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Taiwan Food and Drug Administration

2024 Annual Report

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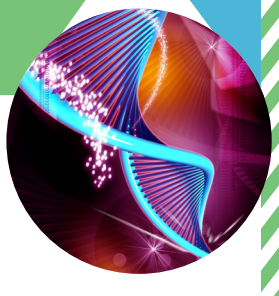

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2024 Director-General's Foreword

The Director Preface

For the sake of people's health and quality of life, Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA) has remained dedicated to its mission of "Safe and effective medicinal products, safe and healthy food." TFDA not only supervises and manages products in the four major categories of foods, pharmaceuticals, medical devices, and cosmetics, but also ensures their safety and effectiveness, and continues to promote important relevant policies and regulations. By advancing food and drug safety improvement plans and safeguarding the safety and quality of food, drugs, medical devices, and cosmetics, TFDA is an important promoter of people's health and well-being. To record its important policies and administrative accomplishments, TFDA publishes annual reports summarizing the achievements of the previous year's major policies, plans, and administrative efforts, which provide a reference for domestic and foreign readers.

Covid-19 restrictions were gradually lifted in 2023. While the Covid pandemic caused incalculable harm, it also increased the public's attention and sensitivity to health and safety. Responding to needs of the post-pandemic era, TFDA has continued to assiduously safeguard the sanitation, safety, and quality of foods, medicinal products, medical devices, and cosmetics throughout each stage of the product life cycle. TFDA also utilizes AI technology to enhance control of products at customs, monitor product distribution, inspection and consulting assistance to create a reassuring consumer environment. In addition, TFDA provides a high-quality network of consultation services and adjustable review mechanisms to protect the public's right to effective medication. We also strive to harmonize regulations with their international counterparts, are working to develop smart food and drug testing and inspection techniques, and use innovative communication strategies to provide citizens more correct knowledge concerning food, drugs, medical devices, and cosmetic safety.

In the area of food safety management, TFDA has actively gathered and consulted international food management standards and techniques, performed the rolling review and revision of regulations associated with the *Act Governing Food Safety and Sanitation*, and developed new food testing methods. At the same time, we have instituted horizontal and vertical communication and cooperation mechanisms with local and central authorities to facilitate border inspections, food audits, and aftermarket monitoring and testing. Furthermore, we apply big data analysis to boost the effectiveness of risk management and warning detection, which safeguards the hygiene, safety, and quality of food.

In the area of pharmaceutical management, TFDA actively participates in international activities, and stays abreast of pharmaceutical review and inspection trends. We have implemented a patent linkage system, are continuously updating regulations and standards in light of the domestic pharmaceutical industry's state of development, and are steadily improving Taiwan's pharmaceutical management regulatory environment. We have announced the *Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief*. We are steadily improving pharmaceutical quality testing methods, ensuring that pharmaceutical manufacturers comply with GMP Regulations, and implement pharmaceutical businesses to obtain pharmaceutical GDP distribution permits; as of the end of 2023, a cumulative total of 1,010 firms had obtained such permits, ensuring that the public can obtain safe, high-quality medications.

Responding to drug abuse detection and control needs, TFDA has added new items to the list of controlled drugs and active pharmaceutical ingredients (APIs), established drug abuse monitoring mechanisms, and engaged in technology sharing with investigative and interdiction agencies. As a participant in joint efforts to prevent drug abuse, we are working in collaboration with Non-Governmental organizations (NGOs), indigenous communities, online media, and other ministries to conduct drug abuse prevent education. We held 382 of the "Fun in Preventing Drug Abuse" touring awareness sessions in 2023, in which we cooperated with 11 private organizations to prevent drug abuse through fun educational activities.

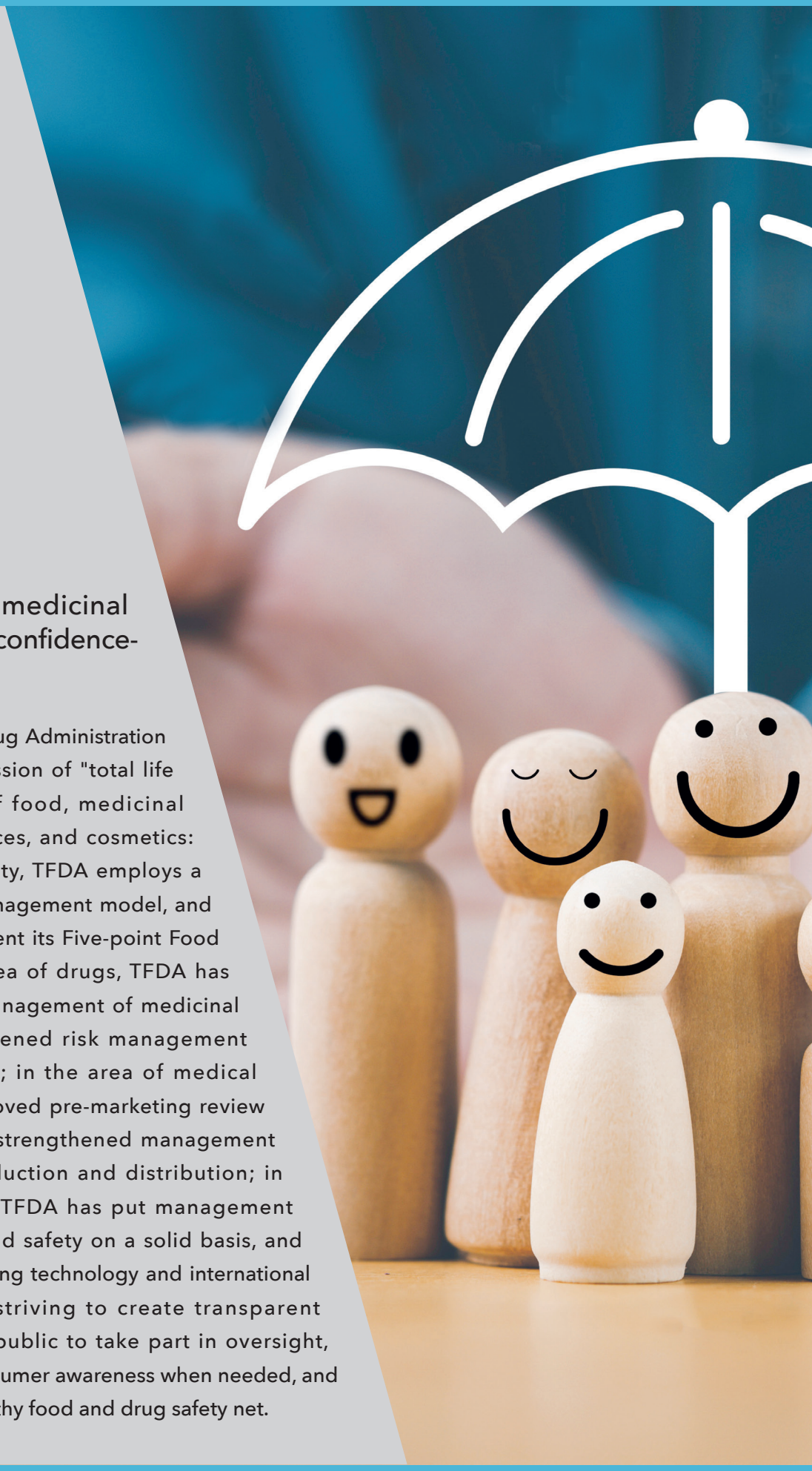
In the area of medical device management, we established classified management regulations consistent with international norms, strengthened medical device pre-marketing review and management, and expanded the functions of the medical device digital management system. This has accelerated the marketing of innovative and intelligent medical devices, and we are also ensuring that the manufacture and distribution of medical devices complies with quality management system (QMS) and GDP standards. We have made the QMS review process more transparent, which has yielded a win-win outcome for the public, industry, and medical device management. TFDA actively participates in the conferences of international organizations, promotes the harmonization of medical device regulations in the Asia-Pacific region. Participation in the Medical Device Single Audit Program (MDSAP) and the establishment of the Technical Cooperation Program (TCP) with the EU help promote greater alignment of audit resources, streamlining the review of regulatory requirements. This has boosted the international competitiveness of Taiwan's medical device industry.

In the area of cosmetic management, to respond to changes in the cosmetic management system and increase management flexibility, TFDA has accelerated the implementation of the new management system for specific purpose cosmetics, and is promoting the use of the product information file (PIF) system for cosmetic products. We are also continuing to hold GMP-related activities intended to help manufacturers of specific purpose cosmetics meet GMP requirements as quickly as possible after July 1, 2024. Our active participation in the activities of international organizations has facilitated the exchange of cosmetics testing technologies, and enabled TFDA to stay current with international trends in cosmetic management.

TFDA had numerous international breakthroughs and successes in 2023, including the following notable achievements: TFDA became an affiliate member of the International Medical Device Regulators Forum (IMDRF), and is continuing to share its management system knowledge and methods through IMDRF participation; Taiwan was successfully included on the list of third countries able to export active pharmaceutical ingredients (APIs) to the EU, which will shorten the time needed to apply for the export of APIs to Europe; TFDA cooperated with the Asia-Pacific Self-medication Industry (APSMI) Association in holding an international pharmaceutical conference, which promoted friendly interchange with other countries. These positive results are continuing to broaden and deepen Taiwan's international influence and industrial competitiveness.

TFDA bears a crucial public mission as the trusted guardian of food and drug safety. We consistently uphold our sacred duty to maintain people's health in our management of food, drugs, medical devices, and cosmetics.We rely on forward-thinking perspectives to constantly improve ourselves and prepare ourselves to tackle future challenges. At the same time, we also organize resources from different sectors and cooperate with international partners to establish a comprehensive safety network. We are striving to upgrade our testing technology, strengthen source management, and maintain effective supervision to ensure the safety and quality of food, drugs, medical devices, and cosmetics. TFDA will continue to take determined steps to create a safe consumer environment for food, drugs, medical devices, and cosmetics, and to protect the public's health and safety.

Director-General, Taiwan Food and Drug Administration, Ministry of Health and Welfare



Safe and effective medicinal products, safe and confidence-inspiring food

The Taiwan Food and Drug Administration (TFDA) has the core mission of "total life cycle management" of food, medicinal products, medical devices, and cosmetics: In the area of food safety, TFDA employs a "farm-to-table" food management model, and is continuing to implement its Five-point Food Safety Policy; in the area of drugs, TFDA has improved the digital management of medicinal products, and strengthened risk management for medicinal products; in the area of medical devices, TFDA has improved pre-marketing review and management, and strengthened management of medical device production and distribution; in the field of cosmetics, TFDA has put management of cosmetics hygiene and safety on a solid basis, and promoted cosmetics testing technology and international interchange. TFDA is striving to create transparent platforms, inviting the public to take part in oversight, providing intensified consumer awareness when needed, and jointly creating a trustworthy food and drug safety net.

01

Organization and Policies

01

Organization and Policies

The Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA) was founded on July 23, 2013 in conjunction with the organizational reform of the Executive Yuan. In keeping with the Ministry of Health and Welfare's commitment to the health and well-being of the public, TFDA takes "Safe and effective medicinal products, safe and healthy food" as its mission, and has "Being a reliable guardian of food and medicinal product safety, creating a safe food and medicinal consumer environment" as its vision (Fig. 1-1). Upholding its core value of "total life cycle management" of foods, medicinal products, and cosmetics, TFDA has relied on source, production, and distribution management to establish a comprehensive safety management system for food and drugs, and ensure the safety and quality of food, drugs, medical devices, and cosmetics.

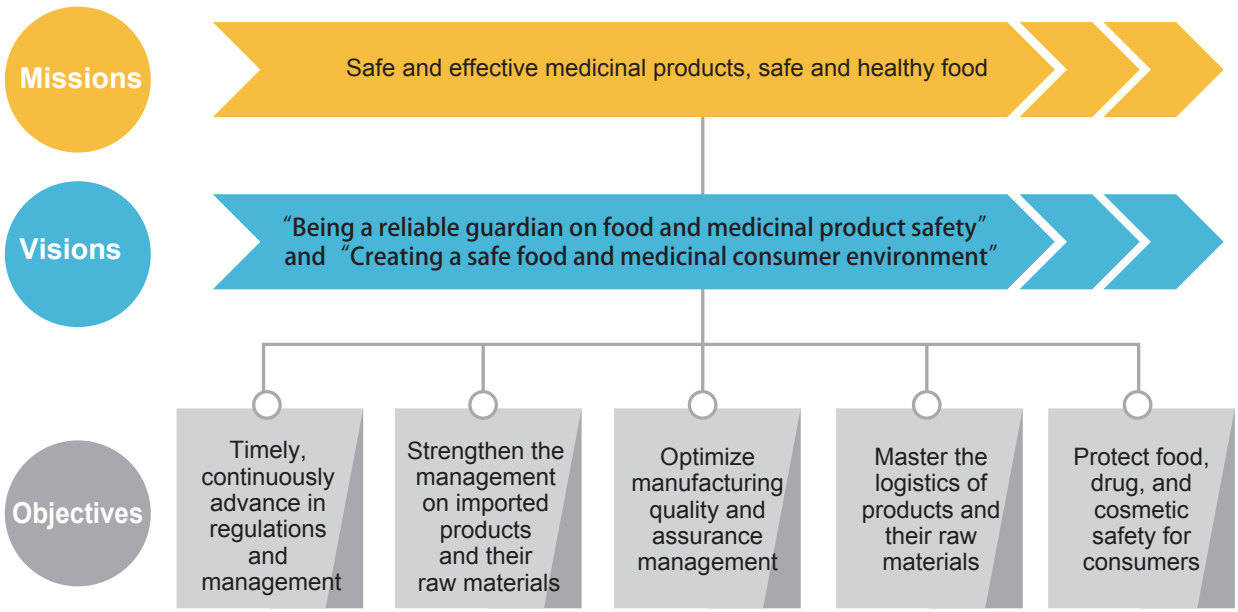


Figure 1-1 Missions and Visions of TFDA

Section 1 Organizational Framework

Led by the Director-General, TFDA's organization comprises two deputy director-generals, one Chief Secretary, and seven business divisions, which include the Division of Planning and Research Development, which is responsible for planning and management, technical project management, international cooperation, communication, legal affairs, and consumer protection; the Division of Food Safety, Division of Medicinal Products, Division of Medical Devices and Cosmetics, and Division of Controlled Drugs, which are responsible for the drafting of management policies and regulations addressing their managed products; the Division of Research and Analysis, which is responsible for the testing of foods, medicinal products, and cosmetics, the development and evaluation of methodologies, and the editing and compilation of pharmacopeias; and the Division of Quality Compliance and Management, which is responsible for the management and inspection of the manufacture of medicinal products, medical device, and cosmetics, laboratory management and certification, inspection of human organ banks, and verification of secondary food.

TFDA has designated three district centers (North, Central, and South), which are responsible for laboratory testing of imported foods, medicinal products, and cosmetics, and distribution audits and inspections. Apart from the business divisions, to assist in administration, TFDA has also established five administrative units, which consist of the Secretarial Office, HR Office, Civil Service Ethics Office, Accounting and Statistics Office, and IT Office, and two task groups, namely the Factory for Controlled Drugs and Decision Support Center. Lastly, TFDA provides professional information and assistance through professional consulting units such as the Center for Drug Evaluation and the Taiwan Drug Relief Foundation (Fig. 1-2).

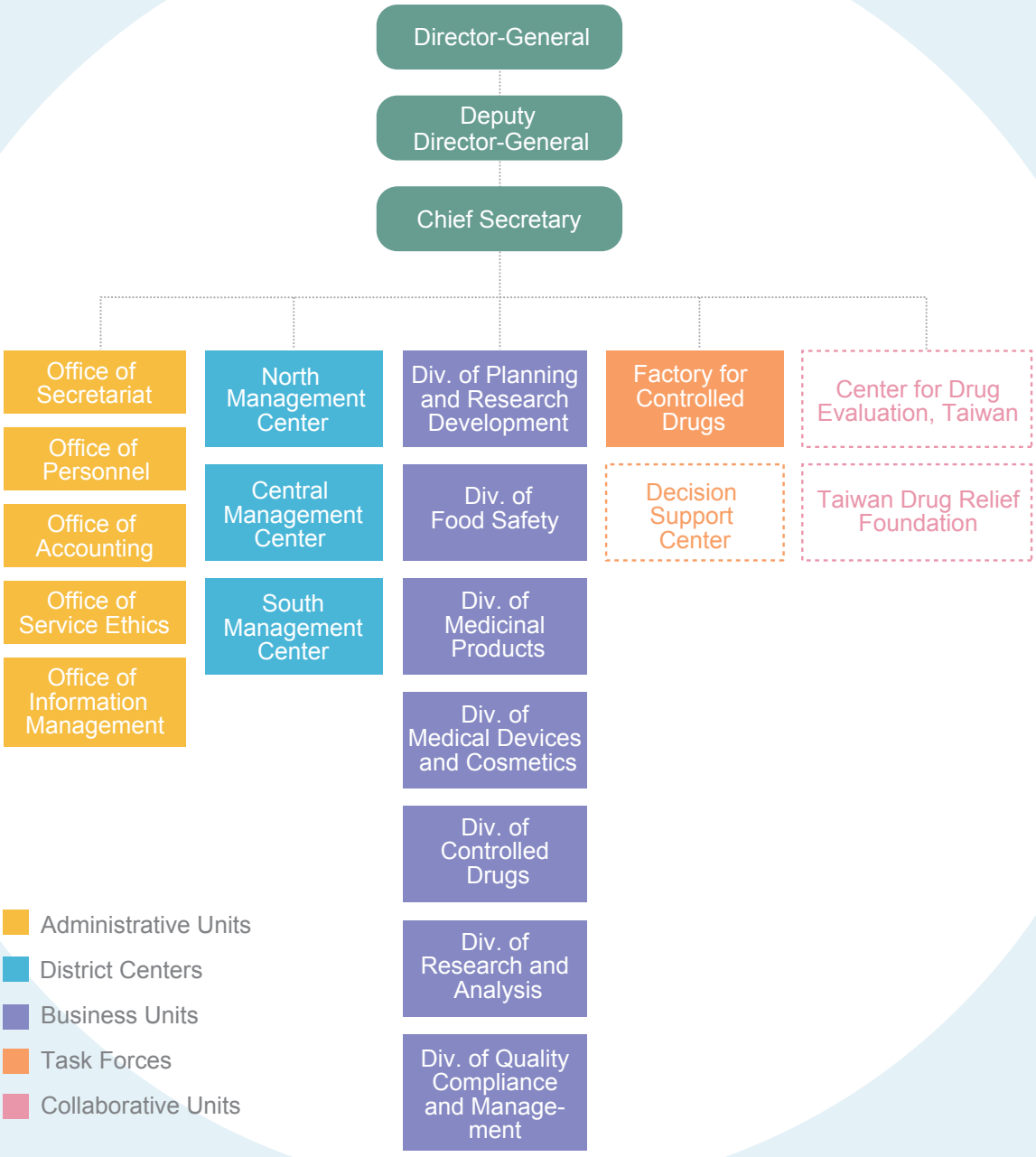


Figure 1-2 The Organizational Chart

Section 2
Administrative Goals

TFDA sets the following administrative goals in conjunction with the Executive Yuan's administrative plan, along with its annual budget to reflect development highlight and meet social needs on current food, medicinal product, medical device, and cosmetic management and development focal points:

1. Creation of consumer environment, by ensuring the food production and distribution networks and the sanitation, safety, and quality of medicinal products, medical devices, and cosmetics throughout each stage of the product life cycle, and use of smart technology to improve product border control, distribution monitoring, inspection and consulting assistance.
2. Safeguarding the public's right to medication through the provision of a highly-effective product consulting network and flexible review mechanisms; enhancement of the supply resilience of medicinal products and medical devices and ensuring effective dispatching capabilities; monitoring of supply shortage reports; and strengthening of oversight of quality and safety.
3. Strengthening harmonization with international laws and regulations; use of intelligent food and drug inspection and testing technologies; promoting innovative food, drug, and cosmetic safety communication strategies to ensure that citizens have a correct understanding of relevant issues.

Section 3
Overview of Food Management

Food safety is closely connected with human health. With global trade liberalization, rapid technological progress, and a host of emerging food safety issues, food management has had to adapt to an increasingly diversified, novel, and informatized operating environment. TFDA has adopted a "farm-to-table" full life cycle management concept and risk-based food management model, and is also strengthening autonomous management at businesses, as it works to ensure the health and safety of food at every stage of the process from raw materials to production to distribution to sale. TFDA has further stepped up implementation of its "Five-point Food Safety policy" (Fig. 1-3), which seeks to create an effective food safety protection network through government management, industry self-discipline, and public participation.

We are actively gathering and referring to international food management regulations and technologies, and reviewing and revising food health and safety management laws and regulations connected with the Act Governing Food Safety and Sanitation on a rolling basis. We are also developing testing methods for emerging foods, and realizing horizontal and vertical communication and cooperation mechanisms between central and local governments for the purpose of border inspection, special food audits, and post-marketing monitoring. Other actions include use of big data to improve risk management and early warning effectiveness, as part of our efforts to ensure the healthfulness, safety, and quality of food.

Section 4
Overview of Management of Medicinal Products and Controlled Drugs

1. The medicinal products management framework

Good manufacturing processes must be followed throughout the life cycle of medicinal products, which includes the stages of product development, preclinical

Figure 1-3 Five-Point Food Safety Policy

studies, clinical trials, marketing authorization application, production/manufacturing, and post-marketing. Unlike most ordinary products, medicinal products can only be sold on the market after having obtained marketing authorization issued by the central health competent authority. TFDA is continuing to strengthen its quality management policy throughout the full life cycle of medicinal products (Fig. 1-4) through harmonization with international regulations, establishment of various mechanisms for priority review, digital management of medicinal products, standardization of quality and safety supervision, investigation and elimination of illegal drugs, and management of pharmaceutical vendors and product distribution. These measures aim to ensure that people in need have access to safe, effective, high-quality medicines, facilitate the development of Taiwan's biotech and pharmaceutical industry, and thereby create a win-win situation among consumers, industry, and the government.

2. The management framework of controlled drugs

Controlled drugs refer to addictive narcotic drugs, psychotropic drugs, and other drugs requiring regulation, and that may only be used for medical and scientific purposes. If controlled drugs are used improperly or illegally, they may easily cause health hazards.

In accordance with the *Controlled Drugs Act*, controlled drugs are classified into four schedules by their potential for habitual use, dependence abuse, and danger to the society. The source management of various types of users (such as institutions, businesses, physicians, dentists, veterinarians, veterinary assistants, and approved medical or educational

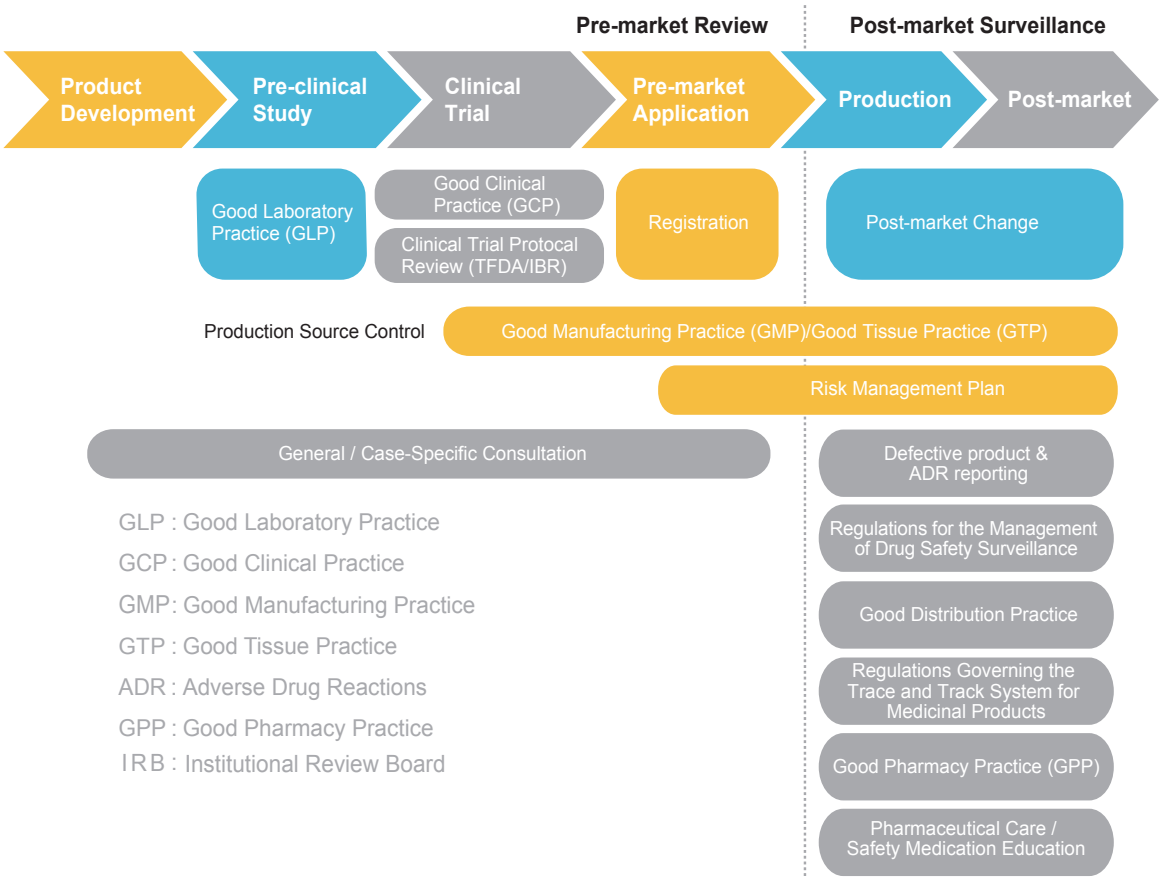


Figure 1-4 Full Life-cycle Management Structure for Medicinal Products

researchers) is conducted through certifications such as controlled drugs registration certificates, controlled drugs prescription licenses, and permit for exporting, importing, and manufacturing. Furthermore, to prevent the unapproved use or abuse of controlled drugs, TFDA has also stepped up flow management by requiring users to record the increase and decrease of stocks and the inventory amount, which must be reported. The management framework of controlled drugs is shown in Fig.1-5.

Section 5

Overview of Medical Device and Cosmetic Management

1. The medical device management framework

With the advancement of technology and increasing demand for high-tech medical and healthcare applications, the medical device industry has become one of the most promising biotech industry areas in Taiwan. In response to the thriving development of the domestic medical device industry, TFDA has established a full product life cycle management system for medical devices (Fig. 1-6). This system encompasses such aspects as the internationalization of regulation and management, source control at the production stage, pre-market inspections, post-market monitoring, and management of medical devices dealers and product distribution. This system can effectively ensure the safety, effectiveness, and quality of medical devices, while

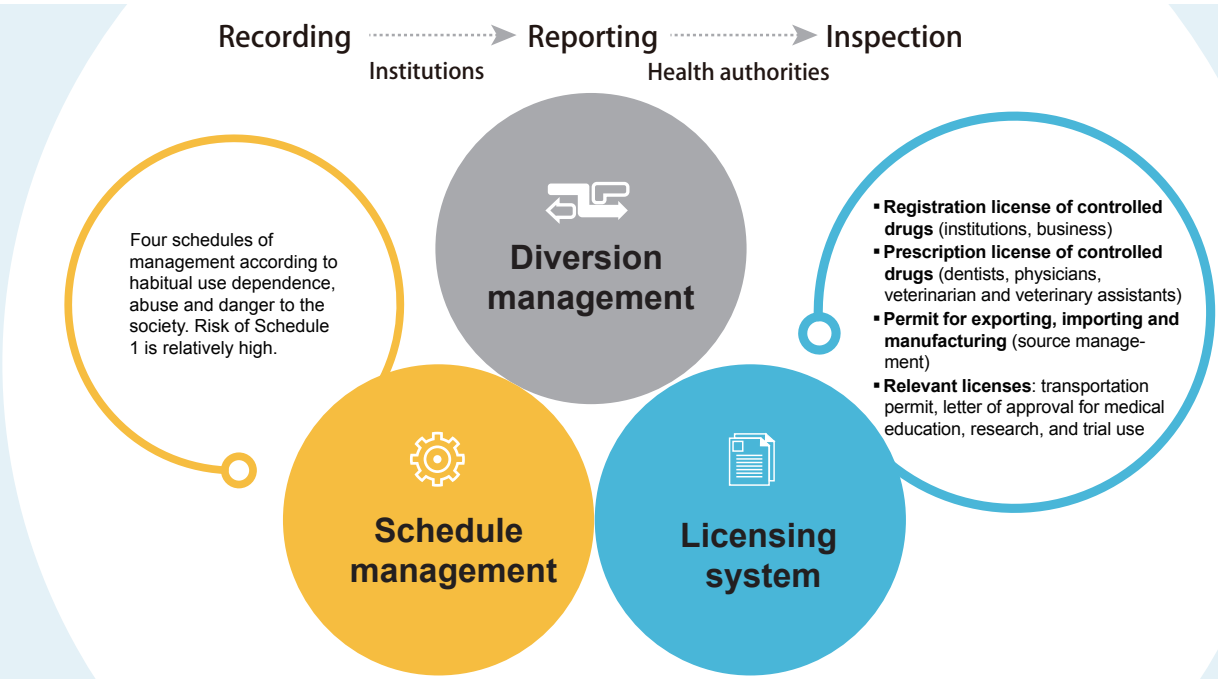


Figure 1-5 Management Framework of Controlled Drugs

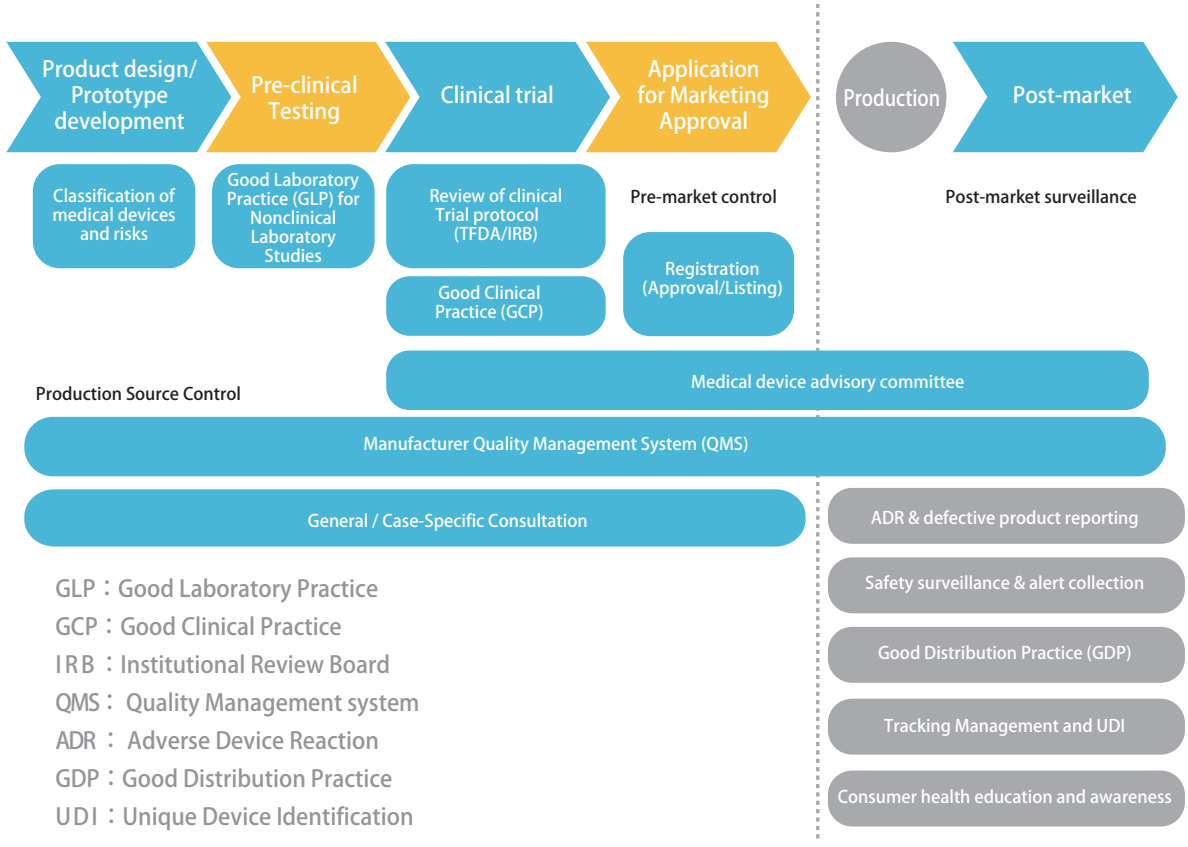


Figure 1-6 Total Product Life Cycle Management System for Medical Devices

facilitating the development of the domestic biotech and pharmaceutical industry, and yielding a win-win outcome for consumers, the industry, and government.

