2017

Taiwan Food and Drug Administration Annual Report

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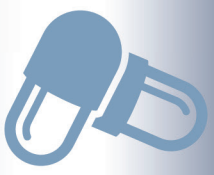
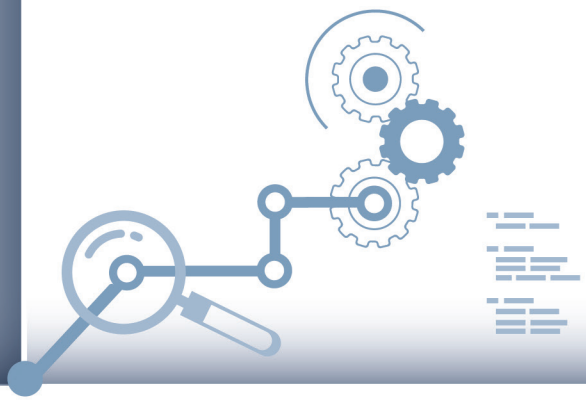


2017 Taiwan Food and Drug Administration Annual Report



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2017 Taiwan Food and Drug Administration Annual Report

A healthy and beautiful life is closely related to the quality and safety of the food, medicinal products, medical devices and cosmetics in our daily living, which are the greatest responsibility of Taiwan Food and Drug Administration (TFDA). To help the public understand the contents and progress of administration, TFDA complies and publishes the administrative outcomes and associated statistics for the public's reference.

For TFDA, 2016 was a challenging but prosperous year. In food management, TFDA repeatedly amended food provisions and issued administrative rules over products that were commonly used or bought or problematic previously. The key program included requesting 17 categories of food business to take their responsibilities of self-inspection. In addition, for vendors that using toys to market meals, a significant labeling with alerts is required to help the consumers understand food information.

For administration of food safety in circulating field, TFDA promoted the "Three-tier quality control system": The first tier focused on self-management by the business, which was also the most important cornerstone of the system; the 2nd tier included a 3rd party certification body audit, including on-site inspection by verification institutes; and the 3rd tier was the government inspection and test to complete a three-party monitoring system.

2017 Taiwan Food and Drug Administration Annual Report: Foreword

By reviewing the outcomes of food source management of the year 2016, the public was able to search for registration data as well as updated announcements regarding 420,000 businesses via the food businesses registration system, and government could effectively control the conditions of the businesses.

In pharmacy administrative management, TFDA approved a total of 136 new medicinal products in 2016, which was the 2nd highest record in the past 6 years. Some of those products were for novel drug therapies or medicinal products containing new ingredients, including anti-neoplasm, anti-HCV or quadrivalent flu vaccines, so the patients could have more treatment options. More importantly, with the consultations and assistance of TFDA, a total of 19 domestic medical devices were approved for marketing, 12 devices entered into clinical trials and 5 academic research technologies were successfully transferred to the industry by the end of 2016, two of which were the first domestic "blood sugar monitoring system" collaborating with smart phone and the marketing of the first global cervical cancer screening kit "carcinogen methylation detection kit".

To control the quality of medicinal products or medical devices on the market, TFDA established the "*Act governing medicinal products traceability system application and management*" in 2016 to request the pharmaceutical companies establishing a product source and distribution management system. TFDA also primarily planned to include three categories of medicinal products including blood preparations, vaccines and botulinum toxin (BTX) into stage 1 advanced traceability scope.

It is worth mentioning that due to the amendments on related regulations and laws in national cosmetics management, the registration of cosmetics has been replaced with products registration, and the businesses have been asked to comply with the regulations for GMP, to greatly align with international management trends.

The amount of online shopping had steeply increased in recent years. Among the sampled inspections from hundreds of cosmetics purchased from online shopping platforms by TFDA in 2016, the quality of those products all met the related requirements. However, 20% of the package labeling still violated the regulations. In addition, TFDA also performed joint auditions over high-violation, high-profiling and high-risk medical devices as well as cosmetics. Among

229 samples, 61 of them violated against related regulations. Of these, the dental interosseous implants and perm agents were at the highest violation rates. In addition to prosecution/ punishment according to the laws, TFDA also released real-time information to remind and alert the public.

In addition to routine management policies and post-marketing surveillance, the security management of TFDA shall gradually achieve the goal of "Being ahead of the enemy" by conducting focused works including the construction of big data and the introduction of surveillance system. TFDA established "Food and Drug Intelligence Center (Intelligence Center)" to collect national and international information of food/drug forums and trends, complied with inter-departmental information, and utilized big data to explore and evaluate risks for the effective prevention and reduction of food safety problems. For example, the TFDA integrated data derived from multiple departments and controlled the transaction records of industrial oils, feed oils and wasted cooling oils as inspection references to reveal high-risk businesses; performed long-term analysis over six high-risk imported foods to uncover the prediction indicators of the increased non-conformity rate, and to assist high-risk targets screening for the goal of real-time surveillance.

TFDA also achieved excellent outcomes on the establishment of brilliant new analytical approaches! Such as, a new developed, world-leading, and rapid colorant screening method expended the capacity of the test from only 8 items to 46 items. This technology applied into the boarder inspection greatly and effectively prevented illegal products from being imported into domestic markets. Moreover, the analytical approaches helped the police authority detecting the firstly-seen synthetic cassinones (6-methoxy Methylone) in the confiscated samples which contained similar contents as well as toxicities to the schedule 2 drugs (MDMA) that might cause serious health problems if misused.

In the future, "Safe and healthy food, safe and effective medicinal products" will still be the primary mission of TFDA. Under the vision of "Being a general-trusted food and medicinal product safety guardian" and "creating a safe food and medicinal products consumer environment", TFDA is committed to establishing a new order of production and management for food, medicinal products and cosmetics by combining source management, effective monitoring, inspection technology, and consumer-based core value.

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

01

Management Overview

Section 1. Food Management Overview

Section 2. Medicinal Products and Cosmetics Management Overview

Product Life Cycle

Source Management & Manufacturing Control

Food businesses management (Registration/ GHP/ HACCP mandatorily conduct tests/ food safety monitoring plan/ traceability system)
PICS/S GMP
Cosmetics manufacturing & management

Registration

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

Pre-market control

Post-market Surveillance

Distribution Management

Food GHP Inspection
GDP Inspection

Customers

Information transparency
Risk communication
Food poisoning, unanticipated reaction report
Food safety foundation
Adverse medicinal product/ adverse event report
Adverse cosmetics event report

Product Quality Surveillance

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

01 Management Overview

Taiwan Food and Drug Administration (TFDA) has taken up the mission of constructing a sound and safe food and medicinal products management system and building a public trustworthy food and medicinal products consumer environment. Under the vision of "Safe and healthy food, safe and effective medicinal products", TFDA upholds the core concepts of food and medicinal products "Total product life cycle management"(Figure 1-1), and serves as the guardian of public health through the management of sources, manufacturing, circulation and surveillance.

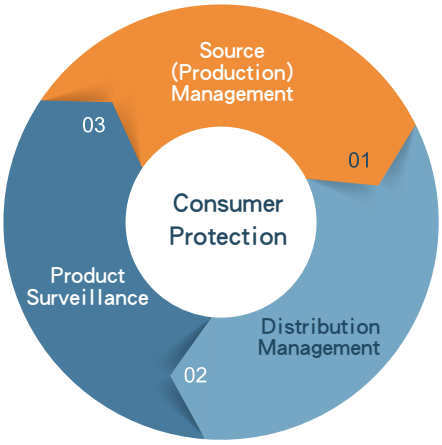


Figure 1-1 Product life cycle management

Section 1. Food Management Overview

To maintain public confidence in food sanitation and safety, TFDA continues to compile and reference international standards and revise laws related to food sanitation and safety management provision. TFDA also actively promotes food business registration system, establishes food traceability system, and strengthens domestic food businesses self-management in order to implement border inspection of imported food, specific food registration and source control. TFDA works with local governments and health bureaus to carry out programs for the inspection, sampling and testing, as well as post-marketing

surveillance of food products, in order to ensure food sanitation, safety and quality. TFDA also uses multiple channels to communicate with consumers in order to promote and provide correct knowledge and risk management concepts (Figure 1-2).

