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Taiwan Food and Drug Administration
2016 Annual Report

Food and Drug Administration, Ministry of Health and Welfare
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Taiwan Food and Drug Administration
2016 Annual Report

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Foreword

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Yu-Mei Chiang

Creating a Safer Consumer Environment for Food and Drug

The Taiwan Food and Drug Administration (TFDA) has the heavy responsibility of safeguarding the health of our fellow citizens. In order to safeguard national health and lead the nation to a new era of food and drug management, TFDA continuously improve upon the comprehensiveness of our food and drugs safety management system by the principles of Professionalism, Service, Quality, and Innovation. The comprehensive system creates a consumer environment for foods and drugs that all citizens can put their faith in.

To help everyone gain a better understanding of our administrative efforts, we annually compile and publish a Taiwan Food and Drug Administration Annual Report outlining the administrative actions and results for various food and drugs topics of the previous year. This year's Report focuses on the four major topics of (1) policies and organization; (2) results of key administrative efforts; (3) major events; (4) data and statistics. This report shows our efforts to fellow citizens and provides a set of references and guidelines for society at large.

Creating a Comprehensive Legal System to Establish a First-rate Management Environment

To strengthen Taiwan's food safety and sanitation management system, TFDA took active measures in stipulating the *Act Governing Food Safety and Sanitation (Food Safety Act)* as well as the promulgation and revisions of secondary laws. TFDA also manages the *Food Business Registration System* which oversaw more than 300,000 food businesses by the end of 2015. To extend food supply chain management and encourage self-management amongst businesses, a food traceability system for 19 categories of food businesses has been progressively built up. Meanwhile, the *Food and Drug Decision Support Center (DSC)* is established in order to carry out an effective big data analytics initiative, and to manage food safety risks and crises. TFDA also carries out border inspections, post-market surveillance, and factory inspections to implement comprehensive product management and ensure food sanitation and safety.

For the improvement of life cycle management for drugs and pharmaceuticals, a historical record of 170 new drugs have been approved in 2015, where two of these drugs were domestically produced novel immune and antibody drugs for cancer therapy, ensuring that the drugs are available for patient treatment as early as possible. In 2015, comprehensive implementation of PIC/S GMP was enforced for local drug companies and pharmaceutical manufacturers that export drugs to Taiwan in order to better align drug manufacturing quality with international standards. To lay down a robust pharmaceutical supply chain management with excellent quality, TFDA also provided consultation to businesses to support compliance with Good Distribution Practice (GDP) for pharmaceuticals. TFDA also listed propofol (colloquially referred to as milk of amnesia) as a controlled drug in order to reduce potential abuse.

To provide a standard reference for medical device companies during product development as well as product registration and inspections, and to promote the development of this industrial sector, TFDA promulgated the *Reference Guidance for Medical Software Categorization and Classification.* In 2015, mail order purchases and sales of Class II medical devices and items were legalized for the general public, providing people with greater convenience and options when purchasing medical devices. The voluntary Good Manufacturing Practice (GMP) for cosmetics was also promoted to enhance product source management.

TFDA actively formulated inspection methods, improved inspection technologies, and quickly released clear testing methods for sea cucumbers soaked in glacial acetic acid and dyed durian. Addendum to the *7th Version of the Chinese Pharmacopoeia* was also published to provide a standard reference for testing purposes. TFDA also strategically employed civilian-owned resources and testing capacities of local health bureaus and departments to achieve specialization of testing work. As of the end of 2015, a total of 163 labs have been accredited, allowing them to perform tests in response to emergencies.

Joint Partnership, International Collaboration, and Consumer Protection

To enhance international visibility, promote bilateral activities, and expand Taiwan's global market, TFDA played active roles in global harmonization organizations, signed a *Joint Declaration for Drugs and Medical Devices with Germany*, and organized the *Third Joint Conference of Taiwan and Japan on Medical Products Regulation*. Pursuant to the *Cross-Strait Food Safety Agreement* and *Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs*, TFDA established notification and exchange systems required under these agreements to promote collaboration and joint developments in the pharmaceuticals and health sectors.

To achieve consumer protection and risk communication, TFDA maintains a *Busting Myths about Food and Drugs* on its website, where expert opinions and scientific experiments are employed to dispel misunderstandings and resolve public concerns. Also, in order to expand food safety networks and communicate accurate information, TFDA also set up the first multiple-departmental *1919 National Food Safety Helpline* that offers an integrated telephony service for food incidents related to whistle-blowing, inquiries, consumer concerns, fresh produce, and questions from small and medium enterprises (SMEs).

Working Around the Clock to Establish a Homeland with Safe Food and Pharmaceuticals

TFDA has taken up the mission of ensuring the quality and safety of food and medical products and adopted the vision of serving as a trustworthy public guardian of food and drugs safety to create a safe consumer environment. We shall continue to strengthen our capacities of food, drugs, and cosmetics management and risk assessment, implement source management, ensure the comprehensiveness of import management systems, and develop core testing technologies to attain the ultimate goal of establishing a universal and consumer-oriented food and drug management.

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Part I

Policy and Organization

Taiwan Food and Drug Administration

Chapter 1

Administrative Objectives and Highlights

Part I Policy and Organization

Chapter 1. Administrative Objectives and Highlights

Quality, safety, and performance of food, drugs, and cosmetics are closely linked with public health. To achieve effective management of food, drugs, and cosmetics sold on the market, prohibit illegal products, assess and management product risks, prevent and control drug abuse, promote national programs for developing biotechnology, strengthen consumer protection, and align international trends of global food and drugs safety, the original Food and Drug Bureau has been reorganized to become the Food and Drugs Administration, Ministry of Health and Welfare (TFDA) in the hopes of strengthening food and drugs safety management (Figure 1-1-1).

TFDA shall refer to administrative guidelines of the Executive Yuan, policy implementation and developments, and current state of the general society in order to enhance food and drug regulations and management, strengthen the control of sources, manufacturing, and distribution of food and drugs, achieve effective control over raw materials and imported products, establish transparency of product information, safeguard consumer safety, and provide the public with a consumer environment that promotes Safe Food and Safe Drugs.

Figure 1-1-1 TFDA management efforts in response to growing product diversity and complexity

Section 1. Administrative goals

1. Promote total product life cycle quality management of food, drugs, and cosmetics and establish a modern policy and legal environment aligned with international standards based upon product quality and safety to restore the reputation of Made In Taiwan (MIT) food and drug products.
2. Promote cross-departmental collaboration for the prohibition of illegal drugs, intentionally adulterated food products, and reduce drug abuse, and integrate central and local monitoring and work specialization systems to safeguard the rights and interests of fellow citizens relating to food and drugs.
3. Continue to enhance source management of food imports based upon risk assessment, implement the three division strategy for food additives, and promote cloud-based management system for food products in order to achieve transparency of food information and build a food safety defense network.(Figure 1-1-2)

▲ **Figure 1-1-2** TFDA objectives and vision

Section 2. Administrative Highlights

1. Promote Food and Drugs Management Capacity, Implement Source Management and Safeguard Consumer Safety.

(1) Amendments for Product Management Regulations.

(2) Strengthen Management of Product Manufacturing.

(3) Comprehensive Product Review Management.

(4) Strengthen Product Distribution Audits and Quality Monitoring.

(5) Strengthen Laboratory Testing Capabilities.

(6) Strengthen International Collaboration and Cross-Straits Exchanges.

(7) Reinforce Risk Management.

2. Enhance and Strengthen the 5 Circles of Cross-Departmental Food Safety Policies and Actions.

(1) 1st Circle: Source management and establishment of a regulatory authority for toxic compounds.

(2) 2nd Circle: Re-establish production management.

(3) 3rd Circle: Conduct 10 times more market inspections to improve safety 10 fold.

(4) 4th Circle: Increase the legal penalties for manufacturers that intentionally adulterate their products.

(5) 5th Circle: Total monitoring of food safety.

3. Continue developing the biotechnology and pharmaceutical industries.

(1) Ensure comprehensive development of the biotechnology sector and establish systems to promote drugs safety and quality.

(2) Establish and harmonize legal environments for medical drugs trade and commerce.

Chapter 2

Organization Framework

Chapter 2. Organization Framework

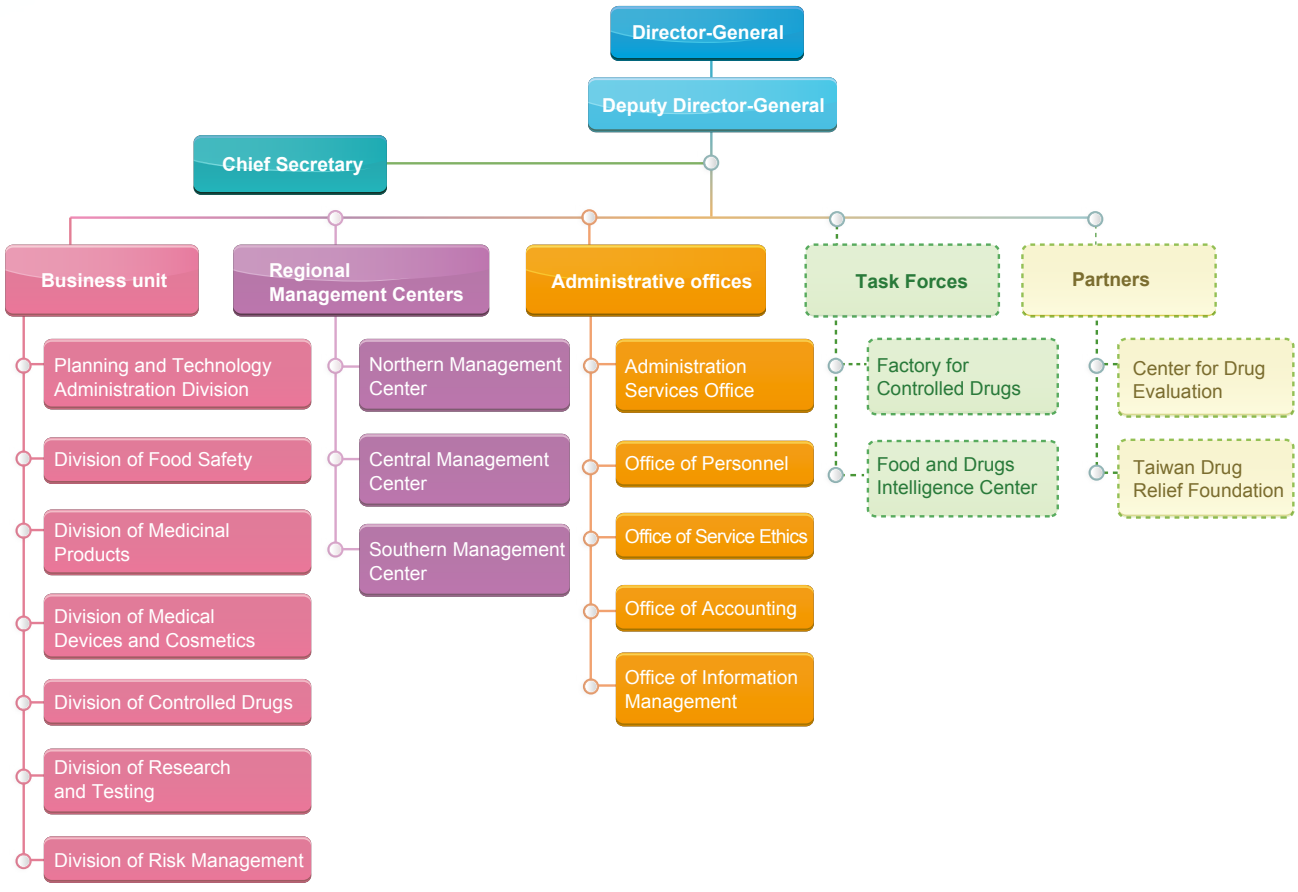
The original Food and Drug Bureau was reformed to form TFDA as part of the reorganization of the Ministry of Health and Welfare of July 23, 2013. The reformed TFDA shall continue to carry out its responsibilities with professional care and demonstrate its post-reorganization performance in order to ensure public safety and interests in the use of food products, drugs, medical devices, and cosmetics.

Section 1. Responsibilities

1. Planning and implementation of policies for managing food, drugs, and cosmetics, and formulate relevant laws.
2. Inspection, registration, review, licensing, and archiving of food, drugs, and cosmetics, and the review and monitoring of human subject drug trials.
3. Production process management, import inspection (and testing), distribution, auditing, approval, and consultation for food, drugs, and cosmetic businesses.
4. Food, drugs, and cosmetics testing, research, and laboratory accreditation; risk assessment and risk management; testing of traditional Chinese medicinal herbs and medicinal plants.
5. Monitoring of food, drugs, and cosmetics safety; investigation and handling of hazard incidents.
6. Auditing, notification, early warning, and educational announcements of controlled drugs; import, export, manufacturing, and sales of Schedule 1 and Schedule 2 controlled drugs.
7. Promotion of consumer protection measures for food, drugs, and cosmetics.
8. International collaboration and overseas management of food, drugs, and cosmetics.
9. Other management activities related to food, drugs, and cosmetics.

Section 2. Organization Framework

1. TFDA comprises seven functional units for the planning and management of food, drugs, and cosmetic products and relevant laws, namely: Division of Food Safety, Division of Medicinal Products, Division of Medical Devices & Cosmetics, Division of Controlled Drugs as well as the Division of Planning & Research Development responsible for overall planning of the entire organization. TFDA also has a Division of Risk Management, Division of Research & Analysis as well as Northern, Southern, and Central centers for managing product quality assurance, factory management, distribution, and auditing. An additional five administrative offices were also established to support TFDA's administration and management, namely: the Office of the Secretariat, Office of Personnel, Office of Service Ethics, Office of Accounting, and Office of Information Management (Figure 1-2-1).



▲ **Figure 1-2-1** Organizational structure of the Food and Drugs Administration, Ministry of Health and Welfare (TFDA)

2. TFDA also has two task force organizations of the Factory for Controlled Drugs and the Food and Drugs Intelligence Center to cater to changing social trends. The Factory for Controlled Drugs proposes relevant business activities according to the nature of its tasks and specific project requirements, and initiates close partnerships with professional consultants such as the Center for Drug Evaluation and Taiwan Drug Relief Foundation. The Food and Drugs Intelligence Center was established by TFDA on September 2nd 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, implement source management, and safeguard the health of the entire population.

Section 3. Future Prospects

Food and drugs safety are tied with the health of fellow citizens. Globalization of commerce, rapid advancements in technology, release of novel food and drug products, and environmental impact due to chemicals generated by technological activities have made food sanitation and safety issues increasingly complex. Food and drugs safety management must therefore include comprehensive considerations and multiple levels of control and introduce management measures. Functional specialization and activities across multiple departments are to be employed in order to improve management capabilities of food and drug businesses, assign responsibilities to these businesses, ensure safety, and defend consumers' rights and interests. Given the importance of food and drugs and the expectations of various segments of society, TFDA brings together multiple departments, businesses, and consumers, expanding public participation to jointly establish a comprehensive product safety defense network spanning from the farm to the dinner table and creating a safe and excellent environment that is conducive for Safe Foods and Safe Drugs. To ensure that food and drugs safety and quality levels are on par with international standards and to ensure food sanitation and safety for the entire population, TFDA also encouraged businesses to enforce and improve self-management capabilities, heralding a new era for food and drugs management.

02

Part II

Key Administrative Results

Taiwan Food and Drug Administration

Chapter 1

Food Management

Part II - Key Administrative Results

Chapter 1. Food Management

To maintain public confidence in food safety, TFDA continued to compile and reference international standards and revise laws related to food provision. TFDA also actively promoted food business registration management, food traceability system, and Three-Tiers quality control policy for food products in order to effectively improve self-management capacities of food businesses, establish third-party verification systems, and significantly expand auditing capacities and capabilities of central and local authorities. Proper enforcement and implementation of the *Act Governing Food Safety and Sanitation* shall build public confidence in food safety.

Section 1. Food Laws and Regulations and Product Review

Current status

In order to strengthen food safety and management, TFDA actively pushed for the promulgation and revision of the *Act Governing Food Safety and Sanitation* as well as secondary laws related to the Act. To further safeguard public and consumer safety and health, TFDA established product verification and registration control systems at the front end of food production for food items targeted at specific consumer populations or where the special effects of the food item must be verified.

Policies and Outcomes

1. Revisions to the *Act Governing Food Safety and Sanitation*

Recent key revisions to the *Act Governing Food Safety and Sanitation* include establishment of a Food Safety Board whose members span multiple departments, strengthening of food business management, and raising the penalties for violators. To strengthen food safety management and performance, safeguard the health of fellow citizens, and defend the rights and interests of consumers, a number of articles to the Act were revised on February 4 and December 16, 2015. Table 2-1-1 lists the revisions.

2. Addenda and Revision to Food Safety and Sanitation Regulations

Key regulations promulgated and revised in 2015 include [Regulations Governing the Registration of Food Businesses], [Food Businesses that Belong to a Category and Scale Desingnated by the Central Competent Authority in a Public Announcement Shall be Equipped with Laboratories], [Regulations for the Nutrition Labeling of Prepackaged Food], [Guiding Regulations for the Labeling of Genetically Modified Food], and Standards for Specification, Scope, Application and Limitation of Food Additives. For details, refer to Table 1 in Annex I.

3. Registration of Specific Food Products

Table 2-1-2 shows the number of approved permits issued for each of the eight categories of food items that must undergo registration as of the end of 2015. In 2015, 1,980 registration applications were received for food additives, of which 1,797 items were reviewed while 1,530 items were approved (85.14%). For health foods, 33 permits were approved and released, of which 26 permits were issued via the case-by-case review process, while 7 permits were issued via the standard specification review process. Approval permits were also issued for 47 genetically modified (GM) food items. Refer to Table 2 in Annex I for details on permit statistics and data.

Table2-1-1 **Revisions to the *Act Governing Food Safety and Sanitation* in 2015**

Date promulgated	Key revisions
February 4	• Food businesses of categories and scales announced by the central competent authority shall refer to the food sanitation and safety management system and pro-actively undergo third party external audits and surveillance. Corresponding penal provisions were also added (Articles 8 and 48). • Added other items that shall be labeled for venues that directly serve food and drinks as well as sites that handle bulk food. • Clearly stipulated that a business with domestic agricultural production approval shall provide traceability and source labeling for its products. A business that has a production system listed by the competent agricultural authority must also label its production system (Article 25).
December 16	Authorized the central competent authority to enforce restrictions up on the methods or conditions of manufacture, processing and preparation, edible parts, usage quantity, product form, or other matters of raw materials for food use as well as corresponding penal provisions (Articles 15-1 and 48).

Table2-1-2 **Number of registration licenses approved and issued for specific food products as of the end of 2015**

Food categories to be registered	Effective licenses
Imported food in tablet or capsule form	7,706
Domestic vitamin products in tablet or capsule form	1,689
Food additive	6,406
Infant and follow-up formula	171
Formula for certain diseases	166
Genetically modified (GM) food	107
Vacuum-packed ready-to-eat soybean food	139
Health food	312

Section 2. Food Products Source Management

Current status

In response to the frequent incidences of food safety issues, TFDA actively promoted the Food Business Registration System, implemented measures for controlling food traceability and food factory sanitation and risks, and continued to strengthen inspection and management along border customs and imports. TFDA also expanded relevant specifications, requiring food businesses to record the source of food supplies and product distribution during food production and supply processes in order to strengthen self-management of food businesses, making them responsible for ensuring food safety, and creating records of that.

Policies and Outcomes

1. Comprehensive Implementation of the Food Business Registration System

(1) The Food Business Registration System has been promoted since 2014. As of the end of 2015, the System effectively monitored the status of over 300,000 food businesses which included about 150,000 retail venues, 110,000 food services, 30,000 food production and processing businesses

and their factories / plants, 10,000 food importers, over 700 food utensil containers and packaging businesses, over 300 food additive businesses, and over 77 food cleanser businesses. TFDA shall continue to strive towards registering every food-related business in Taiwan.

(2) Consumers and food businesses can both access the Food and Medicinal Business Registration Platform (http://fadenbook.fda.gov.tw/) to check information on food business registration and quickly acquire the latest announcements and information. The system also made the government more effectively control over the distribution of food businesses and improve management efficiency.

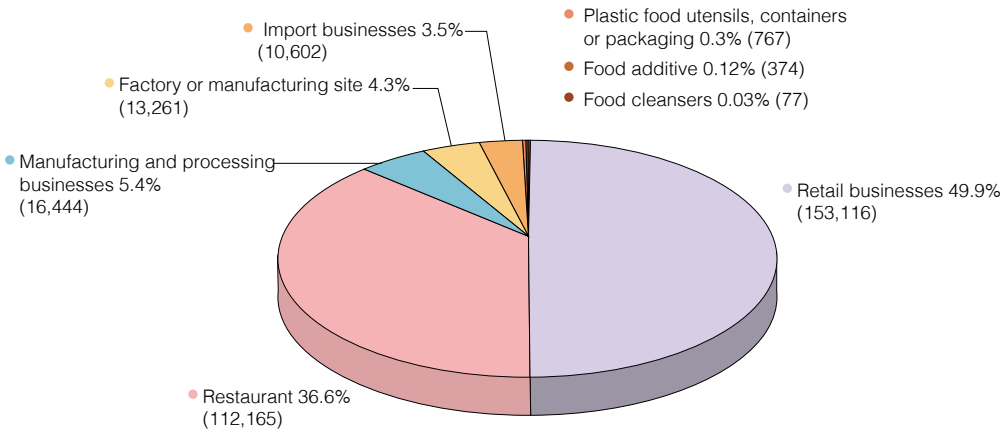


Figure 2-1-1 Food Business Registration Platform statistical chart

2. Enforcing the Food Traceability System

To expand the scope of food supply chain management and enforce self-management among food businesses, Food Businesses that Shall Establish Traceability System of Food Products promulgated on July 31, 2015 included 19 categories of food businesses required to establish food traceability systems at the respective phases. This included food business categories announced in 2014 as well as 12 new categories added in announcements made in 2015, which included seven bulk food items (soybeans, wheat, maize (corn), wheat flour, starch, salts, and sugar) and two categories of tea products (tea leaves and prepackaged tea drinks), soybean products, infant and follow-up formula, prepackaged milk powder and modified milk powder products. The aforementioned food businesses must refer to the implementation schedule as well as the provisions of the Regulations Governing Traceability of Foods and Relevant Products to establish food traceability systems, upload traceability information to the website (https://fracebook.fda.gov.tw) and use electronic uniform invoices.

3. Improving Sanitation and Risk Control Measures of Food Factories

To strengthen independent management of food businesses in Taiwan and improve the ability of food businesses in implementing risk management measures, TFDA has required high-risk businesses to simultaneously enforce Good Hygienic Practice (GHP) as well as Hazard Analysis and Critical Control Points (HACCP) for their food products. TFDA also commissioned relevant agencies to support local governments and health bureaus and departments to carry

out compliance audits (Table 2-1-3), maximizing the effectiveness of limited resources for food factory supervision and management efforts. TFDA also rated food factories according to the results of factory audits, using these data as a reference for planning factory inspection policies while encouraging food businesses to place greater importance on consumer food safety and enforce proper controls over sanitation and safety.

Table2-1-3 **Number of compliance audits carried out according to the Food Safety Control System in 2015**

Product category	Businesses audited
Seafood processing industry	64
Meat processing industry	73
Food service - Food services within international tourist hotels	69
Food service - Box meal factory	77

4. Management of Imported Foods

(1) Key import control measures for imported foods

a. TFDA has continued to strengthen import food management on border inspections via the stipulations of customs commodity codes with food related requirements according to Article 30 of the *Act Governing Food Safety and Sanitation*. Dated to December 31, 2015, import products belonging to 2,364 customs commodity codes are required to apply for import food inspections to TFDA if the products are destined for food purposes.

b. The following products with specific risks required evidentiary documentation in 2015.

(a) Since January 26, 2015, edible oil in large or bulk packaging shall be attached with official certificate for sanitation so as to prove the products are fit for human consumption.

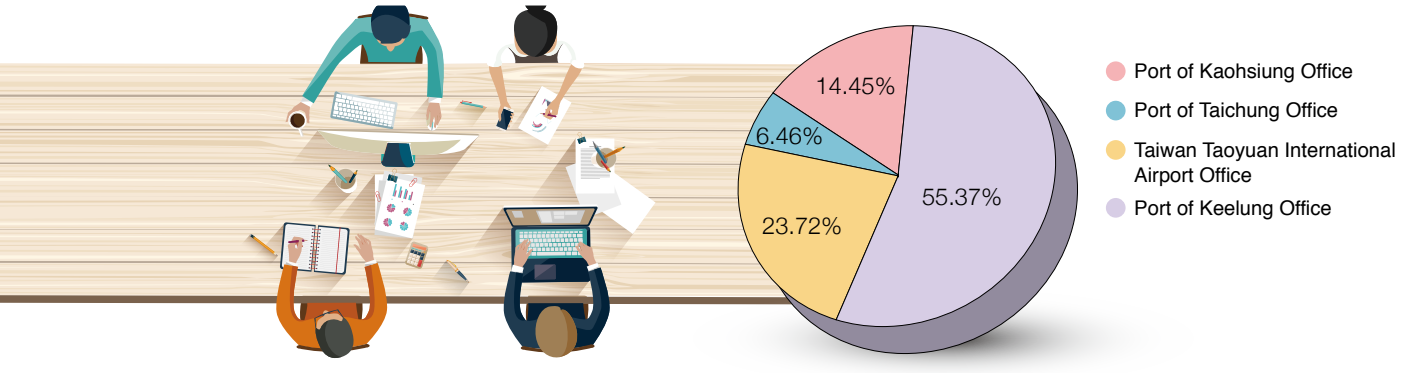
(b) Two public announcements were made on May 15, 2015 which all imported food products from Japan must be accompanied with evidentiary documentation for place of origin provided by official or officially authorized agencies (institutions) of the Japanese government or those approved by TFDA, while specific food products from specified regions must also be attached with proof of radioactive inspections before initiating import applications. No incident of untruthful reporting of the place of origin has been reported since border and customs controls were enforced.

(c) Black tea in bulk imported from Vietnam must be accompanied with test report for pesticide residual.

(2) Border Inspection of Imported Foods

Food imports and related products must undergo and pass border inspections for food imports at harbors, ports, and customs before the importation may proceed. Refer to Table 3 in Annex I for detailed statistics on such inspections. Figure 2-1-2 shows the distribution of import applications amongst TFDA offices in various ports in Taiwan during 2015. The Port of Keelung

received the largest number of applications (accounting for 55.37% of the total). 640,003 batches of food import inspections were carried out, a figure that grew by 3.85% compared to 2014. Among these, 50,149 batches (7.84% of the total) underwent random sampling and testing, and 1.90% were found to have failed to conform to the regulations. The number of nonconformities, in descending order, were fresh, chilled, or frozen vegetables, food utensils, fresh, chilled, or frozen fruits, and tea products, with most nonconformities pertaining to residual agricultural chemicals or heat resistance tests. Such products were either returned or destroyed according to law to prevent their sales in Taiwanese markets.



▲ **Figure 2-1-2** Distribution of inspections handled by TFDA offices at various ports

(3) Inspection of Overseas Factories

To effectively achieve source management of food products, TFDA referenced risk assessment results to inspect and audit overseas factories. In 2015, eight countries and their products were inspected (Table 2-1-4). According to Article 35 Paragraph 1 of the ***Act Governing Food Safety and Sanitation***, systematic inspections may be implemented for the management and control of foods with higher risk of safety. In 2015, TFDA conducted the systematic inspections of Austria, Poland and New Zealand. For the market re-access of Canadian beef applied by Canada government, TFDA also conducted systematic inspections of Canadian beef.

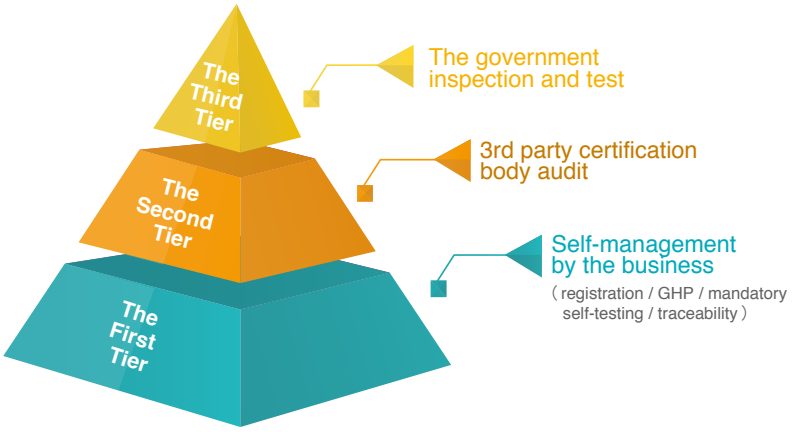
Table2-1-4 Countries and items of overseas factories inspection in 2015

No.	Country	Product inspected
1	Austria	Pork products
2	Poland	Poultry products
3	Canada	Beef products
4	New Zealand	Aquacultural and dairy products
5	Spain	Lard
6	Australia	Tallow
7	United States	Beef
8	PRC	Chinese mitten crab

Section 3. Food Product Safety Chain Monitoring

Current status

To strengthen food safety management, TFDA has established a comprehensive Three-Tiers quality control system for food products (Figure 2-1-3). TFDA has continued to provide guidance to food businesses in stipulating enacting food safety monitoring plans and self-testing (The First Tier) as well as establishing laboratories and other amenities equipped with laboratories to help food businesses take up the responsibility of self-management. For testing and verification carried out by independent 3rd party certification body agencies (The Second Tier), TFDA provided support to establish or strengthen the capacities of independent testing institutions and expand their human resources so that these agencies and institutions would be able to conduct Good Hygienic Practice (GHP) and Food Safety Control System (HACCP) audits for food products in addition to carrying out food safety testing. A top-down inspection system (The Third Tier) shall be maintained according to risk management concepts and improve inspection and testing capacities of the market. Such measures include the joint inspection program for food products that involve multiple ministries and departments, specific product inspection and test of annual monitoring programs of the central government, and routine inspection and test carried out by local health bureaus. Monitoring and management efforts of the government and private agencies were combined in order to encourage food producers and businesses to fulfill their social responsibilities and jointly safeguard food safety for the public.



▲ **Figure 2-1-3** Three-Tiers Quality Control System for Food Safety

Policies and Outcomes

1. Three-Tiers Quality Control System for Food Safety

(1) The First Tier: Encourage producers and food businesses to implement self-management

a. To enhance food businesses in implementing self-management, TFDA announced 17 categories of food businesses (including edible oils, processed meat products, processed dairy products, processed aquatic products, food additives, special dietary foods, soybeans, corn, wheat, flour, starch, salts, sugar, soy sauce, tea leaves, prepackged tea drinks, and integrated commodity retail other than department stores) that required food safety monitoring plans and enforce mandatory self-testing requirements to ensure food sanitation and safety.

b. Food businesses must refer to the characteristics, quality assurance systems, and self-testing capacities of the food industry as well as results of hazards analysis, spirit of

critical point controls, and principles of risk management of the food industry in order to independently assess the scale and equipment needed for internal laboratories, and have the said laboratories carry out all or part of food self-testing required. All food businesses that are Exchange-Listed, OTC-Listed required by law to establish their own laboratories since December 10, 2015. Additionally, all companies with a capital sum over NT$ 100 million and factory registration for the production, processing, or mixing of 10 food industry categories that include edible oils, processed meat products, processed dairy product, processed aquatic products, flour, starch, salts, sugar, soy sauce, and prepackaged tea drinks are required to establish their own laboratories as well.

(2) The Second Tier : Implementing third-party verification systems

a.According to the *Act Governing Food Safety and Sanitation*, food businesses of a certain scale and category must have their sanitation and safety management systems verified by a certification body (CB) accredited by the central competent authority; Health and Safety Management System means that the food business needs to be comply with Act Governing Food Safety 8 (5) gudelines (GHP、HACCP).

b.Oil and fat manufacturers were inspected in 2014. In 2015, inspections announcements were released for canned food products, special nutrient foods, dairy products, and food additive industries. By the end of 2015, 308 verification audits were carried out for the sanitation and safety management systems of five types of food manufacturers. Details are listed in Table 2-1-5.

Table2-1-5 **Number of businesses that underwent third-party verification as of 2015**

Type of business	Number verified	Date implemented
Oil and fat manufacturer with a capital sum above NT$ 30 million	32	103.12.05
Canned food manufacturers	149	104.01.01
Special nutrient food manufacturers	9	104.06.04
Dairy product manufacturers	37	104.06.04
Food additive manufacturers	81	104.06.04
Total	308	

(3) The Third Tier : Enhancing inspection capacity and post-marketing surveillance

a.Work with local governments, health bureaus and departments to carry out programs for the inspection, sampling and testing, as well as post-marketing surveillance of food products: Increased inspection, sampling, and monitoring of key administrative targets, high risk food items, and issues with high levels of public concern, and work with health bureaus and departments to carry out various projects. In 2015, 47 project inspection and sampling tests were carried out in addition to four post-marketing surveillance programs for heavy metals, mycotoxins, veterinary drugs, and residual agricultural chemicals. 4,940 items were inspected in 2015. Nonconformities were handled according to law by the local health bureaus. Root cause analysis and improvements were also carried out by an inter-departmental coordination system. Table 2-1-6 shows the results of these TFDA surveillance efforts. Refer to Table 4 in Annex I for detailed statistics on testing for residual pesticides and veterinary drugs in food products.

b.Inspection program of the Executive Yuan Joint Task Force for Food Safety: Audits have been carried out for source production sites or manufacturing plants of food products considered as daily necessities of the average citizen that also cause significant health impacts. TFDA worked with relevant departments and agencies of the central government, local governments, inspectors, and police forces to leverage their respective potentials when implementing key inspection. Ten important joint audits were completed in 2015.

c.Supervising food inspection responsibilities of local governments, health bureaus, and departments: In 2015, a total of 119,927 Good Hygienic Practice (GHP) audits for food products, 340,347 product labeling inspection, and 47,078 product sampling tests were carried out. Refer to Table 5 in Annex I for detailed statistics on food inspection carried out by local governments, health bureaus, and departments.

Table2-1-6 **Results of post-marketing surveillance (PMS) of food products carried out in 2015**

Surveillance items and results	Samples taken	Conforming cases	Compliance (%)
Agricultural chemical residues	3,287	2,938	89.38
Veterinary drug residues	1,745	1,714	98.22
Mycotoxins	574	545	94.95
Heavy metals	761	755	99.21
Total	6,367	5,952	93.48

Section 4. Food Safety and Sanitation Management

Current status

There has been a recent increase in the incidence of consumer disputes and violation of consumer rights related to food fraud such as tampered or untruthful labeling, or using cheap and inferior alternatives to replace costly raw materials. The *Act Governing Food Safety and Sanitation* was greatly expanded with respect to provisions for labeling requirements. To establish effective deterrence, auditing and prohibitive measures have been strengthened in addition to raised fines and penalties. To improve the performance of food safety controls and strengthen the basis for food safety management, TFDA continued to strengthen the use of the food information management system, integrating information systems of various departments to actively provide food businesses with consultation and encourage them to establish self-management systems. TFDA also conveyed information regarding food sanitation and safety policies to the public and food businesses to create a united front for the defense of food safety and sanitation.

Policies and Outcomes

1. Comprehensive New System for Food Product Labeling

Articles 22, 24, and 25 of the *Act Governing Food Safety and Sanitation* amended in 2015 stipulated 11 regulations for food labeling such as the Regulations Governing the Labeling of Soup Bases of Hot Pot at Food Vending Locations and Regulations on the Labeling of Restructured Meat. Refer to Table 6 of Annex I for more information.

