2018
Taiwan Food and Drug Administration
Annual Report

FDA Taiwan Food and Drug Administration

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2018 Taiwan Food and Drug Administration Annual Report: Foreword

PROFESSION
SERVICE
QUALITY
INNOVATION

Taiwan Food and Drug Administration (“TFDA”) aims to pursue the quality and safety of food, medicinal product, medical devices, and cosmetics in our daily life to address Ministry of Health and Welfare's promise of promoting public health and welfare. Every year TFDA compiled and published a annual report to let the public be aware of TFDA’s important policies and administrations outcomes.

2017 was an advanced and prosperous year for TFDA. With regard to food safety management, the five-point food safety policy is revised into the following five subcategories: “Strengthen source control management,” “Re-establish the food production-management system,” “Strengthen government inspection capabilities,” “Increase liability for producers and vendors,” and “Encourage and create oversight platforms.” In terms of food risk analysis, the Decision Support Center applies mega data and the technique of data mining to detect risk levels, and build surveillance models that provide as a reference for other business departments. The ultimate goal of food safety was achieved through the combination of proper management policies and the five-point food safety policy, including the reinforcement of safety control, the promotion of industrial development, and the construction of “safe buying, safe eating” to formulate a safe food environment.

When reviewing the management outcomes of the food source control, TFDA strengthened food hygiene and safety via scientific evidence and the implementation of administrative management, inspection, testing, and audition. The administration is accessible for the public and the food industries through the “Food and Medicinal Products Business Registration Platform,” which includes approximately 450,000 registry data and relevant announcements.

With regard to pharmaceutical affair management, TFDA continuously constructed a biomedical and pharmaceutical regulatory environment that is in line with the international standards, revised relevant pharmaceutical laws

and regulations, and enhanced the quality of drug manufacturing/processing to accomplish pharmaceutical management. In 2017, the TFDA promulgated and implemented three "Refinement Measures on the Review Process of Drug Clinical trial" to greatly shorten the review duration and to improve review efficiency. Moreover, TFDA strived to establish a traceability system on medicinal products. In May 2017, this system was officially released online to provide consultation and promotion services for business declaration. According to the record, this online system provided consultation service for 1,700 individuals in the year of 2017. Moreover, to ensure the quality and integrity of medicinal products throughout the storing and shipping process, TFDA certified 275 Western medicinal product manufacturers/dealers to comply with GDP regulations. TFDA also implemented comprehensive drug distribution management to ensure safe drug use and to fight against adulterated drugs from entering the supply chain. In 2018, TFDA collected suggestions from businesses and local Department of Health to keep on improving the declaration web page and user interface. In the meantime, TFDA planned and analyzed the backstage management and statistical data to cooperate with inspections carried out by local Department of Health, emphasize on drug supply chain management, and ensure safety drug use.

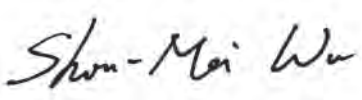
Through Executive Yuan's announcement of amending additional 14 controlled drugs in the regulation and the encouragement of reporting improper use or abuse of addictive substances in clinical cases, TFDA kept substances that are harmful to human health from entering the public. The new manufacturing facility for controlled drug was completed on schedule in mid-2017, which was enlarged by 2.3 times. With this facility, the supply of controlled drugs is now secured. In 2017, to combine novel innovations with anti-drug campaign, TFDA held a hackathon competition for the first time with the theme of "Drug Prevention."

It is also important to note that TFDA separated the regulations on medical devices from the *Pharmaceutical Affair Act*, and drew up a separate law for medical devices to cover both industrial development and the rights/interests of the consumers. The "*Cosmetic Hygiene and Safety Act*" was promulgated on May 2 2018, which strengthened and improved the management framework for cosmetics. Moreover, with the promulgation of 9 related regulations and announcements, which includes "Regulations governing 15 ingredients such as Safrole that are ingredients prohibited for use in cosmetic products," our management on cosmetics is moving forward to be in line with international trends.

In addition to the above achievements, TFDA also established a cross-departmental "Unlawful Food and Drug Events Tackle Platform" and added a "Rumor Buster" section on the TFDA official website. The purpose of this section is to clarify rumors and pass on proper food, drug and cosmetic knowledge by collecting various folk prescriptions or news online, and responding with professional as well as correct information. Up until now, over 300 myths had been debunked, allowing the public to receive accurate information promptly.

In the future, "Safe and effective medicinal products, safe and healthy food" will always be the primary mission of TFDA. Under the vision of "Being a reliable guardian on food and medicinal product safety" and "creating a safe food and medicinal consumer environment," TFDA is committed to integrate source management, effective monitor, and inspectional technology, as well as to maintain the core value of placing consumers' safety in priority, which will eventually establish a new order on food, medicinal and cosmetics management.

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



New Strategies for Food and Drug Safety

Pro-market control

Source Management & Manufacturing Control

- Food businesses management (Registration, GHP, HACCP,1st tier quality control, traceability system)
- Pharmaceutical products manufacturing control (PIC/S GMP)
- Cosmetics manufacturing & management

Registration

- Specific food products (health foods, food additives, etc.)
- Medicinal products
  Medical devices
  Medicated cosmetics

Post-market Surveillance

Distribution Management

- Food GHP inspection
- Pharmaceutical products manufacturing management
- GDP for pharmaceutical products

Product Quality Surveillance

- Distribution inspection
- Advertisement / Labeling inspection
- Complaints report
- Warning collection
- Medicinal product safety surveillance

Customers

- Information transparency
- Risk communication
- Drug injury relief, food safety foundation
- Food poisoning, unanticipated reaction report
- Adverse medicinal product / adverse event report
- Adverse cosmetics event report

01 New Strategies for Food and Drug Safety

Taiwan Food and Drug Administration (TFDA) has taken up the mission of constructing a sound and safe food and medicinal products management system and building a trustworthy public food and medicinal products consumer environment. Under the vision of "Safe and effective medicinal products, safe and healthy food," TFDA upholds the core concepts of food and medicinal products "Total product life cycle management," and serves as the guardian of public health through the management of sources, manufacturing, and circulation.

Section 1 Food Management Overview

To maintain public confidence in food sanitation and safety, TFDA collects and refers to international standards and techniques, promulgates and revises regulations related to "A*ct Governing Food Safety and Sanitation*"(abbreviated as the *Food Safety Act*), strengthens inspection competence and volume, and develops novel inspection methods. TFDA also actively promotes management, including food business registration system, food traceability system, food businesses self-management, border inspection of imported food, specific food registration, system updates and source control, etc. TFDA works with local governments and Health Bureaus to carry out programs for the inspection, sampling and testing, as well as post-marketing surveillance of food products, in order to prevent defective products from listing and to ensure food hygiene, safety and quality.

In addition, TFDA continues promoting "Five-point Food Safety Policy" (Figure1-1). Industry self-regulation, government management and civil participation are three major forces behind the effective implementation of the policy to complete the farm-to-table management process as well as to build up a strong and credible food safety system in which the consumers may purchase with confidence. For food management overview (Figure1-2).

Figure1-1 Five-point Food Safety Policy

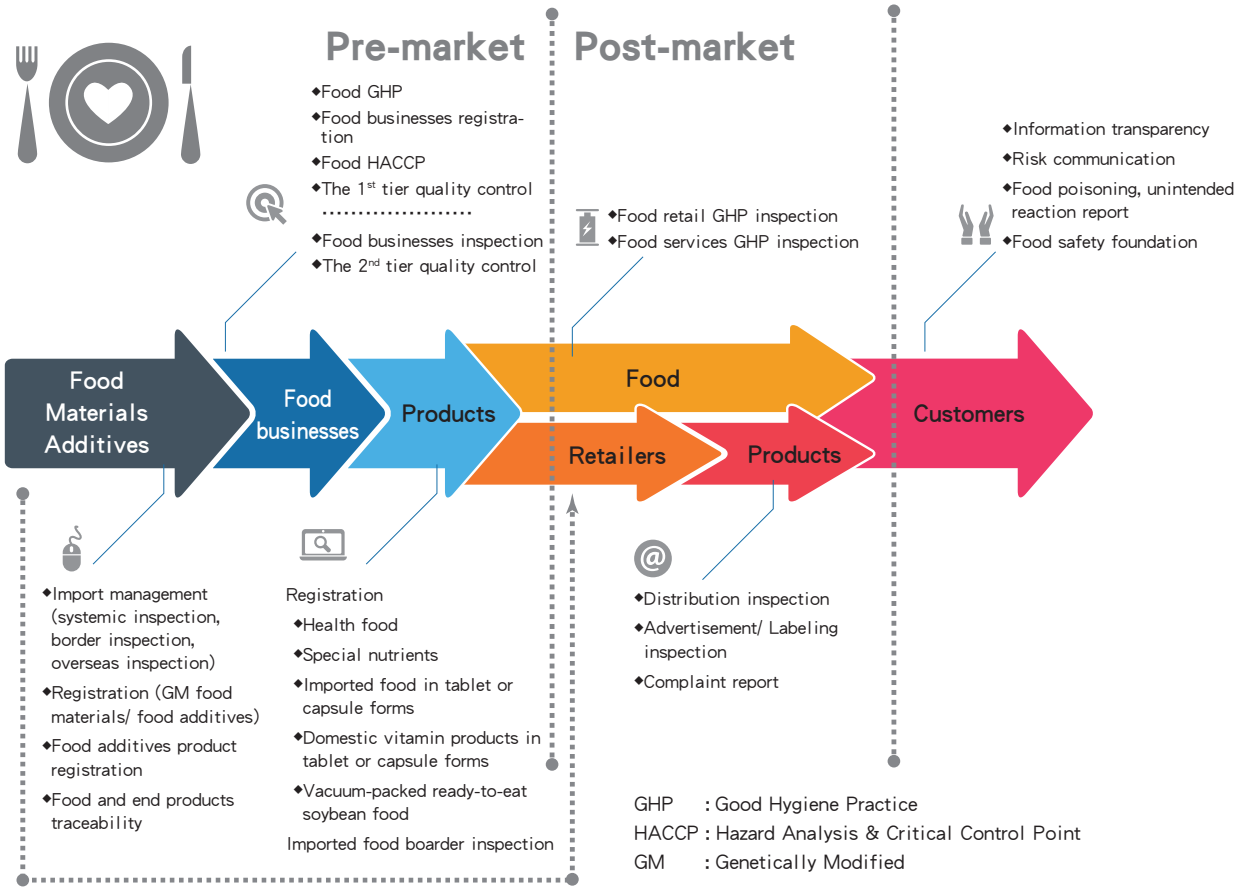


Figure1-2 Food life cycle management

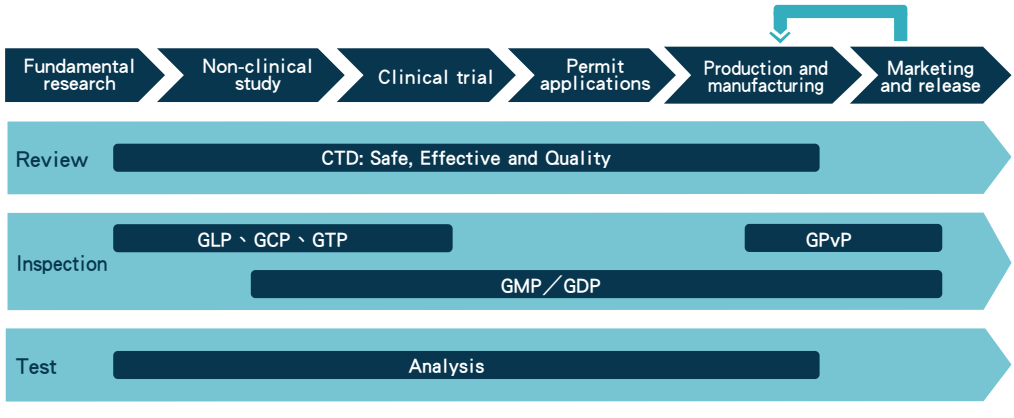
Section 2 Overview of Drugs and Cosmetics Management

In order to promote the safety and quality of medicinal products, and to facilitate the development of the biotechnology industry, TFDA established a regulatory environment in line with international trends to respond to global market development and law harmonization. At the same time, TFDA continued on advancing drug review capacity and impoving product shortage reporting/assessment system; activate search potential cases and establish counseling projects to expedite the production of innovative medical devices and medicinal products in Taiwan, and thus achieve a stable supply chain and provide industry consultation/counseling services and complete product review system. TFDA also strengthened product manufacturing, distribution management, and quality surveillance, to establish medicinal product traceability and follow-up system and accomplished an overall safety and quality control of medicinal products and cosmetics.

Moreover, TFDA is committed to diversify pharmaceutical affairs services, and create a correct and supportive educational environment to increase the awareness of safe drug, medical device, and cosmetics use of the public.

1. Medicinal products management framework

The medicinal product life cycle from research and development to market release include the following steps: fundamental research, non-clinical studies, clinical trials, license applications, manufacturing, and market distribution. Each step should be in compliance with various



CTD ：Common Technical Document
GLP ：Good Laboratory Practice
GCP ：Good Clinical Practice
GTP ：Good Tissue Practice
GPvP：Good Pharmacovigilance Practice
GMP ：Good Manufacturing Practice
GDP ：Good Distribution Practice

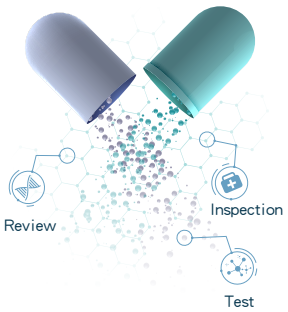


Figure1-3 A comprehensive medicinal product life cycle management framework

specifications (GXP) and to be audited or inspected by the Regulatory Agency, and thereby forming a comprehensive medicinal product life cycle management framework. To ensure study data integrity and reliability, GLP and GCP compliance are required for non-clinical studies and clinical trials respectively. As for the manufacturing processes, GMP shall be followed. TFDA conducted GCP, GLP and GMP audit/inspection following international standard, and where necessary, pre-market release inspection and analysis, as well as post-marketing sampling tests, would be carried out to ensure continuing compliance with Good Pharmacovigilance Practice (GPvP). These measures would improve measures for medicinal product quality and safety surveillance and achievement of all medicinal product life cycle management objectives (Figure 1-3).

2. Controlled drugs management framework

Prescription drug abuse has been a common problem faced by various countries around the world, suggesting that abuse or illegal distribution may lead to major damage caused by addiction problems, which would be as serious as drug issues. Therefore, Prescription drug management is a critical measure to prevent abuse and to ensure public health.

According to "*Single Convention on Narcotic Drugs* (1961)," "*Convention on Psychotropic 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

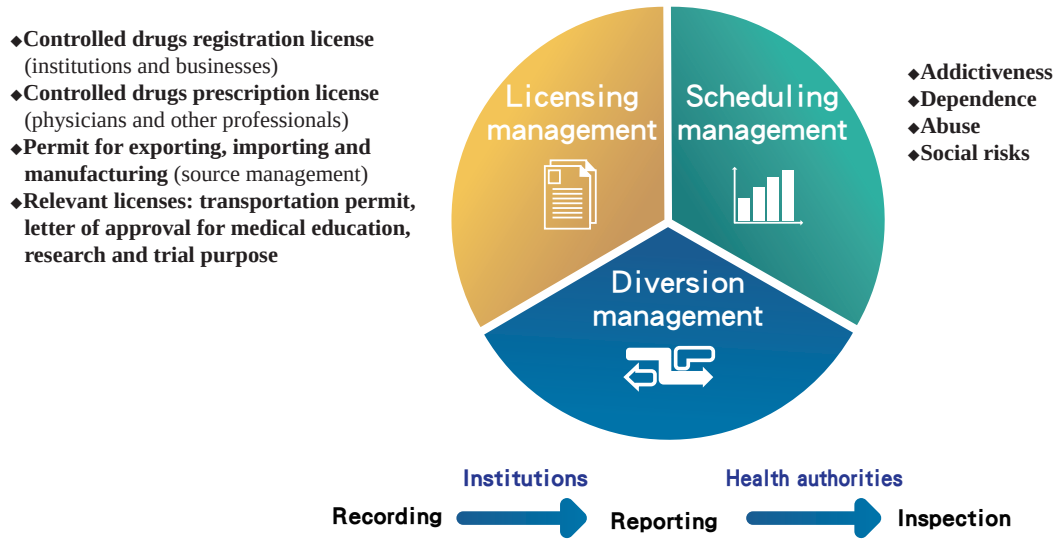


Figure1-4 Controlled drugs management framework

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 1-4)

3. 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, the TFDA has established a Total Product Life Cycle (TPLC) management policy for medical devices (Figure 1-5) 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 to 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.

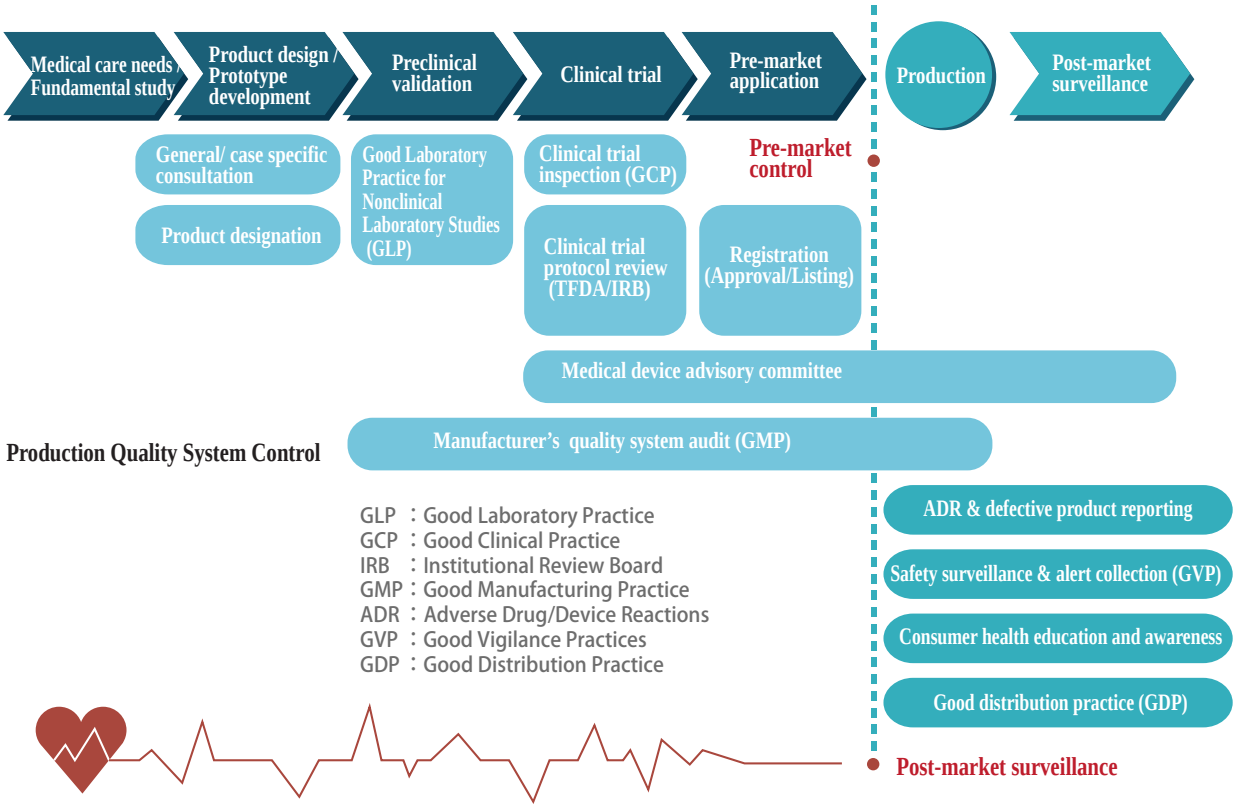


Figure1-5 Total product life cycle management policy for medical devices

4. Cosmetics management framework

The current cosmetics management system is divided into production source control, pre-market management, and post-market surveillance. (Figure 1-6) Source control management includes ensuring that manufacturers comply with Establishment Standards for Cosmetics Manufactory and promoting voluntary Good Manufacturing Practice (GMP) for cosmetics. Pre-market management includes registrations of medicated cosmetics. And post-market surveillance focuses on implementing cosmetics quality surveillance programs with 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.

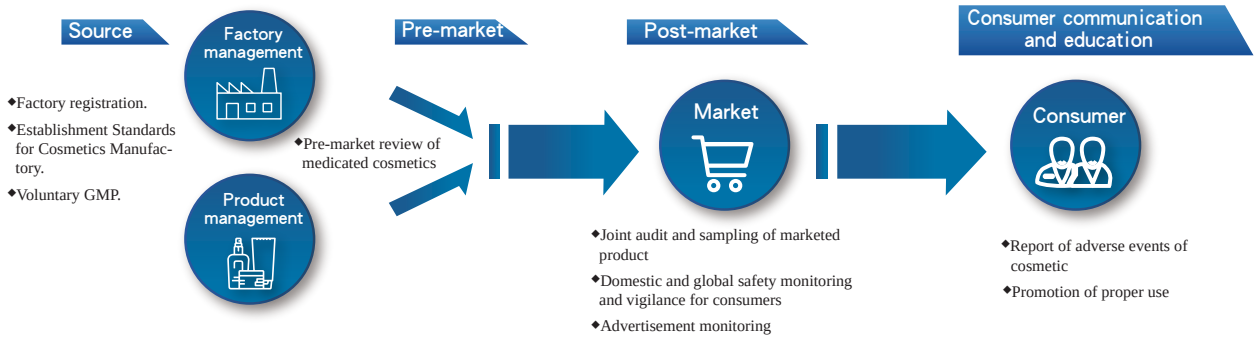


Figure1-6 Cosmetics management framework

Note: The amended draft of the Cosmetic Hygiene and Safety Act was reviewed and approved by the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan on December 20, 2017. On December 29 of the same year, the Legislative Yuan decided to send the draft for negotiation among party caucuses. The amendment was announced by the President through the Hua-Zong(I)-I-Zi No. 10700045851 order on May 2, 2018, with the enforcement date to be determined by the Executive Yuan. In the future, the term “medicated cosmetics” will be changed to “specific purpose cosmetics” and the product notification and product information file will replace the existing pre-marketing registration system for medicated cosmetics. There is a five-year transition period in place for the switch from the registration system to the new one.

Reinforced Food Safety Management

Food safety Information Network

- Inter-departmental system integration
- Establish automated risk identification
- Promote food safety information

The New System of Food labeling

- Enhancing the food information transparent e.g. labeling for chocolate, food utensils, food containers or packaging, vinegar, etc.

New Food Test Technology

- Assistance in tests on emergency events
- Development of new test technology

- 17 categories food businesses that shall enact food safety monitoring plan and mandatorily conduct tests
- The restaurant within the Five-Star hotels and the transport via railway offering meal boxes shall implement food safety control system (HACCP)
- Expanded "*Regulations for Category and Scale of Food Businesses Required Professional or Licensed Personnel*" to 15 categories
- Reinforced self-management of businesses

- The 3rd party certification system
- "2nd quality control"& "expansion proposal"

Aquatic Product Dairy Product

- Expand the scope of systematic inspections
- Overseas source management of high-risk imported foods

02 Reinforced Food Safety Management

To ensure food safety from the farm to the dining table, it requires joint efforts of the respective government agencies devoting to the total food management, which helps shaping and assuring quality dietary environment. In 2017, the administration had achieved important innovations, including the control of the imported sources, acceleration of exports, revelation of product information on the food labels, self-management enhancement of food industry, the third-party certification system, promotion of "New Southbound Policy," food safety perfection via the information system, and the development of new testing technologies for food.

Section 1 The New Management System for Exported and Imported Food

Origin of Policy

Since Taiwan imports a large number of foods and raw materials, to strengthen risk management on the imported foods is necessary. TFDA has promoted new management measures on the imported food in 2017, including expanding the scope on implementation of systematic inspections and strengthening the management of imported edible shellfish products.

In addition, with the development of technologies, the government's digital service transformation has been promoted, and the "free sales certificate" application has been fully processed online.

Implementation Measures

1. Expand the scope of systematic inspections

Strengthening the source management of imported foods is the first point of the Five-point Food Safety Policy. Furthermore, the systematic inspection measures are generally adopted by most countries around the world for imported animal-derivative products. On August 4, 2017, the

amendment of the "*Regulations for Systematic Inspections of Imported Food*" was issued and the systematic inspection on the imported aquatic products and dairy products started since January 1, 2018.

2. Strengthening the management of imported edible shellfish

Shellfish products such as scallops, oysters, abalone, clams and mussels are the favorite foods in Taiwan, but they are susceptible to water pollution of the growing and harvesting areas, resulting in the potential risk of shellfish poisoning toxin and norovirus. The relevant food poisoning cases and international food safety warnings often occur.

For the purpose of strengthening the management of imported edible shellfish in foreign sources, a new measure was issued on October 31, 2017, the edible shellfish listed in 0307 of the Harmonized System Codes (HS codes) imported to Taiwan shall be accompanied with a health certificate including the information of harvesting area, and this new measure was implemented since January 1, 2018. The food safety management of imported shellfish product has entered a new phase (Figure 2-1).

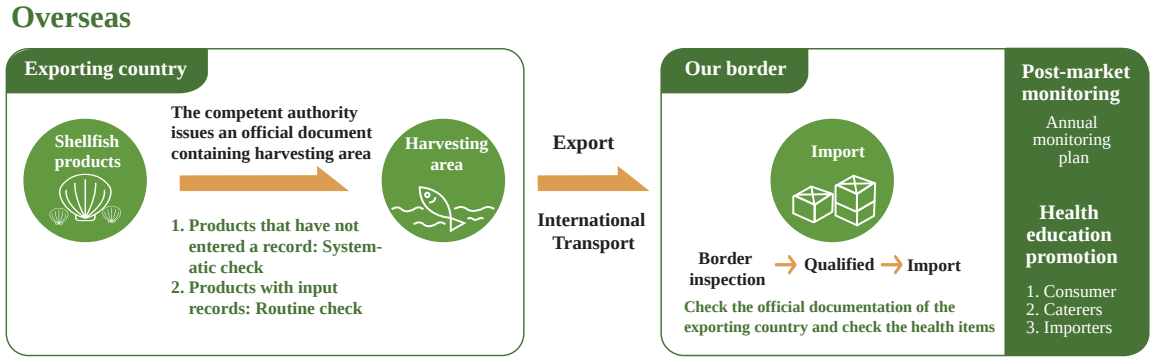


Figure2-1 Imported shellfish products food safety management of our country

3. Introduction of online applications of the supporting documents for export

The executions of the Government have been closely following the international technology development trends, to drive the shift toward the digital services.

From May 9, 2016, the new version of the Application System for Export of Food Sanitation

Certification (http://asefsc.fda.gov.tw/) was launched. The food manufacturers may apply the English version of sanitation certifications of food (and additives) for export, the inspection reports and the free sales certifications online. For these who meet the requirements after reviewing, the certificates will be issued (Figure 2-2).

Figure2-2

The digitization of various certificates for food export has become more convenient

Outcomes and Benefits

1. Strengthening management for imported foods and promoting the sanitary condition and safety of products

(1) Systematic inspection management measures are generally adopted by most countries around the world for managing imported animal-based products. It helps to determine whether the food safety management system of the exporting country is equivalent based on the systematic inspection. Through these management measures, source control against high-risk imported foods become more comprehensive and the safety of imported foods is more assured.

(2) The purpose of health certificate requirement for shellfish products is to strengthen the management in foreign source. Once a contamination event occurs, the imported countries can adopt to the control measures exclusively at the affected harvesting area. Hence, it reduces the impact on trading.

2. Introduction to online applications of the supporting documents for export

Since the launched of the online application system at the end of December 2017, there were 586 cases of online applications. Moreover, in response to the environmentally-friendly paperless operations, the application of free sale certificate was completely filed online since March 1, 2018.

To facilitate the companies' familiarity with the system, an operation manual is available online for download. In addition, several seminars have been held in recent years, and the hotline is also available. For more information, please visit http://asefsc.fda.gov.tw/ (Figure 2-3), or call the toll-free hotline 0800-676-668.

Figure2-3 The operations of online applications for export certificates of food.

Section 2 New System of Food Labeling

Origin of Policy

The food label is one of the important references when buying food. The producer shall label the nature of the food on its package. The label not only serves as a communication channel between the producers and the consumers, but also represents the producers' responsibilities to their own products. To enhance the regulations of labeling, Ministry of Health and Welfare (MOHW) has revised the *Food Safety Act* and related regulations, to enable the food producers perform their obligations of revealing correct information.

Implementation Measures

To make the food information transparent, according to Article 22, 24, and 26 of the *Food Safety Act*, many regulations of labeling foods have been enacted in 2017, as demonstrated in Table 2-1. On November 15, 2017, the "*Guidelines for Front of Package Nutrition Labeling* (FoP)" was issued to encourage producers compile a "visualized" nutrition labeling, which help people understand nutritional composition (Figure 2-4).

Figure2-4 The Sample of FoP

Outcomes and Benefits

In recent years, the Administration has promoted the labeling regulations, such as name labeling (e.g. chocolate labeling), and the labeling for certain sales channels (e.g. vending machines). The execution has been expanded to the information disclosure, such as GMO, glued meat, in the direct food service venues (e.g. drink shops, and restaurants). Hence, with the food labels that indicate the nature of food, consumers are able to buy what they need. To help the food business better understand the labeling regulations, many promotion materials are produced (Figure 2-5). In the future, the Administration will keep on enhancing the label management policy by referring the international standards and focusing on the food information sought after by the consumers.

