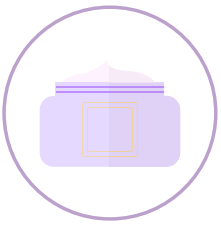
5 Improve Management of Medical Devices and Cosmetics

Enhance the Medical Devices Act and Relevant Regulations

- "*Medical Devices Act*" came into effect on May 1, 2021
- Diversified pre-market review mechanisms
- Strengthen product source and circulation management
- Promote medical devices UDI for better tracking management

Expand the International Exchanges and Collaboration on Medical Device Regulations

- Hold "2021 APEC Medical Devices Regulatory Science Center of Excellence Workshop"
- Actively participate in GHWP and IMDRF in vitro diagnostic (IVD) medical device related activities
- Completion of the signing of the third generation of the "Taiwan-Europe Technical Cooperation Program on Exchange of Medical Device Quality Management System (QMS) Audit Reports" (TCP III)
- Produce Japan-Taiwan Medical Device Cooperation Position Paper and Product Registration Q&A



Optimize the Hygiene and Safety Management of Cosmetics

- Promote cosmetic PIF system by announcing "*Cosmetics Preservative Efficacy Test Guidelines*"
- Amend "List of Ingredients Prohibited in Cosmetic Products"
- Amend "List of Microorganisms Limits in Cosmetic Products"
- Participate in the 15th ICCR
- Promote Cosmetics Good Manufacturing Practice Regulations (GMP)
- Implement the "Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products"

05 Improve Management of Medical Devices and Cosmetics

After years of efforts, the "*Medical Devices Act*", an independent law governing medical devices in Taiwan, came into effect on May 1, 2021. The new Act enables the establishment of a flexible and diversified pre-market review mechanism; strengthens tracking management of medical devices; promotes a number of new management systems, such as the medical device UDI system and tracking management; and builds a full lifecycle management framework and risk management system for medical devices. Starting from July 1, 2021, general toothpaste and mouthwash are regarded as cosmetic products; at the same time, the cosmetic products notification system and new labeling regulations of cosmetics have been implemented, thus signifying the completion of a milestone of the "*Cosmetic Hygiene and Safety Act*". Moreover, TFDA promoted technical cooperation programs for quality management systems between Taiwan and European manufacturers through actively participating in international organizations for medical devices and cosmetics. At the same time, TFDA has announced test and verification methods for medical devices and cosmetics; strengthened the registration management of molecular testing laboratories. TFDA intends to build a safer and high-quality environment for the use of medical devices and cosmetics for a new era in the management of medical devices and cosmetics.

■ Section 1

Enhance the Medical Devices Act and Relevant Regulations

▪ Introduction of the Policy

Globally, product development and categories of medical devices have become more and more diversified. At the same time, business practices, classification and management of medical devices have different requirements than those of pharmaceutical products. The "Medical Devices Act" was thus enacted to improve the management of medical devices in Taiwan. After years of efforts, the Act was promulgated by the President on January 15, 2020, and was officially announced by the Executive Yuan to be implemented on May 1, 2021.

▪ Implementation Strategy

The "*Medical Devices Act*" enables TFDA to offer diversified pre-market review mechanisms in accordance with the management structure and risk management principles of the full lifecycle of medical devices, to implement the classification management of medical devices. Also, considering the characteristics of the medical device industry, medical device repairers are included in the management of medical device dealers. In terms of product circulation and post-marketing medical device safety surveillance and management, the new Act requires that dealers selling medical devices with certain risk classes establish a system to provide information on direct supply sources and the flow of products. Medical device firms are also required to implement the Good Distribution Practice (GDP).

▪ Achievements and Benefits

I. The *Medical Devices Act* takes effect on May 1, 2021

In 2021, TFDA completed the publication of 22 supporting sub-regulations and 16 rules and orders; prepared 25 presentations, QA and guide for dummies; conducted 26 regulation briefings and education and training sessions, and 28 consultation sessions; and revised about 110 applications, forms and administrative documents. In addition, TFDA updated the content related to medical device management and regulations on its official website to ensure that all the new policies can be enforced for the establishment of a full lifecycle medical device management system that is in line with international standards.

