2020

Taiwan Food and Drug Administration Annual Report

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FDA

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Contents

Foreword by the Director-General

The mission of the Taiwan Food and Drug Administration (TFDA) advanced public health by helping them to have safe and effective medicinal products, safe and healthy food. Under the vision of "Being a reliable guardian on food and medicinal product safety" and "Creating a safe food and medicinal consumer environment." TFDA aims to regulate the safety and quality of food, drugs, medical devices, and cosmetics that are daily used by the public, and promote every citizen's health and the public welfare at the same time. In order to document the important policies and implementation of TFDA, an annual report that summarizes various important policies, plans, and achievements in the previous year is prepared every year and published domestically and internationally for reference.

In 2019, TFDA continued to improve its work in various aspects and achieved excellent results. For food safety management, in order to tackle the current rapid food developments such as diversification, novelty, and digitalization, we adopted the full life-cycle management model of farm-to-table to ensure the hygiene and safety of food in the food production chain. Moreover, TFDA stipulated the "*Guidelines of Hygiene Self-Management for Online Food Delivery Platform Business Operators*" to strengthen hygiene management. TFDA also intensified the implementation of the "Five-Point Food Safety Policy" and continued to carry out food safety related work. In addition, TFDA has created a comprehensive management system to ensure a "Safe and Healthy" food environment for consumers through the cross-departmental coordination, multiple review, and risk management by implementation of big data.

The management of the drug life cycle must be in compliance with good operating practices, furthermore, to effectively ensure the safety, efficacy, and quality of pharmaceutical products, TFDA has put considerable effort into improving drug management regulations and its vital participation in international events to enhance Taiwan's participation in the management of pharmaceutical administration internationally as well as create a regulatory environment that is in line with international standards. In order to reinforce risk management, we continue to improve the drug registration and review mechanism, pharmaceutical distribution and marketing regulations, digital management, quality and safety management, and quality inspection technology, to achieve a win-win situation for consumers, business operators, and the government.

Regarding the management of controlled drugs, TFDA conducts periodic reviews and revises the laws and regulations related to the "*Controlled Drugs Act*" to enhance the precautionary monitoring of drug abuse. TFDA also actively cooperates with Executive Yuan to develop diverse channels for drug abuse prevention and launch a series of programs to raise the public's awareness of drug abuse in rural areas, communities, and workplaces.

It is worth mentioning that in 2019 TFDA completed the promulgation of 30 regulations and provisions related to the "*Cosmetic Hygiene and Safety Act*" to create a safer environment for cosmetic users. The Legislative Yuan also passed the third reading of the "*Medical Devices Act*" on December 13, 2019, to respond to the current development of global medical devices and diversity of medical devices products. These two policies signify the beginning of a new era for the management of medical devices and cosmetics and accelerate the development of smart medical devices. The two policies also demonstrate that TFDA makes efforts to respond to the development of emerging technologies.

TFDA continues to develop testing methods and enhance its inspection capacity and capability. TFDA actively engages in international cooperation, including extensive participation in ICH related conferences to demonstrate Taiwan's strength in the field of medicine, participation in affairs regarding the IMDRF regulatory and conducting seminars to amplify Taiwan's international recognition. Also, implement the framework agreement on pharmaceutical regulatory cooperation between Taiwan and Japan, and encourage the information exchange on pharmaceutical regulations with the targeted countries in New Southbound Policy. With active participation in various international events, the international image and influence of our country are enhanced significantly, and the multilateral cooperation opportunities are encouraged to achieve a win-win situation for the participating countries.

Given the health education and information obtained by the public is no longer limited to traditional media, TFDA has set up "TFDA LINE@" in March 2019 to effectively provide correct information in order to put a stop to false facts while being positive and friendly. As of 2019, TFDA has more than 64,000 friends!

With the rapid development of technology, the hygiene and safety issues on food and drug are becoming more complicated. TFDA will stay forward-thinking to face future challenges through integration of cross-departments, businesses and consumers, and encourage public participation to establish a comprehensive safe network for food, drug, and cosmetic.

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

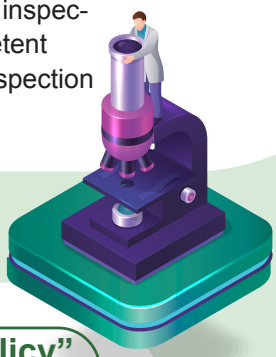
Ch1

Organization and Policies

Forward-looking Infrastructure Development Program (infrastructure to ensure food safety)

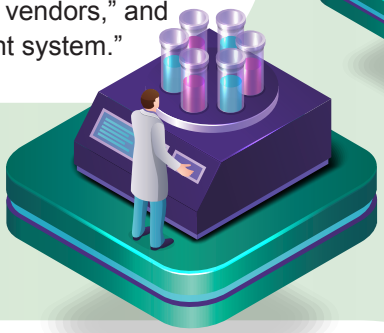
Execute 4 sub-programs

"The construction plan of modern national food and drug laboratory and educational training buildings" "Efficiency improvement program to expedite border inspection system," "Program to strengthen health department's food safety audition and inspection capacity" and "Program to strengthen central competent authority's food safety, safe drug use, and illegal drug inspection capacity."



Implement "Five-Point Food Safety Policy" reform plan

"Source control and management," "Strengthen government inspection capabilities," "Encourage and create oversight platforms," "Increase liability for producers and vendors," and "Re-establish the food production-mamagement system."

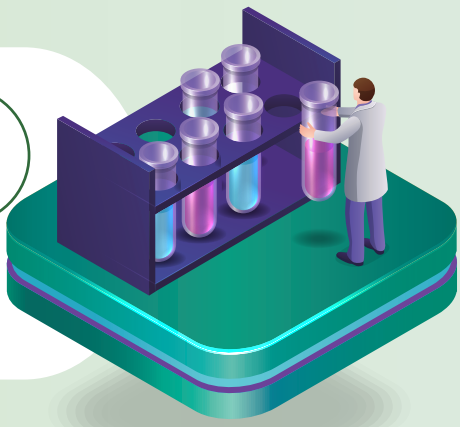


Improve the comprehensiveness of the regulatory environment

Strengthen the control of the drug supply chain, and promote the regulation of the Management of Regenerative Medicinal Products to ensure the safety of drug use for the citizens in Taiwan.

Actively promote the legislation of the *Medical Device Act* and announced the relevant sub-regulations such as the *Cosmetic Hygiene and Safety Act*

To meet the international standards, enhance consumer protection, and facilitate the development of medical devices and the cosmetics industry.



01 Organization and Policies

Taiwan Food and Drug Administration of the Ministry of Health and Welfare (TFDA) was founded on July 23, 2013, as part of the organizational reform in the Executive Yuan. To fulfill 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 source, production, and distribution management, TFDA continues to devote in establishing a comprehensive safety management system for food and drugs to ensure the safety and quality of food and drugs for consumers.

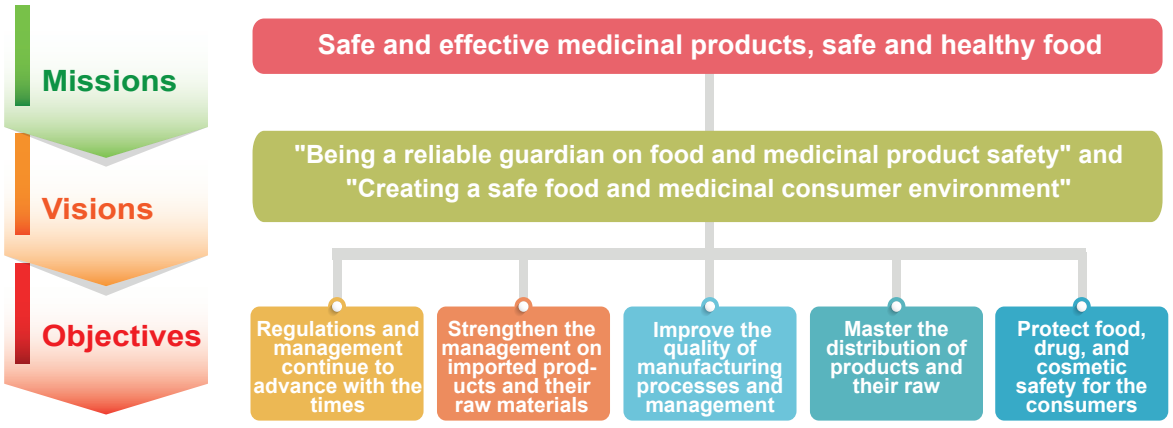


Figure1-1 TFDA visions and mission

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, TFDA is also composed of 5 Administrative Units (Office of Secretariat, Office of Personnel, Office of Accounting, and Office of Information management) to support administrative/management matters (Figure 1-2). Also, TFDA has two Task Forces (i.e. Manufacturing facility for controlled drug and Decision Support Center) to provide professional information and assistance through professional consultation units such as Center for Drug Evaluation, Taiwan and Taiwan Drug Relief Foundation.

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 2019.

I. Enhance international regulatory harmonization and increase the R&D capacity and capability, strengthen food supply chain and drug full life-cycle management strategies, and reinforce the policy environment for food and drug safety.

II. Re-inforce the risk management and analysis mechanism, improve the trace and track system, and optimize the effectiveness of the food and drug safety protection framework.

III. Actively promote the communication and dissemination of food and drug safety to enhance the knowledge of the general public and the transparency of information, as well as to protect the safety of usage for consumers.

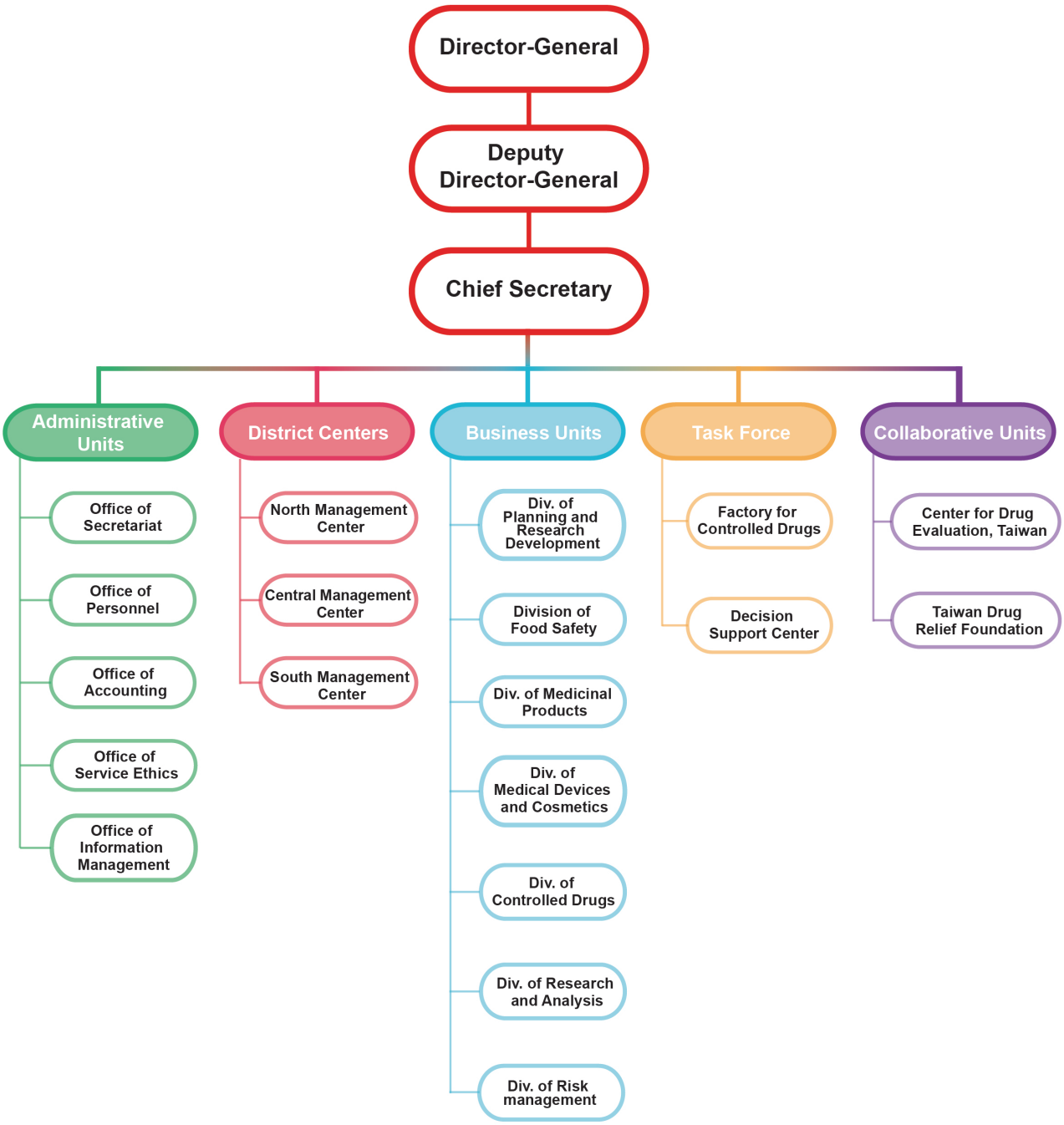


Figure 1-2 The Organization Framework

Section 3 Food Management Overview

Food safety is closely related to the health of the citizens. With free global trade, booming development of technology and the constantly changing food safety issues, the diversified, innovative, and information-based management aspect is the current trend. TFDA adopts a full life-cycle food management model of "farm-to-table" to ensure the hygiene and safety of products from the manufacturing of raw materials to the sales and circulation process (Figure 1-3); and reinforces the implementation of the "Five-Point Food Safety Policy," (Figure 1-4) which is an across-domain integration from five aspects such as the source management, production management, market inspection, manufacturer's responsibility and supervision by the citizens, to establish a comprehensive food safety protection network.

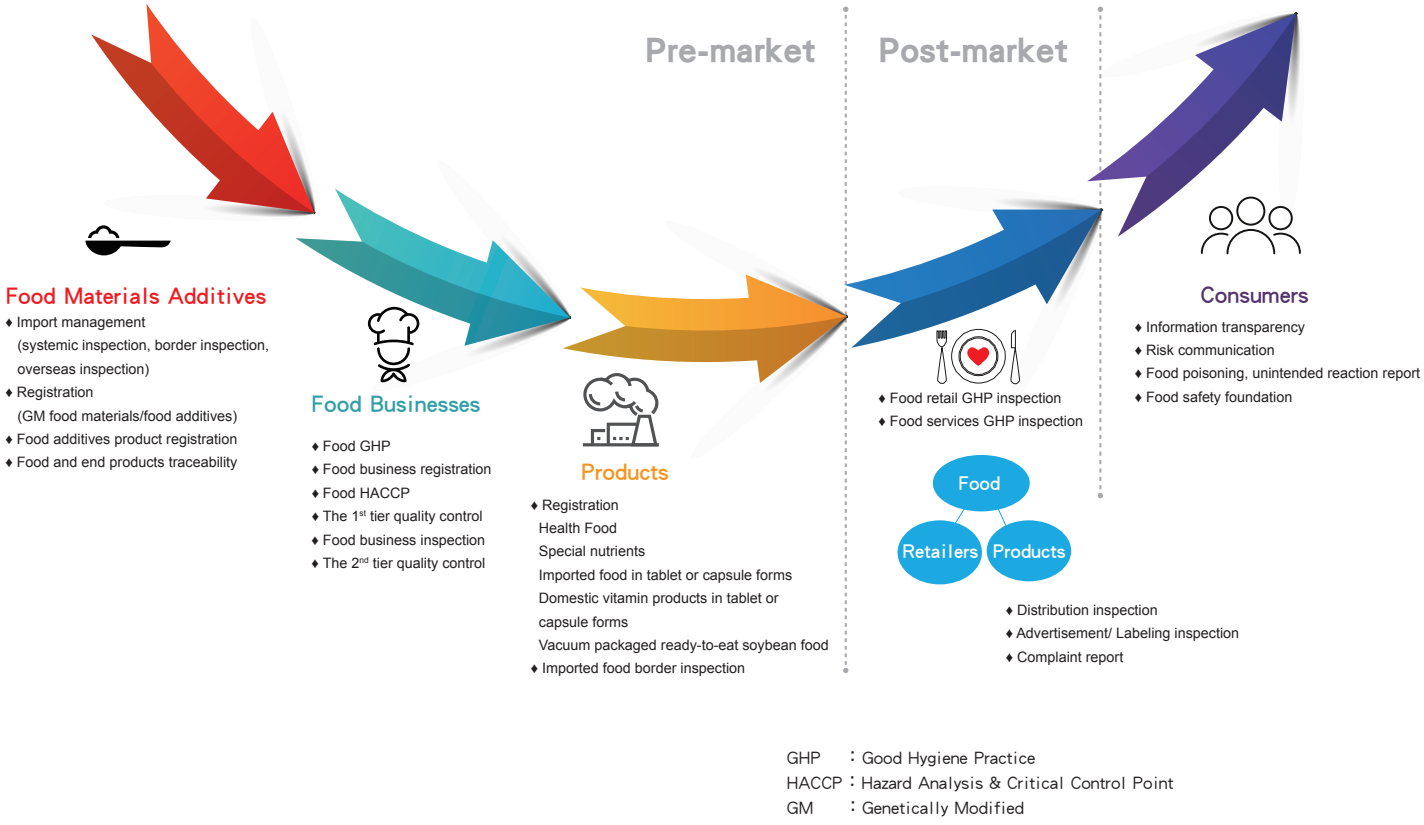


Figure1-3 Food management framework

TFDA aggressively collects and refers to international food management standards and technologies, and conducts rolling reviews for addition and revision of relevant regulations related to the "*Act Governing Food Safety and Sanitation*" and develops new food inspection methods. Meanwhile, TFDA practically implements the vertical cooperation mechanism between the central and local governments to conduct inspection at borders, food inspection projects, and post-market monitoring, putting more effort into food safety.

Figure1-4 Five-Point Food Safety Policy

Section 4 Overview of Drugs and Controlled Drugs Managment

I. Medicinal products management framework

In the life cycle management of medicinal products, from product development, preclinical trials, clinical trials, marketing application, manufacturing to marketing, etc., various good operating practices must be followed. Different from general consumer goods, medicines can only be sold on the market after obtaining a marketing authorizations issued by the central health authority. In order to ensure the safety of the public, TFDA continues to strengthen the quality management policy throughout the drug life-cycle (Figure 1-5) by the international harmonization of regulatory management, the establishment of various priority review mechanisms, digital management, standardization of quality and safety surveillance, inspection of illegal drugs, management of pharmaceutical vendor and drug circulations, etc. All of these measures are to ensure the safety, efficacy, and quality of drugs, so that those in need can obtain them as soon as possible. These measures can also promote the development of biotechnology industry in Taiwan and create a win-win situation for patients, business owners, and the government.

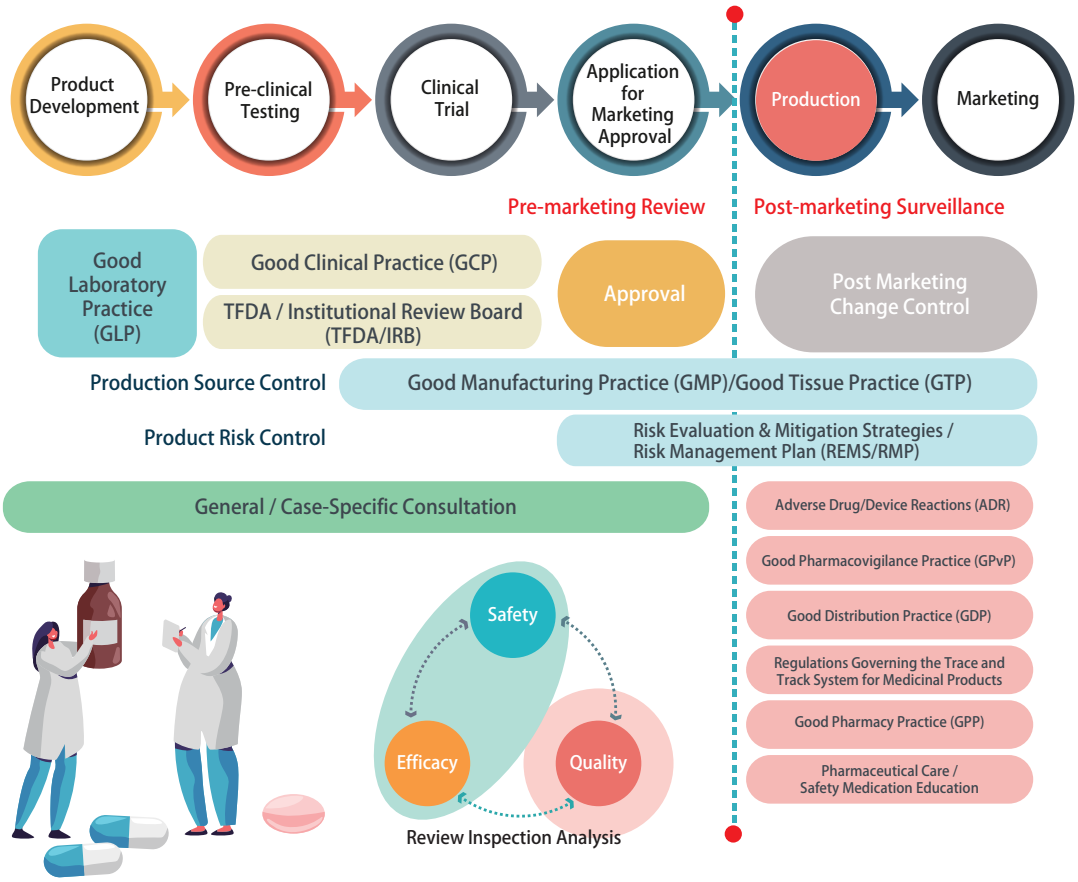


Figure 1-5 Life cycle management framework for medicinal products

II. Controlled drugs management framework

All countries value the importance of drug abuse issue nowadays, especially the addictive controlled drugs, as they will be likely to harm the citizens' health due to improper or illegal use. Therefore, the management of addictive controlled drugs and prevention of drug abuse are important issues to the society and the public health nowadays. According to "Single Convention on Narcotic Drugs (1961)," "Convention on Psychoactive Substances (1971)," and "Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of the United Nations (1988)," Taiwan has imposed controls on narcotics, psychotropic substances and their preparations through the "*Narcotics Hazard Prevention Act*." However, due to the necessity of controlled drugs in medical or scientific application, the "*Controlled Drugs Act*" has been established to give a control framework, which is composed of licensing, scheduling, and diversion management (Figure 1-6) to complete the management of controlled drugs.

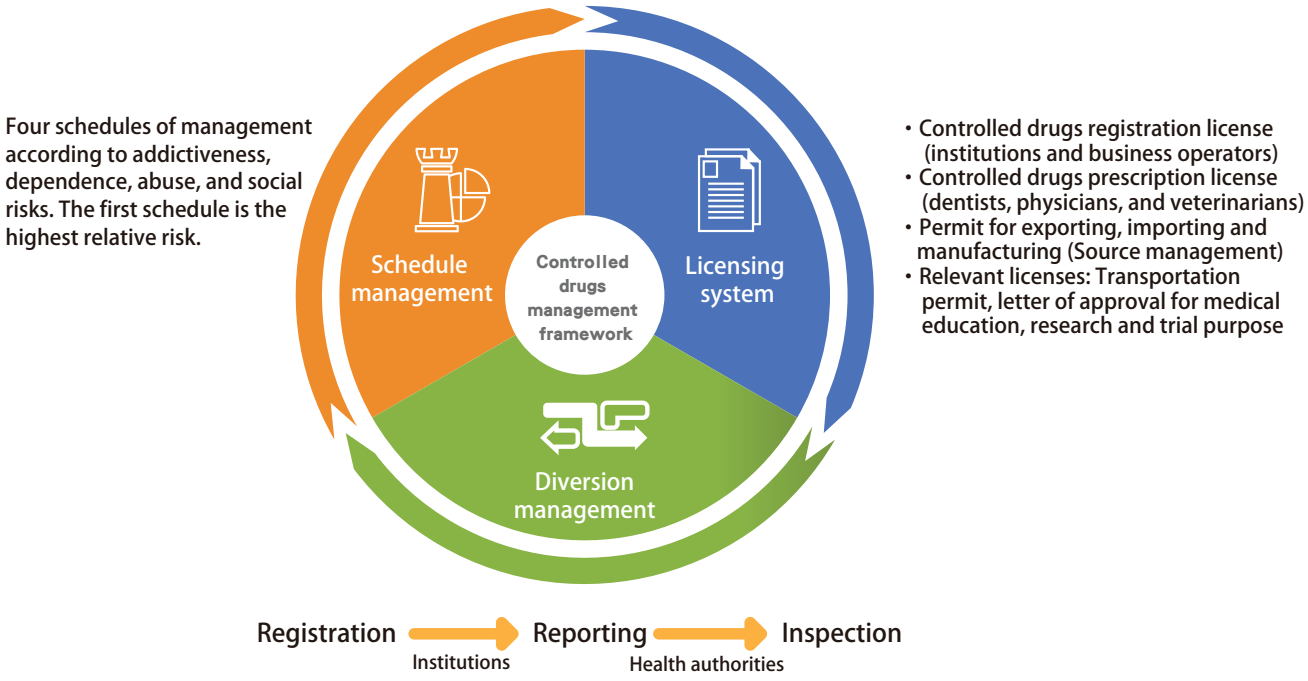


Figure1-6 Controlled drugs management framework

Section 5 Overview of Medical Devices and Cosmetics Management

I. Medical devices management framework

The medical device industry is poised to become Taiwan's leading biotech industry in terms of development potential, given its rapid developments in technology and growing demands for healthcare technologies. In response to the growing prospects of the medical device industry in Taiwan, TFDA has established a Total Product Life Cycle (TPLC) management policy for medical devices (Figure 1-7) that includes harmonization with international standards and regulations, production source control, pre-market control, post-market surveillance, management of pharmaceutical companies and product distribution channels, and provision of professional counseling services. The purpose of the TPLC policy is effectively control the safety, performance, and quality of medical devices, and to promote the developments of Taiwan's biotech and pharmaceutical industry, in order to create an environment beneficial for consumers, industry, and government.

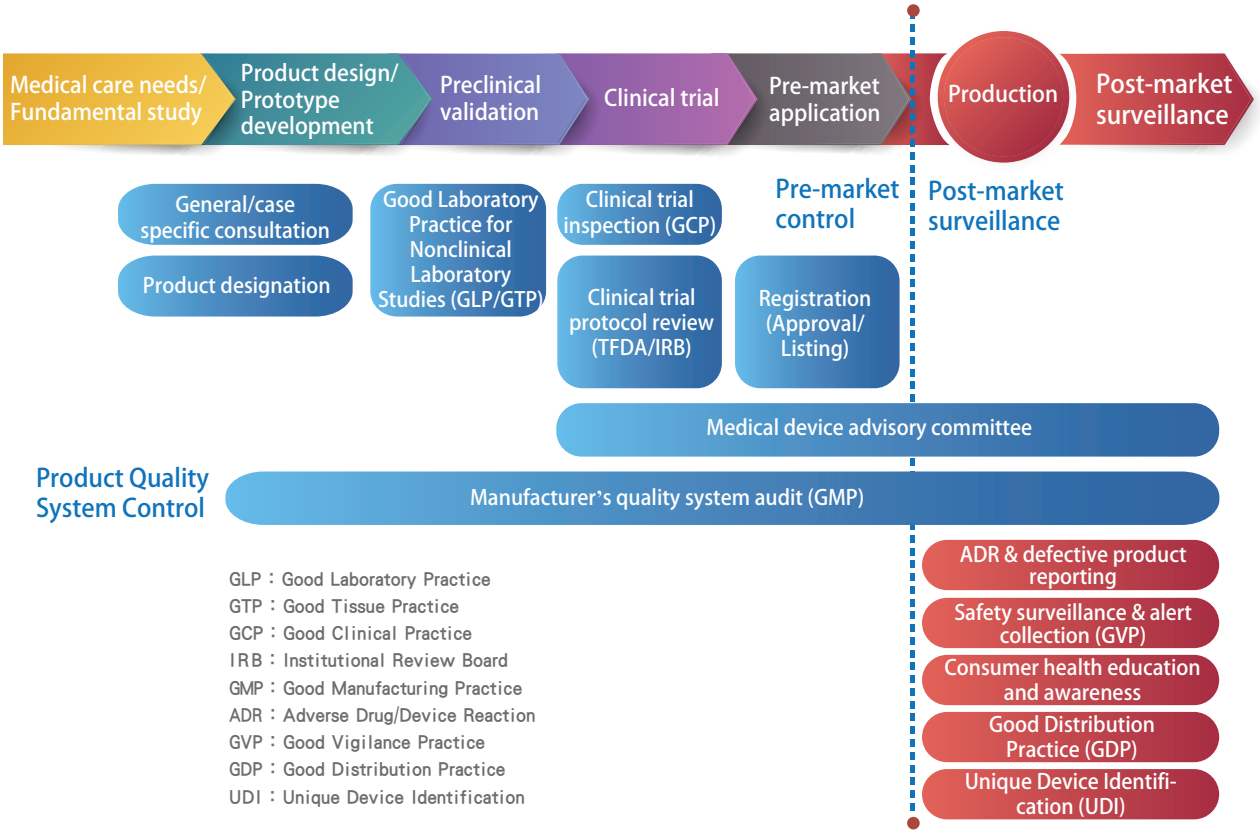


Figure1-7 Total product life cycle management policy for medical devices

II. Cosmetics Management framework

The current cosmetics management system is dividing into production source control, premarket management, and post-market surveillance. (Figure 1-8) Source control management includes ensuring that manufacturing facilities comply with Establishment Standards for Cosmetics Manufactory and Cosmetics Good Manufacturing Practice (GMP) Regulations. The pre-marketing management includes product notification and establishment of product information files to replace the registration of specific-purpose cosmetics after the 5-year transition period; post-market surveillance focuses on implementing cosmetics quality surveillance programs, joint audits spanning multiple counties and cities, establishing a product adverse event reporting system for cosmetics, monitoring of domestic and global cosmetic safety alerts regularly, and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.

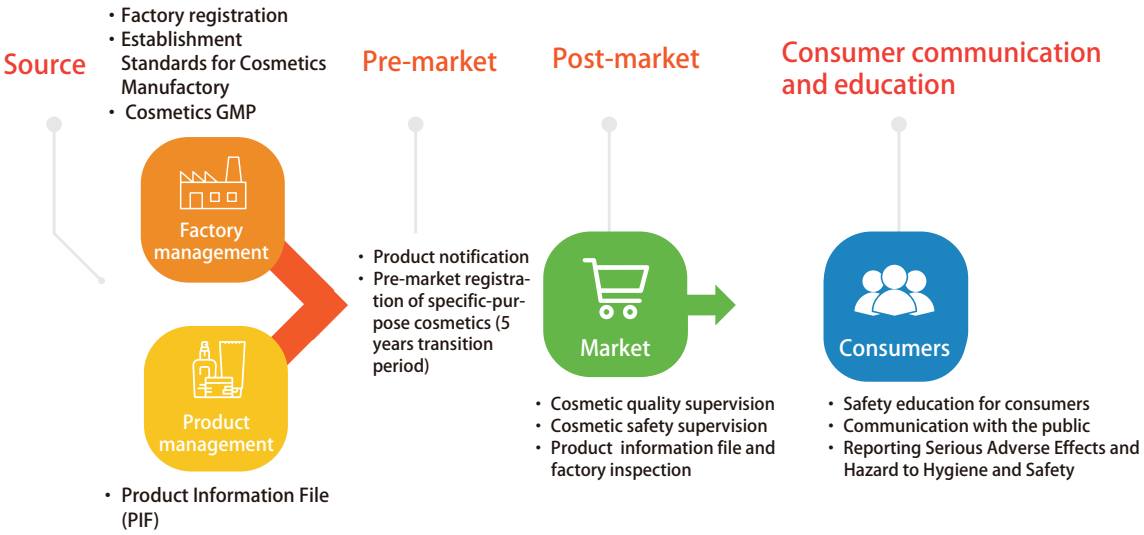


Figure 1-8 Cosmetics Management Framework

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 plans include:

I. Adopting the Forward-looking Infrastructure Development Program (infrastructure to ensure food safety) to respond to future challenges, and execute 4 sub-programs, i.e. "The construction plan of modern national food and drug laboratory and educational training buildings," "Efficiency improvement program to expedite border inspection system," "Program to strengthen health department's food safety audition and inspection capacity," and "Program to strengthen central competent authority's food safety, safe drug use and illegal drug inspection capacity."

