2023
Taiwan Food and Drug Administration Annual Report

SERVICE PROFESSION QUALITY INNOVATION

2023

Taiwan Food and Drug Administration

2023 Annual Report

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2023 Foreword by the Director-General

Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA), for the sake of protecting people's health and creating a safe living environment, with "Safe and effective medicinal products, safe and healthy food" as its mission, manages the quality and safety of food, medicinal products, medical devices and cosmetics that people are exposed to on a daily basis and continues to promote various important policies, laws and regulations and advance in food and drug safety reforms, solutions and measures while fulfilling its crucial mission to defend and protect national health. In order to document relevant important policies, achievements, and performance, TFDA prepares annual reports summarizing various important policies, plans and implementation achievements of the previous year and publishes them domestically and internationally for reference.

In 2022, people's lives were still affected by COVID-19. TFDA accelerates support for the industry to quickly devote themselves to the fight against the pandemic. Besides the reduced time required to prepare and produce standard products and real-time preparation and production of viral nucleic acid standards for mainstream strain, auditing of commercially available self-test kits took place; applicable regulations governing random border inspections of medical devices were amended; random border inspections were increased; and test methods were prepared and made known to the public. All were meant to protect the efficacy of in-vitro diagnostic test kits used by our people and to boost individuals' capability of protecting themselves against the pandemic throughout the nation.

As far as food safety management is concerned, in order to ensure control over the process from production to distribution of food and to identify potential risk items, TFDA worked with other ministries and departments and the prosecution, police, and investigation authorities, to reinforce food auditing and other multiple supervisory mechanisms, adjusted the inspection methods and items on a rolling basis reflective of domestic and international information, boosted the production random inspection rate and advanced in subsequent label management; all are meant to protect the rights of consumers. Meanwhile, smart technologies such as big data analysis have been applied to help with risk management. Cross-checking, comparison, contrast and analysis of linked cloud food data are applied to keeping track of potentially risky businesses. Meanwhile, applicable laws and regulations are proactively revised and food

management regulations are improved to continue safeguarding people's health.

In pharmaceutical administration, TFDA continues to advance in e-management of the reviews of medicinal products. Besides the reporting system that has been established, safety and quality information on domestic and international medicinal products are being monitored. Meanwhile, commercial product quality monitoring and manufacturer audits are conducted in order to strengthen the mechanism available for the trace and track management of medicinal products and risk control over the quality and safety of medicinal products. In addition, assistance was given to related pharmaceutical businesses in helping them familiarize themselves with and consolidate Good Distribution Practice (GDP) requirements. As of the end of 2022, 940 pharmaceutical dealers had obtained their GDP permits. Distribution management over medicinal products has been gradually enforced to protect medication safety.

In addition, TFDA is proactively reflecting upon and amending applicable requirements in the "*Controlled Drugs Act*". Every year, a controlled drug audit project plan is formulated to strengthen the inspection of the prescription rationality of controlled drugs and to prevent iatrogenic addiction or abuse. Meanwhile, TFDA works with non-governmental organizations and other ministries and departments in promoting the prevention of and education on substance abuse in diversified ways by reaching out to workplaces, communities, aboriginal tribes, and online populations. TFDA collaborated with 12 NGOs in total throughout 2022 and held a meme creation campaign to communicate to people how to prevent substance abuse.

The "Medical Device Quality Management Application Platform" set up by TFDA was officially launched on January 1, 2022. Medical device businesses can apply for inspections and track the status of an application quickly through the e-platform. Moreover, TFDA has actively taken part in international organizations in an effort to (1) help domestic medical device businesses enhance their international competitiveness; (2) improve and optimize laws and regulations and related support mechanisms concerning medical devices; (3) encourage multi-lateral cooperation on to create win-win situations for all parties.

In order to increase the familiarity of cosmetic businesses with the applicable requirements and to successfully establish production information files, the amendment of the "Guidelines on the Establishment of Cosmetic Product Information File" was announced in 2022. Moreover, in order to protect children's health and avoid mistaking cosmetics for food, the amendment of the "Guidelines for Safety of Children Cosmetics" was announced; this would protect the health and safety of children in the use of cosmetics.

What is worth mentioning is that 2022 marked the 10th anniversary of the Joint meeting between Taiwan and Japan, the 40th anniversary of Good Manufacturing Practice (GMP) for medicinal products, and the 10th year of accession to PIC/S. Both Taiwan and Japan realize the importance of international collaboration and hence are prepared to embark on action items and the development blueprint for the coming 10 to 15 years. Meanwhile, TFDA will continue to work with the industry and boost the professionalism of the pharmaceutical industry concurrently internationally with solid GMP as its cornerstone so that the general public gets access to pharmaceutical products of the same quality as advanced countries.

Given overall environmental changes, health, and safety concerning food, drugs, medicine, and cosmetics will constantly be met with stern tests and challenges. For the sake of fulfilling its mission as a "guardian of the public to ensure food and drug safety," TFDA will cope with challenges in the future with a forward-thinking approach by integrating ministries/departments, businesses, and consumers and also connecting and working with international counterparts in a joint effort to build a comprehensive safety protection network for the four major types of products in our country.

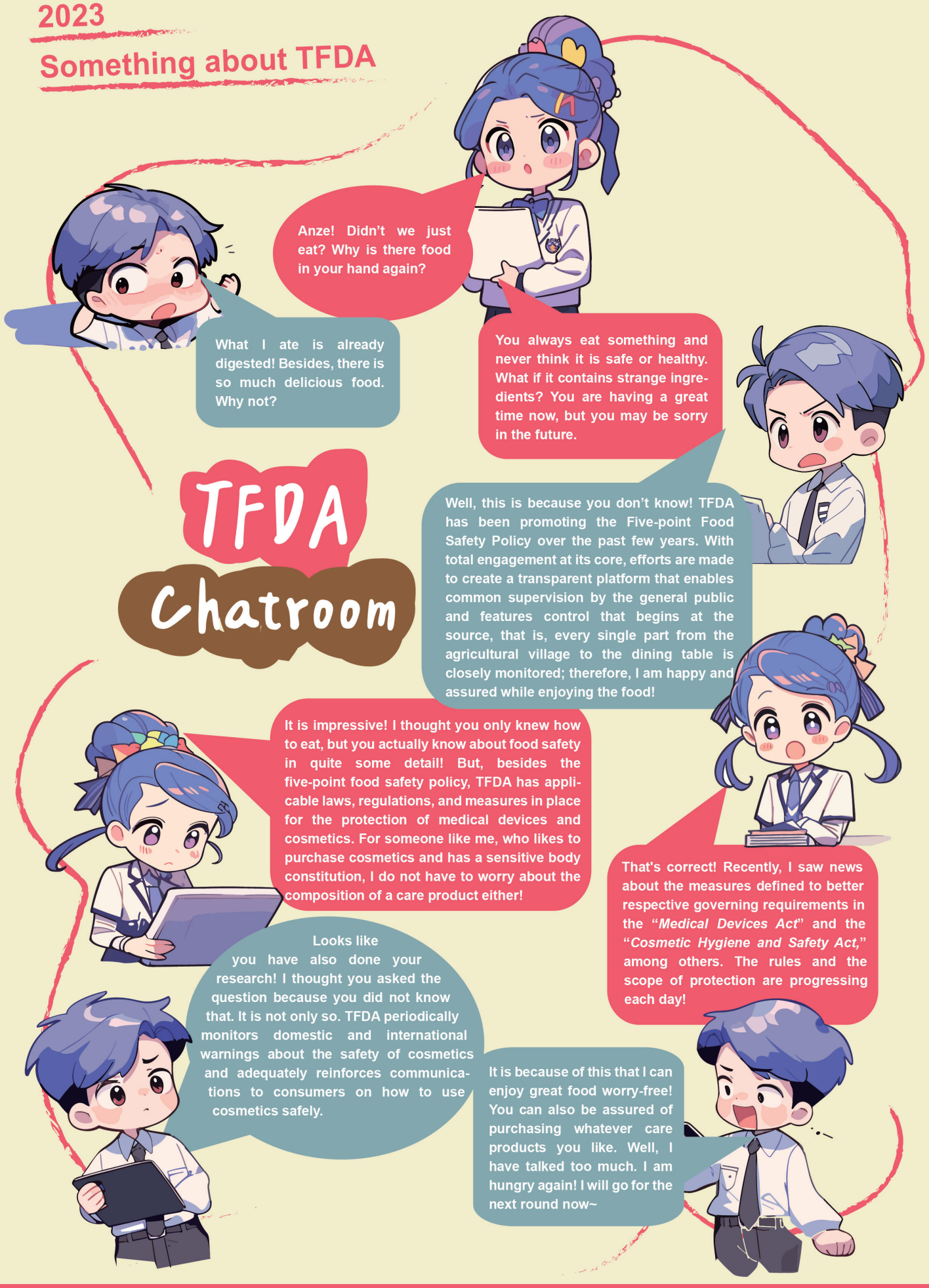
Director-General, Taiwan Food and Drug
Administration, Ministry of Health and Welfare

1 Organization and Policies

1

2023

Something about TFDA



1 Organization and Policies

Taiwan Food and Drug Administration was founded on July 23, 2013, as part of the organizational reform in the Executive Yuan. To fulfill the Ministry of Health and Welfare's commitment to promoting the health and well-being of the public, TFDA takes "Safe and effective medicinal products, safe and healthy food" as its mission, with the vision of "Being a reliable guardian of food and medicinal product safety, creating a safe food and medicinal consumer environment."(Figure 1-1) Upholding the core value of "total life cycle management" of food, medicinal products, medical devices, and cosmetics, through the source, production, and distribution management, TFDA continues to devote itself to establishing a comprehensive safety management system for food and drugs to ensure the safety and quality of food and drugs for consumers.

Figure 1-1 Visions and Missions of TFDA

Section 1

Organizational Framework

Led by the Director-General, TFDA is composed of two Deputy Director-Generals, one Chief Secretary, and seven business units. Including the Division of Planning and Research Development, which is responsible for planning and management, technical planning management, international cooperation, communications, legal system, consumer protection, etc.; the Division of Food Safety, Division of Medicinal Products, Division of Medical Devices and Cosmetics as well as Division of Controlled Drugs are responsible for products management, policies, and relevant regulations of their managed products; Division of Quality Compliance and Management is responsible for the manufacture, management, and inspection of medicinal products, medical devices, and cosmetics, management, and certification of laboratories, storage, and inspection of human organ banks, and authentication of secondary food; Division of Research and Analysis is responsible for the testing of food, medicinal products, and cosmetics, methodological development and evaluation, pharmacopeia editing and compilation.

TFDA also designated 3 District Centers (North, Central, and South) which are responsible for laboratory testing of imported food, medicinal products, and cosmetics; as well as distribution examinations and inspections. In addition to the business divisions, we have also established five administrative units, including the Secretarial Office, the HR Office, the Civil Service Ethics Office, the Accounting and Statistics Office, and the IT Office, to assist in administrative management. Moreover, there are two task groups configured, including Factory for Controlled Drugs and Decision Support Center. We also provide professional information and assistance through professional consulting units such as the Center for Drug Evaluation and the Taiwan Drug Relief Foundation (Figure 1-2).

Section 2

Administrative Goals

TFDA sets the administrative goals and focuses based on the administrative policies of the Executive Yuan and administrative programs of the MOHW for 2022 to go with the budget plans and reflect on current development highlights and social needs on food, medicinal products, medical devices, and cosmetics management.

I. Ensure the health, safety, and quality at each segment of the food production and distribution network and throughout the

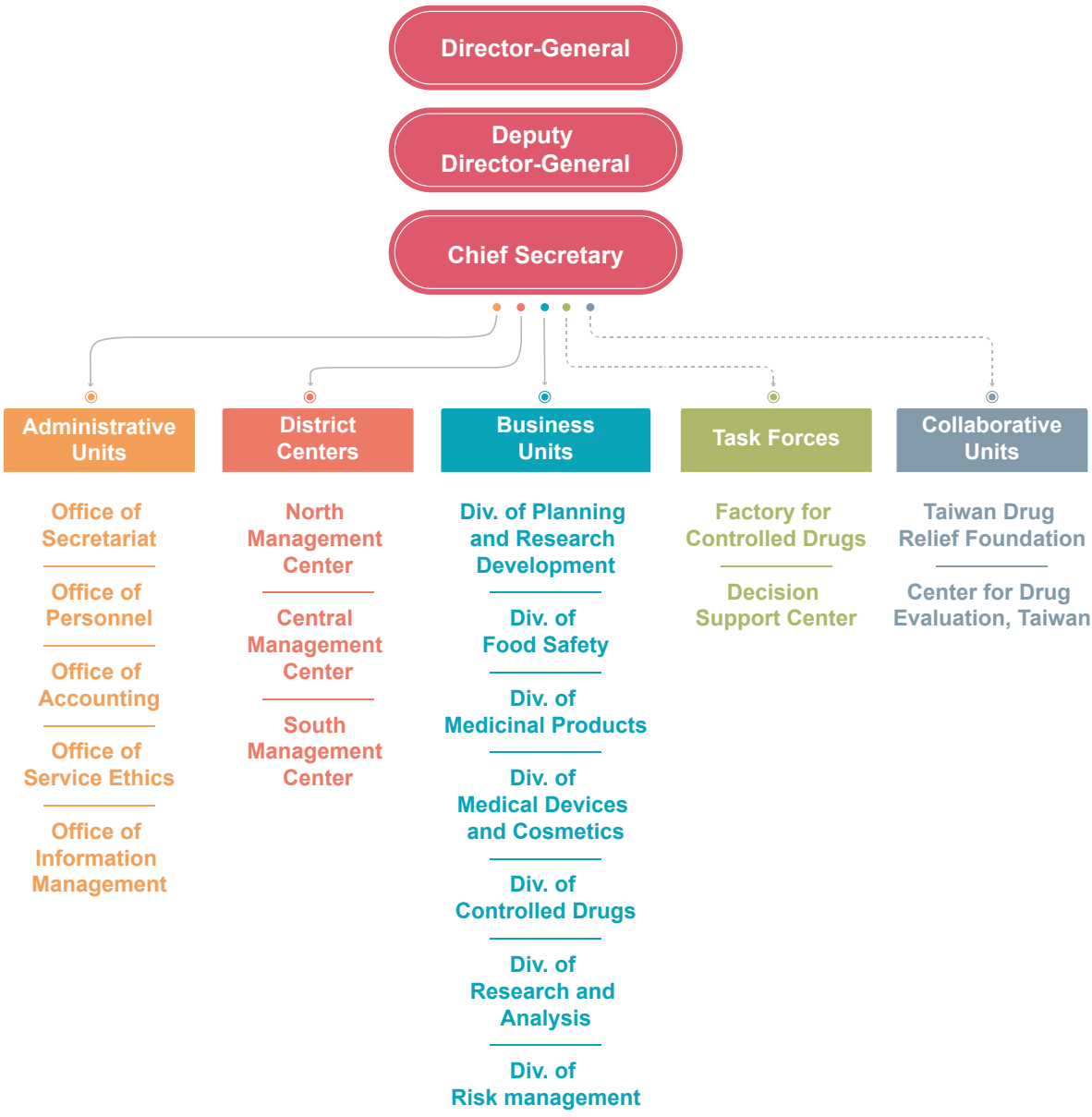


Figure 1-2 The organizational chart

life cycle of medicinal products, medical devices, and cosmetics; perfect retroactivity, tracking, and circulation management, reinforce border inspections, auditing, and autonomous management of businesses; normalize the quality monitoring system and create an assuring consumer environment.

II. Promote a quality consultation, assistance, and review system for emerging products; keep track of the momentum in supplying key medicinal products and medical devices; enhance shortage-reporting, evaluating, and processing efficacy; and assist in stabilizing the supply of medical resources.

III. Strengthen international harmonization of laws and regulations; intelligent food and drug testing technologies and capabilities; innovate on food and drug safety communication strategies; broaden the correct knowledge about food and drugs and deepen the awareness among our people.

Section 3

Food Management Overview

Enabling consumers to enjoy "Safe and Health Food" is the core value of the food management policy. As food safety issues around the world continue to evolve, food management appears to become more diversified, innovative, and informative.

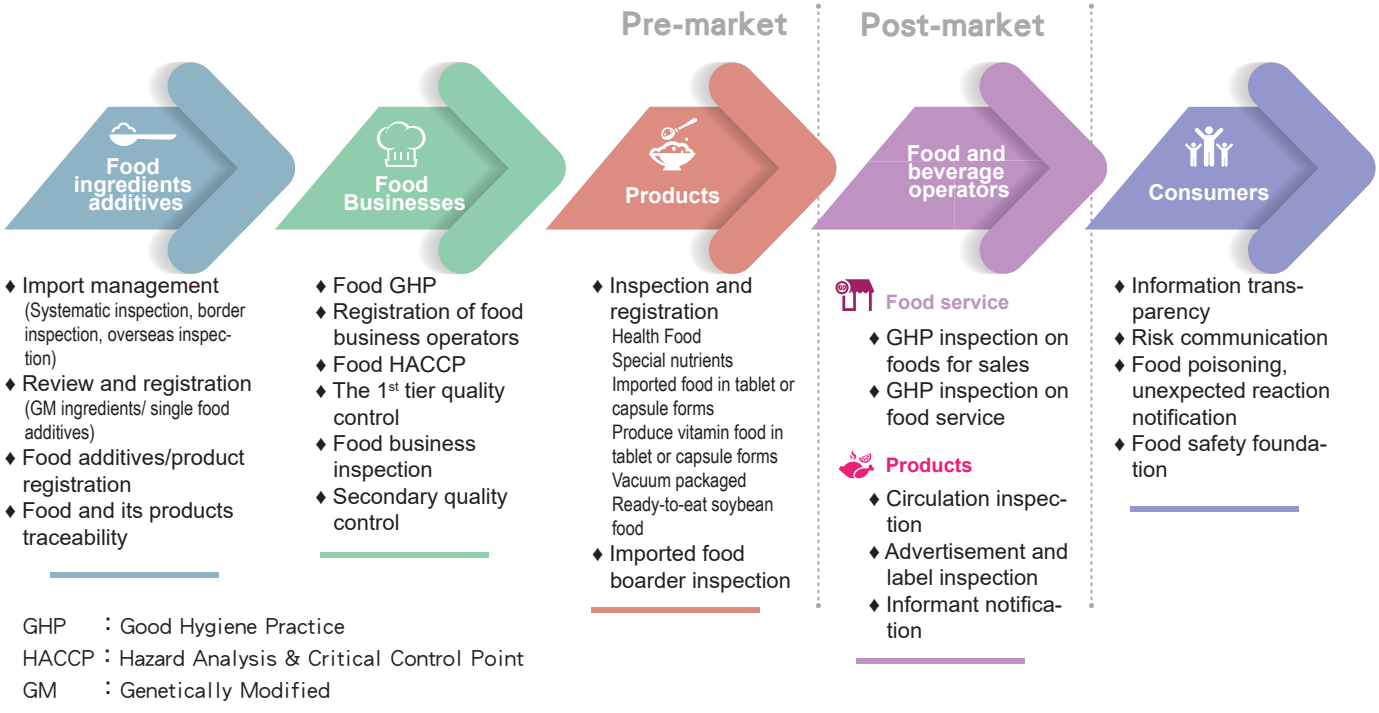


Figure 1-3 Food management structure

TFDA adopts the "farm-to-table" management concept to ensure the hygiene and safety (Figure 1-3) of foods from the production of raw materials to sales and circulation the process implementation of the "Five-points Food Safety Policy" (Figure 1-4) to achieve food safety through government management and self-discipline of the industry and public participation.

The Administration proactively adds or modifies to international food management regulations collects and refers applicable laws and regulations on a rolling basis, strengthens inspection capabilities and capacity, and proactively develops new food inspection methods. In addition to continuously improving imported food at origin management, the Administration established a central-local collaboration practice to conduct specialized inspections, random inspections, and post-market monitoring of food. It uses big data to improve risk management and early warning detection efficiency.

Figure 1-4 Five-points food safety policy

Section 4

Overview of Drugs and Controlled Drugs Management

I. Medicinal products management framework

In the life cycle management of medicinal products, from product development, preclinical studies, clinical trials, marketing authorization application, production/manufacturing to post-marketing, etc., various good operating practices must be followed. Unlike ordinary commodities, medicinal products can only be sold on the market after having obtained the marketing authorization issued by the central competent authority. TFDA continues to reinforce the quality management policy for the full life cycle of drugs (Figure 1-5) through the harmonization with international regulations, establishment of various mechanisms for priority review, digital drug management, standardization of quality and safety supervision, inspection of

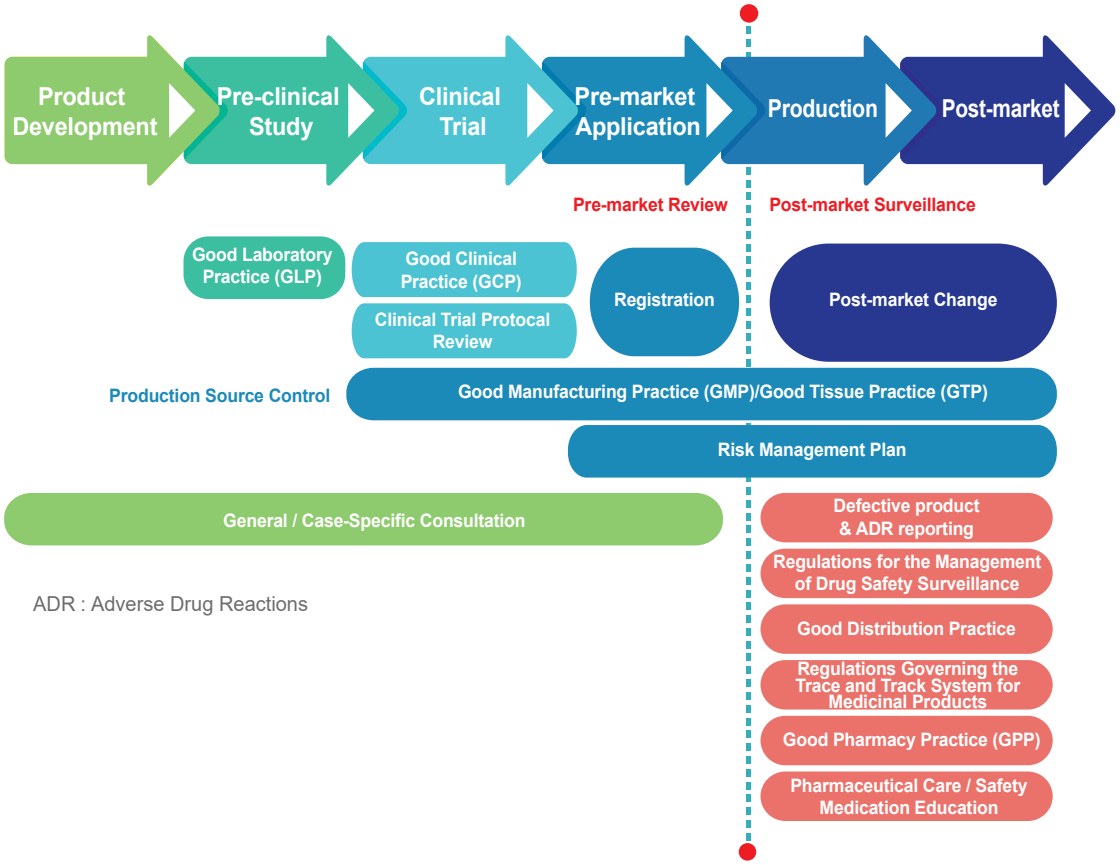


Figure 1-5 Full Life-cycle Management Structure for medicinal products

illegal drugs, and pharmaceutical vendors and product circulation management. All the measures aim to ensure the safety, efficacy, and quality of medicinal products, to increase timely access to medicine for people in need, to facilitate the development of the biotechnology industry in Taiwan, and hereby create a win-win situation among consumers, industries, and the government.

II. Controlled drugs management framework

Controlled drugs refer to addictive narcotic drugs, psychotropic drugs, and other drugs believed to require regulations and may only be used for medical and scientific purposes. If used improperly or illegally, they can easily cause health hazards.

According to the "*Controlled Drugs Act,*" controlled drugs are categorized into four categories: their potential for habitual use, dependence, abuse, and danger to society. The source management of various types of users (such as institutions, industry operators, physicians, dentists, veterinarians, or veterinary assistants) is conducted through certifications such as controlled drug registration certificates, use licenses, and export, import, and manufacturing agreements. The flow management is also strengthened, requiring users to register and declare the income, expense, and balance of controlled drugs in ledgers, to prevent the use or abuse of controlled drugs. Its management structure is shown in Figure 1-6.

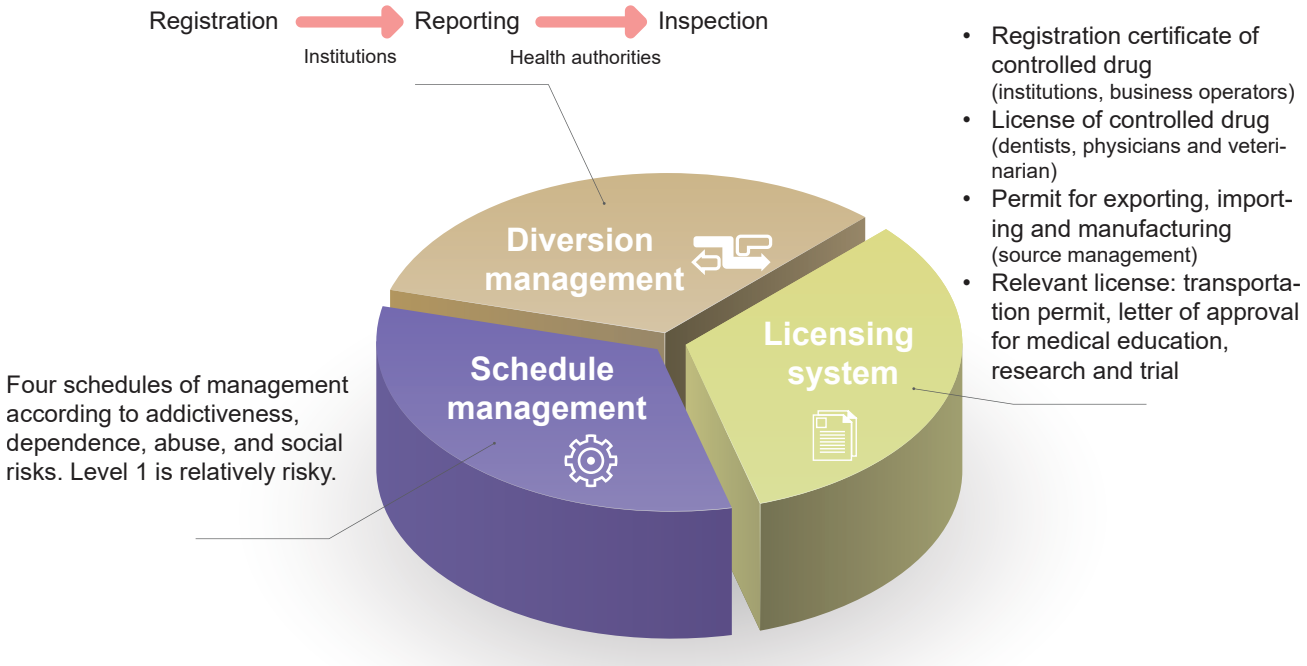


Figure 1-6 Management structure of controlled drugs

Section 5

Overview of Medical Devices and Cosmetics Management

I. Medical devices management framework

Following technological advancement and facing increasing demand for technological medical and health devices, the medical device industry has become one of the most promising biotechnology industries in Taiwan. In response to the booming development of the domestic medical device industry, TFDA has established a full product life-cycle management system for medical devices (Figure 1-7) covering various aspects, including internationalization of regulatory management, production quality control, pre-market inspections, post-market surveillance, and distribution practice of medical device

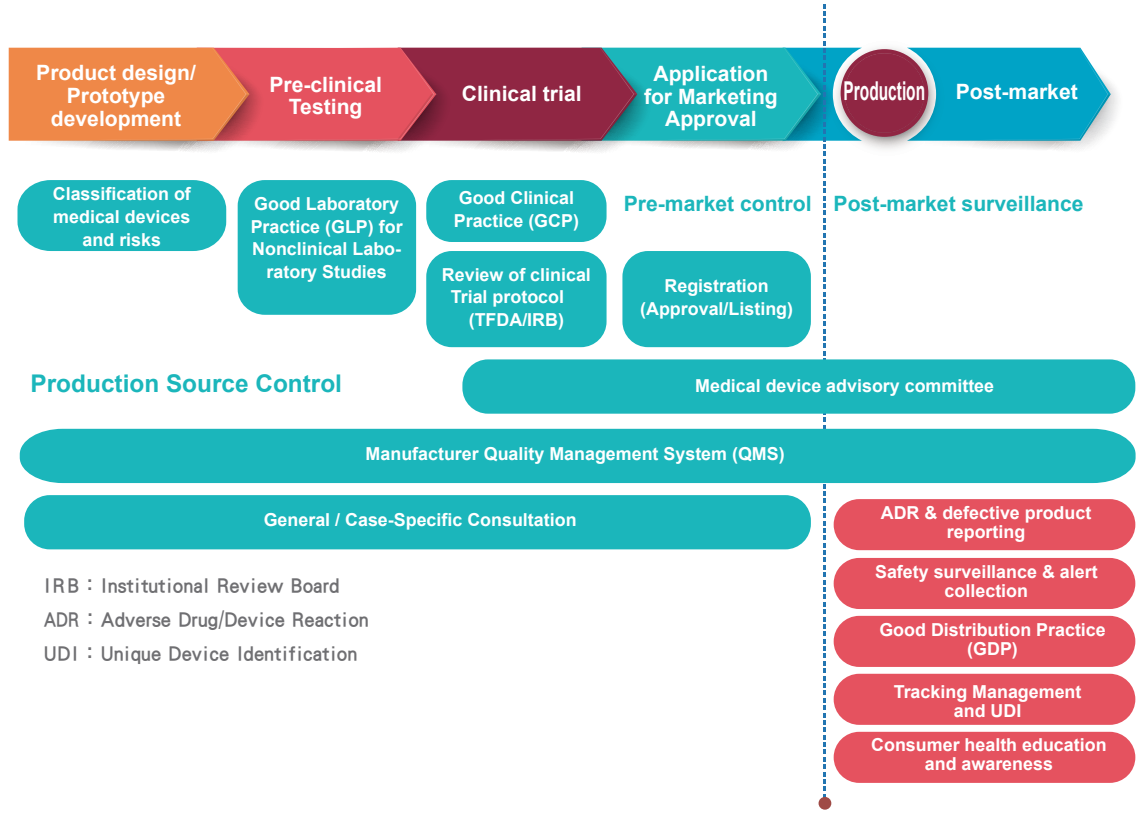


Figure 1-7 Total Product Life Cycle management system for medical devices

dealers and products circulation management. The system can effectively manage the safety, effectiveness, and quality of medical devices while facilitating the development of the domestic biotechnology and pharmaceutical industry, so as to create a win-win situation for consumers, business operators, and the government.