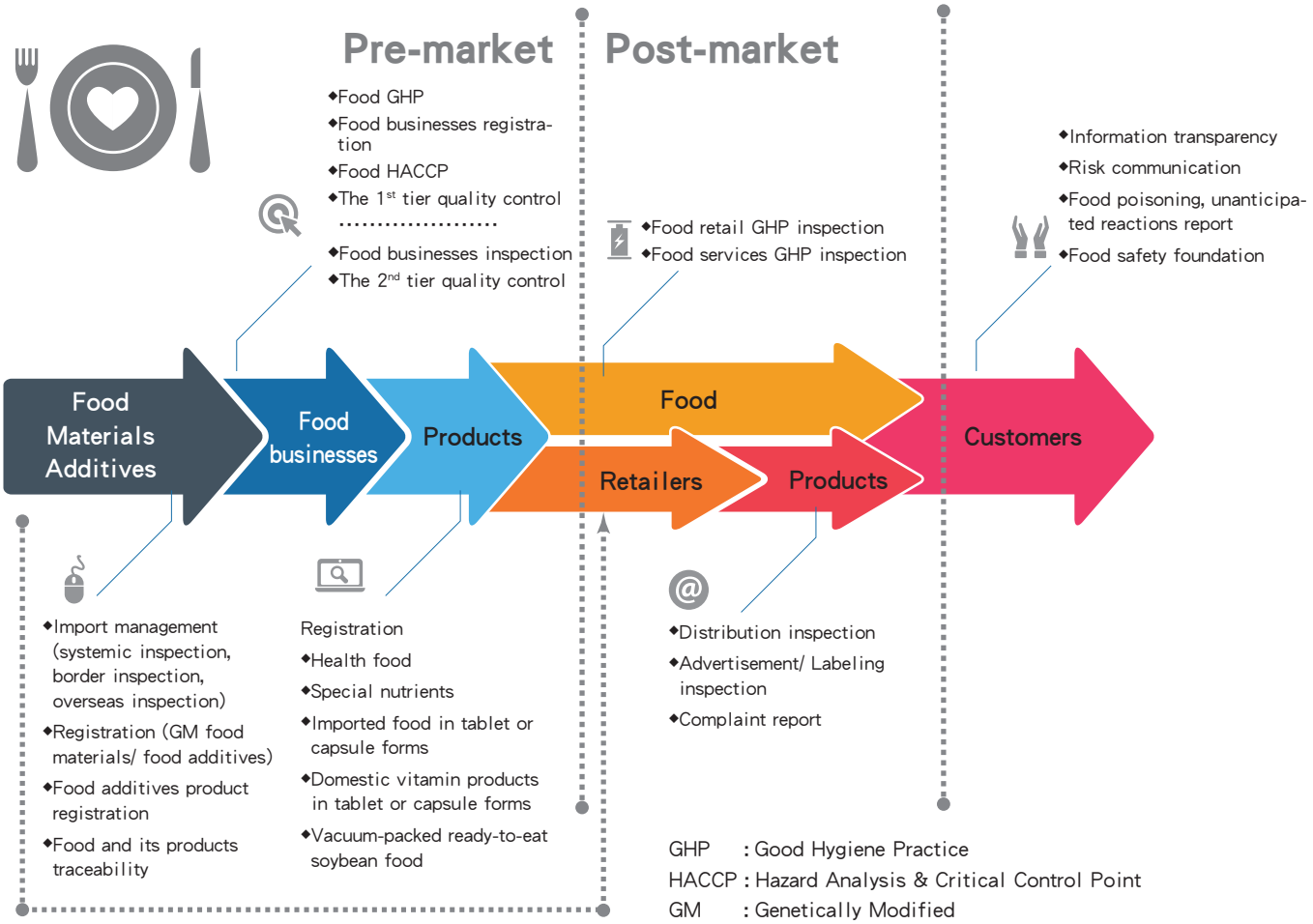


Figure 1-2 Food life cycle management

Section 2. Medicinal Products and Cosmetics Management Overview

1. Medicinal product management framework

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, establishing expedited review processes, monitoring the sources, distribution, and quality of drug manufacturing, thus prohibiting illegal drugs, and enforcing controlled drug management measures.

Medicinal product life cycle from research and development to market release include following steps: fundamental research, non-clinical studies, clinical trials, registrations, 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 1-3). For example, GLP and GCP inspections will be carried out to ensure study 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-market 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.

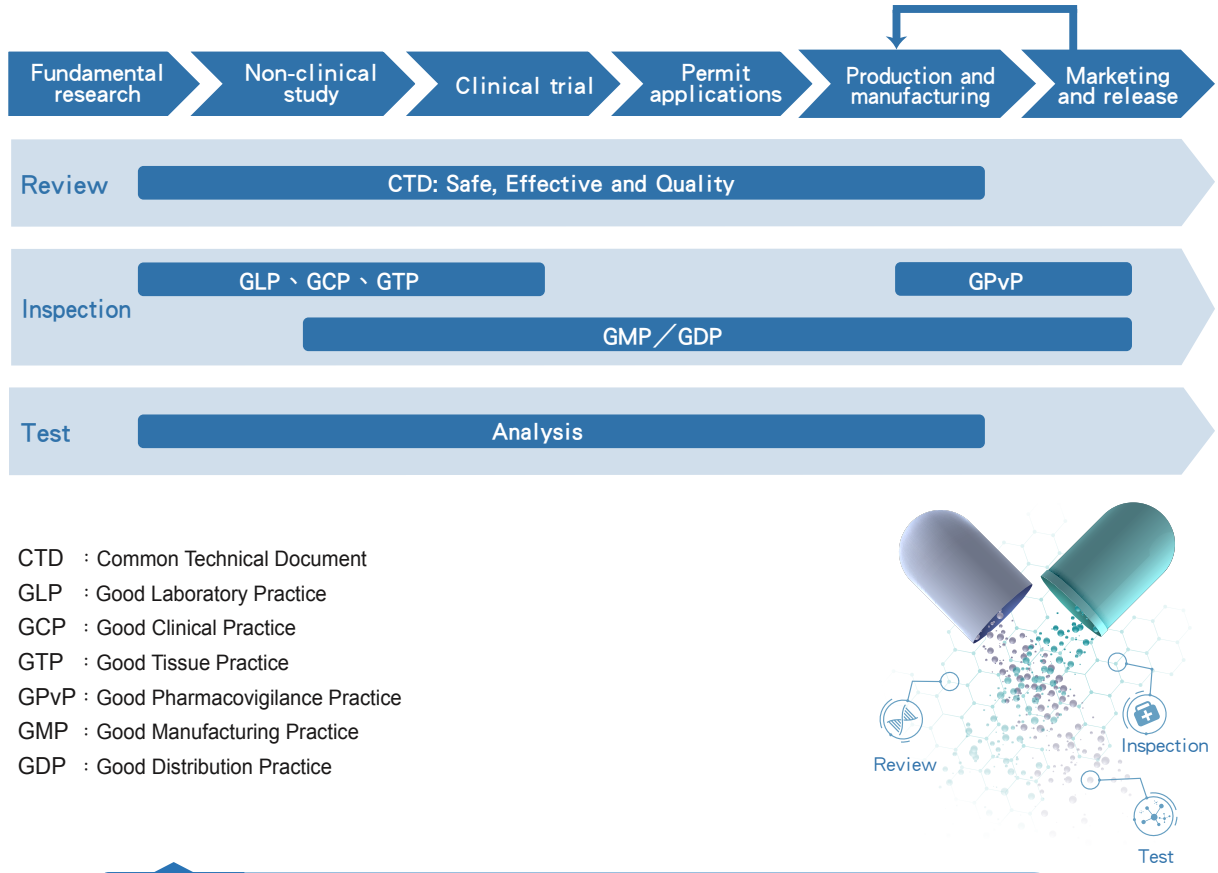


Figure 1-3 A comprehensive medicinal product life cycle management framework

2. Controlled drug management framework

Drug abuse has been a common problem which is faced by various countries around the world. Therefore, the control of addictive drugs becomes more important. At the same time, TFDA prevents controlled drugs from abusing or illegal distributing with vigilance monitoring, abuse prevention and control measures to ensure the physical and mental health of fellow citizens and promote social stability.

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*" , Taiwan has imposed controls on narcotics, psychotropic substances, and their preparations through The "*Narcotics Hazard Prevention Act*". However, due to the necessity of controlled drugs in medical applications or scientific research, the "*Controlled Drugs Act*" has been established to give a control framework which is composed of license, scheduling, and distribution management (Figure 1-4).

