2021
Taiwan Food and Drug Administration Annual Report

PROFESSION

SERVICE

QUALITY

INNOVATION

2021
Taiwan Food and Drug Administration Annual Report

PROFESSION

SERVICE

QUALITY

INNOVATION

Contents

Foreword by the Director-General

The Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare was established to promote every citizen's health and the public welfare. Based on its mission of "Providing safe and effective medicines, safe and healthy food", TFDA aims to become a trusted guardian of food and medicine safety for the people, managing the policies for food, medicine, medical devices, and cosmetics which ensure that the people are guaranteed the safety and quality of food and medicine. In order 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 response to the COVID-19, which can cause severe acute respiratory infection, have ravaged the world since 2020, the government has established the Central Epidemic Command Center (referred to as the CECC) to facilitate cross-functional coordination. TFDA introduced advanced deployment measures such as making an inventory of drugs and medical devices, accelerating the reviews of emergency use authorizations, establishing project teams for consultation services, tracking the essential supplied for pandemic control, and assisting in the research, development, and introduction of pandemic control drugs and medical devices. Besides, in response to the imbalance in the supply and demand of masks during the pandemic, the CECC coordinated efforts between the public and private sectors to establish the Mask Rationing Plan and quickly solve problems to improve the self-defense capabilities against the pandemic for everyone.

During the joint fight against the pandemic, TFDA has achieved great results in refining various works. In terms of food safety management, TFDA has implemented several measures, including announcing comprehensive regulations, enhancing the supervision of manufacturing, sale, import, and export, and improving advanced inspection technologies and big data risk analysis capabilities, to reinforce the management from farm to table throughout the life cycle of food and build a complete food-based safety net.

In order to ensure the safety, efficacy and quality of drugs, TFDA not only implements product lifecycle management model and also actively collaborates with other parties around the world to improve drug risk assessment, quality control and digital management. TFDA also provides a regulatory environment which is harmonized with international standards. Meanwhile, TFDA actively establishes relative standards for regenerative medicine preparations to accelerate the development of the domestic industry to respond to the emerging biomedical tech-

nology nowadays.

In recent years, TFDA has continued to review and amend the relevant regulations of the *"Controlled Drugs Act"*, having prevented the abuse or illegal use of controlled drugs through inspections on the distribution of controlled drugs and advocacy anti-drug campaigns.

It is worth mentioning that the much-anticipated *"Medical Devices Act"* has been promulgated by the President on January 15, 2020. TFDA has also established 22 sub-regulations drafts, including categorization and classification of medical devices, issuance of medical device license, listing and registration, flow management, etc., to build a complete lifecycle management system for medical devices. In addition, after announcing the guidelines for inspection and registration of Artificial Intelligent-Based Software as a Medical Device, TFDA has worked closely with companies by providing consultation to promote the research and development of relevant medical devices in Taiwan.

Facing the COVID-19 pandemic, it has been difficult for countries to have face-to-face communications. However, using video-conferencing technology, TFDA has exchanged ideas with various international organizations on regulatory management and inspection techniques. In 2020, TFDA became an official member of the APEC RHSC Medical Devices Regulatory Science Center and a member of the International Cooperation on Cosmetics Regulation (ICCR). Through active participation in international activities, TFDA worked to ensure that domestic laws and regulations follow international standards and improve Taiwan's visibility in the international arena.

With the continuing emergence of novel substances and the impact of emerging technologies and new chemical substances, the hygiene and safety management of food and drug have become a complicated issue. TFDA will have adhered to ensure food and drug safety for the people by integrating cross-functional coordination, industry players, and consumers to expand public participation. Source management, effective supervision, and inspection technology are incorporated into the core values of consumer safety to establish a comprehensive safety net for food, medicine, medical devices, and cosmetics.

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

Shou-Mei Wu

Ch1

Organization and Policies

CHAPTER
01

Administrative Goals

Point 1

Enhance the management of the life cycle of food, medicine, medical devices, and cosmetic to maintain the hygiene, safety and quality and create a safe environment for consumption.

Point 2

Strengthen source control management and traceability system, and implement audits and border inspections to improve the sound quality monitoring system.

Point 3

Reinforce international harmonization of laws and regulations, develop inspection capacity, improve the illegal drugs inspection network; promote the communication and advocacy of food and drug safety to raise the public's awareness of hazards and improve the quality of consultation services provided by agencies.

Ch1 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.

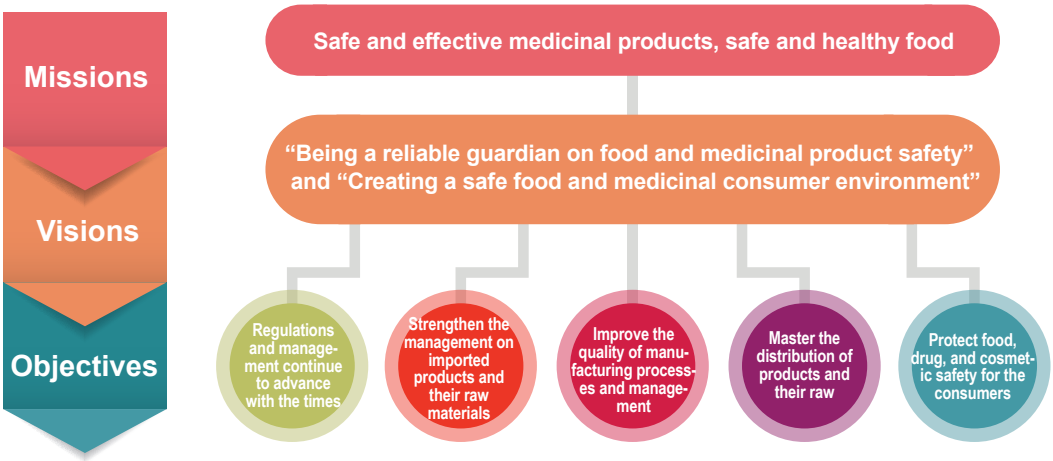


Figure1-1 TFDA's visions and missions

Section 1

Organizational Framework

Led by the Director-General, TFDA is composed of two Deputy Director-Generals, one Chief Secretary, and seven business units. Including: 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 laboratory management and authentication, manufacturers management and inspection of pharmaceutical and cosmetic products, and inspection of human organ bank; Division of Research and Analysis is responsible for the testing of food, medicinal products, and cosmetics, methodological development and evaluation, pharmacopeia editing and compilation; TFDA also sets 3 District Centers (North, Central, and South) which are responsible for laboratory testing of imported food, medicinal products, and cosmetics; as well as distribution examinations and inspections. In addition to the business divisions, we have also established five administrative units, including Office of Secretariat, Office of Personnel, Office of Accounting, Office of Service Ethics, and Office of Information Management, to assist in administrative management (Figure 1-2). Also, TFDA has two Task Forces (i.e. Factory for Controlled Drugs and Decision Support Center) to provide professional information, getting professional assistances from consultation units such as Taiwan Drug Relief Foundation and the Center for Drug Evaluation, Taiwan.

Section 2

Administrative Goals

TFDA sets the administrative goals and focuses based on the administrative policies of Executive Yuan and administrative programs of MOHW along with the budget plans, current development highlights, and social needs on food, medicinal products, and cosmetics management in 2020.

I. Enhance the management of the life cycle of food, medicine, medical devices, and cosmetic to maintain the hygiene, safety, and quality and create a safe environment for consumption.

II. Strengthen source control management and traceability system, and implement audits and border inspections to improve the sound quality monitoring system.

III. Reinforce international harmonization of laws and regulations, develop inspection capacity, improve the illegal drugs inspec-

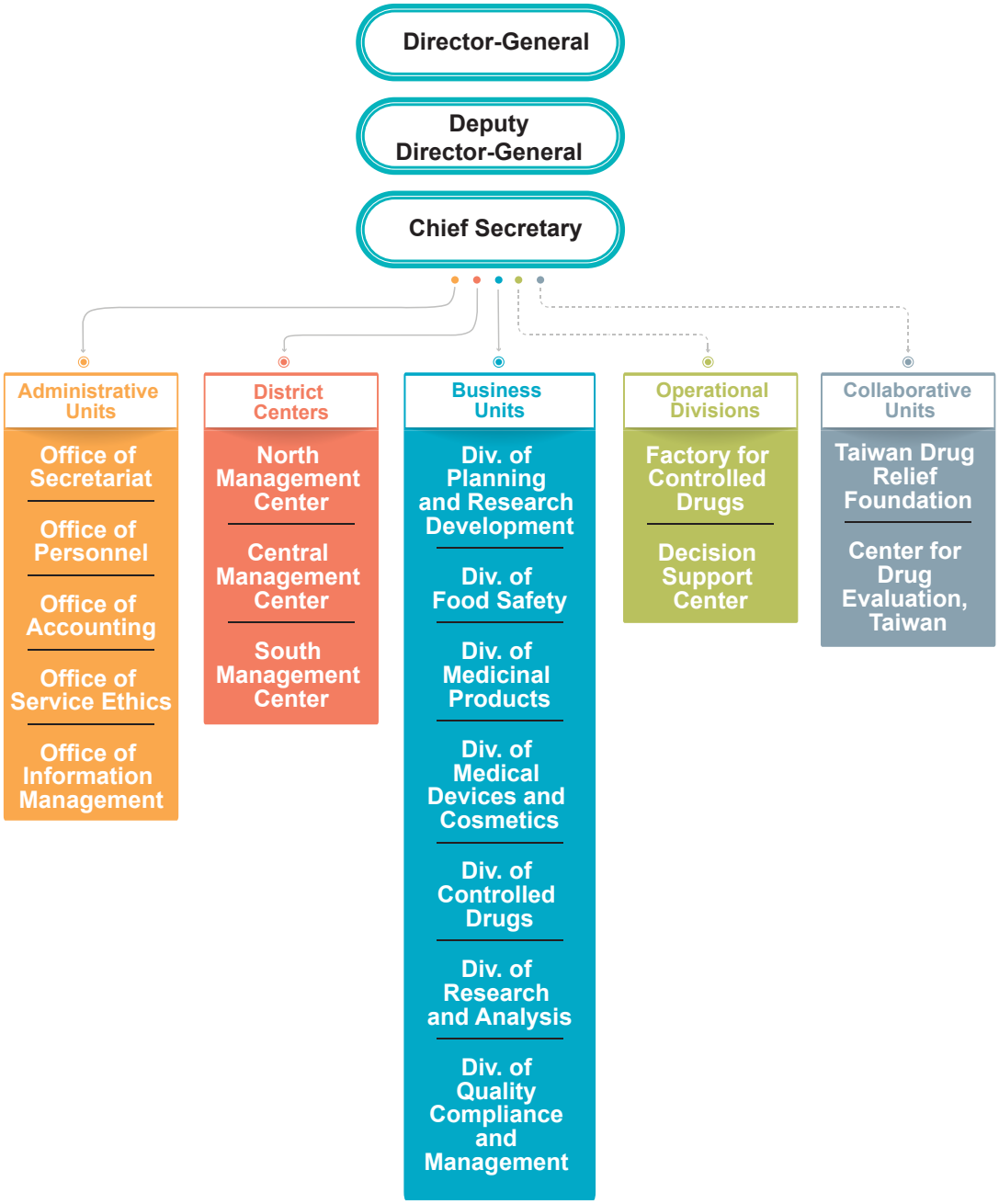


Figure1-2 The organization framework

tion network; promote the communication and advocacy of food and drug safety to raise the public's awareness of hazards, and improve the quality of consultation services provided by agencies.

Section 3

Food Management Overview

Enabling consumers to enjoy "Safe and Health Food" is the core value of a food management policy. As food safety issues around the world continue to evolve, food management appears to become more diversified, innovative, and informative. TFDA adopts the "farm-to-table" management concept to ensure the hygiene and safety (Figure 1-3) of steps from the manufacturing of raw materials to sales channels and reinforces the implementation of the "Five-point Food Safety Policy" (Figure 1-4) to achieve food safety through government management and self-discipline of the industry and public participation.

TDFA actively collects and refers to

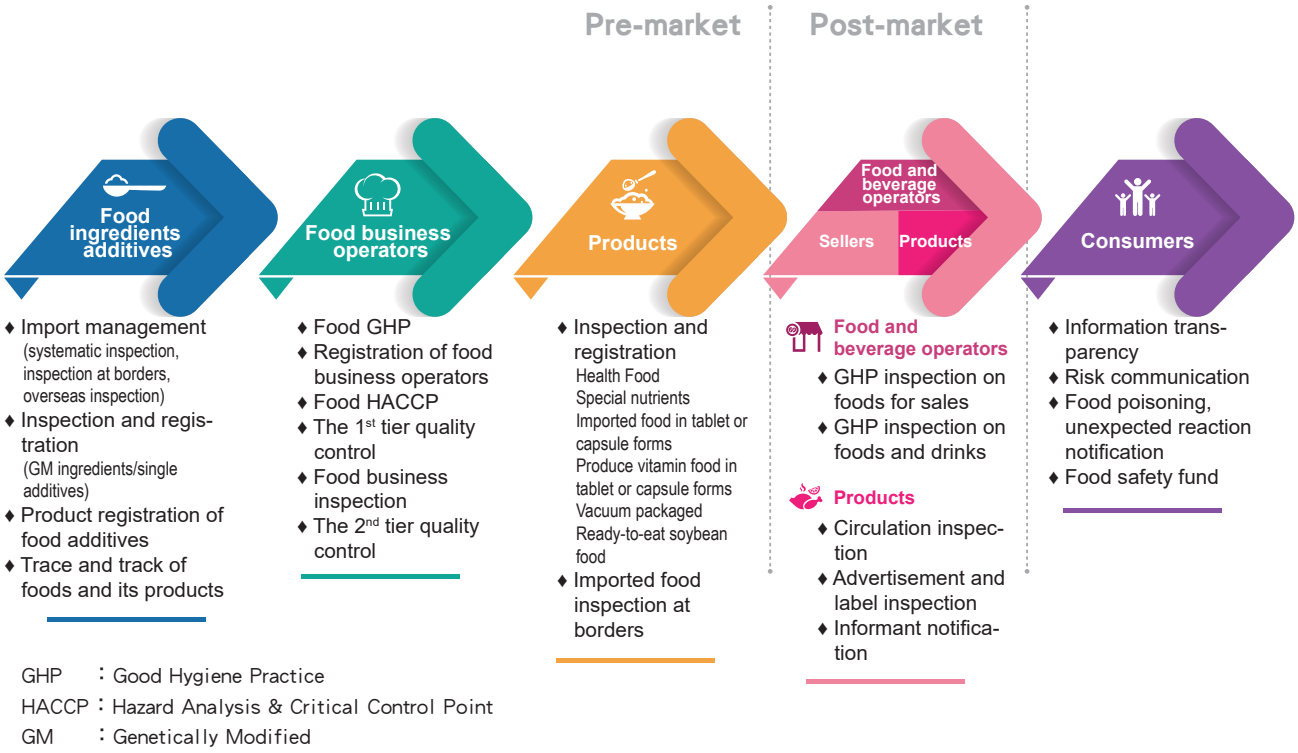


Figure1-3 Food management structure

international food management regulations, continuously updates regulations relevant to the "*Act Governing Food Safety and Sanitation*" to strengthen inspection capabilities and capacity, and actively develops new food inspection methods. In addition to continuously improving source management of food imports, the Agency establishes a central-local collaboration practice to conduct specialized inspections, random inspections, and post-market monitoring of food. It uses big data to improve risk management and early warning detection efficiency, ensuring food hygiene, safety, and quality.

Section 4

Overview of Drug and Controlled Drug Management

I. Medicinal products management framework

Different from general consumer goods, medicines can only be sold on the market after obtaining marketing authorizations issued by the central health authority. In terms of the life cycle management of medicinal products, product development, preclinical

Figure1-4 Five-Point Food Safety Policy

trials, clinical trials, marketing application, manufacturing to marketing, and various good operating practices, etc., must be followed. To ensure the safety of the public, TFDA continues to reinforce the quality management policy throughout the drug life-cycle (Figure 1-5) through harmonization with international regulatory standards, digital drug management, standardization of quality and safety supervision, ban and inspection of illegal drugs, drug business operators and product circulation management, etc. All of these measures are ensuring the safety, efficacy and quality of drugs, so that those in need can obtain the medicines in a timely manner. These measures would also facilitate the development of biotechnology industry in Taiwan and create a win-win situation among patients, pharmaceutical industries and the government.

II. Controlled drug 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*

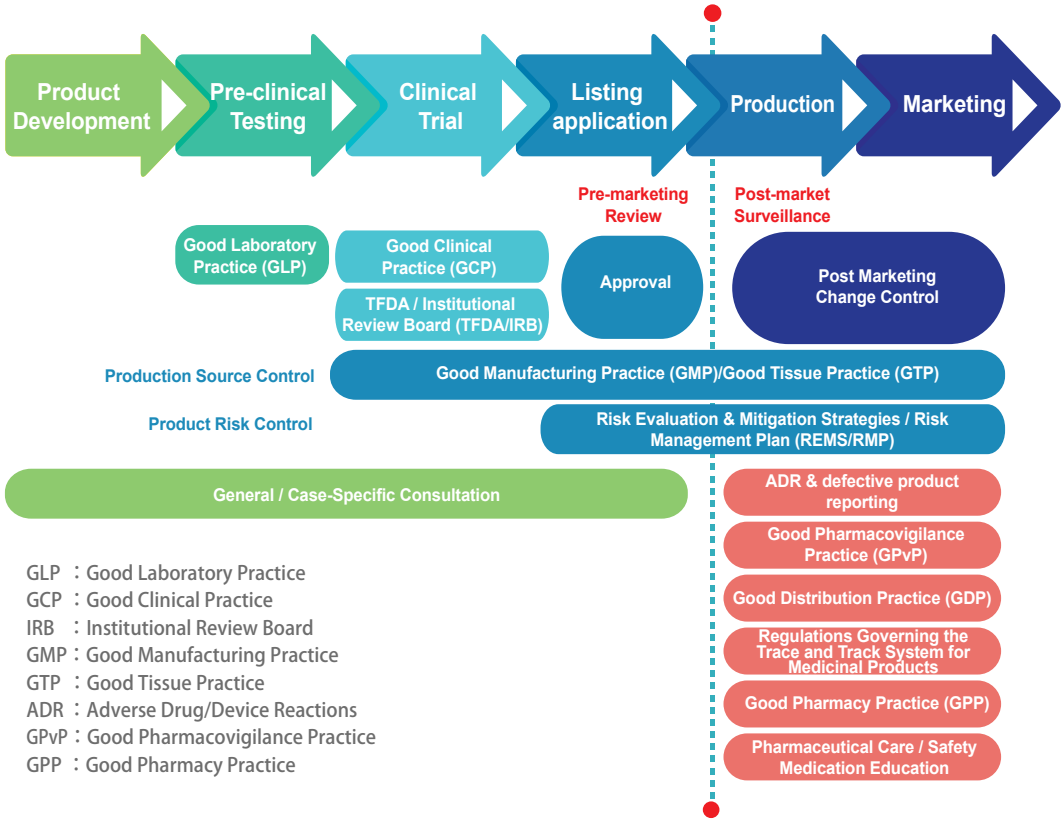


Figure1-5 Life cycle management structure of drugs

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

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 domestic medical device industry, TFDA has established a quality

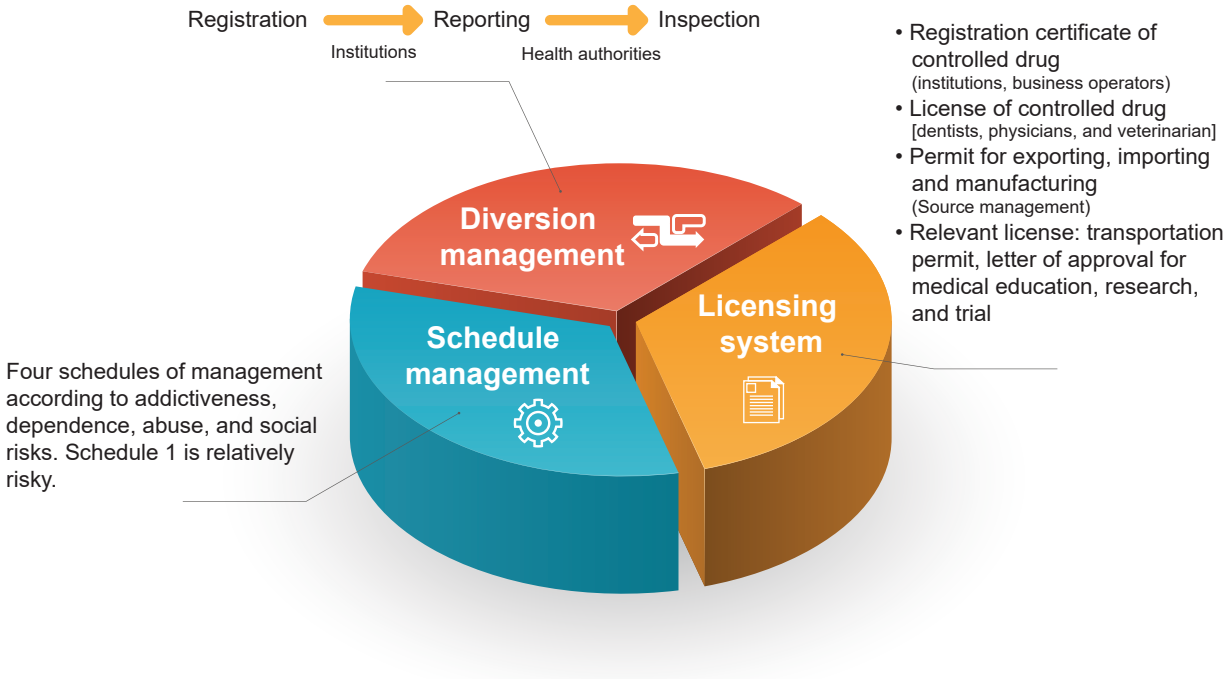


Figure1-6 Management structure of controlled drugs

lifecycle management system for medical devices covering various aspects, including internationalization of regulatory management, flow control, pre-market inspections, post-market monitoring, management of medical device firms, and product circulation management (Figure 1-7). The system can effectively control the safety, efficacy, and quality of medical devices ; at the same time, it can continue to facilitate the development of the biotechnology and the pharmaceutical industry, so to create a win-win situation for consumers, business operators, and the government.

II. Cosmetics Management framework

The current cosmetics management system includes three parts: 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 Manufac-

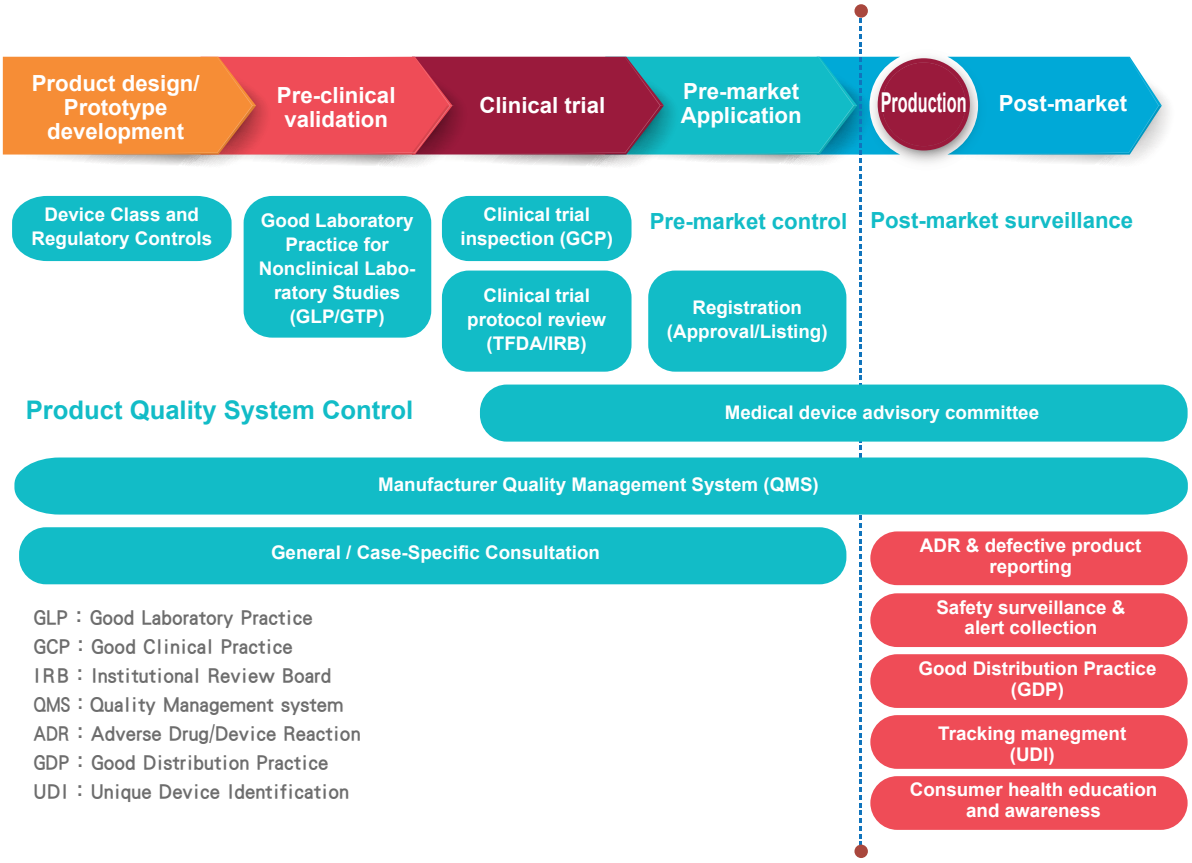


Figure1-7 Full life-cycle management structure for medical devices

tory and promotion of Good Manufacturing Practices (GMP); the pre-marketing management includes notification of cosmetic products and establishment of product information file to replace the registration of specific purpose cosmetics during 5-year transition period; post-market surveillance focus 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.

Section 6

Future Perspective

With the trends of global trade and the development of technology, the discovery of novel substances, and the impact of emerging technologies and new chemicals, the safety and sanitary issues of food and medicinal products gradually become critical. In view of the importance of food and drug safety and the expectations from the public, TFDA integrates different departments and businesses , and expand the participation of the public to construct a safe protection network for food, medical products, and cosmetics. Future important administrative

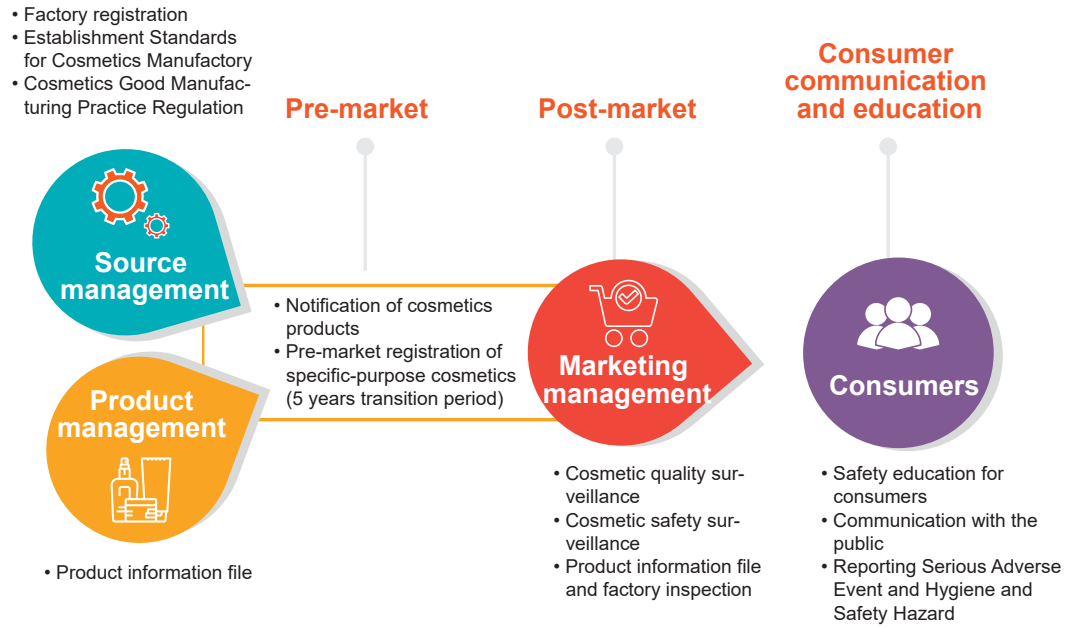


Figure1-8 Cosmetic Hygiene and Safety Management Framework

plans include:

I. Implementation of 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 program to strengthen health department's food safety audition and inspection capacity, the program to strengthen central competent authority's food safety, safe drug use and illegal drug inspection capacity, and the program to improve the capacity and standardization of emerging infectious disease drugs and food-borne pathogen testing research, to build a modern national food safety laboratory complying with international standards, purchase high-precision inspection equipment, comprehensively improve the efficiency of food safety testing and research and development, further strengthen the management capacity of local and central governments agencies.

II. Implement "Five-Point Food Safety Policy" reform plan, continue to expand the food safety management resources, combining business self-management and public participation to maximize the effectiveness of limited resources by executing these management strategies, the three-tier product quality management, and market inspection will be practically carried out. In addition, the big data approach for food will be adopted to plan the risk strategies to enhance the domestic food management capacity.

III. Improve the comprehensiveness of medicinal products legal environment, strengthen drug supply chain control and the GMP/GDP management, build a management system for regenerative medicine, implement precision medicine pilot programs, expand diversified pharmaceutical services, and improve international coordination of medical regulations.