II. Cosmetics Management framework

The current cosmetics management system includes three parts: source control for production, pre-market management, and post-market supervision (Figure 1-8). Source control for production includes the requirements for manufacturers to fulfill the Establishment Standards for Cosmetics Manufactory and the Good Manufacturing Practice (GMP); pre-market management consists of product notification and the establishment of a product information file to replace in the 5-year transition period the registration for specific-purpose cosmetics; post-market supervision, on the other hand, focuses on quality monitoring and cross-county/city joint inspections, establishment of a reporting system for adverse events of cosmetic products, regular monitoring of domestic and overseas safety warnings, communications to consumers on the safe use, and construction of a comprehensive safety and quality network of cosmetics.

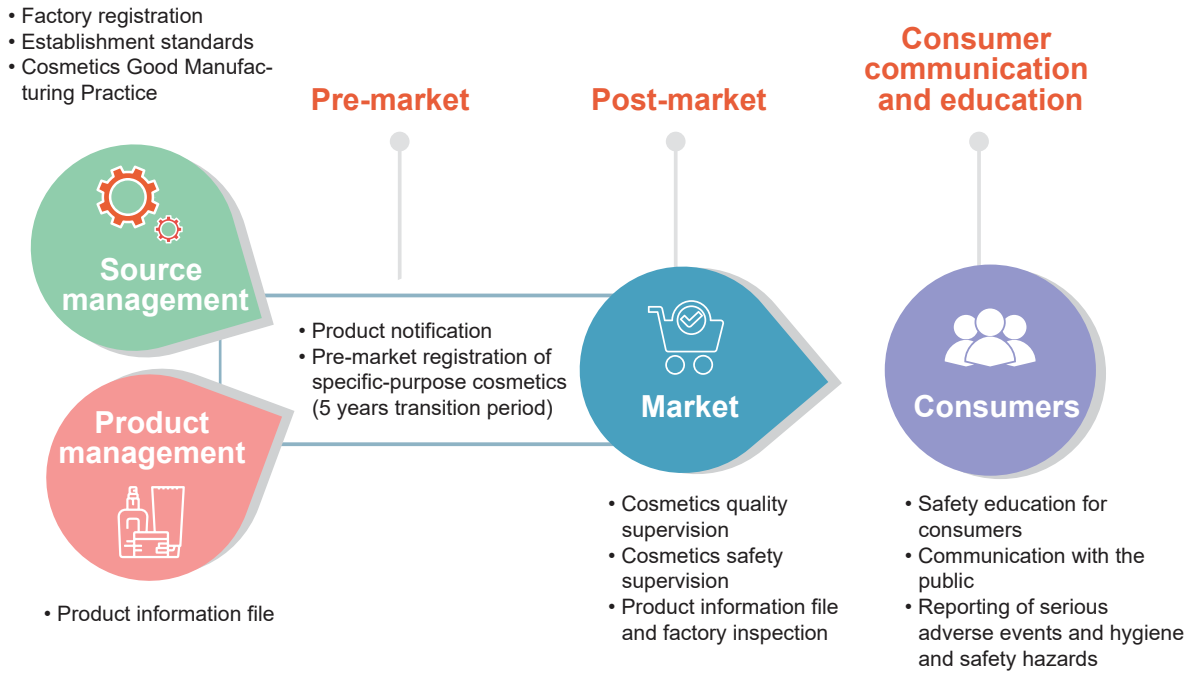


Figure 1-8 Cosmetics hygiene and safety management framework

Section 6

Future Perspective

With the discovery of novel substances and the impact of newly emerging technologies and chemicals, the management of the hygiene and safety of food and medicinal products is getting complicated each day. By integration of different ministries and departments as well as the expansion of the business operators and the participation of the public, TFDA is constructing a comprehensive protection network for food, medicinal products, and cosmetics safety. Future important administrative plans include:

I. Strengthen the applicable intelligent technology and combine it in food and drug safety and risk management and continue to optimize the "Five-Point Food Safety" policy setting by integrating cross-ministerial and departmental resources, maximizing food safety management resources, consolidating tracking and follow-up, reinforcing border inspections, audits, and autonomous management among business operators in order to enhance the food management capacity in our country and to protect public health.

II. Continue to complete the regulation structure for regenerative medicinal products, promote electronic management of drug administration, bridge smart medicine, reinforce the mechanism of drug shortage reporting, and ensure the balance between supply and demand in the healthcare system while at the same time consolidating pharmacovigilance to ensure medication safety for the general public.

III. TFDA will continue to improve various regulations under the "*Medical Devices Act*" and the "*Cosmetic Hygiene and Safety Act*"; to enhance exchange and collaboration with international laws and regulations; and to build a modern regulatory environment that is harmonized with international regulations. A diversified and flexible review mechanism for pre-market inspections will be in place and TFDA will provide dedicated support to medical device businesses in terms of regulatory compliance as they develop innovative medical devices. The medical device digital clinical trial management platform will be launched and TFDA will continue to improve production source control, tracking management, and distribution practice, to accelerate the market approval of medical device products so as to satisfy domestic demands with better consumer protection.

IV. Implement the forward-looking "Food Safety Construction Plan," which includes the "construction plan for a modern food and drug national laboratory building coordinated with functional

administration and training building," "enhancing the efficacy of the border inspection and customs clearance and management system," "strengthening the food safety governance and inspection efficacy and quality of health authorities," "strengthening the food safety inspection capacity of central authorities," and "enhancing the inspection and research capacity and standardization of the medicinal products for infectious diseases and food-borne pathogens," to build a modern national food safety laboratory complying with international standards, purchase high-precision inspection equipment, comprehensively improve the efficiency of food safety testing, research and development, and further strengthening the management capacity of local and central government agencies.

Model photo of TFDA National Experimental Building and Administrative and Training Building of Forward-Looking Infrastructure

2 Consolidated Management over Food Safety

Section 1 Normalization of Food Management Regulations

Section 2 Reinforced Supervision of Food Production and Distribution Chains

Section 3 Improvement of Imported and Exported Food Management

Section 4 Implementation of Second tier Quality Control Certification

Section 5 Apply Artificial Intelligence to Assist in Food Safety Risk Decisions

Section 6 Development of New Food Testing Technologies

2023

Something about TFDA

TFDA Chatroom

Mention the BBQ, did you know that meat can be composed in different ways?

BBQ smells so good! Let's have a BBQ for dinner!

What? How can I tell? It's all meat. What's the difference?

To be honest, I didn't know about that. Is there any other food for which reinforced labeling is imposed?

There is a huge difference! The restructured meat or artificially marbled meat we buy is marked with relevant words or wake-up words on the outer packaging.

Of course! For example, freshly made beverages, packaged honey, and syrup products are also the key targets for TFDA to strengthen the implementation of labeling!

Exactly! Furthermore, the method for assessment of the health care effects of healthy food is constantly perfecting (such as subject criteria, study data, and results determination regulations, among others). Meanwhile, TFDA is gradually reinforcing the management of foods imported into and exported from the country so that people know more clearly the evaluation and management process when dealing with foods from other countries, as well as local foods.

Wow! So, the drinks I love on a daily basis are included, too. I really need to pay attention to whether they are properly labeled in the future.

Wonderful! So, people can eat more at ease!

2

Consolidated Management over Food Safety

In order to strengthen food safety from a farm to the table, TFDA continues to enforce related management tasks, including refining comprehensive regulations of food management, strengthening the supervision of food manufacturing, and marketing chain, reinforcing import and export management, advancing the management of imports from overseas, and assisting domestic businesses in exploring export opportunities and implement secondary quality control and qualification over foods, apply artificial intelligence to risk decision-making and consolidate inspection technologies for emerging and underlying risk matters in foods in an effort to build a sound food safety protection net.

Section 1

Normalization of Food Management Regulations

Introduction of the Policy

In order to improve regulations governing foods in our country and to boost the professional capabilities of businesses in autonomous management, more than 30 provisions in total were added or revised throughout 2022; they will help perfect food governing regulations in our country.

Implementation Strategy

I. Stipulation and Revision of food hygiene and safety standards

Based on the principles of risk assessment and taking into consideration international regulations, scientific evidence, toxicological tests, and diet and ingestion data among nationals, etc., applicable standards were sorted out, evaluated, stipulated, and revised in an effort to comply with international management standards.

II. Refinement of methods for assessing health care effects

The “The efficacy assessment method of health food for assisting in the regulation of blood pressure” was amended to make the experiment method and experiment implementation-related regulations more defined and thorough..

III. Addition of the requirement that the dairy processing industry shall comply with the Regulations on Food Safety Control System

Besides the existing establishment registration, business or company registration is added. For a business with 5 or more practitioners and with a capital size of NTD 30 million or more, the scope of implementation is extended to also include dairy ice cream and whey, among others, and implementation begins on January 1, 2023.

IV. Sound work guide

(I) Referring to international management practice, the quality assurance system is included in the "Guidance of Food Manufacturers to Enact the Food Safety Monitoring Plan."

(II) Common issues encountered in the implementation of a food traceability management system among businesses are compiled and updated in the "Frequently Asked Questions for Food Businesses Who Should Establish the Food Traceability System."

V. Improvement of measures to protect personal data taken by food businesses

In order to protect personal data and to prevent theft, alteration, damage, destruction, or leakage, for specific types of businesses where the company, business, or establishment registration is completed, the capital size is NTD 30 million or above, and which recruit members or obtain personal data through transactions, safety measures such as a personal data protection plan shall be imposed.

VI. Reinforcement of food labeling management requirements

In order to have sound food labeling and for the sake of information transparency, 4 requirements about artificially marbled meat, drinks, etc. were amended or defined in 2022 to urge practitioners to enforce labeling and provide consumers with sufficient information for their reference while making purchases.

Achievements and Benefits

I. Harmonization of international regulations

Cumulatively, 7,552 pesticide residue limits, pesticide residue limits for 373 animal products, 1,530 veterinary drug residue limits, 17 sanitation standards, 38 food ingredient restrictions, and 796 food additives on the positive list were defined throughout 2022 and for each of them, the scope of use, limits, and specifications/standards are defined.

II. Refinement of methods for assessing health care effects

"The efficacy assessment method of health food for assisting in the regulation of

blood pressure" was amended in 2022 with an emphasis on animal ethics and the 3Rs principle (Replace, Reduce, Refine). At the same time, the criteria for subjects, the rules for determining research data and results, and the health care claims were revised. At present, there are three health foods that have been approved for this health care effect. Previous studies were conducted on human consumption experiments, no animal experiments.

III. Completion of a system compliant with the Regulations on Food Safety Control System

It is announced that the "Provision for Dairy Product Plants Shall Meet the Regulations on Food Safety Control System." The applicable scale is specifically defined and the scope of implementation is maximized, with the addition of dairy ice cream and whey products, among others. For the time being, a total of 77 dairy businesses are subject to the Regulations on Food Safety Control System.

IV. Enhancement of business knowledge and skills

(I) As of the end of 2022, a total of 1,699 food manufacturers shall enact their food safety monitoring plan. The "Guidance of Food Manufacturers to Enact the Food Safety Monitoring Plan" is updated based on risk assessment and hazard analysis with industrial characteristics and serves as a reference for food manufacturers while they implement self-management and enact their food safety monitoring plan. It helps ensure that food manufacturers fulfill their management responsibilities in all segments, including purchase, acceptance, manufacturing, storage, and distribution.

(II) The "Frequently Asked Questions for Food Businesses Who Should Establish the Food Traceability System" is updated, with the addition of 6 frequently asked questions for practitioners' reference.

V. Urge of protection over personal data imposed by food businesses

There were a total of 6 food businesses reported suspicious violations of the *Personal Data Protection Act* and meeting the criteria set forth in the "Regulations for the Security and the Maintenance of Personal Information Files in Food Businesses" and respective county/city governments have been asked to help with administrative inspections and urge the businesses to define their personal data file safety protection plan for enhanced protection of personal data.

VI. Consolidation of food labeling

(I) To avoid the misunderstanding among consumers that artificially marbled meat is original meat, the

"Regulations Governing the Labeling of Restructured Meat Products" was amended and the title was changed to "Regulations Governing the Labelling of Restructured and Artificially Marbled Meat Products," which shall take effect on July 1, 2022.

(II) In response to the reinforced labeling of information about freshly made beverages, the "Regulation for the Labeling of Freshly Made Beverages in Chain Drink Stores, Convenience Stores, and Fast Food Restaurants" was amended; it expanded the range of products that should be labeled with total caffeine content, which shall take effect on January 1, 2023.

(III) For more defined nutrition content labeling of packaged foods to meet the practical situation, some of the requirements in the "Regulations on Nutrition Labeling for Prepackaged Food Products" were amended, which shall take effect on July 1, 2024.

(IV) The "Regulations Governing the Labeling of Prepackaged Honey and Its Syrup Products" was defined to require that the content of honey, the name of the honey and syrup product, and the place of origin of honey as the raw material shall be labeled on the package as required for related products, which shall take effect on July 1, 2023.

Section 2

Reinforced Supervision of Food Production and Distribution Chains

Introduction of the Policy

Food hygiene and safety are closely related to the daily activities of people. By controlling the production, manufacturing, circulation, and distribution process and combining ministerial/departmental efforts and collaboration among prosecutors and police investigation units, the multi-supervision mechanism, including reinforced food inspections, is strengthened. Underlying risks are identified to accordingly adopt preventive and control measures, creating a "safe food" quality environment.

Implementation Strategy

I. Inspection of imported products at border

With reference to inspection records, product characteristics, and domestic and international information, inspection methods and items were reflected upon and adjusted on a rolling basis. Non-conforming products found upon border inspections were returned or destroyed as required and related information was released. Meanwhile, the

random inspection rate was increased for products. When imported products were found to be non-conforming during the post-marketing stage, such information would be provided to the border authority for reinforced control and to strengthen the hygiene and safety supervision mechanism for imported foods.

II. Domestic manufacturing processing and circulation supervision

For items highly susceptible to violations, of high concern, and at high risk, inspections are enhanced and the diversified and constantly innovating dining patterns among our nationals are taken into consideration in the planning and organization of audit and random inspection projects.

III. Inspection of border and post-marketing for Ethylene oxide (EtO)

In response to international warnings and public reports that pesticide residue - EtO - had been detected in various types of foods, related products were inspected at borders, and post-marketing was performed on applicable manufacturing facilities and food distribution channels in the country.

IV. Collaborative cross-department inspection

Local tea products and oysters mixed with imported products have been issues concerning the general public over the past few years. Cross-ministerial/departmental joint inspections were conducted on the labeling of tea products available on the market and the whereabouts and labeling of imported oysters and efforts were made to ensure subsequent labeling management for the sake of protecting the rights of consumers in 2022.

V. Cooperative investigation between prosecutors and police

Through collaboration between prosecutors police investigation units and health authorities, the professionalism and resources of respective agencies were combined for enhanced inspections capacity. For suspicious criminal and illegal cases, the food and drug crackdown correspondence platform is available. With the food and drug offense crackdown group as the correspondence and coordination center, respective authorities were gathered, given instructions, and coordinated to take on investigations for enhanced processing efficacy.

Achievements and Benefits

I. Inspection of imported products at border

Among the total of 724,180 batches of food and related products to be inspected upon border customs clearance in 2022, 65,680 batches were randomly inspected; the inspection qualification rate was 99%.

II. Domestic manufacturing processing and circulation supervision

47 food inspection projects were completed in 2022. Domestic businesses were inspected 120,717 times. The qualified rate of GHP food business operator the re-inspections reached 90% and above. 590,000 cases of food and related products were inspected and randomly inspected, with a qualification rate of up to 99%.

III. Inspection of border and post-marketing for Ethylene oxide (EtO)

(I) Boarder

A total of 1,347 batches of ethylene oxide were inspected at borders in 2022; among them, up to 39 batches were disqualified. The non-conforming products were returned or destroyed as required.

(II) Post-market

In 2022, products with the EtO risk were included in a total of 4 projects for the random inspection. 79 cases in total were randomly inspected; among them, 4 were disqualified and processed further by the health authority that has jurisdiction.

IV. Collaborative cross-department inspection

(I) As part of the "Joint Audit Project for Labeling of Place of Origin of Commercial Tea Products," a total of 57 businesses were audited (88 sites), with 221 tea products submitted for laboratory testing. Among them, 38 were found with suspicious overseas teas. All were turned into the District Prosecutors' Office for investigation. Health authorities would also provide proactive assistance to prosecutors in search maneuvers.

(II) As part of the "Joint oyster origin labeling inspection project," businesses were audited 107 times in total; among them, 91 were about the labeling of oyster products or menus containing oyster dishes. Except for 12 bulk oyster products that were found without the product name and place of origin information on the label (all have been corrected), the remainder fulfilled the requirements.

V. Cooperative investigation between prosecutors and police

In 2022, TFDA collaborated with prosecutors and police investigation units and audited a total of 10 food cases; violators found were all penalized as required by law.

Section 3

Improvement of Imported and Exported Food Management

Introduction of the Policy

To consolidate management over imported foods at origin, systematic inspections were performed on meat products, dairy products, egg products, fishery products, animal oil products, and products of cervidae origin. Such products from countries that have gained approval through systematic inspection may apply to TFDA for import inspection. Meanwhile, the customs commodity code to be inspected upon application for importation was added or revised on a rolling basis to strictly safeguard foods and related products imported into our country so that they are conforming in terms of hygiene and safety.

Implementation Strategy

I. Persistent consolidation of systematic inspection

Systematic inspection shall be applied for in writing with TFDA by the competent authorities of the exporting country (region) before the review and inspection are performed by TFDA; the equivalence between the country and our country in terms of the food hygiene and safety management system and supervisory measures of competent authorities will be evaluated.

II. Reflection upon and modification of border inspection items

TFDA and the Customs Administration, Ministry of Finance, established the customs clearance reporting mechanism for "imported goods without applicable food import requirements yet declared as food". Applicable data and results of audits performed by the regional administrations and public health bureaus are compiled on a quarterly basis and the classification number of goods to be inspected upon application for importation is reflected upon and its amendment is announced.

III. Streamlining of the exportation and distribution application procedure

To help the industry understand the requirements of the exporting countries, TFDA, through the food exportation and distribution hygiene and safety integrated management platform, enables food businesses to quickly search for laws and regulations, the exportation and distribution application procedure in the destination country, declare their intent to export/distribute and upload the exportation/distribution application documents, which effectively streamlines the application procedure.

IV. Optimization of the application process for the sanitary-related certificates for the exportation of processed foods

In order for processed foods manufactured in our country to be exported successfully, TFDA processes applications submitted by businesses for sanitary-related

English certificates for processed foods to be exported, e.g., additives. Applications and notifications as well as diversified payment options are now available comprehensively online to go with the government's transformation towards digitalization of service.

Achievements and Benefits

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

The systematic inspection procedure was completed for 4 cases in 2022, including egg products from the United States, beef products from Mexico, dairy and fishery products, processed egg products from Lithuania, and pork products from Paraguay. The foregoing products met the designated importation criteria, were produced/manufactured at the approved production facilities, and designated supporting documents were enclosed and hence were allowed to apply for the import inspection with TFDA.

II. Addition/Revision of a field for the import inspection number for enhanced management intensity

Amendment announcements of commodity classification numbers codes were completed for 40 items and the food import requirements were being added/revised. In total, 2,719 listed items to be imported need to be inspected by TFDA at borders in order to be imported as food-related products.

III. Assistance to businesses in expanding presence on overseas markets

Proactive assistance was provided to businesses in 2022 in exportation/distribution, including the residue monitoring plan for eggs and residue monitoring results submitted by our country, which were reviewed and approved by the European Commission. Additionally, our country's Official Biosecurity Program of Processed (heat-treated) Meat Products was also approved by New Zealand. Assistance was provided to food businesses in applying for registration of overseas production enterprises exporting/distributing imported foods from China; once it is confirmed that the documentation prepared by the specific business is complete, it will be submitted to the China Government for review.

TFDA helped businesses submit application documents according to the product and application method designated in the destination country. Continuous efforts will be made in the future on cross-ministerial/departmental collaboration in exports to help businesses explore overseas markets.

IV. Proactive assistance to businesses in applying for sanitary-related certificates for the exportation of processed foods

Throughout 2022, a total of 2,345

sanitary-related certificates were successfully applied for by businesses for the exportation of processed foods, e.g., additives, and three online briefing sessions were completed for businesses where the procedure to apply for such certification was explained and how to operate the online system was demonstrated. The headcount of participants came to 446. Overall, more than 90% of businesses were satisfied.

Section 4

Implementation of Second tier Quality Control Certification

Introduction of the Policy

The tertiary quality control mechanism for food safety and sanitation was defined in the *Act Governing Food Safety and Sanitation*. As far as second tier quality control is concerned, it is a "third-party qualification of the hygiene and safety management system" in order to provide consumers with healthy and safe foods and help food businesses improve the quality of their products to be on par with their international counterparts.

Implementation Strategy

I. Announcement of compulsory regulation

TFDA has announced that second tier quality control certification shall be fulfilled for manufacturers in ten sectors, namely, canned food, food additives, special nutrients, and processed dairy products with establishment registration, and sugar, salt, starch, powder, soy sauce, and edible oil with a capital size of NTD 30 million and above. Food manufacturers that are not included in the announcement can also voluntarily apply for the said certification.

II. Normalization of accreditation and certification systems

Accreditation and certification were completed as required by the "Accreditation of Certification Body and Sanitation and Safety Control of Food Businesses of Certification Regulations" and the "Operating Procedure for Verification of Food Hygiene and Safety Management System" and the food sanitation and safety management accreditation and certification information system (https://facs.fda.gov.tw) was created for enhanced management efficacy. Food businesses that have been verified are subject to regular and irregular follow-up inspections and need to be verified again once every 2 years.

III. Reinforced certification quality

TFDA completes certifying body accreditations as required to ensure that ISO/TS 22003 certification eligibilities are retained; that full-time auditors are in place; and that applicable regulations governing

recusal upon conflicting interests are fulfilled. TFDA also accredits certifying bodies and auditors and goes on-site visits on a yearly basis to reinforce the quality and efficacy of third-party certifying bodies.

Achievements and Benefits

I. Combination of certification capacity of an impartial third party for consolidation of second tier quality control certification

Certifying bodies that are approved by TFDA include the Food Industry Development Research Institute, China Grain Products Research & Development Institute (CGPRDI), National Animal Industry Foundation, and Taiwan Excellent Agricultural Products Development Association. Among the 600 food businesses subject to certification in 2022, 92% have been verified and those yet to be verified are constantly monitored for their application or certification status (Table 2-1) for enhanced food hygiene and safety supervision.

Table 2-1 2022 implementation results of secondary quality control

Clarifications	Number of industry operators
Number of companies that should pass the second tier quality control certification	600
Number of companies that have passed the second tier quality control certification	552
Number of companies that have not passed the second tier quality control certification	48*

* Application for certification is ongoing.

II. Linking of second tier quality control certification information to streamline the application for exports of foods

Verified businesses can waive site visits by the competent health authority with a show of the certification certificate while applying for the hygiene certification in order to streamline the application procedure for exports of foods.

Section 5

Apply Artificial Intelligence to Assist in Food Safety Risk Decisions

Introduction of the Policy

In light of the diversified types of foods imported and their continuous growths and the prevalent online consumption in the post-pandemic era, for the sake of reinforcing food safety management, big data analysis and technology have been incorporated into risk management to ensure public health. In addition, the "TFDA African Swine Fever Emergency Response Working Group" continues to conduct regular response notifications and education training based on the guidelines of risk management and crisis management from various agencies under the Executive Yuan.

Implementation Strategy

I. Advancement of AI machine learning algorithm technology

Through the BPI system, the hit rate of inspections across a total of 12 food categories was improved by a factor of 1.21 compared to the period before its implementation, effectively enhancing the efficiency of border food safety management.

II. Development of web crawlers for the supervision and management of emerging web-based food businesses

In order to keep track of the e-commerce platform, supervision and management of emerging web-based food businesses are reinforced. Web crawlers are applied to automatically extract information on food sales from various online platforms, including e-commerce websites, food delivery platforms, and blogs. This information is then used to build databases and is cross-referenced and analyzed against food cloud data to keep track of potentially risky businesses.

III. Deal with African Swine Fever emergency response and notification

In order to block the smuggling and importation of swine products from swine fever areas in Africa, responsive measures continued. Representatives were sent to participate in the meetings of the "African Swine Fever Central Disaster Response Center" to keep track of the inter-departmental coordination work.

Achievements and Benefits

I. Advancement of AI machine learning algorithm technology

Through the BPI system, the hit rate of

inspections across a total of 12 food categories was improved by a factor of 1.21 compared to the period before its implementation, effectively enhancing the efficiency of border food safety management.

II. Development of web crawlers for the supervision and management of emerging web-based food businesses

Web crawlers were applied to extract information from various prominent food platforms and define the Top 10 popular products each month for each of the e-commerce platforms. Meanwhile, the food registration number was used to cross-reference against The Registration Platform of Food and Medicinal Businesses to explore potentially risky businesses and keep track of characteristics of emerging web-based distributors (such as cloud-based businesses) in violations, and to generate the list of businesses prioritized for audits; the list is provided to the competent authority for reference during the auditing process. A total of 26 businesses were audited in 2022; among them, 9 were qualified (34.6%) and 17 demanded correction by a given deadline (65.4%). All of them were qualified upon follow-up audits.

III. Deal with African Swine Fever emergency response and notification!

Tip station

An algorithm is a kind of logical thinking for solving problems !

It refers to a well-defined set of instructions that a computer can execute automatically, typically used to achieve specific objectives.

What is "Machine Learning?

Machine learning (ML) is a type of artificial intelligence (AI) that allows software applications to become more accurate at predicting outcomes without being explicitly programmed to do so. Design some algorithms that the computer can execute automatically. These algorithms can analyze and obtain the rules from data, and use the rules to predict unknown data.

Risk factor means:

In BPI, the Risk factor refers to variables associated with high risk. The BPI system, which stands for Border Prediction Intelligent system.

To keep up in response with the "African Swine Fever Central Disaster Response Center," representatives continued to be sent to attend meetings held at the Center. A total of 3 meetings were attended in 2022, during which we collaborated with the Center on matters related to African swine fever management. TFDA also formed the "TFDA African Swine Fever Emergency Response Working Group" and activated response tasks to cope with evolving pandemic circumstances.

Section 6

Development of New Food Testing Technologies

Introduction of the Policy

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 test methods that are environmentally friendly, fast, and precise. TFDA continues to advance its laboratory testing and analysis capabilities, define emerging test technologies for foods, and also organize related technical exchange and training events in response to the inspection of sudden food events for enhanced domestic food safety test capacity.

Implementation Strategy

I. Promotion of domestic food analytical techniques interaction

TFDA planned and held technical exchange events where domestic and international experts and scholars were invited to share the current status of analytical techniques and their experience for the sake of boosting technical exchange enhancing the technical level and quality of domestic test units and nurturing talent.

II. Advancement in high-risk and high-end food analytical techniques to protect people's dietary safety

For related food items that are at high risk and of high interest, develop credible and fast testing methods to quickly clarify the events and to protect public dietary safety. In addition, in light of the fact that the scope of food matrices is highly broad and the food composition is complex, interference from various types of matrices needs to be overcome upon testing. The high-end analytical techniques from TFDA are applied to develop quick and highly precise test methods that may be referred to or adopted by applicable domestic testing institutions in order to strengthen border inspection, commercial product monitoring, and autonomous management among businesses.

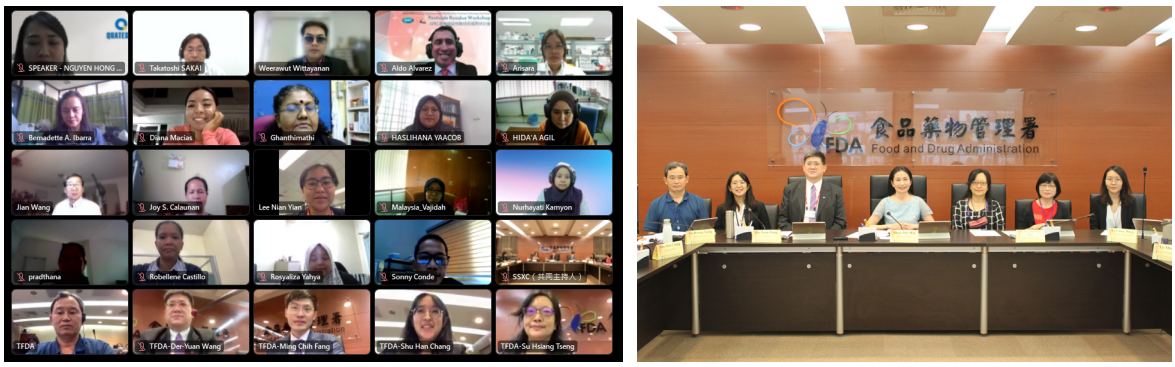


Figure 2-1 APEC Online Communication Platform for Testing Techniques for Food-Pesticide Residue Workshop

Achievements and Benefits

I. Organization of APEC Online Communication Platform for Testing Techniques for Food-Pesticide Residue Workshop

The 2022 APEC Online Communication Platform for Testing Techniques for Food-Pesticide Residue Workshop (Figure 2-1) was held. Experts and scholars from TFDA, Canada, Peru, Japan, Thailand, and Vietnam gave keynote speeches and shared their experience in pesticide residue analytical techniques and monitoring. There were around 150 participants from related official authorities such as Australia, Canada, Japan, Malaysia, Mexico, Peru, the Philippines, TFDA, respective public health bureaus, and the Taiwan Agricultural Chemicals and Toxic Substances Research Institute attending the workshop. Through experience sharing and exchange, participants gained additional new knowledge about novel testing techniques of pesticide residues increased cooperation with member economies of APEC, and strengthened the testing R&D capabilities of related staff within our country.