2. Strengthening Distributor Management

Distributors have corporate responsibilities that include ensuring product sanitation, safety, and quality. Self-management and enforcement shall also comply with relevant laws and regulations such as the Consumer Protection Act and the *Act Governing Food Safety and Sanitation*. TFDA promulgated the Guide to Ideal Corporate Distributors of Food and Agricultural Products on November 20, 2015, using it as a reference for providing consultation to distributors in compliance with source control, product safety, sanitation management, information transparency, consumer protection, emergency response, and quality improvements (Figure 2-1-4). The aim is to ensure that all distributors are capable of establishing and improving the effectiveness of their self-management systems.

▲ Figure 2-1-4 Food Safety Wardens - a declaration of ideal distributors

3. Prevention of Food Poisoning

(1) There were 632 foodborne disease outbreaks reported in 2015. Analysis revealed that most of these outbreaks were caused by bacterial infections and that schools and cafeterias are venues where foodborne disease outbreaks most commonly occur. These outbreaks were mostly caused by improper sanitation and safety concepts that led to cross-contamination of food processing equipment and processes, improper storage conditions, or environment (refer to Table 7 in Annex I for detailed statistics on food poisoning).

(2) To raise awareness of foodborne disease and prevent such outbreaks, TFDA established a special webpage dedicated to foodborne disease prevention. TFDA also compiled data from foodborne disease to publish the Annual Report Foodborne Disease Outbreaks and their Prevention as a reference by the relevant fields.

4. Digitalization of Food Business Management

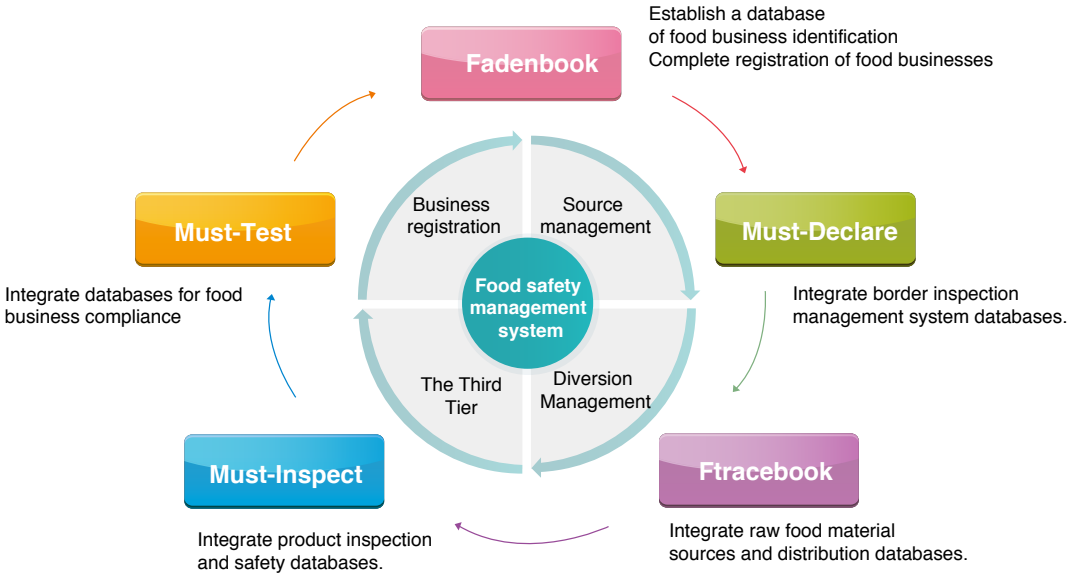
(1) Five-Must Food Safety Policy

To establish a comprehensive food safety management information framework, TFDA established five information systems as the core (Figure 2-1-5) and continued to enhance its food information management system that includes the registration platform of food businesses (fadenbook), imported food inspection system (Must-Declare), food traceability management

information system (ftracebook), testing system (Must-Test), and product management distribution system (Must-Inspect). TFDA also established food inter-agency verification and monitoring websites to manage the list of food businesses in the country and food product information, customs entry information, upstream and downstream relationships in the supply chain, and results of testing and auditing processes. Information sharing, data connections, and data integration were employed to achieve the goals of risk management and early warning.

(2) Connecting information systems of various departments

In addition to active integration of information systems within TFDA, TFDA also started connecting to information management systems related to food safety under various ministries and departments in 2015 in order to enhance data connection and verification. By the end 2015, TFDA built connections to eight information systems and channels of four ministries, including Clearance Information, Electronic Invoice Financial Data from the Ministry of Finance (MOF), Production Selection Chenical Substances System, Business Rsgistration System from the Ministry of Economic Affairs (MOEA), Chemical Cloud, Waste Oil Declaration Management System from the Environmental Protection Administration (EPA), and Feed Oil Tracking System from the Council of Agriculture (COA). TFDA shall refer to policy plans and continue to connect to new systems. Recently, TFDA has established a link to the MOEA for the import, production, and distribution of general industrial oils and fats to achieve articulation and analysis of potential risks. Data comparison and articulation between different systems can help avoid untruthful business registration. Connections to food product supply chain and distribution information systems were established to analyze potential hazards or risks, allocate manpower, supplies, and finances to achieve desired management capacities, attaining desired objectives while expending fewer resources.



▲ **Figure 2-1-5** The Five-Must information system for food safety management

5. Enhancing and Building a Strong Foundation for Food Safety Management

To encourage local governments to take a proactive stance in punishing illegal activities and solve food safety problems, the Executive Yuan appointed the Ministry of Health and Welfare (MOHW) to work with the Council of Agriculture (COA), MOEA, EPA, and Ministry of Education (MOE) and formulate relevant plans. To reward local governments with outstanding performance in identifying and handling of food safety issues, stipulated the 2015 Pilot Project for Rewarding Local Governments in Strengthening Food Safety Management Plans.

Evaluations were carried out along the two major themes of building strong foundations for food safety management and strengthening processes for selecting benchmarks for excellent performance in food safety. Project rewards and various assessment indicators were used to provide guidelines and encourage local governments in strengthening and enforcing total management of the sources, production process, preservation, and sales of food products or their raw materials. The rewards provided can help compensate the lack of resources for implementing food safety management, allowing agencies to effectively apprehend businesses engaging in illegal activities and safeguard food safety for the general public.

6. Diverse Measures for Implementing Food Sanitation and Safety Policies

(1) TFDA has continued to integrate resources from central and local health bureaus to strengthen measures for advocating food safety laws. 43 interpretation meetings attended by 3,765 individuals were held for food safety and sanitation laws in northern, central, and southern Taiwan. These meetings were used to convey correct understanding of current laws, provide consultation visits, and improve professional knowledge of food businesses for carrying out self-management.

(2) Activities held in 2015 include promotional activities for business registration and food labeling, orientations for Food Safety Wardens promotion towards food distributors and for food utensils and container manufacturers, and promotional courses for food businesses (including food production and processing, food services, food utensils, containers and packaging manufacturers, importers, food additives manufacturers, and retailors). These activities were attended by 1,650 individuals.

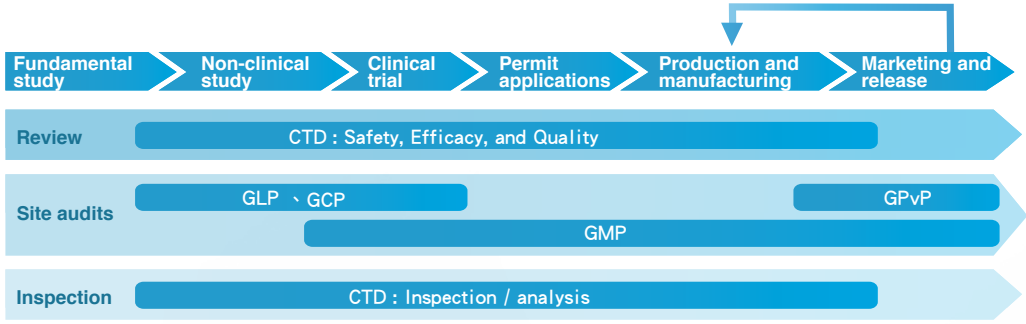
Chapter 2

Medicinal Products Management

Chapter 2. Medicinal Products Management

Unlike general consumer products, medicinal products are closely associated with the health and lives of fellow citizens. Medicinal products are therefore subject to strict regulations and must acquire approved drug permit licenses from the central health authority before they may be sold on the market. TFDA is constantly reviewing and strengthening medicinal product monitoring systems to ensure drug use safety amongst the general public by revising pharmaceutical laws and harmonizing them with international standards, simplifying review processes and unifying management systems, monitoring the sources, distribution, and quality of drug manufacturing, prohibiting illegal drugs, and enforcing controlled drug management measures.

Medicinal product life cycle from research and development to market release include these steps: fundamental research, non-clinical studies, clinical trials, license applications, manufacturing, and market distribution. Reviews, audits, and inspections were conducted at each step to ensure compliance with various specifications (GXP), forming a comprehensive medicinal product life cycle management framework (Figure 2-2-1). For example, GLP and GCP audits must be carried out to ensure testing quality during non-clinical studies and clinical trial phases. Manufacturing processes shall be audited for compliance with GMP. Where necessary, pre-market release inspection and analysis as well as post-marketing sampling tests shall be carried out to ensure continuing compliance to Good Pharmacovigilance Practice (GPvP). These measures will improve measures for medicinal product quality and safety surveillances and achievement of all medicinal product life cycle management objectives.



CTD ：Common Technical Document
GLP ：Good Laboratory Practice
GCP ：Good Clinical Practice
GPvP：Good Pharmacovigilance Practice
GMP ：Good Manufacturing Practice

▲ **Figure 2-2-1** Medicinal product life cycle management framework

Section 1. Medicinal Product Regulations and Product Review

Current status

Post-marketing quality demands of medicinal products prescribed by international laws are becoming increasingly stringent every year, National laws must therefore maintain adequate alignment. TFDA has therefore continued to inspect, revise, and formulate relevant management specifications, reference global trends in drug management, and direct management efforts towards medicinal products with higher levels of risk or those consumed by a specific population. Medicinal product registration and management systems were established along with continuous revision of medicinal product management laws to ensure consistent product quality and efficacy.

Policies and Outcomes

1. Comprehensive Regulations and Standards

A number of key addenda and revisions were made to medicinal product management laws and related standards in 2015. Revisions include the following: *Pharmaceutical Affairs Act and the Rare Disease and Orphan Drug Act*, Regulation of Bioavailability and Bioequivalence Studies, regulations for applying for drug hazard relief, and regulations for registration of medicinal products. Promulgated laws include the following: Regulations for Medicament Recall, standards for the registration of monoclonal antibodies for biosimilars, standards for determining the adequacy of donors of cell therapy products, and standards for the inspection, registration, and review of medicinal products. TFDA also announced the need to include the composition or name of the excipient upon the package inserts of the medicinal products and that the active pharmaceutical ingredient (API) used within the preparation must be compliant with Good Manufacturing Practice (GMP) for pharmaceuticals. Refer to Table 8 of Annex I for details on the revisions as well as promulgation of new laws.

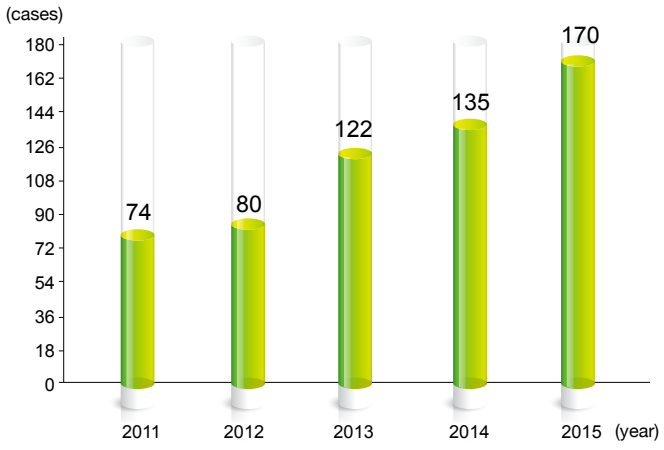
2. Medicinal Product Registration Management

Medicinal product registration can be divided into active pharmaceutical ingredients (API) and its preparations, the latter of which can be further divided into new drugs, bioagents, generic drugs, and orphan drugs. Where local clinical trials or bioavailability (BA) and bioequivalence (BE) study results must be provided as attachments for inspection and registration applications, the corresponding project plans and reports must be reviewed and approved as well. The number of drug permit licenses approved by TFDA every year is listed in Table 9 of Annex I.

(1) Pre-market Inspection and Registration for Medicinal Products

a. In 2015, a total of 170 new drug applications have been approved (Figure 2-2-2), a historical high and a 26% increase compared to the figures of 2013. Of which, two of the applications in 2015 involved novel drugs made in Taiwan, creating a new record for global firsts in the industry.

b. Among 170 new drug applications (NDAs) in year 2015, a total of 27 NDAs were manufactured domestically while 143 NDAs were imported. 49 involved new drugs containing new chemical entities (NCE) and 44 NDAs were biopharmaceuticals. Therapeutic areas included anti-cancer drugs, anti-viral drugs, drugs for rare diseases, and vaccines required by public health services. To encourage the provision of new treatment options, TFDA expedited the approval and market authorization of 2 anti-cancer antibody immunotherapy drugs in 2015 to benefit those afflicted by rare diseases or cancers.



▲ **Figure 2-2-2** Number of new drugs approved throughout the years

(2) Clinical Trial Reviews

a. Reviews were conducted according to the Application Guidelines for the Clinical Trial of Medicinal Products and Ethical Review for the Clinical Trial of Medicinal Products (Central IRB) to ensure the comprehensiveness of documents submitted by the applicants and improve the efficiency of case review processes.

b. In 2015, new clinical trials and change applications in Taiwan totaled 346 and 3,130 cases respectively. These figures amounted to a near 21.5% increase in the total number of cases compared to the previous year.

c. To safeguard the rights and interests of trial subjects and maintain the quality of clinical trials, all clinical trials must be implemented in compliance with the Good Clinical Practice (GCP) Standards for Medicinal Products. A total of 52 GCP audits were completed in 2015.

(3) Reforms to Medicinal Product Review Systems

In 2015, revisions to the Priority Review System and Accelerated Approval Mechanism for New Drug Applications were promulgated to expand the applicable scope of new drugs with new chemical entity (NCE) to include other new drugs which are detined in Article 7 of the Pharmaceutical Affairs Act (namely: NCE, new therapeutic compound, and new method of administration). In order to improve the transparency of the review process, manufacturers were invited to consultation meetings in order to improve the transparency of the review process. TFDA also introduced benefit and risk evaluation systems for new drug reviews and initiated pilot for online new drug application systems in order to expedite the approval of new drugs and achieve the vision of establishing advanced technologies in Taiwan to and expanding global markets. Fifteen priority review cases were completed, with review time greatly reduced to 171 days (median value).

3. Promoting Professional Consultation for Pharmaceutical Projects

(1) To support the Taiwan Biotech Industries Take off Action Plan of the Executive Yuan, TFDA committed itself to improving pharmaceutical industry consultation and establish a Professional Consultation System for Pharmaceutical Projects for new drugs being researched and developed in Taiwan. Items were evaluated and selected according to the four selection indicators of: (1) innovativeness; (2) contribution; (3) early benefits; (4) legal compliance. Legal inquiries and consultation were provided from the research and development (R&D) phase to ensure that drugs are released as early as possible for the patients and encourage new drug R&D in Taiwan.

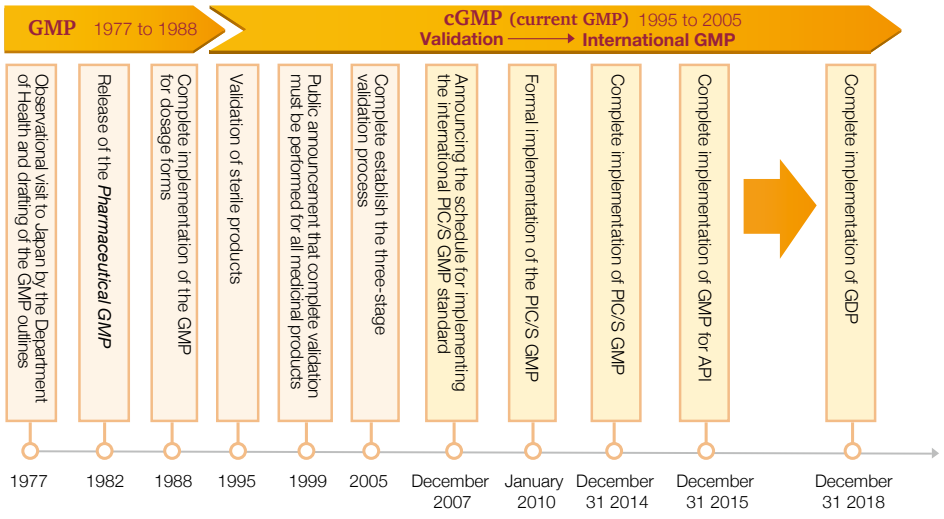
(2) From 2010 to the end of 2015, TFDA provided consultation to 32 projects, and approved a novel new drug that was domestically produced in 2014. In 2015, another two novel and domestically produced new drugs were approved as well, generating a new record for world firsts in Taiwan. Approved indications for these drugs were adult hemodialysis patients with chronic kidney diseases and hyperphosphatemia (API name: Ferric Citrate) and metastatic pancreatic cancer patients that previously received chemotherapy with gemcitabine (API name: Irinotecan liposome).

Section 2. Medicinal Products Source Management

Current status

To improve manufacturing quality of medicinal products and align to international standards, Taiwan began enforcing increasingly stringent laws and international harmonization for the management of medicinal product factories. In 1982, Taiwan began implementing Good Manufacturing Practice (GMP) for pharmaceuticals and enforced the current Good Manufacturing Practice (cGMP) in 1995. In 2007, Taiwan began promoting GMP standards of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S GMP), and attained total enforcement by the end of 2014, achieving complete harmonization of Taiwan's pharmaceutical manufacturing standards with international standards. To strengthen production quality management, Taiwan promulgated GMP standards for active pharmaceutical ingredients (APIs) in 2013 and achieved complete enforcement by the end of 2015. The GMP for Modern Pharmaceutical Products (Part 3) was released in 2015 with complete enforcement scheduled by the end of 2018. The GMP implementation road map is illustrated in Figure 2-2-3.

After complete enforcement of PIC/S GMP for pharmaceutical manufacturers, the overall scope of GMP management in Taiwan was further expanded to include GMP for APIs to achieve source management in upstream industries as well as Good Distribution Practice (GDP) of downstream industries to ensure the manufacturing quality of medicinal products and achieve total quality management of the entire pharmaceutical supply chain. Complete enforcement of PIC/S GMP in modern pharmaceutical manufacturers improved quality management at the manufacturer' s end for pharmaceuticals. Measures were also taken to improve source and distribution management of pharmaceuticals to achieve safer drug use for the general public.



▲ Figure 2-2-3 Roadmap for implementing GMP amongst modern pharmaceutical manufacturers

Policies and Outcomes

1. Complete Compliance to the PIC/S GMP by Modern Pharmaceutical Manufacturers

(1) Promotion of PIC/S GMP

a. Taiwan formally became a member of the PIC/S organization on January 1, 2013, ahead of Japan and South Korea, which proved that GMP management and auditing practices of pharmaceutical companies in Taiwan have been successfully aligned to international standards. To improve the quality of pharmaceutical manufacturing, TFDA took active measures in strengthening pharmaceutical production quality and ensure the safety of medicinal products for the public by enforcing complete compliance to PIC/S GMP in all domestic and imported western pharmaceutical manufacturers before December 31, 2014.

b. To maintain stringent management of pharmaceutical manufacturing, follow-up management for modern pharmaceutical manufacturers include routine and non-periodic inspections. Unannounced site inspections were also carried out for specific incidents (such as whistle-blowing incidents, nonconforming products identified during post-marketing quality surveillances, and news events). Theme-based audits were also initiated to further verify the current status of quality management in western pharmaceutical companies. On-site sampling and testing were conducted as part of the quality monitoring process to ensure that quality of medicinal products are maintained within the stated period of expiry.

c. As of the end of December 2015, a total of 120 modern pharmaceutical manufacturers in Taiwan are compliant with PIC/S GMP standards (Table 2-1-1) and 893 overseas manufacturers of imported medicinal products have been assessed as compliant. Also, by the end of December 2015, a total of 251 foreign modern pharmaceutical manufacturers have passed on-site inspections, ensuring a stable market supply of medicinal products.

d. To improve the quality of medicinal gases, consultation and promotion for GMP and PIC/S GMP have been provided since 2002. Total compliance and enforcement of PIC/S GMP was achieved by January 1st 2014. By the end of 2015, a total of 33 medicinal gases manufacturers achieved compliance to PIC/S GMP.

Table2-1-1 **Assessment and qualification of domestic and overseas pharmaceutical companies**

Year	Number of GMP-compliant domestic modern pharmaceutical manufacturers	Total number of PIC/S GMP-compliant domestic modern pharmaceutical manufacturers	Total number of foreign pharmaceutical manufacturers found to be PIC/S GMP compliant after on-site inspections
2007	160	-	93
2008	151	-	118
2009	154	5	140
2010	155	22	157
2011	149	33	180
2012	145	44	209
2013	140	57	213
2014	98	98	246
2015	-	120	251

Note: The numbers of domestic and foreign pharmaceutical manufacturers that have passed the assessments are cumulative every year

2. Sources Management for Modern Pharmaceutical Manufacturers

(1) The Drug Master File (DMF) system has been established to strengthen import management for self-use active pharmaceutical ingredients (API). From October 2009 to the end of 2015, a total of 3,690 DMF applications have completed review process. Among them, 63% were approved, 2,323 cases were approved and 1,367 cases were rejected.

(2) To ensure the safety of drug usage for general public, TFDA has focused on strengthening the quality management of pharmaceutical composition. Based on the promulgation on July 31, 2015, since January 1, 2016, license holders of medicinal products must provide API GMP-compliance certificate to the authority; upload API source information electronically, including manufacture name, address and country; provide API GMP-compliance certificate when the application for license extension is submitted.

(3) PIC/S GMP Guide for API was adopted on May 22, 2013, and complete compliance with GMP for API was achieved by December 31, 2015 to strengthen quality management of API manufacturers. As of the end of December 2015, a total of 223 items from 21 API manufacturers were found to be compliant to GMP regulations, while a total of 1,313 imported API items with product license were verified to be GMP-compliant.

Section 3. Medicinal Products Quality Chain Monitoring

Current Status

After a medicinal product is approved and marketed, uncertainties such as post-approval changes, distribution and storage environments may affect product quality. Therefore it is essential to establish a comprehensive post-marketing supply chain quality monitoring system in order to ensure the quality of medicinal products.

Policies and Outcomes

1. Quality Monitoring of Medicinal Products

(1) Reporting System of Medical Product Defects

A Reporting System of Medical Product Defects was established in 2004 so that healthcare professionals and the general public may immediately report any medicinal products with suspected defects and facilitate subsequent investigation and handling of the incident. A total of 943 reports were received in 2015, of which recalls were initiated for 16 medicinal products.

(2) Quality Monitoring of Medical Products Released to the Market

Quality monitoring items have been selected in response to medicinal product management and policies, risk assessment factors, and requirements of local health bureaus in order to safeguard the quality and safety of medicinal product usage by the general public. In 2015, a total of 212 random samples were taken for testing, of which 211 were compliant with pharmacopoeia regulations while 1 was found to be nonconforming. An official request has been sent to local health bureaus in order to handle the incident by law and recall the medicinal product. Table 2-2-2 shows the results of various monitoring projects. Refer to Table 10 of Annex I for detailed statistics on the post-market quality surveillance of medicinal products throughout the years.

Table2-2-2 **Results of quality monitoring and testing of medicinal products in 2015**

Project title	Total cases	Pass Items	Compliance (%)
Surveillance on the Quality of Uric Acid Synthesis Inhibitors, Corticosteroids, Antibiotics, Hypnotics and Antiepileptic Preparation	115	114	99.1
Sterility Survey of Steroid Eye Drops in Taiwan	57	57	100.0
Surveillance on the Quality of Gentamycin and Vancomycin injections	25	25	100.0
Sterility Survey of SVP in Taiwan	15	15	100.0
Total	212	211	99.5

(3) Monitoring of Global Medicinal Product Quality Alerts

Medicinal product quality alerts around the world are monitored on a daily basis to achieve real-time monitoring potential imports of products that were recalled in other countries, and initiate recalls of these products where necessary. In 2015, a total of 1,104 alerts were monitored, of which six medicinal products recalled overseas were found to have been imported. The importers have been requested to recall these products and withdraw them from the domestic market.

(4) Biological Products Lot Release

457 batches of biological products lot releases have been implemented in 2015. A total of 14,723,496 doses, while two batches of about 228,520 doses were blocked due to temperature nonconformities during the transportation process. Please refer to Table 11 in Annex I for detailed statistics of Biological Products Lot Release.

(5) Monitoring of Virility Drugs on the Market

Illegal addition of pharmaceutical additives to virility products were monitored in 2015. A total of 101 samples were taken and tested, and no virility ingredients had been found. However, two products were found to contain caffeine that was not indicated on the label. All these cases were transferred to local health bureaus for subsequent handling.

(6) Enhancing the Medicinal Product Quality Monitoring Information System

The enhanced Medicinal Product Quality Surveillance Mangement Information System formally came online in January 2015. In addition to improving the convenience of the reporting process, quality information of medicinal product from the product life cycle was also integrated in this system in order to improve handling efficiency of quality incidents.

(7) Promulgation of the Regulations for Medicament Recall

There is a need to enhance medicinal product recall procedures, increase medicinal product license holde's liabilities, and prevent medicinal products with suspect quality from being used by consumers. To establish these regulations, TFDA referred to provisions stipulated in Article 80 Paragraph 3 of the Pharmaceutical Affairs Act to promulgate the Regulations for Medicament Recall, and suspended the corresponding Directions on Implementation of Recall Action of Pharmaceuticalson August 5, 2015.

2. Good Distribution Practices (GDP) Management of Medicinal Products

(1) Medicinal product quality requirements of various health authorities around the world have expanded from the production-oriented GMP to the transport-oriented GDP in order to maintain and safeguard product quality during storage, transportation, and delivery processes.

(2) To ensure the comprehensiveness of the medicinal product quality management system across the entire supply chain, TFDA started gradual establishment of a medicinal product distribution management system in Taiwan since 2011. From 2012 to the end of 2015, TFDA carried out consultation visits with 145 businesses and 290 sites that include pharmaceutical manufacturers, agents, and logistics businesses, of which 107 businesses were given excellent ratings for supporting the medicinal product GDP consultation visits. During the period, TFDA also held training courses to improve quality management concepts for medicinal products amongst transportation and sales businesses.

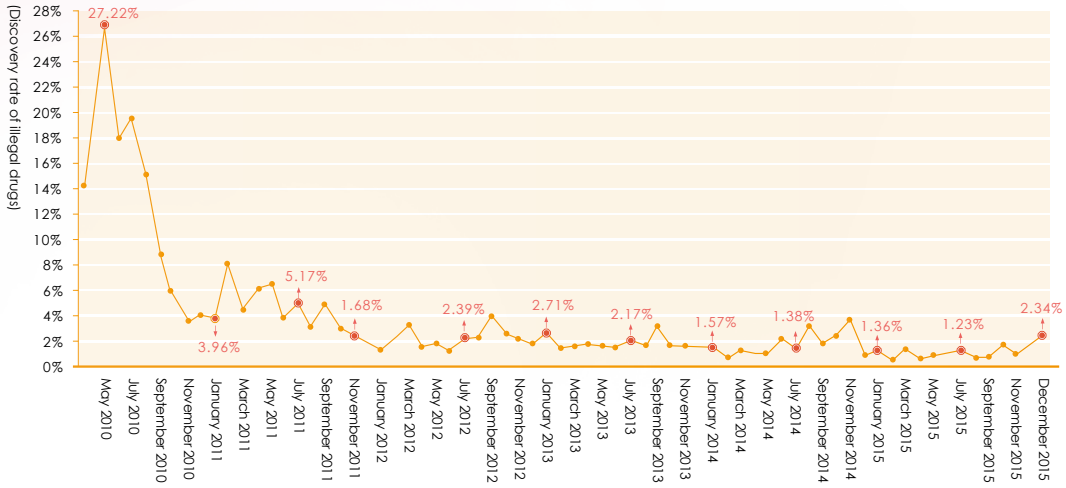
(3) TFDA released the GMP for Modern Pharmaceutical Products (Part 3): Distribution on July 16, 2015 that includes details, items, and schedule for implementing these standards. All manufacturers and dealers holding permits for modern pharmaceutical products must comply with the provisions of the GMP standards by January 1, 2019 to successfully build a comprehensive management system for the pharmaceutical supply chain.

3. Prohibition of Illegal Drugs, Food Products, and Cosmetics

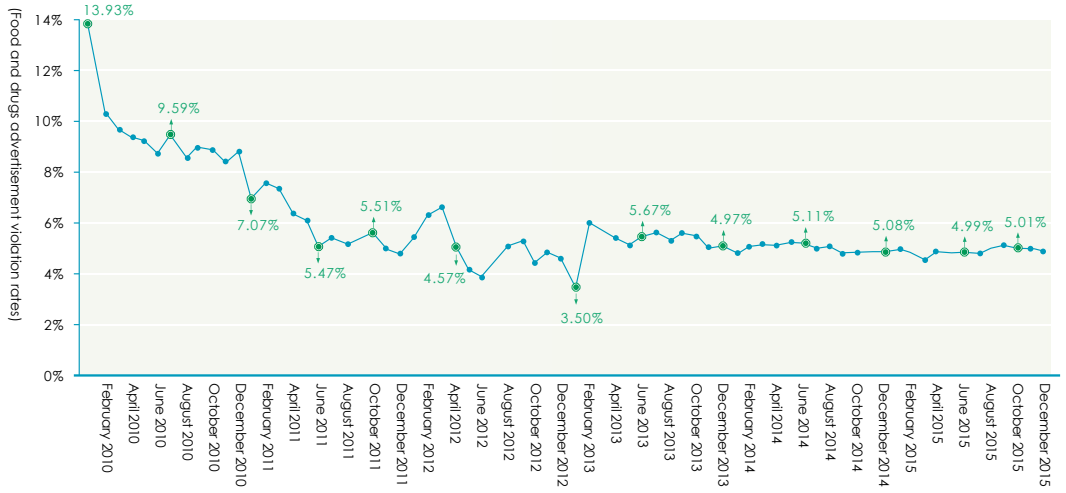
The MOHW assembled the Joint Task Force for the Prohibition of Counterfeit and Inferior Drugs on April 30, 2014, working jointly with various government ministries and agencies such as the Ministry of Justice, National Police Agency, Coast Guard Administration, Customs Administration, and National Communications Commission to strengthen measures for identifying and intercepting illegal drugs and monitor illegal food, drugs, and cosmetic advertisements. Results of activities implemented by the Joint Task Force are listed in the following:

(1) Continued to monitor illegal food, drugs, and cosmetics in the market. In 2015, a total of 659 illegal drugs were identified, of which administrative actions were initiated against 122 cases, with total fines amounting to NT$ 4.324 million. The rate of identifying and intercepting illegal products dropped from 27.22% in 2010 to 2.34% in 2015 as shown in Figure 2-2-4.

(2) In 2015, a total of 7,618 cases of illegal advertisements for food, drugs, and cosmetics products were formally handled by health agencies, with total fines amounting to NT$ 221.138 million. Rate of illegal advertisements dropped from 13.93% in 2010 to 5.01% in 2015 as shown in Figure 2-2-5.



▲ **Figure 2-2-4** Discovery rate of illegal drugs from 2010 to 2015



▲ **Figure 2-2-5** Discovery rate of illegal food and drugs advertisements from 2010 to 2015

(3) Joint Audit Project of Illegal Drugs and Cosmetics

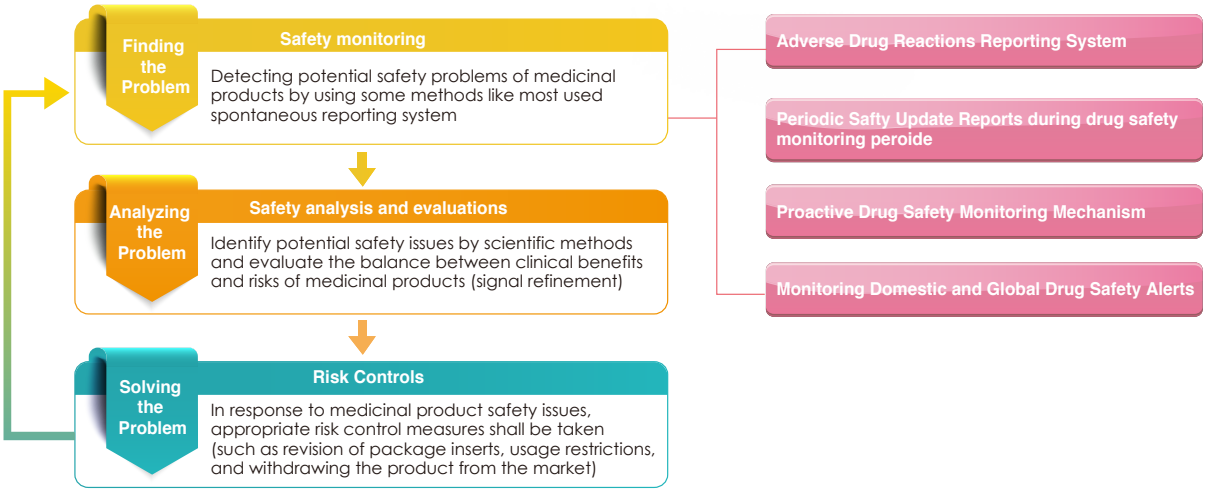
In addition to strengthening the management of upstream active pharmaceutical ingredients (APIs), API manufacturers, and pre-market inspection and registration, TFDA also increased inspection efforts of downstream sales channels for medicinal and cosmetic products. News reports were also aired at the appropriate opportunity to sever sales channels of businesses with ill intent and to effectively deter illegal activities. In 2015, a total of nine joint audit programs were implemented for drugs and cosmetics, during which a total of 1,149 businesses were audited. The sum of fines levied amounted to NT$ 4.714 million.

Section 4. Medicinal Products Safety Management

Current Status

Although the therapeutic efficacy and safety of medicinal products must be preliminarily confirmed by clinical trials before marketing, unknown or unexpected risks of medicinal products

may still surface after marketing due to inherent limitations of clinical trials. Therefore it is an important matter to establish comprehensive post-marketing safety monitoring systems and legal environments for medicinal products (Figure 2-2-6).



▲ Figure 2-2-6 Procedure for post-marketing safety monitoring and risk management of medicinal products

Policies and Outcomes

1. Strengthened Medicinal Product Safety Surveillance

(1) Adverse Drug Reaction Reporting System

The Adverse Drug Reaction (ADR) Reporting System was established in 1998, allowing healthcare professionals, the public, and pharmaceutical companies to report any suspected cases of ADRs. A total of 12,815 ADR reports were received in 2015.

(2) New Drug Safety Monitoring

The Regulations for Drug Safety Monitoring was promulgated in 2004, and stipulated that medicinal product lisence holders of new drugs must submit periodic safety update reports during the preliminary period after approval. A total of 356 medicinal products are under new drug safety monitoring at the end of 2015.

(3) Monitoring Domestic and Global Drug Safety Alerts

Drug safety alerts from Taiwan and overseas are monitored on a daily basis. Where necessary, early warnings as well as re-evaluation of drug safety shall be initiated accordingly. A total of 131 safety alerts were monitored in 2015.

(4) Proactive Drug Safety Monitoring Mechanism

The Proactive Drug Safety Monitoring Mechanism was sequentially established since 2010 realizing the safety profile of medicinal products with important potential risks in Taiwan in order to provide a reference for drug safety re-evaluations and determining risk management measures. Overall safety analysis projects were carried out for 10 medicinal products in 2015.

