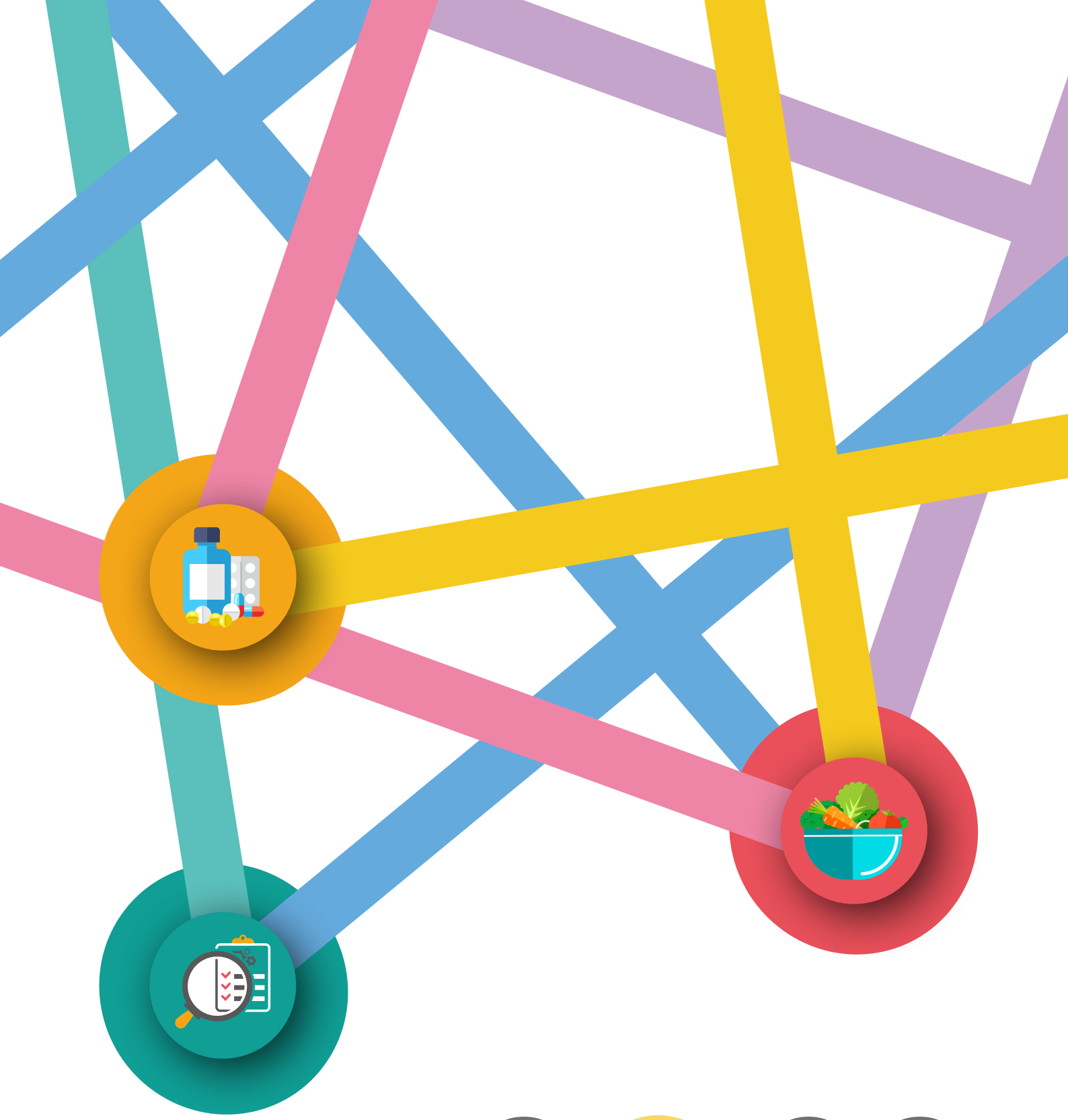

2022

Taiwan Food and Drug Administration
2022 Annual Report

2022

Taiwan Food and Drug Administration
2022 Annual Report

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2022

Foreword by the Director-General

Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare was established to manage the four categories of products that citizens concern, namely, food, drugs, medical devices and cosmetics. In 2021, TFDA continues to focus on eliminating food safety risks, ensuring drug safety, improving cosmetic safety and implementing medical device regulations to ensure that the public is assured of food and drug safety and quality. To document relevant important policies and implementation, TFDA prepares an annual report that summarized various important policies, plans, and achievements in the previous year, publishing them domestically and internationally for reference.

In 2021, COVID-19 has still caused an impact on people's lives. In accordance with the epidemic prevention policy and Article 48-2 of the *Pharmaceutical Affairs Act*, TFDA issued Emergency Use Authorization (EUA) to COVID-19 vaccines and accelerated the development of the domestic COVID-19 vaccines. To ensure the efficacy and safety of the marketed vaccines, an active vaccine safety surveillance system has been established. At the same time, TFDA established green channel of regulations to speed up the issuance of domestic manufactured medical devices to enrich our country's epidemic prevention capacity. In addition, to avoid importing of poor-quality medical masks, TFDA strengthened the border control of medical masks' quality to protect public health.

During the joint efforts of combating the pandemic, TFDA continues to refine its operations. In the management of food safety, TFDA has taken strict border inspection measures for pork products, provided guidance to manufacturers on the implementation of origin country labeling and strengthened post-market random inspections to ensure that the public can eat without fear. In terms of export, TFDA actively assist food industry in exporting to developing overseas markets.

To ensure a secure supply of pharmaceuticals, TFDA not only strengthened the ability to produce critical pharmaceuticals and Active Pharmaceutical Ingredients (APIs) domestically, but also implemented a mechanism for dealing with drug shortages and timely announcing relevant information. At the same time, TFDA has improved the traceability and Trace and Track system for Medicinal Products, quality control and digitalization management. TFDA also actively revise the laws and regulations to meet international standards in line with domestic conditions.

Taiwan Food and Drug Administration

Regulations regarding TFDA profession has also been largely improved in year 2021, including the "*Medical Device Act*" which came into effect on May 1, making Taiwan's medical device management system more complete. In addition, to promote medical device using artificial intelligence/machine learning (AI/ML) based software, TFDA also established the Smart Medical Device Office to promote the development of the domestic smart medical device industry, create forward-looking smart medical device regulations, and to establish the smart medical devices management system in Taiwan.

In terms of cosmetics, some of the provisions of the Cosmetic Hygiene and Safety Act came into effect on July 1, 2021, which not only brought non-medicinal toothpaste and mouthwash products into cosmetics management, but also implemented a cosmetic notification system and new regulations, which would provide better protections for consumers.

It is worth mentioning that, in order to encourage the research and development of domestic pharmaceuticals and medical devices, TFDA, together with the Industrial Development Bureau, organized the Pharmaceutical Technology Research & Development Award (PTRD), which entered its 20th year in 2021. The quality and quantity of applications have increased significantly in recent years, and a total of 13 projects received the Award.

Due to the impact of the COVID-19, science and technology innovations and international collaborations, the management of food, drug, medical device and cosmetic safety has become increasingly complex. TFDA upholds the spirit of safeguarding the public while keeping in line with international standards; incorporating testing technology, strengthening source management and keeping effective supervision, in order to maintain the safety of the four major categories of products. TFDA shall follow through its mission of being "the trusted guardian of food and drug safety for the people".

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

Shou-Mei Wu

1 Organization and Policies

Policy Objectives

- Optimize the production and marketing network of food products and the life cycle management of drugs
- Enhance the source flow management and complete the traceability system
- Reinforce the border inspection, audit, and self-regulation of industry operators
- Strengthen international harmonization of laws and regulations, upgrade food and drug testing technology capabilities
- Top up the effectiveness of food and drug safety communication

Section 1 Organizational Structure
Section 2 Policy Objectives
Section 3 Food Management Overview
Section 4 Overview of Drugs and Controlled Drugs Management
Section 5 Overview of Medical Devices and Cosmetics Management
Section 6 Future Prospective

01 Organization and Policies

Taiwan Food and Drug Administration of the Ministry of Health and Welfare (TFDA) 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 of promoting the health and wellbeing of the public, TFDA takes "Safe and effective medicinal products, safe and healthy food." as its mission, under the vision of "Being a reliable guardian on food and medicinal product safety, creating a safe food and medicinal consumer environment." (Figure 1-1) Upholding the core value of "total product life cycle management" of food, medicine, and cosmetics, through the source, production, and distribution management, TFDA continues to devote itself in establishing a comprehensive safety management system for food and drugs to ensure the safety and quality of food and drugs for consumers.

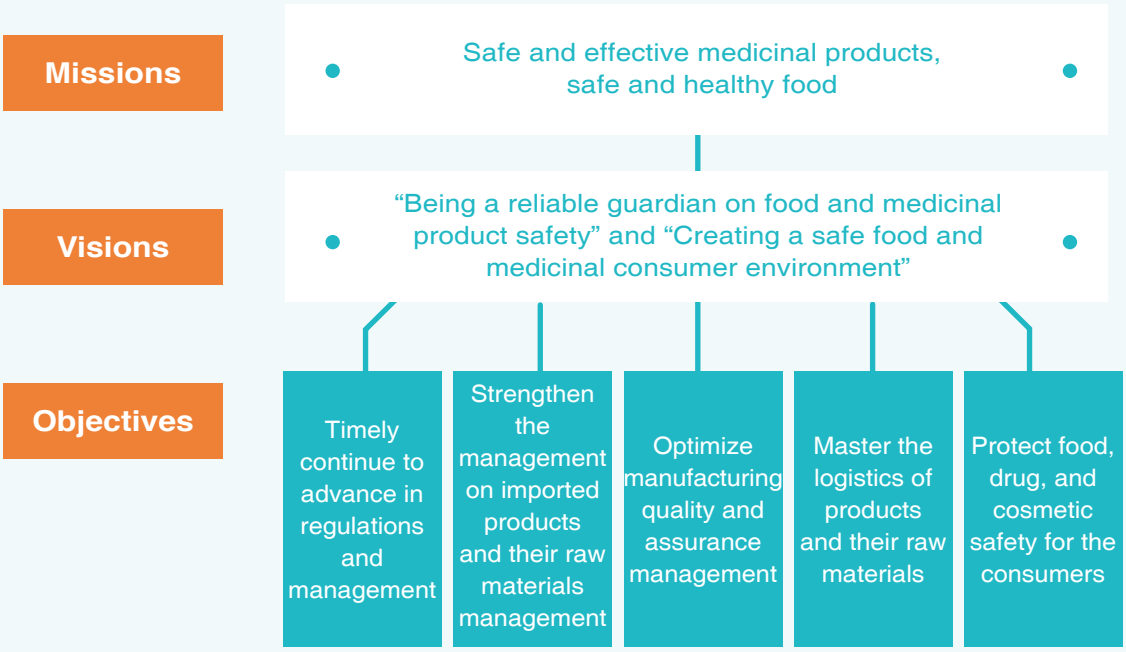


Figure 1-1 Visions and Missions of TFDA

■ Section 1

Organizational Structure

Led by the Director-General, TFDA is composed of two Deputy Director-Generals, one Chief Secretary and seven business units. Including: Division of Planning and Research Development, which is responsible for planning and management, technical planning management, international cooperation, legal system, consumer protection, etc.; 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 manufacturers management and inspection of pharmaceutical, medical devices, and cosmetic products, laboratory management and authentication, inspection of human organ bank, and second tier food inspection; Division of Research and Analysis is responsible for the testing of food, medicinal products, medical devices and cosmetics, test methods development and evaluation, pharmacopeia editing and compilation; TFDA also sets 3 District Centers (North, Central and South) which are responsible for inspections, distribution examinations, and laboratory testing of imported food, medicinal products, and cosmetics. In addition to the business divisions, we have also established five administrative units, including Office of Secretariat, Office of Personnel, Office of Service Ethics, Office of Accounting, and Office of Information Management, to assist in administrative management (Figure 1-2). In addition, TFDA sets up two Task Forces of Factory for Controlled Drugs and Decision Support Center. TFDA also obtains professional information and assistance from its consultation units such as Center for Drug Evaluation and Taiwan Drug Relief Foundation.

■ Section 2

Policy Objectives

In accordance with the 2021-year policy direction of the Executive Yuan and the policy plan of the Ministry of Health and Welfare, and in line with the budget, in response to the current development priorities and social needs in the management of food, drugs, medical devices and cosmetics, TFDA sets the following policy objectives:

I. Optimize the production and marketing network of food products and the life cycle management of drugs, medical devices and cosmetics; guard the hygiene and quality of food and drug and create a safe consumer environment.

II. Enhance the source flow management and complete the traceability system; reinforce the border inspection, audit, and self-regulation of industry operators to improve the quality monitoring system.

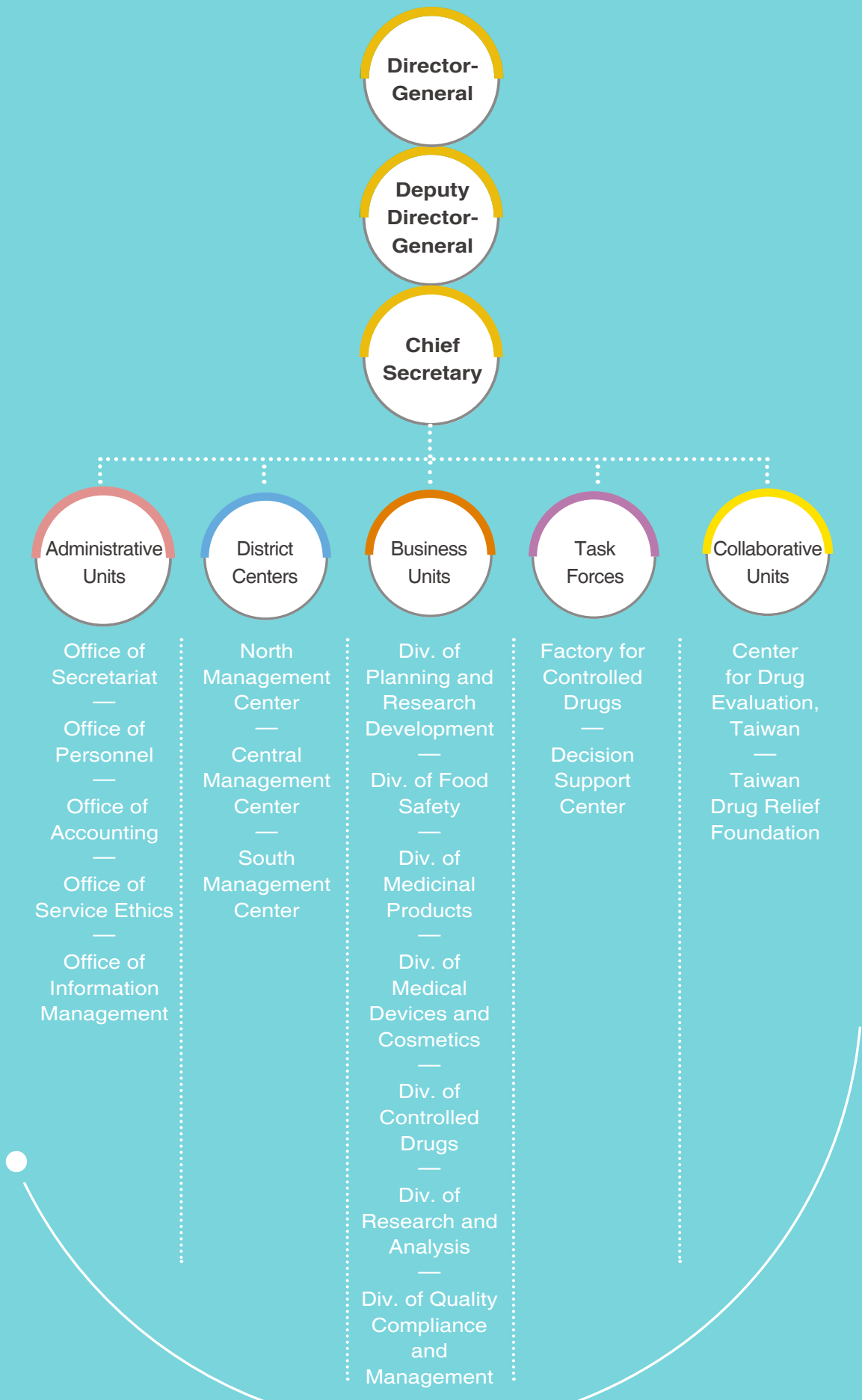


Figure 1-2 Organizational Chart

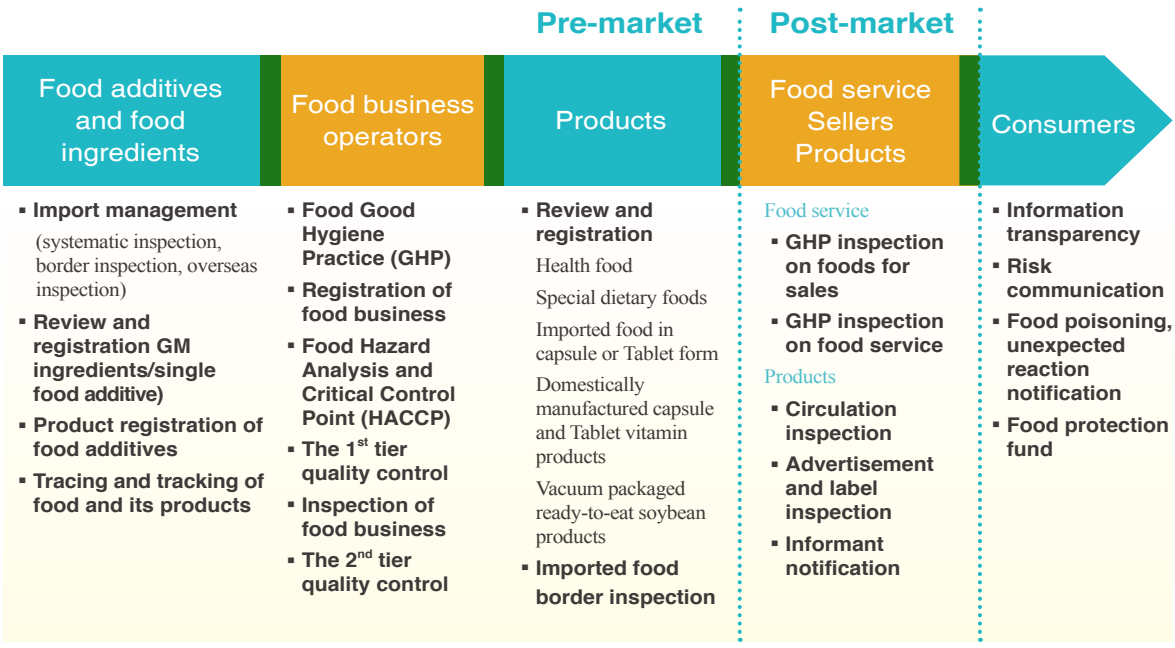
III. Strengthen international harmonization of laws and regulations, upgrade food and drug testing technology capabilities; top up the effectiveness of food and drug safety communication to raise public's correct awareness.

■ Section 3

Food Management Overview

Food safety is closely related to the health of the people. With the liberalization of global trade, booming technology, and rapidly changing food safety issues, aspects of food management appear to become more diversified, innovative, and informative. TFDA adopts the "farm-to-Table" whole life cycle management model to ensure the product hygiene and safety (Figure 1-3) in each step from the manufacturing of raw materials to the sales and circulation process. Reinforce the implementation of the "Five-points Food Safety Policy" (Figure 1-4) to co-construct the food safety protection net through government management and self-discipline of the industry and public participation.

TFDA actively collects and refers to international food management regulations and technologies, continuously updates regulations relevant to the "*Act Governing Food Safety and Sanitation*", and actively develops novel food analytical and testing methods. In addition, TFDA establishes a central-local vertically and cross-agency collaboration practice to conduct border inspection, special food projects inspection and post-market monitoring. TFDA also utilizes big data to improve risk management and early warning detection efficiency to ensure food hygiene, safety, and quality.



GHP: Good Hygiene Practice HACCP: Hazard Analysis & Critical Control Point GM: Genetically Modified

Figure 1-3 Food Management Framework

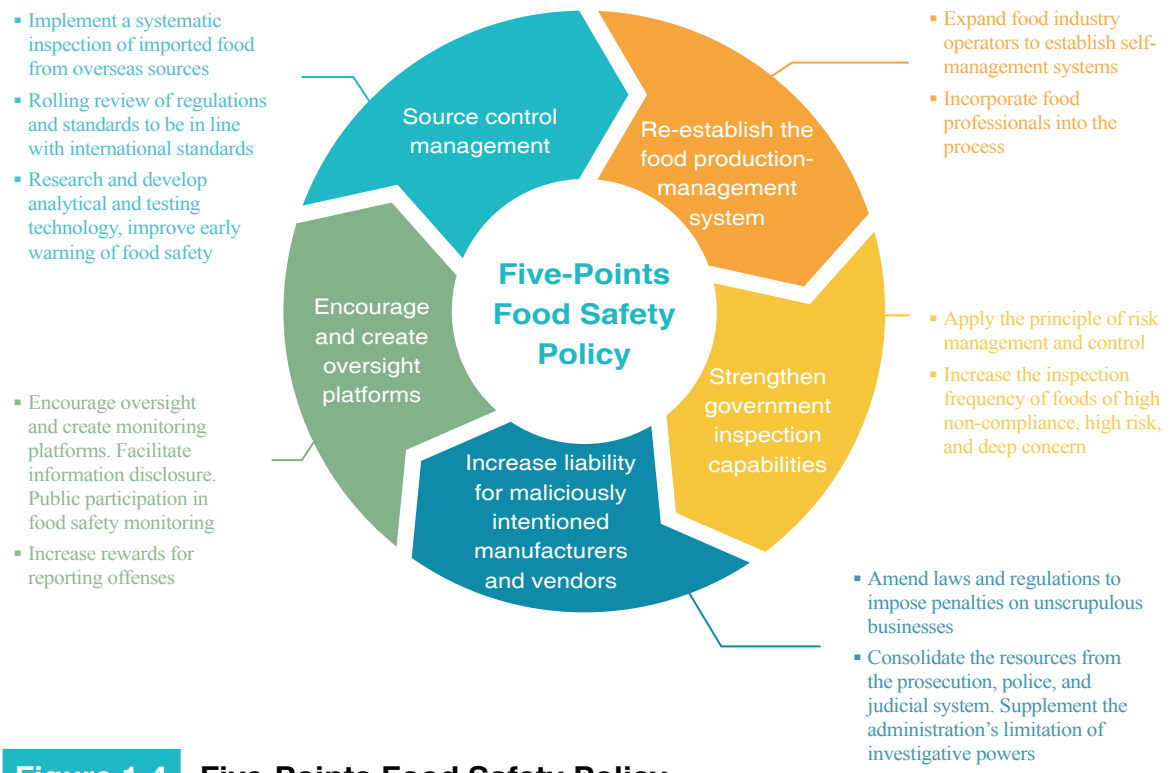


Figure 1-4 Five-Points Food Safety Policy

■ Section 4

Overview of Drugs and Controlled Drugs Management

I. Medicinal products management framework

In the life cycle management of medicinal products, including product development, preclinical trials, clinical trials, marketing authorization application, manufacturing and marketing, etc., must be followed by each good operating practice. Unlike general consumer goods, medicines can only be sold on the market after obtaining marketing authorizations issued by the central competent health authority. To ensure the safety of the public, TFDA continues to strengthen the quality management policy throughout the drug product life-cycle (Figure 1-5) through the following aspects, harmonization with international regulations, establishment of various priority review mechanisms, digital management, standardization of quality and safety surveillance, inspection of illegal drugs, and the management of pharmaceutical vendor and drug circulations, etc.

All the measures aim to ensure the safety, efficacy and quality of medicinal products, to increase the timely access to the medicines for people in need, to facilitate the development of biotechnology industry in Taiwan, and hereby creates a win-win situation among consumers, industries and the government.

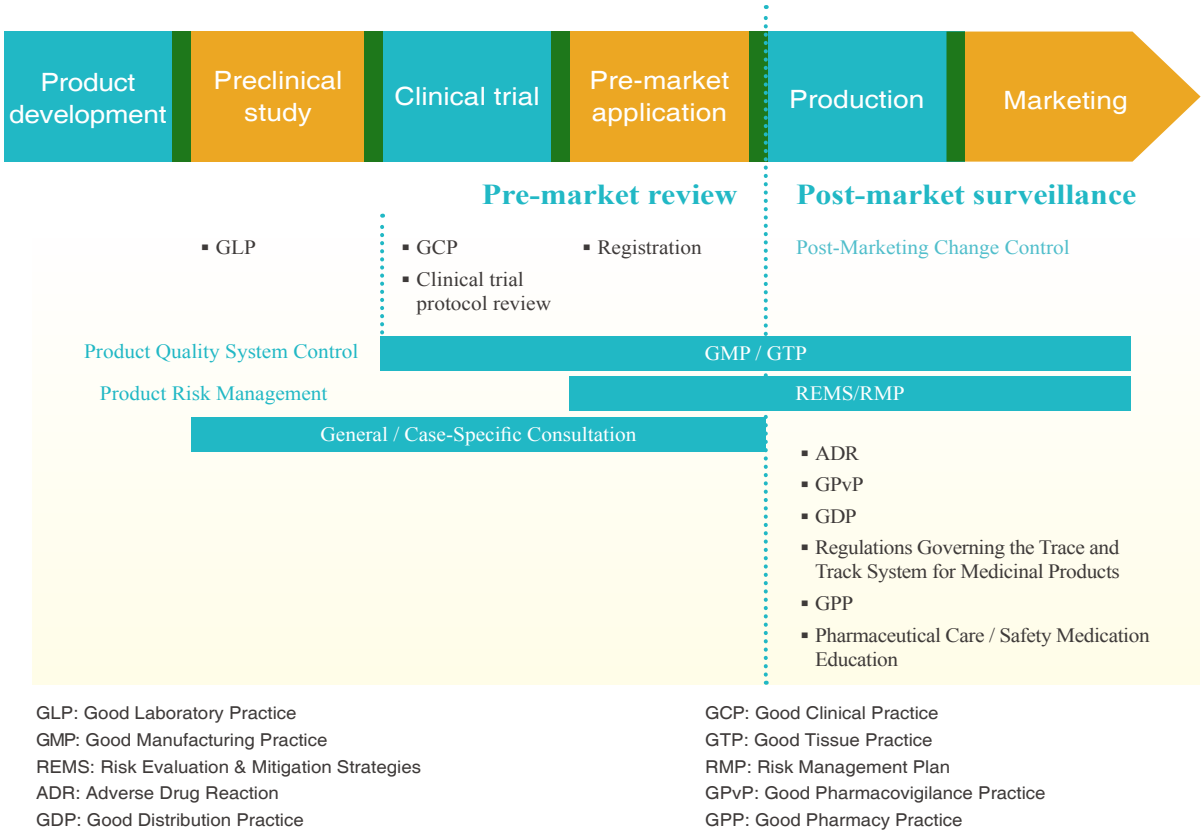


Figure 1-5 Life Cycle Management Framework for Medicinal Products

II. Controlled drugs management framework

Controlled drugs refer to addictive narcotic drugs, psychotropic drugs, and other drugs that require regulations and may only be used for medical and scientific purposes. If used improperly or illegally, they can easily cause health hazards to the people. According to the "*Controlled Drugs Act*", controlled drugs are categorized into four Schedules according to their potential for addictiveness, dependence, abuse and danger to society. The source management of various types of users (such as institutions, industry operators, physicians, dentists, veterinarians or paraveterinary workers) is conducted through certifications such as controlled drugs registration license, prescription license, and export, import and manufacture permit. The flow management is also strengthened, users are required to register and declare the income, expense and balance of controlled drugs in ledgers to prevent the misuse or abuse of controlled drugs. Its management structure is shown in Figure 1-6.