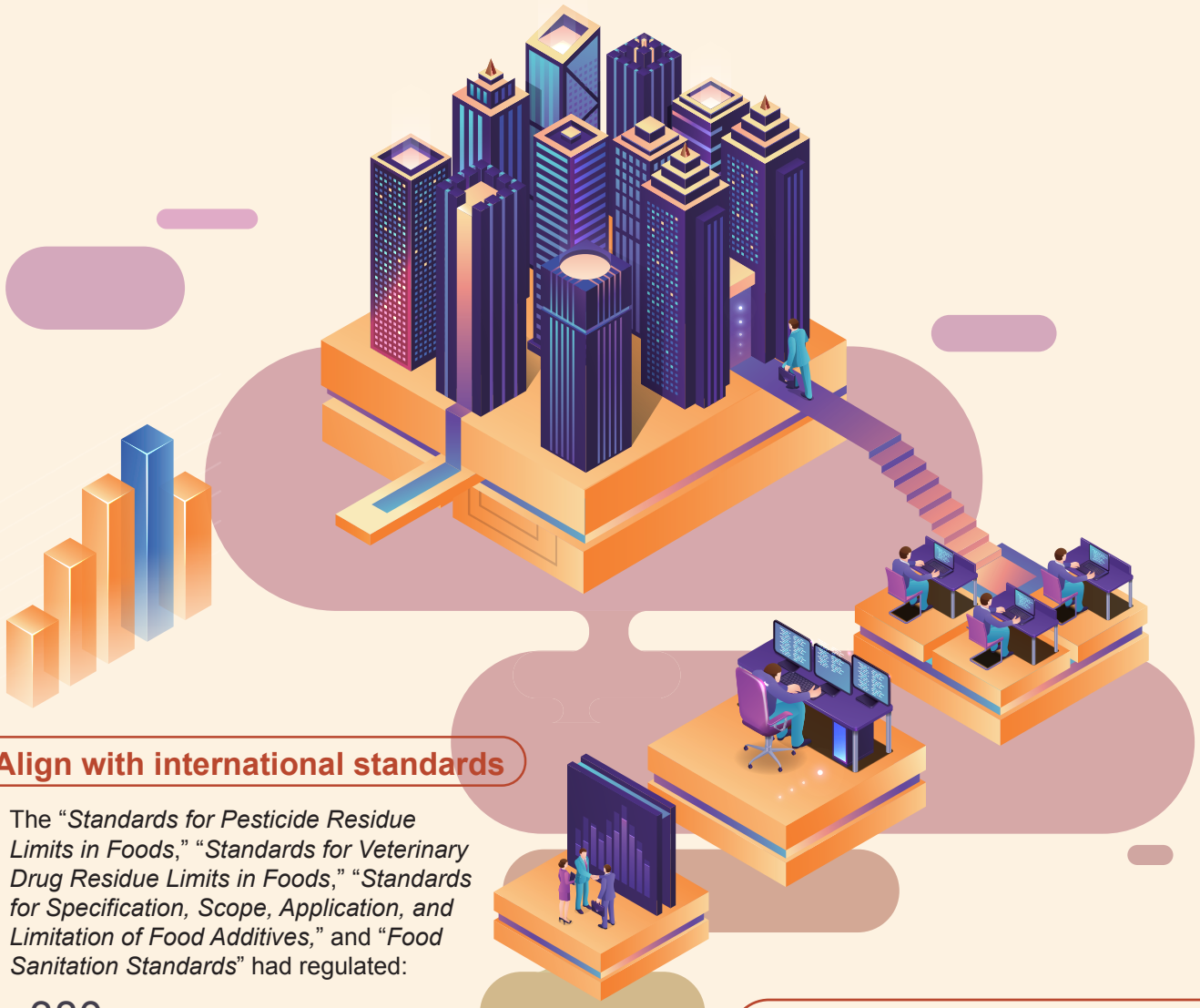
II. Implement "Five-Point Food Safety Policy" reform plan, continue to expand the food safety management resources, combining business self-management and public participation to maximize the effectiveness of limited resources by executing these management strategies, the three-tier product quality management will be practically carry out, and the domestic food management capacity will be enhanced.

III. Improve the comprehensiveness of regulatory environment, strengthen the control of drug supply chain, and promote the regulation of the Management of Regenerative Medicinal Products to ensure the safety of drug use for the citizens in Taiwan.

IV. Actively promote the legislation of the *Medical Device Act* and announced the relevant sub-regulations such as the *Cosmetic Hygiene and Safety Act* to meet the international standards, enhance consumer protection, and facilitate the development of medical devices and cosmetics industry.

Ch2

Strengthen the Management of Food Safety



Align with international standards

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:

380	Pesticides
7244	Residue limits for pesticides
142	Veterinary drugs
1439	Residue limits for veterinary drugs
792	The scope of use, limits and specifications for food additives
28	Sanitation standards

Improvement of Drug Quality Inspection Technology

Food promulgated methods stipulate and amend 25 articles and 640 items.

The recommended method for food test stipulates and amend 43 articles and 433 items.

Improve the Regulations of Food Management

Reviewed the "*Act Governing Food Safety and Sanitation,*" *and the "Health Food Control Act.*"

Specified the "*GHP Guidelines for Manufacturers of Liquid Egg Products,*" "*Sanitation Standard for Liquid Eggs,*" and "*Regulations Governing the Labeling of Liquid Egg Products.*"

Specified the "*Regulations Governing the Labeling of Health Food.*"

Specified the "*The Online Food Delivery Platform Safety and Health Management System Guidelines.*"

02 Strengthen the Management of Food Safety

To ensure and provide a safe and healthy "food" environment for the citizens in this country. TFDA will continues to reinforce the food safety management with so called "Five-Point Food Safety Policy," including enhance the import and export management to overseas markets, to improve the existing regulation of food management, to reinforce the inspection and monitoring in food product and supply chain, to upgrade the verification system for food industry hygiene and safety management, to cross supervise and application via current food safety digital systems and research of inspection technology for new substances to avoid unexpected risk. Furthermore, we established a comprehensive farm-to-table food safety management system under cross-checking coordination mechanism to complete subject program.

Section 1 Improvement of Imported and Exported Food Management

Introduction of the Policy

The "*Regulations for Systematic Inspection of Imported Food*" was revised in 2019 , as added items of import products subject to systematic inspections to strengthen the management of import foods and control the high risk products from the beginning of the source; TFDA announced the control measure that the official certificates from the exporting country should be attached for specific imported foods. In addition, according to Article 30 of the "*Act Governing Food Safety and Sanitation*" rolling reviews of items that should apply for inspection are conducted by TFDA to ensure the safety and sanitation of the imported foods.

On the other hand, TFDA also promotes exporting food products. Other than simplifying the application process of export proof documents of processed foods, we cooperation with interagency and put efforts on assisting Taiwan food products to export to Singapore and Korea or etc. In 2019, Directorate General for Health and Food Safety (DG SANTE) had conducted the on-site inspection in Taiwan regarding to the application of exporting animal origin food products to the EU. To expand our overseas markets as well as enhance Taiwan's international competitiveness in food industry.

Implementation Strategy

I. Strengthen the systemic and border inspection system and reinforce food safety control by health certificate mechanism

To strengthen the food safety management of imported animal source products, we refer to the international management models and conduct the overall systemic inspection to evaluate the equivalence of the food safety management system and the supervision measure of the exporting country. Moreover, the official certificates of the exporting country are required for the import of specific animal-source foods.

In addition, TFDA through the customs notification platform mechanism of "declared as food usage for imported goods without import food regulations" that was established with the Customs Administration, Ministry of Finance, by the cross-departmental coordination consolidates import food related information on a quarterly basis and the inspection results of TFDA's regional administrations and public health bureaus, as well as announced the amendments to application of inspection product commodity classification number.

II. Assist food businesses to export food products to the EU

On the basis of the EU regulations, it is required for competent authority to submit an application to DG SANTE and fill in the relevant questionnaires and residue plan in non-EU member countries who intend for export animal origin food products to the EU. DG SANTE will conduct an on-site inspection to assess whether the official control systems is in line with the requirements laid down in the EU legislation. TFDA cooperate with domestic food businesses, and submitted the relevant questionnaires to DG SANTE for applying exported meat, dairy, and egg products to the EU.

III. Improve the application process for the sanitary certificates of processed foods for export

(I) Starting on April 15, 2019, by connecting with the "Food and Drug Operator Registration Platform" (FadenBook system) and optimized the "Application System for Export Food Sanitary Certificates" (Asefsc system), the application documents that were originally required to be attached such as the factory or company registration certificates and the statements have been simplified. TFDA also integrated the audit records and simplified the application process for the "Sanitary Certification" which the manufacturers have been audited by the competent authority and comply with the Good Hygiene Practice (GHP) within 6 months.

(II) From July 1, 2019, the online application for those sanitary certificates of processed food for export has been fully implemented. And followed by October 1, 2019, TFDA has also provided multiple payment services and changed the notice of receiving certificates from a paper document to an electronic notice.

Achievements and Benefits

I. Expand the scope of inspection items and reinforce border control

In 2019, three dairy products and products of deer-derived were added and expanded the scope of products subject to systemic inspection to six types; moreover, the animal-source imported foods includes eggs and egg products, gelatin and its derivative products are required to attach the official certificates to prove the products are human consumption or to prove the products are in accordance with food safety and sanitation regulations of the original exporting country.

Another 27 item numbers were completed the revision, including the pumpkin seeds, genetically modified or non-genetically modified corn shoots, fresh or frozen aquatic products, etc. Thus, a total of 2,640 item numbers that required to be inspected at the border.

II. Promote bilateral communications between Taiwan and European Commission, and gradually expand the overseas markets

The DG SANTE had sent the audit team to Taiwan during October and November 2019, to conduct on-site inspection for animal origin food products intended for export to the EU. TFDA hosted the inspection, and the audit team visited 10 export products manufacturers and the Department of Health, Taipei City Government, the Kaohsiung Port, the Kaohsiung Branch of the Animal and Plant Quarantine Bureau of the Council of Agriculture, Executive Yuan and the Kaohsiung City Animal Protection Office. Based on the evaluation results, DG SANTE will assess Taiwan's animal origin food management system, the production system of business operators and the equivalence of the EU regulations (Figure 2-1).

With the on-site inspection and interaction between in Taiwan and the audit team of DG SANTE, TFDA had a better understanding of the EU food management regulations. The

Figure2-1 The closing meeting between the audit team of DG SANTE and Taiwan. DG SANTE visited the border inspection operations of TFDA's Southern Center for Regional Administration Center in the Kaohsiung Port.

interaction will facilitate Taiwan's food industry to enter the international market. TFDA continues to reinforce the bilateral cooperation between Taiwan and the EU to facilitate the diverse development of Taiwan's export market and products.

III. Simplified the application process for the sanitary certificates of processed food for export

With the measures such as online applications, simplified the application process and provide multiple payment methods, the reviewing days for the application has been shortened by 2 working days. The application for "Sanitary certification" those who meet the specified conditions can greatly save the application time. In addition, the electronic notice also improves the efficiency of document delivery. The applicant's average satisfaction with the relevant measures reached 93%.

Section 2 Improve the Regulations of Food Management

Introduction of the Policy

In order to improve the food management regulations in Taiwan, The "*Act Governing Food Safety and Sanitation*" was reviewed three times in 2019, the precautionary principles for the case of important or emergency food hygiene and safety incidents, the management regulations for the processed aids and the penalty for spreading false food safety information were included in the provisions of the "*Act Governing Food Safety and Sanitation*"; the relevant food safety regulations were reviewed and a total of more than 40 regulations have been added or revised, including various food hygiene and safety standards, regulations for logistics operators, regulations for liquid egg management, the hygiene management personnel system of food factory, and the efficacy evaluation and labeling regulations for health food. We also promote multiple policies to enhance the professionalism of business operators' self-management, to ensure the hygiene and safety in the food production and supply chain.

Implementation Strategy

I. Food hygiene and safety standards

We refer to the international standards and adopt the risk assessment principles to conduct comprehensive evaluation on research results and standards according to the scientific evidence and toxicological tests, including "*Standards for Pesticide Residue Limits in Foods,*" "*Standards for Veterinary Drug Residue Limits in Foods,*" "*Sanitation Standards,*" and "*Standards for*

Specification, Scope, Application and Limitation of Food Additives," to align with international management standards.

II. Full registration system of food businesses

We establish a comprehensive food registration system in order to strengthen the management of basic information of business operators in the food industry, including logistics business operators, and enhance the management efficiency.

III. Hire professionals in the food industry

As more and more types of food industry and management, to improve food hygiene and safety professionalism is more important. According to the business operators' capital and number of employees and conduct implementation in various years and stages, we expand the scope and strengthen the management of food manufacturing factories to ensure food hygiene and safety. For example, food businesses belonging to a category and scale designated by the central competent authority in a public announcement shall have sanitation control personnel in accordance with Article 11 of the "*Act Governing Food Safety and Sanitation.*"

IV. Improve the management of liquid eggs

TFDA has clearly specified the "*GHP Guidelines for Manufacturers of Liquid Egg Products,*" "*Sanitation Standard for Liquid Eggs,*" and "*Regulations Governing the Labeling of Liquid Egg Products*" in order to establish the relevant specifications of liquid egg products for liquid egg manufacturers to follow; we practically implement the source management of the production to prevent unqualified or poor hygiene liquid egg products from being used in the food production supply chain.

V. Strengthen the management regulations for health food

The assessment of the health care effects for health food have been revised in order to update the evaluation and test methods for the "health care effects" of health food and related specifications, to ensure the validity of the health care effects assessment experiments and enhance the product quality. In addition, in order to provide consumers with clear information and prevent misunderstanding in regard to health food, it is stipulated and specified the "*Regulations Governing the Labeling of Health Food*" and "precautions" shall be labeled on the external package depending on the type of health food products.

VI. Re-inforce the management of online food delivery platform

The online food delivery platform is a new type of business. Consumers order food via the Internet and the delivery service personnel deliver the food to an appointed location. The conduct in regard to the provision of food delivery service should comply with the regulations related to the "*Act Governing Food Safety and Sanitation*." We have also stipulated relevant management guidelines for the business operators to follow.

Achievements and Benefits

I. Align with international standards

As of December in 2019, 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 7,244 residue limits for 380 pesticides; 1,439 residue limits for 142 veterinary drugs; the scope of use, limits, and specifications for 792 food additives; 28 sanitation standards.

II. Improved the registration system of food business operators

We announced the amendment to the "Category, Scale, and Implementation Date of Food Business Operators that Require Registration Before Operation" on April 26, 2019; and we specified the scale and implementation timeline of logistics business operators that are required to be registered, to accurately management the information of logistics business operators. As of the end of 2019, a total of about 470,000 food business operators had been registered, including food manufacturing and processing, import, sale, food service, and 1,400 logistics business operator.

III. Enhancement of self-management in food manufacturers

In 2019, "all categories" of food manufacturing factories shall have sanitation control personnel. It is expected to implement food safety management in the factory and enhance the self-management ability of food business operators with the implementation of professional personnel.

IV. Reinforce the egg industry chain management

(I) Stipulate the regulatory standards and operating guidelines

1. "*Sanitation Standard for Liquid Eggs*" and "*Regulations Governing the Labeling of Liquid Egg Products:*" Announced on November 7, 2019 to strictly regulate the types of shell eggs can be used for making liquid eggs and standard for microorganisms in liquid eggs; as for the labeling of liquid egg products, they are required to label the name of the product with the wording "pasteurized" or "unpasteurized," as well as the expiry date and storage condition. For unpasteurized liquid egg products, an additional labeling of "The product must be used in the production of foods that will be sufficiently heated or other processing methods sufficient for effective pasteurization" or other synonymous terms is required.
2. "*GHP Guidelines for Manufacturers of Liquid Egg Products:*" They were issued on March 14, 2019 and the monitoring key points for the manufacturing process of raw material acceptance, sterilization, and storage temperature are provided for reference as well as for the liquid egg manufacturers to follow.

(II) The counseling and introduction workshop for business operators: To enhance the understanding of laws and regulations for egg product manufacturers, we conducted a total of 47 counseling sessions for manufacturers as of the end of 2019; and 2 workshops

regarding the "*Act Governing Food Safety and Sanitation*" for product manufacturers were held, with a total of about 100 participants.

V. Improve the assessment method for health care effects and the product precautions

(I) On March 28, 2019, "The efficacy assessment method of health food to enhance iron bioavailability" was amended and announced to optimize the assessment method of health care effects, as well as to ensure the consistency of iron bioavailability in experimental method and relevant regulations.

(II) Regulations Governing the Labeling of Health Food:

1. Health food in capsule and tablet form shall have containers or packages labeled with the following precautions (Figure 2-2):
   (1)"This product is not medicine and only for health care purpose. Any person having the disease shall seek medical treatment."
   (2)"Please take recommended volume and avoid excessive intake."
2. Health food other than capsule and tablet form shall have containers or packages labeled with the following precautions (Figure 2-3): "This product is only for health care purpose, please take recommended volume."

VI. Enhance the hygiene management of food delivery

The "*Guidelines of Hygiene Self-Management for Online Food Delivery Platform Business Operators*" were stipulated on September 19, 2019 and the content includes: the delivery personnel are required to regularly take the hygiene education and training and the delivered food must be kept clean and hygienic.

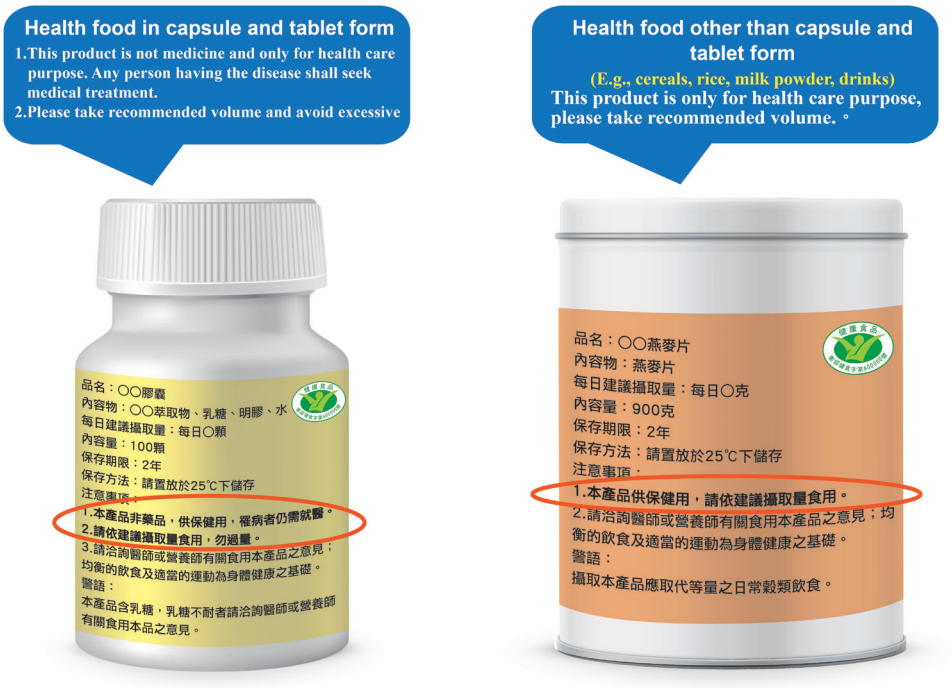


Figure2-2、2-3 Regulations governing the labeling of health food

Section 3 Reinforce Supervision of Food Production Chain

Introduction of the Policy

In order to offer a reliable food safety environment for all consumers, we precede the farm-to-table program as 3-tier food quality of management system. The competent authority is responsible for supervision and inspection through overseas source inspection, imported product inspection at borders, post-market inspection, and cooperation with police to enhance the inspection of food and drugs, to identify the potential risks and product items and adopt the warning and control measures in advance.

Implementation Strategy

I. Overseas on-site inspection

For the management of source control, the central competent authority refers to the imported records over the years, and dispatches personnel to the exporting country to conduct on-site inspection for the food safety and hygiene of imported foods.

II. Inspection of imported products at borders

The annual inspection plan will be stipulated every year in order to ensure the safety of imported food products, and we will review and adjust the inspection methods and items with the rolling approach according to the criteria such as inspection records, characteristics of products, and domestic and foreign information, etc. The foods that do not pass the customs clearance inspection at borders will be returned or destroyed according to the regulations, furthermore, the information of these products such as company name, address, product name, and illegal status may be revealed to the public. At the same time, TFDA will increase the product sampling rate up to inspection batch by batch if necessary.

III. Domestic manufacturing processing and circulation supervision

We plan national food inspection projects with reference of the food inspection data in the past, public opinion and concerned subjects, violation patterns of incidents and market distribution, production and sales models, to reinforce the inspections on high-concern, high percentage of violation and high-risk projects. We also supervise and assist the health bureaus of local governments to conduct implementation of food inspection and management and adopt the two-way inspection of source manufacturing and distribution sales to strengthen the food hygiene and safety.

IV. Collaborative cross-department inspection

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

V. Cooperative investigation between prosecutors and police

Every year, we conduct the "Strengthen the Food and Drug Crime Study Seminar" with the Ministry of Justice, to create good communication channels with the prosecutorial authorities, reinforce the mutual assistance in judicature, we also invited the Seventh Special Police Corps to participate in the seminar to enhance the efficiency of food and drug investigation.

Achievements and Benefits

I. Overseas source inspection

In 2019, we conducted the routine overseas inspection for countries and processing manufacturers with import records, with a total inspection of 18 factories. The overall evaluation in the food production processes of the inspected foods meets the relevant domestic regulations.

(I) 1 special dietary foods factory in the United States.

(II) 1 beef factory and 5 pork factories in Canada.

(III) 6 beef factories in the United States.

(IV) 5 kimchi factories in Korea.

II. Inspection of imported products at borders

A total of 718,766 batches of food related products were inspected at the customs clearance in 2019, including 89,639 batches were inspected on site and 58,108 batches were inspected by random sampling. A total of 786 batches failed to meet the inspection requirements, accounting for 1.4% of the sampling batches and the rate of passing the inspection was 98.6%.

III. Domestic manufacturing, processing and distribution supervision

In 2019, the inspected number of domestic business operators in the industry was over 150,000. The qualified rate of GHP food business operators for initial inspection reached 80% and the pass rate for re-inspection was higher than 90%. The number of inspected products and random inspection is 460,000 and the qualified rate attained 99%.

IV. Collaborative cross-department inspection

Two food collaborative inspection projects of the Executive Yuan were conducted in 2019. The collaborative inspection was implemented for commercial longan-honey and washed eggs, 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. In 2019, the inspection for a total of 168 egg products from the chain stores was completed. The inspection results indicate that there is no veterinary drug residue in the eggs and feed of the livestock farms; as for the liquid egg products of the liquid egg manufacturers, there is only one case that was tested positive with Salmonella in the sterilized liquid egg that did not meet the regulations and the case has been penalized. In addition, 29 cases of commercial longan-honey were randomly inspected for 373 pesticides and antibiotics (tetracycline, chloramphenicol) residues and the entire results passed the inspection.

V. Cooperative investigation between prosecutors and police

In 2019, a total of 76 companies were inspected by the prosecutors, and police, and the busted circumstances such as selling expired food and the use of expired ingredients for making food were conducted in accordance with the laws.

TFDA continues to improve the supervision mechanism of the food production and marketing chain and enhance the efficiency of food management to establish a reliable food safety of consumption environment.

Section 4 Implement the 2nd Tier Quality Control Policy

Introduction of the Policy

The "*Accreditation of Certification Body and Sanitation and Safety Control of Food Businesses of Certification Regulations*" was announced on March 11, 2016, setting a new milestone for the 2nd tier quality control with third-party verification; the regulations were revised on June 4, 2019 to further strengthen the 2nd tier quality control management system. Moreover, TFDA assisted the business operators to export the nutritional supplements to Malaysia; both parties agreed to pass the "2nd tier quality control" with "expansion proposal" verification practices. TFDA aimed to facilitate GMP system to be aligned with international standards; improve the quality of MIT products to export successfully.

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 a capital of more than 30 million company manufacturer sugar, salt, starch, flour, soy sauce, and edible oils shall pass the verification. In addition to the preceding announced categories, the food manufacturers can also volunteer to apply for verification.

II. Specification of the verification content

In accordance with Paragraph 2 of Article 8 in the "*Act Governing Food Safety and Sanitation,*" the announced business category shall comply with the Regulations on Food Safety Control System. Therefore, in addition to the Regulations on Good Hygiene Practice (GHP) for Food, the dairy, canned, and oil and fat manufacturers need to conduct the Regulations on Food Safety Control System (Hazard Analysis and Critical Control Points, HACCP) verification.

III. Inspection implementation agencies and personnel

The inspection is conducted by the inspection agency (Food Industry Development Research Institute, China Grain Products Research & Development Institute (CGPRDI) and Central Livestock Industry Association) certified by TFDA. The inspection agency must have ISO/TS 22003 certification 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 inspection 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 inspection agencies and their auditors on a yearly basis to ensure the quality and effectiveness of inspection.

Achievements and Benefits

I. Reinforced the 2nd tier quality control inspection to improve product quality

In 2019, a total of 486 companies were inspected, of which about 93% of the companies passed the inspection. The 2nd tier quality control combines the inspection capability of a fair third-party agency to re-inforce the supervision and management of food hygiene and safety, as well as establish a comprehensive food safety protection system.

II. Simplify the application process of food export to develop export markets

Those business operators who passed the verification can use the 2nd tier quality control with a third-party verification certificate to simplify the process of applying for food export and reduce the waiting time and cost. In 2019, a total of 12 business operators passed the 2nd tier quality control and the "expansion plan" inspection or the regular follow-up inspection. Their related products were successfully exported and we continue to accept the inspection application from the business operators in the industry.

Section 5 Food Safety Risk Management

Introduction of the Policy

As the food safety incidents happen frequently in the world, where most of the incidents are caused by improper use of food additives or illegal use of chemical substances that put human health as risk. In 2019, we conducted supervision on food additives-related to chemical substances in the upstream and downstream direction.

Furthermore, to comply with "African Swine Fever Central Disaster Emergency Response Center," TFDA created the "TFDA African Swine Fever Emergency Response Work Group" to regularly conduct meetings, workshops, education, and training programs based on the Executive Yuan risk management and crisis management standards SOP.

Implementation Strategy

I. Initiated the monitoring and inspection for the flow of food additives and chemical substances

In 2019, TFDA integrated the food cloud, toxic chemical substances, selected chemical substances, and other cross-departmental data. The department applied the big data analytical techniques to track suspicious transactions and looked into the illegal use of food additives from the past three years, to establish a "monitoring module that could link the data from the food cloud to the chemical cloud" in order to better trace the substance.

II. Conducted the 2019 risk management and crisis management workshop

In response to the subject "Crisis management by the government when countering the food safety incidents" and "Risk Management of Multiple Disasters and Distribution of Medical

Supplies," we invited experts and scholars to join the seminar, conducted by experts in this field including Mr. Xu Fu, the Director of the Food Safety Office of the Executive Yuan; Mr. Otsuka Kazuko, the Director of the Ministry of Health, Labour and Welfare, Japan; the Director Mr. Cai MingZhe from the News Center of FTV; and Professor Zhou GuiTian, Director of the National Development Research Institute of the National Taiwan University, for a total of 289 attendees.

III. Convened a meeting of the Central Disaster Emergency Response Center for African Swine Fever

To comply with launching of the "African Swine Fever Central Disaster Emergency Response Center" in December 18, 2018, TFDA conducted 15 meetings and created the "TFDA African Swine Fever Emergency Response Working Group" on December 19, 2018 to respond to the development of the epidemic.

Achievements and Benefits

I. Initiated the monitoring and inspection for the flow of food additives and chemical substances

We convened the "Detection, Analysis, and Inspection Seminar for High-risk Food Business Operators" and chose high-risk business operators generated by the module. In line with the inspection project during Chinese New Year, we found that the GHP food additives of two business operators failed to meet the three special regulatory systems and effectively achieved the risk management goal of food safety with big data.

II. Conducted the 2019 risk management and crisis management workshop

This seminar provided an opportunity for experts to share experience, inheritance, and reinforces the concept of risk and crisis management to the staff of the central and local government, as well as to disseminate and promote the shaped awareness to enhance the ability of strategy planning when they are facing encountering emergency circumstances.

III. Convened a meeting of the Central Disaster Emergency Response Center for African Swine Fever

In 2019, a total of 8 emergency meetings were convened to discuss relevant emergency responses such as online platform management, control measures at borders, post-market inspection, and dissemination of epidemic prevention.

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 such as pesticide or veterinary drug residues as well as to identify unpredictable, unknown or illegal additives may intentionally added and contaminants may generated from manufacturing process that may affect human health, establishing fast and accurate testing methods is required. TFDA continued improving inspection capabilities, and establishing new testing methods to react to emergency incidents, as well as to hold technical exchange and training activities to strengthen domestic testing capacity for food safety.

Implementation Strategy

I. Promoted domestic food inspection technology interaction

We plan to conduct workshops and invite domestic experts and analysts from the laboratories in the industry, government, and academia to share the status and experience of testing technology. Analysts can also learn from each other and expand the network of experts in the field of analytical chemistry. The workshops would enhance the level and quality of domestic inspection institutions and training of the inspection professionals.

II. Aggressively develop 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 the emergency incident. 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. Conducted the "2019 Annual Food Safety and Analytical Techniques Symposium"

TFDA held the "2019 Annual Food Safety and Analytical Techniques Symposium" on August 21 and 22, 2019, to promote the research trend of the domestic food hygiene inspection technology and enhance the technology interactions (Figure 2-4); there is a total of about 200 participants from various industries, academia and research fields. We invited the official scholar

Figure2-4 2019 Annual Food Safety and Analytical Techniques Symposium

Dr. Susanne Ekroth from the Swedish National Food Agency, and Professor Gu GuoLong from department of Applied Chemistry, National Chiayi University to conduct special lectures on analytical methods of pesticide residue and multiple analysis technique. A total of 86 research papers were published, including 14 oral presentations and 72 posters. It is expected to enhance the inspection capabilities of central, local and private laboratories, with the interaction and information exchange from various fields through the seminar.

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

(I) Establish the methods for testing dioxin and dioxin-like polychlorinate biphenyls residues in hairy crabs

TFDA published “Method of Test for Residual Dioxins and Dioxin-Like Polychlorinated Biphenyls in Hairy Crabs (GC-MS/MS Method);” with the liquid-liquid extraction instead of the conventional freeze-dry and Soxhlet extraction, the test time was shortened from 6 days to 4 days which will help speed up the customs clearance of imported hairy crab at the borders to reduce the illegal selling of the products due to the short product shelf life.

(II) Developed the test methods for hydrocyanic acid in cassava products

If the linamarin in cassava was not handled properly, it may cause poisoning as the hydrocyanic acid may be generated in the gastrointestinal tract after intake. TFDA has developed and revealed two inspection methods such as the use of High Performance Ion Chromatograph (HPIC) with electrochemical detector, or the use of High Performance Liquid Chromatograph (HPLC) with fluorescence detector for the analysis of total hydrocyanic acid in cassava products. We conducted the inspection projects at borders and small scale post-market inspection and the inspection results indicated that imported cassava chips have a high risk of cyanic acid residues and hence we increased the sampling rate of cassava chips at borders to prevent the risk from entering the country.