Figure2-5 The promotional materials for the new system of food labeling

Table2-1 Promulgation and implementation of the food labeling regulation in 2017

No.	Date	Title of announcement	Details	Date enforced
1	February 4, 2016	*Regulations Governing the Warning Label of Prepackaged Foods Co-mingled with Toys*	To prevent children from eating toys in the prepackaged food, the package food co-mingled with toys shall state a warning label on the package.	January 1, 2017
2	March 8, 2016	*Food Additives Shall Significantly Label Registration Number Product*	Food additives shall be clearly labelled with wording like “registration number of the product” and its registration number on the product container or outer packaging.	January 1, 2017
3	April 18, 2016	*The Regulations of Labeling for the Food Utensils, Food Containers, or Packaging*	If any food utensils, food containers or packaging with plastics contact food surface, the product name, name of materials, thermal resistance temperature, whether it is disposable, and other matters shall be indicated before selling.	July 1, 2017

No.	Date	Title of announcement	Details	Date enforced
4	May 16, 2016	*Regulations on the Product Names and Labeling of "Barley" Food*	The exterior package of "Barley" product shall not only be labeled with product name as "foreign barley", "small barley" or "pearl barley", but also be listed with actual ingredients such as "barley (foreign barley)", "barley (small barley)" or "barley (pearl barley)", and the contents shall be labeled as "barley" truthfully.	January 1, 2017
5	May 16, 2016	*Regulations on the Product Names and Labeling of "Corn Flour"*	As of "corn flour" products, the used contents shall be labeled truthfully. In addition, for "corn flour" as one of the food ingredients, the contents shall be labeled as "tapioca flour" or "potato flour" truthfully.	January 1, 2017
6	June 24, 2016	*Regulations Governing the Product Name and Labeling of Chocolate*	Products with the name "black chocolate," "white chocolate" or "milk chocolate" shall be labeled with its ingredients and amount of contents.	January 1, 2017
7	July 14, 2016	*Regulations on the Product Named of Specific Fish*	For product named by specific fish, the contents shall contain the claimed specific fish.	January 1, 2017
8	November 1, 2016	*Regulations on Iodine Labeling for Prepackaged Food Grade Salt Products*	Both reminder and nutrition labeling of prepackaged food grade salt products that add potassium iodide or potassium iodate shall be handled in accordance with the provisions.	July 1, 2017
9	November 10, 2016	*Regulations Governing the Product Names and Labeling of Prepackaged Coffee Creamer (奶精 Nai-jing) Products*	Prepackaged coffee creamer products that are labeled or claimed as"奶精(Nai-jing)" in Chinese characters shall be labeled with reminder information	July 1, 2017
10	December 19, 2016	*Regulations Governing the Labeling of Formula for Certain Disease*	The name and source of regulation and the related legal terms are revised. To protect the safety of the consumers, the conspicuous alert shall be labeled.	January 1, 2017
11	February 6, 2017	*Regulations Governing the Product Names and Labeling of Prepackaged Butter, Cream, Margarine and Fat Spreads*	Regulates the name and the fat content of "butter," "cream," "margarine," and "fat spreads".	July 1, 2017
12	June 2, 2017	*Regulations Governing the Labeling of Food Products Sold by Vending Machines*	The food sold by vending machines shall be labeled as required; except for the food information, the vending machines shall be labeled conspicuously with the company information.	July 1, 2017
13	June 6, 2017	*Regulations Governing the Labeling of Prepackaged Vinegar*	It is required to indicate in readily visible areas on the package that vinegar made of specific raw materials is ""blended" or "artificial".	July 1, 2018
14	July 26, 2017	*The use restrictions of Cordyceps militaris and warning label requirements of food products containing Cordyceps militaris*	The conditions of manufacture and usage quantity of *Cordyceps militaris* provided for food use is proposed to be restricted, and food products containing *Cordyceps militaris* shall be labeled with warning information.	July 26, 2017
15	December 29, 2017	*Regulations Governing the Labeling of Health Food*	With the different types of health foods available, there should be caution statements to indicate the purpose, distinctions between drug and food, and reminders of the dose to be used each time.	January 1, 2018

Section 3 Food Production Transformation and Enhancement of Soft Power

Origin of Policy

To promote the "Five-point Food Safety Policy," the related regulations have been established based on the *Food Safety Act*. With the transformation of food production, and the participation of professionals in the food industry, the self-management system of food industry sanitation, and the holistic monitoring of food safety are achieved.

Implementation Measures

1. The first tier quality control

The first tier quality control is the spontaneous management imposed by food businesses. Article 7 of the *Food Safety Act* stipulates that food businesses whose category and scale have been announced should establish a food safety monitoring plan and enforce mandatory tests to ensure food sanitation and safety. The *"Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Test and Meet the Minimum Testing Cycle and Other Relevant Matters"* were announced on April 21, 2016. The amended draft was made known on June 7, 2017, with the addition of five types of business that should hold a business registration, company registration or factory registration certificate. Manufacturers, processors, and reconstitution businesses with a factory registration certificate and a capital size of NTD 30 million and above were added and food business of a specific scale were asked to implement the amendment by schedule.

2. The system of food safety management

(1) Article 8 of the *Food Safety Act* specifies that the food businesses shall meet the *Regulations on Good Hygiene Practice for Food*, and the announced categories shall also meet the *Regulations on Food Safety Control System* (Hazard Analysis and Critical Control Point, HACCP).

(2) From 2003, the aquatic processing industry, meat processing industry, food service -box meal factory, dairy process industry, and food service within international tourist hotels have been implemented the system of HACCP.

(3) On September 29, 2017, TFDA announced that the food businesses registered as "edible grease," "canned food," "egg products," "aquatic products processing," and "meat

processing," would implement the HACCP by stages.

(4) On October 27, 2017, TFDA announced the draft of "*Businesses Supplying Meal Boxes for Railway Passengers Shall Conform to the Regulations on Food Safety Control System,*" which the kitchens of the railway operators or the commissioned meal box manufacturers shall implement the *Regulations on Food Safety Control System*.

(5) On November 17, 2017, the regulation "*Restaurants in Hotels Should Comply with the Regulations on Food Safety Control System*" had been promulgated; the regulations required at least one of the restaurants in the international tourist hotels or five-star hotels shall implement the system of HACCP.

3. Food professionals

(1) Article 12 of the *Food Safety Act* specifies that the food businesses belong to the category and scale designated by the central competent authority in a public announcement shall have a certain percentage of professionals with vocational or technical certification in food, nutrition, catering etc.

(2) On September 29, 2017, TFDA announced that the draft of the *Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification* was revised. Food businesses designated by the central competent authority shall hire at least one professional such as the food technician, dietitian, livestock technician, veterinary or fishery farming technician. Moreover, the announced food service and bakery businesses shall employ a certain percentage of professionals with technical certification. The food service businesses may hire the Chinese cuisine cookery technician, western culinary technician or food preparation technician; the bakery businesses may hire food baking technician, Chinese noodle style wheat flour processing technician, Chinese style rice processing technician.

(3) On September 29, 2017, TFDA also announced the expansion of the "*Categories and Scales of Food Businesses that Shall Place the Professionals with Vocational or Technical Certifications*" to 15 categories. By introducing the professionals like food technicians, these experts may practice their expertise, and be responsible for the HACCP system of the food manufacturers, the traceability system, the contingency plan for the hygienic safety incidents, the hygiene and safety of raw materials, quality control, risk assessment and management, quality assurance of labs, and trainings, and thus enhanced the production management and self-discipline of the food businesses.

Outcomes and Benefits

1. Reinforced self-management and risk control of businesses

Since the promotion of first tier quality control in 2014, a total of 23,800 businesses in 17 categories have enforced their food safety monitoring plan and mandatory conduct tests (Figure 2-6). It was announced in advance in 2017 that the practice would be extended to all food manufacturing categories in phases and a total of around 32,139 businesses would be included in the management.

By enhancing the self-management and risk-control principles of the food businesses, food safety and hygiene are improved. Retail sale in non-specialized stores other than department stores implement the first level management as Table 2-2.

1st tier Quality Control　Food safety monitoring system

17 Categories of Food Industry have been designated

	1 Edible grease	2 Meat processing 3 Diary product processing 4 Aquatic products processing	5 Food additives	6 Special Nutrient supplements	7 Soybeans 8 Corns 9 Wheats 10 Tea leaves	11 Starches 12 Flour 13 Sugar 14 Salt 15 Soy Sauce	16 Tea drink	17 Retail sale in non-specialized stores other than department stores.
Import	★	—	★	★	★	★	—	—
Manufacture	★	★	★	★	—	★	★	—

Note: The announced scale is implemented by stages

Figure2-6 Enact food safety monitoring plan and mandatorily

Table2-2 The businesses with retail sale in non-specialized stores other than department stores implement the first level quality management

Item	Details		
Objectives	The business with retail sale in non-specialized stores other than department stores, with three or more independent non-specialized chain stores, and the capital is more than NTD 30 million.		
Scope/Date	Food safety monitoring plan	60 brands 15,000 stores in total	Implementation started from July 31, 2017
	Conduct tests	60 brands	Implementation started from July 31, 2016
Guidelines	On October 2, 2017, the "Guideline for the business with retail sale in non-specialized store establishing the food safety monitoring plan" has been established to facilitate the comprehensive retailers adhere to the related regulations and carry out the risk control principles.		

2. HACCP for food service in hotels and meal boxes offered by Railway Corporation

The tourism in Taiwan is well developed. The hotels not only provide accommodation, but also provides catering and meal services. Transport via railway also offers the meal boxes to serve their passengers as well. In order to call attention to the safety of food served in hotels and offered by transport via railway and to enhance control over the sanitation and safety of the food manufacturing process, the concept of preventive food safety management is introduced. One after another, the regulations that the restaurant within the Five-Star hotels and the transport via railway offering meal boxes shall implement food safety control system (HACCP) were promulgated. Thus, a total of 74 HACCP-implemented businesses were guided to enhance self-management over the sanitation and safety of food, and would eventually ensure dietary sanitation and safety for the consumers.

3. Empowering professionals devoted to improve the food industry

Daily necessities and high-risk foods of high interest have been included as part of the categories in the food industry for which food professionals should be available. It is mandatory to hire professionals in the following 15 food manufacturing, processing, or reconstitution categories: meal box, dairy products processing, aquatic products processing, meat processing, canned food, cooking oils and fats, egg products, noodles and vermicelli, soy sauce, vinegar, seasonings, non-alcoholic beverages as well as international tourist hotel or five-star hotel with catering, and businesses supplying meal boxes for railway passengers.

Though investing more professionals on food to join the industry, and reducing the production risk with preventive approach, the self-management capability of food business is strengthen. Thus, the quantity and quality of the domestic food industry are enhanced.

Section 4 The 2nd Tier Quality Control Policy

Origin of Policy

The "Regulations Governing the Certification and Qualification of Food Sanitation and Safety Management System Qualifying Institutions" was announced on March 11, 2016, setting a new milestone for the 2nd tier third-party certification of quality control. Due to the different regulatory standards and product determination criteria of nutritional supplements between Malaysia and Taiwan, the governments negotiated and approved the "2nd quality control" and "expansion proposal" qualification practices to facilitate such exportation.

Implementation Measures

1. The third party certification system

The following ten manufacturing businesses: canned food manufacturers, food additives manufacturers, special nutrient manufacturer, dairy products manufacturers with factories registered, and the edible grease manufacturer, starch, flour, sugar, salt, and soy sauce manufacturers with capital more than NTD 30 million, announced must be certified (Figure 2-7).

Figure2-7 The categories for the certifications of the 2nd tier quality control

2. Certifications for "2nd tier quality control" and "expansion proposal"

To solve the problem that our nutritional supplement manufacturers are unable to export their products to Malaysia, the Administration has negotiated with the Malaysian government to provide the substitutions for the businesses, which with the certifications of the 2nd tier quality control and the expansion proposal, the businesses will receive the approval letter that meets the "Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements" in Malaysia, and then the application of inspection may be submitted to NPRA, Malaysia. (Figure 2-8)

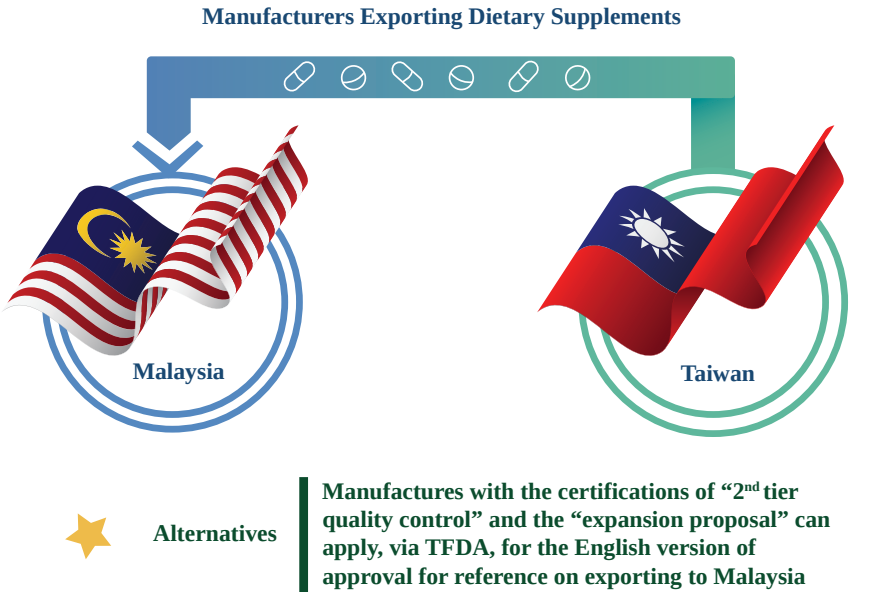


Figure2-8 Assisting the businesses to solve the problem on exporting to Malaysia

Outcomes and Benefits

1. Simplify the application process

By the end of 2017, there had been 496 accepted businesses' applications, and about 92% of these applications successfully obtained the certifications. The third-party certification of 2nd tier quality control was completed in October 2017, and thus the food export process has been simplified, and the waiting time and costs of the businesses have been reduced.

2. Advancement of new southbound policy in exportation of nutritional supplements

There was one business submitted the application in 2017. This business passed the "2nd quality control" and the "expansion proposal," and eventually obtained the approval letter from the Administration to apply to Malaysia in 2018. The products have been sold to Malaysia smoothly. In addition, there are nine other businesses currently in the processes of the inspection.

Section 5 Food Safety Information Network

Origin of Policy

Since food safety issue has to do with the responsibilities of respective ministries and departments and the fact that related information is scattered among ministries and departments, to consolidate such information, it requires collaboration and sharing of information among these ministries and departments. Hence, the Administration applies the "five musts" to enhance the food safety management information system, including the Food and Medicinal Products Business Registration Platform(must register), the Border Inspection System (must apply), the Food Traceability Management Information System(must trace), the Testing System (must test), and the Audit System (must audit) (Figure 2-9). The food articulating and monitoring web page has been established to grasp the name list and product information.

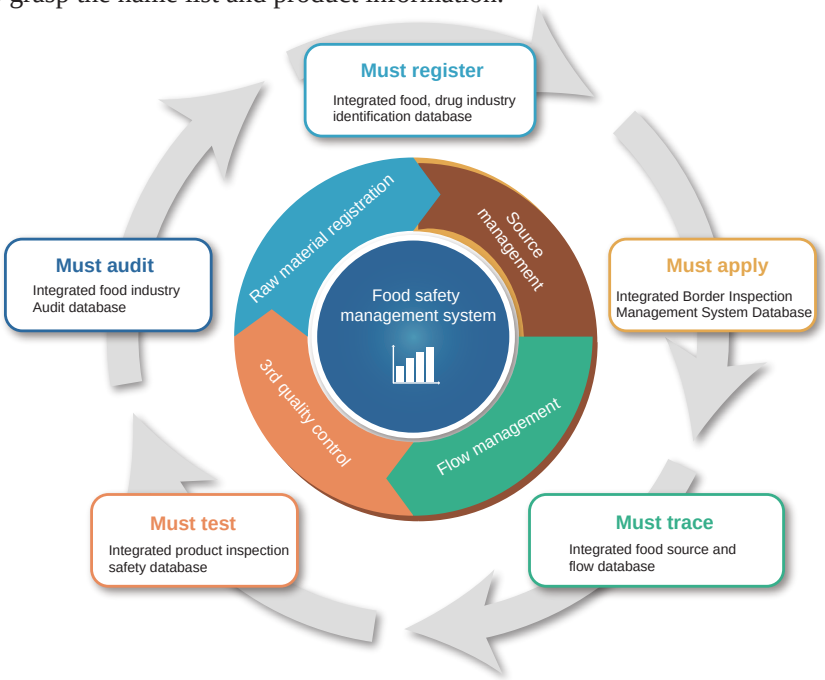


Figure2-9 "Five Must" Food Safety Management Information System

Implementation Measures

1. Integrate inter-departmental system

To understand and track the transaction flow of oil products, chemicals, and risk products in real time, the Administration has incorporated the information supervised by various ministries (EPD, MOEA, COA, and MOF) into the Food Cloud and form a Pan-Food Cloud structure through integration and quality verification process.

2. Establish automated risk identification

In 2017, the Administration had established an automated risk identification module which can be used to quickly generate a list of industries with different risk levels through logical calculations and visual displays with the use of inter-departmental information, and provide to relevant units as follow-up inspection reference. The module has greatly improved the operation efficiencies and reduced more error of interpretation than manual review.

3. Promote food safety information

In 2017, the Administration used the existing system resources to set up the “Food Information Counter” to reveal information in the “must trace” system, carry out promotional activities, and enable the food safety information to be checked at any time through the interaction among the public, the food industry and the government.

Outcomes and Benefits

1. Integrate inter-departmental system

By the end of 2017, Food Cloud had completed the integration of 16 information systems channels in 6 ministries. In the future, we will continue to increase the interface system, strengthen data integration and risk factor control, and apply big data analysis on possible risks. Up till now, more than 100 visualized monitors for 27 categories have been configured to help responsible units effectively tracking high-risk businesses and products and provide dynamics analysis reports to serve as a reference for policy management and performance of tasks.

2. Establish automated risk identification

Through the inter-departmental information and the “Must Register” system, the Administration can identify the upstream and downstream identification (such as non-food operators selling to food traders), and use risk identification logic to produce a list of industries of various risk levels as inspection or management policy research reference, which effectively decrease the time of risk identification (Figure 2-10).

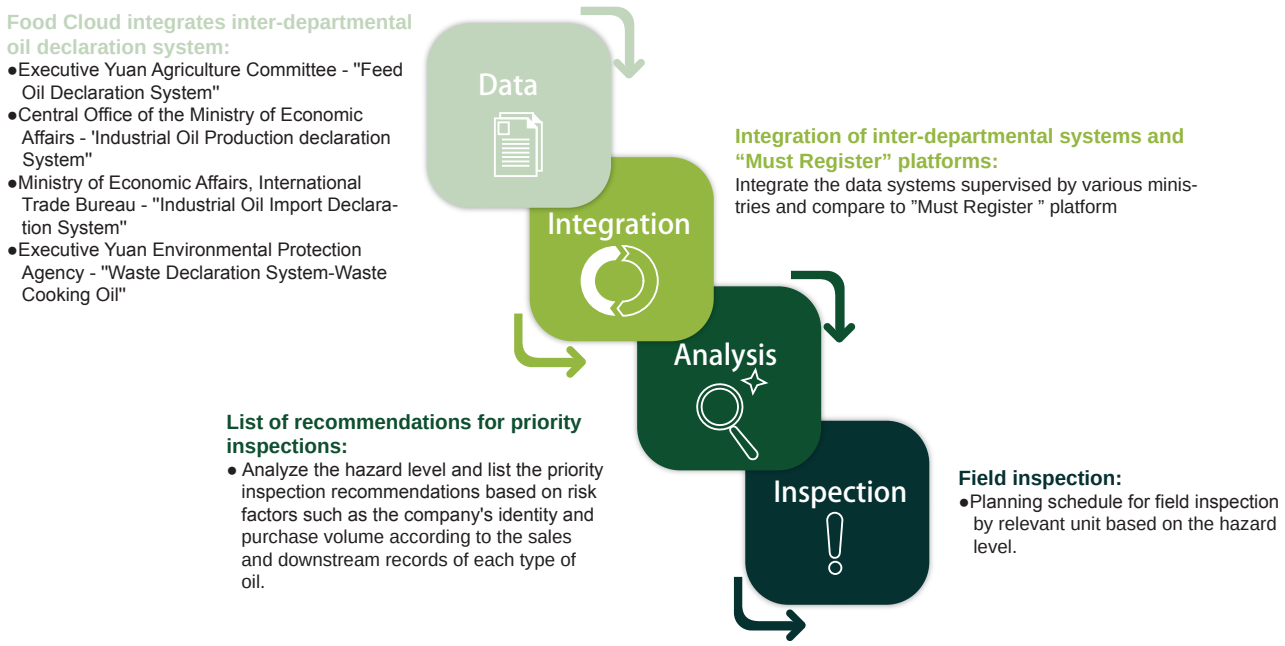


Figure2-10 Inter-department flow analysis process

3. Convenient search for food safety information

(1) Multiple promotional events were organized in 2017, including the “Search-and-Find Campaign” in January (Figure 2-11). The public can take part in the supervisory process through these events to confirm the accuracy of the registered data. It helps the government effectively keep track on information of food businesses and enhance the efficiency of food sanitation management. In September, there was the “Excellence and Good for Food” map established to promote the rating of GHP of food businesses (Figure 2-12). People are able to directly browse through the ratings (excellent or good) of food businesses through satellite positioning, a feature that is available in the online map to find new dining choice. The “Government IT Month” event in December (Figure 2-13) made it easy for people to find

Figure2-11 Press conference to hold “Search-and-Find Campaign”

Figure2-12 Press Conference on “Excellence and Good for Food” Enquiry Map Promotion

Figure2-13 Participation in the “Government IT Month” booth display

information through the exposure of the “Food Safety Department store” and consolidated the supervision over food safety.

(2) The “Food Safety Department store” website created by the Administration can be accessed through the home page of the TFDA website (http://fadobook.fda.gov.tw/foodsafetystore/) (Figure 2-14). People can search for desired food safety information at any time as they wish. The “Food Information Counter” is used by the food industry to upload relevant information to the “Food Traceability Management Information System (must trace).”

People can check the pictures, packaging labels and inspection report information of the market products according to the product category. (Figure 2-15)

Figure2-14 The "Food Safety Department store" Website

Figure2-15 Food Information Counter Website

Section 6 Development of New Food Test Technology

Origin of Policy

Given the diverse choices of food available, it is impossible to know in advance on any unknown substances or illegal components mixed on purpose by ill-intentioned businesses. Also, in light of the fact that requirements for the testing capability and testing validation efficacy are getting stricter both domestically and internationally, the TFDA has advanced the testing and analytical capabilities of laboratories and developed quick and convincing testing methods to help with the identification of unknown substances and in cases of accidents.

Implementation Measures

1. Assistance in testing emergency food safety events

(1) Fipronil residue test in eggs

In August 2017, European countries and South Korea successively broke out the contamination of eggs with Fipronil and caused great concern. Although eggs in these areas have not been imported into Taiwan, in order to understand whether domestic eggs are contaminated, TFDA immediately developed the testing methods of pesticides and their metabolites in eggs and chickens, and published them as a reference for the national inspection authorities.

In order to implement the source management, the Animal and Plant Epidemic and Quarantine Bureau of the Executive Yuan Agricultural Committee conducted 45 samples for the chicken farms and used the method developed by TFDA to verify that 3 domestic eggs had Fipronil residues, and continued to launch a comprehensive survey of the source livestock farms. In cooperation with the local inter-departmental department, a large-scale inspection of 1,459 eggs from chicken farms at the end of August was completed in just 5 days from the sampling inspection to the completion of the inspection results. TFDA also assisted in the inspection of 50 eggs sent from the Tainan City Insurance Office (Figure 2-16).

TFDA actively develops inspection methods to help agricultural management units master the information on contaminated chicken farms, conduct timely mobile control, speed up the recovery of eggs, and develop administrative standards for residue tolerance to ensure consumer safety.

Figure2-16 Egg samples sent from the Insurance Office

(2) Investigation of Sudan IV Residues in Salted Egg Yolk

Mooncakes are the best-selling products during Mid-Autumn Festival. In 2017, some salted egg yolks in the mooncakes were found containing Sudan red dyes which was recognized as carcinogens and not allowed to be added in foods. TFDA developed the rapid testing method to simultaneously detect Sudan I, II, III, and IV in poultry products by liquid chromatography-tandem mass spectrometer. This method was applied to 10 cases of egg yolk (Fig. 2-17), and Sudan IV was found in 7 of them with concentrations between tens to thousands ppb. The results were further referred to the related authorities including bureau of prosecution and investigation, and health bureau to clarify the case.

Figure2-17 Salted egg yolk specimens

(3) Lotus leaf steamed pork ribs case

In May 2017, the Department received a report from Taipei Municipal Government Health Bureau that a person came home from the restaurant with “steamed pork ribs” to reheat and eat had suspected food poisoning symptoms such as sore throat and mouth pain. The Health Bureau immediately sent staff to sample for the Department to inspect.

After rapid detection of real-time PCR combined with DNA species identification technology developed by the Department, it was confirmed that the outer layer of the “steamed pork ribs in leaves” was from a poisonous plant “Giant Elephant's Ear.” The Department immediately informed the test results and issued a press release (Figure 2-18), calling on the restaurant operators to confirm the ingredients and teaching the public how to identify toxic Giant Elephant's Ear and implement the techniques to safeguard the health of the people.

Figure2-18 Comparison of the appearance of poisonous plants and edible ones

2. Identification of unknown compounds

(1) Nitenpyram and Chlorantraniliprole derivatives were block at the border

In recent years, international express delivery is getting popular. In 2017, the number of simple customs imports more than 30 million items. However, the international express route has also become a pathway for illegal commodity imports. Unscrupulous people are hiding drugs, chemicals, medicinal products and others in the delivery goods and using the runaround mailing route to increase the difficulty of inspection.

Two express post parcels were confiscated by the Customs Administration as the declared items did not matched with the actual. The two parcels were identified as unknown powder and found negative on routine pesticide tests. TFDA investigated these two samples by using high-resolution mass spectrometer. The unknown compound structure elucidation was done by the combination of the accurate molecular weight, isotope ratio, and fragments of the unknown. Two

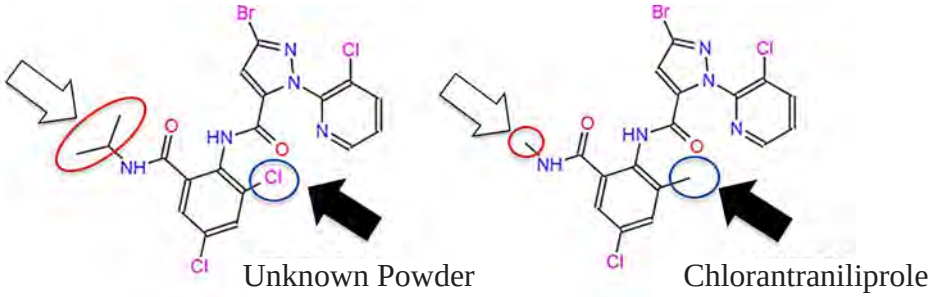


Figure2-19 Comparison of the structure of unknown powder (new pesticide) and chlorantraniliprole

rare pesticides named Nitenpyram and Chlorantraniliprole derivatives were identified.

Nitenpyram is an animal acaricide and is banned for use on animals destined for human consumption. The chemical structure of nitenpyram is very similar to Fipronil and is not allowed to be used in food. The derivative of chlorantraniliprole is first discovered and reported in the literature. Its chemical name (IUPAC) is 3-bromo-1-(3-chloro-2-pyridinyl)-N-[2,4-dichloro-6-(isopropyl carbamoyl)phenyl.]-1H-pyrazole-5-carboxamide, and is a newly synthesized pesticide (Figure 2-19). Because the compounds could not be detected by any routine inspection, it is fortunate that these illegal materials were blocked at the border and not delivered to the market.

(2) The development and application of high throughput screening technique

TFDA employed the newest international trend high-resolution mass spectrometer with a non-target analysis mode, and applied high-throughput technique for screening the unknown hazardous substances in foods through the database comparison. The database covered more than 3000 compounds of preservatives, antioxidants, and other additives and chemicals. The self-established 47 colorants database was constructed with the retention time, the exact molecular weight of precursor ion, and two pairs of product ions. TFDA keeps on updating and increasing the item of colorants in the database. A survey of 80 commercial beverages and candy showed that 3 samples were not complied with labeling regulation. On the other hand, for the other 79 sample (62 cases form the border and 17 cases form the local inspection centers), 17 samples were found with illegal colorants, and 2 were found with unlabeled legal colorants.

Figure2-20 Samples of Potatoes

(3) Inspection case on genetically modified potato

The genetically modified potato strain E12 was developed by Simplot Company of the United States with the characteristics of less acrylamide production and fewer dark spots. The United States and Canada had approved the strain for food usage and planting in 2014 and 2016, respectively.

