Innovation in medical devices and cosmetics: Joining forces with international partners

With the coming of digital technology, medical devices have made rapid advances, and cosmetics are also experiencing robust international circulation across global markets. The medical device industry has always been one of Taiwan's most promising industries. To accelerate the development of innovative medical devices, TFDA has actively established the classified management of medical devices in line with international norms, improved premarketing review and management of medical devices, strengthened management of medical device production and distribution, and expanded international interchange and cooperation concerning medical device laws and regulations. TFDA's cosmetic management work has also adopted an international dimension through monitoring of international cosmetic development, the promotion of good manufacturing practice standards for cosmetics, and the establishment of the cosmetic product information file system. At the same time, TFDA has actively participated in international organizations, established testing and verification methods for emerging smart medical devices, and achieved technical advancements in the testing of cosmetics and medical devices. These efforts have greatly boosted Taiwan's testing capabilities and the industry's development.

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Sound and Effective Management of Medical Devices and Cosmetics

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In conjunction with the continued implementation of various management systems instituted under the *Medical Device Management Act*, TFDA revised medical device inspection and registration management regulations, announced a number of review guidelines, and actively adopted an online case submission and review system, which has served to make premarket management more effective. Responding to advances in technology, TFDA has sought to accelerate the development of innovative medical devices through the revision of medical device classification management regulations, and improvement of regulatory consulting service for industry. In the field of international cooperation, TFDA has actively participated in international organizations, including APEC, the International Medical Device Regulators Forum (IMDRF), the Global Harmonization Working Party (GHWP), and the International Cooperation on Cosmetics Regulation (ICCR), and made vigorous efforts to host major international conferences and activities, which have strengthened Taiwan's degree of international participation and influence. In the area of cosmetic management, TFDA has established an outstanding cosmetic management environment through the continued compilation of cosmetic product information files, and its efforts to ensure that manufacturers comply with GMP and other quality management standards. In addition, we have also drafted many testing and verification methods for medical devices and cosmetics, and broadly improved the testing technology, which has helped ensure the quality and safety of medical devices and cosmetics.

Section 1 Enhancement of Medical Device Management Regulations

Introduction

To ensure product safety and effectiveness at a time of rapidly advancing technology and medical device diversification, TFDA has taken active steps to improve its management performance, including accelerated harmonization with frequency-updated international medical device classification management and premarket review regulations, the active promotion of an online case submission and review system encouraging public applications. Other measures intended to promote the development of innovative and intelligent medical devices in Taiwan have included the continued improvement and optimization of regulations governing innovative medical devices and relevant guidance mechanisms.

Implementation Strategies

1. Improvement of the classified management of medical devices

Since medical devices are based on a large range of scientific fields, involve a bewildering array of types, categories, and components, and their identification and description must be constantly revised and clarified on a rolling basis in response to the state of product usage, TFDA has reviewed and revised the Annex attached to Article 4 of the *Regulations Governing the Classification of Medical Devices*, and ensured that it is in harmony with international management models.

2. Updating medical device premarket review and management

Since it took effect in 2021, the *Medical Device Management Act* has attracted numerous comments and opinions concerning medical device inspection and registration. To put the management of medical devices on a stronger footing, TFDA has revised the *Medical Device Permit Issuance and Registration and Annual Reporting Regulations* in accordance with Article 29 of the Medical Device Management Act. Furthermore, in view of the current state of medical device development in Taiwan, TFDA has also drafted and announced medical device preclinical testing standards/guidelines as a reference for medical device developers.

3. Adoption of an online case submission and review system improving management effectiveness

Responding to international development trends, TFDA established an online medical device inspection and registration case submission system in harmony with the International Medical Device Regulators Forum's (IMDRF) electronic medical device case submission table of content in 2021, and began use of the online case submission system in January 2022. This system allows the developers of Class 2 and 3 medical devices to apply for inspection and registration, outsourced manufacturing, and permit changes, and allows cases to be conveniently submitted and reviewed online.

4. Strengthening regulatory consulting service for industry

While many domestic electronics and information companies are entering the field of medical device development, these firms' knowledge of medical device laws and regulations is often inadequate, and their lack of communication with clinical practitioners frequently delays product marketing. To promote the development of the domestic medical device industry, and accelerate the introduction of innovative medical devices, TFDA has continuously updated its industry consulting and assistance mechanisms, improved

the effectiveness of its smart medical device project office, provided matchmaking service to industry and hospitals.