(III) In line with the ban of using the pesticide Paraquat and the use of veterinary drug Fluralaner to establish a test method

TFDA utilizes the liquid chromatography-tandem mass spectrometry (LC-MS/MS) with ultrasonic extraction technology for the development of pesticide Paraquat and utilizes the LC-MS/MS with QuEChERS extraction technology for the development of veterinary drug Fluralaner test method, to ensure the food safety for consumers.

(IV) Establishment of the identification technology for coffee adulteration

In 2019, a local coffee chain was found to be mixing relatively lower price Robusta coffee beans in to the products declared 100% Arabica. Since 16-O-methylcafestol (16-OMC) is a remarkable indicator to distinguish Robusta from Arabica. TFDA quickly developed a method for 16-OMC quantification using a 500 MHz nuclear magnetic resonance (NMR) (Figure 2-5) within 1 week and applied it for case testing. As a result, the local coffee chain was detected the existing of 16-OMC on its products and the behavior of adding Robusta into 100% Arabica coffee products was confirmed. In this case, TFDA utilizes the analytical capabilities of the national laboratory to develop the analysis method for coffee adulteration with the advanced inspection technology, so that the prosecutors could have the concrete evidence to process relevant legal actions.

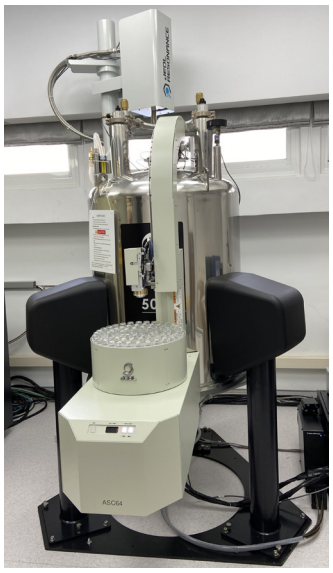


Figure2-5 500 MHz nuclear magnetic resonance (NMR)

III. Identification of toxic Poisonous frogs (Bufo bankorensis) with molecular biotechnology

TFDA received a report from the Hualien County Health Bureau that some people had symptoms such as nausea, vomiting, diarrhea, headache, dysphagia, dyspnea and paralysis after eating the frog soup and one of them was not breathing and had stopped heartbeat before arriving at the hospital; one case of the remaining food (frog soup) was sent for food inspection. With the genetic identification technology developed by TFDA and comparison with DNA sequence, the results indicated that the people had eaten the poisonous toad (*Bufo bankorensis*). TFDA immediately reported the inspection results and issued a weekly journal on drug and food safety, to remind the public not to catch and eat unknown frogs to prevent getting poisoned, to achieve the goal of safeguarding the public's food safety.

Ch3

Advancement of Drug Management

Improve the review mechanism for new drug registration

Announced the "*Points to Consider on Drugs for Pediatric or Rare Disease Designation.*"

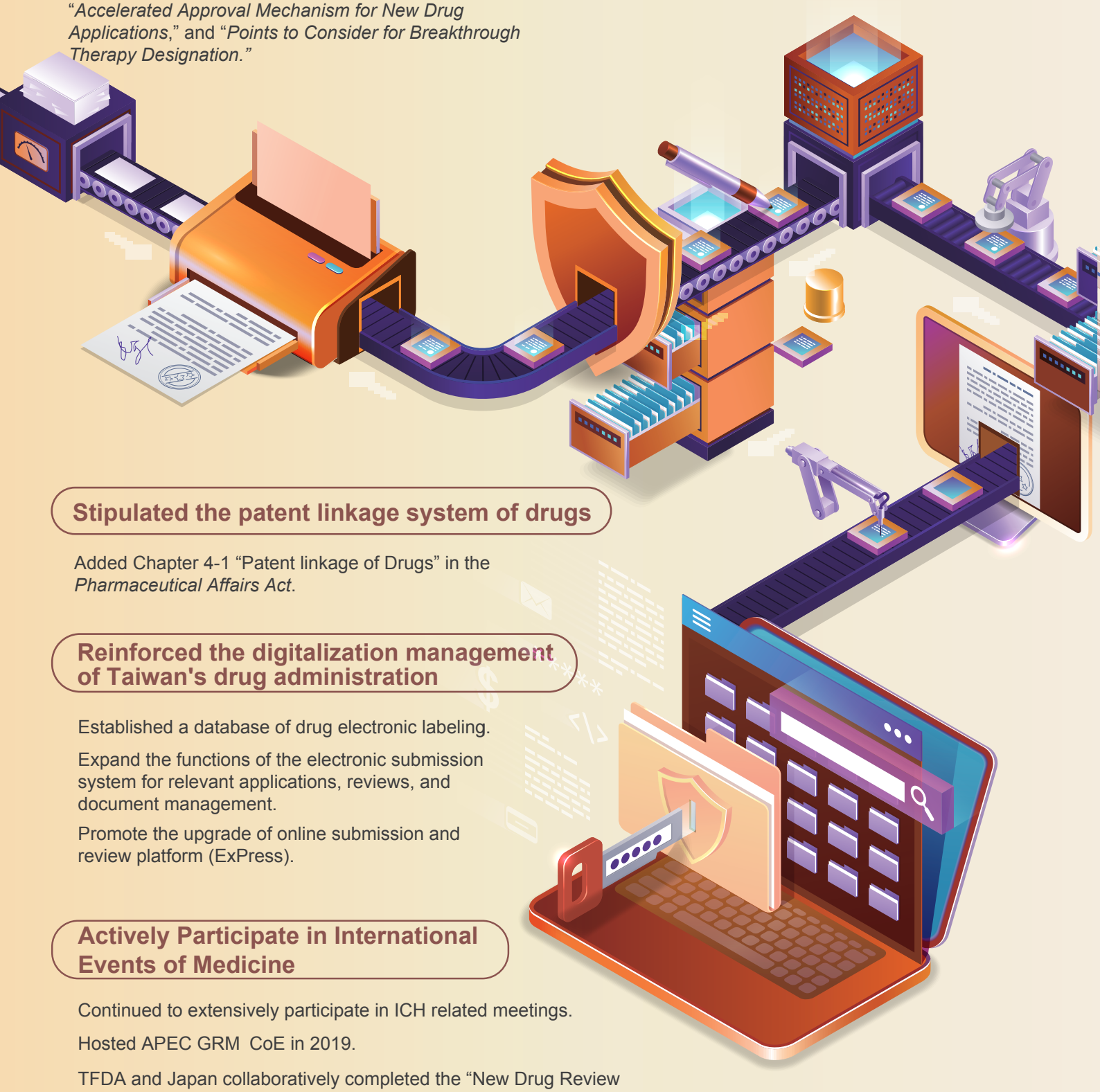
Revision of the

"*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.*"

Expanded the standards for indicator drugs

Announced and added the standards for "External Hemorrhoid Preparations" and "Touch on (Spray) Nasal Preparations."

The drug review standards have been revised to 18 categories with about 355 ingredients.



Stipulated the patent linkage system of drugs

Added Chapter 4-1 "Patent linkage of Drugs" in the *Pharmaceutical Affairs Act*.

Reinforced the digitalization management of Taiwan's drug administration

Established a database of drug electronic labeling.

Expand the functions of the electronic submission system for relevant applications, reviews, and document management.

Promote the upgrade of online submission and review platform (ExPress).

Actively Participate in International Events of Medicine

Continued to extensively participate in ICH related meetings.

Hosted APEC GRM CoE in 2019.

TFDA and Japan collaboratively completed the "New Drug Review Scheme between MHLW/PMDA and TFDA/CDE " in 2019.

Hosted the 1st PIC/S Expert Circle Meeting on Control of Cross Contamination in Shared Facilities.

Hosted the "2019 Taiwan-ASEAN Drug Regulatory Symposium."

03 Advancement of Drug Management

In order to implement the life-cycle management of medicinal products and effectively ensure the safety, efficacy, and quality of medicinal products, TFDA proactively improved management regulations, joined international organizations, and builds a regulatory environment that was in line with international standards. In the meantime, TFDA continue to improve drug registration and review mechanisms, drug distribution practices, digital management, quality and safety surveillances, and testing and analysis technology. Thus to strengthen drug risk management and hence provide a safe environment for the public, as well as facilitate the development of the domestic pharmaceutical industry.

Section 1 Enhance the Drug Management Regulations

Introduction of the Policy

In order to increase the accessibility of drugs for the public, expedite the drug approval process, and encourage the drug developments that fulfill the medical needs of the public, TFDA continues to establish a comprehensive drug management system by referring to the international standards, trends in non-prescription drug management and patent linkage system. At the same time cooperating with the current development status of the domestic pharmaceutical industry. Moreover, TFDA continues to improve the relevant regulations to provide a better drug regulatory environment for the public.

Implementation Strategy

I. Improve the review mechanism for new drug registration

In order to enhance the efficiency of new drug review and speed up the timeline for new drug approval, on November 18, 2019, TFDA announced 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*." The purpose is to encourage the development and reach early approval for new drugs targeting rare disease, or drugs that have significant improvements comparing with the existing treatment, by utilizing approaches such as providing regulatory consultation and technical issue consultations during new drug developments.

II. Amendment to the standards and regulations of non-prescription drugs

To comply with the international trend of non-prescription drugs, and to promote the development of pharmaceutical industries in Taiwan, with reference to the drug managements in Europe, USA, Japan, and Australia, as well as taking into account the domestic pharmaceutical market, TFDA continues to review the standards and regulations of non-prescription drugs, expend the list of non-prescription drugs, implement the professional role of pharmacists, and increase the usage of non-prescription drugs.

III. Stipulated the patent linkage system of drugs

By referencing regulations of the US, Canada, and South Korea and the current status of the pharmaceutical industry development in Taiwan, TFDA added Chapter 4-1 "Patent linkage of Drugs" in the *Pharmaceutical Affairs Act* and it was announced for implementation on August 20, 2019. The drug permit holder deems it necessary to submit patent information regarding substance, composition or formulation and medical use within the statutory limitation. The application of generic drug market approval is required to provide the patent status of the approved new drug. The applicant for a generic drug market approval must inform the license holder, patent owner and exclusive authorized person of the novel drug in advance. Thus to allow the person of interest to validate the patent or the potential patent infringement. The central competent health authorities may continue reviewing the application of the generic drug application. However, the market approval of a drug may be temporarily suspended under special circumstances within 12 months. A 12-month exclusive period for market sales will be given to the first successful applicant of a generic drug market approval without the fact of a patent infringement.

Achievements and Benefits

I. 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 reinforce the two-way communication between the regulators and industries, promoting regulatory harmonization, improving drug review and management system. Among the 100 new drugs approved in 2019, 37 are new drugs with new chemical entities and 22 are biological products.

The number of new drugs applications, closed cases and the review time in the past few years are as shown in Figure 3-1.

II. Expanded the standards for indicator drugs

In 2019, TFDA announced and added the standards for "external hemorrhoid preparations" and "touch on (spray) nasal preparations." The current drug review standards have been revised to 18 categories with about 355 ingredients, which can be used by the public based on their needs and significantly improve the accessibility of medication.

III. Implemented the patent linkage system of drugs

With the implementation of the patent linkage system, the legislative intent of protecting inventors' patent rights with the patent law can be implemented. The research and development efforts devoted by the new drug license holder can be recognized and thereby they will continue to put more effort in drug research and development; on the other hand, it is helpful for the generic drug license holder to learn relevant patents before the drug is on the market and to encourage pharmaceutical companies to avoid patent infringement, in order to increase the volume of generic drug development and achieve the governmental goals of promoting emerging industries and enhancing our international competitiveness. The "*Regulations for the Patent Linkage of Drugs*" was announced on July 1, 2019 and the patent linkage system of drugs stipulated in Chapter 4-1 of the *Pharmaceutical Affairs Act* was announced by the Executive Yuan to take effect on August 20, 2019. Moreover, TFDA has also completed the establishment of Registration System for Patent Linkage of Drugs in order to provide new drug license holders with the function of registration and disclosure of patent information. Based on the statistical data, there were 4 cases of challenged patent avoidance as of the end of 2019.

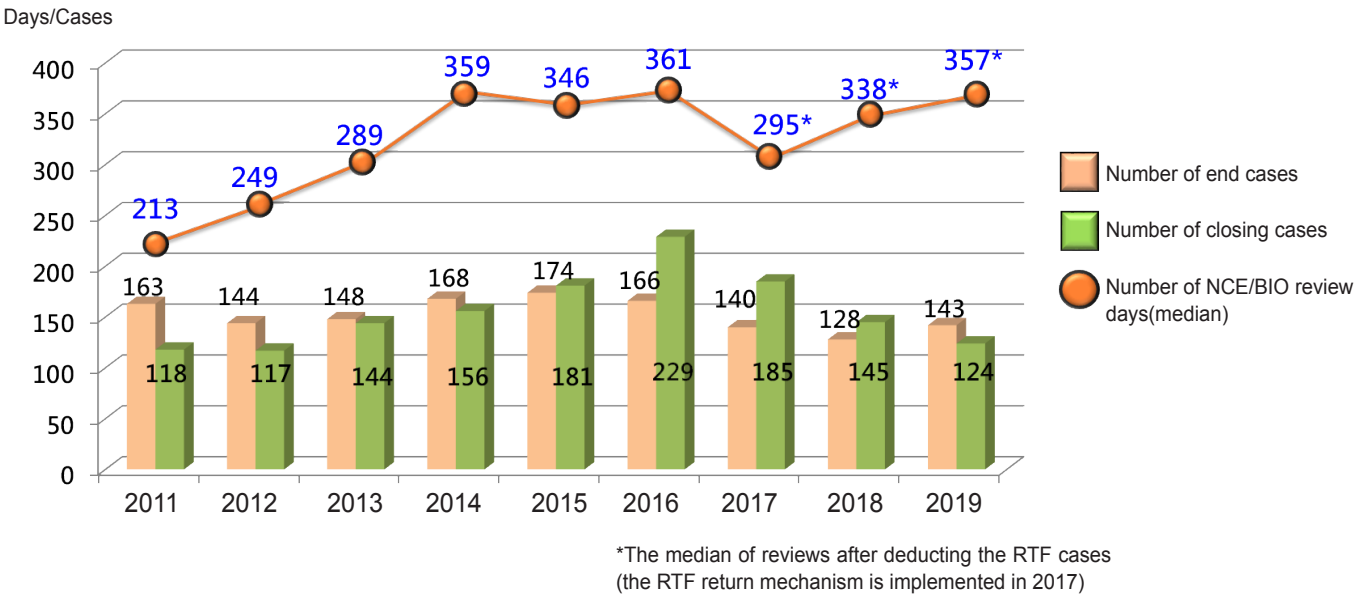


Figure3-1 Number of applications, closed cases and review time of new drugs in past few years

Section 2 Reinforced the Drug Risk Control and Digital Management

Introduction of the Policy

With the advancement of international regulatory environment and digital management of drugs, many countries have developed electronic systems for the applications of drug registration, cross-platform compatibility, and drug information exchange. To align with international standards, to promote international harmonization regarding the application of drug registration, to expedite administrative process and increase the submission quality, as well as facilitating drug information sharing and exchange, and enabling the public to easily obtain the drug safety information, TFDA encouraged online applications of drug registration since 2018, and planned to establish a database of electronic drug labeling since 2019.

Implementation Strategy

I. Improved Taiwan's electronic submission system

TFDA continues to expand the functions of the electronic submission system for relevant applications, reviews and document management in order to be in line with the digitization of drug administration and in accordance with the regulations of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and international standards, to reduce the administrative process for the applicants and enhance the review efficiency and strengthen the function for document management in various types of cases for review and inspection.

II. Reinforced the drug safety surveillance and analysis

TFDA continues to monitor and analyze drug safety through the post-market adverse drug reaction reporting system and actively monitors the safety information about domestic and foreign drugs in order to ensure the safety of the public's drug use; we also utilize the nation's drug safety related database to monitor and analyze drug safety.

III. Established a database of drug electronic labeling and promote package inserts for non-prescription drugs

TFDA plans to establish a database of drug electronic labeling taking the trend in international electronic labeling of drugs as reference. The new system will have the drug electronic labeling using computerized structure format rather than PDF files. It allows the

exchange of drug labeling information between computer systems. It is easier and efficient for medical institutions and pharmacies to use and can improve the effectiveness of medical services. In addition, in order to enhance the safe use of non-prescription drugs, we comprehensively promoted the simple wording on the outside of the package and also printed the QR codes on the boxes too.

Achievements and Benefits

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

TFDA has conducted training courses to guide local industry to get familiar with relevant systems. In 2019, we conducted 4 workshops for industry with the satisfaction of 80% through 416 feedback surveys. A total of 1,557 applications using the online submission for drug registration had been completed. TFDA will continue to promote the upgrade of online submission and review platform (ExPress), and strengthening the digitalization of Taiwan's drug management with the enhancement and expansion of the functions for online submission system, and finally improves Taiwan's drug review and management efficiency.

II. Reinforced the drug safety surveillance and analysis

In 2019, there were 15,747 adverse drug reaction reports, 88 safety information about the domestic and foreign drugs, 34 drug safety assessments, 21 drug risk communication forms were issued and 4 drug safety newsletters quarterly were issued for reminding the medical staff and the public, to ensure the safety of the public’s medication.

III. Established a database of electronic labeling and promote easy-to-read and easy-to-understand for package inserts of non-prescription drugs

Users could search package inserts of non-prescription drugs via simple and easily understood structured information. And we continue to communicate with pharmacies, pharmaceutical companies and medical information exchange groups to establish a user-friendly electronic labeling management system. In addition, the outside of the non-prescription medicines boxes has been inserted the easy-to-read and easy-to-understand wordings for the public. Based on the statistical data, the completion rate of valid non-prescription medicine certificate attained 94% as the end of 2019.

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 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 in 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 drug by promoting the GDP system that meet 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 business engaged in the wholesaling, importing and exporting of western medicines should meet the requirements in the "*Western Pharmaceuticals Good Distribution Practice Regulations,*" 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 line with the amendment to the *Pharmaceutical Affairs Act*, the "*Western Pharmaceuticals Good Distribution Practice Regulations*" were released on December 28, 2017 as the standard for Western pharmaceuticals dealers. Furthermore, the "*Regulations for the Issuance and Management of Western Pharmaceuticals Distribution Licenses and Certificates*" were stipulated and released on May 28, 2018, to specify the management regulations for inspection application and issuance of licenses.

II. Implementation timeline of GDP

On February 18, 2016, the Ministry of Health and Welfare announced that manufacturers

of western medicines and pharmacy operators who have obtained a drug license for western medicine preparations should fulfill the regulations in the "*Western Pharmaceuticals Good Distribution Practice Regulations,*" starting from January 1, 2019. This is the first stage of GDP timeline.

The Ministry of Health and Welfare continued to implement the second stage of GDP timeline. On May 10, 2019, it was announced that pharmacy operators of western medicine preparations who require cold chain storage and transportation should fulfill the regulations in the "*Western Pharmaceuticals Good Distribution Practice Regulations,*" starting from January 1, 2022.

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 lesson for pharmaceutical firms. TFDA also invited GDP experts to provide on-site counseling; TFDA actively communicate 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 announce the GDP regulations to be used as a reference for the business operators.

Achievements and Benefits

As of the end of 2019, 691 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 Participate in International Events of Medicine

Introduction of the Policy

TFDA continues to promote international cooperation in pharmaceutical products in order to enhance the international participation and influence of Taiwan's pharmaceutical administration. TFDA actively participates 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) and strive to hold relevant international conferences in Taiwan, to strengthen the bilateral and multilateral cooperation through interaction and experience sharing with international regulatory institutions.

Implementation Strategy

I. Continued to extensively participate in ICH related meetings

Taiwan had become the 10th ICH pharmaceutical regulatory member in June 2018. It is a major achievement of Taiwan's efforts on stipulating international drug management regulations in the past few years and it is also the best proof of that Taiwan's drug management regulations meet the international standards. After becoming a member of ICH, TFDA continues to extensively attend the ICH Assemblies, participate in the working group to collaboratively stipulate the global drug technical guidelines; moreover, TFDA organized relevant training to assist the domestic pharmaceutical industry to carry out the ICH related standards.

II. Hosted APEC seminar in 2019

To promote the quality and efficiency improvement of pharmaceutical registration in the APEC region and enhance regional regulatory convergence, TFDA held a three-day "2019 APEC Good Registration Management Regulatory Science Center of Excellence Workshop (GRM CoE)" from September 17 to 19, 2019, to discuss the implementation of the principles of good registration management of drugs in drug life-cycle management such as the pre-application consideration, preparation of application dossiers, review mechanisms of various countries and post-market safety management of drugs.

III. Conducted the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation

To promote cooperation between Taiwan and Japan, TFDA hosted the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation on October 1, 2019. It was organized by TFDA and the Center for Drug Evaluation, the Ministry of Health, Labor and Welfare of Japan and Pharmaceuticals and Medical Devices Agency (MHLW/PMDA) and the pharmaceutical and medical devices industries from Taiwan and Japan participated in this conference. In the conference, both Taiwan and Japan shared the latest information regarding the pharmaceutical regulations, precision medicine and regulations for in vitro diagnostic devices, ICH E17, e-labeling and promotion policies of indicator drugs. Furthermore, an official closed-door meeting was held on October 2 in the same year, to further discuss the cooperation of drug review and relevant experience sharing.

IV. Strived to host the 1st PIC/S Expert Circle Meeting on Control of Cross Contamination in Shared Facilities

In view of the fact that cross-contamination in the shared pharmaceutical facilities will affect the quality of drugs products, the PIC/S organization established the "Expert Circle Meeting on Control of Cross Contamination in Shared Facilities" in 2017. Taiwan actively strives to host the first expert circle meeting in Taipei. The conference was held from June 19 to

21, 2019. A total of 82 inspectors and experts from 20 countries participated in the conference, including Britain, the United States, Germany, Italy, Canada, Japan, South Korea, and Southeast Asian countries. The conference empowers all the inspectors from various countries to learn the meaning and inspection skills the risk management of cross-contamination which emphasized by the PIC/S GMP regulations.

Achievements and Benefits

I. Contributed to ICH-related meetings

As an official regulatory member, we attended the meeting in Amsterdam, Netherlands, and Singapore in 2019. Led by Director Wu, TFDA attended the meeting held in Amsterdam (Figure 3-2) and Director Wu also served as the chairman of the sub-meeting, which is a demonstration of Taiwan's strength in the field of medicine and health. In the aspect of working groups, Taiwan's expert representatives were selected to join 6 newly established working groups in 2019, including design and conduct of clinical trials, analytical methods, post-approval safety data management, and generic drug discussions. As of now, more than 30 experts have participated in more than 20 expert work groups which is a demonstration of our actively 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 we conduct guidance training and actively implement ICH guidelines, so that these guidelines can be effectively implemented in Taiwan's pharmaceutical industry.

Figure3-2 The 1st International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) in 2019

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

Through the APEC workshop, TFDA invited domestic and foreign experts to share practical experience to enhance Taiwan's pharmaceutical administration capabilities. In 2019, a total of 67 seed instructors from the industry, government, and academia in 12 member economies (including Brunei, Chile, Hong Kong, Indonesia, South Korea, Malaysia, Papua New Guinea, Peru, Philippines, Thailand, Vietnam, and Taiwan) were trained in the workshop. In the near future, these seed instructors will be able to promote the implementation of good registration management and capability building in various economies and achieve the goal of facilitating regulatory convergence, capability building and interaction and cooperation (Figure 3-3, Figure 3-4).

Figure3-3 A group photo of all the participants from the "2019 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence Workshop"

Figure3-4 A group photo of the Director General of TFDA and the representatives of pharmaceutical regulatory authorities and industry from various APEC economics.

III. Reinforced bilateral medical interaction between Taiwan and Japan

TFDA and Japan collaboratively completed the "New Drug Review Scheme between MHLW/PMDA and TFDA/CDE" in 2019, to fulfill the urgent medical needs for both countries as well as the accessibility of medicines, establish a practical operation model for the new drug review cooperation between two parties, enhance the participation of Taiwanese and Japanese business operators and speed up the launch of new drugs from both countries. This is an important milestone for Taiwan-Japan medical interaction and cooperation (Figure 3-5).

Figure3-5 2019 The 7th Joint Conference of Taiwan and Japan on Medical Products Regulation

IV. Conducted international conferences through the PIC/S platform

Taiwan held the "PIC/S Expert Circle Meeting on Control of Cross Contamination in Shared Facilities" and once again was well recognized by all participants. At the same time, we interacted with international experts to facilitate international cooperation and continue to facilitate the goal of aligning Taiwan's GMP regulations with international standards (Figure 3-6).

Figure3-6 The 1st PIC/S Expert Circle Meeting on Control of Cross Contamination in Shared Facilities in 2019

Section 5 Deepen the New SouthBound Exchange in Drug Regulatory Management

Introduction of the Policy

TFDA continues to cooperate and interact with the drug competent authorities of the countries in New Southbound Policy in order to line with Taiwan's New Southbound Policy and globalization strategy; we also collect and study the drug management policies and pharmaceutical industry information of ASEAN countries to understand the international development trends. In addition, we also plan to promote the development of the Good Laboratory Practice (GLP) certification and testing institutions for non-clinical drug trials through interaction, cooperation and rapid development from Southeast Asian countries. By doing so, we can strengthen the competitiveness of Taiwan's products in the markets and facilitate the global development of Taiwan's biotechnology and pharmaceutical industry.

Implementation Strategy

I. Hosted the "2019 Taiwan-ASEAN Drug Regulatory Symposium"

TFDA hosted the "2019 Taiwan-ASEAN Drug Regulatory Symposium" from November 13 to 14, 2019 in order to strengthen the interaction with the pharmaceutical regulatory authorities of ASEAN countries and assist the domestic pharmaceutical industry to understand the latest pharmaceutical regulatory information on generic drugs. We invited representatives of pharmaceutical regulatory authorities from Malaysia, Philippines, Thailand, and Japan to join the meeting in Taiwan and the invited representatives shared the regulatory policies of generic drugs in their countries. In addition, TFDA organized a face-to-face forum to help Taiwan's pharmaceutical industry expand business opportunity and enter the markets in the south through the two-way sharing, consultation, and interaction.

II. Promoted interaction regarding certification system of inspection institutions

We collected the information of the certification system of inspection institutions from eight countries, including Cambodia, Sri Lanka, Bhutan, Brunei, Pakistan, Bangladesh, Nepal, and Laos, to learn more about the inspection institutions of countries in the New Southbound Policy.

From July 1 to 5in 2019, we invited officials from Malaysian to Taiwan to participate in the seminar of medical product GLP supervision institutions and observe the inspection of testing institutions. By doing so, we share experience and exchange technology from both parties; from September 15 to 21 in 2019, we invited officials from Australia, Vietnam, and Philippines to Taiwan to give speeches for interaction (Figure 3-7); from October 20 to 26 in 2019, we sent representatives to conduct interaction with the national surveillance agency in Australia.

Achievements and Benefits

I. Facilitated Taiwan's pharmaceutical exchange and the development of the biotechnology and pharmaceutical industry

By collecting information on relevant laws and regulations of ASEAN countries and hosting the two-day "2019 Taiwan-ASEAN Drug Regulatory Symposium," TFDA facilitated the industry to communicate with the representatives of the regulatory authorities of participating ASEAN countries on the various issues of the application of pharmaceutical products. There were a total of 144 industry participants joining the exchanges with officials from Malaysia, the Philippines, Thailand, and Japan. TFDA promoted good communication with ASEAN countries through exchange activities, establishing contact channels, and information sharing, and leads the domestic pharmaceutical industry to have more opportunities for developing the market in the New Southbound countries.

II. Strengthened the interaction for the certification system between testing institutions

In order to enhance the mutual understanding between Taiwan and the ASEAN countries in the management and certification system of drug inspection institutions, we assess the differences between the two parties and figure out the possibility of mutual acceptance regarding certification between Taiwan and ASEAN countries. We could reduce unnecessary trading costs, increase the quality and circulation of medical products, and promote the development of Taiwan's drug testing institutions and related manufacturers to catch the opportunities in ASEAN countries with the premise that consumers are safe.

Figure3-7 Seminar on New Southbound Countries Pharmaceutical Products GLP Regulations and Principle

Section 6 Improvement of Drug Quality Inspection Technology

Introduction of the Policy

In view of the drug incidents containing nitrosamine impurities such as the *N*-Nitrosodimethylamine (NDMA) happening around the world, TFDA has collected international literature and has identified 44 high-risk drugs that may produce or contain NDMA by initially checking; in addition, referring to international rules/regulations, the nitrosamine impurities has been included to drugs inspection with scientific methods of monitored the high-risk products by TFDA, and through the alerts and reporting system as well as international cooperation to control the notification and ensure to enhance our capacity and capability of inspection.

Implementation Strategy

I. Inspection specifications for nitrosamine impurities

TFDA requires all of the active pharmaceutical ingredients such as Sartans, Ranitidine and Metformin to be comprehensively tested batch-by-batch for the content of nitrosamine impurities; TFDA also conducts risk assessment at the same time and requests to include the nitrosamine impurities in the inspection specifications. At the same time, TFDA also included NDMA and *N*-Nitrosodiethylamine (NDEA) for the inspection specifications of Sartans in the supplemental articles for the eighth edition of the Chinese Pharmacopoeia (3).

II. Evaluation of 44 drugs for possible residue of nitrosamine impurities

TFDA initially screened 44 high-risk drugs that may produce or contain NDMA according to the international journals and research papers. With reference to the dosage of national health insurance, long-term usage, dosage and intake types, etc., TFDA required the manufacturers on November 13, 2019 to prioritize the evaluation and testing for the risk of nitrosamine impurities that may be generated in the manufacturing process. For the active pharmaceutical ingredients possessing the risk of residue of nitrosamine impurities, they shall be tested for the residue with the analysis method and if necessary, the manufacturing process should be modified.

III. Self-assessment on other drugs that shall not contain nitrosamine impurities

TFDA initially prioritized them to include NDMA and NDEA for the inspection specifications of Sartans in the supplemental articles for the eighth edition of the Chinese

Pharmacopoeia (3) by referring to the information from the European Medicines Agency (EMA). Subsequently, the manufacturers should conduct self-evaluation for other drugs and submit the evaluation report to TFDA. In the future, for the control of nitrosamine impurities in various drugs, TFDA will continue to track international information and update accordingly.

IV. Establish a method for quantitative analysis of nitrosamine impurities in sartans drugs

TFDA quickly established a quantitative analysis with LC-MS/MS (Figure 3-8) for NDMA, NDEA or *N*-Nitroso-*N*-methyl-4-aminobutyric acid (NMBA) and released on the official website of TFDA. TFDA actively established an analysis method with LC-MS/MS for simultaneous analysis of 12 nitrosamine compounds such as NDMA in drugs in order to expand the application scope of the analysis method and find out whether there are other nitrosamine impurities in the drugs. TFDA also lowered the quantitative limit to meet the regulatory standard.