II. Development of methods for testing food-related items that are at high risk and of high interest

(I) Establishment of test methods in real time reflective of public opinions

1.For the out-of-spec herbicide Glyphosate detected in the honey exported to Japan from New Zealand, TFDA published the “Method of Test for Pesticide Residues in Honey-Test of Glyphosate, an Herbicide”.

2.For the suspicious illegitimate use of phosphine by food businesses that was found by the local health bureau, TFDA referred to multiple international publications while developing qualitative and quantitative approaches and also sent representatives to the EU reference laboratory to exchange the analysis experience. Eventually, the limitations of qualitative testing were overcome and a

quantitative test method entitled "Method of Test for Pesticide Residues in Foods - Test of Phosphine" was published.

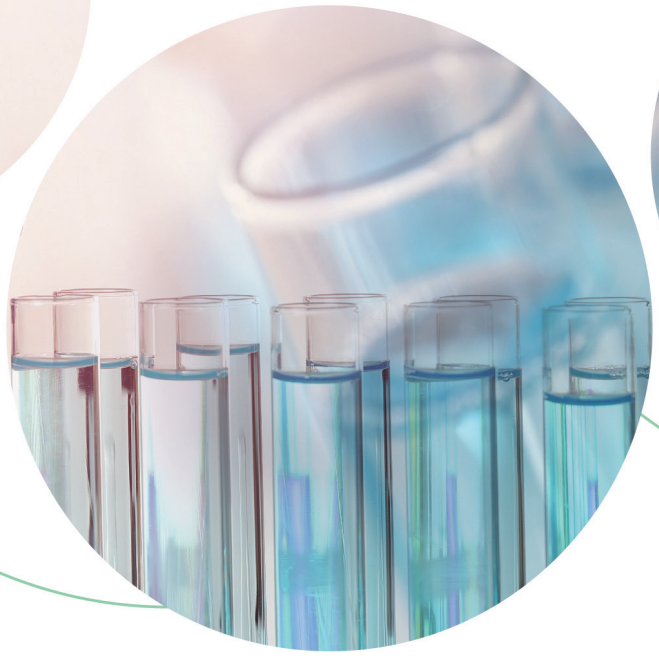
3. For the continuous detection of ethylene oxide in capsules and ice cream products internationally, the "Method of Test of Ethylene Oxide and its Reaction Product, 2-Chloroethanol, in Foods" was revised with the addition of applicable matrices - edible empty capsules and ice cream products, and illegal products were later successfully intercepted at borders.
4. In response to the establishment of Reference Points for Action (RPA) for malachite green (MG) by EU and the controversy over the detection of the MG and crystal violet (CV) in grouper exported from Taiwan to China, TFDA advanced and published the "Method of Test for Veterinary Drug Residues in Foods - Test of Malachite Green, Crystal Violet and their Metabolites."
5. In response to the exports of eggs to Europe, TFDA advanced and published the "Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Antiprotozoal Drugs (2)"; the limits of quantification in eggs for the four drugs, including dimetridazole have been reduced.

(II) Advancement of testing methods

In 2022, to go with testing requirements under food-related sanitation standards, TFDA promulgated or amended 28 testing methods for pesticides, veterinary drugs, heavy metals, and dioxin in foods. For the "Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (5)", the number of analytical items increased from 380 to 410. TFDA also published 31 recommended testing methods. For the "Method of Testing Pesticide Residues in Foods - Multiresidue Analysis (6)", the number of analytical items increased from 20 to 31, and for the "Method of Test for Pesticide Residues in Livestock and Poultry Products - Multiresidue Analysis", those increased from 129 to 138, which effectively improved the testing efficiency. Meanwhile, at least 8 testing methods were new or were revised for food microorganisms and genetically modified foods. In response to the "Standards for Specification, Scope, Application and Limitation of Food Additives", the liquid chromatography/tandem mass spectrometry (LC-MS/MS) was utilized to develop the "Method of Test for Thiamine Dilaurylsulfate in Soy Sauce" for public use.

(III) Identification of toxic plants such as *Alocasia odora* by the DNA molecular biotechnology to protect public food safety

One person tried the traditional taro cake sold in a restaurant and developed symptoms such as a throbbing sensation and numbness in the mouth. The decorative leaf at the bottom of the food was suspected to be the culprit. TFDA applied DNA molecular biotechnology to identify the species and clarify the cause of poisoning. The leaf was confirmed to be that of *Alocasia odora*. The weekly news released hence included the call upon catering businesses to confirm the accuracy of food ingredients used and to avoid contact of the leaves of *Alocasia odora* with foods.



3 Advancement of Drug Management

Section 1 Normalization of Drug Management Regulations

Section 2 Reinforcement of Drug Risk Control and Digital Management

Section 3 Improvement in Manufacturing and Distribution Management of Western Medicinal Products

Section 4 Actively Participate in Events of International Organizations for Medicinal Products

Section 5 Improve Drug Quality Inspection Technology

Section 6 Investigate and Analyze Information on Laws and Regulations Governing Medicinal Products in New South-bound Countries

2023

Something about TFDA

Oh no! I have a cold again. Seeing a doctor and getting the required medicine is suffering. There are so many pills, large and small, in one pack and I have no idea what effects they have on my body.

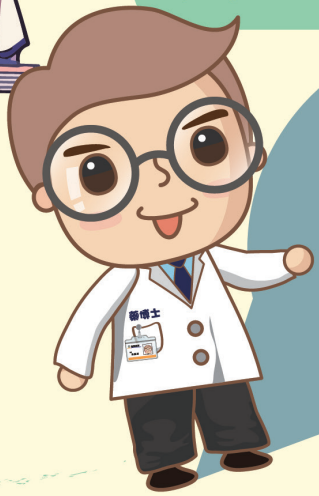
Don't worry! TFDA has taken a step further recently in terms of risk control and digitalized management of medicinal products. Both the management over reviews of medicinal products and safety assessments of medicinal products have become better. Meanwhile, the reporting system is defined to proactively monitor the safety of medicinal products both domestically and internationally.

TFDA Chatroom

I see! Sometimes I purchase medicine in a pharmacy. Is that medicine also within the scope of risk control?

Definitely! All medications, obtained in large healthcare facilities, clinics, or anywhere else, are closely monitored by TFDA! At the same time, TFDA implements quality monitoring on commercial medicinal products and inspects pharmaceutical plants periodically.

Wow! I feel assured hearing that. I was always afraid of taking too much medicine without knowing if it was safe or of good quality.



You do not have to be worried about these things at all! For the safety and quality of medicinal products, TFDA strives to improve western medicinal products manufacturing and distribution management constantly, including supervising drug companies to implement PIC/S GMP and GDP, all to ensure the quality of medications for the public.

Great! I do not have to be worried anymore.

3 Advancement of Drug Management

TFDA continues to construct a robust regulatory environment and harmonizes with international standards throughout the life cycle of medicinal products through improved regulations of medicinal product distribution, digitalized management, the supervision of quality and safety, and the inspection technology for quality, among others, to effectively ensure the safety, efficacy, and quality for medicinal products, to provide the general public with a safe environment for medicinal products usages as well as facilitate the development of the domestic pharmaceutical industry. TFDA also strengthens the medical exchange and cooperation with the new south-bound countries through our experience gained a long-term commitment to establishing an international pharmaceutical regulation environment and the relevant industry advantages.

Section 1

Normalization of Drug Management Regulations

Introduction of the Policy

In order to cope with the development trends around the world and to increase the accessibility of medicinal products, TFDA constantly refers to the international regulations of regenerative medicinal products, the regulation of intellectual property rights, as well as cooperating with the current development status of the domestic pharmaceutical industry, we continue improving the relevant regulations and providing a better medicinal product regulatory environment.

Tip station

The spirit of NCE-2 is:

The medicine is approved by the A10 countries regulatory management units and has been approved for listing for a long time. Those medicines usually have considerable technical information on quality, safety, and effectiveness, and with experience in human use after the medicine has been on the market for a long time. It should be reasonably applicable to support the safety and effectiveness of drugs with the same ingredients.

Implementation Strategy

I. Announcement of the "*Regenerative Medicinal Products Act (draft)*"

TFDA announced the "*Regenerative Medicinal Products Act (draft)*" on January 13, 2022. The Act covers the whole lifecycle management of regenerative medicinal products, including product registration, conditional approval, and specific requirements on the manufacture, distribution, and post-marketing management of regenerative medicinal products for the industry, aiming to promote the development of the biotechnology industry in Taiwan. In addition, TFDA continues to establish relevant review guidances for regenerative medicinal products as a reference for research and development for the industry, improving the regulatory environment for regenerative medicinal products.

II. Amendment of the "Key Points of Review for new chemical entities (excluding biological medicinal products) that have been approved for market in A10 countries for over 5 years" (NCE-2)

In order for the general public to have access to new chemical entities as early as possible, with the quality, safety, and efficacy

of medicinal products ensured and under the condition that the review criteria are consistent for all new chemical entities, the original 2013 announcement amended to include domestic new chemical entities (excluding biological medicinal products) that have been approved for market for over 5 years in A10 countries, with quality, safety, and efficacy having been approved by the regulatory authorities and consumer reception available that may be used to support the review.

III. Implementation of linkage to patents of Drugs

The Drug linkage system was enforced on August 20, 2019. The registration system for patent linkage of drugs was created in compliance with Article 48-8 of the "*Pharmaceutical Affairs Act*". The new drug owner registered patent information provided and released, it perfects the intellectual property protection setting for medicinal products in our country and boosts the willingness of developers to invest in the R&D of new drugs in Taiwan.

Achievements and Benefits

I. Improving the regulations for regenerative medicinal products

The "*Regenerative Medicinal Products Act (draft)*" was submitted to the Executive Yuan for review on May 3 and September 22, 2022; once reviewed and approved by the Executive Yuan, the Act will be sent to the Legislative Yuan for examination. The "Guidance on NDA for Gene Therapy Medicinal Products" was announced on July 1, 2022. Besides, the revised "Guidance on NDA for Cell Therapy Medicinal Products" was announced on November 7, 2022, in order to improve the regulatory environment for regenerative medicinal products.

II. Increased accessibility of new drugs

For medicinal products already approved for market overseas subsequently applying for registration in Taiwan, under the premise that patents of medicinal products owned by others are not infringed upon, the released data and patient reception of the specific medicinal product may be reasonably used to support part of the reference materials required for the review of the quality safety, and efficacy of the medicinal product. It was announced on September 30, 2022, that the NCE-2 requirements were amended; new chemical entities that have been approved for marketing for over 5 years in A10 countries apply, allowing for early introduction of a medicinal product to the market, helping to increase the accessibility of new drugs.

III. Strengthening of the transparency of the patent linkage system

Besides enforcing the "*Patent Act*" to protect the patent holder, it is encouraged that pharmaceutical companies engage themselves in the research and development of design-around by clarifying related concerns about infringement prior to marketing taking advantage of public and transparent patent information so that marketed medicinal products are not at risk of discontinuation as a result of tort, undermining the right to medication of patients. As of the end of 2022, there had been 31 cases challenging design-around and 14 permits had been issued.

Section 2

Reinforcement of Drug Risk Control and Digital Management

Introduction of the Policy

In order to promote drug administration and to comply with the requirements of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other international standards, TFDA continues to advance electronic management over the review of drugs, expedite operations, and improve submission quality and protects medication safety by enhancing the trace and track management mechanism for medicinal products and risk control over the quality and safety of medicinal products.

Implementation Strategy

I. Improving electronic management for reviewing medicinal products

The Electronic Common Technical Document (eCTD) Platform was officially launched on January 1, 2022. TFDA also continues to strengthen and expand the functions of the platform and provide more diversified services to enhance the review efficiency for medicinal products.

II. Reinforcement of drug safety reassessment

Besides creating the reporting system, TFDA spontaneously monitors information about the safety or quality of medicinal products domestically and internationally and the quality of products available on the market and audits manufacturing facilities. In cases of safety issues or major quality abnormalities of medicinal products, once found, safety re-evaluation or quality investigation will be embarked on. Meanwhile, the National Health Insurance Research Database (NHIRD) will be analyzed in order to know how clinical medicinal products are used in the country and such information will serve as a reference in the assessment of risk control efficacy and in the preparation of policies in the future.

III. Advancement of the traceability and tracking mechanism for medicinal products

Pay close attention to the use of NHI-covered medicinal products. Screen and modify items subject to a declaration of medicinal products in the category of high interest on a rolling basis. Perform cross-check statistical analyses of medicinal products in respective categories. Provide spontaneous warnings on abnormal whereabouts of medicinal products and cooperate with the local public health bureau during site visits in order to ensure legitimate supply and avoid illegitimate circulation of medicinal products. In addition, by holding communication workshops, providing friendly assistance to businesses in the declaration of the traceability and tracking system for medicinal products, and providing related advisory services to improve businesses' compliance with the declaration.

Achievements and Benefits

I. Enhanced efficacy in the review of medicinal products

Since 2022, TFDA has accepted eCTD submissions for the registration of medicinal products and a total of 9 cases were approved through systematic verification, which further promotes the milestone of electronic management of drug registration. Meanwhile, the application for bioavailability and bioequivalence studies, bridging studies, and clinical trials could be submitted online. This service has been available since January 1, 2023.

II. Enhanced drug safety surveillance and analysis

Throughout 2022, there were a total of 13,339 adverse drug reactions reported domestically, 97 domestic and international drug safety warnings, 45 safety warnings on COVID-19 vaccines, and 49 drug safety assessments; 16 drug risk communication forms were released; and 4 quarterly publications containing short-text messages on the safety of medicinal products were issued; 708 suspicious quality defect events were reported; and 1,714 international quality warnings on medicinal products were spontaneously monitored.

III. Ensured legitimate supply of medicinal products

Three communication workshops on the declaration process of businesses and educational training of the public health bureau were held throughout 2022 and were participated in by a total of 316 people. In addition, information on the raw material ephedrine of the controlled drug system has been integrated into the Trace and Track system for medicinal products, and the pre-warning feature is created for the commissioning of ephedrine in order to alert license holders

that hold ephedrine but haven't declare a manufacturing; this is to avoid the non-medical purposes that ephedrine is used for.

Section 3

Improvement in Manufacturing and Distribution Management of Western Medicinal Products

Introduction of the Policy

In order to ensure the quality and safety of medicine used by the public, the *Pharmaceutical Affairs Act* stipulates that the manufacturers of western medicinal products should comply with Good Manufacturing Practice (GMP), in order to continuously and steadily manufacture medicinal products that are consistently in safety, quality, and can achieve expected efficacy. The *Pharmaceutical Affairs Act* also stipulates that Good Distribution Practice (GDP) should be implemented for the distribution of western medicinal products in stages to ensure that their quality and integrity are maintained during distribution, storage, and delivery. Currently, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) GMP and GDP guides are adopted in our country. TFDA refers to PIC/S guides to conduct GMP compliance inspections of western medicinal products (including API) manufacturers and to promote western medicinal products companies to comply with GDP.

Implementation Strategy

I. Supervise medicinal products manufacturers to implement PIC/S GMP

With the advancement of science and technology, the development of advanced pharmaceutical technologies, and the innovation of quality concepts, international GMP standards are constantly updated and quality risk management has been introduced. TFDA continues to revise GMP regulations referred to the latest GMP standards promulgated by PIC/S and conducts GMP inspections based on risk to supervise the compliance of GMP of manufacturers.

II. Promote medicinal products companies to mplement GDP

Following the completion of GDP implementation by Western Pharmaceutical manufacturers, pharmaceutical companies holding the Western Pharmaceutical Product licenses, and pharmaceutical companies engaged in products required cold chain storage and transportation at the end of 2018 and 2021, TFDA further announced active pharmaceutical ingredients (APIs)

manufacturers (including those dedicated for export) and pharmaceutical companies engaged in wholesaling, importing and exporting APIs should comply with GDP before December 31, 2022. TFDA assists the industry in familiarizing with and implementing GDP through holding training courses and on-site visits to implement the distribution management of medicinal products gradually.

Achievements and Benefits

I. Ensured fulfillment of the GMP in the manufacturing of medicinal products

As of the end of 2022, a total of 149 domestic pharmaceutical manufacturers and 958 overseas pharmaceutical manufacturers have been approved through the GMP inspections performed by TFDA; it ensures the medication quality for the public. TFDA announced the addition of "Annex 2A: Manufacture of Advanced Therapy Medicinal Products for Human Use" and the revision of "Annex 2B: Manufacture of Biological Medicinal Substances and Products for Human Use" on July 27, 2022; the GMP regulations keep pace with the times and international.

II. Ensured fulfillment of the GDP in the distribution of medicinal products

The implementation of GDP on APIs was completed in 2022, and a total of 29 API manufacturers and 155 pharmaceutical companies engaged in wholesaling, importing, and exporting APIs have obtained the western pharmaceutical distribution license (GDP licenses). By the end of 2022, a total of 940 pharmaceutical dealers have obtained GDP authorization.

Section 4

Actively Participate in Events of International Organizations for Medicinal Products

Introduction of the Policy

In order to deepen and promote international exchange and collaboration, TFDA has been proactively taking part in APEC (Asia-Pacific Economic Cooperation), ICH, and PIC/S events, maximizing the engagement and influence of our country in international drug administration and strengthening bilateral and multi-lateral cooperation by exchanging with and sharing experience with international regulatory authorities.

Implementation Strategy

I. Involvement in ICH meeting-related events

To go with the new ICH procedure for revising its technical guidance, TFDA periodically attends its general assembly and expert working group meetings, substantially takes part and cooperates in the preparation of international regulatory harmonization, continues to translate and define applicable guides to the safety, effectiveness, and quality of medicinal products, and holds ICH guidance-implementation industrial educational training to help industries comply with and keep track of the latest international standards.

II. Organization of 2022 APEC Workshop

The "2022 APEC Good Registration Management Regulatory Science Center of Excellence Workshop (GRM CoE)" was held from August 15 through September 15, 2022. The current workshop took place through digital courses along with online meetings to train science professionals on laws and regulations in APEC economies and to jointly and continuously promote and consolidate GRM beliefs in the APEC region through the trained seed teachers for enhanced overall quality and efficiency in medicinal review.

III. Attendance in 10th Joint Conference of Taiwan and Japan on Medical Products Regulation

The 10th Joint Conference of Taiwan and Japan on Medical Products Regulation took place on October 20, 2022 (Figure 3-1). The workshop was organized by the Japan MHLW/PMDA and TFDA through onsite and online meetings. Taiwanese and Japanese representatives gave presentations on the regulatory progress of medicinal products, the application of digital tools for clinical trials, measures in response to COVID-19 and shared the implementation status of the MOU for the collaboration in medical device quality management systems and regulatory updates on medical devices in Taiwan. In addition, upon the 10th anniversary of the Joint meeting, both parties retrospected the achievements over the 10 years and the future prospects.

IV. Continue to participate in the PIC/S activities

As a Participating Authority of PIC/S, TFDA has sent representatives to various sub-committees to actively engage in the organization's affairs; TFDA also involve to participate in expert circles and working groups dedicated to discussions on the revision of GMP and GDP regulations and standards, in collaboration with international experts. In 2022, TFDA participated in several meetings and events, including the "2022 PIC/S Committee Meeting & Annual Seminar" and "PIC/S Training Event and Meeting of the Expert Circle on Quality Risk Management (QRM)".

Figure 3-1 10th Joint Conference of Taiwan and Japan on Medical Products Regulation

Achievements and Benefits

I. Contributed to ICH-related meetings

As of the end of 2022, TFDA had selected 45 experts to join 28 ICH expert working groups and they attended phone conferences of expert working groups more than 196 times. They prepared the ICH Guidance together with international experts. Besides proactively making contributions, continuous efforts are made to build a regulatory setting that is internationally competitive.

II. Promoted cooperation and interaction of pharmaceutical management in the Asia-Pacific region

Through the APEC Workshop, proactive efforts were made to promote regional harmonization in laws and regulations and ideas about GRM, advance talent construction and international collaboration and exchange, and provide a platform that allows communications and conversations among the industry, the government, and the academia; it helps reinforce the overall medicinal capacity in our country. Throughout 2022, 104 seed teachers from the industry, the government, and academia in 12 APEC economies were trained.

III. Reinforced bilateral medical interaction between Taiwan

Tip station

The A10 countries：

Including Germany, US, UK, France, Japan, Switzerland, Canada, Australia, Belgium, and Sweden.

and Japan

Besides governmental representatives from Taiwan and Japan, up to around 500 people from the medicinal product and medical device sectors attended the current Joint Conference of Taiwan and Japan on Medical Products Regulation. The exchange allowed industries to understand regulations on medicinal products and medical devices further and strengthened mutual trust and collaboration; it laid out a new blueprint for Taiwan and Japan in the collaboration over regulations on medicinal products and medical devices.

IV. Continue to strengthen GMP inspection through the PIC/S platform

By appointing representatives to engage in PIC/S affairs and activities, TFDA aims to directly express its opinions, stay updated on the latest international regulatory trends, strengthen its involvement in international affairs, and enhance TFDA's visibility and influence. Additionally, TFDA assigns inspectors to participate in various training events organized by PIC/S, allowing them to interact with inspectors from countries such as Europe, the United States, Japan, Korea, and Singapore, to discuss topics like GMP inspection of Pharmaceutical Quality Systems and Quality Risk Management,

with the objective of aligning Taiwan's GMP management system with international standards.

Section 5

Improve Drug Quality Inspection Technology

Introduction of the Policy

In response to the international drug safety report of the possible presence of the derivative, *N*-nitroso salbutamol, in salbutamol-based asthma drugs, as nitrosamines can be mutagenic, for the sake of protecting medication quality and safety, TFDA developed the test method within the shortest time possible for respective parties' reference and adoption. In addition, in light of the fact that emerging biomedicine products such as virus-vectored vaccines are current trends in medicinal research and development and safety concerns such as gene sequence variance may be present in the complex process, it is urgent to define key test methods for the quality of the said products and to introduce international novel test technologies reflective of the international development trend for enhanced control over the quality risk of emerging biotech medicinal products in our country.

Implementation Strategy

I. Introduction of diversified new technology for the testing of medicinal products

Reflection of the nature of the compound, TFDA applies liquid chromatography-tandem mass spectrometry (LC-MS/MS) in the establishment of quick, sensitive, and accurate analytical methods through simple pre-treatment of samples.

II. Leading in novel technologies for the quality test of emerging vaccines

TFDA introduces novel test technologies of international interest that are highly sensitive and feature complete sequencing capacity - next-generation sequencing (NGS), to develop test methods for sequence identification and sequence variance analysis within an automatic analytical process. These methods were verified with the reference viral substances produced by the UK National Institute for Biological Standards and Control (NIBSC); it was successfully proven that the technology is capable of analyzing variations in the viral nucleic acid sequence, effectively enhancing test accuracy and credibility.

Achievements and Benefits

The recommended methods for testing *N*-nitroso Salbutamol in the active pharmaceutical ingredient salbutamol (including their English versions) were released and made available to all parties

for their reference and adoption to boost the test capacity and international publicity of our country and to facilitate the exchange of information on medicinal products internationally. In addition, while the quality control model for emerging biotech medicinal products such as nucleic acid drugs is yet to be standardized internationally, TFDA has already defined the novel NGS test technology to lead the innovative test capacity of our country in medicinal products. Such technology has been applied in the testing of 49 batches of COVID-19 vaccines, with accumulated capabilities in monitoring the quality and coping with the quality risk of emerging biotech medicinal products.

Section 6

Investigate and Analyze Information on Laws and Regulations Governing Medicinal Products in New South-bound Countries

Introduction of the Policy

Given the quick global economic and trade developments and restructuring of the supply chain, the Ministry of Health and Welfare implemented the “Mid-to-Long-term Plan for New Southbound Medicial Health Collaboration and Industrial Chain Development” to go with the new southbound policy of our country. With the implementation of the Plan, TFDA hopes to strengthen collaboration with new southbound countries in medicine applying our experience from the long-term devotion to the establishment of an international management setting for laws and regulations on medicine and our strengths in the industry. Stage 2 (2022-2025) is planned to stabilize partnerships with new southbound countries and to advance into the international market for the medicinal industry by investigating the supervision and management strategies and regulatory updates for medicinal products in new southbound countries.

Implementation Strategy

I. Collection and analysis of regulatory information on laws and regulations governing medicinal products in new southbound countries and strategies adopted by advanced countries in entering the new

southbound market

To continue establishing long-term steady partnerships with new southbound countries and for our country to enter the new southbound market for medicine, TFDA exchanges medicinal management information and technologies, and collects information on medicinal laws, regulations, and industrial trends through related seminars held in these new southbound countries, including medical and health-related online seminars held in Thailand, Singapore, and Malaysia, three sessions in total. In addition, to allow substantial partnerships, strategies adopted by Japan in helping the medical industry enter the Indonesian market (a new southbound country) were collected and analyzed.

II. Organization of managerial courses on medicinal policies adopted in new southbound countries and on applicable laws and regulations

TFDA held the course entitled "Medicinal Policies/Laws and Regulations in New Southbound Countries" on June 17 and August 12, 2022, respectively. The course began with an overview of trends in laws and regulations on medicine and the local market, followed by an analysis of the application practice and sharing of related experience. Meanwhile, experts and scholars in the field of healthcare and representatives from the medicinal industry shared information on strategies adopted in Indonesia and ASEAN countries on the supervision and management of medicinal products, regulatory updates, trends, and reforms. It was an advanced course meant to help learn in-depth medicinal developments in new southbound countries and in favor of enhancing the attainments of the governing authority in regulatory fields while the promotion of international harmonization of laws and regulations on medicinal products continues.

Achievements and Benefits

TFDA is proactive in getting information on international laws regulations and trends concerning medicine and has managed to appear and give presentations in healthcare-related seminars, share, and exchange through managerial courses regulatory practices concerning medicine, create a model that allows the collection of regulatory information, and exchange and sharing of strategies, continue to reinforce information exchange and bilateral or multi-lateral collaboration and investigate and analyze strategies to help the medicinal industry enter new southbound countries with assistance from advanced countries to broaden its international presence.

4 Reinforced Management over Controlled Drugs and Prevention Against Drug Abuse

Section 1

Promote Amendment to the Regulations on Controlled Drugs and Diversion Management

Section 2

Advancement in the Quality of Schedule 1 and 2 Controlled Drugs

Section 3

Enhance drug abuse early warning mechanism

Section 4

Reinforced Prevention Against Drug Abuse and Education on Illicit Drugs

Section 5

Results of testing for new psychoactive substances

2023

Something about TFDA

I do not know why there is so much news about drug or substance abuse...I feel shocked each time and sorry for those people.

Agreed! Particularly those who are young. If someone had provided them with proper guidance or correct information, maybe it would help prevent them from going astray.

I know! In fact, TFDA has been proactive in the prevention and control of drug abuse, by constantly improving the pre-warning/monitoring mechanism and perfecting the reporting mechanism in healthcare facilities against drug/substance abuse so that the first-line healthcare providers can report any suspicious case right away and it will help TFDA keep track of drug/substance abuse status in the very beginning.

TFDA Chatroom

TFDA is constantly bettering its management over accredited testing institutions capable of drug abuse urine testing in pursuit of better quality.

Wow! But, there are so many patients in healthcare facilities every day. Once a case is reported, laboratory testing needs to take place. I feel that healthcare professionals will be too busy to be efficient in this regard, won't they?

Exactly! Meanwhile, TFDA also continues to strengthen education on how to prevent substance abuse and the use of illicit drugs. With both control and prevention taking place at the same time, people can live happily and healthily and say no to illicit drugs!

4

Reinforced Management over Controlled Drugs and Prevention Against Drug Abuse

To guide the proper use of controlled drugs and prevent drug abuse, TFDA has established a mechanism for monitoring drug abuse trends, collecting domestic and international information, and providing reference for the Ministry of Justice while the latter adds or revises the list of controlled substances. 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*." The Executive Yuan also enforces multiple anti-drug measures and enhances education on the prevention of substance abuse. Meanwhile, technologies to help detect new psychoactive substances and substance abuse are developed and the drug spectrum database is expanded in addition to technical exchange with the authorities to jointly fight against illicit drugs.

Section 1

Promote Amendment to the Regulations on Controlled Drugs and Diversion Management

Introduction of the Policy

To prevent and curb the abuse or illegal 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, while enforcing inspections on the distribution of controlled drugs. Meanwhile, auditing over the circulation of controlled drugs is enforced.

Tip station

Controlled Drugs

In the *Controlled Drugs Act*, Controlled Drugs means addictive narcotic drugs, psychotropic drugs, and other drugs requiring regulation.

In order to avoid iatrogenic addiction or abuse of controlled drugs, they may only be used for medical and scientific purposes.

Implementation Strategy

I. Periodic Review and Evaluation of Controlled Drugs

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

II. Project-based Auditing and Training of Healthcare Professionals on Knowledge about Drug Addiction

Every year, a controlled drug audit plan is formulated to strengthen the auditing over the legitimacy of prescribed use of controlled drugs and to prevent improper prescription of controlled drugs that leads to addiction or abuse; teaching aids are developed and educational training is organized on addictive pain-killing narcotics to further knowledge among healthcare professionals about addictive narcotics.