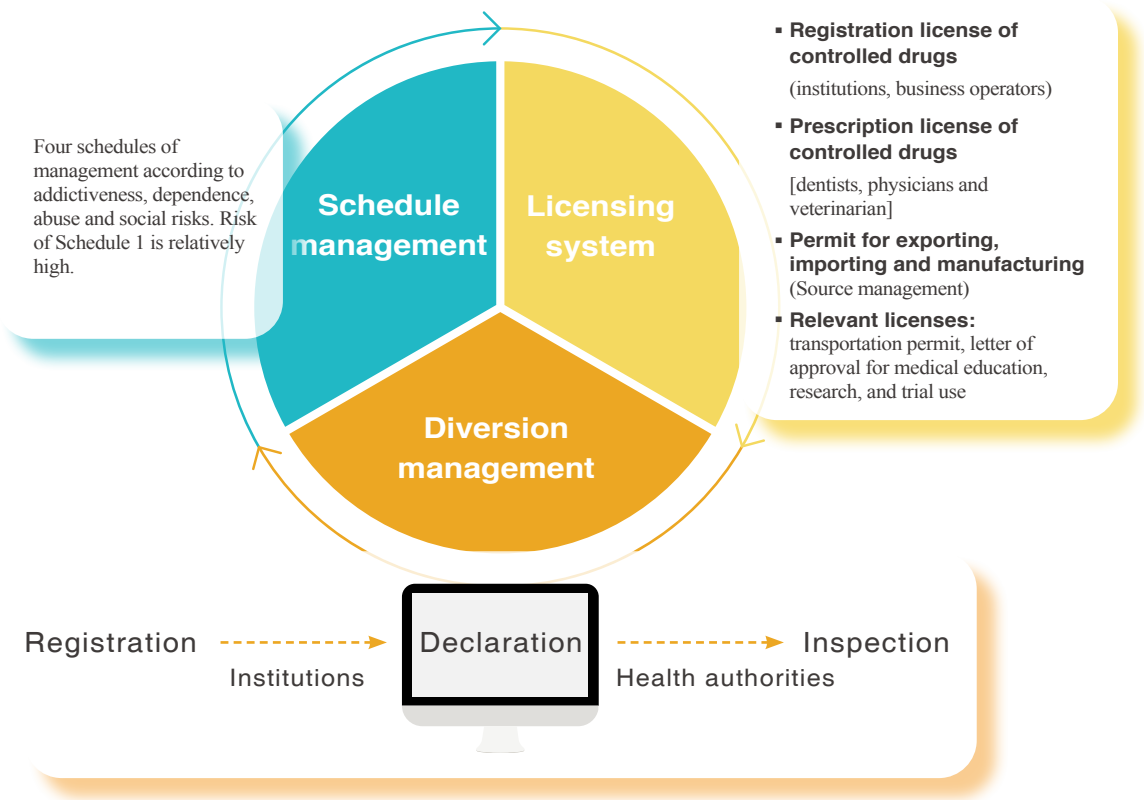


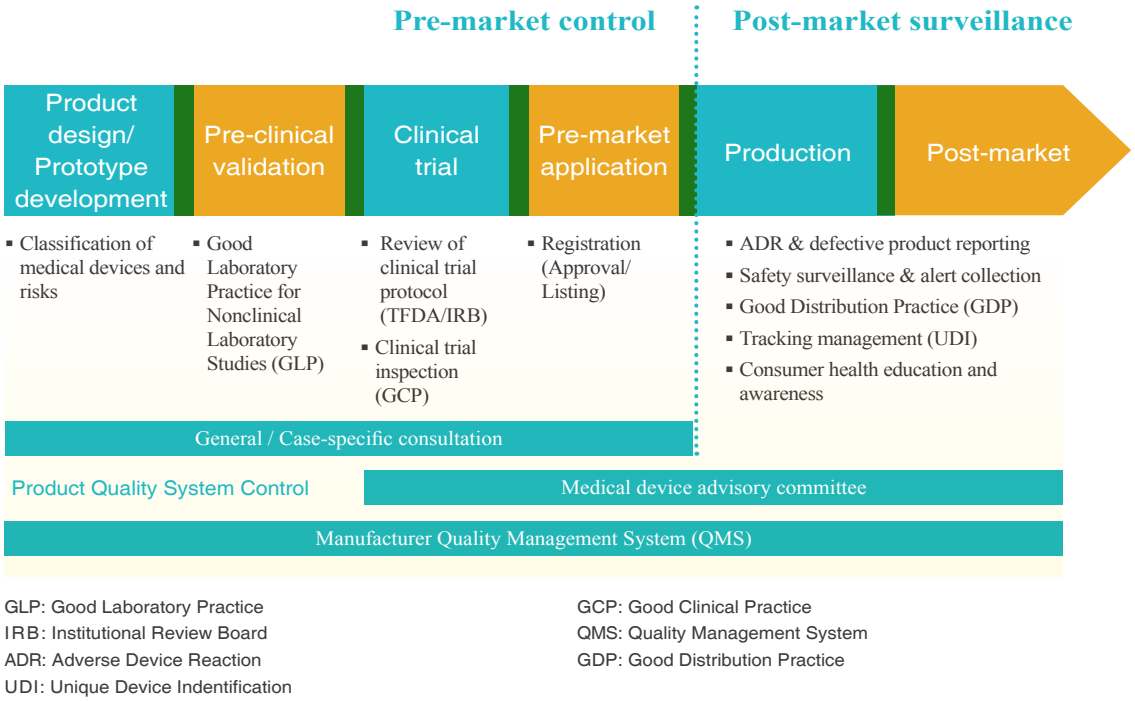
Figure 1-6 Management Framework for Controlled Drugs

■ Section 5

Overview of Medical Devices and Cosmetics Management

I. Medical devices management framework

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



GLP: Good Laboratory Practice
IRB: Institutional Review Board
ADR: Adverse Device Reaction
UDI: Unique Device Indentification
GCP: Good Clinical Practice
QMS: Quality Management System
GDP: Good Distribution Practice

Figure 1-7 Full Life-cycle Management System for Medical Devices

control the safety, efficacy, and quality of medical devices; at the same time, it can facilitate the development of biotechnology and the pharmaceutical industry, so to create a win-win situation for consumers, business operators and the government.

II. Cosmetic Management Framework

The current cosmetics management system includes three parts: production source control, pre-market management and post-market surveillance (Figure 1-8). The production source control includes ensuring that manufacturers comply with the Establishment Standards for Cosmetics Manufactory and promotion of Cosmetics Good Manufacturing Practice Regulations (GMP); the pre-marketing management includes notification of cosmetic products and establishment of product information file to replace the registration of specific purpose cosmetics; post-market surveillance focuses on the quality monitoring plan and inspections of the cosmetic products across counties and cities, the establishment of product adverse event reporting system for cosmetics, regular monitor of the safety alert for domestic and global cosmetics and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.

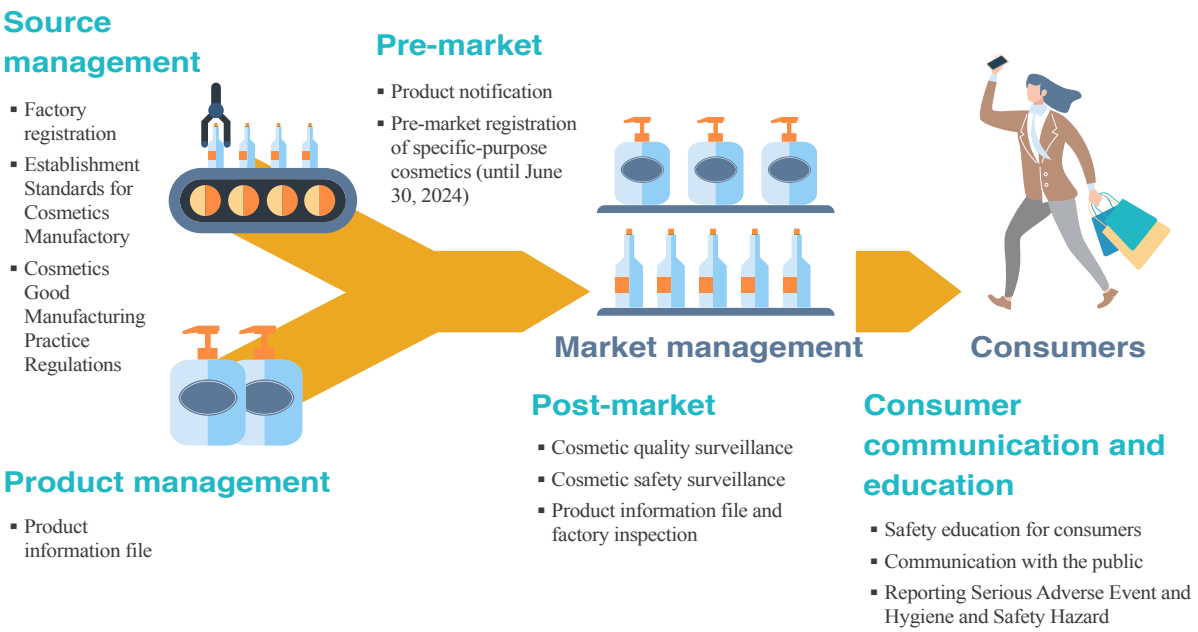


Figure 1-8 Cosmetic Hygiene and Safety Management Framework

■ Section 6

Future Prospective

With more novel substances, the impact of emerging technologies and new chemicals, the safety and sanitary issues of food and medicinal products have gradually become complicated. TFDA integrates different government departments, industries, and consumers to expand the participation of the general public to construct a safe protection network for food, medicinal products, and cosmetics. Key future policy plans include:

I. Implement the forward-looking "Food Safety Construction Plan", which includes the construction plan for a modernized food and drug national laboratory and educational training building, the enhancement of border inspection and clearance management system, the program to strengthen health department's food safety governance of testing effectiveness and quality, the program to strengthen central competent authority's food safety testing capacity and the program to improve the testing research capacity and standardization of medical products for emerging infectious disease and foodborne pathogens. Build an international standard modern national food safety laboratory, purchase high-precision testing equipment, comprehensively improve the efficiency of food safety testing and research and development, further strengthen the management capacity of local and central government agencies.

II. Complete the regulation framework for regenerative medicinal products, continue to provide guidance to the research and

development industry, speed up the reviews of COVID-19 vaccines and medicinal products, establish an anticipatory management system, improve the mechanism for handling shortages of essential drugs, fully electricize the clinical trial applications, strengthen the self-production capacity of key pharmaceuticals and APIs, grasp the supply capacity of critical pharmaceuticals, improve the efficiency of shortage notification and evaluation, and help stabilize the supply of medical supplies.

III. Continue to promote various regulations stipulated in the "Medical Device Act" and the "Cosmetic Hygiene and Safety Act"; enhance harmonization and communication of international regulations; respond to innovative technologies and product developments; establish forward-looking management regulations; provide comprehensive regulatory consultation and assistance in order to facilitate industry growth, improve post-market product safety regulation and strengthen consumer protection.

IV. Strengthen the incorporation of intelligence technology into food and drug safety risk management and continue to optimize the "Five-Point Food Safety Policy" environment. Enhance the country's food management capacity and to protect public health through inter-ministerial resource integration and expansion of food safety management resources; reinforce trace and track system, border inspection, inspection, and industry self-management.

2 Strengthen the Management of Food Safety

Complete Food Management Regulations

- Amend "*The Efficacy Assessment Method of Health Food for Fatigue Resistance*"
- Amend *"Regulations on Nutrition Labeling for Prepackaged Food Products"*
- Amend *"Categories and Scales of Food Enterprises Subject to Compulsory Registration and Dates of Implementation"*
- Amend "*Regulations Governing the Product Name and Labeling of Chocolate*"
- Amend "*Regulations Governing the Labeling of Small Prepackaged Food*"
- Publish "Guidance of COVID-19 Prevention for the Food Service" and related FAQs

Strengthen International Harmonization of Laws and Regulations

Up to 2021, stipulated a total of

- 393 Pesticides
- 7,500 Pesticide residue limits
- 147 Veterinary drug
- 1,522 Veterinary drug residue limits
- 794 food additives usage scopes, limits, and specifications
- 17 food hygiene standards
- 36 food ingredient limits and specifications

Section 1 Enhance the Food Management Regulations

Section 2 Reinforce Supervision of Food Production Marketing Chain

Section 3 Improvement of Imported and Exported Food Management

Section 4 Implement the 2nd Tier Quality Control Policy

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

Section 6 Development of Emerging Analysis Technologies for Foods

02 Strengthen the Management of Food Safety

In order to strengthen a comprehensive farm-to-table food safety management system, TFDA continues to implement relevant tasks, including refine comprehensive regulations of food management, strengthen the supervision of food manufacturing, marketing chain, reinforce import and export management, and promote the 2nd tier quality control management system. TFDA utilizes artificial intelligence to assist in decision making for food safety and risk management. In addition, TFDA enhances inspection technologies applied to the emerging and risky substances in foods to protect the consumption environment of "safe and healthy food" for consumers.

■ Section 1

Enhance the Food Management Regulations

▪ Introduction of the Policy

In order to improve the regulations of food management, provide clear information to consumers, and enhance the professionalism of business operators' self-management, nearly 30 regulations were reviewed in 2021, protecting customers' right to know.

▪ Implementation Strategy

I. Revision of food hygiene and safety standards

Based on the principles of risk assessment, TFDA has taken into considerations of international regulations, the scientific evidence, toxicological studies along with national food consumption data to comprehensively evaluate relevant standards and strive to comply with international management standards.

II. Update the health care effects assessment methods

Revised the "*The Efficacy Assessment Method of Health Food for Fatigue Resistance*" to make the experimental method and experiment execution related regulations clear and comprehensive.

III. Harmonize the management of special dietary foods

Amended the "*Regulations on Nutrition Labeling for Prepackaged Food Products*" to include "*Regulations on Nutrition Labeling for Prepackaged Infant and Follow-up Formula and Formula for Certain Disease*" to align with general food labeling requirements.

IV. Expand the scope of registered food business operators

Amended Point 1 in "*Categories and Scales of Food Enterprises Subject to Compulsory Registration and Dates of Implementation*" to expand the scope of registration to include "farmers or farmer's groups registered for primary processing plant of agricultural products" and "import businesses with taxation registrations".

V. Add requirement of food business should be insured product liability insurance

Expanded the requirement that food or food additive manufacturing, processing, or blending establishments with "tax registration" or "primary processing plant registration for agricultural products" and importing establishments with "tax registration" should take out product liability insurance for their imported or manufactured products from January 1, 2022.

VI. Transparency of labeling information

In order to make the information on chocolate products containing fillings and non-solid chocolate products more transparent, TFDA announced the amendment of "*Regulations Governing the Product Name and Labeling of Chocolate*", effective January 1, 2022. The "*Regulations Governing the Labeling of Small Prepackaged Food*" shall exempt prepackaged food where the largest surface area is less than 20 cm2 and being sold in the market from partial labeling. In addition to the traditional labeling method, innovatively introducing electronic labeling, part of the product information can also be disclosed by "QR Code" or other electronic means, providing diverse and convenient labeling methods.

VII. Improve pandemic prevention knowledge in the food service

To ensure the health of catering workers and the dining public while preventing COVID-19 cluster infections, TFDA announced the "*Regulations of COVID-19 Prevention and Management for the Food Service*" (Figure 2-1) and published the "*Guidance of COVID-19 Prevention for*

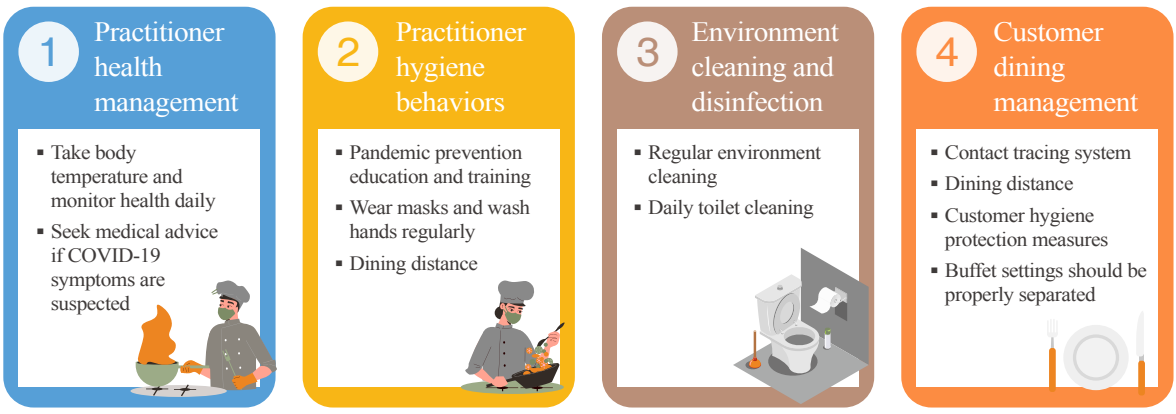


Figure 2-1 **Regulations of COVID-19 Prevention and Management for the Food Service**

the Food Service" and Q&A to provide pandemic prevention and management for food service operators.

▪ Achievements and Benefits

I. Harmonization of international standards

In 2021, TFDA stipulated 7,500 residue limits in foods for 393 pesticides; 1,522 residue limits in foods for 147 veterinary drugs; usage scopes limits, and specifications for 794 food additives; 17 food safety sanitation standards, and 36 food ingredients restrictions.

II. Enhance health food assessment methods and special dietary food labeling

"*The Efficacy Assessment Method of Health Food for Fatigue Resistance*" was amended in 2021 to revise the measurement items and testing methods for physical performance parameters and mechanism parameters, and revise the criteria for determining data and results, as well as the claims of health care effects. Under the 3R principles of Replace, Reduce, and Refine, the animal experiments were removed with priority given to the welfare of experimental animals.

In addition, the "*Regulations on Nutrition Labeling for Prepackaged Infant and Follow-up Formula and Formula for Certain Disease*" will be incorporated into the "*Regulations on Nutrition Labeling for Prepackaged Food Products*" to facilitate reference and compliance by the industry.

III. Complete the food business registration system

TFDA announced to expand the targets that should be registered to make the information of food business more complete. In 2021, the total number of food business registration was about 600,000, an increase of 15% over the total number of registrations in 2020.

IV. Protect consumer rights

TFDA expanded the requirement of product liability insurance for about 500 establishments with "tax registration" and "primary processing plant registration for agricultural products", making a total of about 19,000 food manufacturers insured against. In case food safety incidents occur, consumers are granted substantial guarantee.

V. Implement food labeling

To strengthen the labeling related regulations, TFDA established "*Regulations Governing the Labeling of Small Prepackaged Food*" and amended the "*Regulations Governing the Product Name and Labeling of Chocolate*" in 2021 to provide consumers with sufficient information to choose, and also take into account the development of the industry.

VI. Strengthen the management of food service epidemic control

Adjusted the "*Regulations of COVID-19 Prevention and Management for the Food Service*" and related guidelines on a rolling basis according to the Central Epidemic Command Center's pandemic control measures; in order to lower COVID-19 occurrence probability in dining places and downsize scales, then to reduce the risk of community transmission.

■ Section 2

Reinforce Supervision of Food Production Marketing Chain

▪ Introduction of the Policy

To implement the Five-Point Food Safety Policy, TFDA works to control the process from production to sales, enhance the food industry's regulatory capacity and combine collaborative cross-department inspection and cooperative investigation between prosecutors and police to strengthen the investigation and detection of multiple monitoring mechanisms. TFDA implements early warning and control measures for projects with potential risks to ensure that each step is in compliance with food safety and hygiene.

▪ Implementation Strategy

I. Inspection of imported products at borders

(I) With reference to inspection records, product characteristics, and domestic and foreign information, TFDA conducts rolling reviews and adjust inspection methods and items. For foods that do not comply with border clearance inspections, TFDA returns or destroys them in accordance with regulations, and may announce relevant information and increase the sampling rate of products at the same time. If imported products are found not up to standard in the post-market stage, the nonconformity information will be delivered to the border to reinforce control of the imported food hygiene and safety supervision practices.

(II) In line with the Executive Yuan's openness policy of imported pork information, starting from January 4, 2021, a pork dashboard is published on the homepage of TFDA's website at 11:00 a.m. every business day to update imported pork information (Figure 2-2).

自 110.01.01 累計至 110.12.31

產地	豬肉 重量（噸）	豬肉 占比	豬肝、豬腎、豬其他可食部位* 重量（噸）	豬肝、豬腎、豬其他可食部位* 占比
臺灣豬	456,819.80	88 %	421,470.30	95 %
進口豬	61,340.93	12 %	21,178.91	5 %

進口國別	豬肉 批數	豬肉 重量(噸)	豬肝 批數	豬肝 重量(噸)	豬腎 批數	豬腎 重量(噸)	豬其他可食部位 * 批數	豬其他可食部位 * 重量(噸)	檢出萊劑 批數	檢出萊劑 重量(噸)
澳大利亞	-	-	-	-	-	-	7	126.02	0	0.00
奧地利	11	106.19	-	-	-	-	39	809.53	0	0.00
加拿大	819	15,657.43	-	-	-	-	473	7,692.88	0	0.00
丹麥	566	10,304.74	-	-	-	-	22	472.07	0	0.00
芬蘭	9	213.92	-	-	-	-	-	-	0	0.00
法國	61	1,439.11	-	-	-	-	46	880.10	0	0.00
義大利	73	1,537.50	-	-	-	-	59	1,187.77	0	0.00
荷蘭	378	8,695.32	-	-	-	-	182	3,855.81	0	0.00
紐西蘭	-	-	-	-	-	-	-	-	-	-
西班牙	1,164	20,912.82	-	-	-	-	91	1,691.35	0	0.00
瑞典	37	388.00	-	-	-	-	71	762.15	0	0.00
英國	14	265.15	-	-	-	-	81	1,418.88	0	0.00
美國	136	1,820.75	-	-	-	-	136	2,282.35	0	0.00

* 豬其他可食部位：如 豬蹄、大腸頭、肝連、瓣膜肉、豬頭皮、豬眼皮等

Figure 2-2 Pork Dashboard

II. Domestic manufacturing processing and circulation supervision

TFDA conducts special projects of audition and random inspections on items of high violation, high risk, high concerned and while taking into consideration of the changing eating habits of people and the emerging dining patterns. In response to Covid-19 pandemic, the food industry is urged to implement health management inspections on-site and strengthen self-prevention measures.

III. Collaborative cross-department inspection

To fully implement the Five-Point Food Safety Policy of "strengthen government inspection capabilities" and "Increase liability for malicious intentioned manufacturers and producers and vendors", cross-department inspection programs were conducted in 2021 on the following items: the country of origin labeling of tea products, the flow and labeling of imported oysters, and the food manufacturer (including ham, bacon, hot dogs and cured meat) and their raw material supply chain, etc. According to the results of the audit, TFDA will carry out follow-up management to improve food hygiene and safety.

IV. Cooperative investigation between prosecutors and police

The inspection capacity will be strengthened through the cooperation mechanism between the prosecutor/police/investigator and the health authorities. The food and drug crime investigation team serves as the contact and coordination center responsible for supervising, directing, and coordinating the investigation efforts of various agencies. With the help of the food and drug case contact platform established, it can play a coordinating role in the investigation of food and drug crime cases.

- Achievements and Benefits

I. Inspection of imported products at borders

(I) A total of 715,929 batches of food and related products were inspected at the customs clearance in 2021, including 57,601 batches were tested by random sampling. A total of 846 batches failed to meet the test requirements, and the rate of passing was 98.5%.

(II) In 2021, 3,268 batches of imported pork with a net weight of 61,340.93 metric tons; 1,207 batches of pork liver, pork kidney and other edible parts of pigs with a net weight of 21,178.91 metric tons, went through the inspection of TFDA, Bureau of Animal and Plant Health Inspection and Quarantine and the Customs Administration; with 0 batch of ractopamine detected. All information have been published on the Pork Dashboard.

II. Domestic manufacturing processing and circulation supervision

TFDA completed 45 food inspection projects in 2021. The inspected numbers of

domestic business operators were 139,400 times. The qualified rate of GHP food business operator for re-inspection was higher than 90%. The numbers of inspected products and tested random sampling are 520,000 and the qualified rate attained 99%.

III. Collaborative cross-department inspection

In 2021, under the "Tea Products Origin Labeling Inspection Project" 186 products were sampled, 36 of which were suspected to contain foreign tea and were referred to the prosecutor for investigation, violations of the administrative law were fined in accordance with the relevant provisions of the Act Governing Food Safety and Sanitation. Under the "Joint oyster origin labeling inspection project", 15 batches of oyster products imported from Vietnam were inspected, and the outer boxes were all labeled with the product name and country of origin information. In "Manufacturers of Semi-finished Food Ingredients for Commercial Use Joint Inspection Program", 20 businesses were inspected in accordance with "The Regulations on Good Hygiene Practice for Foods", and all of the violations have been corrected within the time limit prescribed.

IV. Cooperative investigation between prosecutors and police

In 2021, TFDA collaborated with prosecutors and police investigation units to handle 8 food violations, all of which were dealt with in accordance with the law.

■ Section 3

Improvement of Imported and Exported Food Management

▪ Introduction of the Policy

In order to manage the source of imported food, systematic inspection was implemented for meat products, dairy products, egg products, fishery products, animal oil products and products of cervidae origin. Products from countries that have passed systematic inspection may apply to TFDA for import inspection. TFDA has been amending the customs commodity code and classification for imported food on rolling reviews to ensure that the imported foods and related products meet the sanitation and safety requirements.

In addition, in line with the overall national export policy and the export needs of the food industry, TFDA shall submit public health or food safety assessment questionnaires and/or lists of potential exporters to the importing countries for review, in accordance with the regulations of importing countries and cross-department collaboration, to assist domestic food industry to open up new opportunities to export.

▪ Implementation Strategy

I. Continuous Implementation of Systematic Inspection System

Systematic inspection request that the government agencies of the exporting country (district) to submit a written application to TFDA. TFDA reviews and checks

to assess the equivalence between the food hygiene and safety management system and government supervision measures of the exporting country and our country.

II. Review and amend border inspection product items

TFDA and Customs Administration, Ministry of Finance established the customs notification platform mechanism of "declared as food usage for imported goods without import food regulations," which consolidates the related information of imported food on a quarterly basis and the inspection results of TFDA's regional administrations and local governments. Accordingly, TFDA shall review and announce the amendments of the customs commodity code and classification for imported foods that shall apply for import inspection to TFDA.

III. Actively assist industry exporting to various countries

(I) International food safety control has become stringent. In order to ensure that the imported food products meet the requirements, countries are required to submit relevant documents or exporters' lists for examination by the countries exported to, and to submit official export certificates for animal-derived food before they can be exported. In line with the new system of "*Regulations on the Registration and Administration of Overseas Manufacturers of Imported Food*" in Mainland China, TFDA set up a special area on the official website (Figure 2-3) for the industry operators to fill in information. Some industry operators are required to provide supporting documents for food hygiene and safety from the exporting country competent authorities during the border inspection.

(II) In order to assist the export of processed food manufactured in Taiwan, TFDA accepts applications for the issuance of sanitary-related English certificates for exported processed foods (additives). TFDA also established "Pandemic Response Measures for the issuance of sanitary-related English certificates of exported processed foods (additives)" to adjust the issuance measures on a rolling basis in accordance with the pandemic control policy.

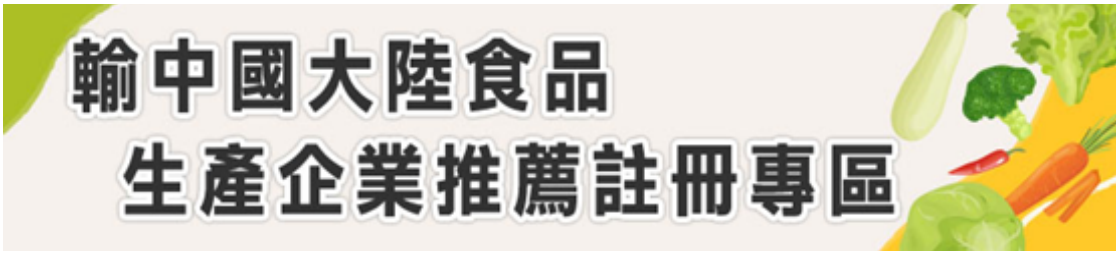


Figure 2-3 **Recommended Registration Site for Food Manufacturers Exporting to Mainland China**

▪ Achievements and Benefits

I. Complete systematic inspection and conduct stringent control on imported food hygiene and safety

In 2021, TFDA agreed that the fishery products from Thailand, Australia and Canada passing the systematic inspection. The above-mentioned countries' fishery products produced by the approved facilities can apply to TFDA for import inspection.

II. Amendment of customs commodity code and classification for imported food to improve management intensity

In 2021, 8 new commodity classification codes of imported inspection goods were revised, including new codes of fresh ginseng and salicylic acid as well as adjusting the commodity code specification of live giant scallops and other products. A total of 2,694 coded imported goods shall be inspected at the border before imported.

III. Explore the global market to create export business opportunities

(I) In 2021, 1,165 applications for exporting food have been submitted to China; TFDA has facilitated 2 operators to obtain approval from the Singapore Food Agency to export canned/retort pork products to Singapore.

(II) The Ministry for Primary Industries of New Zealand agreed that beef and canned meat products other than beef from Taiwan can be exported to New Zealand after they are attached by a mutually agreed quarantine certificate for export animal products.

(III) Since 2019, Taiwan has been submitting the information of residue monitoring program for egg to Europe for review. In 2021, the European Commission has included Taiwan in the approved list.

(IV) In 2021, TFDA completed 2,248 cases for sanitary-related English certificates applications for exported processed foods (additives); of which, 53 cases were issued under temporary measures in response to the pandemic control policy of COVID-19. TFDA completed 3 online sessions to explain the application process, key points, and demonstration of application system operation; a total of 293 people attended the sessions, and the overall satisfaction rate reached 90%.

■ Section 4

Implement the 2nd Tier Quality Control Policy

▪ Introduction of the Policy

In order to promote the three-tier product quality management mechanism for food safety and hygiene, TFDA established the "*Accreditation of Certification Body and Sanitation and Safety Control of Food Businesses of Certification Regulations*"; reinforce the third-party certification management system for the tier 2 quality control in the three tiers; and assist the food

industry operators in improving their product quality to align with the international standards.

▪ Implementation Strategy

I. Compulsory regulated industry categories

The food manufacturers that have a factory registration canned food, food additives, special nutritional products, dairy products, and manufacturers with at least a capital of NT$30 million that producing sugar, salt, starch, flour, soy sauce, and edible oils, a total of 10 product categories, shall apply for the certification. In addition to the preceding announced categories, the food manufacturers can also volunteer to apply for certification.

II. Specification of the certification content

In accordance with Paragraph 5, Article 8 of the *Act Governing Food Safety and Sanitation,* food industry operators whose categories and scales meet the criteria announced by the central competent authority shall acquire certification from the sanitation and safety management system.

III. Agencies and personnel for certification implementation

The certification is conducted by the TFDA recognized certification agencies, i.e., Food Industry Research and Development Institute (FIRDI), China Grain Products Research & Development Institute (CGPRDI), National Animal Industry Foundation (NAIF) and Taiwan Premium Agricultural Products Development Institute. The certification agency must have accreditation (ISO/TS 22003) certificate and hire professional dedicated auditors. The organization and its auditors shall obey relevant regulations to avoid conflicts of interests with the food business operators, to ensure the independence of the certification. In addition, the academic experience and auditing capabilities of the professional dedicated auditors are clearly regulated to ensure their professional capabilities. TFDA also conducts agency and personnel assessment and review assessment of the certification agencies and their auditors on a yearly basis to ensure the quality and effectiveness of certification.

▪ Achievements and Benefits

I. Reinforce the 2nd tier quality control certification to improve product quality

In 2021, a total of 547 food factories shall be certified, of which about 96% of them passed the certification, the remaining companies that have not be certified are in either the application stage or the certification stage. (Table 2-1) The 2nd tier quality control combines the certification capability of fair third-party agencies to reinforce the supervision and management of food sanitation and safety, as well as establish a comprehensive food safety protection system.

Table 2-1 2021 2nd Tier Quality Control Results 2021

Description	No. of operators	Remark
Should obtain the 2nd Tier Quality Control Certification	547	For those operators who have not obtained the certification, TFDA has referred them to the district health agency to improve by deadline.
Obtained 2nd Tier Quality Control Certification	525	
Not yet obtained 2nd Tier Quality Control Certification	22	

II. Simplify the application process of food export for 2nd tier quality control verified

Those business operators who passed the certification, when applying for sanitary certificate, can be exempted from on-site inspection by health authorities by submitting a third-party certified verification for the 2nd tier quality control; therefore, simplify the food export application process.