2. The cosmetic management framework

The cosmetic management framework consists of the three aspects of source control during production, pre-market management and post-market supervision (Fig. 1-7). Source control during production includes ensuring that manufacturers meet the establishment standards for cosmetic manufactory and promoting compliance with the cosmetic Good Manufacturing Practices (GMP); pre-market management includes product notification and the establishment of product information files, which will replace the registration system for specific-purpose cosmetics; and post-market supervision includes quality supervision, inter-county/city joint inspections, the establishment of adverse event reporting system for cosmetic products which regularly monitors domestic and overseas safety alerts, and the promotion of consumer awareness regarding the safe use of cosmetics, in order to establish a comprehensive network dedicated to protecting the safety and quality of cosmetics.

Section 6 Future Outlook

With the development of novel substances and in the wake of emerging technologies and chemicals, the management of the healthfulness and safety of foods and medicinal products is growing increasingly more complex. By integrating the efforts of various agencies, enlisting the support of industry, and expanding public participation, TFDA is constructing

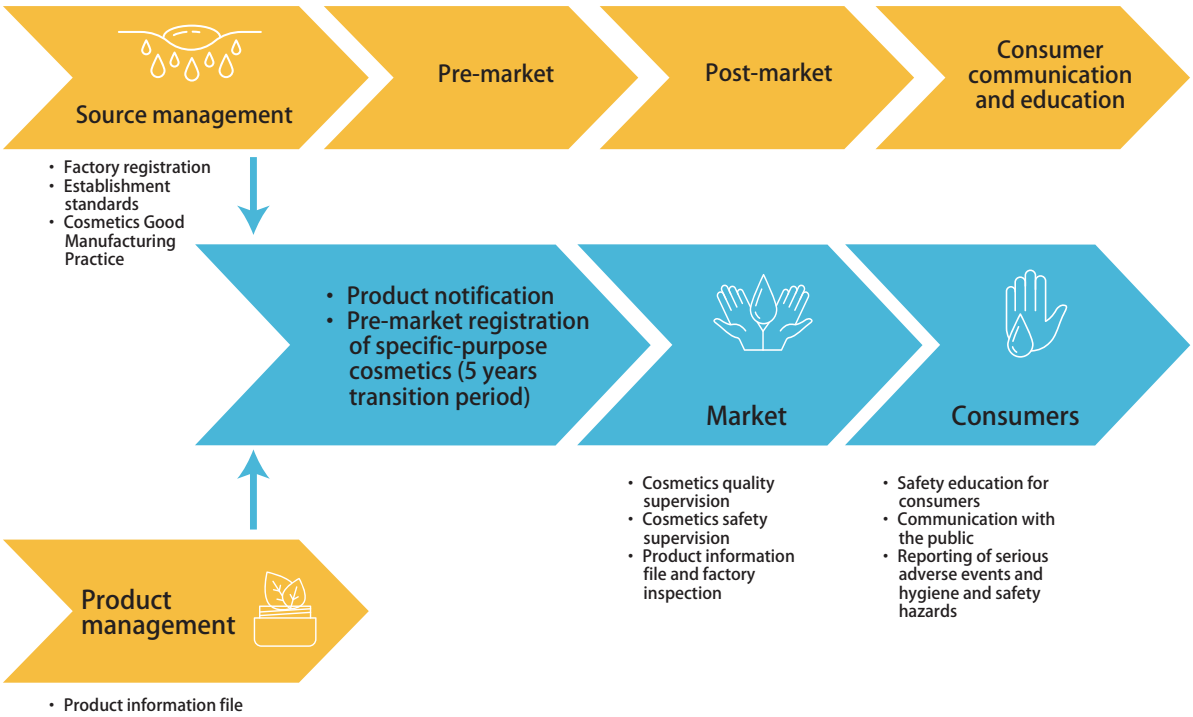


Figure 1-7 Cosmetic Hygiene and Safety Management Framework

a comprehensive safety protection network for foods, medicinal products and cosmetics. Major future administrative plans include the following:

1. Enhancing domestic food management capacity and protecting the public's health by strengthening the use of smart technologies in food and drug safety risk management, continuing to optimize the "Five-points Food Safety" policy environment, integrating the resources of various agencies and departments, increasing food safety management resources, performing effective tracking and follow-up, and strengthening border inspections, audits, and autonomous management by businesses.
2. Continued establishment of an effective legal and regulatory environment for regenerative medical products, assistance in taking products to market, promotion of electronic pharmaceutical management, and linkage with smart medicine, strengthening medicinal product supply shortage notification and response mechanisms, and ensuring balanced supply and demand in the healthcare system, while simultaneously implementing the management of drug safety surveillance, ensuring that citizens can use safe pharmaceuticals.
3. In order to establish a modern regulatory environment consistent with international norms, TFDA will continue to improve management regulations associated with the "Medical Device Management Act" and "Cosmetic Hygiene and Safety Act," and enhance international interchange and cooperation concerning laws and regulations. Establishment of a diversified, flexible review

mechanism for pre-market inspection, and provision of dedicated regulatory compliance assistance to the makers of innovative medical devices. To accelerate the marketing of new products, meet citizens' needs, and strengthen consumer protections, optimization of the digital clinical trial management platform for medical devices, and improvement of product source, flow, transport, and sale management.

4. Implementation of the forward-looking "Food Safety Construction Plan," which includes the "construction plan of the TFDA National Experimental Building and Administrative and Training Building of Forward-Looking Infrastructure," "enhancing the effectiveness of the border inspection and customs clearance and management system," "strengthening the food safety governance and inspection performance and quality of health authorities," "strengthening the food safety inspection capacity of the central authorities," and "enhancing the inspection research capacity and standardization of drugs targeting emerging infectious diseases and food-borne pathogens." This Plan calls for the establishment of a modern national food safety laboratory complying with international standards, and purchase of high-precision inspection and testing equipment. It will comprehensively improve the effectiveness of food safety testing, research, and development, and further strengthen the management capacities of local and central government agencies.

• Model Photo of the TFDA National Experimental Building and Administrative and Training Building of Forward-Looking Infrastructure

Farm-to-Table Five-point Food Safety

Effective food safety management will have a positive effect on citizens' health. To ensure the healthfulness and safety of products from production using raw materials to sale, TFDA has adopted a "farm-to-table" total food life cycle management model, and is vigorously implementing a "five-point food safety policy". TFDA is also working to improve food management laws, strengthen oversight of food marketing chains, tighten management of exported and imported foods, assist domestic enterprises in expanding their overseas markets, and promote second tier quality control certification in order to guard food safety. At the same time, TFDA is further applying artificial intelligence to master potential food safety risks, and reinforcing testing technologies for emerging and potentially hazardous substances in food, in an effort to create an effective food safety protection net allowing people to enjoy their food with greater confidence.

02

Consolidating Food Safety Management

02

Consolidating Food Safety Management

In order to strengthen food safety from farm to table, TFDA continues to implement relevant management tasks, including refining comprehensive regulations of food management, strengthening the supervision of the food production and marketing chain, reinforcing import and export management, assisting domestic businesses in exploring export opportunities, promoting second tier quality control certification, and applying artificial intelligence to assist in risk assessment and decision-making. TFDA is working hard to develop and apply testing technologies for emerging and potentially hazardous substances in foods, and thereby establish an effective food safety protection net.

Section 1
Putting Food Management Regulations on a Sound Footing

Introduction

To improve regulations governing foods, and to boost businesses' autonomous management capabilities, TFDA revised 29 provisions in 2023, which strengthens food management regulations in our country.

Implementation Strategies

1. Drafting of food hygiene and safety standards

Based on risk assessment principles and international standards, scientific evidence, toxicological experiments, and dietary intake data for citizens, etc., TFDA has drafted relevant standards reflecting the foregoing data, and has striven to maintain agreement with international management standards.

2. Updating health care effects assessment methods

Revised the "Efficacy Assessment Method of Health Food for Dental Care" to ensure that standards for experimental methods and experiment implementation are clear and thoroughgoing.

3. Revision of food and related product inspection, registration, and permit document management regulations

Adoption of the "Directions on Registration of Food Additive," and addition of inspection and registration provisions for infant and follow-up infant formula and formula for certain disease.

4. Promulgation of Standards for Good Manufacturing Practices of Health Food

In order to improve the production management of health food manufacturers, MOHW has promulgated the "Standards for Good Manufacturing Practices of Health Food," which is based on "Regulations on Good Hygiene Practice for Food" in Taiwan and international good manufacturing practice operating standards, and content concerning management of quality, R&D, food safety controls, stability, flow tracking, audit systems, and documents and records.

5. Expanding autonomous inspection items

TFDA announced the revised Article 18 of "Food Businesses that shall Enact the Food Safety Monitoring Plan and Food Inspection, Minimum Testing Cycle, and Other Related Matters," which adds inspection items and minimum inspection period for frozen fruit by general merchandise retailers which not include department stores.

6. Enhancing labeling management

TFDA initiated two new labeling measures in 2023, namely "Regulation for the Labeling of Freshly Made Beverages in Chain Drink Stores, Convenience Stores, and Fast Food Restaurants" and "Regulations Governing the Labeling of Prepackaged Honey and Its Syrup Products."

7. Strengthening autonomous management among businesses

Food manufacturers have been progressively adopting food hygiene and safety management measures. To strengthen management implementation and ensure that food businesses realize their autonomous management responsibilities, TFDA abolished the requirement that "Vacuum-Packed Soybean Ready-To-Eat Food Shall Be Registered

with The Central Competent Authority," and drafted the "Guidelines for Manufacturers of Vacuum-Packed Soybean Ready-To-Eat Food to comply with the Regulations on Good Hygiene Practice for Food.

Achievements and Benefits

1. Harmonization with international regulations

TFDA determined a cumulative total of 7,771 pesticide residue limits, pesticide residue limits for 458 animal products, 1,551 veterinary drug residue limits, 17 sanitation standards, 44 food ingredient restrictions, and 797 food additives on the positive list during 2023, and defined scope of use, limits, and specifications/standards for each.

2. Refinement of health food assessment methods

The "Efficacy Assessment Method of Health Food for Dental Care" was revised in 2023 with greater emphasis on ethical treatment of experimental animals and the 3Rs principle (Replace, Reduce, Refine). At the same time, the criteria for subjects, rules for judging research data and results, and health care effect description were revised. At present, health foods in seven cases with this health care effect have been approved and registered. Assessment of these foods was conducted via human consumption study, and no animal experiments were conducted.

3. Refinement of the registration management system

By ensuring that the registration of food additives, infant and follow-up infant formula and formula for certain disease was updated and better met practical needs, TFDA made the food registration management system more effective and thoroughgoing.

4. Improvement of the health food manufacturing management system

To ensure that the production management systems of health food manufacturers comply with international norms and boost the overall international competitiveness of Taiwan's health foods, the enforcement date of the "Standards for Good Manufacturing Practices of Health Food" is January 1, 2025.

5. Strengthening autonomous management of food safety by businesses

Starting from July 1, 2024, new hygiene management items for frozen fruits that that general merchandise retailers that are not department stores must comply with when inspecting their finished products for microbes and other hygiene and safety risks was added to the existing hygiene management items that general merchandise retailers that are not department stores must comply with when inspecting their finished products for microbes and other hygiene and safety risks.

6. Protecting consumers' right-to-know

(1) To improve disclosure of labeling information for freshly made beverages on the market, starting in 2023, TFDA expanded the scope of products requiring the labeling of total caffeine content. In accordance with regulations, all freshly made beverages containing caffeine must have markings stating caffeine content. To provide a range of labeling options, TFDA also began allowing labeling via QR code or other electronic methods.

(2) To improve product name and labeling management regulations for products containing prepackaged honey and its syrup products, starting on July 1, 2023 (based on the products manufacturing date), products containing prepackaged honey and its syrup products must be labeled with names based on the amount of honey content. If products containing prepackaged honey and its syrup contain honey from different places of production,

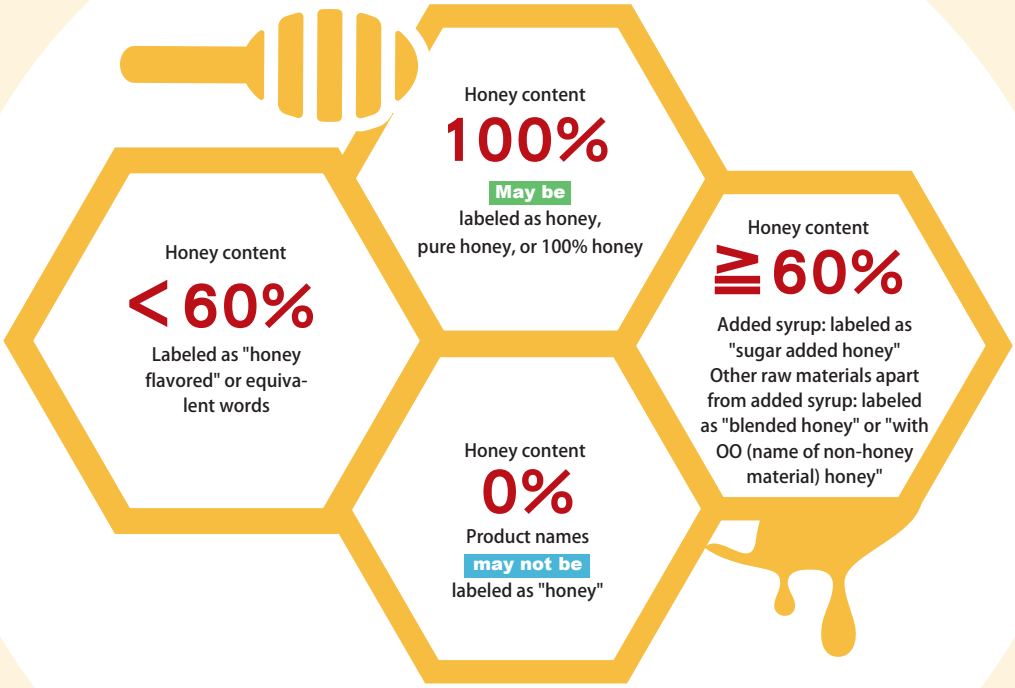


Figure 2-1 Regulations Governing the Labeling of Prepackaged Honey and Its Syrup Products

the places of raw honey production shall be labeled on the basis of the amount of honey content.

7. Accelerating food time-to-market

By exempting vacuum-packed soybean ready-to-eat foods from pre-market inspection and registration procedures, TFDA shortened time-to-market for accelerating vacuum-packed soybean ready-to-eat foods by at least 60 days.

Section 2
Reinforced Supervision of Food Production and Distribution Chains

Introduction

Food hygiene and safety is a vital matter closely connected with people's everyday lives. By monitoring production, manufacturing, distribution, and sale processes, TFDA has enabled potential risks to be discovered, allowing warning and control measures to be taken, which will enhance consumer trust and confidence.

Implementation Strategies

1. Border inspection of food and related products

TFDA reviewed and adjusted inspection methods and items on a rolling basis in reference to inspection records, product characteristics, and foreign and domestic information. Nonconforming products found in order inspections are returned or destroyed as required, and relevant information is announced. At the same time, the product random inspection rate has been increased. When imported products are found to be nonconforming during the product circulating in the domestic market (referred to as the post-market), relevant information is provided to the border authority for reinforced control, which

has strengthened hygiene and safety supervision mechanisms for imported foods.

2. Supervision of domestic manufacturing, processing, and distribution

In conjunction with the Five-points Food Safety policy and in consideration of citizens' diverse dietary habits, TFDA's supervision of food production and distribution chains has included the planning and organization of intensified audit and random inspection cases targeting items prone to violations, of high concern, or at high risk.

3. Border and post-marketing phosphine inspections and audits

To better monitor residual phosphine pesticide in at-risk foods, TFDA has included phosphine among border inspection items, and has also included the use and management of phosphine among the focal items of post-marketing audits. TFDA further monitors whether domestic manufacturers use phosphine in violation of regulations, and performs random inspections for phosphine residues.

4. Collaborative cross-department joint inspection

Cross-departmental joint inspections were conducted on the origin labeling of tea products and imported oysters available on the market, imported egg product businesses, and packaged and containerized drinking water manufacturing plants in 2023. These audits protected consumers' rights by tightening the regulatory compliance of the relevant products.

5. Cooperative police investigations with prosecutors and police

TFDA has relied on cooperation mechanisms involving the police and public health units to integrate various agencies' expertise and resources for the purpose of improving audit capabilities. TFDA has established a liaison platform for the investigation of suspected criminal cases involving foods and drugs, and a food and drug crime investigation team serves as a liaison and coordination center. By planning, directing, and coordinating investigation efforts by various agencies, this system has enhanced the effectiveness of investigation and handling.

Achievements and Benefits

1. Border inspection of food and related products

A total of 735,752 batches of food and related products were inspected at the border in 2023, of which 61,515 batches were sampled and tested with a pass rate of 98.8%.

2. Supervision of domestic manufacturing, processing, and distribution

TFDA completed 44 food inspection cases in 2023. A total of 139,599 inspections of domestic businesses were conducted, and the GHP compliance rate was 99.9%. A total of 520,000 inspections of foods and related products were conducted, and the compliance rate was 99.6%.

3. Border and post-marketing phosphine inspections and audits

(1) Border

A total of 234 batches of possible phosphine-containing products were inspected at the border in 2023, of which 12 batches were found to contain nonconforming products, which were returned or destroyed in accordance with regulations.

(2) Post-market

There were seven sampling inspection projects for high-risk products with phosphine residues in 2023. In these projects, 258 businesses were inspected and 101 products were sampled to detect phosphine residues, and the results were all qualified.

4. Collaborative cross-department joint inspection

(1)"Cross-departmental joint inspections of the origin labeling of tea product on market" in 2023: Inspected 411 tea products, of which 42 were suspected of containing foreign tea. These suspected cases were referred for investigation and prosecution by the District Prosecutors Office.

(2)"On-sale oyster place of origin labeling joint audit project" in 2023: Conducted 38 inspections on businesses and sampled 36 oyster products. There is one domestic bulk oyster product that does not indicate the origin information in accordance with regulations. The above-mentioned non-compliances have been corrected and all others are in compliance with the regulations.

(3) "Imported egg product business joint audit project" in 2023: Inspected labeling of 28 products at 22 businesses, and all products were in compliance.

(4)"Packaged and containerized drinking water manufacturing plant joint audit project" in 2023: GHP deficiencies were found in inspections of 37 businesses. All were in compliance at the time of follow-up inspections. Of the 41 product labels inspected, five noncompliant product labels have been fully corrected, and 33 cases in sampling inspection were in compliance.

5. Cooperative police investigations with prosecutors and police

In 2023, TFDA collaborated with prosecutors and police investigation units to handle 16 suspected violations of food regulations, all of which were dealt with in accordance the law.

Section 3

Improvement of Imported and Exported Food Management

Introduction

To ensure effective source management of imported foods, TFDA conducts systematic inspections of meat products, dairy products, egg products, fishery products, animal oil products, and products of cervidae origin. Products of these types from countries that implement systematic inspection may apply to TFDA for import inspection. In addition, TFDA has been adding or revising import regulations for different food categories. TFDA is committed to maintaining the hygiene and safety of imported foods and related products.

Furthermore, TFDA also compiles food safety assessment questionnaires and/or lists of prospective exporting firms on the basis of exporting country regulations and its division of labor with the responsible agencies in Taiwan; these questionnaires and lists are provided to the exporting countries for use in review, which assists domestic food businesses in obtaining imported food sale qualifications.

Implementation Strategies

1. Continued implement of a systematic inspection system

The governments of exporting countries (territories) must perform systematic food inspections. After these governments have submitted written applications to TFDA, TFDA shall perform examination and review to assess whether the exporting country's food hygiene and safety management system and government agency supervisory measures are equivalent to those of the ROC.

2. Continued revision and addition of border inspection items

TFDA and the Customs Administration, Ministry of Finance have established a customs clearance reporting mechanism for "imported goods without applicable food import regulations that are declared

as having food uses." After gathering and analyzing quarterly data and the results of audits by TFDA's regional administrations and local public health bureaus, TFDA reviewed and announced revisions to the classification codes of products for which import inspection applications must be made to TFDA.

3. Streamlining business consulting channels and providing legal information

(1) TFDA established the "Food Manufacturer Legal Knowledge Customer Service System," and has continued to update the system's Q&A section. This system helps businesses to enhance their autonomous management ability and better understand regulations concerning the export sale of foods.

(2) To enhance the competitiveness of Taiwan's food exports, TFDA has continued to update the information on its integrated export food hygiene and safety management platform, including the relevant laws of the importing country, import/export application procedures, and online learning videos.

4. Boosting the efficiency and quality of application for exported processed food sanitary verification

To facilitate the successful export of domestic processed foods, TFDA conducts explanatory meetings for businesses, which ensure that businesses understand key application points and reduces the chance that applications will be rejected or more documents needed. To improve case handling performance, quality, and consistency, TFDA also holds internal education and training classes and compiles case review principles.

Achievements and Benefits

1. Strict control over the hygiene and safety of imported foods

TFDA completed systematic inspection procedures in seven cases in 2023, including Indonesian fishery products, Japanese pork, Lithuanian beef, British lamb, Australian dairy products, Canadian all-age beef, and Vietnamese fishery products. All of the foregoing products complied with the specified import criteria, were produced at the source using approved production facilities, and verifying documents were issued so that businesses can apply to TFDA for import inspection.

2. Addition and revision of import inspection codes, enhancing management effectiveness

TFDA completed revision and enlargement of 47 product classification codes in food import regulations. Imported food products under a total of 2,765 codes require undergoing TFDA border inspection before they may enter the country.

3. Assisting businesses to expand their overseas markets

(1) Helping businesses to submit export application documents

In 2023, TFDA continued to actively assist businesses in exporting their products to China, Singapore, Malaysia, and Saudi Arabia, and also helped businesses export submit application documents in accordance with the specified products and the application procedures of the countries they plan to export to.

(2) Monitoring the hygiene standards of prospective export products

TFDA continued to submit egg product residue monitoring plans and implementation results for the export of egg products to the EU, as well as verification and guarantee information concerning composite foods containing processed dairy products, and these materials all passed review by the European

Commission. TFDA also continued to submit to Korea residue monitoring plans for the raw ingredients of egg and dairy products for export to Korea.

(3) Inter-agency assistance for overseas market expansion

TFDA relies on lateral inter-agency cooperation to actively promote domestic businesses' applications for the export of processed (cooked) meat products, and provides Taiwan's food hygiene and safety management and government supervisory measures in accordance with the planned country to which the products are to be exported.

4. Continued assistance to businesses needed English export verification

TFDA helped provide businesses applying to exported processed foods (additives) with 2,371 export sanitary relevant documents of processed foods in 2023, and held three explanatory meetings for businesses attended by 222 persons. The average satisfaction rate of these participants with the assistance provided by TFDA exceeds 90%.

Section 4

Implementation of Second Tier Quality Control Certification for Foods

Introduction

In accordance with the *Act Governing Food Safety and Sanitation*, TFDA has established a three-tier food hygiene and safety quality control system. In this system, second-tier QC consists of "third-party qualification of the hygiene and safety management systems," which seeks to provide consumers hygienic and safe food, while assisting food businesses in upgrading product quality and meeting international standards.

Implementation Strategies

1. Announcement of industries subject to compulsory regulation

TFDA has announced that second tier quality control certification must be performed by manufacturers in 10 industry areas, including firms with registered factories in 10 producing canned foods, food additives, special nutrients, and processed dairy products, as well as manufacturers of sugar, salt, starch, flour, soy sauce, and edible oil with capital in excess of NT$30 million. In addition, food manufacturers not on the announced list may voluntarily apply for certification.

2. Putting the accreditation and certification system on a sound footing

TFDA performs accreditation and certification tasks in accordance with the *Food Hygiene and Safety Management System Accreditation and Certification Management Regulations* and *Food Hygiene and Safety Management System Certification Operating Procedures*, and has established a food hygiene and safety management accreditation and certification information system (https://facs.fda.gov.tw) to boost management effectiveness. Food businesses that have been certified are subject to regular and occasional follow-up inspections, and must be re-certified again every two years.

3. Continued strengthening of certification quality

TFDA has completed certifying body accreditations in accordance with regulations to ensure that all certifying bodies retain ISO/TS 22003 accreditation qualifications, have professional auditors, and that applicable regulations governing avoidance of conflict of interest are upheld. In an effort to boost the certification quality and effectiveness of third party certifying bodies, TFDA performs on-site assessment

of certifying bodies and auditors, witness assessment, and audit consensus education and training classes on an annual basis.

Achievements and Benefits

1. Implementation of second tier quality control certification, protecting citizens' food safety

Certifying bodies accredited by TFDA include the Food Industry Development Research Institute, China Grain Products Research & Development Institute, National Animal Industry Foundation, and Taiwan External Agricultural Products Development Association. Among the 631 food businesses subject to certification in 2023, 91.4% have been certified, and TFDA is continuing to track the certification applications or certification of those businesses yet to be certified (Table 2-1). TFDA is relying on the second tier quality control certification system to help businesses discover and promptly resolve problems, and realize food hygiene and safety.

2. Linking of second tier quality control certification information, streamlining food export applications

Businesses that have received certification can waive on-site audits by the sanitation competent authority via possession of a certification certificate during the application period for hygiene verification, which has streamlined the food export application process.

Section 5

Apply Artificial Intelligence to Assist in Food Safety Risk Decisions

Introduction

In light of the diversification and continuous growth of imported foods, and the prevalent online consumption in the post-Covid era, in order to improve food safety management, TFDA has been using big data analysis and other smart technologies to assist with risk management and safeguard public health. In addition, in response to the incident where hepatitis A virus was detected in berries from Costco, TFDA immediately formed an emergency response task force to properly handle various emergency measures.

Implementation Strategies

1. Apply artificial intelligence technology

TFDA's Border Prediction Intelligent (BPI) relies on big data in conjunction with AI and machine learning technology, to enhance the

Table 2-1 Second Tier Quality Control Certification Results in 2023

Explanation	Number of businesses
Businesses subject to second tier quality control certification	631
Businesses that have received second tier quality control certification	577
Businesses that have not yet received second tier quality control certification	53*

*Have already applied for certification.

system by expanding new factors, adjusting model hyperparameters, refining the criteria for selecting the best models, strengthening feature learning for declarations that were not effectively captured, and establishing a model decaying monitoring mechanism; this system can immediately grasp risk information as a reference for decision-making, and has strengthened management of border food inspections.

2. Integrating from food cloud information to detect food safety risks

TFDA's automated post-marketing monitoring system, which was established on the basis of a cloud food database, assists the post-marketing tracking of abnormal chemicals transactions involving food cloud businesses and chemical cloud businesses. This system relies on big data analysis of historical audit records and data mining technology to assist post-marketing audit projects on high-risk businesses, and thereby address potential food safety risks.

3. Inspiring innovative thinking to enhance risk management capabilities

To accelerate the incorporation of smart technology in food and drug safety risk management, TFDA held the "Food and Drug Big Data Competition: In-depth Analysis, Precise Decision-making, Innovative Transformation, and Cutting-edge Excellence" in 2023. This event stimulated innovative thinking and breakthrough insights on the part of central and local government colleagues, and enhanced risk management and emergency response strategy drafting capabilities.

4. Holding emergency response meetings to address urgent incidents

TFDA continuously monitors international alerts, has been keeping track of the US FDA's recall alerts for frozen organic strawberries. TFDA expanded border and post-marketing inspections. After the hepatitis A virus was detected in berries form Costco, TFDA immediately activated third tier response mechanisms in response to the changing situation.

Achievements and Benefits

1. Advancement of applications of AI machine learning algorithm technology

Through the BPI system, 12 categories of food products were refined. The detection rate of violation for declarations using AI has increased by 1.19 times compared to those not using AI, effectively enhancing the efficiency of border food safety management.

2. Improving the automated post-marketing monitoring system to grasp potential food safety risks

TFDA gathered a total of 1,394 records from the food safety rapid reporting system, international food consumers red and green lights, and RASFF, etc. concerning public sentiment about food additives and chemicals. This allowed TFDA to add 44 types of food additives and chemicals that are prone to misuse, and determine their food risk combinations. After extrapolating based on food characteristics or additive uses, a total of 306 combinations were derived. This assist competent authority in planning more precise post-marketing food audits, and thereby preventing the occurrence of food safety incidents.

3. Holding a food and drug big data competition

The food and drug big data competition held by TFDA in 2023 attracted participants consisting of 170 government personnel, experts, and scholars on 11 teams. The assembly of participating teams from central and local government units facilitated interchange and cooperation, and boosted the ability to

Figure 2-2 The 2023 Food and Drug Big Data Competition

use data and draft strategies for responding to various events (Fig. 2-2).

4. Activation an emergency response meeting for the "Costco berries" incident

Responding to the detection of the hepatitis A virus in berries from Costco, TFDA immediately formed an emergency response task force, and established business processing, administrative support, inspection technology, staff operations, and distribution audit teams and a spokesperson. Nine response conferences were held and 24 work reports were compiled during the alert period, and all emergency response measures were conducted satisfactorily.

Section 6
Development of New Food Testing Technologies

Introduction

In order to fulfill hygiene criteria such as allowed limits set forth in food-related laws and regulations and to identify in real-time unknown or illegitimate additives and pollutants that may be generated to impact health during the process, it is required to define testing methods that are environmentally friendly, fast, and precise. TFDA continues to advance its laboratory testing and analysis capabilities, establish novel testing technologies for foods, and also organize related technical exchange and training events in response to the inspection of sudden food events for enhancing domestic food safety testing capacity.

Implementation Strategies

1. Promotion of domestic food testing technology interchange

TFDA has held testing technology interchange events allowing domestic and foreign experts and scholars to share testing technology advances and experience. These events are intended to achieve the goals of promoting interchange in testing technology,

boosting the technological level and quality of domestic testing laboratories, and training technical personnel.

2. Application of advanced analytical technology for high-risk foods, protecting the public's food safety

Targeting food items that are high risk and of high concern, TFDA has developed highly credible, rapid testing methods that can protect the public's food safety by quickly clarifying the details of emerging food incidents. Due to the extremely broad and complex range of food matrices, matrix interference effects must be overcome during testing. TFDA has advanced testing technologies to develop rapid and high precision testing methods for strengthening border inspections, monitoring of products on the market, and autonomous management by businesses.

Achievements and Benefits

1. Holding the 2023 APEC Communication Platform for Analytical Techniques - Food from Biotechnology-Derived Crops Workshop

The "2023 APEC Communication Platform for Analytical Techniques - Food from Biotechnology-Derived Crops Workshop" held by TFDA in 2023 combined an on-site symposium with an online videoconference. Six experts and scholars from Japan, Korea, Malaysia, Vietnam, Academia Sinica and TFDA were invited to share their knowledge on testing techniques, monitoring, and experiences related to innovative biotechnology foods, including genetically modified foods, in their respective countries. A total of 148 experts participated in the event, representing official organizations from Indonesia, Japan, Korea, Malaysia, Mexico, Peru, the Philippines, Singapore, Vietnam, and Taiwan, as well as the Ministry of Agriculture (Taiwan), TFDA, and local health bureaus. The workshop fostered the exchange of international experiences to enhance domestic testing standards, align with global practices, and promote cooperation opportunities between Taiwan and other APEC member economies in the Asia-Pacific region (Fig. 2-3、2-4).