Achievements and Benefits

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

The Ministry of Health and Welfare convened the 45th and 46th Controlled Drugs Review Committee meeting in 2022 to add a total of 311 items of controlled drugs and APIs.

II. Implemented project-based audits and enhanced knowledge and skills of healthcare professionals in the use of controlled drugs

The audit project was enforced for controlled drugs in 2022; a total of 188 companies were inspected and 37 were found with violations, with a violation rate of 19.68%. Meanwhile, the "Pain Care Reference Handbook for Patients on Palliative Care" and the "Pain Care Reference Handbook for Non-cancer Patients with Suspected Substance Use Disorders" were prepared in addition to a total of 6 sessions of online educational training. Knowledge and skills of healthcare professionals on the use of controlled drugs in patients were enhanced to prevent iatrogenic addiction. In addition, the "2022 U.S.-Taiwan Web Conference on Controlled Drugs" took place on October 18, 2022. US DEA Supervisor Jennifer Jimenez, UCLA Professor Yih-Ing Hser, and many other domestic experts and scholars were invited to exchange with one another and share what they knew about the management of controlled drugs in Taiwan and the US and the use of controlled drugs for medical purpose, among others.

Section 2

Advancement in the Quality of Schedule 1 and 2 Controlled Drugs

Introduction of the Policy

In 2020, multiple R&D projects commenced at TFDA's pharmaceutical factory (hereinafter referred to as the Factory) for controlled drugs with the aim of enhancing product quality and expanding capacity. The plan is to produce products that are currently outsourced or imported from other countries independently. Renovated workshops were also completed and commissioned in 2021 to fulfill the goal of local manufacturing of essential drugs and ensuring a sufficient supply.

Figure 4-1 Solution production line equipment chart - filling equipment

Figure 4-2 Solution production line equipment chart - packaging equipment

Implementation Strategy

The plan is to add production lines for new formulations in the newly renovated workshops. The goal is to build production lines for solutions, capsules, and patches and maximize space for production and warehousing each year. Injections and solutions are given priority for R&D products, followed by capsules and patches, which require more advanced technology.

Achievements and Benefits

In 2022, the Factory completed the production line for solutions and obtained permits for Methadone Oral Concentrate and Morphine Sulfate Oral Solution. Approval for the manufacturing and self-mass production of solutions was also received and research and development of Oxycodone Hydrochloride Immediate Release Capsules, Morphine Sulfate Prolonged Release Capsules, and Matrix Patches are ongoing. The Factory's future product range will include injections, tablets, solutions, capsules, and patches, with a self-production rate of up to 70%. The filling equipment and packaging equipment for the solution line are shown in Figures 4-1 and 4-2.

Section 3

Enhance Drug Abuse Early Warning Mechanism

Introduction of the Policy

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 Strategy

I. Reporting mechanism for healthcare facilities on drug abuse

TFDA built the Drug Abuse Reporting System (DARS) to receive information reported monthly by healthcare facilities in the country on drug abuse cases.

II. Advancement in the management of accredited testing institution for drug abuse urine tests

To meet the demand for substance abuse testing and monitoring over the past few years and to reflect the revisions made to the "Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions" and the "Regulations Governing Drug Abuse Urine Testing Operations," TFDA finished amending the "Guide to Site Visit to Substance Abuse Urine Testing Institutions" on September 27, 2022, with the addition of the requirement for applying mass spectrometry to initial test validation and revision of the technical requirement for quality control in an effort to fulfill current test technology and practical needs. It will be enforced on January 1, 2023.

III. 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.

IV. Emerging department drug abuse surveillance

In 2022, TFDA continued to commission the "Monitoring Plan for NPS in Emergency Departments (ED)" to conduct expanded

screening of urine specimens of 150 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

I. Reporting situation of drug abuse from healthcare facilities

According to the DARS data, there were a total of 14,741 cases of drug abuse reported by healthcare facilities throughout 2022, a decrease of 48.8% from 2021. The top three drug abused were heroin (7,699, 52.2%), (meth) amphetamine (5,241, 35.6%), and benzodiazepine (1,433, 9.7%), which was generally identical to the trends in 2021.

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

As of the end of 2022, 19 testing institutions had been accredited and there were 2 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 accreditated and submit their NPS test method validation data for review in order to maximize the capacity of urine testing for NPSs.

In 2022, the total number of urine tests performed throughout Taiwan came to 274,569, among them were 64,668 positive results, accounting for 23.6% of all tests. The top three drugs detected were methamphetamine, ketamine, and morphine. Compared with the number of urine tests from 2022, the percentage of methamphetamine decreased by 10.3%, while cases of ketamine and morphine increased by 34.7% and 15%.

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

In 2022, 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 248,500, a decrease of 3.8% from 2021. Of which, there were 23,255 cases of methamphetamine, 18,395 cases of ketamine, and 25,186 cases for heroin.

IV. Taiwan Emergency Department Drug Abuse Surveillance

In 2022, a network of 139 collaborating hospitals and a platform for expanded extensive screening of urine specimens of 150 NPSs were in place. The number of samples received came to 3,274 and among them were 886 positive cases, accounting for

27.1% of all samples. With the 192 found with medicines consistent with those prescribed by doctors excluded, there were 694 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 18 to 24 years old. Twenty-four NPSs were detected and among them were mostly synthetic cathinone, identical to the program in 2021. 4-methyl methcathinone (4-MMC) was the most detected drug, followed by ketamine, and then 3,4-Methylenedioxy-α-pyrrolidinohexiophenone (Pentylone).

Section 4

Reinforced Prevention Against Drug Abuse and Education on Illicit Drugs

Introduction of the Policy

TFDA works with non-governmental organizations (NGOs) and other ministries and departments in promoting the prevention against and education on substance abuse in diversified ways by reaching out to workplaces, communities, aboriginal tribes, and online populations.

Implementation Strategy

I. Fun in Preventing Drug Abuse

TFDA collaborated with the Ministry of Justice, the Ministry of Education, and the National Police Agency of the Ministry of the Interior and implemented the "Fun in Preventing Drug Abuse" program. In 2022, circuit tours to communities, workplaces, and high-risk areas in six counties and cities, Chiayi County, Chiayi City, Tainan City, Kaohsiung City, Pingtung County, and Penghu County took place throughout 2022 and on the tours, anti-drug information was provided to the general public through mobile display cases and large playground equipment.

II. Collaboration with non-governmental organizations (NGOs)

TFDA works with NGOs in the prevention of drug abuse by communicating via local assemblies or celebrations.

III. Prevention against drug abuse in aboriginal tribes

In 2022, TFDA reached out to aboriginal tribes in Hualien County, Taitung County, Chiayi County, Kaohsiung City, and Pingtung County to train talent and educate them on the prevention against drug abuse and to boost the capacity of aboriginal tribes in the prevention against drug abuse.

Figure 4-3 Meme creation

Figure 4-4 Joint communication efforts with Pingtung Home of Hop

Figure 4-5 Joint communication efforts of Shambala Theater Group

IV. Online anti-drug promotional games

TFDA held the "Anti-Drug Campaign: I'm in, and You?" meme creation campaign together with the online illustrator Incrediville (Figure 4-3). First, people were invited to learn the 5-tips to stay away from drug hazards and then to create their own memes to hopefully boost their knowledge and skills about how to prevent drug abuse.

Achievements and Benefits

I. Fun in Preventing Drug Abuse

TFDA implemented the "Fun in Preventing Drug Abuse" program in 2022, which consisted of 388 sessions in total in 6 counties and cities; A headcount of 91,823 benefited from the program.

II. Collaboration with non-governmental organizations

TFDA joined efforts with 12 NGOs in total throughout 2022 in communicating to people on how to prevent drug abuse through educational and fun activities (Figures 4-4 and 4-5). In total, 201 sessions were held to benefit a headcount of 29,583 people. The Chinese Cartoonists Union, in particular, produced the comic handbook communicating the "Using Sleeping Pills Correctly 5 Principles" and prepared 1,000 copies that were distributed to libraries and community sites.

III. Communication on the prevention against drug abuse in aboriginal tribes

TFDA reached out to aboriginal tribes in 2022, with 6 sessions of health education courses held and attended by 144 students.

Figure 4-6 Promotion of drug abuse prevention at aboriginal tribes

Among them, 15 students returned to the tribes they belonged to and held 39 sessions for health education that were participated in by a total of 896 people. They were deeply supported and recognized by tribal communities (Figure 4-6).

IV. Online anti-drug promotional games

In 2022, TFDA held the "Anti-Drug Campaign: I'm in, and You?" meme creation campaign. The online illustrator "Incrediville" helped post information about the campaign and promote it. In total, 1,264 memes were received. The post reached a headcount of 442,991 people.

Section 5

Results of testing for new psychoactive substances

Introduction of the Policy

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

Implementation Strategy

I. Promotion of NPS combating and experience exchange on analytical technology

The "Workshop for Raman Spectroscopy Database Sharing and Experience Exchange" was held on August 2, 2022. Authorities concerned including the Criminal Investigation Bureau and the Customs Administration et al. were invited to share and exchange information on NPS testing.

II. Strengthening the capability for NPS testing

To demolish the restriction on NPS identification from insufficient built-in database, TFDA has built up its own spectrum database of hand-held Raman spectrometer which covers 2,234 items of NPS and medicinal products. In addition, 1,165 standard spectra have been built up and updated to the Drug Abuse Test Report System for sake the drug testing laboratories to review and download.

Achievements and Benefits

I. Promotion of combating and experience exchange on analytical technology for NPS

TFDA and the concerned authorities are working together through sharing the Raman spectrum database to keep illicit drugs out of borders.

II. Strengthening the capability for NPS testing

The national laboratories of TFDA are evolving strengthening the capability for NPS testing, including applying gas chromatography-mass spectrometry and liquid chromatography-tandem mass spectrometry for seizures identification, sharing the spectra database which 3,979 reviews in total were done by 19 laboratories, and providing standards which 99 items in total were given to 23 laboratories for developing analytical methods or for NPS identification. The aforementioned efforts have brought out diverse fronts for combating illicit drugs from prevailing.

5 Improving Management of Medical Devices and Cosmetics

Section 1 Advancement of Regulations Governing Medical Devices

Section 2 Reinforced Management over Manufacturing Quality and Distribution of Medical Devices

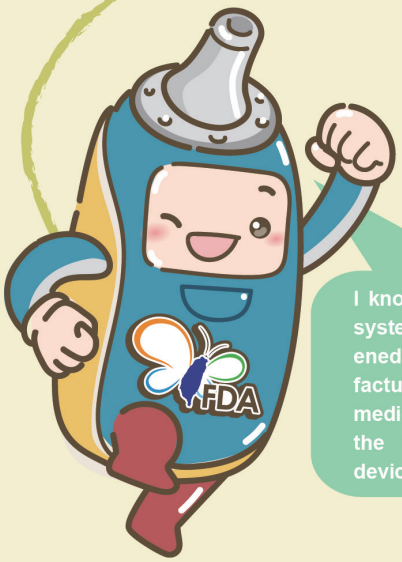
Section 3 Maximized international exchange and collaboration on medical device regulations

Section 4 Normalization of Management over Hygiene and Safety of Cosmetics

Section 5 Improved Testing Technologies for Medical Devices and Cosmetics and Management over Molecular Testing Laboratories

2023

Something about TFDA

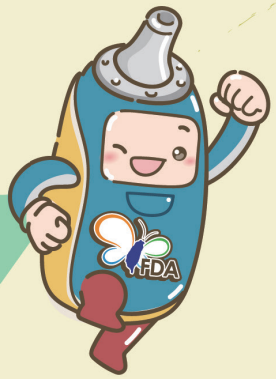


Ian! Ian! Did you know that TFDA has introduced the e-submission and review system for medical devices? Once you sign up, you can enjoy the convenience of digital management.

I know! Besides the e-submission system, TFDA has also strengthened the management of the manufacturing quality and distribution of medical devices to strictly monitor the quality and distribution of devices after marketing.

The management of cosmetics was also improved! For more comprehensive management, TFDA has established the system for cosmetics notification with basic product information to ensure transparency of cosmetics. The product information file system was established to strengthen the management of cosmetics ingredients and cosmetics for children to better protect consumers!

TFDA Chatroom



I think that these systems of cosmetics notification and product information files, as well as GMP, all help ensure product quality and safety and shorten the time needed for products to be made available in the market.

Exactly! For both medical devices and cosmetics, TFDA is improving the management system each year to ensure that both the quality and administrative efficiency become better, smoother, and more convenient!

5 Improving Management of Medical Devices and Cosmetics

To implement various systems under the "*Medical Devices Act*"; to respond to the technological and innovative development of medical devices; and to improve the total life cycle management system for medical devices, TFDA has announced multiple review guidances related to the management of medical devices; launched the e-submission system for the registration and market approval of medical devices; improved the consultation and support mechanism for businesses; and reinforced the Quality Management System (QMS) of medical devices.

Regarding international collaboration, Taiwan took part in meetings of various international organizations, including the Asia Pacific Economic Cooperation (APEC), Global Harmonization Working Party (GHWP), and International Cooperation on Cosmetics Regulation (ICCR). Taiwan also worked hard to secure opportunities to host important international meetings and events in order to expand the international engagement and influence of Taiwan.

Regarding the management of cosmetics, TFDA continues to promote the production of product information files for cosmetics and establish the system for Good Manufacturing Practice (GMP) so as to build a high-quality environment for the use of cosmetics. In addition, a variety of test and verification methods for multiple medical devices and cosmetics have been prepared to boost the test level and to ensure the quality and safety of medical devices and cosmetics.

Section 1

Advancement of Regulations Governing Medical Devices

Introduction of the Policy

Considering the rapid advancement of medical devices, TFDA has been making efforts to boost its managerial efficacy by expediting the harmonization of Taiwan's regulations with frequently updated

international regulations of medical devices and digitalization of applications, submissions, and reviews. In addition, many electronic technology and IT companies have started to conduct R&D of medical devices, but they usually have insufficient knowledge about medical device laws and regulations and face challenges like lacking experience in clinical practice and communication which results in delays in launching products. In light of this and to promote the development of the domestic medical device sector, TFDA has continued to make efforts to optimize laws and regulations governing medical devices and improve mechanisms to provide assistance and support.

Implementation Strategy

TFDA has compiled and analyzed regulations management governing medical devices or relevant guidances released by developed countries and international organizations. At the same time, TFDA has also collected feedback on the implementation of the *Medical Devices Act* from all parties in Taiwan and adjusted applicable measures under the *Medical Device Act* to reflect the development and current status of the medical device industry. TFDA has also prepared and announced managerial or review guidances related to medical devices. To improve the efficiency of digital management, the e-submission system for applications of various medical devices was set up in phases. At the same time, the digital review and archiving features have been optimized to improve review and submission quality and efficiency. In addition, the consultation and counseling mechanism has been improved to optimize the implementation efficiency and effectiveness of the Intelligent Medical Device Project Office; to provide matchmaking service between the industry and hospitals; to accelerate the development of innovative medical devices.

Achievements and Benefits

I. Enforcement of the Medical Devices Act

TFDA implemented risk classification for management. Statistics as of the end of 2022 showed that a total of 3,323 medical devices had completed the procedures online to be listed as Class 1 medical devices and 383 of the registered businesses had completed the annual declaration procedures between October and December. This approach has helped strengthen the autonomous management and accountability of manufacturers and built a management system that is internationally harmonized. Meanwhile, the *Medical Device Act* also allows medical device designers to be considered as medical device dealers. At present, 10 academic, research, and legal entities have successfully obtained business permits as medical device manufacturers, including National Cheng Kung University, National Yang Ming Chiao Tung University, and Industrial Technology

Research Institute, which has greatly boosted the zeal of all parties to devote themselves to the R&D of medical devices. Furthermore, to increase the professionalism of practitioners, TFDA has promoted the medical device professional technician system. As of the end of 2022, a total of 6,800 people had been registered as medical device technicians and 41 online courses had been provided as part of continuing education for technicians.

II. Establishment of sound and internationally harmonized laws and regulations to govern medical devices

In 2022, a total of 12 guidances or guidelines related to laws and regulations of medical devices or review were added or revised, including 4 guidances or guidelines related to artificial intelligence/machine-learning based technologies and pre-clinical testing/technical criteria for 8 preclinical testing/benchmarks and guidance that manufacturers can use as references during the phases of product development, verification, and registration and market approval. In addition, the "Reference for the Use of Real World Data and Real World Evidence To Support Regulatory Decision-Making for Medical Devices" was announced to facilitate proper utilization of such data by all parties and to expedite product development.

III. Introduction of the e-submission and review system to improve the efficiency of digital management

On January 21, 2022, the e-submission system for the registration and market approval of medical devices was officially launched to facilitate the e-submission and review of applications for registration and market approval, contract manufacturing, alteration, and extension of Class 2 and Class 3 medical devices. As of the end of 2022, with a total of 957 applications, one can see that the system has helped to improve the convenience of submitting pre-market applications for medical devices. In addition, on March 8, the 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" was made in an effort to promote paperless practice and digitalization.

IV. Advancement in development of innovative medical devices

To improve the service efficiency and effectiveness of the Intelligent Medical Device Project Office, in 2022, the Office actively solicited applications, which resulted in 10 applications related to domestically manufactured Artificial Intelligent/Machine Learning-Based Software as a Medical

Device (AI/ML-based SaMD) for Class 2 and 3 medical devices, and 76 projects received consultation and support from the Office. In the end, 6 applications of domestically manufactured AI/ML-based SaMD successfully obtained market approval. The results were highly recognized by all parties. To integrate information related to medical devices, the "Intelligent Medical Device Information and Matchmaking Platform" was established with 195 registered members. On the platform, 29 authorities have activated their membership have activated their membership to be matchmakers and have served up to 280 thousand members already. In 2022, 5 matchmaking meetings were held to facilitate the technical collaboration for 7 medical device businesses, evaluation of investment collaboration for 1 investment team, and collaboration between 3 businesses and hospitals happen in clinical fields.

Section 2

Reinforced Management over Manufacturing Quality and Distribution of Medical Devices

Introduction of the Policy

For the sake of ensuring management at the source and over the distribution of medical devices and to go with the "*Medical Devices Act,*" which came into force on May 1, 2021, TFDA reinforced the QMS and included GDP in the management in an effort to normalize management over the quality of medical devices throughout their life cycle.

Implementation Strategy

I. Enhancement of 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). The manufacturers establish a quality management system in accordance with the regulations, so that all stages of a medical device are under the control of the manufacturer's quality management system, including design and development, production, storage, distribution, installation, service, decommissioning, and disposal. Through QMS compliance inspections, TFDA supervises manufacturers to enforce the implementation of QMS, thus ensuring the quality and safety of devices in the market.

II. Promotion of GDP for medical devices

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 of the 45 items 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.

III. Promotion of e-application for management over quality of medical devices

TFDA created the "Medical Device Quality Management Application Platform" that became officially operative on January 1, 2022; medical device businesses can now apply for inspections, check the status of the application process quickly, and receive the latest information about announcements and communications through the application platform.

Achievements and Benefits

I. Ensured Conformity fulfillment of QMS and GDP in the manufacturing and distribution of medical devices

As of the end of 2022, a total of 6,528 valid medical device manufacturing licenses have been issued following QMS inspections, including 1,331 domestic manufacturers and 5,197 importers, and a total of 63 valid distribution licenses have been issued following GDP inspections. Through the manufacturing licenses and distribution licenses, TFDA could ensure the quality and safety of medical devices.

II. Transparency in the review of quality management system

Through the application platform, TFDA effectively keeps track of the dynamics of businesses to assist in the early market launch of medical device products in Taiwan and to achieve a triple-win situation for the general public, the industry, and the management of medical devices. Throughout 2022, inspections were completed for 1,419 devices applied for through the platform.

Section 3

Maximized International Exchange and Collaboration on medical Device Regulations

Tip station

Global Harmonization Working Party (GHWP)

Founded in 1996, GHWP is an important voluntary organization in the world for the harmonization of international medical device regulations and Chinese Taipei is one of the founding members. Having been elected as the Chair of Working Group 2 since 2012 and leading a total of 50 members from 20 countries or regions, Chinese Taipei actively participate in GHWP-related activities and works jointly to harmonize pre-market regulations for in vitro diagnostic (IVD) devices. Over the years, a total of 15 IVD guidance documents have been produced and endorsed at the GHWP Meetings.
Since 2015, under the leadership of Chinese Taipei, Working group 2 has collaborated regularly with the World Health Organization (WHO) and provided technical comments on 10 IVD documents. The results of which have been recognized by countries globally.

Introduction of the Policy

In light of growing emerging technologies and the quick changes in standards and regulations concerning medical devices internationally, TFDA is devoted to the promotion of international collaboration on medical devices, proactively taking part in international organizations, and seeking opportunities to hold international conferences and events in order to maximize international publicity and impacts and to help boost the international competitive advantages of local medical device manufacturers.

Implementation Strategy

I. Continued effort in promoting harmonization of international medical device regulations as an APEC RHSC Regulatory Science Training Center of Excellence for Medical Devices

TFDA became a formal APEC RHSC Regulatory Science Training Center of Excellence for Medical Devices in 2020 and has been holding related workshops endorsed by the APEC Regulatory Harmonization Steering Committee (RHSC). The “2022 TFDA Medical Devices Regulatory Science Center of Excellence Workshop” was held from August 26 through September 11, 2022 (Figure 5-1) through video conferencing and

Figure 5-1 2022 TFDA Regulatory Science Center of Excellence Workshop

online courses, which facilitated the sharing of principles for evaluating medical device safety and effectiveness with international standards and related experiences. TFDA also conducted activities such as keynote speeches, group discussions, case studies, and relevant courses and activities.

II. Proactive participation in GHWP in vitro diagnostic medical device related events

As the chair of the In Vitro Diagnostic Medical Device Working Group (WG2-Premarket: IVDD) of the GHWP Technical Committee (TC), Taiwan has attended important GHWP meetings and held working group discussion meetings regularly.

III. Promotion of third-generation Technical Cooperation Programme (TCP III)

The TCP started in 2004 and entered the second generation in 2013. In 2019, due to regulatory changes concerning the management of medical devices in both Taiwan and Europe, TFDA continued to plan and announce the third-generation TCP (TCP III) which will come into effect on January 1, 2022; thus effectively improving the quality of medical devices and help domestic medical device manufacturers strengthen their international competitiveness.

IV. Organization of workshops for exchange on international medical device regulations

The 2022 Conference on International Medical Device Regulations took place online from November 7 to December 2, 2022. Government officials from Indonesia, Malaysia, Saudi Arabia, Tanzania, Thailand, and Australia were invited to share their regulations governing medical devices. Regulatory experts from the EU and Singapore were also invited to share the post-market regulation of medical devices in the EU and the regulatory policy on AI/ML medical devices.

Achievements and Benefits

I. Holding the 2022 TFDA Medical Devices Regulatory Science Center of Excellence Workshop

TFDA Medical Devices Regulatory Science Center of Excellence Workshop was held in 2022. The overall satisfaction among participants was 4.5 (out of 5). A total of 53 trainees from the industry and academic sectors of 13 different economies were in attendance. After the completion of training, trainees were able to assist in promoting the concept of medical device standards to APEC member economies and to help achieve harmonization of regulations. This event fully demonstrates the regulatory capacity and review capability of Taiwan.

II. Spearheading GHWP in vitro diagnostic medical device working group related events

For GHWP TC WG2, which is led by Chinese Taipei, there are 15 global guidance documents relevant to in vitro diagnostic medical devices so far that have been endorsed at the GHWP Meetings. The accomplishments are well received internationally. The WG2 hosted a member meeting on August 24 (taking place both physically and online). Members from the WG1 and WG3 were invited to take part in discussions about revising the draft on "Categorisation of Changes to a Registered Medical Device" to strengthen the communication between Taiwan and New Southbound or other member countries and to increase Taiwan's visibility and involvement in international organizations.

III. Bonding audit resources in Taiwan and Europe to benefit supply of medical devices in both Taiwan and Europe

In response to the revision of EU medical device regulations and to effect of Taiwan's "*Medical Device Act*" on May 1, 2021, the third generation of Taiwan-Europe Technical Cooperation Program (TCP III) is being

promoted to take over the ongoing TCP II in order, to integrate international audit resources and advance management effectiveness.

IV. Organizing the Conference on International Medical Device Regulations

The 2022 Conference on International Medical Device Regulations was attended by a total of 350 representatives from the industry, government, academia, and research sectors. It has helped enhance stakeholders' understanding of the latest regulatory systems available for medical devices around the world and facilitated their expansion to the international market.

Section 4

Normalization of Management over Hygiene and Safety of Cosmetics

Introduction of the Policy

Since the *Cosmetic Hygiene and Safety Act* was officially enforced in 2019, the promotion of cosmetics notification and the cosmetic product information file system, the reinforced management over manufacturing sites throughout product life cycles, and the revisions made to the sanitation criteria for cosmetics have been ongoing in order to build a quality user setting for cosmetics, boost the hygiene and safety of cosmetics, and protect the rights of consumers. In view of the active circulation of cosmetics around the world, it is necessary to strengthen exchanges and collaboration with the competent authority for cosmetics and the industry in various countries in order to keep track of the latest status and development trends in the management of cosmetics.

Implementation Strategy

TFDA promoted cosmetics notification and the establishment of product information files in order to replace the specific purpose cosmetics registration system, expedite the introduction of products to the market, and allow consumers to search for product information online. Meanwhile, in light of the fact that the GMP for cosmetics was enforced on July 1, 2019, in order to reduce the impacts on manufacturers, a 5-year grace period was given to manufacturer. From July 1, 2024, onwards, the GMP for cosmetics will be implemented in phases for each type of product, in order to ensure the steady production of quality cosmetics. To cope with the frequent updates of laws and regulations concerning cosmetics around the world, TFDA continues to take part in related ICCR events, in order to keep the cosmetics management system in our country on par with its international counterparts and boost the

Tip station

International Cooperation on Cosmetics Regulation, ICCR

The International Cooperation on Cosmetics Regulation（ICCR）is an international organization composed of multinational cosmetics authorities and industry associations on a voluntary basis. The purpose is to promote and advocate the harmonization of international cosmetics regulations through multilateral communication, and reduce barriers to international trade, achieve and maintain the highest levels of global consumer protection.

In 2016, TFDA and Taiwan Cosmetics Industry Association joined ICCR as observers and became full members in 2020.

During this period, we actively participated in ICCR-related activities, to share and exchange experience in cosmetics management in Taiwan, and jointly produce work results reports.

TFDA will also take over as the chair of ICCR-18 in July 2023, further deepening the link of multilateral international relations and enhancing international visibility, to increase international visibility.

international competitiveness of our cosmetic industry.

Achievements and Benefits

I. Advancement in the Product Information File (PIF) system

On June 16, 2022, the amendment to Article 4 of the “Regulations for Cosmetic Product Information File Management” was released; those who graduated from the department of chemistry or chemical engineering-related departments in a domestic or international university, having met the criteria, may sign off on safety data. It helped the industry comply with the new system and reduce the compliance cost. The amendment to the “Guidelines on the Establishment of Cosmetic Product Information File” was announced on July 28, 2022. The PIF sample documents were prepared for different types of cosmetics (sun protection agents, hair dyes, perm agents, and balancing gels) and listed in the appendices to the “Guidelines on the Establishment of Cosmetic Product Information File” in order to increase familiarity among businesses with the applicable requirements and to successfully establish product information file.

II. Reinforced management over the composition of cosmetics and cosmetics for children

The amendment to the "List of Prohibited Ingredients in Cosmetics" was announced on April 27, 2022, with the addition of ingredients with related toxicities or pharmacological effects that will harm the skin or mucous membrane and are banned internationally such as Inula racemosa oil, rauvolfia serpentina, alkaloids and their salts, and Tripterygium wilfordii in order to protect the health of consumers. In addition, for the sake of protecting the health and safety of children in the use of cosmetics, the amendment to the "Guidelines for Safety of Children Cosmetics" was announced on August 17, 2022, with the addition of requirements such as clear distinction between cosmetics for children and foods in the appearance, and the need for children's cosmetics containing talc to include information about keeping the products away from the mouth and the nose, etc.

III. Improved international influence and attendance in the 16th ICCR meeting as official member

TFDA attended the 16th ICCR annual meeting online from June 28 to 30, 2022 as a full member to exchange and share information with the regulatory authorities and industries of 15 countries around the world and continued to take part in related events of the ICCR in order to keep track of the cosmetics developments around the world and to strengthen the connection between our country and the world in the cosmetic management system.

IV. Ensured product quality with the promotion of Good Manufacturing Practice (GMP) for cosmetics

In order to help cosmetic manufacturers meet GMP requirements as early as possible, TFDA held a total of 59 briefing/workshop/seminar sessions on laws and regulations between 2020 and 2022. By way of GMP experts visit manufacturing sites to help manufacturers review premises, facilities and documents, and give some suggestions for manufacturers to meet the GMP requirement. There were 546 such assistance/visit tours finished. Meanwhile, the GMP Self-Assessment Form was released for cosmetics manufacturers to use. GMP-related events continued to be held in the hope that manufacturers fulfill GMP requirements prior to implementation for respective stages.

Section 5

Improved Testing Technologies for Medical Devices and Cosmetics and Management over Molecular Testing Laboratories

Introduction of the Policy

Emerging medical devices and cosmetics are growing at a rapid rate and hence it is urgent to create technical platforms to support the qualification of various types of products, maximize test items, and develop or optimize the test methods to cope with domestic needs for the management of products. Meanwhile, the status and trends of tests around the world shall be kept track of through international technical exchange and collaboration in order to comprehensively boost the technical level of tests and to reinforce the research capabilities of TFDA to be comparable to those of international counterparts. In addition, for the sake of ensuring the quality of molecular testing laboratories for precision medicine in the nation, TFDA established the relevant operating regulations for registration of precision medicine molecular testing laboratories and embarked on related operations in 2019. The Ministry of Health and Welfare also announced on January 3, 2022, to entrust TFDA with laboratory certification.