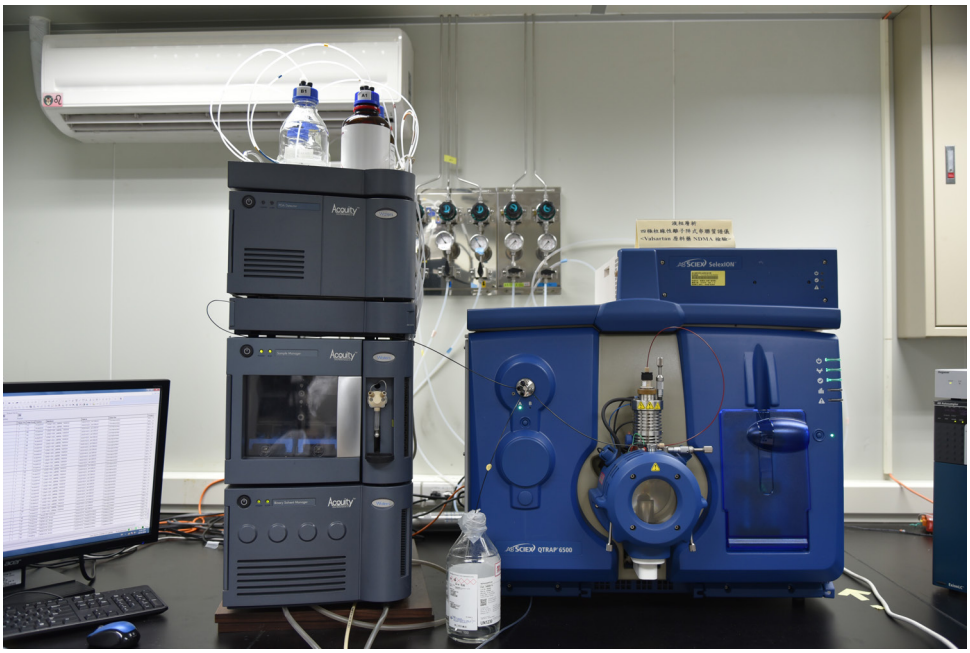
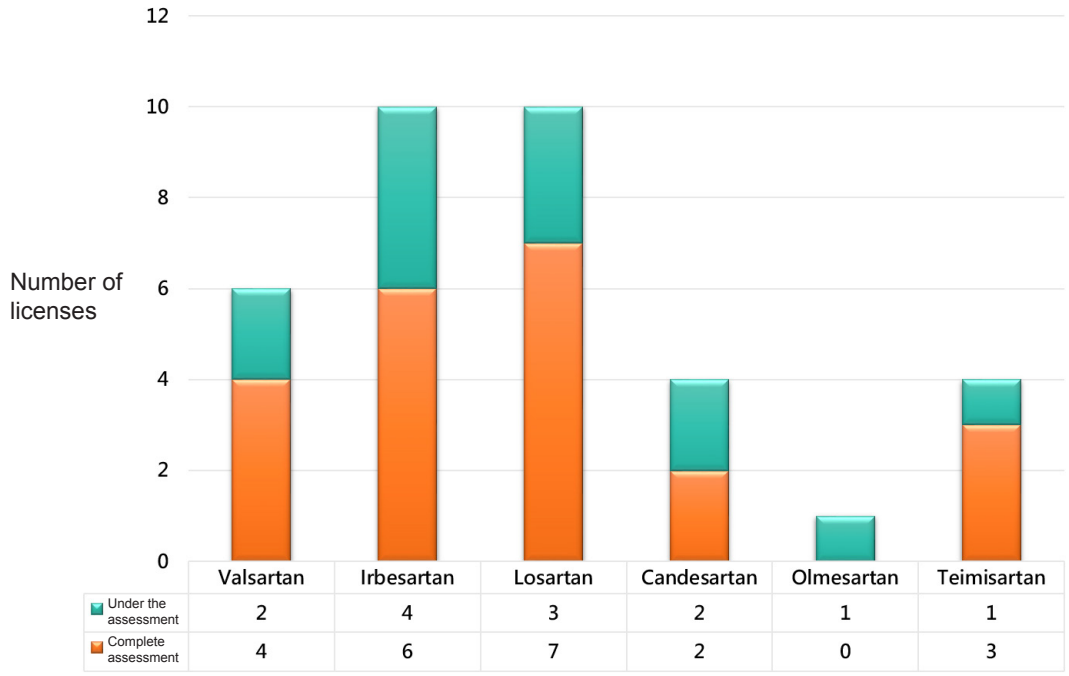


Figure3-8 LC-MS/MS

Achievements and Benefits

TFDA has completed the risk assessment for the residue of nitrosamine impurities in active pharmaceutical ingredients such as Sartans and the assessment objects include 6 items such as Valsartan, Irbesartan, Losartan, Candesartan, Olmesartan, and Teimisartan that are known to have residue of NDMA or NDEA, with a total of 35 licenses for active pharmaceutical ingredients, please refer to Figure 3-9 for the assessment progress. There is a total of 3 licenses for Ranitidine active pharmaceutical ingredients, none of which are applied for import due to safety concerns. There are 12 licenses for Metformin active pharmaceutical ingredients and they are currently under review and assessment. TFDA has also continued to conduct risk assessment of nitrosamine impurities; TFDA will control or adopt relevant administrative measures in the future for drugs that may generate nitrosamines.

From September to December, 2019, TFDA completed the NDMA test for 261 gastric drugs (contain Ranitidine, Cimetidine, Famotidine, and Nizatidine ingredient) and hypoglycemic drugs (contain Metformin ingredient), of which the NDMA has been tested positive in Ranitidine and Nizatidine drugs and we request the manufacturers to verify the NDMA content in these drugs to make sure it meets the regulations before the products can be on the market.

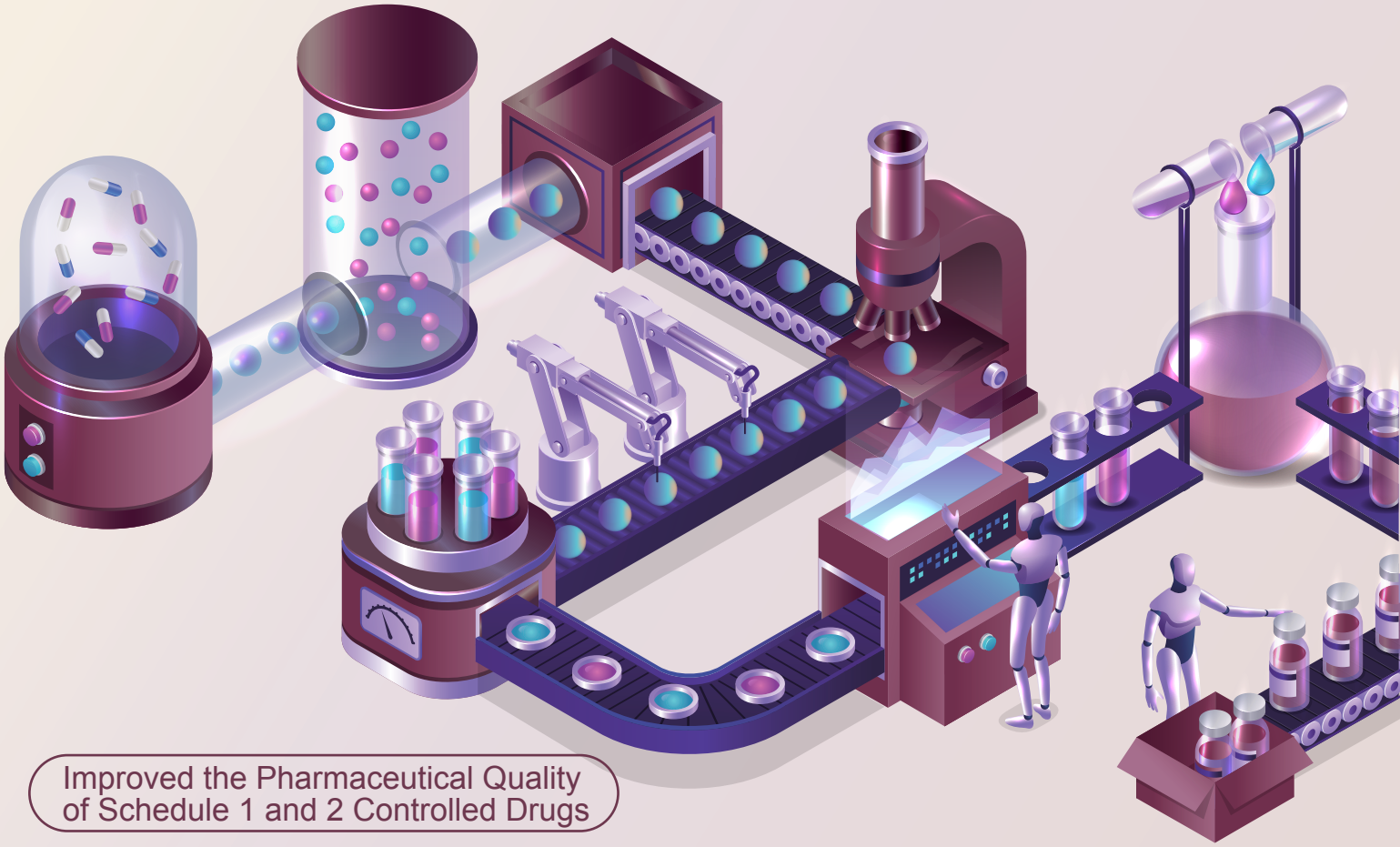


	Valsartan	Irbesartan	Losartan	Candesartan	Olmesartan	Teimisartan
Under the assessment	2	4	3	2	1	1
Complete assessment	4	6	7	2	0	3

Figure3-9 The assessment progress of Sartan drugs containing nitrosamine impurities

Ch4

Management of Controlled Drugs and Prevention of Drug Abuse



Improved the Pharmaceutical Quality of Schedule 1 and 2 Controlled Drugs

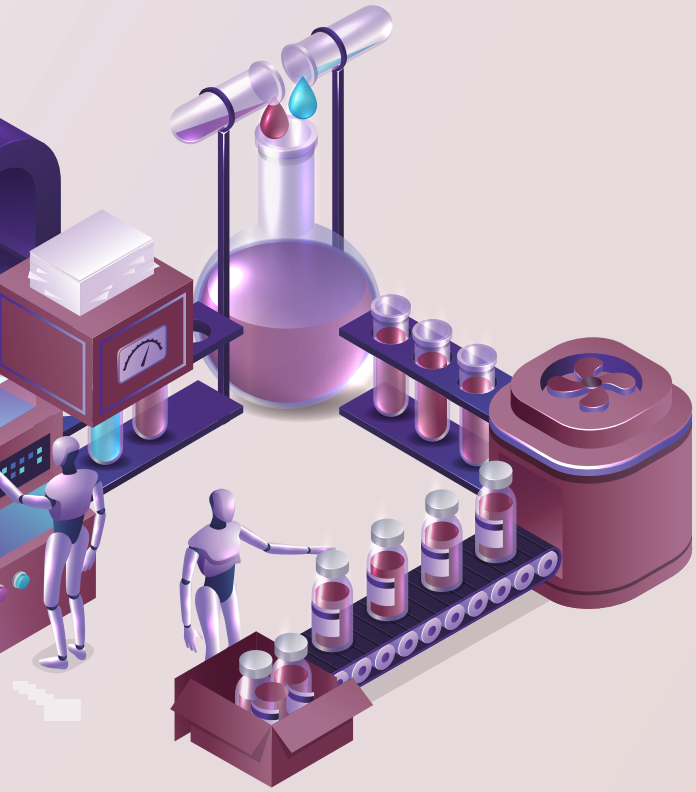
Pharmaceutical Manufacturing Facilities for Controlled Drugs resumed the production of controlled drugs under Schedule 1 and Schedule 2 in 2019.

The short-term target :

- Increase and reach the self-produce for the injections from commissioned or imported scope.
- 1ml/bottle injection was increased to 35,000 injections per batch.
- 2ml/bottle of fentanyl injection has been back to self-production.
- Conducted the research and development of alfentanil injection.

The medium-term and long-term target :

- Continue to the R&D and self-production of new drug types to achieve the goal of domestic drug production.
- The initial prescription development of morphine sulfate sustained-release capsules.
- The evaluation plan for the R&D and production line establishment of oral solutions and patches.



The concept of “Care Avoid refuSe Help”

Action 1　Care

1. Establish a good lifestyle and Time management.
2. Establish a correct working attitude and professionalism.
3. Cultivate Healthy relationships.

Action 2　Avoid

1. Avoid the temptation of drugs.
2. Avoid using addictive drug substances.
3. Avoid unsuitable places.

Action 3　refuSe

1. Refuse drugs.
2. Refuse bad influence friends.
3. Refuse acceptance consignment.

Action 4　Help

1. Caring for relatives, friends and colleagues.
2. Supporting drug addicts for rehab.

04 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, Ministry of Justice places the emerging drugs with scientific use 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 the anti-drug dissemination.

Section 1 Promote 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.

Implementation Strategy

The meeting was held by "Controlled Drugs Review Committee of the Ministry of Health and Welfare" in every six months to conduct the assessment and management for the new narcotics that have necessary to use under scientific consideration. In addition, the seminar of "2019 International Conference on Narcotics: Safe Use and Management" was held on September 4, 2019 to share and exchange the current status of the management of controlled drugs in various countries and measures to prevent and iatrogenic treatment addiction.

In addition, the "*Regulations Governing Management of Manufacturing Schedule 1 and 2 Controlled Drugs Commissioned to Pharmaceutical Firms*" was announced on May 23, 2019 in accordance with Article 4 of the *Controlled Drugs Act* amended and announced on June 4, 2017.

Achievements and Benefits

I. The "Controlled Drugs Review Committee of the Ministry of Health and Welfare" convened the 39th and 40th meeting in 2019 and add a total of 30 items to new controlled drugs and active pharmaceutical ingredients.

II. We invited the official delegation and experts from EU, the United States, Japan and Thailand to Taiwan (Figure 4-1); for the seminar of "2019 International Conference on Narcotics: Safe Use and Management." This is a meaningful and fruitful event for more than 100 attendees of the medical and public health policy category.

III. In order to prevent drug shortage and to enhance the risk control/ management and the capacity of production. We stipulated the "*Regulations Governing Management of Manufacturing Schedule 1 and 2 Controlled Drugs Commissioned to Pharmaceutical Firms,*" and contacted the qualified private pharmaceutical/companies to provide those controlled drugs through public and private sector coordination, in case If necessary.

Figure4-1 2019 International Conference on Narcotics: Safe Use and Management

Section 2 Improved the Pharmaceutical Quality of Schedule 1 and 2 Controlled Drugs

Introduction of the Policy

In order to expand the space and improve the condition of equipment and increase the new production lines as well as R&D capacity in the factory under TFDA's controlled. A new factory has established according to the plan of "New Constructions and Renovations of Pharmaceutical Manufacturing Facilities for Controlled Drugs," by TFDA in July 2017; Furthermore it passed the assessment from the PIC/S GMP on December 28, 2018, and resumed the production of controlled drugs under Schedule 1 and Schedule 2 in 2019.

Implementation Strategy

The new factory is planned to expand the current production lines and capacity of the production (Figure 4-2), to achieve the goal of self-production step by step enabling the replacement of the current commissioned and imported products scope. The short-term target is to increase and reach the self-produce for the injections from commissioned or imported scope; the medium-term and long-term target are to add new production lines for solutions, capsules, and patches to enough supply the Schedule 1 and Schedule 2 controlled drugs for all of the medical institutions to provide more options for the drug use.

Figure4-2 Ampoule labelling machine , Enload cartoner & Tamper-Evident Labeler

Achievements and Benefits

The short-term target has been gradually achieved: the original self-produced 1ml/bottle injection was increased from 30,000 to 35,000 injections per batch since 2019; the original commissioned for manufacturing 2ml/bottle of fentanyl injection has been back to self-production in June 2019; we conducted the research and development of alfentanil injection since 2019 and it is expected to be mass-produced after obtaining a drug license in 2021.

The medium-term and long-term targets included the initial prescription development of morphine sulfate sustained-release capsules is completed at the end of 2019 and pilot batch manufacturing and clinical trials will be conducted in 2020; the evaluation plan for the R&D and production line establishment of oral solutions and patches was initiated in 2019 and the R&D and production of new drug types will be completed. In the future, we will continue to properly use human resource and space for the R&D and self-production of new drug types, to achieve the goal of domestic drug production for domestic usage as well as to stably supply high-quality, Schedule 1 and Schedule 2 controlled drugs with multiple options for the nation's citizens.

Section 3 Improve Warming and Monitoring Mechanism of Drug Abuse

Introduction of the Policy

In recent years, the New Psychoactive Substances (NPS) had a wide range of varieties and 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 incident reported through healthcare facilities and other statistics such as drug abuse urine sample tests, tests performed with non-urine specimens in suspicious drug and controlled drug cases, drug seized, etc., and monthly compiled into the "Drug Abuse Case and Testing Statistics" to provide to TFDA and relevant units.

Implementation Strategy

I. Reporting mechanism for healthcare facilities on drug abuse

In order to expand inspection capabilities in urine testing of NPS, TFDA invited various approved inspection institutions to conduct introduction sessions and seminars of inspection

technology, to discuss the technical details and administrative regulations of NPS urine testing. Moreover, the "*Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions*" was amended to enhance the regulatory flexibility at the end of 2019, to facilitate the testing capabilities and speed up to obtain the certificates for inspection institutions.

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 in the nation.

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

As of the end of 2019, there were totally 16 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 TFDA Urine Test for Drug Abuse Reporting System (UDARS) on a monthly basis. The routine performance monitoring for the approved institutions will be conducted every season, and 64 times combined for the approved institutions in 2019.

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 11 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 of the testing institutions regularly report the illegal drugs testing results to TFDA UDARS, then TFDA collects the statistical data on a monthly basis, including the positive results of non-urine specimens in suspicious drug and controlled drug cases; the statistical data can be used as a reference for TFDA and all departments to stipulate illegal drug prevention strategy.

Achievements and Benefits

I. Reporting situation of drug abuse at healthcare facilities

The analysis data of DARS showed that there were 34,195 cases in total reported for drug abuse by healthcare facilities in 2019. The top three types of drug abuse case number included heroin(16,981, 49.7%), (meth)amphetamine(13,038, 38.1%) and ketamine(1,760, 5.1%). Compare with the data of drug abuse reporting in 2018, the percentage of (meth)amphetamine reporting decreased from 39.6% in 2018 to 38.1% in 2019. 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 2019, 4 approved institutions for drug abuse urine tests had been allowed in testing cathinone group. Moreover, 6 approved institutions and 1 health bureau had been approved for testing the 4-methylmethcathinone, Nimetazepam and Nitrazepam which were detected frequently, hence expanding the capabilities in urine testing of illegal drugs, in order to effectively share the inspection workload of government's laboratories.

In 2019, there was a total of 231,928 urine tests performed throughout Taiwan, among them, 59,727 were positive, and the positive rate was 25.8%. The headcount of positive cases for first three types of drugs abused was (meth)amphetamine, ketamine, and morphine. Comparing with the data of urine tests in 2018, the case number of methamphetamine, ketamine, and morphine were decreased by 59.2%, 6.1%, and 35.5% respectively.

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

In 2019, there was a total of 157,077 cases with positive test results in non-urine specimens of suspicious drug and controlled drug cases in Taiwan, of which 22,681 were methamphetamine cases, 18,291 were ketamine cases, and 20,172 were heroin cases. Comparing to the data in 2018, 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 methamphetamine cases, 24.9%.

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

Introduction of the Policy

In order to improve and promote anti-drug knowledges, TFDA planned a multiple drug abuse prevention propaganda programs and link together with professional, educational and for-fun elements to propagandize in remote areas, communities and workplaces.

Implementation Strategy

I. The anti-drug squadron "Swinhoe's Pheasant"

Since November 2018, the Executive Yuan has planned & exercised the "Anti-drug Touring Mobiles" as promotional activities in all of the place of Taiwan, which run by the Ministry of Health and Welfare, the Ministry of Education, the Ministry of Legal Affairs and the Ministry of the Interior. TFDA is responsible for the "Swinhoe's Pheasant" and conducted the anti-drug promotional activities in campuses, communities and remote areas in five counties and cities including Kaohsiung City, Tainan City, Chiayi County, Pingtung County, and Chiayi City in 2019, providing drugs abuse prevention knowledge and information to the public.

II. The anti-drug propaganda with Internet celebrities

The young age group has high uses of online social media. TFDA adopted the social media marketing to approach Internet celebrities to enhance the adolescents and young adults' awareness in regard to the dangerous of drugs.

III. Promote the concept of "Love and Care (CASH): enterprises fight against drugs and win wealth" in the workplace

The workplace is another essential anti-drugs target, TFDA has established eight anti-drug education resource centers to promote the CASH concept at enterprises in order to build up the prevention of drug abuse with the emphasis of self-(Care) to establish a good lifestyle and work attitude; (Avoid) unsuitable places and addictive drug substances; (refuSe) bad influence friends and drugs; (Help) caring for relatives, friends and colleagues and supporting drug addicts for rehab in the workplace and safeguard the physical and mental health of employers and employees.

Achievements and Benefits

I. "Swinhoe's Pheasant" promotion tour

TFDA "Swinhoe's Pheasant" completed the tour of 374 sessions in 2019, which had benefited a total of 46,328 people. With explanations of lecturers, short films for anti-drug promotion, simulation display boxes for drugs and simulation odor boxes for drugs, to promote the public's anti-drug knowledge, as well as to stay away from drugs abuse(Figure 4-3).

II. Interactive activities with 5 ways for anti-drug and self-defense by the internet celebrities

On September 21, 2019, TFDA held the "5 Ways to Say No to Drugs" typesetting flash crowd activity (Figure 4-4) and invited well-known online sports celebrities to show the 5 techniques for refusing to including: direct rejection, leave immediately, changing chat topics, self-deprecation and persuasion of friends, and photo with fans. A total of 212 fans signed up for the activity and the number of Internet volume reached 1,169,000.

Figure4-3 The promotion activities of the anti-drug squadron "Swinhoe's Pheasant"

III. The propaganda activity of "Love and Care (CASH): enterprises fight against drugs and win wealth" in workplace

In 2019, eight anti-drug education resource centers worked with 267 organizations to collaboratively promote anti-drugs education. They conducted dissemination in 404 workplaces and social groups and provided consulting services for 43,472 people; a total of 601 creative teaching sessions were conducted nationwide which had benefited a total of 33,062 people. In addition, the ceremony of outcomes presentation was held on December 3, 2019 (Figure 4-5) and two companies were invited to share their experience as well as display the promotional teaching materials, teaching tools, and the results for the year.

Figure4-4 The "5 Ways to Say No to Drugs" typesetting flash crowd activity

Figure4-5 The presentation of "Love and Care (CASH): enterprises fight against drugs and win wealth"

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 980 NPS found until the end of 2019 and 157 have been detected in Taiwan including Mephedrone and Bath salts. The problem causes negative effects to health and our society that can not be neglected and has been considered as an important issue need to solved.

Implementation Strategy

I. Actively conducted international interaction and learning

(I) Host the "2019 International Conference on New Psychoactive Substances"

The "2019 International Conference on New Psychoactive Substances(NPS)" was held in July 10 to 11, 2019 and we invited experts in the field of drug abuse prevention who was from Taiwan and other countries, as well as government representatives, (Figure 4-6) to share their experiences and exchange information on three major topics, such as the current global situation of NPS, toxicological assessment, and epidemiology.

(II) Conducted the "APEC International Workshop on Food Safety and Threat from New Psychoactive Substances"

Figure4-6 The 2019 International Conference on New Psychoactive

TFDA strives for the approval from the Sub-Committee on Standards and Conformance (SCSC) of the Asia-Pacific Economic Cooperation Conference (APEC) to host the "2019 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances" (Figure 4-7) on June 11, 2019; we invited the representatives from the European Council, the United States and domestic representatives of agencies, scholars, and experts to introduce the current status of NPS abuse and inspection technologies in different countries. In the closed-door meeting, they also conducted interaction with their views on topics such as "Experience Sharing of Using Raman Apparatus" and "Management Mechanism and Inspection Regulations of Laughing Gas in Different Countries."

II. Enhance 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

Figure4-7 The 2019 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances

2019, the database stored 1,669 items of new narcotics ingredients and drug spectrogram and we had created 336 of standard quality spectrograms and uploaded them to TFDA Urine and Drug Abuse Report System (UDARS) for the narcotics inspection laboratory's review and download. In addition, a flight mass spectrometer was purchased and the data of 88 items of narcotics and controlled drugs have been created.

Achievements and Benefits

I. Facilitated international interaction on the control and inspection technology of new psychoactive substances

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.

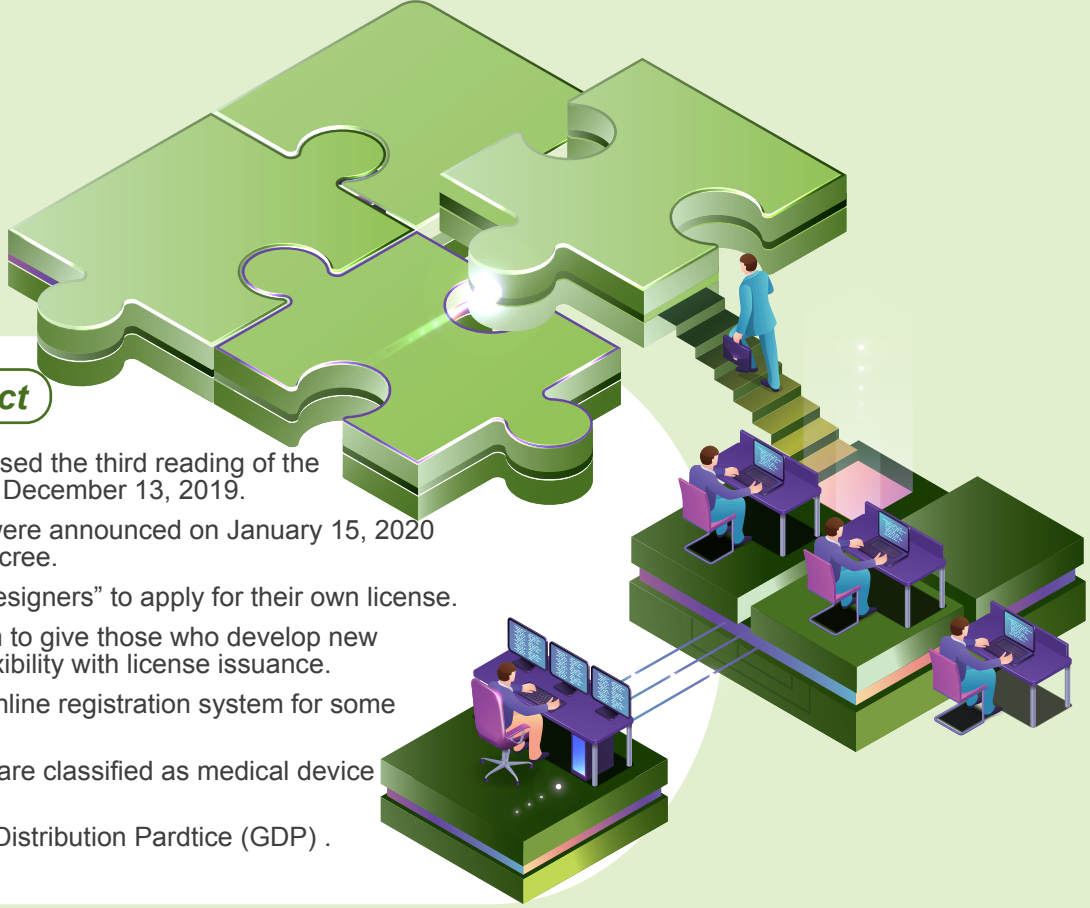
II. Improved the testing effectiveness of new abused drugs

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 nation. In the white unidentified crystal specimen sent by the police station for inspection in 2019, the 2-Fluorodeschloroketamine was tested positive (Figure 4-8). The 2-Fluorodeschloroketamine is a arylcyclohexylamine compound and its appearance and structure are similar to the ketamine ingredients. To prevent the 2-Fluorodeschloroketamine from circulating in the country, it had been included as the Category three narcotics and the Schedule 3 controlled drugs in November and December 2019, respectively, to effectively implement the anti-drug monitoring capability.

Figure4-8 Ingredients of "2-Fluorodeschloroketamine"

Ch5

Consummated Medical Devices and Cosmetics Management



Medical Device Act

- The Legislative Yuan passed the third reading of the "*Medical Devices Act*" on December 13, 2019.
- The Act with 85 articles were announced on January 15, 2020 under the Presidential Decree.
- Allows medical device "designers" to apply for their own license.
- Establishes a mechanism to give those who develop new medical devises more flexibility with license issuance.
- Adopting the electronic online registration system for some low-risk medical devices.
- Medical device repairers are classified as medical device dealers.
- Implementation of Good Distribution Pardtice (GDP) .

International Cooperation

- Hold the APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop.
- Strive to join the IMDRF Working Group and continue to send staff to participate in the annual meeting.
- Conduct the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation.
- Conduct the Conference on International Medical Device Regulations in South East Asia and Brazil.
- Hosted the Conference on Analytical Techniques for Cosmetics.

Cosmetic Hygiene and Safety Act

- The act was announced by the President on May 2, 2018.
- The date of implementation was also be set on July 1, 2019 by the Executive Yuan, except for the relevant provisions of the information that shall be labeled on outer packaging or containers of cosmetics will be implemented on July 1, 2021.
- Announced 30 sub-regulations and orders in 2019.
- The cosmetics businesses shall establish product information file before the product is introduced on the market.
- Cosmetic manufacturing sites shall comply with GMP for the implementation of quality management.
- The cosmetics manufacturers should employ a pharmacist or a professional cosmetic technical personnel to be stationed in the factory to supervise the production and manufacturing.
- Stipulated the implementation methods of recycling, Establish product source and flow data, and proactive notification system.
- Formulate relevant regulations such as promotional phrases and incentives.

05 Consummated Medical Devices and Cosmetics Management

To improve Taiwan's medical devices and cosmetics management systems and to align domestic laws and regulations with international regulations and standards, the "*Medical Devices Act*" was drafted and the Act has been promulgating according to the Presidential Decree issued on January 15, 2020. Moreover, as the "*Cosmetic Hygiene and Safety Act*" has been promulgate according to the Presidential Decree issued on May 2, 2018, TFDA has completed promulgation of 30 relevant regulations in 2019, marking the beginning of a new era for Taiwan's management of cosmetics. In addition, through active participation in various international organizations, including Asia-Pacific Economic Cooperation (APEC) and the International Medical Device Regulators Forum (IMDRF), TFDA worked to enhance Taiwan's international visibility and influence.

In response to the rapid development of smart medical devices, TFDA announced the "*Guidance for Manufacturers: Cybersecurity for Networked Medical Devices*" with new test and verification methods for smart medical devices to ensure the cybersecurity and quality of smart medical devices. In 2019, several different quality inspection methods on medical devices and cosmetics were revised or added, to comprehensive improve the Taiwan's inspection standards. TFDA also actively conducts the listing and registration management of precision medicine molecular diagnostics laboratories to facilitate the development of precision medicine industry.

Section 1 Improving the Medical Device Act and Relevant Regulations

Introduction of the Policy

With diversifying development of global medical devices and diversified types of products, businesses operation model, and classification management system are different from the pharmaceutical industry; hence, to improve the management of medical devices in Taiwan, it is necessary to stipulate a special medical devices management act to respond to the demands in domestic market and to align with international standards. Moreover, in recent years, with rapid development of smart medical devices with communications technology, it is necessary to establish regulations to govern the management of smart medical devices that suit Taiwan's conditions and help businesses overcome legal obstacles they faced during the product development process and speed up the development process.

Implementation Strategy

I. Completed the legislation of the "Medical Devices Act"

After years of effort, the Legislative Yuan passed the third reading of the "*Medical Devices Act*" on December 13, 2019 and the Act with 85 articles were announced on January 15, 2020 under the Presidential Decree. The Act allows medical device "designers" to apply for their own license and establishes a mechanism to give those who develop new medical devices more flexibility with license issuance, to encourage all industries to invest in technology research and development. Moreover, the Act has deregulated some low-risk Class I medical devices, so registration and approval of such low-risk medical devices can be complete via online listing, such change enhances classification management of medical devices. In addition, medical device repairers are also classified as medical device dealers. Medical device firms that sell medical devices with certain level of risk are required to provide information regarding the place of origin and flow of products; medical devices firms are also required to manage the storage conditions, transportation and personnel who transport the products, and to follow Guidance for Good Distribution Practice for medical devices. See Figure 5-1 for the key points of the "*Medical Devices Act*."