Achievements and Benefits

1. Establishing a medical device classification system in harmony with international norms

In light of the rapid development of software as a medical device (SaMD), and in reference to international management regulations and the domestic medical device industry's state of development, TFDA announced revised Article 7 and Annex attached to Article 4 of the *Regulations Governing the Classification of Medical Devices* on August 22, 2023. This revision adds 5 new SaMD items to classified management regulations, and revises the names and classification scope of relevant items, which ensures that Taiwan's SaMD classified management model complies with both international norms and the current state of domestic device management. Furthermore, in response to the revised medical face mask/disposable dust mask standards announced by the Bureau of Standards, Metrology and Inspection, Ministry of Economic Affairs, TFDA has required that medical face mask comply with the revised standards, which will boost the safety, effectiveness, and quality of medical face masks.

2. Updating medical device premarket review and management

In order to update and improve the premarket review of medical devices, TFDA announced the revision of certain articles and attached appendices in the *Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration* on November 27, 2023. This revision seeks to put Taiwan's medical device management practice on a stronger footing by adding items that permit-holding product developers may change on their own initiative, and adding Class 2 medical device items eligible for simplified review. TFDA has further announced seven medical device premarket testing standards/guidelines, including the "Technical Standards for SARS-CoV-2 Antigen Test Reagents" and "Technical Standards for Coagulation Function In Vitro Diagnostic Reagents," which will enhance the consistency and transparency of review, while ensuring the safety and effectiveness of medical devices.

3. Establishment of an online management system for medical devices

TFDA has expanded the functions of its online medical device inspection and registration case submission system, improved the user interface and functions, established a system operating consulting hotline, and held education and training sessions and system operation workshops. As of the end of 2023, a total of 2,000 medical device inspection and registration cases had been submitted online. This environmentally-friendly system has greatly reduced paper use, shortened document transmission time, and reduced energy consumption and carbon emissions, while enhancing the quality and effectiveness of medical device case information.

4. Accelerating the marketing of innovative medical devices

TFDA's smart medical device project office provided assistance in 62 application cases for domestically-produced medical devices employing AI/ML technologies in 2023, and successfully helped 11 domestically-produced AI-based medical devices to obtain marketing approval; three of these medical devices were global firsts, namely the "PANCREASaver" AI-assisted pancreatic cancer detection system, HippoScreen Neurotech's Youkeshi stress EEG assessment system, and Huede Healthtech's AI acute kidney injury prediction software. TFDA also held the Smart Medical Device Innovation Cross-

boundary Matchmaking Expo, and conducted three matchmaking panel discussions, which strengthened linkage in the smart medical device industry chain and promoted the formation of inter-industry alliances. Apart from AI/ML–based medical devices, TFDA also successfully helped bring three innovative domestically-produced medical devices to market.

Section 2
Intensifying Management of Medical Device Manufacturing Quality and Distribution

Introduction

To ensure effective management of medical devices at the source and during distribution, TFDA has worked to strengthen medical device quality management systems (QMS) in conjunction with the implementation of the *Medical Device Management Act* on May 1, 2021, and has included medical device good distribution practice (GDP) within the scope of its management efforts, which has ensured quality management of medical devices throughout their full life cycle.

Implementation Strategies

1. Strengthening medical device QMS management

TFDA has established the "Medical Device Quality Management System Regulations" (QMS) to harmonize with the latest international standard for medical device quality management systems (ISO 13485:2016). So that all stages of a medical device are under the control of manufacturers' quality management system, including design and development, production, storage, and distribution, installation, service, decommissioning and disposal. Through QMS compliance inspections, TFDA supervises manufacturers to enforce the implementation of QMS, thus ensure the quality and safety of medical devices into the market.

2. Promotion of medical device GDP management

To ensure that the quality of a medical device is maintained throughout the distribution activities after releasing from the manufacturer to the dealers, TFDA has established the "Regulations of Medical Device Good Distribution Practice" (GDP). The dealers with the license among the announced list in force on 18 March 2021 and those authorized for import shall comply with GDP and obtain a distribution license since 1 May 2023 to ensure that people access to good quality, safe, and effective medical devices.

3. Promotion of online medical device quality management applications

Following of the establishment of the "Medical Device Quality Management Application Platform" by TFDA in 2022, medical device businesses can use this online platform to submit applications for inspection, upload data, and query case processes. TFDA added online certificate application and registration change application functions in 2023 as part of its continuing improvement of the platform's effectiveness.

