05

Strengthening Medical Device and Cosmetics Management

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With the rapid advancement of medical technology and the cosmetics industry, product quality and safety have become key concerns. TFDA continues to enforce the Medical Devices Act, enhancing pre-market review and post-market surveillance, as well as optimizing electronic submission and review processes to improve administrative efficiency and transparency. In cosmetics management, a product notification system and product information file management have been introduced, alongside the promotion of Good Manufacturing Practices (GMP) for cosmetics, ensuring regulation covers everything from production to market distribution. At the same time, TFDA actively participates in international conferences and collaborations to advance regulatory harmonization and technical exchange, aligning with global standards to establish a trustworthy usage environment—ensuring public confidence and enabling the industry to thrive.

05

Strengthening Medical Device and Cosmetics Management

TFDA continues to promote the implementation of the Medical Devices Act management system by establishing the "Medical Devices Act," issuing various review guidelines, and announcing advanced measures for inspection and registration management. Additionally, the electronic submission and review system for medical devices has been optimized to enhance pre-market management and strengthen post-market surveillance effectiveness. Additionally, starting in July 2024, Taiwan fully implemented the cosmetic product notification system. These new regulations are being rolled out in three phases, covering the Product Information File (PIF) and Good Manufacturing Practice (GMP) guidelines for cosmetics. It establishes comprehensive oversight from the source through production, manufacturing, and distribution, ensuring a safe environment for the use of cosmetic products.

In terms of international cooperation, we actively participate in organizations such as the Asia-Pacific Economic Cooperation (APEC), the International Medical Device Regulators Forum (IMDRF), the Global Harmonization Working Party (GHWP), and the International Cooperation on Cosmetics Regulation (ICCR). We also strive to host international conferences to strengthen our country's international involvement and influence. In addition, testing and verification methods for medical devices and cosmetics have been developed to enhance testing technical standards and ensure the quality and safety of these products.

Section 1 Improving the Medical Device Act and Relevant Regulations

Introduction of the Policy

Medical device products are constantly evolving. To ensure product safety and effectiveness, TFDA actively enhances management efficiency. This includes promoting international harmonization of medical device regulations, announcing pre-market review guidelines, publicizing advanced measures for registration and inspection management, and continuously refining electronic application submission and review systems. Additionally, TFDA consistently improves medical device regulations and support mechanisms to foster the development of innovative and smart medical device products domestically.

Implementation Strategy

1. Continuously Promoting the Adoption of Medical Device Standard

Given the broad scientific scope and complex variety, items, and compositions involved with medical devices, we continuously review and update the “List of Recognized Standards for Medical Devices” This ensures that the adoption of medical device standards continuously advances alongside industry developments and aligns with international management practices.

2. Enhancing Pre-Market Review and Post-Market Surveillance for Medical Devices

Since the "Medical Devices Management Act" came into effect in 2021, we have been developing and publishing preclinical testing standards/ guidelines and announcing advanced measures for related inspection and registration management. This is done to improve our pre-market and post-market practical management of medical devices, taking into account the current state of medical device development in Taiwan, and to provide references for medical device developers. To enhance the resilience of the medical device supply chain, TFDA has established a medical device supply chain monitoring system and announced a list of essential medical device items.

3. Optimizing Electronic Submission and Review System Functions Towards a Digital Medical Device Management System

In 2021, the electronic submission system for medical device registration and inspection was completed and went live in 2022. In 2024, system functions and interfaces for medical device registration, contract manufacturing applications, license changes, and extension cases were optimized to enhance accessibility and efficiency in electronic submission and review processes.

4. Strengthening Industry Regulatory Consultation and Guidance

Domestic electronics and information companies are increasingly entering medical device research and development. However, they often face challenges such as limited understanding of medical device regulations and insufficient communication with clinical practices. These factors can delay product launch timelines and use in clinical settings. Therefore, to promote the development of the Taiwan's medical device industry, TFDA continues to revise our industry consultation and guidance mechanisms, refine the operational efficiency of the

Smart Medical Device Project Office, and provides matchmaking services between industry and hospitals to accelerate the development of innovative medical device products.