2. Development of testing methods for high-risk and high-concerned food related items

(1) Rapid establishment of testing methods in response to public opinion and reliance on inter-agency cooperation to publish testing methods

1. Responding to the establishment of Reference Point for Action (RPA) for malachite green (MG) by EU and the dispute concerning the detection of malachite green and crystal violet in grouper exported from Taiwan to China, TFDA amended the "Method of Test for Veterinary Drug Residues in Foods - Malachite Green, Crystal Violet, and their Metabolites".
2. Responding to the need of exporting aquatic products to the EU, TFDA published the "Method of Test for Veterinary Drug Residues in Aquatic Products - Multiresidue Analysis of Nitroimidazoles and their Metabolites" which can be applied in product quality control before export, and will reduce trade barriers.
3. TFDA advanced the "Method of Test for Pesticide Residues in Foods - Test of Phosphine" to added applicable matrices, and has been used to successfully block the import of noncompliant mung bean and black sesame products at the border.
4. TFDA optimized the "Method of Test for Ethylene Oxide and its Reaction Product, 2-Chloroethanol, in Foods" for testing the carcinogenic substance ethylene oxide in cheese.

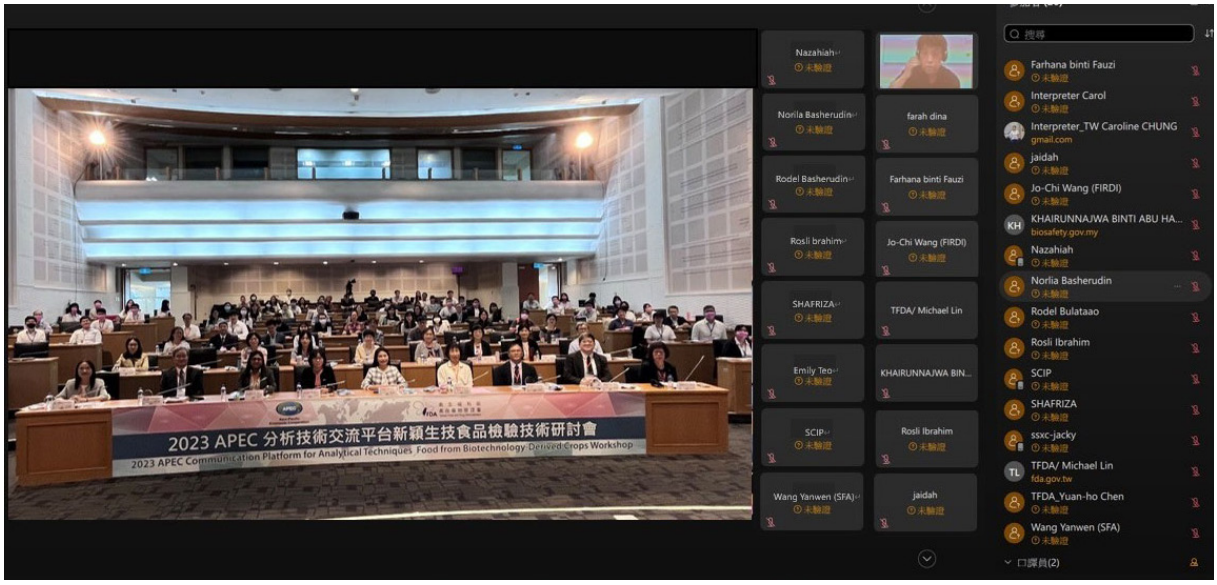


Figure 2-3　2023 APEC Communication Platform for Analytical Techniques - Food from Biotechnology-Derived Crops Workshop (online meeting)

Figure 2-4　2023 APEC Communication Platform for Analytical Techniques - Food from Biotechnology-Derived Crops Workshop

5. Responding to the discharge of radioactive water by Japan, through inter-agency cooperation, TFDA assisted the National Atomic Research Institute in publishing the "Method of Test Tritium in Foods" which will help the need of testing for the radioactive substance tritium in foods.

6. To prevent the sale of imported oysters mixed with domestic oysters, which would impact the income of local oyster dealers and oyster raisers, the Fisheries Research Institute, Ministry of Agriculture submitted the oyster place of origin identification technologies—the "Method of Test for Multielement

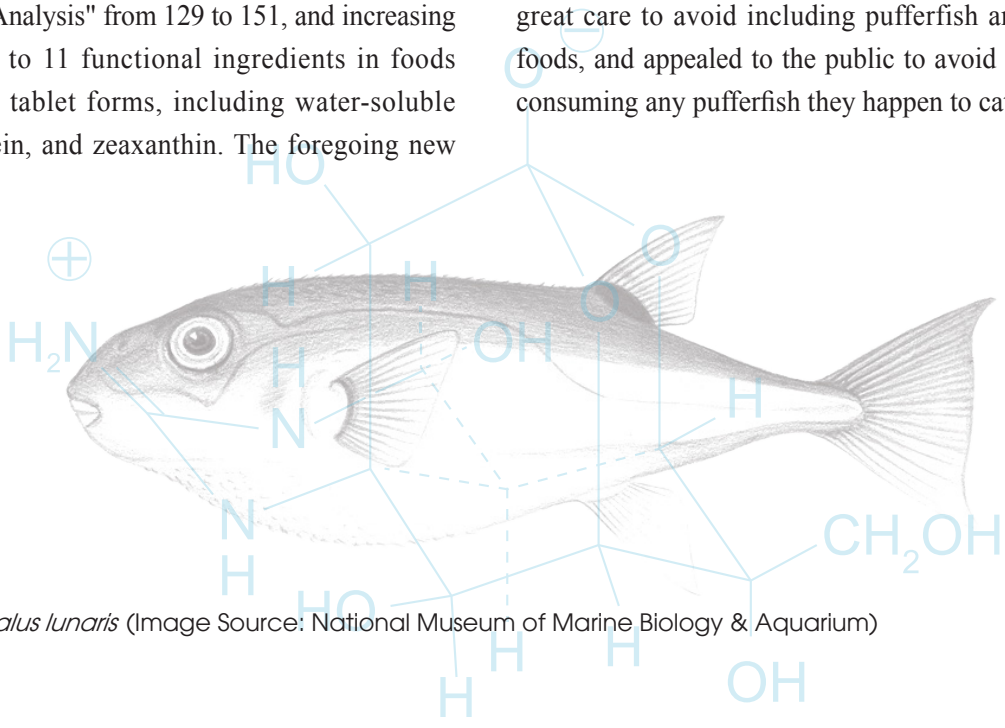
in Oyster" and the "Method of Test for Oyster Species Identification"—to TFDA's testing methods review committee for review. These methods were approved and released as recommended testing methods to provide the industry with a scientific basis for testing, and to protect consumers' right to know and the rights of Taiwan's oyster raisers by determining whether imported oysters have been mixed with domestic oysters.

(2) Advancement of testing methods

In 2023, in order to meet the need of testing requirement under food-related sanitation standards, TFDA promulgated or amended 8 testing methods for pesticides, veterinary drugs, heavy metals in food and food utensils, containers and packages including, promulgate two testing methods for alloy food utensils, containers and packages. TFDA also published 21 recommended testing methods, which included updating the "Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis Methods (5)", increasing the number of analytes in "Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6)" from 20 to 31, increasing the number of analytes in "Method of Test for Pesticide Residues in Livestock and Poultry Products - Multiresidue Analysis" from 129 to 151, and increasing testing items to 11 functional ingredients in foods in capsule or tablet forms, including water-soluble vitamins, lutein, and zeaxanthin. The foregoing new test methods and analytes will effectively boost testing performance. In addition, TFDA also added or revised five testing methods for identification of microbes and biological organisms in foods. Responding to the need for testing in connection with food additive usage scope, permissible limits, specifications, and standards, TFDA developed the "Method of Test for Extracts of Rosemary in Foods," which has been provided for general use.

(3) Identification of fish species and toxin analysis responsible for pufferfish poisoning to protect public food safety

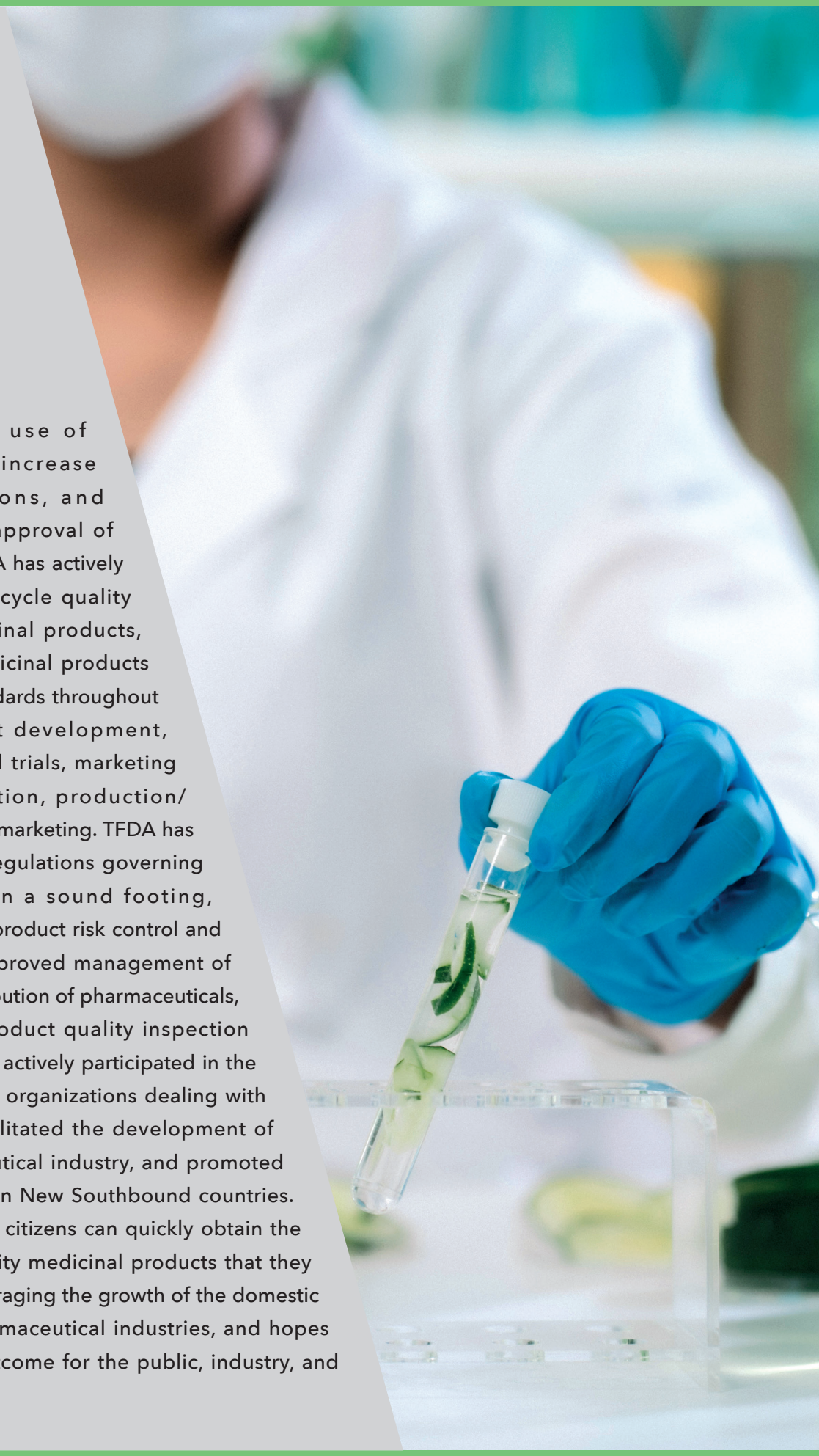
Responding to a food emergency incident of pufferfish poisoning cases occurring after people consumed pufferfish sashimi or pufferfish soup that they cooked by themselves, TFDA applied DNA molecular biotechnology to identify pufferfish species and liquid chromatography/tandem mass spectrometry to analyze tetrodotoxin. Using these technologies can clarify the cause of poisoning cases. The results of DNA species identification confirmed that the foregoing cases were caused by the lunartail puffer (Lagocephalus lunaris), and tetrodotoxin was detected through mass spectrometry. Furthermore, TFDA held a press conference to remind restaurants to take great care to avoid including pufferfish among their foods, and appealed to the public to avoid risk by not consuming any pufferfish they happen to catch.



• *Lagocephalus lunaris* (Image Source: National Museum of Marine Biology & Aquarium)

Ensuring safe medication use; improving classified drug management

To ensure the safe use of medicinal products, increase access to medications, and accelerate marketing approval of medicinal products, TFDA has actively implemented total life cycle quality management of medicinal products, which ensures that medicinal products meet good practice standards throughout the stages of product development, preclinical trials, clinical trials, marketing authorization application, production/ manufacturing, and post-marketing. TFDA has also put management regulations governing medicinal products on a sound footing, strengthened medicinal product risk control and digital management, improved management of the production and distribution of pharmaceuticals, upgraded medicinal product quality inspection and testing technologies, actively participated in the activities of international organizations dealing with medicinal products, facilitated the development of the domestic pharmaceutical industry, and promoted the opening of markets in New Southbound countries. Apart from ensuring that citizens can quickly obtain the safe, effective, high-quality medicinal products that they need, TFDA is also encouraging the growth of the domestic biotechnology and pharmaceutical industries, and hopes to achieve a win-win outcome for the public, industry, and government.



03

Advancement of Medicinal Product Management

03

Advancement of Medicinal Product Management

To ensure quality throughout the full life cycle of medicinal products, and effectively maintain the safety, efficacy, and quality of medicinal products, TFDA has actively established a robust regulatory environment and participated in international organizations to ensure that Taiwan's regulatory environment is in harmony with international norms. TFDA has further improved the digital management of medicinal products, management of the manufacture and distribution of drugs, monitoring of quality and safety, and testing technology. These efforts have resulted in better risk control and ensured a consumer environment promoting the safe use of medication, and have also promoted the development of the domestic pharmaceutical industry. TFDA has additionally deepened ties with Southeast Asian countries, and helped the domestic pharmaceutical industry to enter and develop markets in New Southbound countries.

Section 1
Strengthening Medicinal Product Management Regulations

Introduction

To keep pace with international development trends, increase the accessibility of medicinal products, accelerate the marketing approval of medicinal products, and encourage the pharmaceutical industry to develop medicinal products meeting citizens' healthcare needs, TFDA has been keeping up with international drug review trends and establishing a drug patent linkage system. In addition, to better facilitate the domestic pharmaceutical industry's development, TFDA has continued to update relevant laws and regulations, which has put Taiwan's medicinal product regulatory environment on a stronger footing. Furthermore, TFDA has also announced the *Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief* to strengthen drug injury relief review procedures.

Implementation Strategies

1. Updating the new drug review and management system

TFDA has formulated various tangible measures to improve the efficiency of drug review and accelerate the approval and marketing of new drugs, including the "Priority Review Mechanism for New Drug Applications," "Accelerated Approval Mechanism for New Drug Applications," "Abbreviated Review Mechanism for New Drug Applications," "Points to Consider for Breakthrough Therapy Designation," and "Points to Consider on Drugs for Pediatric or Rare Disease Designation."

2. Implementing the drug patent linkage system

Taiwan implemented a pharmaceutical patent linkage system on August 20, 2019. In response, TFDA has announced the *Regulations for the Patent Linkage of Drugs and Regulations for the Notification of Drug Patent Linkage Agreements* and has established the "Registration System for Patent Linkage of Drugs" allowing the owners of new drugs to register and disclose patent information.

3. Announcement of the "Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief "

Responding to the need to provide relief in instances of drug injury, TFDA has integrated application and review procedures and payment standards for drug injury relief and strengthened drug injury relief review procedures. TFDA consequently issued the Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief on June 15, 2023, and concurrently abolished the Regulations Governing Reviewing Procedure of Drug Injury Review Committee of Ministry of Health and Welfare, Regulations for Drug Injury Relief Application, Drug Injury Relief Payment Standard, and Establishment Directions for the Drug Injury Review Committee of the Executive Yuan, the Department of Health."

Achievements and Benefits

1. Accelerating New Drug Approval

A review of 40 new drugs with new chemical entity (NEC) and biomedical product cases was completed via standard review mechanisms in 2023, and the average review time was shortened to 330 days. In addition, a review of 21 cases was completed via priority review mechanisms during the year, and the average review time was shortened to 226 days (Fig. 3-1). TFDA approved 101 new drug cases in 2023,

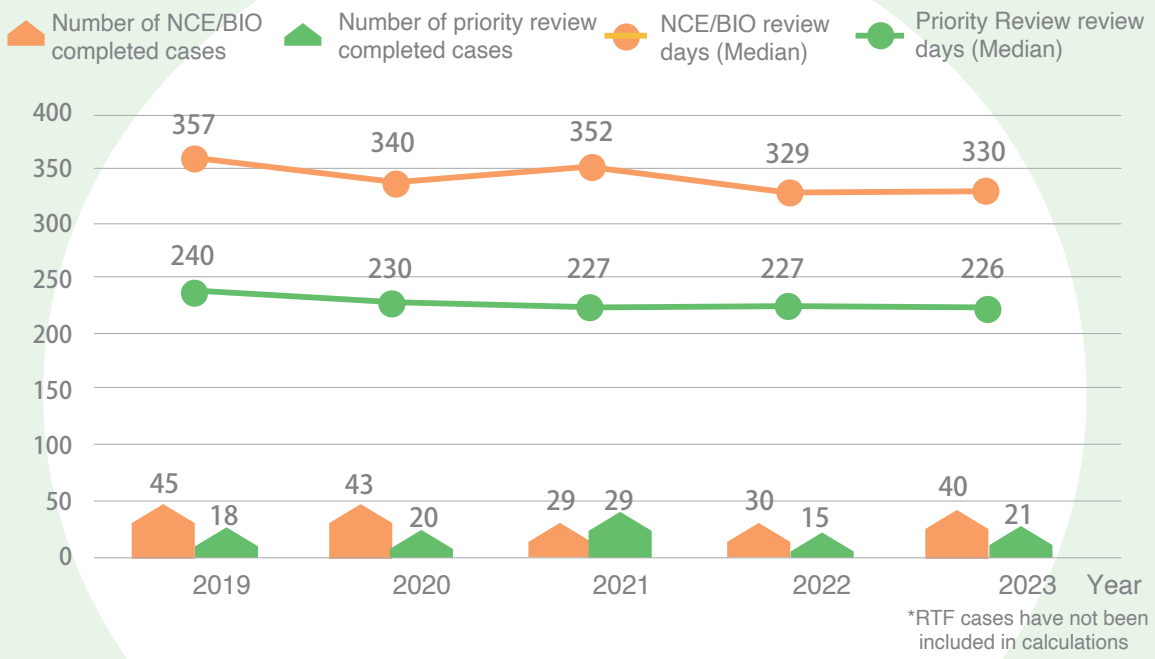


Figure 3-1 Comparison of the Review Days between the Standard Review and the Priority Review for New Drugs of NCE/Biomedical Products

of which 32 were new drugs with NCE and 39 were biomedical products. This work helped make urgently -needed drugs available as quickly as possible.

2. Implementation of drug patent linkage

To better protect the rights of patent holders by the Patent Act and ensure that the R&D contributions of new drug and drug permit holders are recognized, TFDA relies on patent information disclosed by generic drug manufacturers to monitor the patent status of drugs. TFDA encourages drug manufacturers to develop patent circumventing designs, and clarify any possible infringement before taking their products to market. This will help the domestic pharmaceutical industry to upgrade its R&D and expand its international markets. As of the end of 2023, domestic firms had developed 56 patent circumventing designs.

3. Improving drug injury relief review procedures

The *Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief* encompasses drug injury relief application procedures, payment amounts, review committee organization, review procedures, etc., and will help to make drug injury relief review procedures more effective. These Regulations were applied in 96 cases during 2023.

Section 2

Strengthening Medicinal Product Risk Control and Digital Management

Introduction

To promote effective drug administration and comply with the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other international standards, TFDA has continued to improve the electronic management of medicinal product review, and this work has accelerated the review process and boosted the quality of submitted cases. TFDA is also continuing to improve active and passive medicine monitoring mechanisms, and these risk control measures are enhancing the quality and safety of medicines in Taiwan. Furthermore, the ongoing improvement of medicine supply shortage mechanisms is helping ensure that people have the right to safe and effective medications.

Implementation Strategies

1. Improving electronic management for reviewing medicinal products

TFDA has continued to expand the functions of the application side, review side, and document management, improving the quality of the submission, and has integrated electronic review service systems, which has created a comprehensive medicinal product review environment. TFDA has also expanded system platform functions, and provided a wider range of service items. These enhancements to the electronic management for reviewing medicinal products have made the review of medicinal products more efficient.

2. Strengthening safety re-assessment mechanisms for medicines on the market

(1) TFDA has established a reporting system, and also actively monitors safety and quality information concerning domestic and foreign medicines. If any medicinal products are found to have safety concerns or major quality abnormalities during manufacturer audits or quality monitoring of products on the market, we will then initiate a full-scale analysis and risk-benefit assessment.

(2) We are progressively establishing comprehensive drug safety surveillance, and require pharmaceutical firms to maintain vigilance, draft drug safety monitoring plans, collect data, and write safety reports. To maintain the public's medicine use safety, pharmaceutical firms are also responsible for reporting any adverse reactions.

3. Improving domestic drug shortage handling mechanisms

(1) TFDA reviews the list of essential drugs in Article 27-2 of the Pharmaceutical Affairs Act on a rolling basis every two years. The number of drugs on this list was increased from 398 items to 481 items in 2023.

(2) Information concerning shortages of drugs is announced on the "Drug Supply Management System." Relevant drug shortage information is sent weekly via official documents to medical associations for forwarding to their members, and the National Health Insurance Administration assists by passing on information to contracting organizations. TFDA's establishment of open data concerning drug supply information has facilitated importing the information into medical organizations' care order systems and pharmacy management systems.

(3) TFDA continuously monitors international drug shortage warning letters and domestic drug demand, and actively checks stocks and supplies of relevant drugs. When necessary, TFDA helps companies to increase supply, such as by placing early orders for active pharmaceutical ingredients, and assists in expediting the relevant medicines review process.

(4) By establishing the "Drug Distribution Monitoring System" and cooperating with large domestic pharmaceutical distributors, TFDA has integrated information on drug stocks and can more effectively monitor the supply of medicines.

Achievements and Benefits

1. Online application improving the efficiency of medicinal product review

(1) In 2023, all post-approval changes, clinical trial applications, and changes, clinical trial concluding reports, and registration and clinical trial inquiry letters were submitted online. In addition, starting on January 1, 2024, applications for drug bioavailability and bioequivalence studies and bridging study assessment can be made online.

(2) A total of 13,419 online application cases were accepted in 2023, an increase of 3,870 cases compared with 2022, and the submission rate increased to approximately 40.5%.

2. "Reinforcing drug safety surveillance and analysis

A total of 13,357 domestic drug adverse reaction reports were received in 2023, along with 95 domestic and international drug safety alerts and 9 COVID-19 vaccine safety alerts, and 53 drug safety assessments following drug monitoring periods, issued 11 drug risk communication forms. TFDA received 935 reports of alleged quality defects, of which 26 were recalled after thorough assessment (including the active report from the manufacturer), and actively monitored 1,368 international drug quality alerts.

3. Making drug supply management more effective

By continuing to update and improve regulations governing drug supply management, strengthening drug supply monitoring, improving drug shortage notification and response mechanisms and information transmission, putting drug permit license management on a stronger footing, and stepping up relevant education and awareness efforts, TFDA has helped ensure a stable domestic supply and appropriate distribution of medications, and safeguarded people's right to obtain needed medications.

Section 3

Upgrading Pharmaceutical Drug Manufacturing and Distribution Management

Introduction

To ensure pharmaceutical quality and safety, Article 57, Paragraph 2 of the *Pharmaceutical Affairs Act* specifies that the production of pharmaceuticals must comply with Good Manufacturing Practice (GMP), and must pass inspection, and a drug manufacturing permit must be obtained before manufacture may begin. According Article 53-1 of the *Pharmaceutical Affairs Act*, wholesale, import, and export pharmaceutical distribution, storage, and delivery must comply with Good Distribution Practice (GDP), and must pass inspection, and a distribution permit must be obtained before distribution may be performed.

The harmonized standards issued by the Pharmaceutical Inspection Co-operation Scheme (PIC/S) form the basis for GMP and GDP inspection in Taiwan, which seeks to ensure that the manufacture and distribution of drugs complies with international quality standards.

Implementation Strategies

1. Supervising the compliance of GMP standards of pharmaceutical manufacturers

TFDA has continued to draft and revise pharmaceutical GMP standards on the basis of the latest GMP standards issued by the International PIC/S organization, and has incorporated quality risk management, while fully implementing pharmaceutical plant GMP inspection and management. In 2023, we strengthened the system to put an authorized person in charge of each pharmaceutical plant, where this person must confirm that each lot of drugs complies with domestic regulations and marketing permit requirements.

2. Promotion of GDP at pharmaceutical firms

In accordance with Article 53-1 of the *Pharmaceutical Affairs Act*, TFDA has continued to promote the implementation of GDP at pharmaceutical firms in stages, including through the provision of training and assistance to ensure that companies full implement GDP. Those pharmaceutical firms targeted these promotional efforts include drug manufacturing plants, active pharmaceutical ingredient plants, pharmaceutical firms holding drug permits, and pharmaceutical firms dealing in active pharmaceutical ingredients and cold chain medicinal products. Pharmaceutical firms of other types have to obtain distribution permits before December 31, 2026.

Achievements and Benefits

1. Ensuring that drug manufacturing meets GMP standards; safeguarding medication quality

As of the end of 2023, a total of 239 domestic and 958 foreign pharmaceutical companies had passed TFDA's GMP inspections. To strengthen and align with international standards on the batch release management and sterile medicinal product requirements, TFDA announced the revised GMP "Annex 13: Manufacture of investigational medicinal products" and new addition of "Annex 16: Certification by the authorized person and batch release" and the revised "Annex 1: Manufacture of sterile medicinal products" on February 24 and June 14 in 2023.

2. Ensuring that drug distribution meets GDP standards; maintaining drug quality and safety

As of the end of 2023, a total of 1,010 pharmaceutical manufacturers and firms had obtained pharmaceutical GDP distribution permits. TFDA announced the "The Types of Pharmaceutical Product, Firms, Requirement, Methods and Schedules of Western Pharmaceuticals Good Distribution Practice Implementation" on July 26, 2023.

Section 4
Active Participation in International Pharmaceutical Organizations

Introduction

To deepen and promote international interchange and cooperation, TFDA has been actively participating

in the activities of various international organizations, including APEC (Asia-Pacific Economic Cooperation), ICH, PIC/S, etc., which has expanded Taiwan's international participation and influence in the area of pharmaceutical administration. In addition, Taiwan has also increased bilateral and multilateral cooperation through interchange and experience sharing with international regulatory units.

Implementation Strategies

1. Participation in ICH conferences

Regular participation in ICH member conventions and expert working group meetings gives TFDA substantive opportunities to take part in the drafting of international drug regulations. TFDA has also engaged in interchange and experience sharing concerning regulatory issues with the pharmaceutical competent authorities of various countries, and continues to revise guidelines concerning pharmaceutical safety, efficacy, and quality. Various relevant training sessions conducted by TFDA help domestic firms to be aware of and comply with international standards.

2. Holding the APEC Good Registration Management Center of Excellence Workshop

TFDA held the "APEC Good Registration Management (GRM) Center of Excellence Workshop" (CoE) during the period of September 6-8 in 2023 (Fig. 3-2). This symposium, which was held physically again for the first time in the wake of the COVID-19 pandemic, trained regulatory and science specialists from various APEC economies to serve as seed instructors. These personnel can spread and realize the good registration management (GRM) concept in the Asia-Pacific region, improving medical review quality and effectiveness.

3. Active participation in PIC/S activities

As a member of PIC/S, TFDA’s representatives regularly participate in its official committee meetings and the sub-committee. TFDA also actively participate in expert circles and working groups, where they are involved in the drafting and revision of pharmaceutical GMP- and GDP-related regulations and guideline document with experts from other countries.

4. Taiwan-Japan Joint Conference on Regulation of Medical Products

The 11th Joint Conference of Taiwan and Japan on Medical Products Regulations (Fig. 3-3) was held on October 5, 2023, allowing onsite and online. Taiwan and Japan representatives gave presentations on the regulation progress of medicinal products and medical devices, the application of real-world data to accelerate clinical trial development, new drug review cooperation between Japan and Taiwan, regulation of regenerative medicine, cybersecurity for medical devices and the latest medical device issues. This conference served to promote the exchange of information and consensus on medical information among Taiwan and Japan.

Achievements and Benefits

1. Making contributions at ICH conferences

TFDA has selected 46 experts to participate in 27 ICH expert working groups and they have taken part in online conferences of expert working groups more than 292 times and drafted ICH guidelines and training materials in conjunction with international experts affiliated with industry, government, and academia. TFDA has also participated in ICH member conventions as a formal member and actively

Figure 3-2 The APEC Good Registration Management Center of Excellence Workshop

Figure 3-3 11th Joint Conference of Taiwan and Japan on Medical Products Regulations

shared its pharmaceutical management experience. At the same time, TFDA continued to enhance our professional capabilities to build a more effective and internationally competitive regulatory environment.

2. Promoting cooperation and interaction of pharmaceutical management in the Asia-Pacific region

Through the APEC Workshop, TFDA has actively maintained good relations with various economies and has provided an effective platform that allowed communications and conversations among the industry, government, and academia, which has strengthened Taiwan's overall medical and pharmaceutical capabilities. In 2023, 80 trainees affiliated with the government, academia, and industries from 5 APEC economies were trained as the seed lecturers to promote the concept of GRM. TFDA has been reporting periodically on the results of promoting regulatory harmonization to APEC, which further expands and accumulates our international impacts.

3. Continuing improvement of GMP assessment via the PIC/S platform

In 2023, TFDA's representatives participated in the PIC/S official committee, seminar annual symposium, expert circles, and various subcommittee meetings. TFDA expressed Taiwan's perspectives views as a member of the PIC/S, monitored regulatory development trends, and burnished its own international visibility and influence. In addition, TFDA also leverage the resource from the PIC/S platform to continue participation in PIC/S inspector training, which spans such subjects as blood, tissue, cells, advanced therapy medicinal products (ATMPs), new revisions to GMP Annex 1, pharmaceutical GDP, and JAP audits training. This training has harmonized Taiwan's GMP assessment standards with their international equivalents.

4. Strengthening bilateral trust and cooperation with Japan

The sharing of regulatory information and mutual understanding between Taiwan and Japan has strengthened mutual trust and cooperation at both the government and industry levels and helped the two countries' companies expand their international markets. Apart from the government representatives of Taiwan and Japan, approximately 690 participants from the pharmaceutical and medical device industries of Taiwan and Japan joined the conference.

Section 5

Enhance Analytical Techniques in Pharmaceutical Analysis

Introduction

A global safety alert has been issued for sitagliptin, an anti-diabetic agent, due to the potential presence of a mutagenic nitrosamine impurity, 7-Nitroso-3-(trifluoromethyl)-5,6,7,8-tetrahydro-[1,2,4]triazolo[4,3-a]pyrazine (NTTP). To ensure the quality and safety of medications for the public, TFDA has

developed and provided testing methods for reference. In addition, responding to the rapid development of the biotech industry and steady stream of new vaccines reaching the market in recent years, TFDA has continued to improve biomedical product testing methods and established national biological standards. New testing techniques are also being used to test and maintain quality and monitor the safety and efficacy of new vaccines. TFDA has prepared national biological standards since 2004, and its preparation and supply of standards can help the industry maintain quality control in production of vaccines, such as enterovirus vaccine recently self-developed by a domestic firm, improve standardized process control and testing, and thus promote the domestic pharmaceutical industry's sustainable development.

Implementation Strategies

1. Establish an analytical method for testing pharmaceutical impurities by liquid chromatography-tandem mass spectrometry (LC-MS/MS)

Based on the physical and chemical properties of the compound, TFDA developed a rapid, sensitive, and precise analytical method using LC-MS/MS, along with a straightforward sample preparation process, to test for NTTP, the nitrosamine impurity in the hypoglycemic medicine Sitagliptin.