Achievements and Benefits

1. Ensuring that medical device manufacturing and distribution comply with QMS and GDP standards

As of the end of 2023, a total of 7,036 medical device manufacturing permits had been issued following QMS inspection, and this total included 1,441 domestically production cases and 5,595 import cases. TFDA also issued 291 distribution permits

following GDP inspection. The foregoing permits helped safeguard the quality of medical device manufacturing and distribution.

2. Making QMS review more transparent

TFDA processed 3,204 QMS applications (including 596 domestically-produced items and 2,608 imported items) and 201 GDP applications via its online application platform in 2023. This platform has greatly reduced businesses' need to prepare and transmit paper materials, and will disclose case progress at appropriate times. By boosting manufacturing permit inspection and management synergy, the platform can also help businesses to obtain medical device permits, and therefore achieves a win-win outcome for the public, industry, and medical device management.

Section 3

Expanding International Interchange and Cooperation Concerning Medical Device Regulation

Introduction

In view of the development of emerging technologies and the rapid evolution of international medical device standards and regulations, TFDA seeks to promote international cooperation in the field of medical devices, actively participates in the activities of international organizations, and strives to secure opportunities to host international conferences. We hope that by strengthening our international participation and influence, we will assist the domestic medical device industry to increase its international competitiveness.

Implementation Strategies

1. Holding the 2023 APEC Medical Devices Regulatory Science Center of Excellence Workshop

TFDA became a medical device regulatory science training center of excellence in 2020, and hosts relevant conferences in conjunction with the APEC Regulatory Harmonization Steering Committee (RHSC) on an annual basis. The 2023 APEC Medical Devices Regulatory Science Center of Excellence Workshop, which was held August 29-31, 2023, shared international standards, principles for assessment of the safety and performance of medical devices, and relevant experience, and promoted international regulatory harmonization (Fig. 5-1).

2. Active participation in IMDRF and GHWP working group activities

Taiwan is the chair of the in vitro diagnostic device working group (WG2 - Premarket: IVDD) and SaMD working group (WG3 - Premarket: Software as a Medical Device) of the technical committee of the Global Harmonization Working Party (GHWP), participates in major GHWP conferences, regularly holds working group discussion meetings, and guides the drafting and revision of the organization's guidelines (Fig. 5-2). In addition, TFDA participates in the activities of the International Medical Device Regulators Forum's (IMDRF) artificial intelligence/machine learning-enabled working group in the status of affiliate IMDRF member and representative of the GHWP.

3. Promotion of the third-generation Technical Cooperation Programme

Taiwan initiated the Technical Cooperation Programme (TCP) in 2004. The revised third-generation TCP (TCP III), which corresponds to the renewal of bilateral medical device management

regulations, took effect on January 1, 2022. Through the exchange of audit report information, the TCP has helped to simplify the Conformity Assessment for Foreign Manufacturers of Imported Medical Devices (Quality System Documentation, QSD).

4. Joining the Medical Device Single Audit Program

TFDA has submitted an application for affiliate membership in the Medical Device Single Audit Program (MDSAP) to the MDSAP Regulatory

Figure 5-1 The 2023 APEC Medical Devices Regulatory Science Center of Excellence Workshop

Figure 5-2 Joint Conference of the GHWP Technical Committee's Working Groups 1, 2, and 3

Authority Council (RAC) in June 2023 and received approval on September 25, 2023. TFDA will subsequently assess the application of MDSAP certificates and audit reports, which will streamline the QSD review process.

Achievements and Benefits

1. Continued promotion of the harmonization of medical device regulations in the Asia-Pacific region

Trainees at the 2023 APEC Medical Devices Regulatory Science Center of Excellence Workshop held by TFDA expressed satisfaction scores of 4.8 points (out of 5 points). A total of 36 persons from industry, government, and academia in 13 countries attended this workshop, and the trainees were afterwards able to promote the medical device standard concept to the APEC member economies and assist in regulatory harmonization. This event showcased Taiwan's medical device management expertise and capacity.

2. Contributing professional capabilities to GHWP and IMDRF working groups

While leading working group 2 of GHWP's technical committee, Taiwan drafted or revised 19 international guidelines for in vitro diagnostic medical devices that were accepted by GHWP's general assembly. In addition, after being elected chair of working group 3 of GHWP's technical committee in 2023, Taiwan updated four documents, including the white paper on SaMD guidelines. All of the foregoing accomplishments received extensive international recognition. Furthermore, Taiwan participated in IMDRF's working group meetings in the status of affiliate IMDRF member and representative of the GHWP, during which it assisted in developing superior machine learning guidance documents. This work boosted Taiwan's visibility, participation, and contributions in a major international organization.