2. Re-evaluation of Drug Safety and Risk Management

Dosmetic and international information related to medicinal products with suspected safety issues were compiled to re-evaluate drug safety and initiate risk management measures if necessary. In 2015, a total of 45 medicinal products were re-evaluated, of which risk management measures were initiated for 17 medicinal products, such as revision of package inserts, usage restrictions.

Chapter 3

Controlled Drugs Management

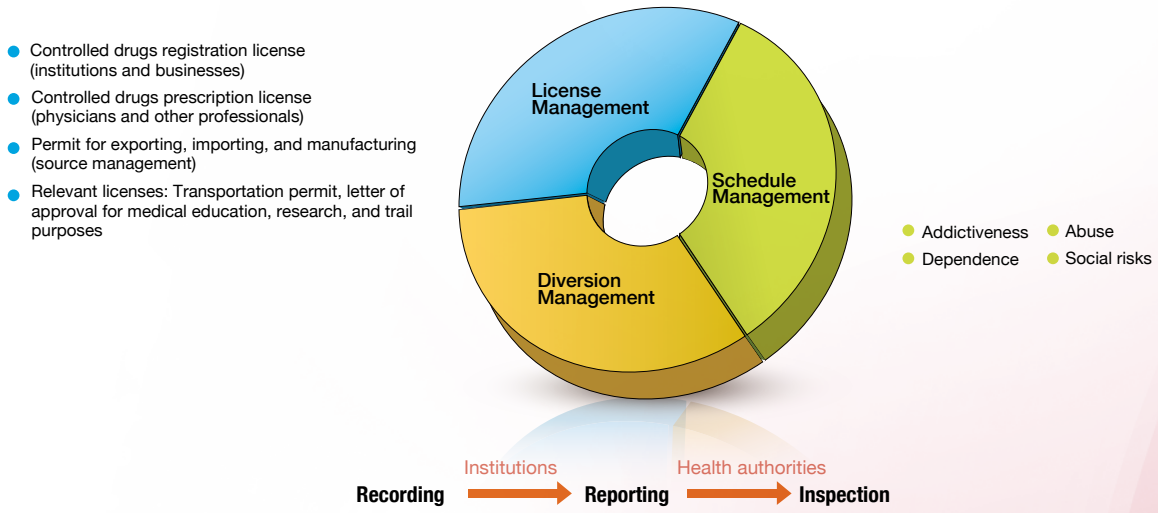
Chapter 3. Controlled Drugs Management

In order to strengthen management of controlled drugs used for medical and scientific purposes in Taiwan, TFDA has established management systems that include regulations, certification, distribution management of controlled drugs as well as early warning, monitoring, and abuse prevention. Total quality validation was also implemented for the Factory of Controlled Drugs in order to improve drug quality and to prevent abuse or illegal use of controlled drugs. Usage for Schedule 1 and Schedule 2 controlled drugs has been increasing because of Taiwan's aging society and increased incidence of various diseases. There was also a drastic growth in the use of sedatives and hypnotics in Taiwan, which was accompanied by incidents of improper prescriptions. In order to prevent improper or illegal use of controlled drugs, management of controlled drugs must be strengthened accordingly.

Section 1. Controlled Drugs Regulations and Distribution Management

Current Status

Drug abuse is a common problem faced by various countries around the world. Improper use of addictive controlled drugs or its illegal distributions make such drugs as dangerous as illegal drugs. Taiwan has imposed controls on narcotics, psychotropic substances, and their preparations according to the Single Convention on Narcotic Drugs, Convention on Psychotropic Substances, and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of the United Nations. *The Narcotics Hazard Prevention Act* was also established to enforce stringent controls. However, some drugs and substances are classified as controlled drugs because of their usefulness in medical applications or scientific research, and are subject to the provisions of the *Controlled Drugs Act* and a control framework composed of license, scheduling, and distribution management (Figure 2-3-1).



▲ Figure 2-3-1 Controlled drugs management framework

Policies and Outcomes

1. Amendments to the Schedules of Controlled Drugs

Controlled drugs are divided into four Schedules according to their addictiveness, dependence, potential for misuse, and social hazards. These Schedules are reviewed by the Ministry of Health and Welfare Controlled Drugs Review Committee and submitted to the Executive Yuan to be publicly announced accordingly. The Committee held two meetings in 2015 and added five additional controlled drugs (listed in Table 2-3-1) in the following Executive Yuan announcement. Table 2-3-2 lists the number of controlled drugs as of the end of 2015.

Table2-3-1 Revisions to controlled drugs schedules in 2015

Date	Regulated Schedule	Name of the controlled drug	Reason for control
March 26	Schedule 2	Methoxymethcathinone	A central nervous system stimulant with hallucinogenic properties. It can be abused and has the potential for causing social hazards.
March 26	Schedule 2	Beta-Keto-Methylbenzodioxolylpentanamine (Pentylone)	A central nervous system stimulant with hallucinogenic properties. It can be abused and has the potential for causing social hazards.
October 7	Schedule 2	Lisdexamphetamine	A derivative of amphetamine can be metabolized as such in the body, so it is controlled as amphetamine.
October 7	Schedule 3	N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, AB-CHMINACA	The effect is like the cannabinoids and it may be abused and caused social hazards.
March 26	Schedule 4	Propofol	It is known colloquially as niunaizhen (milk of amnesia) and used to induce and maintain general anesthesia. It has been abused by drug addicts to stave off addictions, leading to multiple incidents of death or loss of consciousness.

Table2-3-2 Statistics on the number of controlled drugs in each Schedule as of 2015

chedule of Controlled Drugs	Schedule 1	Schedule 2	Schedule 2	Schedule 2	Schedule 4 API	Total
Number	9	179	38	73	7	306

2. Management for the Medical-Use of Controlled Drugs

In 2015, a total of 3 *Medical-Use Controlled Drug Monitoring Committee* meetings were carried out to review 134 cases submitted by regional hospitals or larger medical institutions on long-term use of narcotic drugs for patients with chronic intractable non-cancer pain. In 2015, cases suspected of improper medical prescriptions of controlled drugs found by health agencies were reviewed. The outcomes verified a total 6 cases of improper medical prescriptions of controlled drugs. These said cases were penalized according to law.

3. Management of Controlled Drug Licenses

Refer to Table 12 of Annex I for statistics and data of businesses with controlled drugs registration licenses and individuals with controlled drugs prescription licenses as of the end of 2015. A license, letter of agreement, or letter of approval must be applied for and acquired before manufacturing, importing, exporting, or using controlled drugs for medical, educational, research, and trail purposes. A total of 1,727 such licenses or letters were approved and issued in 2015.

4. Management of Controlled Drugs Inspection

Refer to Table 13 of Annex I for detailed statistics of controlled drug inspection carried out in 2015. Institutions that exhibited relatively higher growth or usage quantities of prescriptions of hypnotics issued in 2013 were screened and selected for the inspection process. 237 institutions were audited. 25 were found to be nonconforming with a violation rate of 10.55%, including 2 cases of medical improper prescriptions. The said violations were penalized according to the relevant laws.

5. Training for Controlled Drugs

To improve familiarity with laws and management practices related to controlled drugs amongst local health agencies, a total of three basic courses and two advanced courses on controlled drug management and laws were held in 2015. These courses were attended by a total of 442 individuals.

Section 2. Pharmaceutical Plant of Controlled Drugs Management

Current Status

According to the Controlled Drugs Act, import, export, manufacture, and sales of Schedule 1 and Schedule 2 controlled drugs can only be carried out by the TFDA Pharmaceutical Plant of Controlled Drugs. The mission of the Pharmaceutical Plant of Controlled Drugs is to meet the pain control medical requirement of Schedule 1 and Schedule 2 controlled drugs, and to supply the relative pharmaceutical products during disasters and emergency mobilization.

The TFDA Pharmaceutical Plant of Controlled Drugs must comply with PIC/S GMP as well as regulations pertaining to the management, production, distribution, and loss of controlled drugs provided in the Controlled Drugs Act in order to ensure the quality and safety of the controlled drugs.

Policies and Outcomes

1. Supply of Schedule 1 and Schedule 2 Controlled Drugs

In order to provide a sufficiency of Schedule 1 and Schedule 2 controlled drugs needed by medical services in Taiwan, Pharmaceutical Plant of Controlled Drugs apply three main methods of self-production, commissioned production, and imports. The following lists the outcomes of such measures:

(1) Pharmaceutical Plant of Controlled Drugs independently produces nine products in compliance with the PIC/S GMP specifications to ensure product quality, safety, and therapeutic efficacy. The turnover from selling drugs amounted to NT$ 586,406,000 in 2015. Refer to Table 14 of Annex I for statistics for the revenue of Pharmaceutical Plant of controlled drugs.

(2) Production for a total of five Schedule 1 and Schedule 2 controlled drugs with greater demands in medical institutions and the market was commissioned to domestic pharmaceutical manufacturers that have demonstrated excellent performance, under the conditions that the said manufacturers must enforce safety and quality management measures aligned with those of Pharmaceutical Plant of Controlled Drugs.

(3) To provide more diverse selection for pain medication during treatment, the TFDA developed new chemical entities (NCE), new delivery paths, and new dosage forms of opioids according to the needs of the medical institutions and patients. In 2015, the fentanyl buccal soluble films was imported for the first time as an acute moderate to severe painkiller agent, benefiting patients suffering from severe pain.

2. Continuing Improvement to Product Quality and Standards of Pharmaceutical Plant of Controlled Drugs

(1) The Morphine Sulfate Sustained Release FC Tablets - 30 mg were rewarded with the Symbol of National Quality (SNQ) in the modern pharmaceuticals category in 2014 as well as in 2015.

(2) Post-marketing tracking studies were carried out for Morphine Sulfate - 15 mg to ensure product quality, safety, and therapeutic efficacy.

(3) On-job-training for personnel was enhanced for PIC/S GMP, controlled drugs, and medicinal product management

3. Building New PIC/S GMP Factories

To expand independent production capacities for Schedule 1 and Schedule 2 controlled drugs and improve product quality, the TFDA initiated the New Production Building Construction and Renovation Project for Pharmaceutical Plant of Controlled Drugs. Every step of the construction project monitored closely which allowed the progress to be slightly ahead of schedule. The new factory building was set for completion in 2017 and shall be used for production purposes after qualifying PIC/S GMP assessments in order to supply public and medical institutions with Schedule 1 and Schedule 2 controlled drugs they require.

Section 3. Controlled Drug Alerts and Monitoring

Current Status

Drug abuse is becoming an increasingly global and complex challenge. Abuse of illegal drugs gravely affects physical and mental health, economic development, social stability, public security, and may even impact overall national competitiveness.

To effectively prohibit and prevent drug abuse and build a healthy society well-protected from the hazards of narcotics, prevention must be regarded as the main goal of policies for preventing drug abuse which shall start with source management and early warning systems.

Core activities include compilation of drug abuse reports and information, establishing a comprehensive early warning system, enhancing management efforts for controlled drugs, and strengthening regional strategic alliances against drug abuse in order to achieve early warning functions and eliminate rampant drug abuse in Taiwan.

Policies and Outcomes

1. Collecting and Compiling National Drug Abuse Information

To get an insight to status of domestic drug abuse and control the medication patterns in Taiwan, monitor current status of national drug abuse, and identify trends drug abuse behaviors, statistics such as drug abuse urine tests, non-urine tests of suspected drugs and controlled drugs cases, and discovery of illegal drugs in the Taiwan region shall be compiled to form the Drug Abuse Cases and Testing Statistics.

2. Notification on the Prevention of Controlled Drugs Abuse

(1) To achieve effective understanding of epidemic trends in the abuse of controlled drugs, the TFDA established the Drug Abuse Reporting System (http://dars.fda.gov.tw/) that compiles analyses and report data every month. In 2015, a total of 18,399 drug abuse cases were reported by medical institutions. The top 3 drug abuse categories were heroin with 11,697 individuals (63.6%), (meth) amphetamine with 5,672 individuals (30.8%), and ketamine with 1,556 individuals (8.5%).

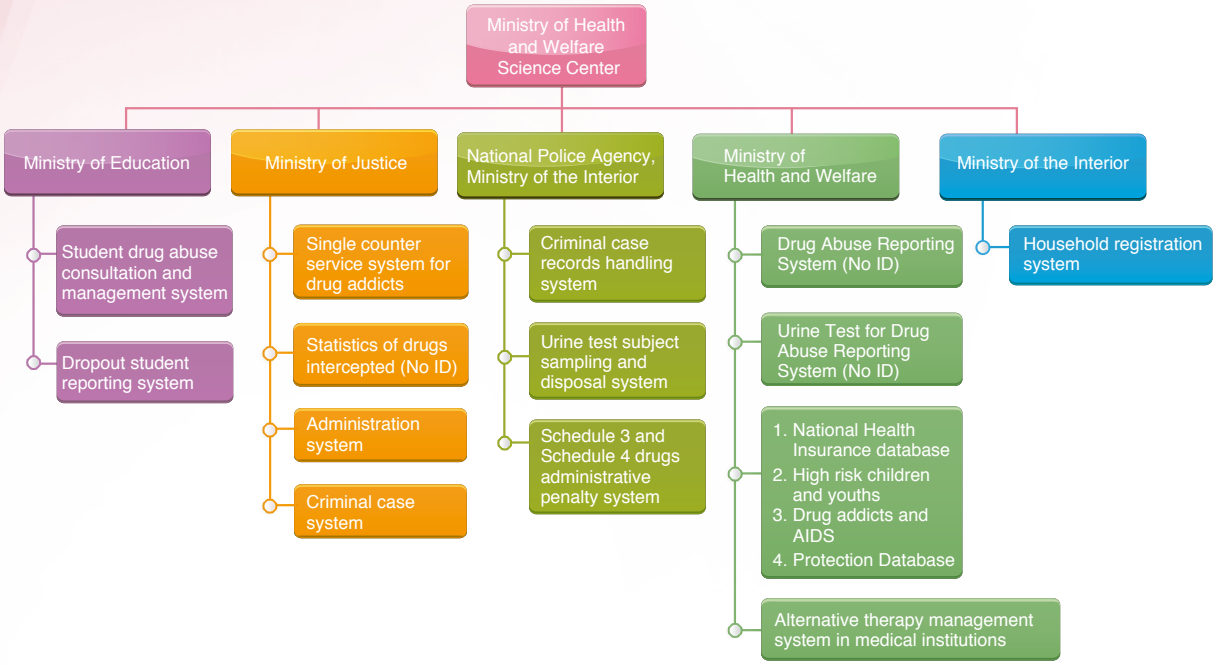
(2) Demographics of the reported cases were analyzed, the drug abuse cases by gender consists of male and is mostly distributed in between 30 years and 40 years old (35.9%) and between 40 years and 50 years (32.9%). Among the drug categories used by all age groups, ketamine was the most common drug abused by those below 19 years of age, (meth) amphetamine was the most common drug abused by those of 20 to 29 years of age, and heroin was the most common drug abused by those over 30 years of age . Individuals aged over 70 years (inclusive) primarily abused zolpidem.

(3) Analysis for the most common sites for drug abuse were friend's residence, on streets, and at the dance clubs/pub/hotel. The leading sources of illegal substances were drug dealers/ vendors followed by friends. The top reasons for drug abuse were dependence (36.3%) followed by stress relief (17.5%).

2. Integrating the Cross-departmental Narcotics and Drug Abuse Reporting System Database

(1) The drug abuse issue is extremely complex. The Ministry of Justice (MOJ), Ministry of the Interior (MOI), Ministry of Education (MOE), Ministry of Health and Welfare (MOHW), and Ministry of Labor (MOL) have been authorized to tackle this issue. To accurately observe the state of drug abuse in Taiwan, the Executive Yuan has assigned all relevant ministries to contribute their ideas and build a consensus to integrate various narcotics and drug abuse reporting system databases from multiple ministries and departments. The aim was to employ big data analytics to clarify the three major aspects of drug abuse: (1) Narcotics User Profile, (2) Effective Treatment Model, and (3) Narcotics Production and Marketing Course, an accurate understanding of drug related data and analysis. These information can then be used as a reference to propose various preventive strategies.

(2) As of December 2015, a total of 17 narcotics and drug abuse reporting system database (from the MOJ, MOI, MOE, and MOHW) were integrated and placed under the data science center of the MOHW (Figure 2-3-2) as a reference for implementing early warning or preventive strategies.



▲ **Figure 2-3-2** Integration of narcotics and drug abuse reporting system database from multiple departments

3. Establishment of Technology and Database for Drug Abuse

In response to the deteriorating drug abuse and addiction issues, TFDA continues to dedicate the developing new technology and establishing databases to achieve the prevention effectively and control of drug abuse. Important outcomes of 2015 are listed in Table 2-3-3.

Table2-3-3 Major achievements of drug abuse assay technologies and database establishment in 2015.

Results	Benefits
Completed the synthesis of 13 standards, including five synthetic cannabinoids, six aminophenones, two stimulants ,phenazepam, and establishment standard spectrum database.	Established standards and spectrum database for comparing test results and meet the techniques for drug abuse.
Established the 96-well solid phase extraction plate for urine pre-treatment and UPLC-Q-LIT mass spectrometer and developed a high performance assay to 210 abuse drugs in urine.	Accelerated the development and optimization of systematic techniques for drug abuse.
Established a pre-treatment technique for solid phase extraction and GC-MS/MS quantitative urine assays for 38 drugs that include synthetic cathinones and synthetic phencyclidines.	To accelerate analysis time for synthetic cathinones and synthetic phencyclidines.

Section 4. Preventing the Abuse of Controlled Drugs

Current Status

Drug abuse and addiction issues have recently became a crucial problem that is in urgent need of solution by the health agencies of government. Drug abuse can easily harm personal health, even lead to mental problems, and also increased unemployment rate and crime which

cause negative impacts to social stability and national development. Therefore, it' s necessary to make efforts in strengthening knowledge of controlled drugs abuse prevention amongst the public, and draft a more effective strategy. Educate actively on the harm of drug abuse and camouflage drugs patterns to enhance people's self-protection ability.

Policies and Outcomes

1. Multi-agency Collaboration for the Prevention of Drug Abuse

(1) Worked with the MOJ and MOE to implement the Anti-Drug Abuse Education and Advocation Project. TFDA joined forces with drug abuse prevention centers in every cities to organize 10 Freedom from Drugs advanced instructor training courses attended by a total of 3,241 individuals. The TFDA also hosted the art competition of creative performing against drug abuse named Theatrical Anti-Drug Abuse-Show Yourself. A total of 8 winning teams were selected, and performances of the winning entries were compiled in a digital video disk and sent to every local health bureaus, medical institutions, NGOs, and drug abuse education resource centers for reference purposes.

(2) Worked jointly with the MOHW Health Promotion Administration (HPA) to host the Integrated Marketing Plan for Promoting Educational Programs on the Prevention of Addictive Substance Abuse. In 2015, an alliance was formed with 52 businesses, allowing pharmacists to hold 53 sessions of educational seminars for preventing the abuse of addictive substances at business locations. The 4 Cell Manga Competition against Cigarette Smoking, Betel Nuts Chewing, and Drug Abuse was held. Youths, college students, and adults alike unleashed their creativity to highlight the health hazards caused by tobacco products, drugs, and betel nuts. Total of 565 entries submitted by the colleges, universities, and adults category as well as the youth category, 8 winning works were selected from each group.

2. Seed Instructor Training for the Prevention of Drug Abuse

(1) In 2015, a total of six sessions of advanced seed instructor training were held for 319 candidates in northern, central, and southern Taiwan. These seed instructors shall then lead training courses to strengthen public understanding on correct usage of controlled drugs and prevention of drug abuse.

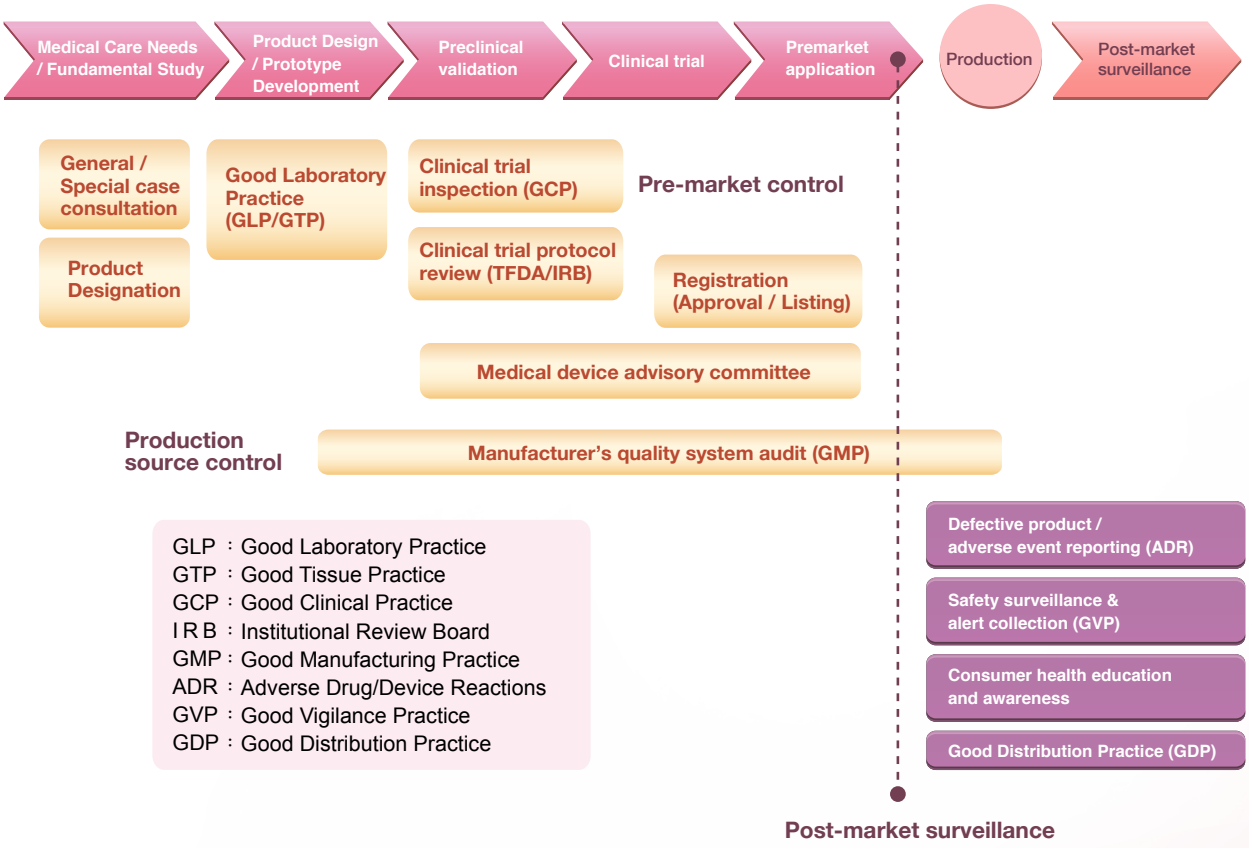
(2) In 2015, a total of 12 sessions of Training on the Correct Usage of Controlled Drugs were held in northern, central, southern, and eastern Taiwan for 903 physicians from anesthesiology, psychiatry, and family medicine departments to improve their familiarity with the proper issuance of prescriptions as well as laws on controlled drugs.

Chapter 4

Medical Devices Management

Chapter 4. Medical Devices Management

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 due to the aging of Taiwan's society. In response to 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 2-4-1) that includes harmonization with international standards and regulations, production source control, pre-market gatekeeping, 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, effectiveness, and quality of medical devices, and to promote developments of Taiwan's biotech and pharmaceutical industry, creating an environment beneficial for consumers, industry, and government.



▲ Figure 2-4-1 Total product life cycle management system for medical devices in Taiwan

Section 1. Medical Device Regulatory Standards and Product Review

Current Status

To strengthen the pre-market management over medical device safety, effectiveness, and quality, TFDA implements regulatory review of pre-clinical testing, clinical trials, and product testing standards for registration. The provision of regulatory consultation and special case assistance for domestic applications of innovative research and development is a key foundation to facilitate the development of the industry.

Policies and Outcomes

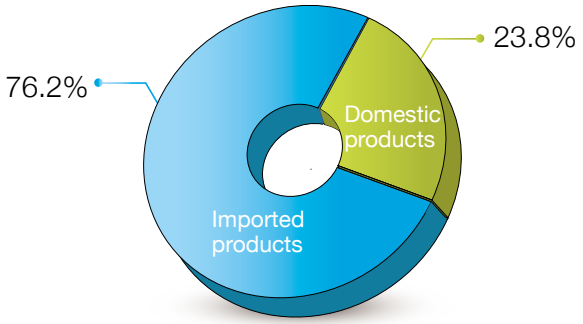
1. International Harmonization of Regulatory Standards

Medical device regulations and standards promulgated and revised in 2015 include *Reference Guidance for Medical Software Categorization and Classification, List of Recognized Standards for Medical Devices, and Regulation of Unique Device Identification (UDI) System for Medical Devices*. Refer to Table 15 of Annex I for more details. In 2015, a total of five communication meetings and 24 work meetings with experts and stakeholders were held, and global regulatory practices of medical devices were referenced to develop a full text draft of act specifically governing the medical devices in Taiwan.

2. Review of Medical Devices

(1) Categorization and Classification of Medical Devices

Medical devices in Taiwan are divided into three classes and 17 major categories (with over 6,200 items) according to their different characteristics and risk levels. They include Class 1 (low risk), Class 2 (medium risk) and Class 3 (high risk) medical devices. As of the end of 2015, a total of 40,841 valid medical device licenses had been issued, of which 23.8% were for domestic products while 76.2% were for imported products (Figure 2-4-2).



▲ Figure 2-4-2 Proportion for the number of valid licenses of domestic and imported medical devices in 2015

(2) Comprehensive Review Mechanisms for the Registration of Medical Devices

a. Recognized Standards and Product Guidances for Medical Devices

To improve the quality of medical device reviews and shorten review time, TFDA adopted recognized international standards on medical devices and developed product technical guidance documents on medical devices. As of the end of 2015, TFDA had recognized a total of 918 international standards on medical devices and 90 medical device product guidances from the U.S. Food and Drug Administration (FDA), as well as announced 50 product technical guidances on medical devices.

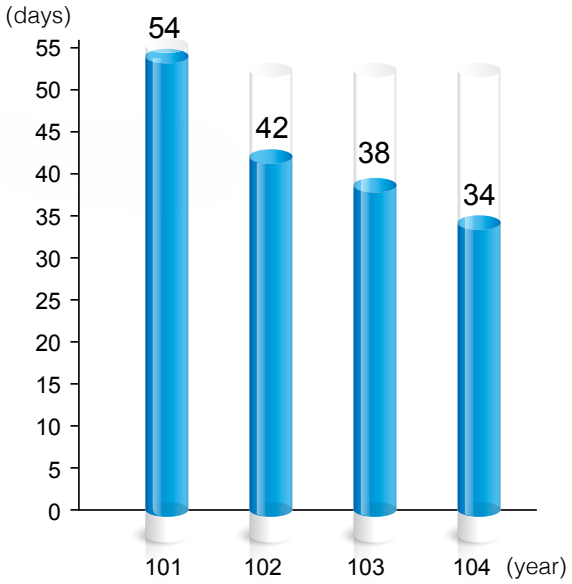
b. Optimization Measures for Review Processes of Medical Device Registration

Since November 2015, a pilot run of a 2-phase administrative and technical review system was initiated for the registration of Class 2 and Class 3 (medium and high risk) medical devices. Upon receiving an application, the TFDA will complete a preliminary screening of administrative documents within 10 days before initiating expedited review of technical data to optimize the review process. In 2015, a total of 5,321 medical device registration reviews were completed, including 123 innovative medical devices with no similar products. This was a 9% increase (113 applications) compared to 2014, improving public accessibility and utilization of emerging medical devices in Taiwan.

(3) Establishing a Quality Environment for Medical Device Clinical Trial Regulations

a. In 2015, TFDA promulgated the *Good Clinical Practice for Medical Devices (GCP)* that was harmonized with ISO 14155:2011 and revised the Application Notes for Medical Device Clinical Trial Protocols, providing a reference for manufacturers and hospitals intending to conduct clinical trials of medical devices.

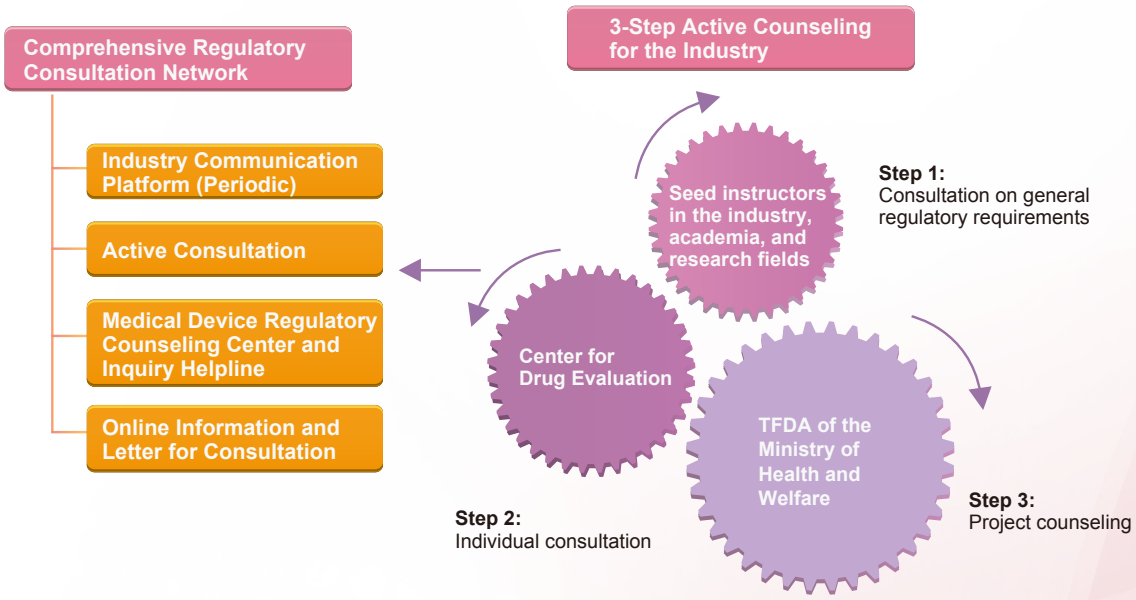
b. In 2015, a total of 74 clinical trial application reviews were completed. The average number of review days was 34, which was a significant reduction by 37% compared to 54 days in 2012 (Figure 2-4-3).



▲ Figure 2-4-3 Average number of review days for clinical trial applications throughout the years

(4) Comprehensive Regulatory Counseling Mechanism for the Industry

a. In response to the development boom of the medical device industry in Taiwan, and to encourage the research and development of innovative medical devices, TFDA established a comprehensive regulatory inquiry and consultation network, strengthened the seamless three-step counseling mechanism, and actively seeking out high-end innovative medical devices with promising potential to provide them with consultation (Figure 2-4-4).



▲ Figure 2-4-4 Comprehensive regulatory consultation network for medical devices

b. Outcomes of the Regulatory Inquiry and Consultation for the Industry
As of December 2015, a total of 16 domestically manufactured medical devices were approved for marketing, 10 were approved for clinical trials, and five outcomes of R&D efforts were successfully transferred to the industry. This included the world' s first clinical trial for high level treatment of cartilage defect, the world's first portable negative pressure wound therapy (NPWT) system, computer-aided ultrasound diagnostic system for thyroid glands, and the approval for marketing of Taiwan's first domestically manufactured bio-tissue adhesive.

c. Expanding the Medical Device Inquiry and Consultation Center
A total of six helplines for medical device inquiry (with four dedicated personnel and two voice message lines) were established. The helplines received a total of 19,926 incoming calls in 2015, which were 3,650 more calls compared to 2014. TFDA also worked with the Biomedical Science Park and provided four inquiry and consultation sessions to companies within the park.

d. Training Seed Regulatory Personnel
In 2015, seed personnel were newly recruited from units in the centers of industry-academia partnerships, innovation & incubation, and medical device research & development. After the annual training and assessment, there were 45 qualified seed personnel and 11 reserved seed personnel who were announced publicly on the TFDA website, allowing external parties to contact them for inquiry services.

Section 2. Medical Devices Source Management

Current Status

To ensure the stable production and management of medical devices are maintained, a source management system for medical devices has been enforced in Taiwan in order to supervise the quality management system and support product quality improvements of medical device manufacturers. A systematic management to align with international GMP regulatory mechanisms for medical devices were also employed to improve the competitiveness of the medical device industry in Taiwan and allow the industry to export their products to the international market. Through a two-track system of on-site audit and quality system documentation review for medical device manufacturers, objectives of source management would thereby be achieved.

Policies and Outcomes

1. Enhancing the Consistency of Inspections Carried out by Auditing Organizations

There are four GMP auditing organizations for medical devices in Taiwan, including the Center for Measurement Standards of the Industrial Technology Research Institute (ITRI), Taiwan Electronics Testing Center (ETC), Metal Industries Research Development Centre (MIRDC), and Plastics Industry Development Center (PIDC). In 2015, a Quality and Competence Improvement Program for Medical Device Inspection was carried out to review case studies of inspection processes and suspect issues in order to ensure that the inspection results are traceable to a consistent standard and ensure that relevant systems, regulations, and criteria employed in factory audits are harmonized with international standards. Guidelines for Commissioning GMP Certification of Medical Devices (Draft) were also developed which stipulated responsibilities, competences, experiences, and training required for auditing organizations and personnel commissioned to conduct GMP certification processes.

2. Registration Management of Medical Device Manufacturers

Before a medical device can be placed on the market, the quality system of its manufacturer must comply with Taiwan's medical device GMP standard.

Medical device importers can apply for compliance with Taiwan's Quality System Documentation (QSD) requirement, or apply for on-site audits for overseas medical device manufacturers. For medical device manufacturers located in Taiwan, on-site audits will be the primary means of inspection.

By the end of 2015, a total of 685 valid GMP registration letters for domestic medical device manufacturers were issued, while 3,640 QSD registration letters for imported medical devices were issued (as shown in Figure 2-4-1).

Table2-4-1 **Number of valid GMP/QSD registration letters for medical devices**

Year	Number of valid GMP/QSD registration letters for medical devices	
	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

Section 3. Medical Device Quality Chain Monitoring

Current Status

Risk assessment mechanisms are used every year to target specified items. Resources from local health bureaus are integrated to carry out medical device quality monitoring plans. Post-market quality surveillance is carried out through quality sampling and testing of marketed products from drugstores, pharmacies, medical device vendors, manufacturers or agents.

Policies and Outcomes

1. Post-marketing Quality Surveillance of Medical Devices

Reports and alerts of adverse events of medical devices and other related information are used as a reference to identify medical devices with high potential risks and high levels of hazards and include them in the quality surveillance. In 2015, a total of 46 items were sampled and underwent quality and package labeling checks. All items were found to be compliant with quality checks, while 37 were compliant with package labeling checks (conformity rate of 80.4%). The nine nonconforming products were officially reported to the responsible local health bureaus for handling in accordance with law. Table 2-4-2 shows the results of various surveillance programs.

Table2-4-2 **Results of quality surveillance for medical devices in 2015**

Name of Project	Total cases	Inspection Items			
		Quality		Package labeling	
		Conforming No.	Nonconforming No.	Conforming No.	Nonconforming No.
Survey on the Quality of Non-Invasive Sphygmomanometers in Taiwan	18	18	0	18	0
Sterility Surveillance of Peritoneal Dialysis Catheters and Hemodialysis Catheters in Taiwan	28	28	0	19	9
Total number of medical devices (percentage)	46 (100)	46 (100)	0 (0)	37 (80.4)	9 (19.6)

2. Joint Post-market Audit of Medical Devices

To effectively supervise the compliance of package labeling of marketed medical devices with the approved documentation and to enforce provisions of Article 75 of the *Pharmaceutical Affairs Act*, TFDA selected four medical devices that had high potential for violations, high risks, and were targets of major public concerns, and worked with local health bureaus to conduct joint audits for 1,737 devices. A total of 50 violations (for a violation rate of 2.9%) were found, with the primary form of violation being labeling and package insert contents that failed to conform with the provisions of the *Pharmaceutical Affairs Act*. Violative products had been handled by regional jurisdictions in accordance with law (Table 2-4-3).