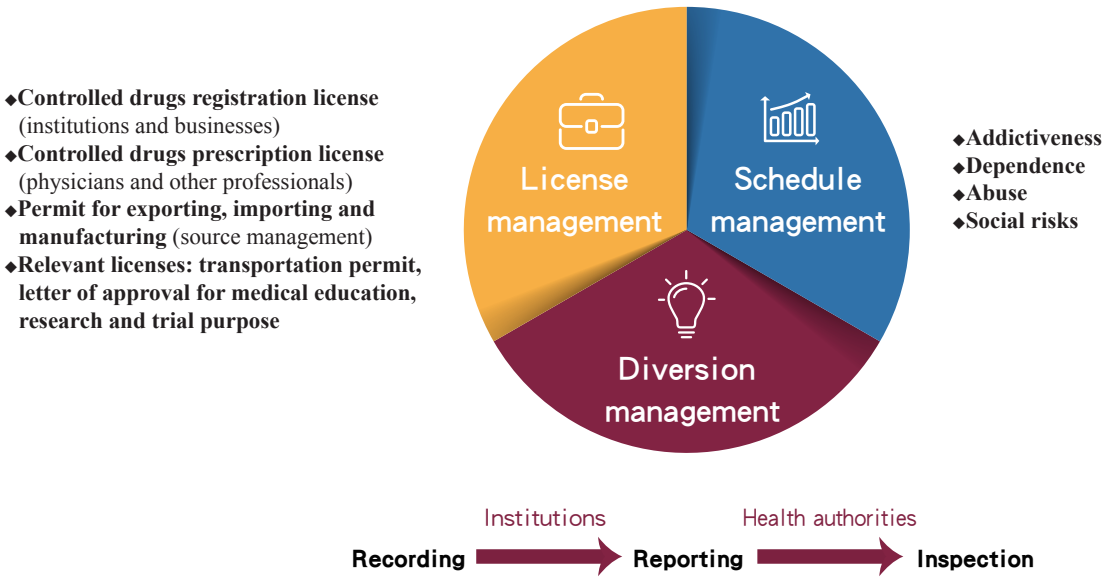


Figure 1-4 Controlled dugs management framework

3. Medical device management framework

The medical device industry is poised to become Taiwan's leading biotech industry in terms of development potential, given its rapid developments in technology and growing demands for healthcare technologies. In response to growing prospects of the medical device industry in Taiwan, TFDA has established a Total Product Life Cycle (TPLC) management policy for medical devices (Figure 1-5) that includes harmonization with international standards and regulations, production source control, pre-market control, post-market surveillance, management of pharmaceutical companies and product distribution channels, and provision of professional counseling services. The purpose of the TPLC policy is to effectively control the safety, performance, and quality of medical devices, and to promote developments of Taiwan's biotech and pharmaceutical industry, creating an environment beneficial for consumers, industry, and government.

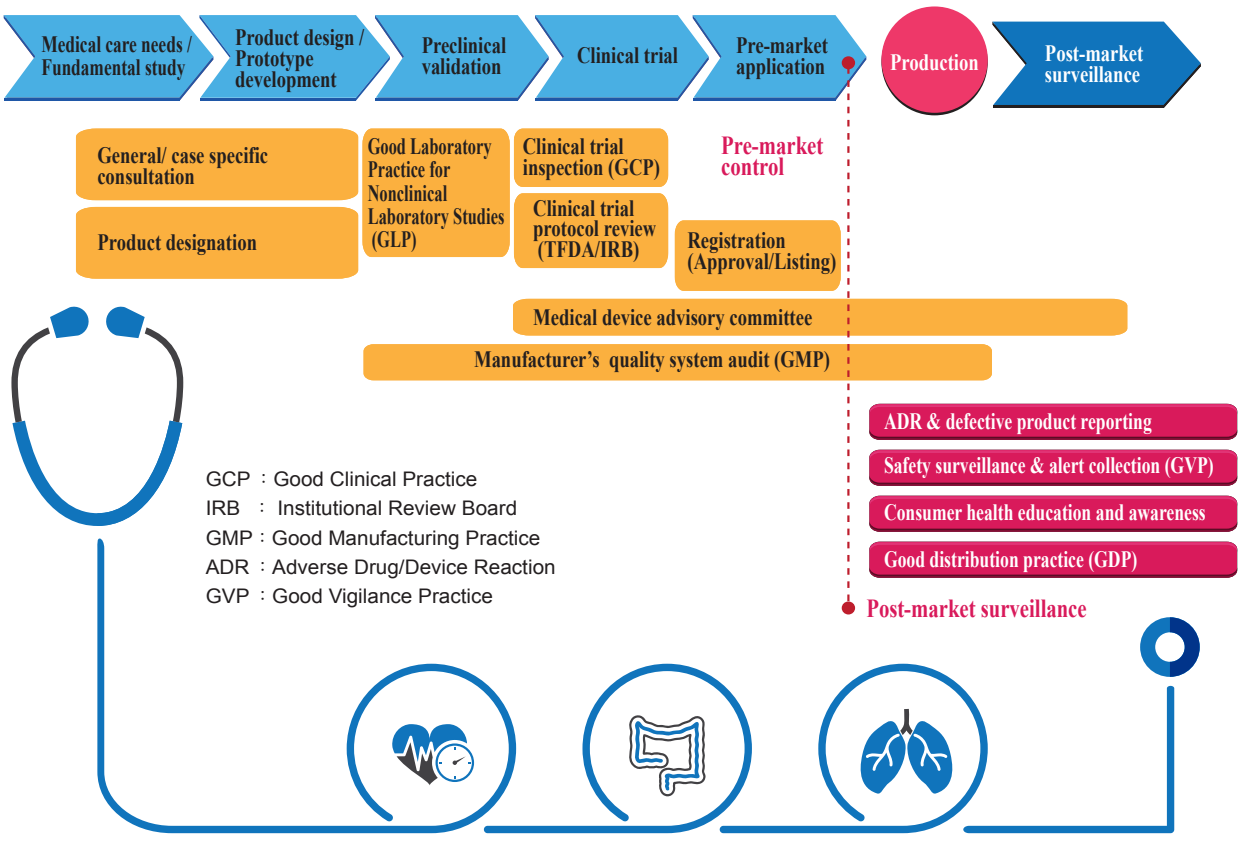
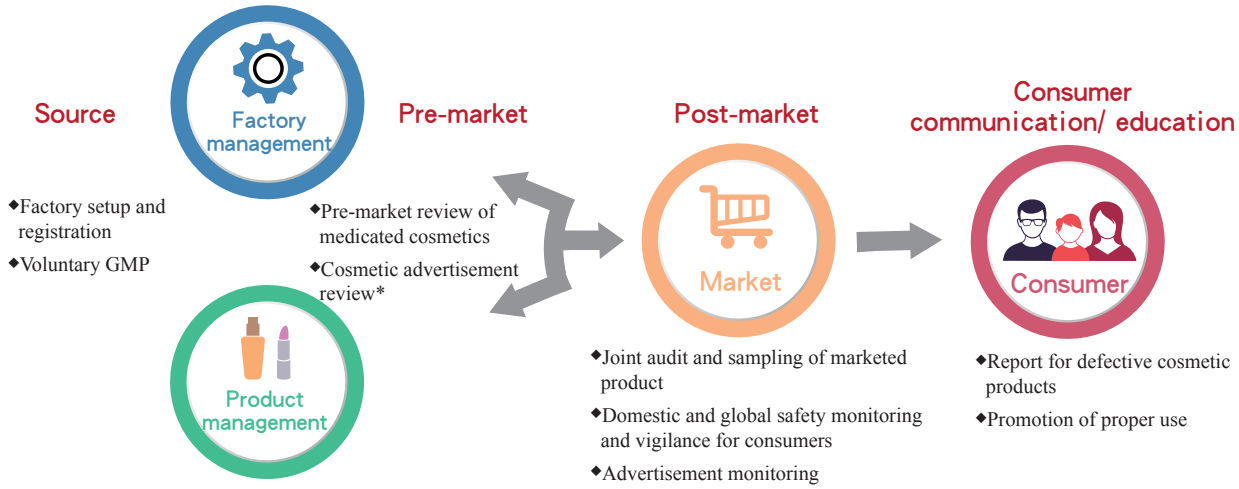


Figure 1-5 Total product life cycle management policy for medical devices

4. Cosmetics management framework

The current cosmetics management system is divided into production source control, pre-market management, and post-market surveillance (Figure 1-6). Source control management includes ensuring manufacturers comply with Establishment Standards for Cosmetics Manufactory and promoting voluntary cosmetic *Good Manufacturing Practice* (GMP) for cosmetics. Pre-market management includes registrations 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.



*Note: According to the Interpretation from Justices of the Constitutional Court, Judicial Yuan, the preview of cosmetic advertisement shall be discontinued starting from January 06, 2017.

Figure 1-6 Total product life cycle management policy for cosmetics

02

Legal Environment and Registration

Regulation addition and amendment in 2016

Food

Food businesses that shall establish food safety monitering plans and conduct tests and meet the minimum testing cycle and other relevant matters	**Benefits** ・Construct food businesses mandatory self-testing ・Implement food traceability system, strengthen raw material control ・Improve food labeling system, help consumers understand food information
Regulations Governing Traceability of Foods and Relevant Products	
Rgulations for labeling of plastic utensils, containers or packaging, special dietary foods, barley, tapioca starch, chocolate, fluorine and iodine in salts, and creamer	

Medicinal Products

Regulations for the format of outer box/package insert of over-the-counter drugs	**Benefits** ・Increase drug accessibility for the public ・Expedited review system for new drug applications ・Reduce risks caused by medicinal product shortage ・Strengthen the needs of emergency drugs
Expedited review system for new drug applications	
Reporting and registration of essential drugs and Regulations governing project approval for drug manufacturing and import	
Projects/regulations governing approval for manufacturing and import specific drugs	

Medical devices

Guidance for Hyaluronic Acid Dermal Implant with Drug	**Benefits** ・Establish and recognize guidances for medical devices, provide as references for industries in product research and development as well as preparation of documents when applying for product registration.
Pre-clinical Testing Guidance for Electrosurgical Devices for General Surgery	
Technical Guidance for Human Leukocyte Antigen Typing System	
List of Recognized Medical Device Product Guidances	

Cosmetics

Safety guidelines of cosmetics for children use	**Benefits** ・Strengthen safety for children use ・Strengthen safety management of national cosmetic hygiene to better align with international regulations
Baby Wipes are subjected to management as cosmetics	
Add Ban on Animal Testing for Cosmetics in Statute for Control of Cosmetic Hygiene	

Registration

1,643 food additives

1,172 medicated cosmetics

39 health foods

3,818 medical devices

Approve the 1st domestic "blood glucose monitoring system" incorporating with a smart phone. The 1st global product "Testing reagents for methylated carcinogens" assisting physician in performing cervical cancer screening. Strengthen review efficiency

682 medicinal products

A total of 136 new drug approvals. Approval for new drugs with new ingredients account the most (44 cases). Actively provide new treatment options to patients. Implement medicinal product review system reformation

02 Legal Environment and Registration

To provide safe drug use and safer consumer environment to the fellow citizens, TFDA is committed to optimizing food, medicinal products, cosmetics regulations and registration management, to align with international standards and enhance competitiveness. Promote the establishment and amendment on related laws such as "*Act Governing Food Safety and Sanitation"*, "*Act Governing Health Food Management*", *"Pharmaceutical Affairs Act", "Act Governing Medical Devices Management"*, and *"Statute for Control of Cosmetic Hygiene"*.