3. Linking the audit resources of Taiwan and Europe, facilitating the supply of medical devices

Following the formal implementation of TCP III on January 1, 2022, by the end of 2023, a total of 9 EU Notified Bodies and 4 Taiwan Designated Auditing Organization had formally signed the TCP III agreement and become TCP partners. In addition, the QSD review process was streamlined in 433 cases via TCP III, assisting medical device suppliers from both parties.

4. Participating in MDSAP, building connections with the international medical device industry

TFDA has expanded the application of MDSAP certificates or audit reports in the QSD review process to streamline some of the required review documents. This will promote consistency in regulatory requirements and international standards, and help medical devices companies obtain manufacturing permits.

Section 4

Putting Cosmetic Hygiene and Safety Management on a Sound Footing

Introduction

In view of the fact that the registration regulations for specific purpose cosmetics will cease to apply on July 1, 2024, TFDA has continued to promote the product information file (PIF) system for cosmetics and is strengthening management of manufacturing facilities. Our goals are to establish an optimal environment for cosmetics use, improve cosmetic

hygiene and safety, and protect consumer rights. Furthermore, in light of the lively international trade of cosmetics, TFDA recognizes the importance of the communication and cooperation with the cosmetics competent authorities and industry representatives of other countries to stay current with the latest international development in cosmetic management.

Implementation Strategies

1. Responding to evolving cosmetic management systems and increasing management flexibility

Responding to the discontinuation of the regulations regarding issuance of license for specific purpose cosmetics from July 1, 2024, TFDA announced the revised Article 2 of the *Particulars of Specific Purpose Cosmetics that May Be Voluntarily Modified* on September 6, 2023. This revision allows businesses that have obtained a specific purpose cosmetics license to delete the originally-approved "specific purpose ingredients and their content" field at their own discretion, while specifying that businesses must label the names of all ingredients in accordance with the regulations and must state the content of the specific purpose ingredients alongside the ingredient names.

2. Supporting the establishment of cosmetic product information files (PIF)

TFDA announced the revised "Guideline for Cosmetic Product Information File," "Introduction to Cosmetic Product Information File (PIF)" and "Checklist for Cosmetic Product Information File" on October 2, 2023, which provide examples of different types of cosmetic PIFs for businesses. Furthermore, TFDA continues to provide PIF training courses, workshops, and assistance to businesses for the establishment of PIFs prior to each stage of implementation.

3. Boosting international influence through participation in ICCR

TFDA participated in the 17th annual meeting of the International Cooperation on Cosmetics Regulation (ICCR) held by the Brazilian Health Regulatory Agency (ANVISA) in Brasilia over the period of July 11-13, 2023. This event provided an opportunity to exchange experiences with the competent regulatory authorities and industry association representatives of 15 countries. After July 2023, TFDA assumed the role of the chair for the 18th cycle of the ICCR. TFDA's participation in such organizations can help TFDA keep pace with international development in the cosmetic field, and will accelerate the harmonization of Taiwan's cosmetic management system with regulatory practices around the globe.

4. Promoting of cosmetics GMP

Following the promulgation of the Cosmetic Hygiene and Safety Act on July 1, 2019, TFDA has sought to ease the impact of the requirement of compliance with cosmetics GMP at manufacturing facilities on businesses by providing a 5-year transition period. The implementation will begin in stages according to different cosmetic types from July 1, 2024, and TFDA is actively assisting businesses to achieve compliance, while ensuring the stable production of high-quality cosmetics.

Achievements and Benefits

1. Accelerating the transition to a new management system for specific purpose cosmetics

As of the end of 2023, a total of 13,921 specific purpose cosmetics licenses have been issued. Following the implementation of the new regulations, license holders can modify the originally-approved ingredient labels at their own discretion without acquiring approval, provided that the labeling is in accordance with the "labeling

requirements for cosmetic packaging, containers, labels or directions." This can enable cosmetic businesses to comply with the new regulations efficiently and promptly.