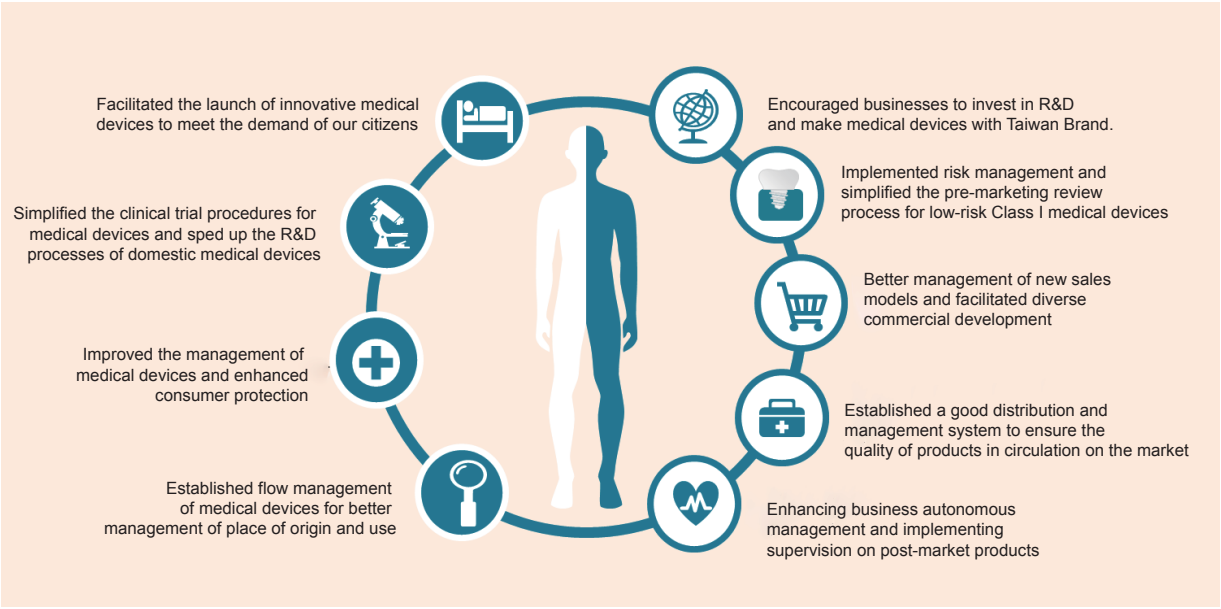


Figure5-1 Key Points of the "*Medical Devices Act*"

II. Improving the management of smart medical devices to facilitate the development of the industry

"*Guidance for Industry: Cybersecurity for Networked Medical Devices*" was drafted after consolidating guidance and standards of advanced countries and international organizations on cybersecurity of networked medical devices. The Guidance announced on December 15, 2019. For medical device manufacturers, the Guidance provides key points related to cybersecurity for product design, research and development, application of registration and market approval, and post-market considerations. To improve manufacturers' understanding of regulations governing smart medical devices, TFDA invited international experts and organized four information meetings on management regulations governing smart medical devices and pre-market review, with a total about 500 participants(Figure 5-2). TFDA also assisted R&D firms of smart medical devices in Taiwan and provided advice on various issues related to registration and market approval. In total, six firms received such support.

Achievements and Benefits

After the "*Medical Devices Act*" takes effect in Taiwan, it is expected that the Act can help ensure the safety, efficiency, and quality of medical devices used by our citizens. Medical device firms can use the Act as the legal basis for conducting their businesses. The public can have better access to medical devices. In other words, citizens in Taiwan can use medical devices that meet international standards and the Act opens a new chapter for management of medical devices in Taiwan. TFDA announced the "*Guidance for Industry: Cybersecurity for Networked Medical Devices*" to ensure cybersecurity of medical devices. In addition, by improving laws and regulations, speeding up pre-market review, providing consultation and training of talents, at present, two domestically manufactured innovative computer-assisted detection software are now on the market.

Figure5- 2 Workshop on the pre-market review system of smart medical devices from different countries

Section 2 Expand the International Cooperation on Medical Devices

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 2019, the implementation priorities include applying for conducting a pilot workshop of the 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 ASEAN countries.

Implementation Strategy

I. Hold the APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop

At the end of 2018, TFDA applied to APEC Life Sciences Innovation Forum's Regulatory Harmonization Steering Committee (APEC LSIF-RHSC) for conducting a pilot workshop of the Regulatory Science Training Center of Excellence (CoE) for medical devices and the application was approved by the RHSC on March 21, 2019. The "2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop" was held from October 22 through 24, 2019 (Figure 5-3), to share principles and experience for evaluating medical device safety and effectiveness with international standards. TFDA also conducted activities such as keynote speeches, group discussions, case studies, and factory visit.

II. Strive to join the IMDRF Working Group and continue to send staff to participate in the annual meeting

The International Medical Device Regulators Forum (IMDRF) is a voluntary international organization consisted of global medical device regulatory agencies. With the approval of IMDRF Management Committee in June 2019 and as a representative of Asian Harmonization Working Party (AHWP), TFDA became a member of the Principles of IVD Medical Devices Classification Working Group to participate in the development of relevant guidance. In addition, TFDA also represented APEC to join IMDRF Management Committee meetings in March and September of 2019 and reported the work progress of APEC during open forum.

Figure5-3 2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop

III. Conduct the 7th Joint Conference of Taiwan and Japan on Medical Products Regulation

In order to implement the Taiwan and Japan medical products regulation cooperation framework arrangement, the Joint Conference of Taiwan and Japan on Medical Products Regulation was held in Taipei on October 1, 2019. For medical devices, the industry and government representatives of both sides shared regulations on in vitro diagnostic medical devices and priority review mechanism. Several topics were discussed extensively, including guidance on medical device cybersecurity, review focus of in vitro diagnostic medical devices and development trend of products, post-market supervision and regulatory mechanism for high-risk medical devices, and simplified submission for medical device registration.

IV. Conduct the Conference on International Medical Device Regulations in South East Asia and Brazil

The "Conference on International Medical Device Regulations in South East Asia and Brazil" was held at the International Convention Center of National Taiwan University Hospital on August 12, 2019. Representatives from Singapore, Thailand, and Brazil were invited to share their medical device regulations.

Achievements and Benefits

For the APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop, overall satisfaction rate of trainees was 4.7 points (out of 5 points). A total of 41 trainees from the industry and academic sectors of 8 different APEC member economies participated. After the completion of training, trainees are able to assist in promoting the concept of medical device standards to APEC member economies and help achieve the harmonization of regulations. This event also fully demonstrates the regulatory capacity and capability of Taiwan while facilitating the establishment of cooperative agreement and mutual recognition. In addition, TFDA actively participates in annual 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 Implementation of Cosmetic Hygiene and Safety Act

Introduction of the Policy

In response to the marketing globalization and enhancement of cosmetics management, the "*Cosmetic Hygiene and Safety Act*" was announced by the President on May 2, 2018. The date of implementation was also be set on July 1, 2019 by the Executive Yuan, except for the relevant provisions of the information that shall be labeled on outer packaging or containers of cosmetics will be implemented on July 1, 2021. This new law was stipulated in accordance with the international regulations. It enables to strengthen the management of manufacturing facilities and product full lifecycle as well as to build up a safe environment for high-quality cosmetics and more comprehensively regulate and protect the rights of consumers.

Implementation Strategy

I. With the authorization of the parent law, TFDA announced 30 sub-regulations and orders in 2019. TFDA has conducted about 162 education and training sessions and explanation

sessions for the draft of sub-regulations since 2013 and will continue to conduct more related sessions in the future, to assist the businesses to understand the new laws.

II. TFDA has stipulated the "*Regulations Governing Notification of Cosmetic Products*" with reference to the regulations of the European Union and the ASEAN. Starting from July 1, 2021, the registration and management system for general cosmetics and specific-purpose cosmetics will be implemented in two stages. The "*Regulations for Cosmetic Product Information File Management*" was also stipulated. As it is a new management system, we plan a five-year period to bridge the transformation between the old and new system.

III. The GMP will be implemented by three phases starting from July 1, 2024 to facilitate the implementation of quality management for cosmetic manufacturers, and based on the different cosmetic categories the cosmetic manufacturing sites should follow the relevant GMP regulations including newcomers. In addition, we stipulated the "*Regulations for Qualifications and Training of Cosmetics Professional Technicians,*" to enhance the professional knowledge of cosmetics supervisors to ensure that the product manufacturing processes are under professional supervision and management.

IV. We stipulated the "*Regulations for Cosmetics Recall*" and the "*Regulations Governing the Source and the Flow Data of Cosmetic Products*" to establish the recall management system of cosmetics in Taiwan; we also regulated the cosmetics businesses to establish and maintain data on direct supply sources and destinations of products.

V. To enhance the safety of the cosmetics, we stipulated the "*Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety.*" It is clearly specified and requested that the cosmetics businesses should report to TFDA via the system of the post-market quality management for medicinal products, food, and cosmetics when serious adverse effects of consumers happen under the regular use of cosmetics, or the products may pose hygiene and safety hazard or risks of harm, to provide the accurate information to the health agency to investigate immediately.

VI. To regulate cosmetics advertisements and the declaration of false products, TFDA worked with relevant departments, health bureaus of counties and cities, public associations, and consumer protection associations to stipulate the "*Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical efficacy of Cosmetic Products*" with the certification guidelines based on general certification standards supplemented by positive and negative examples; in order to encourage the public and internal employees to report illegal cosmetics circumstances, TFDA has discussed with the health bureaus of counties and cities to stipulated the "*Regulations on Cosmetic Hygiene and Safety Violation Report and Reward.*"

Achievements and Benefits

I. The implementation of the "*Regulations Governing Notification of Cosmetic Products*" enabled the government and businesses to better control the products on the market and its condition of the distribution. Moreover, since 2024, cosmetic categories that are specified by the central competent authority as per public announcement, the cosmetics businesses shall establish product information file before the product is introduced on the market. After that, it would ascertain hygiene and safety management, strengthen the professional capabilities of the business, facilitate the export of our local products and develop Taiwan's cosmetics industry in the world.

II. Cosmetic manufacturing sites shall comply with GMP for the implementation of quality management, to enable the inspection standards aligning with international standards, to enhance the quality image and competitiveness of Taiwan's cosmetics on the international markets and to facilitate the development of the industry. Other than the announced "Cosmetic Manufacturing Sites that can Be Exempted from Factory Registration," we specify that the cosmetics manufacturers should employ a pharmacist or a professional cosmetic technical personnel to be stationed in the factory to supervise the production and manufacturing; and the professional cosmetic technical personnel should have the relevant professional knowledge to ensure the implementation and in-house supervision of cosmetic preparation and manufacturing meet the cosmetics good manufacturing practices, as well as inspection and guidance of maintenance for cosmetic manufacturing sites, facilities and equipment, to further enhance the safety and hygiene of the cosmetics manufacturing process.

III. If the competent authority finds that the cosmetic businesses violate the regulations or the cosmetics have hygiene and safety hazard, relevant necessary measures may be taken such as ordering the illegal products to be withdrawn from the market, recalling or destroying the products, etc. Furthermore, after the data base of the source and the flow of those products are established, the businesses can promptly notify the upstream and downstream manufacturers to recall the products if the products have hygiene and safety hazard. It enables consumers to avoid contacting the unqualified products, to strengthen the capability to promptly response to the emergencies case, and to clarify the responsibilities of those products.

IV. We continued to conduct the monitoring of user reaction from consumers to ensure the citizen's health and safety and help improve the product formulation in a timely manner as well as discover the unexpected problems.

V. We stipulated the standard regulations for cosmetic products under control of which the labeling, promotion, and advertisement that being involved the deception, exaggeration, or medical efficacy recognition to stabilize the relative rules/regulations review and maintain

the creative promotion of cosmetics promotion as well as take into consideration of the development in the industry; The consumers might give incentive reward for reporting violations of cosmetics or their business operators; the regulations are stipulated to safeguard the health of the citizens in Taiwan and protect the rights and interests of consumers which will be reviewed from time to time for improvement in the future.

Section 4 Improved the Testing Technology and Quality of Medical Devices and Cosmetics in the Laboratory

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, we interact and cooperate with countries across the world in order to keep pace with the current global development and to catch up with the future trend in analytical technology. The following were included in the "*Cosmetic Hygiene and Safety Act*" announced on May 2, 2018, the central competent authority may entrust cosmetics and cosmetics business operators to conduct random inspection and conduct certification for the entrusted institutions to enhance business efficiency and ensure the quality and credibility of random inspection.

Implementation Strategy

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

We established a verification method for patch-type dynamic electrocardiogram monitoring modules and wearable blood oxygen detection systems in 2019, with the collection of relevant testing technology and international standards for wearable measurement devices such as electrocardiography (ECG) and blood oxygen detection system and we referred to the IEC 60601-2-25 and IEC 60601-2-27 standards to establish a electrocardiography functional test method. In addition, we established the functional test methods for blood oxygen sensors by referring to various standards such as FDA Guidance-Mobile Medical Application, ISO 80601-2-61, IEC 60825-1 and the results were published on the Industrial Economics & Knowledge Center (IEK) to strengthen the effectiveness of dissemination.

II. Improved the analytical techniques for medical devices and cosmetics

In 2019, we published 3 recommended test methods including "Method of Identification for Asbestos Fibers in Cosmetics," "Method of Test for Imperatorin, 5-Methoxypsoralen, 8-Methoxypsoralen, 6-Methylcoumarin, Musk Ambrette, Safrole, and Trioxysalen in Cosmetics," and "Method of Test for Residual Cross-linking Agents in Hyaluronic Acid Dermal Fillers – Test of 1,4-Butanediol Diglycidyl Ether". We also revised 2 of the announced recommended test methods such as "Method of Test for Whitening Ingredients in Cosmetics". A total of 5 articles equivalent to 66 testing items in cosmetics and medical devices were stipulated and revised.

III. Hosted the "Conference on Analytical Techniques for Cosmetics"

The "Conference on Analytical Techniques for Cosmetics" (Figure 5-4) was held in 2019 and four foreign experts from Japan, Italy, Malaysia, and India were invited to Taiwan to share the latest cosmetic analytical technology development from their countries. A variety of issues like cosmetics quality monitoring in various countries, illegal adulteration in cosmetics, unexpected residual substances monitoring in cosmetics and new analytical techniques for cosmetics, etc., was widely discussed in the meeting. Six keynote speeches were conducted and nearly 160 representatives form industries, governments, academia and research fields were attracted to participate in the event.

IV. Stipulated "Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions"

After authorization from the "*Cosmetic Hygiene and Safety Act*" and discussion with testing institutions and regulatory experts, TFDA has stipulated the draft of "*Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions*" including six chapters as below. General rules, certification requirements and procedures of

Figure5-4 2019 Conference on Analytical Techniques for Cosmetics

the testing institution, management of certification and testing institutions, the procedures of entrusted certification operations, management of entrusted certification agencies, and annexes, which were officially announced on August 5, 2019 as the basis of conducting related certification of testing institutions.

Achievements and Benefits

By continuously improving the inspection 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. TFDA aggressively facilitated the international interaction of analytical technology, to strengthen the inspection and analysis capabilities to meet the international standards through interaction and sharing of the global progress in analytical technology as well as challenges in the future. In accordance with the "*Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions,*" a total of 15 cosmetic inspection institutions have been certified, with 51 certification inspection items, to strengthen the supervision and management of inspection institutions and ensure the inspection quality.

Section 5 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 announced the "*Guidance on Laboratory Developed Tests and Services (LDTS) for precision medicine molecular testing*" and conducted the listing management of precision medicine molecular testing laboratory to improve the testing quality.

Implementation Strategy

To conduct the registration management of precision medicine molecular testing laboratory, TFDA invited experts with expertise in pathology, medical inspection and molecular testing to

form a review and inspection team and an auditing team; the related issues such as verification standards and techniques are discussed through meetings and activities such as the expert meetings, inspectors training, and the review and inspection team meeting, to reach a consensus on the inspection standards.

To establish a management mechanism for testing quality, TFDA plans to conduct written inspection 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 and inspection team and then it can be registered for management. In addition, the registered laboratories must undergo proficiency tests and periodic 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. At the same time, TFDA fully disseminated the related regulations and operating procedures for registration through counseling, consultation, laboratory workshop and seminar.

Achievements and Benefits

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

According to the "*Guidance on Laboratory Developed Tests and Services (LDTS) for precision medicine molecular testing,*" TFDA established the operating regulations in 2019, including the key points for registration management of precision medicine molecular testing laboratory, application instructions, application review, and aperiodic review operation principles; moreover, TFDA conducted 2 expert meetings, 1 inspector training, and 2 review and inspection team meetings, so that the registration review and management mechanism can be more comprehensive with the discussion and opinions in the meeting.

II. Conducted counseling and introduction workshop

As of the end of 2019, TFDA has conducted counseling for 3 laboratories as well as 3 laboratory introduction sessions and 1 seminar, so that the laboratories can have a better understanding of the relevant regulations for registration.

III. Registration operations

We started to accept applications for registration of precision medicine molecular testing laboratories in 2019. Three laboratories have applied for registration. TFDA will continue to conduct the registration operations and to enhance the testing quality of precision medicine molecular testing laboratories.

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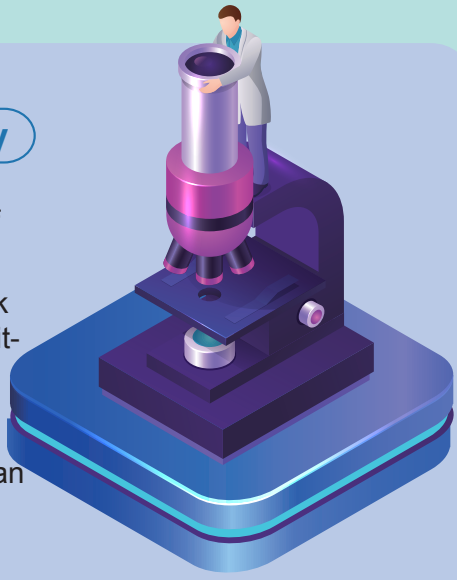
Special Project

Section 1 Establishment of a Special Area for Stopping the Spread of Rumors and Myths of Food and Drugs

Section 2 Improve the Capability of the National Laboratory

Improve the Capability of the National Laboratory



– Actively participated in the events held by the European Network of Official Cosmetics Control Laboratories (OCCLs).

  Sent our delegates to join the 4th joint meeting of European Network of Official Cosmetics Control Laboratories (OCCLs) and the Committee for Cosmetics and Consumer Health (CD- P-COS) held in France.

– Signed the Memorandum of Understanding (MoU) with the European Union Official Control Authority network (EU OCABR network).

06 Special Project

In this chapter, we compile important information of TFDA in 2019. In the year, we created "TFDA LINE@" which integrated "special corner for consumer food and drug fraud prevention" to deliver the information to the consumers through diverse channels.

TFDA's National-Scale laboratory continues to improve and keep in line with international standards. In 2019, we actively participated in international activities for testing, signed memorandums, passed kinds of proficiency tests as well as interlaboratory comparisons and joined collaborative studies in various fiels. We continued to safeguard the safety of drugs, medical devices, foods, and cosmetics for the nation's citizens through international interaction and enhancement of analytical technology.

Section 1 Establishment of a Special Area for Stopping the Spread of Rumors and Myths of Food and Drugs

Introduction of the Policy

In the past few years, the rise of social media and mobile communication applications have sped up the spread of untruthful rumors and exaggerated advertising in food, drugs, cosmetics, and medical devices. In view of the fact that the online circulation of folk remedies and false rumors affected public life and the health education and information obtained by the public was no longer from conventional media, TFDA attempted to establish a new model for health education and policy dissemination through emerging propagation channels. Combining the current events and public opinions, we designed to disseminate important policies of TFDA through the new media channels with a lively and friendly interactive approach.

Implementation Strategy

I. We collected the misinformation from various communication software, social networks, and online forums. We also publish information regarding the suspected violation of advertisements and illegal wordings on the foreign website, to be used as a reference for the public when they are in inquiry or purchasing the relevant products.

II. In order for all age groups people to get the accurate informations, TFDA continuously reinforces the function of its official social media channels to share the correct information by applying this "O2O, online to offline" model, it further expands the influence driven by the internet for all consumers in optimized time.

Achievements and Benefits

I. In March 2019, we created the "TFDA LINE@"(Figure 6-1) to quickly disseminate correct information and stop the spread of rumors/false information in a timely manner. A total of 7 mind power gathering activities were conducted to attract people to join our official LINE@. As of the end of 2019, TFDA has 64,702 online friends.

II. The platform of "Section of Misleading Advertisement of Food and Drugs" was created for publish the illegal advertisement information on foreign websites. As of the end of 2019, 82 warning messages have been published. Among them, food illegal advertisement on foreign websites is the most of more than 80%, with a total of more than 5.88 million cumulated views. And the central and local governments cooperate to crack down illegal advertisements on foreign websites.

Figure6-1 "TFDA LINE@"

III. As of the end of 2019, the “Drug and Food Safety Weekly” has a total of 427,018 subscribers, published 745 issues, and an average of 5,457 views per issue.

IV. The “Section of Rumor Buster of Food and Drugs” had busted more than 442 rumors and released them to the public. The number of food-related rumors was the most, which accounts for nearly 60%, followed by drugs, cosmetics and medical devices. The official website had 35 million cumulated views, with more than 2,500 cited by domestic and foreign media.

V. The TFDA delivers correct knowledge of food, drugs, and cosmetics through diverse channels, including TFDA’s official website, TFDA Facebook fan group (with more than 100,000 fans), and “TFDA News” to enhance the stop rumors with various approaches such as know-how at a glance, videos, pictures, and chartsthe promotional effect and stop rumors with various approaches such as know-how at a glance, videos, pictures, and charts.

Section 2 Improve the Capability of the National Laboratory

Introduction of the Policy

TFDA is responsible for research and analysis of pharmaceuticals, foods and cosmetics in the nation, including development and amendment of analytical test methods, investigation and research, supply of standards and provision of technical support and assistance in analytical techniques. With the root founded in Taiwan, we look forward to aggressively promoting international collaboration and establishing communication channels as well as international networks in order to learn the latest analytical technology and management trends, as well as continuously improve the capability of the national laboratory to reach the international level.

Implementation Strategy

I. Actively participated in the events held by the European Network of Official Cosmetics Control Laboratories (OCCLs)

In 2019, we sent our delegates to join the 4th joint meeting of European Network of Official Cosmetics Control Laboratories (OCCLs) and the Committee for Cosmetics and Consumer Health (CD- P-COS) held in France. During the meeting, we reported TFDA's newly developed method for the identification of asbestos fibers in cosmetics and exchanged opinions with experts from EU countries. We also actively participated in OCCLs' activities such as peer reviews of analytical methods for nitrosamines in cosmetics and post-market surveillance of allergens in aroma products. Our aggressive participation in the international organizations establishes communication channels and international networks, enhances our international visibility and improves the capability of national laboratories to meet the requirements of international standards.

II. Signed the Memorandum of Understanding (MoU) with the European Union Official Control Authority network (EU OCABR network)

In view of the fact that most of human vaccines used in Taiwan came from European pharmaceutical companies and many fraud vaccine incidents happened around the world in the past few years, TFDA and EU OCABR network signed the Memorandum of Understanding (MoU) concerning the participation in the activity of European Union Official Control Authority Batch Release in 2019. TFDA collaborates with EU OCABR network to ensure the quality of biologics through mutual information exchange. It would be helpful for us to timely keep up with the unqualified drug news happened in Europe, which will help Taiwan trigger a response mechanism to response to international incidents and safeguard the use of drugs for the citizens in Taiwan.

III. Results of proficiency tests and collaborative studies

The National Laboratory of TFDA has participated in 16 proficiency tests and 4 collaborative studies (Table 6-1) in 2019, which demonstrated its competence in analytic aspects and earned full recognition from the world for its analytical ability.

Table 6-1 Participation in the international proficiency tests and collaborative studies in 2019

Organizer	Proficiency tests/international collaborative studies Research name	Research results
Central Science Laboratory (CSL), England	Test for Pesticide Residues in Honey	Satisfied
	Test for Aflatoxins in Hazelnut (water/nut slurry)	Satisfied
	Test for Metallic Contaminants in Offal (Liver)	Satisfied
	Test for Illegal Dyes in Hot Pepper Sauce	Satisfied
	Salmonella spp. Detection in Sprouting Seeds and Lettuce Test	Satisfied
	Egg, Gluten, and Milk in Cake Mix Proficiency Test	Satisfied
	Listeria monocytogenes Enumeration in Smoked Fish Test	Satisfied
	Escherichia coli O157:H7 Detection in Beef Proficiency Test	Satisfied
	Enterobacteriaceae Enumeration in Milk Powder	Satisfied
	Authenticity of Fish Proficiency Test	Satisfied
	Authenticity of Lamb Proficiency Test	Satisfied
United States Department of Agriculture, Grain Inspection, Packers and Stockyards Administration (USDA/GIPSA)	Testing for the presence of biotechnology-derived events in soybeans	Satisfied
	Testing for the presence of biotechnology-derived events in corn	Satisfied
US Collaborative Testing Services. Inc. (CTS)	Forensics testing proficiency tests	Satisfied
Australian ENERSOL Pty Ltd	Interlaboratory Proficiency Trial of Male Condom Testing Laboratories	Satisfied
European Directorate for the Quality of Medicines and HealthCare (EDQM)	PTS 196-Dissolution test	Satisfied
	WHO Establishment of the 3rd international standards for amphotericin B	-
	Anti-TNF-alpha Bioassays for method verification	-
	BSP154-LMM Heparin for assay BRP collaborative study	-
National Institute for Biological Standards and Control (NIBSC)	WHO 6th International Standard for hepatitis C virus for NAT	-

* The International Collaborative Study (ICS) is indicated by the symbol "-".

Achievements and Benefits

TFDA obtained valuable analytical techniques and learns the management trends through participation in regular meetings and testing events organized by international organizations. Aligning with the international community not only enhanced the quality and capabilities of analytical technology but also established communication channels with international laboratories and analytical experts, which is a great help in terms of International cooperation and enable more opportunities of technology interaction for ensuring the health of the citizens in Taiwan.

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Annex

Appendix 1 Important Events

April	April 2	Convened the "2019 Foreign Pharmaceutical Factory GMP Management and Communication Meeting" and invited 5 public associations related to pharmaceutical imports to join the meeting to continuously improve and implement the management of foreign pharmaceutical factories.
	April 25	Attended the forum "Promoting the Development of Taiwan to Become the R&D Biotechnology Center in Asia Pacific" and served as the representative speaker to report the registration mechanism for new drugs; we focused on the simplified review, priority review, accelerated approval and breakthrough therapy mechanism, as well as the description of multi-regional clinical trials review procedures.
May	May 2	We were invited to the "Practices on Foreign Pharmaceutical Factory Management and Inspection Seminar" to explain the current GMP management status and management system of foreign pharmaceutical factories.
	May 8	The "Regulations for the Management of Regenerative Medicine Preparations" were reviewed by the Sanitation and Environment Committee of the Legislative Yuan (at the 7th meeting in the 9th session).
June	June 1 to June 6	TFDA attended the 1st meeting in 2019 held by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and its work group in Amsterdam, Netherlands, as well as the meeting held by the International Pharmaceutical Regulators Program (IPRP) and the Drug Regulatory Authority (DRA). During the meetings, we communicated and interacted with representatives of pharmaceutical regulators from various countries and continuously enhanced the international visibility and influence of Taiwan regarding pharmaceutical regulations.
	June 5	In response to the first year of "World Food Safety Day," the Ministry of Economic Affairs, the "Cross-Ministry Press Conference for the World Food Safety Day" was jointly organized by the Ministry of Education, the Council of Agriculture of the Executive Yuan and the Environmental Protection Administration, to reinforce our determination for the protection of food safety from farm to table.
	June 11 to June 12	TFDA conducted the "2019 APEC International Workshop on Food Safety and Threat from New Psychoactive Substances" to share and exchange information about the testing technology for NPS and illegal drug with experts from various countries to enhance the domestic testing technology to protect the health and drug safety of the citizens in Taiwan.
	June 19	Conducted the "Excellent Food Suppliers Award Ceremony on the World Food Safety Day" to publicly present awards to 16 excellent food suppliers. With the award and recognition, it is expected to encourage more businesses to voluntarily apply for verification to enhance the overall safety and hygienic quality of the food industry in the nation.
	June 19 to June 21	TFDA hosted the "1st PIC/S Expert Circle Meeting on Control of Cross Contamination" in Taipei in 2019, to learn and discuss the inspection skills of the risk management of cross-contamination in shared facilities with inspectors and experts from various countries.

	June 23 to June 27	TFDA attended the 55th "Drug Information Association Annual Meetin g (DIA Annual Meeting)" held in San Diego, USA; on June 24, we held the "TFDA Town Hall" with the topic of Regenerative Medicine, to share the new policy of management system for regenerative medicine, views on the regenerative medicine preparation management and inspection experience from Taiwan's competent authorities.
July	July 10 to July 11	Organizing the "International Conference on New Psychoactive Substances(NPS)," we invited international scholars and experts from Malaysia, the United States, Japan, South Korea, etc., as well as specialists and government representatives in Taiwan, to share their experiences and exchange information on three major topics, such as the current global situation of NPS, toxicological assessment and epidemiology.
	July 25	TFDA hosted the "Conference on Analytical Techniques for Cosmetics" to promote global collaboration in cosmetic analytical technology. Forgien experts and sholars from Japan, Italy, Malaysia and India were invited to Taiwan to share the experiences and information on the latest development of cosmetic analytical technology from their countries.
	July 26	Held the "2019 FDA Outstanding and Novice Chefs Award Presentation Ceremony – the Golden Chef Award" to commend the award-winning chefs for their devotion to sanitation management and enhance the image of chefs as well as inspire more chefs to work together to improve the hygiene and quality in the food service industry.
	July 30 to August 2	Participated in the "APEC Pilot CoE in Advanced Therapy" and the "Asia-US Roundtable on Advanced Therapies" held in South Korea by the Northeastern University and the US Food and Drug Administration. Information and experience were exchanged among representatives of regulatory agencies and international scholars, TFDA had also demonstrated efforts on promoting regenerative medicine development and on improving the regulatory environment.
August	August 12	Conducted the "Conference on International Medical Device Regulations in South East Asia and Brazil" to enhance the industry understanding on the New Southbound Policy and the medical device regulations in Brazil.
	August 14 to August 18	We attended the LSIF-RHSC meeting and the Planning Group meeting and we reported the good registration management roadmap as well as the progress of the Regulatory Science Center of Excellence. We were invited to attend the Policy Dialogue on Regulatory Convergence meeting and shared the results of TFDA's active participation in international organizations and the process of speeding up the medical device regulatory convergence for the past few years.
	August 21 to August 22	Conducted the "2019 Annual Food Safety and Analytical Techniques Symposium" to improve the testing quality and promote international exchange and interaction on testing technology.