Achievements and Benefits

1. Establishing Internationally Aligned Medical Device Standards Management

To promote international harmonization of medical device regulations and assist manufacturers in having clear references during research and development, TFDA has issued 12 announcements between 2004 to 2023. In 2024, we announced the "2024 List of Recognized Standards for Medical Devices." incorporating a total of 1,298 medical device standards.

2. Enhancing Pre-Market Review and Post-Market Surveillance for Medical Devices

For pre-market review, TFDA published advanced measures for inspection and registration management, including the “Issuance, Evaluation, and Management Mechanism for Flexible Expiry Date Permits for Medical Devices” and the “Application Guidelines and Writing Instructions for Predetermined Change Control Plans (PCCP) for Medical Device Software Using Artificial Intelligence/Machine Learning Technologies.” Seven preclinical testing standards and guidelines for medical devices were announced to enhance the consistency and transparency of regulatory reviews.

For post-market surveillance, TFDA announced a list of essential medical device items, strengthening manufacturers’ early notification mechanisms and enabling quicker responses. This stabilizes domestic medical capacity, and improves the resilience of medical device supply chain. Additionally, we've established a single- point of contact for medical device shortage notifications and expanded the online notification function for medical devices on the on the “Drug Supply Management System,” continuously improving the handling mechanisms.

3. Building a Digital Medical Device Management System

By expanding functionalities, improving interfaces, and enhancing the features of the “Medical Device Inspection and Registration Electronic Submission System,” the application scope of the system has been broadened. As of the end of 2024, a total of 4,000 inspection and registration cases have been submitted electronically, significantly reducing paper usage and submission time, while improving the quality and efficiency of medical device submission data.

4. Accelerating the Market Launch of Domestic Emerging Medical Devices and Smart Medical Devices

We provide comprehensive consultation and guidance services to domestic emerging medical device and smart medical device manufacturers. In 2024, TFDA successfully assisted three domestic emerging medical devices in entering the market. To continue supporting the development of Taiwan’s smart medical device industry, TFDA announced revisions to the “Key Points for Project Consultation and Guidance for Domestic Artificial Intelligence/ Machine Learning Medical Devices” in 2024. These amendments enhance consultation and guidance effectiveness, and successfully assisted 10 domestic AI-based medical devices in entering the market.

Section 2 Enhancing Medical Device Manufacturing Quality and Distribution Management

Introduction of the Policy

To ensure robust management of medical devices from their source through distribution management, TFDA continuously enhances the Quality Management System (QMS) and Good Distribution Practice (GDP). This strengthens the comprehensive quality management of medical devices across their lifecycle.

Implementation Strategy

1. Strengthening Medical Device QMS Management

TFDA has established the "Medical Device Quality Management System Regulations" based on the requirements of the International Organization for Standardization's Medical Device Quality Management System standard (ISO 13485:2016). This system integrates quality management across all stages of a product's lifecycle, from design and development, production, storage, distribution, and installation, to service, and finally, product delisting or destruction. Through QMS compliance inspections, TFDA supervises medical device manufacturers to ensure proper implementation of manufacturing quality management.

2. Promoting Medical Device GDP Management

To ensure that the quality of medical devices is maintained throughout the distribution process, TFDA manages medical device distributors who hold product licenses for the announced list (totaling 45 items) and those authorized to import medical devices. Based on the " Regulations of Medical Device Good Distribution Practice" and relevant regulations announced on March 18, 2021, the aforementioned distributors must obtain a distribution license by May 1, 2023. This guides the medical device businesses in implementing quality management throughout their distribution operations.

3. Implementing "Certificate Login Mode" for Medical Device Quality Management Application Platform

Since January 1, 2022, the electronic submission "Medical Device Quality Management Application Platform" has been in use for medical device manufacturing permit inspections. In 2024, a "Certificate Login Mode" was introduced, allowing medical device businesses to log into the application platform using business certificate IC cards, personal certificate IC cards, or National Health Insurance cards, thereby enhancing the cybersecurity protection mechanisms of the electronic platform.