II. Establish diversified pre-market review mechanisms

To manage medical devices by classification, the listing system for Class I medical devices was established and announced on April 13, 2021 that a total of 68 items of medical devices should obtain marketing authorization by means of listing. By the end of 2021, 3,303 products were listed in the system. TFDA also established a mechanism to simplify the review process of Class II medical devices with predicate products. On April 28, 2021, TFDA announced that an affidavit can be used to replace the technical documentation of product safety and performance for 8 medical device items. On April 29, 2021, Appendix 3 of "*Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration*" was announced. The Regulations stipulate that 34 items could use "Product Comparison and Declaration of Conformity" to replace the technical documentation of product safety and performance, to simplify the review process and enhance the review efficiency. In addition, the new Act introduces a mechanism to approve the license validity period with more flexibility to accelerate the launch of innovative new medical devices.

III. Strengthen product source and circulation management

To improve regulatory harmonization with Medical Devices-Quality Management Systems-Requirements for Regulatory Purposes published by the International Standard Organization (ISO 13485:2016), on April 14, 2021, TFDA released the "*Medical Device Quality Management System Regulations*". The new regulations emphasize that the concept of risk management should be expanded from the product realization process to all processes within the quality management system. Moreover, on April 13, 2021, TFDA announced the "*Regulations of Medical Device Good Distribution Practice*" to ensure that the quality of medical devices will not be compromised during the transportation and distribution processes to provide the public with high-quality medical devices.

IV. Promote medical devices UDI for better tracking management

TFDA announced the "*Requirements for Indicating the Unique Device Identifier on Medical Device Labels*" on April 6, 2021, stipulating that single packages or the main unit of Class II and Class III medical devices should be labeled with a UDI, along with the timeline and the requirements to upload the information to the UDI Database (UDID). By the end of 2021, the UDID has accumulated 49,702 entries of product data. On April 28, 2021, TFDA announced "Medical Devices that Shall Establish and Maintain Sources and Flow Data", stipulating that for a total of 202 items of Class II and Class III implantable medical devices, their source and flow data should be retained by the medical device firms for reference. On April 28, 2021, TFDA an-