September

September 4	Conducted the "2019 International Conference on Narcotics: Safe Use and Management." We invited official representatives and experts from EU, the United States, Japan, and Thailand to Taiwan to share the current situation in the management of addictive narcotics from various countries and the strategies for the prevention of addictive narcotics with the medical professionals and public health policy management personnel.
September 17 to September 18	Conducted the "Training for International Food Safety Inspection and Management." We invited officials form New Zealand and Australia with practical experience to Taiwan to share their inspection management for the food industry, border management measures as well as the system and practice for the duty training of inspectors from their country.
September 17 to September 19	TFDA conducted the "2019 APEC Good Registration Management Regulatory Science Center of Excellence Workshop" and invited 21 representatives from the domestic and international pharmaceutical regulatory authorities and experts in the industry to train 67 seed instructors from the industry, government and academe of 12 APEC member economies.
September 21	Held the "Safety of drugs and care of pharmacists" carnival at the Calligraphy Greenway in Taichung.
September 25	Conducted the "Workshop We Symposium on Opportunities and Challenges of the Intelligent Medical Equipment Development in Taiwan."
September 25	Conducted the "International Food Cold Chain Logistics Management Regulations Symposium" we invited experts and scholars to share the development trends of the cold food chain and management in the food industry and the Japanese Yamato International Logistics shared the related specifications of Japanese low-temperature delivery service and the requirements of Publicly Available Specifications (PAS) 1018.
September 25 to September 27	Participated the "6th Bio Investment Asia - Radical Transformation of Life Sciences in Asia" organized by the Thailand Life Science Center of Excellence. This meeting aims to promote the development of biotechnology in Asia and facilitate biotechnology-related commercial investments. In the meeting, TFDA introduced the regenerative medicine related management in Taiwan and our active promotion in related industries.
September 27	Conducted the "Workshop on the Pre-market Review System of Smart Medical Devices from Different Countries."

October

October 1 to October 2	Conducted the "7th Joint Conference of Taiwan and Japan on Medical Products Regulation in 2019". The representatives from both parties shared the progress and trends of pharmaceutical regulations, regulations for precision medicine and in vitro diagnostic reagents, the International Council for Harmonization (ICH), Guidelines E17 of Multi-Regional Clinical Trials (MRCT), electronic package insert, promotion policies for instructed drug and priority review mechanism for medical devices, to strengthen the information exchange between the officials and business operators from the two parties as well as facilitate the business operators' deployment in the international market.
October 19	Conducted the "Sports Day for Medical device and PK with Partners" event to promote the safe use of medical device.

October

October 21	Organized the "International Medical device Regulations Workshop" to help the domestic business operators to better understand the latest international medical equipment regulations.
October 22 to October 24	Held the "2019 APEC Medical Devices Regulatory Science Center of Excellence Pilot Workshop" to train the seed instructors of medical devices and regulatory science for APEC member economies.
October 22 to November 1	Directorate General for Health and Food Safety, (DG SANTE) had conducted the on-site inspection in Taiwan regarding to the application of exporting animal origin food products to the EU.
October 24	Conducted the "Risk and Crisis Management Workshop" to enhance our staff's overall concept of risk identification and crisis prevention as well as establish the risk management culture of the organization.
October 28 to October 30	TFDA participated in the "2019 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop" held in Thailand and was invited to deliver welcome remarks and lectures at the meeting.

November

November 13 to November 14	TFDA held the "2019 Taiwan-ASEAN Regulatory Symposium". We invited the governmental officials from the health authorities of Thailand, Malaysia, and the Philippines to Taiwan to exchange views on the review systems of generic drugs in participating countries. The program included a closed-door workshop for regulators and an open seminar for industry. We invited the ASEAN officials to share the latest status of its their generic drug regulatory system.
November 14 to November 21	Attended the 2nd meeting in 2019 held by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) and its working group in Singapore, as well as the meeting held by the International Pharmaceutical Regulators Programme (IPRP) and the Drug Regulatory Authority (DRA); and participated in the discussion on the stipulation of ICH regulations and guidelines.
November 21	TFDA organized the "Food Safety Management Workshop" and invited the governmental representatives from Federal agency for the Safety of the Food Chain (FASFC) to give speeches on the topics: "Food Safety Barometer," "Traceability Exercise of Food Incident," and "Imported and Exported Food Management". In order to enhance the bilateral food safety cooperation between Belgium and Taiwan, we also invited people in the Office of Food Safety, Council of Agriculture and Environmental Protection Administration, Executive Yuan, and food associations and groups, etc.
November 26	Held the "2019 Annual Press Conference for the Chinese New Year Dishes and the Promotional Award Ceremony for the Effective Use of Food Ingredients in Food Service Businesses" and we invited chef representatives who won the 2019 "FDA Excellent Chef" Golden chef Award to teach the general public to use the leftover food materials to make hygienic and delicious New Year dishes. At the same time, we also awarded the food service businesses who actively devote in the reduction of food waste to commend their contribution on food waste reduction.
November 27	Conducted the "Symposium on the Food Management System of Japanese Foods with Function Claims." Mr. Masashi Hashimoto was invited, the chairman of the Health Food Industry Association of Japan, to share views on the subject of Foods with Function Claims (FFC).

Appendix 2 Important Achievements and Statistics in 2019

Table 1 Addendum/amendment to the regulations and standards related to food safety and health management in 2019

Date of announcement	Name	Important content
January 17	Amended Articles 11 and 12 of the "Enforcement Rules of Health Food Control Act"	In line with the additional clauses and amendment to the labeling regulations in Article 13 of the Health Food Control Act by the Presidential Decree on January 24, 2018, as its subparagraph 2 in paragraph 1 have been added and the number of subparagraphs has been shifted accordingly, thereby the authorization foundation and quoted clauses were revised and the substantive content is in accordance with the original regulations without any changes.
	Stipulate the "Regulations Governing the Labeling of Health Food"	In line with the additional clauses and amendment to the labeling regulations in Article 13 of the Health Food Control Act by the Presidential Decree on January 24, 2018, as its subparagraph 2 in paragraph 1 have been added and the number of subparagraphs has been shifted accordingly, thereby the authorization foundation and quoted clauses were revised and the substantive content is in accordance with the original regulations without any changes; and the original regulations were announced to be abolished on the same day.
	Abolished the "Regulations Governing the Labeling of Health Food" with the announcement Wei-Shou-Shi-Zi No. 1061303745 on December 29, 2017	
	Stipulated the "Health Food Shall Be Clearly Indicated the Content of Ingredients with Health Care Effects in the Product Container or Packaging"	In line with the additional clauses and amendment to the labeling regulations in Article 13 of the Health Food Control Act by the Presidential Decree on January 24, 2018, as its subparagraph 2 in paragraph 1 have been added and the number of subparagraphs has been shifted accordingly, thereby the authorization foundation and quoted clauses were revised and the substantive content is in accordance with the original regulations without any changes; and the original regulations were announced to be abolished on the same day.
	Abolished the "Health Food Shall Be Clearly Indicated the Content of Ingredients with Health Care Effects in the Product Container or Packaging" with the Announcement Bu-Shou-Shi-Zi No. 1041301610 on June 9, 2015	
January 28	Amended Table 1 of Article 3 and Table 4 of Article 5 in the "Standards for Pesticide Residue Limits in Foods" and Article 3 in the "Standards for Pesticide Residue Limits in Animal products"	1.Added and revised 168 residue limits for 27 pesticides. 2.Added 3 pesticides' and deleted 1 pesticide's residue limits in poultry and livestock products.
March 19	Stipulated "The Use Restrictions and Labeling Requirements of the Food Ingredient Chitosan Produced from Shrimp, Crab Shells or the Mycelium of *Aspergillus Niger*"	The regulation specifies the use restrictions and labeling requirements for the chitosan produced from shrimp shells, crab shells or the mycelium of *Aspergillus niger* for food purposes.
March 27	Stipulated "The Use Restrictions and Labeling Requirements of the Food Ingredient Olive (*Olea europaea*) Pomace Extract Containing Hydroxytyrosol"	Stipulated the regulation of olive (*Olea europaea*) pomace extract containing hydroxytyrosol for food purposes, including the manufacturing method, the content of hydroxytyrosol, the daily intake and the warning statement.

Date of announcement	Name	Important content
March 28	Revised the "The Efficacy Assessment Method Of Health Food to Enhance Iron Bioavailability"	1.Revised the name of the assessment method. 2.Deleted *in vitro* measurement method, *in vitro* digestion and dialysis method and *in vitro* digestion Caco 2 cell iron absorption method. 3.Revised the regulations for trial institution and principal investigator. 4.Revised the inclusion and exclusion of trial subjects and experimental measurement as well as added the safety assessment. 5.Revised the evaluation criteria for results. 6.Added the description for the health care effect.
April 3	Revised Article 4 of the "Act Governing Food Safety and Sanitation"	Revised the regulations concerning the formation, proceedings, procedures and other matters to be complied with council advisory committee.
April 9	Amendment to the" Regulations Governing the Establishment of the Sanitation Control Personnel of Food Manufacturing Factory"	Added: the sanitation control personnel for the food manufacturing plants with a capital of less than NTD30 million is eligible by senior staff with vocational education from relevant departments after receiving relevant education and training.
	Amendment to "Categories and Scale of Food Manufacturing Factory Shall Have Sanitation Control Personnel"	The expansion of regulations for other food manufacturing industries shall have sanitation control personnel.
April 10	Amendment to "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products"	The original regulations regarding the scope of application for registration of special dietary food the required documents the operational methods precautions, etc., are included in the "Regulations Governing the Management of the Review, Registration and Issuance of Permit Documents for Food and Related Products."
	Abolished the "Regulations for Special Dietary Food Registration"	
April 16	Stipulated the "Requirements for Exemption from Inspection Application for Import of Food and Related Products and Their Applicable Custom Codes"	1.The self-use import amount and quantity restrictions are applied for foreign embassies and consulates in Taiwan or personnel with diplomatic immunity. 2.Imported plastic containers are not included in the scope. 3.The definition of a single item is clearly stipulated in the new announcement as in the advance notice. 4.Deleted the first and second Table in point 5-2 of the original announcement "meats, tissues, organs, derivatives of bovine or those containing the preceding products from the countries with mad cow disease (bovine spongiform encephalopathy) (BSE)."
	Abolished the "Requirements for Exemption from Inspection Application for Import of Food and Related Products and Their Applicable Custom Codes" with the Announcement Bu-Shou-Shi-Zi No. 1041303340 on November 5, 2015	
April 17	Added Article 18-1 and amended Article 3, Article 47 and Article 51 of the "Act Governing Food Safety and Sanitation"	Revised the definition and usage regulations for the processing aids; it was raised to the Act level to specifically manage products with this ingredient.

Date of announcement	Name	Important content
April 22	Amended Article 3 of the "Standards for Veterinary Drug Residue Limits in Foods"	In coordination with the Guidelines on veterinary drugs of aquatic animals amended by the Council of Agriculture, Executive Yuan, we added the maximum residue limits of Florfenicol for Testudines.
April 26	Amendment to the "Categories, Scale, and Implementation Date of Food Business Operators Required Registration Prior to Business Operations"	Specified the scale and implementation date of logistics businesses that are required for registration as follows: the implementation date is from the announcement date for new factory registration, commercial registration or company registration; for those companies that already have a factory registration, commercial registration or company registration, the implementation starts from July 1, 2019.
May 2	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	1.The products with schedule number of 2106.90.96.00-5 are changed to be listed in the "Complex import regulation for commodities containing F01 category list." 2.In line with the Bureau of Foreign Trade of the Ministry of Economic Affairs to amend the Chinese and English product name for products with commodity classification number of 2103.90.90.30-8. 3.Added the import regulations F02 for products with commodity classification number of 6912.00.10.00-3.
	Amendment to the "Import Regulation of 508 in Import Commodity Classification of Republic of China".	Added 4 item numbers to the import regulations 508.
	Amendment to the "Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China"	1.The product commodity classification number 2106.90.96.00-5 is changed to be listed in the "Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China." 2.In accordance with the announcement of the Bureau of Foreign Trade of the Ministry of Economic Affairs to amend the import regulations for product commodity classification number of 2811.29.90.10-1 to 838.
May 20	Stipulated the "Import Eggs and Egg Products for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	Imported eggs and egg products for food purpose shall be accompanied with official certificates issued by the competent authority of the exporting country that shall be attested the products are "for human consumption", or "in compliance with relevant food safety and sanitary regulations."
May 23	Stipulated the "Import Gelatin and Its Derivatives, Other Glues of Animal Origin and Peptones and Their Derivatives for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	Imported gelatin and its derivatives, other glues of animal origin and peptones and their derivatives for food purpose shall be accompanied with official certificates issued by the competent authority of the exporting country that shall be attested the products are "for human consumption", or "in compliance with relevant food safety and sanitary regulations."
June 12	Amendment to the "Import Regulation of 508 in Import Commodity Classification of Republic of China"	In line with the Bureau of Foreign Trade of the Ministry of Economic Affairs to announce and revise in accordance with the amendment to the toxic chemical substance management number by the Environmental Protection Administration of the Executive Yuan.

Date of announcement	Name	Important content
June 18	Amendment to Table 1 of Article 3, Table 3 of Article 4, Table 4 of Article 5 and Table 5 of Article 6 in the "Standards for Pesticide Residue Limits in Foods"	1.Added and amended 129 residues limits in 34 pesticides for agricultural products. 2.Added *Beauveria bassiana* A1 and *Bacillus. amyloliquefaciens* YCMA1 as MRL omitted pesticides. 3.Added Propaphos (50 % EC) as pesticide prohibited for use. 4.Added the regulations: dried peas are classified in the dried beans and mitsuba is classified as small leafy vegetables.
June 26	Amended the "Import Gelatin and Its Derivatives, Other Glues of Animal Origin and Peptones and Their Derivatives for Food Purpose Shall Be Accompanied with Official Certificates Issued by the Competent Authority of the Exporting Country"	The name and scope of product implementation were changed.
July 12	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	1.Added 4 item numbers to the import regulations F01". 2.Deleted the number "1212.99.40.00-6, Pumpkin or squash seed" in accordance with the management requirement by the Council of Agriculture and added the import regulation F01 for 3 item numbers. 3.Deleted "0805.29.00.00-4, Wilkings and similar citrus hybrids, fresh or dried" in accordance with the management requirement by the Council of Agriculture and added 2 item numbers to the import regulations F01.
July 25	Stipulated "The Use Restrictions and Labeling Requirements of Green Coffee Bean Extract as a Food Ingredient"	Stipulated the regulations of green coffee bean extract for food purposes, including the source of green coffee beans, used parts, types, manufacturing method, daily intake and the warning statement.
August 2	Amendment to Table 1 of Article 3 and Table 5 of Article 6 in the "Standards for Pesticide Residue Limits in Foods."	1.Added and revised 238 residue limits for 34 pesticides. 2.Added the regulations: durum wheat is classified as wheat and buckwheat is classified as miscellaneous grains.
August 15	Amended 7 sanitation standards including the "General Food Sanitation Standards"	1.A total of 7 standards were revised. Due to the setting of "Sanitation standard for contaminants and toxins in food", the duplicate clauses in these 7 standards are deleted and only the requirement for microorganisms are retained. 2.Due to the setting of "Sanitation Standard for Contaminants and Toxins in food," 12 sanitation standards such as the "Sanitation Standards for Eggs" thereby the relevant provisions are abolished.
	Abolished 12 sanitation standards including the "Sanitation Standards for Eggs," etc.	
August 29	Amended Article 3 of the "Standards for Veterinary Drug Residue Limits in Foods"	In coordination with the use of Fluralaner in chickens approved by council of Agriculture, Executive Yuan, therefore we added the maximum residue limit in muscle, liver, kidney, fat (including the skin) and eggs for Fluralaner in chickens.
September 26	Revised on Article 4 and 6 and the appendix of Article 3 of "Regulations for Systematic Inspection of Imported Food"	Revised the scope of "meat products" and "dairy products" added "other deer-derived products" and deleted "other bovine-derived products."

Date of announcement	Name	Important content
October 18	Stipulated 19 regulations such as "The Use Restrictions and Labeling Requirements of Coenzyme Q10 as a Food Ingredient"	To update the legal authorization basis, the title and terms for the regulations of 19 food ingredients. The original regulations were abolished while the relevant regulations were stipulated simultaneously for completing the legal procedures. The substantial content of new regulations is in accordance with the original regulations.
	Abolished 19 regulations such as "Permit and Warning Label Requirement of Coenzyme Q10 Used as a Food Ingredient"	
November 6	Amendment to Table 1 of Article 3 in the "Standards for Pesticide Residue Limits in Foods" and Article 3 in the "Standards for Pesticide Residue Limits in Animal products"	1.Table 1 of Article 3 in the "Standards for Pesticide Residue Limits in Foods:" Added 16 residue limits for 10 pesticides. 2.Article 3 in the "Standards for Pesticide Residue Limits in Animal products:" Addition of 9 pesticide residue limits in bee pollen.
November 7	Amendment to "Regulations of Nutrition Label for Packaged Vitamins and Minerals in the Form of Tablets and Capsule"	1.Revision of nutrition labeling form, If the vertical form can't be fully presented, it can be labeled in horizontal continuous form. 2.Revision of the ways of labeling in terms of the contents of nutrients and units about g, mg and μg. 3.Revision of the principles of data formatting, and added the method of rounding half up.
	Amendment to Article 1 and Article 4, Appendix 1 of Appendix 2 and Table 2 of Article 3 in the "Standards for Specification, Scope, Application and Limitation of Food Additives"	The nitrous oxide is changed to the food additive management and the scope, limits, restrictions, specifications and standards for food usage are stipulated.
	Stipulated the "Sanitation Standard for Liquid Eggs" and "Regulations Governing the Labeling of Liquid Egg Products"	1.Strictly regulate the types of shell eggs can be used for making liquid eggs and standard for microorganisms in liquid eggs. 2.The liquid egg products should be clearly labeled with the wording "pasteurized" or "unpasteurized" on their product names and the expiry date and storage conditions should be labeled. For unpasteurized liquid egg products, in addition to the aforementioned requirements, it should be clearly labeled in Chinese at an obvious location on the outer packaging of the product with the following or similar warning message: "The product must be used in the production of foods that will be sufficiently heated or other processing methods sufficient for effective pasteurization" or other synonymous terms.
December 10	Amendment to the "Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China"	Deleted "0304.49.90.90-8, Other fish fillets, fresh or chilled" in accordance with the management requirement by the Council of Agriculture and added 18 item numbers to the import regulations F01.

Remarks:
Commodity classification number 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 number list. As of the end of 2019, there are 2,640 announced commodity classification numbers for the inspection of imported foods, of which 2,063 are in the import regulation F01, 122 are in the import regulation F02 and 371 are in the import regulation 508, the 84 are in the complex import regulation.

Table 2 The guidance of food hygiene management and operations was announced in 2019

Numbering	Announcement date	Announcement name	Description
1	March 14	"GHP Guidelines for Manufacturers of Liquid Egg Products"	It happened in the past that domestic egg manufacturers used the problematic raw materials of eggs to make liquid egg products. These guidelines were stipulated for the liquid egg manufacturers to follow, so that the sanitation and safety in the production process of liquid egg products can be ensured.
2	July 22	Revised the "Good Hygienic Practice Guidelines for Food Manufacturers of Soy Sauce Products"	To avoid cross-contamination in different types of soy sauce during the production process of soy sauce, such as the content of levulinic acid should meet the limit of 0.1% for label processing method as "fermentation", thereby these guidelines were revised for the soy sauce manufacturers to follow.
3	September 19	Guidelines of Hygiene Self-Management for Online Food Delivery Platform Business Operators	The "food delivery platform" business type has emerged in Taiwan in recent years. These guidelines have been stipulated for platform operators in order to ensure the hygiene, safety, quality and information disclosure of the food provided by the food delivery platform business operators.

Table 3 Registration of specific food and food additive in 2019

The food category should be registered		Number of permit documents
Imported food in tablet or capsule form		6,982
Health Food		388
Food Additives		6,033
Genetically modified food		149
Special dietary food	Formula for certain disease	230
	Infant and follow-up formula	118
Domestic capsule and tablet vitamin products		1,239
Vacuum-packed ready-to-eat soybean food		72
Total		15,211

Table 4 2019 Food Random Inspection Project

Numbering	Project name	Result
1	HACCP Inspection Project for Processed Meat Industry	I. Inspected: 155 companies (I) GHP: 86 companies were required to make improvements within a deadline, of which 85 passed the re-inspection and 1 did not pass the re-inspection. (II) HACCP: 105 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Tracing and tracking: 26 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Mandatory inspection: 17 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Others: 1.3 companies stored expired food and food additives. 2.5 companies did not hire professional staff or technical personnel. 3.4 companies did not have hygiene inspector. II.Random inspection: 320 cases, all comply with the regulations.
2	HACCP Inspection Project for Dairy Processing Industry	I. Inspected: 12 companies (I) GHP: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 1 company was required to make improvements within a deadline and it passed the re-inspection. (IV) Mandatory inspection: 7 companies passed the inspection and 5 companies are not applicable. (V) Food safety monitoring plan: 5 companies passed the inspection and 7 companies are not applicable. (VI) Tracing and tracking: All are in compliance with the regulations. (VII) Electronic declaration required to be traced: 1 company was required to make improvements within a deadline and it passed the re-inspection. II.Labeling: 29 cases, of which 1 case does not meet the regulations. III.Random inspection: 19 cases, all are in compliance with the regulations.
3	HACCP Audit Project for Aquatic Food Industry	I. Inspected: 104 companies (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 77 companies were required to make improvements within a deadline, of which 76 had passed the re-inspection and 1 did not pass the re-inspection. (III) Registration: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Mandatory inspection: 27 are not applicable, 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Food safety monitoring plan: 72 are not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. (VI) Tracing and tracking: 20 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Others: 1.1 company stored expired products. 2.1 company did not hire professional staff or technical personnel. 3.3 companies did not have a hygiene inspector. II.Labeling: 225 cases, of which 3 cases do not meet the regulations. III.Random inspection: 97 cases, all are in compliance with the regulations.
4	HACCP Inspection Project for Meal Box Factory	I. Inspected: 86 companies (I) GHP: 45 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 67 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. (III) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Must trace: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Waste flow: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Others: 1.2 companies used expired ingredients. 2.2 companies did not hire professional staff or technical personnel. 3.1 company did not have a hygiene inspector. 4.The outer package label of 1 company does not meet the regulations.

Numbering	Project name	Result
4	HACCP Inspection Project for Meal Box Factory	II.Random inspection: 205 cases (I) 86 finished products and all are in compliance with the regulations. (II) 100 semi-finished products and 1 product is not in compliance with the regulations. (III) All of the 19 tableware cases are in compliance with the regulations.
5	Hotel Food Service HACCP Inspection Project	I. Inspected: 60 companies (I) GHP: 40 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. (II) HACCP: 51 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: All are in compliance with the regulations. (IV) Standard form contract: 2 companies do not meet the regulations. (V) Others: 1.6 companies stored expired ingredients. 2.1 company did not hire professional staff or technical personnel. 3.1 hotel uses the ‘‘non-food grade baking soda’’ for soaking food ingredients. 4.1 company’s menu label does not match with the actual food ingredients. II.Random inspection: 121 cases, of which 3 cases do not meet the regulations.
6	HACCP Inspection Project for an Edible Oil Factory	【First stage】 I. Inspected: 33 companies (I) GHP: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Tracing and tracking: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Login, mandatory inspection and food safety monitoring plan are in compliance with the regulations. II.Random inspection: 35 cases, all are in compliance with the regulations. III.Labeling: 48 cases, all are in compliance with the regulations. 【Second stage】 I. Inspected: 7 companies (I) GHP: 1 company was required to make improvements within a deadline and it passed the re-inspection. (II) HACCP: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Registration: 1 company was required to make improvements within a deadline and it passed the re-inspection. (IV) Tracing and tracking: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Mandatory inspection: all comply with the regulations. (VI) Food safety monitoring plan: 1 company was required to make improvements within a deadline and it passed the re-inspection. II.Random inspection: 9 cases, of which 1 case did not meet the regulations. III.Labeling: 12 cases, all are in compliance with the regulations.

Numbering	Project name	Result
7	HACCP Inspection Project for Canned Food Factory	【First stage】 I. Inspected: 46 companies (I) GHP: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) HACCP: 22 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) Electronic declaration: 19 are not applicable, 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Tracing and tracking: All are in compliance with the regulations. (VI) Food safety monitoring plan: 1 company was required to make improvements within a deadline and it passed the re-inspection. (VII) Others: 1 company did not hire professional staff or technical personnel. II.Random inspection: 73 cases, of which all are in compliance with the regulations. III.Labeling: 124 cases, of which 1 did not meet the regulations. 【Second stage】 I. Inspected: 31 companies (I) GHP: 9 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: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Tracing and tracking: 1 company was required to make improvements within a deadline and it had passed the re-inspection. (V) Electronic declaration: 16 are not applicable and all the others are in compliance with the regulations. (VI) Mandatory inspection: 1 company is not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Food safety monitoring plan: 5 are not applicable, 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Random inspection: 40 cases, of which all are in compliance with the regulations. III.Labeling: 73 cases, all are in compliance
8	Inspection Project for *Antrodia Cinnamomea* Food Manufacturers	I. Inspected: 42 companies (I) GHP: 11 companies are not applicable, 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Source of ingredients: 6 are not applicable, 36 are in compliance with the regulations. II.Labeling: 37 cases, of which 3 cases (2 companies) do not meet the regulations.
9	Inspection Project for Health Food Factory	I. Inspected: 65 companies (I) Good operating practice for health food factories: 15 are not applicable and 1 did not meet the regulations. (II) Registration: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Tracing and tracking: 22 are not applicable and all the others are in compliance with the regulations. (IV) Mandatory inspection: 22 companies are not applicable and all the others are in compliance with the regulations. (V) Compliance of the registration permit: 74 cases, of which 1 did not meet the regulations. (VI) Others: 1 company stored expired products. II.Labeling: 74 cases, of which 1 did not meet the regulations.
10	Domestically Produced Vitamin Tablet and Capsule Food Factory Inspection Project	I. Inspected: 40 companies (I) GHP: 4 companies are not applicable, 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Tracing and tracking: 16 are not applicable and all the others are in compliance with the regulations. (IV) Food safety monitoring plan: 16 are not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. (V) Mandatory inspection: 16 companies are not applicable, 1 company was required to make improvements within a deadline and all of them passed the re-inspection. (VI) Product recall and the processing workflow: 4 companies are not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Compliance of the registration permit: 90 cases, of which 9 cases do not meet the regulations. (VIII)Others: 1 company stored expired ingredients. II.Labeling: 79 cases, of which 11 cases did not meet the regulations.

Numbering	Project name	Result
11	Inspection Project for Special Nutritional Food Manufacturers and Importers	I. Inspected: 29 companies (I) GHP: 1 company is not applicable, 3 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) Compliance of the content and registration permit: 63 cases, of which 1 did not meet the regulations. (IV) Tracing and tracking: 6 companies are not applicable and all the others are in compliance with the regulations. (V) Electronic declaration: 16 are not applicable, 1 company was required to make improvements within a deadline and it passed the re-inspection. (VI) Food safety monitoring program: 7 companies are not applicable and the remainders are in compliance with regulations. (VII) Mandatory inspection:3 are not applicable and all the others are in compliance with the regulations. II.Labeling: 62 cases, all are in compliance with the regulations. III.Random inspection: 63 cases, of which 1 case did not meet the regulations.
12	Inspection Project for Food Additive Manufacturers and Import Businesses	I. Inspected: 51 companies (I) GHP: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Mandatory Inspection: 4 companies were required to make improvements within a deadline, of which 3 passed the re-inspection and 1 did not pass the re-inspection. (IV) Electronic declaration: 1 is not applicable; 9 companies were required to make improvements within a deadline, of which 8 passed the re-inspection and 1 did not pass the re-inspection. (V) Tracing and tracking: 2 are not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Food safety monitoring plan: 9 are not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Labeling: 72 cases, all are in compliance with the regulations. III.Random inspection: 49 cases, all are in compliance with the regulations.
13	Inspection Project for Bean Products Manufacturers	I. Inspected: 104 companies (I) GHP: 48 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 15 companies were required to make improvements within a deadline and all of them had passed the re-inspection. II.Random inspection: 185 cases, of which 7 cases do not meet the regulations; additional Random inspections on 28 sampling cases of hard tofu, dried tofu products, tofu skin and processed products meet the requirements. III.Labeling: 78 cases, of which 2 cases do meet the regulations; additional Random inspection on 28 cases of vegetarian food with full packaged products: all are in compliance with the regulations.
14	Inspection Project for Pickled Vegetables	【First stage】470 inspection cases, of which 46 cases do not meet the regulations. 【Second stage】 I. Inspected: 96 companies (I) Registration: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) GHP: 50 companies were required to make improvements within a deadline and all of them had passed the re-inspection. (III) Others: 1 company stored expired ingredients. II.Random inspection: 88 finished products, of which 86 cases passed the inspection and 2 cases did not meet the regulations. III.Labeling: 111 cases meet the requirements and 3 cases do not meet the regulations.
15	Inspection Project for Liquid Egg Manufacturers	I. Inspected: 53 (I) GHP: 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: All are in compliance with the regulations. (III) Product liability insurance: All are in compliance with the regulations. (IV) Others: 1 company was under work suspension but did not follow. II.Random inspection: (I) Fresh raw eggs: 44 cases, of which 1 did not meet the regulations. (II) Sterilized liquid egg: 12 cases, of which 1 did not meet the regulations.

Numbering	Project name	Result
16	Inspection Project for Preserved Eggs and Salted Eggs Manufacturers	I. Inspected: 48 companies (I) GHP: 18 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 improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All are in compliance with the regulations. (IV) The waste store area with disposal and transportation record: 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: the labeling of 2 companies do not meet the regulations. II.Random inspection: (I) Fresh raw eggs (residues of veterinary drugs): 46 cases, all are in compliance with regulations. (II) Preserved eggs (lead, copper): 48 cases, all are in compliance with the regulations. (III) Salted eggs (preservatives and Sudan pigments): 38 cases, all are in compliance with the regulations.
17	Compliance of Labeling on Friendly Production System of Egg Labeling and Eggs on the Market	Labeling: 256 cases, all are in compliance with the regulations.
18	Random Inspection Project for Dried Lily Mushroom Products	I. Inspected: 402 companies were registered for inspection, of which 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Random inspection: 504 cases, of which 7 cases did not meet the regulations. III.Labeling: 274 cases, of which 1 did not meet the regulations.
19	Inspection Project for Edible Ice Manufacturers	I. Inspected: 100 companies (I) GHP: 45 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 6 companies are not applicable and 1 company is not in compliance with the regulations. II.Random inspection: 98 cases, of which 13 cases do not meet the regulations.
20	Inspection Project for Soy Sauce Manufacturers	I. Inspected: 75 companies (I) GHP: 45 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) Product liability insurance: All are in compliance with the regulations. II.Labeling: 201 cases, of which 3 cases did not meet the regulations. III.Random inspection: (I) Finished products of soy sauce: 76 cases, all are in compliance with the regulations. (II) Claim or labeled as brewed soy sauce: 59 cases, of which 2 cases do not meet the regulations. (III) Non-brewed soy sauce: 23 cases, all are in compliance with the regulations. (IV) Caramel pigment: 19 cases, all are in compliance with the regulations.
21	Random Inspection Project for Drinks Made on Site	I. Inspected: 291 companies (I) GHP: 115 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 19 companies are not applicable, 34 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Others: 1 stored expired ingredients. II.Labeling: (I) On-site labeling: 170 franchised beverage companies, of which 15 companies do not meet the regulations. (II) Packaged food labeling: 1 does not meet the regulations. III.Random inspection: 447 cases (I) Raw material of tea: 80 cases, of which 4 cases do not meet the regulations. (II) Coffee drinks: 47 cases, of which 10 cases do not meet the regulations. (III) Edible ice: 65 cases, of which 9 cases do not meet the regulations. (IV) Tea drinks and ingredients: 255 cases, of which 18 cases do not meet the regulations.
22	Random Inspection Project for Ice Products Made on Site	I. Inspected: 91 companies (I) GHP: 47 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 7 companies are not applicable, 14 companies were required to make improvements within a deadline and all of them had passed the re-inspection. II.Random inspection: 178 cases (I) Edible ice or ice products: 110 cases, of which 19 cases do not meet the regulations. (II) Ingredients: 68 cases, all are in compliance with the regulations.