■ Section 5

Apply Artificial Intelligence to Assist in Food Safety Risk Decisions

▪ Introduction of the Policy

The total items and amount of food imports has continued to grow in recent years. In order to reinforce 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 provide response notifications and training periodically based on the guidelines of the risk management and crisis management from various agencies under the Executive Yuan.

▪ Implementation Strategy

I. Establish an intelligent monitoring system for food chain trace and track of abnormal flow to assist in the traceability of food safety incidents

Using Food Cloud and inter-departmental data, TFDA combines social network analysis, time flow and SANKEY abnormal flow monitoring to detect the role and market relevance of food operators in the trading network. TFDA grasps the key operators to strengthen counseling and inspection, so when abnormal events occur, TFDA can effectively grasp the upstream and downstream trading flow of operators to reduce the impact on the public.

II. Organize risk management and crisis management seminars

In order to strengthen the integration of intelligence technology into risk management on food and drug safety, a seminar on risk and crisis management was held in 2021 with the theme of "Digital Elite Wisdom Pilot. Food and Drug Big Data Competition".

III. Deal with African Swine Fever emergency responses and notification

In 2021, in response to the incident of "smuggled Vietnamese pork tested positive for African swine fever", TFDA continued to implement contingency measures and sent staff to participate in the meetings of the "African Swine Fever Central Disaster Response Center" to grasp the inter-departmental coordination work.

▪ Achievements and Benefits

I. Effectively improve the food Trace and Track Capability

In 2021, TFDA continues to develop items in intelligent monitoring system for trace and track of food chain, including dairy products, dairy powder, baby food, soy products and bulk materials (sugar), etc., and set up early warning fences through automated monitoring and rolling correction analysis to strengthen trace and track capability of foods.

II. Organize risk management and crisis management seminars

In 2021, TFDA organized a seminar on risk management and crisis management (Figure 2-4) with the participation of local governments, experts and scholars. A total of 151 participants and 13 competing teams attended the seminar. A speech on "Trends and Innovative Applications of Artificial Intelligence in Healthcare" was delivered. Through the central and local cross-unit exchange and cooperation team, we increased the capacity of data-assisted strategy formulation.

III. Deal with African Swine Fever emergency responses and notifications

In 2021, TFDA continues to participate in the meetings of the African Swine

Figure 2-4 2021 Risk Management and Crisis Management Seminar

Fever Central Disaster Response Center and to initiate works including "source inspection for marketed meat products" and "inspection from e-commerce platforms" and continues to monitor products on well-known shopping portals with keywords to keep abreast of changes in the pandemic. As of December 31, 2021, an accumulation of 27,060 web page views have been conducted since the September meeting, and no non-conformities have been detected.

■ Section 6

Development of Emerging Analysis Technologies for Foods

▪ Introduction of the Policy

In response to the needs of food-related regulations and hygiene standards such as tolerances, immediate identification of unknown or non-statutory additives and pollutants produced during processing which may affect health, it is necessary to establish environmentally friendly, rapid and accurate analysis methods. Therefore, TFDA continues to improve analysis capabilities of our laboratory and establish new testing methods for emergency response to food safety incidents, as well as hold technical interchange and training activities to strengthen domestic testing capacity for food safety.

▪ Implementation Strategy

I. Promote the exchange of food analysis technology in Taiwan

TFDA planed and held technical exchange activities, invited central and local health agencies to share the status and experience of inspection technology and to promote analysis technology exchanges. TFDA improves the technical level and quality of domestic analysis units, in the meantime develop analysis talents.

II. Refine food analysis technology to protect the safety of the public's diet

In response to high-risk and highly concerned subjects related to the general public's livelihood, we have developed reliable and fast test methods to quickly identify and clarify the incidents and to protect the food safety of the public. Further, to deal with the wide ranges of food matrices and complex composition, analysis methods must overcome various matrix interferences; TFDA applied the advanced analysis technology in national laboratories to develop rapid and highly accurate analysis methods to referencing and adaptation. These measures would strengthen the governing at borders, to monitor marketed products, and to enhance self-management of business operators, so to ensure a sound food safety management system.

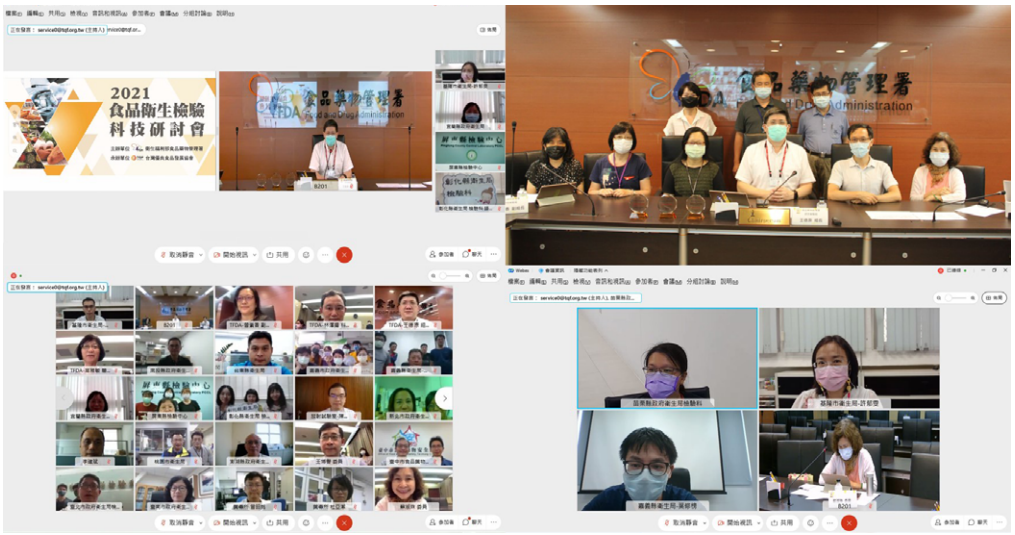


Figure 2-5 2021 Annual Food Analytical Techniques Online Symposium

▪ Achievements and Benefits

I. Organize online seminars on food analysis technology

Nearly 200 participants from central and local health authorities, private certified laboratories, and industry, academia, and research sectors participated in the 2021 Annual Food Analytical Techniques Online Symposium (Figure 2-5). TFDA invited domestic and foreign scholars to share topics on food analytical techniques and chemical residues and contaminants. Participants interacted and exchanged through oral presentations and poster competitions to expand new knowledge, improve analytical techniques, promote cooperation between central and local labs, and strengthen domestic analysis capabilities.

II. Develop relevant analysis methods for high-risk and high-interest items related to people's livelihood

(I) Establish analysis methods in real-time in response to public opinions

In response to a number of reports in the European Union Rapid Alert System for Food and Feed (RASFF), drug ethylene oxide (EO) has been detected in a number of food products that are not permitted to be used in Taiwan since 2020; TFDA developed and published the "Method of Test for Pesticide Residues in Foods - Test of Ethylene Oxide", which can be used to test soybean gum, spice plant specimen, ice cream, edible empty capsules, sesame seeds and high fat specimen. In response to the public opinion on the import of pork from the U.S. and the revision of the legal residue tolerance standards, the test method of multiresidue analysis of β-Agonists was expanded to include fat base. In

response to the public opinion on methoxsalen in imported honey beverages, "Method of Test for Methoxsalen in Foods" was quickly established for public reference and applied to border and post-market surveillance to ensure public safety.

(II) Advance analytic methods to improve food management

In 2021, in response to the test requirements in accordance with food-related health regulations and standards, we established the "Method of Test for Heavy Metals in Infant and Young Child Foods" and revised the "Method of Test for Polycyclic Aromatic Hydrocarbons in Foods", expanding the scopes to dried bonito/fish, dietary supplements containing plant or plant extracts, and cocoa bean shells. In addition, a simple, rapid analytical method for the simultaneous detection of 8 ginsenosides (health care effect ingredients) in health food products, including ginsenoside Re, was established to facilitate the quality monitoring of health food products in the post-market quality control.

In response to the revision of domestic and international regulations on the use of food additives and flavors, TFDA developed "Method of Test for Pyridine, Styrene and Eugenyl Methyl Ether in Flavorings" using gas chromatography coupled with high resolution mass spectrometry (GC-HRMS). To improve the monitoring efficiency of flavors and safeguard the health of consumers, TFDA also published the method as a recommended method for all. Moreover, in view of the ever-changing techniques for honey adulterations, TFDA developed a method besides "Method of Test for C4 Plant Sugars in Honey" for detecting stable carbon isotope ratio of sugars in honey by liquid chromatography coupled with isotope ratio mass spectrometry (LC-IRMS) in order to prevent the adulteration of C4 and C3 sugars in honey. TFDA continues building up databases as background information, hoping to enhance diverse analysis techniques and protect consumer rights.

(III) Use molecular biotechnology to identify toxic mushrooms (*Chlorophyllum molybdite*) by accidental ingestion

In response to the suspected food poisoning cases from accidental ingestion of toxic wild mushrooms that cause vomiting and diarrhea, TFDA used molecular biological detection method to identify species and quickly differentiate confusing mushrooms, so TFDA could confirm that the accidentally ingested toxic mushroom was *Chlorophyllum molybdites* and issued a press release to urge people to avoid picking and eating unknown mushrooms. TFDA leveraged the testing capabilities of the national laboratory, used advanced molecular biotechnology to quickly identify the cause of the poisoning, and achieved the goal of protecting public food safety with testing technology.

3 Reinforce Management of Medicinal Products

Enhance Regulatory Environment for Medicinal Product Management

- Draft "*Regenerative Medicine Development Act (Draft)*"
- Implement the Patent Linkage system of Drugs
- Facilitate on new drug approvals and shorten the average review time

Reinforce Medicinal Product Digital Management and Risk Control

- Implement electronic submission system for drug registration
- Improve drug safety surveillance and analysis
- Increase critical pharmaceuticals domestic production

Actively Participate in International Pharmaceutical Organizations

- Expand participation in ICH related meetings
- Host the 2021 APEC International Conference
- Hold the 9th Joint Conference of Taiwan and Japan on Medical Products Regulation
- Continue to participate in the PIC/S activities

Section 1 Enhance Regulatory Environment for Medicinal Product Management
Section 2 Reinforce Medicinal Product Digital Management and Risk Control
Section 3 Complete the Regulations for the Distribution of Medicinal Products
Section 4 Actively Participate in International Pharmaceutical Organizations
Section 5 Improvement of Drug Quality Analysis Technology
Section 6 Deepen the Medical Information Exchange of the New Southbound Policy

03 Reinforce Management of Medicinal Products

In order to implement the product life-cycle management and effectively ensure the safety, efficacy, and quality of medicinal products, TFDA actively participates in international organizations which constructs a robust regulatory environment and harmonizes with international standards to improve regulations of medicinal products management. We continue working on various aspects, such as the regulations of medicinal product distribution, digital management, the supervision of quality and safety, and the inspection technology for quality, in order to further strengthen the risk management and thus provide a safe environment for medicinal products usages as well as facilitate the development of the domestic pharmaceutical industry. In addition, TFDA works on medical information exchange with New Southbound countries to expand the visibility and influence of Taiwan within the New Southbound countries.

■ Section 1

Enhance Regulatory Environment for Medicinal Product Management

▪ Introduction of the Policy

In order to cope with the development trends around the world, TFDA not only increases the accessibility of medicinal products, expedites the drug approval process, but also encourages the drug development to fulfill the medical needs to the public. At the same time, we continue improving the relevant regulations and the patent linkage system of drugs, as well as cooperating with the current development status of the domestic pharmaceutical industry, to provide a better medicinal product regulatory environment.

▪ Implementation Strategy

I. Promote the legislation of "*Regenerative Medicinal Products Act*"

In order to promote the sustainable development of regenerative medicine, the Ministry of Health and Welfare has been promoting the formulation of the "*Three Laws of Regenerative Medicine*" since 2021, using the "*Regenerative Medicine Development Act" (Draft)* as the supreme law to establish the overall goal and direction of regenerative medicine development in Taiwan. The "*Regenerative Medicine Implementation Act" (Draft)* and the "*Regenerative Medicinal Products Act*"

(Draft) were then formulated based on the regenerative medicine implementation management and regenerative medicinal products. Among above, TFDA is in charge of the "*Regenerative Medicinal Products Act" (Draft)*. In addition, TFDA continues to announce the stipulation of relevant review guidance on regenerative medicinal products as reference for the industry developing regenerative medicinal products, and further improving the regulatory environment for regenerative medicinal products.

II. Implement the Patent Linkage of Drugs

In order to improve the intellectual property protection environment in medicinal products, an amendment to the Chapter 4-1 of the *Pharmaceutical Affairs Act*, Patent Linkage of Drugs was announced under the Presidential Decree on January 31, 2018. In addition, TFDA announced the sub-regulation and implemented the Registration System for Patent Linkage of Drugs to provide new drug owner list and to publish patent information. The implementation of the Patent Linkage of Drugs has been launched since August 20, 2019.

III. Improve the review mechanism for new drug registration

TFDA has announced a series of specific measures in recent years, including the announcements of the "*Points to Consider on Drugs for Pediatric or Rare Disease Designation*", the revision of the "*Abbreviated Review Mechanism for New Drug Applications*", "*Priority Review Mechanism for New Drug Applications*", "*Accelerated Approval Mechanism for New Drug Applications*", "Points to Consider for Breakthrough Therapy Designation" to improve the efficiency of drug review and accelerate the approval of new drugs.

- **Achievements and Benefits**

I. Draft the "*Regenerative Medicinal Products Act" (Draft)*

In line with the promotion plan of the "*Three Laws on Regenerative Medicine*", TFDA has been drafting the "*Regenerative Medicinal Products Act" (Draft)* since 2021, which covers the management of registration of regenerative medicinal products, the relevant regulations on conditional approval, the protection of the rights of the providers, and the regulations on the manufacture, sale and post-marketing management of regenerative medicinal products.

II. Implementation of the Patent Linkage of Drugs

TFDA implemented the Patent Linkage of Drugs to achieve the legislative intent of the patent law to protect patentees, affirm the research and development efforts of new drug license holders; and provide generic drug industry with transparent patent information and firsthand patent status, so as to encourage generic pharmaceutical companies to engage in design around of patent. In addition, we clarify infringement-related concerns before going on the market, so that the launched generic drugs

will not be subjected to the risk of suspension of sales at any time due to infringement issues, which can further affect the rights and interests of patients. As of the end of 2021, there were 22 cases of drug patent linkage challenging design around and 9 drug licenses were issued.

III. Facilitation on New Drug Approvals

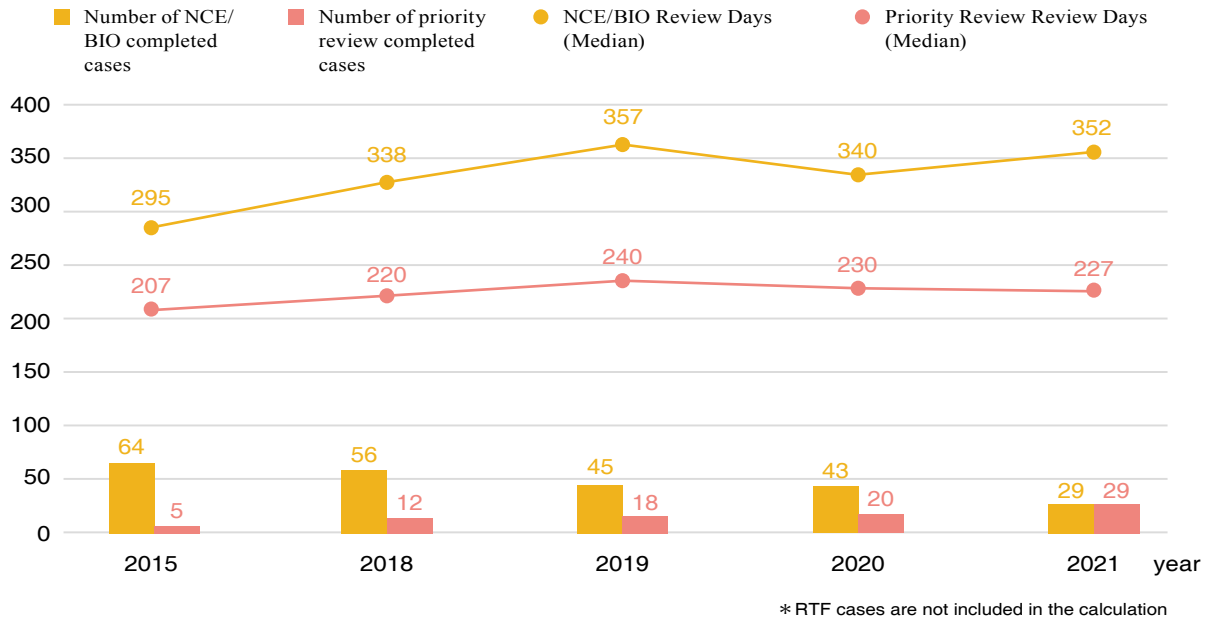
Among the 134 new drugs approved in 2021, 61 were new drugs with new chemical entities (NCE) and 42 were biological products. In order to accelerate the launch of drugs to fulfill the medical needs in our country, TFDA significantly adopted more cases of new drugs with NCE and biological products under the priority review mechanism. There were 29 cases were reviewed under the priority review mechanism in 2021, and the average review time was shortened to 227 days (Figure 3-1).

■ Section 2

Reinforce Medicinal Product Digital Management and Risk Control

▪ Introduction of the Policy

With the advancement of international pharmaceutical regulations and electronic drug policy administration, the development of electronic submission for drug registration has become the current international trend. TFDA continues to enhance and expand the functions of the online submission system for drug registration, in order to accelerate operations and improve submission quality, and also to strengthen the active and passive drug monitoring mechanism for better risk management and quality control. In addition, TFDA enhances the domestic production capacity of critical pharmaceuticals and Active Pharmaceutical Ingredients (APIs) in Tai-



＊RTF cases are not included in the calculation

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

wan and provide domestic pharmaceutical manufacturers with consultation and fast review process to gradually strengthen and consolidate the supply chain of APIs.

▪ Implementation Strategy

I. Strengthen Taiwan's electronic management of drug administration

In order to implement electronic drug administration, and comply with the regulations of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and other international standards, TFDA continues to expand the functions of the electronic submission system for the application side, review side and document management, improve the quality of the submission and the digital integration of the electronic review task, further improving the drug registration and review environment. TFDA has announced the launch of the electronic Common Technical Document (eCTD) system since January 1, 2022.

II. Reinforce drug safety surveillance and analysis

In addition to the reporting system, TFDA also actively monitors domestic and international drug safety and quality information, conducts quality surveillance of commercial products and manufacturers audits. TFDA shall initiate safety re-assessment or quality investigations if new safety issues or major quality abnormalities are found. At the same time, in order to understand the clinical use of medicines in Taiwan, TFDA also uses the national health insurance database to analyze the drug usage in Taiwan as reference for the evaluation of the effectiveness of risk control measures and future policy making.

III. Strengthen critical pharmaceuticals and increase domestic production capacity

TFDA completed the item evaluation of critical pharmaceuticals, which based on the domestic list of essential drugs, national health insurance data, current status of drug license applications and sources of API supply; TFDA also drafted a list of the "critical pharmaceuticals" and convened domestic pharmaceutical manufacturers to jointly discuss R&D strategies to enhance R&D willingness with regulatory guidance and efficient review. The relevant items shall be adjusted annually in accordance with the status of drug supply on a rolling evaluation base.

▪ Achievements and Benefits

I. Implement electronic submission system for drug registration

Through the integration of pharmaceutical regulations and information management, TFDA has been promoting the electronic registration of drugs since 2021. A total of 31 companies have been assisted to complete the eCTD submission test and pass the system verification. In addition, a number of new online application items were added in 2021, such as new clinical

trial applications, changes clinical trial amendments and clinical trial study report applications, to provide a wide range of online applications.

II. Drug safety surveillance and analysis

In 2021, there were 13,615 domestic adverse drug reaction reports, 75 domestic and foreign drug safety alerts, 220 COVID-19 vaccine safety alerts, 32 drug safety assessments, 5 drug risk communication forms and 4 drug safety quarterly newsletters were issued; TFDA received 893 reports of suspected product quality defects and actively monitored 1,470 foreign drug quality alerts. These measures were taken to raise the health care professionals' and the public awareness to ensure the safety of the public medication.

III. Increase critical pharmaceuticals domestic production

TFDA selected 259 "critical pharmaceuticals" to communicate with the domestic pharmaceutical manufacturers about the willingness to produce. In 2021, 1 case of domestic critical API development was identified, and TFDA assisted in evaluating and providing project counseling on compliance with the relevant regulations and reviews for marketing applications. In addition, TFDA provided consulting services on the R&D process and marketing regulations for 5 critical pharmaceuticals development cases.

■ Section 3

Complete the Regulations for the Distribution of Medicinal Products

▪ Introduction of the Policy

The Good Distribution Practice (GDP) is a measure to extend the rigorous quality management spirit of Good Manufacturing Practice (GMP), covering the overall pharmaceutical supply chain to ensure the quality and integrity of medicinal products can be maintained during the process of delivering to the pharmaceutical companies, medical institutions, and pharmacies from the pharmaceutical manufacturers.

Many organizations and countries around the globe have implemented the GDP for Medicinal Products. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) had also officially announced the Good Distribution Practice for Medicinal Products in June 2014. Therefore, TFDA has been promoting yearly the GDP system that meets the international standards, to complete the drug distribution quality management, ensure medicine work safely for publics and increase international competitiveness.

▪ Implementation Strategy

I. Revise GDP-related regulations

To actively improve the related laws and regulations, TFDA issued an amendment to Article 53-1 of the *Pharmaceutical Affairs Act* under the Presidential Decree

on June 14, 2017. The regulations specify that businesses engaged in the wholesaling, importing and exporting of western medicines should meet the requirements of the GDP, and their businesses can only be implemented after passing the inspection and obtaining the western pharmaceuticals distribution license by the central health competent authority.

In conjunction with the amendments to the *Pharmaceutical Affairs Act*, relevant management regulations were formulated on December 28, 2017, and May 28, 2018, respectively, specifying regulations on the application for inspection and issuance of licenses.

II. Implementation timeline of GDP

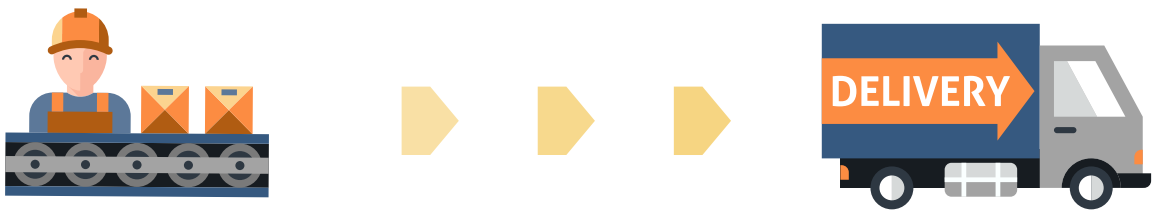
(I) On February 18, 2016, Ministry of Health and Welfare (MOHW) announced that pharmaceutical manufacturers and pharmaceutical companies holding the Western Pharmaceutical Product licenses shall comply with the GDP for Medicinal Products starting January 1, 2019.

(II) On May 10, 2019, it was announced that pharmaceutical companies of the western pharmaceutical products that require cold chain storage and transportation shall comply with the GDP for Medicinal Products starting January 1, 2022.

(III) On July 27, 2020, it was announced that pharmaceutical companies that handle the distribution, import, and export of active pharmaceutical ingredients of western medicine shall comply with the GDP for Medicinal Products starting January 1, 2023.

III. Implement the GDP related supplementary measures

TFDA has progressively promoted the distribution management system of western medicines since 2011 and provided consultation and educational training to the industry, including continuing to conduct topic forums, technical seminars, and teaching observation of pharmaceutical companies. TFDA also invited GDP experts to provide on-site counseling. TFDA actively communicates with the industry to disseminate related management policies and timelines; moreover, TFDA and the industry reach a consensus; We created a PIC/S GDP area on TFDA official website for announcement of the relevant GDP regulations to be used as references for the business operators.



▪ Achievements and Benefits

By the end of 2021, a total of 827 western pharmaceutical manufacturers and companies have fulfilled the GDP standard to ensure the quality of drug storage and transportation as well as the quality and safety of drug use.

■ Section 4

Actively Participate in International Pharmaceutical Organizations

▪ Introduction of the Policy

In order to deepen and promote international collaboration, TFDA continues to participate in important international organization events, such as Asia-Pacific Economic Cooperation (APEC), ICH, and PIC/S, etc., and also strengthen bilateral and multilateral cooperation through exchange and experience sharing with various international regulatory institutions, further enhance our international participation and influence of Taiwan's pharmaceutical administration.

▪ Implementation Strategy

I. Expand participation in ICH related meetings

After officially becoming a member of the ICH, TFDA has continuously expanded its participation in the ICH Assembly Meeting and worked with expert working groups to formulate global drug technical guidelines to keep up with international standards and improve international regulatory environment. In addition, TFDA organized relevant training to support the domestic pharmaceutical industry to implement ICH-related regulations.

II. Host the 2021 APEC International Conference

TFDA hosted the "2021 APEC Good Registration Management Regulatory Science Center of Excellence Workshop (GRM CoE)" from August 24 to September 16, 2021. TFDA collaborated with teams of experts from industries, regulatory authorities and academia across countries and institutions to provide trainings for regulatory science professionals among APEC economies. We also invited experts among over the world to share and exchange their experiences in the pharmaceutical administration.

III. Conduct the 9th Joint Conference of Taiwan and Japan on Medical Products Regulation

TFDA hosted the "9th Joint Conference of Taiwan and Japan on Medical Products Regulation" on October 14, 2021, via video conference with Japan. Both Taiwan and Japan shared the latest information of medical products regulations, as well as other important topics such as COVID-19 measures, orphan drugs regulations, implementation for new medical devices regulations and emerging topics of medical devices.

IV. Continue to participate in the PIC/S activities

As a Participating Authority of PIC/S, TFDA sent representatives to sev-

eral sub-committees to participate in the organization affairs; also, to participate in the expert circles and working groups discussing the revision of GMDP regulations and standards with international experts. In 2021, the participated meetings include the first and second "Virtual Committee Meeting", "Inspectors Training on ICH Q12 Webinar", "PIC/S-IES Joint Webinar on Distant Assessment/Remote Virtual Inspection", "2021 PIC/S Virtual Seminar" on "GMP Assessment Approaches in Post COVID-19 Era" organized by MFDS of Korea, and "The 2nd PIC/S Expert Circle Meeting on Controlling Cross Contamination in Shared Facilities" organized by WHO.

- Achievements and Benefits

I. Contribution to ICH-related meetings

TFDA attended the ICH Assembly Meeting as a full member in June and November, 2021. Towards the end of 2021, 44 experts were nominated to participate in 28 ICH expert working groups and participated in the formulation of ICH guidelines with other international experts to make an active contribution. In 2021, TFDA completed two drug guidelines, and also conducted ICH guidelines training in Taiwan to enhance the familiarity within the industry, so that emerging regulations of pharmaceuticals can be more effectively implemented in Taiwan's pharmaceutical industry.

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

Through organizing APEC workshops, TFDA actively maintains good relations with various economies and seeks opportunities for close cooperation. TFDA also provides a platform for communication and dialogue between industries, regulatory authorities, and the academia, which helps strengthen Taiwan's overall capacity. In 2021, 69 seed participants from 12 member economies completed the training. In addition, TFDA has been reporting periodically on the results of promoting regulatory harmonization to APEC, which further expands and accumulates our international impacts.

Figure 3-2 **2021 9th Joint Conference of Taiwan and Japan on Medical Products Regulation**

III. Reinforce bilateral medical product interaction between Taiwan and Japan

Apart from the official representatives of Taiwan and Japan, more than 800 participants from industries joined the conference. Through the Joint Conference of Taiwan and Japan, business operators from both sides were able to have a better understanding of pharmaceutical and medical device regulations, and to enhance mutual understandings and collaborations between the officials and the industries, creating a blueprint for Taiwan-Japan collaboration in medical product regulations (Figure 3-2).

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

(I) Assign representatives to participate in PIC/S affairs and activities, TFDA could express opinions directly, keep abreast of the latest international regulatory trends, ensure the quality of Taiwan's pharmaceuticals, strengthen our participation in international affairs, and enhance the TFDA's visibility and influence.

(II) TFDA participated in several meetings held by PIC/S in 2021, which included the introduction and updating of latest GMP regulations and interacted with Regulatory Authorities in the field of GMP from various countries to share information as well as the experiences and mechanisms of remote assessment of pharmaceutical manufacturers; in order to understand the change of management system of pharmaceutical manufacturers in the world, and the future status of GMP assessment approaches in post COVID-19, to align the GMP management system of Taiwan to harmonize with international standards.

■ Section 5

Improvement of Drug Quality Analysis Technology

▪ Introduction of the Policy

In response to the international incidents of the possible presence of the mutagenic azido impurities such as AZBT and 5-AMBBT in sartan medicines, an analytical method is required for detecting the contaminants in pharmaceuticals to ensure the medication safety for the public. Further, in response to the international development trend in the field of regenerative medicine and to meet the large demand for quality control testing of pharmaceutical R&D in Taiwan, it is also necessary to introduce innovative preparation methods and new testing technologies of international standards and establish human cytomegalovirus nucleic acid national standards to support the industry's testing needs and to meet the quality regulations of related products.

▪ Implementation Strategy

I. Introduction of multi-analytical technologies to detect drug impurity

Based on the characteristics of the compounds, TFDA developed a new method to detect the azido impurity AZBT in five sartan drugs, using HPLC-MS/MS with simple sample preparation along with addition of internal standards for calibration. Besides, TFDA conducted quantitative analysis of 5-AMBBT azide impurity in Losartan with HPLC-DAD.

II. Introduction of international innovative technology for producing national standards

For the first time, TFDA produced and established credible human cytomegalovirus nucleic acid national standards in Taiwan. We introduced WHO's virus culture method by using cell line; then the General European Official Medicines Control Laboratory compiled Digital Polymerase Chain Reaction (DPCR) detection technology was used to quantify the candidate standard. Three foreign official control laboratories and two domestic biotechnology-related laboratories have been invited to join the collaborative study organized by TFDA to ensure the prepared standard credible as a standard control of raw materials for cell therapy products.