Implementation Strategy

By constantly advancing the testing and analysis capabilities of laboratories, introducing emerging testing technologies, extablishing testing methods, and preparing technical documents for reference and use by all parties, TFDA comprehensively improves the technical level of tests performed, ensures the quality and safety of products and boosts the test capacity in our nation. Proactively taking part in periodic meetings and technical events of international organizations, exchanging and sharing progress made in testing technologies to keep track of the international testing status and trends as well as obtaining the latest information on substances of international interest enhance the testing technologies in our country to be in line with international counterparts. Establish the “Application Guidelines for Accreditation of Precision Medicine Molecular Testing Laboratories” and help businesses know for sure related application requirements. Accreditation has been available since July 1, 2022. Laboratories are confirmed to meet requirements through document review, on-site inspections, and reviews, among other procedures and the quality of tests performed by laboratories continues to be monitored through systems such as proficiency testing, aperiodic inspections, and inspections for an extension of the effective period, etc.

Achievements and Benefits

I. Establishment of testing and verification methods for innovative intelligent medical devices

In response to the needs of the post-pandemic era and the populatin aging trend, a draft method named "Ventilator System Test and Pressure Relief Test" was drawn in 2022, which helps ensure the safety and effectiveness of ventilators in the country. In light of the rapid developments of AI/ML in the medical imaging industry, the draft method for testing the stability of computer-assisted diagnostic software for ultrasound medical imaging was completed in 2022 to help ensure the accuracy of related diagnostic results.

II. Advancement in test technologies for cosmetics and medical devices

Eight testing methods, including the "Method of Test for Preservatives in Cosmetics (5)," have been published and 4 methods for testing cosmetics, including the "Method of Test for Colorants in Cosmetics," have been revised, that is, a total of 12 recommended testing methods for 94 items of cosmetics and medical devices have been published or revised in 2022.

III. Promotion of international exchange on test technologies for cosmetics

TFDA attended the 9th and 10th periodic joint meetings of CD-P-COS (European Committee for Cosmetics and Consumer Health) and OCCLs (European Network of Official Cosmetics Control Laboratories) in 2022 and discussed with experts from respective EU states issues such as the progress in the joint effort to establish methods for testing nitrosamines in cosmetics, proficiency test results of whitening cosmetic products, and post-marketing monitoring results of free formaldehyde in cosmetics, etc. Through proactive involvement in events of international organizations, TFDA strengthens collaboration and exchange with official EU network of cosmetics laboratories, secures channels and connections for international communications, and promotes test technologies for cosmetics in our country to be in line with international levels.

IV. Enhanced precision medicine molecular testing quality

As of the end of 2022, a total of 16 precision medicine molecular testing laboratories had been accredited. Most of them adopt next-generation sequencing (65%), with test items focusing primarily on cancer screening, diagnostics, treatment, and prognostic genetic testing (50%), for the sake of improving the quality of molecular testing in precision medicine.

6 Special Edition

Section 1 New Prospects for the Biological National Standard System

Section 2 The 10th anniversary on Joint Conference of Taiwan and Japan on Medical Products Regulation

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Section 4 Journal of Food and Drug Analysis (JFDA) for the Past 30 Years

2023

Something about TFDA

I just heard that another friend of mine has COVID-19. Since it first broke out, I have come to realize that the pandemic is becoming more common and it feels more and more like the flu.

Right. The last time I had it, you also told me not to make a fuss about it. Now, it is common for people to have COVID-19 and they only need to take a good rest and everything will be back to normal in a couple of days again.

Nevertheless, I have found that despite how widespread the pandemic is these days, there is a sufficient number of test kits to meet people's needs and there is no panic buying or shortages at all. You can get a test kit anywhere!

TFDA Chatroom

I'm surprised that you keep track of this! In fact, in order to cope with changes in the pandemic in real time and to gradually get back to business as usual as the pandemic becomes a part of everyday life, TFDA particularly conducted the co-calibration study with the UK National Institute for Biological Standards and Control (NIBSC) and 6 topnotch domestic laboratories, which would expedite the national standard preparation procedure while at the same time contributing to the improved credibility of test kits.

Wow! I was worried about the quality of readily available test kits. After having heard what you said, I am almost worry-free now!

Relax! Besides the co-calibration study, TFDA is constantly maximizing the scope of application for standards by devoting itself to the testing of the quality of COVID-19 antigen commercially available self-test kits and periodically inspecting commercial self-tests. It is meant to ensure that the diagnostic test kits that everyone uses are effective; otherwise, it is truly tiring to repeatedly qualify the accuracy each time a test is completed.

Right! With these protective measures, I do not have to be worried about an invalid test with the quick test kit after having poked my nose two to three times and repeatedly sneezing!

6

Special Edition

In 2022, TFDA welcomed multiple significant milestones. Besides coping with the pandemic and quick preparation of national standards by applying the many years of experience and control over medicinal products and medical devices, both the Taiwan-Japan Joint meeting and accession to PIC/S marked their tenth anniversary of gradually deepening international collaboration. The release of the JFDA and the implementation of GMP for medicinal products, on the other hand, reached their 30th and 40th year, respectively. All the accomplishments are well received.

Section 1

New Prospects for the Biological National Standard System

Introduction of the Policy

To support quality control over medicinal products and *in-vitro* diagnostic medical devices during research and development, a total of 20 biological national standards have been made available since 2004. In the early days, most standards were meant as controls for the quality of *in vitro* diagnostic reagents used in routine blood tests of viruses. Each standard usually takes 2 years to be prepared. However, in response to the urgent nature of the pandemic and the need to support businesses so that they could e fight against the pandemic. Therefore, TFDA strived to shorten the time required to establish a new standard.

Given the quickly changing nature of the pandemic, TFDA prepares the mainstream viral strain nucleic acid standards in real time and maximizes the scope of the application. At the same time, TFDA keeps close tabs on the quality of rapid test kits is safeguarded. New prospects for the application of standards are explored and expanded.

Implementation Strategy

I. Real-time response to pandemic changes to expedite the procedure for preparing national standards

TFDA managed to quickly prepare and supply the first-generation SARS-CoV-2 national standards within a year after COVID-19 first broke out in 2020. As of the end of 2022, it was already provided to 34 organizations. TFDA also assisted was provided to 7 of them in obtaining emergency use authorization (EUA). Such standards were already recognized through the symbol of national quality (SNQ) in 2021. Given the quickly changing nature of the pandemic, TFDA mobilized the standard preparation team in real-time by expediting the preparation of respective mainstream SARS-CoV-2 viral strains within a year. TFDA applied the WHO international standard preparation method and whole genome sequencing made possible with NGS to ensure genetic correctness. Meanwhile, the virus inactivation results were verified to ensure the safety of operators. In addition, the NIBSC and 6 topnotch laboratories throughout the nation were invited to conduct the collaborative study; the credibility and traceability of the standards were boosted by concurrently using the same international standards in the study.

II. Maximized scope of the application of standards as quality control standards for COVID-19 rapid antigen test

The Central Epidemic Command Center (CECC) announced in May 2022 that a positive rapid test result would be considered as a confirmed diagnosis, which significantly drove up the demand for rapid tests in the nation. TFDA initiated the auditing of commercial rapid self-tests in June 2022 and amended the “Regulations Governing Border Inspection and Examination of Imported Medical Devices” in July, with the implementation of border inspections for “COVID-19 rapid antigen tests”. Only those qualified products will be released. There were, however, no test methods, regulations, and applicable standards available around the world yet. In order to ensure the accuracy of rapid antigen tests, TFDA drafted and published the test method for the “COVID-19 rapid antigen tests” in compliance with the WHO guidance and guidelines announced by competent health authorities in respective countries. Two antigen standards (Wuhan strain and Omicron strain) were prepared and applied in quality control of COVID-19 rapid antigen tests in order to provide qualified *in vitro* diagnostic devices to our compatriots.

Achievements and Benefits

I. Enhanced capability in preparing national standards to deploy advanced epidemic control strength

In response to COVID-19, supplying safe and effective anti-pandemic resources to the public is the unchanged principle followed by TFDA. Our national laboratories devote themselves to prepare biological SARS-CoV-2 standards immediately, including the new generation of SARS-CoV-2 national standard, containing the Wuhan strain and 5 different variants (alpha, beta, gamma, delta, and omicron strain) and the antigen standard for the quality control of COVID-19 rapid test. Furthermore, the antigen standard has been used to ensure the quality of 20 brands (more than 50 batches) of COVID-19 rapid tests. In addition, TFDA published the method for testing "COVID-19 rapid antigen test" and it makes the academic and biotech industrial laboratories be able to gain the techniques required for COVID-19 rapid test development and standardization. It also harmonizes differences among laboratories and boosts the capacity to test the quality of rapid tests.

II. Internationally recognized capabilities of national laboratories in preparing standards

In order to assure the credibility of our national standards, TFDA invited international control laboratories in advanced countries such as the NIBSC in the UK to conduct the collaborative study in compliance with applicable WHO guidelines to the preparation of international biological standards where they could not only help one another define international or national standards but also cooperate with and supervise one another so that Taiwan is capable of preparing standards comparable to our international counterparts. In addition, the UK NIBSC is an international laboratory for preparing WHO biological standards. In the past, the world's topnotch laboratories in related fields were invited to join the collaborative study of international standards. TFDA is one of the few Asian national laboratories invited to take part in the collaborative study of the WHO first generation of SARS-CoV-2 international standards and again in 2023 for the second generation, indicating that the capabilities of our national laboratories are recognized by the international community.

Section 2

The 10th Anniversary on Joint Conference of Taiwan and Japan on Medical Products Regulation

Introduction of the Policy

In order to advance the collaboration between Taiwan and Japan on regulations of medicinal products and medical devices, the Taiwan-Japan Relations Association and the Japan-Taiwan Exchange Association signed the "Framework Agreement on Collaboration between Taiwan and Japan" on November 5, 2013. Since then, the Joint Conference of Taiwan and Japan on Medical Products Regulation began under this collaboration framework. Under the framework, TFDA, Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) formed the governmental working group that exchanges the latest regulations on medicinal policies in Taiwan and Japan. The parties take turns each year holding seminars on the bilateral side, and 2022 is marked as the tenth anniversary.

Implementation Strategy

I. In order to expand the domains and levels involved in the Taiwan-Japan collaboration on medicinal products and medical devices and to address globalization trends in the medical field, TFDA holds meetings with industries every year, to help directly communicate between regulatory authorities and industries, and also provide ideas on governing regulations or administrative measures, and discuss further in the general assembly.

II. Taiwan and Japan exchange information on regulations and review experiences through official working groups such as new drugs, generic drugs, good clinical practice and good manufacturing practice, non-prescription drugs, quality management systems, product registration, information exchange, mutual visits, and observations and learning from each other, and collaboration within the industry for deepened substantial exchange.

Achievements and Benefits

I. Taiwan-Japan interaction and developments in medical field

(I) Taiwan and Japan formed the preliminary framework for collaboration in the

review of new drugs in 2018 and have collaborated in the review of two pilot cases, and mutually signed the "New Drug Review Scheme between MHLW/PMDA and TFDA/CDE" in 2019, which marks an important milestone for the mutual exchange and collaboration in medicinal products. Through the substantial collaboration between Taiwan and Japan in the review of new drugs, we have completed 3 new drug reviewsand expedited the new drugs to the market. In addition, taking advantage of the bilateral collaboration experience, Taiwan and Japan jointly prepared the "FAQs on Taiwan-Japan Collaboration on New Drugs" in 2022, which will help industries in both Taiwan and Japan understand more clearly the application procedure and review mechanism available for the collaborative reviews of new drugs, contribute to transparent collaboration procedures, and expedite the new drugs to the market in both countries.

(II) Since November 30, 2018, when Taiwan-Japan Relations Association and the Japan-Taiwan Exchange Association signed the "Taiwan-Japan Medical Device Quality Management System Collaboration Memorandum" (QMS MOC), the parties have officially committed themselves to improving the manufacturing quality of medical devices. The "Medical Device Registration Scheme between MHLW/PMDA and TFDA/CDE" was established jointly in 2021 in an effort to promote bilateral collaboration on medical devices. In addition, the "FAQs on Quality Management Systems for Medical Devices between Taiwan and Japan" and the "FAQs on Registration of Medical Devices between Taiwan and Japan" were prepared to help medical device industries in both countries familiarize themselves with regulatory requirements while marketing their products to the market as soon as possible. Statistics up to the "Tenth Joint Conference of Taiwan and Japan on Medical Products Regulation" show a total of 44 Japanese manufacturers and 67 Taiwanese manufacturers benefited from the implementation of QMS MOC.

II. Gradual deepening of collaboration in medical field

(I) The parties continue to explore and exchange in related medical fields, including issues such as "applicable COVID-19 countermeasures," "orphan drugs," "harmonization strategy for regulations on medicinal products in Taiwan and in Japan," real-world

data," "self care therapy," "cross-regional clinical trials," "regulations on regenerative medicine," "nano-medicine drugs," "regulations on unique device identification (UDI)," "tumor testing instruments for next-generation sequencing," "medical device software," "in-vitro diagnostic devices," "3D-printing devices," and "artificial intelligence instruments," on order to gradually deepen bilateral collaboration.

(II) 2022 happened to mark the 10th anniversary of Taiwan-Japan exchange. In light of the far-reaching impacts of COVID-19 on public health around the world, both Taiwan and Japan have realized the importance of international collaboration and have prepared goals and development blueprints for the next 10 to 15 years to be followed. Action plans containing substantial items to be worked on together are jointly discussed and planned to be followed in future exchanges. Meanwhile, continuous efforts are being made in the promotion of mutual exchange and deepening, in enhancing medicinal management and review capacity in Taiwan, and in boosting harmonization between regulations and those internationally for the increased international competitiveness of the medicinal industry in Taiwan.

Section 3

Fortieth Anniversary of the Implementation of GMP for Western Medicinal Products and Tenth Anniversary of PIC/S Membership

Introduction of the Policy

In order to ensure the medication safety of the public, the GMP has been implemented since 1982 in our country. It had been upgraded to cGMP in 1995 (validation process) and further upgraded to PIC/S GMP in line with international norms since 2010. TFDA become a member of PIC/S in 2013, and the manufacturing quality of domestic medicinal products has been upgraded to international standards. The year 2022 coincides with the 40th anniversary of the implementation of GMP for western medicinal products and the 10th

Figure 6-1 Pictures taken during milestone event for the 40th anniversary of GMP and 10th anniversary of PIC/S membership

Figure 6-2 Vice President Ching-Te Lai presents awards to those contributing to the promotion of GMP for medicinal products

anniversary of PIC/S membership. TFDA host the "40th Anniversary of GMP Implementation for western medicinal products and the 10th Anniversary of PIC/S Membership" event on 12th September 2022 to review the progress of the implementation of GMP for Taiwan's pharmaceutical industry over the past 40 years as well as future prospects.

Implementation Strategy

I. Salute to heroes behind the scenes in promoting GMP for medicinal products

Vice President Ching-Te Lai attended the event. He presented awards to 11 contributors in the implementation of GMP for medicinal products, thanked those crucial promoters of the policy to be in line with the international GMP, and the heroes behind the scenes who had helped the industry grow and upgrade. He also encouraged the pharmaceutical industry to continue developing precision medicine and health digitalization based on a firm foundation of PIC/S GMP so that Taiwan will become an important hub for the global precision health industry.

II. Guardance of pharmaceutical quality and up to internationalization

Becoming a PIC/S member is an important milestone for pharmaceutical administration in our country and also the starting point for TFDA to devote itself to international affairs and to safeguard the manufacturing quality around the world with the other 54 PIC/S members. Paul Gustafson, the PIC/S chairman, expressed his congratulations via video and praised TFDA for its proactive involvement in the revision of international GMP regulations. GMP inspectors around the world have atteneded conferences in Taiwan many times to discuss the harmonization of GMP regulations together and to deepen collaborated partnerships with other countries. The efforts TFDA has made in quality management for medicinal products are seen by everyone and he also gives TFDA an affirmation of contribution in safeguarding medication quality in the international society.

III. Elites gathered together to be prepared for the future

Elites gathered at the event. Minister Jui-Yuan Hsueh of the Ministry of Health and Welfare had an opening speech, encouraging pharmaceutical industry to produce medicinal products with high-quality

so that medicinal products from Taiwan gain prominence internationally. Representatives from the medical, and pharmaceutical industry and the government were invited to attend the event; they explored strategies to transform the domestic pharmaceutical industries and to enhance competition from the perspectives of clinical medication in hospitals, suppliers of medicinal products, and government administrators. They gave keynote speeches on the topic of "Future Development Opportunities and Blue Ocean for the Pharmaceutical Industry in Taiwan" and shared the research on the clinical use of domestic drugs, issues and challenges faced by the pharmaceutical industry, the development trends and layout of the pharmaceutical industry, and cases of how the industry has successfully transformed on the basis of a firm GMP foundation, to provide learning and encouragement to the participants and give valuable suggestions to the government.

Achievements and Benefits

I. Pharmaceutical industry in Taiwan are united to create a new situation

The event was attended by more than 300 people. Elites from the medical community brainstormed and provided advice on opportunities and challenges for the pharmaceutical industry and how to boost confidence in medicinal products produced by domestic manufacturers. After the event, TFDA also published a publication in memory to witness the important moments throughout the 40th anniversary of the implementation of GMP in Taiwan and the 10th anniversary of PIC/S membership. TFDA will continue to work with the industry and improve the professionalism of the industry in sync with the international based on the firm GMP foundation, so that the public can access to medicine with the same quality as advanced countries and it is hoped that Taiwan will become a crucial hub of the global biotech chain for the future.

II. Safeguarding global medication together with PIC/S

Since TFDA accessed the PIC/S in 2013, we have used the PIC/S rapid alert to grasp warnings on GMP violations of international pharmaceutical manufacturers in real-time and to activate dispositions for medicinal products imported to Taiwan to implement consumer protection. The PIC/S has been devoted to the promotion of GMP Inspection Reliance in recent years. TFDA also deepens collaborated partnerships with other countries. The accomplishments in the GMP management of pharmaceutical manufacturers are obvious. Results are accepted directly by other

Figure 6-4 Pictures taken in the experience-sharing session of JFDA on October 13, 2022

countries such as the 10 ASEAN countries, Switzerland, Hong Kong, Principality of Liechtenstein, Ukraine, Sweden, Australia, Canada, the Netherlands, and South Africa, and international organizations such as the European Directorate for the Quality of Medicines & HealthCare (EDQM), etc. In the future, on the PIC/S international stage, TFDA will continue to establish collaborative mechanisms with other countries, integrate international resources, and make efforts to supervise the quality of medicinal products continuously.

Section 4

Journal of Food and Drug Analysis (JFDA) for the Past 30 Years

Introduction of the Policy

The Journal of Food and Drug Analysis (JFDA) was published for the first time in January 1993 by the former National Laboratories of Foods and Drugs (NLFD) under the Department of Health, Executive Yuan (the Agency, which was consolidated

under TFDA in 2010) for the purpose of releasing research accomplishments of its staff in foods and drugs such as testing and analysis of foods, medicinal products, medical devices, cosmetics, and herbal medicines through research papers, research notes, or review articles to allow exchanges with respective academic researches and to advance the research and development in applicable fields within our country. It was published in English (Chinese) in the beginning accompanied by Chinese (English) abstracts and gradually grew and has been published in English paper copies only since 2004.

Implementation Strategy

The JFDA has been available for more than 30 years and has managed to grow under the leadership of Editor-in-Chief over the years and devoted efforts of editing members as well as the collective wisdom of experts and scholars.

I. Defined as international scientific journal

The JFDA has been expected to become an international scientific journal since it was first created. In the beginning, it was published bilingually (Chinese and English) and has been gradually adjusted ever since. In 1996, when the Internet was yet to be popular, the English abstract was released on the official website to facilitate inquiries by readers. Meanwhile, overseas resources of papers were proactively explored, and international editing members were hired. It was qualified to be included in the Science Citation Index Expanded (SCIE) in 2003. Since 2013, it has been outsourced to the largest publishing company in the world for publication, and a full-text registry in the US medical literature database MEDLINE was successfully applied for in 2014 to make the Journal known to the world. In 2016, taking care of both environmental protection and promotion, it was published electronically instead; no paper copies have been available ever since.

II. Formation of outstanding editing team to strictly safeguard quality of papers

In the past, the Editor-in-Chief of the JFDA was a deputy chief of a government agency and staff of the specific agency would take care of its publication. Upon inception, for example, the Editor-in-Chief was the incumbent Deputy Director-General Erick Tsi-Tee Suen of the NLFD. Since 2012, professors of academic units have been asked to serve as Editor-in-Chief, such as Professor Lucy Sun Hwang from the National Taiwan University and outstanding scholars in the academia and research community in respective countries have been hired for the editing group. The online submission and review system was created by an international publishing company to facilitate the submission of papers by authors and reviews by editing members. In 2018, Professor Gow-Chin Yen of the National Chung Hsing University served

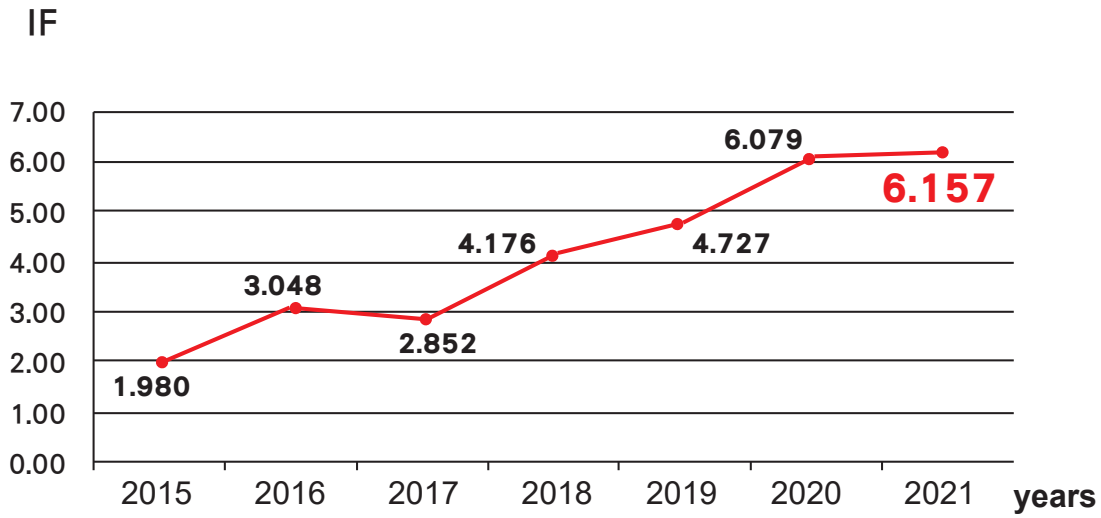


Figure 6-3 Trends in the IF over the years of JFDA

Table 6-1 History of awards conferred by the Ministry of Health and Welfare upon JFDA in publication rating campaigns

Year	Award
2014	Honorable mention - 3rd place among serial publications
2015	Outstanding - 3rd place among serial publications
2016	Honorable mention - 3rd place among serial publications
2017	Outstanding - 1st place among serial publications
2018	Outstanding - 2nd place among serial publications
2020	Outstanding - 2nd place among serial publications
2021	Honorable mention - serial publications

as Editor-in-Chief, and outstanding academic researchers in respective fields have been helping with reviews to safeguard the quality of submitted papers.

Achievements and Benefits

I. Expansion of international visibility of the Journal so that the world can see Taiwan

For the 30 years since the JFDA was first created, it has been published on the exclusive website electronically on a quarterly basis and special research topics have been released in exclusive editions. As of the end of 2022, 1,825 papers had been released in all, including 194 review articles, 1,631 original articles, and case reports. The number of countries of origin for the articles was up to 71 and the number of citations was up to 5,700. From the exclusive website, 136 countries had access to downloading journal articles, and such downloads were attempted 101,473 times. Articles in the Journal have also been registered in 11 topnotch databases around the world, including PubMed/MEDLINE, BIOSIS Previews, Excerpta Medica, Chemical Abstracts, International Food Information Service, Science Citation Index Expanded, and Scopus to make a difference.

II. Safeguarded quality of articles in the Journal and increased chances to be cited

Since 1998, the JFDA has been included as part of the Journal Citation Report (JCR) and the journal impact factor (IF) is adopted as the basis for the international ranking of the Journal. The IF of journal articles cited in the preceding year is released around July each year by the JCR. Since 1998, the IF of the JFDA has been growing from 0.145 and broke 1 for the first time in 2015. It reached 3.048 in 2016 and has been climbing each year ever since. The IF released in 2022 was 6.157 (Figure 6-3). All of these have been made possible thanks to the careful reviews of submitted articles by members of the editing group; because of them, quality articles get to be published.

The JFDA is the only SCI in the food and drug field released by the government throughout the nation now and submission and publication of articles are free of charge. Readers can also download the articles from the official website free of charge. It has spared no effort to help with academic promotion and has been recognized by the Ministry of Health and Welfare as a publication in its rating campaign (Table 6-1). High-quality articles will continue to be released in the future to hopefully create another 30 glorious years.



7 Appendix

Appendix 1 Important Events

Appendix 2 Important 2022 achievements and statistics

Appendix 3 Important achievements and statistics over the years

Appendix 4 TFDA Publications in 2022

Appendix 5 Related websites

Appendix 1. Important Events

Jan

January 1

Four medical device inspecting institutions approved by the Food and Drug Administration in our country and 6 European Notified Bodies (NBs) officially signed TCP III, which would officially take effect on January 1, 2022; it allows medical device manufacturers in Taiwan and in the EU to apply for expedited qualification of their medical device quality management systems.

Mar

March 8

The Taoyuan City Government held the “Launch Conference for the Taoyuan Food Safety Information Platform” and the Director-General of the Food and Drug Administration was invited to speak a few words and preside over the opening ceremony. Businesses can spontaneously release information about the origins of ingredients for foods prepared on the platform and it is linked with TFDA’s systems (The Registration Platform of Food and Medicinal Businesses, Food Traceability Management Information System, PMDS) and the smart agriculture shared information platform of the Council of Agriculture to provide people with correct information on food safety.

March 17

The Taipei Bakery Association held the “Taipei International Bakery Show,” which had more than 400 stands and multiple contests were organized throughout the show. President Tsai and the Director-General appeared for the opening ceremony.

May

May 5

The OTN of the Executive Yuan had the “Taiwan-US TIFA Mid-term Discussion Meeting” with the US.

Jun

June 26

TFDA held the “Pharmacist's Care: Safeguarding Medication Safety” Fair in Taipei Expo park. The President and other distinguished guests were invited to this event. TFDA, health departments from 17 towns, and regional pharmacist associations collaborated to construct booths for the event that were specifically focused on promoting medications. Through interactive techniques, the booths educated the public about appropriate pharmaceutical habits.

June 28-30

TFDA attended the 16th ICCR meeting online as an official member to exchange and share information with regulatory authorities and industries from 15 countries around the world. The meeting enabled TFDA to keep track of cosmetics developments around the world and helped connect Taiwan's cosmetics management system with the international community.

Jul

July 11 through August 11

The manufacturing plant of TFDA for controlled drugs was approved through the GMP review. It also received the manufacturing permit for the additional solution formulation and drug permits for Methadone Oral Concentrate and Morphine Sulfate Oral Solution. Mass production successfully began for solutions.

Aug

August 2

The 2022 National Pharmaceutical Control and Administration Conference was held with a total of 80 representatives, including those from the Department of Chinese Medicine and Pharmacy, the Food and Drug Administration under the Ministry of Health and Welfare and local health bureaus. The Conference helped to facilitate communication among health authorities for the promotion and implementation of various pharmaceutical affairs.

August 22-23

The “2022 Food Sanitation Management General Assembly” was held and health authorities from local governments were invited to take part. They discussed trends in the developments of emerging foods, the new food sanitation and safety management system, and other points and there were keynote speeches on diet-related pandemic surveys, national pesticide residue monitoring principles, and food safety challenges in the post-pandemic era, among others.

August 24

TFDA served as the chairperson of the second working group (for in-vitro diagnostic medical devices, WG2) of the GHWP and organized the WG2 meeting (in hybrid mode), where members of the first and third working groups of GHWP were invited to take part in discussions about cross-working-group in an effort to promote international harmonization of laws and regulations governing medical devices and to increase Taiwan’s international visibility.

August 26 through September 11

TFDA held the 2022 Medical Devices Regulatory Science Center of Excellence Workshop which consisted of online courses and online meetings. The workshop attracted a total of 53 students from 13 countries. It was hoped that the workshop could encourage relevant authorities in different countries to adopt international standards and improve the harmonization and consistency of criteria for the pre-market review of medical devices.

Sep

September 12

The “GMP Implementation 40th Anniversary and 10th Anniversary of PIC/S Membership” event was held. Vice President Ching-Te Lai appeared in person to encourage and present awards to contributors in the implementation of GMP for medicinal products and with the hope to boost industry-government-medical community-academia and research community collaboration and to continue helping the pharmaceutical industry of Taiwan in line with international.

September 13

The “APEC Online Communication Platform for Testing Techniques for Food-Pesticide Residue Workshop” was held. Six experts and scholars from TFDA, Canada, Peru, Japan, Thailand, and Vietnam gave keynote speeches and shared their experience in pesticide residue test technologies and monitoring. Through international experience sharing and exchange, attendees gained additional new knowledge about emerging pesticide test technologies and got to work with APEC member states.

Sep

September 14

The Engineering Audit Group of the Ministry of Health and Welfare visited TFDA for the maintenance and management of the "MOHW Controlled Drug Manufacturing Premises Construction and Renovation Project". The project consisted of the maintenance of the management system and the maintenance of operational quality and documentation; the total score was 90, an excellent rating.

September 15

TFDA held the "2022 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence (CoE) Workshop". More than 100 regulatory sciences experts from industries, regulatory authorities, and the academia among 12 APEC economies participated the workshop.