IV. Promote various regulations of the *"Medical Devices Act"* and the *"Cosmetic Hygiene and Safety Act",* and accelerate the integration with international regulations. In response to the development of innovative medical devices and cosmetics, establish forward-looking and flexible management regulations. Reinforce consumer protection, and improve post-market surveillance to promote the development of domestic medical devices and cosmetics industries.

Ch2

Strengthened the Management of Food Safety

CHAPTER
02

Enhanced the Food Management Regulations

- Retain source documents in written or electronic forms
- *"The Safety Assessment Method of Health Food"* was amended
- Established *"Regulations Governing the Labeling of the Disease-specific Formulas"*
- Established the regulations for the labeling of origin of raw materials
- Full registration system of food businesses

Harmonization of International Standards

As of December 2020, the *"Standards for Pesticide Residue Limits in Foods," "Standards for Veterinary Drug Residue Limits in Foods," "Standards for Specification, Scope, Application and Limitation of Food Additives,"* and *"Food Sanitation Standards"* had regulated drugs：

1	388	Pesticides
2	7,376	Residue limits for pesticides
3	145	Veterinary drugs
4	1,511	Residue limits for veterinary drugs
5	786	The scope of use, limits and specifications for food additives
6	27	Sanitation standards

Ch2 Strengthened the Managementof Food Safety

In order to strengthen a comprehensive farm-to-table food safety management system, TFDA has continued to implement relevant tasks, including announcing comprehensive regulations of food management, strengthening the supervision of manufacturing, sale, import, and assisting domestic operators in creating export business opportunities. TFDA also has implemented the 2nd tier quality control management system and the big data analysis for risk management, in addition, TFDA has developed inspection technologies applied to the emerging and risky substances in foods to construct a comprehensive food safety net and protect the consumption environment of "safe and healthy food" for consumers.

Section 1

Enhanced the Food Management Regulations

Introduction of the Policy

In order to improve the regulations of food management and enhance the professionalism of business operators' self-management, nearly 40 regulations were reviewed in 2020, including various food hygiene and safety standards, "*The Safety Assessment Method of Health Food,*" "*Regulations governing the labeling of the disease-specific formulas*," and "*Regulations Governing the Registration of Food Businesses*," etc.

Implementation Strategy

I. Rolling revision of food hygiene and safety standards

Based on the principles of risk assessment, TFDA has taken the scientific evidences of international standards along with toxicological studies into account to comprehensively evaluate relevant standards and strive to comply with international management standards.

II. Retention of the source documents

Starting January 1, 2020, TFDA has required all food businesses to retain their supplier signature records or source certificates of raw materials, semi-finished products, and finished products and other documents in written or electronic forms for at least 5 years; for example: purchase orders of upstream manufacturers, invoices, import declarations, and other relevant information.

III. Reinforcement of the management of health food and special dietary foods

In order to make the methodologies of health food safety assessment clearer, more comprehensive, and harmonized, "*The Safety Assessment Method of Health Food*" was amended. On August 20, 2020, TFDA also communicated the safety assessment method of health food to the Environment and Animal Society of Taiwan. In addition, in line with the "*Regulations Governing the Management of the Review, Registration, and Issuance of Permit Documents for Food and Related Products,*" TFDA reclassified the disease-specific formulas, establishing "*Regulations governing the labeling of the disease-specific formulas.*"

IV. Clearer labeling, safer choices

(I) The establishments and amendments of relevant laws and regulations

In order to make the information on the origin (country) of pork and edible parts of pigs more transparent and protect the rights and interests of consumers, TFDA established the regulations for the labeling of origin of raw materials, including packaged, bulk, and directly supplied food, to allow consumers making more informed choices.

(II) Preparation of the promotion and the labeling materials

TFDA created the "Guidebook on the Origin of Pork Raw Materials" and the related labels, making the relevant information of the regulations for the labeling of origin of raw materials, including online courses, posters (Figure 2-1), promotional leaflets, labels, Q&A, etc., to be placed on Food Labeling and Consulting Service Platform.

Figure2-1 The poster for labeling pork origin

V. Full registration system of food businesses

TFDA has established a comprehensive food registration system in order to strengthen the management of basic information of food businesses, adjusting the period for the businesses to reconfirm the contents of the registration to improve the efficiency of registration system.

Achievements and Benefits

I. Harmonization of international standards

As of December 2020, the "*Standards for Pesticide Residue Limits in Foods,*" "*Standards for Veterinary Drug Residue Limits in*

Foods," "*Standards for Specification, Scope, Application and Limitation of Food Additives,*" and "*Food Sanitation Standards*" had regulated 7,376 residue limits for 388 pesticides; 1,511 residue limits for 145 veterinary drugs; the scope of use, limits, and specifications for 786 food additives; 27 sanitation standards.

II. Enhancement of the management of food sources and the food traceability system

All food businesses, regardless of their business category and scale, should retain documents related to raw materials, semi-finished products, and finished products. In addition to encouraging food businesses to be responsible for the source of products and implementing self-management, the practice can improve the food traceability system to achieve the goals of food hygiene and safety through the management of source documents.

III. Amendments of "*The Safety Assessment Method of Health Food*" and "*Regulations Governing the Labeling of the Disease-specific Formulas*"

(I) *The Safety Assessment Method of Health Food*

TFDA specified the criterion of assessment methodologies needed to be complied with "*The Safety Assessment Method of Health Food.*"

(II) *Regulations Governing the Labeling of the Disease-specific Formulas*

1. Labeling content for all types of the disease-specific formulas should add certain labels, such as "Exceeded consumption will not help alleviate this type of disease."
2. Labeling content for different types of the disease-specific formulas should add certain labels, such as "This product is not suitable as the sole source of nutrition."

IV. Collaboration of health agencies and the private sector to improve the efficiency of assistance

(I) A total of 72 sessions of communication and regulation briefing for industry operators were held to provide explanations to the public and guide the industry to correctly apply labels.

(II) TFDA organized the "2020 Annual Imported and Domestic Beef Safety Seminar," where domestic experts and scholars in the fields of veterinary medicine, zoology, neuromedicine, animal epidemiology, public health, food safety, and law shared international standards of safe trade and implementation of different countries (Figure 2-2).

(III) Assistance of the labeling of pork origin:

1.TFDA assisted the Minister of Health and Welfare to visit 8 night markets and commercial districts to understand the status of implementations of pork labeling (Figure 2-3).

Figure2-2 2020 Annual Imported and Domestic Beef Safety Seminar

Figure2-3 On site visits for the implementations of pork labeling

2.TFDA cooperated with local health bureaus to help food businesses establish demonstration areas for labeling in food courts, old streets, night markets, traditional wet markets, and sightseeing hotspots.

3.As of the end of 2020, a total of 170,000 businesses have been completed in 22 counties and cities, with completion rates reaching 100%.

V. Refinement of the registration system of food businesses

On April 29, 2020, TFDA announced the amendment of the Article 7 of "*Regulations Governing the Registration of Food Businesses*," which the reconfirmation period after completing the registration platform of the food industry is adjusted from July to any month of the year, to verify the actual operating conditions of the food businesses. The number of food business operators registered to the platform is about 520,000 in 2020, and increase of 50,000 over the 470,000 in 2019. TFDA will continue to promote the registration of other food business operators.

Section 2

Reinforced Supervision of Food Production Chain

Introduction of the Policy

In order to offer a reliable food safety environment for all consumers, the competent authority is responsible for supervision and inspection through overseas source inspection, strengthened government inspection capabilities at borders, post-market inspection, and collaboration with various agencies and police force to enhance the inspection of food and drugs, identify the potential risks and product items and adopt the warning and control measures in advance.

Implementation Strategy

I. Inspection of imported products at borders

Plans are made every year to conduct border inspections. With reference to inspection records, product characteristics, and domestic and foreign information, conduct rolling reviews and adjust inspection methods and items. For foods that do not comply with border clearance inspections, return or destroy them in accordance with regulations, 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. Domestic manufacturing processing and circulation supervision

For key implementations, severe violations, high-risk and high-concern projects, conduct special inspections and random inspections. In response to the novel coronavirus pandemic, the food industry is urged to

implement health management inspections on-site and strengthen independent pandemic control measures.

III. Collaborative cross-department inspection

For foods that are frequently consumed in our daily lives, we plan inspection projects for abnormal circumstances through precautionary information and statistical data analysis, which the central departments and local governments will collaboratively conduct inspection projects to ensure the hygiene and safety of the traceable products in the supply and marketing chain.

IV. Cooperative investigation between prosecutors and police

The food and drug crime investigation team serve as the contact and coordination center responsible for supervising, directing, and coordinating the investigation efforts of various agencies. The establishment of a contact platform for the investigation of food and drug cases can play a coordinating role when investigating such criminal cases.

Achievements and Benefits

I. Inspection of imported products at borders

(I) A total of 697,284 batches of food related products were inspected at the customs clearance in 2020, including 24,392 batches were inspected on site and 52,435 batches were inspected by random sampling. A total of 832 batches failed to meet the inspection requirements, accounting for 1.6% of the sampling batches and the rate of passing the inspection was 98.4%.

(II) On April 22, 2020, online electronic notification measures were launched. During the novel coronavirus pandemic period, the measures taken can reduce personnel contact and infection risks, save inspection operators' time to pass documents, add an attachment of documents and online notification for supplementary information, etc., promote the government's paperless policy, and enhance the convenience of application and improve the efficiency.

II. Domestic manufacturing processing and circulation supervision

Completed 40 food inspection projects in 2020. The inspected number of domestic business operators in the industry was 136,374. The qualified rate of GHP food business operators for re-inspection was higher than 90%. The number of inspected products and random inspections is 450,000 and the qualified rate attained 99%.

III. Collaborative cross-department inspection

Food collaborative inspections were conducted in 2020. The collaborative inspection was implemented for commercial

longan-honey and washed eggs and chemical raw materials suppliers that also sell food additives to manage the production as well as the trace and track management, facilitate the development in the industry, strengthen the self-management of business operators, maintain product safety and hygiene and protect consumers' rights and interests. The test results of the veterinary drug residues of eggs and feed of laying hens were not detected at 15 different farms; 31 samples of liquid egg products were all qualified. In addition, 20 business operators related to longan-honey supply chain and 81 food additives supplier were inspected for their GHP, and the pass rate for re-inspection was 100%.

IV. Cooperative investigation between prosecutors and police

In 2020, TFDA collaborated with prosecutors and police investigation units to handle 22 food violations, all of which were investigated and dealt with according to the law.

Section 3

Improvement of Imported and Exported Food Management

Introduction of the Policy

In order to effectively control the imported foods that are at higher risk, TFDA announced the control measure that specific certificates issued by competent authority of exporting country should be attached for imported foods. In accordance with Article 30 of the "*Act Governing Food Safety and Sanitation,*" the application for inspection of goods imported is amended in a rolling manner to ensure that the foods meet the sanitation and safety requirements.

In accordance with the regulations of exported countries and cross-department collaboration, TFDA has submitted the food safety assessment questionnaire and/or the list of food manufacturers to the exported countries in order to assist the domestic food businesses exported food to their target countries.

Implementation Strategy

I. Improvement of the source management system

In 2020, TFDA announced that the import of dairy products should have the official certificates of the country of origin. The control measure ensures that the exporting country provides its qualified products from legal suppliers, further strengthening the source management of imported products.

II. Expanding scope of border inspection

TFDA and the 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, for TFDA to announce amendments of commodity classification code that shall apply for import inspection to TFDA.

III. Assistances in exported food products to various countries

Affected by the novel coronavirus pandemic in 2020, countries have adopted corresponding measures, and some exporting countries have adopted document review or submission of specified documents to ensure that foods exported from our country meet their regulations. For example TFDA submitted a list of 23 aquatic products manufacturers to the Saudi Food and Drug Authority (SFDA) in 2020, and the SFDA has updated the list of 23 manufactures to its website and illustrated that SFDA has reviewed our national assessment questionnaire, once the pandemic eased down, they will confirm a date for on-site inspection.

Achievements and Benefits

I. Enhancement of border control to improve product hygiene and safety

In 2020, TFDA announced the amendments to the "*Regulation of Imported Beef and Beef Products from the United States and Canada*" and the "*Operational Procedures for Imported Beef Quarantine and Inspection.*" As for imported dairy products for food purposes, official certificate that indicates "fit for human consumption" or compliance to the food safety and sanitation regulations of the exporting countries shall be attached.

II. Amendment of import inspection numbers to improve management intensity

TFDA announced addition and revision of 63 items of imported goods for inspection, including the original CCC code list of pork products were further subdivided into kidney of swine, offal of swine, and other items, in accordance with the comprehensive management measures for imported pork, where a total of 2,689 imported goods shall be inspected at the border before imported.

III. Exploration of the global market to create the opportunities of exported business

In 2020, dairy products were permitted to be exported to Japan, newly added 18 food manufacturers could export canned foods that contain poultry, pork, or eggs to Singapore, and 23 food manufactures could export aquatic products to Saudi Arabia. TFDA and the Bureau of Standards, Metrology, and Inspection of the Ministry of Economic Affairs involved in the written questionnaire application and on-site inspection of thermally treated salmon products exported to Australia, completing the equivalent assessment of official control review.

Section 4

Implemented the 2nd Tier Quality Control Policy

Introduction of the Policy

The Agency has established the "*Accreditation Of Certification Body And Sanitation And Safety Control Of Food Businesses Of Certification Regulations*" to reinforce the third-party certification management system for tier 2 quality control, and help the food industry operator improve their product quality to align with the international standards.

Implementation Strategy

I. Compulsory types of management

The food manufacturers that have registered to TFDA such as canned food, food additives, special nutritional products, dairy products, and companies with at least a capital of NT$30 million producing sugar, salt, starch, flour, soy sauce, and edible oils, a total of 10 product categories, shall pass 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 have met the standard announced by the central competent authority shall acquire the certification of the sanitation and safety management system.

III. Standards for certification implementation agencies and personnel

The certification is conducted by the certification agency (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) accredited by TFDA. 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 operator, to ensure the independence of the certification implementation. In addition, the academic experience and auditing capabilities of the professional dedicated auditors are clearly regulated to ensure their professional capabilities. TFDA also conducts assessment of headquarters and review assessment for the certification agencies and their auditors on a yearly basis to ensure the quality and effectiveness of certification.

Achievements and Benefits

I. Reinforced the tier 2 quality control certification to improve product quality

In 2020, a total of 510 food factories shall be certified, of which about 94% of them passed the certification, including 184 food additives manufacturers, 178 canned food manufacturers, 59 general consumer goods manufacturers (sugar, salt, starch, flour, soy sauce and edible oils), 54 dairy products manufacturers, 13 special nutrition food manufacturers and other 80 industries operators of voluntary certification, for a total of 568 company visits. Deducting the factories of duplicate types under the same company, a total of 480 factories have passed the certification, and the remaining companies that shall be certified are in either the application stage or the certification stage. The 2nd tier quality control combines the certification capability of a fair third-party agency to reinforce the supervision and management of food sanitation and safety, as well as establish a comprehensive food safety protection system.

II. Simplified the application process of food export to develop export

Those business operators who passed the certification can use a third-party certification certificate for the 2nd tier quality control to simplify the process of applying for food export and reduce the waiting time and cost. As of the end of 2020, a total of 34 Good Manufacturing Practice (GMP) certification documents required for export have been issued to companies that can start exporting to Malaysia, Vietnam and other countries.

Section 5

Food Safety Risk Management

Introduction of the Policy

The total amount of food imports has continued to grow in recent years. In order to reinforce food safety management, big data analysis and statistics compilation 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 based on the guildines of the risk management and crisis management from various agencies under the Executive Yuan.

Implementation Strategy

I. Established an artificial intelligence food risk prediction system to assist in the risk decision-making process of border inspections

By using big data analytic techniques to establish a Border Prediction Intelligent System (BPI) which can provide real-time detection of high risk imports to support the inspection decision making.

II.Incorporated statistical science into post-market risk detection to actively supervise the food safety and take precaution of the potential violators

Integrates the data the from the Food Cloud establish a “Post-market interdepartmental big data risk detection system” which can detect high-risk merchants and take preventive actions in advance and initiate audits.

III. Dealt with African Swine Fever emergency responses and notifications

TFDA continues to participate in the meetings of the emergency response center and establishes the TFDA African Swine Fever Emergency Response Working Group to execute response actions and report work progresses.

Achievements and Benefits

I. Effectively improved the performance of border inspections

In 2020, AI predictive models were established and have been incorporated into the Imported Food Inspection System (IFI). The models have contained with 78 categories of products. The accuracy rate of AI-suggested inspections was increased by 1.4 times than before, which has effectively improved the management practices of food inspections at the border and block out unqualified products.

II. Assisted in post-market risk detection to improve the audit accuracy rate

The development of the market risk prediction model was completed in 2020. Smart monitoring practices are assisting to highlight the products of high concern, high risk and high media attention to serve as reference for on-site audits. In 2020, the food auditors found a total of 61 violations of food safety regulations, which was 2.6 times greater than that of the 23 violations found in 2019. Food risk information and audit results are constantly collected to revise the analysis methods on a rolling basis, further improving the performance of post-market monitoring.

III. Dealt with African Swine Fever emergency responses and notifications

In 2020, TFDA continued to participate in the meetings of the African Swine Fever Central Disaster Response Center. TFDA also took actions such as the “Management of research and discussion network platform”, “Border control measures”, “Post-market inspections” and “Pandemic control promotion” etc., and completed a total of 12 notifications of relevant response tasks. In 2020, there were 39,207 food auditing tasks executed by health agencies among merchants of meat stalls, supermarkets, meat processing plants, catering, food and beverage and boxed meal operators to trace back to the sources of pork.

Section 6

Development of New Food Test Technologies

Introduction of the Policy

In order to meet the requirements of food-related regulations and sanitary standards, establishing fast and accurate analytical methods are required. The methods can also apply for the identification of unknown or illegal additives and contaminants from the manufacturing process. Therefore, TFDA continues to improve analysis capabilities, and establish new testing methods for emergency response to food safety incidents, as well as to hold technical interchange and training activities to strengthen domestic testing capacity for food safety.

Implementation Strategy

I. Promoted domestic food inspection technology interaction

Plan and hold technical exchange activities, invite central and local health agencies to share the status and experience of inspection technology, promote inspection technology exchanges, improve the technical level and inspection quality of domestic inspection units, and develop inspection talents.

II. Aggressively developed the food inspection methods by national laboratories with high-end inspection technology

In response to high-risk and highly concerned subjects related to the general public's livelihood, we actively developed reliable and time-saving test methods to quickly identify and clarify incidents. These test methods were immediately released to inspection related laboratories, which would strengthen the governing at borders, monitoring market products, enhance self-management of business operators and ensured the safety of citizens in the nation.

Achievements and Benefits

I. Organized the "2020 Food and Drug Inspection Technical Exchange Consensus Workshop"

In order to promote the collaboration between the central government and various inspection agencies and reinforce domestic inspection capabilities, the Agency organized the "2020 Food and Drug Inspection Technical Exchange Consensus Workshop" on September 8 and 9, 2020 (Figure 2-4). More than 120 inspection personnel from the Agency and other health bureaus attended the workshop. Keynote speeches on topics such as food chemical inspection, food biological inspection, food adulteration and additives, and drugs and cosmetics inspection were held. The attendees engaged in exchanges of opinions and discussions on food and drug inspection technologies. The workshop

Figure2-4 2020 Food and Drug Inspection Technical Exchange Consensus Workshop

also provided sales network and discussion opportunities for inspection personnel to promote sharing and improvement of inspection technologies.

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

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

An investigation by the Consumer Council of Hong Kong in 2020 revealed the risks of 3-monochloropropanediol esters and glycidyl esters in infant formula. TFDA quickly published the relevant inspection methods within 3 months.

In response to the public opinions on the import of American pork and the revision of standards on residues, the rapid extraction method for multiple residues of β-Agonists was immediately published. The test method for levulinic acid in soy sauce was published as a reference for monitoring whether soy sauce is naturally fermentated.

(II) Consolidation and optimization of inspection methods for heavy metals in food

In 2020, TFDA consolidated and optimized the inspection of inorganic arsenic in various foods, 5 types of heavy metal elements in food grade salt, and various heavy metal elements in animal products, which shortened the inspection time by more than 2 times and improved inspection efficiency.

(III) Improve multiple inspection methods for pesticides and animal drugs

In 2020, TFDA expanded the inspectable items of multiresidue analysis methods from 380 to 397 in pesticide method (5), from 23 to 31 in pesticide method (6), from7 to 23 in the antiprotozoal drugs method and from 8 to 19 in the β-lactam antibiotics method. A SweEt method (Swedish ethyl acetate method) for multi-residue analysis of pesticide was also established. By using ethyl acetate as an extraction solvent, 6 pesticides in fruits and vegetables which cannot be extracted by the multiresidue analysis method (5) and method (6) can be analyzed. It is complementary to the existing methods, increasing inspectable items and effectively expanding the coverage of inspection methods.

(IV) Identification of unknown substances in commercial space biscuits

Space biscuit products sold in the Internet have been reported to have a psychedelic effect. TFDA conducted the analysis of unidentified psychedelic compounds mixed in the biscuits, and general routine drug screening (GC-MS method), 73 cathinone component inspections (LC-MS/MS method) and 30 types of cannabis (LC-MS/MS method) were included. Liquid chromatography with high resolution mass spectrometry as also employed to detect the unknown substances of the products. The products were found to contain myristicin and elemicin, indicating the space biscuits might contain nutmeg.

Nutmeg can be used as a spice or Chinese herbal medicine. It contains myristyl ether and elemenin, which can cause hallucinogenic effects. Therefore, foods should not contain too much nutmeg. Besides the poor taste, excessive consumption of such foods can cause poisoning. For these incidents, TFDA elaborated on its strength as a national laboratory to actively conduct analysis on this space biscuit products. It quickly clarified that the products did not contain western medicine or drug ingredients; they were made with a large amount of nutmeg. The analytical technology keeps public health and demonstrates the capabilities of TFDA to identify unknown substances, not only calming the public, but also deterring illegal trader and preventing potential threats.

Ch3

Reinforced Drug Management

CHAPTER

03

Actively Participate in International Events of Medicine

- Expand participation in ICH related meetings
- Continue to participate in APEC international conferences
- Conducted the 8th Joint Conference of Taiwan and Japan on Medical Products Regulation
- Continue to participate in the PIC/S conferences
- Organized an online international conference to share COVID-19 pandemic control experience

Stipulated Relevant Guidances on Regenerative Medical Products

- Amendment of the *"Guidance on Investigational Cell Therapy Products"*
- Announcement of the *"Guidance on Investigational Gene Therapy Products"*
- The *"Guidance on management of traceability of cell and gene therapy products"* (*Draft*) was announced respectively
- The *"Guidance on donor informed consent of cell and gene therapy products"* (*Draft*) was announced respectively

Improvement of Drug Quality Inspection Technology

- Establish a platform for multi-residue analysis and detection of nitrosamines for high-risk drugs
- Completed the development of 44 screening and analysis methods for 11 kinds of nitrosamine impurities, including NDMA

Ch3 Reinforced Drug Management

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 regulatory environment and harmonises with international standards to improve domestic regulations of medicine management. We continue working on various aspects, such as the management of drug reviewing, the regulations of drug distribution, digital management, the supervision of quality and safety, and also the inspection technology for quality to further strengthen the risk management and thus provide a safe environment for drugs usages as well as facilitate the development of the domestic pharmaceutical industry.

Section 1

Enhanced the Drug Management Regulations

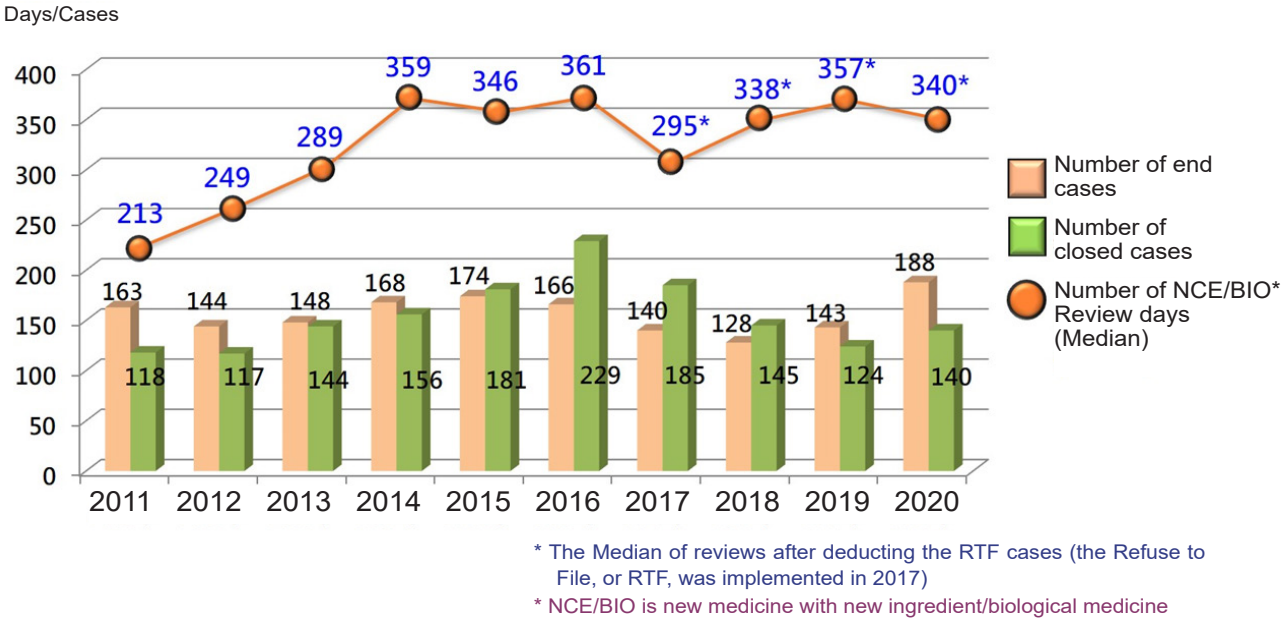
Introduction of the Policy

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

Implementation Strategy

I. Guidances improvement regarding regenerative medicinal products

The *"Regenerative Medicinal Products Management Act" (Draft)* has been submitted to the Executive Yuan, and the regulations have also been submitted to the Legislative Yuan for deliberation. TFDA continues to announce the stipulation of relevant guidances on regenerative medicinal products as a reference for the industry developing regenerative medicinal products, and further improving the regulatory environment.



* The Median of reviews after deducting the RTF cases (the Refuse to File, or RTF, was implemented in 2017)

* NCE/BIO is new medicine with new ingredient/biological medicine

Figure3-1 Number of applications, closed cases and review time of new drugs in past few years

II. Continuous improvement of the review procedures for new drug registration

TFDA has announced a series of specific measures in recent years, including the announcement of the "*Points to Consider on Drugs for Pediatric or Rare Disease Designation*," and 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,*" and "*Points to Consider for Breakthrough Therapy Designation,*" to improve the efficiency of drug review and accelerate the approval of new drugs.

III. Implemented the patent linkage system of drugs

In order to improve the protection of intellectual property rights for pharmaceutical products, TFDA has revised the Chapter 4-1 of the *Pharmaceutical Affairs Act*, "*Patent Linkage of Drugs*", which was announced and implemented on August 20, 2019. The implementation of the patent linkage system represents a milestone in the country's intellectual property protection of medicines.

Achievements and Benefits

I. Stipulated relevant guidances on regenerative medicinal products

TFDA announced the amendment of the *"Guidance on Investigational Cell Therapy Products"* on May 1, 2020. The

announcement of the amendment of the *"Guidance on Investigational Gene Therapy Products"* has been announced on November 2. On June 30 and August 25 of the same year, the *"Guidance on management of traceability of cell and gene therapy products" (Draft)*, and the *"Guidance on donor informed consent of cell and gene therapy products" (Draft)* were announced respectively. Both guidances mentioned above continue to improve the regulatory environment for regenerative medicinal products.

II. Facilitation on New Drug Approvals

With the core objectives of quality, consistency, clarity, efficiency, and transparency in review of drugs, and with the expectation to reach early access of new drugs, TFDA reinforces the two-way communication between the regulators and industries, promoting regulatory harmonization, improving drug review and management system. Among the 121 new drugs approved in 2020, 41 are new drugs with new main ingredients and 35 are biological medicines. The number of new drugs applications, closed cases, and the review time in the past few years are as shown in Figure 3-1.

III. Implementation of the patent linkage system of drugs

The patent linkage system can achieve the legislative intent of the patent law to protect patentees, affirm the research and development efforts of new drug licensees, and provide generic drug companies with transparent patent information to learn of the drug patent status in advance and clarify related infringement concerns before going on the market. The launched generic drugs then will not be subject to the risk of suspension of sales at any time due to infringement issues, which can affect the rights and interests of patients. As of the end of 2020, there were 14 cases of drug patent linkage challenging design around.

Section 2

Reinforced the Drug Risk Control and Digital Management

Introduction of the Policy

Many countries have successively developed electronic submission specifications for drug registration and a cross-platform electronic drug information exchange model that is compatible and structured, with the advancement of international pharmaceutical regulations and electronic drug policy management. In order to strengthen the management of the drug supply chain, TFDA has established the trace and track system of drugs in accordance with Article 6-1 of the "*Pharmaceutical Affairs Act*" to deter the

entry of counterfeit drugs into the legitimate supply chain. At the same time, it continues to enhance and expand the functions of the online submission system for drug registration, accelerate operations and improve delivery quality, and actively strengthen active and passive drug monitoring practices for better risk management and control.