▪ Achievements and Benefits

Two fast, sensitive and accurate analytical methods have been established and published as recommended methods, which can be adopted by private laboratories, for testing azido impurities in sartan APIs. TFDA's work will help increase the testing capacity in Taiwan. The established analytical methods have been applied to 78 API sample testing, and the affected drug products have been recalled from the market according to the test results to ensure drug safety. The methods were also published on the General European OMCL Network website. TFDA makes effort in promoting international cooperation through the continuous exchange of pharmaceutical information to enhance international visibility. TFDA not only has been recognized interna-

tionally for production of biological standards through the innovative preparation methods and quantitative techniques, but also supplies to domestic industry for quality control of raw material testing, hence enhances self-sufficiency of Taiwan's testing capacity.

■ Section 6

Deepen the Medical Information Exchange of the New Southbound Policy

▪ Introduction of the Policy

To implement Taiwan's New Southbound Policy, TFDA acts in concert with the Ministry of Health and Welfare to promote the "New Southbound Medical and Public Health Collaboration and Industrial Chain Development" flagship project, which aims to deeply cultivate the medical and health network and expand Taiwan's influence in the New Southbound countries through Taiwan's medical and health care soft power, and to promote Taiwan's medical and health care industry development while linking the comprehensive medical and health care industry chains. In the post-epidemic era, TFDA not only strengthens the medical exchange and cooperation with New Southbound countries through our experience gained through long-term commitment in establishing an international pharmaceutical regulations environment, border pandemic control concept, and the relevant industry advantages; but also reinforces health industry partnership with New Southbound countries to assist our health industry to enter the New Southbound market and to accelerate the development economy and trade of the regional networks.

▪ Implementation Strategy

I. Collect and analyze healthcare product regulations information in new southbound countries

In order to conduct in-depth research on the new southbound national pharmaceutical-related regulation information and exchange of medical management information technology to establish long-term and stable partnerships, TFDA has been collecting information on regulations and industrial trends through the related seminars held by the New Southbound countries, including 3 online seminars on medical and health-related topics held by Singapore, Australia and Thailand. In addition, the Director General of TFDA was invited as a lector at the "2nd APEC Virtual Workshop on Facilitated Regulatory Pathways" on September 16, 2021. By sharing the review, approval of drugs for rare diseases and related regulations and management system and exchanging the experience of regulatory decision-making with health authority representatives of many countries, not only the multilateral interactive partnership was strengthened, but information on relevant national laws and regulations was also collected.

II. Conduct courses on new southbound countries medical and health policies and regulations

On September 30, 2021, TFDA conducted courses on the pharmaceutical regulations system and application practices of the new Southbound countries. Experts and scholars in the medical and health fields and representatives of the pharmaceutical industry were invited to share information on the regulatory strategies, regulation updates and changes in trends in New Zealand, Australia and Singapore. These courses would help to strengthen authorities' regulatory attainment and benefit the international harmonization of pharmaceutical regulations in Taiwan.

▪ Achievements and Benefits

In the post-epidemic era, digital technology is used to actively understand international pharmaceutical regulations and trends, including completing attendance reports of medical and health-related seminars and sharing regulatory practice management courses, which benefits the exchange of information, the establishment of communication channels, as well as the promotion of bilateral or multilateral cooperation. TFDA expects to use this model to strengthen practical exchanges with new southbound countries and other countries to optimize medicinal product management and expand international cooperation opportunities.

4 Reinforce Management of Controlled Drugs and Prevention of Drug Abuse

Reinforce Management of Controlled Drugs

- Set up controlled drug management system in accordance with *"Controlled Drugs Act"*
- Conduct the assessment and management of the emerging narcotics that are necessary in medical or scientific uses
- Strengthen the inspection of rational use of controlled drugs prescription
- Prevent doctors from improperly prescribing controlled drugs which may contribute to patients' iatrogenic addiction or abuse

Enhance Anti-drug Abuse Propaganda Strategies

- Reinforce the accredited testing institutions' capabilities in urine testing of illegal drugs
- Collect drug abuse reporting data from healthcare facilities with non-urine specimens in suspected drugs
- Plan diversified anti-drug abuse propaganda strategies, as well as promoting in workplaces, communities, online community and remote areas

Section 1 Promote Amendment to the Regulations on Controlled Drugs and Strengthen Diversion Management

Section 2 Improve the Quality of Schedule 1 and 2 Controlled Drugs

Section 3 Improve Warning and Monitoring Mechanism of Drug Abuse

Section 4 Reinforce the Propaganda of NPS Prevention and Anti-drug Campaigns

Section 5 Attainments in Development of Testing Methods for New Psychoactive Substances

04 Reinforce Management of Controlled Drugs and Prevention of Drug Abuse

TFDA has established a drug abuse monitoring mechanism to effectively manage the proper use of controlled drugs and prevent drug abuse; as well as to understand the trend of drug abuse by collecting the international and domestic information to provide to Ministry of Justice as a reference for the amendment of items of Narcotics. In addition, the Ministry of Justice places the emerging narcotics with medical and scientific uses into the "Controlled Drugs Act" for controlling to avoid improper use and abuse. TFDA has also actively acts in concert with the Executive Yuan to implement multiple anti-drug measures and strengthen anti-drug propaganda.

■ Section 1

Promote Amendment to the Regulations on Controlled Drugs and Strengthen Diversion Management

▪ Introduction of the Policy

Taiwan regularly reviews and makes amendments to the regulations related to the "*Controlled Drugs Act*" to prevent the abuse or illegal use of controlled drugs; and to link and follow international trends of the issue through the international interactions, while conducting audits on the distribution of controlled drugs to implement management policies.

▪ Implementation Strategy

The meeting was held by the "Controlled Drugs Review Committee of the Ministry of Health and Welfare" every six months to conduct the assessment and management of the emerging narcotics that are necessary in medical or scientific uses.

Every year, a controlled drugs audit project plan is formulated to strengthen the inspection of rational use of controlled drugs prescription, and prevent doctors from improperly prescribing controlled drugs which may contribute to patients' iatrogenic addiction or abuse, in order to maintain the drug safety of the general public.

▪ Achievements and Benefits

(I) The "Controlled Drugs Review Committee of the Ministry of Health and Welfare" convened the 43rd and 44th meeting in 2021 and announced to add a total of 6 items of controlled drugs

and APIs. Under the controlled drugs audit project plan, TFDA and the local health bureaus jointly inspected a total of 234 units, of which 54 violations were found, with a violation rate of 23.08%.

(II) In 2021, 5 in-person education and training courses were conducted, namely, the "Exchange Seminar on Regulation of Controlled Drugs" in the North, Central and South regions and the "Seminar on the Use of Controlled Drugs in the Medical Educational Research and Experimental Program" in the North and South regions.

■ Section 2

Improve the Quality of Schedule 1 and 2 Controlled Drugs

▪ Introduction of the Policy

In order to continuously improve product quality and expand production capacity, the Pharmaceutical Plant of Controlled Drugs, TFDA (hereinafter referred to as the Pharmaceutical Plant) initiated a number of research and development projects in 2020 and planned to bring back contract manufactured and imported products to in-house production; and the renovated plant was also started to function in 2021 to attain the goal of domestic manufacturing of sufficient supply.

▪ Implementation Strategy

Newly constructed and renovated Plants are planned to add production lines for new dosage forms, with the goals to establish production lines for solutions, capsules, and patches year by year. The Pharmaceutical Plant has been remodeled to expand the production area and the storage space to better accommodate the production space. Product development is given priority to injections and solutions, followed by the capsule dosage form, and the patch types with a higher technicality level.

▪ Achievements and Benefits

The Pharmaceutical Plant's Alfentanyl injection received approval from the TFDA in 2021 and has been in mass production. Meanwhile, the Pharmaceutical Plant is also engaged in establishing of solutions production line, and the research and development of oxycodone hydrochloride immediate release capsules, morphine sulfate prolonged-release capsules and fentanyl matrix-type patches. In the future, Pharmaceutical Plant will provide 5 dosage forms of self-produced products, including injections, tablets, oral liquids, capsules, and patches, reaching 70% of self-production rate. Figure 4-1 and Figure 4-2 show the solutions filling machine and automatic round bottle labeling machine of solutions production line.

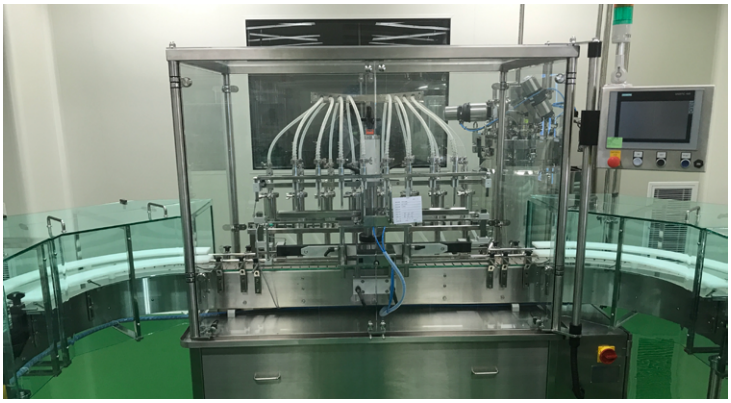


Figure 4-1 Solutions Production Line Equipment-liquid Filling Machine

Figure 4-2 Solutions Production Line Equipment-automatic Round Bottle Labeling Machine

■ Section 3

Improve Warning and Monitoring Mechanism of Drug Abuse

▪ Introduction of the Policy

New Psychoactive Substances (NPS) have a wide range of varieties and develop rapidly. In order to effectively monitor the NPS, TFDA continues to reinforce the accredited testing institutions' capabilities in urine testing of illegal drugs. Meanwhile, we collect monthly drug abuse reporting data from healthcare facilities, and other statistics such as drug abuse urine sample tests, tests performed with non-urine specimens in suspected drugs and controlled drugs cases, drug seizures, etc., then compiling into the "Drug Abuse Cases and Testing Statistics."

▪ Implementation Strategy

I. Drug abuse reporting mechanism for healthcare facilities

TFDA established a Drug Abuse Reporting System (DARS) to receive drug abuse cases reported monthly by healthcare facilities, in order to obtain the relevant epidemiological information of drug abuse cases.

II. Management of accredited institutions for drug abuse urine testing

In view of the increasing variety of abused drugs in recent years, TFDA completed the amendment of the "*Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions*" on June 30, 2021. The regulations implemented on July 1, 2021, and started to accredit the institutions replacing the original item-by-item accreditation mechanism, in order to improve the flexibility of the system and to quickly complete the testing volume, thus prevent and curb abuses.

III. Non-urine (drug) testing and reporting of drug abuse

According to the division of labor in drug testing of the Ministry of Justice, there are 15 institutions in Taiwan at present to help prosecution, police, and investigation authorities test non-urine specimens for drug abuse. In accordance with Article 9-3 of the "*Enforcement Rules of Narcotics Hazard Prevention Act,*" each inspection agency and institution should report drug test results to the Urine Test for Drug Abuse Reporting System (UDARS) every month. TFDA will count the tested positive results of non-urine samples of suspected drug and controlled drugs cases on a monthly basis and to provide reference for the development of drug control strategies by various departments.

IV. Taiwan emerging department drug abuse surveillance

In 2021, TFDA continued to commission the "Monitoring Plan for NPS in Emergency Departments (ED)" to conduct expanded screening of urine samples of 150 NPS for suspected drug poisoning cases in ED of medical institutions nationwide. The results of the expanded screening can be the reference to diagnosis and treatment for ER physicians, as well as to understand the drug abuse situation from the medical sides.

▪ Achievements and Benefits

I. Reporting situation of drug abuse from healthcare facilities

According to the DARS data, there were 28,785 cases reported for drug abuse by healthcare facilities in 2021, an increase of 13.1% comparing to 2020. The top three types of drug abuse cases were heroin (15,574, 54.1%), (meth) amphetamine (12,598, 43.8%) and benzodiazepines (1,276, 4.4%), with the similar trend as in 2020.

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

As of the end of 2021, there are 17 accredited institutions and 2 health bureaus, 14 of which can conduct NPS urine testing and report the test results to UDARS every month. TFDA continues to encourage private testing institutions to apply for accreditation and submit the

NPS testing methods validation data for review in order to expand urine testing capacity for NPS, hence protecting the citizens' health.

In 2021, a total of 221,666 urine tests were conducted in Taiwan, of which 56,705 were tested positive and accounts for 25.6% of the total number of the test. The top three drugs detected were methamphetamine, morphine and ketamine. Compared with the number of urine tests in 2020, the percentage of methamphetamine and ketamine decreased by 4.9% and 32.6%, while cases of morphine increased by 68.5%.

III. Reporting situation of drug abuse non-urine (drug) tests

In 2021, there were a total of 258,358 cases with positive test results in non-urine specimens of suspicious drug and controlled drugs cases in Taiwan, a decrease of 18.6% compared with in 2020. Of which, 29,600 were methamphetamine cases, 14,816 were ketamine cases, and 15,769 were heroin cases.

IV. Taiwan emerging department drug abuse surveillance result

In 2021, a network of 131 collaborating hospitals and expanded urine sample screening platform for 150 NPS were established. 3,303 samples were collected with tested positive cases of 1,013 or 30.7%. The final number of tested positive cases was 858 when excluding 155 cases in which the detected drugs were the same drugs prescribed by the physicians. Of the 858 cases, males accounts for the majority; in terms of the age group distribution, 25-34 years old was the majority, followed by 35-44 years old, and then 45-54 years old. There were 32 NPS items detected, with the synthetic cathinones being detected the most, showing the same pattern as in 2020. Mephedrone was the most detected drugs, followed by Ketamine, then by 4-Methyl-N,N-DMC.

■ Section 4

Reinforce the Propaganda of NPS Prevention and Anti-drug Campaigns

▪ Introduction of the Policy

To propagate drug abuse prevention, TFDA integrated professional knowledge, online media, fun games, and local resources to plan diversified anti-drug abuse propaganda strategies, as well as promoting in workplaces, communities, online community and remote areas.

▪ 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 to implement the "Fun in Preventing Drug Abuse" program. From March 1 to December 31, 2021, the program toured Chiayi County, Chiayi City, Tainan City, Kaohsiung City, Pingtung County, and Penghu County which are under TFDA's

responsibility. TFDA utilized anti-drug operation tour display boxes, X-shaped display rack teaching aid boxes and large game equipment to promote the program at communities, workplaces, high-risk sites, campuses, etc., providing the public with rich knowledge on anti-drug policies and the information for help.

II. Prevention of drug abuse in aboriginal tribes

In 2021, TFDA reached out to the aboriginal tribes in the eastern part of Taiwan to conduct training courses and lectures for drug abuse prevention talents, training locals with local teachers in order to enhance the drug abuse prevention capacity of the aboriginal tribes.

III. Online game for anti-drug promotion

In light of young adults having high usage of online social media, TFDA consolidated resources of games, online social networks, and new media, and incorporated narcotic hazard prevention and anti-drug self-defense 5 techniques, to launch an online game named "I'm proud that I'm anti-drug, let's fight against drug" (Figure 4-3) to help players understand the danger of drugs and learn the skills to refuse drugs through a gopher game (Figure 4-4).

Figure 4-4 Game Promotion Information

Figure 4-3 "I'm proud that I'm anti-drug, let's fight against drug" Online Game

▪ Achievements and Benefits

I. Fun in Preventing Drug Abuse

In 2021, TFDA implemented the "Fun in Preventing Drug Abuse" program to provide the public with of abundant education and information about anti-drug through scientific and practical cases and anti-drug touring display boxes with large game equipment. 273 promotion tours were organized in 6 cities and counties, benefiting 30,111 people.

II. Prevention of drug abuse in aboriginal tribes

In order to improve the knowledge of preventing drug abuse in the aboriginal tribes, TFDA reached out to the tribes in 2021 to hold 5 sessions of drug abuse prevention courses and train 108 trainers. Through the 10 trainers, TFDA was able to organize 28 educational sessions within the aboriginal tribes, benefiting 716 people, earned supports and affirmation from the tribe communities (Figure 4-5).

III. Online game for anti-drug promotion

From July 14 to August 13, 2021, TFDA launched "I'm proud that I'm anti-drug, let's fight against drug" lucky draw online game; and recruited two popular internet celebrities among young people, Ling Xiao-Lu and CaoTun Boys, to post messages for propagating. The campaign attracted 13,095 participants and the posts achieved 534,258 total reach.

■ Section 5

Attainments in Development of Testing Methods for New Psychoactive Substances

▪ Introduction of the Policy

The outlaws keep rolling out new substances by imitating and modifying the chemical structures of the controlled drugs so as to evade the law control. Since the problem of NPS (new psychoactive substances) abuse comes up incessantly and becomes a concerned issue,

Figure 4-5 Aboriginal Tribes' Drug Abuse Prevention and Control Campaign

actions should be taken immediately to prevent the worsening situation.

▪ Implementation Strategy

I. Promoteexperience sharing on NPS combating and drug testing techniques

With the supports of Asia-Pacific Economic Cooperation (APEC), TFDA hosted the "2021 APEC International Workshop on Food Adulterated with Drugs and Illegal Products" from August 10th to 11th, 2021. The invited representatives, scholars, and experts from France, Belgium, Australia, Taiwan, etc. shared their experiences on-line for the latest testing techniques.

II. Enlarge the applicability of drug testing

TFDA established its own database to break the constraints of insufficient spectra of the built-in database of hand-held Raman spectrometer which a total of 2,191 spectra of NPS and controlled drugs were established. TFDA also established and uploaded 819 chromatographic mass spectra of reference standards to UDARS as reference for the drug testing laboratories.

▪ Achievements and Benefits

I. Promote experience sharing on NPS combating and drug testing techniques

TFDA devotes efforts to cooperating with the local health agencies, Customs Administration, and law enforcement agencies. The current information for international prevalence of NPS, drug testing techniques, and future challenges is shared through the workshops to master the latest transnational crime patterns and precautions for drugs, as well as improve the combating strategies of drugs in Taiwan.

II. Enlarge the applicability of drug testing

The national laboratory of TFDA has been actively enhancing the efficacy of drug testing which the GC-MS and LC-MS/MS have been utilized in assisting the identification of seized cases. The established Raman spectra database was applied in the inspection of drugs for the border and shared with the law enforcement agencies to help combat the drug trafficking. "The library of Raman Spectra: Abuse Drugs (I)" (Figure 4-6) has been published to inspire the response and attention for public anti-drug actions so as to engage the effectiveness of drug combating.

Figure 4-6 **Book of "The library of Raman Spectra: Abuse Drugs(I)"**

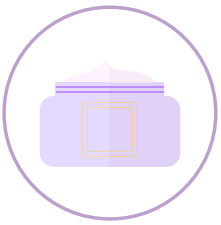
5 Improve Management of Medical Devices and Cosmetics

Enhance the Medical Devices Act and Relevant Regulations

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

Expand the International Exchanges and Collaboration on Medical Device Regulations

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



Optimize the Hygiene and Safety Management of Cosmetics

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

Section 1 Enhance the Medical Devices Act and Relevant Regulations
Section 2 Expand the International Exchanges and Collaboration on Medical Device Regulations
Section 3 Optimize the Hygiene and Safety Management of Cosmetics
Section 4 Improve the Testing Technology of Medical Devices and Cosmetics
Section 5 Reinforce Laboratory Management of Precision Medicine Molecular Testing

05 Improve Management of Medical Devices and Cosmetics

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

■ Section 1

Enhance the Medical Devices Act and Relevant Regulations

▪ Introduction of the Policy

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

▪ Implementation Strategy

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

▪ Achievements and Benefits

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

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

II. Establish diversified pre-market review mechanisms

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

III. Strengthen product source and circulation management

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

IV. Promote medical devices UDI for better tracking management

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

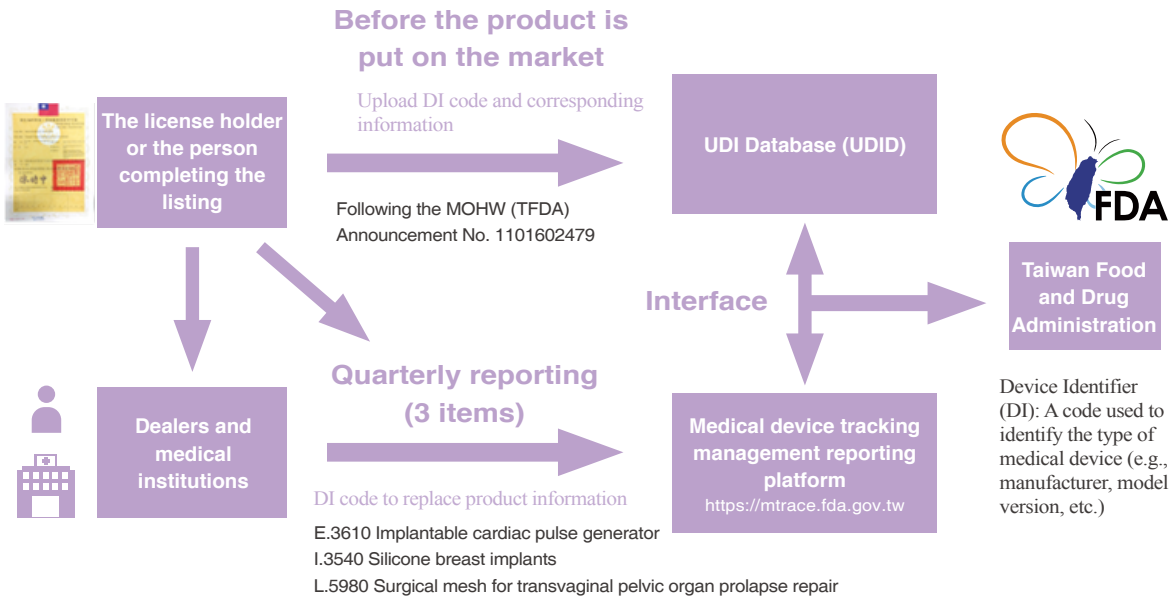


Figure 5-1 Medical Device UDI Registration and Tracking

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

■ Section 2

Expand the International Exchanges and Collaboration on Medical Device Regulations

▪ Introduction of the Policy

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

▪ Implementation Strategy

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

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

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

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

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

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

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

IV. Hold international conferences on medical device regulations

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

- Achievements and Benefits

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

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

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

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

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

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

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

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

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

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

■ Section 3

Optimize the Hygiene and Safety Management of Cosmetics

▪ Introduction of the Policy

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

▪ Implementation Strategy

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

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

▪ Achievements and Benefits

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

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

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

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

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

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

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

III. Reinforce the hygiene and safety management of cosmetics

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

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

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

V. Promote Cosmetics Good Manufacturing Practice Regulations (GMP)

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

VI. Cosmetics Advertisements Management

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

■ Section 4

Improve the Testing Technology of Medical Devices and Cosmetics

▪ Introduction of the Policy

Due to the rapid development of modern and new medical devices and cosmetics, there is an urgent need to establish the quality test technology platform for various products, to expand the testing items, and to develop or optimize the analytical methods for the fulfillment of the needs of domestic products management. In addition, through international technology exchange and collaboration, TFDA understands and grasps the current status and trends of testing in the world, comprehensively improves the level of analytical techniques and strengthens research capabilities to be in line with the world's standards.

▪ Implementation Strategy

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

▪ Achievements and Benefits

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

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

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

II. Improve medical device and cosmetics analytical techniques

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

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

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

■ Section 5

Reinforce Laboratory Management of Precision Medicine Molecular Testing

▪ Introduction of the Policy

Different from conventional medicine, the precision medicine not only refers to conventional medical information but also information such as the genetic composition, background environment,

and lifestyle of an individual or specific group. It is able to stipulate more accurate and personalized plans for disease prevention, diagnosis, and treatment through the comparison and analysis of the human genetic database. In view of the prosperous development of molecular testing relevant services, TFDA conducted the registration for Laboratory Developed Test and Service (LDTS) for precision medicine molecular testing laboratory to improve the testing quality.

▪ Implementation Strategy

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

▪ Achievements and Benefits

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

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

II. Improve the follow-up management practices for registration

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

III. Conduct laboratory consultation and industry briefing sessions

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

IV. Registration operations

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

6 Special Planning

Innovations in the Management of Drugs and Medical Devices during the Pandemic

- Accelerate COVID-19 vaccines launch and continuously support emergency epidemic prevention needs
- Accelerate support for emergency public health policy needs and fostering R&D capacity for epidemic prevention test
- Ensure the supply of safe and effective medical devices for epidemic prevention

A New Era of Smart Medical Device Management

- Establish Smart Medical Device Office
- Accelerate the product launch of domestically manufactured smart medical devices
- Construct a comprehensive regulatory environment for smart medical devices
- Help cross-sector business operators, reviewers, and inspectors enhance their knowledge about smart medical devices regulations
- Establish AI/ML Medical Devices Information & Matchmaking Platforms

National Award for Research and Development of Pharmaceutical Technology

- Expand reputation of operators internationally
- Demonstrate the R&D capacity of Taiwan's medical and biotechnology industry
- Promote Medical and Biotechnology Innovation Excellence and Global Presence

Section 1 Breakthroughs and Innovations in the Management of Drugs and Medical Devices during the Pandemic

Section 2 A New Era of Smart Medical Device Management

Section 3 National Award for Research and Development of Pharmaceutical Technology

06 Special Planning

In 2021, under the impact of COVID-19 pandemic and emerging technologies, TFDA was facing new challenges. TFDA flexibly addressed these challenges through the combination of emerging technologies in different fields and the cooperation between domestic and foreign experts and industry operators. In addition to solving the urgent epidemic problems from the administrative aspects, TFDA also lay the foundation for the development of AI/ML-based medical devices from the legal and technical aspects.

At the same time, in order to support the outstanding pharmaceutical and medical device manufacturers and business operators in Taiwan, TFDA actively promotes the consultation mechanism, improves relevant laws and regulations, and continues to held Pharmaceutical Technology & Research Development Award to encourage the industry to invest in the research and development of innovative products and related production technologies so as to keep promoting the development of domestic pharmaceutical and medical device technologies.

■ Section 1

Breakthroughs and Innovations in the Management of Drugs and Medical Devices during the Pandemic

▪ Introduction of the Policy

The COVID-19 pandemic is still ravaging the world. To ensure the quality, safety and supply of drugs and related medical devices during the pandemic, TFDA assisted to accelerate the development and production speed of domestic COVID-19 vaccines, and also shortened the mass production time of domestic vaccines to market. In addition, TFDA expedited the lot releases in response to the urgent demand for the vaccines, and improved the smooth supply of the pandemic prevention drugs supply chains to support the capacity of domestic COVID-19 testing technology, thus to strengthen the resilience of Taiwan's emergency response system.

▪ Implementation Strategy

I. Accelerate the review of COVID-19 vaccine and drug under EUA for import or manufacture, and provide guidance for domestic vaccine development

Vaccines and drugs are powerful tools to prevent the spread of infectious diseases. To fulfill the needs to the public health, besides importing vaccines and drugs, developing the earlier availability of domestic vaccines was also an important prevention strategy. Through the measures such as active project counseling mechanism, flexible regulatory adaptations, and rapid review efficiency, TFDA expedited the import and manufacture of COVID-19 vaccines and drugs under EUA during the COVID-19 pandemic.

II. Ensure that vaccine manufacturing and storage comply with international standards

TFDA dispatched auditors with biologic products inspection expertise to the domestic COVID-19 vaccine manufacturers, including bulk solution production (cell amplification culture and protein purification) and pharmaceutical product production (formulation and filling) then subsequently conducted GMP inspections in accordance with PIC/S GMP regulations to ensure the quality of vaccine manufacturing. In addition, TFDA also provided the list of pharmaceutical companies with cold chain permits and conducted GDP inspections, to allow the Centers for Disease Control to plan the cold chain storage and transportation operations after vaccine procurement.

III. Accelerate the vaccine test mechanism and continue to support the supply of national reference standards

TFDA established and published the immunogenicity test method for COVID-19 vaccines, also produced the first generation SARS-CoV-2 neutralizing antibody national standard to support domestic manufacturers in evaluating the vaccine efficacy. In response to the domestic epidemic and vaccine demand, task teams were set up to handle the lot releases of the domestic and imported COVID-19 vaccines. A rapid alternative method for sterility testing of the vaccines was established to speed up the vaccine lot release process. Since the outbreak of the pandemic, TFDA has continued to supply SARS-CoV-2 nucleic acid standards and respiratory virus panels in order to ensure the objectivity and credibility of COVID-19 testing and improve the testing capacity of national epidemic prevention.

IV. Real-time information on the supply and demand of medical devices for prevention of outbreaks and strengthen quality control

By establishing a contact point for dealers of epidemic prevention medical devices, TFDA can collect real-time information regarding the supply and demand of relevant medical devices. At the same time, following Article 35 of the *Medical Devices Act*, TFDA has started to approve specific medical devices to be manufactured or imported with special approval, and a consultation team has been set up to provide consultation services to support domestic manufacturers as they develop SARS-CoV-2 antigen test reagents. As the COVID-19 virus continues to mutate, TFDA has revised its guidance for manufacturing specific medical devices as a special case and TFDA will continue to monitor the performance of SARS-CoV-2 antigen test reagents manufactured with special approval. In addition, TFDA has also strengthened border control and quality monitoring of medical masks.

- Achievements and Benefits

I. Acceleration of COVID-19 vaccines launch and continuous support of emergency epidemic prevention needs

(I) In order to accelerate the early launch of domestic vaccines and ensure the vaccine quality, efficacy and safety, TFDA and the Center for Drug Evaluation (CDE) formed a project consulting and counseling team, which held weekly meetings with domestic vaccine manufacturers, and provided timely professional regulatory and technical consultations. In the meantime, TFDA adopted a rolling review mechanism to significantly accelerate the review time for applications of clinical trials and EUA manufacturing. Since the beginning of the pandemic, the consulting and counseling team has held up to 111 consultation meetings with domestic vaccine manufacturers.