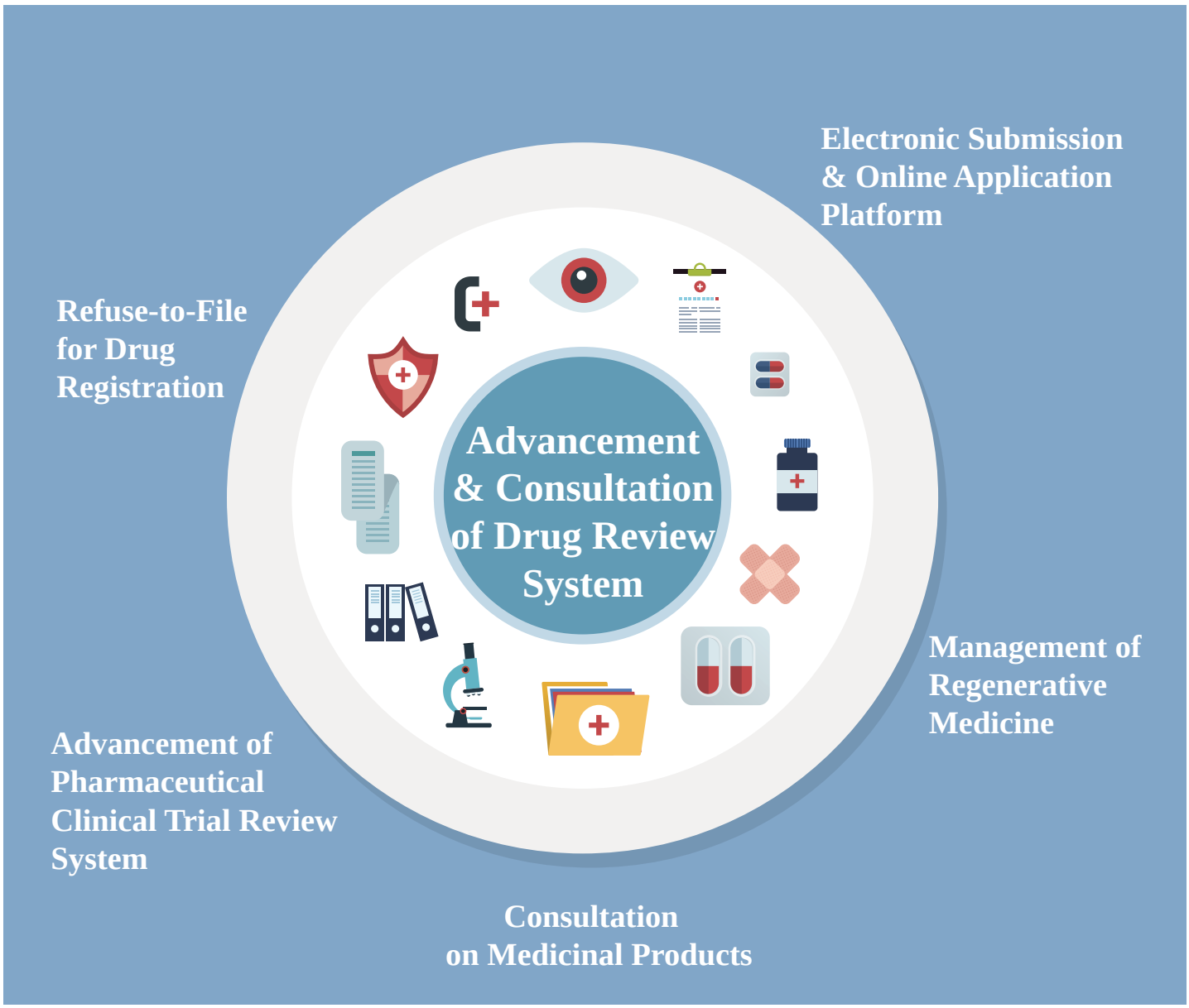
TFDA used molecular biotechnology to analyze its genetic composition and established an event-specific qualitative test method for the transgenic potato E12. This technology was also used in border inspection to confirm that the E12 had not flowed into Taiwan (Figure 2-20).

To ensure no influx of the other GM potatoes, the Department also developed a construct-specific qualitative test method to simultaneously screen Simplot's other series of GM potatoes and prevent potential threats in response to inspection needs.

Outcomes and Benefits

In response to food incidents, quick and creditable testing methods was developed and provided to the testing authorities throughout the nation, which help investigators and health authorities quickly clarify the detail of the incidents, and address public concerns. TFDA constantly advance and strengthen laboratories' testing and analytical capabilities on unknown substances, emerging genetically modified matters, emerging pollutants, the mixture of illegal substances, and unknown microorganisms in order to prevent illegal substances from entering the market and protect public health through these testing technologies.

Refinement and Improvement of Drug Safety



APEC Regulatory Science Training Center of Excellence

TFDA Organized the “2017 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence Workshop.”

- Policy on Orphan Drug Management
- Management Policy on Medicinal Product Trace and Track System
- Establish Drug Patent Linkage System
- Good Distribution Practice (GDP)
- Advancement of testing technology on illegal drugs
- PIC/S Meeting

03 Refinement and Improvement of Drug Safety

To complete the national drug management system and promote drug administration that in line with international provisions, TFDA has established corresponding regulations in accordance with International Conference on Harmonization (ICH) and World Health Organization (WHO) to gradually perfect the management system in Taiwan. As the quality requirements of post-marketing medicinal products by international laws and regulations are becoming more stringent every year, corresponding provisions in Taiwan are in need of keeping up with the updates. TFDA thereby reviews existing regulations and revises accordingly and establishes novel rules for drug management following the global trends in advance therapeutic products regulations. Moreover, to ensure the consistency of quality, safety and effectiveness of drugs, TFDA optimized the drug review system and set up registration/post-approval management scheme for medicinal products with high-risks or targeting specific populations. Meanwhile, TFDA actively works on international collaboration and participate and international activities to reach regulatory convergence and take part in global standard harmonization.

Section 1 Advancement and Consultation of Drug Review System

Origin of Policy

To facilitate the accessibility of new drugs and support the development of domestic biomedical/biotechnology industry, TFDA has optimized measures for clinical trial protocol reviews, which include established the expedited review track for regenerative medicinal products clinical trials, refined the review process of clinical trial protocol amendments and created a comprehensive regulatory consultation network/project counseling system to help applicants to prepare complete submission package, and thus accelerate new drug development as well as reducing relevant costs. In addition, TFDA continues advancing the review process of drug registration, implementing the refuse-to-file (RTF) policy for new drug registration, and promoting the online review and application platform (ExPRESS) to facilitate correct document submission and shorten the review/approval process.

To keep up with the emerging biotechnologies and ensure product safety and efficacy of regenerative medicines, TFDA actively develop regulations for the management of advanced biotechnology, and construct a specified regulatory framework for regenerative medicines based on the heterogeneity of regenerative medicinal products and its complexity in clinical applications and specialty in manufacturing processes. This regulatory framework is expected to achieve an independent and straight forward management on regenerative medicinal products.

Implementation Measures

1. Advancement of pharmaceutical clinical trial review process

The TFDA released three "Advancement Measures for Pharmaceutical Clinical Trial Protocol Review Process" on August 10, 2017. The details are as follows:

(1) Simplify the review process of "First-in-human medicinal products" clinical trials review process, i.e. change the review process from "consult with external experts case-by-case and forward to advisory committee meeting for further discussion if needed" to "reviewed by Center for Drug Evaluation (CDE) and consult with external experts if needed; forward to advisory committee meeting for further discussion if any further issue exists," to shorten the case-by-case consultation period.

(2) Establish the "Expedited Review Track for Regenerative Medicinal Product Clinical Trials," introduce a 30-day expedited review track for multinational (must be carried out at least in one of the 10 medically advanced countries, multicenter, non-first in human trials, and for investigator-initiated clinical trials which the regenerative medicinal product has been used in other clinical trials conducted in Taiwan and manufactured by the same laboratory with identical manufacturing processes for academic purposes, to encourage the development of emerging regenerative medicinal products in Taiwan.

(3) Refine the review process of clinical trial protocol amendments based on the risk levels and implement diverse review flows (i.e. technical review, administrative review, and retained by the applicant for future inspection) to enhance the review efficiency.

2. Refuse-to-file for the application of drug registration

The refuse-to-file (RTF) scheme for the application of drug registration was initiated since 2017 in order to strengthen the review efficiency. Upon submission for registration, the submission will be rejected if the applicant (1) fails to provide complete administrative documents in accordance with the Regulations for Registration of Medicinal Products; or (2) fails to provide complete technical documents in accordance with the format stipulated in the Common Technical Documents (CTD); or (3) fails to pay the submission fee based on the Fee Charging Standards for Registration of Western Medicinal Products and Medical Devices.

3. Electronic submission and online application platform for review of medicinal products

In order to harmonized with international standards, the paper-less application and review system of medicinal products procedure has been step wisely implemented since 2015, while submissions using paper-based copies and CDs are gradually reduced with the establishment of e-submission platform. The paper-less pharmaceutical management system was refined in 2018 and firstly implemented on the applications of license extension and cancellation, and the on-line submission system is design to be gradually integrated with the official documentation system. The comprehensive E-service system is expected to be fully implemented in 2020 and further enhance the review efficiency and to help the subsequent real-time data inquiries and updates.

4. Management of regenerative medicinal products

TFDA stipulated a draft of "Regenerative Medicinal Product Ordinance" in 2017, which clearly defines the regulatory scope as regenerative medicinal products that are "commercialized, manufacturing standardized and normalized for the purpose of batch production and marketing sales." This regulatory scope is distinguished from the regulation for regenerative medicinal therapies, which is defined as medical technologies that are "practices clinically performed to treat certain patient in certain medical institute." The contents of the draft Ordinance involves assessment of donor eligibility and informs consents, the management of conditional approval, post-marketing surveillance and tracking system. The regulatory framework is designed to ensure the quality, safety, and effectiveness of regenerative medicinal products and protect donor/patient's rights for proper treatments. By reinforcing the management policies and escalating the law hierarchy, it is expected to create a standard for the biomedical/biotechnology industry to comply with and support the development of regenerative medicine in Taiwan. Legislation of the Ordinance is expected to be finalized in the end of 2018.

5. Consultation and counseling on medicinal product projects

To facilitate pharmaceutical industry development, encourage novel drug research and development and provide consultations/counseling on new drugs, biologics, biosimilars, regenerative medicinal products that are under development or filing for registration, TFDA specifically stipulates the "Point for Project Consultation for Medicinal Products" to help applicants prepare documents adequately, and thus accelerate the approval new drugs and reduces corresponding costs.

Applications for the Project Consultation approach are assessed based on 4 indicators, including "innovation," "contribution," "early achievement" and "regulatory compliance." For applications qualified to the above criteria, TFDA organizes a project team to provide consultation

services and delineate potential defects, allowing the applicants to prepare complete submission package that fulfill review requirements, and thus facilitate review efficiency. TFDA also announced review points of all types of new drug registration, which provides references for the preparation of technical documents and helps increasing transparency of review, facilitating submissions and expediting new drug approval.

Outcomes and Benefits

In total, TFDA processed 298 new applications for pharmaceutical clinical trials in 2017; among them, 72% were multi-reginal and multi-center clinical trials (Figure 3-1). In addition, the ratios of Phase I and Phase II clinical trial applications have shown increasing trends for the past few years (Figure 3-2), indicating that the ability of related institutions in our country to conduct clinical trials and their quality level are recognized internationally.

In order to continue enhancing our country's competitive advantages in clinical trials and to advance the research and development of new drugs, the Administration streamlined the review procedure and review time efficiency for pharmaceutical clinical trial protocols. Three "Advancement Measures for Pharmaceutical Clinical Trial Protocol Review Process" were announced and enforced on August 10, 2017. The number of days required for processing the applications and the overdue rate has both significantly dropped (Table 3-1).

Regarding the review of drug registration, TFDA announced the refuse-to-file mechanism for applications of drug registration on January 1, 2017. Except for some applications that are rejected due to incomplete submission package, rest of the other applications have been able to enter the review process successfully. Ratio for the reviewed applications to total applications are 84.3% in new drug registration and 68.3% in generic drug registration. The time needed for repeated modifications of cases has been reduced and the time efficiency in the review of cases by TFDA has been improved.

To facilitate the development of the pharmaceutical industry in Taiwan, TFDA provides project consultation/counseling approach on medicinal products. As of the end of 2017, TFDA has successfully assisted the registration of 5 new drug by providing consultation services. Two of these new drugs, which are domestically developed new drugs, set new records as been first approved new drug for certain indication in the world: one of the two "Global No. 1" product with ferric citrate was approved for CKD patients receiving hemodialysis to control hyperphosphatemia; the other with liposomal irinotecan was approved for patients with metastatic pancreatic cancer treated with chemotherapy (gemcitabine).

Table3-1 Outcomes of "Advancement Measures for Pharmaceutical Clinical Trial Review System"

Implementation Measures	Outcomes
Simplify the review process of first-in-human medicinal products clinical trials	Shorten the average period from 68 days to 47 days
Establish the expedited review track for regenerative medicinal product clinical trials	Shorten the average period from 94 days to 26 days
Refine the review process of clinical trial protocol amendments	Reduce the overdue rate from 15% to 4%

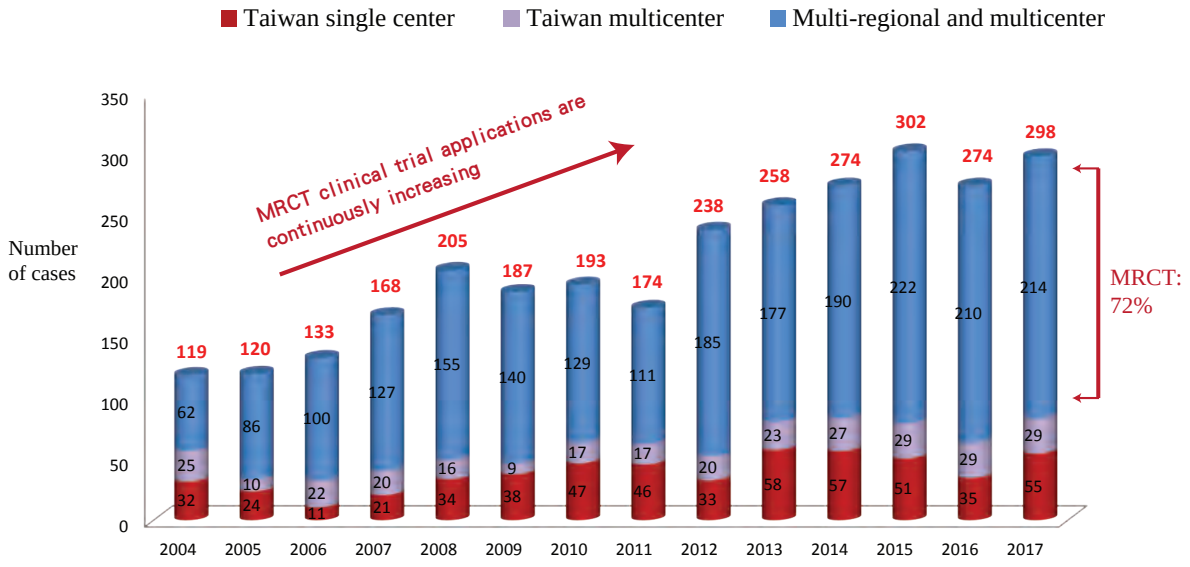


Figure3-1 The Applications for Clinical Trials of Medicinal Products (By Trial Scale)

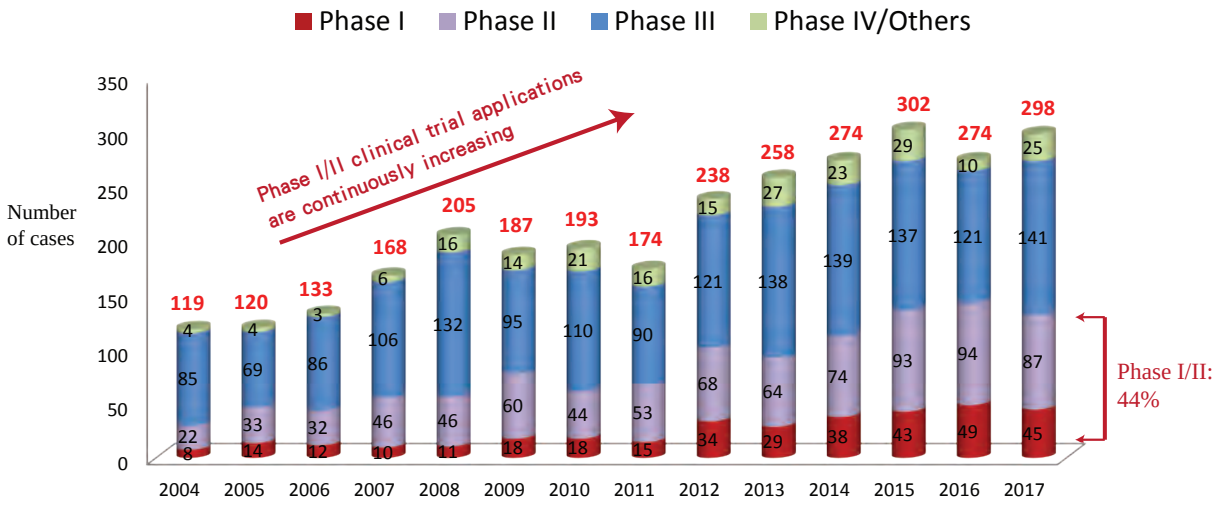


Figure3-2 The Applications for Clinical Trials of Medicinal Products (By Study Phase)

Section 2 Establish Drug Patent Linkage System

Origin of Policy

The focused topics of intelligence protection among international medicinal products lately consist of the linkage system ("patent linkage system") between exclusive protection, drug patent and listing approval in terms of drug permit applications.

Patent linkage system refers to the linkage between new drug listings and disclosure of patent information and the linkage between the review process of generic drug listings and the possibility of infringing new drug patents which allows pharmaceutical companies to resolve disputes (patent infringement issues) over patent-related issues within a certain time frame (before the listing of generic drugs). It is also a reference for central competent health authorities to approve/reject the listing of generic drugs.

Implementation Measures

By referencing regulations of the US, Canada and South Korea, and the current status of the pharmaceutical industry development in Taiwan, the TFDA added Chapter 4-1 "Patent Linkage of Drugs" in the *Pharmaceutical Affair Act*, and promulgated this section in the Government Official (Presidential Order) on January 31, 2018. The contents included that the holder of a new drug permit permit to submit patent information regarding substance, composition or formulation and medical use within the statutory limitation. The applicant for a generic drug permit must provide a statement describing the patent status of the approved new drugs. The applicant for a generic drug permit must notify the holder of the new drug permit, the Central Competent Health Authority, patentee or the exclusive licensee, in advance to allow the person of interest to clarify the validity of a patent or the possibility of patent infringement. After that, the Central Competent Health Authorities may continue reviewing the application of the generic drug permit application. However, the issuance of a drug permit may be temporarily suspended under special circumstances within 12 months. The first successful application of a generic drug permit without the fact of a patent infringement or patent around will be granted a 12-month period of marketing exclusivity.

Outcomes and Benefits

By implementing the patent linkage system and issuing patent rights to the inventor, it is expected to advocate the idea of patent right protection and affirm the great contribution of the drug permit holder, encouraging them to devote themselves to the development of medical/pharmaceutical research. It is also helpful to allow the holder of a new drug permit to control relevant patents before listing and to encourage and urge pharmaceutical companies devoted to novel drug development or patent around designs, in order to increase the volume of generic drug development, facilitate industrial potential and international competitiveness, and achieve the governmental goals of promoting emerging industries (e.g. biomedicine/pharmaceuticals/biotechnology).

Section 3 Management Policy on Medicinal Product Trace and Track

Origin of Policy

To strengthen the management of medicinal products distribution, TFDA stipulated the *"Regulations governing the trace and track system for medicinal products" based on Pharmaceutical Affairs Act* Article 6.1, paragraph 3 on September 6, 2016. The regulations specifically require vendors and manufacturers to establish a trace and track system based on the quality, efficacy, safety and risk levels to connect the source and distribution of medicinal products. The establishment of trace and track system is expedited in a faster manner due to the counterfeit CRESTOR incident on March 2, 2017.

Implementation Measures

Starting on July 1, 2017, the Administration has prioritized three classes of drugs, namely blood preparations, vaccines, and Botulinum toxins for Stage 1 trace and track system. Throughout 2017, a total of 351 businesses were helped to complete their declaration process. For the 116 items, the fulfillment rate of the declaration by the businesses exceeded 90%. In addition, in order to maximize the categories and items available for traceability reports, the Administration, on January 1, 2018 and July 1, 2018, respectively, based on the risk assessment and screening principles of high use volume and high value of NHI-covered drugs and with items such as orphan drugs, controlled drugs, and those with high technical thresholds and low counterfeiting risk excluded, announced in phases inclusion of 20 and 30 items of high interest in the traceability reporting system. Holders of permits for such drugs and distributors engaged in the wholesale of such preparations shall upload information such as sources and whereabouts of drugs from the previous month by the 10th day of the current month to the drug trace and track system.

Outcomes and Benefits

The drug trace and track reporting system became operational in May 2017 and is user-friendly with diversified interfaces; users can report by submitting Excel files (Comma Separated Values, CSV files), Web API and by completing an online form. In addition, to boost the familiarity of businesses and local health authorities with the drug trace and track system, the Administration added the trace and track section on its website, created the page promoting the exclusive zone for businesses in the reporting system, and set up the system consultation window. Throughout 2017, a headcount of up to 1,700 people received consultations. In addition, the Administration organized a total of 8 workshops and educational training sessions in 2017 for businesses and public health centers, which were participated in by a headcount of 375 people in total. The cooperation among businesses in reporting the required information and the reporting efficiency was improved to consolidate the drug tracking or follow-up reporting system.

To collect feedback from local applicants and health bureaus and optimize application platform and user's interface, TFDA establishes a back-stage management and statistical analysis area in 2018 to strengthen the management of drug supply chain, comply with local health bureau's inspections and ensure safe drug use.

Section 4 Good Distribution Practice (GDP)

Origin of Policy

The goal of implementing GDP is to extend the requirements on medicinal products quality control from GMP (in terms of manufacturing) to GDP (in terms of distribution), to ensure the quality and the integrity of medicinal products during storage and transportation, to effectively respond to emerging drug recall incidents, to properly distribute to the consumer within a reasonable time frame and to prevent falsified medicinal products from entering the supply chain. The ultimate goal is to ensure drug quality and safety of the public.

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) officially released GDP in June 2014, which has then become a well-recognized GDP in the world. GDP is now well practiced in many international organizations and countries, including WHO, EU, Singapore, Malaysia, UK, Germany, Switzerland, USA, and Australia. To implement quality management of drug distribution, ensure drug safety, upgrade international competitiveness, the TFDA promotes global well-recognized GDP policy accordingly.

Implementation Measures

1. GDP-associated measures

Starting from 2011, the TFDA has initiated GDP policy by providing consultation and educational training sessions (e.g. focused forum, technology seminar, observation tour in pharmaceutical companies, etc.), organizing 710 sessions of on-site GDP experts/consultants counseling, and awarding 107 manufacturers with excellent performance. The TFDA also actively participates in communications and promotion activities, organizes several orientation meetings, convenes negotiation meetings and public hearing and reaches consensus on management policies and schedules with the industry. In addition, the TFDA not only convenes an advisory board meeting composed of industrial/official/academic experts to discuss about management system and technology regulations and summarize a frequent Q&A for the applicant's reference, but also establishes a PIC/S GDP zone (including approval lists, counseling programs, Q&A and educational

training programs) on the official webpage to promulgate policies and official directions as references for applicants.

2. Schedule and related laws of GDP implementation

On February 18, 2016, the TFDA promulgated the implementation details, and schedules of "*Good Manufacturing Practice (GMP) Part III: Distribution.*" Manufacturers and permit holders of Western medications are expected to meet all regulations starting from 2019. To achieve full-GDP implementation, the MOHW actively revises corresponding laws by promulgating the drafts of *Pharmaceutical Affair Act* Article 53-1 and Article 92 amendments. Such amendments have been promulgated under official Presidential Order on June 14, 2017. The "*Western Pharmaceuticals Good Distribution Practice Regulations*" were then released on December 28, 2017, as the GDP standard for Western drug dealers. Furthermore, to form a well-established management system, the MOHW also stipulated the "*Regulations for the Issuance and Management of Western Pharmaceuticals Distribution Licenses and Certificates*" to meet the requirements for a subsequent application and approval issuance.

Outcomes and Benefits

By promoting and implementing global well-recognized GDP, ensuring drug safety and improving drug distribution quality, 275 manufacturers and dealers of Western pharmaceuticals have met the criteria of GDP as of the end of 2017. (Figure 3-3)

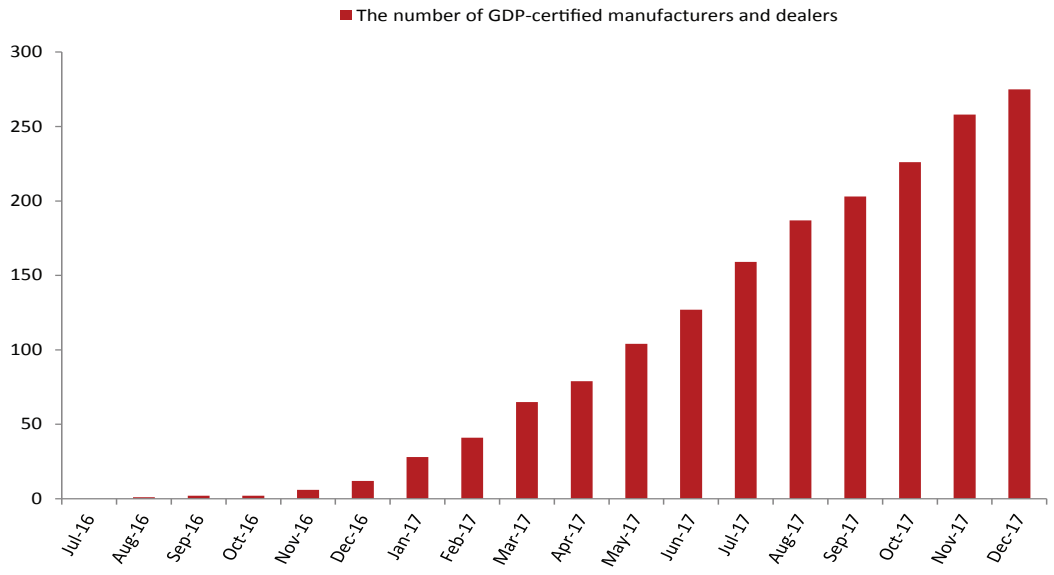


Figure3-3 The number of GDP-certified business undertakings as of the end of 2017

Section 5 Policy on Orphan Drug Management

Origin of Policy

The "*Rare Disease and Orphan Drug Act*" was finalized on January 14, 2000, and became effective from August 9 the same year. Since then, Taiwan has become the 5th region which had passed rare disorder-related acts in the world (after the US (1983), Japan (1993), Australia (1997) and EU (2000)), indicating that Taiwan keeps in step with global trends regarding the fulfilment of patient needs.

Although the US is the first country in the world stipulating regulatory systems regarding rare disorder and orphan drugs, whereby promulgated the "*Orphan Drug Acts*" long ago in 1983, Taiwan displays a more inclusive attitude toward such topic by combining the "*Rare Disorder Act*" and "*Orphan Drug Act*". The "Rare Disease and Orphan Drug Act" covers topics such as preventive eugenic health, health education, patient welfare, international collaboration and medical team staffing. The comprehensive scope of the Act suggesting that the management of rare diseases in Taiwan is not limit to orphan drug regulation, but has been referred to multidisciplinary teamwork (including disease prevention, medical assistance public health, etc.).

Implementation Measures

To encourage pharmaceutical companies to manufacture or importing orphan drugs, "*Rare Disease and Orphan Drug Act*" specifies that the valid duration of orphan drug licenses has been extended up to 10 years. During the 10-year period, no other drug registration of similar classifications will be approved to protect the interest of the thereof pharmaceutical company. In addition, under the premises of quality, efficacy and safety of medicinal products, the required application documents for orphan drug registration could be simplified (e.g. cancelling the requirement of certification of approval issued by one of the top 10 advanced countries, exemptions from sample testing, lower registration fee, etc.) to facilitate the manufacturs and importation of orphan drugs, therefore extend the lifespan of patients with rare diseases.

Outcomes and Benefits

As of the end of December 2017, a total of 99 drugs are launched to be subject to "*Rare Disease and Orphan Drug Act*" and a total of 85 orphan drug licenses have been issued.

According to Article 21 of the "*Rare Disease and Orphan Drug Act*", the central competence authorities are required to publish a list of approved orphan drugs on the annual report, indicating information such as the number of uses, number of indicated patients, adverse events and other relevant reports. Starting from the 1st issue of the "Annual Report on Drugs for Rare Disease"

published in 2002, all drugs of rare disease-related information is summarized and collected from paper-based information reported by medical institutes or pharmaceutical companies. In 2017, TFDA initiated the online reporting system for drugs of rare disease to encourage and facilitate relevant reports.

Section 6 APEC Good Registration Management Regulatory Science Training Center of Excellence (CoE)

Origin of Policy

To facilitate international collaboration and regulatory convergence for medicinal product management, the TFDA has become a regular participant in APEC Life Science Innovation Forum and is actively involved in the work promoted under the Regulatory Harmonization Steering Committee (RHSC). The TFDA has been serving as the co-champion of Good Registration Management priority work area (PWA) with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan. By promoting training and implementation of “good review practice” and “good submission practice” under the collaboration of regulatory authorities and industry, this work advocates the concept of “good registration management,” promotes mutual trust between regulatory authorities and the pharmaceutical industry, and expedite regulatory convergence between APEC member economies by 2020.

Implementation Measures

In cooperation with RHSC to implement the platform of the APEC Regulatory Science Training Center of Excellence (CoE), each CoE hosting institution is responsible for developing and hosting training programs following the core curriculum developed by the PWA champions. The CoE serves as a platform to promote capacity, cooperation and regulatory convergence among different APEC member economies.

The TFDA hosted an APEC Good Registration Management Regulatory Science Training Center of Excellence Pilot Workshop in Taiwan in November 2016 and submitted an application to RHSC together with RAPS Taiwan Chapter for recognition as a formal CoE in February 2017. The application was endorsed without any objections in the RHSC Meeting on February 21, 2017.

TFDA, RAPS Taiwan Chapter, and APEC Life Science Innovation Forum have signed

a memorandum of understanding (MOU) in CoE operations in July 2017 based on the CoE Operating Model stipulated by RHSC. This achievement is credited as a milestone for TFDA because the capability in organizing regulatory science training has been well-recognized by a regional harmonization initiative, and is attributed to our long-term involvement of APEC activities.

Outcomes and Benefits

The TFDA hosted the "2017 APEC Good Registration Management Regulatory Science Center of Excellence (CoE) Workshop" in Taipei between October 31 and November 2, 2017. PMDA (Japan), RAPS Taiwan Chapter and Asia Partnership Conference of Pharmaceutical Associations (APAC), Ching-Kang Foundation for Pharmacy Promotion (CKF) and National Yang-Ming University were the co-organizers of this training event (Figure 3-4).