Achievements and Benefits

1. Ensuring Medical Device Manufacturing and Distribution Comply with QMS and GDP Regulations

As of the end of 2024, a total of 7,239 medical device manufacturing licenses have been granted following successful QMS inspections, including 1,175 domestic products and 6,064 imported products. Additionally, 330 distribution permits have been issued after GDP inspections, ensuring the quality of medical device manufacturing and distribution.

2. Strengthening System Cybersecurity and Enhancing Case Management Convenience

The “Medical Device Quality Management Application Platform” has enhanced cybersecurity protection through the implementation of the “Certificate Login Mode,” which prevents the leakage of confidential internal company information due to improper handling of personal data. Additionally, to facilitate case management for businesses, company applications can be managed via business certificates, and authorization can be granted to individual personal certificates or National Health Insurance cards, enabling entrusted handling of cases and improving the convenience of case management.

Section 3 Expanding International Exchange and Cooperation in Medical Device Regulations

Introduction of the Policy

With the rapid development of emerging technologies and the rapid evolution of international standards and regulations for medical devices, TFDA is committed to promoting international cooperation in medical devices. We actively participate in international organizations and strive to host international conferences to enhance our international engagement and influence. This strengthens Taiwan’s international involvement and influence, helping our medical device industry enhance its global competitiveness.

Implementation Strategy

1. Hosting the "2024 APEC Medical Devices Regulatory Science Center of Excellence Workshop"

In 2020, TFDA was designated as a Regulatory Science Training Center of Excellence for Medical Devices. Each year, we cooperate with the APEC Regulatory Harmonization Steering Committee (RHSC) to host related seminars. From August 28 to 30, 2024, TFDA held the "2024 APEC Medical Devices Regulatory Science Center of Excellence Workshop," sharing principles and experiences on assessing the safety and effectiveness of medical devices based on international standards, thereby promoting regulatory harmonization among countries (Figure 5-1).

2. Actively Participating in IMDRF and GHWP Working Group Activities

Taiwan serves as the Chair of the In Vitro Diagnostic Medical Devices Working Group (WG2 – Premarket: IVDD) and the Medical Device Software Working Group (WG3 – Premarket: Software as a Medical Device) within the GHWP Technical Committee. We actively participate in key GHWP plenary meetings and regularly convenes working group discussions, leading the development and revision of guidelines within the organization (Figure 5-2). Additionally, as an associate member of IMDRF, Taiwan has joined four of its working groups focused: Quality Management Systems, Artificial Intelligence/Machine Learning, In Vitro Diagnostic Medical Devices, and Personalized Medical Devices. This allows us to exchange regulatory issues and experiences with medical

Figure 5-1 2024 APEC Medical Devices Regulatory Science Center of Excellence Workshop

Figure 5-2 Joint Meeting of GHWP Technical Committee Working Groups 1, 2, and 3

device regulatory authorities from various countries and provide recommendations on medical device-related guideline content.

3. Ongoing Implementation of the Third-Generation "Taiwan-Europe Medical Device Technical Cooperation Programme" (TCP)

Taiwan initiated the Taiwan-Europe Medical Device Technical Cooperation Programme (TCP) in 2004. Regarding regulatory adjustments on both sides in 2019, Taiwan launched the third-generation Taiwan-Europe TCP (TCP III). Through the exchange of audit report information, TCP III streamlines the review process for manufacturing licenses (QSD) of imported medical devices.

4. Joining the Medical Device Single Audit Program (MDSAP)

On September 25, 2023, TFDA was approved by the Medical Device Single Audit Program (MDSAP) Regulatory Authority Council (RAC) to become an affiliate member. We actively participated in MDSAP relative activities, including the 2024 MDSAP Annual Forum held on June 25–26, 2024, in Essen, Germany. Moving forward, TFDA will refine the recognition measures for MDSAP certificates and audit reports according to regulatory management needs to enhance the effectiveness of manufacturing license inspections.