2. Application of Nucleic Acid Sequencing technology to the quality control testing of virus related preparations

Since 2021, TFDA has been developing and implementing next-generation sequencing (NGS) technology for the quality control testing of viral vaccines. This approach includes information procedures for analyzing viral sequence integrity and variability, integrating multiple aspects of sequence quality control, alignment, and variation analysis, etc. The method allows for automated genotype identification of the viral vector and detection of extraneous agents; it provides 14 extra quality analysis data points, such as active ingredient mapping rate, variant sequence frequency, and unexpected sequence detection, etc. The system also offers high-throughput detection effectiveness, capable of simultaneously identifying 8,079,113 potential viral contaminants in multiple lots of products. TFDA will continue to upgrade testing methods in pace with international trends.

3. Collaborative study of an enterovirus A71 (EV-A71) antigen national standard with domestic and international laboratories

In conjunction with the domestic development of an enterovirus vaccine, TFDA prepared one batch of formaldehyde inactivated EV-A71 subtype B4 bulk solution as a candidate antigen national standard in 2022, and invited five domestic and international enterovirus research laboratories to perform a collaborative study in 2023. The WHO's international inactivated enterovirus vaccine reference standard (code: 18/156) served as a reference, and an enzyme-linked immunosorbent assay (ELISA) was employed to assign the antigen content of the candidate

standard. The research participants included National Institute for Biological Standards and Control (NIBSC, UK), National Cheng Kung University, Medigen Vaccine Biologics Corporation, and Adimmune Corporation. Statistical analysis indicated that the results of the participating laboratories had good repeatability and reproducibility. Finally, the national antigen standard was assigned with an antigen content of 12,765 IU/mL.

Achievements and Benefits

1. Publish the recommended testing method for general reference

TFDA published the English and Chinese versions of the testing method for analyzing NTTP in the active pharmaceutical ingredients of Sitagliptin, which can be a recommended method. The outcome enhanced the competence of pharmaceutical testing and international prominence of Taiwan. TFDA continues its ongoing efforts in the international collaboration and information exchange of pharmaceutical testing.

2. Use of next-generation sequencing technology to monitor adenovirus-vectored vaccine

TFDA used next-generation sequencing technology to monitor the quality of 43 batches of adenovirus-vectored COVID-19 vaccine. The data showed that residual impurities consisted of residual genomic DNA from HEK-293 cells used in the manufacturing process, and accounted for approximately 0.0072-0.06% of the vaccine. This residual amount was estimated to be roughly 1.1 ng/dose, lower than the upper limit of the WHO's recommended nucleic acid residue content (10 ng/dose). TFDA will continue to improve this testing method, and hopes to achieve a testing capability that cannot be matched by current conventional testing methods. Even if not all unexpected nucleic acid components can be fully monitored, this method will certainly enhance Taiwan's ability to maintain the quality of new biologicals.

3. Release of a domestically-developed enterovirus 71 vaccine

Since there had long been no effective medical means of preventing infection by enterovirus 71, the domestic self-development and marketing of an EV-A71 vaccine represents an important milestone. In 2023, TFDA received applications for lot releasing tests for enterovirus 71 vaccines from Medigen (Envacgen) and from Enimmune (EnVAX-A71). A total of 14 lots, consisting of 232,516 doses, of domestically-produced EV-A71 enterovirus vaccine had been released by the end of the year. Starting in 2024, the enterovirus A71 (EV-A71) antigen national standard will be used as a reference for comparisons in potency testing and for internal quality control. TFDA is dedicated to improving testing quality and protecting the young children of Taiwan from the threat of enterovirus.

Section 6

Analysis of Pharmaceutical Regulations in New Southbound Countries

Introduction

In accordance with the Ministry of Health and Welfare's "New Southbound medical cooperation and industrial chain development program," TFDA has continued to develop New Southbound policies. During the second phase of the plan (2022-2025), TFDA will

continue to collect and analyze the pharmaceutical regulation policies of the New Southbound countries, look for trends, and compare them with Taiwan's regulations and policies. This information will be used to develop strategies for entering the New Southbound countries' pharmaceutical markets. We look forward to increasing the competitiveness of Taiwan's pharmaceutical industry in New Southbound markets.

Implementation Strategies

1. Analyzing strategies employed by advanced countries to enter the medical market of New Southbound countries

TFDA actively engages in the exchange of pharmaceutical management information and technology with New Southbound countries with long-term partner relationships, and has gradually established trust and understanding with them. TFDA has participated in online pharmaceutical and healthcare seminar conducted by Vietnam, and visited the Medical Device Management Bureau of Vietnam's Department of Health. TFDA has further established a contact window with the Vietnamese medical device regulatory unit, and looks forward to further exchange information between the two countries. Furthermore, TFDA has also collected and analyzed Korea's strategy for assisting its pharmaceutical industry to enter the Vietnamese market.

2. Gathering information on pharmaceutical regulation and industry trends in the New Southbound countries

To gain a better understanding of recent regulatory and industry trends in the New Southbound countries, and provide a reference to guide decision-making, TFDA has been gathering regulatory and policy information from the "One Country, Multiple Center" countries Vietnam, Indonesia, and Malaysia during the second phase of the Ministry of Health and Welfare's "New Southbound medical cooperation and industrial chain development program."

3. Holding classes on "regulatory and management policies of pharmaceuticals in the New Southbound countries"

The "Regulatory and Management Policies of Pharmaceuticals in New Southbound Countries Class" held by TFDA on June 20, 2023 provided an overview of Malaysia's pharmaceutical and medical device supervisory and regulatory strategies and trends, and provided an opportunity for healthcare experts, scholars, and pharmaceutical industry representatives to share information concerning smart medicine, "software as a medical device" (SaMD), and use of AI to assist pharmaceutical development. This event gave participants a deeper understanding of regulatory developments in Malaysia.

Achievements and Benefits

Pharmaceutical regulations and industries have evolved rapidly in the New Southbound countries. Apart from gathering documents and information, the sharing and exchange information in all forms is also very important. By drafting strategies for specific New Southbound countries, analyzing differences in regulatory trends, and sharing information in different ways, TFDA has successfully promoted many international cooperation opportunities and advanced into international markets.

Stepping up awareness: Use and not abuse

With the aging of society and increases in depression, anxiety, and insomnia in recent years, TFDA has been intensifying efforts to promote the rational use of controlled drugs and prevent drug abuse. TFDA has been actively revising regulations concerning controlled drugs and managing their circulation; apart from classifying and managing controlled drugs in four schedules by their potential for habitual use, dependence, abuse, and danger to the society in accordance with the Controlled Drugs Act. TFDA has also been conducting source management targeting various types of users, strengthening flow management, and also improving the production quality of schedule 1 and 2 controlled drugs in order to achieve the goal of domestic mass production. In addition, TFDA has established a controlled drug abuse notification system, improving monitoring and early warning of drug abuse, and cooperating with NGOs, indigenous communities, online media, and other ministries in public awareness concerning the correct use of controlled drugs and prevention of drug abuse.

04

Reinforced Management over Controlled Drugs and Prevention Against Drug Abuse

04

Reinforced Management over Controlled Drugs and Prevention Against Drug Abuse

To ensure the proper use of controlled drugs and prevent drug abuse, TFDA has established a mechanism for monitoring drug abuse trends, and gathers relevant domestic and international information, which provided to the Ministry of Justice as a reference for updates to its list of controlled drugs. When illicit drugs included by the Ministry of Justice in the control are needed medically and scientifically, they will be subject to the "Controlled Drugs Act." In compliance with the Executive Yuan's drug abuse prevention measures, TFDA has also increased awareness of the harm caused by illicit drugs. Furthermore, TFDA has developed testing methods for emerging and frequently-abused drugs, expanded its drug spectrogram database, and shares technical information with investigative agencies as part of a joint effort to eliminate the use of illicit drugs.

Section 1

Promote Amendment to the Regulations on Controlled Drugs and Diversion Management

Introduction

To prevent the abuse and illicit use of controlled drugs, the relevant regulations of the "Controlled Drugs Act" are periodically reviewed and amended, and international trends are closely monitored through exchange, and performs audits of controlled drug distribution.

Implementation Strategies

1. Periodic Review and Evaluation of Controlled Drugs

The "Controlled Drugs Review Committee of the Ministry of Health and Welfare" was held every half-year to assess and regulate the new psychoactive substances found internationally that may only be used for medical or scientific purposes.

2. Project-based audits and training of medical personnel

The controlled drug audit plans drafted by TFDA on an annual basis seek to reinforce assessment of the reasonableness of the prescribed use of controlled drugs and ensure that the improper prescription of controlled drugs by doctors does not lead to iatrogenic addiction or abuse of the drugs by patients. TFDA has also developed the handbooks of pain care and offered seed instructor training classes intended to spread knowledge of narcotic drugs causing addiction among medical personnel.

Achievements and Benefits

1. Added/Revised controlled drugs and active pharmaceutical ingredients included in control

The Ministry of Health and Welfare convened the 47th Controlled Drugs Review Committee meeting in 2023, and 21 additional controlled drug items were announced. This includes the reclassification of phenobarbital compound preparations and chlordiazepoxide compound preparations to schedule IV controlled drugs. The new regulations will take effect on December 1, 2023.

2. Conducting audits; enhancing knowledge of medical personnel in the use of controlled drugs

The project-based audits of 203 firms conducted by TFDA in 2023 found 62 firms to be in violation of regulations, for a noncompliance rate of 30.54%. TFDA also compiled two Chinese/English handbooks, the Handbook of Cancer Pain Care (Public Version) and Handbook of Non-Cancer Chronic Pain Care (Public Version), and provided three training sessions for pain management seed instructors. These handbooks and training are boosting understanding of controlled drug use by patients on the part of medical personnel, and preventing iatrogenic addiction.

Section 2

Enhancing the Quality of Schedule 1 and 2 Controlled Drugs

Introduction

To improve controlled drug production quality and expand capacity, since 2020, TFDA's official pharmaceutical plant has conducted several R&D projects and drafted plans for the self-mass production of products that are currently produced under commission and imported. The aim is to help boost the supply of domestically produced pharmaceuticals.

Implementation Strategies

TFDA's pharmaceutical plant is continuing to build new dosage form production lines, with plans calling for the addition of solution, capsule, and patch production lines in the near future, and the plant is also expanding production and storage capacity. The development of injections and solution has been prioritized, followed by capsules and patches that solutions a higher level of technical difficulty. Production lines for solutions and 10 ml injections were completed in 2022 and 2023 respectively.

Achievements and Benefits

TFDA's pharmaceutical plant completed the purchase of equipment and establishment 10mg fentanyl for injection production line in 2023, and plans to restore self-mass production in 2024. At the same time, the plant is also conducting R&D on the production of Oxycodone Hydrochloride Immediate Release Capsule and Morphine Sulfate Prolonged Release Capsule and Matrix patches. Looking ahead to the future, plans call for the plant to produce five dosage forms–injections, tablets, solutions, capsules, and patches–and achieve a self-mass production rate of over 70%. See Fig. 4-1 and 4-2 for photos of filling and packaging equipment on the 10mg fentanyl for injection production line.

Figure 4-1 10mg Fentanyl for Injection Production Line Equipment — Filling Machine

Figure 4-2 10mg Fentanyl for Injection Production Line Equipment — Packaging Machine

Section 3
Enhancing Early Warning of Drug Abuse

Introduction

New psychoactive substances (NPSs) have a wide range of varieties and have developed rapidly. In order to effectively monitor NPSs, TFDA continues to reinforce the capacity of domestic accredited institutions in urine testing of illegal drugs.

Meanwhile, TFDA compiles the statistics such as drug abuse reported by healthcare facilities, urine testing for drug abuse, non-urine specimen testing for suspected illicit drug and controlled drug abuse, and confiscation of illicit drugs on a monthly basis, and prepares the "Drug Abuse Cases and Testing Statistics" in order to effectively monitor and control NPSs.

Implementation Strategies

1. Reporting mechanism for healthcare facilities on drug abuse

TFDA has established the Drug Abuse Reporting System (DARS), and compiles drug abuse cases reported by healthcare facilities on a monthly basis.

2. Upgrading the management of accredited organizations for urine test of abused drug

Responding to a growing demand for testing and monitoring of abused drugs, TFDA has revised the quality control requirements in the *Guide to On-site Assessment of Organizations for Urine Test of Abused Drug*. Based on the NPS commonly detected in urine over recent years, TFDA assisted seven organizations for urine test of abused drug in optimizing the testing methods to continuously polish the skills for testing in 2023. Routinely, those commonly-detected NPS substances have also used as performance specimens to monitor quality of test among accredited organizations.

3. Non-urine (Drug) testing and reporting upon drug abuse

According to the division of labor table in drug testing of the Ministry of Justice, there are 15 agencies (institutions) in Taiwan at present to help prosecutors, police and investigation units test non-urine specimens for drug abuse. As is required by the "Enforcement Rules of the Narcotics Hazard Prevention Act," respective test agencies (institutions) shall report drug test results to the Urine Test for Drug Abuse Reporting System (UDARS) on a monthly basis. TFDA will then count the tested positive results of non-urine specimens of suspected illicit drugs and controlled drug cases and provide a reference for the development of drug control strategies by various departments.

4. Emergency department drug abuse surveillance

In 2023, TFDA continued to commission the "Monitoring Plan for NPS in Emergency Departments (ED)" to conduct expanded screening of urine specimens of 175 NPSs for suspected drug poisoning cases in ED of medical institutions throughout the nation. The results can be the reference to diagnosis and treatment for ER physicians, as well as to understand the drug abuse situation from the medical side.

Achievements and Benefits

1. Reporting situation of drug abuse from healthcare facilities

According to the DARS data, a total of 12,585 drug abuse cases were reported by healthcare facilities in 2023, and this figure represented a drop of 14.6% compared with 2022. The top three drug abused were heroin (6,412, 50.9%), (meth) amphetamine(5,511, 43.8%), and benzodiazepine (2,240, 17.8%), which was generally identical to the trends in 2022.

2. Reporting situation of accredited institutions for drug abuse urine testing

As of the end of 2023, 18 drug testing institutions had been accredited and there were two designated public health bureaus. Among them were 15 that had been performing urine testing for NPSs and they need to report test results each month to the UDARS. TFDA continues to encourage private test institutions to get accredited and submit their NPS test method validation

data for review in order to maximize the capacity of urine testing for NPSs.

In 2023, the total number of urine tests performed throughout Taiwan came to 319,853; among them were 71,816 positive results, accounting for 22.5% of all tests. The top 3 substances detected were methamphetamine, ketamine, and morphine, an increase of 1.4%, 10.3% and 11.2%, respectively from 2022.

3. Reporting situation of non-urine testing for drug abuse

In 2023, the total number of cases with positive test results in non-urine specimens testing for suspected illicit drug and controlled drug abuse in Taiwan came to 348,736, which represented an increase of 40.3% compared with 2022. Methamphetamine, ketamine, and heroine were found in 21,087 cases, 18,655 cases, and 28,357 cases, respectively.

4. Emergency department drug abuse surveillance

In 2023, a network of 144 collaborating hospitals and a platform for expanded extensive screening of urine specimens of 175 NPSs were in place. The number of samples received came to 4,086 and among them were 1,032 positive cases, accounting for 25.3% of all samples. With the 218 found with medicines consistent with those prescribed by doctors excluded, there were 814 cases that were truly positive. Among them, males were accounted for the majority. In terms of the age group distribution, 25 to 34 years old was the majority, followed by 35 to 44 years old, and then 45 to 54 years old. Twenty-nine NPSs were detected and among them were mostly synthetic cathinone, identical to the program in 2022. 4-methylmethcathinone (4-MMC) was the most detected drug, followed by ketamine, and then 4-methyl-N,N-dimethylcathinone (4-MDMC).

Section 4

Strengthening Awareness of Correct Use of Controlled Drugs and Prevention of Drug Abuse

Introduction

TFDA is cooperating with non-governmental organizations (NGOs), indigenous communities, online media, and other ministries in the use of multiple channels to enter workplaces, communities, indigenous areas, and the online user population to provide health education awareness promoting correct use of controlled drugs and prevent drug abuse.

Implementation Strategies

1. Fun in Preventing Drug Abuse

TFDA has cooperated with the Ministry of Justice, Ministry of Education, and National Police Administration, Ministry of the Interior to implement the "Fun in Preventing Drug Abuse Program ." This plan, which was conducted in Chiayi County, Chiayi City, Tainan City, Kaohsiung City, Pingtung County, and Penghu County in 2023, involved the use of touring display boxes and large play equipment to promote an anti-drug message and provide the public with drug abuse prevention information in communities and workplaces.

2. Cooperation with NGOs

TFDA is cooperating with NGOs to promote the correct use of sedative hypnotics and provide drug abuse prevention awareness at community gatherings and festival activities.

Figure 4-3 Health Education Graphics and Text Created with Graphic Artist tooooozitw

Figure 4-4 Health Education Graphics and Text Created with Graphic Artist Taiwan Bar

3. Promoting correct use of sedative hypnotics and drug abuse prevention in indigenous communities

In 2023, TFDA conducted training classes and awareness talks on such topics as the correct use of sedative hypnotics and drug abuse prevention personnel in indigenous communities in New Taipei City, Yilan County, Hualien County, Taoyuan City, Nantou County, and Pingtung County. TFDA also promoted correct medication use knowledge in indigenous communities by providing instructor training to local people.

4. Online awareness of correct use of controlled drugs and drug abuse prevention

TFDA enlisted the online illustrators "Tooooozitw" and "Taiwan Bar" to create health education graphics and text concerning the correct use of controlled drugs and drug abuse prevention (Fig. 4-3, 4-4), and designed the online game and prize drawing activity "Recognizing Drugs Dojo: Hand and Eye Competition" (Fig. 4-5), which helped game participants to learn about the dangers of drug abuse and five methods for avoiding drugs. TFDA hopes that these measures will enhance people's knowledge in drug abuse prevention.

Achievements and Benefits

1. Implementation of Fun in Preventing Drug Abuse

In 2023, TFDA conducted 382 touring awareness sessions in six cities and counties under the Fun in Preventing Drug Abuse Program, and these sessions benefited a total of 91,117 persons.

2. Cooperation with NGOs

In 2023, TFDA cooperated with 11 NGOs in holding fun activities intended to spread awareness of drug abuse prevention (Fig. 4-6), and the total of 210 such sessions benefited 36,464 persons. In particular, after the Chinese Cartoonists Union created the "Five Key Skills to Ensure the Correct use of Sedative hypnotics" manga handbook, TFDA printed 1,500 copies for distribution to libraries and other public locations in communities.

3. Promoting correct use of sedative hypnotics and drug abuse prevention in indigenous communities

TFDA conducted 10 drug abuse prevention classes in indigenous communities in 2023, which provided training to 205 members. There are 27 of these members hold 37 classes in drug abuse prevention in their respective villages, and 972 persons of the public took part in these activities. Indigenous communities gave these activities their full support and affirmation.

4. Correct use of controlled drugs and drug abuse prevention online health education

TFDA held the online game and prize drawing activity "Recognizing Drugs Dojo: Hand and Eye Competition" in 2023, and posted the drug abuse prevention awareness work of online illustrators, which reached 442,991 persons.

Section 5

Results of Testing for New Psychoactive Substances (NPS)

Introduction

The gangsters keep synthesizing new compounds through mimicking the chemical structures of the scheduled substances to evade the law control. The unscrupulous activities have led to worldwide NPS prevalence which must be addressed and curbed.

Implementation Strategies

1. Promote the experience exchange on prevention and testing techniques for NPS

To demolish the restriction on NPS identification from insufficient built-in database, TFDA has built up its own spectrum database of portable Raman spectrometers. TFDA and the concerned authorities are working together through sharing the Raman spectrum database to keep illicit drugs out of borders.

2. Expand inspection capability for NPS

TFDA establishes standard spectra of NPS using gas chromatography (GC-MS) and liquid chromatography-tandem mass spectrometry (LC-MS/MS), and upload to the Analytic Laboratory Urine and Drug Abuse Report System (UDARS) for the sake of the drug testing laboratories to review and download.

Achievements and Benefits

1. Promote the experience exchange on prevention and testing techniques for NPS

The database of portable Raman spectrometers which covers 2,337 items of NPS and pharmaceuticals. The "Workshop for Raman Spectroscopy Database Sharing and Experience Exchange" was held on August 23, 2023. Authorities concerned including the Criminal Investigation Bureau and Customs Administration et al. were invited to share their experience of NPS testing techniques.

2. Expand inspection capability for NPS

TFDA has been working hard to consolidate its

Figure 4-5 "Recognizing Drugs Dojo: Hand and Eye Competition" Online Game

Figure 4-6 Drug Abuse Prevention Awareness Via a Sack Puppet Show by the Wu Chou Yaun Palm Puppet Troupe

drug testing expertise, and 1,428 standard spectra have been established to assist drug identification and seizures identification. A total of 6,999 click-through rates were achieved from 19 laboratories, and 108 NPS standards were provided for 27 turns from various laboratories for developing testing methods or for NPS identification. TFDA supports efforts on combating drug trafficking in a variety of ways.

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.

05

Sound and Effective Management of Medical Devices and Cosmetics

05

Sound and Effective Management of Medical Devices and Cosmetics

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.

A great leap forward for medical devices and medicines; A year of impressive results

After many years of effort and deepening of international cooperation, Taiwan's medical devices and medicinal product and services enjoyed extensive international recognition in 2023. Among some very encouraging breakthroughs in recent years, TFDA became an affiliate member of the International Medical Device Regulators Forum (IMDRF), and has continued to exchange management system and technology knowledge in this role. Taiwan's active pharmaceutical ingredients have successfully been included on the list of active ingredients from third countries that can be imported into the EU, which will shorten the time needed to export active pharmaceutical ingredients to the EU. TFDA cooperated with the Asia-Pacific Self-Medication Industry Association in holding an international symposium on pharmaceutical affairs. These three achievements not only promoted the international exchange of technology and helped the country tackle emerging technological challenges, but also boosted the competitiveness of domestic industry and greatly enhanced Taiwan's international visibility.

06

Special Edition

06 Special Edition

TFDA enjoyed numerous international breakthroughs and positive results in 2023. Thanks to its cumulative efforts in many previous years, TFDA has successfully ensured that Taiwan's medical device and pharmaceutical industries are receiving due international recognition. The following are three particularly notable results: 1. Taiwan became an affiliate member of the International Medical Device Regulators Forum, (IMDRF), enabling it to share management system and technological know-how. 2. Active pharmaceutical ingredients (APIs) were successfully included on the list of third countries exporting APIs to Europe, which shortened the time needed to obtain approval for export of APIs to the EU. 3. TFDA cooperated with the Asia-Pacific Self-medication Industry Association (APSMI) in holding an international pharmaceutical symposium, which promoted positive interchange with other countries. The foregoing three accomplishments are also continuing to boost Taiwan's international influence and industrial competitiveness.

Section 1
TFDA Becomes an Affiliate Member of IMDRF

Introduction

The International Medical Device Regulators Forum (IMDRF) is an international organization established by the representatives of medical device regulatory bodies in countries worldwide. The IMDRF was founded in October 2011, and currently has 11 management committee members, which include the competent authorities of the Australia, Brazil, Canada, China, the EU, Japan, Russia, Singapore, South Korea, Britain, and the United States. The IMDRF's members hope to use strategic thinking to accelerate the international harmonization of regulations governing medical devices, and it has established a working group to draft regulatory guidance documents, which may serve as a reference for medical device industry personnel and officials worldwide.

Implementation Strategies

TFDA has participated in the IMDRF's annual conferences since this organization was founded, and is in active contact with relevant officials from various other countries. TFDA attended the IMDRF's management committee conference as representative of the Asian Harmonization Working Party (AHWP) in 2013, and has given reports and shared management experience at IMDRF conferences as a representative of the APEC Regulatory Harmonization Steering Committee (RHSC) in 2014, 2015, and from 2019 until the present (Fig. 6-1).

After joining the IMDRF's Principles of the In Vitro Diagnostic Medical Devices Classification Working Group as a representative of the AHWP in 2019, TFDA participated in physical and online conferences, and provided opinions concerning the revision of draft regulations, which assisted the formulation of a final document in 2021. Furthermore, TFDA joined the Clinical Evidence for In Vitro Diagnostic Medical Devices Working Group in 2022, and jointly engaged in research and promotion work with other working group members.

At the end of December 2022, IMDRF announced the identity and classification of new affiliate members, and allowed the competent authorities of more countries to apply for membership. Upon learning this information, TFDA promptly prepared the required materials, and applied to join the IMDRF as an affiliate member in early 2023. TFDA then gave a report at the IMDRF's 23rd annual conference in March, and after deliberation by IMDRF's management committee, was approved for affiliate member in August. At the IMDRF's 24th annual conference on September 24

Figure 6-1 TFDA Personnel Gave Reports Representing the APEC RHSC at the IMDRF's 23rd and 24th Annual Conferences

of the same year, TFDA participated in an IMDRF conference as an affiliate member for the first time. After several years of its own hard work and assistance from friendly countries, TFDA finally became an affiliate member of the IMDRF.

Achievements and Benefits

Looking ahead to the future, TFDA will continue to attend IMDRF management committee conferences, which will allow it to learn about the newest medical device management strategies in different countries, and quickly understand regulatory development trends. In addition, TFDA plans to join more relevant IMDRF working groups, which will provide opportunities to contact and interact with other countries' technical officials and industry experts, and will consequently strengthen Taiwan's technological diplomacy and international person-to-person contacts. The joint development and drafting of documents will allow TFDA to gain a better understanding of the background of their drafting and key management points, which will facilitate subsequent adoption in Taiwan's management systems and implementation work. TFDA's continuing status as an affiliate member of the IMDRF will facilitate the harmonization of Taiwan's management systems with systems in other countries, and will boost the competitiveness of domestic industry. Technological interchange with other countries will help Taiwan cope with technological challenges, increase protection of people's health and safety, and boost Taiwan's international visibility, which will serve to deepen Taiwan participation and contributions to international regulatory harmonization efforts.

Section 2

Inclusion of Taiwan on the List of Third Countries Allowed to Export APIs to the EU

Introduction

According to EU regulations, from July 2, 2013, APIs exported from non-EU countries into the EU must be accompanied with written confirmation (WC) issued by the health competent authority of the exporting country or area, and this WC shall guarantee that production complies with standards equivalent to the EU's GMP requirements. If the EU determines that the "GMP requirements and compliance management system" of API manufacturer are equivalent to those of the EU, the country may be assessed and approved for inclusion on the list of third countries to exempt from the WC requirement.

Implementation Strategies

1. Application for inclusion on the list of API exporting third countries

To facilitate the export of Taiwan's APIs to the EU, TFDA formally submitted an application to the Directorate-General for Health and Food Safety (DG SANTE) for inclusion on the "List of third countries with a regulatory framework applied to active substances exported to the Union and the respective control and enforcement activities ensuring a level of protection of public health equivalent to that in the Union" on December 8, 2021. Assessment of Taiwan's application involved a total of 78 indicators in ten topics, which included legislative and regulatory requirements and scope (23 indicators), regulatory directives and policies (2 indicators), GMP standards (2 indicators), inspection resources (6 indicators), inspection procedures (18 indicators), quality management systems (7 indicators), surveillance programme (6 indicators), analytical capability (6 indicators), alert and crisis systems (2 indicators), and enforcement powers and procedures (6 indicators).

2. EU representatives conduct on-site assessment in Taiwan

After completing the review of the submitted documents, the EU sent personnel to conduct an on-site assessment in Taiwan during the period of April

20-27, 2023. This assessment team consisted of one representative each of the EU and EU member states; during the on-site assessment period, the team reviewed documents and interviewed personnel at TFDA, which confirmed whether Taiwan's API regulations and management system, inspection resources, determination of risk assessment and audit frequency, inspection scheduling and approval tasks, audit tasks and procedures, inspection report format, review procedures and result issuance tasks, and penalties for pharmaceutical plants violating GMP requirements, as well as actual cases and records provided by TFDA, had been implemented in accordance with regulations. Additionally, the EU assessment officials selected two API plants for on-site visits, accompanied by TFDA inspection team, to simulate an actual inspection process, including pre-inspection meetings and on-site audit simulations. The EU assessment officials were impressed by TFDA's performance, and expressed a high degree of approval and praise for TFDA's GMP audit quality system and assessment capacity (Fig. 6-2).

Achievements and Benefits

1. Successful inclusion of Taiwan on the list of third countries

The assessment report issued by the EU on June 20, 2023 concluded that Taiwan's API GMP management system, regulatory standards, and degree of implementation complied with the EU's requirements. Following several months of administrative procedures, on November 9, 2023, the European Commission issued Decision No. 2023/2484 pursuant to Decision 2017/715, and this Decision was published in the Official Journal of the European Union on the following day. The Decision took effect 20 days after publication in the Official Journal, and Taiwan was thereupon successfully included on the list of third countries.

2. Benefits of inclusion on the EU list of third countries

The 9 countries currently on the list of third countries permitted to export APIs to the EU include Taiwan, Canada, South Korea, Australia, Brazil, Israel, Japan, Switzerland, and the United States. Being included on the EU's list of third countries indicates that Taiwan's API supervision and management system, which includes production, quality management, and GMP standards and enforcement, is equivalent to that in the EU, and APIs produced in Taiwan meet the highest international standard. Listing will effectively shorten the time needed to export Taiwan's APIs to the EU, and boost the global competitiveness of Taiwan's pharmaceutical industry.

Figure 6-2 Kick-off Conference at the Start of On-site Assessment for Taiwan's Inclusion on the List of Third Countries Permitted to Export APIs to the EU

Section 3

Sharing International Regulatory Progress and Experience Concerning Pharmaceutical Services and Self-care

Introduction

With the rise of smart technology, the application of innovative high-tech tools to fields including pharmaceutical R&D, precision medicine, healthcare, and pharmaceutical services has recently made great progress. This has not only greatly improved the safety and effectiveness of drugs and medical devices, but also accelerated medical service procedures, boosted the effectiveness of pharmaceutical systems, ensured that patients can readily obtain needed treatment and care, and provided safer and more individualized pharmaceutical services.

To promote better understanding among nearby Asian countries, and try to bridge the discrepancies in different countries' non-prescription drug management regulations, the APSMI Association has established the Self-Medication Collaborative Asian Regulator Expert Roundtable (Self-CARER), which brings together representatives of industry, government, academia, and institutes from different countries for the purpose of establishing the complementarity of concepts between each other based on an understanding of the individual countries' newest regulations and current state of their social medicine. This conference is having a highly positive influence on the promotion of self-care.

Implementation Strategies

1. Holding the Building Better Pharmaceutical Care with Technology international pharmaceutical conference

Starting in 2012, TFDA has promoted pharmaceutical care service, including the joint promotion of the provision of pharmaceutical care services by pharmacists in conjunction with the Pharmacists Association and local health departments. To ensure that pharmacists had a better understanding of international trends in the application of technology to pharmaceutical services, TFDA held the Building Better Pharmaceutical Care with Technology international pharmaceutical conference on October 25, 2023 (Fig. 6-3). TFDA invited domestic and international heavyweight experts and scholars from the International Pharmaceutical Federation (FIP), Japan, Korea, and Taiwan to this event, where they shared the promotional policies and clinical experience concerning the medical applications of technology in their respective countries. The conference brought innovative applications of technology in medicine and pharmaceutical services, which will inject new thinking and development in Taiwan's medical and pharmaceutical services.

2. Holding the 5th Self-CARER international conference

The 5th Self-Medication Collaborative Asian Regulator Expert Roundtable (Self-CARER) conference, which was jointly held in Taiwan by TFDA and APSMI on September 20, 2023 (Fig. 6-4), invited regulatory personnel from major Asian countries to share self-care and self-medication regulatory developments. The conference explored international trends in non-prescription drug regulations, discussed actions to promote the sustainable development of healthcare systems, and shared relevant information and individual countries' regulatory trends. The conference also provided important reference information to aid in drafting self-medication and self-care policies in Asian countries.

Achievements and Benefits

1. Enhancing pharmaceutical service quality through a broader international perspective

The Building Better Pharmaceutical Care with Technology international pharmaceutical conference was attended by 141 domestic and international participants. At this conference, experts and scholars shared various countries' successful policies and clinical practice experience, and the event provided an in-depth understanding of actual applications of AI, cloud computing, and mobile devices, etc. in pharmaceutical services, assisted the participating countries to more effectively use technology to boost pharmaceutical service quality, and promoted the in-depth fusion of technology and pharmaceuticals. The conference made participants consider the possibility of the expanded application of technology to the field of pharmaceuticals, broadened their international perspective, and further promoted the improvement of pharmaceutical service standards on a global basis.