The training event lasted for 3 days, including common sessions, reviewer-specific sessions and applicant-specific sessions. A total of 70 (industry, academy, and official) participants from 10 APEC member economies took part in this training event, including Hong Kong (China),

Figure3-4 Group photo of the "2017 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence Workshop"

Indonesia, South Korea, Malaysia, Papua New Guinea, the Philippines, Singapore, Thailand, Vietnam and Taiwan. The trainees should take part in organizing training sessions at their respective institutions, associations or companies to promote the concept of Good Registration Management to more APEC member economies. In addition, experts from Canada, Japan, the Philippines, Singapore, and UK were invited as speakers at the meeting to share their opinions and practical experience about Good Registration Management principles.

The event was well-recognized and obtained positive feedbacks from participants of different APEC member economies. After the event, the TFDA received requests from several APEC member economies for providing training materials and lecturers to help their organization of local training sessions. Serving as a hosting institution of the APEC Good Registration Management Regulatory Science Training Center of Excellence (CoE) not only increases the international visibility of TFDA but also facilitates our opportunities in international collaboration.

Section 7 Participation in PIC/S

Origin of Policy

The Pharmaceutical Inspection Co-operation Scheme ("PIC/S") refers to the official international organization composed of regulatory authorities in the field of Good Manufacturing Practice (GMP) of medicinal products from all over the world. The organization devoted to the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates and facilitating the co-operation and networking of competent authorities. Every year, the PIC/S Committee Meeting and annual seminar will be hosted by different PIC/S Participating Authority, as the largest PIC/S event, the seminar will focus on a particular aspect of GMP topic and open to inspectors from PIC/S Participating Authorities and other interested Medicine Regulatory Authorities.

Implementation Measures

1. PIC/S Committee Meeting

A 2-day PIC/S Committee Meeting was convened between September 11-12, 2017, discussing long-term developing road map (e.g. strategies and projects for harmonizing the GMP regulations and enhancing the international collaboration, including reviewing the progress of work plans on revising the standard, global inspector training, etc.) and short- to mid-term assignments and progress. During this meeting, the Chairperson, Deputy Chairperson, and Chairs of Sub-Committees of PIC/S in 2018-2019 were also elected. The representatives of TFDA were also candidates of positions of PIC/S Sub-Committee, to actively participate in PIC/S affairs and events, consolidate Taiwan's membership, increase our international visibility and explore more substantial collaboration opportunities with other competent authorities from other countries through PIC/S platform.

2. PIC/S annual seminar

PIC/S Annual Seminar was then hosted between September 13-15, 2017 (Figure 3-5), which was the grandest annual gathering of PIC/S that brings together global GMP inspectors to discuss pharmaceutical GMP-related topics every year. The theme of 2017 was "Quality Control Laboratories: How to Inspect." Quality Control is part of GMP which is concerned with sampling procedures, specifications, testing methods and release to ensuring that the necessary and relevant tests are actually carried out and materials and products will only be released for use and supply until their quality has been judged to be satisfactory. Discussions involve "the latest GMP requirements," "out-of-specification (OOS) and out-of-trend (OOT) investigation," "data integrity," "technical transfer of test methods," and "inspection skill of quality control laboratories at pharmaceutical manufacturers." Through keynote speeches given by experts from the US, UK, France, Australia, Canada, Japan and Taiwan and workshops discussions with participants, a more complete quality standard, improving inspection regulations and skills to ensure the integrity, authenticity, reliability and traceability of the data, effectively supervise quality control laboratories of pharmaceutical manufacturers, and eventually achieve the goal of public benefit.

Outcomes and Benefits

1. Become a member of PIC/S

After becoming a PIC/S participating authority since 2013, the TFDA actively participates in PIC/S events and has organized PIC/S meetings and activities in Taiwan several times. All events/activities went very successfully and helped the TFDA win the opportunity to host “2017 PIC/S Committee Meeting and Annual Seminar” in Taiwan.

2. PIC/S handover ceremony

The finale of 2017 PIC/S Annual Seminar is the handover ceremony. By receiving the walking stick of PIC/S from the previous Organizer (MHRA, UK, 2016) and passing it to the next Organizer (US TFDA, 2018) (Figure 3-6), Director-General (TFDA) Shou-Mei Wu declared the event conclude successfully. A total of 170 official inspectors of 60 regulatory authorities and international organizations from 50 countries participated in the event. As the event was well-recognized by both the PIC/S and the participants, the international visibility of Taiwan and professionalism of TFDA is greatly acknowledged.

Figure3-5 PIC/S annual seminar between September 13-15, 2017

Figure3-6 PIC/S handover ceremony

Section 8 Advancement of Testing Technology on Illegal Drugs

Origin of Policy

The TFDA uses evidence-based method to uncover high-risk and high-violation rate products, prevent illegal drugs from being distributed. The TFDA has also actively improved its testing volume and capacity by participating in international meetings and experience exchange/ sharing.

Implementation Measures

1. Suspicious counterfeit drugs

As the counterfeit “CRESTOR” incident in March 2017 (Figure 3-7) severely compromised safe drug use in Taiwan, the TFDA completed 79 CRESTOR sample testing within a week. Non-conforming samples derived from lot MV503, MK479 and MF414 contained the counterfeit substance Atorvastatin.

During sampling and testing, 28 samples derived from illegal factories and warehouses, the TFDA also seized suspicious evidence of a counterfeit drug, including ingredients for “Januvia,” Januvia tablets and packaging materials. For these reasons, the TFDA immediately activated audition/inspection on a total of 462 commercialized products, i.e. 184 Januvia samples (ingredient: sitagliptin), 150 VYTORIN samples (ingredient: Simvastatin/Ezetimibe), 117 LIVALO (ingredient: Pitavastatin), 11 ZYTHROCIN (ingredient: Azithromycin). After inspecting the appearances, components and amounts, all of the above products met the manufacturer’s specifications and thus all doubts have been cleared.

The TFDA responds very quickly to prevent counterfeit drugs from being distributed. A total of 569 samples were tested in 2017. By adopting evidence-based science, the TFDA is able

Figure3-7 Samples of blood lipid lowering agent

to provide prosecution and justice department real-time audition and inspection results/analysis as the foundation for administrative procedures. Besides that, the TFDA is also keen to develop short-acting testing methods, in order to prevent illegal drugs from being distributed and to maintain safe drug use.

2. Successfully prevent illegal BTX preparations from being distributed into Taiwan

Under the assistance of TFDA, MOF seized unapproved BTX preparations imported from South Korea (Figure3-8). The test results showed that the illegal preparations contained Botulinum Toxin Type A, indicating that the importer has violated the *Pharmaceutical Affair Act* Article 22-1, Paragraph 2: Self-import medicinal products without approval. Such information then was launched on the TFDA website to suggest to the public how to choose legal products rather than use medicinal products without approved sources; and to help custom officers be aware of similar incidents. In 2017, with the assistance of TFDA, MOF successfully stopped 5 batches of similar BTX preparations (either through posted packages or tourists) from entering Taiwan and thus preventing illegal drugs from being distributed into the Taiwan market.

Figure3-8 BTX preparation samples

3. TFDA hosted the "2017 APEC Conference on Management and Related Scientific Detection Technology for Adulteration of Dietary Supplements with Drug and Drug Analogs"

TFDA hosted the "2017 APEC Conference on Management and Related Scientific Detection Technology for Adulteration of Dietary Supplements with Drug and Drug Analogs" at NTUH International Convention center between June 28-29, 2017 (Figure 3-9), more than 200 industry, academy and official prestigious guests from the US, Europe, Japan, Singapore, South Korea and

Malaysia participated in the event.

Many international experts were invited to deliver speeches sharing testing technology or management experiences in their countries. Speakers from Taiwan (e.g. Deputy Director-General Dr. Hui-Fang Cheng, Prosecutor Hsin-Pei Shen from Taipei District Prosecutors Office and Officer Wen-I Liao from MOF) also gave talks regarding topics such as “Experiences of Illegal Drugs in Taiwan,” “Experiences of Counterfeit Drugs Investigations in Taiwan” and “Custom Boarder Measures of Drugs in Taiwan,” and the participants can understand and discuss about current challenges on seizing illegal drugs through communication and sharing.

Figure3-9 2017 APEC Conference on Management and Related Scientific Detection Technology for Adulteration of Dietary Supplements with Drug and Drug Analogs

Outcomes and Benefits

Testing methods are energetic developing in usual, and can be quickly mobilized upon occurrence of emergencies (such as incidents involving illicit drugs) to successfully intercept unknown drugs and prevent illicit drugs from entering the market. TFDA will continue to participate in related conferences, exchange and discuss the experiences with international experts, as well as further improve our analytical techniques in order to protect public health.

Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

New-generation Anti-drug Strategy

Two Core Sub-Strategies about drug monitoring

Drug Abuse monitoring mechanism System

新興濫用藥物資訊專區

New Psychoactive Substances and Drugs Abuse Information

1 Prevention against the importation of illicit drug raw materials in the name of the active pharmaceutical ingredient

Three lines of defense

- the first line of defense ：Customs increase the check ratio of imported raw materials.
- the second line of defense ：Requirement F04 would be established that spontaneous application for importation checks should be applied for in compliane with the Regulations for the Inspection and Examination of Imported Medicaments for active pharmaceutical ingredients.
- the third line of defense ：Strengthen the inspection of raw materials in pharmaceutical factories, High-risk active pharmaceutical ingredient control.

2 Expand inspection capabilities to detect emerging drugs by establishing standard analytical profiles for them

- Established the new substance magnetic resonance (NMR) testing mechanism.
- Illicit drugs and new substances collected and the mass spectrometer database with standard items created.
- Organizes the referral program for laboratories to perform urine tests for new illicit drugs.

The Case of Drug Seized by Prosecution, Investigation Authorities and Police

Healthcare Facilities

The Urine / Non-urine specimens

The Drug testing agencies / The government accredited drug abuse urine testing institutions

The Case of Drug Abuse diagnosed by Physician

TFDA Drug Abuse Test Report System (UDARS)

TFDA Drug Abuse Reporting System (DARS)

Drug Abuse Cases & Testing Statistics

04 Reinforced Management of Controlled Drugs and Prevention of Drug Abuse

For addictive narcotics and substances with psychotic effects and their products, there is the "*Narcotics Hazard Prevention Act*" in our country to strictly govern their use. Those with medical or scientific research value, however, are listed as controlled drugs. To effectively govern the reasonable use of controlled drugs and to prevent against drug abuse, the Administration established the drug abuse monitoring mechanism that helps with an understanding of the trends of drug abuse in our country and the evaluation of new psychoactive substances (NPS) that have been abused internationally or recently. We also provide the Ministry of Justice with advice on the addition and revision of items listed as controlled at the same time. In addition, to reinforce the management of controlled drugs, when it is necessary to use NPS that are newly included in the controlled list by the Ministry of Justice over the past few years to fulfill scientific needs, such drugs will be regulated as controlled drugs in order to prevent unjustified usage or abuse that is hazardous to national health.

The Administration has cooperated with Executive Yuan to promote "New-generation Anti-drug Strategy" for the general public to get an understanding of the government's determination to and the action it has taken to fight against drug abuse, the Administration set up the "New-generation Anti-drug Strategy" section on its official website to periodically provide the latest information on drug testing, monitoring, analysis, and drug hazards and also to educate people on staying away from drugs. Meanwhile, the anti-drug hackathon competition had all the experts in civil to brainstorm and come up with anti-drug technological and digital services.

Section 1 Assessment and Addition of Regulated Controlled Drugs Products

Origin of Policy

In order to eradicate abuse or illegal use of controlled drugs, according to the "*Controlled Drugs Act*," the Ministry of Health and Welfare set up the "MOHW Controlled Drug Review Committee" to perform classified and itemized reviews reflective of the habits, dependency, extent of abuse, and hazards to society associated with controlled drugs and report the results to the Executive Yuan for approval and announcement.

Implementation Measures

In order to reinforce the management over controlled drugs and to prevent them from entering the market and trigger abuse, the Administration convenes the "MOHW Controlled Drug Review Committee" once every six months to assess the necessity to include emerging substances that have been abused internationally or recently under control. We also provide the Ministry of Justice with advice on the addition and revision of items listed as controlled at the same time.

The 35th and 36th MOHW Controlled Drug Review Committee had been held on June 21, 2017, and December 19, 2017, respectively to discuss listing of emerging drugs recently included by the Ministry of Justice under control that is needed for scientific purpose as controlled drugs and classifying them accordingly. Then, they are reported to the Executive Yuan according to the administrative procedure for the latter to announce their listing under control.

Outcomes and Benefits

A total of 14 controlled drugs were announced to have been added or revised in 2017. Detailed items and classes they belong to are shown in Table 4-1. None of the controlled substances mentioned above have been approved for use medically in the country at the moment. To meet scientific needs, they are listed as controlled drugs reflective of their existing classes as drugs for reinforced management over their whereabouts and for preventing against misuse or abuse that jeopardize national health.

Table4-1 2017 Addendum to Classification of Controlled Drugs

Date of amendment	Schedules	Promulgate the names of the controlled drugs	Descriptions
January 5	Schedule 2	Methoxymethamphetamine or MMA, including 3 isomers (*i.e.* 2-MMA, 3-MMA and 4-MMA)	CNS stimulant, a type of Amphetamine chemical synthetics.
January 5	Schedule 2	2-Methylaminopropyl, Benzofuran or MAPB, including 6 isomers (*i.e.* 2-MAPB, 3-MAPB, 4-MAPB, 5-MAPB, 6-MAPB and 7-MAPB)	
June 23	Schedule 2	Chloromethyl carbamazone 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone 1-phenyl-2-(1-pyrrolidinyl)-1-pentanone, Alpha-PVP	CNS stimulant, a type of Cathinone chemical synthetics.
December 13	Schedule 2	Bromomethcathinone (BMC) or Methyl-α-pyrrolidinohexiophenone (MPHP), including 3 isomers (*i.e.* 2-MPHP, 3-MPHP and 4-MPHP)	

Date of amendment	Schedules	Promulgate the names of the controlled drugs	Descriptions
January 5	Class 3	Methoxyethylamphetamine, methoxy-N-ethylamphetamine or MEA, including 3 isomers (*i.e*. 2-MEA, 3-MEA and 4-MEA)	CNS stimulant, a type of Amphetamine chemical synthetics.
January 5	Class 3	Fluoroamphetamine (FA)	
January 5	Class 3	5-Methoxy-N-methyl-N-isopropyltryptamine (5-MeO-MIPT)	
January 5	Class 3	Butylone or bk-MBDB	CNS stimulant, a type of Cathinone chemical synthetics.
June 23	Class 3	Methyl-α-ethylaminopentiophenone (MEAPP), including 3 isomers (*i.e*. 2-MEAPP, 3-MEAPP, 4-MEAPP)	
June 23	Class 3	2-(Dimethylamino)-1-(3,4-methylenedioxyphenyl)-1-butanone, Dibutylone, Methylbutylone, bk-DMBDB	
June 23	Class 3	Methyl-N-((1-(5-Fluoropentyl)-1H-indazol-3-yl)carbonyl)valinate (5-Fluoro-AMB)	CNS stimulatnt, a type of cannabis active substances.
December 13	Class 3	(Methyl-α-methylamino-valerophenone, Methylpentedrone or MPD, including 3 isomers (*i.e.* 2-MPD, 3-MPD and 4-MPD)	CNS stimulant, a type of Cathinone chemical synthetics.
December 13	Class 3	3,4-methylene bisoxyphenyl ethylamine pentanone [1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone, N-ethylpentylone, Ephylone]	
December 13	Class 3	Chloroethcathinone, CEC or Chloro-N-ethylcathinone, including 3 isomers (*i.e*. CEC, 3-CEC and 4-CEC)	

Section 2 New Constructions and Renovations of Pharmaceutical Manufacturing Facilities for Controlled Drugs

Origin of Policy

Existing manufacturing facilities where controlled drugs are manufactured of the Administration have been in use since 1988. The obsolete premises and equipment and also space is no longer sufficient for use. In order to meet international PIC/S GMP regulations and increase production lines and productivity that help prevent against risk of shortage in Class 1 and Class 2 controlled drugs and also to take into consideration the need for increasing the R&D space to add items to be manufactured and to increase the local production rate, the Administration raised NTD 494 million for the Controlled Drug Manufacturing Premises Construction and Renovation Project that started in 2012 and would be completed in March 2019.

Implementation Measures

In order to build such a national manufacturing facility, during as early as the planning stage, expertise of the Administration in PIC/S GMP, medicinal product manufacturing regulations, professional process equipment and requirements for the clean area and the expertise of the handling agency, that is, the Construction and Planning Agency in building and spatial design, have combined the review of construction devices, greening and energy-saving, smart buildings, among others. Meanwhile, we worked closely with design, construction surveillance, earthwork, air-conditioning, and water system service providers so that the project could be completed as scheduled in July 2017 (Figure 4-1).

Outcomes and Benefits

Respective systems, pharmaceutical equipment, and machines are being qualified in the newly built facility at the moment. Once the whole building is completed and the whole facility is PIC/S GMP certified, it is expected that the total area of all premises, old and new, of the manufacturing facility for controlled drugs, will increase by 2.3 folds; the number of production lines for injections and tablets will increase from 1 to 2. There will be reserved room for the R&D and production of oral solutions and patches to be added if needed. Production items may be expanded and added and productivity will be enhanced to ensure steady supplies of such medicinal products that are needed during wartime and in case of emergency. In addition, this new manufacturing facility was awarded “excellent” in the Public Construction Gold Award (Figure 4-2) and also the first project of the Ministry of Health and Welfare to win that award.

Figure4-1 New manufacturing facility for controlled drugs

Figure 4-2 The 17th Public Construction Gold Award

Section 3 Domestic Drug Abuse Investigation

Origin of Policy

Drug abuse jeopardizes the national health and undermines social order; it has become an important social and public health issue. To effectively prevent against drug abuse, the Administration has created a drug abuse monitoring mechanism to help collect drug abuse incidents reported through healthcare facilities and other statistics such as drug abuse urine tests, tests performed with non-urine specimens in suspicious drug and controlled drug cases and uncovered drugs. After analysis and compilation, the monthly “drug abuse cases and tests statistics” is prepared and provided to respective ministries, departments and health authorities throughout the country for their reference.

In light of the fact that NPS are getting more and more popular, in order to monitor and prevent against abuse of NPS concurrently with the international society, the Administration started this year to compare and contrast NPS reported through the “United Nations Office on Drugs and Crimes Early Warning Advisory System” and the items detected by and reported by drug authentication institutions throughout the country through the Administration’s “Drug Abuse Test Reporting System” in order to reflect the status of abuse of such NPS in the country and related statistical charts such as “National detected status of NPS” to serve as reference while anti-drug strategies are being stipulated in Taiwan.

Implementation Measures

1. Reporting mechanism for healthcare facilities on drug abuse

Healthcare facilities are encouraged to report patients they receive with inappropriate or excessive use of addictive substances. The information to be reported includes the type, consumption method and where it is acquired, among others. The abuse information is reported to the Administration's "Controlled Drug Abuse Reporting Information System" on a monthly basis.

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

Article 33-1 of the "*Narcotics Hazard Prevention Act*" requires and authorizes that the former Department of Health to stipulate and announce the Regulations Governing Accreditation and Management of Drug Abuse Urine Testing and Medical Institutions, the Regulations Governing Drug Abuse Urine Testing Operations and the Standards Governing the Drug Abuse Urine Testing Laboratories Established by Government Agencies in 2003 in order to specifically govern management of drug abuse urine testing and medical institutions and improve quality of tests performed at such institutions.

In order to enhance the quality of drug abuse urine tests performed by approved institutions, 15 of them were routinely accredited in 2017 and 10 were inspected from time to time. In addition, routine performance tests occurred once a quarter and four times in total per institution and 56 times combined for the approved institutions.

Testing institutions report test results periodically, on a monthly basis, to the Administration's Drug Abuse Test Reporting System for the Administration to produce the monthly statistics.

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

There are many institutions throughout the country at present to help prosecution, police and investigation authorities test non-urine specimens for uncovered drugs. According to the division of labor in drug testing under the Prosecutors Office for Taiwan High Court, by the end of 2017, there had been 8 drug testing institutions in northern, 1 in central, 3 in southern and 1 in eastern parts of Taiwan. The Administration produces statistics of positive results with non-urine specimens for suspicious drug and controlled drug cases on a monthly basis and provide it to respective ministries and departments for their reference.

Outcomes and Benefits

1. Drug abuse reporting status at healthcare facilities

The analysis data of the Controlled Drug Abuse Reporting Information System showed a headcount of 30,350 users in total reported for drug abuse by healthcare facilities throughout 2017. The headcount of people for the first three types of drugs abused was 16,062 for heroin (52.9 %), 8,914 for methamphetamine (29.4%), and 1,547 for ketamine (5.1%). The headcount of users of heroin and that of methamphetamine reported in 2017 increased from those in the previous two years.

2. Reporting status of approved institutions for drug abuse urine tests

As of the end of 2017, 14 institutions had been approved by the government for performing drug abuse urine tests. The approved items included morphine, codeine, methamphetamine, MDMA, MDA, cannabinoid metabolites, ketamine, and norketamine, 9 in total. For the list of institutions that may perform drug abuse urine tests and the approved items, you may visit the Administration's official website (website: http://www.fda.gov.tw). There was a total of 258,531 urine tests performed throughout Taiwan in 2017; among them, 70,941 were positive. The positive rate was 27.4%.

3. Reporting data of drug abuse non-urine (Drug) tests

Among the cases submitted for testing by the prosecution, policy, and investigation authorities in Taiwan in 2017, there were 131,397 with positive results with non-urine specimens for suspicious drug and controlled drug cases. Among them, methamphetamine accounted for 30,860 (23.5%), heroin 24,943 (19.0%), and ketamine 21,429 (16.3%). Mephedrone (4-methylmethcathinone, MCAT) in particular, significantly increased in the detection rate compared to the past, followed by chloromethcathinone. Among the drug cases submitted for testing by the prosecution, policy and investigation authorities, however, as far as the new psychoactive substances are concerned, cathinine accounted for a majority, with a total of 63,266 cases (such as methylone, ethylone, chloromethcathinone, etc.), followed by dissociative 21,492, tryptamine 4,110, phenethylamine 3,168, cannabinoid active substance 1,263, piperazine 89 and others 3,198. The Administration sorted out the history of NPS detected and released the information in its NPS information section to act as a reference for respective anti-drug authorities.

Section 4 Strategies for NPS Prevention

Origin of Policy

As of the end of 2017, up to 800 NPS around the world have been reported to the United Nations Office on Drugs and Crimes (UNDOC). To help understand the status of abuse with emerging drugs in the country, the Administration created a monitoring mechanism and prepares the "drug abuse cases and tests statistics" on a monthly basis and provided it to respective ministries, departments, and health authorities throughout the country for their reference.

Implementation Measures

In order to enhance anti-drug performance and to deter emerging drugs, the Executive Yuan initiated the "New-generation Anti-drug Strategy" that focuses on five aspects, namely drug monitoring, drug prevention, drug sweeps, drug rehabilitation treatment and strategies for amending laws and regulations. As the authority in charge of the anti-drug strategy, the Administration introduced, in terms of drug monitoring, the two core sub-strategies, namely "prevention against the importation of illicit drug raw materials in the name of the active pharmaceutical ingredient" and "expand inspection capabilities to detect emerging drugs by establishing standard analytical profiles for them." Border checks and control are performed on active pharmaceutical ingredients and the capabilities in the testing of new drugs are reinforced through cross-ministerial/cross-departmental collaboration in order to block NPS so that they cannot spread in the country.

Outcomes and Benefits

In order to prevent ill-intentioned manufacturers from turning imported active pharmaceutical ingredients into precursors for producing illicit drugs, the Administration announced on October 31, 2017 that Requirement F04 would be established (to be officially announced on March 22, 2018) that spontaneous application for importation checks should be

applied for in compliance with the Regulations for the Inspection and Examination of Imported Medicaments for active pharmaceutical ingredients. In addition, Raman analyzers were purchased to test on site if imported active pharmaceutical ingredients contain illicit drugs. Meanwhile, active pharmaceutical ingredients warehoused in the field at a pharmaceutical company were inspected to confirm if they are consistent with the purchased ingredients in order to prevent illegal acts in the disguise of legal activities.

Emerging drugs are constantly changing for the past few years to make testing more and more difficult each day. In order to detect illicit drugs in real time, the Administration integrated testing resources available at the respective ministries and departments throughout the country and established the new substance nuclear magnetic resonance (NMR) testing mechanism, with 91 reference standards of illicit drugs and new substances purchased and the mass spectrometer database with 160 reference standard items created. Such testing information is shared with testing units throughout the country. The Administration concurrently organizes the referral program for laboratories to perform urine tests for emerging drugs. The Drug Abuse Test Center of the Tzu Chi University and Taiwan Advance Bio-Pharmaceutical Inc. have applied to become a laboratory for testing methcathinone in urine. In the future, proactive efforts will be devoted to extending the developed emerging drug urine test items and methods to private testing institutions to comprehensively enhance the testing capabilities throughout the country.

The Administration has created on its official website (Figure 4-3) the exclusive section for information on NPS being abused. Diversified anti-drug information is provided to make it easier for the general public to inquire about them.

Figure 4-3 New Psychoactive Substances and Drugs Abuse Information

Section 5 New-Generation Anti-drug Strategy

Origin of Policy

The Executive Yuan approved the “New-generation Anti-drug Strategy Action Framework” on July 21, 2017 that combines the five major aspects, namely drug monitoring, drug prevention, drug sweeps, drug rehabilitation treatment and strategies for amending laws and regulations of the New-generation Anti-drug Strategy for 2017 through 2020, 4 years in total to strengthen integration of functionalities across ministries and departments so that the government can propose substantial anti-drug action plans to hopefully effectively reduce derivative crimes of drug abusers, inhibit the increase in the population of new drug abusers, and protect the health of the generation.

Implementation Measures

Different from traditional, serious, and dogmatic anti-drug campaigns in the past, the Administration took advantage of the open data available from related ministries and departments involved in the anti-drug operation of the government and applied the idea of citizen participation to involve people in different fields. By means of technology and digitalization, the first hackathon in the country with “prevention against illicit drugs” as its theme was organized (Figure 4-4).

Figure 4-4 2017 Anti-drug Hackathon

The current anti-drug hackathon gathered experts to brainstorm and apply the open databases of the government and big data with the inclusion of people's enthusiasm and creativity so that they could jointly come up with anti-drug technological and digital services in different forms, such as the Internet, APP, software and games. The Allies Day occurred in the afternoon of May 13, 2017, to clarify on the open data of the government available for the campaign and to invite non-governmental organizations to share their experience in drug rehabilitation and their experiences in fighting against illicit drugs. Then, on May 27 and 28, 2017, the two-day marathon-like collaboration began. Within limited time and space, contestants from different fields utilized anti-drug datasets and related anti-drug website resources from respective ministries and departments and developed three innovative and practical cases on the theme "prevention against illicit drugs," including "Anti-drug Data Integration Platform," "Illicit Drug Identification," and "Management of Discovered Drug Abusers."

Figure 4-5 2017 Anti-drug Hackathon

Outcomes and Benefits

A total of 32 groups registered for the contest, including families, local government grassroots employees, university and college students and representatives from society, fully demonstrating the diversity of the campaign (Figure 4-5). Participating teams were all characteristic and creative. The final 10 winning teams selected had works that included web pages that fully displayed information of drug rehabilitation centers available throughout the country, designs to help locate auxiliary therapy by searching for biological information, APPs that helped drug abusers record their feelings, data of urine test and the information about medical attention, provided users exclusive digital inquiries and reporting by Line, experienced what drug addicts really feel by playing desktop games, personal dashboards to visualize data, and RPG games to help users understand the dangers of illicit drugs.

Vice President Chen Chien-Jen presented the awards to the above-mentioned winners during the National Anti-Drug Conference on June 3 (Figure 4-6) and explained the “New-generation Anti-drug Strategy” introduced by the Executive Yuan. Non-governmental organizations, experts and scholars were invited to discuss and exchange with one another.

In addition, the Ministry of Health and Welfare has completed the Drug Rehabilitation website, through the website, people can search for drug rehabilitation institutions throughout the country. The Ministry of Health and Welfare has used it to help country-level and city-level health authorities and private institutions establish administrative resources that facilitate drug abusers return to society.

Figure4-6 National Anti-drug Conference

05

Medical Devices and Cosmetics Management Reforms

The Draft of Medical Device Act

Advancing R&D and Product Innovation in the Medical Device Industry.

Promoting Diversified Management of the Medical Device Industry.

Normalized Product Destination and Distribution Quality Management.

Consolidation of Medical Device Risk Management System.

Medical Device Clinical Trials Management.

Promoting Listed Medical Device Safety Surveillance Management.

Advancement in Management of Medical Device & Consultation

Training 47 Seed Regulators in Medical Device Management.

Successfully Assisted 8 Domestic Innovative Medical Devices into Market.

20 Thousand Times Telephone Counseling.

739 Items of Medical Devices Available for Online Sale.

Successfully Assisted 4 Medical Devices for Clinical Srials.

Guidelines for the 3D Printing of Medical Devices (Draft).

New System for the Management of Cosmetics

Additional Information Requirement for Nail Cosmetics.

Regulations Governing the Application of Animals Testing for Cosmetics or Cosmetic Ingredients.

Regulations Governing 15 Ingredients such as Safrole that are Ingredients Prohibited for Use in Cosmetic Products.