Section 1. Food Legal Environment and Registration

Current Status

TFDA actively pushed for the promulgation and revision of the "*Act Governing Food Safety and Sanitation*" (*Food Safety Act*) as well as secondary laws related to the Act. To further safeguard public and consumer safety and health, TFDA established pre-market product registration control systems for food items targeted at specific consumer populations or where the special effects of the food item must be verified.

Policies and Outcomes

1. The promulgation and amendment of regulations related to food safety and sanitation

The promulgation and amendment of regulations related to food safety and sanitation in 2016 include *"Regulations Governing Traceability of Foods and Relevant Products*", "*Regulations Governing the Product Names and Labeling of Chocolate"*, "*Regulations for Application of Health Food Permit* " and the "*Import Regulation of F01 and F02 in Import Commodity Classification of Republic of China*". Please refer to Table 2-1 for details. For detailed food labels containing barley, corn flour and specific fish products described in 2016 Letter, please refer to Table 2-2.

Table 2-1 The promulgation and amendment of regulations and standards related to food safety and sanitation in 2016

Date	Title	Key amendments
January 21	Revise partial articles of "*Regulations for Application of Health Food Permit*"	The new application for health food registration has two-stage reviews, i.e. initial and secondary reviews. The documents and related regulations required for two-stage review system have also been determined.
February 17	Establish the "*Regulation Governing the Warning Label of Prepackaged Foods Co-mingled with Toys*"	Prepackaged foods co-mingled with toys shall be labeled with warning information, "This product contains toys, do not swallow or inhale. Adult supervision recommended ", or other synonymous expression.
March 8	Establish the "*Food Additives Shall Significantly Label Registration Number of Product*"	Food additives shall significantly label wording like "registration number of product" and its registration number on the product container or outer packaging.
April 18	Revise "*Food Utensils, Containers or Packaging Items Required for Labeling*" and promulgate "*Regulations Related to Food Utensils, Containers or Packaging Labeling*"	Starting from July 1, 2017, the produced food utensils, containers or packaging containing plastic materials on their food-contacting surfaces, when produced after July 1, 2017, should be labeled before selling with information such as its product name, material name, heat-resistance temperature, for food contact use, and disposable or for repetitive use.
April 21	Revise "*Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Test and Meet the Minimum Testing Cycle and other Relevant Matters*"	17 categories of food businesses shall enact food safety monitoring plan from July 31, 2016 by stages. Add "edible oil importer and general commodity retailers, excluding department store, should conduct tests since July 31, 2016".
April 22	Revise "*Contents in Description Column for Import Regulation F02*"	Change to "The following products shall apply for import registration by complying with the "*Rules Governing Food and Related Product Import Registration*" if they are for food relevant purposes such as food, utensils, containers, packaging materials, detergents, or containing the previous objects".
April 25	Revise "*Efficacy Assessment Method of Health Food for Protecting the Liver (Chemically Induced Liver Damage)*"	Rename the method as "*Efficacy Assessment Method of Health Food for Protecting the Liver*". Add 4 assessment methods for liver damage-induced models to evaluate liver protection effects.
May 10	Revise "*Certain Food Imported from Japan Shall Attach Radiation Test Certificate Before Applying for Import Registration*" in Annex 1	In response to the announcement of commodity category numbers added, amended and deleted by Bureau of Foreign Trade (MOEA) on February 4, 2016 "0304.99.90.00-6 other frozen fish (whether or not minced)", and becomes effective back to February 15, 2016.

Date	Title	Key amendments
June 8	Revise partial articles of the "*Regulations Governing Traceability of Foods and Relevant Products*"	Add regulations for "Food Business Registration Number" records.The amended record shall be retained for at least 5 years to comply with *Food Safety Act* and GHP, to immediately follow-up or effectively prevent from food safety incidents.
June 15	Establish the "*Regulations on Fluorine Labeling for Prepackaged Food Grade Salt Products*"	The name, reminder and nutrition labeling of prepackaged food grade salt products that add potassium fluoride or sodium fluoride shall be handled in accordance with the following provisions.
June 24	Establish the "*Regulations Governing the Product Names and Labeling of Chocolate*"	The "chocolate" referred to herein is a food preparation of cocoa products mixed with the addition of sugar, milk or food additivies; solid state dark chocolate, milk chocolate and white chocolate without fillings. It regulates its contents of total cocoa solids, cocoa butter or milk solids.
August 31	Abolish "*Range of Allowable Error for Nutrition Labeling Values of Infant Formula and Follow-up Infant Formula and Additional Labeling Requirements for Follow-up Infant Formula*"	Abolish old regulation with the implementation of "*Regulations on Nutrition Labeling for Prepackaged Infant and Follow-up Formula and Formula for Certain Disease*" on July 1, 2016.
September 19	Announce in advance to revise the draft "*Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Test and Meet the Minimum Testing Cycle and Other Relevant Matters*"	Add factories of 5 categories: "agricultural and vegetable products", "noodles, bean noodles products", "edible vinegar", "egg products" and "flour products" shall register, and manufacturers, processing and distributors with capital more than NT$30 million dollars, as well as importers of 5 categories: "agricultural and vegetable products", "meat processing food", "dairy processing food", "seafood products" and "baby or infant food products" with business, company or factory registration, must enact food safety monitoring plan and mandatory conduct test.
October 4	Announce in advance to revise draft "*Food Business Shall Establish Food Traceability System of Food Products*"	Add manufacturers, processing and distributors of 2 categories: "egg products" and"edible vinegar" with factory registration, as well as importers of "baby or infant food products" with business, company or factory registration, must establish food traceability system based on regulated stages.

Date	Title	Key amendments
November 1	Establish the " *Regulations on Iodine Labeling for Prepackaged Food Grade Salt Products*"	The name, reminderand nutrition labeling of prepackaged food grade salt products that add potassium iodide or potassium iodate shall be handled in accordance with the following provisions.
November 10	Establish the "*Regulations Governing the Product Names and Labeling of Prepackaged Coffee Creamer (Nai-jing) Products*"	Prepackaged coffee creamer products that are labeled or claimed "*(Nai-jing)*" in chinese characters shall be labeled with reminder information, if the products do not contain milk or contain less than 50% of milk. The reminder label "Non-dairy" or "Not dairy based" in chinese shall be manifested after the product name on the product's outer package.
November 30	Revise "*Governing the Outsourcing of Food and Related Product Review and Registration Procedures*"	Amend article 1 authorized act title and its foundations.
December 14	Revise "*Food Businesses Must Retain Import food (including Genetic Modification Food Materials) Corresponding Records, Documents and Electronic Files or Database*"	Establish regulations for data require for retention, method of retention, years of retention and person responsible for retention.
December 19	Revise "*Regulations of Labeling Requirements for Special Dietary Food for Patients*"	Rename the regulations as *"Regulations Governing the Labeling of Formula for Certain Disease"*
January to December	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 377 types of pesticides for 6,379 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 797 types of food additives; added 39 food sanitation standards.