2. Enhancing the international influence of Taiwan's non-prescription drug management

The 5th Self-CARER international conference invited 25 foreign officials and industry experts from 10 major Asian countries, including Japan, Thailand, Korea, the Philippines, Malaysia, Vietnam, Indonesia, Cambodia, India, and Laos. Apart from boosting understanding of these countries' regulatory developments, the conference also discussed the improvement of non-prescription drug category conversion, simplification of drug inspection and registration, and use of digital prescriptions. This conference boosted Taiwan's friendly international interchange, amplified the international impact of Taiwan's non-prescription drug regulatory management, and promoted industry's sustainable development.

Figure 6-3 Building Better Pharmaceutical Care with Technology International Pharmaceutical Conference

Figure 6-4 The 5th Self-CARER International Conference

Sharing the achievements of 2023

This 2023 annual report includes important milestones, major achievements, statistical information, important results and statistics for past years, and 2023 publications. Addressing the revision of food sanitation management laws and standards, TFDA issued a food sanitation management and practice guide. TFDA also revised laws and standards concerning food inspection and registration for specific foods and food additives, revised pharmaceutical management regulations and standards, announced approval of new drugs, revised the schedules of controlled drugs, revised cosmetic management laws and standards, and announced results of joint audits of foods, medicinal products, and cosmetics. All of these results are described in detail in this annual report, and we hope that this will help the public understand TFDA's tangible achievements in ensuring the safety of drugs, foods, and cosmetics.

07

Appendix

07 Appendix

Appendix 1 Important Events

1	January 7	Announcement of the list of 9 medical device EU Notified Bodies under the third-generation Technical Cooperation Programme (TCP III), which will allow medical device manufacturers in Taiwan and the EU to apply for simplified Conformity Assessment of medical device quality management system.
2	February 1	Announcement of the drafting of "Regulations Governing the Labeling Which Shall Be Labeled of Infant and Follow-up Formula," which will take effect on January 1, 2025. These regulations combine four regulations governing the labeling and items that may not be labeled in the case of infant formula and follow-up infant formula, namely "Regulations Governing the Labeling of Infant Formula and Complete Formula for Infants over Four Months Old," "Regulations Governing the Labeling of Infant Formula in Liquid Form," "Regulations Governing the Labeling Which Shall Not Be Labeled of Infant Formula and Complete Formula for Infants over Four Months Old," and "Infant and Follow-up Formula Shall Have a Recognized Label Directly Printed onto the Container for Ease of Identification."

February 1	To improve autonomous hygiene management among manufacturers of vacuum-packed soybean ready-to-eat foods, and ensure compliance with the *Act Governing Food Safety and Sanitation* and relevant regulations, TFDA drafted the "Guidelines for Manufacturers of Vacuum-Packed Soybean Ready-To-Eat Food to comply with the Regulations on Good Hygiene Practice for Food" to guide manufacturers' practice, and urged firms to continuously strengthen their food safety and hygiene.
February 9	Announcement of the revised "Categories Which the Track and Trace System for Medicinal Products Should Be Implemented According to Article 6-1 of Pharmaceutical Affairs Act," which added 17 categories and took effect on April 1, 2023.
February 10	Conducted the Keelung session of the 2023 "Minister of Health and Welfare's inspection visit to the Taiwan Food and Drug Administration's Center for Regional Administration and panel discussion on local involvement in food and drug services," which was hosted by Dr. Hsueh Jui-yuan, Minister of Health and Welfare; personnel from the Department of Health, Taipei City Government, Department of Health, New Taipei City Government, and Keelung City Health Bureau were on hand for discussion and interchange.
February 14	The Research Center for Biotechnology and Medicine Policy held the "SNQ National Quality Mark and National Biomedicine Quality Awards" conference at the Grand Mayfull Hotel Taipei. At this event, Vice President Lai Ching-te gave a speech and issued the National Biomedicine Quality Awards' gold, silver, and bronze awards for hospitals to representatives of the award-winning units. Dr. Hsueh Jui-yuan, Minister of Health and Welfare, was also in attendance, and issued the National Biotech Medicine Quality Awards' gold, silver, and bronze awards for pharmaceuticals to representatives of the award-winning units.
February 14	Drafting of the "Infant Formula and Follow-up Infant Formula Advertisement Principles." The key points of these Principles include information that must be provided when selling infant formula and follow-up infant formula through an online channel and information disclosure when selling such formula through a physical channel. The Principles took effect on the day of promulgation.
February 15	Conducted the Taichung session of TFDA's 2023 "Minister of Health and Welfare's inspection visit to the Taiwan Food and Drug Administration's Center for Regional Administration and panel discussion on local involvement in food and drug services," which was hosted by Minister of Health and Welfare Hsueh Jui-yuan; personnel from the Department of Health, Taichung City Government, Changhua County Public Health Bureau, Nantou County Public Health Bureau, and Lienchiang County Public Health Bureau were on hand for discussion and interchange.

2

February 16	The Executive Yuan passed the *MOHW's Draft Regenerative Medicine and Draft Regenerative Medicinal Products Act*, and requested the Legislative Yuan to perform deliberation. The two acts on regenerative medicine will encourage innovation and promotion of regenerative medicine biotechnology in Taiwan, and accelerate the application of regenerative medicine R&D results to clinical medicine. The two acts will also strengthen management and linkage of regenerative medicine biotechnology and relevant medicinal products, and protect the rights of patients by ensuring the quality, safety, and effectiveness of regenerative medicine.
February 17	The Control Yuan's Social Welfare, Health, and Environment Committee conducted an on-site tour of TFDA's Factory for Controlled Drugs, National Food and Drug Laboratory, and Decision Support Center, and afterwards conducted a panel discussion concerning services. Control Yuan member Su Li-chiung led the visiting team of more than 10 investigators, and the accompanying MOHW contingent led by Vice Minister Wang Pi-sheng included TFDA's director-general, two TFDA deputy director-generals, and secretary general. The Control Yuan team listened to a briefing on services and took part in a tour of the facilities and panel discussion. The Control Yuan members expressed concern about issues including food and drug advertising, the constant problem of inflated and untruthful advertising claims, and state of relevant penalties; the management mechanisms for betel nut additives suspected of causing cancer; safety supervisory and testing mechanisms for the small-scale food manufacturing industry; issues connected with the Food Cloud; management of foods with trace levels of radiation; GMO food policy directions; and testing of emerging drugs. Vice Minister Wang Pi-sheng and TFDA's director-general variously responded to the key points of the issues raised by the visiting Control Yuan members.
February 22	Conducted the Taoyuan session of the 2023 "Minister of Health and Welfare's inspection visit to the Taiwan Food and Drug Administration's Center for Regional Administration and panel discussion on local involvement in food and drug services," which was hosted by Dr. Hsueh Jui-yuan, Minister of Health and Welfare; personnel from the Department of Public Health, Taoyuan, Public Health Bureau, Hsinchu City, Hsinchu County Public Health Bureau, and Miaoli County Public Health Bureau were on hand for discussion and interchange.

3	March 27	TFDA revoked the "Disease Prevention Management Measures for the Dining Industry," and concurrently delisted related guidelines and Q&A sections, in conjunction with the MOHW's revision of the "Severe Pneumonia with Novel Pathogens (Covid-19) Prevention Measure and Punishment Regulations" on February 20, 2023, which deleted the "Notice of the COVID-19 control and management measures for the Food Service," and the resulting easing of disease prevention policy.
5	May 1	For medical devices announced by the MOHW and their dealers, a good distribution system must be established in accordance with the criteria specified in Article 24 of the Medical Device Act. Medical device dealers may proceed with wholesale, import, or export after completing a compliance inspection and obtaining a distribution license.
	May 11	Due to the detection of the hepatitis A virus in imported frozen berries, to promote public safety and encourage bakery, Minister of Health and Welfare Dr. Hsueh Jui-yuan and Deputy Director-general Tu Wen-chen of the Council of Agriculture (currently deputy minister of the Ministry of Agriculture) visited a bakery and checked on the status of berries used in baked goods commonly purchased by people for Mother's Day.
	May 22	Conducted a food ingredient registration platform sharing session, and invited the Taipei, New Taipei, and Taoyuan public health departments to share the results of their food ingredient registration platforms. The Executive Yuan's Food Safety Office, the health bureaus of 22 cities and counties, and relevant TFDA units were also invited to conduct on-site and online instruction.
	May 19 to May 27	MOHW organized the 76th WHA mobile team. TFDA Director-General Wu Shou-Mei participated on behalf of TFDA.
6	June 7	The theme of this year's World Food Safety Day was "Food standards save lives." For this event, TFDA invited experts and industry representatives to a press conference, at which the participants jointly kicked off World Food Safety Day and promoted awareness of food safety.
	June 10	To promote the correct selection and use of medical devices and cosmetics, TFDA conducted the "Healthy and Beautiful Living Day" health education activity at the Taipei Zoo. Together with the representatives of various organizations and associations, TFDA Director-General Wu Shou-Mei kicked off the event and gave a speech, and the activity was concluded very successfully.
	June 15	TFDA announced the revised "Regulation of Imported Beef and Beef Products from the United States and Canada," which allows the import Canadian all-age beef and its products, and revises relevant codes in the Customs Import Tariff Import/Export Commodity Classification Table.

6	June 15	Announcement of "Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief" and revocation of the "Regulations Governing Reviewing Procedure of Drug Injury Review Committee of Ministry of Health and Welfare," "Regulations for Drug Injury Relief Application," and "Drug Injury Relief Payment Standard." Separately, the "Establishment Directions for the Drug Injury Review Committee of the Executive Yuan, the Department of Health" ceased to apply. The "Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief" govern drug injury application procedures, payment amounts, committee organization, and review matters. The drafting of these regulations will facilitate the drug injury relief review process.
7	July 5	Conducted the Kaohsiung session of the 2023 "Minister of Health and Welfare's inspection visit to the Taiwan Food and Drug Administration's Center for Regional Administration and panel discussion on local involvement in food and drug services," which was hosted by Dr. Hsueh Jui-yuan, Minister of Health and Welfare; personnel from the Yunlin County Public Health Bureau, Chiayi County Public Health Bureau, Chiayi City Public Health Bureau, Tainan City Public Health Bureau, Department of Health, Kaohsiung City Government, Pingtung County Public Health Bureau, Penghu County Public Health Bureau and Kinmen Public Health Bureau were on hand for discussion and interchange.
	July 6	Issuance and promulgation of the "Guidelines for Food Safety Assessment of Genetically Modified Foods Derived from Recombinant-DNA Organisms" and repeal the previous version, which came into effect on the same day.
	July 10	Conducted the Hualien session of the 2023 "Minister of Health and Welfare's inspection visit to the Taiwan Food and Drug Administration's Center for Regional Administration and panel discussion on local involvement in food and drug services," which was hosted by Dr. Hsueh Jui-yuan, Minister of Health and Welfare; personnel from the Yilan County Public Health Bureau, Hualien County Public Health Bureau, and Taitung County Public Health Bureau were on hand for discussion and interchange.
	July 11 to July 13	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. This event provided an opportunity to exchange regulatory experiences with the competent authorities and industry representatives from 15 countries, and helped TFDA keep pace with international cosmetic development and accelerate the harmonization of Taiwan's cosmetic management system with regulatory practices around the globe.

7	July 14	Dr. Hsueh Jui-yuan, Minister of Health and Welfare and TFDA Director-General Wu Shou-Mei met with a visiting delegation led by Paraguayan president-elect Santiago Peña, and the two parties discussed topics including Taiwan's health insurance system and ways of deepening cooperation in the field of healthcare between Taiwan and Paraguay.
	July 26	Announcement of the "Implementation of Pharmaceuticals and the Types of Pharmaceutical Firms, Requirement, Methods and Schedules Regulated Under Western Pharmaceuticals Good Distribution Practice Regulations," which will take full effect on December 31, 2026, and will boost Taiwan's pharmaceutical distribution management quality and ensure citizens' medication safety.
8	August 1 to August 3	TFDA holds a joint conference (physical) of working groups 1, 2, and 3 (WG1-WG2-WG3) of the technical committee of the Global Harmonization Working Party (GHWP). The participants at this conference, who consisted of 26 government officials and experts from various countries, chiefly discussed guidance documents spanning different working groups' areas of expertise. The conference yielded very substantive results from the interchange between Taiwan's participants and the officials and industry representatives from other countries, and highlighted Taiwan's active contributions to the harmonization of international medical device laws and regulations.
	August 25	The Ministry of Labor performed an on-site inspection of TFDA's factory for controlled drugs for the 2023 "Government Agency Occupational Health and Safety Promotion Performance Evaluation," and investigated the state of environmental sanitation and occupational safety for personnel. Among the items examined in this inspection were water system pressure vessels and noise prevention, handling of laboratory chemical waste and other hazardous materials, and accident prevention training and actions. The plant received an Excellence Award on the basis of its outstanding occupational health and safety review assessment.
	August 29-31	To encourage countries in the Asia-Pacific Region to adopt international medical device standards as a basis for medical device safety and effectiveness, and to harmonize regulations throughout the region, TFDA held the "APEC Medical Devices Regulatory Science Center of Excellence Workshop" in both physical and virtual form to train 36 seed instructors affiliated with industry, government, and academia from 13 countries. In the future, these seed instructors will help jointly extend medical device life cycle regulatory science training throughout the Asia-Pacific Region, and promote the international harmonization of medical device regulations.

September 4	Issued the revised "Drug Injury Relief Measurement Table." This revision was pursuant to the issuance of the "Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief" on June 15, 2023, and contains textual revisions in the form intended to improve it further.
September 5	To accelerate the application of smart medical devices, TFDA held the "Smart Medical Device Innovation Cross-boundary Matchmaking Expo," which featured representatives of 20 members of the smart medical device industry chain, who introduced their companies' notable characteristics. The event also included a one-on-one matchmaking session, which sought to make precision matches and reinforce the event's matchmaking effectiveness, and thereby promote cross-domain matches and collaboration opportunities.
September 6 to September 8	TFDA held the "2023 APEC Good Registration Management Center of Excellence Workshop," at which foreign and domestic pharmaceutical and health competent authorities and relevant experts and scholars shared GRM regulatory experience and practice. The workshop also provided training to more than 80 seed instructors affiliated with industry, government, and academia from five countries, who will spearhead promotion of the GRM concept.
September 12	TFDA announced revised grades and items on the "Schedules and Items of Controlled Drugs": 1. Added 4F-MDMB-BUTICA as a schedule III controlled drug, added 2-Bromo-chloropropiophenone, 5-Nitro-2- (bromoacetamido) benzophenone, 1-Methylphenyl-1-propanone, and P2NP as schedule IV controlled drug APIs, deleted the 178th item, Pentylone, from the list of schedule II controlled drugs and added it to the list of schedule III controlled drugs; the foregoing revisions took effect on the day of announcement. 2. Deleted the note in the remarks column that compound preparations containing the 10th schedule IV controlled drug Chlordiazepoxide or the 52nd controlled drug on the same schedule, Phenobarbital, are not subject to the management regulations of the "Controlled Drugs Act"; this revision strengthened the flow management of these preparations, and took effect on December 1, 2023.
September 18 to September 20	Held the 5th Self-Medication Collaborative Asian Regulator Expert Roundtable (Self-CARER) conference. The 25 government officials and industry experts from 11 major Asian countries attending this conference shared their countries' self-care and self-medication regulatory developments, and discussed how to advance research and how to integrate and improve relevant systems.

10	October 2	Responding to the approaching implementation of the cosmetic product information file (PIF) system on July 1, 2024, TFDA announced the revised "Guideline for Cosmetic Product Information File," "Introduction to Cosmetic Product Information File," and "Checklist for Cosmetic Product Information File," which contain added cosmetic PIF example documents, and will help businesses successfully establish product information files.
	October 2	Held the "FDA Outstanding Chef and Newcomer Chef Award Ceremony" in Building 1 of the Taipei World Trade Center. MOHW Vice Minister Wang Pi-sheng was in attendance and, together with TFDA Director-General Wu Shou-Mei, bestowed awards to 27 outstanding chefs and 5 excellent newcomer chefs.
	October 5 to October 6	Held the "11th Joint Conference of Taiwan and Japan on Medical Products Regulations." This event invited Taiwan and Japan representatives to share new developments in the regulation of pharmaceuticals and medical devices, and had substantial attendance from the Taiwan and Japan pharmaceutical and medical device industries. This conference promoted the sharing and mutual understanding of the two parties' regulatory information, and strengthened official and industry ties between Taiwan and Japan.
	October 17	TFDA hosted the "APEC Analytical Technology Exchange Platform—Symposium on Novel Biotech Food Testing Technologies" physical/online conference. At this event, experts and scholars from Japan, Korea, Vietnam, Malaysia, Taiwan's Academia Sinica, and TFDA exchanged GMO food testing and monitoring method knowledge through keynote talks and experience sharing. Approximately 100 experts and scholars from Indonesia, Japan, Korea, Malaysia, Mexico, Peru, the Philippines, Singapore, and Vietnam, as well as persons affiliated with government, industry, and academia in Taiwan attended the conference, at which they studied and shared the newest international testing methods. This conference contributed to the improvement of testing methods in Taiwan, boosted harmonization with international norms, and provided opportunities for international cooperation.

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October 20	TFDA announced the revised "Regulations for Drug Recall" and Article 37 of the "Pharmaceutical Affairs Act Enforcement Rules": 1. According to Article 58, Paragraph 3 of the "Medical Devices Act," which went into effect on May 1, 2021, medical devices subject to recall, and their grading, recall operating methods, handling methods, and other matters requiring compliance shall be subject to the regulations of the Regulations for Medical Device Recall, and requirements concerning medical devices in the Regulations for Drug Recall are no longer applicable. Furthermore, since the drugs subject to recall, subsequent handling of the drugs, and length of the recall period in Article 37 of the Enforcement Rules of the Pharmaceutical Affairs Act overlap the requirements of the Regulations for Drug Recall, the Regulations for Drug Recall have accordingly been revised, and Article 37 of the "Enforcement Rules of the Pharmaceutical Affairs Act" has been deleted. 2. The key points of this revision are as follows: (1) Regulations for Drug Recalls: a.Revision of style throughout document in reference to "Regulations for Medical Device Recalls." b.Deletion of clauses concerning medical devices from the Regulations, and revision of "drugs" to "pharmaceuticals." c.Addition of exemption from seal checking requirements in pharmaceutical recall operating procedures in Article 5. (2) Article 37 of the "Enforcement Rules of the Pharmaceutical Affairs Act": Since the "Regulations for Pharmaceutical Recall" already specify pharmaceuticals subject to recall, subsequent pharmaceutical handling, and recall time limits, etc., in order to avoid regulatory redundancy, Article 37 has been deleted from the "Enforcement Rules of the Pharmaceutical Affairs Act."
October 25	TFDA held the "Building Better Pharmaceutical Care with Technology" international pharmaceutical conference, at which international pharmaceutical experts shared pharmaceutical service experience. This conference will help boost the quality of pharmaceutical service in Taiwan, and raise Taiwan's international visibility.
October 26 to October 28	Gave a talk on "New Era of Drug Regulatory Management in Taiwan" at the 29th annual conference of the Federation of Asian Pharmaceutical Associations (FAPA), and set up a stand during the conference period to publicize the positive results of TFDA's pharmaceutical management policies.

10 October 30 to November 3	TFDA became a formal member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) in 2013, and a PIC/S audit team (chief auditor Rosmarie Neeser/Switzerland's Swissmedic, team members Hirofumi Suzuki/Japan's PMDA and Cheok Xin Yin/Malaysia's NPRA) visited TFDA for a PIC/S membership re-assessment, to confirm that Taiwan's pharmaceuticals GMP management system continued to comply with PIC/S standards.
11 November 1	To strengthen the supply and monitoring of pharmaceuticals, TFDA announced the revised "List of Essential Drugs in Article 27-2 of the Pharmaceutical Affairs Act." This revision increased the number of essential drugs to 481 items (with 117 newly-added items and 34 deleted items). The top three categories with the most newly-added drugs consisted of anti-infection drugs (29 items), anti-tumor and immunomodulator drugs (19 items) and cardiovascular drugs (12 items).
November 3	Announced the revocation of the requirement that "Vacuum-Packed Soybean Ready-To-Eat Food Shall Be Registered with The Central Competent Authority," which took effect on the day announced.
November 6 to November 8	TFDA personnel attended the "14th Annual Meeting Of The Asian Cellular Therapy Organization (ACTO)," and shared the state of regulatory management in Taiwan while participating in discussion. This event enhanced the international visibility of Taiwan's regenerative medicine industry.
November 8	To promote the international harmonization of medical device management, foster bilateral and multilateral cooperation opportunities, and boost the international image of Taiwan's medical device regulations and management, TFDA held the "2023 International Symposium on Medical Device Regulation," which was attended by 250 domestic representatives of industry, government, academia, and the research community. This symposium helped domestic firms to better understand international medical device laws and regulations, and will boost the competitiveness of domestic companies in international markets.
November 10	Revised Point 2 of the marking fine handling principles in Subparagraphs 8 and 10 of Article 47 of the "Act Governing Food Safety and Sanitation," and these revisions took effect on the day announced.
November 10	EU personnel visited Taiwan during the period of April 20-27 of 2023 to perform an on-site assessment for addition of Taiwan to the "list of active pharmaceutical ingredients from third countries that can be imported into the EU." The result of this assessment was that Taiwan's GMP management system, legal standards, and degree of implementation for active pharmaceutical ingredients (APIs) met the EU's requirements. As a result, the EU formally announced on November 10, 2023 that Taiwan had successfully been added to the list of third countries.

11 November 21	TFDA held the "2023 National Pharmaceutical Technology & Research Development Awards" ceremony, at which Dr. Hsueh Jui-yuan, Minister of Health and Welfare, and Wang Mei-hua, Minister of Economic Affairs, were on hand to announce the winners of the gold, silver, and bronze awards in the pharmaceutical, medical device, and manufacturing technology categories. An R&D project results display area and media interview area were established outside the awards room, which gave more exposure to the award-winning projects and to these awards. A total of more than 200 persons took part in this event.
November 30	TFDA assisted in implementing the "Six Core Strategic Industries Promotion Plan" in conjunction with presidential policy and the Executive Yuan by conducting the "Medical Device Domestic Production and Domestic Use Awareness Meeting." TFDA's introduction to the leading domestically-produced medical devices increased the willingness of domestic hospitals and clinics to purchase these devices, and boosted Taiwan's medical device supply resilience.
12 December 1	TFDA joined forces with the Industrial Development Administration, Ministry of Economic Affairs, in holding the "Joint Launching of New Era in Smart Medical Devices Smart Medical Device Assistance and Results." This event arranged talks exploring topics including smart medical device R&D from a clinical perspective and the disposition of international industry. The event also included posters showing the results obtained by firms receiving assistance from TFDA and the Industrial Development Administration, and industry personnel shared their successful experience of receiving assistance and obtaining medical device permits. The participants at this activity consisted of 157 persons affiliated with government agencies, hospitals and clinics, research organizations, groups, associations, and companies. The event let companies understand available government resources, and the government's intention to help Taiwan's smart medical devices successfully enter overseas markets, and encourage the industry to invest more in R&D.
December 15	Revised Point 2 concerning fine handling principles for markings that are untruthful, exaggerated, or easily misunderstood in Article 45, Paragraph 1 of the "Act Governing Food Safety and Sanitation," which took effect on the day announced.
December 25	Executive Yuan Premier Chen Chien-jen inspected the Taoyuan Airport African swine fever border quarantine arrangements at Taoyuan Airport terminal no. 1. This visit included inspection of border quarantine arrangements and carry-on luggage and express cargo inspection procedures, and Premier Chen also thanked quarantine personnel for their hard work and relevant units for their cooperation in strict quarantine enforcement. With the New Year approaching, Premier Chen called on foreign and domestic travelers to avoid trying to bring meat products into the country, and reminded border control personnel to increase their vigilance, and continue to protect citizens' health and the domestic pig-raising industry.

Appendix 2 Important 2023 Achievements and Statistics

Attached Table 1 Additions and revisions to food safety and sanitation laws, regulations, and standards in 2023

Date announced	Name	Key content
January 11	Announcement of the revised "Sanitary Standards for Food Utensils, Containers and Packages"	1. Revision of sources of law on the basis of name, addition of text that plastic containers may not be reused. 2. Adds testing regulations for metal and alloy food containers and utensils.
February 1	Drafting of "Regulations Governing the Labeling Which Shall Be Labeled of Infant and Follow-up Formula"	Integration of relevant regulatory content in "Regulations Governing the Labeling of Infant Formula and Complete Formula for Infants over Four Months Old," "Regulations Governing the Labeling of Infant Formula in Liquid Form," "Regulations Governing the Labeling Which Shall Not Be Labeled of Infant Formula and Complete Formula for Infants over Four Months Old" and "Infant and Follow-up Formula Shall Have a Recognized Label Directly Printed onto the Container for Ease of Identification."
February 7	Announcement of the revised two items in Article 3: "Use of Genetically Modified Escherichia coli Strains to Produce the Food Ingredient 2'-fucosyllactose by Fermentation."	1. Revision of the scope of use to "infant formula, follow-up infant formula, and powdered milk and similar products intended exclusively for children under the age of 7." 2. Addition of scope of use consisting of "infant formula for special medical purposes."
February 8	Announcement of the drafting of "The Use Restrictions of Eucalyptus Leaves (Eucalyptus globulus) and Their Extracts"	Eucalyptus leaves and their extracts may not be used as food ingredients, and may only be used as a food additive spice.
February 8	Announcement of the revised "Special Dietary Foods for Rare Diseases"	1. Addition of special dietary food "PKU Lophlex Powder (orange and strawberry flavor)" and its indication "Phenylketonuria-special nutritional supplements." 2. Addition of indications for 5 special dietary foods: (1) Addition of the indication "Methylmalonic acidemia-special nutritional supplements" for the special dietary food "L-ISOLEUCINE." (2) Addition of the indication "Methylmalonic acidemia-special nutritional supplements" for the special dietary food "L-VALINE." (3) Addition of the indication "Propionic acidemia" for the special dietary food "MMA/PA Anamix Junior." (4) Addition of the indication of "Familial Hyperchylomicronemia" for the special dietary food "-MONOGEN." (5) Addition of the indication "Congenital Urea cycle disorders" and "Citrullinemia" for the special dietary food "PFD 2."

Date announced	Name	Key content
February 17	Announcement of the revised Table 1 in Article 3 of the "Standards for Pesticide Residues Limits in Foods "	Announcement of the revised Table 1 in Article 3 of the "Standards for Pesticide Residue Limits in Foods."
March 8	Announcement of the revised "Efficacy Assessment Method of Health Food for Dental Care"	1. Deletion of animal experiments. 2. Revision of human trial subject conditions, number of subjects, and safety monitoring items. 3. Revision of statistical data analysis methods, result assessment standards, and health care effect description.
March 20	Announcement of the revised "Import Regulation of F01 and F02 in Import Commodity Classification of the Republic of China," which took effect on April 10, 2023.	To meet the management needs of the Fisheries Agency, Council of Agriculture, 10 commodity codes were added, including CCC0301.99.29.55-9 "Scalloped hammerhead shark (Sphyrna lewini), live," and 2 commodity codes were deleted, including CCC0304.56.00.00-6 " Dogfish and other sharks meat (whether or not minced), fresh or chilled."
March 27	Announced the revocation of the "Notice of the COVID-19 control and management measures for the Food Service"	FDA revoked the "Disease Prevention Management Measures for the Dining Industry" in conjunction with the MOHW's revision of the "Severe Pneumonia with Novel Pathogens (Covid-19) Prevention Measure and Punishment Regulations" on February 20, 2023, which deleted the "Notice of the COVID-19 control and management measures for the Food Service," and consequently eased disease prevention policy.
March 29	Announcement of the revised "Sanitation Standards for Natural Edible Colorants"	1. Revision of sources of law on the basis of name, citing regulations for solvent source, regulations restricting excipients and other additives, standardization of sources, chief components, and specification requirements in the form of attached tables, and adjustment of some colorant item, source, and chief component regulations. 2. Addition of some specifications and requirements.
June 1	Announcement of the drafting of "Use Restrictions and Labeling Requirements of 2'-fucosyllactose Produced by Genetically Modified Escherichia coli Strain K-12 MG1655 INB000846 as a Food Ingredient"	1. Specifies regulations that must be followed when using 2'-fucosyllactose as a food ingredient. 2. 2'-fucosyllactose complying with regulations may be used in infant formula and follow-up infant formula, and milk powder and similar products for children under the age of 7; the maximum amount used shall be no more than 1.2g/l (calculated on the basis of ready to consume form or in prepared ready to consume form after mixing in accordance with the label instructions).
June 8	Announcement of the drafting of "Use Restrictions and Labeling Regulations of Broccoli (*Brassica oleracea var. italica*) Seed Extract as a Food Ingredient"	Broccoli seed extract made from broccoli seeds and used as a food ingredient must comply with these regulations, which include processing methods, specifications, scope of use (in foods for adult use), daily consumption limit (115mg), and warning text that must be included in labels.
June 8	Announcement of the drafting of "Use Restrictions and Labeling Requirements of Hen Egg White Lysozyme Hydrolysate as a Food Ingredient"	Specifies regulations that must be followed when using chicken egg white lysozyme hydrolysate as a food ingredient, including initial raw materials, processing methods, specifications, scope of use (for use by adults as a dietary supplement), consumption limit (1g), and warning text that must be included in labels.

Date announced	Name	Key content
June 15	Announcement of the revised Table 1, Article 3; Table 3, Article 4; and Table 5, Article 6 of the "Standards for Pesticide Residue Limits in Foods" and Article 3 of the "Standard for Pesticide Residue Limits in Animal products"	1. "Standards for Pesticide Residue Limits in Foods": (1) Revision or addition of 52 residue tolerance items for 10 pesticides, including Benzovindiflupyr; deletion of 14 residue tolerance items for 7 pesticides, including MALS (methylarsine bislauryl sulfide). (2) Addition of statement that Bacillus amyloliquefacines CL3, cinnamaldehyde, and sodium chlorate constitute pesticides that do not require tolerances. (3) "Chickpeas (fresh)" are listed as beans and bean sprouts, while "chickpeas (dry)" are listed as dried beans. 2. "Standard for Pesticide Residue Limits in Animal products": Revision or addition of tolerances for residues of 11 pesticides, including Cyproconazole, in poultry and animal products.
June 15	Revision of "Regulation of Imported Beef and Beef Products from the United States and Canada"	In conjunction with the adjustment of the scope of opening to the import of Canadian beef and its products, revision of remark content regulations for relevant verifying import documents that must be attached, including adjustment of wording for consistency with laws, and also adjustment of CCC code in attached tables in response to CCC code changes.
June 29	Announcement of the drafting of "Use Restrictions and Labeling Requirements of trans-Resveratrol Produced by Genetically Modified *Saccharomyces cerevisiae* Strain EFSC4687 as a Food Ingredient"	Specifies regulations that must be followed when using trans-resveratrol produced via fermentation using genetically modified *Saccharomyces cerevisiae* strain EFSC4687 as a food ingredient, including processing methods, specifications, scope of use (can be used as a dietary supplement for adult use), daily consumption limit (150mg), and warning text that must be included in labels.
June 29	Announcement of the revised "Special Dietary Foods for Rare Diseases"	1. Addition of special dietary food "Glycosade" and its indication "Glycogen storage disease." 2. Addition of indications "Nonketotic hyperglycinemia," "Homocystinuria," and "Methylmalonic acidemia" for the special dietary food "PFD 2."
July 6	Revision of "Import Regulation of F01 and F02 in Import Commodity Classification of the Republic of China," "Import Regulations Containing F01 in Import Commodity Classification of the Republic of China," and "Import Regulations Containing 508 in Import Commodity Classification of the Republic of China," which took effect retroactively on June 23, 2023.	1. In accordance with the Ministry of Finance's revision of some tariffs in the Customs Import Tariffs and relevant announcements by the International Trade Administration, MOEA. 2. In conjunction with the foregoing revisions, TFDA announced the revised "Import Regulation of "F01" and "F02" in Import Commodity Classification of the Republic of China," "Import Regulation Containing F01 in Import Commodity Classification of the Republic of China," and "Import Regulations Containing 508 in Import Commodity Classification of the Republic of China," which took effect retroactively on June 23, 2023.