Numbering	Project name	Result
23	Random Inspection Project for Breakfast and Popular Brunch Business Operators	I. Inspected: 212 companies (I) GHP: 99 companies were required to make improvements within a deadline, of which 98 companies passed the re-inspection and 1 company is no longer in business. (II) Registration: 57 companies are not applicable, 32 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 99 companies are not applicable and 113 companies are in compliance with the regulations. (IV) Others: 1 company stored expired ingredients. II.Indication on the site: (I) Origin of raw beef: 103 are not applicable and 109 are in compliance with the regulations. (II) Restructured meat products: 104 companies are not applicable and 108 companies are in compliance with regulations. (III) Genetically modified foods: 70 companies are not applicable and 2 companies do not meet the regulations. III.Random inspection: (I) Soymilk: 25 cases, of which 2 cases do not meet the regulations. (II) Eggs: 47 cases, of which 2 cases do not meet the regulations. (III) Lettuce salad: 25 cases, of which 5 cases do not meet the regulations. (IV) Ready-to-eat cooked foods: 57 cases, of which 1 case does not meet the regulations. (V) Beverage: 52 cases, of which 3 cases do not meet the regulations.
24	Inspection Project for Food Package and Lunch Box Food Service	I. Inspected: 218 companies (I) GHP: 106 companies were required to make improvements within a deadline, of which 104 companies passed the re-inspection and 2 companies are no longer in business. (II) Registration: 31 companies were required to make improvements within a deadline, of which 30 companies passed the re-inspection and 1 company is no longer in business. (III) Product liability insurance: 25 companies are not applicable and 193 companies are in compliance with the regulations. (IV) On-site labeling: 1 company did not meet the regulations. II.Random inspection: (I) Combo food products: 66 cases and 4 of them did not meet the regulations. (II) Free drinks offered with the meals: 52 cases, of which 17 cases do not meet the regulations. (III) Fresh meat: 36 cases, all are in compliance with the regulations. (IV) Fresh vegetables: 51 cases, of which 6 cases do not meet the regulations. (V) Processed products: 31 cases, all are in compliance with the regulations.
25	Inspection Project for Banquet Restaurants	I.Inspected: 303 companies (I) GHP: 130 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 41 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: All are in compliance with the regulations. (IV) Others: 18 companies stored expired ingredients. II.Random inspection: 160 cases, all are in compliance with the regulations.
26	Inspection Project for Popular Restaurants	I.Inspected: 173 companies (I) GHP: 69 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 21 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) Labeling: 1 company did not meet the regulations. (V) Others: 5 companies stored and used expired ingredients. II.Random inspection: 343 cases, of which 15 cases do not meet the regulations.
27	Inspection Project for the Cultural and Creative Park and the Old-Street Food Service	I.Inspected: 239 companies (I) GHP: 100 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 24 companies are not applicable, 26 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 4 companies did not comply with the regulations. (IV) Others: 3 companies stored expired products. II.Random inspection: 292 cases, of which 3 cases do not meet the regulations.

Numbering	Project name	Result
28	Inspections Project for Food Businesses in the Food Court	I.Inspected: 280 companies (I) GHP: 87 companies were required to make improvements within a deadline, of which 86 companies passed the re-inspection and 1 company is no longer in business. (II) Registration: 21 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 7 companies are not applicable and all the others are in compliance with the regulations. (IV) Labeling at food and drink places: 1 company did not meet the regulations. (V) Others: 3 companies stored expired products. II.Random inspection: 108 cases, of which all are in compliance with the regulations.
29	Inspection Project for Food Utensils, Food Containers or Package Containing Plastic and in Contact with Food	Inspected: I. Manufacturer: 26 manufacturers (I) GHP: 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: All are in compliance with the regulations. (III) Random inspection: 52 cases, of which all are in compliance with the regulations. II.Retail business: (I) Labeling: 211 cases, of which 8 cases did not meet the regulations. (II) Random inspection: 53 cases, of which 1 case did not meet the regulations.
30	Inspection Project for the Food Logistics and Storage Industry	Inspected: 143 companies I. GHP: 28 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.Others: 3 companies stored expired products.
31	Inspection Project for Chinese New Year	Inspection on online order food manufacturers for Chinese New Year I. Inspected: 57 companies (I) GHP: 37 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 18 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Standard form contract: 13 companies are not applicable, 22 companies were required to make improvements within a deadline and all of them passed the re-inspection. (IV) Product liability insurance: 2 companies are not applicable and 4 companies are not in compliance with the regulations. (V) Use and management of food additives: 25 are not applicable, 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VI) Waste management: 3 companies are not applicable, 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (VII) Others: 2 companies stored expired products. II.Random inspection: 166 cases, of which 2 cases do not meet the regulations. III.Labeling: 145 cases, of which 6 cases did not meet the regulations.
		Random inspection for food sold during the Chinese New Year holidays I. Inspected: 505 companies (I) GHP: 11 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. II.Random inspection: 1,894 cases, of which 31 cases do not meet the regulations. III.Labeling: 1,743 cases, of which 4 cases do not meet the regulations.
		Random inspection for food served in the restaurants during the Chinese New Year holidays I. Inspected: 54 companies (I) GHP: 25 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 7 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: all of them are in compliance with the regulations. (IV) Standard form contract: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: 1.3 companies used expired ingredients. 2.1 company did not hire professional staff or technical personnel. II.On-site labeling: 2 companies do not meet the regulations. III.Random inspection: 61 cases, all are in compliance with the regulations.

Numbering	Project name	Result
32	Inspection Project for Dragon Boat Festival	Inspection project for source manufacturers of the rice dumplings I. Inspected: 27 companies (I) GHP: 13 companies were required to make improvements within a deadline, of which 12 passed the re-inspection and 1 did not pass the re-inspection. (II) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Use and management of food additives: 7 companies were required to make improvements within a deadline and all of them had passed the re-inspection. (IV) Waste management: 8 companies were required to make improvements within a deadline and all of them had passed the re-inspection. (V) Others: 1 company stored expired ingredients. II.Labeling: 9 cases, all are in compliance with the regulations. III.Random inspection: 74 cases, of which 2 cases do not meet the regulations.
		Inspection on Dragon Boat Festival products Random inspection: I. Other seasonal foods for Dragon Boat Festival: 581 cases, of which 2 cases do not meet the regulations. II.Livestock products: 136 cases, all are in compliance with the regulations. III.Salted egg yolk: 88 cases, all are in compliance with the regulations. IV.Fresh eggs: 57 cases, all are in compliance with the regulations.
		Inspection on online order the rice dumplings manufacturers I. Inspected: 25 companies (I) GHP: 16 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 8 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Use and management of food additives: 10 companies are not in compliance with the regulations. (IV) Standard form contract: 2 companies are not applicable, 10 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Labeling: 19 cases, all are in compliance with the regulations. III.Random inspection: 46 cases, of which 1 case did not meet the regulations.
33	Inspection Project for Mid-Autumn Festival	Inspection on the moon cake and stuffing manufacturers I. Inspected: 193 companies (I) GHP: 85 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. (II) Registration: 25 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 1 company does not comply with the regulations. (IV) Standard form contract: 30 companies were required to make improvements within a deadline and all of them passed the re-inspection. (V) Others: 6 companies stored expired foods. II.Labeling: 188 cases, of which 1 case did not meet the regulations. III.Random inspection: 382 cases, all are in compliance with the regulations.
		Inspection on food served during Mid-Autumn Festival I. Inspected: 174 restaurants (I) GHP: 48 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) Product liability insurance: 8 companies are not applicable and all the others are in compliance with the regulations. II.Random inspection: 185 cases, all are in compliance with the regulations.
		Mid-Autumn Festival food inspection:1,446 cases I. Livestock and aquatic products and their processed products: 433 cases, all are in compliance with the regulations. II.Fresh vegetables and the processed products: 297 cases, of which 8 did not meet the regulations. III.Others: 716 cases, of which 5 cases do not meet the regulations.

Numbering	Project name	Result
34	Random Inspection Project for Lantern Festival	I. Inspected 242 companies (I) GHP: 45 companies were required to make improvements within a deadline, of which 44 companies passed the re-inspection and 1 company is no longer in business. (II) Registration: 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Product liability insurance: 4 companies did not comply with the regulations. II.Random inspection: 433 cases, of which 4 cases do not meet the regulations.
35	Random Inspection Project for Tomb Sweeping Day	Random inspection: 764 cases, of which 14 cases do not meet the regulations.
36	Random Inspection Project for Ghost Festival	Random inspection: 912 cases, of which 7 cases do not meet the regulations.
37	Random Inspection Project for Frozen Treats and Drinks in the Summer	Random inspection: 1,017 cases, of which 105 cases do not meet the regulations.
38	Random Inspection Project for Foods in the Winter	Random inspection: 539 cases, of which 3 cases do not meet the regulations.
39	Random Inspection Project for Lunch on Campuses	I. Inspected: 2,138 companies GHP: 66 companies were required to make improvements within a deadline and all of them had passed the re-inspection. II.Random inspection: (I) Labeling: 2,128 cases, of which 1 case did not meet the regulations. (II) Semi-finished products: 132 cases, all are in compliance with the regulations.
40	Inspection Project of Catering Businesses for Providing Lunch to Schools	I. Inspected: 504 companies GHP: 97 companies were required to make improvements within a deadline and 1 of them did not pass the re-inspection. II.Random inspection: 669 cases, of which 32 cases do not meet the regulations.
41	New Sales Model - Inspection Project for Food, Drugs and Cosmetics in the Claw Machine	【First stage】 Investigation: A total of 79 claw machine shops (with 2,006 claw machines) in the nearby area of 36 elementary schools, junior high schools and senior high schools in the non-municipal cities, of which 2.7% of the machines contain food, 1.3% of them contained cosmetics and 0.1% of them contained medicine. 【Second stage】 Inspection: 288 shops (7,994 machines), of which 100 shops (226 machines) contain food, medical equipment and cosmetics. I. Food on display: 163 machines, of which 16 machines are not in compliance with regulations. II.Medicines on display: 0 machines. III.Medical equipment on display: 1 machine, of which 1 machine did not comply with the regulations. IV.Cosmetics on display: 62 machines, of which 35 machines did not comply with the regulations.
42	Inspection Project for Multi-Schedule Marketing Businesse	Labeling inspection: 5 companies, with a total of 23 cases I. Food products: 13 cases, of which 1 does not meet the regulations. II.Cosmetics: 10 cases, all are in compliance with the regulations.
43	Inspection Project for Food Ingredient in the Baking Industry	I. Inspected: 64 companies (I) GHP: 18 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) Labeling: 2 companies do not meet the regulations. II.Random inspection: 44 cases, all are in compliance with the regulations.

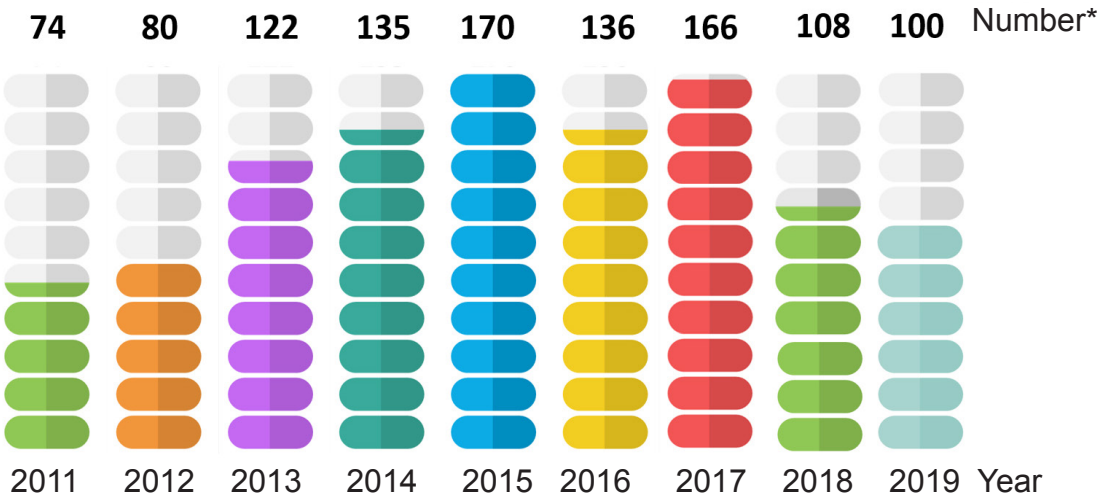
Numbering	Project name	Result
44	Inspection Project for Bakery and Food Service	I. Inspected: 136 companies (I) GHP: 59 companies were required to make improvements within a deadline, of which 58 passed the re-inspection and 1 did not pass the re-inspection. (II) Registration: 1 company is not applicable and 13 companies do not meet the regulations. (III) Tracing and management for the source of ingredients: 30 are not applicable, 6 are not in compliance with the regulations. (IV) Use and management of food additives: 29 companies are not applicable and 29 companies did not meet the regulations. (V) Waste treatment: 1 company is not applicable and 9 companies are not in compliance with the regulations. (VI) Others: 6 companies stored expired products. II.Random inspection: 243 cases, of which 17 cases do not meet the regulations.
45	Inspection on the Manufacturers of Sennosides Products in the Market	【First stage】 I. Inspected: 20 companies (I) GHP: 2 companies are not applicable, 4 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: All are in compliance with the regulations. (III) Inspection on the use of senna products: 9 cases, of which 5 cases are not applicable and 4 cases are in compliance with the regulations. II.Labeling: 8 cases, all are in compliance with the regulations. III.Random inspection: 2 cases, all are in compliance with the regulations. 【Second stage】 I. Inspected: 29 companies (I) GHP: 5 companies are not applicable, 9 companies were required to make improvements within a deadline and all of them passed the re-inspection. (II) Registration: 6 companies were required to make improvements within a deadline and all of them passed the re-inspection. (III) Inspection on the use of senna products: 7 cases, of which 3 cases are not in compliance with the regulations. II.Labeling: 23 cases, of which 4 cases did not meet the regulations. III.Random inspection: 12 cases, all are in compliance with the regulations.
46	Inspection Project for Nuclear Radiation in Japanese Food on the Market and Labeling Check	I. Inspection on radiation (iodine-131, cesium-134, cesium-137): 530 cases, all are in compliance with the regulations. II.Labeling: 530 cases, all are in compliance with the regulations.

Table 5 Addendum/amendment to the regulations and standards related to pharmaceutical administration in 2019

Date of announcement	Name	Important content
January 19	Updating the list of drugs for The Rare Disease and Orphan Drug Act	Adding "Patisiran (Solution for infusion, 2mg/mL)" and "Icatibant (Injection, 10mg/mL)."
February 14	Revised part of the articles of "Regulations for Registration of Medicinal Products"	Amended the some of the clauses in the "Regulations for Registration of Medicinal Products" in order to keep up with the trend of international drug management, in line with online E-submission, simplify the review process, enhance international competitiveness and enable consumers to easily see the labeling of the manufacturing date and shelf life.
March 6	Stipulated the "Regulations for the Notification of Drug Patent Linkage Agreements"	On the basis of paragraph 2, Article 48-19 in the Pharmaceutical Affairs Act, we stipulated the "Regulations for the Notification of Drug Patent Linkage Agreements" in order to prevent unfair agreements or agreements with restrictive competition that hinder other generic drugs to be on the market and improperly affect patient's access of medicine, public health and transaction order on the market.
April 2	Announcement of the stipulation of "Guidelines for Good Preparation Operations of Positron Emission Tomography"	The "Guidelines for Good Preparation Operations of Positron Emission Tomography" was announced to effectively enhance the quality of self-prepared positron medicines of medical institutions and ensure the safety of the people's use of the medicine.
April 11	Amendment to Article 4 of the "Regulations on Management of Medicament Samples and Gifts"	In line with the government to facilitate the development of biomedical industry and enhance Taiwan's competitiveness in clinical trials in the world, we manage the materials and equipment required for clinical trials based on the level of risk; For the low-risk of consumable sample collecting sets in clinical trials are simplified their application procedures , therefore a proviso was added in the first paragraph. In line with the residency policy of the Ministry of the Interior, the Alien Resident Certificate (ARC) and Alien Permanent Resident Certificate (APRC) are deemed as an identity document with the same effect as a passport. Therefore, paragraph 2 was amended and the documents required for foreigners to apply to import self-use drugs were relaxed.
May 10	Announcement of the "Implementation Details and Transition Periods of the Western Pharmaceuticals Good Distribution Practice (GDP) Regulations for Pharmacy Operators	The business undertakings of western pharmaceutical preparations that require cold-chain storage and transportation for wholesaling, importing and exporting processes should apply to TFDA for inspection of the "Western Pharmaceuticals Good Distribution Practice Regulations," and they shall fulfill the requirements of the regulations before December 31, 2021.
May 20	Reassessed the risk factors of medicinal products containing Benzocaine used in children	When the drug products containing benzocaine are used in children, it may occasionally cause rare but potentially fatal blood disorder, "methemoglobinemia." Therefore, TFDA re-assess the risk factors of these drugs used in children according to Article 48 of the Pharmaceutical Affairs Act.
	Abolished the "Announcement of Required Remarks in Package Insert for Drugs Containing Benzocaine"	The principle for the use of drugs containing benzocaine was announced and hence the former Shu-Shou-Shi-Zi No. 1011406106 "Announcement of required remarks in package insert for drugs containing benzocaine" announced by the Department of Health, Executive Yuan on September 13, 2012 was abolished.
May 30	Updating the list of drugs in The Rare Disease and Orphan Drug Act	Adding "Migalastat(capsule, 123mg)," indication for the treatment of ≧16 year-old patients with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (GLA) variant based on in vitro assay data.

Date of announcement	Name	Important content
July 1	Stipulated the "Regulations for the Patent Linkage of Drugs"	The Pharmaceutical Affairs Act was amended on January 31, 2018 in accordance with the patent linkage system of medicines and the "Regulations for the Patent Linkage of Drugs" were stipulated with regards to related matters to facilitate the implementation of the patent linkage system of medicines.
July 18	Updating the list of drugs in The Rare Disease and Orphan Drug Act	Adding "Tafamidis" (soft capsule, 20mg) and "Stiripentol" (capsule, 250, 500mg; powder, 250, 500mg).
July 19	Amended the "Administration and Technical Data Table for Inspection and Registration of Generic Drugs" and the name was changed to "Table of Refuse to File (RTF) for Generic Drugs"	The name was changed to "Table of Refuse to File (RTF) for Generic Drugs."
July 31	Amendments to Article 6-1 of the "Pharmaceutical Affairs Act" that a drug category of trace or track system shall be established	Revised 38 items in the high concern category and added preparations containing ephedrine or pseudoephedrine (not including the controlled drugs) to the declaration of drug trace and track.
August 5	Revised the "Review Standards for Indicators"	Added the standards for "external hemorrhoid preparations" and "touch on (spray) nasal preparations."
September 24	Updating the list of drugs in The Rare Disease and Orphan Drug Act	Adding "Lanadelumab (injection, 150mg/ml)," with indication for prophylaxis to prevent attacks of hereditary angioedema (HAE). Explanation: 1. Patients who experienced at least 3 HAE attacks per month or 5 attacks per 6 months. 2. Patients who experienced life-threatening circumstances.
November 18	Announced the "Points To Consider on Drugs for Pediatric or Rare Disease Designation"	In order to encourage pharmaceutical industries to develop medicines for pediatrics or rare diseases, TFDA has stipulated the designation criteria and designed review mechanisms to simplify and speed up the drug review process so that the medicines can be available on the market sooner to benefit the patients.
	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"	1.For the new drugs with new chemical entities that have obtained marketing authorization from the US Food and Drug Administration (FDA), European Union European Medicines Agency (EMA) and/or the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), we take regulatory reliance approach for our good communication and cooperation experience with these stringent regulatory authorities. Therefore the Abbreviated Review procedure was stipulated. 2.The Priority Review procedures was stipulated for new drugs with urgent needs for public health in Taiwan. 3.To fulfill the unmet medical needs for the citizens in Taiwan, the Accelerated Approval Mechanism for New Drug Application was stipulated for increase drug accessibility for unmet medical needs by accepting method of surrogate endpoint clinical trial design based on scientific evidence. 4.The Points to Consider for Breakthrough Therapy Designation was stipulated for the designation on drugs that have significant improvement with clinical evidence in treating serious diseases or rare diseases in Taiwan. To support and facilitate the development and approval of these drugs, we provided a two-way communication channel through consultation for clinical trial and registration related issues.

Table 6 Number of new drugs approved in 2019



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

Remarks: Among the 100 new drugs, 37 are new drugs with new chemical entities and 22 are biological products. Main indications of the approved new drugs includes cancer, nervous system, infection (bacteria or virus, such as HIV) and rare diseases. The approval of these new drugs provide new treatment options and are beneficial to the patients.

Table 7 Addendum/ amendment to the schedule of Controlled Drugs in 2019

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
January 2	Schedule 3	Methyl (1-(4-Fluorobenzyl)-1H-indazol-3-carbonyl) valinate, AMB-FUBINACA, FUB-AMB, MMB-FUBINACA	A central nervous stimulant. No therapeutic effects which is a synthetic cannabin.
		1-(Chlorophenyl)-2-(1-pyrrolidinyl)-1-pentanone, Cl-Alpha-PVP, Cl-PVP, C-PVP, including three isomers (i.e. 2-Cl-Alpha-PVP, 3-Cl-Alpha-PVP and 4-Cl-Alpha-PVP).	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Kratom, Ketum, Mitragyna speciosa	Its leaves contain Kratom. It is an opioid substance which is a central nervous stimulant.
		N-Ethylhexedrone, N-Ethylnorhexedrone, α-Ethylaminocaprophenone, Hexen, NEH	It is a stimulant of central nervous and is a chemical compound of cathinone.
	Schedule 4	Chlorodimethylcathinone and CDMC, including three isomers such as 2-CDMC, 3-CDMC and 4-CDMC.	It is a stimulant of central nervous and is a chemical compound of cathinone.
April 11	Schedule 2	Khat, Qat, Kat, Chat, Abyssinian Tea, Arabian Tea, Catha Edulis Forsk	Its leaves contain Cathinones, which is a central nervous system stimulant.
	Schedule 3	4-ethyl-2,5-dimethoxyphenethylamine, 2,5-dimethoxy-4-ethylphenethylamine, 2-(4-ethyl-2,5-dimethoxyphenyl) ethanamine, 2,5-dimethoxyphenethylamine, 2C-E	It is a stimulant of the central nervous system and is a chemical compound of amphetamines.
		N-[(2S)-1-amino -3-methyl-1-oxobutan-2-yl]-1-pentylindazole-3-carboxamide, AB-PINACA	A central nervous stimulant. No therapeutic effects which is a synthetic cannabin.
		Ethylmethcathinone and EMC, including three isomers such as 2-EMC, 3-EMC and 4-EMC.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Mitragynine, 9-Methoxycorynantheidine	It is an opioid substance which is a central nervous system stimulant.

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
December 5	Schedule 3	1-(Chlorophenyl)-2-(1-pyrrolidinyl)-1-propanone, Chloro-α-pyrrolidinopropiophenone, Chloro-α-PPP , Including three isomers such as 2-Chloro-α-PPP, 3-Chloro-α-PPP and 4-Chloro-α-PPP.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Deschloro-N-ethyl-Ketamine, 2-(ethylamino)-2-phenylcyclohexan-1-one, 2-DCNEK	An inhibitor of central nervous which is a chemical compound of Ketamine.
		Ethylethcathinone, EEC, including three isomers such as 2-EEC, 3-EEC and 4-EEC.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Fluoro-α-pyrrolidinohexanophenone, 1-(Chlorophenyl)-2-(1-pyrrolidinyl)-1-pentanone, Fluoro-α-PHP), including three isomers such as 2-Fluoro-α-PHP, 3-Fluoro-α -PHP and 4-Fluoro-α -PHP.	It is a stimulant of central nervous and is a chemical compound of cathinone.
		2-Fluorodeschloroketamine, 2-(2-Fluorophenyl)-2-methylamino-cyclohexanone, Fluoroketamine, 2-FDCK	An inhibitor of central nervous which is a chemical compound of Ketamine.
		3,4-Methylenedioxy-α-pyrrolidinohexiophenone, MDPHP	It is a stimulant of central nervous and is a chemical compound of cathinone.
		(1-Pentyl-1H-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl) methanone, UR- 144	It is a stimulant of central nervous and is a chemical compound of cathinone.
		Etizolam	An inhibitor of the central nervous system which is a chemical compound of Benzodiazepine.
		Methyl-N,N-Dimethylcathinone, Methyl-N,N-DMC, including three isomers such as 2-Methyl-N,N-DMC, 3-Methyl-N,N- DMC and 4-Methyl-N, N-DMC.	It is a stimulant of central nervous and is a chemical compound of cathinone.

Date of amendment	Schedule	Promulgate the names of the controlled drugs	Description
December 5	Schedule 4	Chlorodiazepam, including three isomers such as 2-Chlorodiazepam (also known as Diclazepam), 3-Chlorodiazepam and 4-Chlorodiazepam.	An inhibitor of the central nervous system which is a chemical compound of Benzodiazepine.
	Schedule 4 Active Pharmaceutical Ingredients of Controlled Drugs	Hydroxylimine HCl	Precursors of ketamine
		o-Chlorphenyl cyclopentylketone, 2-Chlorophenylcyclopentylketone, o-Chlorobenzoylcyclopentane	Precursors of ketamine.
		Alpha-Acetylphenylacetonitrile, APAAN	Precursors of amphetamines
		Phenyl-2-propanone, P2P	Precursors of amphetamines
		Chloroephedrine (alkaloid)	Precursors of amphetamine or cathinone.
		Chloropseudoephedrine (alkaloid)	Precursors of amphetamine or cathinone.
		2-Bromo-4-methylpropiophenone	Precursors of cathinone.
		N-Boc-Norketamine	Precursors of ketamine.
		4-anilino-N-phenethylpiperidine, ANPP	Precursors of fentanyl.
		N-phenethyl-4-piperidone, NPP	Precursors of fentanyl.

Table 8 Addendum/amendment to the regulations and standards related to medical devices management in 2019

Date of announcement	Name	Important content
January 17	Announced the "Examples of Proper and Improper Advertisement Wording of Class I Medical Devices" for 11 items	This provide clear and specific basis for businesses to revise or edit their advertisement wording for Class I medical devices and to prevent unintentional violation of laws and regulations.
May 22	Amendment to the "Fee-Charging Standards for Registration and Market Approval and Cosmetic Advertisements of Medical Devices"	Fees related to medical devices are independently specified in the "Fee-Charging Standards for Registration and Market Approval and Cosmetic Advertisements of Medical Devices" This fee-charging standards are effective on July 1, 2019.
June 20	Announced that "for medical devices that require inclusion of specified text in accordance with the provisions of Administrative Regulations on Low Power Radio Waves Radiated Devices, firms shall follow the regulations and do not need to submit application of registration and market approval to TFDA."	For medical devices that require inclusion of specified text in accordance with the provisions of Administrative Regulations on Low Power Radio Waves Radiated Devices, firms shall follow the regulations and do not need to submit application of registration and market approval to TFDA.
July 17	Announced the "Examples of Proper and Improper Advertisement Wording of Class I Medical Devices" for 10 items	This provide clear and specific basis for businesses to revise or edit their advertisement wording for Class I medical devices and to prevent unintentional violation of laws and regulations.
July 29	Revise Annexes for Articles 8 and 3 of Regulations for Governing the Management of Medical Device	Amended medical devices classification, categorization, item names and identification to clarify identification, use and align with international management model for businesses to follow.
August 14	Announced the "2019 List of Medical Devices Recognized Standards"	Announced that 1,051 international medical device standards would be recognized, so medical device manufacturers can choose to follow these standards when they develop and test medical devices to ensure the safety and effectiveness of products in the market.
September 2	Announced the pre-clinical testing guidance for "tooth shade resin material (F.3690)" and "vascular graft prostheses (E.3450)"	Business 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.
September 4	Modified the pre-clinical testing guidance for "infrared lamp (therapy apparatus)," "oximeter," "electronic sphygmomanometers," and "electrocardiograph"	
November 18	Announced the "Guidance for Manufacturers: Cybersecurity for Networked Medical Devices"	For medical device manufacturers, the guidance provides key points related to cybersecurity for product design, research and development, application of registration and market approval and post-market considerations, to ensure that medical devices can meet the cybersecurity requirements.

Table 9 Addendum/amendment to the regulations and standards related to cosmetics management in 2019

Date of announcement	Name	Important content
May 22	Stipulated the "Regulations Governing the Source and the Flow Data of Cosmetic Products"	Stipulated the scope, items, content, establishment and expiration date, methods and other compliance matters for the cosmetics industry to create and maintain the information on direct source of supply and product flow.
	Stipulated the "Regulations for Cosmetics Recall"	Stipulated the classification, disposal methods, implementation methods of recycling, completion timeline, contents of plan and report, record keeping, and other compliance matters for the cosmetics manufacturers or importers.
	Stipulated the "Regulations for Reporting Cosmetics Serious Adverse Effects and Hazards to Hygiene and Safety"	Stipulated the notification target, notification method, notification period and notification content of incidents such as serious adverse reactions in cosmetics.
	Stipulated the "Regulations for Issuance and Management of the Cosmetics Certificates"	Stipulated the application criteria, review procedures and standards, validity term, revocation, return, cancellation, and other compliance matters regarding the issuance of certificates, to specifiy the application criteria and review standards for the issuance of cosmetics certificates.
May 28	Stipulated the "Regulations for Issuance of License of Specific-Purpose Cosmetics"	The issuance, modification, revocation and rescission of license of specific-purpose cosmetics for cosmetic manufacturers or importers, as well as the application procedures and other matters need to be followed for license extension of cosmetics containing medical or poisonous drugs.
	Stipulated the "Regulations for Authorizing the Applications of Import of Non-licensed Specific-Purpose Cosmetics"	The regulations regulated the application qualification and purpose of the specific purpose cosmetics for the application for registration or for use in research and trial, the required documents and information for applicants, and the required quantity. The regulations also stipulated that the competent authority may revoke and rescind the grant for documents that are false or the actual usage is inconsistent with the content of approval. These applications will be refused by the competent authority within 2 years.
	Revised the "Fee Standards for Cosmetics and Cosmetics Dye Registration" and the name was amended to "Standards of Administrative Fees for Cosmetics"	Stipulated the required inspection fees and certificate fees of the notification of cosmetics, the permission of animal testing for the safety assessment of cosmetics or cosmetic ingredients, specific-purpose cosmetics registration, the manufacturing quality inspection and certificate of Cosmetics Good Manufacturing Practice Regulations.