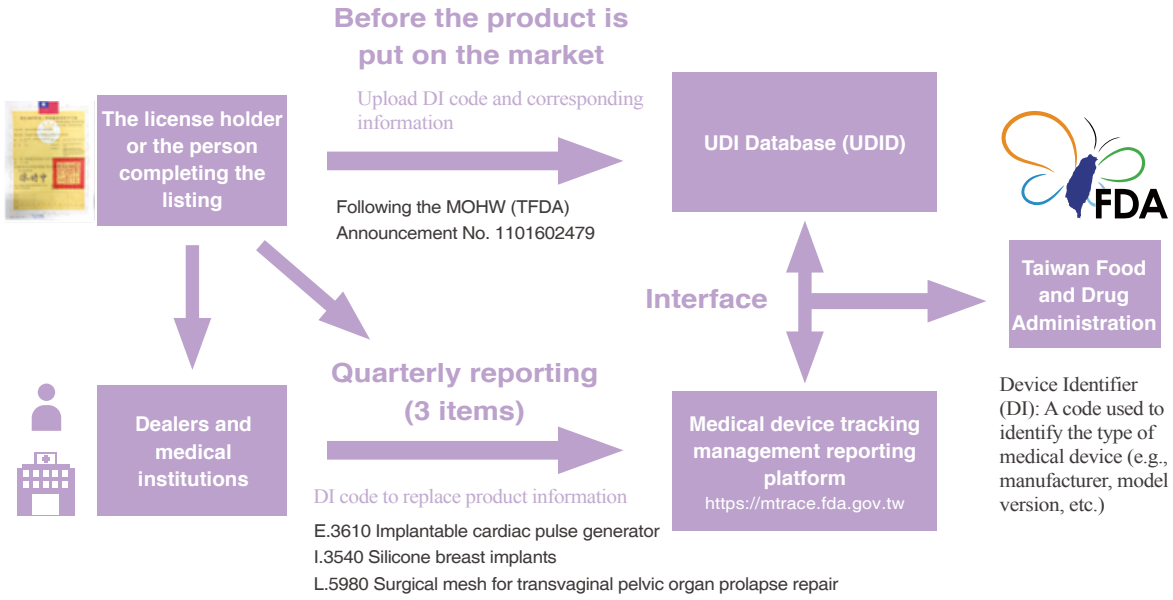


Figure 5-1 Medical Device UDI Registration and Tracking

nounced that 3 items have been included in the "Product Items that Shall Report Sources and Flow Data". By strengthening the application of UDI, TFDA can strengthen its tracking management to ensure the traceability of medical devices, and to better supervise and manage high-risk medical devices.

■ Section 2

Expand the International Exchanges and Collaboration on Medical Device Regulations

▪ Introduction of the Policy

With the development of emerging technologies and rapidly changing international standards and regulations related to medical devices, TFDA has been committed to promoting international cooperation on medical devices and actively participating in international organizations to strive for hosting international conferences and activities in order to enhance Taiwan's international participation and influence, as well as to assist domestic medical device industry in strengthening their international competitiveness.

▪ Implementation Strategy

I. Help to promote harmonization of international medical device regulations by being the APEC RHSC Regulatory Science Training Center of Excellence for medical devices.

TFDA became a formal APEC RHSC Regulatory Science Training Center of Excellence in 2020. The "2021 APEC Medical Devices Regulatory Science Center of Excellence Workshop" was held from August 28 through September 11, 2021, in the form of online courses and meetings to share principles and experience for evaluating medical device safety and effectiveness with international standards. TFDA also arranged keynote speeches, group discussions, case studies, relevant courses and activities.

II. Actively participate in GHWP and IMDRF in vitro diagnostic (IVD) medical device related activities

The Global Harmonization Working Party (GHWP) and International Medical Device Regulators Forum (IMDRF) are currently the world's most important voluntary organizations for the harmonization of international medical device regulations. As the Chair of GHWP Technical Committee's WG2-Premarket: IVDD, TFDA has participated in important meetings of the GHWP and held regular work group discussion meetings. Additionally, as a representative of

the GHWP, TFDA has participated in activities of the IMDRF Working Group on Clinical Evidence for IVD Medical Devices.

III. Promote the third generation of Taiwan-Europe Medical Device Technical Cooperation Program (TCP III)

In response to the revision of EU medical device regulations and come to effect of Taiwan's "*Medical Device Act*" on May 1, 2021, the third generation of Taiwan-Europe Technical Cooperation Program (TCP III) is being promoted to take over the ongoing TCP II in order to integrate international audit resources and advance management effectiveness.

IV. Hold international conferences on medical device regulations

In 2021, TFDA used online meeting method to hold the 9th Joint Conference of Taiwan and Japan on Medical Products Regulation, the Conference on International Medical Device Regulations, and the 2021 Taiwan FDA Medical Device UDI International Virtual Workshop (Figure 5-2).

- Achievements and Benefits

I. Hold "2021 Medical Devices Regulatory Science Center of Excellence Workshop"

For the APEC Medical Devices Regulatory Science Center of Excellence Workshop held in 2021, overall satisfaction rate of trainees reached 4.5 points (out of 5 points). A total of 66 trainees from

Figure 5-2 2021 Taiwan FDA Medical Device UDI International Virtual Workshop

the government, industry, and academic sectors of 14 APEC member economies participated. After the completion of training, trainees would be able to assist in promoting the concept of medical device standards to APEC member economies and help achieve regulatory convergence. This event also fully demonstrates Taiwan's regulatory capacity in medical device review.