Date announced	Name	Key content
July 13	Issuance of revised Article 3 of "Standards for Veterinary Drug Residue Limits in Foods"	1. Addition of statement that no residue tolerances are required for "Buserelin" in beef muscle, liver, kidneys, fat, and milk. 2. Addition of residue tolerances for "Fenbendazole" in chicken muscle, liver, kidneys, fat (including skin), and eggs. 3. Addition of statement that no residue tolerances are required for "gonadotrophin releasing hormone; Gonadorelin)" in beef muscle, liver, kidneys, fat, and milk. 4. Addition of residue tolerances for "Paromomycin" in beef and pork muscle, liver, and kidneys.
July 27	Revision of "Import Regulation of F01 and F02 in Import Commodity Classification of the Republic of China" and "Import Regulation Containing F01 in Import Commodity Classification of the Republic of China"	1. To meet the management needs of the Fisheries Agency, Council of Agriculture, 21 commodity codes were added, including CCC0302.81.00.52-4 "Blue shark (Prionace glauca), fresh or chilled," and the 1 commodity code CCC0304.96.90.00-9 "Dogfish and other sharks meat (whether or not minced), frozen" was deleted. 2. In conjunction with the Council of Agriculture's response to domestic seed and seedling businesses' need to import seeds for planting, deleted 13 commodity codes, including CCC0713.20.00.00-4 "dried chickpeas (garbanzos), whether or not skinned or split," and added 26 commodity codes, including CCC0713.20.00.10-2 "dry chickpeas (garbanzos) seed, for planting." 3. To strengthen food import inspection, addition of "F02" import regulations for 2 commodity codes CCC0507.90.19.00-8 "Lu Jung (Cervi parvum cornu) (incl. for Chinese drugs)" and CCC0507.90.20.00-5 "Deer velvet (Lu jung (Cervi parvum cornu) (incl. for Chinese drugs)), dried."
August 10	Revision of Article 4; Table 1, Article 2; and Table 2, Article 3 of " Standards for Specification, Scope, Application and Limitation of Food Additives"	1. Addition of scope of use and limits for activated acid clay, and revision of item names of acid clay (activated clay), L-carnitine, L-carnitine tartrate, and steviol glycosides. 2. Revision of specification standards for steviol glycosides, calcium citrate, acid clay (activated clay), Brilliant Blue FCF Aluminum Lake, Indigo Carmine Aluminum Lake, Tartrazine Aluminum Lake, Sunset Yellow FCF Aluminum Lake, Fast Green FCF Aluminum Lake, Erythrosine Aluminum Lake, Allura Red AC Aluminum Lake, monosodium L-aspartate, L-valine, α-glycosyl-isoquercitrin, and glacial acetic acid and addition of specification standards for L-carnitine and activated acid clay.
October 5	Announcement of the drafting of "Use Restrictions and Labeling Requirements of Liquid Mycelia Culture Powder of Morel Mushroom (*Morchella esculenta*) as a Food Ingredient"	1. Specifies sources of morel mushroom (*Morchella esculenta*) liquid mycelia culture powder and processing methods, and relevant regulations when used as a food ingredient. 2. Morel mushroom liquid mycelia culture powder complying with regulations may be used only in foods for adult use, and the daily consumption limit is 1,200mg.

Date announced	Name	Key content
November 3	Revocation of "Vacuum-Packed Soybean Ready-To-Eat Food Shall Be Registered with The Central Competent Authority"	1. Inspection and registration case applications will no longer be accepted from the date of the revocation announcement. Starting from the date of revocation announcement, the outer packaging of products produced by those businesses that obtained inspection and registration in accordance with the original regulations will not be required to bear the printed vacuum packed food mark. 2. Those foods that bear the vacuum packed food mark that had already been produced prior to the date of the revocation announcement may continue to be stocked, sold, imported, exported, used as gifts, and publicly displayed until their expiration date.
November 10	Issuance of the revised Table 1, Article 3 and Attached Table 3, Article 4 of "Standards for Pesticide Residue Limits in Foods" and the revised Article 3 of "Standard for Pesticide Residue Limits in Animal products"	1. "Standard for Tolerances of Pesticide Residues": (1) Revision or addition of 81 residue tolerance items for 26 pesticides, including abamectin; addition of "Pyriofenone," with a common name of its Chinese equivalent. (2) Listing of Bacillus amyloliquefacines strain D747 as a pesticide not required to have a tolerance limit. 2. "Standard for Tolerances of Pesticide Residues in Animal Products": Revision or addition of residue tolerances in honey, poultry, and animal products for 11 pesticides, including Acetamiprid.
November 30	Article 18 of "Food Businesses that shall Enact the Food Safety Monitoring Plan and Food Inspection, Minimum Testing Cycle, and Other Related Matters"	To strengthen and increase management of the general merchandise retail industry, drafting of the requirement that testing and inspection must be performed for "frozen fruit" and specifying the minimum testing and inspection cycle.
November 30	Announcement of the revised "Special Dietary Foods for Rare Diseases"	Addition of the indication "Isovaleric acidemia (1-10 years of age)" for the special dietary food "IVA ANAMIX JUNIOR."
November 30	Issuance of the revised "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products"	1. The original "Directions on Registration of Food Additives" are incorporated into the "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products." 2. Addition of relevant text content in conjunction with the practical needs of review and registration of infant formula, follow-up infant formula, and formula for certain disease.

Date announced	Name	Key content
December 4	Promulgation of "Standards for Good Manufacturing Practices of Health Food"	Based on the management standards of the current "Good Manufacturing Practice Regulations for Health Food Factories," the new Standards partly incorporate and are harmonized with Taiwan's food manufacturing regulations and international good manufacturing practice standards for food. Newly-added management content concerns quality management, R&D, food safety controls, stability, flow tracking, the audit system, and documentary records. The new Standards emphasize that health food manufacturers must possess the spirit of autonomous management, which will ensure that these standards are both localized and in harmony with their international equivalents. This will help boost the overall international competitiveness of Taiwan's health food industry. The "Standards for Good Manufacturing Practices of Health Food" will take effect on January 1, 2025.
December 14	Announcement of the revised "Import Regulation of F01 and F02 in Import Commodity Classification of the Republic of China" and "Import Regulations Containing 508 in Import Commodity Classification of the Republic of China"	1. In conjunction with the Ministry of Agriculture's control of the amount of imported frozen condensed milk, the International Trade Administration held the 1193rd meeting of the Commodity Classification Committee on May 10, 2023; this meeting resolved to delete commodity code CCC0402.91.90.00-5 "Other milk and cream, not containing added sugar or other sweetening matter," and add 5 commodity codes, including CCC0402.91.90.10-3 "Evaporated milk (concentrated milk), not containing added sugar or other sweetening matter, and a fat content, by weight, not exceeding 1%, frozen." 2. In conjunction with the use of nitrogen gas in Type 7 quality improvement, and as an agent in fermentation and food manufacturing, and the establishment of testing methods for nitrogen gas, in order to manage the import of nitrogen gas, TFDA added the item CCC2804.30.00.00-8 "Nitrogen" to the "508" import regulations.

Remarks:

1.Up to 2023, accumulated addition/revision of 7,771 pesticide residue limits; 1,551 veterinary drug residue limits; 17 food sanitation standards, 44 restrictions for food ingredients, and 797 food additives on the positive list had been defined in addition to the respective scope of use, limits, and specifications/standards.

2.Commodity classification code list: according to Article 30 of the Act Governing Food Safety and Sanitation, the import of food and other related products announced by the central competent authority shall be in accordance with the commodity classification code list. By the end of 2023, 2,765 items of goods subject to inspections upon importation had been announced, including 2,157 in the import regulation F01, 132 in the import regulation F02, 382 in the import regulation 508, and 94 in the complex import regulation.

Attached Table 2 Guide to food sanitation management and actions announced in 2023

No.	Announcement date	Name	Explanation
1	February 1	Guidelines for Manufacturers of Vacuum-Packed Soybean Ready-To-Eat Food to comply with the Regulations on Good Hygiene Practice for Food	To strengthen autonomous sanitation management among manufacturers of vacuum-packed soybean ready-to-eat foods, and to ensure compliance with the Act Governing Food Safety and Sanitation and relevant regulations, TFDA drafted the "Guidelines for Compliance with Good Manufacturing Practice (GMP) Standards for Manufacturers of Vacuum-Packed Soybean Ready-To-Eat Food" to provide businesses with a basis for implementation, and urges businesses to continue to improve food safety and sanitation.
2	February 6	Guidelines for Food Donation Safety and Hygiene	To safeguard the sanitation, safety, and quality of gift foods, TFDA drafted the "Guide to the Sanitation and Safety of Food Gifts" for gift-givers (including businesses, non-profit organizations, and members of the public).
3	June 8	Guidelines for washed egg Plants to comply with the Regulations on Good Hygiene Practices for Food	1. Revision of guide name from "Guide to Fresh Egg Washing and Sorting Operations" to "Guide to Good Food Sanitation Standards for Egg Washing and Sorting Plants." 2. Revision of and addition to the scope of applicability in Article 2: (1) Revision of the Subparagraph 1 as "This guide shall be applicable to the management of egg washing and sorting plants." (2) The added Subparagraph 2 states "When there are other relevant regulations from various industry competent authorities, the requirements of those regulations shall be complied with." 3. Since there are rolling revisions of all relevant regulations, TFDA accordingly revised regulations and reference information connected with the Act Governing Food Safety and Sanitation in Article 4.
4	June 26	Guidelines for liquid egg manufacturers to comply with the Regulations on Good Hygiene Practices for Food	1. Revision of guide name from "Guide to Good Sanitation Practice for Liquid Egg Manufacturers" to "Guide to Good Food Sanitation Standards for Liquid Egg Manufacturers." 2. Revision of and addition to the scope of applicability in Article 2: (1) Revision of Subparagraph 1 as "This guide shall be applicable to liquid egg manufacturers." (2) The added Subparagraph 2 states "When there are other relevant regulations from various industry competent authorities, the requirements of those regulations shall be complied with." 3. Revision of Article 3 of Practical Principles for Liquid Egg Product Manufacturing: The raw materials used by businesses must fundamentally comply with the Act Governing Food Safety and Sanitation and its relevant sanitation standards and regulations, and acceptance procedures and liquid egg labeling regulations must be established. The names and content of regulations are consequently not specified in depth, and 3., (1), c.-f. of this article have been deleted, or selectively incorporated into Article 3, 3., (1), a.-b. 4. Since relevant regulations will be revised on a rolling basis at appropriate times, Article 3, 3., (8) and Article 4 have been accordingly revised.

No.	Announcement date	Name	Explanation
5	July 6	Guidelines for Food Safety Assessment of Genetically Modified Foods Derived from Recombinant-DNA Organisms	1. Merger of the "Guideline for Food Safety Assessment of Genetically Modified Foods Derived from Recombinant-DNA Organisms" revised on September 9, 2010 and the "Combined Genetically Modified Food Safety Assessment Principles" announced on May 6, 2008. 2. Deletion of the submission of agronomical variation experiment data in Appendix 2.
6	September 22	Guidelines for manufacturers of edible fats and oils to comply with the Regulations on Good Hygiene Practices for Food	1. Revision of guide name from "Guide to Good Operating Practice for Manufacturers of Edible Oils and Fats" to "Guide to Good Food Sanitation Standards for Manufacturers of Edible Oils and Fats." 2. After referring to the Office of Food Safety, Executive Yuan's "Strengthened Pig Lard Raw Material Management Matters," management content including raw material source, need for a separate license for separate plants, and the requirement to note "May be used as food" on invoice documents has been added. 3. Relevant content has been added in order to ensure a consistent framework with various other food manufacturing guidelines.

Attached Table 3 Inspection and Registration of Specific Foods and Food Additives in 2023

Categories of food that should be registered		Number of valid permit document
Imported food in tablet and capsule form		7,684
Health Food		421
Food Additives		6,054
Genetically modified food raw material		160
Special dietary food	Formula for certain disease	348
	Infant and follow-up infant formula	142
Domestically produced vitamin tablet and capsule food		1,480
Vacuum packaged ready-to-eat soybean food		37
Total		16,326

Attached Table 4 Food audits and inspection in 2023

No.	Project name	Audit results
1	Lunch box food manufacturer audit project	I. Audited: 68 companies 1. GHP: 52 companies were given a time limit for improvement, and all passed re-inspection. 2. HACCP: Not applicable to 9 companies, 47 companies were given a time limit for improvement, 2 companies failed re-inspection. 3. Food business registration: 16 companies were given a time limit for improvement, and all passed re-inspection. 4. Traceability: Not applicable to 12 companies, 14 companies were given a time limit for improvement, and all passed re-inspection. 5. Food safety monitoring project: Not applicable to 56 companies, and the remaining 12 companies all passed. 6. Mandatory tracking: Not applicable to 12 companies, 21 companies were given a time limit for improvement, and all passed re-inspection. 7. Preservation of source documents: 4 companies were given a time limit for improvement, and all passed re-inspection. 8. Waste flow: 15 companies were given a time limit for improvement, and all passed re-inspection. 9. Warehouse management: 25 companies were given a time limit for improvement, and all passed re-inspection. 10.Disclosure to downstream of information concerning source and place of production of beef and pork raw materials: 1 company was not applicable, 67 companies passed. 11. Other: (1) 4 companies were found to have kept expired food. (2) 1 company failed to assign sanitation management personnel. (3) 6 companies failed to assign specialized personnel. II. Random inspections: 202 cases 1. Finished products: 68 cases, all met requirements. 2. Semi-finished products: 68 cases, of which 3 cases did not meet requirements. 3. Pork raw materials: 66 cases, all met requirements.
2	Processed dairy food business HACCP audit project	I. Audited: 38 companies 1. GHP: 10 companies were given a time limit for improvement, and all passed re-inspection. 2. HACCP: 18 companies were given a time limit for improvement, and all passed re-inspection. 3. Food business registration: 2 companies were given a time limit for improvement, and all passed re-inspection. 4. Mandatory inspection: Not applicable to 3 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 5. Traceability: 1 company was not applicable, 2 companies were given a time limit for improvement, and all passed re-inspection. 6. Online reporting: 1 company was not applicable, 7 companies were given a time limit for improvement, and all passed re-inspection. 7. Food safety monitoring project: Not applicable to 15 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 8. Product liability insurance: 38 companies all passed. 9. Standard form contracts: Not applicable to 30 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 10.State of gas use: Not applicable to 34 companies, and the remaining 4 companies all passed. 11.Other: (1) 3 companies failed to assign specialized personnel or technicians. (2) 1 company failed to assign approved and recorded sanitation management personnel. II. Labeling: 67 cases, all met requirements. III. Random inspections: 45 cases, all cases met requirements.

No.	Project name	Audit results
3	Food additive manufacturer audit project	I. Audited: 49 companies 1. GHP: 8 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 6 companies were given a time limit for improvement, and all passed re-inspection. 3. Mandatory inspection: 3 companies were given a time limit for improvement, and all passed re-inspection. 4. Traceability: 2 companies were given a time limit for improvement, and all passed re-inspection. 5. Online reporting: 10 companies were given a time limit for improvement, and all passed re-inspection. 6. Food safety monitoring project: Not applicable to 12 companies, 1 company was given a time limit for improvement, and has passed re-inspection. II. Labeling: 73 cases, of which 1 case did not meet requirements. III. Random inspections: 25 cases, all met requirements.
4	Audit project for domestic source businesses for health foods, domestically-produced encapsulated foods in the form of vitamin tablets, and special nutritional foods	I. Audited: 40 companies 1. GHP/health food factory good manufacturing practice standards: Not applicable to 11 companies, 6 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 6 companies were given a time limit for improvement, and all passed re-inspection. 3. Mandatory inspection: Not applicable to 17 companies, and the remaining 23 companies all passed. 4. Food additive use and management: Not applicable to 20 companies, 4 companies were given a time limit for improvement, and all passed re-inspection. 5. Use of gases in foods: Not applicable to any of the 40 companies. 6. Traceability: Not applicable to 17 companies, and the remaining 23 companies all passed. 7. Food safety monitoring project: Not applicable to 17 companies, and the remaining 23 companies all passed. 8. Mandatory tracking: Not applicable to 17 companies, and the remaining 23 companies all passed. 9. Preservation of source documents: Not applicable to 6 companies, and the remaining 34 companies all passed. 10. Waste flow: Not applicable to 11 companies, 4 companies were given a time limit for improvement, and all passed re-inspection. 11. Inspection and registration: Audited 63 cases, of which 5 cases failed. 12. Audit of the vitamin content of general encapsulated foods: 19 cases, all passed. II. Labeling: 63 cases, of which 5 cases failed. III. Random inspections: 16 cases
5	Canned food factory audit project	I. Audited: 51 companies 1. GHP: 39 companies were given a time limit for improvement, 2 companies failed re-inspection. 2. HACCP: Not applicable to 9 companies, 36 companies were given a time limit for improvement, 1 company failed re-inspection. 3. Food business registration: 17 companies were given a time limit for improvement, and all passed re-inspection. 4. Mandatory inspection: Not applicable to 30 companies, 4 companies were given a time limit for improvement, and all passed re-inspection. 5. Traceability: Not applicable to 30 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 6. Online reporting: Not applicable to 30 companies, 4 companies were given a time limit for improvement, and all passed re-inspection.

No.	Project name	Audit results
5	Canned food factory audit project	7. Food safety monitoring project: Not applicable to 36 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 8. Product liability insurance: 51 companies all passed. 9. Other: (1) 2 companies were found to have kept expired food ingredients. (2) 2 companies failed to assign sanitation management personnel. II. Labeling: 116 cases, of which 3 cases failed. III. Random inspections: 83 cases 1. Canned products: 76 cases, all met requirements. 2. Crop raw materials: 7 cases, all met requirements.
6	Dried seafood manufacturer audit project	I. Audited: 65 companies 1. GHP: 37 companies were given a time limit for improvement, and all passed re-inspection. 2. HACCP: Not applicable to 33 companies, 27 companies were given a time limit for improvement, 1 company failed re-inspection. 3. Food business registration: Not applicable to 1 company, 17 companies were given a time limit for improvement, and all passed re-inspection. 4. Mandatory inspection: Not applicable to 44 companies, 8 companies were given a time limit for improvement, and all passed re-inspection. 5. Traceability: Not applicable to 39 companies, 7 companies were given a time limit for improvement, and all passed re-inspection. 6. Online reporting: Not applicable to 39 companies, 16 companies were given a time limit for improvement, 1 company failed re-inspection. 7. Food safety monitoring project: Not applicable to 55 companies, and the remaining 10 companies all passed. 8. Product liability insurance: Not applicable to 1 company, 1 company failed. II. Labeling: 140 cases, of which 2 cases did not meet requirements. III. Random inspections: 90 cases, all met requirements.
7	Edible oil and fat manufacturer audit project	I. Audited: 30 companies 1. GHP: 27 companies were given a time limit for improvement, and all passed re-inspection. 2. HACCP: Not applicable to 20 companies, 9 companies were given a time limit for improvement, and all passed re-inspection. 3. Food business registration: Not applicable to 1 company, 6 companies were given a time limit for improvement, and all passed re-inspection. 4. Traceability: Not applicable to 15 companies, 5 companies were given a time limit for improvement, and all passed re-inspection. 5. Online reporting: Not applicable to 15 companies, 8 companies were given a time limit for improvement, and all passed re-inspection. 6. Food safety monitoring project: Not applicable to any of the 30 companies. 7. Other: 1 company failed to assign sanitation management personnel. II. Labeling: 56 cases, of which 9 cases did not meet requirements. III. Random inspections: 51 cases, all met requirements.

No.	Project name	Audit results
8	Audit project for domestically-produced cereal based foods for infants and children	I. Audited: 22 companies 1. GHP: 8 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 8 companies were given a time limit for improvement, and all passed re-inspection. 3. Use of gases in foods: Not applicable to any of the 22 companies. 4. Traceability: Not applicable to 18 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 5. Online reporting: Not applicable to 17 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 6. Food safety monitoring project: Not applicable to 18 companies, and the remaining 4 companies all passed. 7. Other: 1 company failed to assign sanitation management personnel. II. Labeling: 61 cases, all met requirements. III. Random inspections: 37 cases, all met requirements.
9	Processed meat food manufacturer audit project	I. Audited: 139 companies 1. GHP: Not applicable to 12 companies, 78 companies were given a time limit for improvement, 2 companies failed re-inspection. 2. HACCP: Not applicable to 30 companies, 84 companies were given a time limit for improvement, 6 companies failed re-inspection. 3. Food business registration: Not applicable to 6 companies, 24 companies were given a time limit for improvement, and all passed re-inspection. 4. Mandatory testing: Not applicable to 30 companies, 18 companies were given a time limit for improvement, and all passed re-inspection. 5. Traceability: Not applicable to 30 companies, 26 companies were given a time limit for improvement, 1 company failed re-inspection. 6. Other: (1) 6 companies were found to have kept expired food. (2) 8 companies failed to assign sanitation management personnel. II. Labeling: 386 cases, of which 7 cases did not meet requirements. III. Random inspections: 236 cases 1. Raw material meat: 161 cases, of which 2 cases did not meet requirements. 2. Processed finished products: 75 cases, all met requirements.
10	Liquid egg manufacturer audit project	I. Audited: 54 companies 1. GHP: 20 companies were given a time limit for improvement, and all passed re-inspection. 2. HACCP: Not applicable to 33 companies, 13 companies were given a time limit for improvement, and all passed re-inspection. 3. Food business registration: 5 companies were given a time limit for improvement, and all passed re-inspection. 4. Traceability: Not applicable to 45 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 5. Other: 1 company failed to assign sanitation management personnel. II. Labeling: 137 cases, all met requirements. III. Random inspections: 176 cases 1. Fresh raw material eggs: 52 cases, all met requirements. 2. Liquid egg finished products: 124 cases, all met requirements.

No.	Project name	Audit results
11	Preserved egg and seasoned egg manufacturer audit project	I. Audited: 48 companies 1. GHP: 22 companies passed, 26 companies were given a time limit for improvement, and all passed re-inspection. 2. HACCP: Not applicable to 44 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 3. Food business registration: Not applicable to 1 company, 10 companies were given a time limit for improvement, and all passed re-inspection. 4. Other: 1 company failed to assign sanitation management personnel. II. Random inspections: 85 cases 1. Fresh raw material eggs: 38 cases, all met requirements. 2. Preserved egg and seasoned egg finished products: 47 cases, all met requirements.
12	Soy sauce manufacturer audit project	I. Audited: 77 companies 1. GHP: 37 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 7 companies were given a time limit for improvement, and all passed re-inspection. 3. Other: 1 company was found to have kept expired food. II. Labeling: 200 cases, of which 3 cases failed. III. Random inspections: Soy sauce finished product: 117 cases, all met requirements.
13	Chinese-style bakery product manufacturer audit project	I. Audited: 159 companies 1. GHP: 93 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 4 companies, 35 companies were given a time limit for improvement, and all passed re-inspection. 3. Product liability insurance: Not applicable to 12 companies, 1 company was not in compliance with regulations 4. Other: (1) 3 companies were found to have kept expired food. (2) 1 company failed to assign sanitation management personnel. II. Labeling: 447 cases, of which 3 cases did not meet requirements. III. Random inspections: 294 cases, of which 2 cases did not meet requirements.
14	Soybean product manufacturer audit project	I. Audited: 100 companies 1. GHP: 60 companies were given a time limit for improvement, 3 companies failed re-inspection. 2. Food business registration: Not applicable to 2 companies, 32 companies were given a time limit for improvement, and all passed re-inspection. 3. Other: 4 companies failed to hire sanitation management personnel. II. Labeling: 50 cases, of which 1 case did not meet requirements. III. Random inspections: 115 cases 1. Soybean products: 103 cases, of which 3 cases did not meet requirements. 2. Raw material soybeans: 12 cases, all met requirements.
15	Pickled vegetable seller random inspection and audit project	I. Audited: 285 companies 1. GHP: 19 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 19 companies, 20 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 17 companies were given a time limit for improvement, and all passed re-inspection. II. Labeling: 561 cases, of which 2 cases did not meet requirements. III. Random inspections: 545 cases, of which 54 cases did not meet requirements.

No.	Project name	Audit results
16	Pickled vegetable manufacturer audit project	I. Audited: 74 companies 1. GHP: 35 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 3 companies, 12 companies were given a time limit for improvement, and all passed re-inspection. 3. Other: 2 companies failed to assign sanitation management personnel. II. Labeling: 86 cases, of which 1 case did not meet requirements. III. Random inspections: 63 cases, of which 2 cases did not meet requirements.
17	Chocolate product manufacturer audit project	I. Audited: 24 companies 1. GHP: 13 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 6 companies were given a time limit for improvement, and all passed re-inspection. 3. Legality of raw materials: 24 companies all passed. 4. Mandatory inspection: Not applicable to any of the 24 companies. 5. State of gas use: Not applicable to any of the 24 companies. 6. Food additive use and management: Not applicable to 17 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 7. Traceability: Not applicable to any of the 24 companies. 8. Food safety monitoring project: Not applicable to any of the 24 companies. 9. Mandatory tracking: Not applicable to any of the 24 companies. 10. Preservation of source documents: 2 companies were given a time limit for improvement, and all passed re-inspection. 11. Waste flow: 9 companies were given a time limit for improvement, and all passed re-inspection. 12. Product liability insurance: 1 company was not in compliance with regulations 13. Standard form contracts: Not applicable to 12 companies, 8 companies were given a time limit for improvement, and all passed re-inspection. 14. Other: (1) 1 company was found to have kept expired food. (2) 1 company failed to assign approved and recorded sanitation management personnel. II. Labeling: 141 cases, of which 6 cases did not meet requirements. III. Random inspections: 39 cases 1. Chocolate raw material: 30 cases, all met requirements. 2. Cacao bean raw material: 9 cases, all met requirements.
18	Dry seasoned instant noodle product manufacturer audit project	I. Audited: 56 companies 1. GHP: Not applicable to 8 companies, 13 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 12 companies were given a time limit for improvement, and all passed re-inspection. 3. Legality of raw materials: Not applicable to 8 companies, and the remaining 48 companies all passed. 4. Mandatory inspection: Not applicable to 36 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 5. Use of gases in foods: Not applicable to any of the 56 companies. 6. State of phosphine use: Not applicable to any of the 56 companies. 7. Food additive use and management: Not applicable to 25 companies, 7 companies were given a time limit for improvement, and all passed re-inspection. 8. Traceability: Not applicable to 36 companies, 3 companies were given a time limit for improvement, and all passed re-inspection.

No.	Project name	Audit results
18	Dry seasoned instant noodle product manufacturer audit project	9. Food safety monitoring project: Not applicable to 36 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 10. Mandatory tracking: Not applicable to 36 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 11. Preservation of source documents: Not applicable to 8 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 12. Waste flow: Not applicable to 8 companies, 5 companies were given a time limit for improvement, and all passed re-inspection. 13. Standard form contracts: Not applicable to 23 companies, 10 companies were given a time limit for improvement, and passed re-inspection. 14. Other: (1) 1 company kept expired food. (2) 2 companies failed to assign sanitation management personnel. (3) 2 companies failed to assign specialized personnel or technicians. (4) 1 company used food additives not marked with license numbers. II. Labeling: 101 cases, of which 6 cases did not meet requirements. III. Random inspections: 154 cases, all met requirements.
19	Animal-based source functional beverage manufacturer audit project	I. Audited: 38 companies 1. GHP: 19 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 8 companies were given a time limit for improvement, and all passed re-inspection. 3. Legality of raw materials: 1 company failed. 4. Mandatory inspection: Not applicable to 26 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 5. Use of gases in foods: Not applicable to any of the 38 companies. 6. Food additive use and management: Not applicable to 25 companies, 6 companies were given a time limit for improvement, and all passed re-inspection. 7. Traceability: Not applicable to 26 companies, and the remaining 12 companies all passed. 8. Food safety monitoring project: Not applicable to 26 companies, and the remaining 12 companies all passed. 9. Mandatory tracking: Not applicable to 26 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 10. Preservation of source documents: 5 companies were given a time limit for improvement, and all passed re-inspection. 11. Waste flow: 29 companies were given a time limit for improvement, and all passed re-inspection. 12. Standard form contracts: Not applicable to 19 companies, 6 companies were given a time limit for improvement, and all passed re-inspection. 13. Other: (1) 4 companies failed to assign approved and recorded sanitation management personnel. (2) 2 companies used raw materials with labels that did not comply with regulations II. Labeling: 57 cases, of which 5 cases did not meet requirements. III. Random inspections: 53 cases, all met requirements.

No.	Project name	Audit results
20	Frozen dessert and ingredient manufacturer audit project	I. Audited: 69 companies 1. GHP: 40 companies were given a time limit for improvement, 1 company failed re-inspection. 2. Food business registration: 12 companies were given a time limit for improvement, and all passed re-inspection. 3. Legality of raw materials: 69 companies all passed. 4. Mandatory inspection: Not applicable to 56 companies, and the remaining 13 companies all passed. 5. State of gas use: Not applicable to any of the 69 companies. 6. Food additive use and management: Not applicable to 16 companies, 17 companies were given a time limit for improvement, and all passed re-inspection. 7. Traceability: Not applicable to 56 companies, 2 companies were given a time limit for improvement, and all passed re-inspection. 8. Food safety monitoring project: Not applicable to 56 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 9. Mandatory tracking: Not applicable to 56 companies, 1 company was not in compliance with regulations 10. Preservation of source documents: 2 companies were given a time limit for improvement, and all passed re-inspection. 11. Waste flow: 15 companies were given a time limit for improvement, and all passed re-inspection. 12. Standard form contracts: Not applicable to 49 companies, 9 companies were given a time limit for improvement, and all passed re-inspection. 13. Other: 3 companies failed to assign sanitation management personnel. II. Labeling: 151 cases, of which 12 cases did not meet requirements. III. Random inspections: 119 cases 1. Frozen dessert: 55 cases, of which 2 cases did not meet requirements. 2. Ingredients: 64 cases, all met requirements.
21	Food delivery platform audit project	I. Food delivery platform operators: 9 companies 1. GHP: Not applicable to 4 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 2. Food business registration: Not applicable to 1 company, and the remaining 8 companies all passed. 3. Standard form contracts: Not applicable to 2 companies, and the remaining 7 companies all passed. II. Food and beverage businesses cooperating with food delivery services: 454 companies 1. GHP: 182 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 35 companies, 60 companies were given a time limit for improvement, and all passed re-inspection. 3. Product liability insurance: Not applicable to 78 companies, 1 company was not in compliance with regulations 4. Other: 2 companies kept expired raw materials. 5. Labeling: 3 companies were not in compliance with regulations 6. Random inspections: 454 cases, of which 2 cases did not meet requirements. III. Food delivery platform and general food and beverage business delivery personnel: 236 persons, all met requirements.

No.	Project name	Audit results
22	Beverages and frozen desserts prepared on-site audit project	I. Audited: 380 companies 1. GHP: 143 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 2 companies, 32 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 24 companies were given a time limit for improvement, and all passed re-inspection. 4. Product liability insurance: Not applicable to 33 companies, 2 companies failed. 5. Other: 1 company was found to have kept expired food. II. On-site labeling: 230 companies, of which 34 companies were not in compliance with regulations III. Random inspections: 413 cases, of which 6 cases did not meet requirements.
23	Specialty restaurant audit project	I. Audited: 207 companies 1. GHP: 112 companies were given a time limit for improvement, none failed re-inspection. 2. Food business registration: Not applicable to 16 companies, 33 companies were given a time limit for improvement, none failed re-inspection. 3. Product liability insurance: Not applicable to 37 companies, 1 company failed. 4. Preservation of source documents: 18 companies were given a time limit for improvement, none failed re-inspection. 5. Standard form contracts: Not applicable to 194 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. 6. Other: 1 company was found to have kept expired food. II. Labeling: Not applicable to 2 companies, and the remaining 205 companies all met requirements. III. Random inspections: 256 cases, of which 1 case did not meet requirements.
24	Audit project for frozen and refrigerated prepared foods on the market	I. Audited: 148 companies 1. GHP: 13 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 2 companies, 5 companies were given a time limit for improvement, and all passed re-inspection. II. Random inspections: 284 cases, of which 1 case did not meet requirements.
25	Audit project for food and beverage businesses near university and college campuses	I. Audited: 206 companies 1. GHP: 116 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 10 companies, 45 companies were given a time limit for improvement, and all passed re-inspection. 3. Standard form contracts: Not applicable to 199 companies, and the remaining 7 companies all passed. 4. Other: 1 company was found to have kept expired raw materials. II. On-site labeling: 3 companies were not in compliance with regulations III. Random inspections: 411 cases, all met requirements.