Table2-4-3 **Statistical analysis of joint audit results of medical devices in 2015**

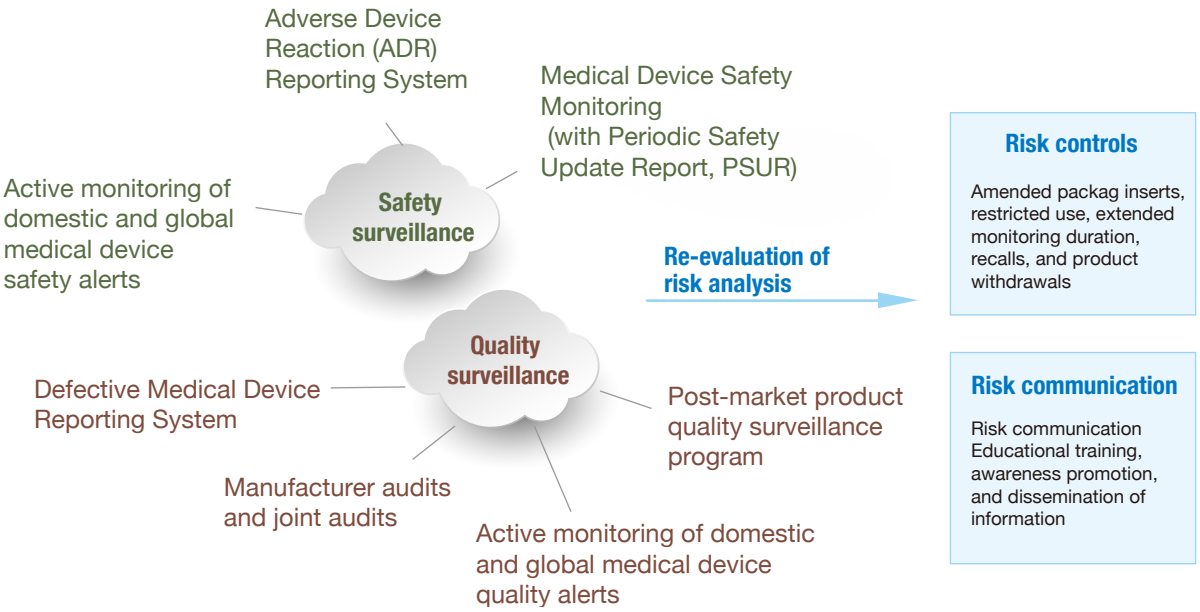
Product category	Counties & cities inspected	Businesses inspected	Product labeling		
			Items inspected	Violations	Violation rate (%)
Platelet storage systems	9	73	16	5	31.2
Transcutaneous electrical nerve stimulators, facial transcutaneous electrical stimulators, ultrasound therapy devices	9	73	70	2	2.9
Powered heating pads	9	73	67	5	7.5
Blood pressure meters	21	370	985	24	2.4
Blood glucose meters (including blood glucose test strips)	21	370	599	14	2.3
Total	69[a]	443	1,737	50	2.9

Note: a: As the audits were carried out in different schedules, a number of counties, cities, or stores/street vendors may have been audited twice.

Section 4. Medical Device Safety Management

Current Status

To establish a comprehensive post-market safety surveillance system, TFDA established an adverse device reaction (ADR) reporting system to receive feedback and alerts from users, actively monitored safety alerts and information in Taiwan and other countries, enhanced post-market distribution management, and improved awareness of relevant regulations and policies (Figure 2-4-5). Effective quality surveillance systems have been employed to quickly acquire product safety alerts and facilitate timely handling, corrective and preventive measures, implementation of risk control and risk communication by regulatory agencies for achieving effective management.



▲ **Figure 2-4-5** Post-market risk control mechanism of medical devices

Policies and Outcomes

1. Strengthening Post-market Safety Monitoring of Medical Devices

(1) Active Monitoring of Domestic and Global Medical Device Safety Alerts

a. In 2015, a total of 375 adverse reactions, 3,453 defective medical devices, 178 adverse events in clinical trials, and 138 periodic safety update reports were uploaded to the Post-market Quality Management System for Food, Drugs, and Cosmetics. These cases have underwent data normalization as well as subsequent analysis and evaluation.

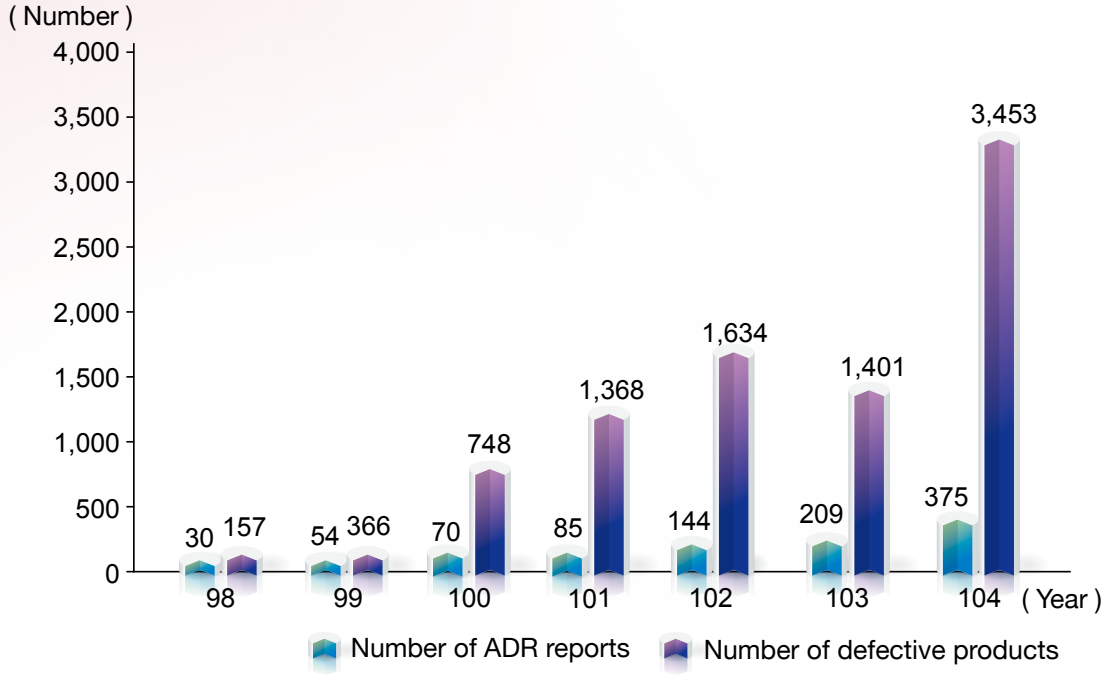
b. In 2015, a total of 1,936 domestic and global safety alerts were actively monitored, including 715 product alerts and 1,221 recall notifications. TFDA selected a total of 136 medical device user safety messages concerning the domestic public, and translated them into summaries for announcement.

(2) Joining the Global Vigilance Report Exchange System

The TFDA is a member of the Safety Alert Dissemination System (SADS) of the Asian Harmonization Working Party (AHWP), which allows access to safety alerts and recalls that are announced internationally. In 2015, a total of 1,416 messages were received. After evaluation, it was revealed that 510 of these messages were related to Taiwan, whereupon notifications were immediately released to the relevant businesses to initiate response measures.

(3) Improving ADR and Defective Product Reporting for Medical Devices

In addition to organizing continuous awareness programs and seminars to better motivate medical institutions, manufacturers, and members of the public to report adverse reactions and defective products, TFDA also established a program in 2015 to support seed hospitals in establishing internal ADR reporting mechanisms. Personnel relevant to the notification process underwent training to improve the number and quality of ADR reports. The number of ADR reports rose from 30 in 2009 to 375 in 2015, while the number of defective product reports rose from 157 to 3,453 (Figure 2-4-6).



▲ **Figure 2-4-6** Defective product / ADR reports of medical devices

(4) Suspension of GMP & QSD Certification

To ensure the quality of medical devices, a phased process for reviewing expired GMP/QSD registration letters were completed in 2015. The review resulted in suspension of 303 medical device licenses relating to 133 pharmaceutical firms. These companies were notified to have their manufacturers re-apply for medicament manufacturing licenses (the GMP/QSD registration letters), or apply for changes to their medical device manufacturing licenses by switching to other manufacturers that have already acquired medicament manufacturing licenses before they can continue the production or import of relevant products.

2. Pharmaceutical Firm and Product Distribution Management

(1) Expanding the Types of Some Class 2 Medical Devices that Can be Sold Online

Revisions to the *Registration Requirements of Mail-Order Purchase for Medical Devices* were promulgated on October 15, 2015, allowing the online sales of 8 items of medium risk Class 2 medical devices, including surgical mask, alcohol pad, providone-iodine pad, vaseline gauze, adhesive bandage, contact lens cleaning and care product, and picture archiving and communication system.

(2) Strengthening Post-market Regulation of Class 1 Medical Devices

The regulation of Class 1 medical devices makes reference to the listing method employed by advanced countries in the Europe and U.S., where suppliers complete an application form and declare that products conform to the scope identified with Class 1 medical devices. Their approved functions shall be restricted to the scope identified in the device category and classification. However, incidents of errors in supplier declarations have occasionally been found. To strengthen the postmarket regulation of Class 1 medical devices, TFDA initiated a Class 1 license re-evaluation program in 2014. By 2015, a total of 36 licenses were found to have stated functions that did not conform to the scope identified in the original declaration. These licenses had all been revoked accordingly.

(3) Promoting Good Distribution Practice (GDP) for Medical Devices

To ensure that medical device importers, dealers, or pharmacies are capable of maintaining product quality specified by the original manufacturer during transport and sales activities, the TFDA began implementing regulatory measures for the distribution of medical devices starting in 2014 and promulgated the Good Distribution Practice (GDP) for Medical Devices on June 18, 2015. As of the end of 2015, TFDA organized six training seminars and two outcome presentation seminars, and completed consultation visits to 35 medical device vendors.

(4) Implementing the Unique Device Identification (UDI) System

The three issuing agencies and their coding specifications (GS1/GS1-128, HIBBC/HIBC, ICCBBA/ISBT 128) recommended by the International Medical Device Regulators Forum (IMDRF) and U.S. FDA were adopted by TFDA to promulgate the Unique Device Identification (UDI) System Regulation on October 30, 2015. This would allow both importers and domestic manufacturers to adopt globally recognized UDI coding and barcode specifications for medical devices in establishing the basis for automated distribution management.

3. Strengthening Awareness of Medical Device Regulatory Policies

(1) Promotion of Key Policies

In 2015, TFDA organized about 30 promotional activities that included training sessions and seminars for Good Distribution Practice (GDP) of medical devices, introduction and use of the UDI system, medical device GCP inspection workshop and regulation revisions, medical device clinical trial IRB forums and symposiums, medical device adverse event analysis and management, for enforcing the implementation of various key policies.

(2) Enhancing Communication With Medical Institutions

To help medical institution personnel acquire an effective understanding of the causes for ADRs as well as user experiences of medical devices, and to gain familiarity with proper handling methods, procedures, and government regulatory practices, TFDA held education and training courses at six medical institutions in northern, central, and southern Taiwan in 2015. The courses targeted non-ideal situations primarily during the process of operating medical devices in local medical institutions, such as failure to perform, malfunction, or anomalies of medical devices, and allowed for information exchanges and sharing of experiences.

(3) Establishing a Communication Platform for Industry Associations

In 2015, TFDA held two communication meetings with industry associations of medical devices. The platform allowed direct dialogue with the industry in order to achieve a mutually beneficial consensus over relevant policies and facilitate the promotion and implementation of future policies.

(4) Strengthening Regulatory Knowledge and Capacity for Medical Devices amongst Academic Research Institutions

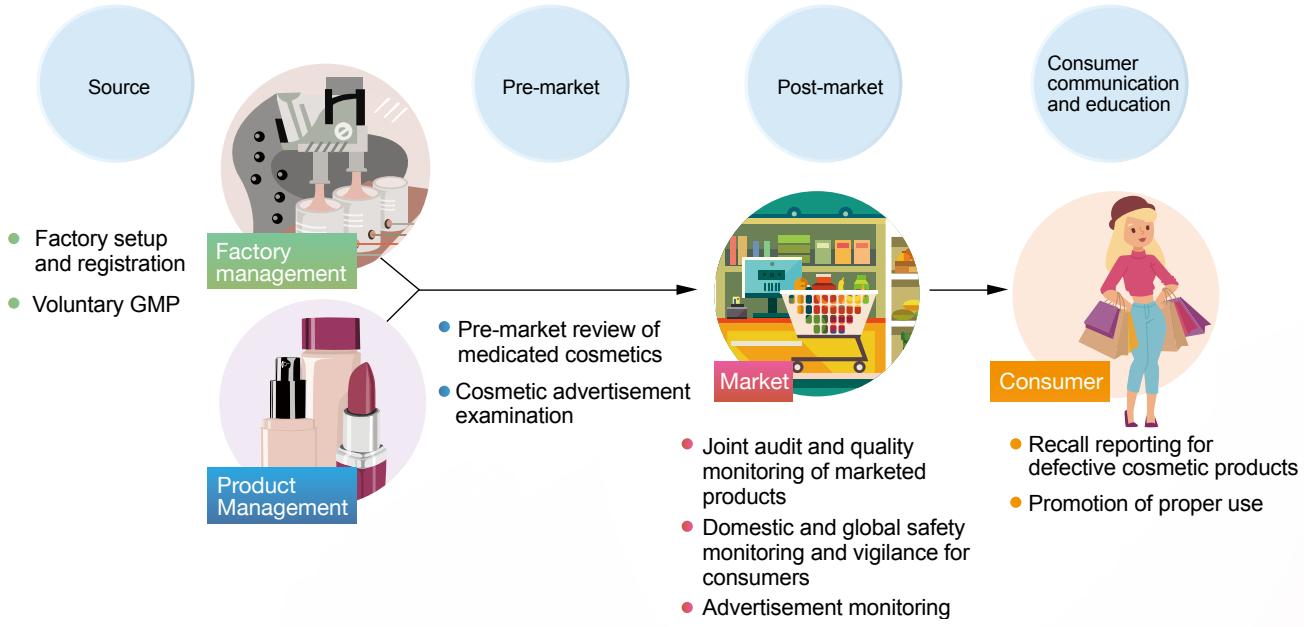
TFDA held three seminars promoting awareness of medical device regulations in various universities, colleges, and medical engineering institutions, with the hope that the academia and industry may promptly apply regulatory concepts pertaining to medical devices in the initial phases of research and development (R&D) in order to shorten R&D cycle time and costs and to commercialize the R&D outcomes as early as possible.

Chapter 5

Cosmetics Management

Chapter 5. Cosmetics Management

The current cosmetics management system is divided into production source control, pre-market management, and post-market surveillance (Figure 2-5-1). Source control includes ensuring manufacturers comply with *Establishment Standards for Cosmetics Manufactory* and promoting voluntary cosmetic Good Manufacturing Practice (GMP) for cosmetics. Pre-market management includes registration of medicated cosmetics and examination of cosmetic advertisements before broadcasting. Post-market surveillance focuses on implementing cosmetics quality surveillance programs, joint audits spanning multiple counties and cities, establishing a product adverse event reporting system for cosmetics, regular monitoring of domestic and global cosmetic safety alerts, and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.



▲ **Figure 2-5-1** Cosmetics life cycle management

Section 1. Cosmetics Regulations and Product Review

Current Status

Current practices of cosmetics management in Taiwan are divided into medicated cosmetics (which must be registered prior to marketing) and regular cosmetics. Cosmetic advertisements must be pre-approved before broadcasting. However, countries in the EU and ASEAN as well as the US currently employ routine inspections to replace pre-market reviews of products, and have been able to effectively direct management resources to market surveillance. To better align with international regulations, achieve effective monitoring of product quality and safety, maintain the hygiene and safety of cosmetic products, and safeguard the public health, TFDA has referenced cosmetic management systems around the world to reform the cosmetic hygiene management system.

Policies and Outcomes

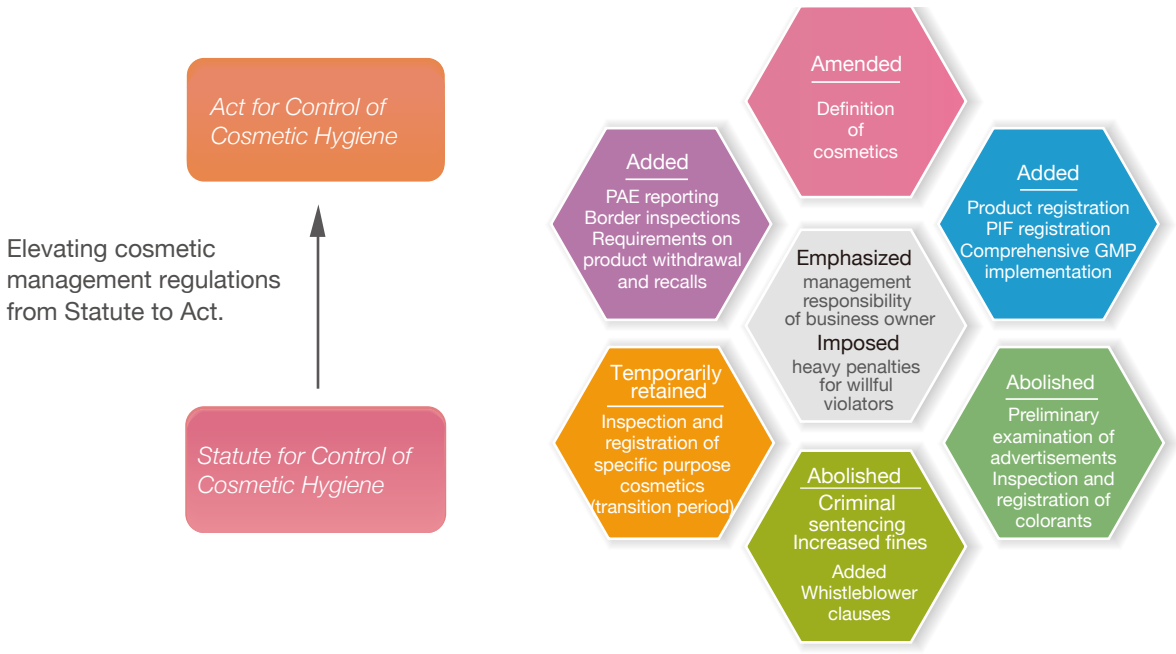
1. Creating the Legal Environment and Harmonization with International Standards

(1) Drafting the Revised Statute for Control of Cosmetic Hygiene

a. TFDA drafted amendment of the *Statute for Control of Cosmetic Hygiene*. Key revisions included the use of Product Notification system and Product Information File (PIF) to replace the medicated cosmetic manufacturers system, the removal of preliminary review requirement of cosmetic advertisements, and the addition of requirements on Good Manufacturing Practice (GMP) that cosmetic companies must comply with, as well as furnishing of information on direct sources of supply and distribution. The revision also required companies to actively withdraw cosmetic products from market, initiate other disposal actions, and inform the competent authority if the products were found to cause severe adverse reactions or were suspected of causing hygiene or health hazards, in order to safeguard the cosmetic hygiene and safety (Figure 2-5-2).

b. The amendment of the *Statute for Control of Cosmetic Hygiene* was notified to the World Trade Organization (WTO) on January 16, 2015. The draft was then submitted to the Executive Yuan for review on June 29, 2015 and handled according to legal procedures of the Executive Yuan.

c. To achieve the objectives of effective public communication and advocate awareness for relevant policies, TFDA hosted one relevant regulation seminar, three training sessions on cosmetic product notification system and system operations, one experience sharing seminar for overseas GMP assessment processes, and one seminar on GMP and PIF systems for cosmetics with respect to the Amendment of the ***Statute for Control of Cosmetic Hygiene.***



▲ **Figure 2-5-2** Key revisions of the Amendment of the *Statute for Control of Cosmetic Hygiene*

(2) Adding and RevisingVarious Regulations and Hygiene Standards

In 2015, TFDA adjusted the *Fee-Charging Standards for the Registration of Cosmetic Products and Cosmetic Colorants and Fee-Charging Standards for the Review of Medicament and Cosmetic Advertisements* to better reflect service costs and user payment principles. Regulations used in other countries were also referenced to formulate *Guidelines for Safety Assessments of Cosmetics Using Nanomaterials as Ingredients* and revise the *List of Legally Permitted Cosmetic Colorants* for the purpose of regulatory harmonization. Table 16 in Annex I lists details on the additions and revisions to regulations and hygiene standards related to cosmetics that were made in 2015.

2. Pre-Market Approval & Registration of Cosmetics and Cosmetic Advertisement Examination

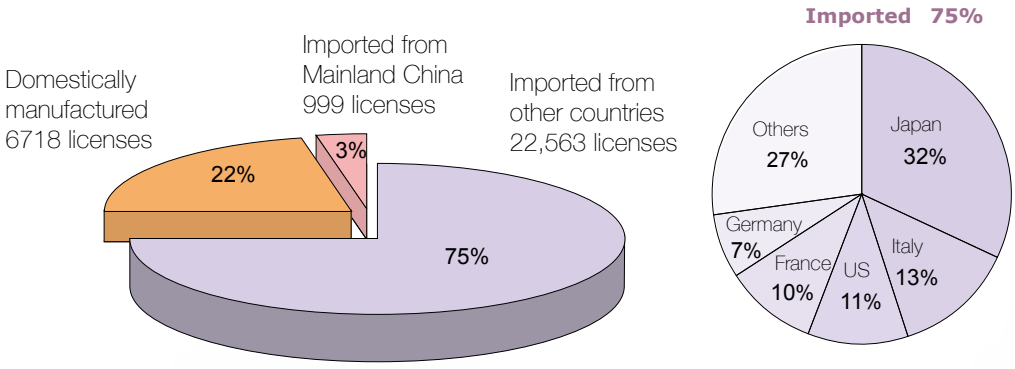
(1) Inspection and registration of medicated cosmetics

a. In 2015, a total of 1,822 applications for medicated cosmetics were received, of which a total of 1,558 were approved (Table 2-5-1).

Table2-5-1 **Number of licenses approved for medicated cosmetics from 2010 to 2015**

Year	Total applications	License approved	Approval rate (%)
2010	1,594	1,437	90.2
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

b. As of the end of 2015, a total of 30,280 licenses for medicated cosmetics were approved and issued, of which 6,718 licenses were issued for cosmetics manufactured domestically and 23,562 licenses were issued for imported products (Figure 2-5-3).



▲ **Figure 2-5-3** Number of medicated cosmetic licenses approved and issued as of the end of 2015

(2) Cosmetic Advertisement Examination

a. To help businesses gain a quick understanding of cosmetic advertisement application procedures, TFDA has promulgated the *Rules for Application of Medicaments and Cosmetics Advertising* as well as the *Guidelines for Cosmetics Advertising* as references for companies when designing advertisements. TFDA also produced leaflets titled *Tips for Identifying Legal Medicament and Cosmetic Advertisements* to help consumers correctly identify legal cosmetic advertisements.

b. To unify cosmetic advertisement review standards amongst health bureaus and departments of the six municipalities of Taiwan and improve the consistency of review quality and results, TFDA has promulgated the *Cosmetics Advertising Act and Examination Manual* and an *Enumeration of Expressions that Are Appropriate or Inappropriate to Be Claimed for Cosmetics*. Additionally, to improve the comprehensiveness of rules governing the examination of cosmetic advertisements, two cosmetic advertisement management and advisory committee meetings were convened in 2015 to discuss special cases and provide professional opinions.

c. In 2015, a total of 1,541 applications for cosmetic advertisements were received, of which 1,273 were approved (83.88%).

Section 2. Cosmetics Source Management

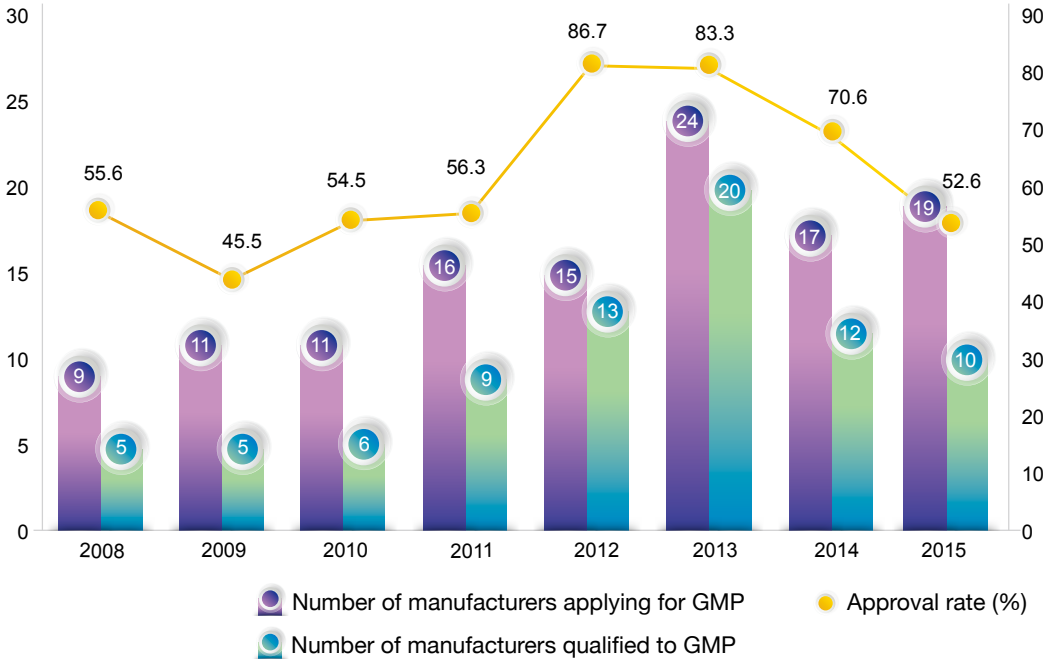
Current Status

Cosmetics manufacturers are currently required to submit documented information to the Industrial Development Bureau (IDB) of the Ministry of Economic Affairs (MOEA). The IDB then assembles an audit team to perform the audit. Manufacturers that pass the audit may then apply for a GMP certificate from TFDA. As management after pre-market registration will be exempted in the future, TFDA is planning to introduce a new section on the Cosmetic Product Notification System in the revised *Statute for Control of Cosmetic Hygiene*. Prior to these legal revisions, business owners are encouraged to voluntarily register themselves at the Cosmetic Product Notification Portal. Once legal revisions are approved and enforced, business registration at the portal will become mandatory in order to achieve the purposes of effective management and consumer protection.

Policies and Outcomes

1. Production Source Control

As of the end of 2015, a total of 122 cosmetic manufacturers have voluntarily applied for GMP audits with the IDB, of which 80 successfully passed the audit. In 2015 alone, 19 manufacturers applied and 10 successfully passed, for a qualification rate of 52.6% (Figure 2-5-4).



▲ **Figure 2-5-4** List of manufacturers that applied for and passed cosmetics GMP from 2008 to 2015

2. Establishing the Cosmetic Product Notification Portal

TFDA referenced global regulatory requirements to promote the Cosmetic Product Notification System and completed the establishment of the Cosmetic Product Notification Portal in 2013. The pre-market notification system for products replaced the pre-market registration system for medicated cosmetics in order to shorten the time of product to market for cosmetic companies

while achieving effective management of marketed products. To familiarize businesses with the use and operations of the notification portal, TFDA organized three training courses in 2015. A total of 903 businesses and 1,694 cosmetic products were successfully registered online.

Section 3. Cosmetics Quality Chain Monitoring

Current Status

Every year, TFDA employs risk assessment mechanisms to select specific items for conducting national medicament and cosmetic quality monitoring programs. Joint audit programs for cosmetics were also carried out regularly every year in order to strengthen post-market safety management.

Policies and Outcomes

1. Quality Monitoring of Cosmetics Sold on the Market

In 2015, five quality monitoring programs were carried out to sample 251 items, of which 244 were compliant with quality monitoring standards (conformity rate of 97.2%) and 212 were compliant with product labeling requirements (conformity rate of 84.5%). The seven cases failed quality monitoring standards as well as the 39 cases whose packaging and labeling failed to display ingredients required as publicly announced by the TFDA were transferred to the respective local health bureaus and dealt with in accordance with the law. Table 2-5-2 shows the results of various monitoring projects.

2. Joint Audit of Marketed Cosmetics

In 2015, a total of five cosmetics were subject to joint audits that covered 2,200 items, of which 82 were found to be nonconforming for a violation rate of 3.7%. Cases of suspected product violations were transferred to the respective local health bureaus and dealt with in accordance with relevant regulations (Table 2-5-3).

Table2-5-2 **Results of quality monitoring and testing of cosmetics in 2015**

Project title	Total cases	Item inspected			
		Quality testing		Package labeling	
		Pass	Nonconforming	Pass	Nonconforming
Survey on Methanol, Benzene and Phthalate Esters in Marketed Nail Polishes in Taiwan	59	57	2	58	1
Survey on Hydroquinone, Mercury, Tretinoin and Steroids in Marketed cosmetics from hospitals in Taiwan	60	60	0	33	27
Survey on the contents of Methylisothiazolinone and Methylchloroisothiazolinone in Cosmetics Products Marketed in Taiwan	71	70	1	62	9
Survey on the Qualities of Commercial Hair Dyes in Taiwan	30	27	3	28	2
Survey on the Qualities of Commercial Sunscreens in Taiwan	31	30	1	31	0
Total item (Conformity rate %)	251 (100)	244 (97.2)	7 (2.8)	212 (84.5)	39 (15.5)

Table2-5-3 **Statistical analysis of joint audits of cosmetics in 2015**

Cosmetics	Number of inspected counties / cities	Number of stores / street vendors audited	Product labeling		
			Audited items	Violation items	Violation rate (%)
Cosmetics with hair dyeing functions	6	48	90	13	14.4
Cosmetics with sunscreen functions	6	48	113	10	8.8
Cosmetics with anti-perspiration and deodorant functions	6	48	64	3	4.7
Cosmetics used as face wash	22	370	1039	22	2.1
Cosmetics used for the eyes	22	370	894	34	3.8
Total	22	418	2,200	82	3.7

Section 4. Cosmetics Safety Management

Current Status

TFDA established the Post-market Quality Management System for Food, Drugs, and Cosmetics to handle reports of defective cosmetics and adverse reactions caused by cosmetic use, to ensure that such notifications are reflected to health competent authorities or companies in a timely manner, and to initiate subsequent investigations and preventive measures. Relevant information such as public announcements and hygiene standards are issued every year. TFDA has continued to strengthen risk communication and bilateral interaction with businesses to accelerate the transmission of information related to cosmetic safety.

Policies and Outcomes

1. Statistics on the Reporting of Adverse Events

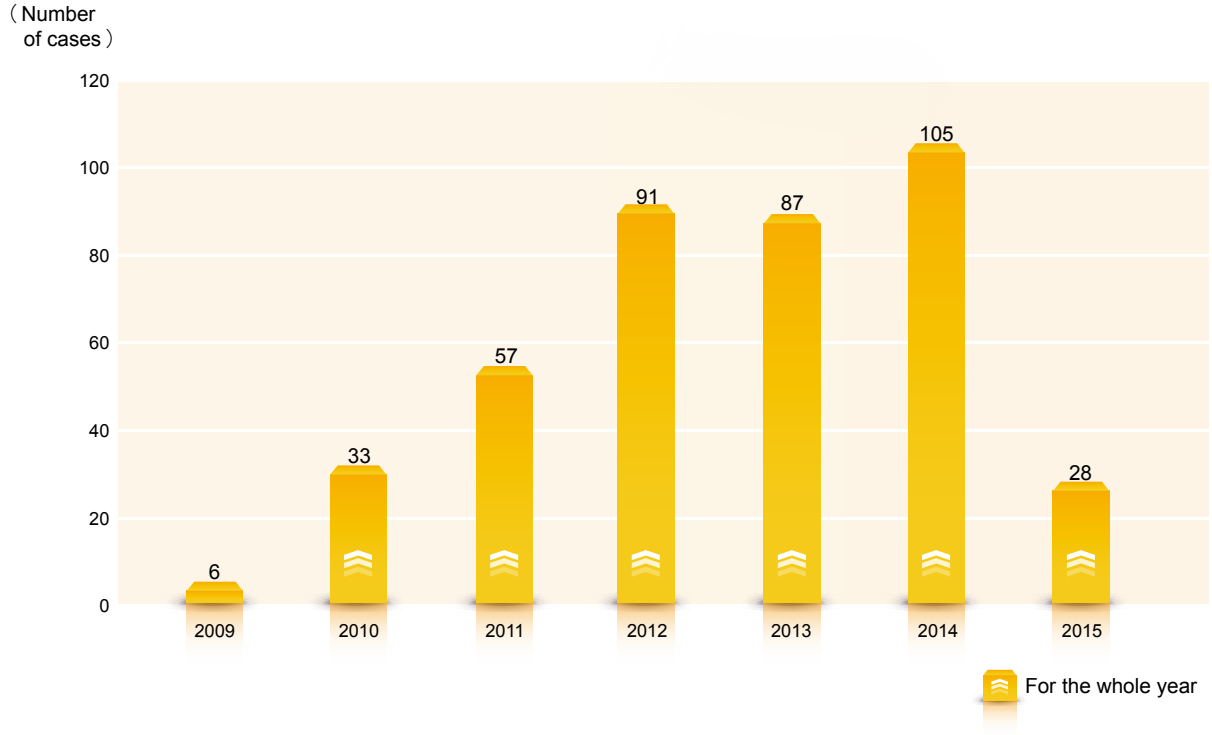
In 2015, a total of 28 adverse events were reported (Figure 2-5-5), of which 17 involved defective products while 11 were adverse reactions. Figure 2-5-6 shows the categories of adverse events (a number of the events included both defective products and adverse reactions).