September 27

The "Promotional Briefing for Domestically Manufactured Medical Device for Domestic Use" was held to introduce high-quality domestically manufactured medical devices (including medical devices for hematology, internal medicine, surgery, and artificial intelligence-assisted diagnostics) to healthcare facilities and medical device businesses. Around 200 people attended the briefing.

Oct

October 3-7

TFDA Inspectorate deploys personnel to attend the Committee Meetings and Annual Seminars of the Pharmaceutical Inspection Co-operation Scheme (PIC/S). This enables us to remain stay updated on the latest GMP standards and regulations, engage in discussions with representatives from member countries regarding international cooperation, delve into the latest trends and challenges within pharmaceutical inspections, acquire professional knowledge and inspection techniques, and incorporate this information to bolster the knowledge and capabilities of our inspection units.

October 18

The "2022 U.S.-Taiwan Web Conference on Controlled Drugs" was held through online video conferencing and part of physical courses. US DEA Supervisor Jennifer Jimenez, UCLA Professor Yih-Ing Hser, Chair Professor Jhi-Joung Wang from the Chi Mei Medical Center, Division Director Chih-Peng Lin from the National Taiwan University Hospital, Deputy Superintendent Chih-Cheng Chien from the Cathay General Hospital, and Director Wei-Jen Chen from the National Health Research Institutes were invited to exchange with one another and share what they knew about the management of controlled drugs in Taiwan and the US and use of controlled drugs for medical purpose. The seminar attracted more than a hundred attendees from related government agencies.

October 20-21

TFDA held the "10th Joint Conference of Taiwan and Japan on Medical Products Regulation". Representatives from Taiwan and Japan shared the latest information of medical product regulations, digital tools for clinical trials, measures in response to COVID-19, and updated medical devices regulations. In addition, the 10th anniversary session was organized to retrospect the achievements between Taiwan and Japan over the past 10 years.

Nov

November 1

The signing ceremony for the “ROC (Taiwan) MOHW FDA and Paraguay DINAVISA Collaboration Agreement” was held. The Agreement was signed jointly by Director-General Show-Mei Wu and Acting Head of DINAVISA Jorge Iliou and witnessed by Deputy Minister of Health and Welfare Li-Feng Lee and Deputy Minister of Health of Paraguay Hernán Martínez. The parties will exchange on issues of mutual interest such as medicinal products, medical devices, and laboratory capabilities under this collaboration agreement framework.

November 7 - December 2

The 2022 Conference on International Medical Device Regulations was held online. Government officials from 6 countries were invited to share the latest developments in laws and regulations on medical devices. The topics covered included the medical device management system in response to COVID-19, post-marketing management of medical devices, and clinical evaluations of medical devices to help participants understand international laws and regulations on medical devices.

November 29

TFDA held the presentation ceremony for the “2022 National Pharmaceutical Technology Research and Development Award”. Minister Rui-Yuan Xue gave the opening speech and presented awards to winners of the gold, silver, and bronze medals for 12 items in the categories of medicinal products, medical devices, and manufacturing technologies. Meanwhile, winners of the gold medal shared their R&D accomplishments. There were the accomplishment display and media coverage sections outside the venue to help boost exposure of award-winning products and publicity of the Award. More than 150 people in total attended the event.

Dec

December 5

As part of the effort to promote the cosmetic manufacturers, compliance with Cosmetics Good Manufacturing Practice Regulations(GMP) and to encourage the cosmetic manufacturers who proactively applied for the inspection of GMP compliance and help to promote the cosmetics GMP policy, the “2022 Cosmetics GMP Commendation Conference” was held. The recommended manufacturers were invited to share their GMP experience of planning and implementation with the hope to boost the quality of cosmetics manufactured.

December 7

In order to encourage catering businesses to create their HACCP system and to boost the ability to manage food safety, catering businesses that were inspected and enforced compulsory HACCP with outstanding performance and those approved through the voluntary catering HACCP for the first time were recognized through the “Recognition Ceremony and Seminar on Food Safety Control Systems Created by Catering Businesses”; there were 109 attendees in total. Businesses and the Food Industry Research and Development Institute were invited to share their feedback on how to create a HACCP system and the trends in the catering industry.

December 13

The “2022 TFDA Smart Medical Device Product Launch” showcased the accomplishments of Taiwan's businesses in the R&D of intelligent medical devices with the support of TFDA.

Appendix 2. Important 2022 achievements and statistics

Exhibit 1. Additions and revisions to laws and regulations and standards on food safety and sanitation management in 2022

Date of announcement	Name	Important content
January 5	Point 36 of the "food businesses that shall enact the food safety monitoring plan and food inspection, minimum testing cycle, and other related matters" was amended.	Contents of the Food Safety Monitoring Plan defined by food manufacturers, processors, preparers, and importers are specified.
January 19	The "Regulations for the Security and the Maintenance of Personal Information Files in Food Businesses" were defined.	It is specified that food businesses of a certain scale and in the specific sector shall enforce applicable safety measures to help manage personal data in order to protect the safety and accuracy of personal data collected by food businesses.
January 27	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China."	1. CCC 0811.90.39.00-5 "Other frozen fruits and nuts, not containing added sugar or other sweetening matter", consisting of 1 item, was deleted. 2. CCC 0811.90.39.10-3 "Frozen sweet sop, not containing added sugar or other sweetening matter (excluding fruit puree and fruit pastes)", consisting of 2 items, was added.
February 10	The "Directions for the Health Authorities Approving the Catering-related Associations or Unions Issuing the Chef Licenses" were defined.	Consolidate the guidelines from the 2001 announcement by the former Ministry of Health and Welfare and introduce new regulations pertaining to the acquisition of chef certification, as well as procedures for staff suspension and resumption.
February 16	The "Regulation for The Use Restriction and Labeling Requirement of the *Ganoderma Microsporum* Globulin-like Protein Concentrate Produced by Genetically Modified *Pichia pastoris* Ey72 as a Food Ingredient" was defined.	It is specified the use restriction and labeling requirement of the *Ganoderma Microsporum* Globulin-like protein concentrate produced by fermentation process using genetically modified Pichia pastoris Ey72 for food purposes, including processing, *Ganoderma Microsporum* globulin-like protein content, daily intake, production source information and the warning statement of food products containing *Ganoderma microsporum* Globulin-like protein concentrate.
February 21	The "Food Types and Their Produced or Manufactured Areas from Japan Whose Imports are Suspended" were defined.	Types for which importation and inspection are discontinued and where they are produced or manufactured: 1. The Ministry of Health, Labor and Welfare of Japan released the "Overview of Restrictions for Exports to the Netherlands" that included the restricted items and products from the regions where they are produced or manufactured. 2. Wild bird and animal meat, mushrooms, and Chengiopanax sciadophylloides from Fukushima, Ibaraki, Tochigi, Gunma, and Chiba.

Date of announcement	Name	Important content
February 21	"Specific food from Japan must submit certificate of radiation test before they enter the food inspection application."	For items that are allowed to import to Taiwan from the five prefectures of Fukushima as well as mushrooms, fishery products, teas, dairy products, and baby foods from specific places of origin, the certificate of radiation testing shall be enclosed.
February 23	"The functional assessment method of health food for assisting in the regulation of blood pressure" was revised and the title was changed to "The efficacy assessment method of health food for assisting in the regulation of blood pressure".	1. Animal experiments were deleted. 2. Subject criteria, number of subjects, and safety monitoring items were revised. 3. The data statistics analysis methods and results determination regulations and health care claims were revised.
March 10	Article 4, Appendix 1 under Article 2, and Appendix 2 under Article 3 of the "Standards for Specification, Scope, Application and Limitation of Food Additives" were revised.	"Nitrogen" for quality improvement, brewing, and for food production and nutrition additive "Calcium L-5-Methyltetrahydrofolate" were added and the scope, limits, and specifications/criteria for the use of the nutrition additive "Lactoferrin" and specifications/criteria for the emulsifier "Diacetyl Tartaric Acid Esters of Mono-and Diglycerides" were modified.
March 17	The "Regulation for The Use Restrictions and Labeling Requirement of Aloe as a Food Ingredient" was defined.	It specified the use restrictions and labeling requirement of aloe for food purposes, including species of aloe, parts used, processing conditions, aloin content, and the warning statement of food products containing aloe.
March 17	The draft "Regulations Governing the Labeling of Restructured Meat Products" was amended and the title was changed as "Regulations Governing the Labeling of Restructured and Artificially Marbled Meat Products".	For artificially marbled foods that are prepackaged or sold in bulk by registered food vendors and supplied directly in a catering location, there shall be readily visible Chinese label that says "Artificially Marbled" or its equivalent and reminders such as "only for well cooked," or its equivalent shall be noted.
April 19	Amended Appendix Table 1 under Article 3 and Appendix Table 5 under Article 6 of the "Standards for Pesticide Residue Limits in Foods".	1. The maximum residue limits for 30 pesticides such as Acetamiprid on 62 crops were amended. 2. Baby mustard was classified in the group of cruciferous leaf vegetables with wrapped leaves.
April 19	Amended Article 3 of the "Standards for Pesticide Residue Limits in Animal Products".	The maximum residue limits (MRLs) of six pesticides including Boscalid were added/revised and the MRLs of 6 pesticides including Azocyclotin were revocated for animal products.

Date of announcement	Name	Important content
May 11	Amended the “Standards for Veterinary Drug Residue Limits in Foods”	Added maximum residue limits for Halquinol and Tildipirosin in the muscle, liver, kidney, and fat (including the skin) of pigs.
May 11	The “Regulations Governing the Labeling of Prepackaged Honey and Its Syrup Products” were defined.	According to the content of honey in packaged honey and its syrup products, the labeling of the product name and the place of origin for the honey as an ingredient was specified.
May 17	The “Notice of the COVID-19 Control and Management Measures for the Food Service” was amended.	1. In the event that foodservice industry personnel exhibit symptoms suggestive of COVID-19, the revised protocol dictates adherence to the pertinent pandemic prevention regulations as stipulated by the CECC. 2. Remove the “real-name registration” system. 3. In the event of confirmed COVID-19 cases in foodservice establishments, they should adhere to the relevant pandemic prevention regulations issued by the CECC. 4. Delete the provision “Those who have not completed improvements shall not provide dine-in services”.
May 25	Amended Appendix Table 1 under Article 3 of the “Standards for Pesticide Residue Limits in Foods”.	The maximum residue limits for Chlorpyrifos on 32 scrops were revocated.
May 31	Article 6 and Exhibit 3 under Article 5 of the “Sanitation Standard for Contaminants and Toxins in Food” were amended.	1. The requirement about restricted glycidyl fatty acid esters (GEs) in edible oils and fats was added. 2. The management over the limits for edible oils and fats supplied as cereal based foods and baby foods for infant and young child was further tightened.
June 7	Amended the “Regulations Governing the Labeling of Freshly Made Beverages in Chain Drink Stores, Convenience Stores, and Fast Food Restaurants.”	1. The labeling objects for total caffeine content were amended. 2. QR Code and other e-labeling options were added; meanwhile, the restrictions over the font size of the label were modified. 3. The items to be fulfilled when disclosure is done through QR Code or any other electronic way were added.
June 23	Amendment on partial articles of Regulations on Nutrition Labeling for Prepackaged Food Products.	1. Revision of the definition of Nutrition claims. 2. Revision of the unit of per serving shown at the nutrition labeling for tablets and capsules. 3. Revision of the units of amino acid to be gram or milligram, and the ways of labeling of vitamins, minerals, and rehydration products. 4. Revision of the consistency of the unit of per serving and the unit of 100 grams (or milliliters). 5. Revision of the conditions for "0" labeling of Caloric and Nutrients Value. And revision of the ways of the values of per serving shown at the nutrition labeling for food products in the form of tablets and capsules, and the labeling for the content of caloric and nutrients values.

Date of announcement	Name	Important content
June 29	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China."	1. CCC 0307.11.90.00-8 "Other oysters, live, fresh or chilled," consisting of 3 items, was deleted. 2. CCC 0307.11.90.10-6 "Ostrea edulis," consisting of 10 items, was added.
July 5	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of the Republic of China."	1. The requirement for the importation of CCC 0308.90.19.90-0 "Other aquatic invertebrates, live, fresh or chilled" was amended. 2. CCC 0712.31.90.00-3 "Other mushrooms of the genus Agaricus, dried" consisting of 3 items, was deleted. 3. CCC 0712.31.90.11-0 "Agaricus Blazei Murril (Agaricus subrufescens), dried" consisting of 11 items, was added.
July 5	Amendment to the "Import Regulation of 508 in Import Commodity Classification of Republic of China"; if the commodities are for food or food additives usage (including flavoring agents), the importer shall follow "Regulations of Inspection of Imported Foods and Related Products" to apply for inspection to the Food and Drug Administration, Ministry of Health, and Welfare.	CCC2906.29.00.00-8 "Other aromatic alcohols and cyclic alcohols and their halogenated, sulphonated, nitrated or nitrosated derivatives" was deleted and Requirement 508 for the importation of CCC2906.29.00.90-9 "Other aromatic alcohols and cyclic alcohols and their halogenated, sulphonated, nitrated or nitrosated derivatives" was added.
July 5	The "Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China" was amended. If the commodities are to be used in foods or as food additives (including flavoring agents), the importer shall follow the "Regulations of Inspection of Imported Foods and Related Products" and apply with the Food and Drug Administration under the Ministry of Health and Welfare for food inspections upon importation.	Requirement 514 for the importation of CCC0210.99.41.00-9 "Lu Pien (Cervi Penis), dried" was added.
July 11	It was defined that "Imported Livestock and Poultry Meat Products Shall Be Accompanied by Official Certificates Issued by the Competent Authority of the Exporting Country."	To import livestock and poultry meat governed by the Regulations for Systematic Inspection of Imported Food, official certificates issued by the competent authority of the exporting country shall be enclosed and importation inspections shall be applied for with the inspecting authority.

Date of announcement	Name	Important content
August 2	Appendix 1 under Article 2 of the “Standards for Specification, Scope, Application and Limitation of Food Additives” was amended.	The scope of use and limits of the nutrition additive L-cystine were revised.
August 3	The “Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China” was amended. If the commodities are to be used in foods or as food additives (including flavoring agents), the importer shall follow the “Regulations of Inspection of Imported Foods and Related Products” and apply with the Food and Drug Administration under the Ministry of Health and Welfare for food inspections upon importation.	1. CCC3002.15.00.00-5 “Immunological products, put up in measured doses or in forms or packings for retail sale” consisting of 1 item, was deleted. 2. CCC3002.15.00.90-6 “Other immunological products, put up in measured doses or in forms or packings for retail sale,” consisting of 1 item, was added.
September 3	The “Provision for Dairy Product Plants Shall Meet the Regulations on Food Safety Control System” was defined.	1. Special dietary foods and their indications were added or revised after they were reviewed and approved in the “Rare Diseases and Orphan Drugs Review Meeting.” 2. Numeration was deleted. Those repeated were combined. Names of manufacturers were added. According to the item and indication, 2 versions were rendered following the English alphabetic order. The systematic integration and modification were meant to facilitate inquiries by users.
September 3	The “Provision for Dairy Product Plants Shall Meet the Regulations on Food Safety Control System” was defined.	Based on the “Provision for Dairy Product Plants Shall Meet the Regulations on Food Safety Control System” announced to be amended in 2014 by the Ministry of Health and Welfare, the “Provision for Dairy Product Plants Shall Meet the Regulations on Food Safety Control System” was defined to make the terms in the existing Provision more defined and to govern the scale and products of applicable businesses.
November 1	Amended Appendix Table 1 under Article 3 of the “Standards for Pesticide Residue Limits in Foods” and Article 3 of the “Standards for Pesticide Residue Limits in Animal Products”.	1. The maximum residue limits (MRLs) 14 pesticides such as Acetamiprid on 68 crops were added or revised and the MRLs for 12 pesticides including Acephate on 30 crops were revocated. 2. The descriptions in Note 5 were amended reflective of amendment to the title of sample types in “Methods of Test for Pesticide Residues in Foods - Multiresidue Analysis (5)”. 3. The common name of the pesticide Pyribencarb was added. 4. The MRLs of chlorpyrifos in poultry and livestock products were revocated.

Date of announcement	Name	Important content
November 7	The "Notice of the COVID-19 control and management measures for the Food Service" was amended.	That "catering practitioners shall have their body temperature taken and health condition monitored" was deleted.
November 8	The "Regulations Governing the Labeling of Health Food" were amended.	1. Merge the regulation of the containers or packages of health food shall be labeled with the ingredients and content with health care effect or quality control. 2. The product conforming to the subparagraph 2 of paragraph 1 of Article 3 of the Health Food Control Act shall be labeled specific statements to disclose the health care effects of the product from academic theory not experiments in the behind of the description of "health care claims." 3. The experiments using animal model to assess the health care effect of the health food shall be labeled specific statements to disclose the health care effects based on the testing results from animal model in the front of the description of health care claims. 4. Health food with additional refined sugar over 17 grams of the recommended daily intake, fish oil, or red yeast rice shall be labeled specific statements on containers or packages to remind the health risk for consumers.
November 17	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China."	1. CCC 0307.79.00.90-7 "Other clams, cockles, and ark shells, dried, salted or in brine, smoked included" consisting of 5 items, was deleted. 2. CCC 0709.99.90.26-7 "Chengiopanax sciadophylloides, fresh or chilled" consisting of 3 items, was added. 3. The requirement for the importation of CCC 4419.19.00.00-6 "Other tableware and kitchenware, of bamboo" consisting of 5 items, was amended.
November 17	The "Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China" was amended.	Requirement 514 for the importation of CCC 0307.79.00.90-7 "Other clams, cockles and ark shells, dried, salted or in brine, smoked included" consisting of 2 items, was added.
November 17	Revise "Import Regulation of 508 in Import Commodity Classification of Republic of China" category list."	Requirement 508 for the importation of CCC 1302.20.00.00-9 "Pectic substances, pectinates, and pectates" consisting of 4 items, was added.

Remarks:

I. As of 2022, cumulatively, accumulated addition/revision of 7,552 pesticide residue limits; 1,530 veterinary drug residue limits; 17 food sanitation standards, 38 restrictions for food ingredients, and 796 food additives on the positive list had been defined in addition to the respective scope of use, limits, and specifications/standards.

II. 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. As of the end of 2022, 2,719 items of goods subject to inspections upon importation had been announced, including 2,122 in the import regulation F01, 130 in the import regulation F02, 378 in the import regulation 508, and 88 in the complex import regulation.

Exhibit 2 Guide to food sanitation management and operations released in 2022

Numbering	Announcement date	Announcement name	Description
1	February 10	Precautions of Applying for Food Hazard Analysis and Critical Control Point health accreditation in catering Industry	The title was amended to “Guide to Application for Food Hazard Analysis and Critical Control Point health accreditation in catering Industry” and so were the application eligibility, application documents, and effective period of the certificate in order to further define the application procedure.
2	March 30	Guidance of Food Manufacturers to Enact the Food Safety Monitoring Plan	According to point 36 of the “food businesses that shall enact the food safety monitoring plan and food inspection, minimum testing cycle, and other related matters,” food manufacturers, processors, and preparers were asked to enact a food safety monitoring plan that shall include four major items, “product manufacturing process and hazard analysis, process-related standard operating procedure, internal audits and supplier management, and training” and the quality assurance system was included in the Guidance with reference to the domestic and international management systems.
3	May 12	Application Process for Suitability of Raw Material in Recycled PET Pellets for Food Container and Packaging	1. The review procedures defined internationally for recycling and reproduction of food utensils in the US and the EU were referred to, including physical reproduction, case review principles, and decontamination test safety evaluation methods. 2. Businesses shall submit their application (manufacturers and importers of recycled PET pellets to be used in food utensils). 3. Following a formal administrative review, a substantive evaluation by experts, and consultation with the Food Risk Assessment Advisory Council, a formal response will be sent to the applicant, and the information will be made public on our TFDA’s website.
4	May 17	Guidance of COVID-19 Prevention for the Food Service Industry	The response measures for confirmed cases appearing in catering establishments have been amended to comply with the relevant pandemic prevention regulations of the CECC in the event of confirmed COVID-19 cases occurring at the venue.
5	May 24	Guidelines for the management of melamine detected in food	Management at international organizations and in respective advanced countries was referred to and guidelines and autonomous quality control measures to prevent and reduce contamination of foods by trace melamine were introduced. Management in respective advanced countries was referred and indicator values were introduced for the actions taken.
6	December 20	Guidelines for Evaluation of Expiry Dates of Prepackaged Food Products	Reflective of the adjustments made to sanitation standards, the “Sanitation Standard for The Microorganism in Foods to be Eaten Raw” cited in the Guidelines was amended as the “Sanitation Standards for Microorganisms in Foods.”

Exhibit 3 Inspection and registration of specific foods and food additives in 2022

Categories of food that should be registered		Number of valid permit document
Imported food in tablet and capsule form		7,543
Health Food		419
Food Additives		6,041
Genetically modified food		161
Special dietary food	Formula for certain disease	321
	Infant and follow-up formula	135
Domestically produced vitamin tablet and capsule food		1,466
Vacuum packaged ready-to-eat soybean food		49
Total		16,135

Exhibit 4 Food project of inspections and random inspections in 2022

Numbering	Project name	Results
1	HACCP Inspection Project for Processed Meat Industry	I. Inspected: 113 companies (I) GHP: 5 companies were not applicable, 77 companies were asked to correct by a given deadline, and 2 companies failed the re-inspections. (II) HACCP: 15 companies were not applicable, 91 companies were asked to correct by a given deadline, and 3 companies failed the re-inspections. (III) Food business registration: 1 company was not applicable, 32 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Mandatory inspection: 22 companies were not applicable, 34 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Traceability: 24 companies were not applicable, 36 companies were asked to correct by a given deadline, and 2 companies failed the re-inspections. (VI) Others: 1.5 companies stored expired foods. 2.5 companies did not have a hygiene inspector. 3.1 company did not hire professional staff or technical personnel. II. Labeling: All 312 cases were qualified. III.Random inspection: 210 cases (I) Raw meat: All 151 cases were qualified. (II) Processed products: All 59 cases were qualified.
2	HACCP Inspection Project for Meal Box Factories	I. Inspected: 72 companies (I) GHP: 1 company was not applicable, 40 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (II) HACCP: 1 company was not applicable, 52 companies were asked to correct by a given deadline, and 1 company failed the re-inspections. (III) Food business registration: 1 company was not applicable, 10 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Food safety monitoring plan: 64 companies were not applicable and the remaining 8 companies were all qualified. (V) Food Traceability Management Information System: 5 companies were not applicable, 19 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VI) Waste management: 1 company was not applicable, 8 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VII) Information about the origins of pork and beef was provided to downstream practitioners: 1 company was not applicable while all the other 71 companies met the requirement. (VIII) Others: 1. 2 companies stored expired foods. 2. 1 company did not hire hygiene inspectors. 3. 2 companies did not hire specialized professionals or technicians. II. Random inspection: 211 cases (I) Finished products: All 71 cases met requirements. (II) Semi-finished products: 4 cases out of 71 cases did not meet requirements. (III)Pork raw materials: All 69 cases met requirements.
3	HACCP Inspection Project for Canned Food Factories	I. Inspected: 69 companies (I) GHP: 29 companies were asked to correct by a given deadline and 2 companies failed the re-inspections. (II) HACCP: 41 companies were asked to correct by a given deadline and 3 companies failed the re-inspection. (III)Food business registration: 13 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV)Mandatory inspection: 22 companies were not applicable;2 companies were asked to correct by a given deadline and all were qualified through the re-inspections.

Numbering	Project name	Results
3	HACCP Inspection Project for Canned Food Factories	(V) Traceability: 19 companies were not applicable, 3 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (VI) Electronic declaration: 19 companies were not applicable, 11 companies were asked to correct by a given deadline and 1 company failed the re-inspections. (VII) Food safety monitoring plan: 37 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (VIII) Product liability insurance: All 69 companies met requirements. (IX) Others: 1.1 company did not hire hygiene inspectors. 2.1 company did not hire specialized professionals or licensed technicians. II. Labeling: 2 cases out of 165 cases did not meet requirements. III. Random inspection: All 115 cases met requirements.
4	Inspection Project for Food Additive Manufacturing	I. Inspected: 31 companies (I) GHP: 12 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 6 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Mandatory inspection: 3 companies were not applicable, 4 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Traceability: 2 companies were not applicable, 3 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (V) Electronic declaration: 3 companies were not applicable, 4 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VI) Food safety monitoring plan: 16 companies were not applicable, 3 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II. Labeling: All 42 cases met requirements. III. Random inspection: All 13 cases met requirements.
5	Inspection project for domestic source providers of health foods, vitamin tables and capsules and specialized nutritious foods	I. Inspected: 40 companies (I) GHP/Good operation practice for health food factories: 9 companies were not applicable, 4 companies were asked to correct by a given deadline and all qualified through the re-inspections. (II) Food business registration: All 40 companies were qualified. (III) Mandatory inspection: 16 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (IV) Use and management of food additives: 12 companies were not applicable, 3 companies were asked to correct by a given deadline, and all were qualified through the re-inspections. (V) Traceability: 17 companies were not applicable and all the remaining 23 companies were qualified. (VI) Food safety monitoring plan: 16 companies were not applicable and the remaining 24 companies were all qualified. (VII) Food Traceability Management Information System: 17 companies were not applicable, 2 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VIII) Retention of source documents: 4 companies were not applicable and the remaining 36 companies were all qualified. (IX) Waste management: 9 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (X) Registration: 1 case out of 82 cases did not meet requirements. II. Labeling: 3 cases out of 80 cases did not meet requirements. III.Random inspection: (I) Infant or follow-up formula food: All 10 cases met requirements. (II) Empty capsule shells: 1 case out of 12 cases did not meet requirements.

Numbering	Project name	Results
6	Inspection Project for Chocolate Products Manufacturers	I. Inspected: 58 companies (I) GHP: 24 companies were required to make improvements within a deadline and 1 company failed the re-inspection. (II) Food business registration: 9 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Mandatory inspection: 48 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (IV) Use and management of food additives: 34 companies were not applicable, 7 companies were asked to correct by a given deadline and 1 company failed the re-inspections. (V) Traceability: 48 companies were not applicable and all the remaining 10 companies were qualified. (VI) Food safety monitoring plan: 48 companies were not applicable and the remaining 10 companies were all qualified. (VII) Food Traceability Management Information System: 48 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (VIII) Waste management: 11 companies were asked to correct by a given deadline and were all qualified through the re-inspections. (IX) Product liability insurance: 1 company did not meet requirements. (X) Standard form contract: 21 companies were not applicable, 17 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (XI) Others: 1.3 companies stored expired foods. 2.1 company was found to have purchased chocolate transfer sheets from other countries online instead of going through inspections upon importation as required. II. Labeling: 6 cases out of 478 cases did not meet requirements. III. Random inspection: 1 case out of 92 cases did not meet requirements.
7	Inspection project for Edible Oil and Fat Manufacturing	I. Inspected: 45 companies (I) GHP: 24 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) HACCP: 40 companies were not applicable, 3 companies were asked to correct by a given deadline, and 1 company failed the re-inspections. (III) Food business registration: 12 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Mandatory inspection: 42 companies were not applicable and the remaining 3 companies were qualified. (V) Traceability: 29 companies were not applicable, 6 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (VI) Electronic declaration: 29 companies were not applicable, 6 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VII) Food safety monitoring plan: 42 companies were not applicable and the remaining 3 companies were all qualified. II. Labeling: 9 cases out of 74 cases did not meet requirements. III.Random inspection: All 79 cases met requirements.

Numbering	Project name	Results
8	Inspection Project for Bakery and Manufacturing Sites	I. Inspected: 172 companies (I) GHP: 84 companies were asked to correct by a given deadline and 1 company of them failed the re-inspections. (II) Food business registration: 2 companies were not applicable, 34 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Legitimacy of sources of food processing gases: 4 companies used such gases and all met requirements. (IV) Retention of source documents: 8 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Product liability insurance: 2 companies were not applicable and 1 company did not meet requirements. (VI) Bakery products labeling: 2 companies did not meet requirements. (VII)Others: 1.5 companies stored expired foods. 2.The labeling of oil and fat raw material product 1 case did not meet requirements. II. Random inspection: 1 case out of 309 cases did not meet requirements.
9	Inspection project for local grain supplements for babies and young children	I. Inspected: 25 companies (I) GHP: 2 companies were not applicable, 8 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (II) Food business registration: 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Gases to be used in foods: 21 companies were not applicable, 2 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (IV) Traceability: 20 companies were not applicable and all the remaining 5 companies were qualified. (V) Electronic declaration: 20 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (VI) Food safety monitoring plan: 20 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (VII) Product liability insurance: 1 company did not meet requirements. (VIII) Others: 2 companies stored expired foods. II. Labeling: 4 cases out of 62 cases did not meet requirements. III.Random inspection: All 30 cases met requirements.
10	Inspection Project for Beverage Ingredient Manufacturers	I. Inspected: 37 companies (I) GHP: 29 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 12 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Mandatory inspection: 36 companies were not applicable and 1 company met requirements. (IV) Use and management of food additives: 8 companies were not applicable, 19 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) raceability: 36 companies were not applicable and 1 company met requirements. (VI) Food safety monitoring programs: 36 companies were not applicable and 1 company met requirements. (VII) Food Traceability Management Information System: 36 companies were not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (VIII) Waste management: 13 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IX) Others: 1.1 company stored expired foods. 2.1 company did not hire hygiene inspectors. II. Labeling: 3 cases out of 43 cases did not meet requirements. III.Random inspection: All 46 cases met requirements.