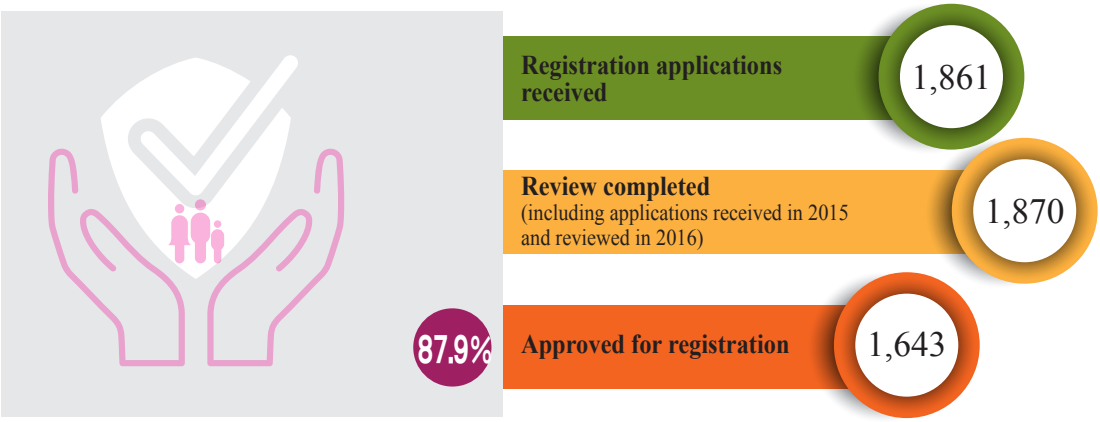
Table 2-2 2016 Food labeling based on descriptions of letters

Date	Title	Key amendments
May 16	The regulations on the product names and labeling of "barley" food.	"Barley" product external packaging not only shall not label product name as "foreign barley", "small barley" or "pearl barley", but should list actual ingredients such as "barley (foreign barley)", "barley (small barley)" or "barley (pearl barley)", and the contents shall be labeled as "barley" truthfully.
	The regulations on the product names and labeling of "corn flour"	As of "corn flour" products, the used contents shall be labeled truthfully (e.g. "tapioca flour" or "potato flour"). In addition, for "corn flour" as one of the food ingredients, the contents shall be labeled as "tapioca flour" or "potato flour" truthfully.
July 14	The regulations on the product named by specific fish	For product named by specific fish, the contents shall in fact contain claimed specific fish. If contents contain specific fish flavor by spices or seasoning rather than claimed specific fish, a significant note of "flavor/taste" must be labeled after or near the product name.

2. Registration and management of specific food products

Figure 2-1 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 2016. Figure 2-2 shows the number of registration applications received, reviewed and approved for food additives in 2016. For detailed statistics and data of health food and genetically modified food permits, please refer to Table 1 in Annex II.

Figure 2-1 As of the end of 2016, number of approved permits issued for specific food products that must undergo registration



Note: Rate of approved for registration (%) refers to the number of cases approved for registration to complete review cases

Figure 2-2 Registration of Food Additives in 2016

Section 2. Medicinal Products and Cosmetics Legal Environment and Registration

Current Status

TFDA drafted the "*Amendment of the Statute for Control of Cosmetic Hygiene*", established the "*Draft for Medical Devices Act*" and revised management regulations related to medicinal products to align with international management trend and improve the comprehensiveness of the laws and standards. Pre-market registration and the acquisition of marketing license are both required for the management of medicinal products, medical devices and medicated cosmetics before manufacturing and sales. Continuous and improved review and management are also required to ensure the quality and safety of the products.

Policies and Outcomes

1. Medicinal products and cosmetics legal environment

(1) To improve the comprehensiveness of medicinal products legal environment

The added and revised medicinal product management laws and related announcements in 2016 included 12 laws and regulations listed in Table 2-3: "*Determination Directions on Complex Drugs*", "*Regulation for Drug Shortage Management*", "*Regulations for Medicinal Product Traceability or Tracking System Management*", "*Regulations for Implementation of Outer Box and Package Insert Format of Western Over-the-Counter Drugs*", "*Article 27.2 List of Essential Drugs in Pharmaceutical Affair Act*", "*Good Manufacturing Practice*".

Table 2-3 Added and revised medicinal product management laws and related announcement in 2016

Date	Title	Key amendments
January 21	Add "*Classification Directions on Combination Products*"	Help to determine the classification of innovative combination products as drugs or medical devices, and enhance review process and product management.
February 18	Promulgate the implementation items and schedules of "*Good Manufacturing Practice (Part III: Distribution)*"	All manufacturers and dealers holding drug permit licenses shall comply with the standards starting from January 1, 2019.
March 8	Revise "*Regulations for Implementation of Outer Box and Package Insert Format of Western Over-the-Counter Drugs*"	Establish package insert outer box format of over-the-counter drugs and related regulations per the habits of public reading and the requirements of vision-impaired population or the elderly.
March 11	Revise "*Testing Standards for Medicinal Product Stability*"	Establish medicinal product stability tests, including objectives, rationale, study design, methodology, labeling and analysis, validation and glossaries by referring to international advanced medical/ pharmaceutical countries and ICH-related management regulations.
April 6	Revise part of the articles of "*Review Guidelines for Medicinal Products Registration*"	A total of 12 articles, including "Factory registration certificates", Regulations for Outer Box Labeling of Imported Drugs, the scope of preparations applied for bridging study examinations, required information of active pharmaceutical ingredients, etc.
May 19	Letter Notice "*Application notes for importing licensed active pharmaceutical ingredients that met GMP regulations*"	Officially inform personnel with API import certificate to submit required documents for GMP inspection in accordance with the application notes.
July 11	Add "*Regulation for Drug Shortage Management*"	Regulate the reporting of essential drug shortage, registration, and applications, review procedures, approval standards and other requirements for project approval of manufacturing and import.
August 1	Revise "*Expedited Review Process for New Drug Registration*"	Medicinal products with two of the FDA (US), EMA (EU) or MHLW (JP) approvals, being identified to have different effects between population and have met related regulations are approved for marketing through expedited review process.
September 6	Add "*Regulations Governing the Trace and track system for Medicinal product*"	For the medicinal product categories promulgated by central health competent authorities, the license holds or distributors shall establish information system for tracing the source and tracking the flow of medicinal procduct. In accordance with the regulations.

Date	Title	Key amendments
September 8	Add "*Regulations for Specific Medicinal Products Project Approval for Manufacturing and Import*"	For prevention, diagnosis and treatment, currently no medicinal products or alternative therapies available in the country for life-threatening or severely disabled illnesses. For those medicinal products required for responding to emergent public health issues but not yet obtaining approvals, a project application for manufacturing or import may apply.
October 26	Revise "*Review Standards for Indicators*"	Revise the warnings and notices stated in the *Review Standards for Indicators*, change the professional or difficult wordings into colloquial descriptions, so the public can understand easily.
October 27	Revise"*Administrative Penalties Criteria for Violating Pharmaceutical Good Manufacturing Practice*"	To reduce arguments and enhance administrative efficiency, the establishment of penalties that meet proportionality and impartiality and focus on violators against *Pharmaceutical Affairs Act* Article 57, paragraph 2 or 4.
December 6	Add the "*List of Essential Drugs in Pharmaceutical Affairs Act* Article 27.2"	If companies with permits of essential drugs on the announced list fail to continue manufacturing, import or supply such drugs, they must inform TFDA in accordance with the regulations of *Pharmaceutical Affairs Act* Article 2.2.
December 12	Revise "*Counseling Directions or Medicinal Products Project*"	Add Advisory Board Meetings and introduce and implement module-base rolling review system.
December 14	Promulgate "Starting from January 1, 2017, for those cases apply for generic drug registration, refuse to file (RTF) and partial refund policies shall apply to applications with serious content defects"	According to the checklist of administrative and technical data for generic drug registration, RTF and partial refund operations shall apply to those defect documents meet RTF standards.
December 26	Revise part of the standards for "*Good Manufacturing Practice (Part I. Appendix) (Part II: Active Pharmaceutical Ingredients)*"	Revise PIC/S GMP (version NO. PE009-11 and PE009-12) Part I, Appendix (biologics, blood preparations, verification and validation), and Part II: API (GMP quality risk management), etc.

(2) Amendments to the schedules of controlled drugs

Four new controlled drugs had been reviewed by the "Ministry of health and Welfare Controlled Drug Review Committee" and submitted to Executive Yuan for promulgation in 2016 (Table 2-4). Refer to Figure 2-3 for the schedule of controlled drugs.

Table 2-4 Revisions to Controlled Drug Schedules in 2016

Date of amendment	Schedules	Promulgate the names of the controlled drugs	Descriptions
March 25	Schedule 3	3,4-methylenedioxy-N-ethylcathinone, Ethylone	A central nervous system stimulant with MDMA-like effects. No therapeutic effects.
March 25	Schedule 3	2-(3-methoxyphenyl)-2-(ethylamin o) cyclohexanone, Methoxetamine, MXE	Has structures similar to ketamine, addictive and produces hallucination.
March 25	Schedule 3	Chloromethcathinone (CMC), including 2-Chloromethcathinone (2-CMC), 3-Chloromethcathinone (3-CMC) and 4-Chloromethcathinone (4-CMC) three position isomers	A central nervous stimulant. No therapeutic effects.
March 25	Schedule 3	Bromomethcathinone (BMC), including 2-Bromomethcathinone(2-BMC), 3-Bromomethcathinone (3-BMC) and 4-Bromomethcathinone (4-BMC) three position isomers	A central nervous stimulant. No therapeutic effects.