2. Seminars for Promoting the Cosmetic Products Adverse Events (PAE) Reporting System

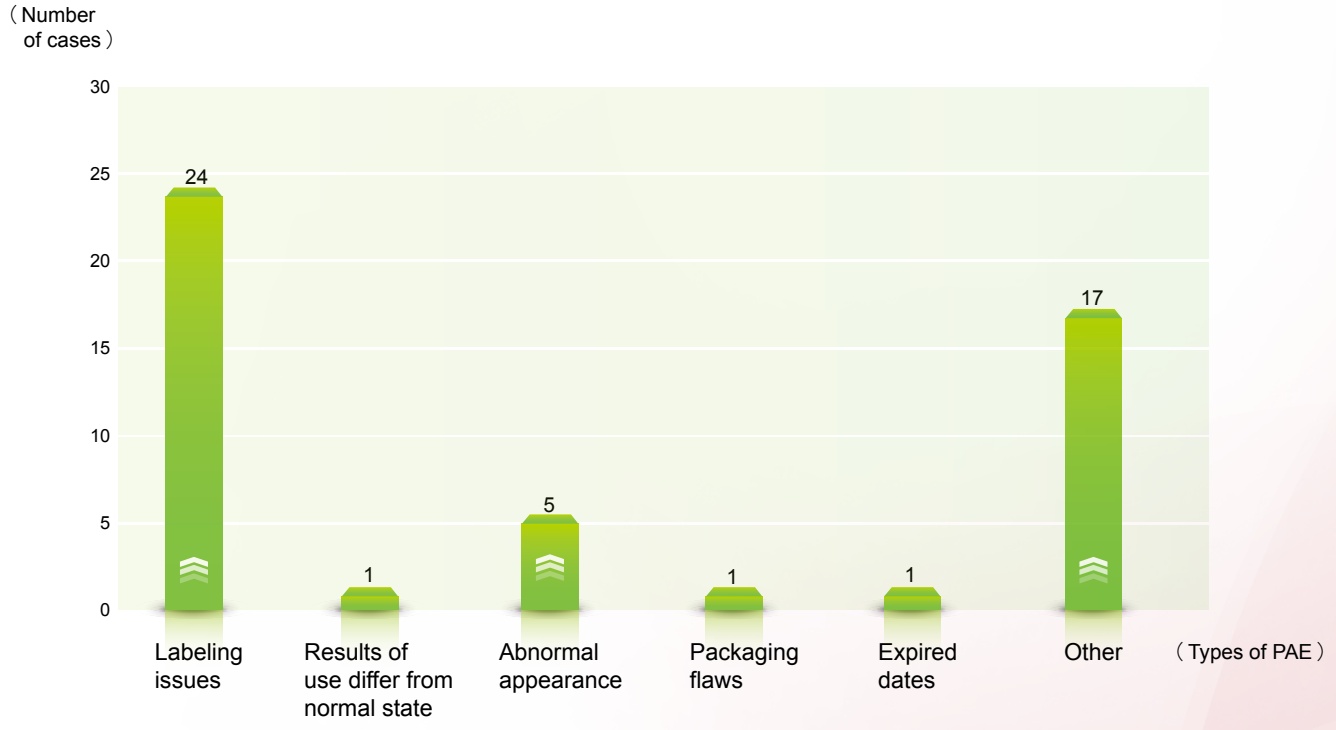
TFDA organized five seminars promoting the Cosmetic PAE Reporting System in 2015 to help medical institutions and the public gain a better understanding of the System and improve reporting rate.

3. Monitoring of Cosmetic Safety Information Around the World

TFDA continued to actively collect the latest news regarding safety and recalls of cosmetics around the world and monitor relevant websites in Taiwan. In 2015, a total of 159 alerts from Taiwan and overseas were monitored and 177 consumer traffic light alerts were issued.



▲ **Figure 2-5-5** Analysis of the number of cosmetic PAE cases reported throughout the years



▲ **Figure 2-5-6** Analysis of the types of cosmetic PAE cases

Chapter 6

Risk Assessment and Management

Chapter 6. Risk Assessment and Management

To ensure the safety and quality of food, drugs, medical devices, and cosmetics and achieve preventive measures or early detection of potential product risks, TFDA continued to promote risk management systems, using risk assessment as the basis to stipulate policies and corresponding management practices. Risk management and crisis handling were incorporated into administrative operations to effectively minimize the impact of an actual crisis.

Section 1. Risk Assessment

Current Status

Risk assessment plays a key role in managing safety risks of food, drugs, medical devices, and cosmetics. To gather risk-related information, TFDA continued to implement routine surveys (such as total diet study and medicinal Product Quality Inspections), establish reporting systems (such as reporting of unintended reactions of food products as well as adverse reactions for drugs, medical devices, and cosmetics) to acquire feedback information, and monitoring of alerts in Taiwan and other countries. TFDA also organized expert or advisory meetings to conduct risk assessments and provide a reference for formulating or revising risk management measures, while post-marketing surveillance was carried out to achieve better understanding of product quality and safety. The principles of scientific evidence, preventive action, and information transparency were employed to build a food and drugs safety management system.

Policies and Outcomes

To accurately assess risk levels, manage specific as well as potential risk factors, identify risks, and collect information, various channels were employed to acquire risk-related data of food, drugs, medical devices, and cosmetics. Information related to potential product risks was collected as well. Inquiry meetings, risk-related data analysis, and risk assessment courses were also provided to train risk assessment professionals.

1. Food Safety Risk Assessments

(1) Risk Identification and Data Compilation

a. Establishing the National Food Consumption Database and Risk Assessment Data

The establishment of the National Food Consumption Database in 2015 was a continuation of the research findings of 2014. An additional food category was added to give a total of four major categories (primary, secondary, minor, and items) while making continuous updates and revisions to national dietary information. Results of food consumption calculations were then publicized in the National Food Consumption Database which can then be downloaded or used in other calculations.

b. Study of Background Risk Factors in Food and Risk Assessments in Total Diet Study.

(a) Investigations and Risk Assessments for Dioxins in Food

Risk assessment and investigations of food-borne dioxins were carried out in 2015. Content analysis and exposure risk assessments of dioxins (including 17 types of polychlorinated dibenzodioxins / dibenzofurans and 12 types of dioxin-type polychlorinated biphenyls) in 126 food items were completed in central Taiwan. The estimated life-time average daily dose (LADD) was 0.422 pg WHO-TEQ /kg BW/day, which was lower than the recommended tolerable daily intake (TDI) of the WHO that ranged from 1 to 4 pg WHO-TEQ /kgBW/day and the tolerable weekly intake (TWI) of 14 pg WHO-TEQ /kg BW/week recommended by the European Scientific Committee on Food (SCF).

Note : Toxic equivalent quotient for dioxin and dioxin like compounds calculated with toxic equivalency factor established by WHO (2005).

(b) Total Diet Study

In 2015, TFDA carried out the first total diet study in Taiwan for residual veterinary drugs in food, targeting production areas, post-marketing surveillance, and residual standards for 70 types of veterinary drugs. TFDA also outlined a recognized list of residual veterinary drugs and implemented a nation-wide hierarchical sampling to assess concentrations of residual veterinary drugs in 90 core food items. These measurements were then combined with estimated exposure data and allowed the completion of total diet study and risk assessments for residual veterinary drugs to estimate veterinary drug exposure risks of three populations in the consumption of 90 core food items. Results showed that risks for every single item are acceptable.

c. Reporting Unintended Reactions of Food Consumption

In 2008, TFDA established the National Reporting System for Unintended Reactions of Health Food and Food in Capsule or Tablet Forms, allowing members of the public to report post-market safety data of unintended reactions via the system. After members of TFDA Consultation Team for Unintended Reactions of Health Food and Food in Capsule or Tablet Forms evaluate reported cases and product safety, the Consultation Team will then immediately initiate relevant measures to minimize potential hazards or contain the scope of the incident. From 2008 to 2015, TFDA received a total of 173 reports of unintended reactions of health foods or food in capsule or tablet forms, and monitored a total of 1,292 food safety alerts.

d. Monitoring International Food Safety Alerts

TFDA has assigned dedicated personnel to monitor international food recall alerts and publish relevant information on a daily basis in order to provide businesses with a reference and help them avoid importing products being recalled by the original manufacturer. In 2015, international alerts were monitored to publish a total of 328 food consumer traffic light alerts on the Food and Drug Consumer Service Network (http://consumer.fda.gov.tw/).

(2) Risk Assessment Mechanism and Controls

Hosting Expert Advisory Meetings to Evaluate and Propose Control Measures

a. Advisory Committee for Risk Assessments of Food Products

The Advisory Committee for Risk Assessments of Food Products is composed of experts and academicians in food safety, toxicology, and risk assessment as well as representatives from non-government organizations (NGOs). The Committee is responsible for conducting risk assessments for food safety or relevant hazardous substances, formulate policies and strategies for risk assessments, formulate risk assessment plans, expand or revise risk assessment guidelines, implement risk assessments, and to carry out or promote other matters related to risk assessments.

b. Bovine Spongiform Encephalopathy (BSE) Expert Consulation Committee

In addition to import meat product reviews, imported beef and beef products are required to conduct food safety risk assessments for the food safety risk derived from Bovine Spongiform Encephalopathy (BSE) and the application will be reviewed by the BSE expert consulation committee. BSE occurred countries which intend to export beef and beef products to Taiwan must submit an application that includes information of epidemiological surveys and monitoring data of BSE cases that have occurred in the country as well as preventive measures, risk assessments, and other information for review. Other review procedures such as risk assessments and on-site inspection are also conducted to ensure the food safety management system of the applicant country before allowing the import of beef products, the risk communication will be concluded under cross ministerial mechanism. A total of 2 BSE expert consultation meetings were convened in 2015.

c. Food Sanitation, Safety and Nutrition Advisory Committee

The Food Sanitation, Safety and Nutrition Advisory Committee is composed of experts and academicians from various fields to carry out inquiry or recommendations on policies, investigations, research projects, standards, science and technical exchange, and handling of major incidents related to food sanitation, safety, and nutrition, and provide a reference for administrative measures and legal revisions. A total of four meetings were held in 2015.

(3) Training of Risk Assessment Professionals

From 2011 to 2014, TFDA has gradually introduced training courses developed by the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) from the University of Maryland in order to improve technological competence of risk assessment procedures in Taiwan and achieve better alignment with international standards. In 2015, the National Health Research Institute (NHRI) also held a series of five food safety risk assessment courses that analyzed practical case studies and conducted various exercises (Figures 2-6-1 and 2-6-2).

▲ **Figure 2-6-1** Food Safety Assessment training course

▲ **Figure 2-6-2** Practical Exercise for Food Safety Risk Assessments training course

2. Risk Assessment for Medicinal Products

(1) Risk Identification and Data Compilation

The following are the various passive and active monitoring mechanisms established in Taiwan that complement each other to moniter the safety and quality of medicinal products:

a. Reporting System

A number of reporting systems for adverse drug reactions (ADR), medicinal product defects and therapeutic inequivalence have established in Taiwan so that the healthcare professionals, the general public and pharmaceutical companies may report such incidents accordingly. A total of 12,815 ADR cases, 943 defective drug products, and 34 therapeutic inequivalence cases were reported in 2015.

b. Monitoring of Global Alerts

Medicinal product safety and quality alerts around the world are monitored on a daily basis in order to immediately investigate and handle. A total of 131 drug safety alerts and 1,104 drug quality alerts were monitored in 2015.

c. New Drug Safety Monitoring

The drug license holders of new drugs must submit periodic safety update reports during the preliminary period after approval to monitor the safety of new drugs. A total of 356 medicinal products are under new drug safety monitoring at the end of 2015.

d. Routine and for-cause inspection

Routine inspections are carried out at manufacturing sites of medicinal products. Where a particular product is suspected of major quality issues, for-cause inspections will carry out accordingly.

(2) Risk Assessment Mechanism and Controls

a. Re-evaluation of Drug Safety and Risk Management

New drugs pass monitoring period and medicinal products with global safety alerts or other safety signals will be re-evaluated.The Medicinal Product Safety Advisory Committee was established to help clarify the safety concerns of medicinal porducts, assess the balance of clinical benefits and risks, and suggest risk management measures such as revision of package inserts, usage restrictions, and implementation of risk management plans. When the risks of a medicinal product outweigh its clinical benefits, the product may be withdrawn from the market (by terminating the drug license). In 2015, a total of 45 medicinal products were re-evaluated, of which risk management measures were initiated for 17 medicinal products.

b. Medicinal Product Quality Survey

(a) In response to quality defects reports of medicinal products, the pharmatheutical companies will be requested to investigate the root cause of drug quality problem and initiate corrective and preventive actions (CAPA) according to GMP regulations.In the case of serious drug quality problem,the pharmatheutical companies will be requested to submit investigation report and CAPA plans to TFDA and initiate drug recall where necessary. In 2015, a total of 147 serious quality defects were monitored, of which 17 medicinal products were recalled.

(b) For the medicinal product recall mechanism, pharmatheutical companies shall be requested to conduct a product recall according to the Regulations for Medicament Recall and correct the quality nonconformance within a limited time in response to the following : product defects reports require product recalls, where products being recalled overseas have been imported, where post-marketing

sampling results failed to meet the specifications, where factory inspection identified quality issues, or where pharmatheutical companies have initiated product recalls voluntarily, and where the drugs have been withdrawal because of safety issue. In 2015, a total of 303 medicinal products were recalled due to quality problem.

c. Drug Safety and Quality Monitoring

(a) Establishing the Proactive Drug Safety Monitoring Mechanism

The Proactive Drug Safety Monitoring Mechanism was sequentially established since 2010 by realizing the safety profile of medicinal products with important potential risks in Taiwan using National Health Insurance Database in order to provide a reference for drug safety re-evaluations and determining risk management measures. Overall safety analysis projects were carried out for 10 medicinal products in 2015.

(b) Enhancing the Medicinal Product Quality Monitoring Information System

The enhanced Medicinal Product Quality Surveillance Mangement Information System was established from 2013 to 2014. The Informatin System has improved the convenience of reporting drug product defects or therapeutic inequivalence and enhanced the management of reported cases, drug recalls and global drug quality alerts.The medicinal product quality information from the product life cycle was also gradually integrated in this system in order to improve handling efficiency of medicinal product quality incidents. The Information System formally came online in January 2015.

(c) Implementing Risk Management Plans for Medicinal Products in Pharmaceutical Companies

Since 2010, the system of Medicinal Product Risk Management Plans for Pharmaceutical Companies was gradually established for medicinal products with specific risk concerns.Pharmaceutical companies and medical institutions are required to work together in order to implement various risk control tools such as patient drug usage instructions, medical staff notification, and special preventive measures. Follow-up assessments of implementation effectiveness are also carried out regularly to ensure the public's drug use safety. Risk management plans are required for diabetic medication that include rosiglitazone, anti-epileptic drugs that contain carbamazepine, TNF-alpha blockers and acne medication with cyproterone acetate and ethinyloestradiol.

(3) Training of Risk Assessment Professionals

In 2015, TFDA held a total of 12 seminars advocating the reporting of ADRs and defective products for health professionals, health bureaus and departments, pharmaceutical companies, and members of the public. TFDA also worked with the Taiwan Pharmacy Forum to provide free online courses over a 2.5-month period in order to promote reporting of ADRs. TFDA also held six training courses for pharmaceutical company personnel responsible for drug safety monitoring in order to help the companies establish safety monitoring and risk management systems.

3. Medical Device Safety Risk Assessments

(1) Risk Identification and Information Collection

a. Monitoring of Medical Device Alerts

In 2015, TFDA continued to collect medical device alert information from official health agency websites of various countries around the world. Such information was then used accordingly to initiate mechanisms of inquiry in Taiwan. In 2015, relevant inquiries of 1,936 alerts were completed.

b. Reporting of Medical Device Adverse Events

In 2015, data standardization, analysis, and assessment were completed for 375 and 614 adverse reaction reports from Taiwan and other countries respectively, as well as 3,453 reports on defective products, 178 reports on adverse events during clinical trials, and 138 periodic safety update reports.

(2) Risk Assessment Mechanism and Control

a. Medical Device Safety Evaluation

For medical devices with adverse event reports, when their monitoring period is over or if other safety concerns arise, TFDA will further collect relevant safety information in Taiwan and other countries for the Medical Device Safety Assessment Consultation Committee to conduct post-market evaluations of clinical usage safety, effectiveness, and risks of medical devices, and will formulate risk control measures (such as revisions to package inserts, conduct unannounced factory audits, or extend the safety monitoring period of medical devices). A total of three Safety Assessment Consultation Committee meetings were held in 2015.

b. Quality Surveys of Medical Devices

Risk rating is carried out according to the extent of hazards described in defective medical devices reports. License holders are notified every quarter to conduct root cause analysis for quality nonconformities and submit preventive and corrective measures according to the requirements prescribed in the medical device GMP.

c. Risk Control Measures for Medical Devices

According to the results of the aforementioned safety evaluations and quality surveys, seven medical devices in 2015 were required to be prioritized for on-site audits or GMP/QSD reviews, four were required to revise package inserts, and seven were required to provide supplementary information.

(3) Training of Risk Assessment Professionals

a. In 2015, causes of medical device defects reported in the past were reviewed by TFDA, and six seminars on adverse device reaction (ADR) reporting system for medical institutions, companies, and members of the public regarding six major topics (disposables, cardiovascular devices, assistive devices, medical cosmetology, periodic safety monitoring of medical devices, and regulations related to medical devices) were held. The purpose of these seminars was to enhance proper understanding of safe use and responsibility of sending reports in order to improve reporting rates.

b. In 2015, projects were carried out to provide assistance to seed hospitals in establishing ADR reporting mechanisms within hospitals in order to raise awareness of the safe use of medical devices amongst medical practitioners and improve the reporting rates and quality of ADRs within medical institutions.

4. Cosmetic Safety Assessments

(1) Risk Identification and Data Compilation

a. Assessment of Reported Adverse Events of Cosmetics

In 2015, a total of 28 adverse incidents of cosmetics were received, which included 17 cases of defective products and 11 cases of adverse reactions. These incidents were analyzed and evaluated accordingly.

b. Monitoring of Cosmetic Alerts

TFDA actively gathered recalls and safety-related messages on cosmetics around the world. In 2015, a total of 159 alerts from Taiwan and overseas were monitored to issue a total of 177 consumer alerts.

(2) Risk Assessment Mechanism and Control

a. Cosmetic Hygiene Management Consultation Committee

In 2015, a total of three Cosmetic Hygiene Management Consultation Committee meetings were held to discuss topics that covered management policies, quality, safety, and safe technologies of cosmetics in order to provide a reference for policy formulation.

b. Formulating Relevant Regulations Governing the Quality and Safety of Cosmetics

After referencing scientific evidence, relevant literature, international regulatory practices on cosmetics, and recommendations from members of the Cosmetic Hygiene Management Consultation Committee, as of the end of 2015, TFDA had issued various hygiene standards and promulgated 183 standards on medicated cosmetics, listed over 300 types of prohibited substances, as well as over 100 types of substances with restricted ingredients for use in preservatives, anti-bacterial agents, reducing and whitening agents.

(3) Training of Risk Assessment Professionals

In 2015, TFDA organized five promotional seminars of Cosmetic PAE Reporting System for health professionals, companies, and the public to improve user familiarity with the reporting system, deliver printed information and promotional materials, and increase reporting rates of cosmetic PAEs.

Section 2. Risk Data Analysis

Current Status

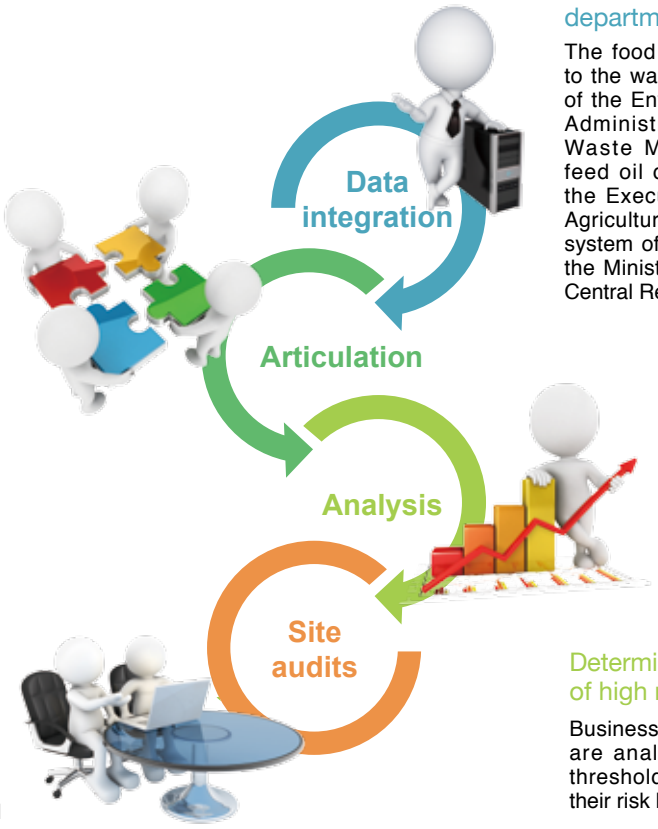
Recent incidences of food safety issues revealed an urgent need to strengthen early warning systems for food safety. TFDA integrated current food safety management systems and established connections to databases in relevant ministries and departments in the Big Data Analytics Training Program, introducing Big Data Analytics to achieve in-depth evaluation of vast amounts of food-related data collected over the years.

Policies and Outcomes

1. Using Data Analysis to Achieve Food Sources Management

(1) To improve traceability and management of edible oils in Taiwan and to safeguard food safety of fellow citizens, the Executive Yuan Office of Food Safety held 5 Cross-Departmental Harmonization Meeting for the Management of Imported Oils since December 10, 2014, supervising the establishment of a cross-departmental organization (Ministry of Finance, Ministry of Economic Affairs, Industrial Development Bureau, Bureau of Foreign Trade, Bureau of Energy, Executive Yuan Council of Agriculture, Executive Yuan Environmental Protection Administration, and Ministry of Health and Welfare) to manage the distribution of oils and fats, achieve higher data transparency of oil supplies, and establish early warning systems.

(2) Information systems of various departments and ministries as well as Big Data Analytics. TFDA utilized cloud connections for the food industry and established links between eight systems under four ministries and 25 dashboards of six major categories. For oil products, connections were established to the Feed Oil Reporting System of the Executive Yuan Council of Agriculture, the Declaration System for Production Factories for the Manufacturing or Importing of General Industrial Oil of the Central Region Office of the Ministry of Economic Affairs (MOEA), and the Waste Declaration System-Waste Edible Oil of the Executive Yuan Environmental Protection Administration in order to integrate and articulate declaration systems of various ministries to the Food Business Registration Platform. Transaction records and information of various oil products such as sales or purchasing counterparties, amount declared, date of declaration, and purpose of use were compared against each other. Statistical analysis tools was used in order to build risk models for each route and generate a recommended list of top businesses that should undergo audits as part of the government's active measures for traceability management of oil products (Figure 2-6-1). In the current phase, food products were established as a risk control model which would be further expanded to include management of medicinal products and medical devices.



Food Cloud connections to information systems of other departments

The food cloud was connected to the waste declaration system of the Environmental Protection Administration Department of Waste Management, animal feed oil declaration system of the Executive Yuan Council of Agriculture, and the declaration system of selected chemicals of the Ministry of Economic Affairs Central Region Office.

Oil products distribution and articulation

Oil products distribution is articulated. Food business counterparts are regarded as high risk of oil product sales. A list of high risk businesses was established for risk assessment.

Determining the risk levels of high risk businesses

Businesses in the high risk list are analyzed using indicator threshold values to determine their risk levels.

On-site audits

On-site audits are scheduled and planned by the auditing agency according to the risk levels.

▲ **Figure 2-6-1** Flowchart for the articulation and risk analysis for the distribution of oil products

2. Using Historical Data to Establish Future Prediction Models

(1) Ensure Data Comprehensiveness

In 2015, historical data gathered by the Five-Must information system of TFDA, namely the automated management system for border inspections (Must-Declare), Product Distribution Management System (Must-Test), Food Business Registration System (fadenbook, Must-Register), inspection system (Must-Inspect), and traceability system (ftracebook, Must-Trace), were integrated to undergo error proofing and data verification. Once data quality and accuracy had been validated, analysis of historical data from different systems was carried out to achieve an overall understanding of food safety issues in Taiwan.

(2) Establishing Risk Prediction Indicators

Statistical analysis tools (such as R, SPSS, Modeler, and Tableau) were used to carry out data analysis and data mining of historical data and information gathered by border inspections and post-marketing sampling and tests of various products. Results were then used to establish preliminary risk prediction indicators for food safety management. In 2015, a total of five major risk prediction indicators were established with analysis techniques to help screen and select high-risk targets, namely: (1) number of inspected batches of imports; (2) net import weight; (3) border sampling rate; (4) multi-year failure rate of testing; and (5) historical trends of test failure rate. Regular discussion meetings were held with the relevant businesses to provide empirical basis in stipulating source management policies.

(3) Establish an Early Warning Analysis Module for Risks

TFDA started using the established risk prediction indicators to build long-term systematic risk warning and analysis modules to automatically select high-risk targets and achieve the objectives of real-time monitoring. TFDA will also update information on a regular basis and continue to evaluate and analyze the suitability of the module. Actual management requirements will also be referenced to revise parameters of the analysis module to effectively achieve the desired monitoring and early warning functions.

Section 3. Crisis Management System

Current Status

Courses were held in 2015 in order to help TFDA staff members improve their familiarity with risk management and crisis handling concepts in order to respond to and handle emergencies. Public opinions and information were reviewed on a daily basis. Regular post-market surveillance was also conducted to maintain the safety of goods sold on the market for the general public. Corresponding response systems to quickly handle and contain the issue are also in place in case of actual emergencies. Once the incident is over, TFDA will formulate improvements to improve crisis handling capabilities.

Policies and Outcomes

1. Organizing, Implementing, and Managing Risk Management Systems

(1) Risk Management and Crisis Handling Training

TFDA continued to provide training in risk management and crisis handling for fellow staff members to strengthen their familiarity for the overall concepts of risk identification and crisis prevention. In 2015, a total of three training sessions for 190 attendants were held.

(2) Management and Evaluation of Risk Management and Crisis Handling Measures

TFDA made regular reports on the implementation status of the risk management and crisis handling program of 2015 to the Ministry of Health and Welfare task force and continues to track program progress according to the Guidelines for Risk Management and Emergency Response of the Ministry of Health and Welfare.

(3) Convening the Risk Management and Crisis Handling Management Review Meeting

The management review meeting was held on December 29, 2015 to review risk items listed by various departments and agencies. Key public opinion incidents of the year, legislator inquiries, and listed items were reviewed during the said meeting to confirm key risk items for 2016.

2. Enhanced Crisis Response and Handling

(1) Response to Emergency Incidents

a. In response to the *Formosa Fun Coast Dust Explosion*, TFDA established the Inventory Data of Burn Medication and Medical Supplies section on its official website on June 29, 2015. Users and visitors may peruse various information posted on this section such as instructions on the donation procedure for medical supplies (medicinal products and sanitation supplies), contact information for emergency purchases of controlled drugs, status on the supply of medicinal products in hospitals, permit information of salves and topical applications, and drug reporting counter. TFDA has purchased 700,000 square centimeters of skin tissue from other countries for emergency use in various hospitals and initiate medicinal mobilization. The Formosa Fun Coast Dust Explosion of Medical Supplies Allocation System were initiated on July 29, 2015. A total of 659 cases were successfully approved through Medical Resource Dispatch and Support System for the Formosa Water Part Blast on July 29, 2015, which carried out the best possible results and accelerated the supplies allocation of administration and management.

b. Due to major emergencies such as the Japanese Food Management Incident, and Tea with residual agricultural chemicals Incident, TFDA has initiated its emergency response systems and other measures that include tracking down of nonconforming products, product handling, removal of products from store shelves for recall / destruction, revision of legal and management systems, improving testing methods and lab capacities, handling of the press, and risk communication.

(2) Revising Documents Related to Emergency Handling

a. To safeguard the dietary health of the general public, enhance food safety systems, build an excellent and safe environment for food products, improve the performance for handling food incidents, enforce event notification and implementation of emergency response measures, TFDA revised the Management Manual for the Handling of Food-related Incidents by Central Government Agencies (Level 1 Document) in 2015.

b. To enforce various standard operating procedures (SOP) such as conducting food event investigations (and audits), handling of incident reports, establishing a hierarchical system, publishing news articles, risk communication, analysis of public opinions, evaluation and improvement, and follow-up inspection and controls, cross-departmental integration were carried out as necessary. TFDA stipulated a total of four Level 2 Documents in 2015, namely (1) SOP for the Handling of Food-related Incidents by Central Government Agencies, (2) SOP for Auditing and Reporting of Food-related Incidents by Central Government Agencies or by Local Agencies, (3) SOP for Hierarchical Notification of Food-related Incidents by Central Government Agencies, and (4) Manual for the Monitoring and Communication of Public Opinion in order to facilitate the

conduct of emergency response after food-related incidents, achieve adequate knowledge of the overall incident, and implement subsequent handling.

c. For the handling, reporting, and responding to emergency incidents related to food and drugs safety, TFDA stipulated the Procedures for Initiating Emergency Response for Level 1 and Level 2 Food Incidents (Level 3 document) and Food, Medicine, and Cosmetics Incidents of Procedures for Initiating Internal Emergency Response in TFDA for Level 3 Incidents (Level 3 document) to achieve the goals of facilitating the rapid handling of emergency situations, eliminating public concerns, and safeguarding the health of fellow citizens.

d. To support the contents of the Management Manual for the Handling of Food-related Incidents by Central Government Agencies, TFDA organized the Exercise for Emergency Response to Food Incidents on December 1, 2015 to implement document verification and rolling revisions.

3. Post-marketing Surveillance System

(1) To monitor the quality and safety of products sold on the market, TFDA has continued to implement post-marketing surveillance (PMS) that involve sampling and testing of marketed products that pose higher risks, have the potential to affect the health of specific groups of the population, are considered key daily necessities, or are targets of domestic and global concerns. Results of surveillance activities or cause analysis from the previous year or earlier periods shall be referenced in order to formulate the PMS plan.

(2) In 2015, a total of 19 PMS plans were implemented, including 11 for food products, three for medicinal products, two for medical devices, and three for cosmetics. Nonconforming rates for food products as well as drugs and cosmetics were 8.4% and 0.6% respectively. Cases of nonconforming products were transferred to the responsible local health bureaus and departments to pursue subsequent legal actions. Consultation was provided to encourage companies to achieve improvement. Where necessary, relevant information shall be released in order to safeguard consumer safety.

a. TFDA has continued to carry out sampling checks and monitor cases of food adulteration, genetically modified (GM) foods, heavy metal contamination of rice and aquacultural products, mycotoxins and residual veterinary drugs in food, heavy metals in vegetables and fruits, and residual pesticides in rice. A total of 5,327 specimens were examined, with a nonconforming rate of 8.4%. TFDA shall continue to carry out monitoring and surveillance activities, and strengthen testing for high risk food products. Results of these activities shall be used as an input for overall assessments and reviews of food safety and health management in Taiwan.

b. Risk-based sampling and testing for Medicinal Product Surveillance.

In 2015, the drugs of allopurinol (gout medication), lorazepam (antidepressant), prednisolone (steroid), cephalexin (antibiotic), nalidixic acid (antibiotic), valoproic acid (antiepileptic drug), and steroid-based eye drops were sampled and tested. A total of 172 samples were all complied with the specification.

c. ADR reports and alerts were referenced to target medical devices with high levels of potential risks and hazards, including them as items that require active monitoring in the annual medical device quality surveillance program. In 2015, a total of 46 items were monitored. Results indicated that every item has conformed to quality surveillance requirements.

d. PMS activities such as quality surveillance and joint audits were carried out for cosmetics sold on the market (those claiming to have hair dyeing and anti-sunburn functions). A total of 242 cases of quality testing and 2,200 cases of labeling audits were carried out for a conforming rate of 97% and 96.3% respectively.

Chapter 7

National Laboratory and Testing Network

Chapter 7. National Laboratory and Testing Network

The growing complexity and diversity of engineering technologies in foods, medicines, and medical devices make the management and measurement of them more challenging than ever before. TFDA continues to advance laboratory testing capabilities and estibilish fast, reliable, and internationally harmonized methods in order to identify and categorize untargets, contingencies, and contaminants which may hurt product qualities and public health.

Section 1. Mission of the National Laboratory

Current Status

The National Laboratory is in charge of testing, formulating testing methods, conducting research and investigations, supplying standards, and providing technical support and assistance to regional centers and health bureaus for medicinal products, food products, and cosmetics in the country. TFDA aggressively promotes the persistent development of the National Laboratory and launches into the perfection.

Policies and Outcomes

1. Testing of Major Food and Drugs Safety Incidents

(1) In April 2015, TFDA was responsible for handling the use of industrial-grade magnesium carbonate, and handled 20 specimens submitted by local health bureaus and departments. Quality testing of magnesium carbonate raw materials was carried out according to the specifications and methodology described in the Chinese Pharmacopoeia or the Standards for Specification, Scope, Application and Limitation of Food Additives. The case involved three food items and 17 medicinal products. Test results showed that these specimens failed to comply with Taiwan's specifications on magnesium carbonate as a food additive, while nine out of the 17 medicinal products failed to comply with the specifications provided on the Chinese Pharmacopoeia.

(2) In May 2015, TFDA handled suspected bacterial contamination of normal saline injections. Relevant products in hospitals and production facilities were sampled and tested, and all were found to be failed in sterility tests. The contaminant bacterial strain identified was *Ralstonia pickettii*. Once test results were confirmed, TFDA immediately held a press conference to explain the incident and recalled three types of medicinal products including 207 batches from the affected production lines to prevent questionable products entering the market.

2. General Testing Activities

With growing requirements for the testing of food, drugs, and cosmetic products, TFDA actively developed rapid and accurate testing methods. In 2015, 49,650 tests were carried out for 8,957 specimens. Details are described in the following:

(1) Basic testing: Registration testing for medical devices, cosmetics, health food, special nutrition supplements, and food additives; lot release for biologics, as well as testing for emergency eventing such as suspected use of industrial-grade magnesium carbonate and suspected bacterial infection of normal saline injections.

(2) Cooperative testing: TFDA provides testing support for the local health bureaus to test the auditing and sampling specimens which the agency is incapable of testing independently, consumer complaints, and complex food poisoning incidents. These include testing for poisoning due to ingestion of poisonous plants, suspected cases of *Clostridium botulinum* poisoning, suspected cases Norovirus poisoning, adulteration of Chinese Medicine or foods with modern pharmaceuticals, adulteration of food with illegal additives, and illegal drugs (including electronic cigarettes).

(3) Collaborative testing: Providing support for paid or commissioned tests as well as testing for forensic purposes for illegal pharmaceutical products, controlled drug and narcotics, and pharmaceutical adulterants in prescriptive Chinese herbal medicines and food products.

3. Formulating and Popularizing Testing Methods

(1) There were thirty-three Official methods announced, including Method of Test for Aflatoxin B_1 in Cereal-based Foods for Infants and Methods of Test for Food Microorganisms-Test of *Cronobacter*. There were forty-three recommended methods for foods, including Method of Test for Dichloromethane Residue in Coffee and Method of Test for Chlorite in Noodles and six recommended methods for cosmetics were published, including Method of Test for Hair Dyes in Cosmetics and Method of Test for Material Identification of Absorbable Surgical Sutures.

(2) TFDA compiled the Minimum Requirements for Biological Products V that added and revised nine items such as glycoprotein and polysaccharide analysis and hosted a seminar to introduce the Minimum Requirements for Biological Products and encourage bidirectional exchange between the industry and competent authorities.

(3) TFDA held a meeting for the Chinese Pharmacopoeia Revision Committee (Figure 2-7-1) to publish the First Supplement to the 7th Version of the Chinese Pharmacopoeia, which incorporated harmonized contents from the three major pharmacopoeia from the US, Europe, and Japan and included Sterility Test, Microbiological Examination of Nonsterile Products, Bacterial Endotoxins Test, and Total Protein. The purpose of the First Supplement was to align with international specifications, establishing a milestone for the development the Chinese Pharmacopoeia.

▲ **Figure 2-7-1** Chinese Pharmacopoeia Revision Committee meeting

4. Preparation and Supply of Standard Specimen

Completed pilot collaborative study for national standard of HBV Genotype C viral nucleic acids. TFDA also worked with the National Institute for Biological Standards and Control (NIBSC) of the UK. Standards prepared by TFDA were included in the collaborative study of the 4th WHO international HBV standard. In addition to promote international collaboration, it is also helpful to the credibility and visibility of national standards prepared by Taiwan. Such standards can be used by TFDA for carrying out pre-market and post-market quality management, and may be supplied to the industry for developing molecular diagnostic reagents and quality control.

5. Key Results of Food and Drugs Testing Technology in 2015

Rapid advancements of process and technologies in food and medicinal products in recent years have led to a drastic increase in the number of specimens to be tested. To effectively safeguard food and medicinal products safety, TFDA actively developed and established new methods. The scope of these development projects includes food chemistry and food biology , biological products, quality of Chinese medicine and medicinal products, medical devices, cosmetics, and specifications for innovative testing techniques.