Numbering	Project name	Results
11	Inspection project for liquid egg manufacturers	I. Inspected: 54 companies (I) GHP: 20 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) HACCP: 36 companies were not applicable, 13 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (III) Food business registration: 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Traceability: 48 companies were not applicable and all the remaining 6 companies were qualified. II. Labeling: All 120 cases of liquid egg products were qualified. III.Random inspection: 177 cases (I) Fresh raw eggs: 1 case out of 54 cases did not meet requirements. (II) Liquid egg products: All 123 cases met requirements.
12	Inspection Project for Pickled Eggs and Ready-to-Serve Eggs Manufacturers	I. Inspected: 25 companies (I) GHP: 16 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) HACCP: 21 companies were not applicable, 2 companies were asked to correct by a given deadline, and all were qualified through the re-inspections. (III)Food business registration: 1 company was not applicable, 9 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV)Others: 1. 1 company stored expired foods. 2. 1 company did not hire hygiene inspectors. II. Random inspection: 56 cases (I) Fresh eggs raw materials: All 19 cases met requirements. (II) Pickled and ready-to-serve eggs: All 37 cases met requirements.
13	Inspection Project for Soy Sauce Manufacturers	I. Inspected: 73 companies (I) GHP: 41 companies were asked to correct by a given deadline, and all were qualified through the re-inspections. (II) Food business registration: 14 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Retention of source documents: 1 company was not applicable and 3 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Product liability insurance: 1 company was not applicable and the remaining 72 companies met requirements. II. Labeling: 9 cases out of 183 cases did not meet requirements. III.Random inspection: All 110 cases of finished soy sauce products met requirements.
14	Inspection Project for Processed Aquatic Food Plants	I. Inspected: 76 companies (I) GHP: 44 companies were asked to correct by a given deadline and 1 company failed the re-inspections. (II) HACCP: 43 companies were not applicable, 25 companies were asked to correct by a given deadline, and 1 company failed the re-inspections. (III) Food business registration: 22 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Mandatory inspection: 50 companies were not applicable, 8 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Traceability: 44 companies were not applicable, 3 companies were asked to correct by a given deadline, and all were qualified through the re-inspections. (VI) Electronic declaration: 44 companies were not applicable, 12 companies were asked to correct by a given deadline and all were qualified through the re-inspections.

Numbering	Project name	Results
14	Inspection Project for Processed Aquatic Food Plants	(VII) Food safety monitoring plan: 64 companies were not applicable, 3 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VIII) Product liability insurance: 1 company did not meet requirements. (IX) Others: 1.3 companies stored expired food ingredients. 2.5 companies did not have a hygiene inspector. II. Labeling: All 146 cases met requirements. III.Random inspection: 1 case out of 115 cases did not meet requirements.
15	Inspection Project for Chinese Steamed Food Manufacturers	I. Inspected: 139 companies (I) GHP: 74 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 5 companies were not applicable, 26 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Product liability insurance: 1 company did not meet requirements. (IV) Others: 1.1 company stored expired food additives. 2.1 company did not hire hygiene inspectors. II. Labeling: 3 cases out of 374 cases did not meet requirements. III.Random inspection: 2 cases out of 210 cases did not meet requirements.
16	Inspection Project for Chicken Essence Products Manufacturers	I. Inspected: 67 companies (I) GHP: 7 companies were not applicable, 40 companies were asked to correct by a given deadline, and 1 company failed the re-inspections. (II) HACCP: 55 companies were not applicable, 9 companies were asked to correct by a given deadline, and all were qualified through the re-inspections. (III) Food business registration: 17 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Mandatory inspection: 55 companies were not applicable, 2 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Use and management of food additives: 65 companies were not applicable, 1 company was asked to correct by a given deadline, and was qualified through the re-inspections. (VI) Traceability: 55 companies are not applicable, 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (VII) Food safety monitoring plan: 64 companies were not applicable and the remaining 3 companies were all qualified. (VIII) Food Traceability Management Information System: 55 companies were not applicable, 2 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IX) Retention of source documents: 7 companies were not applicable and 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (X) Waste management: 7 companies were not applicable, 19 companies were asked to correct by a given deadline and 1 company failed the re-inspections. (XI) Standard form contract: 23 companies were not applicable, 14 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (XII) Others: 1. 1 company stored expired foods. 2. 4 companies did not hire hygiene inspectors. II. Labeling: 4 cases out of 102 cases did not meet requirements. III.Random inspection: 92 cases (I) Finished chicken essence products: All 57 cases met requirements. (II) Raw chicken: All 35 cases met requirements.

Numbering	Project name	Results
17	Inspection Project for Bean Products Manufacturers	I. Inspected: 101 companies (I) GHP: 65 companies were asked to correct by a given deadline and 2 companies were failed the re-inspections. (II) Food business registration: 1 company was not applicable, 31 companies were asked to correct by a given deadline and 1 company failed the re-inspections. (III)Product liability insurance: 3 companies were not applicable and 1 company did not meet requirements. (IV)Others: 9 companies did not hire hygiene inspectors. II. Labeling: 1 case out of 58 cases did not meet requirements. III.Random inspection: 3 cases out of 116 cases did not meet requirements.
18	Inspection Project for Microwave Food Manufacturers	I. Inspected: 40 companies (I) GHP: 1 company was not applicable, 14 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (II) Food business registration: 6 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Mandatory inspection: 8 companies were not applicable and the remaining 32 companies were qualified. (IV) Use and management of food additives: 4 companies were not applicable, 5 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Traceability: 8 companies were not applicable, 2 companies were asked to correct by a given deadline, and all of them were qualified through the re-inspections. (VI) Food safety monitoring plan: 8 companies were not applicable, 3 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VII) Food Traceability Management Information System: 8 companies were not applicable, 8 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VIII) Retention of source documents: All 40 companies were qualified. (IX) Waste management: 1 company was not applicable, 3 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (X) Others: 1 company stored expired foods. II. Labeling: 1 case out of 78 cases did not meet requirements. III.Random inspection: 89 cases: (I) Finished microwave foods: All 76 cases met requirements. (II) Plastic containers or utensils: All 13 cases met requirements.
19	Inspection Project for Pickled Vegetables Manufacturers	I. Inspected: 75 companies (I) GHP: 44 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 6 companies were not applicable, 11 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Product liability insurance: 9 companies were not applicable and 2 companies did not meet requirements. II. Labeling: 3 cases out of 75 cases did not meet requirements. III.Random inspection: 1 case out of 70 cases finished products did not meet requirements.
20	Random Inspection and Inspection Project for Pickled Vegetables Vendors	I. Inspected: 202 companies (I) GHP: 20 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 10 companies were not applicable, 8 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Retention of source documents: 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II. Labeling: 8 cases out of 253 cases did not meet requirements. III.Random inspections: 49 cases out of 444 cases did not meet requirements.

Numbering	Project name	Results
21	Inspection Project for Food Delivery Platform Operators	I. Food delivery operators: 7 companies (I) GHP: 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (II) Food business registration: 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (III) Standard form contract: 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (IV) Customer complaint handling process: 1 company was asked to correct by a given deadline and was qualified through the re-inspections. II. Food and beverage operators collaborating with food delivery platforms: 465 companies (I) GHP: 192 companies were asked to correct by a given deadline and 1 company of them failed the re-inspections. (II) Food business registration: 12 companies were not applicable, 98 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Product liability insurance: 32 companies were not applicable and remaining 433 companies were qualified. (IV) Labeling: 1 company did not meet requirements. (V)Random inspection: 2 cases out of 462 cases did not meet requirements. III.Service staff of food delivery platform: All 228 people met requirements.
22	Inspection Project for Restaurants in Popular Hotels	I. Inspected: 207 companies (I) GHP: 75 companies were asked to correct by a given deadline and were qualified through the re-inspections. (II) HACCP: A total of 19 companies should implement HACCP, of which 18 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Food business registration: 1 company were not applicable, 43 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Standard form contract: 162 companies were not applicable, 2 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V)Others: 1.3 companies stored expired ingredients. 2.2 companies did not hire professional staff. II. On-site labeling: 2 companies out of 207 companies did not meet requirements. III.Random inspection: 1 case out of 244 cases did not meet requirements.
23	Inspection Project for Noodles Restaurant Operators	I. Inspected: 177 companies (I) GHP: 69 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 9 companies were not applicable, 26 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Retention of source documents: 11 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Product liability insurance: 26 companies were not applicable and the remaining 151 companies met requirements. II. On-site labeling: All 177 companies met requirements. III.Random inspection: 2 cases out of 308 cases did not meet requirements.
24	Random Inspection Project for Drinks Made on Site	I. Inspected: 293 companies (I) GHP: 116 companies were asked to correct by a given deadline and no failure was found in the re-inspection. (II) Food business registration: 11 companies were not applicable, 26 companies were asked to correct by a given deadline and no failure was found in the re-inspection. (III)Management of food additives: 288 companies were not applicable and the remaining 5 companies were qualified. (IV)Retention of source documents: 22 companies were asked to correct by a given deadline and no failure was found in the re-inspection. (V)Others: 1 company stored expired foods. II. On-site labeling: 26 companies out of 204 companies did not meet requirements. III.Random inspection: 2 cases out of 401 cases did not meet requirements.

Numbering	Project name	Results
25	Inspection Project for Exotic Cuisine Restaurants	I. Inspected: 289 companies (I) GHP: 131 companies were asked to correct by a given deadline and no failure was found in the re-inspection. (II) Food business registration: 3 companies were not applicable, 53 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Product liability insurance: 33 companies were not applicable and 1 company did not meet requirements. (IV)Retention of source documents: 266 companies were qualified, 23 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V)Standard form contract: 272 companies were not applicable, 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VI)Others: 3 companies stored expired ingredients. II.On-site labeling: 3 companies out of 289 companies were not applicable and 1 company did not meet requirements. III.Random inspection: All 164 cases met requirements.
26	Inspection Project for KTV Catering	I. Inspected: 81 companies (I) GHP: 35 companies were asked to correct by a given deadline and all were qualified through the re-inspection. (II) Food business registration: 16 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Retain the source documents: 4 companies were asked to correct by a given deadline and all were qualified through the re-inspection. (IV)Product liability insurance: 1 company was not applicable and the remaining 80 companies met requirements. (V)Others: 1 company stored expired foods. II. On-site labeling: All 81 companies met requirements. III.Random inspection: 238 cases (I) Finished products: All 157 cases met requirements. (II) Edible ice or drinks: All 81 cases met requirements.
27	Random Inspection Project for Ice Products Made on Site	I. Inspected: 141 companies (I) GHP: 59 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 8 companies were not applicable, 18 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Retention of source documents: 19 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV)Hygiene of transportation vehicle: 117 companies were not applicable and the remaining 24 companies were qualified. II.Random inspection: 6 cases out of 215 cases did not meet requirements.
28	Inspection Project for Commercially Available Frozen and Refrigerated Prepared Foods	I. Inspected: 147 companies GHP: 33 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II.Random inspection: All 281 cases met requirements.
29	Inspection Project for Internet Celebrity Popular Restaurants	I. Inspected: 253 companies (I) GHP: 135 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 2 companies were not applicable, 47 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Labeling: 1 company did not meet requirements. (IV)Product liability insurance: 19 companies were not applicable and 1 company did not meet requirements. II.Random inspection: 3 cases out of 462 cases did not meet requirements.

Numbering	Project name	Results
30	Random Inspection Project for Breakfast and Brunch Businesses	I. Inspected: 319 companies (I) GHP: 154 companies were asked to correct by a given deadline and 1 company of them failed the re-inspections. (II) Food business registration: 14 companies were not applicable, 26 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Retention of source documents: 24 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Product liability insurance: 69 companies were not applicable and 1 company did not meet requirements. (V) Others: 1 company stored expired foods. II. On-site labeling: All 319 companies met requirements. III.Random inspection: 1 case out of 298 cases did not meet requirements.
31	Inspection project for multilevel marketing businesses	I. Inspected: 4 companies II.Labeling: (I) Food Labeling: 4 cases out of 23 cases did not meet requirements. (II) Cosmetics Labeling: All 21 cases met requirements. III.Field advertisement promotional leaflets: None out of 7 cases was found with non-conformity.
32	Inspection Project for the Food Logistics and Storage Industry	I. Inspected: 168 companies GHP: 32 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II.Food business registration: 6 companies were not applicable, 13 companies were asked to correct by a given deadline and all were qualified through the re-inspections.
33	Inspection Project for Food Utensils, Food Containers or Package Containing Plastic and in Contact with Food	I. Inspected: (I) Manufacturers: 25 companies 1.GHP: 6 companies were asked to correct by a given deadline and were qualified through the re-inspection. 2.Food business registration: 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. 3.Labeling: 1 case out of 48 cases did not meet requirements. (II) Distribution, catering: 1.Labeling: 2 cases out of 173 cases did not meet requirements. 2.Random inspections: None out of 26 cases was found with non-conformity.

Numbering	Project name	Results
34	Inspection Project for Chinese New Year	Random Inspection for Chinese New Year Market and Popular Foods Vendors I. Inspected: 317 companies (I) GHP: 12 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 6 companies were not applicable, 13 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Retention of source documents: 3 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II. Labeling: 1 case out of 1,124 cases did not meet requirements. III.Random inspection: 10 cases out of 1,449 cases did not meet requirements.
		Random inspection for New Year's dish restaurant I. Inspected: 55 companies (I) GHP: 30 companies were asked to correct by a given deadline and were qualified through the re-inspections. (II) Food business registration: 13 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Retention of source documents: 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV)Product liability insurance: All 55 companies met requirements. (V)Standard form contract: 1.Information shown in gift certificates: 50 companies were not applicable and 1 company was asked to correct by a given deadline and was qualified through the re-inspections. 2.Contents of standard form contracts concluded through correspondence for food or catering service: 46 companies were not applicable and 2 companies were asked to correct by a given deadline and were qualified through the re-inspections. (VI)Others: 3 companies stored expired foods. II. On-site labeling: 4 companies out of 55 companies did not meet requirements. III.Random inspections: None out of 108 cases was found with non-conformity.
		Inspection of Food Manufacturers for Chinese New Year foods I. Inspected: 45 companies (I) GHP: 22 companies were asked to correct by a given deadline and all were qualified through the re-inspection. (II) Food business registration: 7 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Use and management of food additives: 8 companies were not applicable, 10 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV) Retention of source documents: 2 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Waste management: 11 companies were asked to correct by a given deadline and were all qualified through the re-inspections. (VI) Product liability insurance: 1 company were not applicable and remaining 44 companies were qualified. (VII) Standard form contract: 14 companies were not applicable, 10 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VIII) Transportation vehicle hygiene management: 23 companies were not applicable and 1 company was asked to correct by a given deadline and was qualified through the re-inspections. (IX) Others: 2 companies stored expired foods. II. Labeling: 3 cases out of 132 cases did not meet requirements. III.Random inspection: 2 cases out of 132 cases did not meet requirements.

Numbering	Project name	Results
35	Random Inspection Project for Seasonal Festivity Foods -- Tomb-Sweeping Day	8 cases out of 743 cases randomly inspected did not meet requirements.
36	Hybrid Project for Dragon Boat Festival	Inspection of Rice Dumplings Manufacturers I. Inspected: 85 companies (I) GHP: 37 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 10 companies were not applicable, 19 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Product liability insurance: 18 companies were not applicable and remaining 67 companies were qualified. (IV) Retention of source documents: 9 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V) Standard form contract: 63 companies were not applicable, 4 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II. Labeling: 4 cases out of 186 cases did not meet requirements. III.Random inspection: 1 case out of 222 cases did not meet requirements.
		Inspection for retail businesses and random Inspection of dragon boat festival foods I. Inspected: 228 companies (I) GHP: 14 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II) Food business registration: 12 companies were not applicable, 17 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III) Retention of source documents: 6 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II. Labeling: All 650 cases met requirements. III.Random inspection: 3 cases out of 703 cases did not meet requirements.

Numbering	Project name	Results
37	Hybrid Project for Mid-Autumn Festival	Inspection Project for Moon Cake and Stuffing Manufacturers I. Inspected: 133 companies (I) GHP: 66 companies were asked to correct by a given deadline and 1 company of them failed the re-inspections. (II) Food business registration: 1 company was not applicable, 26 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Management of food additives: 28 companies were not applicable, 34 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV)Retention of source documents: 10 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (V)Standard form contract: 70 companies were not applicable, 20 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (VI)Others: 5 companies stored expired foods. II. Labeling: 5 cases out of 365 cases did not meet requirements. III.Random inspection: All 268 cases met requirements.
		Random inspection for Mid-Autumn Festival Foods: 3 cases out of 984 cases did not meet requirements.
		Inspection of Catering Businesses for Mid-Autumn Festival I. Inspected: 128 companies (I) GHP: 57 companies were asked to correct by a given deadline and 1 company of them failed the re-inspections. (II) Food business registration: 1 company was not applicable, 13 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Retention of source documents: 8 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (IV)Product liability insurance: 1 company were not applicable and remaining 127 companies were qualified. (V)Standard form contract (gift certificate): 123 companies were not applicable and the remaining 5 companies were qualified. (VI)Standard form contract (correspondence): 124 companies were not applicable and the remaining 4 companies were qualified. (VII)Others: 2 companies stored expired foods. II. Labeling: All 128 cases met requirements. III.Random inspection: All 128 cases met requirements.
38	Inspection Project for Seasonal Festivity Foods -- Winter Solstice	Random inspection: All 530 cases met requirements.
39	Inspection Project of Catering Businesses for Providing Lunch to Schools	I. Inspected: 682 companies GHP: 99 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II.Random inspection: (I) Finished products and semi-finished products for lunch: All 676 cases met requirements. (II) Pork-related ingredients: All 237 cases met requirements. (III)Grouper: All 21 cases met requirements. III.Disclosure of information about origins of pork ingredients to the downstream: All 485 cases met requirements.

Numbering	Project name	Results
40	Inspection Project of Lunch-preparing Kitchens on Campus	I. Inspected: 2,476 companies GHP: 151 companies were asked to correct by a given deadline and all were qualified through the re-inspections. II. Pork origin labeling: All 2,682 cases met requirements. III.Random inspection: (I) Finished products for lunch: All 2,232 cases meet requirements. (II) Semi-finished products: All 136 cases met requirements.
41	Commercial Imported Radionuclide Testing and Labeling Project	Random Inspection Project for Radionuclides in Imported Foods Available on the Market I. Random inspection: (I) Japanese foods purchased online: All 100 cases met requirements. (II) Imported foods purchased in physical stores: All 100 cases met requirements. II.Labeling: 100 cases Japanese foods were inspected and all met requirements.
		Maximized Inspection Project for Radionuclides in Japanese Foods Available on the Market Random inspection: All 1,512 cases met requirements.
		Inspection Project for the Labeling of Place of Origin for Japanese Foods Available on the Market 38,247 cases Japanese foods were inspected and all met requirements.
42	Pork, beef, and their edible portions as food ingredients Inspection Project for the Labeling of Place of Origin	Labeling: 22 cases out of 31,128 cases did not meet requirements.
43	Inspection Project for Dioxin in Foods - Aquatic Products	Random inspection: All 33 cases met requirements.
44	Inspection Project for Dioxin in Foods - Meat, Eggs, and Dairy Projects	Random inspection: All 35 cases met requirements.
45	Inspection Project for Dioxin in Foods - Botanical Agricultural Projects	Random inspection: All 32 cases met requirements.
46	Test Project for Residues in Eggs Exported to the European Union	Random inspection: All 120 cases met requirements.
47	Ethylene Oxide Inspection Project for Ice Cream and Instant Noodles Manufacturers	I. Inspected: 18 companies (I)GHP: 4 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (II)Food business registration: 2 companies were asked to correct by a given deadline and all were qualified through the re-inspections. (III)Legitimacy of ingredients: All 18 companies were qualified. (IV)Food safety monitoring plan: 1 company was not applicable and the remaining 17 companies were all qualified. (V)Product liability insurance: All 18 companies met requirements. (VI)Others: 1 company stored expired foods additives. II. Labeling: All 18 companies met requirements. III.Random inspection: None of 18 cases was found with EtO.

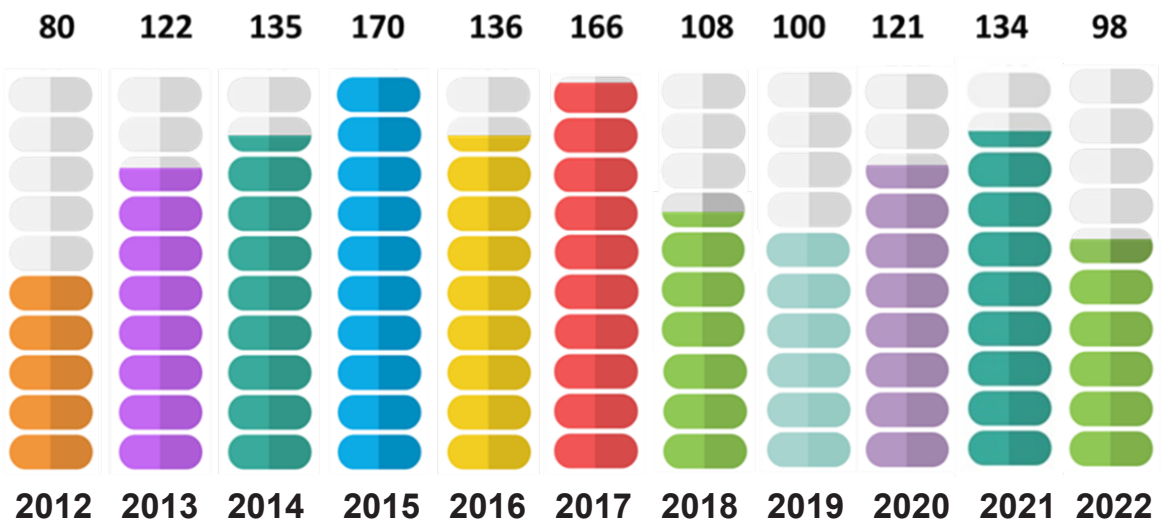
Exhibit 5 Additions and revisions to laws, regulations, and standards on drug management in 2022

Date of announcement	Name	Important content
January 13	The "*Regenerative Medicinal Products Act*" (Draft) was announced.	The Draft Act was established to provide early access to regenerative medicinal products for the general public and to boost the development of the regenerative medicine industry, aiming to provide well-established management for regenerative medicinal products.
January 27	The "ICH Q6B: Guidance on Specifications: Test Procedures and Acceptance Criteria for Biotechnological/ Biological Products" was announced.	The guidance establishes general principles for proteins and polypeptide products that are produced from recombinant or non-recombinant cell-culture expression systems.
February 24	The updated version of "The list of ICH guidelines adopted" was announced.	The list aims to assist the pharmaceutical industry to follow and for reference, describe ICH guidelines key points, scope of applications and the corresponding reference materials in Taiwan.
April 15	The "Regulations for the Management of Drug Safety Surveillance" was amended.	To perfect the pharmacovigilance system in our country, the scope of application of pharmacovigilance, the duration of data storage and data transfer, the Pharmacovigilance Plan, the format of the report prepared, and drug safety inspections, among other applicable requirements were amended, and added in an effort to consolidate the pharmacovigilance system in our country.
April 21	The "ICH Q5B: Guidance on Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products" was announced.	The guidance provides suggestions on the characterization of the expression construct for the production of recombinant DNA protein products in eukaryotic and prokaryotic cells and assessing the structure of the expression construct used to produce recombinant DNA derived proteins.
July 1	The "Guidance on NDA for Gene Therapy Medicinal Products" was announced.	In response to the international trend in the development of regenerative medicinal products, TFDA established this guidance with reference to international standards and described the review considerations for gene therapy medicinal products, providing the basis for the industry during research and development and promoting the development of gene therapy medicinal products in Taiwan.
July 20	The "Regulations on Good Practices for Drug Dispensation" were amended.	For the sake of advancing the domestic pharmaceutical service quality and to connect with the world, international regulations were referenced and the current pharmacy status in our country was taken into consideration while the Regulations were amended for perfecting the dispensing process for medicinal products.
July 27	The "Regulations for Approval of Specific Medicinal Products' Manufacturing or Importing as a Special Case" was amended.	Requirements over materials to be enclosed in the application for approval of specific medicinal products, additional provisions that may be added upon approval, disclosure of information, effective period, and matters that shall be reported and documented following an extension, change, and approval. It will be considered as a safety or medical efficacy concern if the additional provisions or the expected items are not enforced.

Date of announcement	Name	Important content
August 31	The “ICH E2F: Guideline on Development Safety Update Report” was announced.	This guidance includes the criteria for submitting reports on medicinal products researched and developed (including further studies of medicinal products already available on the market) periodically and the recommended contents and formats of the DSUR as well as an overview of important points to be considered while preparing and submitting the report.
September 2	The “Regulations for Reporting Severe Adverse Reactions of Medicaments” (Draft) was announced.	In light of the fact that the Regulations had not been amended for more than 18 years since they were first released and enforced and that current articles and contents no longer reflect applicable international requirements about reporting, it was intended to better applicable regulations. Highlights of the amendment include modified reporting methods, contents, and duration; and pharmaceutical dealers are asked to investigate, evaluate, and follow up on reported cases.
September 30	The “Key Points of Review for new chemical entities (excluding biological medicinal products) that have been approved for market in A10 countries for over 5 years” was amended.	The amendments aim to ensure the quality, safety, and efficacy of medicinal products, as well as the consistency of review standards for all new chemical entities, and promote the accessibility of new drugs.
October 12	The “Guidance on Considerations for Analysis of Sex Differences in Clinical Trials” was announced.	In light of the importance of including sex differences as part of the considerations for clinical trials of medicinal products, this guidance was announced and provided to the medicine community and academic research units for their reference. This guidance is the first clinical trial guide promoting sexual and health equality.
October 24	The “Guidance on The Q3D implementation procedure for the control of elemental impurities” was announced.	To go with the limits, analysis method, and heavy metal testing indicated in General Provisions: Element Impurities of Chinese Pharmacopeia of the 9th edition and with reference to how they are implemented in the European Union, the United States, and Japan, the implementation schedule and method for the control of element impurities in medicinal products in our country were defined and announced.
November 2	The draft amendment to the drug categories in the trace and track system in Article 6-1 of the “*Pharmaceutical Affairs Act*” was announced.	In order to keep illicit drugs out of the legitimate supply chain, TFDA continued to analyze data of NHI-covered drugs that have been declared and modify drug items of high interest on a rolling basis in order to protect medication safety. This is why the amendment was announced in advance.
November 3	Article 19-1 of the “Regulations on Management of Medicament Samples and Gifts” was amended.	For enhanced administrative efficiency and to keep the process flexible, Article 19-1 was added to the Regulations. It specifies that, if necessary, the central competent health authority may delegate all or part of the review of drug samples or gifts applied to any of its subordinate agency or commission to any other related agency (institution), legal entity, or organization.

Date of announcement	Name	Important content
November 7	The “Guidance on NDA for Cell Therapy Medicinal Products” was amended.	Given that cell therapy medicinal products were approved one after another around the world and the development of cell therapy also grew quickly domestically, in order to meet the updated international management standards, TFDA amended this guidance, describing the review considerations for cell therapy medicinal products regarding manufacturing and control, non-clinical, and clinical data.
November 10	The “ICH Q5D: Guidance on Derivation and Characterization of Cell Substrates Used for Production of Biotechnological/Biological Products” was announced.	This guidance provides appropriate standards for the derivation, preparation, and characterization of cell lines, microbial cells from humans and animals and cell banks to be used to prepare biotechnological/ biological products, with recommendations on the information in these areas that should be presented in marketing applications for such products.
November 17	The “Guideline on Conducting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data” was announced.	Real-world Evidence (RWE) is the international clinical application trend. To promote the domestic drug R&D, FDA considered into the latest international management practices and stipulated relevant guidelines as reference for the industry to follow.
November 25	The “ICH E14: Guidance on The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-antiarrhythmic Drugs” and FAQs were announced.	This guidance and its FAQs were announced for the sake of establishing internationally harmonized clinical trial management regulations of medicinal products and to be followed by the outside world on safety update reports of medicinal products being researched and developed.
November 28	The “Regulations for Application and Deliberation of Drug Injury Relief” (Draft) was announced; the “Regulations Governing Reviewing Procedure of Drug Injury Review Committee of Ministry of Health and Welfare” and the “Regulations for Drug Injury Relief Application” would be abolished.	In order to consolidate the drug relief application procedure, the payment, and matters relevant to the organization of the Review Committee and the review performed, the draft amendment of “Regulations for Application and Deliberation of Drug Injury Relief” were prepared and the “Regulations Governing Reviewing Procedure of Drug Injury Review Committee of Ministry of Health and Welfare,” the “Regulations for Drug Injury Relief Application,” and the “Drug Injury Relief Payment Standard” were abolished.
December 6	The “ICH E18: Guideline on Genomic Sampling and Management of Genomic Data” was announced.	The ICH released its ICH E18 guidance in 2017 to serve as the fundamental principles for genomic sampling and genomic data management relevant to clinical trials and provided advice on sampling, storage, and proper use to facilitate genomic studies.
December 8	The draft amendment to the list of essential drugs in Article 27-2 of the “*Pharmaceutical Affairs Act*” was announced.	To strengthen the mechanism for manufacturers to announce in advance the insufficient supply of essential drugs and to normalize the reporting and evaluation management system in case of shortage in the supply of drugs, it was announced in advance that the said List would be amended.
December 29	The “ICH E16: Guideline on Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions” was announced.	This guidance provides recommendations on biomarker qualification for the development of drugs or biological products, and the submitted data shall be complied with the CTD format.

Exhibit 6 Quantity of new drugs approved in 2022



*Based on the number of permits.

Among the 98 approved new drugs, new dosage forms, new administration doses, and new strengths medicinal products, NCE accounted for 29, biological products accounted for 38, and gene therapy medicinal products accounted for 1. They are indicated for diseases such as cancer, rare diseases, endocrine disorders, and diabetes, which provide new treatment options for patients.

Exhibit 7 Additions/Revisions to the classification of controlled drugs announced in 2022

Date of amendment	Schedule	Promulgate the names of the controlled drugs
March 8	Schedule 2	Isobutyrfentanyl and others, 38 items in total, were added.
	Schedule 3	2-Aminoindane (2-AI) and others, 255 items in total, were added.
	Schedule 4	Sibutramine and others, 2 items in total, were added.
	Schedule 4 Active Pharmaceutical Ingredients	Fluoroephedrine and others, 4 items in total, were added.
October 31	Schedule 3	*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-butyl-1H-indazole-3-carboxamide (ADB-BUTINACA) and others, 9 items in total, were added.
	Schedule 4 Active Pharmaceutical Ingredients	Chlorophenylacetone (including its isomers 2-Chloro, 3-Chloro, and 4-Chloro], 3 items in total, were added.