Date of announcement	Name	Important content
	Stipulated the "Particulars of Specific Purpose Cosmetics that May Be Voluntarily Modified"	The label, leaflet or outer packaging for specific purpose cosmetics that meet the announcement content may be voluntarily modified without the approval of the central competent authority.
	Stipulated the "Limited Numbers on Registration of Exemptions from the Inspection of Imported Specific Purpose Cosmetics for Personal Use"	It may exempted from applying for registration if the amount of imported specific-purpose cosmetics for personal use is not over the announced limits by the central competent authority and the supply, sale, public display, consumer trial offer or transfer to other uses of these cosmetics shall be forbidden.
	Revised the "Scope and category list of cosmetics"	In line with the amendment to the definition of cosmetics, MOHW announced to include the non-medicinal toothpaste and mouthwash in cosmetics management as well as the dates for implementation.
May 30	Stipulated the "Regulations Governing Notification of Cosmetic Products"	Stipulated Regulations for the certain scale of cosmetic manufacturers or importers, product items, contents, procedures, changes, validity term, abolitions and cancellations, and other compliance matters.
	Stipulated the "Regulations for Cosmetic Product Information File Management"	Stipulated Regulations for the certain scale of cosmetic manufacturers or importers, product items, contents, procedures, molification, establishment and storage of product information file, validity term, location and qualification of signatory for the safety report, and other compliance matters.
	Stipulated the "Categories of Cosmetics and the Enforcement Date that Business Shall Complete Product Notification"	Stipulated the categories of cosmetics and the enforcement date that manufacturers or importers shall complete product notification.
	Stipulated the "Categories of Cosmetics and the Enforcement Date that Business Shall Establish Product Information File"	Stipulated the Categories of Cosmetics and the Enforcement Date that manufacturers or importers shall establish product information file.
	Stipulated the "Labeling Regulations for Cosmetic Packaging, Containers, Labels or Directions" and abolished the "The Names of All Ingredients Contained in the Cosmetic Product Shall Be Indicated on the Outer Packaging" and "The Indication Requirement for the Label, Leaflet, and Packaging of Cosmetic Products"	According to Paragraph 4 of Article 7 in the Cosmetic Hygiene and Safety Act, the labeling format, method of cosmetic packaging, containers, labels or directions, and other compliance matters were stipulated. The original regulations were abolished.
	Stipulated the "For Imported Cosmetic Products that Are Re-packaged Domestically, the Packaging or Containers Shall Be Labelled "Re-packaged in Taiwan"	For consumers to easily identify the imported cosmetics that are non-originally packaged, it is required for those imported cosmetics that are re-packaged domestically to be clearly labelled the re-package information with the wording "re-packaged in Taiwan."

Date of announcement	Name	Important content
May 30	Stipulated the "List of Specific Purpose Ingredients in Cosmetic Products," "List of Ingredients Prohibited in Cosmetic Products," "List of Ingredients Restricted in Cosmetic Products," "List of Preservatives in Cosmetic Products," "List of Colorants in Cosmetic Products," and "List of Microorganisms Limits in Cosmetic Products"	For importing or manufacturing of specific purpose cosmetics designed by the public announcement of the central competent authority, an application for registration shall be filed with the central competent authority. No manufacturing or import shall be allowed until a license is approved and issued. Cosmetics shall not contain mercury, lead or other ingredients banned for use as per announcement of the central competent authority; the central competent authority may restrict the use of cosmetic ingredients to prevent and avoid causing allergies, irritation, depigmentation, conditions that pose a hazard to human health. Hence the relevant regulations are announced.
June 4	Stipulated the "Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical Efficacy of Cosmetic Products"	The "Regulations Governing Criteria for the Label, Promotion, Advertisement with Deception, Exaggeration, or Medical Efficacy of Cosmetic Products" have been stipulated as the identification standards in order to protect the health of Taiwanese citizens and the rights and interests of consumers, as well as maintain the stability of the laws.
June 25	Stipulated the "Types of cosmetics that are required to meet the Cosmetics Good Manufacturing Practice Regulations"	According to Paragraph 2 of Article 8 in the Cosmetic Hygiene and Safety Act, the types of cosmetics that are required to meet the Cosmetics Good Manufacturing Practice (GMP) Regulations are stipulated.
June 27	Stipulated the "Enforcement Rules of Cosmetic Hygiene and Safety Act"	In accordance with the amendment of the Cosmetic Hygiene and Safety Act, to add the specifications on the person who is responsible for product notification and product information file, the definition of country of origin of the cosmetics, the definition of manufacturing facilities, the exception for hiring and stationing licensed pharmacists or personnel with professional skills in the field of cosmetics at the factory to supervise the dispensation and manufacturing of cosmetics, the storage procedures and the storage obligations of the business operators, and the definition of severe violation in cosmetics promotion or advertisements.
	Stipulated the "Regulations for Qualifications and Training of Cosmetics Professional Technicians"	Stipulated the qualifications, training, responsibilities, and other compliance matters for the cosmetics professional technicians.
	Stipulated the "Regulations for the Inspection and Examination of Imported Cosmetics"	Announced certain cosmetics categories or items that could possibly pose a hazard to hygiene and safety and stipulated the methods, techniques, items, scopes of sampling checks and sampling tests, and other compliance matters. Above cosmetics may only be imported after sampling checks and sampling tests show compliance.

Date of announcement	Name	Important content
June 27	Stipulated the "Cosmetic Manufacturing Facilities Exempted From Factory Registration"	Announced that if the scale of manufacturing facilities for solid handmade soaps that is smaller than the factory standards for product manufacturing and processing scope, area, power capacity and thermal energy and the manufacturing sites is only for the operations of cosmetic packaging, it can be exempted from factory registration.
	Stipulated the "Words and Phrases That Should Be Additionally Labelled on the Outer Packaging or Containers of Imported Cosmetics Which Are Labelled With Words Like 'Medicinal', 'Medicine', 'Medicinal drug', 'Medicate', etc."	With the developing international trade, some foreign products that are regulated as quasi-drugs or OTC drugs, but regulated as cosmetics after importing to Taiwan, such as sunscreens and whitening agents; the outer packaging of these imported cosmetics is labelled with words like "medicine", "medicinal", "medical drug", "medicate", ect. When imported into Taiwan, so we announced that an additional words and pharses is required to be labelled on the outer packaging of these imported cosmetics, to reduce the impact of Cosmetic Hygiene and Safety Act on the imported products and remind Taiwanese citizens not to get confused.
	Stipulated the "Regulations on Cosmetic Hygiene and Safety Violation Report and Reward"	We stipulated the "Regulations on Cosmetic Hygiene and Safety Violation Report and Reward" in order to encourage the public to report unlawful matters, protect the health of the citizens and the rights and interests of consumers, as well as to clarify the relevant regulations for rewarding whistleblowers and issuance of rewards.
June 28	Revised "Regulations Governing the Applications for Animal Testing for the Safety Assessment of Cosmetics or Cosmetic Ingredient"	Specified and amended the regulations in accordance with Cosmetic Hygiene and Safety Act.
August 5	Stipulated the "Regulations Governing Accreditation and Outsourced Accreditation Management of Cosmetic Testing Institutions"	In line with the additional Paragraph 3 of Article 28 in the Cosmetic Hygiene and Safety Act, we stipulated the Regulations for the Management of Certification and Entrusted Certification of the Cosmetic Inspection Agency, including application conditions, certification procedures, validity period, abolishment and matters to be followed.
August 13	Stipulated the "Cosmetics Good Manufacturing Practice Regulations"	On the basis of the requirements of ISO22716, we stipulated the Cosmetics Good Manufacturing Practice Regulations to promote quality management of cosmetic manufacturers and ensure quality, hygiene and safety of the produced cosmetics.

Date of announcement	Name	Important content
August 29	Stipulated the "Establishment Standards for Cosmetics Manufactory"	Revised the relevant requirements for facilities and equipment in the factory according to the operations of the cosmetics manufacturing sites and requirements of dosage form.
October 23	Stipulated the "Usage Precautions for Hair Dyes on the Labels or in the Package and Leaflet," "Usage Precautions for Permanent Wave Agents on the Labels or in the Package and Leaflet," "Usage Precautions for Hair Colour Remover on the Labels or in the Package and Leaflet;" abolished "Usage Precautions for Hair Dyes on the Label or in the Package and Leaflet," "Precautions for Permanent Wave Agents on the Labels or in the Package and Leaflet for Manufacturing or Import," "Usage Precautions for Hair Colour Remover on the Labels or in the Package and Leaflet"	On the basis of Article 7, Paragraph 1, Sub-paragraph 10 of the Cosmetic Hygiene and Safety Act, It is authorized to stipulate that outer packaging or container of cosmetics shall clearly label the matters required by the central competent authority and abolish the former regulation.
December 2	Stipulated the "Technical Guidelines for Water Resistance Test (Test on Human) of Cosmetics with Sunscreen," "Technical Guidelines for Human Skin Patch Test of Cosmetics" and "Technical Guidelines for Human Skin Test of Cosmetics"	To enhance the industrial development of the domestic cosmetics industry as well as strengthen the cosmetic management and protect the safety of the testing subjects, TFDA stipulated the "Technical Guidelines for Water Resistance Test (Test on Human) of Cosmetics with Sunscreen," "Technical Guidelines for Human Skin Patch Test of Cosmetics," and "Technical Guidelines for Human Skin Test of Cosmetics."
December 5	Revised the "List of Preservatives in Cosmetic Products"	In response to non-medicinal toothpaste and mouthwash to be included in the cosmetics management in the future, the regulations for the ingredients of non-medicinal toothpaste and mouthwash are also added and it will take effect on July 1, 2020.

Table 10 Collaborative Inspection of Food, Drugs and Cosmetics in 2019

Inspection type	Numbering	Project name (Implementation time)	Results
Food safety	1	Random inspection plan for honey products (March to May)	Inspected: 29 companies I.Registration: 2 companies are not applicable, 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.Labeling: 6 cases do not meet the regulations.
	2	The collaborative inspection project for egg products (July to November)	Inspected: 18 companies I.GHP: 11 companies were required to make improvements within a deadline and all of them passed the re-inspection. II.HACCP: 4 companies are required for the establishment; 2 companies were required to make improvements within a deadline and all of them passed the re-inspection. III.Registration: 3 companies were required to make improvements within a deadline and all of them passed the re-inspection. IV.Random inspection: 8 liquid egg products, of which 1 case did not meet the regulations.
Medical devices	1	Inspection project for online sales of medical equipment (January to June)	We inspected a total of 162 medical equipment sold on 10 online platforms, of which 61 cases were in violation of the relevant regulations of the Pharmaceutical Affairs Act. The violations included not having a pharmaceutical license, not registered in accordance with the "Medical devices that pharmaceutical companies (drugstores) may sell through the communication-based transaction channels and registration requirement," selling of medical equipment that is approved to be sold through the communication-based transaction channels, not disclosing the information (including incorrect license number, the license number and product name of medical device are not completely revealed, etc.) that should be disclosed at an obvious location for consumers through the communication-based transaction channels and do not match with the approved document.
	2	The collaborative inspection project for medical equipment (January to April)	We inspected a total of 63 cases in 57 clinics and medical institutions, including 45 cases of medical equipment. A total of 4 cases were suspected of violating the regulations of Pharmaceutical Affairs Act and the violations include the labeling and product name not match with the original approved document, etc.
	3	The collaborative inspection project for medical equipment (April to June)	We inspected a total of 70 medical equipment shops and other shops with pharmaceutical licenses and pharmaceutical companies with licenses. We inspected 10 non-powered therapeutic mattresses, including 8 medical equipment license numbers, all of their product packaging, labeling, description, package insert and medical license numbers match with the original approved document and their declared uses are also in compliance with the regulations of Pharmaceutical Affairs Act.
Drugs	1	The collaborative inspection project for drugs (July to August)	Inspected 266 companies and 45 pharmacies and 6 cosmetic and drugstores were found in violation of regulations, including sales of prescription drugs without a prescription, pharmaceutical practices not by pharmaceutical personnel and provision and sale of expired drugs.
Controlled drugs	1	Inspection Project for Controlled Drugs (March to September)	We inspected a total of 376 companies, of which 134 companies had violations, including the fact that the books for keeping accounts did not record the daily income, expenditure and balance in accordance with the regulations and the books for keeping accounts did not record the correct information and improper use of medical devices.
Cosmetics	1	The collaborative inspection project for teeth whitening cosmetics (January to April)	We inspected a total of 40 tooth whitening cosmetic companies with medicated cosmetics licenses, of which 23 companies are not applicable; thus we inspected 17 companies with a total of 28 tooth whitening cosmetic products of which 18 products were brought back for quality inspection (the other 10 products cannot be inspected due to insufficient number of sampling). 5 products were found to have inconsistent labeling, of which the inspection results of 3 products did not meet the requirements (1 inspection sample was not labeled in Chinese and thence the test results could not be verified; and the amount of the main ingredient for the other 2 test results did not match with the originally registered document).
	2	The collaborative inspection project for spices cosmetics (May to June)	We inspected 49 cosmetics and drugstores and there is no violation found in the 87 inspected face powder cosmetic products containing talc. In addition, 30 of the face powder cosmetic products containing talc were brought back for inspection (test for asbestos ingredient) and all the 30 products passed the inspection.
	3	Inspection project for cosmetics manufacturers in violation of advertising rules (September to October)	We inspected 10 companies and 44 cosmetic products, of which 1 product label did not meet the regulations.

Table 11 Amendments for the Chinese Pharmacopoeia and the publication of the "Chinese Pharmacopoeia edition VIII" supplement (3)

Category	Number of articles	Briefing on the contents of the addition and amendment to the "Eighth Edition of the Chinese Pharmacopoeia" supplemental articles (3)
New Monographs	199	1.The test methods and acceptance criteria for nitrosamine impurities in sartan-type active pharmaceutical ingredients were added to provide real-time important information. 2.The following were added：Application of Nuclear Magnetic Resonance Spectroscopy, Mid-Infrared Spectroscopy, Ultraviolet-Visible Spectroscopy, Capsules-Dissolution Testing and Related Quality Attributes, Microbiological Examination of Nonsterile Products: Acceptance Criteria for Pharmaceutical Preparations and Substances for Pharmaceutical Use, Analytical Procedures Recombinant Therapeutic Monoclonal Antibodies, Validation of Alternative Microbiological Methods, etc. 3.Documented the eight active pharmaceutical ingredients such as Potassium Cresolsulfonate, Granisetron, Calcipotriol Monohydrate, Travoprost which were developed and manufactured by domestic companies, to promote the development of domestic industries.
Monographs in Amendments	136	
Active pharmaceutical ingredients with domestic characteristics	8	
New General Chapters	31	
General Chapters in Amendments	29	
Total	403	

Table 12 Additional TFDA Analytical Test Methods Form in 2019

Test method category	Test method name	Stipulate/ Amendment
Food promulgated methods (25 articles, 640 items)	1.Method of Test for Marine Biotoxins in Foods - Test of Neurotoxic Shellfish Poison 2.Method of Test for Heavy Metals in Bottled (Packaged) Drinking Water and Ice Cubes 3.Method of Test for Food Additive Specifications - Sodium γ-Polyglutamate	Stipulation
	4.Method of Test for Food Additive Specifications - Potassium Sorbate 5.Method of Test for Food Additive Specifications - Benzoic Acid 6.Method of Test for Antioxidants in Foods - Multiple Analysis 7.Method of Test for Preservatives in Foods 8.Methods of Test for Specifications of (6S)-5-Methyl-tetrahydrofolic acid, Glucosamine Salt as Food Raw Material 9.Method of Test for Veterinary Drug Residues in Foods - Test of Multiresidue Analysis of β-Agonists 10.Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (5) 11.Method of Test for Food Additive Specifications - Sodium Benzoate 12.Method of Test for Food Additive Specifications - Sodium Erythorbate 13.Method of Test for Veterinary Drug Residues in Foods - Test of Flunixin and Tolfenamic acid 14.Method of Test for Veterinary Drug Residues in Foods - Method for Multiresidue Analysis (2) 15.Method of Test for Food Additive Specifications - Sodium Propionate 16.Method of Test for Food Additive Specifications - DL- Malic Acid 17.Method of Test for Food Additive Specifications - Sodium DL-Malate 18.Method of Test for Food Additive Specifications - Gellan Gum 19.Method of Test for Food Additive Specifications - Calcium Propionate 20.Method of Test for Food Additive Specifications - Calcium Chloride 21.Method of Test for Food Additive Specifications - Acesulfame Potassium 22.Method of Test for Food Additive Specifications - D-Sorbitol 23.Method of Test for Food Additive Specifications - Lactic Acid 24.Method of Test for Food Additive Specifications - Glycine 25.Method of Test for Food Additive Specifications - Propionic Acid	Amendment

Test method category	Test method name	Stipulate/ Amendment
Recommended method for food test (43 articles, 433 items)	1.Method of Test for Polycyclic Aromatic Hydrocarbons in Foods 2.Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of *Dissostichus* spp. 3.Method of Test for Animal-Derived Ingredients in Foods - Qualitative Test of *Hippoglossus* and *Reinhardtius* spp. 4.Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event FG72 (UI:MST-FGØ72-2) 5.Method of Test for Genetically Modified Foods - Event-specific Qualitatively and Quantitatively Test of Soybean Event MON87751 (UI: MON-87751-7) 6.Method of Test for Fluoride and Chloride in Foods 7.Methods of Test for Food Microorganisms - Test of Enterobacteriaceae 8.Method of Identification for Rosin as Hair Removal Agents for Foods 9.Method of Test for Sudan Dyes in Foods (2) 10.Method of Test for Methylsulfonylmethane in Foods in Tablet and Capsule Form 11.Method of Test for Pesticide Residues in Foods - Rapid Screening Mass Spectrometry Technique 12.Method of Test for Residual Dioxins and Dioxin-Like Polychlorinated Biphenyls in Hairy Crabs (GC-MS/MS Method) 13.Method of Test for Pesticide Residues in Foods - Test of Paraquat, a Herbicide 14.Method of Test for Veterinary Drug Residues in Foods - Test of Fluralaner 15.Method of Test for Residual Solvents in Foods in Tablet Form 16.Method of Test for Pesticide Residues in Honey - Test of Carbendazim, Fluvalinate and Iprodione 17.Method of Test for Heavy Metals in Vegetables, Fruits, Jams and Jellies 18.Method of Test for Heavy Metals in Mushrooms 19.Method of Test for Total Hydrocyanic Acid in Cassava Products 20.Method of Test for Veterinary Drug Residues in Foods - Test of Tiamulin (2) 21.Method of Test for Glycidyl Esters in Edible Oils and Fats 22.Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Pecan 23.Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Filbert/Hazelnut 24.Method of Test for Plant-Derived Ingredients in Foods - Qualitative Test of Walnut 25.Method of Test for Plant - Derived Ingredients in Foods - Qualitative Test of Cashew 26.Method of Test for Veterinary Drug Residues in Foods - Multiresidue Analysis of Hormones 27.Method of Test for Dimethyl sulfoxide in Raw Material ethylsulfonylmethane 28.Method of Test for Pesticide Residues in Vegetable Oil - Multiresidue Analysis 29.Method of Test for Veterinary Drug Residues in Foods - Multiresidual Analysis of β-Lactam Antibiotics 30.Method of Test for Veterinary Drug Residues in Foods - Test of Closantel 31.Method of Test for Hydroxytyrosol in Foods in Tablet and Capsule Forms 32.Method of Test for Vitamin K_3 in Milk-Based Infant Formula	Stipulation

Test method category	Test method name	Stipulate/ Amendment
Recommended method for food test (43 articles, 433 items)	33.Method of Test for Niacin in Milk-Based Infant Formula 34.Method of Simple Check for Residual Lipid, Starch and Alkyl Benzene Sulfonate on Tablewares 35.Method of Test for Sudan Dyes in Foods 36.Method of Test for Phosphate in Foods 37.Method of Test for Colorants in Foods - Multiple Analysis (2) 38.Method of Test for Melamine in Foods 39.Methods of Test for Food Microorganisms - Test of Lactic Acid Bacteria - *Enterococcus faecium* 40.Method of Test for Sennosides in Foods 41.Method of Test for Methylsulfonylmethane in Foods in Tablet and Capsule Form 42.List of Recommended Methods of Test for Pesticide Residues in Foods 43.Method of Test for Pesticide Residues in Foods - Multiresidue Analysis (6)	Amendment
Recommended test methods for cosmetics and medical devices (5 articles, 66 items)	1.Method of Test for Imperatorin, 5-Methoxypsoralen, 8-Methoxypsoralen, 6-Methylcoumarin, Musk Ambrette, Safrole and Trioxysalen in Cosmetics 2.Method of Identification for Asbestos Fibers in Cosmetics 3.Method of Test for Residual Cross-linking Agents in Hyaluronic Acid Dermal Fillers – Test of 1,4-Butanediol Diglycidyl Ether	Stipulation
	4.Method of Test for Ingredients in Cosmetics 5.Method of Test for Banned and Restricted Dyes in Cosmetics	Amendment
Recommended methods for testing drugs and controlled drugs including illegal drugs) (5 articles, 76 items)	1.Method of Analysis for Synthetic Phenethylamines in Urine 2.Determination of *N*-Nitroso-*N*-Methyl-4-Aminobutyric Acid in Sartan Drug Substances and Drug Products	Stipulation
	3.Method of Test for Synthetic Cathinones in Urine (2) 4.Determination of *N*-Nitroso-*N*-Methyl-4-Aminobutyric Acid in Sartan Drug Substances and Drug Products 5.Determination of *N*-Nitrosodimethylamine and *N*-Nitrosodiethylamine in Medicines	Amendment

Appendix 3 Important Achievements and Statistics Over the Years

Table 1 Statistics of imported food inspection

Year	Inspection Number of Batches	Total net weight (x10k tons)	Batches tested	Growth rate (%)	Testing rate (%)	Number of non-compliant lost
2011	420,602	717.7	29,801	-	7.1	289
2012	461,665	754.5	38,793	9.8	8.4	467
2013	514,710	713.3	38,460	11.5	7.5	557
2014	616,286	796.6	48,704	19.7	7.9	664
2015	640,003	900.5	50,149	3.9	7.8	953
2016	674,991	882.9	52,722	5.5	7.8	915
2017	694,372	896.9	56,604	2.9	8.2	808
2018	682,575	895.0	58,915	-1.7	8.6	820
2019	718,766	925.7	58,108	5.3	8.1	786

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

Table 2 Statistical analysis of the surveillance of pesticide residues, veterinary drug residues, fungi toxins and heavy metals in food

Year	Monitoring of pesticide residues		Monitoring of veterinary drug residues		Monitoring of fungi toxins		Monitoring of heavy metals	
	Total products	Conformity rate (%)	Total products	Conformity rate (%)	Total products	Conformity rate (%)	Total products	Conformity 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

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

Table 3 Statistics on 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 Death	Aquatic products and their processed products	Meat, eggs, dairy and their processed products	Grain, fruits and vegetables and their processed products	Cake, Candy	compound cooking foods and other types	Total of causes with undefined foods
2007	248	3,231	0	4	6	7	0	13	218
2008	272	2,924	0	10	3	2	2	19	236
2009	351	4,642	0	4	2	3	4	43	296
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338
2014	480	4,504	0	18	12	6	3	60	381
2015	632	6,235	0	17	3	7	1	53	551
2016	486	5,260	0	18	4	2	2	56	404
2017	528	6,232	0	7	3	7	0	44	467
2018	398	4,616	0	5	2	5	1	30	358
2019	503	6,944	2	13	5	5	1	26	458

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

Issued health food licenses (individual case review and specification standard review)					Issued genetically modified food licenses	
Year	Individual case review	Specification standard review	Number of issued licenses in the year	Total number of issued licenses	Number of issued licenses in the year	Total number of issued licenses
2008	33	-	33	144	2	14
2009	26	6	32	176	13	27
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

Note:

1:Two kinds of review process are provided for registration of health food.
Individual case review: The applicants shall provide related documents, including food safety, health care effects, etc. and issued number is Wei Bu Chien Shi Tzu No. Axxxxxx.
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 2019, the total number of issued licenses for health food was 454 (including 384 in type one and 70 in type two), of which 64 were invalid licenses (including expired, revoked and combined). As of the end of 2019, the number of valid licenses was 390.

3. As of December 2019, there were 149 licenses for genetically modified foods, of which 0 of them will be discontinued or not be extended. As of the end of 2019, the number of valid licenses was 149.

Table 5 Statistics of approved medicinal products every year

Year	Generic drugs			Active pharmaceutical ingredients			Novel drug			Biologics			Orphan drugs			Total
	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	
2008	383	44	427	13	59	72	18	76	94	1	25	26	2	2	4	623
2009	449	47	496	5	91	96	24	56	80	0	17	17	0	2	2	691
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

Table 6 Number of valid GMP/QSD registration letters for medical devices every year

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

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

Year	Medical devices				Specific-Purpose Cosmetics	
	Number of issued license in the year	Total number of licenses	Domestic licenses	Imported licenses	Number of issued license in 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

Remarks: 6,253 licenses were announced to be cancelled in 2018; 4,653 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 (%)
2008	12,465	39,467	16,241	270	1.66
2009	12,830	41,157	16,355	245	1.50
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

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(#1)	Domestic Western Medicine Preparation Factories that Passed the PIC/S GMP (#2)	Total number of foreign manufacturers complying to PIC/S GMP
2008	151	-	-
2009	154	5	-
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

Remarks:1. The compiled data are before 2012, given all modern pharmaceutical manufacturers have to be in line with the standards of PIC/S GMP since 31/12/2012.
2. In order to follow the administrative schedule of PIC/S GMP, Taiwan and international collect the data since 2009 and 2010 separately.

Table 10 Statistics of post-market quality monitoring for drugs and cosmetics

Year	Drugs		Biological medicine		Traditional Chinese medicine		Medical devices		Cosmetics	
	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)	Number of cases	Failure rate (%)
2008	164	16.46	0	0	1,000	▲	12	91.67	54	7.41
2009	180	1.11	0	0	720	▲	45	11.11	87	14.94
2010	198	3.03	0	0	660	▲	28	42.86	51	29.41
2011	230	8.70	23	0	664	3.13	14	21.43	204	0.49
2012	168	4.76	23	0	629	4.70	132	15.15	109	16.51
2013	173	1.16	26	0	544	3.47	200	6.50	100	3.00
2014	90	3.33	148	0	134	2.99	216	4.63	520	5.19
2015	212	0	0	0	-	-	46	0	251	2.79
2016	88	5.70	-	-	-	-	193	0	329	1.52
2017	114	4.39	-	-	-	-	57	19.30	102	7.84
2018	348	1.10	-	-	-	-	58	3.40	180	2.80
2019	109	1.70	-	-	-	-	58	13.80	170	1.18

Remarks:1.The investigation of heavy metals, pesticide residues and aflatoxin in traditional Chinese medicine were for background values survey, which is indicated by "▲".
2."-" indicated that there is no quality monitoring plan implemented for this category.

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		Annual Summary	
	Domestic		Imported		Imported		Domestic		Imported		Imported			
	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage	Batch	Dosage
2008	47	4,209,083	159	9,001,470	130	1,019,543	2	2,926	3	27	14	232,549	355	14,465,598
2009	61	6,815,963	139	9,364,656	123	1,013,093	5	5,979	1	20	17	189,915	346	17,389,626
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

Table 12 Statistics on the number of certified laboratories and certified items in calendar years

Year	Food certification Laboratory		Medicated/Cosmetics certification laboratory		Cosmetics certification laboratory		Drug abuse certification laboratory		GLP certification testing institution	
	Number of households	Number of items	Number of households	Number of items	Number of households	Number of items	Number of households	Number of items	Number of households	Number of items
2008	18	280	3	16	-	-	13	9	1	3
2009	23	298	7	55	-	-	13	9	8	16
2010	41	421	24	230	-	-	13	9	9	19
2011	55	481	26	248	-	-	13	9	16	26
2012	61	637	29	405	-	-	13	9	18	42
2013	58	632	31	536	-	-	13	9	20	58
2014	61	665	30	488	-	-	14	9	17	49
2015	72	789	30	370	-	-	15	9	15	53
2016	81	1,046	34	379	-	-	14	9	15	44
2017	87	1,124	37	367	-	-	14	9	14	55
2018	95	1,264	36	365	-	-	16	9	13	56
2019	100	1,364	29	303	15	51	16	25	15	56

Note: The Medicated/Cosmetics certification laboratory was divided into pharmaceutical certification laboratory and cosmetics certification 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

years	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

Remarks:
1. The collaborative team for busting the counterfeit, fake or poor drugs was established in April 2010.
2. A total of 841 illegal drug cases were seized in 2019 with a total fine of NTD 4.495 million, the seizure rate decreased from 11.81 % in 2010 to 2.66% in 2019.
3. The number of violations in food, drugs and cosmetics by the health authorities was 6,275 in 2019, with a total fine of NTD185.51 million. The advertisement violation rate decreased from 13.90% in 2010 to 4.89% in 2019.

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

Unit (thousand dollars)

Year	Income	Expenditure	Pay to the national treasury
2008	477,135	348,335	101,441
2009	507,794	359,321	138,473
2010	484,762	268,215	145,956
2011	491,524	321,823	116,414
2012	494,672	329,731	120,000
2013	513,092	340,359	120,000
2014	533,320	290,570	120,000
2015	593,448	284,359	120,000
2016	701,254	324,564	100,000
2017	791,580	439,074	50,000
2018	823,305	604,566	120,000
2019	881,881	631,176	120,000

Appendix 4 TFDA Publications in 2019

Serial number	GPN	Topic	Responsible unit	Type	Publication year/ month
1	1010800570	2019 Drug abuse cases at the workplace and prevention Q&A manual	Division of Controlled Drugs	books	2019/04
2	1010801423	2019 Drug Abuse Prevention Guide	Division of Controlled Drugs	books	2019/08
3	2010103850	Annual Report on Food Import Management and Inspection	Division of Food Safety	books	2019/09
4	1010802257	The supplemental articles for the eighth edition of the Chinese Pharmacopoeia (3)	Division of research and analysis	books	2019/12
5	1010802361	Prevention case of drug abuse Handbook: Stay Away From Drugs	Division of Controlled Drugs	Digital publications	2019/12
6	1010802362	Food inspection technology and frequently asked questions	Division of research and analysis	books	2019/12
7	1010802620	GO together with cosmetics, play and beauty for myth analysis	Division of Medicated Cosmetics	Digital publications	2019/12
8	2010002894	Annual Report of Foodborne Outbreaks and Prevention	Division of Food Safety	Books and digital publications	2019/12
9	2010301353	TFDA Annual Report	Division of Planning & Research Development	Continuity (Journal)	2019
10	2010302286	TFDA Annual Report (English version)	Division of Planning & Research Development	Continuity (Journal)	2019
11	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning & Research Development	Continuity (Journal)	2019
12	49094052333	Drug and Food Safety Weekly	Division of Planning & Research Development	Continuity (Journal)	2019

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	TFDA Open Data Platform provides original information regarding food and drugs for external access and applications, to enhance the operating transparency of TFDA's governance policy.	
4	TFDA News	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	https://tifsan.fda.gov.tw/workflow/login.jsp	A platform that allows TFDA to communicate internal data, report public opinions and exchange relevant information with public health bureau.	
7	Food and Drug Safety Authority Network	https://fadenbook.fda.gov.tw	A digital system established by government agencies to manage the food and drug business operators in the industry.	
8	The registration platform for food and drug business operators	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	Food Traceability Management Information System	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.	
10	The interpretation and query system for the Act Governing Food Safety and Sanitation	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.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
11	System for Searching the Drafts of Food Additive Standards	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 TFDA; it is for the competent authorities to manage food, drugs and cosmetics in their jurisdiction.	
15	Curriculum management system of food sanitation and safety	https://foodedu.fda.gov.tw	Food hygiene workshops, HACCP workshop resources and course enquiries are available for registration from all walks of life.	
16	Food 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	Drug registration and review Online submission Platform	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.	
18	Trace and track system of medicinal products	https://dtracebook.fda.gov.tw	A system that offers businesses to upload medicinal products traceability or track the uploaded data.	
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 general public, medical professionals and manufacturers can use this system to report adverse drug reaction	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
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 Cosmetics Management System	https://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	A system allowing the public to inquire information on approved advertisements for medical products, medical devices, and cosmetics.	
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 Notification Platform	https://cos.fda.gov.tw	The manufacturers or importers shall notify product information on the“Cosmetic Product Notification 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.	
27	Online Application System of Human Organ Bank	https://oap.fda.gov.tw/B105/	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	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.	

Serial number	Name of the Website in Chinese	URL	Website introduction	QR Code
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	Service Email for the general public	http://faq.fda.gov.tw/	The Mailbox Service of the Director-General is an important communication channel for the public to submit their petitions and express their opinions. The intelligent inquiry service has been created to make the overall service process even more efficient and enhance the satisfaction Schedule of the public.	
33	Online System of the JFDA journal	http://jfda.researchcommons.org/journal/	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.	

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