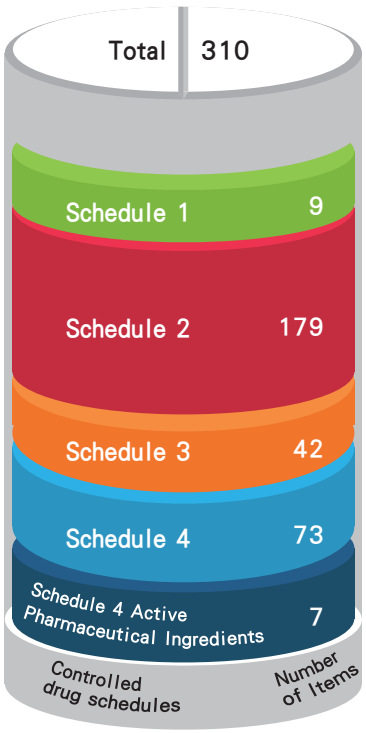


Figure 2-3 Statistics on the number of controlled drugs in each schedule as of 2016

(3) Medical devices and cosmetics legal environment

A. The management and the business running model of medical devices and medicinal products are significantly different. To implement medical device risk classifications, achieve medical device management, establish medical device manufacturing and distribution quality system, reinforce clinical trial regulations for medical devices and complete safety surveillance mechanisms of marketing products, "*Draft for Medical Devices Act*" is established to comprehend the total product life cycle management system for medical device. Five forums and 6 regulatory advisory board meetings were convened in 2016. On December 5, 2016, a draft was promulgated to invite comments from all fields.

B. Draft the "*Amendment of the Statute for Control of Cosmetic Hygiene*" to align with the trend of international cosmetics management and respond to current needs. The key points of the Amendment include replacing registration system of medicated cosmetics to product notification system and product information file (PIF), and establishing mandatory GMP regulation that cosmetic manufacturers must comply with. The Amendment was submitted to Legislative Yuan on September 9, 2016 (Figure 2-4).

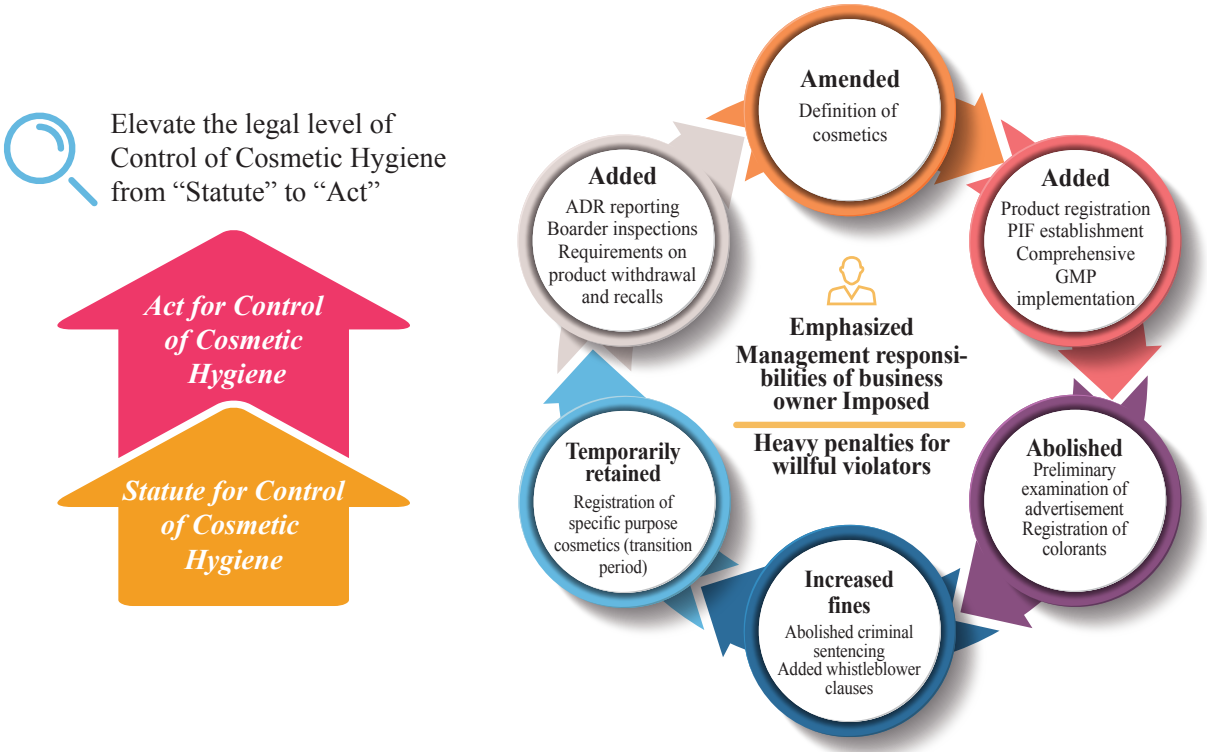


Figure 2-4 Key revisions of the *Amendment of the Statute for Control of Cosmetic Hygiene*

C. Revisions of medical devices and cosmetics laws and related announcements in 2016 are shown in Table 2-5.

Table 2-5 Promulgation and amendment of regulations and standards related to medical device and cosmetics in 2016

Date	Title	Key amendments
January 18	Establish three medical device guidances, including the " *Hyaluronic Acid Dermal Implants with Drug*"	Three medicated medical device guidances for products, including hyaluronic acid dermal implants, Percutaneous Transluminal Coronary Angioplasty (PTCA) Drug-Coated Balloon Catheter and Wound Dressing have been provided to the companies for reference during product development or registration application.
February 3	Establish "*Pre-clinical Testing Guidance for Electrosurgical Devices for General Surgery*"	The "*Pre-clinical Testing Guidance for Electrosurgical Devices for General Surgery*" is to provide the companies for reference during product development or registration application.
February 19	Establish "Cosmetics must not contain Estradiol, Estrone and Ethinyl estradiol"	Starting from May 1, 2016, any cosmetics containing Estradiol, Estrone and Ethinyl estradiol must not be sold, supplied, intended for sales or supplied for presentation.
March 30	"Example of Summary Technical Documentation of In Vitro Diagnostic Device for the Detection or Detection and Differentiation of Human Papillomaviruses"	To harmonize regulations for national and international medical device documentaries, TFDA provides this template to help companies adopt international harmonization methods for safety and efficacy assessments, and offers standardized technical datasheets as of registration application documents, to enhance the international competitiveness of businesses.
April 1	Establish "Baby wipes" are subject to management as cosmetics"	The "Baby wipes" are subject to management as cosmetics" is effective starting from June 1, 2017 and baby wipes shall comply with the regulations for the *Statute for Control of Cosmetic Hygiene* starting from the date of effectiveness.
May 13	Establish two guidances for *in vitro* diagnostic devices including the " Human Leukocyte Antigen Typing System"	The two guidances for *in vitro* diagnostic devices, including the "Human Leukocyte Antigen Typing System" and "Herpes Simplex Virus Types 1 and 2 Serological Assays" provide references for the industries during product development and registration application.
June 24	"Principle of Preparing Chinese Package Insert of Home use Medical Device"	TFDA announced the "Principle of Preparing Chinese Package Insert of Home use Medical Device",and also provides templates of three product instructions for the companies for reference, including the "soft contact lenses", "blood pressure monitor" and "infrared lamp".

Date	Title	Key amendments
June 30	Establish "Cosmetics must not contain Antihistamine"	Starting from January 1, 2017, any cosmetics containing Antihistamine must not be sold, supplied, intended for sales or supplied for presentation.
October 14	Establish "Guidelines of Cosmetics for Safe Children Use"	Any cosmetics indicated or suggested for children use should reduce the contents of fragrance, coloring and preservatives, pay attention to the packaging and prevent the product from being consumed by children. It is recommended to label precautions. At the same time, reiterate current regulations (health safety and labeling) in the announcement.
November 8	Establish "Technical Guidelines for Cosmetics UVA Sunscreen Performance Tests (Human Subject Test)" and "Technical Guidelines for Cosmetics Sunscreen Performance Tests (Human Subject Test)"	To complete the industrial development of domestic cosmetic industries and reinforce cosmetics management and secure the safety of the subjects, TFDA established two Technical Guidelines for Cosmetics SPF Tests (human subject test) as the reference foundations for domestic cosmetic industries to implement UVA as well as SPF efficacy tests of cosmetics.
November 9	Partial revision of the "*Statute for Control of Cosmetic Hygiene*" (Ban on Animal Testing for Cosmetics)	Add "Except one of the special conditions which have been approved by central competent authorities, the safety assessments/tests of cosmetic finished products as well as ingredients on animal models are not allowed in Taiwan.
December 2	Dermal implants within the identification scope of "I.0007 Hyaluronic acid implants" shall be included completely for safety surveillance	After re-evaluate and secondary review of the safety and performance of the products, it is believed that the type of product shall be included completely for safety surveillance. It is hereby announcing the scope and regulations of product safety surveillance
December 13	"*Lists of Recognized Medical Device Product Guidances*"	The "*Lists of Recognized Medical Device Product Guidances*" includes 20 medical devices, which offers medical device industries as references for preparing technical or pre-clinical test documents.