II. Strengthen the benefits of participating in GHWP and IMDRF medical device related activities

The GHWP TC WG2 led by Taiwan has over the years produced a total of 15 IVD-related international guidances endorsed by GHWP, and such achievements have been globally recognized. TFDA held the GHWP TC WG1-WG2-WG3 Joint Meeting and WG2 Meeting from August 24 to 25, 2021, on international guidances of medical device emergency use authorization (EUA). By hosting or participating in related activities of the GHWP and IMDRF annual meetings and working group meetings, TFDA has intensified the harmonization of laws and regulations and regional collaboration, increased exchanges between Taiwan and countries of the New Southbound Policy and expanded Taiwan's global visibility and participation level in important international organizations.

III. Completion of the signing of the third generation of the "Taiwan-Europe Technical Cooperation Program on Exchange of Medical Device Quality Management System (QMS) Audit Reports" (TCP III)

After the selection and evaluation process, we completed the signing of TCPIII between 4 TFDA authorized medical device QMS auditing organizations and 6 EU medical device Notified Bodies (NB), which will come into effect on January 1, 2022; thus effectively improve the quality of medical devices and help domestic medical device manufacturers strengthen their international competitiveness.

IV. Produce Japan-Taiwan Medical Device Cooperation Position Paper and Product Registration Q&A

TFDA cooperated with Japan MHLW/PMDA to jointly produce a Japan-Taiwan medical device cooperation position paper and a Question & Answer compilation on product registration which were confirmed by the "9th Joint Conference of Taiwan and Japan on Medical Products Regulation" and published on November 18, 2021, simultaneously on TFDA and Japan PMDA websites in order to speed up the product registration process as well as benefit the medical device industry on both sides. Through holding Japan-Taiwan medical device regulation conferences, understanding of the latest regulatory system of medical devices has also been facilitated for both sides.

■ Section 3

Optimize the Hygiene and Safety Management of Cosmetics

▪ Introduction of the Policy

In order to build a high-quality cosmetics use environment, improve product hygiene and safety, and protect the rights and interests of consumers, TFDA, in accordance with the "*Cosmetic Hygiene and Safety Act*", has implemented the management systems include of bringing general toothpaste and mouthwash into cosmetics management, the cosmetic product notification system, and the new cosmetic labeling regulations. Also, TFDA has kept strengthening the management of manufacturing sites and the life cycle of products and has revised the hygiene standards of cosmetics. Additionally, in view of the active circulation of cosmetics around the world, it is necessary to strengthen exchanges and collaboration with the cosmetics authorities and industry representatives of various countries in order to grasp the latest trends on international cosmetics management and development.

▪ Implementation Strategy

To replace the registration system of specific purpose cosmetics, and accelerate the launch of the products, TFDA has promoted Notification of Cosmetic Products, and the establishment of product information file (PIF), and has provided the access for consumers to search the product information online. In addition, TFDA has promoted that the manufacturing sites must comply with the Cosmetics Good Manufacturing Practice Regulations (GMP), and keeps holding the activities that are related to GMP, so that the manufacturers can meet the requirements before the implementation of each phase to ensure stable production of high-quality cosmetics.

As international cosmetics regulations update frequently, continuing to participate in relevant activities in International Cooperation on Cosmetics Regulation (ICCR), which accelerates the harmonization of regulations and enhances Taiwan cosmetic industry's international competitiveness.

▪ Achievements and Benefits

I. Promote a number of new cosmetic management systems and was implemented since July 1, 2021

(I) The non-medicinal toothpaste and mouthwash products were brought into cosmetics management. The labeling, ingredients, quality, hygiene and safety, and manufacturing sites of the relevant products must comply with the cosmetic management regulations to strengthen product quality, and hygiene and safety.