Section 2. Strengthening the Testing Capability of National and Local Laboratories

Current Status

TFDA actively develop rapid and accurate testing methods in order to clarify the beginning and end of contingencies, propose response strategies, and use press releases and media broadcasts and presentations to eliminate public confusion and concerns. TFDA continuously enhance instrument, equipment testing techniques and strengthen laboratory quality assurance to obtain accreditation and international recognition.

Policies and Outcomes

1. Strengthening the Testing Capacity of the National Laboratory

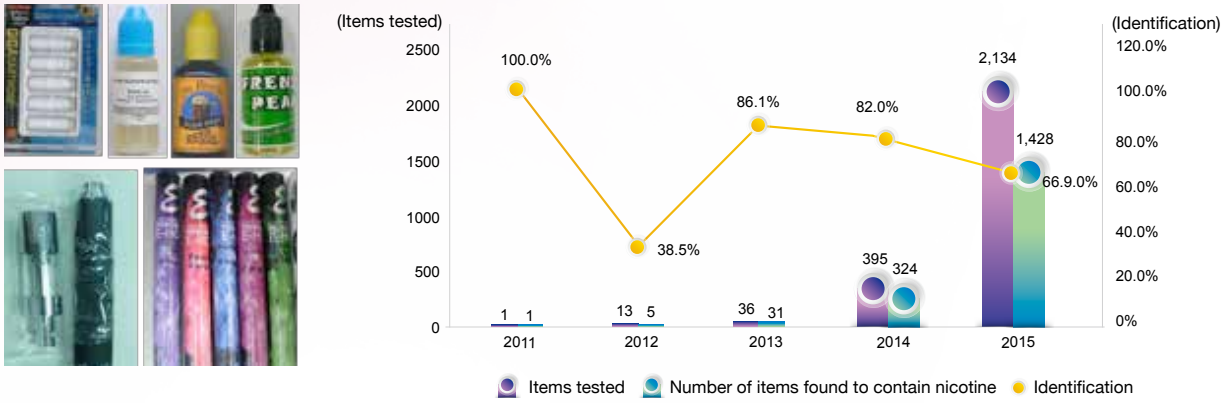
(1) TFDA organized a series of courses such as Identification of Unknown Materials. Course contents included applications of chromatography / mass spectrometry techniques in food testing, organic spectroscopy techniques and applications, and applied analytical techniques for identifying adulterants in honey and its processed products. TFDA also acquired modern equipment and instruments such as high performance liquid chromatography (HPLC) and two-dimensional gas chromatography (GC by GC) coupled with quadruple time-of-flight mass spectrometer (TOF MS) to develop new analysis methods and stipulate technical documents for public use.

(2) TFDA organized large scale international conferences such as the 2015 APEC Conference on Management and Related Scientific Detection of Food Additives in Foods and International Conference on Illegal Drugs in addition to over 10 national conferences or expert meetings to exchange and share technical experiences and establish channels of communication and collaboration.

2. Project Testing

(1) Electronic cigarettes are currently an illegal product in Taiwan but have begun spreading amongst users. To safeguard public health, TFDA carried out tests of specimens submitted by local health bureaus, prosecutor's offices, police departments, and the Customs Administration. The number of specimens received from the Customs Administration in 2015 was a 30-fold increase compared to 2014. From 2013 to 2015, nicotine content was found in 66% of the specimens (Figure 2-7-2). The specimens that contain nicotine were transferred to the original authority for subsequent handling.

(2) TFDA submitted an official request to 11 local health bureaus such as New Taipei City on June 29, 2015 to sample and test cosmetics used for cleansing properties from hotels, tourist housing, or food service businesses found near reservoirs under their jurisdiction. The tests carried out were used to identify nonylphenol and nonylphenol polyethoxylates. 34 specimens were found to comply with the regulations.



▲ **Figure 2-7-2** An illustration of the electronic cigarette and percentage of specimen containing nicotine

(3) In response to the suspected formaldehyde contamination of Sindine Alcoholic Solution (Povidone-Iodine), TFDA worked with the responsible local health bureaus and departments to sample four specimens of Alcohol 95% at the original manufacturer on December 8, 2015. Testing was conducted according to the specifications of the original manufacturer and 38th version of the United States Pharmacopoeia (USP 38). One of the specimens failed to comply with the specifications of the original manufacturer on *aldehydes and other organic contaminants*. Testing for *organic impurities* provided in the *impurities* section of alcohol products in USP 38 published in 2015 also identified acetaldehyde. However, formaldehyde was not found. TFDA then sent an official request to the manufacturer to revise its internal SOPs for nonconforming product testing and testing exemptions for raw materials, and to submit investigation reports.

(4) TFDA developed molecular biological species identification techniques to safeguard food sanitation and safety for the general public.

a. TFDA received a report from Taitung County Public Health Bureau on March 18, 2015 of sore throat, fever, exhaustion, dizziness, amentia, delusion, and diplopia and other symptoms amongst members of the public who had consumed A Bai (rice dumplings) prepared by themselves. The cases were suspected to have been caused by ingesting poisoned plants. Fortunately, the symptoms subsided after emergency medical aid. After DNA analysis for identifying the species of plant, it was found that the leaves contained Angel's trumpet plant (*Brugmansia* spp.) and it was verified that the victims had mistaken the leaves of the poisonous plant (Figure 2-7-3) for the edible jiasuanjiang *(Nicandra physaloides)*.

▲ **Figure 2-7-3** Leaves of the poisonous Angel's trumpet plant (***Brugmansia spp.***)

b. TFDA received a report from Nantou County Public Health Bureau on June 2, 2015 of vomiting, nausea, and abdominal pain after members of the public harvested and consumed mushrooms that grew from a compost heap. Molecular biological technique was employed to identify species of the fungus. The unknown specimen was found to be the poisonous green spored parasol *(Chlorophyllum molybdites)* (Figure 2-7-4) which was mistakenly believed to be edible.

▲ **Figure 2-7-4** Specimen of the poisonous green spored parasol (***Chlorophyllum molybdites***)

c. On November 11, 2015, TFDA worked with Changhua County Public Health Bureau and police inspectors, and identified vendors who adulterated cod with the cheaper catfish (Figure 2-7-5). The vendor imported frozen minced catfish from Vietnam which was sliced, covered with flour, and sold as handmade Japanese-style cod fillet, therefore that was guilty of untruthful labeling. TFDA implemented molecular biological species identification tests for the fish components of the product. Results showed most specimens were made using catfish, and no one oroduct contained cod. TFDA develope new molecular biological technology to identify fish species in seafood, this method was successfully applied to verify and penalize illegal acts, defend the rights of consumers.

▲ **Figure 2-7-5** Specimen of adulterated cod fillet

d. On June 26, 2015, TFDA received a report from Taitung County Public Health Bureau about diarrhea amongst people who have consumed raw oysters which was suspected to be a case of norovirus poisoning. TFDA used molecular biological technology in tandem with gene sequencing to investigate this case. Minute quantities of suspected viral particles were collected from the midgut gland of the raw oyster. Test results revealed contamination by noroviruses GI and GII. After tracing, the oysters were found to be imported from South Korea. Related supplies were quarantined while specimens were preserved (Figure 2-7-6), successfully containing the source of the contamination as well as the scope of the food poisoning incident.

▲ **Figure 2-7-6** Raw oysters with norovirus contamination and preserved specimen

(5) TFDA Actively Develops Rapid and Precise Specimen Testing Methods to Resolve Public Concerns

a. There was an incident in New Taipei City on May 13, 2015 where vendors used non-food grade glacial acetic acid for processing sea cucumbers. Vendors illegally applied industrial-grade glacial acetic acid to soak sea cucumbers so that they would appear like the more expensive heiyu (black jade) sea cucumbers in order to fetch higher profits. In order to clarify the incident, TFDA completed headspace gas chromatography mass spectrometry (GC-MS) analysis to evaluate residual acetic acid of the sea cucumbers within 1 week and implemented training for the testing techniques on May 29, 2015. The 59 specimens of finished products and semi-finished products of the sea cucumbers sampled by the local health bureaus were subject to testing. 52 of the specimens tested positive for the substance. The test results have been notified to the relevant health bureaus and departments as well as inspection agencies for subsequent processing.

b. In mid-June, news reports and Internet videos showing the immersion of Thailand durian in an unknown yellow liquid were circulated. It was rumored that the said liquid could be an unknown pesticide, detergent, or dye. To investigate and clarify this incident, TFDA actively acquired durian imported from Thailand from various stores. Conspicuous yellow deposits were found on the husk which seemed to indicate that the durian may have been immersed in an unknown yellow liquid. After analysis, it was found that the yellow deposits were composed of three compounds found as the major components of natural turmeric extracts (curcuminoids), namely: bisdemethoxycurcumin, demethoxycurcumin, and curcumin. Turmeric is a plant of the ginger family. The yellow powder obtained by grinding the rhizomes is one of the key ingredients of curry and is also responsible for the yellow color of the curry.

3. Precision Testing of the National Laboratory

TFDA was dedicated to its role as a gatekeeper of food and drugs safety for the general public, and has been a long-term participant of international proficiency testing schemes to demonstrate

that the testing competences of TFDA National Laboratory have been recognized around the world (Table 2-7-1).

Table2-7-1 **A list of international proficiency testing schemes that TFDA has participated in**

Organizer	Name of the proficiency test	Results
Central Science Laboratory (CSL), UK	FAPAS proficiency testing (14 items)	Satisfactory
US Department of Agriculture (USDA)	Precision testing competence for genetically modified (GM) soybeans and maize	Satisfactory
ENERSOL Laboratory, Australia	Interlaboratory Proficiency Trial of Glove Testing Laboratories Interlaboratory Proficiency Trial of Male Condom Testing Laboratories	Satisfactory
EDQM Laboratory, Europe	Interlaboratory Proficiency Testing Scheme for Fluorides in Toothpastes Joint research for the 4th International Standard for Streptomycin	Satisfactory
National Institute for Biological Standards and Control (NISBC)	Joint research for the 5th WHO International Standard for HCV Joint research for the 1st WHO International Standard for anti-EV71 serum	Satisfactory
Collaborative Testing Services, Inc. (CTS), US	Forensics testing proficiency tests	Satisfactory

4. Publications

TFDA employed emerging technologies to establish new testing methods, and published 12 papers in international journals and published 59 poster presentations in domestic and international conferences.

5. Enhancing Local Testing Proficiency and Quality

Integration of testing resources, subsidies to local health bureaus and departments, as well as supervision and assessments effectively improved the efficiency and quality of testing activities carried out by local agencies and allowed the establishment of a comprehensive national food safety laboratory network.

(1) Subsidizing Instruments and Equipment, and Enhancing Capacity of the Lab Testing Network

In order to improve the efficiency and quality of specialized testing activities carried out by various health bureaus and departments, TFDA provided support for acquiring precision instruments and standard samples. Testing resources and special regional requirements of the health bureaus and departments were also referenced to establish specialized testing programs in health bureaus and departments in northern, central, southern, municipal, and the nation-wide Regional Joint Testing Specialization System of Health Bureaus and Departments.

(2) Results of Joint Regional Specialization

According to the List of Specialized Food Sanitation Testing in Central and Local Agencies, average independent testing capacity of local health bureaus and departments prior to the subsidies was 35%. This figure was raised to an average of 80% after the subsidies. When compared to 2014, additional Independent Tests introduced in 2015 included tests for 214 modern pharmaceutical product adulterants in food (and traditional Chinese medicine), 3-monochloro-1, 2-propandiol, dimethyl yellow, and diethyl yellow.

(3) Laboratory Certification

To ensure laboratory testing quality, TFDA certified 698 laboratory tests in 22 health bureaus and departments throughout Taiwan by 2015.

Section 3. Comprehensive Private Laboratory Accreditation and Management System

To improve testing proficiency and quality of local health bureaus and departments, TFDA established an efficient testing specialization system to enhance local testing capacities. TFDA also initiated an accreditation program of local laboratories and published a list of accredited laboratories that may be referenced by the general public, helping to conduct testing work for government agencies, consumer groups, independent quality control organizations within factories, and product exports and imports.

Current Status

To effectively leverage testing resources of private laboratories, ensure the quality and credibility of commissioned testing activities, and expand testing capacities, TFDA implemented a pro-active and free accreditation program for private laboratories. The scope of TFDA laboratory accreditation include tests for food, drugs, cosmetics, urine tests for identifying drug abuse, and Good Laboratory Practice (GLP) for non-clinical studies. As of the end of 2015, 163 laboratories throughout Taiwan were accredited (132 private laboratories and 31 government laboratories), including 72 food testing laboratories, 30 drug and cosmetic testing laboratories, 15 urine testing laboratories for identifying drug abuse, and 15 GLP laboratories (Figures 2-7-7 and 2-7-8). As for regional distribution, there were 88, 29, and 46 accredited laboratories in northern, central, and southern Taiwan respectively. 1,221 tests items were accredited, of which 789 were related to food, 370 to drugs and cosmetics, nine to urine tests for identifying drug abuse, and 53 GLP-related tests items (Figure 2-7-9). The accreditation program helped to establish laboratories with adequate testing capacity and credibility able to meet testing requirements for emergencies and sudden events.

Policies and results

1. Accreditation of Food, Drugs, and Cosmetics Laboratories

(1) Expanding Testing Capacities of Laboratories

a. Accreditation programs for food laboratories as well as drug and cosmetic laboratories were initiated in 2004 and 2008 respectively. In 2010, TFDA streamlined and expanded the laboratory accreditation action plan and continued to promote border inspections for food and traditional Chinese medicine, establish quantity limit standards for traditional Chinese medicine, and provide accreditation to commissioned tests for administrative processes in order to accelerate the expansion of testing capacities.

b. As of 2015, the numbers of accredited laboratories and tests were increased to 102 laboratories and 1,159 tests items respectively, with 51, 18, and 33 laboratories in northern, central, and southern Taiwan respectively. 72 of these were food testing laboratories while 30 were drug and cosmetic testing laboratories (Figures 2-7-7 to 2-7-9).

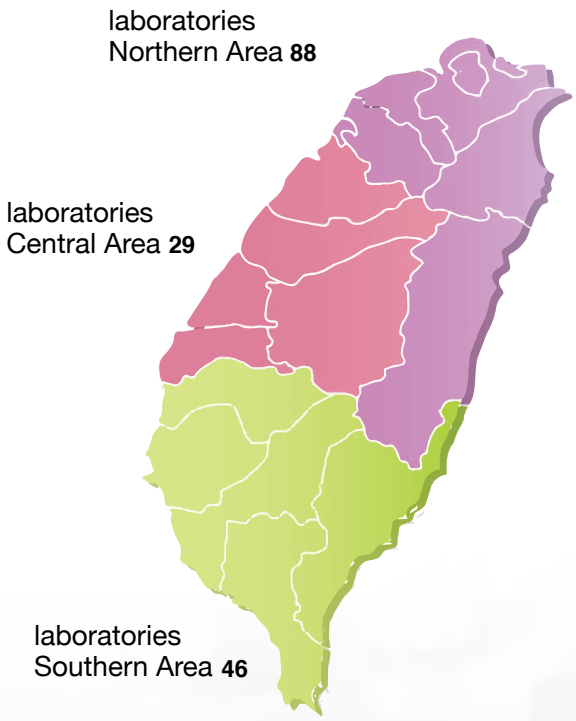
(2) Enhancing Monitoring and Supervision Systems

a. Regular and Unannounced Audits

To effectively monitor and manage accredited test agencies and establish a system for assessing the truthfulness of test data, TFDA audited 133 accredited test agencies, of which 112 of the audits were first-time audits, expansion of test items, change of test items, permit extension, and surveillance audits, while 21 of the audits were unannounced.

b. Implementing Proficiency Testing

TFDA regularly publishes the results of proficiency testing of accredited laboratories. In 2015, 22 proficiency tests were carried out, including 17 food tests and 5 drug and cosmetic tests. 10 accredited laboratories failed re-evaluations and their test accreditations were abolished. TFDA also organized four Laboratory Accreditation Tests Using Double-Blind Samples in order to verify the truthfulness of testing data, and encouraged laboratories to participate in overseas proficiency tests to ensure the quality and independent management capacities of Taiwan's accredited laboratories.



Northern Area

TFDA: Divisions of Research & Analysis and Northern Center (7 units)

Local health bureaus and departments: Northern region joint testing specialization system (10 counties and cities)

Accredited laboratories: Food: 33 laboratories; drugs and cosmetics: 18 laboratories; urine tests for drug abuse: 7 laboratories; and GLP: 13 laboratories (71 laboratories in total)

Central Area

TFDA: Central Center (1 unit)

Local health bureaus and departments: Central region joint testing specialization system (5 counties and cities)

Accredited laboratories: Food: 14 laboratories; drugs and cosmetics: 4 laboratories; urine tests for drug abuse: 3 laboratories; and GLP: 2 laboratories (23 laboratories)

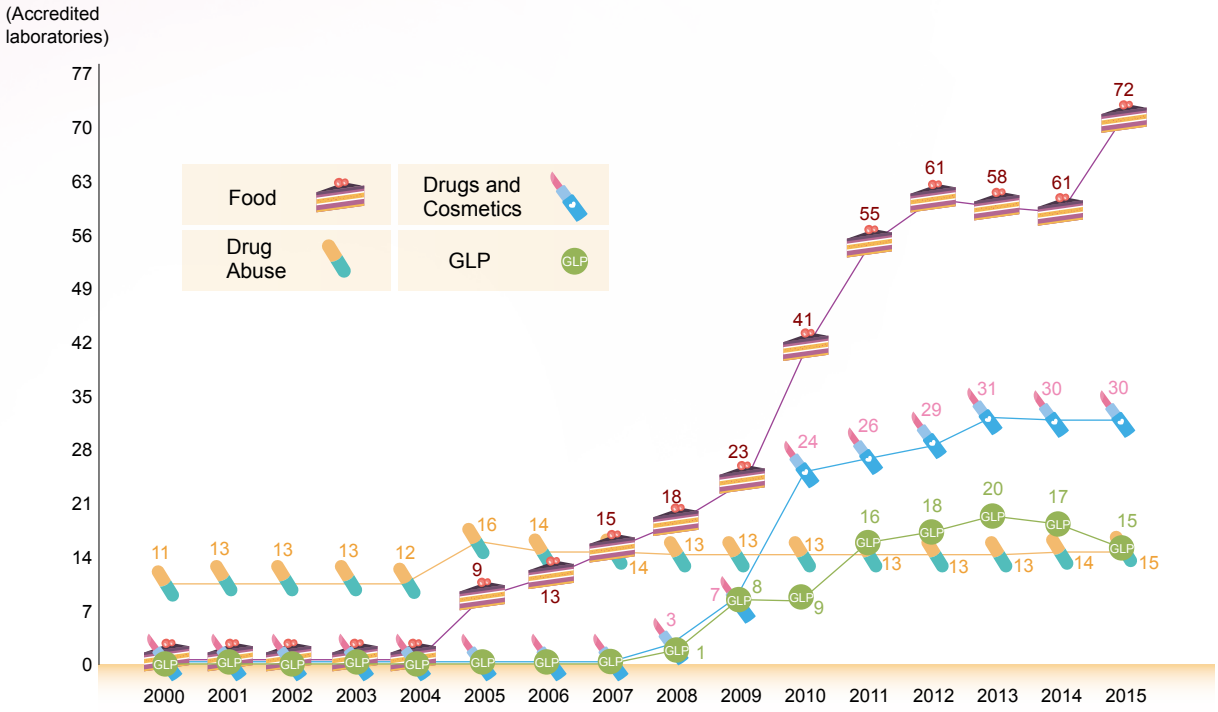
Southern Area

TFDA: Southern Center (1unit)

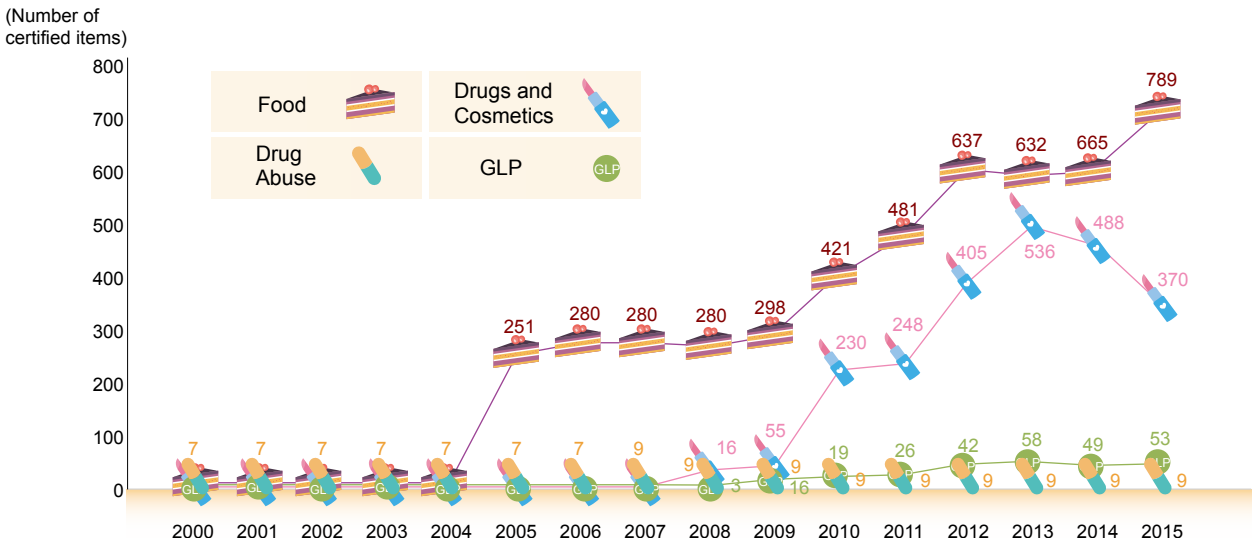
Local health bureaus and departments: Southern region joint testing specialization system (7 counties and cities)

Accredited laboratories: Food: 25 laboratories; drugs and cosmetics: 8 laboratories; urine tests for drug abuse: 5 laboratories (38 laboratories in total)

▲ **Figure 2-7-7** Current state of TFDA laboratory surveillance network and distribution of accredited laboratories



▲ **Figure 2-7-8** Number of TFDA accredited laboratories throughout the years



▲ **Figure 2-7-9** Number of TFDA accredited tests items throughout the years

(3) Exemption from Repeated Testing

In January 2015, TFDA recommended four testing agencies for the list of Class B public testing agencies of exporting countries of the Ministry of Health, Labor and Welfare in Japan, and successfully achieved exemption from border inspection sampling tests for Taiwan's food exports to Japan, helping to accelerate customs clearance, reduce inspection fees, and reduce commercial costs for food companies.

(4) Introducing Accelerated Accreditation Processes

On December 14, 2015, TFDA approved revisions to the List of Tests Not Requiring Measurement Uncertainty Assessment Report for Food Testing Institutions Applying for Quantitative Test Accreditation and updated applicable testing methods to encourage testing institutions to apply for certification. In 2015, two laboratories and nine test items successfully completed accelerated accreditation, providing an additional option and reference for border inspection tests, administrative requirements, and commissioned testing for business requirements.

2. Accreditation of Urine Testing Laboratories for Identifying Drug Abuse

(1) As of the end of 2015, TFDA accredited 15 urine testing laboratories for identifying drug abuse, of which six, three, five, and one were distributed in northern, central, southern, and eastern Taiwan respectively. Accredited tests for urine testing laboratories for identifying drug abuse include 9 types of drugs, namely: morphine, codeine, methamphetamine, amphetamine, MDMA, MDA, cannabis metabolites, ketamine, and norketamine.

(2) To ensure the quality of accredited urine tests for identifying drug abuse, TFDA conducted 15 routine audits and 6 unannounced audits of the accredited institutions. Four rounds of routine proficiency tests of 58 accredited institutions were carried out as well.

(3) In 2015, TFDA held the Drug Abuse Urine Testing Institution Accreditation Review Committee and On-Site Assessment Committee Meeting and the Conference for Drug Abuse Testing Techniques to make the following resolutions: passing urine tests of 1 accredited testing institution, and that the period for preserving urine samples that have tested positive shall be determined by the contractual terms signed by the test commissioner and commissioned test institution.

3. Good Laboratory Practice (GLP) Laboratory Accreditation for Non-clinical Studies

(1) TFDA implemented the GLP for Non-clinical Studies in order to improve the truthfulness and reliability of test data. The scope of TFDA GLP accreditation includes the sectors of medicinal products, medical devices, health foods, and cosmetics, as well as relevant non-clinical safety tests for biological systems during the research and development (R&D) phase of the various sectors.

(2) In 2015, TFDA completed GLP audits and consultations for 10 laboratories and accredited 15 GLP laboratories and 53 tests items, of which 13 and 2 laboratories were in northern and central Taiwan respectively.

(3) In 2015, TFDA implemented auditor training and business management seminars, and introduced the latest information from other countries to establish consistent auditing standards. These activities helped businesses and responsible personnel gain a better understanding of GLP specifications as well as trends in the industry.

Chapter 8

International Cooperation and Cross-Strait Exchanges

Chapter 8. International Cooperation and Cross-Strait Exchanges

Exchanges and technical collaborations between different countries are becoming increasingly important. International politics, economic, and trade would mutually influence each other. One of the key strategies of the government's administration would be to gain an effective understanding of global changes and align with international standards. Also through the Cross-Strait Food Safety Agreement and Cross-Strait Agreement on Medical and Health Cooperation, the TFDA upholds the spirit of creating a win-win environment for all related parties in order to implement the notification and exchange mechanisms by the agreements to promote collaboration and development in the pharmaceutical and health industries.

Section 1. International Cooperation and Exchange

Current Status

To improve the international visibility of Taiwan's food, drugs, medical devices, and cosmetic industries, TFDA actively participates in international harmonization organizations, hosts conferences on international regulations, and establishes platforms for bilateral partnerships. Information on laws and regulations is compiled in order to revise local laws with the aim of achieving global harmonization and aligning Taiwan's laws with international standards.

Policies and Outcomes

1. Participation in International Organizations and Events to Encourage Regulatory Harmonization

(1) Food

The TFDA attended the Asia-Pacific Economic Cooperation (APEC) Sub-Committee on Standards and Conformance (SCSC) meeting as well as the corresponding Food Safety Cooperation Forum from August 23 to 26, 2015. The TFDA also attended the 1st Expert Workshop on Harmonization of Pesticide Maximum Residue Limits (MRLs) for Imported Foods in APEC Member Economies of SCSC to actively exchange food safety standards and activities with other members from April 21 to 22, 2015.

(2) Medicinal Products

a. Since 2011, the TFDA has been serving as the champion of APEC 2020 Roadmap for Good Review Practice on Medical Products in the APEC Regulatory Harmonization Steering Committee (RHSC).The goal of the Roadmap was to improve the performance of health authorities and promote regulatory convergence for medical products in the APEC region by 2020.

   Since 2015, Taiwan has been promoting Good Submission Practices for applicants in the APEC RHSC. Such activities were greatly supported by the Japan Pharmaceutical Manufacturers Association (JPMA), and also promoted collaborations between competent authorities and businesses of both countries. Participation of the APEC platform has promoted Taiwan's regulatory exchange and regulatory convergence for medical products.

b. The TFDA also actively sought collaboration with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), allowing Taiwan to host the 8th Asia Regulatory Conference (ARC) from February 4 to 5, 2015, the very first conference of its kind to be held in Taiwan. Taipei was selected as the venue for the 8th ARC, and representatives of national health authorities governing pharmaceutical affairs as well as industrial experts from the US, EU, Japan, Canada, South Korea, Singapore, Thailand, Malaysia, Australia, and Switzerland were invited

to participate in discussions on promoting Good Review Practices (GRevP), Good Submission Practice (GSP), and regulatory harmonization for pharmaceutical products in the Asia region, making the ARC the perfect discussion platform for industry, government, academia, and research institutions of countries around the world.

(3) Medical Devices

Taiwan is one of the founding members of the Asian Harmonization Working Party (AHWP). Since 2012, a TFDA official has served as the chairperson of the work group for the technical committee of in vitro diagnostic devices (WG2 - Premarket: IVDD) and led the development of five international IVDD guidance standards adopted as AHWP official documents. A TFDA staff person has also become member of the professional committee of work group 3 of the International Standard Organization / Technical Committee 212 (ISO/TC 212).

(4) Cosmetics

a. In September 2015, a TFDA delegation was sent to France and Belgium to visit the European Commission Directorate-General Internal Market, Industry, Entrepreneurship and SMEs as well as the French authority on cosmetics (Figures 2-8-1 and 2-8-2), and had exchanges on laws and regulations governing cosmetic products and status of implementation for a number of specific areas, such as product notification systems, product information files, GMP regulations for cosmetics, and postmarketing management of cosmetics.

▲ Figure 2-8-1 Visiting the European Commission Directorate-General Internal Market, Industry, Entrepreneurship and SMEs

▲ Figure 2-8-2 Visiting the French authority on cosmetics (General Directorate for Competition Policy, Consumer Affairs and Fraud Control, or DGCCRF)

2. Bilateral Activities (including signing of relevant agreements and memorandum of understanding))

(1) The signing of the Joint Declaration of Cooperation for Drugs and Medical Devices by TFDA Director General Yu-Mei Chiang and Prof. Dr. Karl Broich, President of The Federal Institute for Drugs and Medical Devices (BfArM) of Germany, was witnessed by Representative Hwa-Yue Chen, the Taipei Representative Office in the Federal Republic of Germany (Figure 2-8-3). The Joint Declaration of Cooperation was signed on October 13, 2015, allowing both signatories to achieve further exchange of confidential documents and non-public information on medicinal products, active pharmaceutical ingredients (APIs), and medical devices, improve management proficiency of pharmaceutical affairs, and accelerate the market approval of medical products in both countries, creating a mutually beneficial environment.

(2) On November 5, 2013, the Arrangement between the Association of East Asian Relations and the Interchange Associations for the Establishment of the Framework of the Cooperation on the Medical Products Regulation was signed, where both parties agreed to take turns in hosting exchange meetings and conferences. Taiwan held the first session of the meeting as

well as the 3rd Joint Conference of Taiwan and Japan on Medical Products Regulation (Figure 2-8-4) on November 26, 2015 that included conferences and closed-door meetings on topics ranging from medical products regulations, health insurance, to medical devices. Results of these partnerships were discussed in order to promote regulatory, assessment, and industrial collaboration of both parties.

▲ Figure 2-8-3 Taiwan's Representative in the Federal Republic of Germany witnessed the signing of cooperation by the Federal Institute for Drugs and Medical Devices of Germany

▲ Figure 2-8-4 3rd Joint Conference of Taiwan and Japan on Medical Products Regulation

3. Hosting Large Scale International Conferences

(1) The 3rd Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) Expert Circle Meeting on Good Distribution Practice (GDP) was held in Taiwan from March 24 to 26, 2015 (Figure 2-8-5). Attendants of the meeting included 47 senior inspectors from 25 different countries. Official representatives from seven countries, namely the UK, Canada, Switzerland, Ireland, Sweden, Spain, and Taiwan presented trends of management regulatiory and the latest topics related to GDP. Attendants to the meeting also jointly drafted technical documents for medicinal products GDP while sharing GDP inspection standards and experiences, benefitting to improve and align Taiwan's GDP inspectorate management system and regulations to international standards.

(2) From July 16 to 17, 2015, Taiwan hosted the 2015 International Symposium on Safety Management of Imported Foods and invited official representatives from Vietnam, Malaysia, and the Philippines to introduce their respective national management systems as well as border and customs management measures for imported foods. By gaining familiarity with food import management systems adopted by various countries and sharing management experiences, the Symposium helped provide a reference for enhancing sanitation and safety systems of imported foods in Taiwan.

▲ **Figure 2-8-5** The 3rd PIC/S Expert Circle Meeting on Good Distribution Practice (GDP)

(3) The International Symposium on Food Additives was held in Taiwan on July 21, 2015. Experts from the International Food Additive Council (IFAC), the US, Canada, Japan, and other countries were invited to the Symposium to discuss many topics that covered global safety assessments, management measures, and good industrial practices related to food additives.

(4) The 2015 International Symposium on Substance and Prescription Drug Abuse was held in Taiwan during September 1 to 2, 2015 (Figure 2-8-6). Eight experts from the US, Finland, Austria, and Australia were invited to share their experiences and exchange opinions with drug abuse experts and professionals in Taiwan, helping to develop measures for preventing drug abuse and monitoring controlled drug prescriptions in Taiwan.

(5) The International Symposium on Food Nanotechnology, held in Taiwan on September 21, 2015, served as a platform for technical exchange. Experts from Japan, the UK, Hong Kong, and the US were invited to discuss a variety of topics ranging from the use of nanotechnology in the food industry, safety issues, to sources management.

(6) The 2015 International Conference on Medical Devices Regulations in the Asia-Pacific Region was held in Taiwan during October 21 to 22, 2015. Experts on medical device regulations and central health authorities from South Korea, Singapore, Malaysia, and Australia were invited to give talks on the current status and future prospects of pre- and post-market regulations and management for medical devices in the Asia-Pacific region, helping businesses gain a better understanding of overseas regulations to expand their export markets.

▲ **Figure 2-8-6** 2015 International Symposium on the Prevention of Drug Abuse and Monitoring of Controlled Drug Prescriptions

Section 2. Globalization of Laboratory Testing

Current Status

TFDA actively worked with test organizations from developed countries to establish effective partnerships, learn and introduce the latest technologies, and host international conferences to showcase practical experiences to improve testing capacities being researched and developed in Taiwan.

Policies and Outcomes

1. Food Products

(1) TFDA organized the APEC Conference on Management and Related Scientific Detection of Food Additives in Foods on April 29, 2015 and invited representatives and experts on food safety from Taiwan and other countries such as the US, EU, Japan, Hong Kong, and Singapore to share their experiences on early warning and alert systems for unexpected food additives, food safety protection, and sudden incidents related to food additives and contaminants.

(2) TFDA participated in the 129th Annual Meeting of the Association of Official Analytical Chemists (AOAC) of the US held in Los Angeles during September 27 to 30, 2015 (Figure 2-8-7) that was attended by about 1,000 experts and academicians from around the world. During the meeting, TFDA delegate gave an oral presentation on a paper titled New Blood 2015: Developing Methods for the Detection of Chemical Analytes and Contaminants as well as talks addressing various topics during the Taiwan Section Business Meeting of the Annual Meeting, making use of the opportunity to demonstrate Taiwan's testing and analytical competence and capacity and build channels of exchange with experts around the world.

▲ Figure 2-8-7 Joint meeting of the Asia chapter of the AOAC

▲ Figure 2-8-8 2015 International Conference on Illegal Medicines and Adulterated Dietary Supplements

(3) On October 16, 2015, TFDA invited the EU and Belgium representative to attend the meeting of the chemist experts on analytical methods organized by the International Olive Council (IOC) as expert participants. The IOC adopted the testing method for copper chlorophyll in pomace olive oil, presented test results of 16 laboratories from six countries, exchanged technical opinions, and recognized the method developed by TFDA.

(4) November 30 to December 7, 2015: TFDA participated in the Conference of Testing Techniques for Illegal Drugs and Food adulteration hold by U.S. Pharmacopoeial Convention to investigate current cases of economically-motivated adulteration and fraud, and discuss relevant testing techniques and legal systems.

2. Medicinal Products

(1) TFDA organized the International Conference on Illegal Medicines and Adulterated Dietary Supplements from September 1 to 2, 2015 (Figure 2-8-8). Experts, academicians, and representatives of official agencies and industrial associations from the US, the EU, Japan, Singapore, South Korea, and Malaysia were invited to Taiwan to share experiences on testing techniques and management of illegal drugs. The President himself gave a message commending the Conference, helping to greatly improve the prestige of the event.

(2) TFDA attended the 2015 US Pharmacopoeial Convention from April 22 to 26, 2015 to discuss key guidelines of the US Pharmacopoeia (USP) from 2015 to 2020 and other topics such as increased collaboration between the USP Convention with TFDA, modernization of specific medicinal products, and improvements to food safety to achieve bilateral collaboration.