Achievements and Benefits

1. Promoting Medical Device Regulatory Harmonization in the Asia-Pacific Region

In 2024, the APEC Medical Devices Regulatory Science Center of Excellence Workshop was held, achieving an overall participant satisfaction score of 4.9 out of 5. The training included 47 seed instructors from industry, government, and academia representing 17 countries, among whom were 18 regulatory authority personnel from 14 countries. We anticipate that after completing the training, participants will promote the concepts of medical device standards within APEC member economies, thereby advancing international regulatory harmonization and fully demonstrating Taiwan's professional capabilities in medical device management.

2. Contributing Professional Expertise to GHWP and IMDRF Working Groups

Taiwan has long served as the Chair of the GHWP In Vitro Diagnostic Medical Devices Working Group, actively participating in the organization's operations and decision-making for future development. We also lead the compilation of international guidelines for emerging products, such as the "Management of Artificial Intelligence Analysis Software for Digital Pathology Images," guideline, leveraging Taiwan's strengths in the AI industry. Additionally, during our tenure as Chair of the GHWP Premarket Medical Device Software Working Group, Taiwan has produced or revised one international guideline on medical device software recognized by the GHWP plenary meeting. Furthermore, it is planning to develop three additional medical device software documents covering cybersecurity, post-market changes, and artificial intelligence technologies. Additionally, as an associate member of IMDRF, Taiwan actively participates in IMDRF working group meetings, contributing to the development of guidelines for good machine learning practices and the lifecycle management of artificial intelligence medical device software. These efforts enhance Taiwan's visibility, engagement, and contributions within this important

international organization.

3. Linking Taiwan-Europe Inspection Resources to Support Taiwan-Europe Medical Device Supply

The Taiwan-Europe Technical Cooperation Programme (TCP III) officially came into effect on January 1, 2022. By the end of 2024, 10 EU medical device notified bodies and 4 Taiwan's designated auditing organizations had formally signed the TCP III agreement, becoming cooperative partners in Taiwan's medical device management. Through TCP III, a total of 739 QMS applications had been approved under the streamlined review process by the end of 2024, benefiting medical device supply on both sides.

4. Participating in MDSAP to Align with the International Medical Device Industry

On June 25–26, 2024, TFDA participated in the annual MDSAP forum. During the event, it engaged in discussions and exchanges with regulatory authorities from various countries regarding regulatory management and practical application of MDSAP. This deepened understanding of the rights and benefits of MDSAP participation, helping TFDA continuously optimize related management mechanisms and align with international standards.

Section 4 Promoting Cosmetic Hygiene and Safety Management

Introduction of the Policy

In the past, cosmetics management distinguished between general cosmetics and specific-purpose cosmetics (like hair dyes). This often led to difficulties in identification or misunderstandings that cosmetics possessed specific efficacies. To align with the trend of international regulatory harmonization, starting from July 2024, cosmetics were no longer classified, and the term "specific-purpose cosmetics" was abolished. In coordination with the announcement schedule, the cosmetic product notification system has been implemented, Product Information File (PIF) should be established, and manufacturing sites are required to comply with Good Manufacturing Practice (GMP) for cosmetics, ushering in a new era of management.

Implementation Strategy

1. Implementing New Cosmetics Management Systems, Including Product Notification

The comprehensive cosmetics product notification system is being implemented to enhance transparency of product information and monitor items circulating in the domestic market. The public can search product details through the "Cosmetics Product Notification Platform – Public Inquiry" system. Manufacturers and importers are required to establish product information files and conduct product safety assessments by a safety assessor. Additionally, the Cosmetic Hygiene and Safety Standards have been revised to ensure product safety for consumers.

2. Continued Participation in the International Cooperation on Cosmetics Regulation (ICCR)

Since joining the ICCR in 2016, Taiwan has actively participated in related meetings and topic discussions. Through these engagements, we exchange views on international cosmetics regulatory issues, staying abreast of the latest global cosmetics

management practices and development trends.

3. Promoting Cosmetic Good Manufacturing Practice (GMP)

The "Cosmetic Hygiene and Safety Act" came into effect on July 1, 2019. To reduce the impact on cosmetic manufacturers in complying with Good Manufacturing Practice (GMP) standards, a five-year grace period was granted. Starting July 1, 2024, implementation is being carried out in phases by cosmetic categories, accompanied by on-site inspections to ensure the stable production of high-quality cosmetics.