Implementation Strategy

I. Improved Taiwan's electronic submission system

In order to improve the efficiency of the country's drug inspection, drug administration, and drug review operations, 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 develop relevant electronic common technical document guidance and system function enhancements and the digital integration of the electronic review task, further improving the drug registration.

II. Improvement of the trace and track system of drugs

(I) TFDA continues selecting drugs to be included in "Trace and Track System for Medicinal Products." TFDA has included blood preparations, vaccines, and botulinum toxin preparations, high-concerned 50 items that are more likely to be counterfeited, pseudoephedrine, and ephedrine preparations. Additionally, Medicinal nitrous oxide was included on October 1, 2020.

(II) To assist pharmaceutical companies to declare the trace and track data, TFDA has not only established consultation hotlines and multiple ways of declaring, and also continued organizing training courses and educational publicity.

(III) In 2020, the statistical analysis and early warning functions of ephedrine/pseudoephedrine preparations were added to the system to enable the health authorities to inquire data immediately.

III. Reinforced the drug safety surveillance and analysis

TFDA continues to monitor and analyze drug safety through the post-market adverse drug reaction reporting system, domestic and foreign drugs safety information monitoring, and national drug safety related database. In addition, in order to strengthen the practicability and convenience of the adverse drug reaction reporting system, the ICH E2B (R3) adverse drug reaction notification system was formally implemented starting on September 2020.

Achievements and Benefits

I. Reinforced the digitalization management of Taiwan's drug administration

By integrating medical regulations and information management, TFDA has adopted a full online application approach for some application types starting July 2020. The Guidance on Taiwan Electronic Common

Technical Document (eCTD), and the Guidance on Taiwan Electronic Common Technical Document (eCTD) Validation Criteria were announced at the end of 2020. The construction of functions for submission of eCTD was completed, which established a link with the management of international medical regulations.

II. Improvement of the trace and track system of drugs

In 2020, TFDA organized 3 sessions of meeting for distributors and manufacturers, and set up education and training programme for health bureaus, with a total of 161 participants. The hotline and email consultation services reached has served a total of 1,809 people, and the proactive assistance has helped 151 distributors and manufacturers. In 2020, through applying the information on drug declarations, as well as togethering with on-site inspections, the central government and local health bureaus worked together to ensure the legal of drug supply and to avoid misuse.

III. Reinforced the drug safety surveillance and analysis

In 2020, there were 13,366 domestic adverse drug reaction reports, 111 domestic and foreign drugs safety alert, 48 drug safety assessments, and 23 drug risk communication forms and 4 drug safety quarterly newsletters were issued for raising the health care professionals' and the public awareness to ensure the safety of the public medication.

Section 3

Improved the Regulations for the Distribution of Medicinal Products

Introduction of the Policy

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

Many organizations and countries around the globe have begun to implement the GDP of pharmaceuticals. The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) had officially announced the Good Distribution Practice for Drugs in June 2014, and it has become the international implementation standard for drug GDP. Therefore, TFDA implements the distribution and quality management of drugs by promoting the GDP system that meets the international standards, to ensure the safety of drugs, improve the distribution quality of drugs and create international competitiveness.

Implementation Strategy

I. Revised 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 measures 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, the Ministry of Health and Welfare announced that manufacturers of western medicines and drug business operators who have obtained a drug license for western shall comply with the Good Distribution Practice for Western Medicines starting January 1, 2019.

(II) On May 10, 2019, it was announced that pharmaceutical companies of the western medicine preparations that require cold chain storage and transportation shall comply with the Good Distribution Practice for Western Medicines starting January 1, 2022.

(III) On July 27, 2010, it was announced that pharmaceutical companies that handle the distribution, import, and export of active pharmaceutical ingredients of western medicine shall comply with the Good Distribution Practice for Western Medicines starting January 1, 2023.

III. Implemented the GDP related supplementary measures

TFDA has progressively promoted the distribution and management system of western medicines since 2011 and provided consultation and educational training to the business operators in the industry, including continuing to conduct topic forums, technical seminars, and lessons for pharmaceutical firms. TFDA also invited GDP experts to provide on-site counseling, a total of 40 sessions; TFDA actively communicates with the industry to promote related management policies, and timeline and reached a consensus; we created a PIC/S GDP area on the official website of TFDA and announced the GDP regulations to be used as a reference for the business operators.

Achievements and Benefits

As of the end of 2020, a total of 760 western pharmaceutical manufacturers and pharmacy operators have fulfilled the GDP standard, which has attained 99% of the firms in the first stage, to ensure the quality of drug storage and transportation as well as the quality and safety of the public's drugs usage.

Section 4

Actively Participated in International Events of Medicine

Introduction of the Policy

TFDA continues promoting international cooperation in pharmaceutical products and actively participating in important international organization activities, such as the Asia- Pacific Economic Cooperation (APEC) and The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), Pharmaceutical Inspection Co-operation Scheme (PIC/S). TFDA is also working to strengthen bilateral and multilateral cooperation through interaction and experience sharing with various international regulatory institutions, further enhancing our international participation as well as the impact to the world.

Implementation Strategy

I. Expanded participation in ICH related meetings.

In recent years, TFDA has been committed to establishing international drug management regulations and promoting the harmonization of the country's drug regulations and ICH guidelines. After officially becoming a member of the ICH regulations in 2018, TFDA expanded its participation in the ICH conference and worked with expert working groups to formulate global drug technical guidelines to keep up with international standards and build a regulatory environment that has international competitiveness.

II. Continued to participate in APEC international conferences

TFDA actively participates in the work promoted by the APEC Regulatory Harmonization Steering Committee (RHSC), and acts as a leading economy in promoting "Good Registration Management (GRM)", and regularly reports the results of GRM promotion at APEC RHSC international conferences, which continues to make the country's voice heard on the global stage.

III. Conducted the 8th Joint Conference of Taiwan and Japan on Medical Products Regulation

The 8th Joint Conference of Taiwan and Japan on Medical Products Regulation was held on October 15, 2020. Due to the COVID-19 pandemic, teleconferencing was conducted for the first time with the conference attendees in Japan. In addition to the government officials from both Japan and Taiwan, there were about 480 practitioners from the medicine and medical equipment industries in Taiwan and Japan attending the conference.

In the meeting, representatives from Taiwan and Japan shared their experience on

the progress of drug regulations, the challenges faced by medicine and medical device management in response to the COVID-19 pandemic, and the application of the medical device quality management system (QMS) under the "Taiwan-Japan Medical Device Quality Management System Collaboration Memorandum." Furthermore, an official closed-door meeting was held on October 16 in the same year, to further discuss the cooperation of drug review and relevant experience sharing.

IV. Continued to participate in the PIC/S activities

(I) The Agency dispatched personnel to participate in PIC/S Webinar meeting of Expert Circle on Quality Risk Management held by Turkey/TMDA (Turkish Medicines and Medical Devices Agency) on September 24, 2020. A total of 205 people from 53 countries and 3 Associated Partner Organisations attended the meeting.

(II) The Agency dispatched personnel to participate in PIC/S Virtual seminar held by Finland/FIMEA (Finnish Medicines Agency) from December 8 to 10, 2020. The topic was on Distant Assessment of GMP Compliance. A total of 378 people from 48 countries attended the seminar.

Achievements and Benefits

I. Contributed to ICH-related meetings

TFDA attended the 2020 Vancouver Conference in Canada and the Athens Conference in Greece as a full member. So far, 42 experts have been selected to participate in 27 ICH expert working groups and participated in the formulation of ICH guidelines with other international experts. In 2020, 5 drug guidelines were completed and incorporated into the implementation stage to make an active contribution. At the same time, a working group consisted of experts from the industry, government and academia was formed in Taiwan to practically understand the needs of the industry and conduct guidance training on ICH, so that these guidelines can be implemented in Taiwan's pharmaceutical industry quicker and more effectively.

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

TFDA convened the APEC GRM Priority Work Area (PWA) steering committee meeting on July 28, 2020, to lead and discuss the core issues and plans for the future implementation of GRM, and to strengthen the relationship between the country various international pharmaceutical regulatory agencies. The APEC GRM key performance indicator questionnaire analysis refines the management capabilities of the country's drug administration. The results

were submitted to international journals to promote the results of the country's efforts.

III. Reinforced bilateral medical interaction between Taiwan and Japan

The conference promoted the mutual exchange and the understanding of regulations as well as information between the two parties. It hence strengthened trust and the collaboration between the government officials and industry practitioners from the two sides, and also helped the practitioners to plan their strategies in the international market which would further promote the development of domestic industry (Figure 3-2).

IV. Continued to strengthen GMP management through the PIC/S platform

By participating in PIC/S affairs and activities, TFDA could involve directly into the revision of PIC/S guideline documents and Aide-Memoires, and incorporating new knowledge of remote GMP assessment of pharmaceutical manufacturers into current regulation, also greatly improved the inspection skill of inspectors. Besides, remote GMP assessment in response to restrictions on overseas traveling caused by the pandemic would ensure the GMP compliance of oversea pharmaceutical manufacturers.

Figure3-2 8th Joint Conference of Taiwan and Japan on Medical Products Regulation

Section 5

Deepened the Medical Information Exchange of the New Southbound Policy

Introduction of the Policy

In conjunction with the "New Southbound Policy" issued by the President and the Executive Yuan and the New Southbound Medical and Public Health Collaboration and Industrial Chain Development flagship project from the Ministry of Health and Welfare, the concepts of mutual understanding, resources sharing, and creation of business opportunities and goals were realized in the medical and health field, which continue to expand and cultivate the pharmaceutical partnerships between Taiwan and other countries in the New Southbound Policy. The experience gained from our long-term commitment in establishing a management environment for international pharmaceutical regulations and the relevant industry advantages reinforced pharmaceutical collaboration with New Southbound countries, developed their trust with the products made by Taiwan, and improved our access to the international markets to jointly share the regional resources and promote regional development.

Implementation Strategy

Organized an online international conference to share COVID-19 pandemic control experience with partner countries in the New Southbound Policy.

The Agency held an online conference, "Sharing Experience on COVID-19 Pandemic Control" on June 16, 2020, and invited representatives from the countries in the New Southbound Policy, Thailand, Malaysia, the Philippines, the United States, the European Union, Japan, South Korea, Chile, and other pharmaceutical regulatory authorities to attend the meeting. The Agency shared the successful experience of the "Taiwan Model," which included "Accelerated review and project approval for pandemic control drugs, medical equipment, and inspection reagents," "Active inventory of drugs, strengthened notification and evaluation of shortage, and prevention stockpiling and uneven distribution" and "Increased production of pandemic control alcohol, lower tariffs and export controls," etc. Representatives of participating countries were invited to share their experience and measures in pandemic control.

Achievements and Benefits

Platform for sharing experience on pandemic control

Constructing supply chains of medicines and pandemic control materials is a major public health issue that the world faces during the COVID-19 pandemic period. By organizing the international conference

(Figure 3-3), we look forward to having more practical and in-depth exchanges with countries on this platform. The efforts will help us understand the implementation strategies and models adopted by various countries to stabilize the supply chain of medicines and pandemic control materials and establish partnerships with other countries to overcome the pandemic.

Section 6

Improvement of Drug Quality Inspection Technology

Introduction of the Policy

In response to various international incidents of antihypertensive drugs, gastric drugs, and hypoglycemic drugs suspected of containing *N*-nitrosodimethylamine (NDMA) and other nitrosamine impurities, TFDA notified license holders to proactively assess and inspect the risk of nitrosamine impurities that may be generated during the drug manufacturing process, and develop recommended test methods to be published on TFDA's website for reference. Laboratories may modify methods as needed, or establish their in-house methods after self-directed evaluation and verification to control product quality. TFDA also continued to carry out risk assessments of nitrosamine impurities. Based on international journals, 44 pharmaceutical ingredients that may generate or contain NDMA risk were initially screened, and the industry operators were notified to prioritize assessment and inspection.

Implementation Strategy

I. Established a platform for multi-residue analysis and detection of nitrosamines for high-risk drugs

The national laboratory built a multi-residue analysis platform with two technologies: Ultra-high performance

Figure3-3 Online conference sharing experience on COVID-19 pandemic control

liquid chromatography - tandem MS (LC-MS/MS) and gas chromatography - tandem mass spectrometry (GC-MS/MS). The multi-residue analysis platform built with these two technologies expands the scope of application to the detection of nitrosamine impurities in high-risk drugs. The sensitivity, accuracy and precision of the analysis of nitrosamine compounds are improved through sample pretreatment and chromatographic condition adjustment tests. In addition to NDMA, other potentially risky nitrosamine impurities were included in the analysis, and the scope of application was expanded on a rolling basis.

II. Applied research in drug stability investigation, and receive immediate feedback on test results

TFDA used the established and optimized multi-residue analysis and testing platform to conduct drug stability tests, and explores the trends of generation of nitrosamine impurities in the gastric drug Ranitidine and the hypoglycemic drug Metformin and their correlation with time and temperature. The results are immediately returned to the administrative management agencies and the industry operators to be used as a reference basis for impurity control measures.

Achievements and Benefits

Established a platform for multi-residue analysis and detection of nitrosamines for high-risk drugs, and completed the development of 44 screening and analysis methods for 11 kinds of nitrosamine impurities, including NDMA, and related academic results were published in the "17th Taiwan Mass Spectrometry Annual Academic Conference" and won an honorable mention. The recommended test methods for the application of LC-MS/MS and GC-MS/MS on multi-residue analysis for nitrosamine compounds were published on TFDA's website, and presented in the briefing session for relevant agencies to gain an in-depth understanding and use as a reference.

TFDA continued to build testing technologies and databases for nitrosamine impurities in pharmaceuticals to strengthen the testing capacity of national laboratories that may need to take response measures for major incidents, and also provided empirical data from the Chinese Pharmacopoeia to revise relevant general rules. TFDA apply analysis results for immediate feedback to administrative units and industries as a reference for impurity control measures.

Ch4

Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

CHAPTER

04

Improved Management of Controlled Drugs

Establish a controlled drug management system in accordance with the *"Controlled Drugs Act"*, and conduct evaluation and management of new narcotic drugs that need to be used in medicine and science; At the same time, strengthen the inspection of the prescription rationality of controlled drugs, and to prevent doctors from improperly prescribing and using controlled drugs that may contain patients' iatrogenic addiction or abuse.

Reinforced the Propaganda of NPS Prevention

TFDA had reinforced our approved institutions' capabilities in urine testing of illegal drugs, and collected drug abuse incidents reported through healthcare facilities and other statistics such as drug abuse urine sample tests, tests performed with non-urine specimens in suspected drug and controlled drug cases, drug seized, etc.; To propagate drug abuse prevention, TFDA integrated profession, fun, new media and local resources to plan diversified drug abuse advocacy strategies, as well as promoting in workplaces, communities, online community, and remote areas.

Disguised coffee bag


Disguised jelly


Disguised chocolate

Disguised plum powder


Disguised popping candy

Ch4 Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

TFDA has established a drug abuse monitoring mechanism, to effectively manage the controlled drugs and prevent drug abuse, as well as to understand the domestic trend and investigate the international information on the emerging substances of drug abuse, to be used as a reference for the illegal drugs management of Ministry of Justice. In addition, the Ministry of Justice places the emerging drugs with medical and scientific uses into the "*Controlled Drugs Act,*" to avoid drug leakage and endanger the health of the citizens in the nation. TFDA has also actively cooperated with the Executive Yuan to implement multiple anti-drug measures and strengthen anti-drug dissemination.

Section 1

Promoted Amendment to the Regulations on Controlled Drugs

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 go through the international interactions to link and follow international trends of the issue, 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 for the new narcotics that have necessary to use under medical and scientific consideration.

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

Achievements and Benefits

I. The "Controlled Drugs Review Commit-

tee of the Ministry of Health and Welfare" convened the 41st and 42nd meeting in 2020 and added a total of 8 items for new controlled drugs and active pharmaceutical ingredients. The Agency and the local health bureaus implemented the controlled drug audit project plan. A total of 230 companies were checked and 43 violations were found, with a violation rate of 18.7%.

II. In response to the COVID-19 pandemic, on-site education and training courses have been replaced by online courses, and with the four courses, "Summary of Controlled Drugs Management Regulations"; "Management Regulations and Precautions for Applications for the Use of Controlled Drugs in Medical Education Research Programs"; "Key Points of Controlled Drugs Audit and Introduction to Violations; and Sleep Disorders and Use of Sleeping Pill" have been made available online at the "e-Public Service Academy + Learning Platform."

Section 2

Improved the Pharmaceutical Quality of Schedule 1 and 2 Controlled Drugs

Introduction of the Policy

The newly constructed plant of The Pharmaceutical Plant of Controlled Drugs, TFDA (hereinafter referred to as the Pharmaceutical Plant) for controlled drugs was completed in July 2017 in order to improve product quality and expand production capacity. The Pharmaceutical Plant passed the PIC/S GMP compliance assessment at the end of 2018. After the resumption of production in 2019, a number of research and development projects were launched in 2020. The plan was to return the contract manufacturing and imported products to manufacturing in-house, and to start the construction of the plant to achieve the goals of manufacturing drugs domestically and having sufficient supply.

Implementation Strategy

Newly-constructed plants will add production lines for new dosage forms, and the goal is to establish production lines for oral liquids, capsules, and patches year by year. The plant is remodeled to expand the storage space and make the production space more complete. The developed products prioritize injections and oral liquids, followed by the capsule dosage form, and then the patch type with a higher technicality level.

Achievements and Benefits

The Pharmaceutical Plant has prioritized the mass production of 2 mL of fentanyl injection in-house and the trial production of Alfentanyl injection in 2019. The injection

production equipment is shown in Figure 4-1. The research and development of oxycodone hydrochloride immediate release capsules, morphine sulfate prolonged-release capsules and matrix-type patches and the planning of the production area of oral liquid preparations began in 2020. The future production dosage forms will have 5 types, injections, tablets, oral liquids, capsules, and patches, and 20 products made in-house in order to continuously improve the in-house manufacturing capability and production capacity.

In order to expand the storage area of products and raw materials, the whole plant project was started in June 2020. It is expected that after completion of the project, it will pass the PIC/S GMP and GDP compliance assessment, as shown in Figure 4-2 and the production capacity will be increased to sufficiently meet the needs of domestic medical institutions.

Section 3

Improved Warning and Monitoring Mechanism of Drug Abuse

Introduction of the Policy

New Psychoactive Substances (NPS) have a wide range of varieties and have developed rapidly. In order to effectively monitor the NPS, TFDA had reinforced our approved institutions' capabilities in urine testing of illegal drugs, and collected drug abuse incidents reported through healthcare facilities and other statistics such as drug

Figure4-1 Injection production equipment

Figure4-2 As-built drawings of the renovated plant

abuse urine sample tests, tests performed with non-urine specimens in suspected drug and controlled drug cases, drug seized, etc., and monthly compiled into the "Drug Abuse Case and Testing Statistics."

Implementation Strategy

I. Reporting mechanism for healthcare facilities on drug abuse

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

II. Management and reporting of approved institutions for drug abuse urine tests

As of the end of 2020, there were 18 approved institutions for drug abuse urine tests and designated testing institutions in the country. The approved testing institutions will regularly submit the inspection results to the Urine Test for Drug Abuse Reporting System (UDARS) on a monthly basis. TFDA conducted performance monitoring of approved institutions on a quarterly basis. In 2020, a total of 64 cases were handled.

III. Non-urine (Drug) testing and reporting upon 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 UDARS every month. TFDA will count positive results of non-urine samples of suspected drug and controlled drug cases on a monthly basis to provide reference for the development of drug control strategies by various departments.

IV. Taiwan Emergency Department Drug Abuse Surveillance

In 2020, TFDA commissioned the "Reinforced 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 across the country. The results of the expanded screening can be the reference to diagnosis and treatment for emergency physicians, as well as the reference for drug abuse situation in country's EDs.

Achievements and Benefits

I. Reporting situation of drug abuse at healthcare facilities

The analysis data of DARS showed that there were 25,452 cases in total reported for drug abuse by healthcare facilities in 2020. The top three types of drug abuse case number included heroin (14,816, 58.2%), (meth) amphetamine (10,290, 40.4%) and

benzodiazepine (598, 2.3%). Comparing with the data of drug abuse reporting in 2019, the percentage of (meth) amphetamine reporting decreased from 45.5% in 2019 to 40.4% in 2020. It showed that the government had achieved results in (meth) amphetamine control.

II. Reporting situation of approved institutions for drug abuse urine tests

As of the end of 2020, there have been 8 approved institutions and 1 health bureau that can conduct urine testing of illegal drugs such as benzodiazepines, cathinones, and phenethylamines. The authorized test items are all abused drugs that appear more frequently in Taiwan, including benzodiazepines (such as Nitrazepam, Nimetazepam, Flunitrazepam), cathinones (such as Mephedrone, MDPV, MEAPP, *N*-Ethylpentylone), and Phenethylamines (such as MMA, which has a recent increase in fatalities), a total of 22 illegal drugs. TFDA continues to encourage private inspection institutions to apply for accreditation in order to expand the capabilities in urine testing of illegal drugs, effectively easing the inspection load on government's laboratories, hence protecting the citizens' health.

In 2020, a total of 236,521 urine tests were conducted in Taiwan, of which 60,670 were tested positive and accounts for 25.7% of the total number of the test. The top three narcotics are methamphetamine, ketamine, and morphine. Comparing with the number of urine tests in 2019, the percentage of cases tested positive with methamphetamine increased by 15.3%, and ketamine and morphine decreased by 26.9% and 26.3%, respectively.

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

In 2020, there was a total of 317,497 cases with positive test results in non-urine specimens of suspicious drug and controlled drug cases in Taiwan, of which 22,973 were methamphetamine cases, 11,683 were ketamine cases, and 15,561 were heroin cases. Compared to the data in 2019, the numbers of cases with positive test results in non-urine tests of methamphetamine, ketamine, and heroin were all decreased, and the largest reduction was ketamine cases at 39.9%.

IV. Taiwan Emergency Department Drug Abuse Surveillance

In 2020, a network of 118 collaborating hospitals and expanded screening of urine samples of 150 NPS have been established. The project collected 2,952 samples eventually, and the positive cases were 834, accounting for 28.3% of the total number of samples, of which males were the majority. In terms of the age group distribution, 35-44 years old had the most people, followed by 25-34 years old, and then 18-24 years old. There were 33 NPS items detected, with the

synthetic cathinones having the most number of detections. Ketamine was the most detected drugs, followed by 4-methylmethylcathinone (Mephedrone), and then 3,4-Methylenedioxyphenylethylaminobutanone (Eutylone).

Section 4

Reinforced the Propaganda of NPS Prevention and Anti-drug Campaigns

Introduction of the Policy

To propagate drug abuse prevention, TFDA integrated profession, fun, new media, and local resources to plan diversified drug abuse advocacy 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 May 1 to December 31, 2020, the program toured Chiayi County, Chiayi City, Tainan City, and Kaohsiung City, Pingtung County, Penghu County, and other places, by and with anti-drug operation tour display boxes, X-shaped display rack teaching aid boxes, and large play 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 remote areas

In 2020, TFDA visited the indigenous tribes in eastern Taiwan to promote prevention of drug abuse and nurture talents. According to a model of the locals helping other locals, it strengthened the protection network against drug abuse at indigenous tribes in remote areas.

III. Online game for anti-drug promotion

In the light of young adults having high usage of online social media, TFDA consolidated resources of game, online social networks, and new media to launch a game called "Let's Reveal Narcotics in Disguise" (Figure 4-3) by showing players about the look of disguise drugs and the potential risks (Figure 4-4).

Achievements and Benefits

I. Fun in Preventing Drug Abuse

In 2020, TFDA implemented the "Fun in Preventing Drug Abuse" program to provide the public with wealth of knowledge about anti-drug and health through scientific and practical cases. 297 promotion tours were

run in 6 cities and counties, attracting 62,191 participants to join the promotion.

II. Prevention of drug abuse in remote areas

In order to improve the knowledge of preventing drug abuse and using sedatives and sleeping pills correctly, TFDA visited the tribes in 2020 to hold 6 sessions of drug abuse prevention and to train 126 trainees. Through 10 of the trainees then organized 20 promotion sessions at the indigenous tribes, it earned the support and affirmation from the tribal communities (Figure 4-5). In addition,

Figure4-3 "Let's Reveal Narcotics in Disguise" online game

Figure4-4 Game scenarios and warning messages

TFDA also held 50 public health education sessions on using sedatives and sleeping pills correctly in eastern Taiwan, benefiting 1,605 participants. The knowledge above was also transformed into education materials for dummies and animation to be used as reference.

III. Online game for anti-drug promotion

From September 9 to October 11, 2020, TFDA organized "Let's Reveal Narcotics in Disguise" lucky draw online game and recruited two popular internet celebrities among young people, Little Bear and Aaron, to post messages for propagating. The campaign attracted 15,125 participants, of which 68% were under 40. The posts reached a total of 184,053 people.

Section 5

Testing Results of Emerging Narcotics of Drug Abuse

Introduction of the Policy

The NPS abuse problems are emerging. Delinquents modified the structure of known illegal drugs to produce new chemicals in order to avoid seizing and inspection, which has caused an increasing trend of NPS discovered year after year. According to UNODC, there were at least 1,096 NPS found as of the end of 2020, and 175 have been detected in Taiwan. The problem cannot be neglected and will need to be resolved.

Figure4-5 The sessions of drug abuse prevention at tribes (Fata'an Tribe in Hualien)

Implementation Strategy

I. Promoted NPS prevention and exchanges of inspection technologies

TFDA actively strives for the approval from the Sub-Committee on Standards and Conformance (SCSC) of the Asia-Pacific Economic Cooperation Conference (APEC) to host the "2020 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances" (Figure 4-6) on September 16, 2020; we invited the representatives from Japan and Korea and domestic representatives of agencies, scholars, and experts to share their experience and the latest inspection technologies through teleconferencing to jointly prevent the prevalence of NPS.

II. Enhanced the testing capabilities

With the self-created handheld Raman spectrum analyzer spectrogram database, TFDA broke through the limitation of insufficiency of the original built-in database. As of the end of 2020, the database stored 1,758 items of new narcotics ingredients and drug spectrogram and we had created 434 of standard quality spectrograms and uploaded them to the TFDA Urine and Drug Abuse Report System (UDARS) for the narcotics inspection laboratory's review and download.

Figure4-6 The 2020 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances

Achievements and Benefits

I. Promoted NPS prevention and exchanges of inspection technologies

TFDA cooperated with local health agencies, customs administration, police, prosecutors, investigation agencies, and military police headquarters to share the current status of international NPS, inspection technology and future challenges through conducting international workshops, to understand the latest transnational crime patterns of narcotics and prevention measures, as well as to improve our nation's drug control strategy.

II. Enhanced the testing capabilities

The national laboratory actively improves the inspection and analysis capabilities and utilized the liquid chromatography-tandem mass spectrometry. In the testing of narcotics cases that TFDA assisted the prosecution, police, and investigation authorities over the years, we successively tested positive for the new abused drug ingredients of 25B-NBOMe and Desoxy-D2PM, as well as successively tested positive for the 2C-E, MPHP, and 6-methoxy Methylone ingredients for the first time in the country. In 2020, 4-Fluoro MDMB-BUTINACA and 5-Fluoro MDMB-PICA were detected in the light-yellow powder and green liquid samples sent by the Customs Administration and the police station for inspection, both of which are synthetic cannabinoids. The types of samples vary in form, from powder to liquid, and the combined abuse of multiple components has continued to occur, which requires close attention and monitoring in the future.

Ch5

Improved Management of Medical Devices and Cosmetics

CHAPTER

05

Improved Management of Medical Devices

- Implement the *"Medical Devices Act"*, and establish 22 supporting sub-regulations and issue advance notices of relevant drafts
- Improved management of smart medical devices, and *"Artificial Intelligent/Machine Learning-Based Software as a Medical Device (AI/ML-Based SaMD)"* was announced
- Became a formal Regulatory Science Training Center of Excellence (CoE) of APEC RHSC
- Established testing and verification methods for innovative intelligent medical devices, and the verification guidelines of the artificial intelligence medical imaging diagnostic software (draft) have been completed
- Improved the testing quality of precision medicine molecular testing laboratory, 3 of which have been reviewed and approved for registration

Optimize the Hygiene and Safety Management of Cosmetics

- Promote the notification of cosmetic products and the establishment of product information file (PIF) system
- Promote Good Manufacturing Practice (GMP) for cosmetics
- Amendment of the List of Colorants in Cosmetic Products was made and announced
- A total of 17 cosmetics inspection institutions have been certified, with 51 certification and inspection items
- Became formal member of the International Cooperation on Cosmetics Regulation (ICCR)

Ch5 Improved Management of Medical Devices and Cosmetics

The President promulgated the "*Medical Devices Act*" on January 15, 2020. Afterwards, to facilitate the enforcement of the new law, TFDA has established relevant sub-regulations, rules, and orders to ensure that the *"Medical Devices Act"* and all relevant laws are harmonized with international regulations. At the same time, TFDA has been very active to participate in various events organized by international organizations, including Asia-Pacific Economic Cooperation (APEC) and the International Medical Device Regulators Forum (IMDRF). TFDA also strived for opportunities to host international conferences and activities to enhance Taiwan's international visibility and influence. On July 1, 2019, the "*Cosmetic Hygiene and Safety Act"* was officially implemented to accelerate the registration of cosmetics, the establishment of product information files, and ensuring that manufacturers comply with Regulations Governing Good Manufacturing Practices. The purpose is to build a safer environment that produces high-quality cosmetics. Moreover, to improve the management of intelligent medical devices, TFDA announced the "Artificial Intelligent/Machine Learning-Based Software as a Medical Device (AI/ML-Based SaMD)," and amended the "*Reference Guidelines for Categorization and Classification of Medical Software.*" In 2020, multiple inspection methods have been added to inspect and test medical devices and cosmetics and to enhance Taiwan's inspection standards. TFDA also promotes the listing and registration of precision medicine molecular diagnostics laboratories and issues technical guidelines on molecular testing to accelerate the development of the precision medicine industry.