(3) TFDA participated in the 1st European Pharmacopoeia Commission meeting session of 2015 from March 15 to 16, 2015 as an observer of the European Directorate for the Quality of Medicines & HealthCare (EDQM) of the Council of Europe in order to gain an understanding of the compilation, key focuses, and operational models of the European Pharmacopoeia, and to exchange opinions on medicinal product quality and testing techniques with various representatives around the world.

(4) TFDA attended the 8th Edition of the European Pharmacopoeia Training Session - Chemicals of the EDQM from July 9 to 10, 2015 in order to acquire lessons on the compilation and revision of the European Pharmacopoeia, formulation of analytical methods and specifications for impurities in drugs, preparation of standard samples, and suitability of the Certificate European Pharmacopoeia (CEP) for active pharmaceutical ingredients (APIs).

(5) TFDA visited the National Institute of Health Sciences (NIHS) of the Ministry of Health, Labor and Welfare (MLHW) of Japan during November 10 to 19, 2015, and carried out a series of on-site technical studies at the laboratories of Division of Pharmacology and Division of Biomedical Food Research (including illegal drugs) to investigate the practice of medicinal product quality evaluation and research, quality management of traditional Chinese medicinal preparations, current state for the management of abused drugs, identification and analysis of unknown materials, and identification of the botanical sources for biomedical products in Japan.

(6) TFDA was invited to participate in collaborative studies for international standards that included the 4th WHO International Standard for Streptomycin, 5th WHO Hepatitis C Virus for NAT-based assays, and 1st WHO International Standard for anti-EV71 serum.

(7) TFDA attended the 20th anniversary meeting of the Standardisation of Genome Amplification Techniques (SoGAT) in June 2015, to understand the process of establishing international standards of WHO which could then be used to establish standards for blood-borne pathogens in Taiwan.

(8) In September 2015, TFDA attended the 1st Asia Lab-Net workshop organized by the National Institute of Food and Drug Safety Evaluation (NIFDS) of South Korea (Figure 2-8-9), and gave a speech sharing management experiences of lot release of biologics in Taiwan, helping various countries to achieve better understanding on the details of the lot release management system.

(9) US Pharmacopoeia committee member Dr. Edith Chang Yu-Wen was invited to give a speech on Experience Sharing and Process of the Standardization of Biopharmaceuticals in the US Pharmacopoeia (Figure 2-8-10) to achieve better understanding of the compilation of USP, preparation of standards, and standardization of emerging technologies and products. These

lessons could then be applied to the compilation of our pharmacopoeia and have it come up to international standards.

Figure 2-8-9 1st Asia Lab-Net Workshop

Figure 2-8-10 A member of the US Pharmacopoeia giving a speech

3. Medical Devices

(1) In November 2015, TFDA visited the Massachusetts General Hospital (MGH) of Harvard Medical School as well as Medtronic, a manufacturer of medical catheters (Figure 2-8-11) to study and observe quality testing and verification technologies employed for artificial joints, thrombus extraction catheters, and other medical devices.

(2) TFDA visited manufacturers and companies such as Terumo Corporation, SHISEIDO Company, Limited, BOKEN Quality Evaluation Institute, and Fujirebio Inc. in Japan during September 14 to 18, 2015 to study and observe measurement and verification techniques employed for intravenous administration sets, medical-grade hyaluronic acid, far infrared textiles, in vitro diagnostic device (IVD), and other medical devices.

Figure 2-8-11 Visiting the MGH and Medtronic

Section 3. Cross-Strait Exchange

Current Status

After signing the Cross-Strait Food Safety Agreement on November 4, 2008, information notification and exchange systems were established between Taiwan and Mainland China. The Expert Meeting of Cross-Strait Food Safety Competent Authorities and Cross-Strait Food Safety Agreement - Meeting for the Safety of Food Imports and Exports were held every year to conduct exchanges on food standards, risk communication, safety of food imports and exports, and other relevant topics.

For medical products, after Taiwan and Mainland China signed the Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs on December 21, 2010, the TFDA established the Working Group on Safety Administration and Research and Development of Medicinal Products which was further divided into four divisions respectively in charge of drugs and cosmetics, medical devices, health foods, and testing processes to discuss collaborative models between the signatories of the Agreement. The TFDA also established a systematic framework and platform for cooperation on quality optimization and safety management, mechanisms on coordinated handling of major incidents related to medical product safety, and harmonization of standards and regulations. Pilot areas and projects were used to implement cooperation on clinical trials and trial results from the other party were gradually used to explore the maximum utilization of medical product management, research, and development capacities of both parties, and to strengthen medical product quality and safety, and shorten R&D cycle time. These measures would help attain earlier access of safe and effective medical products and safeguard the health of people from Taiwan as well as Mainland China.

Policies and Outcomes

1. Systematic Meetings

(1) Food

TFDA held two meetings with the Mainland China counterparty in 2015 according to the terms of the Cross-Strait Food Safety Agreement and organized conferences to address areas of concern from both parties.

a. On June 16, 2015, the 9th Expert Meeting of Cross-Strait Food Safety Competent Authorities with the National Health and Family Planning Commission of Mainland China was held at Guilin (Figure 2-8-12), continuing the exchange of the latest progress in regulatory addenda and revisions and improving the comprehensiveness of food safety management specifications for both Taiwan and Mainland China.

b. On June 18, 2015, the Cross-Strait Food Safety Agreement - 6th Meeting on the Safety of Food Imports and Exports with the General Administration of Quality Supervision, Inspection, and Quarantine of the People's Republic of China (AQSIQ) was held at Guilin (Figure 2-8-13) to discuss and exchange opinions on issues regarding the safety of food imports and exports. Both parties agreed to enhance notification of nonconforming products and work together for the handling of food safety incidents.

▲ **Figure 2-8-12** The 9th Expert Meeting of Cross-Strait Food Safety Competent Authorities

c. TFDA organized the Cross-Strait Conference for the Specifications and Actual Practice of Food Import Safety Management in Taiwan on May 12 and 14, 2015. Both parties discussed and exchanged opinions on the specifications and practices for the safety management of imported foods. Relevant food businesses from both parties were invited to the Conference as well.

d. TFDA organized the 2015 Seminar on Food Safety Management Specifications in Mainland China in Taiwan from October 13 to 15, 2015. Official personnel from relevant Mainland Chinese agencies were invited to Taiwan to discuss the newly revised Food Safety Law of Mainland China and impacts of the revision on food safety monitoring and food imports management. Various associations and businesses were also invited to attend the seminar.

▲ Figure 2-8-13 Cross-Strait Food Safety Agreement - 6th Meeting on the Safety of Food Imports and Exports

(2) Medical Products

a. In 2015, the Working Group on Safety Administration and Research and Development of Medicinal Products of Taiwan and Mainland China referenced the Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs (Figure 2-8-14) and held 13 conferences and work group meetings (Table 2-8-1). Video conferences were held for significant issues to maintain communications and streamline meeting procedures.

Table2-8-1 **List of Cross-Strait meetings and exchanges on medical products**

Date	Location	Name of the medical product meeting and exchange
April 2015	Shandong, China	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Product and Cosmetic Work Group Meeting (on medicinal products)
April 2015	Beijing, China	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Product and Cosmetic Work Group Meeting (on cosmetics)
April 2015	Beijing, China	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Device (and Instrument) Work Group Meeting
August 2015	Beijing, China	Meeting of the Working Group on Safety Administration and Research and Development of Medicinal Products
September 2015	Taipei, Taiwan	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Device (and Instrument) Work Group Meeting
September 2015	Nantou, Taiwan	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Product and Cosmetic Work Group Meeting (on medicinal products)
October 2015	Taipei, Taiwan	4th Cross-Strait Exchange Conference for Medical Product Testing Techniques
October 2015	Taipei, Taiwan	Working Group on Safety Administration and Research and Development of Medicinal Products - Inspection and Testing Work Group Meeting
November 2015	Taipei, Taiwan	5th Cross-Strait Conference for Collaborative Medical and Medicinal Product Research and Development
December 2015	Wuhan, China	(Summit) Meeting of the Working Group on Safety Administration and Research and Development of Medicinal Products
December 2015	Wuhan, China	Working Group on Safety Administration and Research and Development of Medicinal Products - Health Food (and Supplement) Work Group Meeting
December 2015	Wuhan, China	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Product and Cosmetic Work Group Meeting (on medicinal products)
December 2015	Wuhan, China	Working Group on Safety Administration and Research and Development of Medicinal Products - Medical Product and Cosmetic Work Group Meeting (on cosmetics)

▲ Figure 2-8-14 Summit meeting of the Working Group on Safety Administration and Research and Development of Medicinal Products

b. TFDA participated in the 2015 International Meeting for the Prevention of Substance Abuse in Mainland China, conducting official dialogue and exchanged information with leading experts of the Asia Pacific region in the field of substance abuse as well as discussing various topics related to the epidemiology, treatment, and prevention of drug abuse in the Asia Pacific region.

2. Border Control Information Notification

TFDA and its Mainland China counterpart have established contact windows to notify nonconforming food products information in order to facilitate effective response and handling of these cases. 941 cases were reported by both parties in 2015. Nonconforming food exported from Mainland China to Taiwan were either returned or destroyed. Incidents of food exported to Mainland China from Taiwan that failed to conform to Taiwan's regulations were reported to the responsible local health bureaus. The local health bureaus would take actions against the violating cases. Consultations were provided to businesses that food exports must comply with the regulations of the trading counterparty as well.

3. Harmonization of Regulations and Standards

(1) Cross-Strait notification for addenda and revisions to regulations such as the food additive standards and food safety and sanitation standards was conducted through the contact window in order to promote exchange of relevant opinions and achieve mutual understanding. From the time of its establishment to the end of 2015, in total, both sides made 24 notification on food additive standards and eight notification on food safety and sanitation standards.

(2) In 2015, comparisons and harmonization of test methods and standards were conducted for common tests performed in both Taiwan and Mainland China, with seven tests listed in the Pharmacopoeia compared and harmonized accordingly. The aim of this activity was to establish the feasibility of streamlining or exempting medical product testing requirements for Taiwan and Mainland China.

(3) The 4th Cross-Strait Exchange Conference on Medicine and Medical Products Testing Techniques (Figure 2-8-15) was held in Taipei during October 19 to 20, 2015. The Conference discussed 18 topics that included medicinal products, medical devices, health foods, cosmetics, and laboratory accreditation, and was helpful to harmonize medical product testing standards and technologies in Taiwan and Mainland China.

4. Research and Development Partnerships

(1) Expediting the Market Release of Products Made in Taiwan

a. Since 2012, Taiwan had continued to propose to the China Food and Drug Administration (CFDA) to allow medical devices that were already approved by Taiwan to be reviewed by provincial or municipal food and drug administrations. On 2015, the Fujian Provincial Food and Drug

Administration announced the task for filing a number of Class 1 medical devices manufactured in Taiwan would be officially started.

b. After completing Cross-Strait exchanges on regulatory laws governing cosmetic products in July 2012, results of legal exchange and comparison were used to discuss collaboration between testing institutions in Taiwan and Mainland China. In 2015, both parties initiated proficiency trials and comparisons of testing institutions on micro-organism and heavy metal content testing in cosmetic products. The aim of this activity was to achieve Mainland Chinese recognition of test reports produced by Taiwanese institutions, accelerate and improve the efficiency of the cosmetic product review process, and shorten product release cycle time in Mainland China.

(2) Collaborative Clinical Trials for Medical Products

Medical product agencies of Taiwan and Mainland China jointly formulated the Cross-Strait Collaboration Program for Clinical Trials of Medical Products and assembled a Medical Product Clinical Trial Work Group to accelerate Cross-Strait collaboration for clinical trials of medical products and reduce the need for repeated testing.

(3) Initiating Joint Inquiry and Review Programs

Open soliciting for Pilot Program for Cross-Strait Collaboration in Medicinal Product Research and Development and Pilot Program for Cross-Strait Collaboration in Medical Device Research and Development was carried out in order to build a collaborative framework for the review of medicinal products and medical devices in Taiwan and Mainland China.

(4) Hosting the Cross-Strait Conference for Collaborative Medical and Medicinal Product Research and Development

The 5th Cross-Strait Conference for Collaborative Medical and Medicinal Product Research and Development was held in Taipei from November 23 to 24, 2015. Experts and corporate representatives from Taiwan and Mainland China were invited to the Conference to exchange opinions and share experiences on various topics such as strategies for Cross-Strait collaboration for the clinical trials of novel medicinal products.

(5) Hosting the 2015 Summit Meeting of the Task Force for the Management, Research, and Development of Medical Product Safety

The 2015 Summit Meeting of the Task Force for the Management, Research, and Development of Medical Product Safety was held at Wuhan, Mainland China, on December 17, 2015. Both parties acknowledged the work results of 2015 and discussed work plans for 2016.

▲ **Figure 2-8-15** 4th Cross-Strait Exchange Conference on Medicine and Medical Products Testing Techniques

Chapter 9

Risk Communication and Consumer Protection

Chapter 9. Risk Communication and Consumer Protection

To minimize public fear caused by lack of information or spread of misinformation and to improve public understanding, trust, and confidence, TFDA employs education and a diverse selection of real-time channels to strengthen communication with consumers and media companies and quickly provide them with professional and accurate information.

Section 1. Providing Consumers with Immediate Information

Current Status

In addition to the official website (http://www.fda.gov.tw), TFDA also has various information sections and services that include: Food and Drug Consumer Service Network (http://consumer.fda.gov.tw/), Promoting Food Sanitation and Safety, Busting Myths about Food and Drugs, Illegal Advertisement Query System for Food, Drugs, and Cosmetics, and Digital Interactive Learning Network for Correct Drug Use, allowing the public to immediately access data on food, drugs, and cosmetics and easily acquire needed knowledge on product safety.

Policies and Outcomes

1. Busting Myths about Food and Drugs

(1) In order to bust Internet myths, TFDA established the specialized section titled Busting Myths about Food and Drugs on its official website on April 24, 2015. Experts in various fields were invited to provide professional opinions on myths related to food, drugs, medical devices, and cosmetics, using empirical science to answer and clarify every question and myth. As of the end of 2015, 140 myths were busted, including 90 myths on food, 28 on drugs, 11 on medical devices, and 11 on cosmetics. five press articles were also published to put an end to rumors.

(2) As of the end of 2015, the two leading rumors with the highest number of views were *How many were killed by mushroom poisoning ?* and *Top 10 Carcinogenic Foods from LINE*. Each of these rumors were read by about 4,100 individuals and actively covered by the press, achieving positive press coverage.

2. Use of Facebook Groups

TFDA established the Food Player Facebook Page, Sleep Tight Facebook Page, and TFDA Safe Cosmetic Use Facebook Page that provide interesting and practical lifestyle tips and information as well as the latest events to provide the public with accurate educational materials on health and safety of food, drugs, and cosmetics.

3. Provision of Relevant Information Channels

(1) TFDA published a digital report titled Medical Products and Food Safety Weekly and used mobile devices and website browsers to improve the diversity and convenience of browsing modes and promptly disclose the latest information and top public concerns from Taiwan and other countries.

(2) In 2015, TFDA released over 20 publications related to food and drugs such as the Taiwan Food and Drug Administration Annual Report (Chinese and English versions), Volume 23 of the Journal of Food and Drug Analysis, Addendum to the 7th Version of the Chinese Pharmacopoeia, Anti-Drug Abuse Guide Book for Parents, Manual on Food Labeling Laws, and Overall Perspective for the Management of Sanitation and Safety of Food Services, providing the public diverse options and channels to knowledge (refer to Annex 2 for the list of publications).

Section 2. Consumer Communication and Advocacy

Current Status

The purpose of consumer communication and advocacy is to help the public gain direct understanding of current government policies and acquire correct and accurate knowledge on food safety. TFDA strengthened direct communication and awareness promotion programs for the public and media companies and deployed a diverse selection of communication channels for food safety, proper drug use, and cosmetic management for the purpose of establishing correct knowledge and risk concepts amongst the people.

Policies and Outcomes

1. 1919 National Food Safety Helpline

On December 4, 2015, the government established the *1919 National Food Safety Helpline*, the first cross-departmental single-counter public convenience service helpline in the country. Existing food-related inquiry helplines from four public agencies, namely TFDA, Consumer Protection Committee, Council of Agriculture, and Ministry of Economic Affairs, were integrated. The resulting 1919 Helpline provided five services, namely: (1) receiving complaints of food products, (2) providing food-related consultation, (3) acquiring support for consumer issues, (4) providing consultationto small and medium-sized enterprises (SMEs), and (5) providing consultationon fresh farm produce. Users can dial 1919 directly to avail themselves of instant services (Figures 2-9-1 and 2-9-2), expanding the coverage of the food safety defense network.

Figure 2-9-1 1919 National Food Safety Helpline

▲ Figure 2-9-2 Multiple public agencies working together and declaring their commitment to the Dial 1919 and GO

2. Diversified Inquiry and Communication Services

(1) To encourage whistle-blowing and exposure of illegal acts related to food safety, TFDA promulgated the Regulations on Food Safety and Sanitation Violation Report and Reward to effectively encourage public reporting of illegal acts, improve the likelihood for the exposure of illegal acts, and strengthen the protection of the rights and interests of the informant.

(2) To make it easier for members of the public to inquire, petition, or expose illegal activities, TFDA operates the Tel (02) 2787-8200 inquiry service helpline. 44,660 calls were received in 2015 that primarily addressed food-related issues (49.8% of the calls).

(3) TFDA provided the Director-General's Mail Box which received 13,351 mails in 2015. An additional 2,062 cases were transferred from the Ministry of Health and Welfare (MOHW) and other supervising agencies to TFDA thus making 15,593 cases.

(4) TFDA introduced the food labeling helpline of Tel 0800-600-058, food sales helpline of Tel 0800-676-668, medical device consultation helpline of Tel (02) 8170-6008, and cosmetics inquiry helpline of Tel (02) 6625-2333. These helplines could be used by the general public to clarify doubts and questions.

3. Improving Awareness and Risk Concepts amongst Consumers

To improve public understanding for key administrative measures related to various consumer protection activities on food, drugs, and cosmetic products, TFDA organized 27 Safety, Protection, and Risk Communication for Food, Drugs, and Cosmetic Products training seminars for 1,358 attendants in 2015.

4. Training Program for Food Sanitation Volunteers

Over 3,000 Food Sanitation Volunteers were recruited throughout Taiwan to support local health departments and bureaus in carrying out labeling audits of marketed food products, monitor food advertisements, and assist promotional activities for food sanitation. The Volunteers interacted closely with communities and the general public, using humorous skits, quizzes with prizes, and game challenges to promote awareness of food sanitation and safety information and improve public understanding of proper food safety knowledge.

5. Food Safety Month

(1) The Food Safety Month awareness program was held in 2015. A press conference for the initiation of the Food Safety Month was held on July 1, 2015. Attendants invited to the conference included National Taiwan University Food Safety Center (NTU FSC), local health bureaus and departments, supermarkets and retailers, fast food businesses, and beverage vendors. Results of food safety checks of each department were exhibited as well.

(2) Four sessions of Food Safety for Peace of Mind promotional events were held in Northern, Central, and Southern Taiwan. TFDA also participated in the Taiwan International Culinary Exhibition held from July 17 to 20, 2015, inviting everyone to partake in the festival and acquire proper food safety concepts during various interaction processes.

6. Food Safety Wardens

(1) To support the Food Safety Wardens public participation campaign advocated by the Executive Yuan, TFDA organized the ***Food Safety Wardens***-Support from the Ideal Retailer and Supermarket to improve public understanding of food safety systems established by ideal retailers and how the government, businesses, consumers, and mass media work together to establish an environment for safe food in Taiwan.

(2) TFDA worked with various public agencies such as the Ministry of Economic Affairs (MOEA), Consumer Protection Committee, and Council of Agriculture to jointly establish the Guide to Ideal Corporate Distributors of Food and Agricultural Products which listed seven major principles those corporate distributors can comply with in order to improve management practice and improve corporate image. The Food Safety Warden Consultation Team was also established to improve self-management amongst businesses.

(3) Supermarkets were invited to the press conference to provide an actual demonstration of the results for complying to the corporate guidelines. TFDA also organized the Finding the Ideal Distributor photo upload-and-win event to strengthen public awareness on ideal distributor channels.

7. Promoting Awareness of Food Safety and Sanitation

(1) To promote awareness of relevant policies, TFDA worked with mass media interview programs and created 30 exclusive interviews that were then aired to provide accurate information.

(2) Apple Daily published five articles in its nation-wide circulation on the New Era for Food Safety series (three-tier quality control system, traceability system, Food and Drugs Intelligence Center, 1919 National Food Safety Helpline, and White Paper on Food Safety) which described the government's efforts in building a new era of food safety for the general public that includes establishment of a food safety network, achieving total coverage and understanding of food material distribution, and the use of Big Data Analysis for food and drugs.

(3) TFDA organized the Food Sanitation and Safety Science Camp for school children that employed a scientific perspective for analyzing food safety risks and concepts, helping the students establish correct knowledge and mindsets regarding food sanitation and safety. 10 of these Science Camps were held in various counties and cities for 359 junior high school students.

(4) To remind the public of the safety risks of food products brought in from overseas, TFDA made use of various media such as television, network, printed media, magazines, and free resources from the Executive Yuan (marquee light boxes and radio broadcasts), targeting specific population groups to promote awareness of the said risks and educate the public. In 2015, TFDA promoted public awareness of the new food labeling system, the Food Business Registration System, proper food safety knowledge for arriving travelers at the airport, and gastronomic sciences (on food additives and prevention of norovirus infections).

8. Promoting Awareness for Safe Drug Use and Pharmacist Care Services

(1) To improve public knowledge of drug use, the main theme of Common Drugs - Combination Cold Medicines was selected for the annual awareness promotion program of 2015. On September 25, 2015, TFDA organized the Debunking the Myths and Safeguarding of Drug Usage Press Conference which publicated examples of improper drug usage amongst members of the general public (Figure 2-9-3). On December 3, 2015, TFDA hosted the Taking Medicine Cannot Prevent Colds Press Conference publicizing the results of the Nationwide Schoolchildren Medicinal Use Habit Survey (Figure 2-9-4).

(2) To build an environment that supports proper drug use, TFDA established 25 proper drug use resource centers and 207 community drug use inquiry stations, with at least 180,000 individuals registering and making use of the resources. TFDA also worked with 104 proper drug use centers and seed schools across 17 counties and cities, and held 810 health and education events.

▲ Figure 2-9-3 Press Conference for Debunking the Myths, Safeguarding of Drug Usage

▲ Figure 2-9-4 Press Conference for Taking Medicines Cannot Prevent Colds - Nationwide Medicinal Use Habit Survey amongst Schoolchildren

(3) TFDA made a marquee light advertisement titled Drugs are not souvenirs - Do not bring excessive amounts from overseas. TFDA also Issued promotional videos titled Community Pharmacies - Your Good Neighbor Safeguarding Your Health, Proper use of Comprehensive Cold Medicine, also promotional leaflets and posters titled Taking Medicine Cannot Prevent Colds in order to promote drug usage safety.

(4) TFDA organized various pharmaceutical care training courses in 2015 and trained 1,387 qualified pharmacists in order to provide pharmaceutical care services in various residences, communities, and institutions. 1,767 suspected drug treatment issues were identified from 1,369 cases of care services of various categories. Pharmacists provided training on concepts of correct drug administration methods and importance of seeking medical aid to help reduce wastage of drug resources.

(5) To promote pharmaceutical care and safeguard public drug use safety, TFDA organized a press conference for Pharmaceutical Care Provides You with Safe Drug Use on June 2, 2015 (Figure 2-9-5) encouraging the use of the pharmaceutical care of Integrated Drug Usage Services while advocating use of the Quick Access Pharmaceuticals APP software. These services may be promoted by community pharmacies when patients with prescriptions for chronic diseases obtain their medication. These pharmacies also helped introduce the Bring Your Grandparents to the Pharmacy activity which encouraged the youth to visit pharmacies with their seniors, gaining understanding of the professional services offered by pharmacists.

▲ Figure 2-9-8 Pharmaceutical Care to Provide You with Safe Drug Use press conference

8. Propaganda of Controlled Drugs Abuse Prevention

(1) The TFDA made anti-drugs abuse posters, Categories and Images of Drugs Abuse pamphlets, and Anti-Drugs Abuse Guidebook for Parents to help parents identify intentions or symptoms of drugs abuse of their children.

(2) The TFDA deployed a diverse selection of media channels, including marquee light boxes at bus stations, advertisements on buses, in televisions, magazines, radio broadcasts, gas stations, Internet café computer desktops, and outdoor LED walls, to advocate the prevention of drug abuse, proper use of hypnotics-sedatives drugs, and other advertisements for promoting public awareness for the hazards of drug abuse and proper use of controlled drugs.

(3) To prevent the harm of drugs at specific places, the TFDA hosted the Fiery Fight against Drug Abuse online game challenge from August to October 2015 with the aim of using the Q&A mode of the game as a reminder for observing the surrounding environments, improving vigilance, and self-protection in specific premises.

(4) The TFDA worked with 45 NGOs to support independent initiatives advocating drug abuse prevention within communities by using the educational and entertaining methods, such as talk shows, dances, skits, courses, and large scale events to interact with people. The are 2,650 such events were held and 450,570 individuals benefit from events.

(5) In 2015, TFDA hosted the competition of Facebook fan page creativity named Reversing the Health and Mental Hazards of Drug Abuse. There are seven winning entries were selected from 35 entries. TFDA also held the results exhibition and commendation of Total Defense to Reverse Hazards of Drug Abuse in December to reward winners of the Facebook fan page competition.

9. Advocating Safe Selection of Medical Devices and Cosmetics

(1) TFDA held five press conferences for promoting health education on medical devices such as hearing aids, corneal reshaping plates, implantable defibrillators, dental implant, and medical compression socks. 334 press publications were released to improve public knowledge of medical devices.

(2) The Smart Medical Device figurine and virtual mascot, designed according to tympanic thermometers, was introduced to promote various activities such as prized Q&A for outdoor events in universities, senior high schools, and medical device exhibits (Figure 2-9-6). 570 individuals participated in these interactive games.

(3) Experts were invited to compose articles on five major medical device types of corneal reshaping plates, bone density test devices, hydrophilic dressing, ophthalmology lasers, and pregnancy test agents. These articles were published on magazines such as Evergreen Monthly.

(4) TFDA held two press conferences titled Exciting Cosmetics for the Unique Looks-How Much Do You Know About Eye Cosmetics? and Feel Cool in Summer and Getting Rid of Body Odor-Proper Use of Antiperspirants and Deodorants which was covered by 99 press articles. TFDA also made two promotional short videos on the topics of Proper Preservation of Cosmetics - Regular Replacement to Achieve Safe Use and SPF Numbers Aren't Everything - Dress Properly to Avoid Sunburns to supplement TFDA Safe Cosmetic Use Fan Page to improve public understanding on safe cosmetic use.

(5) To promote awareness for proper concepts and selection of cosmetics, TFDA hosted a 1,017 Triple Safety with TFDA-Buy Smart to Maximize Your Beauty promotional carnival for selecting safe cosmetics (Figure 2-9-7). Fun, educational, and interactive games were used to improve awareness on regulatory requirements when selecting cosmetics, understanding the labels provided on cosmetic products, and proper usage of the cosmetics according to the product instructions and reminders.

(6) In 2015, TFDA held a skit and script writing competition for colleges and universities for Health Education and Promoting Awareness for the Selection of Safe Cosmetics. 10 student groups from colleges and universities participated in this activity, which was the first time that concepts for safe cosmetic use were introduced to colleges and universities.

▲ **Figure 2-9-6** The use of Medical Device Smarts mascot in medical device exhibits

▲ **Figure 2-9-7** Promotional event - carnival for the selection of safe cosmetics

03

Part III

Major Events

List of Major Events in 2015

Taiwan Food and Drug Administration

List of Major Events in 2015

Date	Event summary
January 15	Revision of the Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China by 23 customs commodity code. Including Cocoa powder and so forth.
January 23	Formulated the Regulations on Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules.
	Terminated the Standards on the Nutrition Labeling and Contents for Prepackaged Vitamin and Mineral Tablets and Capsules.
January 26	Terminated the provision of Article 3 Paragraph 1 Subparagraph 4 for the Regulations of Inspection of Imported Foods and Related Products where central competent agencies may require the obligatory inspection applicant to attach evidentiary documentation when necessitated by considerations for food sanitation and safety.
	Formulated Evidentiary documentation that must be attached by the obligatory inspection applicant when importing edible oils, special dietary foods, food in tablet or capsule forms, and other specified imports.
February 4	Revised Articles 8, 48, and 25 of the Act Governing Food Safety and Sanitation.
	Hosted the 8th Asia Regulatory Conference in collaboration with the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA).
February 12	Revised Article 3 Attachment Table 1 and Article 6 Attachment Table 4 of the Standards for Pesticide Residue Limits in Foods.
February 16	Revised the List of Carrying Limits for Personal Medication of Arriving Travelers.
February 24	Formulated records, documents, digital files, or databases that must be retained by food businesses for food imports (including genetically modified food materials).
March 3	Formulated the Regulations on Nutrition Claim for Prepackaged Food Products and Terminated the Regulations on Nutrition Claims for Conventional Foods.
March 5	Formulated clinical literature and data that must be provided when applying for changes of influenza vaccine viral strains.
March 6	Revised a number of articles of the Regulation of Bioavailability and Bioequivalence Studies.
March 24	Hosted the 3rd PIC/S Expert Circle Meeting on Good Distribution Practice (GDP) for Medicinal Products which was attended by 47 inspectorate representatives from 25 countries.
March 26	Published the draft of the bilingual version (Chinese and English) of the Good Manufacturing Practice (GMP) for Modern Pharmaceutical Products - Good Distribution Practice (GDP) Guidelines for Medicinal Products.
March 27	Organized the GDP International Conference.
April 7	Promulgated the termination of the Interpreted regulations for contents and food additives that must be labeled according to Article 22 Paragraph 1 Subparagraphs 2 and 4 of the Act Governing Food Safety and Sanitation.
	Revised the Fee-Charging Standards for the Review of Medicament and Cosmetic Advertisements and Fee-Charging Standards for the Registration of Cosmetic Products and Cosmetic Colorants.
April 8	Revised Articles 1 and 2 of the Regulations for Drug Injury Relief Application.
April 10	Stipulation to give import regulation F01 to CCC codes 3505.10.90.90-4 Other modified starches and 3507.90.00.00-3 Other enzymes, and prepared enzymes
April 15	Revised items for the re-evaluation of drugs containing metformin.
	Revised Article 46 of the Regulations for Registration of Medicinal Products.
	All imported food products from Japan must be accompanied with evidentiary documentation, and specific food products from specified regions must also be attached with proof of radioactive inspection before initiating import applications.

Date	Event summary
April 21	Revised drug categories applicable for Rare Disease and Orphan Drug Act (API name: Teriflunomide; indication: complex, multiple sclerosis).
April 27	Revised Sanitation Standard for Food Cleansers.
April 29	Organized the APEC Conference on Management and Related Scientific Detection of Food Additives in Foods.
May 5	Organized the International Conference on Drug Supply Issues.
May 7	Revised Article 9, Article 39 Article 2 and Article 40 Attachment 4 of the Regulations for Registration of Medicinal Products.
May 13	Revised the Fee-charging standards for registration and review of modern pharmaceutical products and medical devices.
May 26	Formulated Fee-charging standards for registration, review, and certification for food products and food additives.
May 29	Revised the Compliance items for the labeling of packaged foods containing genetically modified food materials and compliance items for the labeling of food additives containing genetically modified food materials.
	Revised the Compliance items for the labeling of bulk foods containing genetically modified food materials.
June 10	Announced the Labeling requirements and enforcement date for class 3 food containers of reusable plastic plates, bowls, and dishes described in Article 18 of the Act Governing Food Safety and Sanitation.
	Announced the Scope and categories of medical devices of specific classes that may be sold via retail at pharmacies. Pharmacies no longer need to re-submit applications for retail permits for class 1 medical devices and class 2 and class 3 non-implanted medical devices.
June 14	Announced that from 2013, the proportion for the collection of funds for drug hazard relief shall be adjusted to 0.0005 of the total sales of pharmaceuticals of the previous year.
	Announced the addition of the MAT heat source testing method to the Chinese Pharmacopoeia.
June 18	Revised the Article 2 Attachment Table 1 and Article 3 Attachment Table 2 in the Standards for Specification, Scope, Application and Limitation of Food Additives.
June 24	Revised Articles 3 Attachment Table 2 of the Standards for Specification, Scope, Application, and Limitation of Food Additives.
	Revised full text of the Standards for Pesticide Residue Limits in Foods.
June 28	Established the Inventory Data of Burn Medication and Medical Supplies on TFDA official website to provide information and allocate medical supplies for burn treatments.
June 30	Initiated emergency acquisition of skin tissue in separate batches to treat victims of the Formosa Fun Coast dust explosion.
	Regulations Governing the Labeling of Soup Bases of Hot Pot at Food Vending Locations.
July 1	Hosted the Press conference of the Food Safety Month to support the Food Safety Challenge and jointly defend food safety for the general public.
July 8	Revision of the Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China by12 custms commodity codes. Including Dates and so forth.
July 9	Revised Methods for evaluating age delaying functions of health foods and renamed it to methods for evaluating age delaying and healthcare functions of health foods.

Date	Event summary
July 10	Formulated Regulations for the Labeling of Bulk Food of the Domestic Certified Agricultural Products.
	Terminated Specifications for the nutritional labeling requirements of packaged foods sold on the market.
	Terminated the Regulations on Nutrition Labeling for Packaged Food.
July 16	Formulated Sanitation Standard for Pork Fat enforced on the date of promulgation.
	Promulgated the GMP for Modern Pharmaceutical Products (Part 3: Distribution).
July 20	Formulated Regulations Governing the Labeling of On-Site-Produced Drinks at Chain of Drinks Industry Convenience Stores and Fast-food Industry.
August 5	Promulgated the Regulations for Medicament Recall with 19 articles (and suspended the use of the Directions on Implementation of Recall Action of Pharmaceuticals).
August 10	Revised Article 1 of the Regulations of recall and destruction for food and related products and Article 1 of Regulations Governing the Establishment of the Sanitation Control Personnel of Food Manufacturing Factory.
August 11	Revised Baby formula food products and infant formula food supplements registered by TFDA and revised the name to special dietary foods - baby and infant formula food products.
	Formulated the Labelling Requirements at Food Vending Locations for Food Containing Ingredients of Genetically Modified Organisms and the Application of Food Items.
August 17	Revised drug categories applicable for the ***Rare Disease and Orphan Drug Act***.
September 1	Organized the International Symposium on the Prevention of Drug Abuse and Monitoring of Controlled Drug Prescriptions.
	Organized the 2015 International Conference on Illegal Drugs.
September 2	Established the Food and Drugs Support Center DSC and introduced Big Data Analytics to understand trends of food and drugs related risks in Taiwan and other countries.
September 8	Organized Regulatory interpretation meetings for medical devices (and instruments) in Mainland China and internal discussion meetings.
September 17	Organized the 2015 International Conference for Good Submission Practice (GSP) of Medicinal Products
September 18	Revised the Food Business Categories and Scale that Must be Registered Before Operations and Enforcement Date.
	Approved the interpretation to Article 26 Subparagraph 2 of ***Act Governing Food Safety and Sanitation*** on regulations of material names and heat resistance temperature.
September 25	Organized the September 25 Drug Use Safety Day.
October 7	Revised a number of schedules of controlled drugs to add Lisdexamphetamine as a Schedule 2 controlled drug, and added the new substance of abuse, AB-CHMINACA, as a Schedule 3 controlled drug.
October 12	Revised the Mandatory and Optional Items to be Included in Standard Contract Terms for Food Services and Merchandise (Service) Coupons.
October 13	TFDA and the Federal Institute for Drugs and Medical Devices (BfArM) signed the Joint Declaration for Drugs and Medical Devices to share unpublished and exclusive information related to medicinal products, APIs, and medical devices.
October 14	Formulated Regulations Governing the Labeling of Restructured Meat Products.
October 16	Revised Article 3 of Standards for Veterinary Drug Residue Limits in Foods.
October 17	Organized the Neighborhood Friendly Food Safety Day with the hope of creating a benchmark area for food sanitation.