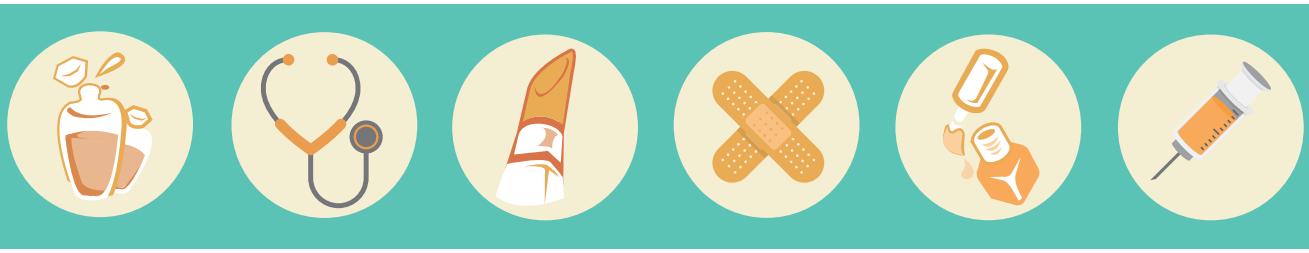
Cosmetic Hygiene and Safety Act

Scope of Management.

Proactive Report.

Product Notification and Product Information File System.

Abolition of Criminal Punishment & Increase of Administration Fines.



05 Medical Devices and Cosmetics Management Reforms

In light of the obvious differences between medical devices and drugs in terms of their characteristics and industrial operation models, and in order for our laws and regulations governing medical devices to comply with their international counterparts, the Administration separated laws and regulations governing medical devices from the *Pharmaceutical Affairs Law* and prepared the *Draft Medical Devices Act*. In addition, in order for the cosmetics management system to comply with the international counterpart and to increase the competitive advantages of Taiwan‘s cosmetics industry around the globe, proactive efforts have been made to amend the *Cosmetic Hygiene and Safety Act* to maintain the hygiene and safety of cosmetics.

To expedite commencement of the clinical trial phase for innovative medical devices or to shorten the time frame needed for marketing and accordingly boost competitive advantages of Taiwan’s medical device industry around the globe, the Administration established the project regulatory consultation and assistance mechanism and prepared the “*Guidelines for Additive Manufacturing (3D Printing) of Medical Devices*.”

Section 1 Preparation of the Medical Devices Act

Origin of Policy

The requirements on the management of medical devices that are available in our country can be found in the *Pharmaceutical Affairs Act*. In light of the obvious differences between medical devices and drugs in terms of their characteristics and industrial operation models, and to improve the management of medical devices for compliance with international laws and regulations, the *Medical Devices Act* was planned separately to help normalize the domestic medical device management system.

Implementation Measures

1. The Administration started to separately plan the medical device law framework and legality assessment in 2014 by reference to international management regulations and our own national conditions, and invited the industrial, governmental, academic, and research representatives to attend the negotiation meeting so as to collect opinions. By the end of 2017, 16 rounds of workshops and discussion meetings had been held to help concerned parties understand highlights of the draft. (See Figure 5-1 for the process of promoting the *Draft Medical Devices Act.)*
2. In order to realize an open and transparent government, the draft was announced on December 5, 2016 to facilitate the collection of diversified opinions. The WTO reporting procedure was completed on January 31, 2017. Respective member states had 60 days to provide opinions. During the period, a total of 34 unions, associations, societies, or institutions submitted letters expressing their opinions and all the opinions were included while the draft was under assessment. It was reviewed and approved by the Executive Yuan on December 14, 2017. The draft consisted of 83 articles in total.
3. The Legislative Yuan passed the first reading of the *Draft Medical Devices Act* on December 29, 2017, and submitted it to the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan for review.

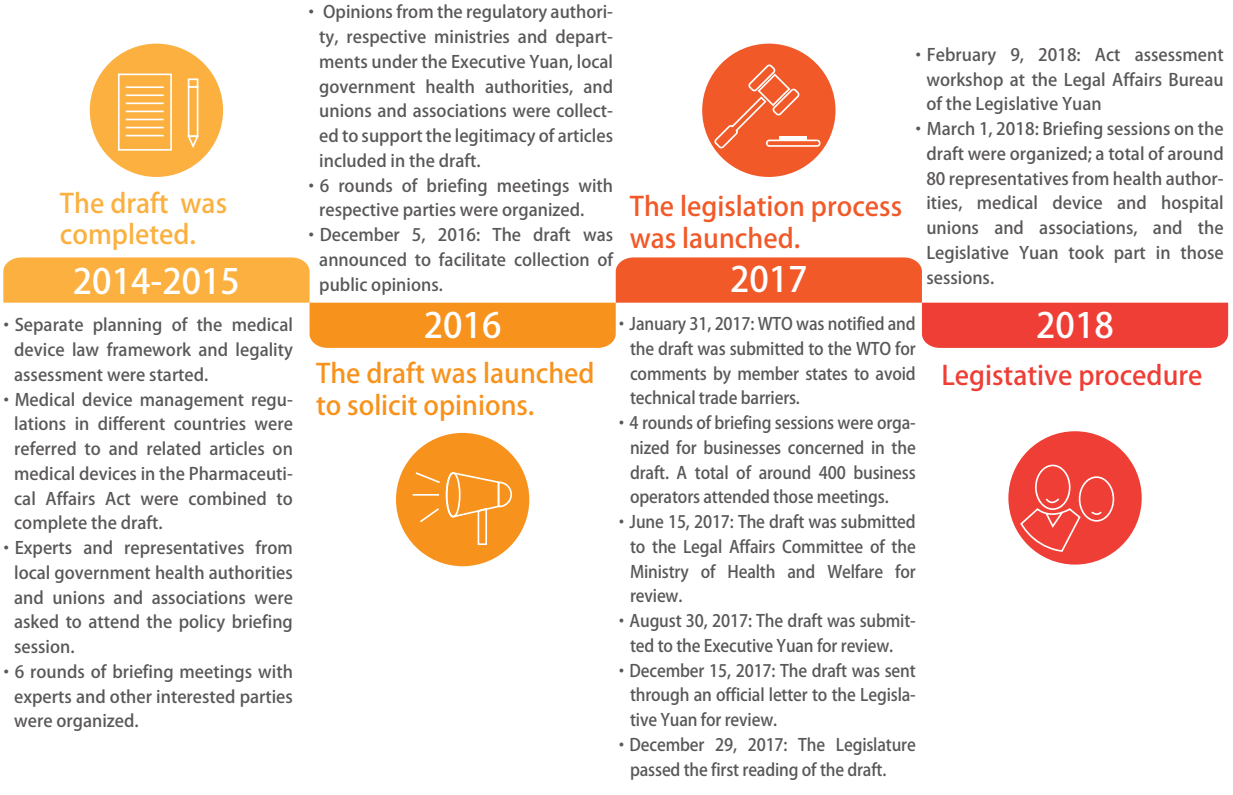


Figure 5-1 The process of promoting the Draft Medical Devices Act

Outcomes and Benefits

1. Advancing R&D and product innovation in the medical device industry

The term of "Medical Device Manufacturer" is defined according to the key process in medical device manufacturing. Medical device designers can also be the permit holders to provide incentives for the industry, academia, and research institutions to research and develop high-end medical devices. The conditional approval mechanism is introduced along with post-approval study or safety surveillance to expedite the entry of innovative medical devices into the market.

2. Promoting diversified management of the medical device industry

Medical device rental or repair businesses are considered as Medical Device Dealers. It is required that technicians be hired for the different sectors in the medical device industry to enhance professional management and ensure product safety.

3. Normalizing product destination and distribution quality management

It is specified that Medical Device Dealers and medical institutions shall create and preserve data of direct supply sources and destinations of products. Medical device distribution quality of medical devices is promoted to ensure that the quality of products is not compromised during transportation.

4. Consolidating medical device risk management system

For certain low-risk medical devices, the electronic online register system is adopted in order to streamline the pre-marketing application process. In addition, annual declaration applied to extend the validity of registration and urge timely update to the information of listed medical devices.

5. Constructing medical device clinical trial management

Applicable regulations on clinical trials of medical devices are separated to improve the management system, ensure the safety and rights of trial subjects, and fulfill the requirements on management of clinical trials on medical devices.

6. Promoting listed medical device safety surveillance management

It is specified that medical institutions shall cooperate to implement the medical device safety surveillance system and urge manufacturers to conduct spontaneous monitoring and management of listed product risks and adopt corrective and preventive measures to protect the safety of consumers. (See Figure 5-2 for Highlights of the Medical Devices Act and Its Benefits.)

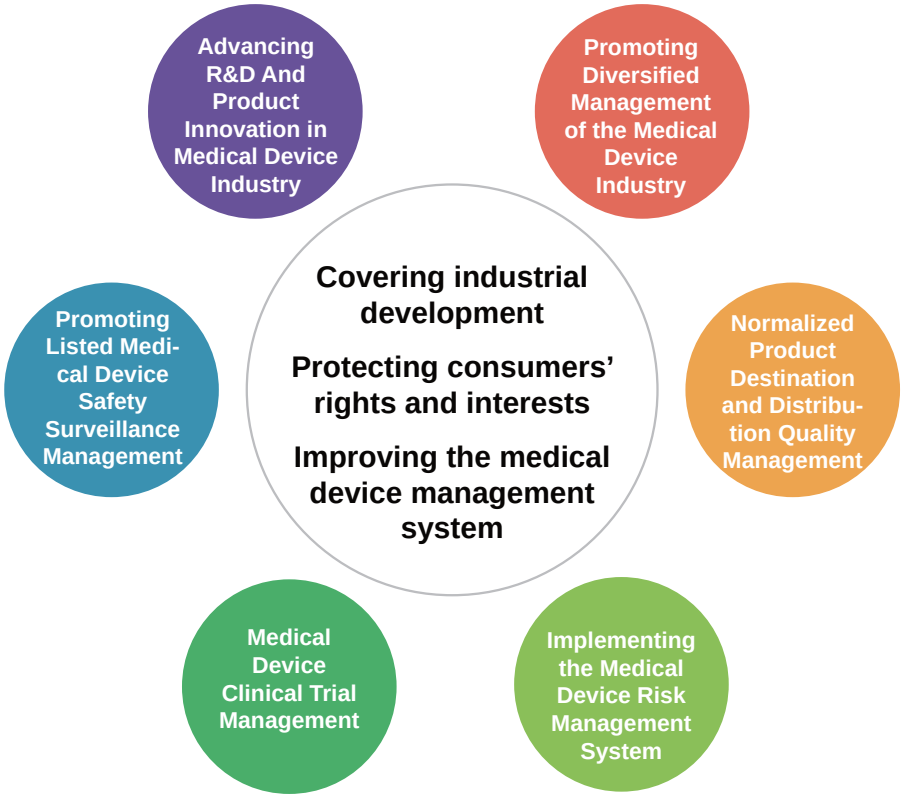


Figure 5-2 Highlights of the Medical Devices Act and Its Benefits

Section 2 Review and Consultation for Innovative Medical Devices

Origin of Policy

The development of medical devices based on innovative technologies has been significantly accelerated in the past few years. Such medical devices usually employ novel technical principles or claim new intended uses, however, researchers and developers are faced with the challenge that there are no similar products or pre-clinical test standards available for reference. In order to support the R&D teams to develop innovative medical devices, the Administration established and updated respective standards applicable to medical devices, created a regulatory consultation network covering the entire product life cycle, and set up a Medical Device Advisory Board formed by members strong in biomedical engineering and experienced with clinical practice (Figure 5-3). When it is considered necessary, external experts will also be invited to take part in the consultation services to provide advice and jointly resolve the regulatory issues confronted by developers during their development of innovative medical devices.

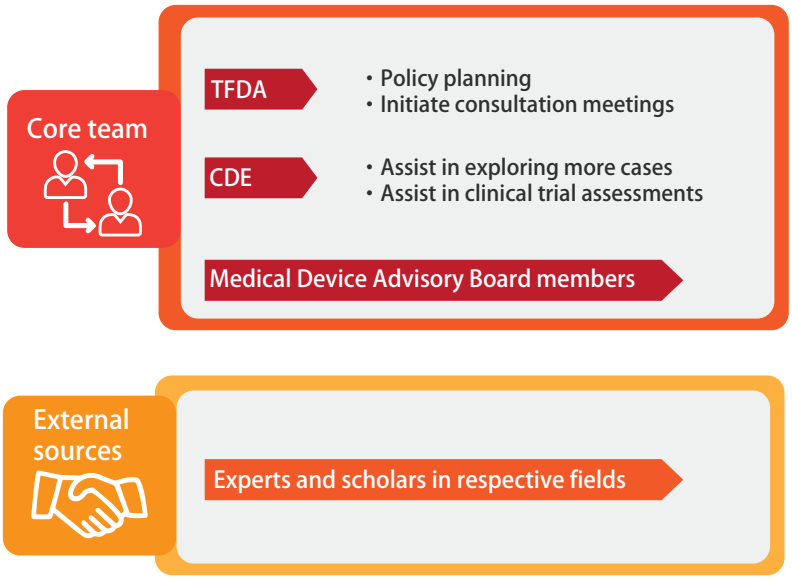


Figure 5-3 Operational framework of the medical device project counseling and assistance team

Implementation Measures

1. In May 2011, the Administration started a program based on the document "Principles for Medical Device Consultation." The program aims to support R&D teams through one-on-one consultation and provide the R&D teams with advice on pre-clinical and clinical validations during their product development. The targeted medical devices of this program are Class II or III medical devices still under development and not available in the domestic market or medical devices seeking for multicenter international clinical trials, in which the medical devices must meet any of the following criteria: first domestic case (FDC), best in class (BIC), new indication in health (NIH), milestone for TFDA (MFT), and multicenter clinical trial (MCT).
2. Through the above program, an R&D team can establish a close correspondence with the regulatory and technical teams within and outside of the Administration since the early R&D phase. The Administration will hold consultation meetings depending on the circumstances, where members of the Medical Device Advisory Board, experts, and scholars will also be invited to help the R&D team to address issues in the consultation meetings.
3. In order to provide manufacturers and the public with quick assistance on medical devices, the Administration has authorized the Center for Drug Evaluation (CDE) to set up a hotline at (02)8170-6008 for basic consultation regarding the regulations of medical devices. The manufacturers and the public can ask questions about laws and regulations on the registration and clinical trials of medical devices on this hotline. In addition, the CDE also trained seeds from local communities to address basic regulatory inquiries, and allows manufacturers from biomedical science parks to reserve in-park regulatory consultation services.

Outcomes and Benefits

1. In 2017, 8 innovative medical devices had been approved and 4 clinical trials of medical devices had been activated with the assistance from the program of "Principles for Medical Device Consultation." The highlighted outcomes includes a Hepatitis B viral load test kit, a Hepatitis D total antibody reagent, a dengue fever NS1 antigen quick test reagent, and an implanted spinal stimulator. The results are considered impressive.
2. In 2017, up to 20,017 regulatory consultations had been provided through CDE's hotline. In addition, several consultation services had been reserved and provided to manufactures in the biomedical science parks to promote innovation of medical devices.
3. With the joint efforts from the Administration, CDE, and 47 seeds trained in 2017 (the completed list of seeds has been published on our website), the scope of regulatory consultation service has been successfully expanded to cover local communities. This regulatory consultation network aims to help businesses to establish regulatory compliance as early as possible.

Section 3 Preparation of Guidelines for 3D-Printing of Medical Devices

Origin of Policy

Many manufacturers, the academic research institutes, and the medical community in our country have devoted to the R&D and manufacturing of 3D-printed medical devices. In order to define related device management scope and regulatory requirements and to also ensure that such products are safe and effective, the Administration referred to management regulations in other countries around the globe and the development status of related industries in our country in 2016 and 2017 to stipulate the "*Guidelines for Additive Manufacturing (3D Printing) of Medical Devices (Draft)*" and officially promulgate it accordingly on January 12, 2018.

Implementation Measures

1. 3D-printing is a new technology applied in the manufacturing of medical devices, and it has a wide scope of application. Thus, regulatory data available for reference in the international realm is quite limited. As such, while the draft was being prepared, one international symposium, three expert meetings (where experts from the industry, government, research institutes, and medical community and related units of the Administration were invited), five visits to domestic and international medical device manufacturing/3D-printing facilities, three internal meetings, and one external and internal briefing session, were respectively organized to extensively collect opinions from all parties, and eventually, the "*Guidelines for Additive Manufacturing (3D Printing) of Medical Devices*" were successfully completed.

2. The Guidelines stipulates its scope of application and includes a list of product attributes in respective parts of the 3D printing technology for management. In addition, special considerations and related verifications and assessments are also covered with regard to the 3D printing software work flow, product quality and manufacturing control, and finished product testing, among others, for industrial reference.

Outcomes and Benefits

Management advice and principles are provided in the Guidelines to expedite review and approval of the 3D-printed medical devices and introduction to the market as early as possible, to create a high-quality industrial development environment, and to push Taiwan's medical device industry onto the world stage. This policy was highly recognized in various respects. So far, a total of 3 permits have been issued for 3D-printed medical devices approved to enter the market, including the dental implant surgical guide and the preformed tooth positioner, among others.

Section 4 Expansion of Medical Devices Available for Online Sale

Origin of Policy

In order to take care of both the demand for and safety of medical devices suitable for use at home, the Administration announced medical devices that may be sold over the Internet shall follow the four major principles of "home use, non-invasion, non-implantation, and no need for instructions from professionals." Medical device companies and drug stores may apply for and obtain approval from the local health authority, in order to sell medical devices through distance sales channels.

Implementation Measures

1. As of November 1, 2012, according to the characteristics of medical devices, the Administration has gradually lifted the ban on items that may be purchased online. Medical Device Dealers with physical operating sites may apply to local health authorities for a permit and once it is approved, they may sell low-risk medical devices in Class 1 through distance sales channels.
2. The ban on five items were lifted on January 2, 2014, including body fat monitors, condoms, and sanitary pads as Class 2 medical devices that were suitable for use at home as they were non-invasive, non-implanted, and did not require instructions from professionals.
3. The ban on 8 items were lifted on October 15, 2015, including surgical masks, alcohol prep pads, alcohol cotton balls, iodine prep pads, iodine swabs, iodine gauze, Vaseline gauze, suture-free tape, contact lens cleaning and care products, medical image recording and transmission

software, and magnetic resonance imaging software as Class 2 medical devices.

4. On March 16, 2017, the ban on five Class 2 medical devices was further lifted, including blood pressure tourniquets, the motorized vehicle for medical purposes, powered wheelchairs, and otolaryngology drug application devices.

Outcomes and Benefits

1. So far, the Administration has lifted the ban on sale of 739 items in total, including 721 low-risk Class 1 medical devices and 18 medium-risk Class 2 medical devices, to make it convenient for consumers to purchase medical devices on the Internet.
2. When medical devices are purchased online, frauds and the impossibility to return and replace products, failure to operate a product, or health hazards caused by improper use, and issues with after-sale maintenance of products are likely to happen. The Administration has conducted classification on the overall risk of medical devices into consideration. For the time being, medical devices having fulfilled the four principles indicated above have all been allowed to be sold online. (Table 5-1) (Figure 5-4)

Table 5-1 Medical device items that can be sold by pharmaceutical companies (pharmacies) through distance sales channels

Start Date	Medical Device Items	Product Demo
November 1, 2012	Class I medical devices (721 items)	knee braces, Band-Aid, mechanical wheelchairs
January 2, 2014	E.2770 Impedance plethysmography (impedance peripheral blood flow recorder)	Body fat monitor
	L.5300 Condoms	Condoms
	1.5310 Condoms containing spermicide	
	L.5460 Scented or deodorizing sanitary pads	Tampon
	L.5470 Unscented sanitary pads	
October 15, 2015	I.4040 Medical clothing	Surgical masks
	I.0004 Alcohol prep pads	Alcohol prep pads, alcohol cotton balls
	I.0005 Iodine pep pads	Iodine prep pads, iodine swabs, iodine gauze
	I.4014 External non-absorbent gauze or sponge balls	Vaseline gauze
	J.5240 Medical sticky tape and sticky bandage	Suture-free tape
	M.5918 Rigid gas permeable contact lens preserving products	Contact lens cleansing solution, contact lens care solution
	M.5918 Flexible contact lens preserving products	
	Medical device software	Medical image digitizer, communication and storage device
March 16, 2017	E.1120 Blood pressure tourniquets	Blood pressure tourniquets, blood pressure cuffs, blood pressure measuring armbands
	L.5400 Menstrual cups	Menstrual cups
	O.3800 Motorized vehicle for medical purposes	Motorized vehicle for medical purposes
	O.3860 Powered wheelchairs	Powered wheelchairs, powered walking aids installed on wheelchairs
	G.5220 otolaryngology drug application devices	Nasal irrigation devices, nasal sprays

Figure 5-4 Medical devices that pharmaceutical companies (drug stores) may sell through distance sales channels in 2017

Section 5 Stipulation of Cosmetic Hygiene and Safety Act

Origin of Policy

The *Statute for Control of Cosmetic Hygiene* has been enforced since December 28, 1972, and was amended five times. Given trade liberalization and frequent international correspondence in recent years, current management requirements are becoming more and more insufficient to meet practical demand.

For reinforced quality and safety of cosmetic products that are available on the market and to reflect international management trends, the Administration prepared the amended draft of the *Statute for Control of Cosmetic Hygiene* that highlights replacement of the medicated cosmetics registration system with the product notification and product information file system and addition of the requirement for cosmetic businesses to comply with the Good Manufacturing Practice, among others, in order to strengthen the hygiene and safety management mechanism for cosmetic products and to meet the requirements of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

Implementation Measures

1. The Administration began revising the *Statute for Control of Cosmetic Hygiene* in 2011 and has been proactively communicating with external representatives. The public hearing on highlights

of the revision, industrial impacts forum, external briefing sessions, cross-ministerial/cross-departmental meetings, and notice to the WTO for comments from its member states were completed and opinions from all parties concerned were extensively collected to render the amended draft of the Statute for Control of Cosmetic Hygiene. It was reviewed and approved by the Executive Yuan on September 8, 2016, and the title was changed to *Cosmetic Hygiene and Safety Act*. There are a total of 32 articles.

2. This amended draft was reviewed and approved by the Social Welfare and Environmental Hygiene Committee of the Legislative Yuan on December 20, 2017, and it was decided by the Legislative Yuan on December 29 of the same year to be submitted for negotiation among party caucuses. (Note: The amended draft passed the third reading in the 7th meeting of the Legislative Yuan on April 10, 2018. The President promulgated it through the Hua-Zong(I)-Yi-Zi No. 10700045851 order on May 2, 2018, with the date of enforcement to be determined separately by the Executive Yuan.)
3. The Administration has also called for more than a hundred rounds of training and briefing sessions since 2013 and planned the implementation of GMP and product information file systems in phases according to the risk associated with respective products in order to minimize the impacts of the new system on the industry.

Outcomes and Benefits

1. The current amendment takes international regulations into consideration by including non-pharmaceutical toothpaste and mouthwashes in the management of cosmetics. Once the new Act is enforced, for cosmetics categories specified by the central competent authority, businesses must complete product notification and establish the product information file (PIF) before their products are introduced to the market and their manufacturing site must fulfill the Good Manufacturing Practice (GMP). This measure helps not only shorten the time to market and provide consumers with more diversified options and the possibility of searching for product information online but also reinforce the safety management of cosmetics and ensure steady production of qualified cosmetics to maintain the hygiene and safety of cosmetics.
2. In addition, data on the sources and flows of products and systems such as spontaneous reporting obligations of businesses were added this time. The value of the fine involved was significantly increased, too. Penalties for non-compliant cosmetic advertisements were also increased. For violations involving falsified or exaggerated claims, the fine increased from current NTD 50,000 to NTD 40,000-NTD 200,000. For those involving medical efficacy, the fine is reinforced to NTD 600,000-NTD 5 million. The competent authority may demand posting of correction advertisements and products be removed from shelves when violations in advertising are severe. The even more normalized regulations are meant to protect the rights of consumers.
3. The current amendment is a major systematic reform that helps streamline the administrative efficiency of the government and reinforce source and circulation management to protect the

rights of general consumers. Meanwhile, in light of the relatively extensive scope involved in the current amendment, cosmetics businesses are given adequate and reasonable buffer and preparation periods in order to reduce the impacts on the industry. The Administration will also embark on the stipulation of sub-regulations and package measures according to the post-amended *Cosmetic Hygiene and Safety Act* so that the cosmetic hygiene and safety management system in our country is even sounder and complete.

Section 6 New System for the Management of Cosmetics

Origin of Policy

The use safety of cosmetics is closely related to the general public. Related management laws and regulations shall be constantly updated with time. On November 9, 2016, it was announced through Presidential Order that some articles of the *Statute for Control of Cosmetic Hygiene* were revised: cosmetic businesses shall not subject animals to testing when conducting safety evaluation of cosmetics or cosmetic ingredients in our country. If the ingredient is widely used and its function cannot be replaced by other ingredients or there are evaluation data demonstrating the potential for harming human health, cosmetic businesses must apply for approval with the central competent authority prior to conducting animal tests and the new requirement would take effect on November 9, 2019.

In order to protect the health of consumers, to ensure that natural botanical ingredients in cosmetics came from safe sources, and to promote comparable management systems in our country to international ones, on the other hand, current requirements are revised to prohibit the use of 15 ingredients such as Safrole in cosmetics.

As for commercial nail cosmetics, although it is used on the surface of the nail and contact with skin or inhalation should not occur when used correctly, in light of the fact that it mostly contains organic solvents and that there have been prior events of skin or nail lesions, as a result, improper use and that there is the concern of inhalation of excessive organic solvents during storage and use, in order to protect the safety of users of such products, additional information requirement on such products is included with reference to the requirement for nail cosmetics in the United States and the European Union.

Implementation Measures

1. To go with the amended *Statute for Control of Cosmetic Hygiene* announced on November 9, 2016, the Administration stipulated the Information on Applying for Animal Studies of Cosmetics or Cosmetic Ingredients (Draft). The draft was discussed in the meeting on December 26, 2016, and pre-announced on February 2, 2017. The "*Regulations Governing the Application of Animals*

Testing for Cosmetics or Cosmetic Ingredients" was promulgated on September 14, 2017.

2. In order to protect the safety of consumers while using cosmetics and to promote comparable management systems in our countries to international ones, the Administration pre-announced the stipulation of the "*Regulations governing 17 ingredients such as Safrole that are ingredients forbidden for use in cosmetic products*" on February 2, 2017 and again pre-announced the "*Regulations governing 15 ingredients such as Safrole that are ingredients prohibited for use in cosmetic products*" on August 15, 2017 and announced it on December 8, 2017.
3. Nail cosmetics tend to cause accidents due to improper use. In order to protect the safety of people using nail cosmetics added with organic solvents, the Administration called for the cosmetic industry communication meeting and discussed the issue on November 8, 2016, and announced the stipulated "*Requirements for Additional Information on Nail Cosmetics Added with Organic Solvents*" on May 26, 2017.

Outcomes and Benefits

1. The new cosmetics management systems such as the Regulations Governing the Application of Animals Testing for Cosmetics or Cosmetic Ingredients, Regulations governing 15 ingredients such as Safrole that are ingredients prohibited for use in cosmetic products, and the Requirements for Adding Information on Cosmetics for Nails Added with Organic Solvents were established in 2017.
2. The Administration announced the prohibited importation, manufacturing, distribution, supply, or display of cosmetics containing specific ingredients such as Safrole, Verbena Oil, Woody Root Oil, Fig Leaf Extract, Alocasia Cucullata, Konjac, Alocasia Macrorrhizos, Rose Pericuinkle, Common Cerberustree Seed, Ranunculaceae Ranunculus, Wild Lily, Dioscorea Hispida, Graceful Jesamine, Stellera Chamaejasme, and Hubei Wind flower for intended purposes of distribution or supply on December 8, 2017. The said ingredients were announced to be prohibited for use in cosmetics and the announcement took effect on July 1, 2018.
3. The Administration announced on May 26, 2017, the stipulated "*Requirements for Additional Information on Nail Cosmetics Added with Organic Solvents.*" For nail cosmetics added with organic solvents, it is advised to add information such as "pay attention to ventilation; stay away from fire and heat; avoid use in pregnant women and children under the age of 12; avoid getting on skin, in the eyes, and inhalation; the product is for external use and if swallowed by accident, please seek medical attention" on the label, package insert, or package for enhanced protection of the safety of people using such products.