Achievements and Benefits

1. Strengthening Cosmetics Management Towards a New Era

In line with international trends in cosmetics regulation, in 2024 Taiwan revised the "List of Ingredients Prohibited in Cosmetic Products " and established the " Application for the Review of Documents for the Use of Exosomes from Human Cells in Cosmetics " Additionally, the "List of Ingredients Restricted in Sunscreen Cosmetic Products" and the " List of Ingredients Restricted in Cosmetic Products " were updated. The " Guidance on Risk Assessment of Cosmetics Containing Nanomaterials " were also revised, and the " Table of Scope and Categories of Cosmetics " was amended to include "non-medicinal tooth powder" under cosmetics management.

Additionally, in coordination with the new product notification and PIF systems, on June 26, 2024, TFDA established the “Categories of Cosmetics Required to Complete Product Notification” and the “Categories of Cosmetics Required to Establish Product Information Files and Implementation Dates ” These measures have been implemented in phases starting from July 1 of the same year.

2. Guiding Taiwan’s Cosmetics Industry Toward Internationalization

TFDA served as the rotating chair for ICCR-18, successfully organizing one in-person annual ICCR meeting and eight online quarterly meetings. It actively participated in technical working groups and engaged with regulatory authorities and industry associations from 16 member countries to discuss international cosmetics regulatory trends, ingredient safety assessment principles, and public communication strategies. In July 2024, TFDA hosted the international symposium on “Transformation and Innovation in Cosmetics Industry,” which explored global trends in green and sustainable development within the cosmetics industry. In the future, Taiwan will continue to maintain cooperation with ICCR members and international regulatory authorities to promote the global competitiveness of the country’s cosmetics industry.

3. Enhancing Cosmetic Manufacturers' GMP Compliance

To assist manufacturers in complying with GMP requirements, TFDA has conducted 99 relevant regulatory training sessions by the end of 2024. Additionally, GMP experts provided 991 on-site guidance or inspections at cosmetics manufacturing facilities, assisting businesses review their internal hardware and software infrastructure and offering recommendations for improvement. Furthermore, coinciding with the official implementation of the first phase of cosmetics GMP on July 1, 2024, TFDA conducted 44 on-site inspections during the year to verify compliance with GMP standards

at cosmetics manufacturing sites. TFDA has also continued to organize GMP-related activities to assist manufacturers in meeting GMP requirements.

Section 5 Optimizing Medical Device and Cosmetic Testing Technologies

Introduction of the Policy

With the rapid development of emerging medical devices and cosmetics, it is imperative to establish quality verification technology platforms for various kinds of products, expand testing items, and develop or optimize testing methods to meet domestic product management needs. Moreover, through international technical exchanges and collaboration, we aim to grasp the current status and trends of international testing, comprehensively improve our testing technology standards, and strengthen our research capabilities to align with international practices.

Implementation Strategy

We are continuously improving our laboratory testing and analysis capabilities, introducing emerging testing technologies, and establishing new testing methods. This comprehensively improves our testing technology standards, ensuring product quality and safety. Additionally, we actively participate in regular meetings and technical activities of international organizations, exchanging and sharing advancements in testing technology. This allows us to understand the current status and trends of international testing, acquire the latest information of international concern, and promote the alignment of Taiwan's testing technologies with international standard.

Achievements and Benefits

1. Establishing Testing and Verification Methods for Emerging Smart Medical Devices

In response to the rapid development of artificial intelligence (AI) and machine learning (ML) in medical imaging, in 2024, TFDA completed the collection of domestic and international technical validation data and regulatory standards related to both adaptive and locked algorithm medical imaging models, and post-market change management. One evaluation report was produced, along with an assessment report on the verification process for AI/ML-based software used in magnetic resonance imaging (MRI) medical imaging. These reports serve as reference materials for evaluating software stability.