2. The implementation of registration, review, management and counseling mechanisms for medicinal products and cosmetics

(1) 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, biologics, 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 study protocols and reports must be reviewed and approved as well. The number of drug permit licenses approved by TFDA every year is listed in Table 2 of Annex II.

A. Pre-market registration of medicinal products

A total of 136 new drug permit licenses approved by TFDA in 2016 (Figure 2-5). Among 136 new drug applications (NDA), 44 involve new drugs containing new chemical entities (NCE) and 29 NDAs are biologics. Therapeutic areas include anti-cancer drugs, anti-HCV or anti-HIV drugs, drugs for rare diseases, and vaccines (e.g. DTaP-Hib-IPV and quadrivalent influenza vaccines) required by public health services to benefit those expecting new treatment options.

B. Clinical trial reviews

(A) Revisions 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.

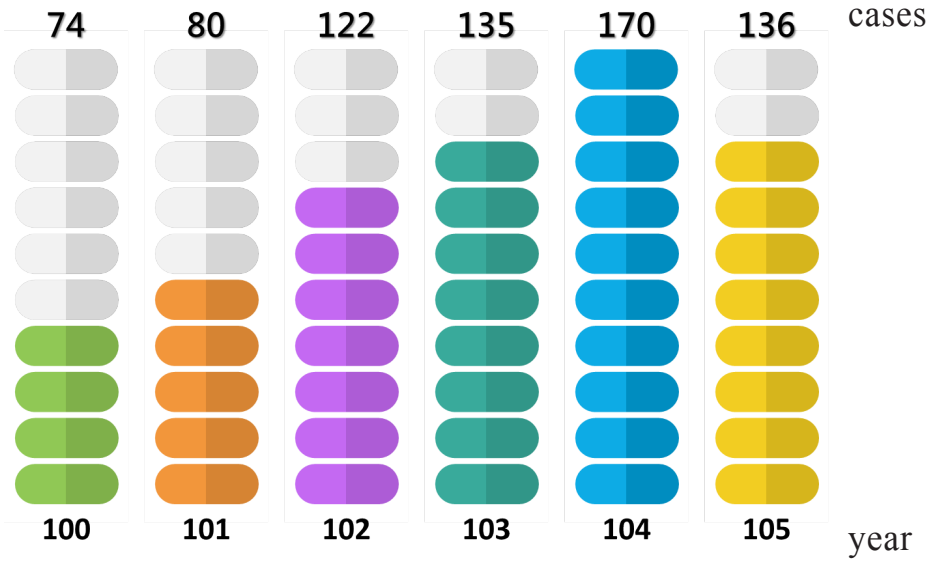


Figure 2-5 Number of new drugs approved throughout the years

(B) In 2016, new clinical trials and amendments applications in Taiwan totaled 309 and 3,297 cases respectively. These figures amounted to a near 3.7% increase in the total number of cases compared to the previous year (new applications and amendments are 346 and 3,130 cases).

(C) To safeguard the rights, safety and welfare 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 41 GCP inspections were conducted in 2016.

C. Reforms to medicinal products review system

Due to the rapid changes and development in medical and pharmaceutical industry, TFDA promotes revisions of new drug review process and timepoint control to elevate the efficiency and transparency of medicinal product review mechanism for businesses to estimate case review progress. At the same time, TFDA promotes new drug RTF mechanisms, and assists businesses in establishing capabilities of medicinal products registration to maximize limited review capacities and resource of the review department. Additionally, TFDA tries to provide "counseling services" to the applicants prior to their NDAs to improve the quality of the documentaries.

(2) Promoting professional consultation for medicinal products projects

A. To support the "Taiwan Biotech Industries Take off Action Plan" of the Executive Yuan, TFDA committed itself to facilitating new drug research and development, and establish a "Professional Consultation System for Pharmaceutical Projects" for pharmaceutical industry consultation. Items were evaluated and selected according to the four selection indicators of "innovativeness", "contribution", "early benefits" and "legal compliance" to facilitate new drug development industry in Taiwan (Figure 2-6).

B. For new drugs ready for marketing or under development, TFDA revised and promulgated "Counseling Directions on Medicinal Products Projects" on December 12, 2016, added company counseling meeting mechanisms, actively provided bilateral communication channels and helped businesses clarify doubts on laws and regulations. TFDA also introduced and implemented module-base rolling review to reduce the frequencies of requesting supplements during official application and thus expedited the marketing of domestic new drugs as well as satisfied the needs of medical care of the fellow citizens.

Figure 2-6 Professional Consultation System for Pharmaceutical Projects

(3) Medical devices and cosmetics registration and advertisement examination

A. Medical devices and cosmetics pre-market registration and advertisement examination

(A) Medical devices in Taiwan are divided into three classes, including Class 1 (low risk), Class 2 (medium risk) and Class 3 (high risk), and 17 major categories (approximately 1,700 items) according to their different characteristics and risk levels. Cosmetics in Taiwan are divided into regular and medicated cosmetics. In addition to regular cosmetics, medical devices and medicated cosmetics must complete registration before marketing. The manufacturing and sales of medical devices and medicated cosmetics can only be implemented after obtaining product marketing permits.

(B) In 2016, 143 innovative medical devices with no similar products registration reviews were completed. This was a 16% increase compared to 2015, improving public accessibility and utilization of emerging medical devices in Taiwan.

Figure 2-7 Medicinal products and cosmetics advertisement leaflets and review brochures

(C) In 2016, TFDA establishes medicinal products and cosmetics advertisement leaflets and review brochures (Figure 2-7) for industries to understand related regulations for advertisement applications and for the facilitation of advertisement review consistency. Additionally, TFDA convened two cosmetics advertisement management advisory committee meetings.

(D) Number of medical devices and cosmetics applications for reviews as of 2016 is showed in Table 2-6.

Table 2-6 Statistics of medical devices and cosmetics applications for reviews as of 2016

Statistics	Medical devices		Cosmetics	
	Medical devices registration	Medical devices advertisement	Medicated cosmetics registration	Cosmetics advertisement
Number of received applications	5,451	334	1,484	1,645
Number of closures	5,118	329	1,508*	1,622
Number of valid licenses: ◆43,328 licenses for medical devices (increase 2,487 licenses compare to 2015; licenses of domestic products: 23.8%, licenses of imported products: 76.2%) ◆15,759 licenses for medicated cosmetics (licenses of domestic products: 23.6%, licenses of imported products: 76.4%) * Companies applied for registration in 2015; however, the applications were closed in 2016, which resulted in the number of closure greater than received.				

B. Optimization and reformation of review mechanisms for medical devices

(A) Recognized international standards and product guidances for medical devices

As of the end of 2016, TFDA had recognized a total of 110 product guidances for medical devices, 918 international standards on medical devices and 56 pre-clinical test guidances for medical device products to improve the consistency and transparency of review processes (Figure 2-8).

(B) Optimize Review Models and Quality of Medical Devices

To fully promote reformation of review processes for medical devices registration, TFDA establishes expedited and prioritized review mechanisms for medical device products based on risk classifications. The associated measures are as follows:

a. For on-site expedited applications and registration of Class 1 medical devices registration, it has been changed to telephone reservation system since February 1, 2016. Additionally, TFDA completed the establishment of online application system for Class 1 medical devices to improve the efficiency of registration.

b. Promote preliminary screening of administrative documents for Class 2 and 3 medical devices registration. Additionally, a total of 32 Class 2

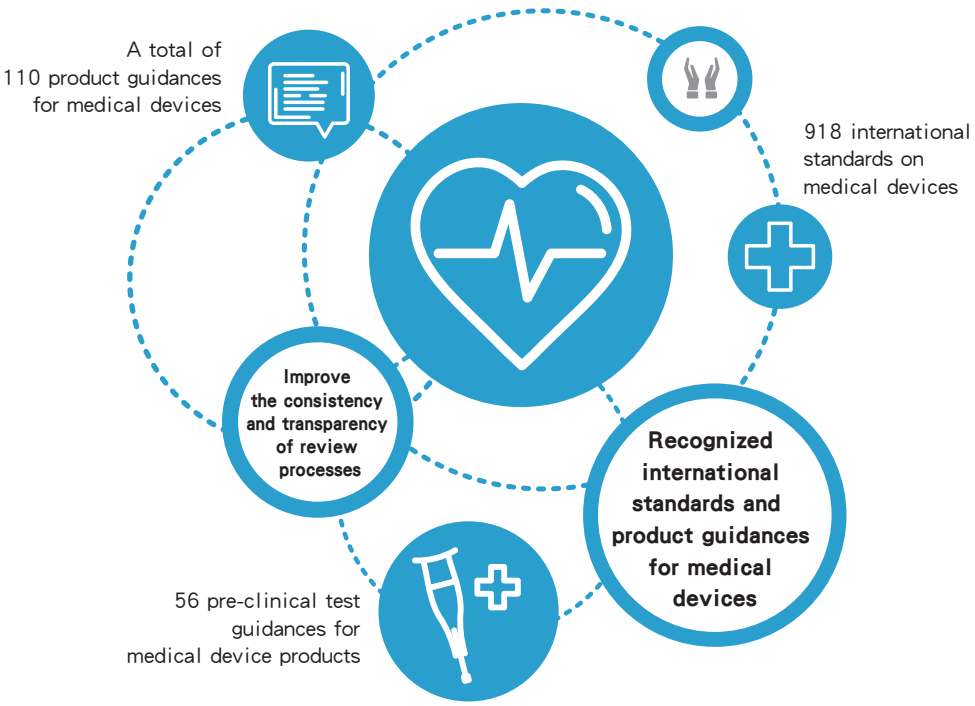


Figure 2-8 Recognized international standards and product guidances for medical devices

medical devices with pre-clinical test guidances were commissioned to Center for Drug Evaluation (CDE) for reviews to enhance submission quality and efficiency.

c. Promulgate four medical devices which industries can use affidavit letters as the pre-clinical test documents for registration application, including the "infrared ear thermometer", to simplify the registration application procedures.