06

Special Project

Establishment of the Food and Drug Crime Platform for Inter-departmental Investigation

Establish inter-departmental collaboration

Meetings on establishment

Discussion forum on the "Enforcement in combating the crime cases involving food and drugs"

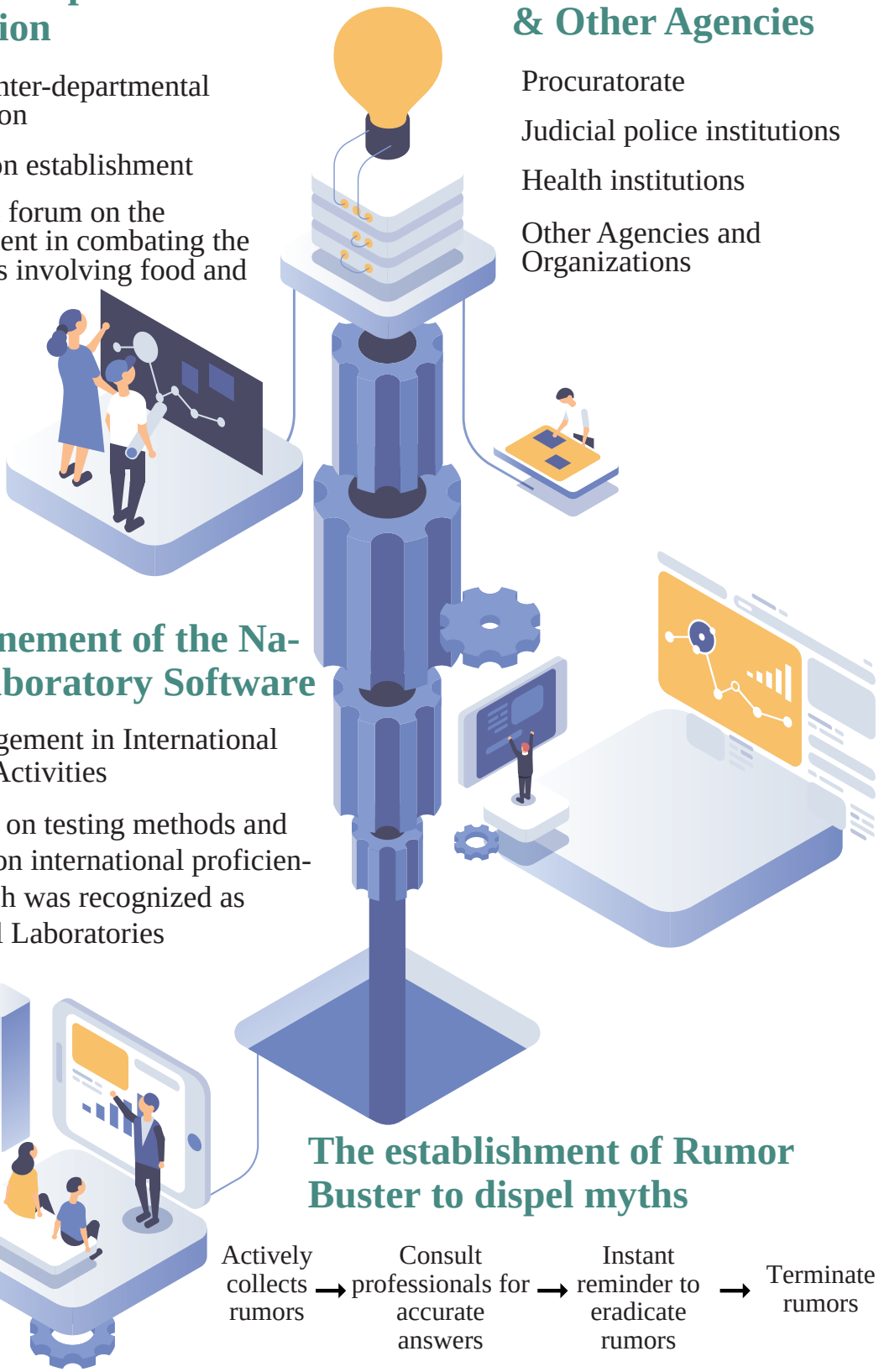
Plans for Procuratorate & Other Agencies

Procuratorate

Judicial police institutions

Health institutions

Other Agencies and Organizations



The Refinement of the National Laboratory Software

Active engagement in International Laboratory Activities

Amendment on testing methods and affirmation on international proficiency test, which was recognized as International Laboratories

The establishment of Rumor Buster to dispel myths

Actively collects rumors → Consult professionals for accurate answers → Instant reminder to eradicate rumors → Terminate rumors

06 Special Project

To improve the efficiency on investigating food and drug crime, an inter-departmental platform has been established to integrate resources from diverse departments, and demonstrate government's active role in combating related crime. To address folk prescriptions and rumors spreading online, TFDA established a "Rumor Buster" online, which clarify rumors with scientific evidences, and resolve public concerns. Moreover, TFDA continuously enhanced national laboratories facilities, and participated in international laboratory events. Through interacting and sharing techniques and experiences with other countries, we strengthen our professional and technical capacities.

Section 1 Establishment of the Food and Drug Crime Platform for Inter-departmental Investigation

Origin of Policy

In order to safeguard the nation in terms of food and drug safety, TFDA established high quality lifestyle and a healthy consumption environment, as well as uplifted the efficacy in processing food and drug related crimes. The Taiwan High Prosecutors Office and the TFDA are expecting to integrate various agencies through the establishment of the Food and Drug Crime Platform, providing active and specific security check on food and drug cases, in order to exhibit the Government's determination in strict prosecution in such aspects.

Implementation Measures

In recent year, the frequency of criminal cases involving food and drugs elevated, which engaged a number of areas ranging from tampering with the expiration date, counterfeit or forgery, applying unauthorized additives into pseudo-drugs, changing drug labels and others. Hence, the Health institution and police departments have to work closely together. TFDA and the

Taiwan High Prosecutors Office has drafted a "*Procuratorate's execution plan for the inspection of criminal cases involving food and drugs,*" and integrated resources among the Prosecutors Office, the Health departments, the judicial police departments to establish a communication platform for food and drug related crimes. Relevant courses are as follow:

1. Meeting with the Taiwan High Prosecutors Office to establish inter-departmental collaboration

On June 2, 2017, Director Hsiu-Mei Wu from the TFDA met with the attorney general Tien-Cheng Wang from the Taiwan High Prosecutors Office, to discuss the details of formulating communication platform for criminal cases involving food and drugs. The Taiwan High Prosecutors Office suggested that by referring to the current co-operation between the Council of Agriculture and the Environment Protective Administration, the platform between the Procurators Office and TFDA can as well become a sustainable operation.

2. The meeting of establishing "Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs"

On June 22, 2017, TFDA drafted the "*Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs.*" Additionally, on July 14, TFDA attended the meeting held by the Taiwan High Prosecutors Office for the "Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs," which explained the backgrounds involved in the established plans, as well as aspects in which the prosecutors should take action of. Discussion on each individual action plan was done. Upon completing the amendments on the same day, District Prosecutors Office, local governmental Department of Health and other relevant units were provided with related information, in order to collect suggestions and feedbacks.

3. Preparatory meeting for the discussion forum on "Enforcement in combating the crime cases involving food and drugs"

On August 8, 2017, the attorney general Tien-Cheng Wang from the Taiwan High Prosecutors Office led his team to visit TFDA. During the meeting, details (time, location and work allocation) on "Strengthening of combating the criminal cases involving food and drugs" were discussed.

4. Discussion forum on the "Enforcement in combating the crime cases involving food and drugs"

On October 18, 2017, the Taiwan High Prosecutors Office and the TFDA co-hosted a discussion forum for "Strengthening the security checks on criminal cases involving food and

Figure 6-1 Discussion forum on the “Enforcement in combating the criminal cases involving food and drugs”

drugs” (Figure 6-1). The Ministry of Health and Welfare minister Shih-Chung Chen and the Minister of Justice minister Tai-San Chiu attended the meeting in person. A total of 108 people from Executive Yuan's food safety office, Council of Agriculture Executive Yuan, Environment Protective Administration, Primary and Secondary Prosecutors Office, the Prosecutor Office of the Ministry of Justice, Investigation Bureau, National Police Administration, the Seventh Special Police Corps of the National Police Agency and the Ministers and representatives from each local Department of Public Health and others attended the “Communication platform for criminal cases involving food and drugs” meeting. In particular, resolutions on the amendments for the “Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs” was done and reported to the Ministry of Justice for approval prior to execution.

Outcomes and Benefits

On April 17, 2018, the Taiwan High Prosecutors Office reported the “*Plans for Procuratorate to carry out security checks on criminal cases involving food and drugs*” to the Ministry of Justice for approval. The formulated plan allowed both the Procuratorate and the Health institution to have necessary information, which would act as a foundation when establishing a collaboration platform between the Procuratorate and the police departments for command and coordinating the communication, investigation and press releases when facing food and drugs related crimes in the future.

Section 2 The Establishment of TFDA Rumor Buster to Clarify Rumors

Origin of Policy

Due to the uprise of Social media and mobile communication apps, the rumors over food, drugs, cosmetics, and medical devices are widely spread. Since those rumors can influence the general public, TFDA establishes a "Rumor Buster" web page on the TFDA official website (www.fda.gov.tw), to stop rumors from spreading and provide people with accurate food and drug information, including professional advice and scientific evidence.

Implementation Measures

1. Actively collects rumors and allows open submission from the general public

Rumors are collected through active search on the Internet and media, questions raised by the general public through TFDA's "Public service mailbox" or Good Articles of Food and Drug website's "Rumors submission box," as well as collaborating with other external professionals. After collecting the public's doubts regarding foods and drugs, relevant scientific information are compiled, and articles addressing public concern are written. Finally, before uploading the articles online, experts from TFDA would thoroughly review the articles.

2. Consults professionals for accurate answers

Professionals from different fields, such as medical, pharmaceutical, toxicology, risk evaluation, nutrition, food sciences, and others, are consulted for professional advice and accurate solutions.

3. Builds instant reminders to eradicate rumors

TFDA incorporates the public concerns from the current news, for instance, imported food from radiation-affected area during Japan's nuclear disaster. TFDA addresses related rumors timely and successfully attracts the general public to visit the "Rumor Buster" web page.

The TFDA also provides clarification towards repetitive rumors, such as "Food Barcodes Starting with '8' Indicate GMO," "Mushroom Toxicity Caused 17 Deaths in Hospitals," "Eating Persimmon and Crab Together will Cause Toxicity," and "MSG is Toxic," on the "Rumor Buster" web page. If any similar rumors emerge, people can go to either this web page or Good Articles of Food and Drug website's "Rumors Submission Box" to search for relevant articles. The e-newsletter is available for subscription from TFDA official website for those who would like to obtain first-hand information from the "Rumor Buster" web page.

4. Terminates rumors by advocating “Stop, Listen and Check”

Many unproven folk remedies can cause harm. TFDA encourages people to establish a healthy lifestyle, exercise adequately, maintain a healthy weight, and get correct information for nutrition intake.

TFDA promotes a 3-step tip “Stop, Listen and Check” to eradicate rumors. The first step is to “Stop the Repost of Rumors.” When the messages are not clarified for validity, stop spreading the messages so that the rumors would not be spread. The second step is to “Read and Learn from Accurate Information.” People should go straight to the “Rumor Buster” web page, check answers from similar rumors, gain the correct knowledge, and clarify the truth. The third step is to “Listen to Experts’ Advice to Clarify Doubts.” When people see health-related rumors, they should first consult the doctors for clarification. It is essential to follow doctors’ advice in terms of treatment. Do not believe in folk remedies or false advices, which may delay the best timing for treatment. Also, never pass unverified information to friends and families.

Outcomes and Benefits

Currently, more than 300 articles have been posted on the Rumor Buster’s web page in response to the rumors. Among them, articles on food-related rumors account for about 60%, followed by drugs, cosmetics, and medical devices in the sequential order. TFDA official website has now accumulated 3.9 million visitors; articles are being referenced more than 1900 times by the national, internal and electronic platforms (Figure 6-2). Moreover, in order to allow the correct information to reach to the public, TFDA uses its official website, Facebook fan pages (Food utility players, Good Articles of Food and Drugs and other media platforms), easy debriefing packages, images and vibrant clips.

TFDA will continue to provide information on various food and drugs topics in response to the up rise of mobile commination apps, internet forums, and social media. People are welcomed to repost the information the TFDA provides with families and friends, and be smart consumers.

Figure 6-2 Diverse pathway to Obtain Accurate Food and Drug Information

Section 3 The Progression of the National Laboratory

Origin of Policy

TFDA is responsible for the inspection work, inspection methods research, investigation and research, standard product supply and technical support on national drug, food, cosmetics, and other. Moreover, TFDA actively promotes the sustainable development of the national laboratory, and marches towards the road of excellence.

Implementation Measures

1. The Refinement of the national laboratory software

As technology advances, patterns of crimes change each day. Purchases of multiple precision instruments and equipment such as mass spectrometers and spectrum analyzers (Figure 6-3 and Figure 6-4) are planned. Quick and precise testing methods are pro-actively developed to be provided to private laboratories for their reference and training sessions or workshops for testing methods, facilitate sharing of R&D results and experiences of national laboratories, and accordingly enhance the ability of national laboratories to identify and differentiate accidents or unknown substances.

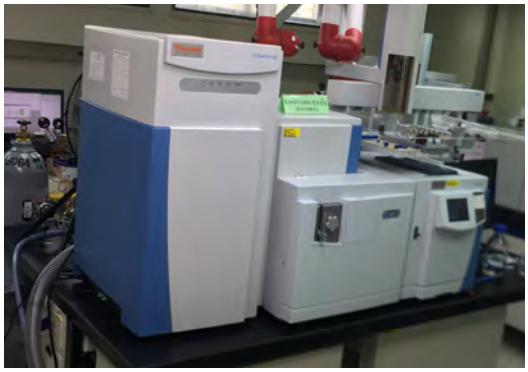


Figure 6-3 Q Exactive GC-MS/MS System

Figure 6-4 Orbitrap Fusion Lumos Tribrid Mass Spectrometer (Lumos)

2. The Progress of active engagement in international laboratory activities

TFDA not only hosts the international and domestic seminars and expert meetings, but also actively attends in the international laboratory activities for the topics on illegal additives, genetic modification, emerging pollutants, adulteration and unidentified micro-organisms.

The 110th AOAC annual meeting took place in Atlanta, Georgia, USA, approximately 900 experts and scholars from around the world attended. TFDA delivered a presentation entitled "Worldwide Perspectives on Contaminants Testing in Food and Environmental Samples Using Advanced Analytical Techniques" and " New Blood 2017–Developing Methods for the Detection of Chemical Residues, Contaminants and Important Analytes" in the meeting and gave a keynote speech in a arranged meeting on "Fipronil Egg Scandal in Taiwan," which showcase the capabilities of Taiwan in the testing and analytical field and establish exchange channels with international experts.

TFDA was assigned to Cyprus and Strasbourg, France to take part in the 15th and 16th OCCLs meetings. During the meetings, we actively engaged in the proficiency tests and peer reviews of analytical methods and other activities. Regarding the results of post-market surveillance program, we provided our experience for OCCLs as references. Additionally, our staff members were assigned to the Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM) to participate in the study for in vitro test technique on sun protection factor (SPF) of sunscreens, which also benefit our organization for promoting skills of examination in this field (Figure 6-5)

Figure 6-5 Participating in the "15th and 16th Online Laboratory Meeting of the EU Official Cosmetic Quality Control"

TFDA staff members attended the 26th International Biomechanics Workshop held in the Brisbane Convention & Exhibition Center (BCEC). We presented “Biomechanical Study of Hybrid Fusion and Non-Fusion Cervical Disc Replacement Surgeries–A Finite Element Analysis”, “In Vitro Enzymatic Degradation Measurement of Hyaluronic Acid Implants Using Rheology” and other poster papers, and received recognition from other foreign research teams. Additionally, Internet resource networks were established with the Australian specialists and other relevant companies, allowing our Government to acquire opportunities for prior arrangement on “New South bound Policy.” (Figure 6-6)

Figure 6-6 The 26th International Biomechanics Workshop, announcement of the Biomechanics and Mechanical inspection techniques.

Outcomes and Benefits

1. Testing methods amendments and affirmation of international proficiency test result

The year of 2017 had been a year of rapid developments: accurate analytical methods, amendments of 28 articles in announced food test methods, 36 articles in recommended food test methods, 6 articles in recommended cosmetic test methods (Table 6-1), publication of “the Chinese Pharmacopoeia 8th edition” supplement (1), Biopharmaceutical test standard Ⅶ , 3 training workshops for promoting testing methods, participation in the inter-international proficiency tests (18 sessions) and 2 sessions of the common calibration studies (Table 6-2). It is no doubt that our national laboratory’s ability was recognized worldwide.

Table 6-1 Addendums/Amendments on test methods of TFDA

Types of testing methods	Number of articles	Items
Announced food test methods	28	521
Recommended food test methods	36	477
Recommended cosmetics/medical devices test methods	6	64

Table 6-2 TFDA participated in international proficiency test and common calibration research

Organizer	Name of the proficiency test	Results
Central Science Laboratory (CSL), England	Food Analysis Performance Assessment Scheme (FAPAS) proficiency testing program (15 items)	Satisfactory
US Department of Agriculture (USDA)	Accuracy test for GM food testing	Satisfactory
Health Sciences Authority (HSA), Singapore	Determination of mass fraction of inorganic elements and arsenic species in brown rice flour	Satisfactory
Collaborative Testing Services, Inc. CTS	Forensics testing proficiency tests	Satisfactory
European Directorate for the Quality of Medicines (EDQM)	4th tetracosactide CRS common calibration research [a]	-
TFDA	The 2nd generation of national HCV nucleic acid standard and working standard common calibration research [b]	-

*International common calibration research is indicated as "-".

a. A total of 6 laboratories: Germany, Switzerland, France, Denmark, Japan and Taiwan participated in the calibration study.

b. A total of 7 laboratories from England, Germany, Japan and Taiwan participated in the calibration study.

2. Becoming international laboratories

The General European OMCL Network (GEON), which was jointly established by the EU Commission and the Council of Europe in 1994, enhanced the ability of members to control over the quality of medicinal products by technical and information sharing. At present, official laboratories of the European Union, Canada, and Australia, and other countries have followed one another to become a member.

Section of Biologics, Research and Analysis of TFDA has been assigned a priority to apply for membership of the General European OMCL Network (GEON). Through rigorous dossier review and on-site audit procedures by EDQM experts, TFDA has finally been officially notified as an associate member of GEON, and become a recognized international laboratory (Figure 6-7), which could allowed for information exchange and resource sharing among the networks.

COUNCIL OF EUROPE

European Directorate for the Quality of Medicines & HealthCare

OMCL NETWORK QUALITY MANAGEMENT SYSTEM

ATTESTATION

Figure 6-7 OMCL certification of internet quality management control system

3. Future plan and goals

TFDA will continue to take part in the In-network inspection method development, and inspection capability testing activities, as well as sharing post-market monitoring result, and cooperating with laboratory testing technology such as pharmaceuticals and cosmetics in the network to boost participation in international research opportunities for testing methods and standards. By keeping in touch with the international contacts, we are able to improve the quality and professionalism in regards to the national laboratory inspection techniques.

In order to meet the challenges in the future and enhance the safety of food safety, TFDA strived for Executive Yuan's approval on "Explanation of the National Food Laboratory and the Education and Training Building Project" and the "Enhanced Central Food Safety Inspection Capacity" to incorporated into the prospective "Food safety construction design." The High-order detection equipment such as Fourier transform mass spectrometry and nuclear magnetic resonance instrument and other high technologies were introduced to the laboratory, providing a fully equipped internationalized facilities, simultaneously allowing the site to be a training center for the Department of Health and local inspection personnel, as well as completing food and drug safety network at national aspect, local level and civil independent inspection.

07

Organization Introduction and Future Perspectives

Public Trustworthy Guardian of Food & Medicinal Product Safety

Creating a Safe Food & Medicinal Product Customer Environment

Regulations and management will continue to advance with the times › Strengthen the management of the imported products and their raw material › Improve the quality of manufacturing processes and management › Master the distribution of products and their raw material › Protect food, drug, and cosmetic safety for the consumers

Future Perspectives

Execute the perspective plan on Food Safety Establishment

Improve food safety management, and implement Five-point Food Safety Policy

Establish a traceability and follow-up system for medicinal products to prevent counterfeits from entering the legal supply chain.

Expedite the stipulation of medical device exclusive laws and the addendum / amendments on sanitary management regulations for cosmetics.

07 Organization Introduction and Future Perspectives

Nowadays, with the development of society and economy as well as the increase of public health awareness, the quality and safety of food, medicinal products and cosmetics have become one of the focused livelihood issues. To be in line with international management trends, and effectively strengthen the control of food, medicinal products, and cosmetics, Food and Drug Bureau was established on January 1, 2010, which integrated relevant units in Department of Health (former “Ministry of Health and Welfare”). Afterward, in response to the organizational reform project proposed by Executive Yuan, Food and Drug Bureau was officially renamed as “Taiwan Food and Drug Administration, Ministry of Health and Welfare” (“TFDA”) on July 23, 2013. TFDA aims to establish a complete and safe food and medicinal product management system to achieve the vision of “Being a reliable guardian on food and medicinal product safety” and “Creating a safe food and medicinal consumer environment.” (Figure 7-1)

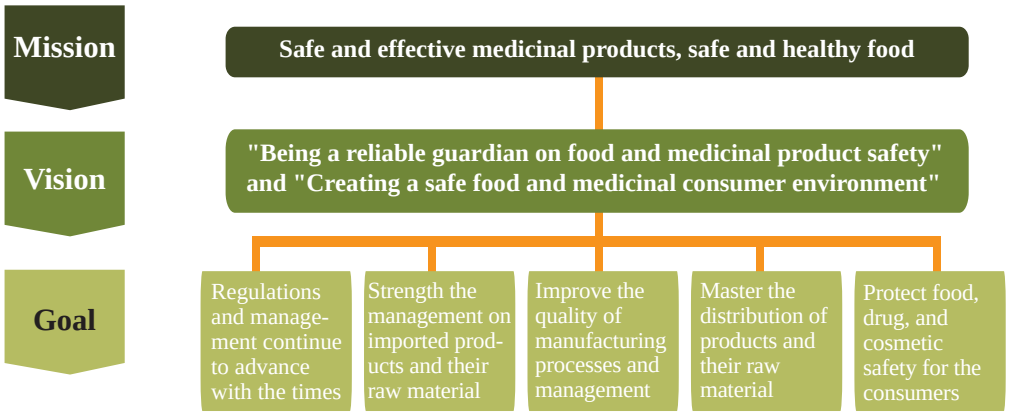


Figure 7-1 TFDA visions and mission

Section 1 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 2017.

1. Promote total product life cycle quality management of food, medicinal products and cosmetics. Under the premises of quality and safety of food, TFDA established a modern policy and legal environment aligned with international standards to restore the reputation of Made-in- Taiwan (MIT) food and drug products.
2. Promote inter-departmental collaboration for the prohibition of illegal drugs, intentionally adulterated food products, and reduce drug abuse. Integrate central and local monitoring and work specialization systems to safeguard the rights and interests of fellow citizens relating to food and drugs.
3. Recognize real-time public opinions, facilitate information transparency, and construct a safe protection network for food and medicinal products.

Section 2 Organization Framework

Director-General is the recommending officer of all TFDA-related businesses, and 2 Deputy Director-General and 1 Chief Secretary directly respond to Director-General's commands. TFDA consists of 7 Business Units, including Division of Planning and Research Development, which is responsible for planning, technology program management, regulatory and international collaboration; Division of Food Safety, Division of Medicinal Products, Division of Medical Devices & Cosmetics, as well as Division of Controlled Drugs are responsible for corresponding products management and the stipulation/amendments of relevant policies and laws; Division of Risk Management is responsible for risk analysis, laboratory management/ certification, and factory management/ inspections; Division of Research and Analysis is responsible for the development and assessment of tests and methods. TFDA also sets 3 District Centers (North, Central, and South) for laboratory testing of imported products, distribution examinations and inspections. In addition, TFDA 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 7-2)

TFDA has two Task Forces (*i.e.* Manufacturing facility for controlled drug and Decision Support Center). The Manufacturing facility for controlled drug is responsible for the import, export, manufacturing, and sales of tier 1 & 2 controlled drugs to sufficiently supply the needs for

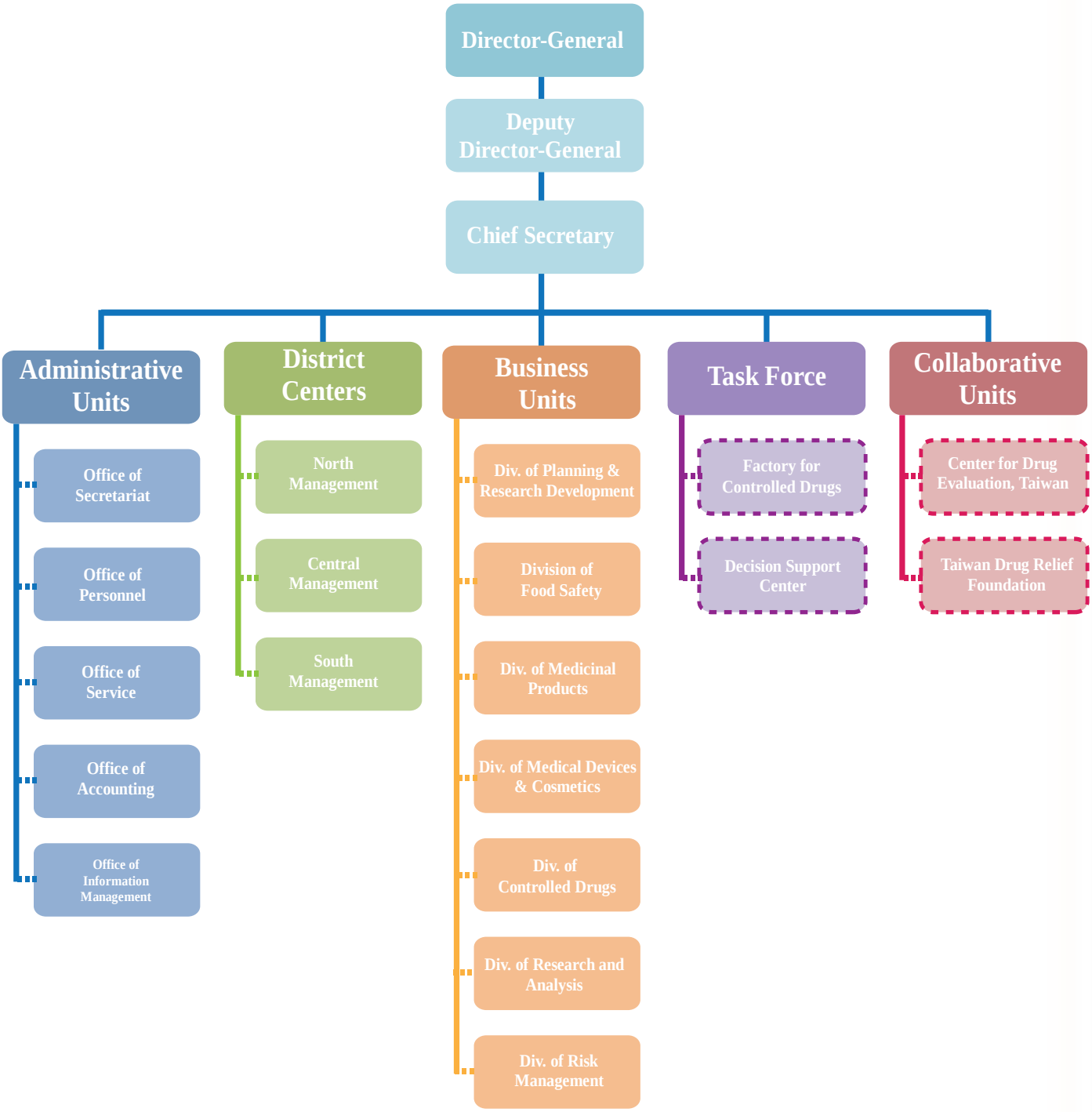


Figure 7-2 Organization framework

domestic medical needs. In addition, to control complete food and medicinal product information, the Decision Support Center was established by TFDA on September 2, 2015 in order to acquire adequate information on food and drugs in Taiwan. This center use big data analysis techniques to assess the risks and trends of food and drugs development in Taiwan and other countries. Moreover, product management requires highly professional information to effectively promote relevant businesses and become the fundamental basis of policies. To achieve proper product management, TFDA actively establishes a close partnership with professional consultation units such as Center for Drug Evaluation, Taiwan and Taiwan Drug Relief Foundation.

Section 3 Future Perspectives

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 agriculture and food industry. Future important administrative plans include:

1. Adopt perspective ideas (Food safety establishment plan) 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."
2. Improve food safety and management, implement five-point food safety policy, and explore food safety management resources through integrating inter-departmental resources, combining the power of business self-discipline and public participation to maximize the benefits of applicable resources. These perspective plans will eventually carry out three-level quality control, expand market inspection by 10 times, and enhance the management competence and inspection capacity on food safety.
3. Establish a traceability and follow-up system for medicinal products to prevent counterfeits from entering the legal supply chain, as well as to detect and recycle suspicious drugs rapidly and effectively.
4. Expedite the stipulation of medical device exclusive laws and the addendum/amendments on sanitary management regulations for cosmetics to strengthen consumer protection and be in line with international trends.

Annex

Annex I Summary of Great Events in 2017

Fabruary

February 10	Handover to and inauguration of new director-general of the Administration
	
February 13	"Workshop on Setting of Import MRLs" was organized where the procedure for setting the import tolerance, minor crops grouping and global zoning concept, progress of the CODEX Commission of Pesticide Residues (CCPR), among other issues and current challenges as well as future cooperation were discussed with the US and the international food standards committee (CODEX).
February 20-22	Participated in the "Implementation of APEC Guidelines on the Harmonization of Import Maximum Residue Limits for Pesticides" in Canberra, Australia.
February 21	Recognized by the APEC as a formal "APEC Good Registration Management Regulatory Science Training Center of Excellence."
February 22-23	Organized the "Pharmacopeia Standards Workshop." Experts with copyediting experience in international pharmacopoeia were invited to share their opinions about drug quality control and regulations. Participants consisted of competent authority officials, pharmacopoeia copyediting experts and healthcare businesses in Taiwan.

May

May 9-13	Attended "APEC Second Senior Officials Meeting & Related Meetings" in Hanoi, Vietnam, and exchange the experience in food safety management between different countries.

May	May 22-31	Director-General Shou-Mei Wu of TFDA accompanied Minister Shih-Chung Chen of MOHW, along with the "WHA lobbyist team", attending the 70th WHA annual meeting in Geneva, Switzerland. The goal is to speak up on an international occasion on behalf of Taiwan and initiate bilateral communication opportunities.
	May 30-June 1	Attended "2017 MRL Harmonization Workshop" in USA.
June	June 3	Organized "2017 National Anti-drug Conference."
	June 5-6	Organized "2017 Communication forum for leaders of Health Departments", allowing participants to discuss reviews of local inspection procedures and the implementation status of "joint and separate inspection systems of individual health departments." Experience sharing about test data reviews were also arranged to strengthen local inspection volume and competence.
	June 22	Organized the "Food Safety Management Policy Symposium-Food safety management in Belgium."
	June 28-29	Hosts the "2017 APEC Conference on Management and Related Scientific Detection Technology for Adulteration of Dietary Supplements with Drug and Drug Analogs" and exchanged and shared experiences in testing technology and management mechanisms of illegal drugs with representatives, experts and scholars from 6 countries to enhance relevant professional competence.
July	July 31-August 4	Organized the "2017 Taiwan-ASEAN Drug Regulatory Symposium" inviting drug administration representatives of competent authorities from ASEAN to share their current status of drug administration.
August	August 1-3	Ministry of Health, Labour and Welfare (Japan) Delegation visited Taiwan to participate in a Bilateral Expert Opinion Meeting. Both parties discussed about the food safety management policy.
	August 18	Organized the "Food Safety Management Policy Symposium-Food safety management in Canada."
	August 18-19	Attended the "The APEC High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB)" in Cần Thơ City, Vietnam to share and exchange modern agricultural management experience.

