesses can promptly notify the upstream and downstream manufacturers to recall the products if the products have hygiene and safety hazard. It enables consumers to avoid contacting the unqualified products, to strengthen the capability to promptly response to the emergencies case, and to clarify the responsibilities of those products.

IV. We continued to conduct the monitoring of user reaction from consumers to ensure the citizen's health and safety and help improve the product formulation in a timely manner as well as discover the unexpected problems.

V. We stipulated the standard regulations for cosmetic products under control of which the labeling, promotion, and advertisement that being involved the deception, exaggeration, or medical efficacy recognition to stabilize the relative rules/regulations review and maintain

the creative promotion of cosmetics promotion as well as take into consideration of the development in the industry; The consumers might give incentive reward for reporting violations of cosmetics or their business operators; the regulations are stipulated to safeguard the health of the citizens in Taiwan and protect the rights and interests of consumers which will be reviewed from time to time for improvement in the future.

Section 4 Improved the Testing Technology and Quality of Medical Devices and Cosmetics in the Laboratory

Introduction of the Policy

Due to the rapid development of modern and new medical devices and cosmetics, there is an urgent need to establish the analytical technology for quality management of various products, to expand the testing items in cosmetics and to develop or optimize the analytical methods for management of domestic products. In addition, we interact and cooperate with countries across the world in order to keep pace with the current global development and to catch up with the future trend in analytical technology. The following were included in the "*Cosmetic Hygiene and Safety Act*" announced on May 2, 2018, the central competent authority may entrust cosmetics and cosmetics business operators to conduct random inspection and conduct certification for the entrusted institutions to enhance business efficiency and ensure the quality and credibility of random inspection.

Implementation Strategy

I. Established testing and verification methods for innovative intelligent medical devices

We established a verification method for patch-type dynamic electrocardiogram monitoring modules and wearable blood oxygen detection systems in 2019, with the collection of relevant testing technology and international standards for wearable measurement devices such as electrocardiography (ECG) and blood oxygen detection system and we referred to the IEC 60601-2-25 and IEC 60601-2-27 standards to establish a electrocardiography functional test method. In addition, we established the functional test methods for blood oxygen sensors by referring to various standards such as FDA Guidance-Mobile Medical Application, ISO 80601-2-61, IEC 60825-1 and the results were published on the Industrial Economics & Knowledge Center (IEK) to strengthen the effectiveness of dissemination.

II. Improved the analytical techniques for medical devices and cosmetics

In 2019, we published 3 recommended test methods including "Method of Identification for Asbestos Fibers in Cosmetics," "Method of Test for Imperatorin, 5-Methoxypsoralen, 8-Methoxypsoralen, 6-Methylcoumarin, Musk Ambrette, Safrole, and Trioxysalen in Cosmetics," and "Method of Test for Residual Cross-linking Agents in Hyaluronic Acid Dermal Fillers – Test of 1,4-Butanediol Diglycidyl Ether". We also revised 2 of the announced recommended test methods such as "Method of Test for Whitening Ingredients in Cosmetics". A total of 5 articles equivalent to 66 testing items in cosmetics and medical devices were stipulated and revised.

III. Hosted the "Conference on Analytical Techniques for Cosmetics"

The "Conference on Analytical Techniques for Cosmetics" (Figure 5-4) was held in 2019 and four foreign experts from Japan, Italy, Malaysia, and India were invited to Taiwan to share the latest cosmetic analytical technology development from their countries. A variety of issues like cosmetics quality monitoring in various countries, illegal adulteration in cosmetics, unexpected residual substances monitoring in cosmetics and new analytical techniques for cosmetics, etc., was widely discussed in the meeting. Six keynote speeches were conducted and nearly 160 representatives form industries, governments, academia and research fields were attracted to participate in the event.

IV. Stipulated "Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions"

After authorization from the "*Cosmetic Hygiene and Safety Act*" and discussion with testing institutions and regulatory experts, TFDA has stipulated the draft of "*Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions*" including six chapters as below. General rules, certification requirements and procedures of

Figure5-4 2019 Conference on Analytical Techniques for Cosmetics

the testing institution, management of certification and testing institutions, the procedures of entrusted certification operations, management of entrusted certification agencies, and annexes, which were officially announced on August 5, 2019 as the basis of conducting related certification of testing institutions.

Achievements and Benefits

By continuously improving the inspection and analysis capabilities in the laboratory, we introduced new analytical technologies to establish test methods and comprehensively improve the analytical techniques and standard to ensure the quality and safety of products. TFDA aggressively facilitated the international interaction of analytical technology, to strengthen the inspection and analysis capabilities to meet the international standards through interaction and sharing of the global progress in analytical technology as well as challenges in the future. In accordance with the "*Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions,*" a total of 15 cosmetic inspection institutions have been certified, with 51 certification inspection items, to strengthen the supervision and management of inspection institutions and ensure the inspection quality.

Section 5 Laboratory Management of Precision Medicine Molecular Testing

Introduction of the Policy

Different from conventional medicine, the precision medicine not only refers to conventional medical information but also information such as the genetic composition, background environment, and lifestyle of an individual or specific group. It is able to stipulate more accurate and personalized plans for disease prevention, diagnosis, and treatment through the comparison and analysis of the human genetic database. In view of the prosperous development of relevant service in medical, TFDA announced the "*Guidance on Laboratory Developed Tests and Services (LDTS) for precision medicine molecular testing*" and conducted the listing management of precision medicine molecular testing laboratory to improve the testing quality.

Implementation Strategy

To conduct the registration management of precision medicine molecular testing laboratory, TFDA invited experts with expertise in pathology, medical inspection and molecular testing to

form a review and inspection team and an auditing team; the related issues such as verification standards and techniques are discussed through meetings and activities such as the expert meetings, inspectors training, and the review and inspection team meeting, to reach a consensus on the inspection standards.

To establish a management mechanism for testing quality, TFDA plans to conduct written inspection and on-site inspections through an inspection team, to verify whether or not the laboratory complies with relevant standards of quality management through the review and inspection team and then it can be registered for management. In addition, the registered laboratories must undergo proficiency tests and periodic inspections and they have to conduct extension of registration every 3 years, so that the laboratories can be continuously monitored for the quality of testing. At the same time, TFDA fully disseminated the related regulations and operating procedures for registration through counseling, consultation, laboratory workshop and seminar.

Achievements and Benefits

I. Stipulated the regulations for registration operations of precision medicine molecular testing laboratory

According to the "*Guidance on Laboratory Developed Tests and Services (LDTS) for precision medicine molecular testing,*" TFDA established the operating regulations in 2019, including the key points for registration management of precision medicine molecular testing laboratory, application instructions, application review, and aperiodic review operation principles; moreover, TFDA conducted 2 expert meetings, 1 inspector training, and 2 review and inspection team meetings, so that the registration review and management mechanism can be more comprehensive with the discussion and opinions in the meeting.

II. Conducted counseling and introduction workshop

As of the end of 2019, TFDA has conducted counseling for 3 laboratories as well as 3 laboratory introduction sessions and 1 seminar, so that the laboratories can have a better understanding of the relevant regulations for registration.

III. Registration operations

We started to accept applications for registration of precision medicine molecular testing laboratories in 2019. Three laboratories have applied for registration. TFDA will continue to conduct the registration operations and to enhance the testing quality of precision medicine molecular testing laboratories.