No.	Project name	Audit results
26	Audit project for food and beverage businesses serving light meals	I. Audited: 98 companies 1. GHP: 64 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 4 companies, 24 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 14 companies were given a time limit for improvement, and all passed re-inspection. 4. Product liability insurance: Not applicable to 11 companies, 2 companies were not in compliance with regulations 5. Standard form contracts: (1) Distance transactions: Not applicable to 81 companies, 7 companies were given a time limit for improvement, and all passed re-inspection. (2) Gift vouchers: Not applicable to 92 companies, and the remaining 6 companies all passed. 6. Technical license holding ratio: Not applicable to 37 companies, and the remaining 61 companies all passed. 7. Other: (1) 2 companies were found to have kept expired raw materials. (2) 1 company used food additives with labeling that did not comply with regulations II. Labeling: 4 companies were not in compliance with regulations. III. Random inspections: 187 cases, all met requirements.
27	Audit project for food and beverage businesses in the vicinity of public transportation stations	I. Audited: 127 companies 1. GHP: 63 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 3 companies, 21 companies were given a time limit for improvement, and all passed re-inspection. 3. Source documents: 15 companies were given a time limit for improvement, and all passed re-inspection. 4. Product liability insurance: Not applicable to 11 companies, and the remaining 116 companies all passed. 5. Other: 2 companies were found to have kept expired raw materials. II. Labeling: Not applicable to 9 companies, 1 company was not in compliance with regulations III. Random inspections: 264 cases, of which 5 cases did not meet requirements.
28	Teppanyaki and steak food and beverage business audit project	I. Audited: 187 companies 1. GHP: 96 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 33 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 16 companies were given a time limit for improvement, and all passed re-inspection. 4. Product liability insurance: Not applicable to 8 companies, 1 company failed. 5. Standard form contracts: Not applicable to 152 companies, 5 companies were given a time limit for improvement, and all passed re-inspection. 6. Technical license holding ratio: Not applicable to 21 companies, 1 company failed. 7. Other: (1) 2 companies were found to have kept expired raw materials. (2) 2 cases of ingredients with intact packaging with labeling that did not comply with regulations. II. On-site labeling: 187 companies, of which 15 companies were not in compliance with regulations III. Random inspections: 271 cases, of which 3 cases did not meet requirements.

No.	Project name	Audit results
29	Audit project for popular food and beverage businesses recommended by media influencers	I. Audited: 207 companies 1. GHP: 104 companies were given a time limit for improvement, 1 company failed re-inspection. 2. Food business registration: Not applicable to 4 companies, 34 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 20 companies were given a time limit for improvement, and all passed re-inspection. 4. Product liability insurance: Not applicable to 20 companies, 3 companies failed. 5. Standard form contracts: Not applicable to 200 companies, and the remaining 7 companies all passed. 6. Other: (1) 3 companies were found to have kept expired food or raw materials. (2) 1 company had untruthful supplier labeling. II. Labeling: Not applicable to 23 companies, 2 companies were not in compliance with regulations III. Random inspections: 419 cases, of which 5 cases did not meet requirements.
30	Audit project for food logistics industry and warehousing and storage industry	Audited: 166 companies 1. GHP: Not applicable to 6 companies, 21 companies were given a time limit for improvement, and all passed re-inspection. 2. Food registration: Not applicable to 7 companies, 11 companies were given a time limit for improvement, and all passed re-inspection.
31	Audit project for food containers and packaging in which surfaces in contact with food contain plastics	Audited: 1. Manufacturers: 27 companies (1) GHP: 3 companies were given a time limit for improvement, and all passed re-inspection. (2) Food business registration: 3 companies were given a time limit for improvement, and all passed re-inspection. (3) Labeling: 29 cases, of which this item was not applicable in 13 cases, and the remaining 16 cases all met requirements. (4) Random inspections: 12 cases, all met requirements. 2. Sales industry: (1) Labeling: 258 cases, of which 82 were not applicable, 8 cases failed. (2) Random inspections: 102 cases, all met requirements.
32	Audit and random inspection project for food detergents	I. Audited: 102 companies 1. Food business registration: Not applicable to 1 company, 4 companies were given a time limit for improvement, and all passed re-inspection. 2. Preservation of source documents: 8 companies were given a time limit for improvement, and all passed re-inspection. II. Labeling: 308 cases, of which 9 cases did not meet requirements. III. Random inspections: 97 cases, all met requirements.
33	Combined Lunar New Year project	Audit of manufacturers making seasonal foods for the Lunar New Year: I. Audited: 73 companies 1. GHP: 43 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 16 companies were given a time limit for improvement, and all passed re-inspection. 3. Food additive use and management: Not applicable to 20 companies, 19 companies were given a time limit for improvement, and all passed re-inspection. 4. Preservation of source documents: 2 companies were given a time limit for improvement, and all passed re-inspection.

No.	Project name	Audit results
33	Combined Lunar New Year project	5. Product liability insurance: 73 companies all passed. 6. Standard form contracts: Not applicable to 21 companies, 12 companies were given a time limit for improvement, and all passed re-inspection. II. Labeling: 201 cases, of which 2 cases did not meet requirements. III. Random inspections: 215 cases, all met requirements.
		Audit and random inspection of New Year market vendors and seasonal food sales industry I. Audited: 274 companies 1. GHP: 30 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 6 companies, 17 companies were given a time limit for improvement, and all passed re-inspection. II. Labeling: 952 cases, of which 5 cases did not meet requirements. III. Random inspections: 1, 393 cases, of which 14 cases did not meet requirements.
		Audit and random inspection of restaurants selling New Year's dishes I. Audited: 79 companies 1. GHP: 34 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 15 companies were given a time limit for improvement, and all passed re-inspection. 3. Product liability insurance: Not applicable to 1 company, and the remaining 78 companies all passed. 4. Standard form contracts: (1) Foods or dining services taking distance orders: Not applicable to 62 companies, 5 companies were given a time limit for improvement, and all passed re-inspection. (2) Product (service) gift vouchers: Not applicable to 67 companies, 1 company was given a time limit for improvement, and all passed re-inspection. (3) Reservation and catering (banquets) services: Not applicable to 46 companies, 3 companies were given a time limit for improvement, and all passed re-inspection. II. On-site labeling: 4 companies were not in compliance with regulations III. Random inspections: 130 cases, all met requirements.
34	Audit and random inspection of seasonal holiday foods -Tomb-Sweeping Festival	Performed random inspections in 599 cases, of which 7 cases did not meet requirements.

No.	Project name	Audit results
35	Combined Dragon Boat Festival project	Audit of glutinous rice dumpling manufacturers: I. Audited: 78 companies 1. GHP: 48 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 7 companies, 26 companies were given a time limit for improvement, and all passed re-inspection. 3. Standard form contracts: (1) Distance transactions: Not applicable to 56 companies, 9 companies were given a time limit for improvement, and all passed re-inspection. (2) Gift vouchers: Not applicable to any of the 78 companies. 4. Other: 1 company was found to have kept expired raw materials. II. Labeling: 180 cases, all met requirements. III. Random inspections: 211 cases, of which 1 case did not meet requirements.
		Audit of the sales industry and random inspection of seasonal foods I. Audited: 201 companies 1. GHP: 15 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 13 companies, 22 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 9 companies were given a time limit for improvement, and all passed re-inspection. II. Labeling: 652 cases, of which 1 case did not meet requirements. III. Random inspections: 515 cases, of which 2 cases did not meet requirements.
36	Combined Mid-Autumn Festival project	Audit of the sales industry and random inspection of seasonal Mid-Autumn Festival foods I. Audited: 217 companies 1. GHP: 14 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: Not applicable to 3 companies, 13 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 3 companies were given a time limit for improvement, and all passed re-inspection. II. Labeling: 736 cases, of which 2 cases did not meet requirements. III. Random inspections: 893 cases, of which 3 cases did not meet requirements.
		Audit of food and beverage businesses selling seasonal Mid-Autumn Festival dishes I. Audited: 129 companies 1. GHP: 61 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 14 companies were given a time limit for improvement, and all passed re-inspection. 3. Preservation of source documents: 10 companies were given a time limit for improvement, and all passed re-inspection. 4. Product liability insurance: 2 companies failed. 5. Standard form contracts: Not applicable to 122 companies, 1 company was given a time limit for improvement, and has passed re-inspection. 6. Other: 3 companies were found to have kept expired food. II. On-site labeling: 129 companies, of which 2 companies were not in compliance with regulations III. Random inspections: 132 cases, of which 1 case did not meet requirements.

No.	Project name	Audit results
36	Combined Mid-Autumn Festival project	Audit of seasonal Mid-Autumn Festival food manufacturers I. Audited: 96 companies 1. GHP: 56 companies were given a time limit for improvement, and all passed re-inspection. 2. Food business registration: 20 companies were given a time limit for improvement, and all passed re-inspection. 3. Food additive use and management: Not applicable to 22 companies, 35 companies were given a time limit for improvement, and all passed re-inspection. 4. State of phosphine use: All 96 companies did not use phosphine. 5. Preservation of source documents: 4 companies were given a time limit for improvement, and all passed re-inspection. 6. Waste flow: 23 companies were given a time limit for improvement, and all passed re-inspection. 7. Product liability insurance: 1 company was not in compliance with regulations 8. Standard form contracts: Not applicable to 52 companies, 14 companies were given a time limit for improvement, and all passed re-inspection. 9. Warehouse management: 29 companies were given a time limit for improvement, and all passed re-inspection. 10. Other: (1) 5 companies were found to have kept expired food. (2) 1 companies failed to assign sanitation management personnel. II. Random inspections: 204 cases, all met requirements. III. Labeling: 277 cases, of which 8 cases did not meet requirements.
37	Audit and random inspection of seasonal holiday foods - Winter Solstice	Random inspections: 583 cases, 1 case did not meet requirements.
38	Audit project for businesses providing group lunches to schools	I. Audited: 523 companies GHP: 84 companies were given a time limit for improvement, and all passed re-inspection. II. Random inspections: 1. Lunch finished products or semi-finished products: 499 cases, all met requirements. 2. Pork-related raw materials: 207 cases, all met requirements. III. Disclosure of pork raw material original place of production information to downstream businesses: 508 cases involving lunch finished products, of which 1 case did not meet requirements.

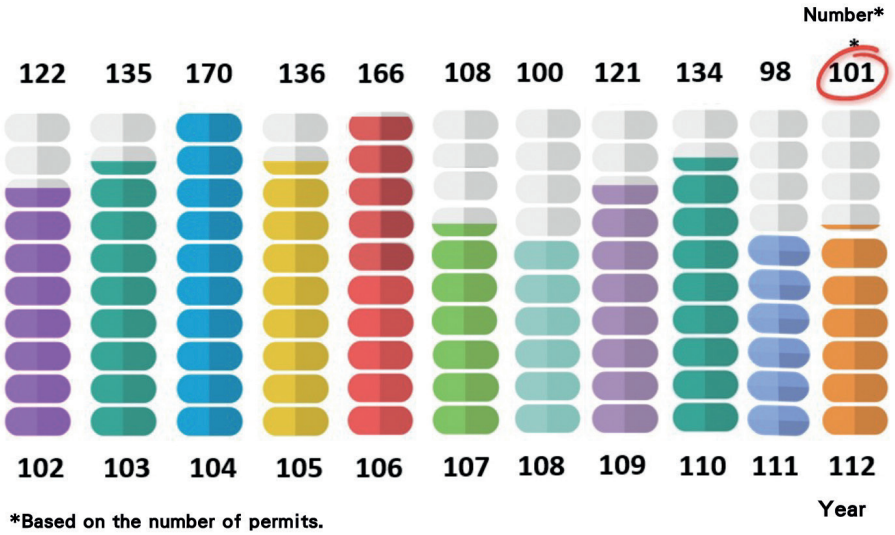
No.	Project name	Audit results
39	Audit project for school kitchens providing school lunches	I. Audited: 1,805 companies GHP: 140 companies were given a time limit for improvement, and all passed re-inspection. II. Pork original place of production labeling: 2,784 cases, all met requirements. III. Random inspections: 1. Lunch finished products: 2,179 cases, all met requirements. 2. Semi-finished products: 206 cases, of which 2 cases did not comply with regulations.
40	Radionuclide testing project for imported food on the market	Random inspection for radionuclides in Japanese food on the market: Random inspections: 1,011 cases, all met requirements.
		Random inspection for radionuclides in imported food on the market: Random inspections: I. Japanese food sold online: 100 cases, all met requirements. II. Random inspection of imported food not from Japan sold in physical stores: 100 cases, all met requirements.
41	Place of production labeling audit project for Japanese food on the market	Audited 24,231 cases, all met requirements.
42	Random testing project for dioxins in food	**Seafood** Random inspections: 33 cases, all met requirements.
		Meat, eggs, and dairy products Random inspections: 35 cases, all met requirements.
		Plant-based agricultural products Random inspections: 32 cases, all met requirements.
43	Testing project for residues in eggs for export to the EU	Random inspections: 121 cases, of which 1 case did not meet requirements.
44	Audit of original place of production labeling of pork, beef, and raw materials made from their edible portions	Audits: 59,780 cases, of which 35 cases did not meet requirements.

Attached Table 5 Additions and revisions to drug management laws, regulations, and standards in 2023

Date announced	Name	Key content
January 7	Announcement of the " Guideline on equivalence of locally applied, locally acting products in the gastrointestinal tract"	These Guidelines have been announced to assist the pharmaceutical industry at the R&D stage by providing a basis for verifying the therapeutic equivalence of gastrointestinal preparations with local effects.
January 18	Announcement of the " Guideline on quality and equivalence of topical products "	These Guidelines have been announced to assist the pharmaceutical industry at the R&D stage by providing a basis for verifying the therapeutic equivalence of topical products.
February 9	Revision of the "Categories Which the Track and Trace System for Medicinal Products Should Be Implemented According to Article 6-1 of Pharmaceutical Affairs Act"	To prevent illicit drugs from entering lawful supply chains and protect people's medication safety, TFDA continues to analyze health insurance pharmaceutical reporting data, and performs rolling revisions of drugs of high concern.
February 24	Revision of the "Guide to Good Manufacturing Practice for Medicinal Products (Part I, Annexes)"	Revision of "Annex 13 Manufacture of Investigational Medicinal Products" and addition of "Annex 16 Certification by the authorized person and batch release", which provide regulations for implementation of GMP by manufacturers.
April 27	Revision of the " Regulations of Bioavailability and Bioequivalence Studies"	These Provisions have been announced to ensure that approved medicinal products have adequate bioequivalence or bioavailability and clinical trial data, and strengthen the management of drugs with components which are not under pharmacovigilance.
April 27	Revision of the "Regulations for Registration of Medicinal Products"	After referring to international management regulations, TFDA harmonized the Guidelines with international regulatory scientific standards by revising the requirements for bioequivalence studies in the case of specific dosage forms and conditions.
May 30	Announcement of the updated "The list of ICH guidelines adopted"	To provide a reference basis for businesses engaged in pharmaceutical R&D and manufacturing, TFDA announced the updated List, which explains the key points of ICH guidelines, applicable scope, and Taiwan's current corresponding reference materials.
June 12	Announcement of the "Guideline on the Implementation of Decentralized Elements in Clinical Trials with Medicinal Products"	Responding to scientific and technological advances and the development of a post-Covid new normal, TFDA announced this Guideline to provide a basis for decentralized elements in the implementation of clinical trials with medicinal products.

Date announced	Name	Key content
June 14	Revision of the "Guide to Good Manufacturing Practice for Medicinal Products (Part I, Annexes)"	To provide a basis for GMP implementation by manufacturers, TFDA issued the revised "Annex 1: Manufacture of Sterile Medicinal Products" in the "Guide to Good Manufacturing Practice for Medicinal Products (Part I, Annexes)"
June 15	Announcement of the "Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief "	Includes drug injury relief application procedures, payment amounts, committee organization, and review matters; the drafting of these Regulations will strengthen drug injury relief review procedures.
July 7	Announcement of the "List of items that can be compounded with non-pharmaceutical preparations and their compounding specifications"	To further improve measures concerning the preparation of pharmaceuticals, protect people's medication safety, and provide standards for pharmacists' work, TFDA announced this list of preparation product items not needing production from preparations and preparation regulations.
September 4	Revision of the "Drug Injury Relief Measurement Table"	This textual revision intended to further improve the Drug Injury Relief Payment Calculation Form was conducted in conjunction with the drafting of the Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief.
September 21	Revision of the "Guidance for contract research organizations performing bioequivalence studies"	In response to changes in pharmaceutical administration in recent years, TFDA has made many revisions to laws governing drug clinical trials and bioequivalence studies. In order to provide research institutions with standards for bioequivalence studies and analysis, TFDA announced amendments to guidance for organizations performing in vivo bioequivalence studies.
October 20	Revision of the "Regulations for Drug Recall" Revision of Article 37 of the "Enforcement Rules of the Pharmaceutical Affairs Act"	These revisions eliminate the requirement that seal checking must be performed before sale after pharmaceutical instructions are changed; in order to avoid redundant regulations, Article 37 of the Pharmaceutical Affairs Act Enforcement Rules is concurrently deleted.
October 30	Announcement of "Real-World Data: Assessing Electronic Health Records and Medical Claims Data To Support Regulatory Decision-Making for Drugs"	The use of real-word evidence is a new clinical trend. To promote relevant domestic R&D, TFDA has drafted this guide after consulting international management actions.
November 1	Revision of the "List of Essential Drugs in Article 27-2 of the Pharmaceutical Affairs Act"	TFDA made this revision in order to strengthen the supply mechanism when drug suppliers report insufficient stock of essential drugs, and to put the drug supply shortage notification, assessment, and response system on a stronger footing.

Attached Table 6 Quantity of New Drugs Approved in 2023



Among the 101 approved new drugs, new dosage forms, new administration doses, and new strengths medicinal products, NCE accounted for 32, biological products accounted for 39. They are indicated for diseases such as cancer, rare diseases, endocrine disorders, and diabetes, which provide new treatment options for patients.

Attached Table 7 Revisions to the controlled drug schedule announced in 2023

Date of revision	Schedule	Name of controlled drug
April 25	Schedule 3	Addition of 5 items, including α-Pyrrolidinoisohexanophenone, α-PiHP
	Schedule 4 API	Addition of 6 items, including Bromophenylacetone (including its 2-Bromo, 3-Bromo, and 4-Bromo isomers)
	Schedule 3	Originally in Schedule 2, Psilocine has been included with the Schedule 3 hydroxy-N,N-dimethyltryptamine, and the Schedule 2 entry has been deleted.
	Schedule 3	The name of methylone has been revised to 3,4-Methylenedioxy- α -pyrrolidinohexiophenone, MDPHP
September 12	Schedule 3	Addition of methyl 2- (1- (4-fluorobutyl) -1H-indole-3-carboxamido) -3, 3-dimethylbutanoate, 4F-MDMB-BUTICA
	Schedule 4 API	Addition of 4 items, including 2-Bromo-chloropropiophenone (including 4-chloro, 3-chloro, and 2-chloro isomers)
	Schedule 3	Originally in Schedule 2, the controlled drug pentylone has been deleted, and changed to a Schedule 3 controlled drug
	Schedule 4	Deletion of text in the Remarks column of chlordiazepoxide and phenobarbital stating that compound preparations containing these drugs as components shall not be subject to control under the "Controlled Drugs Act," etc.

*For details about respective items announced, refer to the official website/scope of operation/controlled drugs/management over controlled drugs of TFDA.

Attached Table 8 Revisions and additions to medical device management regulations and standards in 2023

Date announced	Name	Key content
January 12	Announcement of the drafting of "Technical Criteria for SARS-CoV-2 Virus Nucleic Acid Test Reagents" and "Technical Criteria for SARS-CoV-2 Viral Antigen Test Reagents"	These technical criteria can ensure the safety and effectiveness of relevant products by allowing the makers of nucleic acid and antigen test reagents to obtain the data that must be submitted when these reagents are tested and registered.
January 18	Announcement of "Items Requiring Testing when Applying for Medical Device Inspection and Registration or Change Registration"	To ensure the effectiveness of products of this type, includes the Covid-19 viral antigen test reagent among items that must be tested.
February 13	Announcement of the revised "Regulations Governing the Uniform Identification Code that must be Stated on the Labels of Medical Devices"	This revision furthers harmonization with international regulations and eases restrictions on Class 2 medical devices by not requiring labeling with production identification codes.
February 23	Announcement of the revised "Medical Device Administrative Fee Assessment Standards"	Addition of fee standards for medical device vendor license applications and change registration, etc. for reference by city and county health departments.
March 2	Announcement of "Guidelines for Assessment of Gender Differences in Clinical Trials of Medical Devices"	Provides medical device vendors and research institutions designing clinical trials with guidelines for consideration of gender differences in subject recruiting, study design, statistical analysis, data interpretation, and the disclosure of research results content.
March 29	Drafting and announcement of "Medical Device Product Items Whose Instructions May Be Replaced by Electronic Instructions and Medical Device Firms Shall Indicate the Particulars on the Labels or Package"	Expands the scope of applicable items that are harmonized with international management regulations, and promotes paperless, digital service.
April 11	Announcement of "List of Medical Device Standards Accepted in 2023" and "List of Originally Accepted Medical Device Standards that have been Revoked"	TFDA accepts newly-announced international standards for medical devices, which are provided as a reference to firms developing and producing medical devices.
May 2	Announcement of "Medical Device Human Factor Usability Engineering Assessment Q&A"	Provides vendors with a reference basis when preparing human factor engineering/usability assessment reports
August 10	Announcement of the revised "Technical Criteria for the Comparative Assessment of the Methods used by In Vitro Diagnostic Medical Devices" and "Technical Criteria for In Vitro Coagulation Function Diagnostic Reagents"	Provides businesses with a reference when performing product R&D and preparing data for inspection and registration applications; strengthens the safety and effectiveness of in vitro diagnostic medical devices.

Date announced	Name	Key content
August 15	Announcement of the drafting of "Specifications, Testing Methods, and Performance that must be Complied with By Specific Medical Device Product Items"	These specification and performance requirements are aimed at specific product types in the categories "G.3300 hearing aids, "I.4040 medical apparel," and "O.3825 mechanical walkers," and ensure these products safety and effectiveness.
August 22	Announcement of the revised Article 7 and attached Annex in Article 4 of the "Regulations Governing the Classification of Medical Devices"	Adds and revises classified management requirements for software as a medical device (SaMD) products and updates standards that must be met by medical face masks, increasing harmonization with international management models while maintaining consistency with the current state of management in Taiwan.
September 13	Announcement of the revised "Guidance for Medical Device Good Vigilance Practice," and change of name to "Guidance for Medical Device Post-market Surveillance Practice."	Provides medical device firm and medical institutions with knowledge of post-market medical device management regulations and relevant enforcement principles, including safety monitoring, reporting of severe adverse events, active notification of product safety concerns, corrective and preventive measures, and re-assessment, etc., which will strengthen domestic medical device post-market quality monitoring and user safety.
September 14	Announcement of the revised "Technical Guidelines for the Inspection and Registration of Computer-assisted Detection (CADe) and Computer-assisted Diagnosis (CADx) Medical Devices Employing Artificial Intelligence and Machine Learning Technologies"	Includes new CADe medical device software key technical review cases addressing pulmonary nodule CT imaging and fundus imaging for diabetic retinopathy and provide a reference for the development of relevant medical devices.
October 26	Announcement of "Q&A Concerning Queries Made during the Inspection and Registration Medical Devices Employing Computer-Aided Detection (CADe) and Computer-Aided Diagnosis (CADx) Technologies Based on Artificial Intelligence and Machine Learning"	Provides reference responses to the most common questions asked during the pre-market inspection of medical devices employing artificial intelligence and machine learning technologies, and will help accelerate product R&D.
November 1	Announcement of the revised "Technical Criteria for In Vitro Human Papillomavirus Diagnostic Medical Devices" and "Technical Criteria for In Vitro Influenza Virus Nucleic Acid Diagnostic Medical Devices"	Provides vendors with a reference when performing product R&D and preparing data when applying for inspection and registration, and will enhance the safety and effectiveness of in vitro diagnostic medical devices.
November 7	Announcement of the "List of Products not Managed as Medical Devices"	Clarifies Taiwan's management regulations for products not managed as medical devices.

Date announced	Name	Key content
November 16	Announcement of the revised "Key Consulting and Assistance Guidelines for Medical Device Projects of the Food and Drug Administration, Ministry of Health and Welfare"	Improves medical device project consulting and assistance procedures, and boosts consulting effectiveness.
November 27	Announcement of the revision of certain clauses of " Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration," including Attached Appendix1, Article 5 and attached Appendices 2 and 3, Article 6	Adds items that may be changed by the license holder, strengthens medical device registration management regulations, and adds the provision that Class 2 medical devices are eligible for simplified review items, improving medical device management.

Attached Table 9 Revisions and additions to cosmetic regulations and standards in 2023

Date announced	Name	Key content
September 6	Revision of Article 2 of the "Particulars of Specific Purpose Cosmetics That May Be Voluntarily Modified"	In view of the fact that the registration regulations for specific purpose cosmetics will cease to apply on July 1, 2024, to quickly ensure that all ingredient names are consistent with the names labeled on cosmetic outer packaging, containers, labels, or instructions, a provision has been added allowing the manufacturers to delete at their own discretion the "specific purpose ingredients and their content" field, while requiring that the content of all ingredients must be stated alongside the ingredient names.
October 2	Announcement of the revised "Guideline for Cosmetic Product Information File," "Introduction to Cosmetic Product Information File" and "Checklist for Cosmetic Product Information File"	Responding to the enforcement of the product information file (PIF) system for cosmetics on July 1, 2024, TFDA has added cosmetic PIF example documents, which will help businesses successfully establish PIFs creation.

Attached Table 10 Joint food, drugs, and cosmetics audits during 2023

Audit type	No.	Project name (implementation time)	Results
Food safety	1	On-the-market tea place of production labeling audit project (Sept. 2021 – Dec. 2023)	A total of 411 tea products were inspected, of which suspected imported tea was found in 42 cases.
	2	Imported egg business joint audit project (Nov. 2023 – Jan. 2024)	Product labels were inspected in 28 cases at 22 audited companies, and all results met requirements.
	3	Packaged and bottled drinking water manufacturing plant joint audit project (March-May, 2023)	After conducting audits at 37 companies, companies with GHP deficiencies were asked to make improvement within a limited time period, and all past re-inspection. Product labels were inspected in 41 cases, of which 5 cases failed. Random inspection of 33 finished products was performed, and all passed. Random inspection of 21 non-tap water sources found 1 failing case. One company's bottled water was found to have expired, and the company subsequently applied for an extension in accordance with regulations. The water sources of other companies uniformly complied with legal requirements.
	4	On-the-market oyster place of production labeling joint audit project (May-June, 2023)	The "On-the-market oyster place of production labeling joint audit project" audited 38 businesses, and inspected oyster products in 36 cases. Apart from 1 case in which domestically-produced bulk oysters were not labeled with the place of production in accordance with regulations (this deficiency has already been corrected), the remaining cases all complied with regulations.
Medical devices	10	Low-frequency product audits (March-May, 2023)	Audited 220 companies, of which 55 did not comply with regulations
	2	Contact lens case product audits (March-May, 2023)	Audited 220 companies, of which 79 did not comply with regulations
Pharmaceuticals	1	Flow audit of sellers of chemical agents containing ephedrine (July-August, 2023)	Audited 63 companies, of which 8 did not comply with regulations
Controlled drugs	1	Controlled drug audit project (March-Sept., 2023)	Audited 205 companies, of which 52 did not comply with regulations
Cosmetics	1	Audit of labeling of cosmetics sold at general lifestyle department stores (Sept.-Oct., 2023)	Audited 260 cases, of which 6 cases did not meet requirements.
	2	Audit of product registration by cosmetics manufacturers and importers (Sept.-Oct., 2023)	Audited 231 cases, of which 20 cases did not meet requirements.

Attached Table 11 Additions to TFDA's testing methods in 2023

Type of Testing method	Testing Method	New/ Revised
Promulgated testing methods for food products (16 articles, 152 items)	1. Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Antiprotozoal Drugs (2) (MOHWV0052.00) 2. Method of Test for Veterinary Drug Residues in Foods - Test of Malachite Green, Crystal Violet, and their Metabolites (MOHWV0053.00) 3. Methods of Test for Food Utensils, Containers and Packages - Test of Metal Alloy (the Direct Contact Surface Material with Food is Synthetic Resins) (MOHWU0031.00) 4. Methods of Test for Food Utensils, Containers and Packages - Test of Metal Alloy (the Direct Contact Surface Material with Food is Metal Alloy) (MOHWU0032.00) 5. Method of Test for Food Additive Specifications - Calcium L-5-Methyltetrahydrofolate 6. Method of Test for Food Additive Specifications - Extracts of Rosemary 7. Method of Test for Food Additive Specifications - Ammonium Phosphatide	New
	1. Methods of Test for Food Microorganisms - Test of *Clostridium perfringens* (MOHWM0006.02) 2. Method of Test for Veterinary Drug Residues in Foods - Test of Tetracyclines (MOHWV0036.06) 3. Methods of Test for Food Microorganisms - Test of Aerobic Plate Count (MOHWM0014.02) 4. Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of β-Lactam Antibiotics (MOHWV0051.01) 5. Method of Test for Dioxins/Furans and Polychlorinated Biphenyls in Foods (MOHWO0026.01) 6. Method of Test for Total Glycoalkaloids in Foods (MOHWO0017.01) 7. Method of Test for Food Additive Specifications - Sodium Hydroxide Solution 8. Method of Test for Food Additive Specifications - Brilliant Blue FCF 9. Method of Test for Food Additive Specifications - α-Glycosyl-isoquercitrin	Revised
	1. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Macadamia Nut (TFDAF0033.00) 2. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Wheat, Barley, Rye and Oats (TFDAF0034.00) 3. Method of Test for Crude Fat in Cacao Products (TFDAA0097.00) 4. Method of Test for Veterinary Drug Residues in Foods - Test of Tetracyclines (TFDAV0031.00) 5. List of Recommended Methods of Test for Contaminants in Foods (TFDAO0044.00) 6. Method of Test for Isomaltooligosaccharides in Beverages (TFDAA0098.00) 7. Methods of Test for Food Utensils, Containers and Packages - Test of Metal Alloy (the Direct Contact Surface Material with Food is Metal Alloy) (TFDAU0007.00) 8. Methods of Test for Food Utensils, Containers and Packages - Test of Metal Alloy (the Direct Contact Surface Material with Food is Synthetic Resins) (TFDAU0008.00) 9. Method of Test for Extracts of Rosemary in Foods (TFDAA0100.00)	New

Type of Testing method	Testing Method	New/ Revised
Recommended testing methods for food products (35 articles, 242 items)	10. Method of Test of 2 - Chloroethanol in Grapes (TFDAP0026.00) 11. Method of Test for Pesticide Residues in Foods - Test of Metaldehyde (TFDAP0027.00) 12. Method of Test for Multielement in Oyster (TFDAF0035.00) 13. Method of Test for Oyster Species Identification (TFDAF0036.00) 14. Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of Crustacean (TFDAF0037.00) 15. Method of Test for Veterinary Drug Residues in Aquatic Products - Multiresidue Analysis of Nitroimidazoles and their Metabolites (TFDAV0032.00) 16. Method of Test of Tritium in Foods (TFDAO0045.00)	New
	1. Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis (5) - 8 Items including Afidopyropen et al. (TFDAP0017.04) 2. Method of Test for 2-MCPD Esters, 3-MCPD Esters and Glycidyl Esters in Infant Formula (TFDAO0038.01) 3. List of Recommended Methods of Test for Pesticide Residues in Foods (TFDAP0003.05) 4. Method of Test for Natural Edible Colorants - Test of Heavy Metals in Plant Carbon (TFDAA0099.00) 5. Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis (5) - 9 Items including Afidopyropen et al. (TFDAP0017.05) 6. Method of Test for Pesticide Residues in Foods - Test of Phosphine (TFDAP0025.01) 7. List of Recommended Methods of Test for Nutrients in Special Nutritional Foods (TFDAA0031.01) 8. Method of Test for Isomaltooligosaccharides in Beverages (TFDAA0098.01) 9. Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6) (TFDAP0007.04) 10. Method of Test for Ethylene Oxide and its Reaction Product 2 - Chloroethanol, in Food (TFDAP0022.04) 11. Method of Test for Water-Soluble Vitamins in Foods in Capsule or Tablet Forms (TFDAA0012.04) 12. Methods of Test for Food Utensils, Containers and Packages - Test of Metal Alloy (the Direct Contact Surface Material with Food is Metal Alloy) (TFDAU0007.01) 13. Method of Test for 2-MCPDEs, 3-MCPDEs and GEs in Infant Formula (TFDAO0038.02) 14. Method of Test for C4 Plant Sugars in Honey (TFDAF0030.01) 15. Method of Simple Check for Residual Lipid, Starch, Protein and Alkyl Benzene Sulfonate on Tableware (TFDAU0006.03) 16. Method of Test for Lutein and Zeaxanthin in Foods in Capsule or Tablet Form (TFDAA0051.02) 17. Method of Test for Pesticide Residues in Bee Products - Multiresidue Analysis (TFDAP0015.02) 18. Method of Test for Pesticide Residues in Livestock and Poultry Products for Expansion of Multiresidue Analysis - 22 Items including Ametoctradin et al. (TFDAP0020.02) 19. List of Recommended Methods of Test for Veterinary Drug Residues in Foods (TFDAV0007.02)	Revised

Type of Testing method	Testing Method	New/ Revised
Recommended testing methods for cosmetics and medical devices products (5 articles, 123 items)	1. Method of Test for Aromatic Amines in Hair Dyes (RA03D011.001) 2. Method of Test for Prostaglandin Analogs in Cosmetics (RA03B024.001) 3. Static Destructive Test and Dynamic Loading Test for Endosseous Dental Implants (RA04P004.001)	New
	1. Method of Test for Hair Dyes in Cosmetics (RA03D002.004) 2. Method of Test for Hair Dyes in Cosmetics (3) (RA03D006.005)	Revised
Recommended testing methods for drugs, controlled drugs (including illicit drugs) and biological drugs (4 articles, 37 items)	1. Method of Test for Synthetic Cannabinoids in Urine (2) (RA02I007.001) 2. Method of Test for 1-Methyl-4-Nitrosopiperazine in Rifampin Drug Substance (RA01I010.001) 3. Method of Test for *N*-Nitroso Propranolol in Propranolol Drug Substance (RA01I009.001) 4. Determination of SARS-CoV-2 Infectious Titer (RA05I004.001)	New

Because compliance with PIC/S GMP requirements is gradually being promoted at different types of pharmaceutical plants, starting from 2015, statistics concerning domestic PIC/S GMP pharmaceutical plants will include: preparation plants, active pharmaceutical ingredient plants, medical gas plants, GMP logistics plants, and pilot plants.