Section 1

Enhanced the Medical Devices Act and Relevant Regulations

Introduction of the Policy

After years of effort, the "*Medical Devices Act*" passed the third reading and was approved by the Legislative Yuan on December 13, 2019. The Act was promulgated on January 15, 2020, by the President. To promote the new law, TFDA has established relevant supporting sub-regulations, rules, and orders. In recent years, companies of electronic technology and information technology have engaged in the research and development of smart medical devices. To further promote the development of smart medical devices in Taiwan, TFDA has worked to establish for-

ward-looking management regulations and strengthened our provision of legal consultation and guidance, hoping to accelerate the launch of smart medical device products.

Implementation Strategy

I. Enforcement of the Medical Devices Act

The "*Medical Devices Act*" has a total of 85 articles. To facilitate the implementation of the new law, TFDA took into account international management standards and the current domestic situation to establish 22 supporting sub-regulations and issue advance notices of relevant drafts, including "*Regulations Governing Categorization and Classification of Medical Device, Regulations Governing Issuance of Medical Device License, Listing and Annual Declaration, Regulations of Medical Device Tracking Management,"* and *"Regulations for Management of Medical Devices Technicians*," to build a complete lifecycle management system for medical devices. Buffer time and supporting measures are also put in place to give firms a reasonable period of time to adopt and to minimize the impact to the industry.

II. Improved management of smart medical devices

TFDA made an announcement on December 24, 2020, regarding the amendment of "Guidance for Medical Software Classification." The revision states that medical software used for heart rate measurement, blood oxygen products (including wearable devices), and other products used by the public for daily health management will not be governed as medical devices. The revision should help accelerate domestic firms' research and development in manufacturing health promotion products. As more and more information and communication technology (ICT) companies have invested in the research and development of artificial intelligence medical devices, TFDA issued "FAQ of Smart Medical Devices" on May 14, 2020, to answer frequently asked questions regarding the application, inspection, registration, and market approval process of smart medical devices. In addition, "Artificial Intelligent/Machine Learning-Based Software as a Medical Device (AI/ML-Based SaMD)" was announced on September 11, 2020, to serve as a reference for manufacturers when they develop products. The guidelines also list information and documents firms need to prepare when they apply for inspection and registration of their products. So far, TFDA has provided consultation to 9 manufacturers of smart medical devices in Taiwan on the design of clinical trials and information for market approval. This once again demonstrates that TFDA pays close attention to the development of smart medical devices.

Achievements and Benefits

I. Built an independent and comprehensive medical devices management system

After the "*Medical Devices Act"* was passed, the management of medical devices is removed from the "*Pharmaceutical Affairs Act*." The new law enables the government

to establish a comprehensive management system that takes the properties of medical devices into consideration, such as the repair and maintenance of medical devices, restrictions of sales and supply types, electronic registration and listing systems for some low-risk products, issuance of license with flexible validity, medical device clinical trials, safety monitoring of medical devices and proactive reporting. As international regulations have been taken into consideration during the drafting process, the *Medical Devices Act* can reduce regulatory barriers domestics firms often face in the international market. The new law can also provide consumers with better protection when they use medical devices. At the same time, the Act also facilitates the development of the medical devices industry and enhances Taiwan's competitiveness in the international market.

II. Speeded up market approval of domestic smart medical devices

FAQ of Smart Medical Devices can serve as a reference for firms engaging in the research and development of smart medical devices. The *Technical Guidance for Premarket Application* can be used as a reference when firms are applying for market approval as it is used as the evaluation criteria for inspection and registration. By providing consultation and training, TFDA has issued 2 permits to firms whose smart medical devices with artificial intelligence will be launched soon.

Section 2

Expanded the International Exchanges and Collaboration on Medical Device Regulations

Introduction of the Policy

TFDA has been committed to promoting international cooperation on medical devices over the years and actively participating in international organizations to strive for hosting international conferences and activities, to enhance Taiwan's international participation and influence, as well as to create an internationalized regulatory environment for medical devices. In 2020, the implementation priorities include applying to the APEC RHSC to become a formal Regulatory Science Training Center of Excellence (CoE) for medical devices, participating in IMDRF regulatory affairs, promoting the fulfillment of the cooperation framework between Taiwan and Japan on medical products regulation, and strengthening the regulatory communication on medical products with the EU and ASEAN countries.

Implementation Strategy

I. Became an APEC RHSC Regulatory Science Training Center of Excellence for medical devices

In light of the "2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop" held in 2019 that

earned enthusiastic participation of attendees from many countries, TFDA applied to the RHSC to become a formal Regulatory Science Training Center of Excellence. The application was endorsed by the RHSC in a teleconference on June 15, 2020. The "2020 APEC Medical Devices Regulatory Science Center of Excellence Workshop" was held from August 29 through September 11, 2020 (Figure 5) in the forms 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, and relevant courses and activities.

II. Led the activities of the AHWP in vitro diagnostic medical device work group

The Asian Harmonization Working Party (AHWP) is currently one of the world's most important voluntary organizations for the harmonization of international medical device regulations. As the Chair of In Vitro Diagnostic Medical Device Work Group (WG2-Premarket: IVDD) of the AHWP Technical Committee (TC), TFDA has participated in important meetings of the AHWP and held regular work group discussion meetings.

III. Actively participated in the IMDRF Principles of In Vitro Diagnostic (IVD) Medical Devices Classification Working Group

The International Medical Device Regulators Forum (IMDRF) is a voluntary international organization consisted of global medical device regulatory agencies. As a representative of the Asian Harmonization Working Party (AHWP), TFDA became a member of the IMDRF Principles of IVD Medical Devices Classification Working Group to participate in discussion meetings of the guidance on principles of IVD classification held by the group on August 19 and 27, September 10 and 24, October 15, and December 3, 2020. The guidance has been approved by the IMDRF Management Committee, and was announced on February 18, 2021.

IV. Held international conferences on medical device regulations

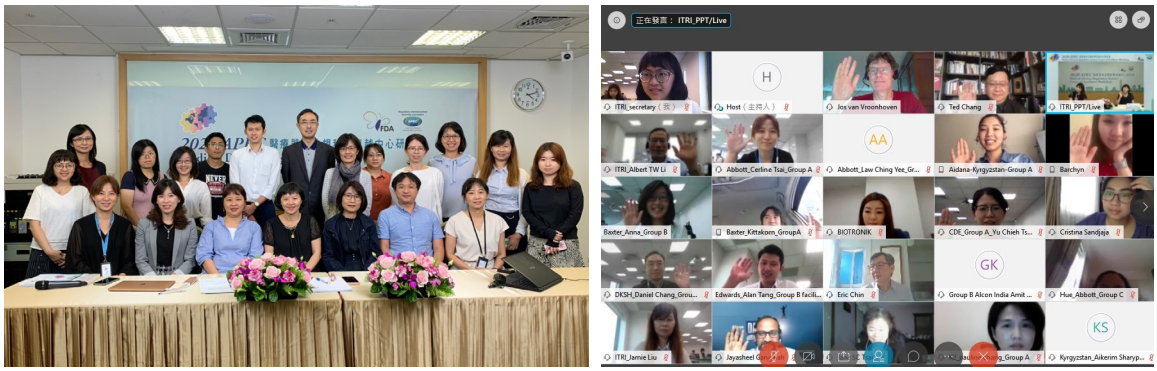


Figure5 2020 APEC Medical Devices Regulatory Science Center of Excellence Workshop

In order to fulfill the framework of the cooperation between Taiwan and Japan on medical products regulation, the 8th Joint Conference of Taiwan and Japan on Medical Products Regulation was held by video conferencing on October 15 and 16, 2020. Representatives of both sides shared experience on the reviewing of COVID-19 diagnostic test kits and principles of medical device cybersecurity regulation. In-depth discussions included topics such as the comparison results of medical device product items between Taiwan and Japan and subsequent collaboration direction of the medical device Product Registration Working Group. The Conference on International Medical Device Regulations was held online from October 31 to November 15, 2020. Industry and government representatives from the EU, Thailand, and Taiwan were invited to exchange information on the EU and ASEAN medical device regulations, artificial intelligence medical devices, risk management, and software validation.

Achievements and Benefits

For the APEC Medical Devices Regulatory Science Center of Excellence Workshop held in 2020, overall satisfaction rate of trainees was 4.5 points (out of 5 points). A total of 61 trainees from the government, industry, and academic sectors of 7 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 the regulatory capacity of Taiwan in medical device review while facilitating the establishment of cooperative agreement and mutual recognition. The AHWP TC WG2 led by Taiwan has produced a total of 12 international guidances related to in vitro diagnostic medical devices over the years, and the results are considered fruitful. Taiwan's efforts and contributions to the international harmonization of in vitro diagnostic medical device regulations have been recognized internationally. The hosting of or participation in AHWP related activities has intensified the harmonization of laws and regulations and regional collaboration, and increased exchanges between Taiwan and countries of the New Southbound Policy. In addition, TFDA actively participates in biannual meetings and working group meetings of IMDRF to help expand Taiwan's global visibility and participation level in important international organizations. And by conducting annual Joint Conference of Taiwan and Japan on Medical Products Regulation, TFDA continues to promote interaction and understanding of regulatory information between both sides, strengthen the collaboration between industry and government, align with international standards, assist the industry to deploy into international markets, and protect the public health and welfare. Years of case review and regulatory communication also enhance the mutual trust between both sides. It is hoped that the product registration process may be accelerated in the future to benefit medical device manufacturers of both sides.

Section 3

Optimized the Hygiene and Safety Management of Cosmetics

Introduction of the Policy

The "*Cosmetic Hygiene and Safety Act*" has been officially implemented on July 1, 2019. In order to build a high-quality cosmetics use environment and protect the rights and interests of consumers, it is still necessary to keep strengthening the management of manufacturing sites and the life cycle of products, and to revise the hygiene standards of cosmetics. 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

I. Promoted the Notification of Cosmetic Products and the establishment of product information file (PIF) system

In order to promote the Notification of Cosmetic Products, we have been continuing to optimize the functions of the Notification of Cosmetic Products platform system and hold seminars since 2020. At present, 3,195 companies have completed online registration voluntarily. TFDA plans to implement the registration of general cosmetics and specific purpose cosmetics in two stages, starting from July 1, 2021, so that the government and industry can better control the circulation of products. PIF is documents set to ensure the quality, safety, and functions of commercially available cosmetics. On March 11, 2020, the "Introductory Manual for Production of Cosmetics Product Information File", the "Cosmetics Product Information File Checklist" and the "Cosmetic Product Information File Guidelines" were announced to serve as reference documents for the industry to create product information files.

II. Promoted Good Manufacturing Practice (GMP) for cosmetics

The Good Manufacturing Practice (GMP) for cosmetics was implemented on July 1, 2019. Considering that this is a new management system, TFDA plans to implement it in phases based on the risk level from July 1, 2024. To assist the industry complying with the regulations, starting from 2020, TFDA held regulation seminars, training courses, and appointed experts to the manufacturing sites for inspection of the facilities and providing suggestion for improvement, so that the industry can meet the requirements before the implementation of each phase.

III. Reinforced the hygiene and safety management of cosmetics

In response to the trends of international cosmetic ingredients management along with the domestic market, an amendment of the

List of Colorants in Cosmetic Products was made and announced on September 29, 2020, regulating the colorants added in cosmetics and the scope of use in order to protect consumers' health and safety.

IV. Improve the quality and credibility of cosmetics inspection institutions

In accordance with the "*Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions*", the Agency is authorized to entrust the sampling inspections of cosmetics and cosmetics companies, and to conduct accreditation of the entrusted parties in order to improve business performance. At present, a total of 17 cosmetics inspection institutions have been accredited, with 51 accredited inspection items. The efforts strengthen the supervision and management of cosmetics inspection agencies, and ensure the quality and credibility of sampling inspections.

V. Became full member of the International Cooperation on Cosmetics Regulation (ICCR)

The International Cooperation on Cosmetics Regulation (ICCR) is a voluntary organization jointly formed by international cosmetics authorities and industry practitioners. TFDA was granted as observer by the ICCR Steering Committee in 2016, and has been participating in ICCR activities and discussing with other jurisdictions about cosmetics safety, regulations, and the consumer communication since then. TFDA became a formal member in the 14th ICCR annual online meeting conducted on December 7, 2020, demonstrating that our efforts have been affirmed.

Achievements and Benefits

The implementation of the "*Cosmetic Hygiene and Safety Act"* requires the industry to complete the Notification of Cosmetic Products and product information file before products entering the market, and the manufacturers must comply with the cosmetics Good Manufacturers Practices (GMP). These mandates are the replacements of current registration system of specific purpose cosmetics that speeds up the products' time to market. Access for customers to search for cosmetic product information online reinforces safety management of cosmetics and ensures the quality of cosmetics manufactured. As international cosmetics regulations update frequently, becoming formal ICCR member helps to grasp the latest international cosmetics managements and trends, which accelerates the harmonization of regulations and enhances Taiwan cosmetic industry's international competitiveness which is an important milestone in Taiwan's cosmetic regulation nationalization.

Section 4

Improved 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 analytical technology for quality management of various products, to expand the testing items in cosmetics, and to develop or optimize the analytical methods for management of domestic products. In addition, TFDA learn of the current status and trends of testing in the world, comprehensively improve the level of analytical techniques and strengthen research capabilities to be in line with the world's standard through international technical exchange and collaboration.

Implementation Strategy

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

In 2020, standardized test procedures were established to evaluate the minimum performance requirements of electric wheelchairs, and a safety test platform for electric wheelchairs was completed to ensure the safety of users. Methods for the quality verification of permanent denture laminates have been established to provide the industry as a reference for product verification. The verification guidelines of the medical imaging diagnostic technology method (draft) and the verification guidelines of the artificial intelligence medical imaging diagnostic software (draft) have been completed. Follow-up plans will improve the draft and then make it published as a reference for the industry for the development and establishment of medical imaging diagnostic software to ensure the accuracy of relevant diagnostic results and to help promote the development of the country's medical imaging industry to be in line with international standard.

II. Improved cosmetics analytical techniques

In 2020, 6 recommended test methods for cosmetics were published, and they were "*Method of Test for Iodopropynyl Butylcarbamate in Cosmetics,*" "*Method of Test for Polysilicone-15 in Cosmetics*," "*Method of Test for Polycyclic Aromatic Hydrocarbons in Cosmetics*," "*Method of Test for Heavy Metals in Cosmetics,*" "*Method of Test for Restricted Dyes in Cosmetics,*" and "*Method of Test for Camphor Benzalkonium Methosulfate and Benzylidene Camphor Sulfonic Acid in Cosmetics*". 2 recommended test methods including "*Method of Test for Hair Dyes in Cosmetics*" and "*Microbiological Methods for Cosmetics*" were revised. A total of 8 articles including 95 items were published or revised, demonstrating fruitful results.

III. Actively participated in international events for cosmetics

TFDA is an associated member of the European Network of Official Cosmetics Control Laboratories (OCCLs). We participated in the 5th and 6th joint session of the "European Committee for Cosmetics and Consumer Health (CD-P-COS) and OCCLs" via video conference in 2020 to continue strengthening the collaboration and exchange

with the OCCLs. As a member of the OCCLs, we shared our experiences on how we established our own cosmetics analytical methods which were listed on the OCCLs official website to be used as reference for all member states, and the analytical techniques were recognized around the world. Our active participation in the international organizations establishes communication channels and international networks, and enhances our international visibility and influence.

Achievements and Benefits

By continuously improving the testing and analysis capabilities in the laboratory, we introduced new analytical technologies to establish test methods and comprehensively improve the analytical techniques and standard to ensure the quality and safety of products. Active participation in international organizations and activities helps promote exchanges in analytical techniques and learn of new development, challenges, current status, and trends of testing around the world, helping the country's analytical techniques in line with the world's standard.

Section 5

Reinforced 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 relevant service in medical, TFDA conducted the listing management 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 plans to conduct documental review and on-site inspections through an inspection team, to verify whether or not the laboratory complies with relevant standards of quality management through the review committee and inspection team, and then it can be registered for management. In addition, the registered laboratories must undergo proficiency tests and aperiodic inspections and they have to conduct extension of registration every 3 years, so that the laboratories can be continuously monitored for the quality of testing.

TFDA established technical guidelines for molecular diagnostics techniques and diagnostics scope frequently used in the domestic precision medicine molecular diagnostics laboratories, so they can be used as a reference by the laboratories.

Achievements and Benefits

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

The Agency established the relevant operating regulations for the registration of precision medicine molecular testing laboratories and began to perform related tasks in 2019. In order to improve management performance, 1 session of inspector training and 2 sessions of review committee meetings were held in 2020 to discuss and collect opinions, revise application guideline, and other rules to make the registration review and management practices more complete.

II. Improved the follow-up management practices for registration

Pilot run of proficiency testing of precision medicine molecular testing laboratory started in 2020. 5 sessions of expert meetings were held to discuss the pilot planning and analysis of testing results, and relevant information was collected. At the same time, information system was established to manage registration change, extension, and proficiency testing through e-management to improve follow-up management.

III. Conducted counseling and introduction workshop

As of the end of 2020, TFDA has conducted counseling for 6 laboratories as well as 1 laboratory introduction session and 2 training sessions for industry practitioners, so that the laboratories can have a better understanding of the relevant regulations for registration.

IV. Registration operations

So far, a total of 10 laboratories have applied for registration, and 3 of them have been reviewed and approved. The Agency will continue to handle the registration operations to improve the testing quality of precision medicine molecular testing laboratories.

V. Established the "Technical Guidelines for the Application of Next-generation Sequencing to the Detection of Inherited Diseases"

TFDA promoted the technical guideline at the 2020 Bio Asia-Taiwan and published it on the TFDA's official website. Briefing sessions for industry practitioners were held to facilitate the technical exchanges between government agencies and domestic molecular diagnostics laboratories. A total of 56 biotech companies and experts from clinical institutions actively participated in the event to help improve the testing quality of domestic laboratories to meet the international standard.

Ch6

Special planning

CHAPTER

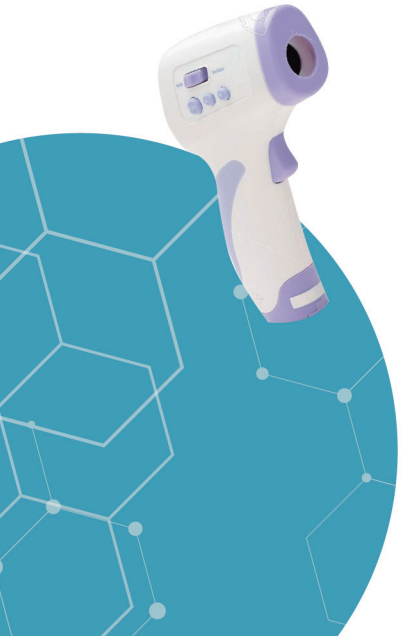
06

Optimize the Hygiene and Safety Management of Cosmetics

- Reinforce drug management during the pandemic control period
- Implementation of relief subsidy measures for pharmaceutical companies
- Accelerated the review process of COVID-19 drugs and assisted the research and development of vaccines

Management of Medical Devices Related to Pandemic Control

- Compiled license information for pandemic control medical devices, ensuring the supply
- Start green regulation channel to accelerate the approval and market launch of pandemic control medical devices
- Strengthen the quality and safety management of medical masks
- Establish a sound environment for the development of the pandemic control medical device industry



Name-Based Mask Distribution System 1.0

- Rolling adjustment of the distributed quantity to improve the convenience of people's purchase
- A total of 84,412 cases of the Name-Based Mask Distribution System 1.0 have been handled by the 1919 food safety consultation hotline
- A total amount of NT$178,540,000 was distributed to reward pharmacies for cooperating with the government in handling the Name-Based Mask Distribution System
- The Masks Distribution and Sale Big Data Analysis System for closing entries, with a total amount of NT$5,170,923,214
- Established the notification and handling of defective mask
- Produced a total of 386 epidemic control messages, of which 164 promoted the Name-Based Mask Distribution System

Ch6 Special planning

2020 was the year for the nation to unite as one to fight against severe acute respiratory infection (hereinafter referred to as COVID-19) pandemic. Under the leadership of the "Severe Acute Respiratory Infection Central Epidemic Command Center" (hereinafter referred to as the Command Center), various agencies collaborated together to organize various pandemic control materials and supplies in advance. The Agency was responsible for managing medical products, successfully providing supplies to the efforts of pandemic control.

In order to illustrate the results of the Agency's efforts in pandemic control, this chapter fully presents the preparation of pandemic control drugs, vaccines, and medical devices, as well as the distribution plan of real-name registration system 1.0 for masks, including coordinating supply and demand, accelerating review and proactive counseling, and facilitating promotion. The joint efforts of the public and private sectors, laid the foundation for pandemic control.

Section 1

Drug Management and Pandemic Control Actions

Introduction of the Policy

In response to the outbreak of the COVID-19 pandemic, TFDA has prepared a number of contingency measures, such as proactive inventory of drugs, formulation of relevant management principles, priority review of API related applications, and accelerated review of pandemic control drugs, in order to prevent the disorder of domestic drug supply and protect the rights and interests of citizens using drugs and receiving treatment. There are relevant counseling measures to continuously track the status of research and development of drugs and vaccines at home and abroad, and help accelerate the R&D and market launch of therapeutic drugs and vaccines.

Implementation Strategy

I. Reinforced drug management during the pandemic control period

(I) Since February 2020, TFDA has prioritized accelerating the review of changes in the source of active pharmaceutical ingredients, importing of raw materials for self-use, etc., and at the same time, we also encouraged the industry to look for alternative sources of active pharmaceutical ingredients in

advance. In terms of alcohol supply, in addition to accelerating the reviewing process to assist medicinal alcohol manufacturers for changing raw material supply, TFDA coordinated with two major state-owned enterprises to produce pandemic control alcohol to ensure the sufficient supply of alcohol.

(II) In order to prevent drug stockpiling and uneven supply caused by the pandemic, TFDA issued the "Management Principles for Drug Supply During the COVID-19 Pandemic" on March 17, 2020, requiring that pharmaceutical companies to distribute drugs to medical care institutions and pharmacies, and medical care institutions or pharmacies to purchase drugs, which is based on the monthly sale in the past year. If the quantity exceeds the average monthly sale in the past year by more than 10%, reasons and supporting documents must be submitted to TFDA for approval.

(III) TFDA announced and implemented the "*Guidelines for the Management of Uneven Distribution of Medicines During the COVID-19 Pandemic*" on April 13, 2020, to effectively handle issues such as excessive order of medical care institutions and an increase of drug inventory caused by the decrease in outpatient visits. Also, a dedicated reporting mailbox (tfdawatch@fda.gov.tw) was established for reporting drug stockpiling, uneven distribution, etc. to facilitate the follow-up investigations.

II. Formulated relief measures for drug sellers with operational difficulties

Since the pandemic affects the drug supply chain, it also increases the cost of APIs and preparations, which also decreases the willingness or capability of drug manufacturers to manufacture or import drugs. Under this circumstance, TFDA has proposed relief subsidies for drug companies in the Compensation and Relief Measures for Medical Institutions, Enterprises, and Industries due to the Impact of Severe Pneumonia with Novel Pathogens, which was announced and implemented on March 12, 2020. Pharmaceutical companies that meet the requirements for operational difficulties can receive subsidies for manufacturing or importing expense of drugs to relieve the pressure of competition of raw materials and supplies. Apart from that, it also stabilizes the drug supply chain and maintains the operation of the medical care system. At the same time, relevant information is also integrated into the webpage of the Ministry of Health and Welfare and which is accessible for industry practitioners.

III. Accelerated the review process of COVID-19 drugs and assisted the research and development of vaccines

(I) In order to speed up the launching of domestic vaccine and maintain the quality and safety of the vaccine, TFDA and the Center for Drug Evaluation (CDE) became a project consulting and counseling team, which held weekly discussion meetings with manufacturers. The rolling review

practice not only shorten the timeline, but also provides the most immediate legal, technical consultation and guidance. On April 13, 2020, the CDE announced the "CDE can Help: COVID-19 Regulatory science counseling program", providing free consultation and counseling for the cases of COVID-19 drugs that have been selected.

(II) TFDA established the "Registration Platform for Intention to Participate in COVID-19 Vaccine Clinical Trials" on November 11, 2020, for those people who are willing to participate in COVID-19 vaccine clinical trials to register online, assisting accelerate the clinical trials in domestic vaccine.

Achievements and Benefits

I. Reinforced drug management during the pandemic control period

In 2020, there were a total of 436 applications for the new APIs source of medicinal products, and nearly 2,700 applications of importing raw materials for domestic pharmaceutical use. TFDA accelerated the review of the sources of new APIs and shortened the announcement period by half to prevent shortages. By strengthening the supply mechanism of drug, the stable supply of drugs was ensured during the pandemic. TFDA also coordinated with the distribution of alcohol supply to ensure that medical institutions had sufficient usage, so as improve the convenient access to the public.

II. Implementation of relief subsidy measures for pharmaceutical companies

Since the implementation of relief subsidy measures for pharmaceutical companies on March 12, 2020, a total of 11 applications from 8 western medicine sellers have applied as of the end of 2020. 6 items of 4 applications for relief subsidies have been approved, with a total of NT$1,039,375.

III. Accelerated the review process of COVID-19 drugs and assisted the research and development of vaccines

(I) As of the end of 2020, 21 applications have been included in project consultation and counseling, which includes 11 for vaccines, 7 for medicines, and 3 for cell products. Three domestic COVID-19 vaccines entered phase 1 clinical trials, one of which entered phase 2 of clinical trials at the end of the same year. A special approval has been granted to the import license of a COVID-19 drug, Remdesivir. TFDA will continue to provide consultation with the COVID-19 drugs and vaccines under the development to help them launch in the market as quickly as possible.

(II) From November 11 to November 30, 2020, the total number of registrations to the "Registration Platform for Intention to Participate in COVID-19 Vaccine Clinical Trials" reached 21,190. The medical institutions which conducts clinical trials can apply for access to the data on the platform to contact potential participants in clinical trials of the domestic vaccines.

Section 2

Management of Medical Devices Related to Pandemic Control

Introduction of the Policy

At the start of the COVID-19 pandemic, countries fought for medical supplies, which resulted in an imbalance between supply and demand. Therefore, as the pandemic continues, it is vital for TFDA to have a clear picture of available medical devices in Taiwan; hence, we need to have information related to the supply and demand of such medical devices, which includes reporting, control and distribution of medical devices. At the same time, it is also important for us to speed up the market approval of medical devices related to the control of outbreaks, so as to ensure the quality, safety, and supply of medical devices required for the control of outbreaks.

Implementation Strategy

I. Took stock of permit license information of medical devices required for the control of outbreaks

In the early phase of the pandemic, TFDA quickly compiled the list of medical devices required licenses, for the control of outbreaks as well as information of their permit licenses. These medical devices include medical masks (N95, general medical and surgical mask), isolation gowns, full-body protective suits, forehead/ear thermometers, test kits, etc., for Taiwan Centers for Disease Control and the Ministry of Economic Affairs. TFDA also surveyed the manufacturing and import status of manufacturers, established points of contact with manufacturers, and held meetings to discuss alternative solutions.

II. Fast lane entry service to accelerate the market approval of medical devices required for prevention of outbreaks

In accordance with Subparagraph 2, Paragraph 1 of Article 48-2 of the "*Pharmaceutical Affairs Act*," the fast lane entry service will be made available to accelerate the application for manufacturing and importing as special cases. TFDA has actively provided firms with consultation services before they submit applications to manufacture medical devices that could help to control the outbreaks as special cases or apply for permits. A special hotline and a taskforce have been established to provide consultation regarding regulations. TFDA has also simplified the procedures by (1) simplifying the documents required for application for manufacturing as special cases; (2) simplifying the quality management system information submitted by the manufacturers; (3) announcing references used to review and test medical devices manufactured as special cases; (4) priority review conducted by assigned specialists. All these measures are taken to speed up the market approval of medical devices needed to control the outbreaks of COVID-19. In addition, to respond to the increasing demand for emergency COVID-19 testing, TFDA prepared SARS-CoV-2 standard and respiratory related virus panel for the qual-

ity control of molecular diagnostic reagents developed by the biotechnology industry, further promoting the domestic industry's efforts in pandemic control.

III. Strengthened quality management and safety management of medical masks

TFDA announced the amendments to the "*Regulations for the Inspection and Examination of Imported Medicaments*." Starting from July 7, 2020, medical masks will be included as one of the items to go through border inspection. At the same time, firms importing both non-medical masks and medical masks, or importing a large volume of non-medical masks will need to pass on-site inspections. Besides, TFDA also announced "*Particulars that Shall Be Indicated on the Labels of Flat Medical Masks*" requiring firms to ensure that flat medical masks should have "MD" and "Made in Taiwan" stamped on the masks starting from September 24, 2020.

IV. Established a sound environment for the development of the medical devices industry for control of outbreaks

To ensure that the capacity for research and development and manufacturing of medical devices for epidemic prevention accumulated during the COVID-19 pandemic can be maintained, TFDA provides special consultation for manufacturers who have obtained permission to manufacture medical devices as a special case to assist such firms to obtain licenses to manufacture medical devices. TFDA will continue to facilitate research and development in research institutions, academic units, as well as public and private sectors to promote the development of the industry.