(II) General cosmetics (except for the solid handmade soap from the factories of the cosmetic manufacturers that are exempt from industry registration)

should complete product notification. This not only conduces to the competent authorities grasping the circulation of cosmetics products in the domestic market, but also allows the consumers using the platform to inquire about product-related information.

(III) The new regulations of the labeling requirements for cosmetic packaging, containers, labels or directions which clearly standardized the arrangement of ingredients orders, the font size of items that should be labeled in Chineses, etc. which facilitates consumers to clearly identify and view product information to protect consumers safety when using cosmetic products.

II. Promote cosmetic PIF system by announcing "*Cosmetics Preservative Efficacy Test Guidelines*"

On May 13, 2021, TFDA announced the "*Guidelines for Cosmetics Preservative Efficacy Test*" for the overall evaluation of cosmetic products protected by the cosmetics preservative system, specifying a series of steps to be taken in evaluating the overall cosmetics preservative efficacy test and evaluation criteria, serving as a reference document for cosmetic manufacturers and importers to establish Product Information File (PIF).

III. Reinforce the hygiene and safety management of cosmetics

On June 17, 2021, TFDA announced the amendment of the "List of Ingredients Prohibited in Cosmetic Products", and on September 7, 2021, to collaborate with the policy of bringing the non-medicinal toothpaste and mouthwash into cosmetics management, TFDA announced the amendment of the "List of Microorganisms Limits in Cosmetic Products"; to reinforce the hygiene and safety management of cosmetics and to protect the health of consumers.

IV. Participate in the 15th ICCR as a full member

TFDA, as a member, participated in the 15th ICCR online annual meeting from June 21 to 23, 2021, to grasp the international cosmetic products development and contribute to Taiwan's cosmetic management system to be in line with international standards.

V. Promote Cosmetics Good Manufacturing Practice Regulations (GMP)

Cosmetics Good Manufacturing Practice Regulations (GMP) will be implemented in phases from July 1, 2024, depending on the product types. To assist the industry in complying with GMP requirements as soon as possible, TFDA has held 15 regulation presentations/seminars and 26 educational training/workshops. From 2020 to 2021, TFDA invited GMP experts to conduct manufacturing sites on-site visits, a total of 255 factory on-site visits and 40 factory on-set counseling visits had conducted, to ensure the high-quality cosmetic products are produced stably.

VI. Cosmetics Advertisements Management

In order to manage cosmetic advertisements, TFDA has implemented the "*Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products*" since July 1, 2019. After the implementation, the cosmetics violation rate has dropped from 2.86% in 2018 to 2.41% in 2021.

■ Section 4

Improve the Testing Technology of Medical Devices and Cosmetics

▪ 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 quality test technology platform for various products, to expand the testing items, and to develop or optimize the analytical methods for the fulfillment of the needs of domestic products management. In addition, through international technology exchange and collaboration, TFDA understands and grasps the current status and trends of testing in the world, comprehensively improves the level of analytical techniques and strengthens research capabilities to be in line with the world's standards.

▪ Implementation Strategy

By continuously improving the laboratory's testing and analysis capabilities, introducing emerging analytical technologies and establishing test methods, TFDA comprehensively improves the level of analytical techniques to ensure the quality and safety of the products. To promote international exchange and collaboration of testing technology, master the current status and trends and obtain the latest international information on substances of concern through exchange and sharing of global progress and future challenges in testing technology enhances Taiwan's testing technology to be in line with international standards.

▪ Achievements and Benefits

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

In view of the aging trend of the population, in 2021, TFDA completed a draft of the proposed method for testing the harmonic distortion rate and equivalent input noise of air conduction medical hearing aid products, which can be used as a reference for domestic

manufacturers' product development and production, as well as TFDA's quality assessment of commercially available products. In 2021, TFDA completed a proposed method draft of "Performance Test for Medical X-ray Imaging of Computer Aided Diagnosis Software", which can be used as a reference for testing laboratories for detecting and verifying the diagnostic software for radiological medical imaging, to ensure the accuracy of the relevant diagnostic results; thus, to enhance the development of the radiological medical imaging industry in Taiwan to keep in line with international standards.