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

Exhibit 8 Addendum/amendment to laws, regulations and standards related to medical devices management in 2022

Date of announcement	Name	Key points
January 20	The “Regulations for the Security and the Maintenance of Personal Information Files in Non-Ionizing Radiation Electronic Medical Device Manufacturers” was amended .	The Regulations specify that electronic medical device and equipment manufacturers shall prepare a personal information file security maintenance plan and other related matters, such as how personal information shall be processed after operations are terminated.
January 21	The “Regulations for the Security and the Maintenance of Personal Information Files in Wholesaling and Retailing Medical Devices” was announced.	The Regulations specify that medical device wholesalers or retailers who retain personal information files shall prepare a personal information file security maintenance plan and adopt various measures to protect such data against data breaches.
February 14	The “Technical Guidance for the Registration and Market Approval of Artificial Intelligence/Machine Learning-Based Computer Aided Triage (CADt) Software as a Medical Device (SaMD)” was announced.	The guidance explains the information to be attached for the registration and market approval of CADt products and foci of review.

Date of announcement	Name	Key points
March 3	The “The Illustrations and Examples of Clinical Trials for AI/ML-Based SaMD with Non-Significant Risks” was announced.	To provide illustrations and examples of clinical trials for AI/ML-Based SaMD with non-significant risks for reference.
March 8	The “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” was announced.	The announcement listed 38 medical devices whose Chinese instructions may be replaced by electronic instructions.
April 22	The “Reference for the Use of Real World Data and Real World Evidence To Support Regulatory Decision-Making for Medical Devices” was announced.	The scope and principles for applying real-world data and evidence to the research and development, marketing, and management of medical devices were provided.
June 10	The “FAQs on Cybersecurity for Pre-marketing Review of Mobile Medical Applications and Medical Devices” and the “FAQs on Applications for Post-marketing Alteration of SaMD” were announced.	The FAQs were provided to be used as references by all parties when they plan for pre-marketing reviews of mobile medical applications and post-market changes of Software as Medical Device (SaMD).
July 8	The “Regulations Governing Border Inspection and Examination of Imported Medical Devices” was amended.	COVID-19 antigen self-test kits were included in random inspections of border inspection.
July 19	The “Operational Guidelines for Importing Medical Device Raw Materials for Self-Use, Food and Drug Administration, Ministry of Health and Welfare” was amended.	The affidavit importing medical device raw materials for self-use and the import permit application form were revised.
July 20	The guidances for pre-clinical testing for 3 medical devices, namely, “portable oxygen generator,” “biological indicator for sterilization,” and “focused ultrasound stimulator system” were announced.	The guidances were provided to be used as references by manufacturers during the phase of product development and verification, as well as for the preparation of registration and market approval materials.
August 31	The “Technical Guidance for the Registration and Market Approval of AI/ML-based Computer Aided Detection (CADe) and Computer-Aided Diagnosis (CADx) Software as a Medical Device” was announced.	The guidance explained information to be enclosed and review highlights for the registration and market approval of CADe and CADx products and foci of review to be used as references.
September 15	The “Guidance for Medical Software Classification” was amended.	Examples of medical software that is not a medical device in nature were added or revised to help respective parties know the types of softwares that are not medical devices.
December 1	The “Guidance for Respiratory Viral Panel Multiplex Nucleic Acid Assay” and the “Guidance for Thyroid Stimulating Hormone and Total Thyroxine Assay” were announced.	The guidances were provided to be used as references by manufacturers during the phase of product development and verification, as well as for the preparation of registration and market approval materials.

Exhibit 9 Additions/Revisions to applicable laws, regulations, and standards for cosmetics in 2022

Date of announcement	Name	Important content
January 27	The “Personal Data File Safety Protection Plan Implementation Guidelines for Cosmetics Wholesalers and Retailers” were announced.	It is specified that cosmetics wholesalers or retailers if they retain personal data files, shall define their personal data file safety protection plan, and adopt respective safety protection measures to prevent disclosure of personal data.
April 27	The “List of Prohibited Ingredients in Cosmetics” was amended.	The “List of Prohibited Ingredients in Cosmetics” was amended for the sake of protecting consumer hygiene, safety, and personal health, and reflecting international management trends.
June 16	Article 4 of the “Regulations for Cosmetic Product Information File Management” was amended.	It was added that those who have a bachelor’s degree or higher in chemistry or chemical engineering-related majors before June 30, 2019, having engaged themselves in safety evaluation-related tasks in the cosmetics industry for at least five years and having completed training programs on cosmetics safety evaluations may serve as safety data signatories.
July 28	The “Guidelines on the Establishment of Cosmetic Product Information File” was amended.	In order to expedite the establishment of product information files, PIF sample documents for different types of cosmetics (sun protection agents, hair dyes, perming agents, and balancing gels) were added to the appendices, and the latest information available internationally was referred to while contents of the Guide were updated.
August 17	The “Guidelines for Safety of Children Cosmetics” was amended.	For the sake of protecting the health and safety of children in the use of cosmetics, requirements such as clear distinction between cosmetics for children and foods in the appearance and the need for children’s cosmetics containing talc to include information about keeping the products away from the mouth and the nose, etc. were added.

Exhibit 10 Joint food, drugs, and cosmetics inspections throughout 2022

Inspection type	Numbering	Project name (implementation time)	Results
Food safety	1	Inspection Project for Origin Labeling of Marketed Tea Products (September 2021 - December 2022)	57 businesses (88 sites) were inspected and 221 tea products were randomly checked; among them, 38 cases were suspected to contain offshore tea.
	2	Joint oyster origin labeling inspection project (December 2021 - December 2022)	Inspected a total of 107 companies. Among them, 91 cases were about the labeling of oyster products or menu descriptions of oyster choices. 12 cases of them were about oyster products in bulk found with the failure to show the product name and information about the place of origin (all have been completely corrected). The remainder met requirements.
Medical devices	1	"Inspection of Add-on Powered Accessories (Electric Swivels) for Mechanical Wheelchairs" (February-April)	Inspected: 54 cases; 3 cases did not meet requirements.
	2	Inspection of pulse oximeters [simple] (oximeters) (April-June)	Physical channels: 6 cases out of 58 cases did not meet requirements. Online platforms: 5 companies out of 68 companies did not meet requirements.
	3	Inspection Project for COVID-19 Antigen Self-tests Importers and Vendors (June-July)	Inspected: 155 companies; none was found with violations of requirements.
Drugs	1	Inspection of Whereabouts of Ephedrine Preparations Sold (April-May)	Inspected: 62 companies; 12 companies did not meet requirements.
	2	Inspection of Whereabouts of Medical Nitrous Oxide (Laughing Gas) Sold	Inspected: 10 companies; 3 companies did not meet requirements.
Controlled drugs	1	Inspection Project for Hypnotic Controlled Drugs (March-December)	Inspected: 193 companies; 20 companies did not meet requirements.
Cosmetics	1	Joint inspection of Commercially Available Non-medicinal Toothpaste and Mouthwash (May-June)	Inspected: 255 cases; 1 case did not meet requirements.
	2	Joint Inspection of Non-conforming Advertisers for Cosmetics (September-October)	Inspected: 44 cases; 7 cases did not meet requirements.

Exhibit 11 Additions/ Elaborations to the Taiwan Pharmacopeia, Ninth Edition, First Supplement

Category	Number of articles	Remarks the addition and elaboration to the Taiwan Pharmacopeia, Ninth Edition, First Supplement
New Monographs	13	I. Referring to the pharmacopeia of advanced countries, the test technologies and quality specifications were elaborated and added, including Microbiological Best Laboratory Practices, Depyrogenation, Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products, Vaccines for Human Use—Bacterial Vaccines, Identification of Fixed Oils by Thin-Layer Chromatography, Near-Infrared Spectroscopy, and Nephelometry and Turbidimetry. II. In order to harmonize with international pharmacopoeias, some monographs were added and elaborated such as Alumina and Magnesium Carbonate Tablets, Amlodipine and Benazepril Hydrochloride Capsules, Abiraterone Acetate Tablets, and Acetaminophen. To retain the domestic characteristics, active pharmaceutical ingredient, Cloperastine Hydrochloride, which was developed and synthesized by domestic manufacturers, was added.
Monographs Elaborations	203	
New General Chapters	15	
General Chapters Elaborations	15	
Total	246	

Exhibit 12 List of TFDA testing methods published in 2022

Type of Testing Method	Testing Method	New/ Revised
Promulgated testing methods for food products (28 articles, 604 items)	1.Method of Test for Heavy Metals in Canned Foods -Test of Lead (MOHWH0031.00) 2.Method of Test for Heavy Metals in Grains (MOHWH0032.00) 3.Method of Test for Heavy Metals in Infant and Young Child Foods (MOHWH0033.00) 4.Method of Test for Inorganic Arsenic in Foods (MIHWH0034.00) 5.Methods of Test for Food Microorganisms - Test of *Listeria monocytogenes* in Foods (MOHWM0029.00) 6.Method of Test for Dioxins/Furans and Polychlorinated Biphenyls in Foods (MOHWO0026.00) 7.Method of Test for Food Additive Specifications - Carob Bean Gum 8.Method of Test for Food Additive Specifications - Guar Gum 9.Method of Test for Food Additive Specifications - Pectins 10.Method of Test for Food Additive Specifications - Nitrogen 11.Method of Test for Food Additive Specifications - Monoglucuronyl Glycyrrhetic Acid 12.Method of Test for Food Additive Specifications - Lactoferrin	New
	1.Method of Test for Phosphoric Acid in Beverage (MOHWA0005.02) 2.Method of Test for Marine Biotoxin in Foods - Test of Tetrodotoxin (2) (MOHWT0013.02) 3.Method of Test for Veterinary Drug Residues in Foods - Test of Carbadox and its Metabolites (MOHWV0002.02) 4.Method of Test for Nonylphenol and Nonylphenol Polyethoxylates in Food Use Detergents (MOHWD0001.02) 5.Method of Test for Eicosapentaenoic Acid and Docosahexaenoic Acid in Fish Oils (MOHWA0001.02) 6.Method of Test for Veterinary Drug Residues in Foods - Test of Chloramphenicols (MOHWV0043.01) 7.Method of Test for Veterinary Drug Residues in Foods - Test of Nitrofuran Metabolites (MOHWV0040.07) 8.Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (5) (MOHWP0055.05) 9.Method of Test for Bromate in Bottled and Packaged Drinking Water (MOHWO0002.02) 10.Method of Test for Sulfur Dioxide in Foods (MOHWA0013.03) 11.Method of Test for Food Additive Specifications - Sodium Hydroxide 12.Method of Test for Food Additive Specifications - Trisodium Phosphate 13.Method of Test for Food Additive Specifications - Diacetyl Tartaric Acid Esters of Mono- and Diglycerides 14.Method of Test for Food Additive Specifications - Calcium Lactate 15.Method of Test for Food Additive Specifications - Tartrazine (Food Yellow No.4) 16.Method of Test for Food Additive Specifications - Food Starches, Modified	Revised

Type of Testing Method	Testing Method	New/ Revised
Recommended testing methods for food products (31 articles, 129 items)	1. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Lactobacillus johnsoni* (TFDAM0024.00) 2. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Lactococcus lactis* (TFDAM0025.00) 3. Method of Test for Ginsenosides in Foods in Capsule and Tablet Form (TFDAA0092.00) 4. Method of Test for Sweeteners in Foods - Test of Acesulfame Potassium, Saccharin, Dulcin and Cyclamate (TFDAA0093.00) 5. Method of Test for Veterinary Drug Residues in Foods - Test of Malachite Green, Crystal Violet and their Metabolites (TFDAV0027.00) 6. Methods of Test for Food Microorganisms - Test of *Listeria monocytogenes* in Foods (TFDAM0026.00) 7. Method of Test for Hydroxycitric Acid in Foods (TFDAA0094.00) 8. Method of Test for Pesticide Residues in Honey - Test of Glyphosate, an Herbicide (TFDAP0024.00) 9. Method of Test for 2′-Fucosyllactose in Foods (TFDAA0095.00) 10. Method of Test for Veterinary Drug Residues in Foods - Test of 8-Hydroxyquinoline and Halquinol (TFDAV0028.00) 11. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Lactobacillus gasseri* (TFDAM0027.00) 12. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Lactobacillus salivarius* (TFDAM0028.00) 13. Method of Test for Veterinary Drug Residues in Foods - Test of Carbenicillin (TFDAV0029.00) 14. Method of Test for Thiamine Dilaurylsulfate in Soy Sauce (TFDAA0096.00) 15. Method of Test for Veterinary Drug Residues in Foods - Test of Flubendazole (2) (TFDAV0030.00) 16. Method of Test for Pesticide Residues in Foods - Test of Phosphine (TFDAP0025.00)	New
	1. Method of Test for Polycyclic Aromatic Hydrocarbons in Foods (TFDAO0030.02) 2. Method of Identification for Bromate in Foods (TFDAA0084.01) 3. Method of Test for Methoxsalen in Foods (TFDAO0043.01) 4. Method of Test for Pesticide Residues in Foods - Test of Ethylene Oxide (TFDAP0022.03) 5. Method of Test for Sodium γ-Polyglutamate in Foods (TFDAA0082.01) 6. Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Hormones (TFDAV0010.01) 7. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event A2704-12 (UI: ACS-GMØØ5-3) (TFDAG0016.01) 8. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Maize Event MON87427 (UI: MON-87427-7) (TFDAG0038.01) 9. Method of Test for Pesticide Residues in Livestock and Poultry Products for Expansion of Multiresidue Analysis - 9 Items including Fluopyram et al. (TFDAP0020.01) 10. Method of Identification for Boric Acid in Foods (TFDAA0086.01) 11. Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Antiprotozoal Drugs (2) (TFDAV0013.03)	Revised

Type of Testing Method	Testing Method	New/ Revised
	12. Method of Test for Veterinary Drug Residues in Foods - Test of Malachite Green, Crystal Violet and their Metabolites (TFDAV0027.01) 13. Method of Test for Sugars in Foods (TFDAO0022.02) 14. Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6) (TFDAP0007.03) 15. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event 40-3-2 (RRS) (UI: MON-Ø4Ø32-6) (TFDAG0009.01)	
Recommended testing methods for cosmetics and medical devices products (12 articles, 94 items)	1. Method of Test for Selenium in Cosmetics (RA03H006.001) 2. Method of Test for *Candida albicans* in Cosmetics (RA03M002.001) 3. Method of Test for Preservatives in Cosmetics (4) (RA03P014.001) 4. Method of Test for Preservatives in Cosmetics (5) (RA03P015.001) 5. Method of Test for Sunscreen Agents in Cosmetics (3) (RA03S006.001) 6. Method of Test of Residual Powder Test for Powder-Free Medical Gloves (RA04P002.001) 7. Method of Test for Sterile Urethral Catheter for Single Use (RA04P003.001) 8. Method of Test for *In Vitro* Diagnostic Device for SARS-CoV-2 Antigens (RA04B001.001)	New
	1. Method of Test for Dichlorophen, Bithionol, and Hexachlorophene in Cosmetics (RA03B001.002) 2. Method of Test for Polysilicone-15 and Tris-biphenyl triazine in Cosmetics (RA03S004.002) 3. Method of Test for Sunscreen Agents in Cosmetics (RA03S001.002) 4. Method of Test for Colorants in Cosmetics (RA03D008.003)	Revised
Recommended testing methods for drugs, controlled drugs (including illicit drugs) and biological drugs (3 articles, 41 items)	1. Method of Test for Synthetic Cannabinoids in Urine (1) (RA02I006.001) 2. Method of Test for *N*-Nitroso Salbutamol in Salbutamol Drug Substance (RA01I008.001) 3. Method of Test for Mammalian Nucleic Acids in Placental Samples (RA05I003.001)	New

Appendix 3. Important achievements and statistics over the years

Exhibit 1 Statistics of inspections upon importation of foods over the years

Year	Inspection Number of Batches	Growth rate (%)	Total net weight (ten thousand metric tons)	Batches tested	Inspection rate (%)	Number of noncompliant lost
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	724,180	1.2	893.7	65,680	9.1	664

Remarks:“-” means that there was no growth rate available for the specific year because TFDA started to conduct food import inspections in 2011.

Exhibit 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

*Source:TDFA high-risk project “Testing plans for veterinary drug residues in foods” and “Testing plans for veterinary drug residues” jointly conducted with public health bureaus under local governments.

Exhibit 3 Statistics of food poisoning over the years

Year	Number of applications	Food poisoning cases		Number of food poisoning cases classified by foods					
		Number of patients	Number of death	Aquatic products and its processed products	Meat, eggs, milk and their processed products	Grain, fruits and vegetables and their processed products	Cake and candy	compound mixture 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	503	6,944	2	13	5	5	1	26	458
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

Exhibit 4 Statistics of licenses for health foods and genetically modified foods over the years

Issued health food permit (individual case review and review of specification standards)					ssued genetically modified food permit	
Year	Track 1	Track 2	Number of permits issued in the year	Total number of issued permits	Number of permits issued 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

Remarks:

1. Two different channels for product registering health foods□

Track 1 (individual case review):

Products with ingredients contributing health care effects supported by scientific assessment of the safety and health care effects. The health food permit shall be issued with Wei-Bu-Jian-Shih-Tze No. AOOOOOO or Wei-Shu-Jian-Shih-Tze No. AOOOOOO.

Track 2 (review of specification standards):

Products with ingredients conforming to the Health Food Specification Standards. The health food permit shall be issued with Wei-Bu-Jian-Shih-Kuei-Tze No. OOOOOO or Wei-Shu-Jian-Shih-Kuei-Tze No. AOOOOOO.

2. Up until December 2022, the total number of issued health food permit was 512, and these are 435 and 77 from Channel 1 and Channel 2, respectively; in addition, the 93 of the total number of issued health food permit have been voided, resulted from expired, canceled, or combined, but the other 419 of those are valid.
3. Up until December 2022, the total number of issued genetically modified foods permit was 161, of which 0 were discontinued or not extended. Number of valid permits by the end of 2022 was 161.

Exhibit 5 Statistics of approved drug permits over the years

Year	Generic drugs			Active pharmaceutical ingredients			Novel drug			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

Exhibit 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

Exhibit 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 from 1 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

Remarks:A total of 6,253 medical device licenses were canceled in 2018; 4,653 medical device licenses were canceled in 2019. 3,223 medical device licenses were directly transferred to the listing system in 2021. 9,326 medical device licenses were directly transferred to the listing system in 2022.

Exhibit 8 Statistics of controlled drug permits and audits over the years

Year	Statistics of controlled drug licenses		Statistics of controlled drug inspections		
	Controlled drug registration	Controlled drug 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

Exhibit 9 Domestic and overseas pharmaceutical manufacturers having been approved through inspections over the years

Year	Domestic Western pharmaceutical manufacturers that Passed the GMP	Domestic Western pharmaceutical manufacturers that Passed the PIC/SGMP	Total number of foreign manufacturers obtained PIC/S GMP approval letter
2010	155	22	527
2011	149	33	720
2012	145	44	760
2013	140	57	820
2014	98	98	870
2015	-	120	893
2016	-	127	936
2017	-	137	937
2018	-	141	943
2019	-	143	937
2020	-	148	964
2021	-	146	974
2022	-	149	958

Remarks: 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.

Exhibit 10 Statistics of post-marketing quality monitoring for drugs, medical devices and cosmetics over the years

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

Exhibit 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

Exhibit 12 Statistics of the number of certified laboratories and certified items over the years

Year	Food accredited laboratory		bDrug accredited laboratory		bMedical device accredited laboratory		aCosmetics accredited laboratory		cDrug 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

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.

Exhibit 13 Unlawful drug seizure rate and violation rate of food and drug advertisements over the years

Year	Illegal drug seizure rate (%)	Advertising violation rate (%)
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

Remarks:

1. The collaborative team for busting the counterfeit, fake, or poor drugs was established in April 2010.
2. A total of 354 illegal drug cases were seized in 2022; the seizure rate dropped from 11.81 % in 2010 to 2.47% in 2022.
3. There were 6,889 violations in the advertising of food, drugs, and cosmetics determined by health authorities in 2022, with a total of NTD 2.58596 billion fined. The advertisement violation rate dropped from 13.90% in 2010 to 9.67% in 2022.

Exhibit 14 Operational statistics of Pharmaceutical Plant of Controlled Drugs over the years

Unit (thousand NTD)

Year	Income	Expenditure	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	932,382	927,446	200,000

Appendix 4. TFDA Publications in 2022

Serial number	GPN	Topic	Responsible Section	Type	Published
1	1010004833	Deep Fry Oil Safety Management Pamphlet	Division of Food Safety	Books	2022/11
2	1011101686	The Superman of My Body	Division of Medicinal Products	Books	2022/11
3	1011102169	Food Container and Utensil Encyclopedia	Division of Food Safety	Books	2022/12
4	2010002894	Annual Report of Foodborne Diseases and Prevention	Division of Food Safety	Books, Digital Publications	2022/12
5	1011101860	Spontaneous Hygiene Management Handbook for Food Delivery and Catering Businesses	Division of Food Safety	Books	2022/12
6	2010103850	Annual Report on Food Import Management and Inspection	Division of Food Safety	Books	2022/12
7	1011101656	“Cat Detective's Food Safety Reasoning Story 2: Grandma’s Defense Battle/Fang Qiuya eslite”	Division of Food Safety	Picture Books	2022/12
8	1011102134	Special Publication on Emerging Food Technology Knowledge-Bringing You Knowledge about Plant-based Foods and Clean Labels	Division of Food Safety	Digital Publications	2022/12
9	1011102173	Taiwan Pharmacopeia. Ninth Edition, First Supplement	Division of Research and Analysis	Books	2022/12
10	1011101820	Cosmetic Girl and Cosmetic Boy	Division of Medical Devices and Cosmetics	Books, Digital Publications	111/12
11	1011102133	Cosmetics Labeling Laws and Regulations and FAQs	Division of Medical Devices and Cosmetics	Digital Publications	2022/12
12	2010301353	TFDA Annual Report	Division of Planning and Research Development	Continuity (Journal)	2022/12
13	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning and Research Development	Continuity (Journal)	2022
14	2009902762	Food and Drug Research Annual Report	Division of Planning and Research Development	Continuity (Journal)	2022
15	49094052333	Food and Drug Consumer Newsletter	Division of Planning and Research Development	Continuity (Journal)	2022

Appendix 5. Related websites

Serial number	Name of the Website in English	URL	Brief Introduction	QR Code
1	Taiwan Food and Drug Administration	Https://www.fda.gov.tw	This system includes introduction to respective agencies, the scope of operation, news, and Section of Rumor Buster of Food and Drugs to allow people to have quick and precise access to the information service.	
2	Online application and the diverse service platform	https://oap.fda.gov.tw	The online application and the diverse service platform integrate various application services of TFDA, to provide a single online application service window with multiple ways of payment for the public.	
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 applications, to enhance the operating transparency of TFDA's governance policy.	
4	TFDA News	https://article-consumer.fda.gov.tw/default.aspx	"TFDA News" is structured around the three topics of "Food Safety, Safety of Drugs, Medical Devices and Cosmetics," aiming to provide the latest and most accurate food safety information and articles and the most correct and practical knowledge for the public.	
5	Food and Drug Consumer Service Network	Https://consumer.fda.gov.tw	Provide the public with integrated services regarding food and drug related information.	
6	Taiwan International Food and Drug Safety Authority Network	https://tifsan.fda.gov.tw	This system is a platform that allows internal information relays of TFDA and public health bureaus in respective counties, handling of cases, and reporting of public opinions.	
7	The Registration Platform of Food and Medicinal Businesses	Https://fadenbook.fda.gov.tw	This is an electronic information system established by government agencies to manage respective sectors, food, drugs, medical devices, and cosmetics, among others, effectively.	
8	Food Traceability Management Information System	Https://ftracebook.fda.gov.tw	The relevant electronic records can be uploaded to the system, including product information, tag identification, supplier information, product flow information, etc., to trace the source and track the flow of foods.	

Serial number	Name of the Website in English	URL	Brief Introduction	QR Code
9	Inquiry System for Interpretation Compilation of the *Act Governing Food Safety and Sanitation*	http://fsas.fda.gov.tw/	This system helps respective parties retrieve regulations, specification documents, and interpretation orders of the *Act Governing Food Safety and Sanitation.*	
10	TSFA online	http://tsfa.fda.gov.tw/	To simplify the inquiry operation of the "Standards for Scope, Application, and Limitation of Food Additives," this system has organized and created a database for the general public to review and search online.	
11	TFDA's online food label information service desk	http://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 business operators in the industry and public health bureaus.	
12	Application System for Export of Food Sanitation Certification	Https://asefsc.fda.gov.tw	This system provides online applications for the proof of exporting foods (additives) such as English health certificate, processing hygiene certificate, inspection report, and certificate of free sales.	
13	Imported Food Inspection System	https://ifi.fda.gov.tw/ifi/main/ap/index.jsp	It allows inquiries about the status of foods, Chinese herbal medicines, and rubber condoms to be inspected upon importation and downloads of food QR-Codes.	
14	Product Distribution Management System	Https://pmds.fda.gov.tw	An inspection data management platform for the health bureaus of local governments and TFDA; it is for the competent authorities to manage food, drugs, and cosmetics in their jurisdiction.	
15	Curriculum management system of food sanitation and safety	Https://foodedu.fda.gov.tw	Food hygiene workshops, HACCP workshop resources, and course enquiries are available for registration from all walks of life.	
16	Food Safety Accreditation & Certification System	Https://facs.fda.gov.tw	This system mainly assists in the implementation of Second tier quality control verification for food. Qualifying institutions are assigned randomly, the qualifying process is controlled, and results are presented through the system in order to boost qualification management efficiency.	

Serial number	Name of the Website in English	URL	Brief Introduction	QR Code
17	E Platform for Drug Review and Submission (ExPress)	https://e-sub.fda.gov.tw/dohclient/Login.aspx	This system provides online submission for drug registration, post-approval changes, and license renewal. Reviewers and applicants can both access this platform to review and check the progress of the application cases, so as to control the review timeline and enhance review efficiency.	
18	Trace and track system of medicinal products	https://dtracebook.fda.gov.tw/	A system that offers businesses to upload the tracking and tracing information of medicinal products electronically.	
19	Drug Supply Management System	https://dsms.fda.gov.tw	The system allows pharmaceutical dealers and healthcare facilities to report shortages in the supply of medicinal products in the nation and real-time evaluations and management in order to prevent against possible impacts that may result of insufficient supply of medicinal products to ensure people's right to medication.	
20	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	The general public, medical professionals, and manufacturers can use this system to report adverse drug reaction	
21	Controlled Drugs Management Information System	Https://cdmis.fda.gov.tw	The institutions, business operators, and related professionals with controlled drug registration certificates can apply for pre-market controlled drugs via the system, to effectively enhance administrative efficiency and service quality.	
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 regular inspection in urine or narcotics test results of drug abuse cases by relevant domestic inspection institutions.	
24	Searching System of Approved Advertisement for Drugs and Medical Devices Management System	https://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	A system allowing the public to inquire information on approved advertisements for medical products, and medical devices.	

Serial number	Name of the Website in English	URL	Brief Introduction	QR Code
25	Post-marketing quality management system for medicinal products, food and cosmetics	Https://qms.fda.gov.tw	This system allows the general public, healthcare professionals, and manufacturers to report adverse events of medicinal products, medical devices, health foods, and cosmetics and serves as an integrated one-stop reporting portal that realizes quick reporting.	
26	Cosmetic Products Notification Platform	Https://cos.fda.gov.tw	To ensure that the management regulations of cosmetics are in line with international standards and regulations and to ensure that government agencies can keep track of products available on the market, manufacturers or importers of cosmetics are required to provide product information on the “Cosmetic Products Notification Platform.”	
27	Online Application System of Human Organ Bank	https://oap.fda.gov.tw/B105/	The system provides online application for the human organ bank, to ensure the completeness of submitted documents and enhance the application efficiency and regulatory compliance through its reminder function.	
28	Materials Transfer Support System for Disaster Rescue and Prevention	http://mrdss.fda.gov.tw/login.aspx	This system provides online reporting of medical supply reserves for both public and private hospitals, assisting in the allocation of medical resources during major disasters.	
29	Laboratory Accreditation Management System	Https://lams.fda.gov.tw	TFDA’s accreditation platform for food, drug, cosmetic, and drug abuse urine testing institutions.	
30	Laboratory information management system	Https://lims.fda.gov.tw	The system provides online application for human organ bank, to ensure the completeness of submitted documents and enhance the application efficiency and regulatory compliance through its reminder function.	
31	Medical Device Quality Management Application Platform	http://mdqms.fda.gov.tw	The platform that allows domestic and international medical device suppliers to apply for quality system inspections.	
32	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.	

Serial number	Name of the Website in English	URL	Brief Introduction	QR Code
33	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.	
34	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 manufacturers, 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.	
35	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.	
36	Inquiry System for Advertisements in Violation	Https://pmds.fda.gov.tw/illegalad/	Illegal food, drug, and cosmetics advertisements are disclosed in real time and quickly to allow inquiries by the general public and to serve as reference while people purchase products so that they are not affected by exaggerated untruthful advertisements.	
37	Service Email for the General Public	http://faq.fda.gov.tw/	The Mailbox Service of the Director-General is an important communication channel for the public to submit their petitions and express their opinions. The intelligent inquiry service has been created to make the overall service process even more efficient and enhance the satisfaction Schedule of the public.	
38	JFDA Online Submission and Review System	https://www.editorialmanager.com/jfda/	The “Journal of Food and Drug Analysis (JFDA)” system for the online submission and review of journals for both domestic and foreign authors, as well as for the online review, edit, and publication of journals.	

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