	August 18-21	Attended the 2017 APEC SOM3 RHSC Meeting, LSIF Planning Group Meeting and the 1st LSIF High Level Dialogue on Innovation, Regulatory Systems, and Regulatory Convergence, and presented TFDA's measures and points of views for promoting life science innovation.
September	September 6	Organized the "2017 International Conference on New Psychoactive Substances: Challenges and Strategies" invited experts, scholars and competent authority representatives from the US and South Korea to come to Taiwan to share their management strategies with our governmental departments and academic associations.
	September 8-9	Organized the "International Conference on Trends and Prospects of Community Pharmacy" and invited experts and scholars from the US, Japan, Australia and South Korea to come to Taiwan to share their experiences.
	September 11-15	Organized the "The 2017 PIC/S Committee Meeting and Seminar."
	September 19	Organized the "2017 Leader communication meeting of certification/testing institutes" to discuss about current status and regulations for testing institute management, inspection experiences, common non-conformities and CAPA, in order to constantly improve the quality of testing institutes.
	September 20-21	Organized the "2017 Innovative Medical Device Regulatory Science Symposium" and invited regulatory experts from Europe, the US, Japan, China and Taiwan to share their experiences in medical device clinical trial preparations and review, as well as regulatory requirements for complex medicinal products listing.
October	October 2	Met with the President along with the International Pharmaceutical Federation, visited domestic community-based pharmacies, and exchanged with domestic pharmaceutical groups.

October

October 12

Organized the “Regulatory conference for medical devices applied in Southbound countries and EU” and invited the officials from EU, Malaysia and India to introduce domestic businesses the most updated situations in terms of regulations for medical devices, in order to help domestic business’s medical products be in line with international development and harmonization trends.

October 12-13

Organized the“2017 Food Safety and Inspection Techniques Workshop.”

October 17

Organized the “2017 International Pharmaceutical Regulatory and Market Workshop” Experts in the conference analyzed pharmaceutical regulatory issues and quality requirements between the US and ASEAN in three different main themes of the conference (i.e. dynamics of international laws, market trends and management strategies).

October 18

Taiwan High Prosecutors Office, TFDA and AAC jointly organized the “Intensified food/drug crime seminar” to invite representatives from Office of Food Safety, Council of Agriculture and Environmental Protection Administration, Executive Yuan discussing about the establishment of food/drug crime seizing platform.

Organized the “2017 Conference on International Medical Device Regulations” allowing representatives from China, the US and EU to share experiences and discuss about UDI pilot studies and its regulatory updates, in order to help medical device management system in Taiwan be in line with international regulations and increase the competitiveness of medical device businesses in the global market.

October

October 20

Organized the "TFDA Outstanding Chefs and Novice Award Presentation Ceremony" to encourage chefs for their devotion to the service and to recognize their contribution to consolidated food sanitation management.

October 24

Organized the "2017 International law experience exchange workshop" to discuss the values and applications of Real World Data/ Real World Evidence.

October 31-November 2

Organized the "2017 APEC Good Registration Management (GRM) Regulatory Science Center of Excellence Workshop" and provide training sessions for 70 (industry, academy, official) participants from 10 APEC member economies.

November

November 2

Organized the "International Workshop on Analysis of Pesticide and Veterinary Drug Residues in Food" inviting a total of 7 keynote speakers, senior experts from official testing institutes located in Canada, Germany, Netherland and Taiwan to give a talk, in order to introduce the current status of pesticide applications, testing methods for veterinary drugs and cutting-edge mass spectrum testing technology in individual countries.

November 22

Organized the "Good Distribution Practice (GDP) Assistance Visits for Medical Devices" outcome presentation.

November 27-28

Attended the "The 4th ANZTEC Sanitary and Phytosanitary Measures(SPS) Joint Management Committee Meeting" organized in Wellington Region, New Zealand to allow experience sharing and opinion exchanging between Taiwan and New Zealand competent authority officials.

November 29

Organized the "Symposium on Import Food Management Policy/Introduction on Import Food Safety Control in South Korea."

December

December 1

Organized the "5th Joint Conference of Taiwan and Japan on Medical Products Regulation." Industry and academic representatives from Taiwan and Japan to jointly discuss about pharmaceutical regulatory updates and collaborations.

December 2	Organized the “International Conference of Taiwan and Japan on the Non-Prescription Drugs Regulation”. Industry and academic representatives from Taiwan and Japan to jointly promote measures and perspectives on OTC business and discuss about future collaboration opportunities.
December 5	Organized the 2017 “MOHW and MOA Pharmaceutical Technology Research and Development Award” presentation ceremony to encourage the development of the domestic biotech industry. 
December 7	Attended the “2017 Food Safety Management Reveiw Forum.”
December 15	Organized the “International Conference on Food Safety and Health Risk on Human Populations Post Nuclear Accident” and invited international representatives from Japan, South Korea, Hong Kong and Germany to exchange opinions and experiences in accident management specifically for the Japan inuclear accident.
December 21	The newly built plant for controlled drug manufacturing is awarded the 17th Public Construction Golden Quality Award, Special Award in Construction Category.

Note: Regulations and instructions as Annex II.

Annex II Important Outcomes and Statistics in 2017

Table 1 The promulgation and amendment of regulation and standard related to food safety and sanitation in 2017

Date of announcement	Title of announcement	Key point descriptions
January 12	Promulgate *"Regulations Governing Fees for Food Sanitation and Safety Management/Certification/ ValidAtion System"*	To organize certification/validation of 2nd tier food quality control certification/validation institutes and carry out the fee regulations, TFDA stipulates the regulation which becomes effective from February 1, 2017.
January 20	Revise *"Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China (Taiwan)"*	Add Item 181, delete Item 148 and revise Item 34.
	Revise *"Complex import Regulations Containing F01 in Import Commodity Classification of Republic of China (Taiwan)"*	Add Item 6 and delete Item 2.
	Revise *"Import Regulations Containing 508 in Import Commodity Classification of Republic of China (Taiwan)"*	Add Item 16, delete Item 5 and revise Item 1.
February 6	Promulgate *"Regulations Governing the Product Names and Labeling of Prepackaged Butter, Cream, Margarine and Fat Spreads"*	Regulates the product name and the fat content of "butter," cream," "margarine," and "fat spreads." In addition, both margarine and fat spreads are not allowed to use "vegetarian butter" as the labeling on the outer packaging of the product.
March 1	Revise *"Food Businesses Shall Establish Traceability System of Food Products"*	Add that food businesses in 3 categories (i.e.food manufactures of edibe vinegars, food manufactures of egg products, and food importers of infant and young child foods) are required to establish food traceability and follow-up system in different stages starting from July 31, 2017.
March 15	Revise*"Standards for Pesticide Residue Limits in Foods, Article 3, Appendix Table 1"*	Add a total of 128 tolerance standards for pesticide chemical residues from 22 types of pesticide (e.g. Chlorothalonil).
May 18	Promulgate *"Order of The Labeling Principles of Food Cleanser"*	Explain *Food Safety Act* Article 27 and 28, Paragraph 1, regarding the labeling principles for food cleansers. Strengthen labeling control on food cleansers and request for disclosure of component information.
May 24	Revise *"Import Regulations Containing 508 in Import Commodity Classification of Republic of China (Taiwan)"*	Add Item 4.
June 1	Revise *"Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China (Taiwan)"*	Add Item 17.

Date of announcement	Title of announcement	Key point descriptions
June 2	Promulgate *"Regulations Governing the Labeling of Food Products Sold by Vending Machines"*	The food sold by vending machines shall be labeled as required; except for the food information, the vending machines shall be labeled conspicuously with the company information.
June 6	Promulgate *"Regulations Governing the Labeling of Prepackaged Vinegar"*	It is required to indicate in readily visible areas on the package that vinegar made of specific raw materials is "blended" or "artificial."
June 7	The 2nd promulgate draft of amendments to *"Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Tests and Meet the Minimum Testing Cycle and Other Relevant Matters"*	The 5 newly added importer categories are still identical to those noticed at the 1st time. The newly added manufacturing, processing and formulating businesses, including food manufacturing businesses with registered plants and capital above NTD 30 million, should develop a food safety monitoring plan and implement mandatory testing based on regular schedules.
	Promulgate draft of amendments to *"Regulations Governing Traceability of Food and Relevant Products"*	Add "product information for products with genetically modified raw materoals," reasons to "recall, inventory or discard" and subsequent measures into a mandatory section in the traceability and follow-up system.
June 8	Revise *"Food Businesses Shall Take Out Product Liability Insurance"*	Expand insurance coverage for food businesses with registered factories but without companies or business registration business (e.g. farmer's association or credit union with registered factories for manufacturing or importing agricultural (processed) products); the above food businesses must take out product liability insurance by July 1, 2017.
June 12	Revise *"Application Scope, Limitation, Specifications, and Standards for Food Additives"* Article 2 Table 1 and Article 3 Table 2	Delete 3 components (i.e. chlorinated lime, sodium hypochlorite solution and chlorine dioxide) listed in category (II) sanitizing agents.
	Revise *"Sanitation Standard for Food Cleansers"* Article 5	1.Add "Washing is required after the application of disinfectant." 2.Revise Appendix 2: The monitoring items for disinfectant residue limit in food.
June 19	Revise *"Regulations for Special Dietary Food Registration"* Point 1	Revise accordingly to meet the title of the legal source, amend on the applicable scope of special dietary foods, including infant formula for special medical purposes, and specifically define formula for certain disease.
June 29	Revise *"Standards for Pesticide Residue Limits in Foods,"* Article 3, Table 1	Regarding the dispute derived from the revision of "*Standards for Pesticide Residue Limits in Foods*" by MOHW on March 15, 2017, TFDA has deleted the tolerance standard for Fluopyram in tea to reflect the public's comments, facilitate communications and reduce unnecessary misunderstanding.
	Revise *"Application Scope, Limitation, Specifications, and Standards for Food Additives"* Article 2 Table 1	Increase the limited standards of potassium iodide and potassium iodate in edible salt.

Date of announcement	Title of announcement	Key point descriptions
July 12	Revise *"Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China (Taiwan)"*	Delete Item 2.
	Revise and promulgate the *"Complex Import Regulations for Commodities Containing "F01" Category List"*	Add Category 514 in Item 2.
July 13	Promulgate *"The Use Restrictions of Food Ingredients "rooster comb extract (containing sodium hyaluronate)" and "fermentation of Streptococcus zooepidemicus ferment products (containing sodium hyaluronate)"*	The conditions of manufacture and usage quantity of rooster comb extract (containing sodium hyaluronate) and *Streptococcus zooepidemicus* fermentation (containing sodium hyaluronate), and the culture strain of *Streptococcus zooepidemicus* provided for food use is proposed to be restricted. The daily intake shall not exceed 80 mg.
	Revise *"Enforcement Rules of the Act Governing Food Safety and Sanitation"*	1. Revise the meaning of approval number used by central competent authorities. 2. Add the definition of the term"sanitation and safety management systems." 3. Revise that food businesses may apply to the competent authorities for documentary proof. 4. Add regulations for labeling product name, net weight, capacity and country of origin of food utensils, food containers or packages and food cleansers; position, methods, dates, and fonts of food cleansers. 5. Food additives and food cleansers need to be repackaged, sub-packaged or go through other processing procedure shall be labeled with product names, manufacturer's names and dates, or other labeling or information for proof of the authenticity of the items. Labeling in Chinese must be completed before selling.
July 17	Revise *"Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China (Taiwan)"*	Delete Item 2 and add Item 26.
	Revise "Review Principles for Health food Registration"	Revise a total of 25 articles and 7 highlighted topics such as document disclosure, test quality, ethical requirements and mandatory regulatory certifications (e.g. animal protection, human protection, radiation safety, etc.) and promote application quality.
July 26	Revise *"Daily Consumption Limitations and Required Warnings of the Ingredient 'Cordyceps militaris' fruiting body",* and change the regulation title to *"The Use Restrictions of 'Cordyceps militaris' and Warning Label Requirements of Food Products Containing Cordyceps militaris"*	1. Revise the regulation title to"The Use Restrictions of *Cordyceps militaris* and Warning Label Requirements of Food Products Containing *Cordyceps militaris.*" 2. In addition to original regulations for the restrictions of "*Cordyceps militaris* fruiting body"provided for food use, the conditions of manufacture and usage quantity of "*Cordyceps militaris* mycelium" use for food are also newly added. 3. Revise the contents of warning informations.

Date of announcement	Title of announcement	Key point descriptions
August 4	Revise *"Regulations for Systematic Inspections of Imported Food"* Article 4, 5, 8 and tables in Article 3	Include "aquatic products" and "dairy products" into the scope of systemic product inspections, and delete "milk and dairy products" in the original "other bovine-derived products." For products not subject to the scope of systemic product inspections, it is required to strengthen source management, add requirements for the origin of country certificate and sanitary certificate.
September 4	Revise *"Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China (Taiwan)"*	Revise Item 50 and delete Item 26.
September 18	Promulgate *"Regulations of Importied Beef and Beef Products from the Netherlands", "Regulations of Importied Beef and Beef Products from Sweden" and "Regulations of Importied Beef and Beef Products from Japan"*	Promulgate regulations for importing beef and bovine products from the Netherland, Sweden, and Japan.
	Promulgate *"Procedures Governing the Inspection and Verification of Imports of Beef and Beef Products"*	Promulgate "*Procedures Governing the Inspection and Verification of Imports of Beef and Beef Products.*"
September 29	Promulgate draft of amendments to *"Regulations Governing HACCP System Used in Edible Oil Product Plants"*	To ensure edible oil safety and sanitation and enhance the industry's ability to establish a sanitary and safe control system, according to *Food Safety and Sanitation Act* Article 8-2, food plants responsible for "edible oil" manufacturing and met the criteria for registration must implement HACCP system in different stages.
	Promulgate draft of amendments to *"Regulations Governing HACCP System Used in Canned Product Plants"*	To ensure canned food safety and sanitation and enhance the industry's ability to establish a sanitary and safe control system, according to *Food Safety and Sanitation Act* Article 8-2, food plants responsible for "canned food" manufacturing and met the criteria for registration must implement the HACCP system in different stages.
	Promulgate draft of amendments to *"Regulations Governing HACCP System Used in Egg Product Plants"*	To ensure egg product safety and sanitation and enhance the industry's ability to establish a sanitary and safe control system, food plants responsible for "egg product" manufacturing and met the criteria for registration must implement the HACCP system in different stages.
	Promulgate draft of amendments to *"Regulations Governing HACCP System Used in Aquatic Product Processing Plants"*	Re-notice in advance to stipulate and specify the scale of aquatic product processing businesses subject to the HACCP system.
	Promulgate draft of amendments to *"Regulations Governing HACCP System Used in Meat Product Processing Plants"*	Re-notice in advance to stipulate and specify the scale of meat product processing businesses subject to the HACCP system.
	Notice in advance to annul "*Regulations Governing HACCP System Used in Aquatic Food Businesses"*	As the original "*Regulations Governing HACCP System Used in Aquatic Food Businesses*" is combined into the draft of "*Regulations Governing HACCP System Used in Aquatic Product Processing Plants*" a notice in advance to annulment of the original regulation is required.

Date of announcement	Title of announcement	Key point descriptions
	Notice in advance to annul *"Regulations Governing HACCP System used in Meat Product Processing Businesses"*	As the original "*Regulations Governing HACCP System Used in Meat Product Businesses*" is combined into the draft of "*Regulations Governing HACCP System Used in Meat Product Processing Plants,*" a notice in advance to annulment of the original regulation is required.
	Promulgate draft of amendments to *"Categories of Food Manufacturing Plants Required Sanitation Control Personnel"*	Add requirements for setting sanitation control personnel in food businesses other than 9 categories of food manufacturing plants that require sanitation control personnel in the current notice.
	Promulgate draft of amendments to "*Regulations for Setting Sanitation Control Personnel in Food Manufacturing Plants*"	Add the requirement for senior staffs (worked more than 4 years) responsible for manufacturing and manufacturing process quality control in food or food additive manufacturing plant within the same business to receive educational training to be able to become sanitation control personnel.
	The 2nd promulgate draft of amendments to *"Regulations for Category and Scale of Food Businesses Required Professional or Licensed Personnel"*	The 10 food manufacturing businesses with registered plant, more than 20 employees and capital up to NTD 30 million or more should employ professional personnel in different stages; catering businesses in 5-star hotels and railway lunch box businesses should also employ professional personnel.
October 2	Promulgate draft of amendments to *"Article 4 of Regulations Governing the Registration of Food Businesses*"	Add mandatory registration information in "Storage place's basic information," and add a new business category "logistics."
	Promulgate*"Guidance for Businesses with Retail Sale in Non-specialized Stores Preparing Food Safety Monitoring Plans"*	Assist businesses in evaluating, preparing and implementing food safety monitoring plans based on the characteristics of the businesses.
October 12	Promulgate draft of amendments to *"Food Business Shall Establish Traceability System of Food Products"*	Add three designated category businesses (*i.e.* food importers of agricultural products plants, mushrooms and algae, manufacturers of other general food businesses, food retailers of box meal) required to implement traceability and follow-up system in different stages.
October 16	Revise *"Standards for Veterinary Drug Residues Limits in Foods"* Article 3	Addendum/amendments on 8 veterinary drugs, which all are veterinary drug items approved by the Council of Agriculture, Executive Yuan.
October 31	Strengthening the management of imported edible shellfish	Strengthening the management of imported edible shellfish in foregin source, a new measure was issued on October 31, 2017, the edible shellfish listed in 0307 of the Harmonised System Codes (HS codes) imported to Taiwan shall be accompanied with a health certificate including the information of harvesting area, and this new measure was implemented since January 1, 2018.
November 1	Revise *"Application Scope, Limitation, Specifications and Standards for Food Additives"* Article 3 Table 2	Revise specifications and standards of 16 food additives, including sorbic acid, potassium sorbate, calcium propionate, sodium propionate, propionic acid, benzoic acid, sodium benzoate, sodium erythorbate, calcium chloride, lactic acid, DL-malic acid, sodium DL-malate, potassium acesulfame, Glycine, D-sorbitol and gellan gum.

Date of announcement	Title of announcement	Key point descriptions
November 15	Under Presidential Order to revise *"Act Governing Food Safety and Sanitation"* Article, 9, 21, 47, 48, 49-1 and 56-1	Specify mandatory document types and duration for food businesses in the parent law to complete the management system in terms of food safety and sanitation. In addition, as new confiscation regulation is stipulated in Criminal Law, regulations regarding confiscation, levy, and compensation in *Food Safety and Sanitation Act* are deleted. Specify the scope and price of illegal income/levy. For those situations found difficult in determination, an estimation price is accepted.
November 17	Promulgate the regulation *"Restaurants in Hotels Should Comply with the Regulations on Food Safety Control System"*	1. It is required that at least one of the restaurants in the international tourist hotels or five-star hotels shall implement the system of HACCP to introduce preventive HACCP concepts and strengthen the business's and customer's awareness of food safety and sanitation. 2. The "*Within the International Tourist Hotels Shall Conform to the Regulations on Food Safety Control System* (HACCP)" is annulled on the date of promulgation.
November 30	Revise *"Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China (Taiwan)"*	Add 3 items, delete 1 item and revise 2 items.
December 21	Promulgate *"Primary Principles of Recognizing Violation Against Food Safety and Sanitation Act Article 15-1, 4 and 16"*	To effectively discipline dishonored businesses, MOHW promulgates thereof recognition principles as references for health departments to execute administrative penalties (suspension or revoke) other than fines.
December 25	Revise *"Mandatory and Prohibitory Provisions of Standard Contract for Food or Food Services Ordered Via Mail Order"*	1.Revise to "*Mandatory and Prohibitory Provisions of Standard Contract for Food or Food Services Ordered Via Distance Sales.*" 2.Pursuant to "*Customer Protection Act*" and its amendments, amend "mail order" to "*distance sales.*" and highlight the mandatory information of the person responsible of the business, liabilities and validation mechanisms for standard contract.
December 29	Promulgate *"Regulations Governing the Labeling of Health Food"*	It is required to add warnings regarding healthcare purposes, drug distinctions and recommended consumption amount in "Notes" of health food labeling.

Notes

1.January-December: Based on "*Standards for Pesticide Residue Limits in Foods,*" "*Standards for Veterinary Drug Residues Limits in Foods,*" "*Application Scope, Limitation, Specifications, and Standards for Food Additives*" and food sanitary standards, the new or amended items are all listed as follows: 379 pesticides, 6,499 items The standard of residual pesticide safety tolerance; 144 kinds of animal medications, 1,456 items of residual animal medication safety tolerance standards; 794 items of food additives have a scope of use, limits, and specifications; a total of 39 food hygiene standards.

2.According to the *Food Safety Act* Article 30, imported food items announced by the competent authorities must be categorized using custom exclusive commodity items. As of the end of 2017, TFDA has promulgated total of 2,582 commodity items subject to import food inspections. Among them, Regulation F01 commodity consists of 2,033 items, Regulation F02 commodity consists of 108 items, Regulation F508 commodity consists of 357 items, and Complex Import Regulations consists of 84 items.

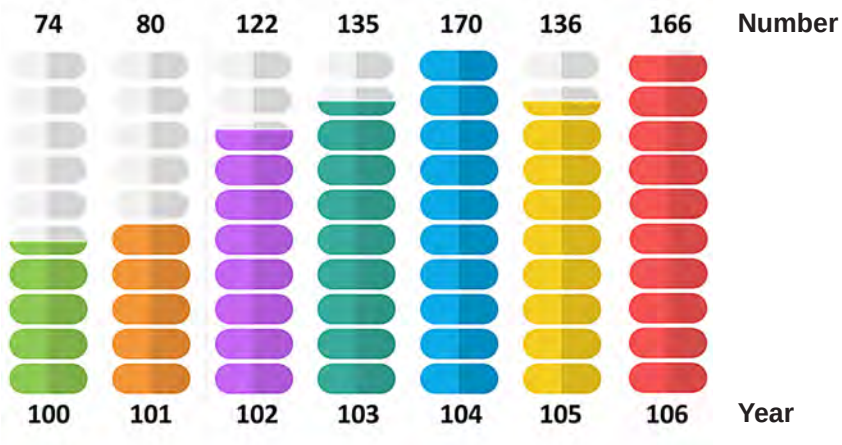
Table 2 Guidelines for food sanitation and safety management procedures in 2017

No.	Date of announcement	Title of announcement	Key point descriptions
1	January 4	Promulgate *"Good Hygienic Practice Guidelines for edible oil manufacturers"*	Strengthen and help manufacturers keep proper sanitation procedures during manufacturing, processing, formulating, packaging, storage, and shipping.
2	January 9	Promulgate *"Good Hygienic Practice Guidelines for food Manufacturers of the Soy Sauce Products"*	Advance the control of sanitation and safety during soy sauce manufacturing process, and release guidelines for manufacturers to comply with.
3	January 25	Promulgate *"Guidelines for Food safety Monitoring Program Established by the Food Importer"*	Importers to implement self-management and establish food safety monitoring plan, in order to allow every part of the process being executed thoroughly.
4	March 13	Promulgate *"Self-sanitation Management Guidelines for Food Sold in a Vending Machine"*	The guideline was released to facilitate a quick and clear understanding of the regulatory requirements to be followed and established spontaneous sanitation management methods by businesses dealing in foods sold through vending machines.
5	March 14	Promulgate *"Guidance on the Registration of Nanomaterial-containing Food Utensils, Containers and Packaging"*	For manufacturing of food utensils/containers/packing materials applied nano-technology, relevant businesses must submit an application to TFDA in accordance with the Guidelines.
6	April 17	Promulgate *"Guidelines for Health care Effect Assessment of Health Food"*	Specify the qualification of the applicant, the application procedures, required review materials, review process and highlights, requirements of supplements and limitations on appeal in the guidelines for effective assessment of health food.
7	June 7	Promulgate *"GHP Guidelines for Manufacturers of Soybean Products"*	Advance the control of sanitation and safety during products manufacturing process, and release guidelines for businesses.
8	July 25	Promulgate *"Guidelines for Fresh Egg Cleaning and Screening"*	The directives are for business's reference to avoid detergent or microbe contamination on the egg products due to improper cleaning or screening process.
9	October 2	Promulgate*"Guidance for Businesses with Retail Sale in Non-specialized Stores Preparing Food Safety Monitoring Plans"*	Assist businesses in evaluating, preparing and implementing food safety monitoring plans based on the characteristics of the businesses.
10	November 15	Promulgate *"Guidelines for Front of Package Nutrition Labeling (FoP) "*	Encourage producers to "visualize" the nutrition labeling for helping people understand the nutrition.

Table 3 Status of specific food and food additive registration

Food categories to be registered		Effective licenses
Imported food in tablet or capsule form		7,053
Health food		358
Food additive		6,403
Genetically modified (GM) food		130
Special dietary foods	The formula for certain diseases	186
	Infant and follow-up formula	125
Domestic vitamin products in tablet or capsule form		1,245
Vacuum-packed ready-to-eat soybean food		3
Total		15,503

Table 4 Year 2017 The number of approved novel drugs



Note : Among 166 new drug applications (NDA), 58 NDAs containing new chemical entities (NCE) and 33 NDAs are biologics. Their treatment indications consist of anti-cancer therapy, rare disorders, diabetes, cardiovascular diseases, anti-HCV or anti-HIV, to provide novel treatment options for patients.

Table 5 Year 2017 Revision of the Regulations and standards related to drug administration

Date of announcement	Title of announcement	Key amendments
January 17	The announcement on the amendments for "*Application procedures for human cell therapy products clinical trials*"	In order to promote the development of human cell therapy products, a double-track application route for human cell therapy products clinical trials will take effect today. The applicants can choose to proceed the consultation processes prior to submission of the clinical trial application or directly submit the clinical trial application to the TFDA.
April 20	Stipulated "*Pharmaceutical Affair Act Article 6-1: Drugs catagories for establishing trace and track system*"	Stipulated "Pharmaceutical Affair Act Article 6-1: Drug items require a trace and track system", which became effective since July 1, 2017. It included categories for plasma preparations, vaccines, and BTX.
August 2	Promulgate "*Clinical benefits and results of risk re-assessment regarding the application of medicinal products containing codeine in children*"	Due to its serious risks and effects on respiratory system (slow respiration, dyspnea, especially in children), "Clinical benefits and results of risk re-assessment regarding the application of medicinal products containing codeine in children" is promulgated based on the national and international data.
August 10	Promulgate "*Advancement Measures for Pharmaceutical Clinical Trial Protocol Review Process*"	In order to enhance the clinical trial review efficiency and to help accelerate new drug development, specific improvement measures were provided in the announcement, including simplified review procedures for first-in-human clinical trials, formulating an expedited review track for cell/ gene therapy product clinical trials refining the review process of clinical trial protocol amendments.
August 22	Promulgate "*Subject ICF format for pharmaceutical clinical trials*"	In this announcement, additional information on "the subject's specimen (including its derivatives), preservation of personal data, the use and reuse of subject's/remaining specimens (including its derivatives) ", as well as information on "This study may further be associated with derived commercial interests and their application" were added based on the requirement of the Article 14 of *the Human Research Act* .
October 31	Revised "*Pharmaceutical Affair Act Article 6-1: Drug catagories for establishing track and trace system*"	Added high-profile categories (30 items) as the report target of the trace an track system.
December 5	Revise partial articles of "*Review guidelines for pharmaceutical registration*": Article 39 Table 2, Article 40 Table 4, Article 42 Table 8 and 9	Focus on excipient package insert renewal and self-uploaded by the manufacturer, and regulations for API and NDA registration.
December 6	Update "*ICH-certified list*"	Update "*ICH-certified list*" as the reference and foundation for businesses during pharmaceutical development and manufacturing, and to establish review standards for medicinal products based on the regulations of ICH.
December 29	The Legislature passed partial article amendment drafts of "*Pharmaceutical Affair Act*" to establish patent linkage system and exclusive patent law for pharmaceutical products with new indications or novel medicinal products	Through updating the patent link system, which means, when a new drug is listed, the drug will be disclosed via the patent information. Which in return, when the generic drug is applying for the review process, the patent dispute will be clarified during the12 months renewal period, as well as temporarily the suspension of handing out the permit. This provides the scientist who had successfully developed the medicines an exclusive 12-month market sales period as a reward. This system allows the future development of the pharmaceutical industries as well as international markets.

Table 6 **Promulgation and amendment of regulations and standards related to medical device and cosmetics in 2017**

Date	Title	Key amendments
January 9	Release of "*Priority Review Program for Medical Devices*"	The document "Priority Review Program for Medical Device" is released to encourage the development of innovative medical devices, as well as medical devices in urgent demand in the domestic market. This program allows the TFDA to shorten the review timeline in order to benefit the life of patients and the public health.
February 3	Revise "*Scope and categories of cosmetics*"	Revise "Scope and categories of cosmetics" based on the international management and the commercial forms of the cosmetics to respond to the diversity of newly developed cosmetics products.
February 15	Promulgate "*List of Antimicrobials Allowed in Cosmetic Products*"	It is required to re-stipulate application limitations of antimicrobial agents due to the overlaps of components in preservatives and antimicrobials, and the differences between application levels and notes among the two products.
February 15	Revise "*List of Preservatives Allowed in Cosmetic Products*"	To protect consumer's health and safety, meet the international trend and stipulate easy-to-follow regulations, the amendment on "List of Preservatives Allowed in Cosmetic Products" is based on the revised table of standards for preservatives.
February 18	Issue official letters to describe "*The principles for the management of labeling and advertisement for cosmetics containing organic ingredients*"	Cosmetics that are certified and licensed as organic products, it is allowed to publish the name or the logo of the certification institute under the approval of the original certification institute. It is the business's responsibility to provide relevant evidence of certification. In addition, the business is not allowed to use terms "organic cosmetics" in any part of the product name.
February 22	Revise "*Operational standards for medicated cosmetics and cosmetics dye registration*"	Include registration and extension requirements in the operational standards to facilitate businesses understand relevant laws and regulations, and then revise the title of the standard to "*Review Criteria for Registration of Medicated Cosmetics and Cosmetic Colorants.*"
March 15	Release of the amendments to "*Guidelines for Registration of In Vitro Diagnostic Medical Device*"	List alternative approaches for use when there is no equivalent IVD available for comparison study. Amend the requirements for high-risk IVDs (e.g., HIV assays). Introduce new requirements specific for reagents used to detect nucleic acids.