2. Promoting cosmetic PIF system

In 2023, TFDA announced the addition of cosmetic PIF examples for five cosmetic categories: teeth whiteners, antiperspirants/deodorants, skin care products, makeups, and skin cleansers. TFDA also held two PIF training courses for businesses and 16 cosmetic PIF workshops, and provided assistance and conducted on-site visits to 162 businesses for the establishment of PIFs. TFDA's goal is to actively help domestic businesses efficiently navigate the complexities of PIF establishment.

3. Keeping abreast of international regulatory development in cosmetic management

Over the course of 2023, TFDA participated in 6 quarterly meetings of ICCR-17, 9 working group meetings, and attended the ICCR-17 annual meeting. Having assumed the role of the chair for ICCR-18, TFDA hosted 4 quarterly Steering Committee meetings and 4 quarterly Regulator-Industry meetings, and participated in 11 working group meetings. Our participation facilitates the international harmonization of cosmetic regulations, boosting the international competitiveness of Taiwan's cosmetic industry.

4. Improving GMP compliance of cosmetic businesses

To assist cosmetic businesses promptly comply with GMP requirements, TFDA held 77 educational events, including briefings, seminars, training courses, and workshops from 2020 to 2023. TFDA also commissioned GMP experts to provide assistance or make on-site visits to cosmetics manufacturing facilities. A total of 805 such visits were conducted. These efforts have facilitated businesses evaluate in-plant hardware and software equipment, and provided them with strategies for improvement. TFDA is continuing to hold GMP-related activities aimed at assisting specific purpose cosmetics manufacturing facilities to achieve compliance with GMP requirements prior to July 1, 2024.

Section 5

Advancing Medical Device and Cosmetics Testing Technology

Introduction

With the rapid development of new medical devices and cosmetics, there is an extremely urgent need for the establishment of quality verification platforms for various kinds of products categories, the expansion of test items, and development or optimization of testing methods in response to domestic product management needs. Meanwhile, TFDA is also relying on international technological interchange and cooperation to learn about and monitor international testing approaches and trends. TFDA looks forward to improving testing technology standards on a broad scale, while bringing its research capabilities up to an international level.

Implementation Strategies

TFDA has been raising its testing technology standards, which will better ensure product quality and safety, through the continuing improvement of laboratory testing capabilities, adoption of emerging testing technologies, and establishment of new testing methods. Active participation in the regular meetings and technical activities of international organizations to share advances in testing technology has enabled TFDA to keep up with current international testing approaches and trends, obtain the newest international information about substances of concern, and promote the raising of domestic testing technologies to an international level.

Achievements and Benefits

1. Establishing testing and verification methods for emerging smart medical devices

Responding to the need of the post-Covid era, TFDA completed a method draft for stability testing of the dynamic airway pressure accuracy in non-invasive ventilator systems in 2023 to ensure the quality and safety of ventilators. Furthermore, in view of the rapid development of artificial intelligence/machine learning in the medical imaging industry, a rolling revision of two method drafts for the stability testing of computer-aided diagnostic software used in X-ray and ultrasound medical imaging has been completed in 2023 to ensure the accuracy of relevant diagnostic results.

2. Upgrading cosmetics and medical device testing technologies

In 2023, TFDA published three recommended testing methods, namely the "Method of Test for Aromatic Amines in Hair Dyes," the "Method of Test for Prostaglandin Analogs in Cosmetics," and the "Static Destructive Test and Dynamic Loading Test for Endosseous Dental Implants," and revised two testing methods for cosmetics, including the "Method of Test for Hair Dyes in Cosmetics" and the "Method of Test for Hair Dyes in Cosmetics (3). " During a highly productive 2023, TFDA completed the publication or revision of a total of 5 testing methods for 123 testing items. TFDA continued to use emerging technologies to advance testing technologies and establish new testing methods, and is drafting technical documents for reference by all users. This work is facilitating the upgrading of Taiwan's testing capabilities and boosting the industry's development.

3. Promoting international interchange in cosmetics testing technology

In 2023, TFDA 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 Network of Official Cosmetics Control Laboratories (OCCLs), discussing the progress of the co-establishment of testing methods for nitrosamines and furocoumarins in cosmetics, and presenting TFDA's achievements in the development of the testing method for the detection of per- and polyfluorinated alkyl substances (PFASs) in cosmetics and its applicability to the commercially available products. Through proactive involvement in events of international organizations, TFDA strengthens the collaboration and interaction with official EU cosmetics organizations, establishes channels and connections for international communications, enhances Taiwan's international visibility and influences, and promotes testing technologies for cosmetics in our country to be in line with international levels.