Achievements and Benefits

I. Ensured the supply of medical devices for epidemic control

(I) As TFDA has sped up the issuance of market approval permits for medical devices needed for epidemic control, our statistics showed that from February 1 to December 31, 2020, 174 permits have been issued for medical masks, 36 permits for isolation gowns, 16 permits for forehead thermometers and 5 permits for respirators, so as to quickly meet the domestic demand for medical supplies to fight the pandemic.

(II) Meetings to discuss alternative solutions and other response measures to get a clear picture of the supply and demand of medical devices required for epidemic control which includes reporting, control and distribution of medical devices to ensure that the sufficient supply of medical devices in Taiwan.

II. Enhanced the R&D and manufacturing capacity of domestic medical devices

(I) With fast lane entry service initiated, from February 1 to December 31, 2020, TFDA has approved 76 applications for manufacturing of medical devices as special cases, including 25 applications for testing reagents, 1 application for

nasopharyngeal swab sampling robots, 1 application for respirators, 3 applications for forehead thermometers, 20 applications for isolation gowns, 17 applications for protective gowns, 7 applications for medical masks and 1 application for small electrocardiogram system. The approval encourages domestic firms to continue to conduct research and develop medical devices. We have also approved 111 applications for importing medical devices import as special cases for control of the outbreaks in Taiwan.

(II) TFDA prepared SARS-CoV-2 standard and respiratory related virus panel, and acquired the SNQ certification for medical peripheral products in 2020, demonstrating the inspection capabilities of Taiwan's national laboratories and the visibility and credibility of the preparation of biological standard products.

III. Strengthened the quality management and safety management of medical masks

To strengthen the quality management and safety management of medical masks, TFDA has announced the amendments of relevant regulations. Firms importing both non-medical masks and medical masks, or importing a large volume of non-medical masks will need to pass on-site inspections. These measures are taken to ensure the safety and effectiveness of imported medical masks from the source. Moreover, domestically manufactured flat medical masks are required to have “MD” and “Made in Taiwan” stamped on the masks to help the public identify authentic medical masks and prevent counterfeiting. For this measure, TFDA has conducted briefings, issued press releases, information for dummies and Q&A to accelerate the implementation of the policy.

IV. Established a sound environment for the development of the medical devices industry for control of outbreaks

TFDA worked closely with companies and research institutions who are interested to engage in R&D and production of medical devices in Taiwan to invest in the R&D and production of medical devices for control of outbreaks, turning the challenge posed by the pandemic into an opportunity for Taiwan to accumulate experience, transform and grow. The ultimate goals are for Taiwan’s industry to acquire the ability to develop and prepare key raw materials; to establish a sound environment for the development of medical devices for epidemic control; and to strengthen the production capacity of Taiwan's biotechnology industry.

Section 3

Name-Based Mask Distribution System 1.0 and Related Measures

Introduction of the Policy

In the early phase of the COVID-19 epidemic, the government immediately implemented a Name-Based Mask

Distribution System 1.0 due to the incidents of rush buying and stockpiling masks. Additionally, due to the increasing demand for medicinal alcohol, the government also assisted the pharmacies with the distribution of medicinal alcohol. These measures ensured the fairness and accessibility of masks and alcohol purchases and enhanced the all citizens' epidemic prevention.

Implementation Strategy

I. Coordinated Name-Based Mask Distribution System and provide consulting services across various agencies.

In addition to regularly participating in cross-functional coordination meetings held by the CECC, TFDA actively held emergency meetings, inviting the associations of pharmacists and assistant pharmacists, the Chunghwa Post Co., Ltd., the Industrial Development Bureau of the Ministry of Economic Affairs, the National Health Insurance Administration of the Ministry of Health and Welfare (hereinafter referred to as the NHI Administration), and the Health Promotion Administration to discuss the response measures (Figure 6-1, 2) regarding the implementation of mask distribution and the encountered difficulties. TFDA then notified the NHI-contracted pharmacies (referred to as pharmacies) of the distribution and the Name-Based Mask Distribution System 1.0 and relevant tasks.

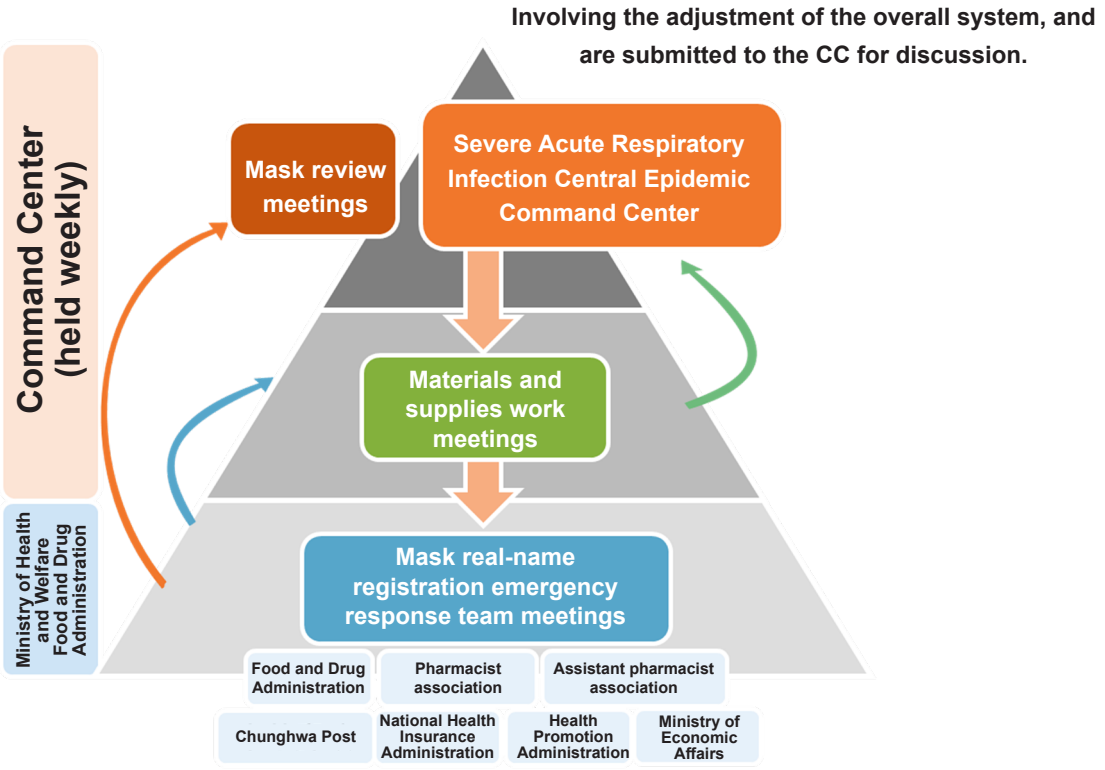


Figure6-1 Name-Based Mask Distribution System 1.0 and related measures

Figure6-2 The Name-Based Mask Distribution System 1.0 emergency response team meetings

TFDA's dedicated line (1919) for food safety consultation also started to support the epidemic control dedicated line (1922) under the instructions of the Executive Yuan to immediately respond to the issues raised by the public and distribution channels related to masks.

II. National mobilization and for the distribution of epidemic control materials and supplies

Under the Executive Yuan's leadership, about 6,000 pharmacies and 340 local health bureaus (including health service centers) participated in the Name-Based Mask Distribution System 1.0.

TFDA provided the distributed locations and quantities for the Name-Based Mask Distribution System 1.0 every day, and Chunghwa Post Co., Ltd. delivered the masks to all sales locations. Citizens purchased the masks with their national health insurance cards, and foreigners used their residence certificate or entry/exit permits to purchase through the NHI card system. TFDA controlled the number of distribution locations and collected the payments of masks through the Masks Distribution and Sale Big Data Analysis System interfacing with the through the Disease Prevention Mask Control System of the NHI.

Packaging envelopes for the Name-Based Mask Distribution System 1.0 were manufactured and provided to all sales locations so they can sell them to the public, and the subsidies on sales and packaging were given to the pharmacies to cover the manpower and working time needed.

In addition to handling the distribution of masks, TFDA helped the Associations of pharmacists and assistant pharmacists obtain 75% Ethyl Alcohol from by Taiwan Tobacco and Liquor Corporation, to the distribution to the pharmacies started from February 19, 2020.

III. Rolling adjustment of mask distribution and registration of quality issues

The distributed locations and quantities were adjusted in accordance with the CECC

and the daily sales and inventory of all sales locations. Considering the fairness of mask purchases, the initial implementation limited the purchase to 2 pieces in 7 days per person. Later on, due to the increase in mask production capacity, the allowance was raised to 9 pieces for adult masks or 10 pieces for children masks every 14 days starting April 9, 2020. A new packaging of 10 masks went into effect from December 31, 2020, and the adjustment measures are shown in Table 6-1.

Considering the quality of masks, TFDA compiled the defective notifications provided from all sales locations starting April, 2020. In order to prevent the mixing of non-medical masks with medical masks, TFDA required that starting September 24, 2020, double stamp of Medical Devices (MD) and Made in Taiwan must be marked on the masks.

IV. Multi-channel promotion

In response to the situations during the epidemic and adjustments of masks distribution, TFDA actively promoted epidemic control communication, including posters used at each sale points participated in the Name-Based Mask Distribution System 1.0, and policy descriptions and pandemic control-related materials used at various channels.

Table6-1 Name-Based Mask Distribution System 1.0 schedule

Date	Measures
February 6	Started implementing the Name-Based Mask Distribution System. Each person was allowed to buy 2 pieces of masks every 7 days, and each mask was charged NT$5. The traffic of buyers was split up based on the even/odd number of the last digit of the personal identification cards. A total of 6,280 NHI-certified pharmacies and 58 local health bureaus participated in the program.
February 16	The number of local health bureaus (including health service centers) that offered the Name-Based Mask Distribution System increased to 340.
February 27	Lifted the restrictions on the even/odd number of last digit of personal ID for children's masks.
March 5	The Name-Based Mask Distribution System for adults increased to 3 pieces for every 7 days, and 5 pieces for every 7 days for children.
April 9	The purchase cycle and quantity were adjusted to either 9 pieces for adults or 10 pieces for children over 14 days, and there were no age restrictions. The restrictions on the even/odd number of the last digit of personal IDs were also lifted.
April 19	Distribution of masks on Sunday was stopped. Pharmacies and local health bureaus could have the day off or voluntarily sell the masks in their inventory.
April 23	Restored the restrictions on the age limit for the purchase of children's masks. Available for purchase only with an NHI card whose cardholder is less than or equal to 16 years old.
June 1	1.Masks were available for all types of purchases. In addition to being available through the Name-Based Mask Distribution program, masks were available through other channels. 2.Local health bureaus would no longer be selling masks on Saturdays from that day.
September 24	Double stamp marks of MD and Made in Taiwan must be applied on the masks.
December 31	The number of pieces and the price of masks through the Name-Based Mask Distribution were changed to 10 pieces/pack for NT$40, available every 14 days.

Achievements and Benefits

I. Achievements of the Name-Based Mask Distribution System 1.0

(I) Rolling adjustment of the distributed quantity to improve the convenience of people's purchase

On the day before the Name-Based Mask Distribution System 1.0 was implemented, the distribution of 6,336 sales locations was completed. Each location was given 200 pieces of masks for adult and 50 pieces for children. The number of distributed pieces was gradually increased, as shown in Table 6-2.

As of December 31, 2020, a total of 1,115,210,000 pieces of adult masks and 187,400,000 pieces of children's masks were delivered, totaling approximately 1,302,610,000 pieces; 1,099,050,000 adult masks and 174,130,000 children's masks were sold, totaling approximately 1,273,180,000 pieces, representing a sales rate of 98%.

(II) Consultation services

As of the end of December 2020, a total of 84,412 cases of the Name-Based Mask Distribution System 1.0 have been handled by the 1919 food safety consultation hotline; a total of 21,630 mask-related cases were handled through the mailboxes of various director-generals and ministers, and other agencies.

(III) Rewards, subsidies and appreciation to professionals handling the epidemic control and pharmaceutical matters

In order to reward pharmacies for cooperating with the government in handling the Name-Based Mask Distribution System (Figure 6-3), those who cooperated and sold Name-Based masks for a total of 20 days (and more)

Table6-2 Mask distribution adjustment table for the Name-Based Mask Distribution System 1.0

Date	Adult masks		Children' masks		Total number of pieces (piece/day)
	Pieces (piece/day)	Person-time serviced (piece/person)	Pieces (piece/day)	Person-time serviced (piece/person)	
February 6 to February 19, 2020	200	100 (2 pieces/person)	50	25 (2 pieces/person)	250
February 20 to March 4, 2020	400	200 (2 pieces/person)	200	50 (4 pieces/person)	600
March 5 to April 8, 2020	600	200 (3 pieces/person)	200	40 (5 pieces/person)	800
April 9 to December 30, 2020	1,800	200 (9 pieces/person)	200	20 (10 pieces/person)	2,000
From December 31, 2020	2,000	200 (10 pieces/person)	200	20 (10 pieces/person)	2,200

Figure6-3 Premier Su, Minister Chen and TFDA Director-General Wu visited a pharmacy to inspect the preparation works of Name-Based Mask Distribution System

between February 6 and June 30, 2020, were given subsidy, and a total amount of NT$178,540,000 were distributed. The Executive Yuan also planned to issue epidemic control medals, and TFDA produced individual epidemic control medals for pharmacists and assistant pharmacists as appreciation for the promotion of sales of masks through the Name-Based Mask Distribution System. Certificates of appreciation were also produced and presented to the pharmaceutical professionals who offered their assistance.

II. The Masks Distribution and Sale Big Data Analysis System for closing entries

TFDA used the Masks Distribution and Sale Big Data Analysis System for the closing entries of all sales locations. The System deducted subsidies from the total amount of mask sales (Table 6-3), performing operations such as accounts receivable and payable, verification, billing, and collection. As of December 31, 2020, the accounts receivables from the pharmacies were accumulated 56,633 times, with a total amount of NT$5,170,923,214; 56,632 entries of accounts receivable from the pharmacies were received, with a total of NT$5,170,199,140, representing a collection completion rate of 99.9%, and the collection is ongoing.

From February 19 to May 10, 2020, a total of 3,850,416 bottles of 75% Ethyl Alcohol were delivered to 5,843 pharmacies for sales. Payments for the 75% Ethyl

Table6-3 Subsidy measures for Name-Based Mask Distribution System 1.0

Date	Description	Remark
February 6 to April 8, 2020	NT$800 per day.	Pharmacies packing
April 9 to December 30, 2020	NT$5.5 per person-time.	Pharmacies packing
From December 31, 2020	The original packaging subsidy was changed to the mask service charge for pharmacies, at NT$5 per person-time.	Factories packing

Alcohol were all collected, for a collection rate of 100%.

III. Notification and handling of defective mask

TFDA compiled the number of defective masks and associated manufacturers every week, providing the information to the Industrial Development Bureau of the Ministry of Economic Affairs to guide manufacturers to improve the qualities of masks. For manufacturers notified more than 900 pieces of defective masks, TFDA provided the information of sale location to the Taiwan Textile Research Institute, coordinating the return and exchange of defective masks. As of the end of December 2020, a total of approximately 1,070 reported cases were received, and there were 81 cases of return or exchange. Manufacturers are encouraged to maintain the quality of masks through user feedback and counseling practices.

IV. Actively promoted epidemic control communication

TFDA promoted epidemic control policies on the TFDA Facebook fan page, TFDA LINE@, weekly report on drug and food safety, the Internet, and news tickers of news channels, and in 2020 produced a total of 386 epidemic control messages, of which 164 promoted the Name-Based Mask Distribution System. Also, TFDA made 4 promotional videos on “How to Buy Masks” with the Department of Information Services of the Executive Yuan to be broadcasted on the requisitioned TV channels.

Ch7

Appendix

Appendix 1 Important Events

January	**January 20 to January 23**	Participated in the Pharmaceuticals and Medical Devices Agency (PMDA) - Asia Training Center (ATC) Multi-Regional Clinical Trial Seminar "PMDA-ATC MRCT Seminar 2020" in Tokyo, Japan, to learn about how countries encourage the multi-regional clinical trials to shorten the time taken for drug approval in different regulatory agencies, and learn the specifications and review standards of various countries to promote the link between Taiwan's MRCT and the world.
February	**February 3 to February 6**	Participated in "The 5th IABS Cell Therapy Conference" organized by the International Alliance for Biological Standardization (IABS) in Tokyo, Japan. The topic of the conference was "Toward international convergence of basic technical requirements and evaluation of human cell therapy products," which was to understand the trends of R&D technology and review management of various countries and international organizations toward cell therapy products.
April	**April 8**	Director-General Shou-Mei Wu accompanied President Ing-Wen Tsai, Vice Premier Chi-Mai Chen, Mayor Wen-Tsan Cheng of Taoyuan City and Deputy Minister Chi-Kung Ho of the Ministry of Health and Welfare to visit "SCI Pharmtech, Inc." in Taoyuan.
May	**May 8**	Launched the "New Lifestyle Movement for Pandemic Control" in collaboration with the Command Center to encourage the public to have a new LOHAS attitude toward their dining habits, and short films were presented on TV.
June	**June 15**	TFDA's application for the APEC Medical Devices Regulatory Science Center of Excellence (CoE) was approved by the RHSC.
	June 15	Participated in the teleconferences held by APEC Life Science Innovation Forum-Regulatory Harmonization Steering Committee and to discuss about the latest development and future planning of the promotion of "Good Registration Management."
	June 16	Held a virtual meeting on COVID-19 pandemic control experience, and invited regulatory authorities such as the USFDA, EMA, and PMDA to discuss topics such as the drug supply chain, alcohol, personal protective equipment, and diagnostic test kits.
July	**July 24**	Participated in the first workshop (online) of the "Trade Facilitation through the Development of an APEC Food Safety Risk Communication Framework" jointly organized by the Food Standards Australia New Zealand and Asian food industry practitioners. The workshop discussed topics on how regulatory authorities handled food safety risk communication framework. The Agency shared the implementation results of food safety communication and presented a short introductory video for the attendees.

July	**July 28**	Co-hosted the "2020 APEC GRM Steering Committee" webex meeting with MHLW/PMDA and invited experts and regulators to jointly discuss about the preliminary thoughts of the "APEC GRM Post- 2020 Vision", in order to plan for the future implementation of the GRM Roadmap.
August	**August 7**	Taiwan Premium Agricultural Products Development Institute became the fifth certification body for food hygiene and safety management system accredited by the Agency.
	August 29	Collaborated with the Biomedical Translation Research Center of the Academia Sinica to organize the "2020 Pharmaceutical Regulatory Science Review Seminar" to enable attendees to understand the domestic pharmaceutical regulations and counseling directions on medicinal products projects and discuss drug reviews and practical cases, to benefit domestically developed drugs meet the regulatory requirements and can be launched on the market as soon as possible, further to benefit domestic patients.
	August 29 to September 11	Held the "2020 APEC Medical Devices Regulatory Science Center of Excellence Workshop" in the forms of online courses and meetings to train 61 seed instructors from 14 countries of the APEC to facilitate the harmonization of international medical device regulations.
September	**September 8 to September 9**	Organized the "2020 Food and Drug Inspection Technical Exchange Consensus Workshop" and invited local health bureaus to exchange and discuss ideas on the keynote speeches about food chemical inspection, food biological inspection, food adulteration and additives, and drugs and cosmetics inspection.
	September 9	TFDA and the Taiwan Drug Relief Foundation jointly organized the "Drug Safety Surveillance Seminar".
	September 9 to September 11	Participated in the Pharmaceuticals and Medical Devices Agency (PMDA) - Asia Training Center (ATC) Quality Control online courses "PMDA-ATC Quality Control Webinar 2020" which introduced topics such as drug review specifications and quality control to improve the review capacity of drug reviewers from regulatory agencies in various countries.
	September 15	Participated in the 2020 Center for Innovation in Regulatory Science (CIRS) international workshop (online). The topic was the "Effectiveness of the Regulatory Approval Process - Moving from measuring performance to operational excellence". The Agency shared its strategy and practical experience on the management of review efficiency, which was helpful for TFDA to optimize its internal review efficiency and collaborations with the drug administration agencies of various countries.

September

September 16	Held the "2020 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances".
September 16 to September 18	Participated in the "2020 KIDS-APEC PV CoE Training" teleconferencing seminar held by KIDS in Korea.
September 17	Organized the "Emerging Biotechnology Food Issues Symposium", and invited biotechnology and social science experts to share issues related to emerging biotechnology.
September 17	Participated in the 18th APEC LSIF Policy Dialogue videoconference. In the meeting, experts and representatives among APEC economies would gather and discuss about 'Looking forward to the next decade of the life science', 'Utilizing digital technology for the innovation' and 'Accelerating the regulatory convergence' and related policies.
September 18	Participated in the 18th APEC LSIF Planning Group Meeting. In the meeting, the Secretariat and working groups would give brief updates, meanwhile, the representatives would endorse several COVID-19 statements. In addition, many experts from industries, regulatory authorities and academia would share different research knowledges.
September 22 to September 24	Held the "Briefing on the Review System of Artificial Intelligence Technology Medical Devices Before Market Launch in Various Countries" in Taipei and Kaohsiung to enhance the understanding of smart medical device management laws and regulations of the telecommunications industry.

October

October 5 to October 6	TFDA held the 2020 National Pharmaceutical Administration Seminar, which includes special reports on pharmaceutical administration and inspection experience sharing of health bureaus. The prosecutors of Pingtung District Prosecutors Office was invited to give a keynote speech. And pharmaceutical administration proposals were discussed with health bureaus.
October 15 to October 16	Participated in the 8th Joint Conference of Taiwan and Japan on Medical Products Regulation.
October 22 to October 23	Held the international video conference of the In Vitro Diagnostic Medical Device Working Group (WG2) of the Asian Harmonization Working Party (AHWP). A total of 26 representatives from governments and industries of various countries attended the conference to promote the development of international guidelines for in vitro diagnostic medical devices (IVD).
October 30 to November 15	Held the "2020 International Medical Device Regulations Seminar", and invited industry and government representatives from the EU, Thailand to discuss topics such as the latest medical devices regulations of the EU and the ASEAN, and introduce AI medical devices, software validation and international standards for risk management.

November	**November 3**	Organized the "Imported and Domestic Beef Safety Seminar", where domestic experts and scholars in the fields of veterinary medicine, zoology, neuromedicine, animal epidemiology, public health, food safety and law shared international safe trade standards for beef and implementation practices of different countries.
	November 10, 12, 17 and 19	Participated in the USP-APEC Center of Excellence for Advanced Therapies Pilot Virtual Workshop, "Starting and Raw Materials for Advanced Therapies", to discuss materials used in emerging therapies, selection of controversial biological materials, risks of using biological materials, and biological drugs, etc., to enhance the review capacity of drug reviewers from regulatory agencies in various countries.
	November 17	Organized the Experience Sharing Symposium of "Japan Introducing the HACCP", and invited Director Hiroshi Asakura of the National Institute of Health Sciences to share the current status of HACCP implementation in Japan through video conferencing. By understanding Japan's policy planning and implementation, we were able to formulate the policy direction of expanding the HACCP in the domestic food industry, further refining the country's food safety management policies.
	November 18	Held a policy briefing session on the "Labeling of Origin of Pork Raw Materials", and invited chain catering and sellers related to pork to communicate the labeling regulations.
	November 30	Held the "Symposium on Labeling Requirements for Pork Product Importers" to explain the requirements for the labeling of origin of pork raw materials and relevant examples, and provided templates for labels and stickers of the origin of pork raw materials and the declaration for imported pork.
December	**December 7 to December 9**	TFDA became a formal member in the 14th International Cooperation on Cosmetics Regulation (ICCR) annual online meeting.
	December 9	Co-organized the "2020 Drug Safety Surveillance Seminar - Development of Drug Safety Surveillance Under the COVID-19 Pandemic" with the Taiwan Drug Relief Foundation.
	December 15	Organized the 2020 "Ministry of Health and Welfare - Ministry of Economic Affairs Pharmaceutical Technology Research and Development Award" ceremony to encourage the development of the domestic biotechnology industry.
	December 15 to December 17	Participated in the online Pharmaceuticals and Medical Devices Agency (PMDA) - Asia Training Center (ATC) Multi-Regional Clinical Trial Seminar "PMDA-ATC Pharmaceuticals Review Webinar 2020", where pharmaceutical administration inspectors shared their experience in drug review.

Appendix 2 Important Achievements and Statistics in 2020

Table 1 Addendum/amendment to the regulations and standards related to food safety and health management in 2020

Date of announcement	Subject of announcement	Key point descriptions
February 5	Stipulated the "Import Dairy Products for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	Official health certificates shall contain one of the following items or descriptions same in meaning: 1. Fit for human consumption. 2. Comply with relevant food safety and sanitation regulations of the exporting country.
February 6	Stipulated the "Regulations governing the labeling of formula for certain disease"	In line with the "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products" to reclassify formula for certain disease, and to enable consumers to use disease-specific formulas correctly, the announcement of "Regulations governing the labeling of formula for certain disease."
	Abolished the "Regulations governing the labeling of formula for certain disease" amended in accordance with the announcement Bu-Shou-Shi-Zhi #1051303909 announced on December 19, 2016	
February 12	Amended the "Fee-Charging Standards for the Registration of Food and Food Additives"	Revised the review fee charged for registering special dietary foods.
April 14	Amended Table 1 of Article 2 and Table 2 of Article 3 in the "Standards for Specification, Scope, Application and Limitation of Food Additives"	Added sweetener mogroside extract, and revised 6 specifications including magnesium stearate, magnesium carbonate, calcium dihydrogen phosphate, sodium benzoate, ferrous lactate and potassium iodate.
April 15	Amended the "Standards for the treatment of foods containing dioxin and dioxin-like polychlorinated biphenyl" and renamed to "Standards for the treatment of foods containing dioxin and polychlorinated biphenyl"	1. Renamed to "Standards for the treatment of foods containing dioxin and polychlorinated biphenyl." 2. Added the limits of 6 indicators of polychlorinated biphenyl that are not dioxin in various foods. 3. Revised the names of some food categories.
April 29	Amended Article 7 of "Regulations Governing the Registration of Food Businesses"	The time reporting the content confirming the registration was changed from "July every year" to every year after the registration is completed on the Registration Platform of Food and Medicinal Businesses to take into account the confirmation of management and the operating status of industry operators registered for the year.
May 8	Amended Point 8 of the Key Points for Inspection of Imported Foods and Related Products	Capping the number of storage locations at two to ensure effective management of early release of commodities with an affidavit attached.
May 20	Amended Table 1 of Article 3, Table 3 of Article 4 and Table 5 of Article 6 in the "Standards for Pesticide Residue Limits in Foods" and Article 3 in the "Standards for Pesticide Residue Limits in Animal products"	1. Standards for Pesticide Residue Limits in Foods: (1)Amended the tolerance of 148 residues of 40 types of pesticides including ametoctradin, and added the common name penthiopyrad. (2)Added liquefied bacillus amyloliquefaciens QST713 as a pesticide exempt from having a tolerance. (3)Added the categorization of string beans as part of dried beans and Japanese mustard spinach and turnip leaves as part of leaf vegetables. 2. Standards for pesticide residue limits in animal products: Amended the residue tolerance of 12 types of pesticides, such as acetamiprid, in poultry and livestock products.

Date of announcement	Subject of announcement	Key point descriptions
June 2	Amended Article 3 and 10 of the "Regulations Governing the Establishment of the Advisory Committee in Genetically Modified Foods"	The term of office for committee members was changed from 3 to 2 years, and the implementation date of the revision was announced.
June 4	Amended Article 4 and 12 of the Food Safety Risk Assessment Advisory Committee Establishment Regulations	The term of office for committee members was changed from 3 to 2 years, and the implementation date of the revision was announced.
June 17	Amended Article 6, Table 1 of Article 3, Table 2 of Article 4 and Table 3 of Article 5 in the "Sanitation Standard for Contaminants and Toxins in Food"	1. Supplementary requirements to inorganic arsenic in aquatic animal fats and oils, adjustments to the limits of 3-monochloropropanediol in soy sauce products and the limits of benzopyrene in grilled aquatic products. 2. Added descriptions of cadmium in the applicable parts of vegetables, fruits and plants. 3. Revised the names of 3-monochloropropanediol and hydrogen cyanide in Chinese, and amended the descriptions in Note 1 of Table 2 and Note 17 of Table 3.
June 19	Amended the "Import Regulations of F01 and F02 in Import Commodity Classification of Republic of China"	1. Added 3 items, such as 3823.19.90.00-9 "Other industrial monobasic fatty acids." 2. Revised the descriptions in the remark field of 3 items, such as 4823.20.00.00-3 "Filter paper and carboard, cut to a specific size."
	Amended the "Import Regulation of 508 in Import Commodity Classification of Republic of China; if the commodities are for food or food additives usage (including flavoring agents), the importer shall follow "Regulations of Inspection of Imported Foods and Related Products" to apply for inspection to the Food and Drug Administration, Ministry of Health and Welfare	1. Added 1 item, 3805.10.00.00-9 "Tar, wood distillate or sulfate turpentine." 2. In accordance with #1081303010 announced by the Ministry of Health and Welfare on November 7, 2019, which amended the "Standards for Specification, Scope, Application and Limitation of Food Additives" nitrous oxide was classified as food additives for management. The content of announcement regarding import regulation 838 was amended, and the complex import regulation containing F01 in import commodity classification was changed to import requirement "508" classification list.
	Amended the "Complex Import Regulation Containing F01 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	In accordance with #1081303010 announced by the Ministry of Health and Welfare on November 7, 2019, which amended the "Standards for Specification, Scope, Application and Limitation of Food Additives"; nitrous oxide was classified as food additives for management. The content of announcement regarding import regulation 838 was amended, and the complex import regulation containing F01 in import commodity classification was changed to import requirement "508" classification list.
July 1	Abolished the "Sanitation Standard for Nitrous Oxide to be Used in Food"	In conjunction with moving nitrous oxide to food additives management, the "Sanitation Standard for Nitrous Oxide to be Used in Food" was abolished.
July 14	Amended the "The obligatory inspection applicants and specific project importers shall attach relevant certified documents for the imported edible oil and fat, special dietary foods, and tablet and capsule foods.", which implements upon announcement	Considering the variety of materials used for the existing oil storage containers, in order to make the regulation more applicable to the actual import situation of edible oil and fat, it now applies to "container" shippers.