2. Developing Multiple Cosmetic and Medical Device Testing Methods, Comprehensively Elevating Technical Standards

In 2024, TFDA published four new cosmetic testing methods: "Method of Identification for Perfluoroalkyl Substances in Cosmetics," "Method of Identification for Pesticides in Cosmetics," "Method of Test for the Identification for Forbidden Ingredients in Hair Dye Products," " Method of Test for Colorants in Cosmetics (3)." We also published one medical device testing method: " Methods of Test for Static Bending and Bending Fatigue of Metallic Bone Plates." Additionally, we revised four cosmetic testing methods, including "Method of Test for Heavy Metals in Cosmetics." A total of

nine methods covering 72 testing items were newly established or updated, yielding fruitful results that will help enhance Taiwan's testing capacity and industrial development.

3. Promoting International Exchange in Cosmetic Testing Technology

In 2024, Taiwan continued to participate as an associated member in two regular joint meetings of the "European Committee for Cosmetics and Consumer Health (CD-P-COS)" and the "European Network of Official Cosmetics Control Laboratories (OCCLs)." Discussions focused on expert review progress for joint research on testing methods for nitrosamines and furocoumarins in cosmetics. Taiwan also participated in post-market monitoring result submissions for children's cosmetics and proficiency testing for nail polish analysis. These efforts help deepen collaboration and exchange with European official cosmetics organizations, establish international communication channels and networks, enhance Taiwan's global visibility and influence, and promote the alignment of Taiwan's testing technologies with international standards.

Section 6 National Awards for Pharmaceutical Technology and Research Development

Introduction of the Policy

The National Pharmaceutical Technology and Research Development Award (hereafter referred to as the NPRDA) is jointly organized by the Ministry of Health and Welfare and the Ministry of Economic Affairs in accordance with the "Regulations Governing Incentive Rewards for Research and Development of Pharmaceutical Technology" and the "Regulations Governing Incentive Rewards for Research and Development of Innovative Medical Devices Technology." The award aims to recognize outstanding teams or individuals in the fields of pharmaceuticals, medical devices, and related production and manufacturing technologies, with the goal of advancing the standard of domestic pharmaceutical manufacturing and the quality of clinical trials.

Implementation Strategy

1. Broad Invitation for Pharmaceutical and Related Production Technology Teams to Participate

We produced promotional posters featuring the NPRDA logo and slogan. Promotion efforts were carried out through multiple channels, including the Awards' event website, TFDA's official website, TFDA Drug and Food Safety Weekly, the official TFDA LINE account, TFDA Facebook fan page "TFDA Food & Drug Player," the Ministry of Economic Affairs Industrial Development Administration website, and biotech park shuttle buses. These efforts aimed to actively encourage enthusiastic participation from relevant organizations.

2. Professional Review and Public Recognition

Based on the nature of the research and development products, submissions are categorized into three main types: pharmaceuticals, medical devices, and manufacturing technology. TFDA appointed experts from relevant fields to conduct preliminary and final reviews. Ultimately, recipients of the Gold, Silver, and Bronze Awards were

selected based on their research outcomes, benefits, and contributions. An awards ceremony was held to publicly recognize and encourage the winning entities.

Achievements and Benefits

The call for submissions for the 2024 NPRDA ran from March 19 to July 31, receiving a total of 34 applications. Following preliminary reviews in early August and final reviews in September, 22 entries were shortlisted. The awards ceremony was grandly held on November 19. Minister Tai-Yuan Chiu of the Ministry of Health and Welfare and Deputy Director Pei-Li Chen of the Industrial Development Administration, Ministry of Economic Affairs, delivered encouraging speeches. Videos showcasing the research and development insights of the 22 finalists were played. The ceremony concluded with the presentation of nine awards—Gold, Silver, and Bronze—in three categories: pharmaceuticals, medical devices, and manufacturing technologies (1 Gold, 4 Silver, and 4 Bronze). Representatives from each category shared their acceptance speeches, fully demonstrating Taiwan's innovative R&D strength and fruitful achievements in the pharmaceutical field.

By hosting the NPRDA, we aim to stimulate innovation in pharmaceutical technology, upgrade industries, enhance independent research and development capabilities, and strengthen Taiwan's visibility and competitiveness in the international pharmaceutical field.

Figure 5-3 Group photo of the 2024 National Pharmaceutical Technology and Research Development Award ceremony