Date	Event summary
October 19	Organized the 4th Cross-Strait Exchange Conference for Medical Product Testing Techniques.
October 21	Organized the 2015 APEC Conference on Medical Device Regulations.
October 26	Revision of the Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China by 32 customs commodity codes. Including Casings of swine and so forth.
October 29	Organized the press conference for Corporate Involvement for Anti-tobacco, Anti-betel nut, and Anti-drug abuse.
October 31	Organized the Food Safety Painters Creating Health New Lifestyles creative poster competition and award ceremony.
November 5	Formulated the Exemption criteria and applicable customs codes from import inspections for food imports and other related commodities.
	Formulated the List of 511 food commodities at customs inspection that may be released by customs inspection and the applicable customs code.
	Terminated the Exemption criteria and applicable customs codes from import inspections for food imports and other related commodities and Regulations for 511 food items imported for self-use, commercial samples, and items for research, development, and testing purposes.
November 23	Organized the 5th Cross-Strait Conference for Collaborative Medical and Medicinal Product Research and Development which discussed the No. 44 public announcement of August 18, 2015 from the State Council of the People's Republic of China regarding the reforms to the review and approval system for medicinal products and medical devices.
November 25	Held the 3rd Joint Conference of Taiwan and Japan on Medical Products Regulation that covered substantial issues on collaboration to promote bilateral exchange and legal harmonization on 3 major themes of medicinal product regulations, health insurance, and medical devices.
November 27	Organized the Food Safety Wardens - Support from the Ideal Retailer and Supermarket press conference and assembled the Food Safety Warden Consultation Team to strengthen independent management amongst relevant businesses.
December 3	Organized the Medicines Cannot Prevent Colds - National Medicinal Use Survey Amongst Schoolchildren press conference.
December 4	Initiated the 1919 National Food Safety Helpline. The helpline integrated existing helplines and services such as food product whistle-blowing, food product inquiry, consumer issues, small and medium-sized enterprises (SME) inquiry, and fresh farm produce inquiry provided by TFDA, Consumer Protection Committee, Council of Agriculture, and Ministry of Economic Affairs for the purposes of providing a single-counter service helpline, promoting public convenience, and establishing channels capable of promptly receiving whistle-blowing reports, appeals, and petitions.
December 16	Revised the Act Governing Food Safety and Sanitation and added Article 15-1 and amended Articles 41 and 48.
December 22	Organized the Commendation and Result Publication Meeting for Medicinal Product GDP Consultation Visits with the main theme of Safe Drugs for Good Fortune. 29 businesses were commended for excellence.
December 25	Formulated the Manufacturers of flour, starch, table salt, sugar, and soy sauce with a capital sum above NT$ 30 million must be first verified by the sanitation and safety management system.
December 28	Promulgated Article 35 Paragraph 4 of the Act Governing Food Safety and Sanitation with the following provision: When food businesses import food additive combinations, they shall attach product ingredients report issued by the manufacturer or responsible manufacturer of the origin country and official sanitary certificate issued by the export country for the examination of the competent authority at all levels.
December 31	API manufacturers for modern pharmaceutical products holding pharmaceutical product licenses for their respective APIs must achieve complete compliance to GMP before December 31, 2015. Production and imports must be suspended starting on January 1, 2016 for APIs that fail in inspections.

04

Part IV

Annex

Taiwan Food and Drug Administration

Annex 1 - Key Results and Statistics

Table 1. Promulgation and amendment of regulations related to food safety and sanitation in 2015

Date	Title	Summary
June 23	Regulations Governing the Registration of Food Businesses	Revised mandatory items for food additive product registration for the manufacturers, processors, or importers of food additives.
July 31	Food businesses shall mandatorily conduct tests and meet the minimum testing cycle and other relevant matters	Added mandatory self-testing requirements for manufacturers and importers of 8 categories of bulk products, and food businesses of 2 categories of tea products.
	Food Businesses Shall Establish Traceability Systems of Food and Relevant Products	Required 19 categories of food businesses including edible oil products sequentially establish food traceability system.
September 18	Revised the Food Business Categories and Scale that Must be Registered Before Operations and Enforcement Date	Revised and added manufacturers, processors, importers of food utensils, containers or packaging made of other materials and food cleansers; registration of food manufacturer and processors; categories and scale of users of stalls (stores), food service vendors, and retailers with business registration and approval from the local authority on economic development that must apply for food registration.
October 15	Food businesses that belong to category and scale designated by the central competent authority in a public announcement shall be equipped with laboratories	Designated that 10 categories of manufacturers, processors, and preparers with factory registration and a capital sum of more than NT$ 100 million shall be equipped with laboratories and perform self-testing.
January to December	Regulations for the Nutrition Labeling of Prepackaged Food	Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules, prepackaged baby and infant formula products and formula for certain disease. Formulated the Regulations on Nutrition Claim for Prepackaged Food Products.
	Guiding Regulations for the Labeling of Genetically Modified Food	Labeling of prepackaged food, food additives, unpackaged foods, and at food vending locations for food containing ingredients of genetically modified organisms and the application of food items.
	Regulations of Labeling	The product name of the labeling of soup bases of hot pot at food vending locations, fungal food products, bulk food with agricultural product registration, beverages prepared on-site, and restructured meat products.
	Standards for Pesticide Residue Limits in Foods, Standards for Veterinary Drug Residue Limits in Foods, Standards for Specification, Scope, Application and Limitation of Food Additives, and food sanitation standards	Stipulated : standard safety limits on residual levels of 366 types of pesticides for 5,852 MRLs; Standards for Veterinary Drug Residue Limits in Foods that included 137 types of veterinary drugs for 1,405 MRLs; scope, limits, and specifications for the use of 800 types of food additives; added and revised Seven food sanitation standards.

Table 2. Statistics of permits for health foods and genetically modified (GM) foods

Health food permit issued (Type 1 and Type 2)					GM food permit issued	
Year	Type 1	Type 2	Year permits issued	Cumulative permits issued	Year permits issued	Cumulative permits issued
2006	12	-	12	87	2	14
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	26	7	33	350	47	131

Note 1: There are two types of registration for health foods.

Type 1 (individual case review):Suppliers must provide testing results and proof of food safety and healthcare functions. The approval permit number shall be Wei Bu Chien Shi Kui Tzu No. Axxxxx.

Type 2 (standard specification review):Product must comply with the specifications and standards stipulated by the Ministry of Health and Welfare (MOHW). The approval permit number shall be Wei Bu Chien Shi Kui Tzu No. xxxxxx.

Note 2: As of December 2015, 350 permits were issued for health foods, including: 291 permits for Type 1 approvals and 59 permits for Type 2 approvals. 32 of the permits were voided (include termination as a result of permit expiration, revocation of the permit, or permit merging). 6 permits were issued for change of formula.

Note 3: As of December 2015, 131 permits were issued for GM foods, of which 24 permits were for products no longer in production or were not extended.

Table 3. Statistics on imported food inspections

Year	Inspection Batches	Total net weight (10,000 tons)	Assay Batches	Inspection ratio (%)	Disqualified batches	Growth rate of inspection (%)
2011	420,602	717.7	29,800	7.09	288	-
2012	461,665	754.4	38,793	8.40	467	9.76
2013	514,710	713.3	38,460	7.47	557	11.49
2014	616,286	796.6	48,704	7.90	664	19.7
2015	640,003	900.5	50,149	7.84	953	3.85

Table 4. Statistics of residual pesticides and veterinary drugs in food

Year	Pesticide residues in agricultural products from markets and packing firms			Veterinary drug residues in food		
	Total cases	Conform	Compliance (%)	Total cases	Conform	Compliance (%)
2006	1,605	1,589	99.00	197	173	87.82
2007	1,761	1,689	95.91	359	339	94.43
2008	1,765	1,557	88.22	252	232	92.06
2009	1,894	1,696	89.55	266	253	95.11
2010	2,051	1,856	90.49	330	324	98.18
2011	2,110	1,878	89.00	481	437	90.85
2012	2,363	2,121	89.76	572	532	93.01
2013	2,340	2,080	88.89	861	703	95.52
2014	2,528	2,205	87.22	830	794	95.70
2015	3,087	2,738	88.69	1,745*	1,714	98.22

*Source: TFDA Annual Testing Program for Residual Veterinary Drugs in Food Products of 2015 as well as residual veterinary drugs testing programs jointly implemented by local governments, health bureaus, and departments.

Table 5. Statistics of food inspection carried out by local health bureaus and departments

Year	Labeling inspection			Sampling tests			Inspection of Good Hygienic Practice (GHP) for food				
	Items of inspection	Number of compliant items	Compliance rates (%)	Samples taken	Number of compliant items	Compliance rate (%)	Number of inspections	Number of consulation requst of corrections within a deadline	Number of penalty	Businesses forced to close	Businesses brought to justice
97	795,119	778,931	97.96	43,545	40,916	93.96	143,779	34,177	65	81	6
98	874,959	857,355	97.99	38,770	36,158	93.26	150,675	32,463	92	18	6
99	796,758	781,645	98.10	38,056	35,394	93.01	136,456	28,967	131	5	3
100	806,324	796,795	98.82	42,372	40,132	94.71	117,420	35,013	6	12	0
101	683,956	676,930	98.97	41,956	39,998	95.33	118,681	49,587	75	13	0
102	635,121	628,266	98.92	40,898	38,608	94.40	123,476	51,324	31	21	0
103	523,045	517,051	98.85	41,085	39,206	95.43	130,005	61,066	38	143	2
104	340,347	338,200	99.37	47,078	44,916	95.41	119,927	54,979	82	11	0

Table 6. Food labeling related regulations promulgated in 2015

Date	Title	Summary
January 23	Regulations on Nutrition Labeling for Prepackaged Vitamin and Mineral Tablets and Capsules	Nutrition labeling for prepackaged vitamin and mineral tablets and capsules must, regardless of the amount of additives added, be provided according to the compliance items. These regulations entered into force on January 1, 2016.
March 3	Regulations on Nutrition Claim for Prepackaged Food Products	Revised the standard of nutrition claims. Revised the foods shall not have nutrition claims for supplementary intake and the descriptive wording of the physiological functions of nutrients. Where a product has two or more nutrients that meets the conditions for nutrition claims, such claim may be made for such product accordingly.These revisions entered into force on January 1, 2016.
April 7	Official interpretations of the Act Governing Food Safety and Sanitation	Terminated the decree for interpreted regulations for contents and food additives that must be labeled according to Article 22 Paragraph 1 Subparagraphs 2 and 4 of the *Act Governing Food Safety and Sanitation*, which entered into force on the same day.
May 29	Compliance Items for the Labeling of Packaged Foods Containing Genetically Modified Food Materials	Added and revised criteria for the highly refined products that need to be labeled Genetically modified or voluntarily display tests that read: not genetically modified and criteria for the products that voluntarily labeled Not genetically modified which entered into force on December 31, 2015.
	Compliance Items for the Labeling of Food additives Containing Genetically Modified Food Materials	Added and revised criteria for the highly refined products that need to be labeled Genetically modified and criteria for the products that voluntarily labeled Not genetically modified which entered into force on December 31, 2015.
	Compliance Items for the Labeling of Bulk Foods Containing Genetically Modified Food Materials	Added and revised criteria for the highly refined products that need to be labeled Genetically modified and criteria for the products that voluntarilily labeled Not genetically modified which completely entered into force on December 31, 2015.
June 30	Regulations Governing the Labeling of Soup Bases of Hot Pot at Food Vending Locations	For registered venues allowed to serve food directly to customers, hot pot foods must be labeled with the preparation method of the soup base. For businesses that label the flavoring of the substance, the contents and names of the flavoring must be listed separately. These regulations entered into force on July 31, 2015.
July 10	Regulations for the Labeling of Bulk Food of the Domestic Certified Agricultural Products	Vendors with business registration selling organic farm produce qualified for production and inspection management regulations, traceable agricultural products, and excellent agricultural products must label the name, address, and telephone number of the source of production. These regulations entered into force on August 4, 2015.
July 20	Regulations for Labeling of Beverages Prepared on-site at Beverage Vendors, Convenience Stores and fast Food Franchises	Beverages prepared on-site at franchise beverage stores, convenience stores, and fast food outlet franchises must label the amount of sugar added, origin of the tea leaves and coffee materials, caffeine contents in coffees, and provide a minimum of 10% fruits and vegetables content for fruits and vegetables juices. These regulations entered into force on July 31, 2015.
August 11	Labelling Requirements at Food Vending Locations for Food Containing Ingredients of Genetically Modified Organisms and the Application of Food Items	Clearly stipulated regulations for food containing ingredients of genetically modified organisms and the application of food items at registered food vending locations. These regulations entered into force on December 31, 2015.
October 14	Regulations for the Labeling of Restructured Meat	Reconstituted meat products that are packaged, provided in bulk, or directly served at eateries must be labeled with texts that read reconstitutted or assembled as well as conspicuous reminders that the food product can only be consumed well-cooked or for cooked foods only. These regulations entered into force on January 1, 2016.

Table 7. Statistics on foodborne disease outbreaks

Year	Outbreaks	Foodborne disease outbreak incidence		Number of cases for the food category responsible for the poisoning					
		Cases	Death cases	Seafood products and processed products	Meat, eggs, and dairy products and processed products	Cereal, vegetables, and fruits and processed products	Confeetionery and candies	Compound cooking food and others	Unknown causes of vehicles
2006	265	4,401	0	7	7	6	1	20	226
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

Note: Number of repeated cases were deducted from the total number of cases where the responsible food causing the poisoning was identified

Table 8. State of promulgated or revised regulations and standards for medicinal product management in 2015

Date	Title	Summary
January 14	Revised Articles 17 and 27-1 of Rare Disease and Orphan Drug Act	Stipulated that with the exception of force majeure, suppliers must continue to supply drugs for rare diseases within the effective period of the permit and formulatedpenal provisions.
March 9	Promulgated revisions to a number of articles of the Regulation of Bioavailability and Bioequivalence Studies	To meet current and actual requirements for medicinal product management, eight articles of this Regulation were revised by referencing international standards, including revisions to the number of medicinal product batches to undergo testing, clearly stipulating the provision of evidentiary information of the study compared to the reference sample, add principles for selecting study evaluation items, add principles for study designs, revise the criteria for using the truncated area under curve (AUC) as an evaluation parameter, and that project plans may state the use of widened acceptance criteria for the 90% confidence interval for maximum plasma concentration (Cmax).
April 9	Revised Articles 1 and 2 of the Regulations for Drug Injury Relief Application	Paragraph 1of Article 2 was revised to remove the attachment table in order to help the public acquire the new version of the application form as early as possible. Added Paragraph 2 of Article 2 that stipulated that the competent authority shall announce the contents and format of the aforementioned application form.
April 22	Revised Article 46 of Regulations for Registration of Medicinal Products	Revised provisions related to the medicinal product batch testing for bioequivalence studies.
May 7	Regulations for Registration of Medicinal Products	Revised Article 9, Article 39 Attachment 2, and Article 40 Attachment 4. The document contained testing specifications, methods and certificate of analysis of raw materials for active pharmaceutical ingredients (API) and every substance of the formula (including auxiliary materials and coloring agents added during the manufacturing process) is necessary for medicinal application.
June 12	Promulgation of the Standards for the Registration of Biosimilars	Referenced management regulations from countries with well-developed medical fields to revise review principles and key considerations for biosimilars of the Ministry of Health and Welfare, to establish a reference for the research and development of biosimilars, and establish a consistent and transparent review system in Taiwan.

Date	Title	Summary
June 29	Promulgated the requirement that medicinal product package inserts must list the ingredient or name of the excipient	Holders of drug permit licenses (with the exception of APIs) must list the ingredient or name of the excipient on the package insert before December 31, 2015. Those that fail to do so before the deadline shall be subject to a fine of no less than NT$ 30,000 and no more than NT$ 150,000 for violating Article 75 of the ***Pharmaceutical Affairs Act***.
July 13	Promulgated standards for the registration and review of human cell therapy products	Referenced management regulations from countries with well-developed medical fields to describe current review considerations for these type of products to ensure product quality, safety, and therapeutic efficacy.
July 16	Promulgated the GMP for Modern Pharmaceutical Products (Part 3: Distribution)	To safeguard public drug use safety and establish a comprehensive drug supply chain, the MOHW promulgated the GMP for Modern Pharmaceutical Products (Part 3: Distribution) to provide suppliers with relevant operational standards.
July 31	Promulgated the implementation and schedule for GMP Compliance for Active Pharmaceutical Ingredient (API) of Preparations	By January 1, 2016, all existing permits for preparations must attach evidentiary documentation demonstrating compliance to API GMP and records for the sources of the API (including name, address, and country of origin of the manufacturing site). Permits that do not involve production or imports currently do not require API source registration, but must attach relevant data and submit them to the MOHW as an affidavit for the lack of production or imports.
August 5	Promulgation of the Regulations for Medicament Recall	The Regulations for Medicament Recall were promulgated to improve medicament recall procedures, increase the responsibilities of medicinal product manufacturers and importers, and minimize public exposure or access to problematic medicament.
September 4	Promulgated revisions to the Guidelines for the preparations of radioactive isotopes for position emission tomography (PET) scan	Revised specifications for preparing PET scans in hospitals in order to improve the quality of medicinal products and safeguard public drug use.
October 5	Promulgated the guidelines for the process of determining the adequacy of donors of human cell therapy products	To eliminate risks of genetic disorders of human cell therapy products for cellular or genetic therapy, the guidelines were promulgated to describe the criteria for determining the adequacy of the donors, including the use of screening and tests for communicable diseases and their pathogens.
October 19	Official notice that allows biopharmaceutical permits to be published for one or more manufacturers	Manufacturing sites of biopharmaceuticals are often changed or added during the process of development or after receiving approval for market release for the purpose of improving production scale and stability of product supply. The MOHW referenced international specifications, collected opinions from various segments of society, and held many discussions. Meeting resolutions were used to build a consensus to enact revisions which were then publicly notified through official letters.
November 2	Promulgation of the Clinical Trials for Medicinal Products - Guidelines for Technical Documents	Formulated which data and information that must be submitted for review at different phases of the clinical trial, allowing new drug researchers and developers to have a clear understanding of data or information that they must provide to enter the next phase of clinical trials, thereby helping to improve the efficiency of new drug development processes.
December 2	Revised a number of articles of the *Pharmaceutical Affairs Act*	Revised the penal provisions, established a traceability system for medicinal products, established a system to report inadequate supplies of required drugs, provided supplementary provisions to improve the ease of reading medicinal product information, established project approval systems in response to emergency requirements, and clearly included the sources of API within the Regulations for Registration of Medicinal Products.
December 4	Promulgated Standards for the registration of monoclonal antibody biosimilars	Monoclonal antibodies can be used to treat a wide range of illnesses that range from immune system disorders to cancer therapy, necessitating the establishment of scientific strategies and review principles. These standards were established by referencing international specifications to describe current review principles and key considerations for monoclonal antibody biosimilars of the MOHW, providing a reference for the research and development of this type of medicinal product.

Table 9. Statistics of drug permit licenses issued every year

Year	Genetic drugs			APIs			NCEs			Biological products			Orphan drugs			Total
	Domestically produced	Imports	Subtotal	Domestically produced	Imports	Subtotal	Domestically produced	Imports	Subtotal	Domestically produced	Imports	Subtotal	Domestically produced	Imports	Subtotal	
2006	367	55	422	15	99	114	18	65	83	0	13	13	1	4	5	637
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

Table 10. Statistics on post-market quality surveillance of medicinal products

Year	Medicinal Products		Biopharmaceuticals		Traditional Chinese Medicine*		Annual total	
	Items	Nonconforming rate	Items	Nonconforming rate	Items	Nonconforming rate	Items	Nonconforming rate
2006	621	2.58	0	0	860	-	1,481	2.58
2007	295	2.37	0	0	480	-	775	2.37
2008	164	16.46	0	0	1,000	-	1,164	16.46
2009	180	1.11	0	0	720	-	900	1.11
2010	198	3.03	0	0	660	-	858	3.03
2011	230	8.70	23	0	664	3.13	917	6.94
2012	168	4.76	23	0	629	4.70	820	4.41
2013	173	1.16	26	0	544	3.47	743	1.75
2014	90	3.33	148	0	134	2.99	372	1.88
2015	212	0.47	0	0	0	0	212	0.47

Note : "_" refers to a background value survey.

Table 11. Statistics of biological products lot releases

Year	Vaccines and toxoids				Blood products		Antivenoms and antisera				Other biopharmaceuticals		Annual totals	
	Domestically produced		Imported		Imported		Domestically produced		Imported		Imported			
	Batch	Dose	Batch	Dose	Batch	Dose	Batch	Dose	Batch	Dose	Batch	Dose	Batch	Dose
2006	48	4,737,601	123	7,484,332	144	964,500	2	2,840	0	0	11	124,532	328	13,312,805
2007	67	6,134626	117	6,447,752	141	955,060	5	7,429	4	24	15	309,017	349	13,853,908
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
2014	64	4,149,722	161	7,201,090	134	988,939	4	5,512	1	20	25	166,494	389	12,511,777
103	72	3,705,462	155	7,607,454	121	962,552	6	8,440	0	0	27	332,558	381	12,616,466
104	123	5,808,339	163	7,548,124	146	1,137,717	3	3,234	0	0	22	226,082	457	14,723,496

Table 12. Statistics of licenses for controlled drugs

Year	Item	
	Controlled drugs registration licenses (number of licenses)	Controlled drugs prescription licenses
2006	12,302	36,112
2007	12,360	37,792
2008	12,465	39,467
2009	12,830	41,157
2010	13,266	42,619
2011	13,745	44,469
2012	14,149	45,844
2013	14,511	47,391
2014	14,857	49,059
2015	15,148	51,111

Table 13. Statistics for controlled drug inspection

Year	Item		
	Number of inspection	Number of violations	Violation rate (%)
2006	16,629	306	1.84
2007	16,451	232	1.41
2008	16,241	270	1.66
2009	16,355	245	1.50
2010	15,154	196	1.29
2011	15,270	147	0.96
2012	16,214	202	1.25
2013	16,197	211	1.30
2014	17,057	304	1.78
2015	17,454	371	2.13

Table 14. Statistics for the revenue of Pharmceutical Plant of controlled drugs

(unit: NT$ 1000)

Year	Total revenue	Sales revenue	Submitted to the national treasury
2006	431,369	426,393	123,385
2007	436,341	433,122	107,105
2008	477,133	470,627	101,441
2009	507,794	505,340	138,473
2010	484,762	483,169	145,956
2011	491,524	489,523	116,414
2012	494,672	491,909	120,000
2013	513,092	510,119	120,000
2014	533,320	527,940	120,000
2015	593,448	586,406	120,000

Table 15. Amendments and revisions to medical device regulations in 2015

Date	Title	Summary
March 12	Promulgated the *Principles for Composing Chinese Language Package Inserts for In Vitro Diagnostic Devices (IVDD)*	The principles provide manufacturers as a reference for composing package inserts and information as well as a means of preparing registration documents to ensure the accuracy and comprehensiveness of package insert contents of IVDD.
April 13	Promulgated the *Reference Guidance for Medical Software Categorization and Classification*	The guidelines give businesses an initial reference for how to categorize and classify their products, and therefore serve as a basis to be followed in developing products and registration applications.
May 5	Promulgated the *Principles for Composing Chinese Language Package Inserts for Medical Devices*	The principles list basic contents that must be included in Chinese language package inserts of medical devices, and provide reference for businesses to compose package inserts and for reviewers to review and approve package inserts.
June 3	Promulgated revisions to Article 8, Article 3 in Attachment 1, and Article 4 in Attachment 2 of the *Regulations for Governing the Management of Medical Device*	To achieve international harmonization and make timely revisions to items subject to medical device management in Taiwan, products such as sports protective goggles (e.g., swimming goggles) with prescription lenses are listed as Class 1 medical devices.

Date	Title	Summary
June 18	Promulgated the *Good Distribution Practice for Medical Devices*	This practice was established to ensure that medical devices can be maintained at the quality specified by the original manufacturer during distribution and sales activities performed by the importers, dealers, and pharmacies while ensuring that product distribution safeguards public health and safety.
July 21	Announced testing guidance documents for 4 IVDD	To ensure the safety and effectiveness of IVDD, TFDA announced 4 IVDD testing guidance documents, including one for human papillomavirus testing, that provide reference for businesses in product research and development as well as preparation of documents when applying for product registration.
September 1	Announced the *List of Recognized Standards for Medical Devices in 2015 and the List of Originally Recognized Standards for Medical Devices that Have Been Withdrawn or Revised*	To provide the industry standards that can be referenced when researching, developing, and manufacturing medical devices, TFDA announced a list of 918 recognized standards for medical devices which included 449 newly recognized standards and 469 originally recognized standards that have not undergone revision changes or withdrawn.
September 24	Promulgated *Reminders for the Management of Nanotechnology Medical Devices*	There is currently no global consensus or recognized standards for the risks or benefits of nanotechnology medical devices. To support the technological development of relevant industries, these reminders were provided as a reference for the quality management systems of related product manufacturers.
October 15	Promulgated an amendment to the Annex of Paragraph 1 in the *Registration Requirements of Mail-Order Purchases for Medical Devices*	After permitting the online sale of 726 items (including Class 1 and some Class 2 medical devices) by pharmaceutical firms starting in 2012, eight more items were added in 2015 to provide consumers the convenience of purchasing medical devices by diverse ways.
October 16	Promulgated the *Good Clinical Practice for Trial Operations of Medical Devices*	Strengthened the protection of rights, safety, and welfare of trial subjects, and provided as a reference for businesses and hospitals engaged in the clinical trials of medical devices.
October 30	Promulgated the *Regulation of Unique Device Identification (UDI) System for Medical Devices*	Announced globally acceptable specifications for unique device identification coding and barcodes that facilitate establishment of the basis for automated distribution management.

Table 16. Additions and revisions to relevant regulations and hygiene standards for cosmetics in 2015

Date	Title	Summary
January 12	Formulated the Ingredient Standards for Triclocarban as Cosmetics Containing Medical or Poisonous Drugs	Triclocarban was listed as an ingredient of medicated cosmetic, and must be registered accordingly on the day that the standards enter into force. No manufacturing or import shall be allowed until a license is approved and issued.
April 7	Fee-charging standards for cosmetic registration and advertisement examination	Revised Fee-Charging Standards for the Registration of Cosmetic Products and Cosmetic Colorants as well as Fee-Charging Standards for the Review of Medicament and Cosmetic Advertisements.
	Revised Basic Technical Information of Medicated Cosmetics with New Compounds as Ingredients for Registration	Added the requirement that safety tests shall prioritize non-animal alternative testing methods that are scientifically sound, reasonable, and supported by evidence.
April 20	Formulated the Prohibition of Coal Tar as Cosmetic Ingredient	Usage and sales of cosmetics containing coal tar were prohibited starting on January 1, 2016.
July 7	Formulated the Guidelines for Safety Assessments of Cosmetics Using Nanomaterals as Ingredients	Promulgated physical and chemical properties and safety evaluation items for cosmetics containing nanotechnology components, which could be provided to businesses as a reference during development phases.
July 15	Revised the List of Legally Permitted Cosmetic Colorants	Re-categorized the list of legally permitted cosmetic colorants, revised the usage scope of various colorants, and removed 20 legally permitted cosmetic colorants including CI 11380.

Annex 2. Publications of 2015

Rank	GPN	Title	Responsible sections	Category	Date of publication
1	1010400870	Reference Manual of Epidemiological Studies of Food Borne Diseases for Food Sanitation Management Personnel	Division of Food Safety	Book	104/6
2	1010401307	Secret Tips to Reverse Drug Hazards and Defending the Community	Division of Controlled Drugs	Book	104/7
3	1010401308	Home-Care Worker's Manual to Give Elderly Citizens a Better Night's Sleep	Division of Controlled Drugs	Book	104/7
4	1010401309	Manual for Effective Parents - Giving Your Kids a Boost at the Starting Line	Division of Controlled Drugs	Book	104/7
5	1010401728	2015 Drug Abuse Prevention Guidelines	Division of Controlled Drugs	Book	104/8
6	1010402600	Overall Perspective for the Management of Sanitation and Safety of Food Services	Division of Food Safety	Book	104/11
7	1010402867	Manual for Conducting Sanitation Audits of Manufacturers of Traditional Soybean Products	Division of Food Safety	Book	104/12
8	1010402921	Manual for Promoting Sanitation Management of Food Businesses of Wheat Flour Products	Division of Food Safety	Book	104/12
9	1010402935	Manual of Locally Produced Vitamin Foods in Tablet or Capsule Forms	Division of Food Safety	Book	104/12
10	1010403158	The New Era of Food	Division of Planning & Research Development	Book	104/12
11	1010403160	Manual for Promoting the Introduction of Mandatory Inspection for Food Businesses	Division of Food Safety	Book	104/12
12	1010403213	Addendum to the 7th Version of the Chinese Pharmacopoeia	Division of Research & Analysis	Book	104/12
13	1010403232	Anti-Drug Abuse Guidebook for Parents	Division of Controlled Drugs	Book	104/12
14	1010403356	Manual on Food Labeling Laws	Division of Food Safety	Book	104/12
15	1010403359	Manual for Food Additives	Division of Food Safety	Book	104/12
16	1010403365	Manual for the Food Additives Traceability System	Division of Food Safety	Book	104/12
17	1010403420	Manual for Managing Sterilization of Food Packaged in Vacuum Containers	Division of Food Safety	Book	104/12
18	1010403531	Minimum Requirements For Biological Products	Division of Research & Analysis	Book	104/12
19	2010002894	Annual Report on Food Poisoning Incidents and Prevention	Division of Food Safety	Continuous publication (journals)	104/12
20	2010301353	2015 Taiwan Food and Drug Administration Annual Report (Chinese version)	Division of Planning & Research Development	Continuous publication (journals)	104/12
21	2010302286	2015 Taiwan Food and Drug Administration Annual Report (English version)	Division of Planning & Research Development	Continuous publication (journals)	104/12
22	2008200056	Scroll 23 of the Journal of Food and Drug Analysis	Division of Planning & Research Development	Continuous publication (journals)	104/ 3,6,9,12
23	4909405233	Medical Products and Food Safety Weekly	Division of Risk Management	Continuous (weekly)	104/1-12

Annex 3. List of Websites

Rank	Name of the website	Website	Website summary
1	TFDA	http://www.fda.gov.tw	This website 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 rapid and accurate information service.
2	Food and Drug Consumer Service Network	https://consumer.fda.gov.tw	This website publishes information and allows convenient data inquiry for people with different requirements, and includes specialized sections such as those busting food and drug myths, dummies pack, browsing of short online videos, and e-books.
3	Online Application and Public Service Platform	https://oaps.fda.gov.tw	The Online Application and Public Service Platform integrated 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.
4	Imported Food Information System	https://ifi.fda.gov.tw	Allows users to enter foods, traditional Chinese medicine, condoms, and other products (by commodity classification codes) to make inquiries about these and check progress on their inquiries.
5	Product Distribution Management System	https://pmds.fda.gov.tw	Audit data management platform for local governments, health bureaus, and departments and TFDA. Allows the competent authority to manage food, drugs, and cosmetics within their area of jurisdiction.
6	Food Business Registration Platform	https://fadenbook.fda.gov.tw	A digital data system that enables government agencies to achieve effective control over food businesses.
7	Taiwan's International Food Safety Authority Network	https://tifsan.fda.gov.tw	Platform that allows TFDA to communicate internal data, report public opinions, and exchange relevant information with local health bureaus and departments.
8	ROC Chef Certificates Information System	https://chef.fda.gov.tw	Provides educational resources for food sanitation, an online course area, and registration services that can be used for learning purposes.
9	Post-Marketing Quality Management System for Food, Drugs, and Cosmetics	https://qms.fda.gov.tw	This system provides a single portal for reporting defective products for medicinal products (including therapeutic inequivalence), adverse incidents of medical devices, unintended reactions of food products, and adverse incidents of cosmetics.
10	Online application platform for medicinal product registration and review	https://e-sub.fda.gov.tw/dohclient	Provides businesses with a means of submitting online documents for medicinal product registration as well as change or extensions of permits and licenses Reviewers and applicants can both access this platform to check case review progresses.
11	National Adverse Drug Reaction Reporting System	https://adr.fda.gov.tw	Allows medical institutions, pharmacies, pharmaceutical companies, and the general public to report any suspected incidents of adverse drug reactions (ADR) and facilitate post-marketing surveillance (PMS) of medicinal product safety.
12	National Reporting System for Unintended Reactions of Health Food Products and Food in Capsule or Tablet Forms	http://hf.fda.gov.tw	Handles reports of unintended reactions of health foods as well as food in capsule and tablet forms reported by the general public and evaluates safety concerns.

Rank	Name of the website	Website	Website summary
13	Controlled Drugs Management Information System	https://cdmis.fda.gov.tw	Provides online application services for institutions, businesses, and professionals holding controlled drugs registration licenses of the aforementioned controlled drugs in order to effectively improve administrative efficiency and service quality.
14	Drug Abuse Reporting System	https://dars.fda.gov.tw	Allows medical institutions and drug addiction rehabilitation agencies to promptly report any cases of drug abuse and allow timely assessment of trends of drug abuse in Taiwan.
15	Urine Test for Drug Abuse Reporting 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.
16	Laboratory Accreditation Management System	https://lams.fda.gov.tw	A platform that allows food, drugs, cosmetics, and urine testing (for drug abuse) agencies to apply for accreditation.
17	Advertisement for Drugs and Cosmetics Management System	https://adms.fda.gov.tw/adms	Allows the public to inquire information on approved advertisements for medicinal products, medical devices, and cosmetics.
18	Illegal Advertisement Query System	http://illegal-ad.fda.gov.tw	Quickly publishes results of illegal advertisement audits and disposals for public inquiry, providing users with a reference for selecting and purchasing products. The system also discloses details of various violations, providing the public with an accurate basis for decision making, preventing them from being influenced by exaggerated and misleading advertisements.
19	Online System of the JFDA journal	http://jfda.fda.gov.tw	Online website for paper submission and review system of the Journal of Food and Drug Analysis (JFDA). Allows authors from Taiwan or other countries to submit their papers as well as providing journal editing and paper review functions.
20	Director-General's Mail Box	https://faq.fda.gov.tw/message/default.aspx	Provides a key channel for submitting public petitions and opinions. Smart inquiry services that have been established allows the overall service procedure to achieve effective communication and public satisfaction.
21	FDA Open Data Platform	http://data.fda.gov.tw	This TFDA open data website that provides raw data related to food and drugs, which can be accessed and employed by external parties for value-added applications.
22	Food Traceability Management Information System	http://ftracebook.fda.gov.tw	System users can upload relevant digital records that include product data, labeling and identification, supplier information, and product distribution to trace sources of product supply or track the destinations of product distribution.
23	Reference and querying system for standard limits and scope of food additives	http://fas.fda.gov.tw/Fasweb/DataQuery/FoodAdditives-QueryForm.aspx	Allows the public and food businesses to search for the specifications of the scope and limits for the use of food additives, and add information for registered food additive businesses.
24	Application System for Export of Food Sanitation Certification	http://asefsc.fda.gov.tw	This system allows online applications of English sanitation certificates, proof of sanitation of food processing, test reports, and free trade permits for food (and food additives) exports.

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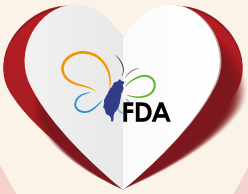

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