Date of announcement	Subject of announcement	Key point descriptions
August 4	Amended Article 4 and Article 6 of the "Regulations Governing of Criteria for the Label, Promotion and Advertisement of Foods and Food Products Identified as False, Exaggerated, Misleading or Having Medical Efficacy"	The amendments to Article 4 and 6 specify that except for the health foods that have been inspected and registered to acquire the associated permits, other foods shall not contain the word "health" as part of the product name, as it may mislead consumers. This regulation will take effect starting July 1, 2022 (subject to the date of production).
August 11	Amended Article 1 and Article 2 of the Sanitation Standard for Processing Aids	1. Amended the legal basis for Article 1. 2. Paragraph 12 of Article 3 of the Act Governing Food Safety and Sanitation has defined processing aids, so Article 2 of the Standard is no longer needed and will be removed.
	Amended the "Standards for Specification, Scope, Application and Limitation of Food Additives" Article 4, Article 2 Table 1 and Article 3 Table 2	Amended the specifications of monosodium phosphate, monosodium phosphate (anhydrous), Red No. 6, monosodium fumarate, sodium lactate, sodium lactate liquid, sodium alginate and fatty acid glycerides, and deleted the two specifications of anhydrous calcium chloride and calcium chloride hexahydrate that have been merged into calcium chloride, and amended part of the text in the specifications of sodium hyposulfite.
August 12	Amended Article 3 of the "Standards for Veterinary Drug Residue Limits in Foods"	Amended the tolerances of 67 residues used in 4 animal drugs, Amitraz, Dicloxacillin, Sulpyrine and Toltrazuril.
August 28	Stipulated the "Regulations on Bulk Food Labeling" and abolished the "Regulations Related to Bulk Food Labeling"	For 20 agricultural livestock and poultry products that can be easily misidentified by or confusing to consumers, and are difficult to identify the place of origin, and are often mixed and sold, the Ministry of Health and Welfare formulated the "Regulations on Bulk Food Labeling" to reinforce the standardized labeling of "Place (country) of origin" to be expanded to all food vendors. The "Regulations Related to Bulk Food Labeling" stipulated by the Department of Health of the Executive Yuan in the announcement Shu-Shou-Shi-Zhi #1011302822, dated September 6, 2012, was abolished.
September 17	Stipulated the "Labeling Regulations on Country of Origin Packaged Products that Contain Pork and Other Edible Parts of Pig"	In accordance with the provisions of Subparagraph 10, Paragraph 1, Article 22 of the Act Governing Food Safety and Sanitation, packaged foods containing pork and edible parts of pigs shall have the place (country) of origin clearly labeled on the container or the outer packaging in Chinese. The place (country) of origin should be based on the place (country) where the slaughtering of pigs occurs.
	Stipulated the "Regulations of the Labeling of Country of Origin of Pork and Other Edible Parts of Pig for Directly Supply Food Served in Catering Place"	In accordance with the provisions of Paragraph 2, Article 25 of the Act Governing Food Safety and Sanitation, establishments directly providing food services shall label the place (country) of origin for pork and edible parts of pigs served. The place (country) of origin should be based on the place (country) where the slaughtering of pigs occurs.
	Amended Point 5 of the "Regulations on Bulk Food Labeling"	Added that bulk foods using pork or edible parts of pigs as raw materials shall label the place of origin of such raw materials.
	Amended the "Standards for Veterinary Drug Residue Limits in Foods"	Added the tolerance of ractopamine residues in pigs.
	Amended the "Regulation of Imported Beef and Beef Products from the United States and Canada"	In conjunction with the adjustments to the import restrictions on beef and beef products from the United States, the requirements on the remarks of certification documents to be attached when import were amended.

Date of announcement	Subject of announcement	Key point descriptions
September 17	Amended the "Operational Procedures for Imported Beef Quarantine and Inspection"	In conjunction with the amendments to the "Regulation of Imported Beef and Beef Products from the United States and Canada," the part of the Procedures regarding the age of cattle was amended.
September 29	Amended the "Standards for Specification, Scope, Application and Limitation of Food Additives" Article 4, Article 2 Table 1 and Article 3 Table 2	1. Revised the specifications of L-Cysteine hydrochloride monohydrate, magnesium sulfate, monopotassium phosphate, sodium phosphate, xylitol, maltitol syrup, synthetic lycopene, β-carotene, sodium L-glutamate, theanine, stevioside, carrageenan, and Quillaja saponaria extract. 2. Consolidated sodium phosphate (anhydrous) items into sodium phosphate, and added lycopene (from Blakeslea trispora), and revised or merged the scope of use and limit standards of related items.
October 5	Amended the "Regulations Governing the Labeling of Freshly Made Beverages in Chain Drink Stores, Convenience Stores and Fast Food Restaurants"	1. Revised the labeling of the amount of sugar added and the calories contained in the sugar to "Total sugar and total calories of the cup of beverage, with the highest value shown". 2. Regarding the labeling of total caffeine content, besides the original labeling in the color of red, yellow and green, the maximum value of the total caffeine of the cup of beverage can also be labeled. 3. Added that the products with fruit and vegetable juice content less than 10% should be labeled as "oo drink", or have words similar in meaning, to better label the fruit and vegetable drinks.
October 6	Stipulated the "Sanitation Standard for Microorganisms in Foods"	Consolidated the requirements for microorganisms in various food hygiene standards into one standard, incorporated sampling plans and updated some indicator pathogens.
November 6	Amended Article 9 of the "Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification"	In conjunction with the amendment to Article 7 of the "Regulations Governing the Registration of Food Businesses", the reporting and confirming of registration in July of each year is changed to an annual basis. In order to make administrative management consistent, Subparagraph 3, Article 9 of the Regulations is amended to reporting on an annual basis, giving industry practitioners the flexibility to complete the reporting within the current year.
November 24	Stipulated the "Regulations on the Use and Labeling of Theobroma Cacao Pod Husk"	1. Cacao pod husks can be used for making tea only after they are dried. 2. Foods that use cacao pod husks as the raw materials should be labeled with a warning "Children and pregnant and breastfeeding women shall avoid taking this product".
December 8	Amended "The Safety Assessment Method of Health Food"	1. The health food safety assessment test shall comply with the "Good Laboratory Practice for Nonclinical Laboratory Studies" issued by the TFDA, or "Good Laboratory Practice (GLP)" issued by other international organizations or countries recognized by the competent authorities. The test must be reviewed and approved in advance by the Institutional Animal Care and Use Committee or group of the executive unit prior to implementation. 2. Consolidate and delete non-essential tests to implement the reduction of experimental animals. 3. The relevant tests may also be carried out in accordance with the OECD Guidelines for the Testing of Chemicals.
December 10	Amended Article 5 and Article 9 of the "General Food Sanitation Standards"	In conjunction with the formulation of the "Sanitation Standard for Microorganisms in Foods", the restriction on microorganisms in Article 5 has been deleted.

Date of announcement	Subject of announcement	Key point descriptions
December 16	Stipulated the "Regulations on the Use and Labeling of 2'-Fucosyllactose, a Food Material Fermented with Genetically Modified E. Coli BL21 (DE3) #1540 Strain"	Specify the relevant rules for 2'-Fucosyllactose fermented with genetically modified E. coli BL21 (DE3) #1540 strain, including the processing, specifications to be met, scope of use, amount allowed for use, and labeling of place of origin of raw materials.
December 25	Amended the "Regulations for Application of Health Food Permit"	1. Submission of supplementary documents: The submission time for the initial and secondary reviews is changed from 2 months to 1 month, respectively, and the rule on 1-month extension, if needed, is retained. The number of submissions of supplementary documents for the initial and secondary reviews is limited to 1 time each only. 2. Delivery for inspection: Written review and product inspection can be carried out simultaneously, shortening the case processing time. 3. Relief channels: Industry practitioners that fail the initial review and secondary review for the first time can file a re-review once each within 6 months, reducing the need for an appeal and conserving administrative resources. 4. Verification practice: Added the requirements of on-site verification according to the actual needs, directly clarifying the information in the applications, and reducing the time for document submission to speed up the process.
	Amended the "Import Regulations of F01 and F02 in Import Commodity Classification of Republic of China", effective starting January 1, 2021	Added CCC codes for kidney of swine and offal of swine and other items.
December 28	Stipulated the "Restrictions on the Use of Fish Oil as Food Materials"	1. The source of fish oil comes from edible fish. When used as a general food ingredient, the daily consumption is less than 2 grams based on the total amount of EPA and DHA. 2. The daily consumption of fish oil raw materials for "Formula foods for specific diseases" that have been inspected and registered and are given permits is less than 5 grams based on the total amount of EPA and DHA.
December 30	Abolished the "Standard for the Tolerance of Polychlorinated Biphenyl in Foods"	In conjunction with the amendment of the "Standards for the treatment of foods containing dioxin and polychlorinated biphenyl", the "Standards for limits of polychlorinated biphenyl in foods" was abolished, and expired on January 1, 2021.

Remarks: Commodity classification code list: according to Article 30 of the *Act Governing Food Safety and Sanitation*, the import of food and other related products announced by the central competent authority shall be in accordance with the commodity classification code list specified by the customs. By the end of 2020, there were 2,689 announced commodity classification code for the inspection of imported foods, 2,108 with the import regulation F01, 125 with import regulation F02, 373 with import regulation 508, and 83 with complex import regulation.

Table 2 The guidance of food hygiene management and operations was announced in 2020

Announcement date	Announcement name	Description
May 18	Guidelines for Management Principles of Hygiene Organizations on Selling Breast Milk Online	Explain the management regulations involving private selling of breast milk, and emphasize that the Ministry of Health and Welfare does not recommend online or private sales of breast milk.
May 20	Taiwan Guidelines on Good Manufacturing Practice for Health Supplements	In addition to the Regulations on Good Hygiene Practice for Food (GHP), the guidelines help the health supplements manufacturers reinforce their production process and quality control.
May 21	Guidelines for Self-directed Hygiene Management of Acidified Canned Food Manufacturers	The acidification process of acidified canned food is extremely important. These guidelines are specified for the industry practitioners in order to facilitate their self-directed hygiene management.
July 1	1. Guidelines for Frozen and Refrigerated Aquatic Product Manufacturers to Comply with Meet the Regulations on Good Hygiene Practice for Food 2. Guidelines for Edible Ice Cubes Manufacturers to Comply with Meet the Regulations on Good Hygiene Practice for Food 3. Guidelines for Dehydrated Fruits and Vegetables Manufacturers to Comply with Meet the Regulations on Good Hygiene Practice for Food	These guidelines are specified for food manufacturers in order to facilitate their self-directed hygiene management.

Table 3 Inspection and registration of specific foods and food additives in 2020

The food category should be registered		Number of valid documents
Imported foods in tablet and capsule		7,069
Health food		396
Food additives		6,020
Genetically modified food		151
Special dietary foods	Formula for certain disease	239
	Infant and follow-up formula	134
Domestic capsule and tablet vitamin products		2,724
Vacuum-packaged ready-to-eat soybean food		68
Total		16,801

Table 4 Food Random Inspection Project in 2020

Numbering	Project name	Results
1	HACCP Inspection Project for Processed Meat Industry	I. Inspected: 87 companies (I) GHP: 56 companies were required to make improvement within a deadline, and all of them had passed the re-inspection. (II)HACCP: 13 companies were not applicable. 65 companies were required to make improvements within a deadline, of which 64 companies had passed the re-inspection and 1 company did not pass the re-inspection. (III)Registration: 28 companies were required to make improvement within a deadline, and all of them had passed the re-inspection. (IV)Traceability: 18 were not applicable, 25 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V)Mandatory inspection: 18 companies were not applicable, 14 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI)Others: 1.3 companies stored expired foods. 2.5 companies did not have a hygiene inspector. 3.2 companies did not hire professional staff or technical personnel. II.Random inspection: 79 cases of raw meat and 56 cases of processed finished products, all complying with the regulations.
2	HACCP Inspection Project for Aquatic Processed Food	I. Inspected: 69 companies (I) GHP: 27 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 43 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 8 companies were not applicable. 4 companies were required to make improvements within a deadline, of which 3 companies had passed the re-inspection and 1 company did not pass the re-inspection. (V) Electronic declaration: 8 companies were not applicable, 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Mandatory inspection: 30 companies were not applicable, 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Food safety monitoring plan: 49 companies were not applicable and the remaining 20 companies were in compliance with regulations. (VIII) Others: 1.1 company stored expired foods. 2.5 companies did not have a hygiene inspector. 3.1 company did not hire professional staff or technical personnel. II. Labeling: 145 cases, of which 7 cases did not meet the regulations. III. Random inspection: 83 cases, of which 3 cases did not meet the regulations.
3	HACCP Inspection Project for Meal Box Factory	I. Inspected: 84 companies (I) GHP: 2 companies were not applicable, 49 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II)HACCP: 5 companies were not applicable. 60 companies were required to make improvements within a deadline, of which 58 companies had passed the re-inspection and 2 companies did not pass the re-inspection. (III)Registration: 2 companies were 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: 70 were not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (V)Traceability: 7 companies were not applicable.23 were required to make improvements within a deadline, of which 22 companies had passed the re-inspection and 1 company did not pass the re-inspection. (VI)Waste management: 2 companies were not applicable, 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII)Others: 1.5 companies stored expired foods. 2.2 companies did not have a hygiene inspector. 3.5 companies did not hire professional staff or technical personnel. II. Random inspection: 164 cases (I) Finished products: 82 cases, of which 2 cases did not meet the regulations. (II)Semi-finished products: 82 cases, of which 2 cases did not meet the regulations.

Numbering	Project name	Results
4	HACCP Inspection Project for an Edible Oil Factory	I. Inspected: 34 companies (I) GHP: 14 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Electronic declaration: 5 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Mandatory inspection: 31 companies were not applicable and the remaining 3 companies were in compliance with the regulations. (VII) Food safety monitoring plan: 31 companies were not applicable and the remaining 3 companies were in compliance with regulations. (VIII) Others: 5 companies did not have a hygiene inspector. II. Labeling: 81 cases, all products were in compliance with regulations. III. Random inspection: 57 cases, all were in compliance with the regulations. 5 cases of edible oil and fat products for non-HACCP standards were randomly inspected, and 1 case did not meet the requirements.
5	HACCP Inspection Project for Canned Food Factory	I. Inspected: 54 companies (I) GHP: 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 44 were not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (V) Electronic declaration: 46 were not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (VI) Mandatory inspection: 45 companies were not applicable and the remaining 9 companies were in compliance with the regulations. (VII) Food safety monitoring plan: 46 companies were not applicable and the remaining 8 companies were in compliance with regulations. (VIII) Others: 1 company did not have a hygiene inspector. II. Labeling: 142 cases, of which 1 case was not applicable, and the remaining 141 cases were in compliance with the regulations. III. Random inspection: 97 cases, of which all were in compliance with the regulations.
6	Audit project for domestic source providers of health foods, vitamin tables and capsules and specialized nutritious foods	I. Inspected: 36 companies (I) GHP: 4 companies were not applicable, 1 company was unqualified, 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Traceability: 18 companies were not applicable and the remaining 18 companies were in compliance with the regulations. (IV) Mandatory inspection: 17 companies were not applicable and the remaining 19 companies were in compliance with the regulations. (V) Food safety monitoring plan: 17 companies were not applicable, 1 company was required to make improvements within a deadline and has passed the re-inspection. (VI) Must trace: 18 companies were not applicable, 3 companies required improvement within a deadline, and all of them had passed the re-inspection. (VII) Waste management: 4 companies were not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VIII) Compliance of the registration permit: 60 cases, of which 9 cases did not meet the regulations. II. Labeling: 50 cases, of which 2 cases did not meet the regulations.

Numbering	Project name	Results
7	Inspection Project for Food Additive Manufacturers and Import Businesses	I. Inspected: 25 companies (I) GHP: 4 companies were not applicable, 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Traceability: 1 company was not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (IV) Electronic declaration: 1 company was not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (V) Mandatory inspection: 1 company was not applicable and the remaining 24 companies were in compliance with the regulations. (VI) Food safety monitoring plan: 9 companies were not applicable and the remaining 16 companies were in compliance with regulations. II. Labeling: 44 cases, all were in compliance with the regulations. III. Random inspections: 24 cases, all were in compliance with the regulations.
8	Inspection Project for Small-Scale Aquatic Product, Dairy Product Processing and Canned Food Manufacturers	I. Inspected: 110 companies (I) GHP: 60 companies were required to make improvements within a deadline, of which 59 companies passed the re-inspection and 1 company did not pass the re-inspection. (II) Registration: 28 companies required to make improvement within a deadline, and all of them had passed the re-inspection. (III) Traceability: 108 companies were not applicable and the remaining 2 companies were in compliance with the regulations. (IV) Electronic declaration: 108 companies were not applicable and remaining 2 companies were in compliance with the regulations. (V) Mandatory inspection: 107 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VI) Food safety monitoring plan: None of the 110 companies were applicable. (VII)Others: 1 company did not have a hygiene inspector. II. Labeling: 122 cases, of which 7 cases did not meet the regulations. III. Random sampling inspection: 92 cases, and the 13 cases (sales) for random inspection were not part of the project inspection, all of which comply with the regulations.
9	Inspection project for liquid egg manufacturers	I. Inspected: 50 companies (I) GHP: 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 28 companies were not applicable, 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Traceability: 44 companies were not applicable and the remaining 6 companies were in compliance with the regulations. (V) Electronic declaration: 44 companies were not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (VI) Others: 1. 1 company stored expired foods. 2. 4 companies did not have hygiene inspector. II. Random inspection: 178 cases (I) Fresh raw materials: 52 cases, all comply with the regulations. (II) Liquid egg finished products: 126 cases, all comply with the regulations.
10	Inspection Project for Preserved Eggs and Salted Eggs Manufacturers	I. Inspected: 32 companies (I) GHP: 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 3 companies were not applicable. 6 companies were required to make improvements within a deadline, of which 5 companies had passed the re-inspection and 1 company did not pass the re-inspection. (III)Registration: 1 company was not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (IV)Retain the source documents: 4 companies were required to make corrections within a deadline, all of which had passed the re-inspection. (V) Vacuum packaging food labeling inspection: 23 companies were not applicable and the remaining 9 companies were in compliance with regulations. II. Random inspection: 76 cases (I) Fresh raw materials: 25 cases, all comply with the regulations. (II) Finished products (preserved eggs, salted eggs/salted egg yolks, wine eggs): 51 cases, all of which comply with the regulations.

Numbering	Project name	Results
11	Inspection Project for Bean Products Manufacturers	I. Inspected: 53 companies (I) GHP: 29 companies were required to make improvements within a deadline, of which 26 companies passed the re-inspection and 3 companies did not pass the re-inspection. (II) Registration: 1 company was not applicable, 14 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Others: 2 companies did not have a hygiene inspector. II. Labeling: 23 cases, all were in compliance with the regulations. III. Random inspection: 58 cases, of which 9 cases did not meet the regulations.
12	Inspection Project for Pickled Vegetables	[First stage] 450 random inspection cases, of which 33 cases did not meet the regulations. [Second stage] I. Inspected: 43 companies (I) GHP: 14 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 5 companies were required to make improvement within a deadline, and all of them had passed the re-inspection. (III)Others: 1 company did not have a hygiene inspector. II. Labeling: 45 cases, all were in compliance with the regulations. III. Random inspection: 41 cases, of which 2 cases did not meet the regulations.
13	Inspection project for edible ice manufacturers	I. Inspected: 60 companies (I) GHP: 24 companies were required to make improvements within a deadline, of which 23 companies passed the re-inspection and 1 company did not pass the re-inspection. (II) Registration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Product liability insurance: 3 companies were not applicable and the remaining 57 companies were in compliance with the regulations. II. Random inspections: 60 cases, all were in compliance with the regulations.
14	Inspection Project for Packaged Ice Manufacturers	I. Inspected: 54 companies (I) GHP: 26 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 5 companies were required to make improvement within a deadline, and all of them had passed the re-inspection. (III)Use and management of food additives: 12 companies were not applicable, 12 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV)Traceability: 42 companies were not applicable and the remaining 12 companies were in compliance with the regulations. (V) Mandatory inspection: 42 companies were not applicable and the remaining 12 companies were in compliance with the regulations. (VI)Food safety monitoring plan: 42 companies were not applicable and the remaining 12 companies were in compliance with regulations. (VII)Waste management: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VIII)Standard form contract: 39 companies were not applicable, 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 160 cases, of which 5 cases did not meet the regulations. III. Random inspection: 109 cases finished products and all were in compliance with the regulations.
15	Inspection project for rice noodle wet product manufacturers	I. Inspected: 72 companies (I) GHP: 46 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 3 companies were not applicable, 12 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Use and management of food additives: 18 companies were not applicable, 32 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV)Waste management: 8 companies were not applicable, 23 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Random inspection: 140 cases, of which 12 cases did not meet the regulations.

Numbering	Project name	Results
16	Inspection project for soy sauce manufacturers	I. Inspected: 99 companies (I) GHP: 35 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Product liability insurance: All were in compliance with the regulations. (IV)Others: 1. 1 company did not have a hygiene inspector. 2. 1 company did not hire professional staff or technical personnel. II. Labeling: 259 cases of finished products, of which 8 cases did not meet the regulations. III.Random inspection: (I) Soy sauce products: 155 cases, of which 1 case did not meet the regulations. (II) Caramel pigment: 12 cases, all were in compliance with the regulations.
17	Inspection Project for Popular Hotel Restaurants	I. Inspected: 208 companies (I) GHP: 93 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: A total of 28 companies should implement HACCP, of which 24 companies were required to make improvements with a deadline; 23 companies passed the re-inspection and 1 company did not pass the re-inspection. (III)Registration: 46 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV)Other: 13 companies stored expired foods. II. Random inspection: 215 cases, of which 4 cases did not meet the regulations.
18	Inspection Project for Banquet Restaurants	I. Inspected: 206 companies (I) GHP: 5 companies were not applicable;72 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 14 companies required improvement within a deadline, and all of them had passed the re-inspection. (III)Product liability insurance: 5 companies were not applicable and the remaining 201 companies were in compliance with the regulations. (IV)Percentage of personnel holding technical licenses: 5 companies were not applicable and the remaining 201 companies were in compliance with the regulations. (V)Other: 5 companies stored expired foods. II. On-site labeling: 5 companies were not applicable and the remaining 201 companies were in compliance with the regulations. III.Random inspection: 106 cases, of which 2 cases did not meet the regulations.
19	Random Inspection Project for Drinks Made on Site	I. Inspected: 259 companies (I) GHP: 116 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 20 companies were not applicable, 28 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Retain the source documents: 29 companies were required to make corrections within a deadline, all of which had passed the re-inspection. (IV)Others: 1.1 company stored expired foods. 2.Food utensils were not labeled as required: 1 case II. On-site labeling: 165 companies, of which 11 companies did not meet the regulations. III.Random inspection: 333 cases, of which 7 cases did not meet the regulations.
20	Random Inspection Project for Ice Products Made on Site	I. Inspected: 105 companies (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 3 companies were not applicable, 14 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Retain the source documents: 17 companies were required to make corrections within a deadline, all of which had passed the re-inspection. (IV)Others: 1.1 company stored expired foods. 2.1 food business was not insured with product liability insurance. II. Random inspection: 183 cases, of which 1 case did not meet the regulations.

Numbering	Project name	Results
21	Random Inspection Project for Eastern and Western Style Breakfast and Brunch	I. Inspected: 203 companies (I) GHP: 105 companies were required to make improvements within a deadline, of which 103 companies passed the re-inspection and 2 companies did not pass the re-inspection. (II) Registration: 30 companies were not applicable, 31 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Product liability insurance: 65 companies were not applicable and the remaining 138 companies were in compliance with the regulations. (IV)Retain the source documents: 22 companies were required to make corrections within a deadline, all of which had passed the re-inspection. (V)Others: 1 company stored expired food. II. On-site labeling: 203 companies, all were in compliance with the regulations. III.Random inspection: 194 cases, of which 3 cases did not meet the regulations.
22	Inspection Project for Noodles Restaurant Operators	I. Inspected: 159 companies (I) GHP: 75 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 28 companies were required improvement within a deadline, and all of them had passed the re-inspection. (III)Product liability insurance: 27 companies were not applicable and the remaining 132 companies were in compliance with the regulations. (IV)Retain the source documents: 23 companies were required to make corrections within a deadline, all of which had passed the re-inspection. (V)Others: Incorrect date labeling on packaged food, 1 case II. On-site labeling: 159 companies (I) Origin of raw beef: 47 companies were not applicable and the remaining 112 companies were in compliance with the regulations. (II) Restructured meat products: 154 companies were not applicable, and the remaining 5 companies were in compliance with the regulations. (III)Genetically modified food raw materials: 29 companies were not applicable, and the remaining 130 companies were in with the regulations. III.Random inspection: 140 cases, of which 2 cases did not meet the regulations.
23	Inspection Project for Gourmet Restaurants at Local Popular Attractions	I. Inspected: 165 companies (I) GHP: 77 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 1 company was not applicable, 28 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 161 companies were in compliance with the regulations. (IV)Other: 3 companies stored expired foods. II. On-site labeling: Inspected the menus of a total of 13 companies, that supplied cod fish, and 8 companies of them were false labeling. III.Random inspection: 342 cases, of which 8 cases did not meet the regulations.
24	Inspection Project for Food Delivery Platform Operators	I. Food delivery operators: 19 companies (I) GHP: 16 companies were not applicable, 1 company was required to make improvement within a deadline, and had passed the re-inspection. (II) Registration: 1 company was not applicable, 1 company was required to make improvements within a deadline and has passed the re-inspection. (III)Standard form contract: 9 companies were not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV)Customer complaint handling process: 7 companies were not applicable, 1 company was required to make improvement within a deadline, and had passed the re-inspection. II. Food and beverage operators collaborating with food delivery platforms: 474 companies (I) GHP: 136 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 32 companies were not applicable,42 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Product liability insurance: 1 company 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. (V)Other: 3 companies stored expired foods. III.Service staff of food delivery platform: 158 people, all in compliance with the requirements.

Numbering	Project name	Results
25	Inspection Project for Food Containers or Packaging Containing Plastics in Contact with Food	I. Inspected: (I) Manufacturers: 28 companies 1.GHP: 4 companies were required to make improvement within a deadline, and all of them had passed the re-inspection. 2.Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Label inspection for food retailers and food services: 171 cases, of which 5 cases did not comply with the regulations. II. Random inspection: (I) Manufacturers: 49 cases, all were in compliance with the regulations. (II) food retailers and food services: 32 cases, and all were in compliance with the regulations.
26	Inspection Project for the Food Logistics and Storage Industry	Inspected: 94 companies I. GHP: 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Registration: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection.
27	Inspection project for multi-Schedule marketing businesses	I. Inspection for labeling: 4 companies (one of them had no products on site), and a total of 21 cases, and all complies with the regulations. 3 cases of single-page advertising leaflet were checked, of which 1 involved false advertisement, exaggeration or misleading information. II. Registration: 1 case of special-purpose cosmetics did not have registration.
28	Inspection Project for Seasonal Festive Food -- Tomb-Sweeping Day	Random inspection: 704 cases, of which 7 cases did not meet the regulations.
29	Inspection Project for Seasonal Festive Food -- Winter Food	Random inspection: 679 cases, of which 2 cases did not meet the regulations.
30	Inspection Project for Chinese New Year	Inspection of festive food manufacturers on hot searches I. Inspected: 70 companies (I) GHP: 32 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Product liability insurance: All were in compliance with the regulations. (IV)Standard form contract: 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V)Others: 1 company stored expired raw material. II. Labeling: 205 cases, of which 3 cases did not meet the regulations. III.Random inspection: 211 cases, of which 1 case did not meet the regulations.
		Inspection on food retailers of festival celebration I. Inspected: 334 companies (I) GHP: 20 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 13 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Labeling: 1,310 cases, of which 5 cases did not meet the regulations. III.Random inspection: 1,847 cases, of which 27 cases did not meet the regulations.
		Random inspection for festival dishes in the famous restaurants I. Inspected: 90 companies (I) GHP: 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Product liability insurance: All were in compliance with the regulations. (IV)Standard form contract: 1 company was required to make improvements within a deadline and had passed the re-inspection. (V)Others: 2 companies stored expired raw material. II. On-site labeling: 2 companies did not meet the regulations. III.Random inspections: 90 cases, all of which were qualified.