(II) In order to formulate the review guidance for COVID-19 vaccines and drugs, TFDA followed the progress of international regulations and also invited domestic experts and scholars to hold meetings, in order to provide professional review and consultation recommendations. A total of 24 advisory committee meetings were held between 2020 and 2021. In June 2021, TFDA announced the establishment of the COVID-19 vaccine Emergency Use Authorization (EUA) review guidelines and technical document checklists for references. Four vaccines and three drugs for COVID-19 EUA reviews were completed. In accordance with Article 48-2 of the *Pharmaceutical Affairs Act*, TFDA approved under EUA vaccines, namely Vaxzevria® (AstraZeneca), Spikevax® (Moderna), Medigen and Comirnaty® (BNT162b2), and drugs, namely Veklury® (Rem-

desivir), Molnupiravir and Paxlovid® (PF-07321332 plus ritonavir) to meet domestic emergency pandemic prevention needs.

(III) Auditors with biological product expertise were dispatched to factories for a total of 259 sessions/319 visits and conducted GMP inspections of Covid-19 vaccine bulk solution and filling manufacturers to ensure that the quality of COVID-19 vaccine used in Taiwan is in compliance with PIC/S GMP regulations. TFDA supported the domestic manufacturers in evaluating the vaccine titers and accelerating obtaining manufacturing permits, to enhance the smooth supply of the pandemic control drug supply chain. By the end of 2021, TFDA has completed 114 batches (41,129,376 doses) release for imported or domestic manufactured COVID-19 vaccines.

II. Accelerate support for emergency public health policy needs and fostering R&D capacity for epidemic prevention test

TFDA has been producing and supplying SARS-CoV-2 nucleic acid reference standards and reference materials since 2020, and has been accredited with the Symbol of National Quality (SNQ) certification, thus indicating that the service quality of the national reference standards is well recognized. By the end of 2021, a total of 374 bottles of reference standards have been supplied to 31 units, to assist the industry to obtain EUA for manufacturing of the test reagents, thus effectively fostering domestic industry in pandemic prevention.

III. Ensure the supply of safe and effective medical devices for epidemic prevention

TFDA has initiated fast track services to review and approve applications more flexibly. By the end of 2021, 334 applications for approval for manufacturing and importing medical devices have been approved, including test reagents, computer-aided diagnosis in chest X-ray images, electronic stethoscopes and respirators, to enhance Taiwan's capacity to cope with the pandemic. In response to the increasing demand for COVID-19 self-test reagents, TFDA announced the "Requirements of performance evaluation for manufacturing SARS-CoV-2 nucleic acid or antigen self-test reagents as a special case" and "Guidance for the public to use COVID-19 self-test kits", to accelerate the approval of 5 applications to manufacture and 19 applications to import COVID-19 self-test kits. A specific area was designated on the official website of TFDA for relevant inquiries. TFDA has also revised and announced 6 guidance documents for manufacturing medical devices as a special case, and inspected the testing performance of 9 COVID-19 antigen testing reagents against Omicron variant. Also, to ensure the safety and the quality of medical masks, TFDA

completed 100 quality monitoring of medical masks available in the market and 532 inspections of packaging labels of medical masks sold in-store or online in 2021.

■ Section 2

A New Era of Smart Medical Device Management

▪ Introduction of the Policy

With the emergence of digital technology, many companies in the information and communications technology (ICT) industry have invested in the research and development of smart medical devices. However, these companies often have to delay the time to launch their products due to insufficient knowledge about medical device regulations, a lack of communication platform for clinical practice, and a lack of talents with expertise in smart technology. To facilitate the development of the smart medical device industry in Taiwan, TFDA has established a "Smart Device Office". The establishment of the office symbolizes the start of a new era of regulatory services that can help to accelerate the product launch of smart medical devices.

▪ Implementation Strategy

The "Smart Device Office" aims to provide a one-stop service with an innovative and multi-faceted consultation model to accelerate the product launch of domestically manufactured smart medical devices. The Office is committed to (1) studying the latest regulatory trends; (2) formulating timely and appropriate management mechanisms and guidelines; (3) incorporating expert opinions on smart medical devices with the establishment of the "Smart Medical Device Advisory Committee"; (4) improving the review process and quality. In addition, educational training courses on smart medical devices are offered to cross-sector business operators as well as reviewers and inspectors working for TFDA to enhance cross-sector personnel's knowledge about smart medical device regulations. Further, to facilitate communication between business operators in the ICT industry and medical institutions, the "AI/ML Medical Devices Matchmaking Platform" has been established to meet the industry's needs to access real-time information and facilitate matchmaking.

▪ Achievements and Benefits

I. Establish the Smart Medical Device Office

On May 7, 2021, TFDA held the grand opening ceremony of the AI/ML Medical Device Office to inform the public of the establishment of the Office. In total, 768 people participated in the event (309 on-site) (Figure 6-1) showing that many people have high expectations and hope that the Office can facilitate the development of the domestic smart medical device industry.

Figure 6-1 **Opening Ceremony of AI/ML Medical Device Office on May 7, 2021**

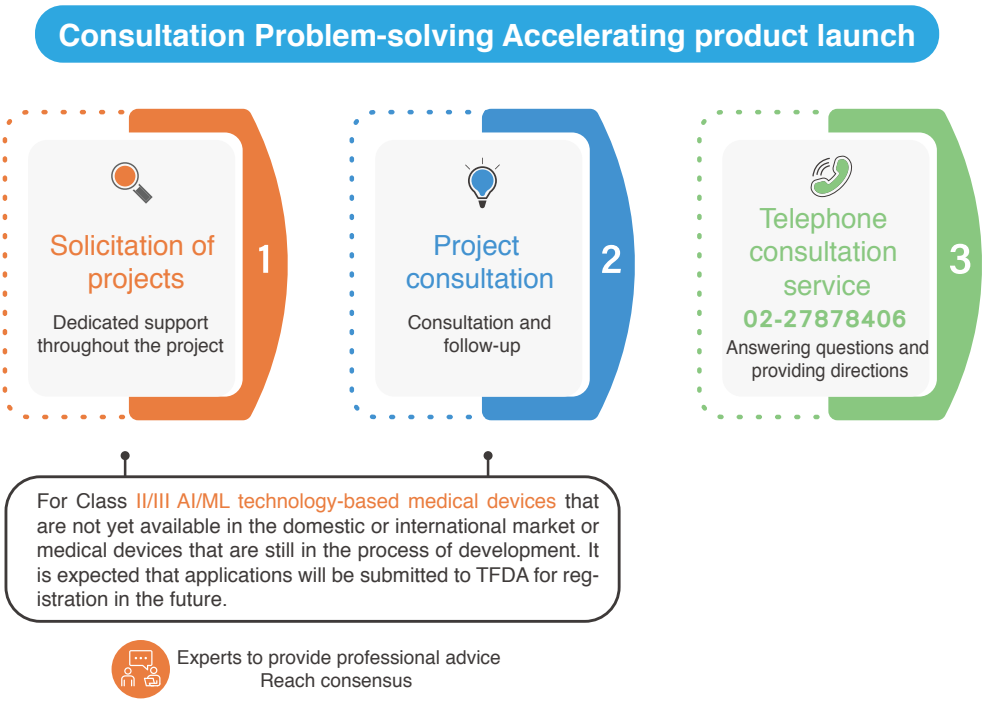


Figure 6-2 **Multi-faced Consultation Model for Smart Medical Devices**

II. Accelerate the launch of domestically manufactured smart medical devices

With an innovative and multi-faceted consultation model (Figure 6-2), TFDA has used public solicitation to select 10 research and development projects that aim to develop Class II/III medical devices using AI/ML technology to actively provide consultation. One of the projects selected has successfully obtained market approval at the end of 2021. In addition, TFDA has completed 13 consultations on the quality management system for manufacturers of smart medical devices. On April 30, 2021, TFDA announced the "*Consultation Guidelines for Domestically Manufactured AI/ML Technology-based Medical Devices*"; and provided consultations for 25 applications. A consultation hotline (02-27878406) has been set up to provide timely consultation related to smart medical devices and has served 1,398 people. Since the Smart Medical Device Advisory Committee was established in 2021, the Committee has provided practical advice to 17 projects related to product development, clinical verification, and statistical analysis of smart medical devices. In total, in 2021, with the support of TFDA, 5 domestically manufactured smart medical devices have been successfully brought to the market, thus benefiting the industry development.

III. Construct a comprehensive regulatory environment for smart medical devices

In 2021, TFDA published and revised 9 guidance documents, templates and FAQs related to smart medical devices (Table 6-1) to be used by operators as references to draft and prepare technical documents prior to product development and application for registration and market approval.

IV. Help cross-sector business operators, reviewers, and inspectors enhance their knowledge about smart medical devices

In 2021, TFDA offered 83 regulation briefings, education and training sessions, workshops, and visits to R&D centers for cross-sector business operators and 29 sessions for reviewers and inspectors working for TFDA. Some of the courses are made available for the general public on "TFDA Digital Learning Platform for Medical Devices and Cosmetics".

V. Establish AI/ML Medical Devices Information & Matchmaking Platforms

On April 30, 2021, TFDA established the AI/ML Medical Devices Information Platform and the platform has accumulated 56,386 visits by the end of 2021. Also, the AI/ML Medical Devices Matchmaking Platform was established on August 31, 2021, and has held two matchmaking events, with 15 preliminary matches to accelerate the establishment of cross-industry alliances and to meet the demand from different fields.

Table 6-1 Guidance Documents, Templates, and FAQs Related to Smart Medical Device

Type of Document	Publication Date	Name of the Document
Guidance Document	May 3,2021	*Guidance on Medical Device Cybersecurity Applicable to Manufacturers* (Revised)
	July 7, 2021	*Guidance on Review of Registration and Market Approval of AI/ML-Based CADe SaMD*
	August 16, 2021	*Technical Guidance for Industry to Register Artificial Intelligence/Machine Learning-based Software as Medical Device (AI/ML-Based SaMD)* (Revised)
	December 30, 2021	*Guidance on Application for Post-market Changes for Software as Medical Device (SaMD)*
	December 30, 2021	*Guidance Document for Quality Management System of Manufacturers of Software as Medical Device (SaMD)*
Technical Document Template	December 6, 2021	Template for Cybersecurity Safety Assessment and Analysis of Medical Device
FAQs	May 7, 2021	FAQs for the Registration and Market Approval of Smart Medical Devices (Revised)
	May 7, 2021	FAQs for Submission of Applications for Registration and Market Approval for AI/ML-based Medical Devices
	December 30, 2021	FAQs on SaMD Manufacturers' Compliance with Medical Device Quality Management System Regulations

■ Section 3

National Award for Research and Development of Pharmaceutical Technology

▪ Introduction of the Policy

In order to improve the pharmaceutical manufacturing standard and the quality of clinical trials, the Ministry of Health and Welfare (MOHW, former Executive Yuan Department of Health) and the Ministry of Economic Affairs (MOEA) have jointly formulated and promulgated the "*Regulations Governing Incentive Rewards for Research and Development of Pharmaceutical Technology*" in accordance with Article 41 of the *Pharmaceutical Affairs Act* in 2000, and held the first Pharmaceutical Technology & Research Development Award (PTRD) in the following year (2001). With the evolution of times and the needs, the MOHW and the MOEA have jointly promulgated the

"*Regulations Governing Incentive Rewards for Research and Development of Innovative Medical Devices Technology*" in accordance with Article 80 of the *Medical Devices Act* in 2021, hoping to encourage more medical device manufacturers to invest in the research and development of innovative medical devices and related technologies.

▪ Implementation Strategy

I. Keeping pace with the times amending related incentive award regulations

MOHW and MOEA have amended some provisions of the "*Regulations Governing Incentive Rewards for Research and Development of Pharmaceutical Technology*" in 2004 and 2013, in order to better clarify the eligibility and the means of the incentive awards. Then in response to the introduction of the *Medical Devices Act* in 2021, issued the "*Regulations Governing Incentive Rewards for Research and Development of Innovative Medical Devices Technology*" on April 29, 2021, so as to keep the regulations up-to-date.

II. Implement for the Pharmaceutical Technology & Research Development Award

The Pharmaceutical Technology & Research Development Award (PTRD) is administered in accordance with the former mentioned two awards regulations, the contents include:

(I) Expand invitation to the pharmaceutical and related production technology industry operators to participate

The promotional posters with the PTRD logo and annual slogan were produced, and were promoted through the official websites of Industrial Development Bureau, MOEA, TFDA, TFDA's Drug and Food Safety Weekly Letter, the TFDA LINE and the Facebook fan page, and biotechnology and medical magazines to encourage related industries to submit outstanding products competing for the PTRD.

(II) Professional review of applications

The industry will submit the award applications in accordance with the eligibility of the PTRD, and their Research and Development (R&D) products will be classified into three categories namely pharmaceuticals, medical devices, and manufacturing technology. Experts in the relevant fields are invited by TFDA to conduct rigorous reviews through preliminary, secondary reviews based on the R&D achievements, benefits, and degrees of contributions, to pick up for the Gold, Silver, and Bronze awards.

(III) Diversified publicity and promotion of incentive award activities

A section for the PTRD on TFDA website was set up to display the call for application rules and award results from previous years. In 2021,

a dedicated website for the PTRD was set up, along with a short promotional animated video, a special 20th anniversary featured articles and a special video, providing the public the access to the 20-year track record of the incentive award.

(IV) Award Ceremony

PTRD has reached its 20th year in 2021, the award ceremony was held publicly to encourage all awardees, also the ceremony scopes were expanded to include the starlight interview area and the finalists honorary exhibition area. The awards were announced live to increase the level of surprise, with the Minister of MOHW presenting the trophies to the awardees who were then invited to deliver their speeches respectively.

▪ Achievements and Benefits

I. National awards benefit industry to expand reputation internationally

The PTRD is the sole national award jointly awarded and presented by MOHW and MOEA. To show the glory of this award, the 20th award ceremony was expanded to hold on November 30, 2021, at the International Conference Hall of the National Biotechnology Research Park (Figure 6-3), with 165 people attending the ceremony, 47 exposures of press releases. The 20th award anniversary publications and videos had been promoted on a dedicated website for the PTRD and has been established to convey Taiwan's promotion and philosophy of pharmaceutical science and technology; the website has been attracting 7,736 page views and at least 1,216 visitors. By publicly recognizing products with outstanding contributions and innovative R&D, would

Figure 6-3 Group Photo of the 20th PTRD

encourage greater pharmaceutical technology research and development teams to participate in the sole national-level award to build the value of Taiwan's pharmaceutical and biotechnology brand, allowing more excellent pharmaceuticals and medical devices to be created and developed for the benefit of public health.

II. Demonstrate the R&D capacity of Taiwan's medical and biotechnology industry

The theme of the year 2021 is "Excellent Pharmaceuticals, Leap 20", symbolizing the 20th year of the event and the upcoming 20 years. There were 13 applicants awarded with gold, silver, and bronze respectively in the 20th year, including 4 in the category of "Pharmaceuticals", 6 in the category of "Medical Devices", and 3 in the category of "Manufacturing Technology".

Among them, 3 products were recognized with "Gold Award", including "ELIXCYTE®", a new stem cell drug for knee osteoarthritis, which can provide early relief of pain and improve joint movement; "An IVD for Rapid Detection and Surveillance of Chronic Kidney Disease: Protein-Bound Uremic Toxin ELISA Kit", which can facilitate rapid test and monitoring of chronic kidney disease for clinicians to evaluate the course of the disease and treatment; and the "Qsep Series Bio-Fragment Analyzers", with capillary electrophoresis as the core technology, and can be used for the detection of acute epidemics, pathogenic bacteria and cancer screening, etc. These results fully demonstrated the achievements and potential of domestic medical research development.

III. Promote Medical and Biotechnology Innovation Excellence and Global Presence

Despite the impact of the COVID-19 pandemic in recent years, PTRD through multiple channels of promotion and soliciting, industry participation has been eager and the number of submissions was still rising with the medical device cases also hit a record high in 2021 (Figure 6-4). From 2001 to 2021, more than 200 PTRD have been given out, the benchmarked awardees have continued to refine their products in terms of R&D, process improvement, and quality technology, to maximize the clinical benefits. They also continue to diversify the development and reach out global market, with the recognition of the PTRD, would help to strengthen the brand awareness and the company image, and create a virtuous cycle in the industry and competitive advantage of the company; hence help Taiwan's Medical Biotechnology Industry to thrive internationally.

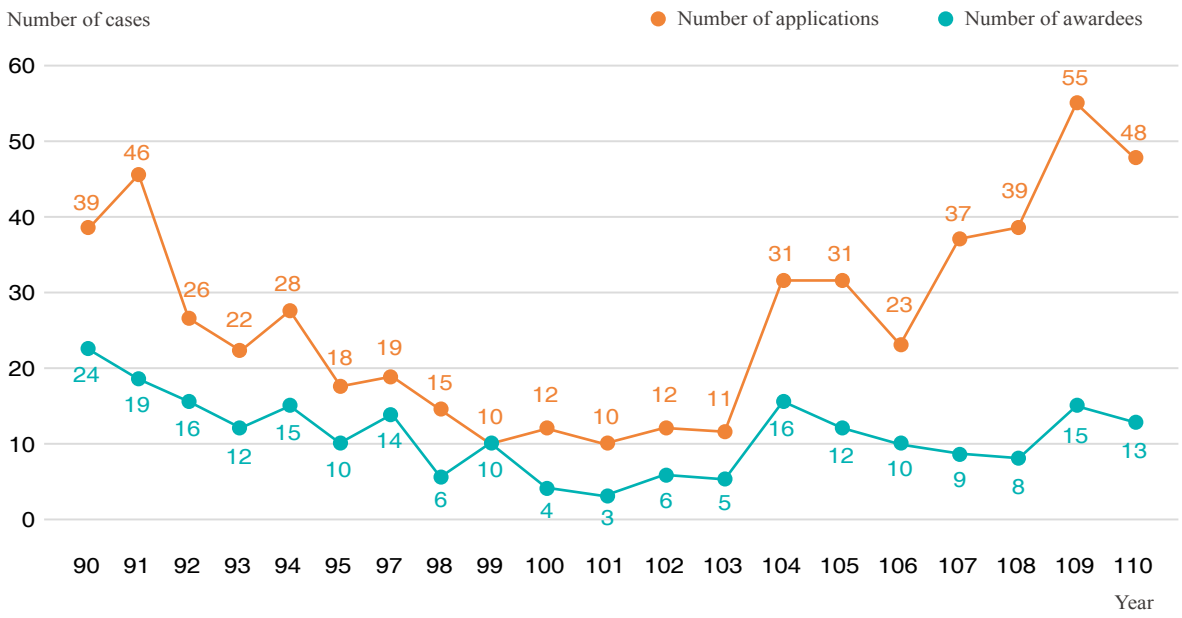


Figure 6-4 **Number of Applications and Awardees for the PTRD Over the Years**

7 Appendix

Appendix 1 Important Events
Appendix 2 Important Achievements and Statistics in 2021
Appendix 3 Important Achievements and Statistics Over the Years
Appendix 4 TFDA Publications in 2021
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Appendix 1 Important Events

Date	Description
April 15	TFDA participated in the 4th APACRM online meeting organized by the Forum of Innovative Regenerative Medicine (FIRM) in Japan, with the participation of regulatory authorities and industry from Japan, China, India, Korea, Singapore, and Taiwan. Representatives from the industry of different countries introduced the updates of regenerative medicine in their countries and discussed in small groups on topics such as drug toxicology, bio-distribution, oncogenicity and comparability, as well as sharing experiences on early approval and health insurance system.
May 7	Smart Medical Device Office was established.
June 3	Held the "Workshop on the Analysis and Application of Artificial Intelligence in Medical Imaging". Experts from National University of Singapore, as well as experts and scholars from Taiwan were invited to share and exchange relevant experiences. More than 80 participants from the industry, government, academia and research sectors attended the workshop to enhance Taiwan's medical imaging diagnostic technology to be in line with international standards.
June 21 to June 23	TFDA, as a full member, attended the International Cooperation on Cosmetics Regulations (ICCR) 15th Annual Meeting (virtual).
July 8	TFDA attended the 2021 DIA-CoRE Singapore Online Meeting organized by Drug Information Association (DIA) and National University of Singapore. With the participation of the pharmaceutical industry, government and academia, the theme of the seminar was to discuss the use of emerging technologies and innovative drug regulatory policies to address the global pandemic and future trends in healthcare. Representatives from TFDA shared accelerated approval mechanism on the emergency use authorization for COVID-19 drugs and vaccine in Taiwan.
July 9	TFDA attended the APEC Life Science Innovation Forum (LSIF) "Building the Right Regulatory Environment for COVID-19 Responses & Long-Term Health Resilience" webinar. Our representative shared the emergency regulatory measures and strategies for accelerating the development of domestic vaccines in response to the COVID-19 epidemic.
August 2 to August 11	TFDA was invited to deliver opening remarks, a pre-recorded lecture and closing remarks at the "2021 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence (CoE) Workshop—Virtual Meeting" organized by the Thai FDA.
August 10 to August 11	Held the "2021 APEC International Workshop on Food Adulterated with Drugs and Illegal Products" and invited representatives from France, Belgium, Australia and other countries, as well as scholars and experts from Taiwan, to share and exchange the latest technological developments of new psychoactive substances, illicit drugs testing technology worldwide online. Over 300 representatives from various fields joined the seminar.

Date	Description
August 24 to August 25	Convened the "Medical Devices EUA" Joint Working Group Meeting for the Asian Harmonization Working Party (AHWP), and WG2 Meeting.
August 24 to September 16	TFDA hosted the "2021 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence (CoE) Workshop". This workshop was composed of online self-learning lectures and video conferences. Over 100 regulatory sciences experts from industries, regulatory authorities, and the academia among 14 APEC economies participated the workshop. The Director General of TFDA, Dr. Wu Shou-mei, shared with the participants TFDA's experiences and strategies to accelerate the development and review of the domestic COVID-19 vaccine.
August 26	Held the "Cross-Sector Smart Medical Devices Summit". Experts from industry, government, and academia were brought together to have cross-disciplinary dialogues and offer suggestions regarding future policies for smart medical devices, and to help the government establish a management system of smart medical devices that is in line with international standards.
August 28 to August 29	TFDA attended the "STEVENS-JOHNSON SYNDROME/TOXIC EPIDERMAL NECROLYSIS (SJS/TEN) 2021 Meeting" online meeting held by Vanderbilt University Medical Center (VUMC). Experts and scholars from the US, Canada, Japan, Taiwan, and the US FDA attended the meeting. The meeting focused on the promotion of pharmacogenetic testing for drug injury prevention. Our representative shared the difficulties and successful cases of supervising ADR and drug relief regulations.
August 28 to September 11	Held the "2021 APEC Medical Device Regulatory Science Center of Excellence Seminar" online.
August 31	Held the "2021 Annual Food Analytical Techniques Online Symposium" to invite scholars from Taiwan and abroad to deliver lectures and exchanges on food analysis technology and chemical residues and contaminants. Nearly 200 people from central and local health authorities, private certified laboratories, and industry, academia and research sectors participated, which helped to expand new knowledge and improve analysis technology.
September 8	Held the "Conference on Analytical Techniques for Cosmetics" and invited experts and scholars from Thailand, Switzerland, the U.S. and Taiwan to give keynote speeches and exchanges online, promoting international exchanges and cooperation in cosmetics analytical technology. A total of about 300 people from the industry, government, academia and research sectors participated.
October 13 to October 15	TFDA attended the 13th Asian Pharmacoepidemiology Online Seminar, co-organized by the International Society for Pharmacoepidemiology (ISPE) and the Korean Society for Pharmacoepidemiology and Risk Management (KoPERM) and invited health authorities from various countries and representatives from Taiwan to share their domestic drug safety trends.
October 14 to October 15	TFDA hosted the "9th Joint Conference of Taiwan and Japan on Medical Products Regulation" to share the progress of pharmaceutical and medical device regulations between Taiwan and Japan, promote the exchange of regulation information and understanding of both parties, strengthen the bilateral cooperation between officials and industry, and to assist industry in developing international markets.
November 2	Organized the "2021 Taiwan FDA Medical Device UDI International Virtual Workshop".
November 26	TFDA co-hosted with the Regulatory Affairs Professionals (RAPS) Taiwan Chapter and convened the "Good Registration Management (GRM) domestic workshop" to promote and exchange the experiences and discussions of among different aspects, and to improve the efficacy and quality of the drug registration management.

Date	Description
November 30 to December 1	Participated in the “25th AHWP/GHWP Annual Meeting”.
December 7	TFDA hosted a seminar for the domestic pharmaceutical industries on guidance and experience sharing in submitting documents for exporting pharmaceutical products. Domestic industries were invited to share experience of regulatory consultations, the strategies of generic drugs in the international market, how to convert the quality information of Taiwan’s submission information into the ASEAN submission format, and the points to note, and the strategy and pre-submission preparation for overseas registration, etc.; so as to help the domestic industry to enter the export market more effectively.
December 8	In order to continue promoting the concepts and spirit of “food service hygiene and safety”, “proper selection of edible ingredients” and “eat with peace of mind”, two representatives of the 2021 annual “FDA Excellent Chefs” were invited to design and demonstrate safe and burden-free New Year’s Eve dishes, allowing the public to cook hygienic, tasty and burden-free New Year’s Eve dishes.

■ Appendix 2 Important Achievements and Statistics in 2021

Table 1 Addendum/amendment to the Regulations and Standards Related to Food Safety and Health Management in 2021

Date of announcement	Subject of announcement	Key point descriptions
January 5	Stipulated "*Regulation for The Use Restriction and Labeling Requirement of Coffee Leaves as Food Ingredients*"	The coffee leaves (*Coffea arabica, Coffea canephora*) shall be dried and can only be used for brewing beverage. The labelling of food products containing coffee leaves shall bear the following warning statement: Children, pregnant women and lactating women shall avoid consuming.
January 25	Amended Annex 1 of Article 2, Annex 2 of Article 3 in "*Standards for Specification, Scope, Application and Limitation of Food Additives*"	Added the Standards for Specification, Scope, Application and Limitation of the antioxidant rosemary extract. Revised the colorant sodium copper chlorophyll scope, application and limitation.
January 27	Amended Article 3 in "*Standards for Pesticide Residue Limits in Animal Products*"	Amended the residue limits for 14 pesticides, including Acephate in animal products. Amended Thymol exempted from the requirement of tolerance in bee products. Revised the common name of "Chlormequat".
February 4	Amended Article 6 and Annex 3 of Article 5 in the "*Sanitation Standard for Contaminants and Toxins in Food*"	Added the limitation standard of glycidyl fatty acid esters in food for infants and young children.
February 4	Stipulated "*Regulation for the Use Restriction and Labeling Requirement of Guayusa Leaves (Ilex guayusa) as Food Ingredients*"	The guayusa leaves (*Ilex guayusa*) shall be dried and can only be used for brewing beverage. The labelling of food products containing guayusa leaves shall bear the following warning statement: Children, pregnant women and lactating women shall avoid consuming.
February 18	Amended the "Complex Import Regulation Containing F01 in Import Commodity Classification" to state that if a product is classified as food or food additives (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.	Announced 1211.20.10.00-7 "Jilin Ginseng" 2 items; if the product is fresh, it should be submitted to TFDA for food import inspection.
February 22	Amended Article 4, Annex 1 of Article 2, Annex 2 of Article 3 in "*Standards for Specification, Scope, Application and Limitation of Food Additives*"	Added standards for specification, scope, application and limitation for the use of carbon dioxide as a food additive.

Date of announcement	Subject of announcement	Key point descriptions
March 2	Amended "*Regulations Governing the Product Name and Labeling of Chocolate*"	Added the requirement for filled chocolate products which the chocolate must make up at least 25% of the total weight of the product, and the product name shall be labeled "filled chocolate" or "processed chocolate" or other synonymous terms. Added the labelling requirements for semi-solid or fluid chocolate products, to require that chocolate spreads and chocolate syrups should contain at least 5% cocoa solids or at least 2% of cocoa butter. Amended the labeling requirement for products with added vegetable oil exceeding 5% of the total weight of the product shall not name as "chocolate".
March 11	Stipulated "*Regulation for The Use Restrictions and Labeling Requirements of Astaxanthin Produced by Genetically Modified Escherichia coli strain Ast12 as a Food Ingredient*"	Regulated the use of astaxanthin produced by genetically modified *Escherichia coli* strain Ast12 as a Food Ingredient should follow the relevant regulations.
March 17	Amended Article 4 and Annex 1 of Article 2, Annex 2 of Article 3 in "*Standards for Specification, Scope, Application and Limitation of Food Additives*"	Added the standards for specification, scope, application and limitation of food additive gum, guanhua bean gum, and locust bean gum.
April 15	Amended and revised "*Evaluation Method of Anti-fatigue Function of Health Food*", and renamed to *"The Efficacy Assessment Method of Health Food for Fatigue Resistance"*	Deleted animal experiments, revised the measurement items and detection methods of physical performance parameters and mechanism parameters. Revised the contents of results determination and health care effects claims.
April 27	Amended "*Regulations on Nutrition Labeling for Prepackaged Food Products*"	Included "*Regulations on Nutrition Labeling for Prepackaged Infant and Follow-up Formula and Formula for Certain Disease*" into "*Regulations on Nutrition Labeling for Prepackaged Food Products*"
April 28	Amended Point 1 in "*Categories and Scales of Food Enterprises Subject to Compulsory Registration and Dates of Implementation*"	Expanded the scope of registration to include "farmers or farmer groups registered for primary processing plant of agricultural products", and "importer businesses with taxation registration" as the ones who should be registered.
May 12	Stipulated "*Regulation for the Use Restriction of Purging cassia (Cassia fistula L.) Fruit*"	The Purging cassia (*Cassia fistula L.*) fruit is not allowed to be used as a food ingredient. However, food products containing Purging cassia fruit can be placed on the market until their expiry date if the production date of domestic products or the imported date of imported products are before the implementation date.