Date	Title	Key amendments
March 16	Revised the "*Registration of Requirements of Distance sales Purchases of medical Devices by pharmaceutical Companies*"	A total of five class II medical devices, namely blood pressure tourniquets, menstrual cups, motorized vehicle for medical purposes, powered wheelchairs and otolaryngology drug application devices, and throat cloth application device, promoting consumers can now be purchases through distance sales. Improve convenience of people's accessing medical devices.
March 30	Partial revision of the "*Regulation for Registration of Medical Devices*"	The rationalized application required documents when registration of medical devices. Open online registration of the class I medical devices is now available. In order to avoid confusion, the English and Chinese product name of registration of medical devices exclusively for export should not be the same as domestic medical devices licenses.
April 14	Revise "*Regulations for cosmetics containing Titanium dioxide*"	Cosmetics containing Titanium dioxide (with the exception of nanomaterials and products in spray form) below 25% are subjected to the regulations for general cosmetics.
May 26	Promulgate "*Requirements for Additional Information on Nail Cosmetics Added with Organic Solvents*"	For nail polish containing organic solvents, it is required to add notes such as "keep good ventilation" and "keep away from fire and heat" to the labeling, package inserts or packaging.
July 17	Release of four guidance documents, include: "*Technical Standard: Control Materials for In vitro Diagnostic Medical Device,*" "*Technical Standard: Dengue Virus Serological Reagents,*" "*Technical Standard: Pretreatment Systems for Nucleic Acids,*" and "*Technical Standard: Reagents for Detecting Nucleic Acids of Influenza Virus.*"	In order to improve the safety and effectiveness of in vitro diagnostic medical devices, the four guidance documents on medical device were released as references for manufacturers which are developing relevant products and preparing submission dossiers for registration.
July 25	Revise "*Regulations for Governing the Management of Medical Device*" Article 3 Annex 1 and Article 4 Annex 2	Through the combination of energies (current, ultrasound, etc.) into the skin, and providing claims that it poses medical efficacy (which is, eliminating fine lines, promoting the proliferation of collagen and elastic fiber and others), incorporated into the management of medical device, allowing both the industries and the general public to have a guideline to follow.

Date	Title	Key amendments
August 3	The "*surgical mesh for transvaginal pelvic organ prolapse repair*" (called transvaginal surgical mesh for short) was announced to be a type of medical device that should be included in the safety surveillance of medical products.	The transvaginal surgical mesh was evaluated and its postmarket surveillance should be enhanced in order to be informed of its signals of risk. This product type was therefore included as a safety surveillance item of medical device.
September 14	Stipulate "*Regulations Governing the Application of Animals Testing for Cosmetics or Cosmetic Ingredients*"	Promulgate "Regulations Governing the Application of Animals Testing for Cosmetics or Cosmetic Ingredients," which becomes effective since November 9, 2019.
December 4	The "*Table for Listing of Products Not Regulated as Medical Devices*" was announced.	The "*Table for Listing of Products Not Regulated as Medical Devices*" announced by the Department of Health Letter Wei-Shu-Yao-Tzu No. 0950321586 on August 9, 2006, was supplemented. Also, various products not regulated as medical devices and whose "function or use" must be viewed jointly were added into the listing.
December 8	Promulgate "*Regulations governing 15 ingredients such as Safrole that are ingredients prohibited for use in cosmetic products*"	Starting from July 1, 2018, the import, manufacturing, sales, supplement or intend to sell, and display cosmetics containing 15 components (e.g. Safrole) is prohibited.
December 15	Promulgated "*Guidance for Medical Device Software Validation* "	Due to the need of the domestic manufacturers in terms of the development of the high spec medical devices software, the announcement of "Guidance for Medical Device Software Validation", providing manufactures with a references when conducting product research and development.

Table 7 Additional chart for TFDA inspection methods

Types of testing methods	Test Methods	Promulgated/ Amended
Announced test methods for food products (28 articles, 521 items)	1.Method of Test for Veterinary Drug Residues in Foods- Test of Amprolium (2) 2.Food additive specification test method－Potassium fluoride 3.Food additive specification test method－Sodium fluoride 4.Method of Test for Sodium Ferrocyanide in Salt 5.Method of Test for Theanine in Foods 6.Method of Test for Veterinary Drug Residues in Foods- Test of Tulathromycin 7.Method of Test for Veterinary Drug Residues in Foods- Test of Acetylisovaleryltylosin and its Metabolite 8.Method of Test for Marine Biotoxin in Foods- Test of Amnesic Shellfish Poisoning Toxin Domoic Acid 9.Method of Test for Methyl Mercury in Foods (3) 10.Method of Test for Inorganic Arsenic in Aquatic Animals 11.Method of Test for Veterinary Drug Residues in Foods- Test of Colistin 12.Method of Test for Fluoride Ion in Salt 13.Method of Test for Iodide Ion in Salt 14.Method of Test for Iodate Ion in Salt 15.Method of Test for Heavy Metals in Edible Offal of Livestock and Poultry- Test of Lead and Cadmium 16.Method of Test for Caffeine in Soft Drinks	Promulgated
	17.Methods of Test for Specifications of Gum Arabic as Food Raw Material 18.Methods for testing the specification－Diacetyl Tartaric Acid Esters of Mono- and Diglycerides 19.Method of Test for Preservatives in Foods 20.Method of Test for Sweeteners in Foods Test of Acesulfame Potassium, Saccharin, Dulcin and Cyclamate 21.Methods for testing for food microbial －*Vibrio parahaemolyticus* 22.Methods for testing for food microbial －*Bacillus cereus* 23.Method of Test for Pesticide Residues in Foods- Multiresidue Analysis (5) 24.Method of Test for Mycotoxins in Foods- Test of Multimycotoxin 25.Methods of Test for Labeling Conformance of Heat Tolerance of Plastic Food Utensils, Containers and Packages 26.Food additive specification test method－guide 27.Method of Test for Formaldehyde in Foods (2) 28.Method of Test for Food Additive Specifications- Appendix B: Reagents, Solutions, etc.	Amended
Recommended test methods for food products (36 articles, 477 items)	1.Method of Test for Bisphenol A in Plastic Infant Feeding Bottles 2.Method of Test for Colors in Foods (2) 3.Methods for testing for Sudan pigment in eggs 4.Methods for testing for animal components in food－Qualitative test of shrimp 5.Method of Test for Total Available Chlorine in Foods 6.Method of Test for Chlorite and Chlorate in Foods 7.Methods of Test for Ingredients with Health Care Effect in Food 8.Method of Test for Pesticide Residues in Foods- Multiresidue Analysis of Polar Pesticides and their Metabolites 9.List of Recommended Methods of Test for Pesticide Residues in Foods 10. Method of Test for Pesticide Residues in Foods– Multiresidue Analysis (6)	

Types of testing methods	Test Methods	Promulgated/ Amended
Recommended test methods for food products (36 articles, 477 items)	11.Method for differentiating Medium Rhodamine B, Acid Red, Oleander Red and Azo Jade Red Colorant in rice products 12.Method of Test for Formaldehyde in Foods (Acetylacetone Method) 13.Method of Test for Sennosides in Foods 14.Methods for testing for food microbial －Lactobacillus: *Lactobacillus casei* 15.Methods for testing for food microbial －Lactobacillus: *Lactobacillus helveticus* 16.Methods for testing for food microbial －Lactobacillus: *Lactobacillus rhamnosus* 17.Method of Test for Pesticide Residues in Eggs- Test of Fipronil and Its Metabolite 18.Method of Test for Pesticide Residues in Chicken Muscle and Eggs- Test of Fipronil and Its Metabolite 19.Method of Test for Pesticide Residues in Livestock and Poultry Products- Multiresidue Analysis 20.Method of Test for Free Amino Acids, Glucosamine and Taurine in Foods 21.Method of Test for Water-Soluble Vitamins in Foods in Capsule or Tablet Forms 22.Method of Test for Vitamin B1 in Milk-Based Infant Formula 23.Method of Test for Sudan Dyes in Foods 24.List of Recommended Methods of Test for Pesticide Residues in Livestock and Poultry Products 25.Method of Test for Pesticide Residues in Livestock and Poultry Products- Multiresidue Analysis 26.Methods for testing GMO- modified soybeans-BPS-CV127-9 (UI BPS-CV127-9): Specificity and quantitative test of transgenic items 27.List of Recommended Methods of Test for Veterinary Drug Residues in Foods 28.Method of Test for C4 Plant Sugars in Honey 29.Method of Test for Phosphate in Foods 30.Method of Test for Sulfur Dioxide in Foods (GC/MS Method) 31.Method of Test for Triethyl Citrate in Foods in Tablet and Capsule Form 32.Method of Test for Colorants in Foods – Multiple Analysis 33.Method of Test for 3-Monochloropropane-1,2-diol in Paper 34.Method of Test for Sudan Dyes in Foods (Revised) 35.Method of Test for Adenosine and Cordycepin in Foods in Capsule and Tablet Form 36.Method of Test for Biotin in Foods in Capsule and Tablet Form	Published
Recommended test methods for cosmetics and medical device products (6 articles, 64 items)	1.Identification and assay for banned dyes in cosmetics 2.Method of test for whitening ingredients in cosmetics 3.Method of test for hair dyes in cosmetics (III) 4.Method of test for persulfate in cosmetics 5.Method of test for hydroquinone, hydroquinone monobenzyl ether, rhododendrol and tretinoin in cosmetics 6.Testing methods of hair dyes in cosmetics (III) (Revised)	Published

Table 8 Important outcomes of food and drug testing technology in 2017

Category	Outcomes	Benefits
Food chemistry and biology	1.Complete establishing testing methods for inorganic arsenic and heavy metals such as Methylmercury in aquatic products, BPA in plastic infant feeding bottles, labeling conformance of heat-tolerant plastic food containers/packages, chlorite and chlorate in food, multiple pesticide residues in poultry and livestock products (including 123 items) and radionuclides in foods 2.Establish a molecular biological method for rapid identification for fishes such as Haddock and Chilean Seabass 3.Complete the establishment of qualitative and quantitative test methods for 4 new GMO items, as well as research and development of a newly digital PCR technology for GMO inspection 4.Establish a quantitative method for the Enterobacteriaceae (hygiene indicator bacteria) and a test method for type A rotavirus in shellfish and water body	A total of 64 articles were publicized in 2017, including a sum of 998 items, which upgrades the national food-related inspections, as well as helping the border inspection to prevent potential food safety issues and maintaining adequate food quality and safety.
Medicinal products	1.Completion establish analytical method and mass spectrometer database for 23 anti-inflammatory steroid drug 2.Completion establish analytical method for steroid preparation (include mirror isomer and impurities) 3.Complete establish 13 standards and spectrum database 4.Use UPLC-Q-LIT and GC-MS to establish analytical methods for 23 phenylethylamine and 34 synthetic cathinones in urine respectively 5.Establish LC-Q-TOF analytical methods for 55 drugs and complete 600 urine sample 6.Development and application of traditional Chinese medicine misuses and multi-component detection technology (*Cistanche* species medicinal herb and preparations of clearing away heat and reducing fire)	1.Applied to clinical practices such as medicinal products routine tests, clinical determinations for drug abuse and criminal identification 2.Establish standards and spectrum database for comparing test results and meet the techniques for drug abuse 3.Apply to Chinese medicines identification, testing and quality management
Biologics and emerging biotechnology medicinal products	1. Establishing a second generation nationally standardized HCV genotype 1 viral nucleic acid and standardized work items 2. Establish the evaluation test mechanisms for the 3 biological agents: heparin products, enterovirus 71 vaccine and others 3. Establish the data analysis platform for protein characteristics and function for monoclonal antibody drug Infliximab 4. Complete 11 articles for the foundation of Biological drug testing, organize the contents and publish a book on “Biopharmaceutical test standard Ⅶ”	1.The biological standard products can be used in the quality management of other relevant products prior and post-marketing, as well as by the industry in product development and quality control. 2.The established analysis method can be used by the marketing quality control to ensure product quality, as well as ensure the safety of the public. 3.The biopharmaceutical test standard can be used as a reference in the Chinese Pharmacopoeia for specific test methods.

Category	Outcomes	Benefits
Medical devices and cosmetics	1. Establish method for cross-linking hyaluronic acid product's cross-linking degree and modification rate 2. Establishing functional testing method for medical nebulizer 3. Establishing test methods for analyze safety and efficacy of Foley Catheter 4. Evaluation the accuracy of in vitro diagnostic glucose test system for commercial home use 5. Establishing the physicochemical properties and in vitro degradation mode test methods for testing hyaluronic acid implants 6. Develop method of test for 25 banned and restricted dyes, N-nitrosodiethanolamine (NDELA) and 18 polycyclic aromatic hydrocarbons (PAHs) in cosmetics 7. Use single particle ICP-MS to develop testing methods detecting the amount of nano-substances or determining their properties in cosmetics	1. The planning is opened resource for providing domestic administrative units and non-governmental inspection units take part in the use of test methods. 2. Post-product market monitoring programs are conducted by utilizing the developed recommended test methods.

Table 9 **Amendments for the Chinese Pharmacopoeia and the publication of the "Chinese Pharmacopoeia 8th edition" supplement (1)**

Categories	Number of articles	The brief descriptions of the amendment contents in the "Chinese Pharmacopoeia 8th edition" supplement (1)
New Monographs	95	1. Harmonizing information from the European, American and Japanese Pharmacopoeia, Near-Infrared Spectrometry, Raman Spectroscopy, Impurities in Drug Substances and Drug Products, Atomic Absorption Spectrometry: Theory and Practice, Peptide Mapping, Amino Acid Analysis, Polyacrylamide Colloidal Gel Electrophoresis and Isoelectric Focusing Electrophoresis such protein assays were added. These shall provide assistance in the development of the domestic pharmaceutical industries. 2. In order to connect with the international trend, new protein drugs such as insulin analogs (e.g., Active Pharmaceutical Ingredients (APIs) and injections for Insulin Aspart and Insulin Glargine), recombinant DNA coagulation factors, including Human Coagulation Factor VIII (rDNA) and Human Coagulation Factor IX (rDNA) Concentrated Solution were added. Moreover, updated drug inspection analytical methods were developed to comply with the development of new drugs. 3. Containing two APIs for the synthesis and the manufacture of Montelukast Sodium and Rizatriptan Benzoate, which were developed and manufactured by our country.
Monographs in Amendments	130	
APIs with domestic characteristics	11	
New General Chapters	25	
General Chapters in Amendments	23	
Total	284	

Annex III Important Achievements and Statistics in Recent Years

Table 1 Statistics of imported food inspection

Year	Inspecti on Number of Batches	Total net weight(x 10k tons)	Batches tested	Growth rate (%)	Testing rate (%)	Number of non-compliant lots
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

Note : Growth rate refers to the increased percentage of registered and inspected number for the year compared to the previous 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 (%)
2007	1,761	95.9	359	94.4	-	-	-	-
2008	1,765	88.2	252	92.1	-	-	-	-
2009	1,894	89.6	266	95.1	-	-	-	-
2010	2,051	90.5	330	98.2	-	-	161	100.0
2011	2,110	89.0	481	90.9	-	-	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

*Source: TFDA 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 Annual Statistics of food poisoning

Year	Number of outbreaks	Outbreaks		type and numbers					
		Number of cases	Death toll	Aquatic products and its processed products	Meats, eggs, dairy products and its processed products	Cereal, vegetables, fruits and its processed foods	Confectioneryand candies	Compound cooking food and others	Vehicle unidentified (Integrated)
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	3	2	3	56	404
2017	528	6,232	0	7	3	7	0	44	467

Table 4 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	
2007	422	32	454	6	115	121	22	47	69	0	16	16	0	0	0	660
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	264	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	682
2017	196	90	286	28	193	221	20	120	140	1	15	16	2	16	18	681

Table 5 Statistics of health food and GM food licenses every year

Issued heath food licenses (case-by-case + standard specifications review process)					Issued GM food licenses	
Year	case-by-case review process	standard specifications review process	Number of passed licenses for the year	Accumulated number of licenses passed	Number of passed licenses for the year	Accumulated number of licenses passed
2007	24	-	24	111	3	17
2008	33	-	33	144	2	19
2009	26	6	32	176	18	37
2010	16	4	20	196	3	40
2011	17	6	23	219	13	53
2012	22	8	30	249	9	62
2013	14	13	27	276	10	72
2014	26	15	41	317	12	84
2015	22	5	27	344	32	116
2016	25	7	32	376	11	127
2017	31	0	31	407	12	135

Note 1: The registration of health food shall adopt a case-by-case + standard specifications review process.
Case-by-case review process: Companies shall provide food safety, and healthcare certificates. The approval number is Wei Bu Chien Shi Tzu No. Axxxxx.
Standard specifications review process: Products shall comply with MOHW specifications and standards. The approval number is Wei Bu Chien Shi Kui Tzu No. xxxxxx.

Note 2: By December 2017, the accumulated number of issued health food licenses is 407 (including 343 case-by-case reviews and 64 standard specifications reviews), of which 52 were invalid (including expired, revoked and combined). By the end of 2017, total valid licenses are 355 licenses.

Note 3: By December 2017, the accumulative number of issued GM food licenses is 135, of which 5 licenses are suspended due to production termination or failure to apply for an extension. By the end of 2017, the total number of valid licenses is 130.

Table 6 The number of approved medicated cosmetics licenses issued from 2011 to 2017

Year	Total applications	Licenses granted	Approval rate (%)
2011	1,634	1,519	93.0
2012	1,721	1,482	86.1
2013	1,650	1,506	91.3
2014	1,900	1,661	87.4
2015	1,822	1,558	85.5
2016	1,484	1,268	84.1
2017	1,499	1,255	85.4

Table 7 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

Table 8 Statistics of controlled drugs licenses and inspection every year

Year	Statistics of controlled drug licenses		Statistics of controlled drugs inspection		
	Controlled drug registration (License)	Controlled drugs prescription licenses (Persons)	Number of inspection	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

Table 9 Assessment and qualifications of domestic and overseas pharmaceutical companies every year

Year	Number of GMP-compliant domestic modern pharmaceutical manufacturers	Total number of domestic and PIC/S GMP-compliant Western pharmaceutical manufacturers	Total number of international and PIC/S GMP-compliant pharmaceutical manufacturers after on-site inspections
2008	151	-	118
2009	154	5	140
2010	155	22	157
2011	149	33	180
2012	145	44	209
2013	140	57	237
2014	98	98	262
2015	-	120	292
2016	-	127	316
2017	-	137	326

Note: The number of national and international pharmaceutical manufacturers that passed inspections is increasing year-by-year. In addition, the number included in the annual report is the summarized statistics of all national and international pharmaceutical manufacturers for various inspection purposes. The number of approved manufacturers between 2013-2016 is the updated results.

Table 10 Statistics of post-marketing medicinal products and cosmetics quality surveillance in recent years

Year	Medicinal products		Biologics		Chinese Medicine*		Medical devices		Cosmetics	
	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity 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	6.5	100	3
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	5.7					193	0	329	1.52
2017	114	4.39					57	19.3	102	7.84

*The surveillance of Chinese Medicine in year 2008 to 2010 were limited in background values investigations (tests for heavy metals, pesticide residue, and aflatozin) and presented as "-".

Table 11 Lot release statistics of biologics in recent years

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum products				Other biologics		Annual summary	
	Domestic products		Import		Import		Domestic products		Import		Import			
	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose
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

Table 12 Number of certified laboratories and statistics of certified items every year

Year	Certified food laboratories		Certified medicated cosmetics laboratories		Certified drug abuse testing laboratories		GLP-certified trial site	
	Number of sites	Number of Items	Number of sites	Number of Items	Number of sites	Number of Items	Number of sites	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

Table 13 The discovery rate of illegal drugs and the violation rate of food and drug advertisements every year

Year	Discovery rate of illegal drugs (%)	Violation rate of food and drug advertisements (%)
2010	13.03	8.97
2011	4.64	6.1
2012	2.30	5.28
2013	1.96	5.46
2014	1.84	5.18
2015	1.18	5.00
2016	1.06	4.83
2017	0.79	4.86

Notes:

1. The joint law enforcement taskforce for seizing counterfeit/inferior/falsified medications has been established since April 2010.
2. 369 cases of illegal drugs are seized in 2017 along with a penalty of NTD 5.155 million. The discovery rate is reduced from 13.03% in 2010 to 0.79% in 2017.
3. In 2017, a total of 8,081 cases of illegal advertisements for food, drug, and cosmetic products were formally handled by health agencies, with total fines amounting to NTD 199.36 million dollars. The violation rate for food and drug advertisements dropped from 8.97% in 2010 to 4.86% in 2017.

Table 14 Business overviews of controlled drug manufacturers every year

Unit: k NTD

Year	Income	Expenses	Costs for setting up	Revenue Remittance 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	13,628	120,000
2013	513,092	340,359	4,102	120,000
2014	533,320	290,570	52,735	120,000
2015	593,448	284,359	112,303	120,000
2016	701,254	324,564	156,890	100,000
2017	791,580	439,074	154,118	50,000

Annex IV Publications in 2017

No.	GPN	Title	Responsible Section	Category	Date of publication
1	1010600329	Fresh vegetables and fruit preparation manual	Division of Food Safety	Books	2017/3
2	1010600330	Guidebook of food and agricultural product distributors	Division of Food Safety	Books	2017/3
3	1010600428	200 Must-know knowledge (Plastics): The sanitation, safety, and labeling of food utensils, containers and packaging	Division of Food Safety	Books	2017/12
4	1010601701	2017 Drug Abuse Prevention Guidelines	Division of Controlled Drugs	Books	2017/10
5	1010601715	Cosmetic knowledge: Dispel common myths	Division of Medicated Cosmetics	Books	2017/11
6	1010602672	Summary of analytical methods for specific components in functional dietary foods	Division of Research & Analysis	Books	2017/12
7	1010602712	Manual of domestic vitamin products in tablet or capsule form	Division of Food Safety	Books	2017/12
8	1010602746	Chinese Pharmacopoeia 8th ed. Addendum (I)	Division of Research & Analysis	Books	2017/12
9	1010602762	Test standards for biologics VII	Division of Research & Analysis	Books	2017/12

No.	GPN	Title	Responsible Section	Category	Date of publication
10	1010602798	2017 Sales and management handbook of food additives	Division of Food Safety	Books	2017/12
11	3610602584	2017 Anti-drug Propaganda Audio and Video Collection	Division of Controlled Drugs	DVD	2017/12
12	2010301353	TFDA Annual Report	Division of Planning & Research Development	Series (journal)	2017
13	2010302286	TFDA Annual Report (English version)	Division of Planning & Research Development	Series (journal)	2017
14	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning & Research Development	Series (journal)	2017
15	49094052333	Food & Drug Consumer Newsletter	Division of Risk Management	Series (weekly)	2017

Annex V Lists of Websites

No.	Name of the website	Website	Website summary	QR Code
1	TFDA	http://www.fda.gov.tw	A website that introduces the administration, special functional sections, information publications, and a section on Busting Myths about food and drugs in order to provide the public with a rapid and accurate information service.	
2	Online Application and Public Service Platform	https://oaps.fda.gov.tw	A platform that integrates various application services provided by TFDA to offer a single counter service to handle a diverse scope of payments, helping to facilitate online application services for the general public.	
3	TFDA Open Data Platform	https://data.fda.gov.tw	A platform that provides raw data related to food and drugs, which can be accessed and employed by external parties for value-added applications to facilitate the transparency of TFDA operation.	
4	TFDA News	https://article-consumer.fda.gov.tw/	A website that provides the most updated, and the most accurate food and drug safety information and articles based on three themes: “Safe dine out,” “Safe medication,” and “Safe medical devices and cosmetics” to help the public obtain the most accurate and practical daily living knowledge.	
5	Food and Drug Consumer Service Network	https://consumer.fda.gov.tw	A website to publish food and drugs information inquiry for people.	
6	Taiwan's International Food Safety Authority Network	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 local Health Bureaus and departments.	

No.	Name of the website	Website	Website summary	QR Code
7	Food and Medicinal Products Business Registration Platform	https://fadenbook.fda.gov.tw	A digital data system that enables government agencies to achieve effective control over food businesses.	
8	Food Traceability Management Information System	https://ftracebook.fda.gov.tw	A system for users to upload relevant digital records, including product data, labeling and identification, supplier information and product distribution, to trace sources of product supply or track the destinations of product distribution.	
9	Application System for Export of Food Sanitation Certification	https://asefsc.fda.gov.tw	A system that allows online applications of English sanitation certificates, proof of sanitation of food processing, test reports, and free trade permits for exported food (and food additives).	
10	Imported Food Information System	https://ifi.fda.gov.tw/ifi/main/ap/index.jsp	A system that allows users to enter and trace the progress of foods, traditional Chinese medicine, condoms registration, as well as download food QR-CODE.	
11	Product Distribution Management System	https://pmds.fda.gov.tw	A system that audits data management platform for local governments, Health Bureaus and departments, and the TFDA, and allows the competent authority to manage food, drugs, and cosmetics within their area of jurisdiction.	
12	The curriculum information of the Food sanitation and safety management system	https://foodedu.fda.gov.tw	A system that provides curriculum information on food sanitation and HACCP for people from various field.	
13	Food sanitation and safety management certification and validation system	https://facs.fda.gov.tw	A system primarily assists the implementation of 2nd tier food quality control and enhances the efficiency of validation management through randomly designating validation institutes, controlling the validation process and the presenting the results.	

No.	Name of the website	Website	Website summary	QR Code
14	Online application platform for medicinal product registration and review	https://e-sub.fda.gov.tw/dohclient/Login.aspx?ReturnUrl=%2fdohclient	A platform that is used to submit online documents for medicinal product registration and renew or extend permits /licenses. Reviewers and applicants can both access this platform to check case review progress.	
15	Medicinal products traceability reporting system	https://dtracebook.fda.gov.tw	A system that offers businesses to upload medicinal products traceability or track the uploaded data.	
16	Information Platform for the Supply of Medicinal Products	https://dsms.fda.gov.tw	A platform used by pharmaceutical companies and medical institutes in Taiwan to report the shortage of medicinal products, facilitate real-time assessment, and handle/reduce the impacts caused by the shortage of medicinal products to protect the rights of the public.	
17	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	A system that allows medical institutions, pharmacies, pharmaceutical companies, and the general public to report any suspected incidents of adverse drug reactions (ADR) and facilitates post-marketing surveillance (PMS) of medicinal product safety.	
18	Controlled Drugs Management Information System	https://cdmis.fda.gov.tw	An online application services for institutions, businesses, and professionals holding controlled drugs registration licenses in order to effectively improve administrative efficiency and service quality.	
19	Drug Abuse Reporting System	https://dars.fda.gov.tw	A system allowing medical institutions and drug addiction rehabilitation agencies to promptly report any cases of drug abuse and assessing the trends of drug abuse in Taiwan in order to instantly control drug abuse and prevent abuse exaggeration.	

No.	Name of the website	Website	Website summary	QR Code
20	Drug Abuse Test Report System	https://udars.fda.gov.tw	A system that allows relevant testing agencies to regularly report results of urine tests or other forms of drug abuse tests.	
21	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 medicinal products, medical devices, and cosmetics.	
22	Post-marketing quality management system for medicinal products, food and cosmetics	https://qms.fda.gov.tw	A system provides an integrated single portal for the public, medical staff and companies to report defective products, such as drugs, medical devices, health food, and cosmetics.	
23	Cosmetic Product Registration Platform	https://cos.fda.gov.tw	A platform used to facilitate the governmental control of products on the market as TFDA encourages manufacturers or importers to register their products on to the platform, in order to align the cosmetic management with international standards.	
24	Online Application System of Human Organ Bank	https://htb.fda.gov.tw	A system provides online applications for human organs to ensure the integrity of submitted documents and facilitate application efficiency as well as provision conformity.	
25	Materials Transfer Support System for Disaster Rescue and Prevention	https://mrdss.fda.gov.tw/Web/	A system provides human organ bank inventory online for the hospitals, pharmaceutical manufacturers and retailers to facilitate the transfer of medical materials during major disasters.	
26	Laboratory Accreditation Management System	https://lams.fda.gov.tw	A platform that allows food, medicinal products, cosmetics, and urine testing (for drug abuse) agencies to apply for accreditation.	

No.	Name of the website	Website	Website summary	QR Code
27	Laboratory Information Management System	https://lims.fda.gov.tw	A system that electronically manage test processes of the laboratories of local government and Health Bureaus .	
28	Illegal Advertisement Query System	https://pmds.fda.gov.tw/illegalad/	A system that quickly publishes results of illegal advertisement audits on food, medicinal products cosmetics and disposals for a public inquiry, and provide as a reference for users on selecting and purchasing products. This system also discloses details of various violations, provides an accurate basis for decision making, and prevents customers from being influenced by exaggerated and misleading advertisements.	
29	Mail Box for Public Service	https://faq.fda.gov.tw/message/default.aspx	A mail box that provides a key channel for submitting public petitions and opinions. Smart inquiry service has been established that allows a more comprehensive and effective service to enhance public satisfaction.	
30	Online System of the JFDA journal	https://ees.elsevier.com/jfda/	A website for the Journal of Food and Drug Analysis (JFDA), which allows authors from Taiwan and other countries to submit their papers as well as facilitates journal editing, reviewing, and publishing.	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