Numbering	Project name	Results
31	Inspection Project for Dragon Boat Festival	Zongzi Manufacturers and Retailers I. GHP: 60 companies, of which 19 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Random inspection: 108 cases, of which 1 case did not meet the regulations.
		Dragon Boat Festival Food Retailers I. GHP: 200 companies, all were in compliance with the regulations. II. Labeling: 426 cases, all were in compliance with the regulations. III.Random inspection: 491 cases, of which 2 cases did not meet the regulations.
32	Inspection Project for Mid- Autumn Festival	Inspection of moon cake and BBQ Combination package manufacturers I. Inspected: 200 companies (I) GHP: 4 companies were not applicable, 82 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 3 companies were not applicable, 34 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 8 companies were not applicable and 1 company was not in compliance with the regulations. (IV) Food safety monitoring plan: 183 were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (V) Mandatory inspection: 183 companies were not applicable and the remaining 17 companies were in compliance with the regulations. (VI) Traceability: 181 companies were not applicable, 2 companies were required to make improvements within a deadline and both of them passed the re-inspection. (VII) Electronic declaration: 182 were not applicable, 3 companies were required to make improvements within a deadline and both of them passed the re-inspection. (VIII) Waste management: 14 companies were not applicable, 38 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IX) Standard form contract: 98 companies were not applicable, 24 companies were required to make improvements within a deadline and all of them passed the re-inspection. (X) Other: 5 companies used or stored expired foods. II. Labeling: 523 cases, of which 11 cases did not meet the regulations. III.Random inspection: 593 cases, of which 2 cases did not meet the regulations.
		Random inspection of Mid-Autumn festival foods: 1,161 cases, of which 11 cases did not meet the regulations. (I) Egg yolk or moon cakes containing egg yolk: 41 cases, all of which met the regulations. (II) Fresh vegetables and fruits: 162 cases, of which 5 cases did not meet the regulations. (III)Poultry, Livestock and aquatic products: 147 cases, all in compliance with regulations. (IV)Food containers: 43 cases, all in compliance with regulations. (V)Other seasonal foods: 768 cases, of which 6 cases did not meet the regulations.
		Inspection on restaurants serving Mid-Autumn Festival foods I. Inspected: 132 companies (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 1 company was not applicable. 20 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Retain the source documents: 4 companies were required to make corrections within a deadline, all of which had passed the re-inspection. (IV)Others: 2 companies stored expired food raw material. II. On-site labeling: 132 companies, all were in compliance with the regulations. III.Random inspection: 158 cases, of which 1 case did not meet the regulations.
33	Inspection Project for School Lunch	I. Inspected: 2,128 companies GHP: 77 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Random inspection: (I) Finished products for lunch: 2,091 cases, all were in compliance with the regulations. (II) Semi-finished products: 70 cases, all were in compliance with the regulations.

Numbering	Project name	Results
34	Inspection Project of Catering Businesses for Providing Lunch to Schools	I.Inspected 560 companies GHP: 86 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Random inspection: 757 cases, of which 1 case did not meet the regulations.
35	Inspection Project for Commercially Available Frozen and Refrigerated Prepared Foods	I. Inspected: 192 companies GHP: 6 companies required improvement within deadline, and all of them had passed the re-inspection. II. Random inspection: 304 cases (I) Health standard: 292 cases, of which 3 cases did not fulfill the requirements. (II) Nutrition labeling: 12 cases, of which 5 cases did not meet the regulations.
36	Inspection Project for Packaged Hotpot Soup Base Manufacturers	I. Inspected: 43 companies (I) GHP: 23 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 12 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Traceability: 27 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (IV)Mandatory inspection: 27 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (V)Food safety monitoring plan: 27 companies were not applicable, 1 company was required to make improvements within a deadline and had passed the re-inspection. (VI)Must trace: 27 companies were not applicable, 2 companies required improvement within a deadline, and both of them had passed the re-inspection. (VII)Waste management: 1 company was not applicable, 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VIII)Others: 1. 1 company stored expired foods. 2. 1 company did not have a hygiene inspector. II. Labeling: 107 cases, of which 8 cases did not meet the regulations. III.Random inspections: 80 cases, all were in compliance with the regulations.
37	Inspection Project for Small-Scale Bakeries With a Storefront	I. Inspected: 211 companies (I) GHP: 97 companies were required to make improvements within a deadline, of which 96 companies passed the re-inspection and 1 company did not pass the re-inspection. (II) Product liability insurance: 6 companies were not applicable and 2 companies were not in compliance with the regulations. (III)Others: 1. 2 companies stored expired foods. 2. Food additives used by 1 of the company did not match the registration information. 3. 1 company evaded an inspection II. Random inspection: 372 cases, of which 12 cases did not meet the regulations.
38	Inspection Project for Food ingredient in the Baking Industry	I. Inspected: 61 companies (I) GHP: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III)Other: 4 companies stored expired foods. II. Labeling: 5 companies did not meet the regulations. III. Random inspections: 90 cases, all were in compliance with the regulations.
39	Inspection Project for Commercially Available Children's Food	I. Labeling: 397 cases, of which 4 cases did not meet the regulations. II. Random inspection: 397 cases, of which 5 cases did not meet the regulations.
40	Inspection Project for Nuclear Radiation in Japanese Food on the Market and Labeling Check	I. Labeling: 350 cases, of which 5 cases did not meet the regulations. II. Random inspections: 350 cases, all were in compliance with the regulations.

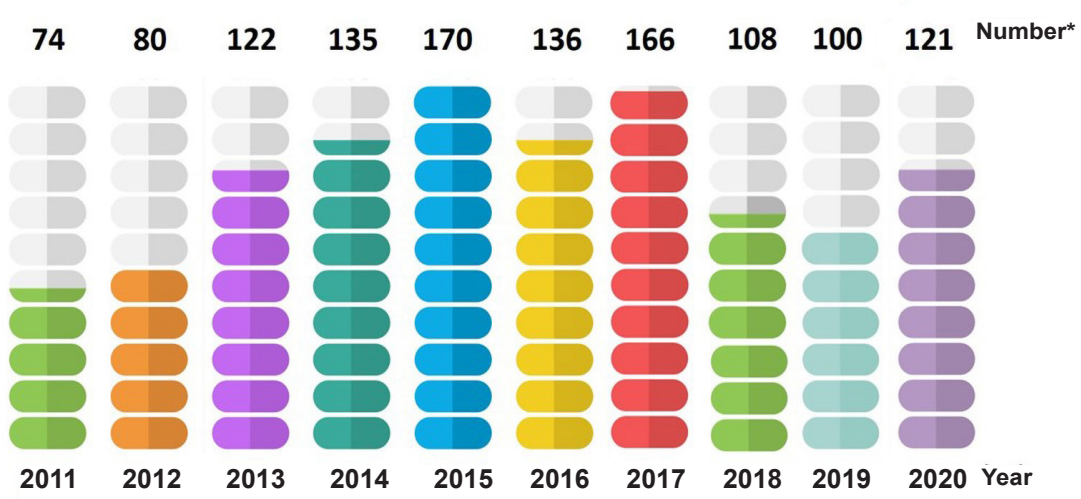
Table 5 Addendum/amendment to the regulations and standards related to pharmaceutical administration in 2020

Date of announcement	Name	Important content
January 14	Announced the "Types of cases in which a drug patent status declaration form is needed to be attached to registration of medicinal products"	If the registration of medicinal products involves any of the following, the drug patent status declaration form mentioned in Article 8 and 17 of the Regulations for the Patent Linkage of Drugs should be attached. The registration will be returned if the declaration form is not attached. 1.New therapeutic indication drug registration (including biological therapy). 2.New combination drug registration (including biological drug). 3.New method of administration drug registration (including biological drug). 4.Generic drug registration. 5.Biosimilar drug registration. 6.Add/change indications. 7.Add/change indications based on the first applicant.
January 21	Announced the "Trial plan for accelerated review of domestic new drugs"	In order to encourage domestic research, development and manufacturing of new drugs, and accelerate their launch, so that patients can receive treatment as early as possible, and to further expand the export market, this plan is formulated to shorten the review period of domestic new drugs.
February 12	Stipulated the "Information Checklist for Investigational Cell Therapy Products"	The checklist is stipulated to enable applicants to understand the types of documents needed for the application and review of Investigational Cell Therapy Products, so they can better prepare the experimental design and information to be delivered, reducing the possibility of delay due to insufficient information causing further mailing and returning of documents submitted, or being unapproved.
March 18	Updating the list of drugs for The Rare Disease and Orphan Drug Act	Adding "Onasemnogene abeparvovec" (solution for intravenous infusion, $2x10^{13}$ vg/mL)
March 20	Amended the "Information Exclusive Period and Domestic and Overseas Clinical Trial Data Sheet"	In order to reflect the GCP transformation, integrate the exclusive protection of data in accordance with Article 40-2 and 40-3 of the Pharmaceutical Affairs Act and Article 22-1 and Article 54 of the Regulations for Registration of Medicinal Products, and improve the administrative efficiency for "extending patent term of drugs" or "additional calculation of drug prices paid by the NHI", the data sheet should be attached to the application for drug registration and adding or changing the indications.
May 1	Amended the "Guidance on Investigational Cell Therapy Products"	These criteria were amended in conjunction with the amendment to the "Administrative Regulation on Special Medical Instruments and Inspection Techniques" in accordance the Wei-Bu-Yi-Zhi #1071665803 order from the Ministry of Health and Welfare dated September 6, 2018, and the addition of management standards for cell therapy.
June 11	Amended Article 21 of the "Guidelines for Bioavailability and Bioequivalence", and the title of the guidelines are changed to the "Operating Guidelines of Bioavailability and Bioequivalence Studies"	Amended Article 21 of the "Guidelines for Bioavailability and Bioequivalence", and the title of the guidelines are changed to the "Operating Guidelines of Bioavailability and Bioequivalence Studies".

Date of announcement	Name	Important content
July 1	Announced the “Streamling measures for clinical trials of medicinal products”	Streamline the review process of clinical trials to improve the competitiveness and efficiency of the domestic clinical trials.
July 21	Established the “Standards of Review Fees for the Registration of Western Medicines”	Charges for various cases of western medicines registration.
July 22	Established the “Basic Considerations in Supporting Drug Research and Development with Real-World Evidence” guidance”	Real-world evidence is the latest international clinical application trend. TFDA has taken into consideration the latest international management practices and established the “Basic Considerations in Supporting Drug Research and Development with Real-World Evidence” as reference for domestic drug R&D.
July 23	Amended the Wei-Shu-Yao-Zhi #0900018043 announcement “Post-market changes of oral solid preparations”, dated March 19, 2001, from the Department of Health of the Executive Yuan	Refer to the international SUPAC-MR to revise the relevant attachments and tables to ensure that the major and minor changes do not affect the quality of pharmaceutical preparations. Basis of amendment: Article 46 of the “Regulations for Registration of Medicinal Products”.
August 25	Renamed the “Application form for adverse drug reaction reporting database” to “Application form for adverse reactions to western medicines and medical devices reporting database”	Title was revised as the “Application form for adverse reactions to western medicines and medical devices reporting database”.
August 26	Updating the list of drugs for The Rare Disease and Orphan Drug Act	Adding “Burosumab” (solution for injection, 10, 20, 30 mg/mL), “Siponimod fumaric acid” (film coated tablet, 0.25, 2 mg), “KH_2PO_4 + Na_2HPO_4 + $NaH_2PO_4 \cdot H_2O$” (tablet, KH_2PO_4 155 mg + Na_2HPO_4 852 mg + $NaH_2PO_4 \cdot H_2O$ 130 mg), and revised “Nusinersen” (injection, 2.4 mg/mL) indications.
August 28	Promulgating “The Review Considerations for Registration of Over-the-Counter Drugs that Have Been Sold in A10 Countries for 10 Years or Longer But Are Regarded as Drugs of New Therapeutic Compounds, New Dosage Forms, New Administration Doses, or New Unit Strength in Taiwan.”	For those drugs are over-the-counter and have been sold in A10 countries for 10 years or longer but are regarded as drugs of new therapeutic compounds, new dosage forms, new administration doses, or new unit strength in Taiwan, we made a specific registration process that require less clinical, pharmacokinetic, and pharmacological/toxicological data since the drugs mentioned above pose a lower risk.
	Amended some provisions of the “Regulations for Good Clinical Trials of Drugs”, and renamed it to “Regulations for Good Clinical Practice”	Amended some provisions of the “Regulations for Good Clinical Trials of Drugs”, and renamed it to “Regulations for Good Clinical Practice”.
September 3	Amending the list of drugs catagorized for tracing the sources and tracking the flow prescribed in Article 6-1 of the “Pharmaceutical Affairs Act”.	“Midicinal nitrous oxide” was included in the items to be traced and tracked for declaration, which was formally implemented on October 1, 2020 to strengthen distribution monitoring and prevent it from being misused.

Date of announcement	Name	Important content
September 22	Formulated the “Guidelines for Good Clinical Practice”	The guidelines were formulated based on the E6 (R2) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) as a supplement to the Regulations for Good Clinical Practice, and reference for the personnel of handling clinical trials.
September 29	Updating the list of drugs for The Rare Disease and Orphan Drug Act	Added and recognized “Givosiran” (injection, 189 mg/mL), “Chenodeoxycholic acid” (capsule, 250 mg), and “Edaravone” (injection, 1.5 mg/mL).
November 2	Established the “Guidance on Investigational Gene Therapy Products”	These criteria were established for the review of the manufacturing process control, non-clinical trials, and clinical trials based on the characteristics of gene therapy products in order to promote the domestic development of gene therapy.
November 11	Amended the “Precautions for the management of home use addictive narcotic drugs by terminal patients”	1. Amended in accordance with international guidelines to enable doctors to prescribe addictive narcotic drugs after evaluating benefits and risks to relieve the symptoms of dyspnea in terminal patients. 2. Amended the number of days for which doctors can prescribe addictive narcotic drugs for oral or topical use. In the future, those in rural areas who use addictive narcotic drugs at home and need to extend their prescriptions can seek medical treatment at the nearest medical institution instead of visiting the hospitals with a “Controlled Drugs Management (Committee)” to increase the accessibility of home-use addictive narcotic drugs for terminal patients living in remote rural areas.
November 12	Formulated the “Regulations for the Security and the Maintenance of Personal Information Files in Wholesaling and Retailing Western Pharmaceuticals”	The Regulations were established to maintain the security and accuracy of personal data, and to establish practices for the management, audit, preservation and improvement of personal data in accordance with the authorization of the Personal Data Protection Act.
November 19	Formulated the “Guidance on Taiwan Electronic Common Technical Document (eCTD) Validation Criteria”	We specifically demonstrated the guidance for using the standardized electronic formats when applying for drug registration and ensuring to compliance with the requirements of the electronic common technical document Requirements from International Council for Harmonization for Pharmaceuticals for Human Use (ICH).
December 25	Updating the list of drugs for The Rare Disease and Orphan Drug Act	Adding “Risdiplam” (powder for oral solution, 0.75 mg/mL), “Ofatumumab” (solution for injection, 50 mg/mL), “Ravulizumab” (concentrate for solution for infusion, 10 mg/mL), “Human C1-esterase inhibitor” (injection, 500 IU), “Ataluren” (granules for oral suspension, 125, 250, 1000 mg).
December 30	Formulated the chart of “Review process and time management for the registration of orphan drugs”	The chart of review process and time management was established to make the registration of orphan drugs more transparent and enable applicants to understand the timing of each phase, further ensuring the efficiency, consistency, transparency and predictability of review.
December 31	Formulated the “Guidance on Taiwan Electronic Common Technical Document (eCTD)”	These Guidelines were formulated to enable applicants to meet the requirements of the ICH eCTD Electronic Common Technical Document Specification V3.2.2.

Table 6 Number of new drugs approved in 2020



* The number of cases is based on the number of permits.

Among the 121 new drugs, 41 are new drugs with new main ingredients and 35 are biological products. The majority of the approved new drugs includes cancer, pain-related (non-NSAID) diseases, rare diseases and blood-related diseases. The approval of these new drugs provides new treatment options and are beneficial to the patients.

Table 7 Addendum/amendment to the schedule of controlled drugs in 2020

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
June 3	**Schedule 3**	3,4-Methylenedioxyphenethylamine (Eutylone, bk-EBDB, N-Ethylbutylone, Euthylone)	It is a synthetic cathinone substance and a central nervous system stimulant.
		3,4-Methylenedioxyphenylethylaminohexanone [N-Ethylhexylone, 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-hexanone]	It is a synthetic cathinone substance and a central nervous system stimulant.
	Schedule 4	Tertiary Butoxycarbonyl-Ketamine (N-Boc-Ketamine, N-t-Butoxycarbonyl-Ketamine)	It is a dissociative anesthetic.
November 16	**Schedule 3**	3,4-Methylenedioxyphenyl butylaminopentanone [N-Butylpentylone, 1-(1,3-benzodioxol-5-yl)-2-(butylamino)-1-pentanone]	It is a synthetic cathinone substance and a central nervous system stimulant.
		[N-Butylhexedrone, 2-(butylamino)-1-phenyl-hexan-1-one]	It is a synthetic cathinone substance and a central nervous system stimulant.
	Schedule 4	(Methyl-3-oxo-2-phenylbutyrate, Methyl alpha-phenylacetoacetate, MAPA)	It is the precursor of amphetamine and methamphetamine.
		Fluorophenylacetone, including three positional isomers such as 2-Fluorophenylacetone, 3-Fluorophenylacetone and 4-Fluorophenylacetone	Can be manufactured into fluoromethamphetamine and fluamphetamine.
		Methoxyphenylacetone, including three positional isomers such as 2-Methoxyphenylacetone, 3-Methoxyphenylacetone and 4-Methoxyphenylacetone	Can be manufactured into methoxy methamphetamine.

Table 8 Addendum/amendment to the regulations and standards related to medical devices management in 2020

Date of announcement	Name	Important content
January 15	The President promulgated the "Medical Devices Act".	The management of medical devices is removed from the "Pharmaceutical Affairs Act"; An independent law was established to govern medical devices management and to ensure that Taiwan's medical devices management follows international standards and meets practical needs.
January 31	Amended "The template for Chinese package insert of medical devices intended for home use Soft contact lenses"	To ensure that the general public can understand how to use soft contact lenses correctly by reading the package insert. The template can also be used as a reference for manufacturers when they draft package inserts.
March 31	Advance notice of the draft of the "Regulations Governing Medical Device Quality Management System"	Established relevant regulations requiring medical device manufacturers to establish medical device quality management system, hoping that manufacturers conform with regulations governing medical device quality management system.
April 6	Advance notice of the draft of the "Regulations Governing Accreditation and Outsourced Accreditation Management of Medical Devices Institutions"	To facilitate the accreditation and outsourced accreditation of medical devices institutions; to enhance the management of accreditation institutions and outsourced accreditation institutions.
April 13	Announced the "Guidelines for Evaluation of Human Factors/Usability Engineering of Medical Devices"	Provide medical device manufacturers with guidelines to evaluate human factors/usability engineering of their products during the phase of product design, research and development, application for registration, and product launch.
April 20	Amended the preclinical testing guidance for "soft contact lenses"	The guidance can be used as a reference when manufacturers are engaging in research and development of similar products and when they apply for registration and market approval; Inspectors can also use the guidance as a reference to ensure the safety and effectiveness of the product in the market.
April 28	Announced the preclinical testing guidance for "mechanical wheelchair with electric power unit"	
May 18	Advance notice of the draft of the "Regulations for the Inspection of the Good Distribution Practice for Medical Devices and Licensing of Distribution License"	Established the regulations for the inspection the good distribution practice for medical devices, including inspection content, inspection methods, conditions for approval, review, issue, effective period, change, cancellation or revocation and other matters that should comply with good distribution practice.
May 26	Advance notice of the draft of the "Regulations of Medical Device Good Distribution Practice"	Established 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.

Date of announcement	Name	Important content
June 12	Announced the preclinical testing guidance for “D5630 nebulizer”, “F6070 UV activator for polymerization” and “M1570 ophthalmoscope”	Businesses can use the guidance 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 15	Announced the preclinical testing guidance for “Dental Bone Grafting Material/Resorbable Calcium Salt Bone Void Filler Device Containing Materials Derived from Animal Sources” and “Polymethylmethacrylate (PMMA) Bone Cement”	
June 17	Advance notice of the draft of the “Regulations Governing the Inspection of the Medical Device Quality Management System and the Issuance of the Manufacturing License”	Govern the application for the inspection of medical device manufacturers’ quality management systems and matters related to the registration particulars, issue and change of manufacturing licenses.
	Advance notice of the draft of the “Regulations on Good Clinical Practice for Medical Devices”	Established the management scope, standard operating regulations, application procedures, examination guidelines, avoidance of conflicts of interest, information disclosure, supervision and management, inspection, the content of the informed consent form, and other matters for compliance with clinical practice for medical devices.
July 6	Advance notice of the draft of the “Regulations Governing Incentive Rewards for Research and Development of Innovative 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 and innovative technologies.
July 7	Advance notice of the draft of the “Regulations Governing Designation or Commission of Medical Devices Test”	Designate a subordinate agency (or institution) or commission a relevant agency (or institution), legal entity, or organization to conduct all or part of the inspection of medical devices, and formulate relevant regulations governing designation, commission and related matters.
	Amended the “Regulations for the Inspection and Examination of Imported Medicaments”	Medical masks are included in the items subject to border inspections for complete flow control and to ensure the safety and effectiveness of such products to be used by the public.
July 17	Announced the “Guidance on In Vitro Companion Diagnostic Devices”	Businesses can use the guidance as a reference for research and development of product 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.
July 20	Advance notice of the draft of the “Regulations for Management of Medical Devices Technicians”	Specify the qualifications, job descriptions, continuing education and other matters related to medical device technicians.

Date of announcement	Name	Important content
August 6	Advance notice of the draft of the "Alternative Way of Written Form to Get Agreement of Using, Collecting or Processing Personal Information for Using Medical Devices"	Specify that research institutions, medical institutions or medical device firms 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 Electronic Signatures Act.
August 18	Advance notice of the draft of "Medical Device Items That Can be Sold by Pharmacies Concurrently Engaging in the Retail Business of Medical Devices"	Specify 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-intrusive Class II and Class III medical devices.
	Advance notice of the draft of the "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.
August 24	Advance notice of the draft of the "Medical Devices and Medical Device Firms That Need to Establish Good Distribution Practice System"	To ensure the quality of medical devices used by the general public, the draft asks medical device firms dealing with high-risk medical devices to implement inspection of the distribution system.
September 2	Announced the "2020 List of Medical Device Recognized Standards" and the "List of Abolished or Revised Medical Device Standards"	Announced the recognition of 1,000 international standards of medical devices for medical device manufacturers to choose from during the developing and testing process so as to ensure the safety and effectiveness of the products on the market.
September 8	Advance notice of the draft of the "Regulations Governing Categorization and Classification of Medical Device"	Specify 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.
September 11	Announced the "Technical Guidelines for Artificial Intelligent/Machine Learning-Based Software as a Medical Device (AI/ML-Based SaMD)"	The guidelines focus 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 product and to check the information required for the application for inspection and registration.
September 16	Amended the "Particulars that Shall Be Indicated on the Labels of Flat Medical Masks", which took effect on the same day	In accordance with Subparagraph 8, Paragraph 1, Article 75 of the Pharmaceutical Affairs Act, domestically manufactured flat medical masks shall be stamped with "MD" and "Made in Taiwan" on medical masks.
	Announced "The Procedures to Recall Domestically Manufactured Flat Medical Masks before September 23, 2020 without the Stamps of "MD" and "Made in Taiwan"	Announced that the flat medical masks legally manufactured in Taiwan before September 23 without the stamps, 2020 can continue to be sold until December 24th, 2020. License holders should withdraw these products before March 23, 2021, and send them together with the inventory to the municipal or county (city) health authority for verification before they can continue to be sold.

Date of announcement	Name	Important content
September 24	Advance notice of the draft of the "Regulations of Medical Device Tracking Management"	Established the regulations governing how medical device firms and medical institutions shall create and store the information on sources and flows of medical devices, including the method of storage, expiration year, declaration and other matters to be followed.
	Advance notice of the drafts of "Medical Devices That Shall Establish and Maintain Sources and Flow Data" and 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.
	Advance notice of the draft of "Regulations Governing the Sale Items and Compliance Matters 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.
October 8	Advance notice of the draft of the "Regulations for Reporting Serious Adverse Events of Medical Devices"	Established the regulations to govern 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.
	Advance notice of the draft of "the Regulations for Management of Medical Device Safety Surveillance"	Established the regulations to govern the medical device safety surveillance data and reports, submission of such data, deadline, content, format, restrictions and maintenance of data collection, surveillance period, evaluation and other relevant matters.
October 15	Formulated the "Categorization and classification of medical device 'O. 3800 motorized vehicle for medical purposes", and 'O. 3860 powered wheelchair' and the required labeling", which took effect on April 15, 2021	Specified that for such products, the vehicle body should be labeled with the medical device license number. If the products have been approved to have the characteristics of a front-facing seat on a motorized vehicle, the packaging, labels and user manuals should clearly show "The product has passed the front impact test required for motor vehicles with a front-facing seat" for the general public to identity legal products and to protect the priority right of the disabled.
October 29	Advance notice of the draft of the "Requirements 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.
November 3	Established "the Guidance For Enterovirus RNA Nucleic Acid Amplification Test Reagents" and the "Guidance For Toxoplasma gondii, Rubella virus, Cytomegalovirus Serological Reagents"	Businesses can use the guidance 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.

Date of announcement	Name	Important content
November 4	Announced the “Guidance on Registration and Market Approval 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.
November 5	Advance notice of the draft of the “Medical Device Product Items That Shall Obtain Marketing Authorization by Means of Listing”	Specified what product items of medical devices may obtain market approval by means of listing in accordance with Paragraph 1, Article 25 of the Medical Devices Act.
	Advance notice of the draft of the “Labels, Instructions or Packaging of Specific Medical Devices Shall Additionally State the Warnings and Cautions”	Mandatory requirements for specifically medical devices to add warnings and cautions of potential risk on product labels and package inserts.
	Advance notice of the draft of “the Requirements for Indicating the Unique Device Identifier on Medical Device Labels”	Established relevant regulations that require the indication of Unique Device Identifier (UDI) on the single packaging or device body of Classes II and III medical devices.
	Announced that natural persons who import medical devices subject to border inspection for personal use should fill in the special certificate code IF000000000001 for customer clearance. The rule took effect on November 18, 2020.	In accordance with Article 2 of the Regulations for the Inspection and Examination of Imported Medicaments, the obligatory inspection applicants refer to medicaments importers. Therefore, the obligatory inspection applicant referred to in the Regulations should not include a natural person. The administrative rules are announced to interpret the regulations and to provide a code for exemption from inspection as a supporting measure for customs clearance.
	The obligatory inspection applicant referred to in Subparagraph 4, Article 2 of the “Regulations for the Inspection and Examination of Imported Medicaments” refer to importers of medicaments. Therefore, natural persons who import medical devices for personal use do not need to apply for inspection according to the “Regulations for the Inspection and Examination of Imported Medicaments”.	
November 6	Advance notice of the draft of “the 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, treatments, and other matters to be followed.
	Advance notice of the draft of the “Designated Product Items for Medical Device Safety Surveillance”	With the announcement of the draft of “Regulations for Management of Medical Device Safety Surveillance”, this draft specified that specific types of medical devices or items should be included in the safety surveillance.
November 13	Advance notice of the draft of “Regulations for Approval of Specific Medical Devices’ Manufacturing or Importing as a Special Case”	Specified the application conditions, review procedures, approval criteria, supply and sale restrictions, return shipment and other matters to be complied with for medical devices manufacturing or importing as a special case.

Date of announcement	Name	Important content
November 15	Advance notice of the draft of the "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.
November 19	Advance notice of the draft of "the Regulations Governing Border Inspection and Examination of Imported Medical Devices"	Established the regulations specifying imported medical device items that require random inspection and tests, and that can only be released after meeting all the requirements, as well as the test items, methods, procedures, scope, charges and other relevant matters.
November 25	Advance notice of the draft: "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 Personnel"	This draft is formulated in accordance with the authorization of Article 44 of the Medical Devices Act. The central competent authority may limit advertisement channels of specific medical devices.
	Advance notice of the draft of the "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.
November 30	Announced: "Examples of Proper and Improper Advertisement Wording of Class I Medical Devices" (for 10 items)	The document can be used as a reference for writing and revision of advertisements for Class I medical devices.
December 10	Established the "Standards for the Establishment of Medical Device Manufacturers"	Specified the premises, work areas, facilities, equipment and hygiene conditions of medical device manufacturers.
December 24	Amended the "Guidance for Medical Software Classification"	Specified Taiwan's management of health promotion products, and provided a reference for companies from other industries entering the medical industry to develop health promotion products.
December 30	Advance notice of the draft of the "Enforcement Rules of Medical Devices Act"	Relevant details and technical specifications have been established in the enforcement rules in accordance with the provisions of the Medical Devices Act (parent law).
December 31	Advance notice of the draft of the "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.

Table 9 **Addendum/amendment to the regulations and standards related to cosmetics management in 2020**

Date of announcement	Name	Important content
March 11	Established the “Introductory Manual for Cosmetics Product Information File”, the “Cosmetics Product Information File Checklist” and the “Cosmetic Product Information File Guidelines”	Provided the basic principles, precautions and examples for product information files in order for vendors to understand the management system and content of product information files.
September 29	Amended the “Restriction table for use of cosmetic colorants”	Given the frequent international trades in recent years, in response to the trends of international management on cosmetics, the “Restriction table for use of cosmetic colorants” was amended to ensure the consumer safety of cosmetics.
November 19	Amended the “Mandatory and Prohibitory Provisions of Standard Form Contracts for Body Shaping and Beauty Industry”	Amended the “Mandatory and Prohibitory Provisions of Standard Form Contracts for Body Shaping and Beauty Industry” in order to make standard form contracts keep up with the ever-changing business environment, reduce the difficulty of adoption for the industry and ensure consumers' rights and interests.
December 3	Announced the draft amendment of the “List of Prohibited Ingredients in Cosmetics”	Referred to international hygiene standards for cosmetics, the draft amendment of the “List of Prohibited Ingredients in Cosmetics” was announced in order to ensure the consumer safety of cosmetics.