Date of announcement	Subject of announcement	Key point descriptions
June 1	Amended the "Import Regulation of 508 in Import Commodity Classification; 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."	Amended additional import regulation of 508 for CCC 2918.21.00.00-2 "Salicylic acid and its salts".
June 16	Stipulated "*Regulation for the Use Restriction and Labeling Requirement of 2'-fucosyllactose Produced by Genetically Modified Escherichia coli strain K-12 DH1 MDO MAP1001d as a Food Ingredient*"	Regulated that "2'-Fucosyllactose Produced by Fermentation of Genetically Modified *Escherichia coli* K-12 DH1 MDO MAP1001d Strain "should be in accordance with the relevant regulations when it is used as food ingredient.
June 23	Amended Article 4 and Annex 1 of Article 2 in "*Standards for Specification, Scope, Application and Limitation of Food Additive*"	Amended the use restriction of each ingredient in the list of flavoring agents in category 10, and the name of pulegone. Specified that Synthetic flavoring agents styrene (Styrene), eugenyl methyl ether (Eugenyl methyl ether) and pyridine cannot be used.
June 24	Amended Article 3 in "*Standards for Veterinary Drug Residue Limits in Foods*"	Added maximum residue limits for Coumaphos (or Coumafos) in cattle muscle, liver, kidney and fat. Added maximum residue limits for Gamithromycin in cattle liver, kidney and fat and in swine muscle, liver, kidney and fat (including skin).
July 16	Stipulated "*Regulation of COVID-19 Prevention and Management for the Food Service*"	The Food Service shall follow the epidemic prevention regulations of the Central Epidemic Command Center and comply with the regulations of these management measures to provide internal services.
August 18	Amended Annex 1 of Article 3, Annex 3 of Article 4, Annex 5 of Article 6 in "*Standards for Pesticide Residue Limits in Foods*".	Amended 187 residue limit standards for 43 pesticides. Added *Bacillus amyloliquefaciens* Tcba05, *Bacillus velezensis* BF and Prohydrojasmon as pesticides exempted from the requirement of a tolerance. Added Gac fruit to the cassification of melon vegetables.
August 18	Amended Annex 1 of Article 2 in "*Standards for Specification, Scope, Application and Limitation of Food Additives*"	Included the regulations of food additives used in dairy products in the "Sanitation Standard for Milk and Milk Products" which was abolished on June 30, 2021.

Date of announcement	Subject of announcement	Key point descriptions
August 24	Amended "*Regulation of COVID-19 Prevention and Management for the Food Service*"	Amended the use of checkerboard seating or partitions at the same table to maintain a distance of 1.5 meters or the use of partitions; added that the same household friends/ relatives and caregivers are not regulated by the distance and partition at same table.
September 1	Stipulated "*Regulations Governing the Labeling of Small Prepackaged Food*"	Prepackaged food where the largest surface area is less than 20 cm² and being sold in the market are exempt from some of the labeling requirements.
September 28	Amended "*Food Business Shall Take Out Product Liability Insurance*"	Expanded the requirement that food or food additive manufacturing, processing or blending establishments with "tax registration" or "primary processing plant registration for agricultural products" and importing establishments with "tax registration" should take out product liability insurance for their imported or manufactured products.
October 5	Amended "*Regulation of COVID-19 Prevention and Management for the Food Service*"	Removed restrictions on the use of partitions or the maintenance of 1.5m spacing for dining in services.
October 6	Amended the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	Deleted CCC code for 2 items such as 0301.99.29.48-9 "Piranha". Added CCC code for 3 items such as 1901.10.00.11-3 "Infant Milk powder (incl. follow up formula), for retail". Amended import regulation for CCC 0307.71.90.21-0, "Giant clams (Tridacnidae spp.), live" from F01 to F02.

Remarks:

1. Up to 2021, accumulated addition/revision of 7,500 pesticide residue limits; 1,522 veterinary drug residue limits; 794 food additives usage scopes, limits, and specifications; and 17 food hygiene standards.
2. Commodity classification code list: according to Article 30 of the *Act Governing Food Safety and Sanitation*, the import of food and other related products announced by the central competent authority shall be in accordance with the commodity classification code and be applied to the central competent authority for inspection. By the end of 2021, there were 2,694 announced commodity classification code for the inspection of imported foods, 2,108 with the import regulation F01, 127 with import regulation F02, 374 with import regulation 508, and 85 with complex import regulation.

Table 2　Guidance of Food Hygiene Management and Operations Announced in 2021

Numbering	Announcement date	Announcement name	Description
1	January 12	Amended the "Operational Guidelines for Reducing the Content of Polycyclic Aromatic Hydrocarbons in Foods"	1. Added PAH4 as monitoring indicators for various food products. 2. Added BaP monitoring indicators for "cocoa bean shells used as food ingredients" and "dietary supplements containing plant ingredients or plant extracts".
2	March 17	Guidelines for Labeling of Ready-to-Eat Fresh Bulk Food Products	1. Amended the name of the guidelines. 2. Added the definition of "Ready-to-eat Fresh Bulk Foods". 3. Added allergen warning information as an additional voluntary labeling item.

Numbering	Announcement date	Announcement name	Description
2	March 17	Guidelines for Labeling of Ready-to-Eat Fresh Bulk Food Products	4. Added the ranges of allowable error for nutrition labeling value, nutrition labeling may be labeled according to the Guidelines for Front of Package Nutrition Labeling for Food Products or be disclosed electronically in the form of a QR Code or others electronic disclosures, and the words "Scan here to view nutrition information" or words of the same meaning shall be indicated above or below the QR Code. 5. Added the font size shall be in accordance with Article 19 of the "*Enforcement Rules of Act Governing Food Safety and Sanitation*"
3	July 12	Guidelines for Manufacturers of jelly products to follow the "*Regulations on Good Hygiene Practice for Food (GHP)*"	The guidelines are based on the "*Act Governing Food Safety and Sanitation*" and the "*Regulations on Good Hygiene Practice for Food (GHP)*", the manufacturers can refer to the content of the guidelines and the actual operating situations to stipulate the standard operating procedures for the manufacturing process.
4	July 16	Guidance of COVID-19 Prevention for the Food Service	For the reference of food service, according to the practical feasibility and applicability, internalize into the suitable management for individual venues, to strengthen the epidemic prevention management measures.
5	September 30	Amended the "Guidelines of Hygiene Self-Management for Online Food Delivery Platform Business Operators"	1. Added the information which should be disclosed on the website or application software. 2. Food delivery platform operators are requested to give priority to choose those operators with food business registration number.

Table 3 Inspection and Registration of Specific Foods and Food Additives in 2021

The food category should be registered		Number of valid documents
Imported foods in tablet and capsule		7,231
Health food		406
Food additives		6,058
Genetically modified food		155
Special dietary foods	Formula for certain disease	290
	Formula and follow-up formula complementary foods	129
Domestic capsule and tablet vitamin products		1,400
Vacuum-packaged ready-to-eat soybean food		55
Total		15,724

Table 4　Food Inspection Sampling Test Project in 2021

Numbering	Project name	Results
1	HACCP Inspection Project for Processed Meat Industry	I. Inspected: 151 companies (I) GHP: 4 companies were not applicable; 94 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 24 companies were not applicable. 105 companies were required to make improvements within a deadline, of which 6 companies did not pass the re-inspection. (III) Food businesses registration: 3 companies were not applicable; 43 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Mandatory inspection: 27 companies were not applicable; 36 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Traceability: 25 companies were not applicable, 48 companies were required to make improvements within a deadline, of which 6 companies did not pass the re-inspection. (VI) Others: 1. 2 companies stored expired foods. 2. 14 companies did not have a hygiene inspector. 3. 2 companies did not hire professional staff or technical personnel. II. Labeling: 151 companies, of which 3 companies did not comply with the regulations. III. Random inspection: 315 cases. (I) 228 cases of raw meat, of which 1 case did not comply with the regulations. (II) 87 cases of processed finished product, all complied with the regulations.
2	HACCP Inspection Project for Meal Box Factory	I. Inspected: 80 companies. (I) GHP: 1 company was not applicable; 53 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 2 companies were not applicable. 59 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (III) Food businesses registration: 1 company was not applicable; 15 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Food safety monitoring plan: 60 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (V) Food Traceability Management Information System: 6 companies were not applicable. 17 were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Waste management: 1 company was not applicable; 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Provide information on the origin of pork or beef to downstream operators: 2 companies were not applicable; the remaining 78 companies were in compliance with regulation. (VIII) Others: 1. 4 companies stored expired foods. 2. 1 company did not have a hygiene inspector. 3. 1 company did not hire professional staff or hygiene inspector. 4. 1 company did not hire professional staff.

Numbering	Project name	Results
2	HACCP Inspection Project for Meal Box Factory	II. Labeling: 80 cases, of which 1 case did not meet the regulations. III. Random inspection: 234 cases (I) Finished products: 78 cases, all complied with the regulations (II) Semi-finished products: 78 cases, of which 1 case did not comply with the regulations. (III) Raw pork: 78 cases, all complied with the requirements.
3	HACCP Inspection Project for Canned Food Factory	I. Inspected:31 companies (I) GHP: 19 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 20 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (III) Food businesses registration: 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Mandatory inspection: 20 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (V) Traceability: 20 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VI) Electronic declaration: 20 companies were not applicable; 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Food safety monitoring plan: 22 companies were not applicable and the remaining 9 companies complied with regulations. (VIII) Product liability insurance: 2 companies were not applicable and the remaining 29 companies complied with the regulations. II. Labeling: 75 cases, of which 4 cases were not comply with the regulations. III. Random inspection: 54 cases, all complied with the regulations.
4	Third tier inspection project for certified 2nd tier quality control Food factory.	I. Inspected: 27 companies (I) GHP：10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP：18 companies were not applicable, 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Food businesses registration:5 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 7 companies were not applicable; 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Electronic declaration: 7 companies were not applicable; 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Food safety monitoring plan: 13 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VII) Mandatory inspection: 7 companies were not applicable; 2 companies were required to make improvements within a deadline and all of them passed the re-inspection.

Numbering	Project name	Results
4	Third tier inspection project for certified 2nd tier quality control Food factory.	(VIII) Others: 1. 1 company did not hire professional staff or technical personnel. 2. 1 company did not have an accreditation of sanitation and safety control. II. Labeling: 62 cases, all complied with the regulations.
5	Inspection Project for Food Additive Manufacturers	I. Inspected: 38 companies (I) GHP: 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory inspection: 1 company was not applicable; 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Electronic declaration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Food safety monitoring plan: 23 companies were not applicable; 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. II. Labeling: 69 cases, of which 4 cases did not comply with the regulations. III. Random inspection: 40 cases, of which 1 case did not comply with the regulations.
6	Inspection Project for Domestic Source Providers of Health Foods, Vitamin Tablets and Capsules and Specialized Nutritious Foods	I. Inspected: 36 companies (I) GHP: 8 companies were not applicable; 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 3 companies were not applicable and the remaining 33 companies complied with the regulations. (III) Mandatory inspection: 19 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (IV) Traceability: 18 companies were not applicable and the remaining 18 companies complied with the regulations. (V) Food safety monitoring plan: 19 companies were not applicable, 1 company was required to make improvements within a deadline and has passed the re-inspection. (VI) Food Traceability Management Information System: 18 companies were not applicable, 2 companies were required improvement within a deadline, and all of them complied with the regulations. (VII) Waste management: 8 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VIII) Product registration permit: 63 cases, of which 4 cases did not comply with the regulations. II. Labeling: 58 cases, of which 8 cases did not comply with the regulations III. Random inspection: 10 cases of infant or follow-up formulas food, all complied with the regulations.

Numbering	Project name	Results
7	Inspection Project for Edible Oils Manufacturers	I. Inspected: 36 companies (I) GHP: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 33 companies were not applicable, 2 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (III) Food businesses registration: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 21 companies were not applicable; 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Electronic declaration: 21 companies were not applicable; 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Food safety monitoring plan: 35 companies were not applicable and 1 company complied with the regulation. II. Labeling: 60 cases, of which 3 cases did not comply with the regulations. III. Random inspection: 55 cases, of which 2 cases did not comply with the regulations.
8	Inspection Project for Liquid Egg Manufacturers	I. Inspected: 74 companies (I) GHP: 6 companies were not applicable; 28 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 54 companies were not applicable; 15 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Food businesses registration: 1 company was not applicable; 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 67 companies were not applicable and the remaining 7 companies complied with the regulations. II. Labeling: 145 cases of Liquid Egg Product Labeling, of which 2 cases did not comply with the regulations. III. Random inspection: 192 cases (I) Fresh raw materials egg: 60 cases, of which 2 cases did not comply with the regulations. (II) Liquid egg finished products: 132 cases, all complied with the regulations.
9	Inspection Project for Edible Ice Manufacturers	I. Inspected: 73 companies (I) GHP: 42 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 4 companies were not applicable and the remaining 69 companies complied with the regulations. II. Labeling: 30 cases, of which 1 case did not comply with the regulations. III. Random inspection: 95 cases, of which 1 case did not comply with the regulations.

Numbering	Project name	Results
10	Inspection project for Packaged Fruit and Vegetable Juice Manufacturers	I. Inspected: 45 companies (I) GHP: 3 companies were not applicable, 10 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (II) Food businesses registration: 2 companies were not applicable; 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory inspection: 21 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (IV) Gas usage: 9 companies used gas during processing and all of them complied with the regulation. (V) Traceability: 21 companies were not applicable, 2 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (VI) Electronic declaration: 21 companies were not applicable, 3 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (VII) Food safety monitoring plan: 21 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VIII) Waste management: 3 companies were not applicable; 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 65 cases, of which 2 cases did not comply with the regulations. III. Random inspection: 67 cases, all complied with the regulations.
11	Inspection Project for Soy Sauce Manufacturers	I. Inspected: 55 companies (I) GHP: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Traceability: 53 companies were not applicable and the remaining 2 companies complied with the regulations. (IV) 1st tier quality control: 53 companies were not applicable and the remaining 2 companies complied with the regulations. (V) Product liability insurance: 1 company was not applicable and the remaining 54 companies complied with the regulations. II. Labeling: 131 cases, of which 4 cases did not comply with the regulations. III. Random inspection: Soy sauce products: 64 cases, all complied with the regulations.
12	Inspection Project for Aquatic Processed Food Factory	I. Inspected: 55 companies (I) GHP: 22 companies were required to make improvements within a deadline, of which 2 companies did not pass the re-inspection. (II) HACCP: 24 companies were not applicable, 19 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (III) Food businesses registration: 12 companies were required to make improvements within a deadline and all of them passed the re-inspection.

Numbering	Project name	Results
12	Inspection Project for Aquatic Processed Food Factory	(IV) Mandatory inspection: 35 companies were not applicable; 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Traceability: 24 companies were not applicable. 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Electronic declaration: 24 companies were not applicable; 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Food safety monitoring plan: 45 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VIII) Product liability insurance: 1 company was not applicable and 1 company did not comply with the regulations. (IX) Others: 1. 5 companies did not have a hygiene inspector. 2. 1 company did not label the selling food additives in accordance with the regulations. II. Labeling: 102 cases, of which 2 cases did not comply with the regulations. III. Random inspection: 103 cases, all complied with the regulations.
13	Inspection Project for Beverage and Ice Ingredients Manufacturing Industry	I. Inspected: 34 companies (I) GHP: 3 companies were not applicable; 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 3 companies were not applicable; 5 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory inspection: 25 companies were not applicable; 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Gas usage: 1 company used gas during processing and complied with the regulations. (V) Traceability: 25 companies were not applicable; 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Electronic declaration: 25 companies were not applicable; 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Food safety monitoring plan: 25 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VIII) Waste management: 3 companies were not applicable; 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IX) Others: 1. 1 company stored expired foods. 2. 2 companies did not have a hygiene inspector. II. Labeling: 54 cases, of which 2 cases did not comply with the regulations. III. Random inspection: 50 cases, all complied with the regulations.

Numbering	Project name	Results
14	Inspection Project for Preserved Eggs, Salted Eggs and liquor Eggs Manufacturers	I. Inspected: 32 companies (I) GHP: 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 25 companies were not applicable; 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Food businesses registration: 2 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. II. Random inspection: 87 cases (I) Fresh egg raw materials: 29 cases, all complied with the regulations. (II) Pickled egg finished products: 58 cases, all complied with the regulations.
15	Random inspection Project for Pickled Vegetables on the Market	I. Inspected: 140 companies (I) GHP: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Others: 1 company stored expired foods. II. Random inspection: 436 cases, of which 33 cases did not comply with the regulations.
16	Inspection Project for Pickled Vegetables Manufacturer	I. Inspected: 55 companies (I) GHP: 28 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Others: 1. 1 company stored expired raw materials. 2. 2 companies did not have a hygiene inspector. II. Labeling: 66 cases, of which 7 cases did not comply with the regulations. III. Random inspection: 54 cases, of which 1 case did not comply with the regulations.

Numbering	Project name	Results
17	Inspection Project for Creamer Product Manufacturers	I. Inspected: 31 companies (I) GHP: 5 companies were not applicable; 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 5 companies were not applicable; 12 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory inspection: 17 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (IV) Gas usage: 1 company used gas during processing and complied with the regulation. (V) Traceability: 17 companies were not applicable; 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (VI) Electronic declaration: 17 companies were not applicable, 6 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (VII) Food safety monitoring plan: 17 companies were not applicable; 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (VIII) Waste management: 5 companies were not applicable; 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IX) Others: 1 company stored expired products II. Labeling: 37 cases, of which 14 cases did not comply with the regulations. III. Random inspection: 23 cases, all complied with the regulations.
18	Inspection Project for Bean Products Manufacturers	I. Inspected: 101 companies (I) GHP: 59 companies were required to make improvements within a deadline, of which 2 companies did not pass the re-inspection. (II) Food businesses registration: 3 companies were not applicable; 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Others: 1. 1 company stored expired food additives. 2. 6 companies did not have a hygiene inspector. II. Labeling: 62 cases, of which 2 cases did not comply with the regulations. III. Random inspection: 178 cases, of which 9 case did not comply with the regulations.
19	Inspection Project for Noodles Restaurant Operators	I. Inspected: 175 companies. (I) GHP: 71 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 6 companies were not applicable; 26 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Product liability insurance: 27 companies were not applicable and the remaining 148 companies complied with the regulations.

Numbering	Project name	Results
19	Inspection Project for Noodles Restaurant Operators	II. On-site labeling: 175 cases, of which 1 case did not comply with the regulations. III. Random inspection: 278 cases, of which 1 case did not comply with the regulations.
20	Inspection Project for Gourmet Restaurants at Local Popular Attractions	I. Inspected: 210 companies. (I) GHP: 86 companies were required to make improvements within a deadline and no failure was found in the re-inspection. (II) Food businesses registration: 3 companies were not applicable; 37 companies were required to make improvements within a deadline and no failure was found in the re-inspection. (III) Product liability insurance: 13 companies were not applicable and 2 companies did not comply with the regulations. (IV) Others: 1 company stored expired foods. II. Labeling: 210 cases, of which 3 cases did not comply with the regulations. III. Random inspection: 474 cases, of which 3 cases did not comply with the regulations.
21	Inspection Project for Drinks Made on Site	I. Inspected: 269 companies (I) GHP: 109 companies were required to make improvements within a deadline and no failure was found in the re-inspection. (II) Food businesses registration: 15 companies were not applicable; 36 companies were required to make improvements within a deadline and no failure was found in the re-inspection. (III) Retain the source documents: 21 companies were required to make improvements within a deadline, all of them passed the re-inspection. II. On-site labeling: 196 companies, of which 35 companies did not comply with the regulations. III. Random inspection: 378 cases, of which 28 cases did not comply with the regulations.
22	nspection and Random inspection Project for KTV Buffet	I. Inspected: 79 companies (I) GHP: 33 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 21 companies were required to make improvements within a deadline and no failure was found in the re-inspection. (III) Retain the source documents: 3 companies were required to make improvements within a deadline, all of them passed the re-inspection. (IV) Product liability insurance: 2 companies were not applicable and the remaining 77 companies complied with the regulations. II. On-site labeling: 79 companies, of which 2 companies did not comply with the regulations. III. Random inspection: 233 cases, of which 3 cases did not comply with the regulations.

Numbering	Project name	Results
23	Inspection Project for Banquet Restaurants	I. Inspected: 268 companies (I) GHP: 108 companies were required to make improvements within a deadline, of which 2 companies did not pass the re-inspection. (II) Food businesses registration: 49 companies were required improvement within a deadline, and no failure was found in the re-inspection. (III) Personnel holding technical licenses: 1 company was not applicable; 5 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Others: 2 companies stored expired foods. II. Labeling: 268 cases, of which 1 case did not comply with the regulations. III. Random inspection: 190 cases, of which 1 case did not comply with the regulations.
24	Inspection and Random inspection Project for Ice Products Made on Site	I. Inspected: 98 companies (I) GHP: 40 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (II) Food businesses registration: 4 companies were not applicable; 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Random inspection: 221 cases, of which 5 cases did not comply with the regulations.
25	Inspection Project for Popular Hotel Restaurants	I. Inspected: 263 companies (I) GHP: 108 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: A total of 27 companies should implement HACCP, of which 20 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Food businesses registration: 56 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Standard form contract: All of 263 companies complied with the regulations (V) Others: 1. 6 companies stored expired foods. 2. 1 company did not hire professional staff II. On-site Labeling: 263 cases, of which 2 cases did not comply with the regulations. III. Random inspection: 322 cases, of which 1 case did not comply with the regulations
26	Inspection Project for Food Delivery Platform Operators	I. Food delivery operators: 10 companies (I) GHP: All of 10 companies complied with the regulations. (II) Food businesses registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Standard form contract: All of 10 companies complied with the regulations. (IV) Customer complaint handling process: 1 company was required to make improvement within a deadline and had passed the re-inspection.

Numbering	Project name	Results
26	Inspection Project for Food Delivery Platform Operators	II. Food and beverage operators collaborating with food delivery platforms: 427 companies (I) GHP: 177 companies were required to make improvements within a deadline, of which 1 company did not pass the re-inspection. (II) Food businesses registration: 22 companies were not applicable; 63 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 61 companies were not applicable and 2 companies did not comply with the regulations. (IV) Standard form contracts of gift vouchers for merchandise or services: A total of 6 companies provided related services, all of which met the requirements. III. Service staff of food delivery platform: 121 people, all in compliance with the requirements. IV. On-site labeling: 427 cases, of which 3 companies were not applicable and the remaining 424 companies complied with the regulations. V. Random inspection: 542 cases, of which 4 cases did not comply with the regulations.
27	Inspection and Random inspection Project for Breakfast and Brunch Food Operators	I. Inspected: 209 companies (I) GHP: 66 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 20 companies were not applicable; 34 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 11 companies were required to make improvements within a deadline, all of them passed the re-inspection. (IV) Product liability insurance: 72 companies were not applicable and the remaining 137 companies complied with the regulations. II. On-site labeling: 209 companies, of which 1 case did not comply with the regulations. III. Random inspection: 221 cases, of which 2 cases did not comply with the regulations.
28	Inspection Project for Multi- Level Marketing Businesses	I. Labeling: (I) Food labeling: 25 cases, of which 6 cases did not comply with the regulations. (II) Cosmetics labeling: 32 cases, of which 11 cases did not comply with the regulations. II. On-site single-page advertising leaflet: 1 case, all complied with the regulations.
29	Inspection Project for Food Containers or Packaging Containing Plastics in Contact with Food	I. Inspected: (I) Manufacturers: 28 companies 1. GHP: 7 companies were required to make improvements within a deadline, and all of them passed the re-inspection. 2. Food businesses registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. 3. Labeling: 41 cases, of which 1 case did not comply with the regulations. (II) Label inspection for sellers, food and beverage operators:180 cases, of which 6 cases did not comply with the regulation. II. Random inspection: (I) Manufacturer: 48 cases, all complied with the regulations. (II) Sellers, food and beverage operators: 26 cases, all complied with the regulations.

Numbering	Project name	Results
30	Inspection Project for the Food Logistics and Storage Industry	Inspected: 186 companies I. GHP: 2 companies were not applicable; 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Food businesses registration: 13 companies were not applicable; 10 companies were required to make improvements within a deadline and all of them passed the re-inspection
31	Inspection Project for Chinese New Year	Inspection for online shopping of festival celebration food manufacturers I. Inspected: 46 companies (I) GHP: 20 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All of 46 companies complied with the regulations. (IV) Standard form contract: 5 companies were not applicable; 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 133 cases, of which 5 cases did not comply with the regulations. III. Random inspection: 159 cases, of which 1 case did not comply with the regulations.
		Inspection and random inspection for New Year's Festival food street sellers I. Inspected: 285 companies (I) GHP: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 1 company was not applicable; 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All of 285 companies complied with the regulations. II. Labeling: 1,061 cases, of which 8 cases did not comply with the regulations. III. Random inspection: 1,775 cases, of which 19 cases did not comply with the regulations.
		Random inspection for New Year's dish restaurant I. Inspected: 56 companies (I) GHP: 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 2 companies were not applicable; 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All of 56 companies complied with the regulations. (IV) Standard form contract: 34 companies were not applicable; 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: 1 company stored expired products. II. Labeling: 56 cases, all complied with the regulations. III. Random inspection: 97 cases, all complied with the regulations.

Numbering	Project name	Results
32	Inspection Project for Dragon Boat Festival	Inspection of zongzi manufacturers I. Inspected: 61 companies (I) GHP: 36 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 4 companies were not applicable; 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory inspection: 59 companies were not applicable and the remaining 2 companies complied with the regulations. (IV) Traceability: 58 companies were not applicable and the remaining 3 companies complied with the regulations. (V) Electronic declaration: 59 companies were not applicable and the remaining 2 companies complied with the regulations. (VI) Food safety monitoring plan: 59 companies were not applicable and the remaining 2 companies complied with the regulations. (VII) Waste management: 6 companies were not applicable; 12 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VIII) Product liability insurance: 16 companies were not applicable and 1 case did not comply with the regulations. (IX) Standard form contract: 46 companies were not applicable; 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 127 cases, all complied with the regulations. III. Random inspection: 221 cases, no violation of regulations.
		Inspection of dragon boat festival food seller, random inspection and labeling I. Inspected: 174 companies (I) GHP: 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 19 companies were not applicable; 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 5 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Standard form contract: 154 companies were not applicable; 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 379 cases, all complied with the regulations. III. Random inspection: 627 cases, of which 3 cases did not comply with the regulations.

Numbering	Project name	Results
33	Inspection Project for Mid- Autumn Festival	Inspection Project for Moon Cake and Filling Manufacturers. I. Inspected: 102 companies (I) GHP: 47 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Food additives management: 21 companies were not applicable; 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Standard form contract: 57 companies were not applicable; 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Others: 2 companies stored expired foods. II. Labeling: 282 cases, of which 2 cases did not comply with the regulations. III. Random inspection: 201 cases, of which 2 cases did not comply with the regulations.
		Random inspection of Mid-Autumn festival foods: 1,130 cases, no violation of regulations.
34	Inspection and Random inspection Project for Seasonal Festive Food – Tomb-Sweeping Day	Random inspection: 670 cases, of which 7 cases did not comply with the regulations.
35	Inspection and Random inspection Project for Seasonal Festive Food - Winter Food	Random inspection: 644 cases, of which 4 cases did not comply with the regulations.
36	Inspection Project for School Lunch	I. Inspected: 2,419 companies GHP: 121 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 2,548 cases, all complied with the regulations. III. Random inspection: (I) Finished products for lunch: 2,273 cases, all complied with the regulations. (II) Semi-finished products: 109 cases, all complied with the regulations.
37	Inspection Project of Catering Businesses for Providing Lunch to Schools	I. Inspected: 415 companies GHP: 85 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Random inspection: 796 cases, all complied with the regulations.

Numbering	Project name	Results
38	Inspection and Sampling Test Project for Commercially Available Children's Food	I. Labeling: 434 cases, of which 2 cases did not comply with the regulations. II. Random inspection: 406 cases, all complied with the regulations.
39	Inspection Project for bakery businesses with selling and manufacturing	I. Inspected: 203 companies (I) GHP: 84 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Food businesses registration: 33 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Retain the source documents: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Product liability insurance: 2 companies were not applicable and the remaining 201 companies complied with the regulations. (V) Standard form contract: 166 companies were not applicable and the remaining 37 companies complied with the regulations. (VI) Percentage of technician certificate holders: 1 company was not applicable and the remaining 202 companies complied with the regulations. (VII) Gift vouchers for merchandise or services: 175 companies were not applicable and the remaining 28 companies complied with the regulations. (VIII) Others: 1 company stored expired foods. II. On-site Labeling: 203 cases, of which all complied with the regulations. III. Random inspection: 420 cases, of which 3 cases did not comply with the regulations.
40	Inspection Project for Commercially Available Frozen and Refrigerated Prepared Foods	I. Inspected: 136 companies GHP: 6 companies required improvement within a deadline, of which 1 company did not pass the re-inspection. II. Labeling: 232 cases, all complied with the regulations. III. Random inspection: 306 cases, of which 1 case did not comply with the regulations.
41	Inspection project for Test of Radioactive Nucleus Imported Food on the Market and Labeling Check	I. Labeling: 560 cases, of which 4 cases did not comply with the regulations. II. Random inspection: 560 cases, all complied with the regulations.
42	Project for Random inspection of Dioxin in – Aquatic Products	Random inspection: 33 cases, all complied with the regulations.

Numbering	Project name	Results
43	Project for Random inspection of Dioxin in – Meat, Egg and Dairy Products	Random inspection: 35 cases, all complied with the regulations.
44	Project Random inspection for Dioxin – in Plant Agricultural Products	Random inspection: 32 cases, all complied with the regulations.
45	Inspection Project for Labeling of Country of Origin of Foods from Retailer, manufacturer/ processor, and Catering Industry That Contains Pork or beef and Other Edible Parts	Labeling: 192,284 cases, of which 59 cases did not comply with the regulations.

Table 5 Addendum/amendment to the Regulations and Standards Related to Pharmaceutical Administration in 2021

Date of announcement	Name	Important content
January 13	Stipulated "Guidance on Donor Recruitment of Cell and Gene Therapy Medicinal Products"	Described the contents of the donor recruitment advertisement, the restrictions on the posting targets, the period of validity, and requires the advertisement approved by the Institutional Review Board (IRB) before posting.
January 13	Revised "Guidance for clinical trial in radiopharmaceutical drugs"	This guidance was revised for review of diagnostic and therapeutic radiopharma-ceuticals drugs in light of the reform of pharmaceutical administration and the amendment of clinical trials related regulations and guidelines in recent years, and also to promote the development of radiopharmaceutical drugs in Taiwan.
January 13	Announced "Clinical Safety Data Management: Definitions and Standards for Expedited Reporting Guideline"	To establish the internationally harmonized guidelines for the reporting of clinical safety data of pharmaceutical products, and to facilitate the management of clinical safety data by the stakeholders, TFDA hereby announced these guidelines.