II. Improve medical device and cosmetics analytical techniques

In 2021, TFDA published 3 recommended test methods, namely, "Method of Test for Hair Dyes in Cosmetics (4)", "Method of Test for Nitrosamines in Cosmetics" and "Method of Test for Oxygen Permeability of Contact Lens-Polarographic method", and revised 5 test methods, including "Method of Test for Camphor, Menthol and Methyl Salicylate in Cosmetics". A total of 8 test methods for 77 items of cosmetics and medical devices were stipulated and revised; using national laboratory high end analytical techniques, TFDA continues to refine the analytical techniques, expand the testing capacity, and develop technical documents for reference by all sectors.

III. Host international seminars to promote international exchange of analytical techniques

In 2021, TFDA held two international seminars, i.e., "Workshop on the Analysis and Application of Artificial Intelligence in Medical Imaging" and "Conference on Analytical Techniques for Cosmetics". Twelve experts and scholars from Singapore, Thailand, Switzerland, the United States and Taiwan were invited to share online the development trend of artificial intelligence in medical imaging technology and the latest development of cosmetics analytical techniques in various countries, attracting about 380 representatives from all sectors to enthusiastically participate. A total of 9 keynote speeches were given covering the topics including the verification of artificial intelligence assisted medical diagnostic system, monitoring of impurity residues in cosmetics in various countries, application and risk safety of plant extracts, and detection technology of asbestos in cosmetics, etc.

■ Section 5

Reinforce 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 molecular testing relevant services, TFDA conducted the registration for Laboratory Developed Test and Service (LDTS) for precision medicine molecular testing laboratory to improve the testing quality.

▪ Implementation Strategy

To establish a management mechanism for testing quality, TFDA conducts documental review and on-site inspections through an inspection team and verifies whether or not the laboratory complies with relevant standards of quality management, and then it can be registered for management through the review committee. In addition, the registered laboratories must undergo such regulations as proficiency tests and aperiodic inspections and they have to conduct extension of registration every 3 years, so that the laboratories can be continuously monitored in terms of the quality of testing.

▪ Achievements and Benefits

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

TFDA established the relevant operating regulations for the registration cases of precision medicine molecular testing laboratories and began to perform related tasks in 2019. In order to improve management quality, 1 session of inspector training and 3 sessions of review committee meetings were held in 2021 to continue discussing and collecting opinions. TFDA also linked to the regulations for the laboratory developed tests management amended on February 9, 2021 "*Regulations Governing the Application of Specific Medical Technique and Medical Device*"; to revise service guideline, application direction and other rules to make the registration review and management practices more complete.

II. Improve the follow-up management practices for registration

In 2021, TFDA continued the pilot scheme of the proficiency testing of precision medicine molecular testing laboratory and added multi-gene mutation variant test items. 5 sessions of expert meetings were held to discuss the pilot program and analysis of testing results, and relevant information was collected for policy references. At the same time, TFDA optimized the management information system to manage registration changes, extension, and proficiency testing activities through e-management to improve quality management.

III. Conduct laboratory consultation and industry briefing sessions

As of the end of 2021, TFDA has conducted consultation for 7 laboratories, 1 session of industry briefing, and 2 education sessions, so that the laboratories can have a better understanding of the relevant regulations for registration.

IV. Registration operations

A total of 17 laboratories have applied for registration as yet, and 9 of them have been reviewed and approved, with part of the cases under review according to the procedures. Furthermore, there were 7 applications that were not accepted, mainly because of incomplete information, not eligible in application items or qualifications, etc. TFDA will continue the registration operations to improve the testing quality of precision medicine molecular testing laboratories.