Table 10 Collaborative Inspection of Food, Drugs and Cosmetics in 2020

Inspection type	Numbering	Project name (Implementation time)	Results
Food safety	1	The collaborative inspection project for egg products (July to December)	Inspected: 22 companies I. GHP: 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Registration: 1 company was required to make improvements within a deadline and it passed the re-inspection. III.Random inspection: 31 cases of liquid egg products, all complying with the regulations.
	2	Project joint inspection action plan for chemical raw material industry project for the sale of food additives (August to October)	Inspected: 111 companies I. GHP: 30 companies were not applicable, 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Registration: 27 companies were required to make improvements within a deadline and all of them passed the re-inspection. III. Labeling: 162 cases, of which 1 case did not meet the regulations. IV. Checked whether there were separately packaged unilateral food additives for distribution: 24 companies were not applicable and the remaining 87 companies were in compliance with regulations.
	3	Joint inspection project plan for supply chain of domestic longan honey products (November to December)	Inspected: 20 companies I. GHP: 4 companies were not applicable, 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. II. Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. III. Labeling: 27 cases, of which 5 cases did not meet the regulations. IV. Product liability insurance: 3 companies were not applicable and the remaining 17 companies were in compliance with the regulations. V. Traceability: 1 company was not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection.
Medical devices	1	Medical device collaborative inspection (August to October)	Inspected 55 medical device stores and online stores, and inspected 42 cases of medical devices, of which 6 cases products were in violation of the relevant provisions of the Pharmaceutical Affairs Act. The violations included the contents of the instruction leaflet, product instructions, product use and maintenance manuals not compliant with the original approvals, no medical device license, on-site product specifications not meeting the specifications contained in the original catalogs. 1 company that sold medical devices did not apply for a pharmaceutical license.
Drugs	1	Joint drug inspection program – Inspection for illegal drugs (June to August)	Audited 64 medical institutions, of which 8 clinics were involved in violations of the provisions of the Pharmaceutical Affairs Act. The violations included that pharmacies did not have a pharmacist's license to sell wholesale drugs to clinics, and that the clinics did not have a pharmacist's license but imported and used the drug without obtaining a drug license, and other circumstances such as the display or storage of expired drugs or the use of expired drugs in clinics.
	2	Joint drug inspection program – Inspection for project import drugs for personal use (June to August)	Audited 5 medical institutions and a total of 20 patients. Among them, 4 medical institutions and a total of 15 patients' medical records were found not consistent with the original medical institution's prescription date or content.
Controlled drugs	1	Inspection Project for Controlled Drugs (June to October)	230 companies were inspected, and 43 companies were found to be in violation of regulations. The violations were listed as top 3, in the form of inaccurate records, failure to comply with the regulations of drug dispensing, and improper medical use.
Cosmetics	1	Joint audit plan for cosmetics claimed to contain negative ions, far-infrared rays, germanium, titanium, etc. (July to October)	36 companies were inspected, all of which met the requirements. 5 products were sampled and sent to the Institute of Nuclear Energy Research of the Atomic Energy Council of the Executive Yuan to test the radiation content, and all of them passed the inspection.

Table 11 Additional TFDA Test Methods Form in 2020

Types of Test Methods	Test Methods	Promulgated/ Amended
Announced test methods for food products (48 articles, 436 items)	1. Method of Test for Volatile Basic Nitrogen in Aquatic Products 2. Method of Test for Food Additive Specifications - Sodium Dihydrogen Citrate 3. Method of Test for Food Additive Specifications - Gold (Metallic) 4. Method of Test for Food Additive Specifications - Gelatinized Starch (Alkaline Treated Starch) 5. Method of Test for Food Additive Specifications - Hydroxypropyl Distarch Phosphate 6. Method of Test for Food Additive Specifications - Oxidized Hydroxypropyl Starch 7. Method of Test for Food Additive Specifications - Bleached Starch 8. Method of Test for Food Additive Specifications - Oxidized Starch 9. Method of Test for Food Additive Specifications - Starch Acetate 10. Method of Test for Food Additive Specifications - Acetylated Distarch Adipate 11. Method of Test for Food Additive Specifications - Monostarch Phosphate 12. Method of Test for Food Additive Specifications - Starch Sodium Octenyl Succinate 13. Method of Test for Food Additive Specifications - Distarch Phosphate 14. Method of Test for Food Additive Specifications - Phosphated Distarch Phosphate 15. Method of Test for Food Additive Specifications - Acetylated Distarch Phosphate 16. Method of Test for Food Additive Specifications - Hydroxypropyl Starch 17. Method of Test for Food Additive Specifications - Starch Aluminum Octenyl Succinate 18. Method of Test for Food Additive Specifications - Starch Sodium Succinate 19. Method of Test for Food Additive Specifications - Distarchoxy Propanol 20. Method of Test for Heavy Metals in Beverages and Milk Products 21. Method of Test for Food Additive Specifications - Ferrous Sulfate, Dried 22. Method of Test for Heavy Metals in Vegetables, Fruits, Jams and Jellies 23. Method of Test for Heavy Metals in Mushrooms 24. Methods of Test for Specifications of Processing Aids - Test of Triacetin 25. Method of Test for Sweeteners in Foods - Multiple Analysis 26. Methods of Test for Specifications of Processing Aids - Test of Hexane 27. Methods of Test for Specifications of Processing Aids - Test of Isopropyl Alcohol 28. Method of Test for Heavy Metals in Metal Canned Foods - Test of Tin 29. Methods of Test for Specifications of Processing Aids - Test of Acetone 30. Methods of Test for Specifications of Processing Aids - Test of Propylene Glycol 31. Methods of Test for Specifications of Processing Aids - Test of Ethyl Acetate 32. Methods of Test for Specifications of Processing Aids - Test of Glycerol 33. Method of Test for Food Additive Specifications - Nitrous Oxide 34. Method of Test for Food Additive Specifications - L-Carnitine Tartrate	Promulgated

Types of Test Methods	Test Methods	Promulgated/ Amended
Announced test methods for food products (48 articles, 436 items)	35. Method of Test for Food Additive Specifications - Food Starches, Modified 36. Method of Test for Pesticide Residues in Livestock and Poultry Products - Multiresidue Analysis 37. Methods of Test for Food Microorganisms - Test of *Listeria monocytogenes* 38. Methods of Test for Food Microorganisms - Test of *Aeromonas* spp. 39. Method of Test for Food Additive Specifications - Sodium Carbonate; Sodium Carbonate, Anhydrous 40. Method of Test for Food Additive Specifications - Sodium Carbonate, Anhydrous 41. Method of Test for Food Additive Specifications - Sunset Yellow FCF (Food Yellow No. 5) 42. Method of Test for Food Additive Specifications - Allura Red AC (Food Red No. 40) 43. Method of Test for Mycotoxins in Foods - Test of Aflatoxins 44. Method of Test for Mycotoxin in Foods - Test of Aflatoxin M_1 in Dairy Products 45. Methods of Test for Food Use Detergents 46. Method of Test for Food Additive Specifications - D-Mannitol 47. Method of Test for Food Additive Specifications - Sodium Benzoate 48. Method of Test for Food Additive Specifications - Magnesium Carbonate	Amended
Recommended test methods for food products (60 articles, 584 items)	1. Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Antiprotozoal Drugs (2) 2. Method of Test for 16-*O*-Methylcafestol in Coffee 3. Method of Test for β-Lactoglobulin from Milk in Foods 4. Method of Test for Ovalbumin from Chicken Eggs in Foods 5. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Lactobacillus plantarum* 6. Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Lactobacillus reuteri* 7. Method of Test for Inorganic Arsenic in Seaweed and Rice 8. Method of Test for Total Hydrocyanic Acid in Cassava Products (2) 9. Methods of Test for Food Microorganisms - Test of Rotavirus A 10. Methods of Test for Food Microorganisms - Test of *Streptococcus pyogenes* 11. Method of Test for Identification of Mequindox and its Metabolites in Foods 12. Method of Test for Ethyl Eicosapentaenoate and Ethyl Docosahexaenoate in Fish Oil 13. Method of Identification for Dimethyl Dicarbonate in Beverages 14. Method of Test for Sweeteners in Foods- Multiple Analysis 15. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event DAS-44406-6 (UI: DAS-444Ø6-6) 16. Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Maize Event MON87427 (UI: MON-87427-7) 17. Method of Test for Heavy Metals in Canned Foods-Test of Lead 18. Method of Test for Heavy Metals in Metal Canned Foods-Test of Tin 19. Method of Test for Heavy Metals in Grains 20. Method of Test for Vitamin E in Edible Oils (2)	Published

Types of Test Methods	Test Methods	Promulgated/ Amended
Recommended test methods for food products (60 articles, 584 items)	21. Method of Test for Food Additive Specifications - Nitrous Oxide 22. Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis (5) - 17 Items including Analycarb et al. 23. Method of Test for Veterinary Drug Residues in Eggs - Test of Piperonyl Butoxide 24. Method of Test for Veterinary Drug Residues in Eggs - Test of Prednisolone 25. Method of Test for Pesticide Residues in Livestock and Poultry Products - Test of 2,4-D, Chlormequat, Cyromazine and Fenbutatin oxide 26. Method of Test for Veterinary Drug Residues in Foods - Test of Antibiotic Substances (Microbiological Method) 27. Method of Test for Heavy Metals in Food Grade Salt 28. Method of Test for Veterinary Drug Residues in Foods - Test of Flavophospholipol 29. Method of Test for Veterinary Drug Residues in Foods - Test of Piperazine 30. Method of Test for Veterinary Drug Residues in Foods - Test of Nitrovin (2) 31. Method of Test for Veterinary Drug Residues in Eggs - Test of Levamisole 32. Method of Test for Veterinary Drug Residues in Foods - Fast Extraction Method for Multiresidue Analysis of *β*-Agonists 33. Method of Test for Pesticide Residues in Livestock and Poultry Products for Expansion of Multiresidue Analysis - Test of Dichlorvos, Aldrin and Dieldrin 34. Method of Test for 2-MCPD Esters, 3-MCPD Esters and Glycidyl Esters in Infant Formula 35. Method of Test for Pesticide Residues in Poultry and Livestock Products - Test of Amitraz and its Metabolite 36. Method of Test for Heavy Metals in Eggs 37. Method of Test for Sodium γ-Polyglutamate in Foods 38. Method of Test for α-Glycosyl-Isoquercitrin in Foods 39. Method of Test for Levulinic Acid in Soy Sauce 40. Method of Test for Bromate in Foods 41. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Pine Nut 42. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Brazil Nut 43. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Sesame 44. Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Pistachio 45. Method of Test for Veterinary Drug Residues in Foods - Test of Nystatin 46. Method of Test for 16-*O*-Methylcafestol in Coffee (2)	Published
	47. Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of *Oncorhynchus* spp. Ingredient 48. Method of Test for Polycyclic Aromatic Hydrocarbons in Foods 49. Method of Test for Total Hydrocyanic Acid in Cassava Products (1) 50. Method of Test for Colors in Foods (2) 51. Method of Test for Adulterants in Chinese Medicine and Foods 52. List of Recommended Methods of Test for Pesticide Residues in Foods	Revised

Types of Test Methods	Test Methods	Promulgated/ Amended
Recommended test methods for food products (60 articles, 584 items)	53.Method of Test for Veterinary Drug Residues in Foods - Multiresidual Analysis of *β*-Lactam Antibiotics 54.Method of Test for Pesticide Residues in Foods for Expansion of Multiresidue Analysis (5) - 17 Items including Analycarb et al. 55.List of Recommended Methods of Test for Pesticide Residues in Foods 56.Method of Test for Ethyl Eicosapentaenoate and Ethyl Docosahexaenoate in Fish Oil 57.Method of Test for Veterinary Drug Residues in Foods - Test of Piperazine 58.Method of Test for Veterinary Drug Residues in Foods - Multiresidual Analysis of β-Lactam Antibiotics 59.Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Antiprotozoal Drugs (2) 60.Method of Test for Histamine in Foods	Revised
Recommended test methods for cosmetics and medical device products (8 articles, 95 items)	1.Method of Test for Iodopropynyl Butylcarbamate in Cosmetics 2.Method of Test for Polysilicone-15 in Cosmetics 3.Method of Test for Polycyclic Aromatic Hydrocarbons in Cosmetics 4.Method of Test for Heavy Metals in Cosmetics 5.Method of Test for Restricted Dyes in Cosmetics 6.Method of Test for Camphor Benzalkonium Methosulfate and Benzylidene Camphor Sulfonic Acid in Cosmetics	Published
	7. Method of Test for Hair Dyes in Cosmetics 8. Microbiological Methods for Cosmetics	Revised
Recommended test methods for drugs, controlled drugs (including illegal drugs) and biological drugs (6 articles, 119 items)	1. Method of Test for Synthetic Phenethylamines in Urine (2) 2. Method of Test for Synthetic Cathinones in Urine (3) 3. Method of Test for Nitrosamines in Medicines - Multiple Analysis (GC-MS/MS Method) 4. SARS-CoV-2 Neutralization Assay	Published
	5. Determination of *N*-Nitroso-*N*-Methyl-4-Aminobutyric Acid in Sartan Drug Substances and Drug Products 6. Method of Test for Nitrosamines in Medicines - Multiple Analysis (LC-MS/MS Method)	Revised

Appendix 3 Important achievements and statistics over the years

Table 1 The statistics of inspection for imported foods over the years

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

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

Table 2 Statistics of inspection on pesticide residue, veterinary drugs, mycotoxins and heavy metals in food 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

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

Table 3 Statistics on food poisoning over the years

Year	Number of outbreaks	Food poisoning cases		Number of food poisoning cases classified by foods					
		Number of patients	Number of deaths	Aquatic products and their processed products	Meat, eggs, dairy and their processed products	Grain, fruits and vegetables and their processed products	Cake and candy	compound cooking foods and other types	Total of causes with undefined foods
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338
2014	480	4,504	0	18	12	6	3	60	381
2015	632	6,235	0	17	3	7	1	53	551
2016	486	5,260	0	18	4	2	2	56	404
2017	528	6,232	0	7	3	7	0	44	467
2018	398	4,616	0	5	2	5	1	30	358
2019	502	6935	2	13	5	5	1	26	457
2020	506	4920	0	4	2	5	2	25	469

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

Health food licenses (phase one + phase two)					Licenses for genetically modified foods	
Year	Phase one	Phase two	Number of issued license in the year	Total number of issued licenses	Number of issued license in the year	Total number of issued licenses
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

Remarks:

1. Health food inspection and registration adopts the two-phase system
   The first phase (case review): The vendors must provide proof documents such as food safety and efficacy, and the certificate will be issued as Wei Bu Jian Shi Zi No. Axxxxx.
   The second phase (Specification standard review): Products shall comply with Ministry of Health and Welfare specifications and standards. The issued number is Wei Bu Chien Shi Kui Tzu No. xxxxxx.
2. As of December 2020, the total number of issued licenses for health food was 473 (including 400 in type one and 73 in type two), of which 77 were invalid licenses (including expired, revoked and combined). As of the end of 2020, the number of valid licenses was 396.
3. As of December 2020, there were 151 licenses for genetically modified foods, of which 0 of them will be discontinued or not be extended. As of the end of 2020, the number of valid licenses was 151.

Table 5 Statistics of approved drug licenses over the years

Year	Generic drugs			Active pharmaceutical ingredients			New drug			Biologicals			Rare medicine			Total
	Domestic	Imported	Sub-total	Domestic	Imported	Sub-total	Domestic	Imported	Sub-total	Domestic	Imported	Sub-total	Domestic	Imported	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

Table 6 Number of valid GMP/QSD registration letters for medical equipment 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

Table 7 Statistics of approved licenses for medical device and cosmetics over the years

Year	Medical devices				Specific-purpose cosmetics	
	Number of licenses approved for the year	Total number of licenses	Domestic licenses	Import licenses	Number of licenses approved for the year	Total number of licenses
2010	3,920	30,140	5,905	24,235	1,437	13,436
2011	4,047	33,865	6,857	27,008	1,519	14,979
2012	3,592	32,821	7,057	25,764	1,482	12,340
2013	3,827	35,705	8,079	27,626	1,456	13,799
2014	3,605	37,967	8,952	29,015	1,565	14,570
2015	3,743	40,579	9,678	30,901	1,558	14,902
2016	3,818	43,328	10,329	32,999	1,172	15,674
2017	3,940	46,797	11,203	35,594	1,142	16,643
2018	3,985	45,890	11,172	34,718	1,220	15,365
2019	3,770	45,839	11,332	34,507	1,257	14,710
2020	3,647	48,293	12,182	36,111	902	15,578

Remarks: 6,253 medical device licenses were announced to be cancelled in 2018; 4,653 medical device licenses were announced to be cancelled in 2019.

Table 8 Controlled drug licenses and inspection statistics over the years

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

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

Year	Domestic western medicine preparation factories that passed the GMP	Domestic western medicine preparation factories that passed the PIC/SGMP	Total number of companies passed the PIC/S GMP evaluation
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

Remarks: The compiled data are before 2014, given all modern pharmaceutical manufacturers have to be in line 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

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

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum				Other biopharmaceutical products		The annual total	
	Domestic		Imported		Imported		Domestic		Imported		Imported			
	Batches	Doses	Batches	Doses	Batches	Doses	Batches	Doses	Batches	Doses	Batches	Doses	Batches	Doses
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

Table 12 Statistics on the number of accredited laboratories and accredited items over the years

Year	Food accredited laboratory		Drugs & Cosmetic / Drugs accredited laboratory*		Cosmetic accredited laboratory*		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
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

*Note: The 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*" on July 1, 2019.

Table 13 Unlawful drug seizure rate and drug advertisement advertising violation rate over the years

Year	Illegal drug seizure rate (%)	Advertising violation rate (%)
2010	11.81	13.90
2011	4.59	6.10
2012	2.35	5.15
2013	1.97	5.46
2014	1.81	5.18
2015	1.14	5.04
2016	1.03	4.83
2017	0.73	4.86
2018	0.90	4.90
2019	2.66	4.89
2020	2.62	4.77

Remarks:
1. The collaborative team for busting the counterfeit, fake or poor drugs was established in April 2010.
2. A total of 830 illegal drug cases were seized in 2020 with a total fine of NTD 2.538 million, the seizure rate decreased from 11.81 % in 2010 to 2.62% in 2020.
3. The number of violations in food, drugs and cosmetics by the health authorities was 5,676 in 2020, with a total fine of NTD198.43 million. The advertisement violation rate decreased from 13.90% in 2010 to 4.77% in 2020.

Table 14 Statistics on the operations of controlled drug manufactures over the years

Unit (thousand NTD)

Year	Income	Expenditure	Pay to the national treasury
2010	484,762	268,215	145,956
2011	491,523	321,822	116,414
2012	494,672	343,359	141,988
2013	513,092	344,461	120,000
2014	533,321	343,305	120,000
2015	593,448	396,662	120,000
2016	701,254	481,454	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

Appendix 4 TFDA Publications in 2020

Serial number	GPN	Topic	Responsible Section	Type	Publication year/ month
1	1010901236	2020 Drug Abuse Cases at the Workplace and Prevention Q&A Manual	Division of Controlled Drugs	Books	2020/09
2	1010901625	2020 Drug Abuse Prevention Guide	Division of Controlled Drugs	Books	2020/10
3	1010901649	2018 National Survey of Substance Use Report	Division of Controlled Drugs	Books	2020/10
4	1010902122	Handbook of Food Manufacturing Regulations	Division of Food Safety	Books	2020/12
5	1010902224	Do Make Up and Learn Packaging	Division of Medicated Cosmetics	Books	2020/12
6	1010902462	Food Labeling Q&A Collection	Division of Food Safety	Books	2020/12
7	1010902511	Manual of Food Labeling Laws	Division of Food Safety	Books and digital publications	2020/12
8	1010902521	Guidebook on Food Labeling Regulations	Division of Food Safety	Books	2020/12
9	2010103850	Annual Report on Food Import Management and Inspection	Division of Food Safety	Books	2020/12
10	2010002894	Annual Report of Foodborne Outbreaks and Prevention	Division of Food Safety	Books and digital publications	2020/12
11	3910900825	GHP Record Template for Food Manufacturers	Division of Food Safety	Non-book materials	2020/12
12	2010301353	TFDA Annual Report (English version)	Enterprise Planning Division	Continuity	2020
13	2010302286	TFDA Annual Report (English version)	Enterprise Planning Division	Continuity (Journal)	2020
14	2008200056	JFDA Journal of Food and Drug Analysis Journal	Enterprise Planning Division	Continuity (Journal)	2020
15	49094052333	Drug and Food Safety Weekly	Enterprise Planning Division	Continuity (Journal)	2020

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 introduction of agencies, business areas, announcements, special Section of Rumor Buster of Food and Drugs, to provide the public with faster services with accurate information.	
2	Online Application and the Diverse Service Platform	https://oap.fda.gov.tw	The online application and the diverse service platform integrate various application services of TFDA, to provide a single online application service window with multiple ways of payment for the public.	
3	Food and Drug Open Data Platform	https://data.fda.gov.tw	The TFDA Open Data Platform provides original information regarding food and drugs for external access and applications, to enhance the operating transparency of the TFDA's governance policy.	
4	TFDA News	http://article-consumer.fda.gov.tw/default.aspx	"TFDA News" is based on the three topics such as "safe eat out foods, safety of drugs, medical devices and cosmetics," to provide the latest and most accurate food safety information and articles and most correct and practical knowledge for the public.	
5	Food and Drug Consumer Service Network	https://consumer.fda.gov.tw	Provide the public with integrated services regarding food and drug related information.	
6	Taiwan's International Food and Drug Safety Authority Network	http://tifsan.fda.gov.tw/tifsan/login.jsp	A platform that allows TFDA to communicate internal data, report public opinions and exchange relevant information with public health bureaus.	
7	The registration platform for food and drug business operators	https://fadenbook.fda.gov.tw	An IT system established by government agencies to manage the food and drug business operators in the industry.	
8	Food Traceability Management Information System	https://ftracebook.fda.gov.tw	The relevant electronic records can be uploaded to the system, including product information, tag identification, supplier information, product flow information, etc., to trace sources of product supply or track product flow.	
9	Inquiry System for Interpretation Compilation of the Act Governing Food Safety and Sanitation	http://fsas.fda.gov.tw/	This system has included all regulations, specification documents and related interpretation orders of the Act Governing Food Safety and Sanitation, for the general public to review and search online.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
10	System for Searching the Drafts of Food Additive Standards	http://tsfa.fda.gov.tw/	To simplify the inquiry operation of the “Standards for Scope, Application and Limitation of Food Additives,” this system has organized and created a database for the general public to review and search online.	
11	TFDA’s online food label information service desk	http://www.foodlabel.org.tw/FdaFrontEndApp#	In addition to the “Nutrition Labeling Format Area” and the “Inquiry Area for Regulations and Announcements,” this platform also provides consulting services of food labeling for 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 applications for the proof of exporting foods (additives) such as English health certificate, processing hygiene certificate, inspection report and certificate of free sales.	
13	Imported Food Inspection System	https://ifi.fda.gov.tw/ifi/main/ ap/index.jsp	It provides functions such as inquiry of case progress for foods, Chinese herb and medicines, rubber condoms and food QR-CODE download.	
14	Product Distribution Management System	https://pmds.fda.gov.tw	An inspection data management platform for the health bureaus of local governments and the TFDA; it is for the competent authorities to manage food, drugs and cosmetics in their jurisdiction.	
15	Curriculum Management System of Food Sanitation and Safety	https://foodedu.fda.gov.tw	Food hygiene workshops, HACCP workshop resources and course enquiries are available for registration from various industries.	
16	Food Sanitation and Safety Management Certification and Validation System	https://facs.fda.gov.tw	This system mainly assists in the implementation of the Schedule 2 food quality control inspection, through the randomly assigned inspection agency by the system, the inspection process control and display of results, to improve the efficiency of inspection management.	
17	E Platform for Review and Submission (ExPRESS)	https://e-sub.fda.gov.tw/dohclient/Login.aspx?ReturnUrl=%2fdohclient	This system provides online submission for drug registration and post approval changes for licence holders. Reviewers and applicants can both access this platform to review and check case progress.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
18	Trace and Track System of Medicinal Products	https://dtracebook.fda.gov.tw	The system allows firms to upload declaration the trace and track data of medicinal products.	
19	Information Platform of Drug Provision	https://dsms.fda.gov.tw	The system provides pharmaceutical companies and medical institutes in Taiwan to report on the shortage of medicinal products to facilitate real-time assessment and handling, reduce the influences caused by the shortage of medicinal products and protect the rights of the public.	
20	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	The medical institutions, pharmacies, pharmaceutical business operators and the public can use this system to report adverse drug reaction incidents, so that the TFDA can monitor the safety of drugs on the market.	
21	Controlled Drugs Management Information System	https://cdmis.fda.gov.tw	The institutions, business operators and related professionals with controlled drug registration certificates can apply for the pre-market controlled drugs via the system, to effectively enhance administrative efficiency and service quality.	
22	Drug Abuse Reporting System	https://dars.fda.gov.tw	The system allows healthcare facilities to promptly report any cases of drug abuse, in order to assess the trends of drug abuse and instantly understand the current status of drug abuse in Taiwan.	
23	Drug Abuse Test Report System	https://udars.fda.gov.tw	A system for the regular inspection in urine or narcotics test results of drug abuse cases by relevant domestic inspection institutions.	
24	Searching System of Approved Advertisement for Drugs and Medical Devices Management System	https://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	A system allowing the public to inquire information on approved advertisements for medicines and medical devices.	
25	Post-marketing Quality Management System for Medicinal Products, Food and Cosmetics	https://qms.fda.gov.tw	The general public, medical professionals and manufacturers can report incidents regarding drugs, medical devices, health foods and cosmetics via the integrated and convenient notification portal.	
26	Cosmetic Product Registration Platform	https://cos.fda.gov.tw	The manufacturers or importers can register product information on the “Cosmetic Product Registration Platform,” so that the government agencies can better understand the products on the market and facilitate the cosmetics management regulations to meet the international standards.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
27	Online Application System of Human Organ Bank	https://htb.fda.gov.tw	The system provides online application for human organ bank, to ensure the completeness of submitted documents and enhance the application efficiency and regulatory compliance through its reminder function.	
28	Materials Transfer Support System for Disaster Rescue and Prevention	https://mrdss.fda.gov.tw/Web/	The system allows the hospitals, drug manufacturers and sales vendors, human organ banks to online report the medical resource reserves, to assist in medical supplies during the time of major disasters.	
29	Laboratory Certification Network	https://lams.fda.gov.tw	The TFDA's certification platform for urine inspection agencies regarding food, drugs, cosmetics and drug abuse cases.	
30	Laboratory Information Management System	https://lims.fda.gov.tw	The inspection process can be managed online by the inspection offices in health bureaus of the local governments.	
31	Inquiry System for Advertisements in Violation	https://pmds.fda.gov.tw/illegalad/	It is able to instantly and quickly reveal the illegal advertisements in food, drugs and cosmetics, to be used as a reference so that the public will not be influenced by the exaggerated advertisements.	
32	FDA Director-General's Mailbox	http://faq.fda.gov.tw/	The Mailbox Service of the Director-General is an important communication channel for the public to submit their petitions and express their opinions. The intelligent inquiry service has been created to make the overall service process even more efficient and enhance the satisfaction Schedule of the public.	
33	Online System of the JFDA Journal	https://www.editorialmanager.com/jfda/	It is TFDA's "JFDA Drug and Food Analysis Journal" system for domestic and foreign authors' online submission and review of journals, as well as for the online review, edit and publication of journals.	

2021 Taiwan Food and Drug Administration Annual Report

Publisher	Shou-Mei Wu
Editor-in-Chief	King-Fu Lin
Editorial Board	Shu-Fen Wang, Der-Yuan Wang, Yu-Roo Chu, Ming-Shin Lee, Pei-Weng Tu, Hsu-Yang Lin, Jiann-Liang Lin, Hsin-Weng Chang, Chao-Kai Hsu, Chien-Wen Hsu, Tzu-Ling Chen, Hwei-Fang Chen, Fang-Ming Liu, Shu-Jean Tsai, Wei-Chih Cheng Lan-Hui Chih, Chia-Hung Chien, Pi-Lien Hsieh, Jen-Ting Wei
Executive Secretary	Pin-Chu Lee
Executive Editor	Yuh-Wen Huang
Publishing Authority	Taiwan Food and Drug Administration, Ministry of Health and Welfare
Address	No.161-2, Kunyang St., Nangang Dist., Taipei City 11561, Taiwan (R.O.C.)
Website	http://www.fda.gov.tw
TEL	+886-2-2787-8000
Date of Publication	2021/12
Date of Initial Issue	2014/11
Publishing Frequency	Annual Report
Design & Printing	Linking Publishing
TEL	+886-2-8692-5588
Cover Price	NTD 300
Sales Center	Government Publications Bookstore, Sung Chiang Branch 1F, No.209, Sung Chiang Rd., Taipei City +886-2-2518-0207 Wu-Nan Bookstore No.6, Zhongshan Rd., Taichung City +886-4-2226-0330
ISSN	2313-5093
GPN	2010301353
Copyright	Taiwan Food and Drug Administration, Ministry of Health and Welfare

Safe and effective
medicinal products,
safe and healthy food

ADD：No.161-2, Kunyang St, Nangang District,
Taipei City 115-61, Taiwan (R.O.C)
TEL：(02) 2787-8000 WEB：www.fda.gov.tw

ISSN 2313-5093
9 772313 509006