Date of announcement	Name	Important content
January 20	Revised "Guidelines and points to consider for physicians prescribing long term narcotic drugs for patients with non-cancer chronic intractable pains"	Revised the contents of new cases lists and reports on the long-term use of narcotic drugs in patients with chronic intractable non-cancer pain.
January 20	Announced "RWE Study Designs- Considerations and Key Points for Pragmatic Clinical Trial"	Real-world Evidence (RWE) is the international clinical application trend. To promote domestic drug R&D, TFDA considered into the latest international management practices and stipulated relevant guidelines as reference for the industry to follow.
February 9	Stipulated "Guidance on Technical Documents Requirements for Bridging Cell Therapy Medical Technique to Cell Therapy Medicinal Products"	For efficacy and safety data obtained from the Specific Medical Technique Regulations, the guidance describes the technical data that should be submitted to support subsequent applications for clinical trials or registration of cell therapy products.
February 9	Announced the updated version of "The list of ICH guidelines adopted"	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.
March 17	Announced "Points to consider in evaluating Real World Data - Relevance and Reliability"	Real-world Evidence (RWE) is the international clinical application trend. To promote domestic drug R&D, TFDA considered the latest international management practices and stipulated relevant guidelines as reference for the industry to follow.
March 23	Revised "Guidance for Pediatric Pharmacokinetic Studies"	The guidance was revised in view of the recent pharmaceutical reform and various amendments to the laws and regulations related to clinical trials of pharmaceutical products, and to promote the development of domestic pharmaceutical products for pediatric groups and improve the standard of clinical trials in Taiwan.
May 4	Amended the list of drugs categorized for tracing the sources and tracking the flow in Article 6-1 of the "*Pharmaceutical Affairs Act*"	The Act aimed to strengthen the control of sale and stock of reserve medicines, to select 4 drugs that have been notified of drug shortage in the past 2 years or also classified as essential drugs, incorporated into Trace and Track system for Medicinal Products Managed; which has been officially implemented since July 1, 2021 to keep track of the stock and flow of reserve medicines.
June 10	Announced "Guidance for EUA Review and Efficacy Evaluation of COVID-19 Vaccines in Taiwan"	Described the key points of the EUA review and efficacy evaluation of the COVID-19 vaccines in Taiwan.
June 15	Revised "Guidance on IND Applications"	In response to the recent pharmaceutical reform and organizational restructuring, the regulations related to clinical trials of pharmaceutical products had undergone a number of amendments. The original application is out of date, hence, this was revised and incorporated the latest regulations and announced the measures to be taken, also simplified the application documents for the benefit of the applicants.

Date of announcement	Name	Important content
June 25	Revised "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic" and "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic: Q & A"	In view of the continued seriousness of the epidemic in Taiwan, it revised the investigational drug administration part and supplemented with a question-and-answer section regarding the execution details, for sponsors and investigational site organizations to follow in conducting clinical trials during the epidemic prevention period.
June 30	Revised the "Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions"	In accordance with the amendment to the *Narcotics Hazard Prevention Act*, the regulation name was amended to "Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions". In addition, considering that the current practice of item-by-item accreditation could not meet the demand for outsourced testing, TFDA hereby amended it to make institutions the target of accreditation, so as to improve testing resources.
July 1	Announced "Guideline for Technical Document Requirements for granting Emergency Use Authorization of COVID-19 vaccines"	Described the specific technical document of CMC, non-clinical and clinical document to be submitted by the COVID-19 vaccine developer applying for EUA of the vaccines.
July 2	Announced "Points to consider for using RWD/RWE as technical documents submitting for drug review application"	Real-world Evidence (RWE) is the international clinical application trend. To promote domestic drug R&D, TFDA considered the latest international management practices and stipulated relevant guidelines as reference for the industry to follow.
August 3	Advance notice the draft amendment of "Regulations for the Management of Drug Safety Surveillance"	Required that all pharmaceutical companies hold drug licenses in Taiwan should review the post-market trend of risk changes of their products and develop relevant measures; also collect relevant safety information, and take relevant risk control measures when necessary to ensure the drug safety of people in Taiwan.
August 10	Revised "API Registration and Drug Master File Refuse to File (RTF) Procedures Checklist"	In order to improve the quality of submissions and increase the rate to permit a substantive review, this checklist had been evaluated and revised with reference to the common deficiencies in the submissions.
August 31	Revised the "Refuse to File (RTF) Checklist for Registration of Generic Drug".	The RTF checklist was announced and implemented in 2016 and was re-evaluated in 2021 in accordance with the revision of the "Regulations for Registration of Medicinal Products", scopes of this revision includes the addition of the confirmation of representative batches of finished products, etc.
September 1	Amended Article 3, Article 4 and Article 5-1 of "Drug Injury Relief Payment Standard"	The maximum amount of drug injury relief payment was increased from NT$2 million to NT$3 million for cases that have been determined to have resulted in death or disability due to adverse drug reactions to protect the rights of the public.

Date of announcement	Name	Important content
September 8	Stipulated "Regulations on Good Practices for Positron Emission Tomography Drug Dispensation"	In order to regulate the dispensation of positron emission tomography drugs in domestic medical institutions, we established relevant regulations for application procedures, drugs inspection, quality control standards, and supporting measures, to protect the medical rights of the public and to strengthen the quality of drugs.
September 10	Revised "Guidelines and points to consider for physicians prescribing long term narcotic drugs for patients with non-cancer chronic intractable pains"	Edited the text to make it more perfect.
September 14	Amended "Regulations for Registration of Medicinal Products"	Amended some Articles and Appendices in order to keep pace with the international drug management trend, cooperate with the electronic submission platform, simplify the review process, improve the quality of drugs, and keep medication safety.
September 22	Advance notice of the draft amendment of the "Guidance on donor eligibility determination of Cell Therapy Medicinal Products"	Ensured that the cell therapy medicinal products are free of communicable disease risks. Described the content of the eligibility determination, the risk factors and clinical evidence to be considered, the communicable pathogens or diseases and the test methods to be used, etc.
September 29	Announced "Standards of Review Fees for the Registration of orphan drug"	In consideration of the rapid changing of orphan drugs, the review requires a highly professional, so the labor and time spent on the review increase accordingly. The fees were stipulated in accordance with the principle of balanced income and expenditure.
October 7	Stipulated "Guidance on Donor Informed Consent of Cell and Gene Therapy Medicinal Products"	Described the donor informed consent items, and that written consent should be acquired beforehand. It is not allowed to coercive or unduly influence the donor. The donor inform consent should also be approved by the IRB in advance.
October 21	Announced "ICH E17: Planning and Design of Multi-Regional Clinical Trials Guidelines	Announced these guidelines in order to establish internationally harmonized standards of clinical trials regulations, and to facilitate the implementation of multi-regional clinical trials in the R&D stage of pharmaceutical products.
October 21	Revised "Guidance on Registration of Biosimilar Medicinal Products"	Revision of the definition of biosimilar medicinal products and the principles of publishing of co-medications in the labeling, etc.
October 21	Advance notice the amendment of "Regulations on Good Practices for Drug Dispensation"	In order to improve the quality of domestic pharmaceutical services and converge with international standards, TFDA considered international standards and the current situation of pharmacy practice in Taiwan, and drafted the amendment to the "Regulations on Good Practices for Drug Dispensation" to improve the drug dispensing practice regulations.
October 26	Announced "ICH Q3A(R2) and Q3B(R2): Impurities in New Drug Substances and New Drug Products Guidelines".	The guidelines were specified in the impurity limits in new drug substances and new drug products to provide guidance for NDA applicants to prepare for impurity data.

Date of announcement	Name	Important content
October 26	Announced "ICH M9: Biopharmaceutics Classification System-Based Biowaivers", at the same time, the Ministry of Health and Welfare Order Bu-Shou-Shi Zi No. 1051406824 announced on August 9, 2016 will cease to apply from now on.	In order to establish an internationally harmonized regulatory framework for bioequivalent study, TFDA announced "ICH M9: Biopharmaceutics Classification System-Based Biowaivers" as attached. According to the ICH M9 principles, the scopes of the Biowaiver conditions were different from the MHW Announcement Bu-Shou-Shi-Zi No.1051406824 dated August 9, 2016, therefore announced to cease the application of the Announcement.
October 26	Revised "Guidelines on Recruiting Study Subjects of Clinical Trials"	The Principles were stipulated under the Regulations for Good Clinical Practice Article 83. In light of the recent pharmaceutical administration reforms and various amendments to the clinical trial related regulations, to provide references for the subjects recruitment for clinical trial operations and to protect the rights of subjects.

Table 6 Addendum/amendment to the Regulations and Standards Related to Medical devices Management in 2021

Date of announcement	Name	Key points
January 29	Announced the "*Regulations for the Inspection of the Good Distribution Practice for Medical Devices and Licensing of Distribution License*"	The Regulations stipulate the contents and methods of inspection of the Good Distribution Practice for medical devices, the requirements, procedures, review, issuance, validity period, changes, revocation, or cancellation of approval, and other relevant matters to be complied with.
February 2	Announced the "*Regulations Governing the Inspection of the Medical Device Quality Management System and the Issuance of the Manufacturing License*"	The Regulations stipulate the application for inspection of medical device manufacturers' quality management systems and the matters related to the registration, issuance and change of manufacturing licenses.
March 18	Announced the "*Medical Devices Classification and Medical Device Dealers Shall Establish a Medical Device Good Distribution System Specified in Article 24 of the Medical Devices Act.*"	To ensure the quality of medical devices used by the general public, TFDA announced that medical device firms dealing with high-risk medical devices to implement compliance inspection of the distribution system.
March 30	Announced the "Scope and Classification of the Medical Devices Which Pharmacies May Engage in the Retail"	Specified the scope and types of medical devices of a certain class of medical devices that can be sold by pharmacies. Such medical devices are limited to Class I, non-implantable Class II and Class III medical devices.
April 1	Announced the "*Regulations for Management of Medical Devices Technicians*"	Specified the qualifications, job descriptions, continuing education and other matters related to medical device technicians.

Date of announcement	Name	Key points
April 6	Announced "*Unique Device Identifier (UDI) Labeling Requirements on Labels of Medical Device*"	The Requirements stipulate that single packages or the main unit of Class II and Class III medical devices should be labeled with a Unique Device Identifier (UDI). The Requirements also stipulate the requirement to upload the information to the UDI Database (UDID) established by TFDA.
April 7	Announced "Principles of Compiling Chinese Instructions for Home-Use Medical Devices"	To ensure the safety and performance of home-use medical devices used by the general public, TFDA stipulated the principles for compiling Chinese instructions for home-use medical devices with three templates (soft contact lenses, electronic sphygmomanometers, and infrared lamps).
April 9	Announced "*Regulations on Good Clinical Practice for Medical Devices*"	The Regulations stipulate the scope of management, operational practices, application procedures, review guidelines, avoidance of conflicts of interests, information disclosure, supervision and administration, inspection, particulars of the content of informed consent, and other matters to be complied.
April 13	Announced "Medical Device Product Items that Should Obtain Marketing Authorization by Means of Listing"	Specified what product items of medical devices should obtain market approval by means of listing in accordance with Paragraph 1, Article 25 of the Medical Devices Act.
April 13	Announced the "*Regulations of Medical Device Good Distribution Practice*"	To ensure that medical devices meet the requirements of the original manufacturer during storage, transportation, and distribution processes, and the integrity of the medical devices can be maintained to ensure the safety of users.
April 13	Announced an example of "A foreign original manufacturer authorization letter"	To provide medical device firms and importers a reference as they apply for registration and market approval.
April 14	Announced "*Medical Device Quality Management System Regulations*"	Medical device manufacturers shall establish a medical device quality management system to govern on-site facilities, equipment, organization and personnel, production, quality control, storage, distribution, handling of customer complaints and other matters, and shall comply with the quality management system regulations.
April 15	Announced "Alternative Way of Written Form to Get the Agreement of Using, Collecting or Processing Personal Information for Using Medical Devices"	Specified that research institutions, medical institutions or medical device firm who collect, process, or use personal information referred to in Article 6 of the *Personal Data Protection Act* due to the nature of using medical devices may use electronic documents to receive written consent in accordance with the provisions of the *Electronic Signature Act*.
April 15	Announced "Regulations Governing Contract Manufacturing of Medical Devices"	Specified the application documents, product responsibilities, contract requirements, labeling, packaging and other related matters for contract manufacturing of medical devices.

Date of announcement	Name	Key points
April 19	Announced the special code (DHM99999999999) and scope of application for imported reagents for research use, experiment use, or not for human use under the regulation of "526" of import regulation.	The announcement specified that those importing reagents for research use, or experiment use, or not for human use under the regulation of "526" of import regulation should list the special code "DHM99999999999" on the import application and is exempted from applying for permit issued by TFDA.
April 20	Announced "*Regulations of Medical Device Tracking Management*"	The Regulations stipulate that medical device firms and medical institutions should establish and maintain information on the supply sources and flow of medical devices, maintenance of data, retention period the report contents and other matters to be complied with.
April 21	Announced the guidance and the "Medical Device Safety and Efficacy Essential Principles (EP) and Summary of Technical Documentation (STED)" and guidance	To provide the format of EP/STED for applying for medical device registration and market approval, and use the EP/STED guidance to help operators understand the contents of the EP/STED and use the guidance as reference to prepare for medical device registration and market approval.
April 22	Announced "Regulations for Approval of Specific Medical Devices' Manufacturing or Importing a Special Case"	To specify the application requirements, review procedures, approval criteria, restrictions on supply and sale, return of medical devices receiving approval to be manufactured or imported as a special case and other matters to be complied with.
April 22	Announced "Except for Daily Wearable Daily Disposable Contact Lenses, Advertisements of Other Contact Lenses Shall be Published Only in the Medical Publications, Mass Media, or Related Medical Academic Activities that are for the Exclusive Participation of Medical Professionals"	With the exception of the advertisements of "daily wearable disposable contact lenses" whose publication channels have not been restricted, the advertisements for other contact lenses should be published in medical publications, mass media, or related medical academic activities that are exclusively participated by medical professionals.
April 22	Announced "Warnings and Cautions that Should be Published in the Advertisements of Disposable Contact Lenses"	To stipulate warnings and cautions that should be added to advertisements of disposable contact lenses and other principles that should be complied with.
April 23	Announced the "Notices for Application for Technical Evaluation of Medical Device Clinical Trial Documents" and "Notices for the Application of Medical Device Clinical Trial Plan"	To provide reference for medical device firms and clinical research organizations in the process of product development, clinical trials and application for technical evaluation.
April 26	Announced "*Enforcement Rules of Medical Devices Act*"	To stipulate relevant details and technical regulations in accordance with the *Medical Devices Act* (the parent Act).
April 27	Announced "Regulations Governing Border Inspection and Examination of Imported Medical Devices"	To stipulate imported medical device items that are subject to random inspection, examination, and medical devices that can only be released after meeting all the requirements, as well as the test items, testing methods, procedures, scope, charges and other relevant matters.

Date of announcement	Name	Key points
April 27	Announced "*Regulations Governing the Classification of Medical Devices*"	Specified what medical device items are included and how medical devices are managed in Taiwan to help businesses understand the characteristics of the products they are researching or developing, or importing.
April 27	Announced "Medical Devices Meeting the Requirements Under Paragraph 4,Article 6 of Regulations for Approval of Specific Medical Devices' Manufacturing or Importing as a Special Case are Eligible for the Facilitated Customs Procedure with a Special Code for Exemption and Declared Quantity"	Specific items of medical devices can go through facilitated customs clearance with a special code for exemption.
April 28	Announced "*Regulations for Medical Device Recalls*"	Specified which medical devices should be recalled by medical device manufacturers and importers, as well as the classification, recall operations, treatment, and other matters to be followed.
April 28	Announced "Regulations for Reporting Serious Adverse Events of Medical Devices"	Specified the unit to be notified, reporting method, reporting period and reporting content for serious adverse events of medical devices so as to ensure the safety of the general public using medical devices.
April 28	Announced "Designated Medical Device Product Items for Medical Device Safety Surveillance"	Specified specific types or items of medical devices subject to safety surveillance in accordance with the "*Regulations for Management of Medical Device Safety Surveillance*".
April 28	Announced "*Regulations for Management of Medical Device Safety Surveillance*"	Stipulated the regulations to govern the medical device safety surveillance data and reports, submission of such data, deadline, content, format, limitations and maintenance of data collection, surveillance period, evaluation and other relevant matters.
April 28	Announced "Charge Standards of Administrative Fees for Medical Devices"	With the implementation of the Medical Devices Act, a number of charges have been added; to balance income and expenditures, some standards of administrative fees have been adjusted.
April 28	Announced "Medical Devices That Shall Establish and Maintain Sources and Flow Data" and "Medical Device Product Items That Shall Report Sources and Flow Data"	After conducting risk assessment, TFDA specified medical devices items that need to establish and maintain sources and flow data. Among the aforementioned items, those with higher risks must complete declaration procedures on the platform established by the central competent authority.

Date of announcement	Name	Key points
April 28	Announced that 8 items, including "infrared ear thermometer" are listed as items specified in Paragraph 1, Article 6 of Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration, and Item 2, Subparagraph 2, Paragraph 7 of Appendix 2 in the same Regulations.	Announced that "infrared ear thermometer", "electronic thermometer", "surgical drape", "surgical gown", "infrared forehead thermometer", "surgical lamp", "static electric therapy apparatus", "infrared lamp (therapy apparatus)" are listed as items specified in Paragraph 1, Article 6, of the "Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration and Item 2, Subparagraph 2, Paragraph 7 of Appendix 2 in the same Regulations.
April 28	Announced "Clinical Trials for Non-Significant Risks Medical Devices"	Specified that clinical trials of medical device without significant risks can be exempted from applying for approval from the central competent authority.
April 29	Announced "*Regulations Governing Commission of Medical Devices Management and Accreditation of Commissioned Institution*"	Specified the regulations for the commission and accreditation of medical device management, as well as recusal due to conflict of interests and other matters to be followed.
April 29	Announced "*Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration*"	Established the regulations governing the registration and market approval of medical devices, the change, transfer, registration extension, replacement for a damaged license, replacement for a lost license, or the rules for the listing and annual declaration of medical devices.
April 29	Announced "Regulations Governing the Sale Items and Compliance Matter of Medical Devices for Distance Sales"	Specified the sales items and compliance matters of medical devices for distance sales in accordance with Article 18 of the Medical Devices Act.
April 29	Announced "*Regulations Governing Accreditation and Outsourced Accreditation Management of Medical Devices Institutions*"	To facilitate the accreditation and outsourced accreditation of medical device institutions; to enhance the management of accreditation institutions and outsourced accreditation institutions.
April 29	Announced "Regulations Governing Incentive Rewards for Research and Development of Medical Devices Technology"	Established the qualifications for awards, review procedures and other related matters in order to encourage agencies and personnel in Taiwan to engage in the research and development of medical devices innovative technologies.
April 29	Announced "Natural Persons Imports Medical Devices Subject to Border Inspection for Personal Use Should Use the Special Code IF000000000001 for Customs Clearance and Exemption from Border Inspection"	Specified that natural persons importing medical devices subject to border inspection for personal use should use the special code for customs clearance, so the medical devices can be exempted from border Sampling test.
April 29	Announced "Principles for Compiling Chinese Instructions of Medical Devices"	The compilation principles were announced to be used as a reference for firms to prepare instructions and the information for registration and market approval and to ensure the accuracy and completeness of Chinese instructions of medical devices.

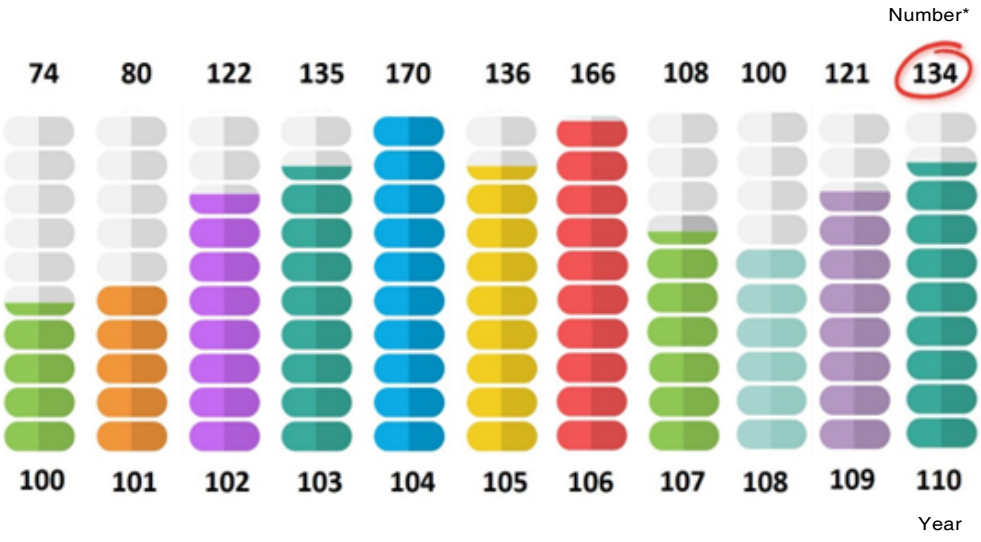
Date of announcement	Name	Key points
April 29	Announced "Principles of Compiling Chinese Instructions for In Vitro Diagnostic Medical Devices"	The compilation principles are announced to be used as a reference for firms to prepare instructions and the information for registration and market approval and to ensure the accuracy and completeness of Chinese instructions of medical devices.
April 29	Announced "Notices for Registration and Market Approval of In Vitro Diagnostic Medical Devices" and "Notices for Registration and Market Approval of Home Use In Vitro Diagnostic Medical Devices"	To provide business operators references to conduct research and development of in vitro diagnostic medical devices and prepare documents for registration and market approval of in vitro diagnostic medical devices.
April 30	Announced "Medical Device Items that Should be Submitted to be Examined to Apply for Medical Device Registration Market Approval and Change in Medical Device License"	As Item 16, Appendix 2, Paragraph 1, Article 6 and Item 21, Appendix 4, Paragraph 1, Article 13 of Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration is applicable to the application for "Class III in vitro diagnostic medical devices for hepatitis, HIV, HTLV and ABO blood types", the medical devices should be submitted to be examined to apply for registration and market approval or and change in medical device license.
April 30	Announced "*Regulations Governing Designation or Commission of Medical Devices Test*"	Stipulated regulations governing its designation, commissioning, and related matters to designate a subordinate agency or commission a relevant agency (or institution), legal entity, or organization to conduct all or part of the testing of medical devices.
April 30	Announced "Medical Device Firms (Pharmacies) Setting up Medical Device Vending Machines Shall Not Be Required to Apply Separately for a Medical Device Dealer Permit at the Business Establishment"	Stipulated in accordance with Paragraph 3, Article 13 of the *Medical Devices Act*.
April 30	Announced "Regulations Related to the Exemption from Labeling Date of Manufacture and the Period of Validity or Shelf-life on the Labels, Instructions or Packaging of Medical Devices"	Established the rules on medical devices that are exempted from labeling date of manufacture and the period of validity or shelf-life on the labels, instructions or packaging of medical devices in accordance with Article 33 of the Medical Devices Act.
May 3	Announced "Guidance for Manufacturers on Management of Cybersecurity for Networked Medical Devices"	This document is provided to be used as a reference for manufacturers to consider matters related to cybersecurity during the process of product design, research and development, application for registration and market approval, and post-market surveillance and help manufacturers prepare documents for application for registration and market approval.
May 7	Published "FAQs for the Registration and Market Approval of Smart Medical Devices"	To answer frequently asked questions related to registration and market approval of smart medical devices and help business operators prepare the documents for registration and market approval.

Date of announcement	Name	Key points
May 7	Published "FAQs for Submission of Applications for Registration and Market Approval for AI/ML-based Medical Devices"	To answer frequently asked questions related to registration and market approval of artificial intelligence/machine learning (AI/ML)-based Software as Medical Device (SaMD) and help business operators prepare the documents for registration and market approval.
May 21	Announced "Process Determine Predicates of Medical Device and Instructions of Written Inquiry"	To help business operators to determine if a product applying for registration and market approval has a predicate approved in Taiwan.
June 1	Announced the revision of "Labels, Instructions or Packaging of Specific Medical Devices Shall Additionally State the Warnings and Cautions"	To add a few new specific medical devices that shall add warnings and cautions to the product labels and instructions.
June 1	Announced revisions of 4 guidances for pre-clinical testing, including "Guidance for Pre-clinical Testing of Absorbable Surgical Suture", "Guidance for Pre-clinical Testing of Non-absorbable Surgical Suture", "Guidance for Pre-clinical Testing of Orthopedic External Fixation Devices" and "Guidance for Pre-clinical Testing of Spinal Intervertebral Body Fusion Device", and established the "Guidance for Pre-clinical Testing of Orthopedic Internal Fixation Devices"	Businesses can use the guidances as a reference for research and development of products and registration and market approval; Inspectors can also use the guidance as a reference to ensure the safety and effectiveness of the products in the market.
June 21	Announced revisions of "Reference Document for Application to Manufacture Respiratory Apparatus as a Special Case for Patients with Respiratory Failure or Respiratory Insufficiency in Response to the COVID-19"	The document is provided to firms who wish to apply for manufacturing as a special case.
June 25	Announced "Medical Device Product Items That May Be Sold by Vending Machines and the Matters That Shall Be Complied with"	Specified the types of medical devices that can be sold by vending machines and relevant matters to be followed in accordance with Article 18 of the *Medical Devices Act*.
July 7	Announced "Guidance on Review of Registration and Market Approval of AI/ML-Based CADe SaMD"	To ensure the safety, efficacy and quality of AI/ML CADe SaMD, the guidance is provided for business operators to use as a reference as they evaluate product development and prepare documents required for application of registration and market approval.

Date of announcement	Name	Key points
August 5	Announced "Regulations on the labels, instructions or packaging of medical devices which were directly listed or whose original licenses were cancelled by the central competent authority in accordance with Paragraph 4 of Article 25 of Medical Devices Act"	The original licenses are converted to a listing number by the competent authority. The product label, instructions or package bearing the original license number may be exempted from labeling the listing number.
August 16	Announced "Technical Guidance for Industry to Register Artificial Intelligence/ Machine Learning-based Software as Medical Device (AI/ML-Based SaMD)"	The guidance focuses on Artificial Intelligent/Machine Learning-Based Software as a Medical Device (AI/ ML-Based SaMD). It can serve as a reference for manufacturers to evaluate their products and to check the information required for the application for inspection and registration.
October 19	Announced "Guidance on Clinical Performance Studies of In Vitro Diagnostic Medical Devices"	The guidance is provided as a reference for medical device firms and clinical research organizations for research and development of product and clinical performance studies of in vitro diagnostic medical devices.
October 19	Announced three guidances for pre-clinical testing, including "Guidance for Pre-clinical Testing of Intramedullary Fixation Devices", "Guidance for Pre-clinical Testing of Porcelain Power for Clinical Use" and "Guidance for Pre-clinical Testing of Infusion Pump"	These guidances are provided for businesses to use as references for product research and development and help them prepare documents for application of registration and market approval.
October 27	Announced two guidances for medical devices, including "Guidance for Influenza Virus Antigen Detection Test System" and "Guidance for Evaluation of Stability of In Vitro Diagnostic Medical Devices"	These guidances are provided for businesses to use as references for product research and development, help them prepare documents for application of registration and market approval, and enhance the safety and efficacy of in vitro diagnostic medical devices.
November 9	The Announced "2021 List of Recognized Medical Device Standards" and the "List of Abolished or Revised Medical Device Standards Over the Years"	Announced that 1,081 international medical device standards would be recognized, so medical device manufacturers can choose to follow these standards when they develop and test medical devices to ensure the safety and effectiveness of products on the market.
November 18	Announced the "Guidance on Inspection and Registration of Reprocessed Single-use Medical Device"	The guidance can be used as a reference for manufacturers or relevant agencies reprocessing single-use medical devices and applying for registration and market approval. Inspectors can also use the guidance for reference.
December 9	Announced the amendment of the Annex of Article 4 of "*Regulations Governing the Classification of Medical Devices*"	International regulations and Taiwan's domestic situations are taken into account; hence, 20 items had been added in the Annex for categorization and classification management of medical devices to meet the current situation and to harmonize with international regulations.

Date of announcement	Name	Key points
December 6	Announced "Template for Medical Device Cybersecurity Risk Assessment Report - General Template" "Template for Medical Device Cybersecurity Risk Assessment Report - Implantable Cardiac Pulse Generator", and "Template for Medical Device Cybersecurity Risk Assessment Report - Glucose Test System"	These templates are provided as references for the stakeholders when they plan for medical device cybersecurity and prepare medical device cybersecurity risk assessment reports to enhance medical device cybersecurity.
December 30	Announced "Guidance on Application for Post-market Changes for Software as Medical Device (SaMD)"	To provide relevant administrative regulations for post-approval changes of software as medical device, which business operators can use as a reference as they apply for license changes.
December 30	Announced "Guidance Document for Quality Management System of Manufacturers of Software as Medical Device (SaMD)"	To provide manufacturers of Software as Medical Device (SaMD) a reference as they carry out quality management for all stages of production, including product design and development, materials, production, inspection, release for shipment and post-market monitoring.

Table 7 Number of New Drugs Approved in 2021



*The number of cases is based on the number of licenses

Among the 134 new drugs, 61 were new drugs with new chemical entities and 42 were biological products. Main indications of the approved new drugs include cancer, immune system, neurological and cardiovascular related diseases. The approval of these new drugs provides new treatment options and were beneficial to the patients.

Table 8 Addendum/amendment to the Schedule of Controlled Drugs in 2021

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
June 10	Schedule 3	4-ethyl-2,5-dimethoxyphenethylamine, 2,5-dimethoxy-4-ethylphenethylamine, 2-(4-ethyl-2,5-dimethoxyphenyl) ethanamine, 2C-E	Amended the English name.
		Fluoro-α-pyrrolidinohexanophenone, Fluoro-α-PHP	Amended the English name.
	Schedule 4 API	4-Anilinopiperidine, 4-AP	New addition. A precursor for the synthesis of ANPP; and ANPP is a precursor for the synthesis of Fentanyl.
October 8	Schedule 4 API	2-Amino-5-nitrobenzophenone	New addition. A precursor raw material for the synthesis of Nitrazepam.
		Benzylfentanyl	New addition. A precursor for the synthesis of Fentanyl.
		2-Iodo-4-methylpropiophenone	New addition. A precursor compound of cathinone derivative (such as 4-methylmethcathinone, Mephedrone, 4-MMC).