Appendix 3 Important Achievements and Statistics Over the Years

Attached Table 1 The statistics of inspection of foods import over the years

Year	Inspection number of batches	Growth rate (%)	Total net weight (10,000 metric tons)	Batches tested	Inspection rate (%)	Number of noncompliant batches
2011	420,602	-	717.7	29,801	7.1	289
2012	461,665	9.8	754.5	38,793	8.4	467
2013	514,710	11.5	713.3	38,460	7.5	557
2014	616,286	19.7	796.6	48,704	7.9	664
2015	640,003	3.9	900.5	50,149	7.8	953
2016	674,991	5.5	882.9	52,722	7.8	915
2017	694,372	2.9	896.9	56,604	8.2	808
2018	682,575	-1.7	895.0	58,915	8.6	820
2019	718,766	5.3	925.7	58,108	8.1	786
2020	697,248	-3.0	891.3	52,434	7.5	832
2021	715,929	2.7	890.3	57,601	8.0	846
2022	724,182	1.2	893.7	65,681	9.1	664
2023	735,752	1.6	882.8	61,515	8.4	710

Remarks: TFDA started to conduct import foods inspections in 2011, so there was no growth rate in that year.

Attached Table 2 Statistics of inspection on pesticide residue, veterinary drugs, mycotoxins, and heavy metals in foods over the years

Year	Monitoring on pesticide residue		Monitoring on veterinary drugs		Monitoring on mycotoxin		Monitoring on heavy metal	
	Total	Qualified rate (%)	Total	Qualified rate (%)	Total	Qualified rate (%)	Total	Qualified rate (%)
2010	2,051	90.5	330	98.2	194	96.4	161	100.0
2011	2,110	89.0	481	90.9	141	90.8	162	100.0
2012	2,363	89.8	572	93.0	356	96.1	410	100.0
2013	2,340	88.9	861	95.9	421	97.9	522	99.2
2014	2,528	87.2	830	95.7	461	97.4	801	99.4
2015	3,087	88.7	1,745*	98.2	512	94.3	601	99.0
2016	3,341	89.1	2,278*	98.6	515	97.5	601	99.5
2017	4,465	87.0	2,732*	99.0	586	97.1	650	99.5
2018	4,467	89.0	3,580*	99.2	570	99.4	553	99.4
2019	5,164	90.6	4,260*	99.5	800	95.1	611	99.2
2020	4,671	90.2	4,688	99.6	800	93.9	600	98.8
2021	4,300	91.6	12,094	99.8	657	95.4	658	98.2
2022	4,616	92.2	7,907	99.8	687	95.3	616	97.9
2023	4,731	90.0	8,045	99.6	676	93.6	600	97.5

*Source: TDFA high-risk project "Testing plans for veterinary drug residues in food" and "Testing plans for veterinary drug residues" jointly conducted with local government health bureaus.

Attached Table 3 Statistics on foodborne disease over the years

Year	Number of outbreaks	Foodborne disease		Number of foodborne disease outbreaks classified by foods					
		Number of patients	Number of deaths	Aquatic products and their processed products	Meat, eggs, dairy and their processed products	Grain, fruits and vegetables and their processed products	Cake and candy	Compound cooking foods and other types	Total of causes with undefined foods
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338
2014	480	4,504	0	18	12	6	3	60	381
2015	632	6,235	0	17	3	7	1	53	551
2016	486	5,260	0	18	4	2	2	56	404
2017	528	6,232	0	7	3	7	0	44	467
2018	398	4,616	0	5	2	5	1	30	358
2019	502	6,935	2	13	5	5	1	26	457
2020	506	4,920	0	4	2	5	2	25	469
2021	498	5,823	0	3	2	6	0	13	475
2022	499	4,495	0	3	3	2	2	15	476
2023	633	5,196	1	9	4	7	1	21	595

Attached Table 4 Statistics of permits for health food and genetically modified food over the years

Health food permits (track 1 + track 2)					Genetically modified foods	
Year	Track 1	Track 2	Number of issued license in the year	Total number of issued permits	Number of issued permit in the year	Total number of issued permits
2010	16	4	20	196	3	30
2011	17	6	23	219	13	43
2012	22	8	30	249	9	52
2013	14	13	27	276	10	62
2014	26	15	41	317	12	74
2015	22	5	27	344	33	107
2016	25	7	32	376	11	118
2017	31	0	31	407	12	130
2018	20	3	23	430	10	140
2019	21	3	24	454	9	149
2020	16	3	19	473	2	151
2021	14	4	18	491	4	155
2022	21	0	21	512	6	161
2023	8	4	12	524	2	163

Note:

1. Health food registration adopts the two-track system

   Track 1 (case review): The applicants must provide supported documents to prove the safety and health care effects of the foods. The permit will be issued as Wei Bu Jian Shi Zi No. Axxxxx.

   Track 2 (specification standards review): Products shall conform to Ministry of Health and Welfare specifications and standards. The permit will issue as Wei Bu Jian Shi Gui Zi No. xxxxxx.

2. As of December 2023, the total number of issued permits for health food accumulated to524 (including 443 in Track 1 and 81 in Track 2), of which 103 were invalid permits (including expired, revoked and combined). As of the end of 2023, the number of valid permits were 421.

3. As of December 2023, the total number of issued permits for genetic modified foods accumulated to 163 permits of which 3 of them will be discontinued or not be extended. As of the end of 2023, the number of valid permits were 160.

Attached Table 5 Statistics of approved medicinal products every year

Year	Generic drugs			Active pharmaceutical ingredients			New drugs			Biologics			Orphan drugs			Total
	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	
2010	323	41	364	15	69	84	11	77	88	2	14	16	0	0	0	552
2011	220	52	272	20	172	192	17	46	63	1	24	25	0	2	2	554
2012	256	60	316	8	203	211	20	42	62	2	25	27	0	9	9	625
2013	247	51	298	7	105	112	23	14	37	0	1	1	0	3	3	451
2014	263	122	385	24	80	104	28	62	90	1	11	12	1	2	3	594
2015	175	86	261	18	81	99	27	90	117	0	35	35	3	5	8	520
2016	202	84	286	48	191	239	12	141	153	0	16	16	1	3	4	698
2017	196	90	286	28	193	221	20	120	140	1	15	16	2	16	18	681
2018	154	48	202	8	166	174	34	97	131	1	29	30	0	12	12	549
2019	171	50	221	4	147	151	36	63	99	0	23	23	2	3	5	499
2020	164	45	209	3	170	173	21	69	90	2	27	29	0	10	10	511
2021	195	47	242	1	152	153	22	62	84	1	33	34	1	14	15	528
2022	126	27	153	2	147	149	19	45	64	0	25	25	0	11	11	402
2023	118	64	182	22	169	191	29	39	68	6	34	40	0	6	6	487

Attached Table 6 Number of valid QMS/QSD registration letters for medical devices over the years

Year	Valid QMS registration letters	Valid QSD registration letters
2010	236	1,340
2011	486	2,777
2012	531	3,065
2013	568	3,213
2014	565	3,057
2015	685	3,640
2016	669	3,800
2017	704	3,925
2018	748	4,177
2019	792	4,338
2020	878	4,720
2021	1,206	4,778
2022	1,331	5,197
2023	1,441	5,595

Attached Table 7 Approved listing/notifications/licenses of medical devices and cosmetics over the years

Year	Medical devices			Specific purpose cosmetics		
	Number of listing	Number of issued licenses by year	Number of valid licenses	Number of notifications	Number of issued licenses by year	Number of valid licenses
2010	The listing system has been implemented for the announced medical device items from1. October.2021	3,920	30,140	General cosmetics should complete product notification before marketing from 1 July 2021	1,437	13,436
2011		4,047	33,865		1,519	14,979
2012		3,592	32,821		1,482	12,340
2013		3,827	35,705		1,456	13,799
2014		3,605	37,967		1,565	14,570
2015		3,743	40,579		1,558	14,902
2016		3,818	43,328		1,172	15,674
2017		3,940	46,797		1,142	16,643
2018		3,985	45,890		1,220	15,365
2019		3,770	45,839		1,257	14,710
2020		3,647	48,293		915	15,595
2021	3,303	2,805	47,635	333,805	944	16,578
2022	3,323	2,687	44,053	371,556	798	14,290
2023	3,140	1,991	45,969	409,412	790	13,921

Note: A total of 6,253 medical device licenses were cancelled in 2018; 4,653 medical device licenses were cancelled in 2019; 9,326 medical device licenses were directly transferred to the listing system in 2022; 4,048 medical device licenses were directly transferred to the listing system in 2023.

Attached Table 8 Controlled drugs licenses and inspection statistics over the years

Year	Controlled drugs licenses		Controlled drugs inspections		
	Controlled drugs registration	Controlled drugs license (persons)	Number of inspections	Number of violations	Violation rate (%)
2010	13,266	42,619	15,154	196	1.29
2011	13,745	44,469	15,270	147	0.96
2012	14,149	45,844	16,214	202	1.25
2013	14,511	47,391	16,197	211	1.30
2014	14,857	49,059	17,057	304	1.78
2015	15,148	51,111	17,454	371	2.13
2016	15,413	52,757	17,145	437	2.55
2017	15,682	54,831	17,230	588	3.41
2018	15,493	56,405	17,598	482	2.74
2019	15,905	58,840	17,678	621	3.51
2020	16,360	61,116	9,720	435	4.48
2021	16,737	63,102	8,018	265	3.31
2022	17,317	65,098	8,068	225	2.79
2023	17,807	66,957	12,127	355	2.93

Attached Table 9 The domestic and overseas pharmaceutical manufacturers that passed the inspection over the years

Year	Domestic pharmaceutical manufacturers that passed the GMP	Domestic pharmaceutical manufacturers that passed the PIC/S GMP	Overseas pharmaceutical manufacturers that passed the PIC/S GMP
2010	155	22	527
2011	149	33	720
2012	145	44	760
2013	140	57	820
2014	98	98	870
2015	-	190	893
2016	-	208	936
2017	-	222	937
2018	-	229	943
2019	-	235	937
2020	-	239	964
2021	-	239	974
2022	-	241	958
2023	-	239	958

Remarks:

1.Column 1 only shows statistics up to 2014 as pharmaceutical manufacturers needed to be approved comprehensively according to the PIC/S GMP standard before December 31, 2014.

2 The statistics from 2015 in "Domestic pharmaceutical manufacturers that passed the PIC/S GMP" column reflex the following categories of pharmaceutical manufacturers including dosage forms, active pharmaceutical ingredients (APIs), medicinal gases, the GMP logistics firms, and pilot plants had been promoted to comply with PIC/S GMP standards in stages.

Attached Table 10 Statistics of post-market quality monitoring for drugs, medical devices and cosmetics

Year	Drugs		Medical devices		Cosmetics	
	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)
2010	198	3.0	28	42.9	51	29.4
2011	230	8.7	14	21.4	204	0.5
2012	168	4.8	132	15.2	109	16.5
2013	173	1.2	200	6.5	100	3.0
2014	90	3.3	216	4.6	520	5.2
2015	212	0.0	46	0.0	251	2.8
2016	88	5.7	193	0.0	329	1.5
2017	114	4.4	57	19.3	102	7.8
2018	348	1.1	58	3.4	180	2.8
2019	109	1.7	58	13.8	170	1.2
2020	95	0.0	84	4.8	152	4.6
2021	82	2.4	44	2.3	200	2.0
2022	32	0.0	21	33.3	149	1.3
2023	54	0.0	37	13.5	80	11.3

Attached Table 11 Statistics of lot release for biological drugs over the years

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum				Other biological products		The annual total	
	Domestic		Imported		Imported		Domestic		Imported		Imported			
	Batches	Doses	Batches	Doses	Batches	Containers	Batches	Containers	Batches	Containers	Batches	Containers	Batches	Doses/Containers
2010	46	5,870,554	115	6,881,397	116	894,973	4	5,923	2	31	18	281,084	301	13,933,962
2011	54	5,182,280	137	5,710,140	113	1,003,875	3	4,025	2	30	20	296,183	329	12,196,533
2012	53	4,509,491	146	6,711,965	115	960,004	3	4,348	1	20	22	498,230	340	12,684,058
2013	64	4,149,722	161	7,201,090	134	988,939	4	5,512	1	20	25	166,494	389	12,511,777
2014	72	3,705,462	155	7,607,454	121	962,552	6	8,440	0	0	27	332,558	381	12,616,466
2015	123	5,808,339	163	7,548,124	146	1,137,717	3	3,234	0	0	22	226,082	457	14,723,496
2016	58	4,122,437	152	6,773,750	146	1,363,462	9	6,078	2	19	29	422,944	396	12,688,690
2017	47	3,459,630	189	8,796,311	152	1,253,072	4	3,103	1	20	28	317,449	421	13,829,585
2018	69	4,923,435	202	8,509,618	145	1,175,986	3	2,976	1	15	33	214,220	453	14,826,250
2019	46	4,159,810	172	8,927,748	167	1,562,290	6	5,897	1	50	40	326,283	432	14,982,078
2020	52	4,736,457	181	10,203,078	163	1609298	6	2,629	0	0	46	259,651	448	16,811,113
2021	76	9,227,243	240	45,782,413	150	1,315,718	8	4,625	1	9	50	319,041	525	56,649,049
2022	36	4,875,673	233	39,864,838	153	1,351,156	9	6,735	0	0	62	387,589	493	46,485,991
2023	75	5,535,721	240	19,809,091	194	2,016,250	5	3,653	0	0	69	481,777	583	27,846,492

Attached Table 12 Statistics of the number of certified laboratories and certified items over the years

Year	Food accredited laboratory		[b]Drugs accredited laboratory		[b]Medical devices accredited laboratory		[a]Cosmetic accredited laboratory		[c]Drug abuse accredited laboratory		GLP accredited testing institution	
	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items
2010	41	421	24	230	-	-	-	-	13	9	9	19
2011	55	481	26	248	-	-	-	-	13	9	16	26
2012	61	637	29	405	-	-	-	-	13	9	18	42
2013	58	632	31	536	-	-	-	-	13	9	20	58
2014	61	665	30	488	-	-	-	-	14	9	17	49
2015	72	789	30	370	-	-	-	-	15	9	15	53
2016	81	1,046	34	379	-	-	-	-	14	9	15	44
2017	87	1,124	37	367	-	-	-	-	14	9	14	55
2018	95	1,264	36	365	-	-	-	-	16	9	13	56
2019	100	1,364	29	303	-	-	15	51	16	25	15	56
2020	92	1,376	29	319	-	-	16	51	18	32	15	16
2021	91	1,372	28	301	4	19	15	57	19	36	17	19
2022	91	1,373	26	286	4	18	15	57	21	39	20	16
2023	86	1,447	26	285	4	17	16	57	20	41	21	16

Remarks:

a. The former drugs & cosmetic accredited laboratory was divided into a drugs accredited laboratory and a cosmetic accredited laboratory in response to the implementation of the "Cosmetic Hygiene and Safety Act" effective on July 1, 2019.

b. The former "Drug Accredited Laboratory" was split into a Drug Certification Laboratory and a Medical Device Certification Laboratory in response to the implementation of the Medical Devices Act effective on May 1, 2021.

c. Lab. name amended in response to the "Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions" effected on July 1, 2021.

Attached Table 13 Seizure rate of illegal drugs and violation rate of food and drug advertisement over the years

Year	Seizure rate of illegal drugs (%)	Violation rate of food and drug advertisement (%)
2010	11.81	13.90
2011	4.59	6.10
2012	2.35	5.15
2013	1.97	5.46
2014	1.81	5.18
2015	1.14	5.04
2016	1.03	4.83
2017	0.73	4.86
2018	0.90	4.90
2019	2.66	4.89
2020	2.62	4.77
2021	1.69	4.85
2022	2.47	9.67
2023	1.6	9.19

Remarks:

1. The collaborative team for busting the counterfeit, fake, or poor drugs was established in April 2010.
2. A total of 372 illegal drug cases were seized in 2023; the seizure rate dropped from 11.81 % in 2010 to 1.60% in 2023.
3. There were 10,525 violations in the advertising of food, drugs, and cosmetics determined by health authorities in 2023, with a total of NTD 432 million fined. The advertisement violation rate dropped from 13.90% in 2010 to 9.19% in 2023.

Attached Table 14 Statistics on the operations of pharmaceutical plant of controlled drugs over the years

Unit (thousand NTD)

Year	Revenus	Expenditures	Pay to the national treasury
2010	484,762	268,215	145,956
2011	491,524	321,823	116,414
2012	494,672	329,731	120,000
2013	513,092	340,359	120,000
2014	533,320	290,570	120,000
2015	593,448	284,359	120,000
2016	701,254	324,564	100,000
2017	791,580	593,192	50,000
2018	823,305	604,566	120,000
2019	881,881	631,176	120,000
2020	884,655	593,181	120,000
2021	890,241	660,063	200,000
2022	932,381	613,235	200,000
2023	935,215	642,090	200,000

Appendix 4 TFDA Publications in 2023

No.	GPN	Title	Responsible unit	Type	Publication date
1	1011200064	Health Education Handbook on Relieving Insomnia and Correct Use of Sleeping Pills	Division of Controlled Drugs	Book	1/2023
2	1011200169	Reference Examples of the Control of Process Hazards for the Manufacturers of Foods Containing Dehydrated and Pickled Fruits	Division of Food Safety	Digital publication	2/2023
3	1011200170	Reference Examples of the Control of Process Hazards for the Manufacturers of Refrigerated and Defrosted Ready-To-Eat Foods	Division of Food Safety	Digital publication	2/2023
4	1011200171	Reference Examples of the Control of Process Hazards for the Manufacturers of Baked Cakes	Division of Food Safety	Digital publication	2/2023
5	1011200172	Reference Examples of the Control of Process Hazards for the Manufacturers of Soybean Processed Foods	Division of Food Safety	Digital publication	2/2023
6	1011200257	Collected Reference Materials (I) Testing for Adulterants in Pharmaceuticals — Weight Loss Drugs	Division of Research and Analysis	Book	3/2023
7	1011200553	Reference Handbook on Pain Care in Palliative Care Patients	Division of Controlled Drugs	Book	6/2023
8	1011200554	Reference Handbook on Pain Care in Non-cancer Patients Suspected of Having Substance Abuse Disorder	Division of Controlled Drugs	Book	6/2023
9	1011200791	The library of Raman Spectra - Abuse Drugs (II)	Division of Research and Analysis	Book	7/2023
10	2010103850	2022 Annual Report on Food Import Management and Import Inspection Statistics	Division of Food Safety	Digital publication	11/2023
11	None	Let's go LiDaWan	Division of Medicinal Products	Digital publication	12/2023
12	1011201555	Cat Detective's Food Safety Reasoning Story ~ Let's Go Camping and Eat Safe!	Division of Food Safety	Book	12/2023
13	2010002894	2022 Annual Report on Food Poisoning Incidents and Prevention	Division of Food Safety	Book, Digital publication	12/2023
14	1011201550	Non-cancer Chronic Pain Care Health Education Handbook (Public Version)	Division of Controlled Drugs	Book	12/2023

No.	GPN	Title	Responsible unit	Type	Publication date
15	1011201553	Cancer Pain Care Health Education Handbook (Public Version)	Division of Controlled Drugs	Book	12/2023
16	1011201754	2023 Drug Abuse Prevention Manga Handbook: Sound of Splendor	Division of Controlled Drugs	Book	12/2023
17	1011201983	Cosmetics Demystified: Buying and Using Cosmetics Correctly	Division of Medical Devices and Cosmetics	Digital publication	12/2023
18	1011202005	Food Labeling Q&A Handbook	Division of Food Safety	Digital publication	12/2023
19	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning and Research Development	Periodical (Journal)	2023
20	2009902762	Food and Drug Research Annual Report	Division of Planning and Research Development	Periodical (Journal)	2023
21	2010301353	TFDA Annual Report	Division of Planning and Research Development	Periodical (Journal)	2023
22	2010302286	TFDA Annual Report (English Version)	Division of Planning and Research Development	Periodical (Journal)	2023
23	4909405233	Food and Drug Consumer Newsletter	Division of Planning and Research Development	Periodical (Journal)	2023
24	2008800098	Controlled Drug Bulletin	Division of Controlled Drugs	Periodical (Journal)	2023

Appendix 5 Related Websites

Serial number	Name of the Website in English	URL	Website introduction	QR Code
1	Taiwan Food and Drug Administration	https://www.fda.gov.tw	The system includes the introduction of the agency, business area, announcements and information on the Section of Rumor Buster of Food and Drugs, etc. to provide the public with quicker and more accurate information services.	
2	Online Application and the Diverse Service Platform	https://oap.fda.gov.tw	The Online Application and the Diverse Service Platform integrates various application services of TFDA and provides a single application window and multiple payment services for the convenience of the public to apply for the services online.	
3	Food and Drug Open Data Platform	https://data.fda.gov.tw	TFDA Open Data Platform provides original information regarding food and drugs for external access and to develop value-added applications to enhance the transparency of TFDA's administration.	
4	TFDA News	https://article-consumer.fda.gov.tw/default.aspx	TFDA News is structured around the four topics of Dining Out Safely, Save Medication Use, Review of Medical Devices, and Analyzing Cosmetics. This website aims to provide the public with the latest and most accurate food and drug safety information and articles, and gathers the most correct, practical, and accessible knowledge for the public.	
5	Food and Drug Consumer Service Network	https://consumer.fda.gov.tw	Provide an integrated food and drug-related information service for the public.	
6	Taiwan International Food and Drug Safety Authority Network	https://tifsan.fda.gov.tw	This system is an information exchange platform for internal information transmission, case processing, and public opinion reporting for TFDA and the Health Bureau of each county and city.	
7	The Registration Platform of Food and Medicinal Business	https://fadenbook.fda.gov.tw	An electronic information system for government agencies to effectively manage various industries such as food, pharmaceuticals, medical devices and cosmetics.	

Serial number	Name of the Website in English	URL	Website introduction	QR Code
8	Food Traceability Management Information System	https://ftracebook.fda.gov.tw	Relevant electronic records, such as product information, mark identification, supplier information and product flow information, are uploaded through the system to trace the source of product supply or track the product flow.	
9	Inquiry System for Interpretation Compilation of the Act Governing Food Safety and Sanitation	https://fsas.fda.gov.tw/	The system facilitates the general public finding the related provisions, regulatory documents and unified interpretation of the *Act Governing Food Safety and Sanitation*.	
10	TSFA online	https://tsfa.fda.gov.tw/	In order to simplify the inquiry operation of the "Scope, Application and Limitation of Food Additives (Draft)", the system has compiled and set up a database providing online reference for the general public.	
11	TFDA's online food label information service desk	https://www.foodlabel.org.tw/FdaFrontEndApp#	In addition to the "Nutrition Labeling Format Area" and the "Inquiry Area for Regulations and Announcements," this platform also provides consulting services of food labeling for businesses operators in the industry and public health bureau.	
12	System for Export of Food Sanitation Certification	https://asefsc.fda.gov.tw	This system provides online application for English health certificate, processing health certificate, inspection report and free sale certificate for exported food products (additives).	
13	Imported Food Inspection System	https://ifi.fda.gov.tw/ifi/main/ap/index.jsp	Provide case progress inquiry and food QR-CODE download for food, Chinese herbal medicine and condoms that should go through import inspection.	
14	Product Distribution Management System	https://pmds.fda.gov.tw	The local government health bureau and TFDA's inspection information management platform. It is used by the competent authorities to keep track of the food and drug hygiene management situation within their jurisdiction.	

Serial number	Name of the Website in English	URL	Website introduction	QR Code
15	Curriculum management System of Food Sanitation and Safety	https://foodedu.fda.gov.tw/tblu	Food Hygiene and HACCP training resources and course enquiry are available on the website, allowing people from all sectors to learn and apply for courses.	
16	Food Safety Accreditation & Certification System	https://facs.fda.gov.tw	This system mainly assists in the execution of the second-tier food quality control accreditation by randomly assigning accredited organizations, controlling the accreditation process and presenting the results through the system to improve the efficiency.	
17	E Platform for Drug Review and Submission (ExPRESS)	https://e-sub.fda.gov.tw/dohclient/Login.aspx?ReturnUrl=%2fdohclient	This system provides online submission for drug registration, post-approval changes and license renewal. The system allows applicants and TFDA Reviewers can both access this platform to review and check case progress to control the timelines and improve the efficiency of review.	
18	Trace and Track System of Medicinal Products	https://dtracebook.fda.gov.tw	This system allows firms to electronically upload drug trace or track information.	
19	Drug Supply Management System	https://dsms.fda.gov.tw	The system provides pharmaceutical companies and medical institutions with information on the drug shortage in Taiwan for timely assessment and handling, in order to prevent and respond to the possible impact from drug shortage and ensure the public's right of drug usage.	
20	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	Provide the medical institutions, pharmacies, pharmaceutical companies and the public to report suspected adverse drug reactions to this system, so that TFDA can monitor the post-market safety of drugs.	
21	Controlled Drugs Management Information System	https://cdmis.fda.gov.tw	The system provides institutions, business operators and related professionals who have obtained a controlled drugs registration license to apply (report) online for controlled drugs business, in order to effectively improve administrative efficiency and service quality.	

Serial number	Name of the Website in English	URL	Website introduction	QR Code
22	Drug Abuse Reporting System	https://dars.fda.gov.tw	The system allows healthcare facilities to promptly report any cases of drug abuse, in order to assess the trends of drug abuse and instantly understand the current status of drug abuse in Taiwan.	
23	Urine Test for Drug Abuse Reporting System	https://udars.fda.gov.tw	A system for the periodically reporting results of drug abuse urine tests or narcotic tests by relevant domestic testing units.	
24	Searching System of Approved Advertisement for Drugs and Medical Devices Management System	https://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	Provide the public with information on approved advertisements for drugs and medical devices.	
25	Post-Marketing Quality Management System for Drugs, Medical Devices, Food and Cosmetics	https://qms.fda.gov.tw	This system provides a single integrated reporting portal for the public, medical professionals and manufacturers to report adverse events of drugs, medical devices, health foods and cosmetics.	
26	Cosmetic Product Notification Platform	https://cos.fda.gov.tw	To align our cosmetic regulations with international regulatory practices, product information is registered in the notification system by the manufacturers and the importers, so the government authorities can better grasp the information of the marketed products.	
27	Materials Transfer Support System for Disaster Rescue and Prevention	http://mrdss.fda.gov.tw/login.aspx	This system provides hospitals, pharmaceutical manufacturers and vendors, and human organ banks to report online of medical supplies reserves to assist in the dispatch of medical supplies in the event of a severe disaster.	
28	Laboratory Accreditation Management System	https://lams.fda.gov.tw	A platform for accreditation of food, drug, cosmetic and drug abuse urine testing institutions.	

Serial number	Name of the Website in English	URL	Website introduction	QR Code
29	Laboratory Information Management System	https://lims.fda.gov.tw	A system provided to local government health laboratories to manage the testing process electronically.	
30	Medical Device Quality Management Application Platform	http://mdqms.fda.gov.tw	The platform that allows domestic and international medical device firms to apply for quality system inspections.	
31	The E-submission System for Registration and Market Approval of Medical Devices	https://mds.fda.gov.tw/	This system allows businesses to submit applications electronically for registration and market approval of Class 2 and Class 3 medical devices, change of license, and extension of license. Reviewers of TFDA can also review the applications on the system.	
32	Medical Device Tracking Management Reporting Platform	http://mtrace.fda.gov.tw/	According to the announcements issued by the Ministry of Health and Welfare, for items of specific categorization and classification, medical device firms and medical institutions shall upload the source and flow data of such items on a regular basis (January, April, July, and October every year) through this system to facilitate follow-up tracking management.	
33	Medical Device UDI Information Management Platform	http://udid.fda.gov.tw/	This system provides the unique device identification (UDI) and product information of medical devices of medical devices available on the market. Uploaded by medical device firms, such information includes product model numbers, specifications, product features, and precautions for inquiries by the general public, and the system also serves as a reference for the e-management of medical devices.	
34	TFDA Digital Learning Platform for Medical Device and Cosmetics	http://mdcel.fda.gov.tw/	The platform provides online courses on medical devices and cosmetics for online learning of all parties as well as reviewers of competent authorities.	

Serial number	Name of the Website in English	URL	Website introduction	QR Code
35	Inquiry System for Food, Drug, and Cosmetic Advertisements in Violation	https://pmds.fda.gov.tw/illegalad/	The information on food, drug, and cosmetics violated advertisements is immediately and quickly revealed, so that the public can make inquiries and use it as a reference for purchasing products without being influenced by exaggerated and untrue advertisements.	
36	Service Email for the General Public	http://faq.fda.gov.tw/	This mailbox service is an important channel for the public to express their views and opinions, and the established Intelligent Enquiry Service allows the overall service process to communicate more effectively and improve public satisfaction.	

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