Table 9 The Promulgation and Amendment of Regulations and Standards Related to Cosmetics Management in 2021

Date of announcement	Name	Important content
May 13	Announced "Guidelines for Cosmetics Preservative Efficacy Test"	In order to assist the industry operators to prepare the cosmetic product information file (PIF) to be in line with the international standard, the "Guidelines for Cosmetics Preservative Efficacy Test" were developed to provide a reference for the industry in Taiwan to establish the PIF file.
June 9	Announced the amendment of "Model of Standard Form Contracts for Body Shaping and Beauty Industry"	In order to facilitate the body shaping and beauty industry smoothly adapted to the amended regulations of "Mandatory and Prohibitory Provisions of Standard Form Contracts for Body Shaping and Beauty Industry", TFDA announced the amendment of the "Standard form contract for Body Shaping and Beauty Industry" to promote the protection of consumer's rights.
June 17	Announced the amendment of "List of Ingredients Prohibited in Cosmetic Products"	In order to maintain the hygiene and safety of cosmetic products and protect the health of consumers, the "List of Ingredients Prohibited in Cosmetic Products" was amended.
September 7	Announced the amendment of "List of Microorganisms Limits in Cosmetic Products"	Non-medicinal toothpaste and mouthwash have been brought into cosmetics management since July 1, 2021. In order to protect the hygiene and safety of consumers, TFDA added the regulations which Candida albicans shall not be detected and amended the product types that must meet the total plate count below 100 CFU/g (mL).

Date of announcement	Name	Important content
October 1	Second advance notice of the promulgation of "Implementation Regulations Governing Personal Information File Security Maintenance Plans in Wholesaling and Retailing Cosmetics"	In order to reinforce the security of personal information file in wholesaling and retailing cosmetics, after evaluating the opinions from all circles, TFDA made the 2nd announcement of the draft for "Implementation Regulations Governing Personal Information File Security Maintenance Plans in Wholesaling and Retailing Cosmetics".
November 11	Advance notice of draft amendment on Article 4 of "Regulations for Cosmetic Product Information File Management"	Before the implementation of the "Cosmetic Hygiene and Safety Act", those who graduated from department of chemistry, and department of chemical engineering or graduate schools, and have been performing safety assessments in the cosmetics industry for at least 5 years with a certain level of expertise, may continue to work in the relevant business. Hereby giving notice of the addition of the regulation that a person with a relevant academic qualification may serve as a signatory for the safety report of product information file.

Table 10 Collaborative Inspection of Food, Drugs and Cosmetics in 2021

Inspection type	Numbering	Project name (Implementation time)	Results
Food Safety	1	Joint Inspection Project for Manufacturers of Semi-products for Commercial Use Joint Inspection Program (September 2021 - April 2022)	I. Inspected: 20 companies GHP: 19 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labelling: 40 cases, of which 2 cases did not comply with the regulations.
	2	Inspection Project for Origin Labeling of Marketed Tea Product (September 2021 - February 2022)	Random inspection: 186 cases, of which 36 suspected to contain foreign tea.
	3	Joint Inspection Project for Origin Labeling of marketed Oyster (December 2021 - January 2022)	I. Inspected: 24 companies. GHP: 13 companies were not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. II. Labelling: 16 cases, all complied with the regulations.
Medical Devices	1	Joint Inspection Project for Medical Devices – Medical Masks and Non-medical Masks (January to April)	Inspected: 278 companies, 670 masks I. Medical mask: 467 cases, of which 9 cases did not comply with the regulations. II. Non-medical mask: 203 cases, of which 2 cases did not comply with the regulations.
	2	Joint Inspection Project for Medical Devices – Medical Devices Online Sale (January to June)	Inspected: 156 cases I. Liquid bandage, denture cleanser tablet, contact lens solution: 37 cases, of which 22 did not comply with the regulations. II. Medical mask: 65 cases, of which 34 cases did not comply with the regulations. III. Non-medical mask: 54 cases, of which 13 cases suspected not compliant with the regulations.

Inspection type	Numbering	Project name (Implementation time)	Results
Drugs	1	Joint Drugs Inspection Project – inspection for import drugs for personal use	Inspected: 7 medical institutions, of which 3 medical institutions did not comply with the regulations.
	2	Joint Drugs Inspection Project – Inspection For Selling Drugs to Unlicensed Pharmaceutical Dealers, Non-pharmacy or Non-Medical Institutions (October to November)	Inspected: 21 distributors, of which 16 did not comply with the regulations.
Controlled Drugs	1	Inspection Project for Hypnotic Controlled Drugs (April to December)	Inspected: 234 medical institutions, of which 54 did not comply with the regulations.
Cosmetics	1	Joint Inspection Project of Cosmetic Products Displayed in Claw Machines	Inspected: 100 companies, of which 32 operators had cosmetic products displayed in claw machines, inspected 69 cases of cosmetic labelling, of which 28 did not comply with the regulations.
	2	Joint Inspection Project of Cosmetics Provided by Hotel Operators for Travelers	Inspected: 58 companies and 223 cosmetic products, in which 29 labeling did not comply with the regulations.

Table 11 Addendum/amendment to the Taiwan Pharmacopoeia and the Publication of the "Taiwan Pharmacopoeia edition IX"

Category	Number of articles	Addendum and amendment to the "Taiwan Pharmacopoeia edition IX"
New Monographs	804	1. In response to the international trend of controlling impurities in pharmaceuticals, new standards were added including "the Detection of Nitrosamine Impurities in Sartan APIs and "the Elemental Impurities—Procedures". 2. In response to the trend of cell and gene therapy development, the general chapters related to cell preparations, including "Gene Transfer Medicinal Products for Human Use", "Cell-based Advanced Therapies and Tissue-based Products" and "Gene Therapy Products", etc. were included. New general chapters related to pharmaceutical microbiology were added, including "Rapid Microbial Tests for Release of Sterile Short-Life Products: a Risk-Based Approach", "Validation of Microbial Recovery from Pharmacopeial Articles" and "Methods of Preparation of Sterile Products". 3. 8 APIs and drug products locally synthesized, developed and manufactured in Taiwan including Azacitidine, Ethyl p-piperidinoacetylaminobenzoate, Cefoperazone Sodium and Sulbactam Sodium for Injection, etc. were added to promote the development of domestic industry.
Monographs Amendments	863	
New General Chapters	140	
General Chapters Amendments	51	
Total	1,858	

Table 12 Addition of Test Methods in 2021

Types of Test Methods	Test Methods	Promulgated/ Amended
Announced test methods for food products (58 articles, 397 items)	1. Method of Test for Veterinary Drug Residues in Foods - Test of Nitrovin (2) (MOHWV0050.00) 2. Method of Test for Veterinary Drug Residues in Foods - Multiresidual Analysis of β-Lactam Antibiotics (MOHWV0051.00) 3. Method of Test for Heavy Metals in Eggs (MOHWH0027.00) 4. Methods of Test for Food Microorganisms - Test of Enterobacteriaceae (MOHWM0028.00) 5. Method of Test for Heavy Metals in Aquatic Animals, Livestock and Poultry Products and Honey (MOHWH0028.00) 6. Method of Test for Heavy Metals in Edible Fat, Oil and Cream (MOHWH0029.00) 7. Method of Test for Heavy Metals in Food Grade Salt (MOHWH0030.00) 8. Method of Test for Food Additive Specifications - Potassium Aluminum Silicate-based Pearlescent Pigments 9. Method of Test for Food Additive Specifications - Mogroside Extract 10. Method of Test for Food Additive Specifications - Calcium Gluconolactate 11. Method of Test for Food Additive Specifications - α-Glycosyl-isoquercitrin 12. Method of Test for Food Additive Specifications - Triethyl Citrate 13. Method of Test for Food Additive Specifications - Lycopene (from *Blakeslea trispora*) 14. Method of Test for Food Additive Specifications - Synthetic Genistein 15. Method of Test for Food Additive Specifications - Chromium Picolinate	Promulgated
	1. Method of Test for Food Microorganisms - Test of Pathogenic *Escherichia coli*. (MOHWM0017.03) 2. Method of Test for Veterinary Drug Residues in Foods - Test of Tetracyclines (MOHWV0036.05) 3. Method of Test for Veterinary Drug Residues in Foods - Test of Multiresidue Analysis of β-Agonists (MOHWV0004.05) 4. Method of Test for Mycotoxins in Foods - Test of Zearalenone (MOHWT0003.03) 5. Method of Test for Mycotoxins in Foods - Test of Fumonisin B_1 and Fumonisin B_2 (MOHWT0011.04) 6. Method of Test for Mycotoxins in Foods - Test of Patulin (MOHWT0005.02) 7. Method of Test for Mycotoxins in Foods -Test of Deoxynivalenol (2) (MOHWT0015.01) 8. Methods of Test for Food Microorganisms - Test of *Listeria monocytogenes* in Dairy Foods (MOHWM0021.02) 9. Methods of Test for Food Microorganisms -Test of *Escherichia coli* (MOHWM0023.02) 10. Method of Test for Mycotoxins in Foods - Test of Ochratoxin A (MOHWT0016.04) 11. Method of Test for Aflatoxin B_1 in Foods for Infant and Young Child (MOHWT0017.01) 12. Method of Test for Preservatives in Foods - Test of Propionic Acid (MOHWA0011.03) 13. Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of Sheep/Goat Ingredient (MOHWF0022.02)	Amended

Types of Test Methods	Test Methods	Promulgated/ Amended
Announced test methods for food products (58 articles, 397 items)	14. Method of Test for Volatile Basic Nitrogen in Aquatic Products (MOHWO0018.01) 15. Method of Test for Mycotoxins in Foods - Test of Citrinin (MOHWT0008.03) 16. Method of Test for Food Additive Specifications - Glycerin Fatty Acid Ester 17. Method of Test for Food Additive Specifications - Calcium Dihydrogen Phosphate 18. Method of Test for Food Additive Specifications - Ferrous Lactate 19. Method of Test for Food Additive Specifications - Magnesium Stearate 20. Method of Test for Food Additive Specifications - Sodium Fumarate 21. Method of Test for Food Additive Specifications - Sodium Lactate (Solution) 22. Method of Test for Food Additive Specifications - Ponceau 4R 23. Method of Test for Food Additive Specifications - Sodium Alginate 24. Method of Test for Food Additive Specifications - Sodium Hydrosulfite 25. Method of Test for Food Additive Specifications - Potassium Dihydrogen Phosphate 26. Method of Test for Food Additive Specifications - Monosodium L-Glutamate 27. Method of Test for Food Additive Specifications - Maltitol Syrup 28. Method of Test for Food Additive Specifications - L-Cysteine Monohydrochloride 29. Method of Test for Food Additive Specifications - Xylitol 30. Method of Test for Food Additive Specifications - Synthetic Lycopene 31. Method of Test for Food Additive Specifications - Ammonium Alum 32. Method of Test for Food Additive Specifications - L-Theanine 33. Method of Test for Food Additive Specifications - Sodium Dihydrogen Phosphate 34. Method of Test for Food Additive Specifications - Steviol Glycosides from *Stevia rebaudiana* Bertoni 35. Method of Test for Food Additive Specifications -*β*-Carotene 36. Method of Test for Food Additive Specifications - Carbon dioxide 37. Method of Test for Food Additive Specifications - Potassium Sorbate 38. Method of Test for Food Additive Specifications - Appendix A: General Tests 39. Method of Test for Food Additive Specifications - Sodium Polyphosphate 40. Method of Test for Food Additive Specifications - Quillaia Extracts 41. Method of Test for Food Additive Specifications - Magnesium Sulfate 42. Method of Test for Food Additive Specifications - Carrageenan 43. Method of Test for Food Additive Specifications - Nitrous Oxide	Amended
Recommended test methods for food products (46 articles, 236 items)	1. Method of Test for Six Non-Dioxin-Like Polychlorinated Biphenyls (ICES-6) in Foods (TFDAO0040.00) 2. Method of Test for Veterinary Drug Residues in Foods - Test of Bacitracin (TFDAV0024.00) 3. Method of Test for Inorganic Arsenic in Food (TFDAH0015.00) 4. Method of Test for Heavy Metals in Aquatic Animals, Livestock and Poultry Products and Honey (TFDAH0016.00)	Published

Types of Test Methods	Test Methods	Promulgated/ Amended
Recommended test methods for food products (46 articles, 236 items)	5. Method of Test for Heavy Metals in Edible Fat, Oil and Cream (TFDAH0017.00) 6. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Soybean (TFDAF0029.00) 7. Method of Test for Lactulose in Foods (TFDAA0085.00) 8. Method of Test for Boric Acid in Foods (TFDAA0086.00) 9. Method of Test for Nisins in Foods (TFDAA0087.00) 10. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event DAS-81419-2 (UI: DAS-81419-2) (TFDAG0039.00) 11. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Maize Event 4114 (UI: DP-ØØ4114-3)（TFDAG0040.00） 12. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria—*Lactobacillus delbrueckii* subsp. *bulgaricus* (TFDAM0023.00) 13. Method of Test for Veterinary Drug Residues in Eggs - Test of Tetracyclines Antibiotics (TFDAV0025.00) 14. Method of Test for Bromate in Bottled and Packaged Drinking Water (2) (TFDAO0041.00) 15. Method of Test for Cocaine in Beverage (2) (TFDAA0088.00) 16. Method of Test for Pesticide Residues in Sesame - Test of Ethylene Oxide (TFDAP0022.00) 17. Method of Test for Veterinary Drug Residues in Foods for Expansion of β-Lactam Antibiotics - Cephaloridine (TFDAV0026.00) 18. Method of Test for Coumarin in Beverages (TFDAA0089.00) 19. Method of Test for $\delta^{13}C$ of Saccharides in Honey (TFDAF0031.00) 20. Method of Test for Pyridine, Styrene and Eugenyl Methyl Ether in Flavorings (TFDAA0090.00) 21. Method of Test for Heavy Metals in Infant and Young Child Foods (TFDAH0018.00) 22. Method of Test for Glucosamine in Foods in Capsule and Tablet Form (TFDAA0091.00) 23. Method of Test for Heavy Metals in Food Grade Salt - Test of Copper, Cadmium and Lead (TFDAH0019.00) 24. Method of Test for Multielement in Tea (TFDAF0032.00) 25. Method of Identification for Methoxsalen in Foods (TFDAO0042.00) 26. Method of Test for Methoxsalen in Foods (TFDAO0043.00) 27. Method of Test for Pesticide Residues in Livestock and Poultry Products - Test of Chlormequat, Cyromazine, Diquat and Paraquat (TFDAP0023.00)	Published
Recommended test methods for food products (46 articles, 236 items)	1. Method of Test for Veterinary Drug Residues in Foods - Fast Extraction Method for Multiresidue Analysis of β-Agonists (TFDAV0022.01) 2. Method of Test for Heavy Metals in Food Grade Salt (TFDAH0013.01) 3. Method of Test for Nitrate and Nitrite in Vegetables (TFDAO0004.01) 4. Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Antiprotozoal Drugs (2) (TFDAV0013.02) 5. Method of Test for Six Non-Dioxin-Like Polychlorinated Biphenyls (ICES-6) in Foods (TFDAO0040.01) 6. Method of Test for Heavy Metals in Grains (TFDAH0012.01)	Revised

Types of Test Methods	Test Methods	Promulgated/ Amended
Recommended test methods for food products (46 articles, 236 items)	7. Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis (5) – 27 Items including Analycarb et al. (TFDAP0017.02) 8. Method of Test for Residual Solvents in Foods (TFDAO0033.01) 9. Method of Test for Pesticide Residues in Foods - Multiresidue Analysis of Polar Pesticides and their Metabolites (TFDAP0006.01) 10. Method of Test for Pesticide Residues in Bee Products - Multiresidue Analysis (TFDAP0015.01) 11. Method of Test for Heavy Metals in Canned Foods - Test of Lead (TFDAH0010.01) 12. Method of Test for Water-Soluble Vitamins in Foods in Capsule or Tablet Forms (TFDAA0012.03) 13. Method of Test for Pesticide Residues in Foods -Test of Ethylene Oxide (TFDAP0022.01) 14. Method of Test for Acrylamide in Foods (TFDAO0003.01) 15. Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis (5) – 31 Items including Analycarb et al. (TFDAP0017.03) 16. Method of Test for Pesticide Residues in Livestock and Poultry Products - Test of 2,4-D and Fenbutatin Oxide (TFDAP0019.01) 17. Method of Test for Pesticide Residues in Poultry and Livestock Products - Test of Amitraz and its Metabolite (TFDAP0021.01) 18. Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6) (TFDAP0007.02) 19. Method of Test for Pesticide Residues in Foods -Test of Ethylene Oxide (TFDAP0022.02)	Revised
Recommended test methods for cosmetics and medical device products (8 articles, 77 items)	1. Method of Test for Nitrosamines in Cosmetics (RA03B023.001) 2. Method of Test for Hair Dyes in Cosmetics (4) (RA03D010.001) 3. Method of Test for Oxygen Permeability of Contact Lens - Polarographic method (RA04P001.001)	Published
	1. Method of Test for Hair Dyes in Cosmetics (3) (RA03D006.004) 2. Method of Test for Banned Phthalate Esters in Cosmetics (RA03B003.002) 3. Method of Test for α-Hydroxy Acids in Cosmetics (RA03A001.002) 4. Method of Test for Camphor, Menthol and Methyl Salicylate in Cosmetics (RA03O004.002) 5. Method of Test for Persulfates in Denture Cleansers (RA04Y003.002)	Revised
Recommended test methods for drugs, controlled drugs (including illicit drugs) and biological drugs (4 articles, 77 items)	1. Method of Test for Azido Compounds in Sartan Drug Substances - Test of AZBT (RA01I006.001) 2. Method of Test for Azido Compounds in Sartan Drug Substances - Test of 5-AMBBT (RA01I007.001) 3. Immunogenicity Determination of SARS-CoV-2 Vaccine (RA05I002.001)	Published
	1. Method of Test for Synthetic Phenethylamines in Urine (1) (RA02I003.002)	Revised

■ Appendix 3 Important Achievements and Statistics Over the Years

Table 1 The Statistics of Inspection of Foods Import Over the Years

Year	Inspection number of batches	Growth rate (%)	Total net weight (10,000 metric tons)	Batches tested	Inspection rate (%)	Number of noncompliant batches
2011	420,602	-	717.7	29,801	7.1	289
2012	461,665	9.8	754.5	38,793	8.4	467
2013	514,710	11.5	713.3	38,460	7.5	557
2014	616,286	19.7	796.6	48,704	7.9	664
2015	640,003	3.9	900.5	50,149	7.8	953
2016	674,991	5.5	882.9	52,722	7.8	915
2017	694,372	2.9	896.9	56,604	8.2	808
2018	682,575	-1.7	895.0	58,915	8.6	820
2019	718,766	5.3	925.7	58,108	8.1	786
2020	697,248	-3.0	891.3	52,435	7.5	832
2021	715,929	2.7	890.3	57,601	8.0	846

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

Table 2 Statistics of Monitoring Test on Residues of Pesticide 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	95.5	421	97.9	472	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	591	97.1	650	99.5
2018	4,467	89.0	3,580*	99.1	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

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

Table 3 Statistics on Foodborne Disease Over the Years

Year	Number of outbreaks	Foodborne disease outbreaks		Number of foodborne disease outbreaks classified by foods					
		Number of patients	Number of deaths	Aquatic products and their processed products	Meat, eggs, dairy and their processed products	Grain, fruits and vegetables and their processed products	Cake and candy	Compound cooking foods and other types	Total of causes with undefined foods
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338
2014	480	4,504	0	18	12	6	3	60	381
2015	632	6,235	0	17	3	7	1	53	551
2016	486	5,260	0	18	4	2	2	56	404
2017	528	6,232	0	7	3	7	0	44	467
2018	398	4,616	0	5	2	5	1	30	358
2019	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

Table 4 Statistics of Permits for Health Food and Genetically Modified Food Over the Years

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

Note:

1. Health food registration adopts the two-route system

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

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

2. As of December 2021, the total number of issued permits for health food accumulated to 491 (including Route I 414 and Route II 77), of which 85 were invalid permits (including expired, revoked and combined). As of the end of 2020, the number of valid permits were 388.

3. As of December 2021, the total number of issued permits for genetic modified foods accumulated to 155 permits of which 0 of them will be discontinued or not be extended. As of the end of 2020, the number of valid permits were 151.

Table 5　Statistics of Approved Medicinal Products Every Year

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

Table 6　Number of Valid GMP/QSD Registration Letters for Medical Devices Over the Years

Year	Valid GMP 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

Table 7 Approved listing/notifications/licenses of Medical Devices and Cosmetics Over the Years

Year	Medical devices			Specific purpose cosmetics		
	Number of listing	Number of issued licenses by year	Number of valid licenses	Number of notifications	Number of issued licenses by year	Number of valid licenses
2010	The listing system has been implemented for the announced medical device items from1. October.2021	3,920	30,140	General cosmetics should complete product notification before marketing from 1 July 2021	1,437	13,436
2011		4,047	33,865		1,519	14,979
2012		3,592	32,821		1,482	12,340
2013		3,827	35,705		1,456	13,799
2014		3,605	37,967		1,565	14,570
2015		3,743	40,579		1,558	14,902
2016		3,818	43,328		1,172	15,674
2017		3,940	46,797		1,142	16,643
2018		3,985	45,890		1,220	15,365
2019		3,770	45,839		1,257	14,710
2020		3,647	48,293		915	15,595
2021	3,303	2,900	47,635	333,805	994	16,578

Note: A total of 6,253 medical device licenses were cancelled in 2018; 4,653 medical device licenses were cancelled in 2019. 3,223 medical device licenses were directly transferred to the listing system in 2021.

Table 8 Controlled Drugs Licenses and Inspection Statistics Over the Years

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

Table 9 The Domestic and Overseas Pharmaceutical Manufacturers that Passed the Inspection Over the Years

Year	Domestic pharmaceutical manufacturers that passed the GMP	Domestic pharmaceuticalmanufacturers 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

Note: The data were compiled before 2014, given all western pharmaceutical manufacturers must in compliance with the standards of PIC/S GMP since 31/12/2014.

Table 10 Statistics of Post-market Quality Monitoring for Drugs, Medical Devices and Cosmetics

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

Table 11 Statistics of Lot Release for Biological Drugs Over the Years

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum				Other biological products		The annual total	
	Domestic		Imported		Imported		Domestic		Imported		Imported			
	Batches	Doses	Batches	Doses	Batches	Containers	Batches	Containers	Batches	Containers	Batches	Containers	Batches	Doses/ Containers
2010	46	5,870,554	115	6,881,397	116	894,973	4	5,923	2	31	18	281,084	301	13,933,962
2011	54	5,182,280	137	5,710,140	113	1,003,875	3	4,025	2	30	20	296,183	329	12,196,533
2012	53	4,509,491	146	6,711,965	115	960,004	3	4,348	1	20	22	498,230	340	12,684,058
2013	64	4,149,722	161	7,201,090	134	988,939	4	5,512	1	20	25	166,494	389	12,511,777
2014	72	3,705,462	155	7,607,454	121	962,552	6	8,440	0	0	27	332,558	381	12,616,466
2015	123	5,808,339	163	7,548,124	146	1,137,717	3	3,234	0	0	22	226,082	457	14,723,496
2016	58	4,122,437	152	6,773,750	146	1,363,462	9	6,078	2	19	29	422,944	396	12,688,690
2017	47	3,459,630	189	8,796,311	152	1,253,072	4	3,103	1	20	28	317,449	421	13,829,585
2018	69	4,923,435	202	8,509,618	145	1,175,986	3	2,976	1	15	33	214,220	453	14,826,250
2019	46	4,159,810	172	8,927,748	167	1,562,290	6	5,897	1	50	40	326,283	432	14,982,078
2020	52	4,736,457	181	10,203,078	163	1,609,298	6	2,629	0	0	46	259,651	448	16,811,113
2021	76	9,227,243	238	45,782,413	150	1,315,718	8	4,625	1	9	50	319,041	523	56,649,049

Table 12 Statistics on the Number of Accredited Laboratories and Accredited Items Over the Years

Year	Food accredited laboratory		[b]Drugs accredited laboratory		[b]Medical devices accredited laboratory		[a]Cosmetic accredited laboratory		[c]Drug abuse accredited laboratory		GLP accredited testing institution	
	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items	Number of laboratories	Number of items
2008	18	280	3	16	-	-	-	-	13	9	1	3
2009	23	298	7	55	-	-	-	-	13	9	8	16
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

*Note:

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

b. The former drugs accredited laboratory was divided into drugs accredited laboratory and medical device accredited 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.

Table 13 Seizure Rate of Illegal Drugs and Violation Rate of Food and Drug Advertisement Over the Years

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

Note:

1. The collaborative team for outlawing the counterfeit or inferior drugs was established in April 2010.
2. A total of 313 illegal drug cases were seized in 2021 with a total fine of NTD 4.323 million, the seized rate decreased from 11.81 % in 2010 to 1.69% in 2021.
3. The number of advertisement violations in food, drugs and cosmetics determined by the health authorities was 5,813 in 2021, with a total fine of NTD219.797 million. The advertisement violation rate decreased from 13.90% in 2010 to 4.85% in 2021.

Table 14 Statistics on the Operations of Pharmaceutical Plant of Controlled Drugs Over the Years

Unit (thousand NTD)

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

■ Appendix 4 TFDA Publications in 2021

Serial number	GPN	Topic	Responsible Section	Type	Publication year/month
1	4711000020	The library of Raman Spectra: Abuse Drugs (I)	Division of Research and Analysis	Books	2021/6
2	1011001324	Self-management manual for food additives business	Division of Food Safety	Books	2021/7
3	2010103850	2020 Annual Report on Food Import Management and Inspection Statistics	Division of Food Safety	Books	2021/10
4	2010002894	2020 Annual Report of Foodborne Disease Outbreaks and Prevention	Division of Food Safety	Books and digital publications	2021/10
5	1011001330	Identification of Commonly Misused Chinese Crude Drug	Division of Research and Analysis	Books	2021/11
6	1011001426	Cat Detective's Food Safety Reasoning Story: Ah! What happened to off-campus teaching?	Division of Food Safety	Books	2021/11
7	1011001505	Forest Pharmacy	Division of Medicinal Products	Books	2021/11
8	1011001667	Taiwan Pharmacopoeia edition IX	Division of Research and Analysis	Books	2021/12
9	1011002029	Makeup for the Skin - Regulations and Myths	Division of Medical Devices and Cosmetics	Books	2021/12
10	1011002273	Manual of Food Labeling Regulations	Division of Food Safety	Books	2021/12
11	1011002274	Guidebook on Food Labeling Regulations	Division of Food Safety	Books	2021/12
12	1011002275	Food Labeling Q&A Collection	Division of Food Safety	Books	2021/12
13	1011002291	Drug Abuse Prevention and Control Cartoon Manual-Youth Without Drugs	Division of Controlled Drugs	Books	2021/12
14	2010302286	TFDA Annual Report (English version)	Planning and Research Development Division	Continuity (Journal)	2021
15	2008200056	Journal of Food and Drug Analysis (JFDA)	Planning and Research Development Division	Continuity (Journal)	2021
16	49094052333	Food and Drug Consumer Newsletter	Planning and Research Development Division	Continuity (Journal)	2021

Appendix 5 Related Websites

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

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

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

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
22	Drug Abuse Reporting System	https://dars.fda.gov.tw	The system allows healthcare facilities to promptly report any cases of drug abuse, in order to assess the trends of drug abuse and instantly understand the current status of drug abuse in Taiwan.	
23	Urine Test for Drug Abuse Reporting System	https://udars.fda.gov.tw	A system for the periodically reporting results of drug abuse urine tests or narcotic tests by relevant domestic testing units.	
24	Searching System of Approved Advertisement for Drugs and Medical Devices Management System	https://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	Provide the public with information on approved advertisements for pharmaceuticals, medical devices and cosmetics.	
25	Post-marketing quality management system for medicinal products, food and cosmetics	https://qms.fda.gov.tw	This system provides a single integrated reporting portal for the public, medical professionals and manufacturers to report adverse events of drugs, medical devices, health foods and cosmetics.	
26	Cosmetic Product Registration Platform	https://cos.fda.gov.tw	To facilitate our cosmetic regulations, align with international standard, through the product information registered to the system by the manufacturers and the importers, so the government authorities can better grasp the information of the marketed products.	
27	Online Application System of Human Organ Bank	https://oap.fda.gov.tw/B105/	The system provides online application processing for human organ bank institutions to ensure the integrity of the information submitted for review and enhances application efficiency and regulatory compliance through the reminding function.	
28	Materials Transfer Support System for Disaster Rescue and Prevention	https://mrdss.fda.gov.tw/Web/	This system provides hospitals, pharmaceutical manufacturers and vendors, and human organ banks to report online of medical supplies reserves to assist in the dispatch of medical supplies in the event of a severe disaster.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
29	Laboratory Accreditation Management System	https://lams.fda.gov.tw	A platform for accreditation of food, drug, cosmetic and drug abuse urine testing institutions.	
30	Laboratory Information Management System	https://lims.fda.gov.tw	A system provided to local government health laboratories to manage the testing process electronically.	
31	Inquiry System for Advertisements in Violation	https://pmds.fda.gov.tw/illegalad/	The information on food, drug, and cosmetic violated advertisements is immediately and quickly revealed, so that the public can make inquiries and use it as a reference for purchasing products without being influenced by exaggerated and untrue advertisements.	
32	Citizen service (Direcotr General's) mailbox	http://faq.fda.gov.tw/	This mailbox service is an important channel for the public to express their views and opinions, and the established Intelligent Enquiry Service allows the overall service process to communicate more effectively and improve public satisfaction.	
33	Online System of the JFDA journal	https:// www. editorialmanager. com/jfda/	The Online System of the JFDA journal is an online submission and review system for the Journal of Food and Drug Analysis (JFDA), which provides domestic and foreign authors with the opportunity to submit manuscripts for review, editing and publication.	

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