(4) Talent cultivation and establishment of excellent medical device clinical trial environment

A. Recommend two talents from academic/research field and professionals in pre-clinical tests to go to the US for advance training. Additionally, TFDA selects two surgeons from orthopedics and thoracic surgery and recommends them to go to the US for learning the most updated medical technology, i.e. 3D printing. In the meanwhile, TFDA promotes clinical trials involving medical devices for academic purposes in Taiwan.

B. TFDA reimbursed the clinical trial centers in two teaching hospitals to help them develop specialized clinical trial centers in order to improve the quality and efficiency of clinical trials in Taiwan.

(5) Comprehensive medical devices and cosmetics consultation/counseling networks

A. TFDA successfully facilitates 19 domestic medical devices approved for marketing, 12 applications entering clinical trials and 5 academic/research outcomes technically transferring into industry. One of which is the first domestic "blood glucose monitoring system" collaborating with smart phone and the marketing of the first global cervical cancer screening kit "carcinogen methylation detection kit".

B. Select 8 advanced seed regulators to serve as pilots to help pass on medical device laws, regulations and knowledge.

C. Establish medical devices and cosmetics counseling helpline. In 2016, the helpline served up to 19,193 times, of which 9,019 for cosmetics-related queries. Additionally, the helpline also served 5 businesses for appointment reservations in Hsinchu Biomedical Science Park.

D. Host two cosmetics GMP internal audition training courses at North, Central and South District respectively to strengthen self-management capacities of cosmetic industries. A total of 668 people participated in the courses.

03

Source and Manufacturing Management

Medicinal Products

- Strengthen import and self-use active pharmaceutical ingredient (API) management – Establishing API Dug Master File (DMF) System
- Implement API registration that has met GMP
- Implement manufacturer meeting with GMP standards
- Implement controlled drug license system

Outcomes

1. Accumulated DMF approvals are 3,038
2. A total of 245 items produced by 24 domestic API manufacturers have met GMP regulations for API; a total of 1,531 API import permits have met GMP regulations
3. A total of 127 domestic pharmaceutical manufacturers meet PIC/S GMP, a total of 268 international pharmaceutical manufacturers have passed on-site inspections
4. Accumulated registered controlled drug institutions and companies are 15,413, accumulated professionals with controlled drug use certificates are 52,757 people

Benefits

1. Control upstream API supply quality
2. All domestic pharmaceutical manufacturers have met PIC/S GMP and align with international standards
3. Uphold controlled drug license management, prevent illegal use and distribution of controlled drugs
4. Medical device manufacturers recognition and management, optimize manufacturing quality and enhance the responsibilities of businesses

Medical devices

- Manufacturer registration & management
- Review expired GMP/QSD certificates

Outcomes

Medical device manufacturers have met national medical device GMP and imported medical device QSD certifications, valid registered licenses are 669 and 3,800, respectively

Benefits

Optimize manufacturing quality and enhance industries responsibilities, ensure product quality

Food

- Promote food businesses registration system
- Strengthen boarder inspection of import food
- Reinforce overseas food factory inspection

Outcomes

1. Over 420,000 food businesses have registered in Food and Medicinal Businesses Registration Platform
2. A total of 676,570 lots of import food for custom inspection, of which sampled 52,725 lots (accounted for 7.81%). The number of failure among sampling lots accounted for 1.74%
3. Overseas factory inspection has covered 9 products across 7 countries

Benefits

1. Control the distribution of food businesses
2. Strengthen import food boarder inspection, prevent products failed testing from import
3. Reinforce overseas food factory inspection, effectively supervise overseas food import

Cosmetics

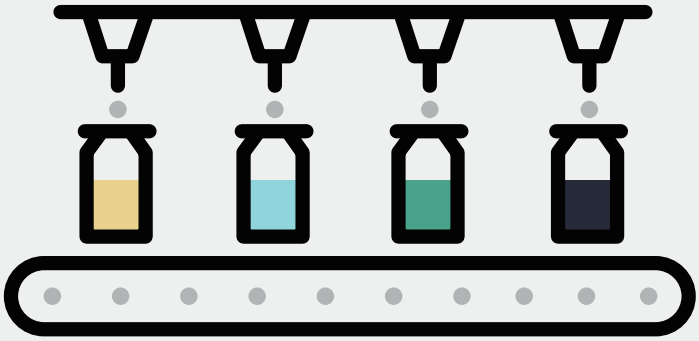
- Encourage cosmetics factories voluntarily to comply with cosmetics GMP

Outcomes

TFDA and IDB (MOEA) jointly promote cosmetic factories voluntarily meeting with cosmetics GMP verification system. A total of 23 factories submitted applications in 2016 and 16 factories passed the inspection

Benefits

Enhance product manufacturing quality



03 Source and Manufacturing Management

Regardless of food, medicinal products, medical devices or cosmetics, the supply management and product manufacturing of raw materials have been classified as priority work. In terms of food, TFDA actively encourages food businesses registration, establishes food factory risk control and reinforces businesses self-management. As to medicinal products and cosmetics, TFDA supervises manufacturer's quality management system to ensure the quality and performance of product manufacturing. Moreover, by complying with international law harmonization, TFDA enhances international competitiveness of manufacturer's products.

Section 1. Food Source Management

Current Status

To strengthen food source management, TFDA encourages food business registration system, food traceability and border import inspection and management. Through expanding the scope of regulations for supply source and product directions in business record, TFDA grants businesses the responsibilities of self-management to establish complete records and associated management information.

Policies and Outcomes

1. Encourage food businesses registration system

The food business registration system has been promoted since 2014. At the end of 2016, the system effectively monitored the status of over 420,000 food businesses which included about 200,000 retail venues, 160,000 food services, 36,000 food production and processing businesses and their factories/plants, 10,000 food importers, over 900 food utensils, containers and packaging manufactureres, over 300 food additive businesses,

and over 100 food cleanser manufacturers. 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 (Figure 3-1) and improve management efficiency.

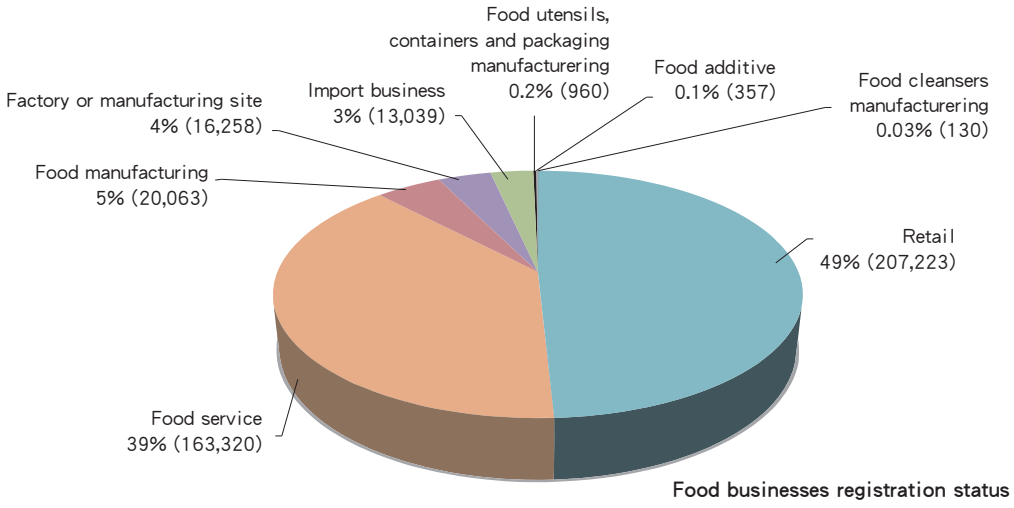


Figure 3-1 Food Business Registration platform statistics chart at the end of 2016

2. Import food management

(1) Import control

According to Article 30 of the *Food Safety Act*, regulations for food import inspection, at the end of 2016, there are a total of 2,489 customs commodity codes for food import inspections to TFDA. Refer to Figure 3-2 for detailed statistics of import regulation numbers.

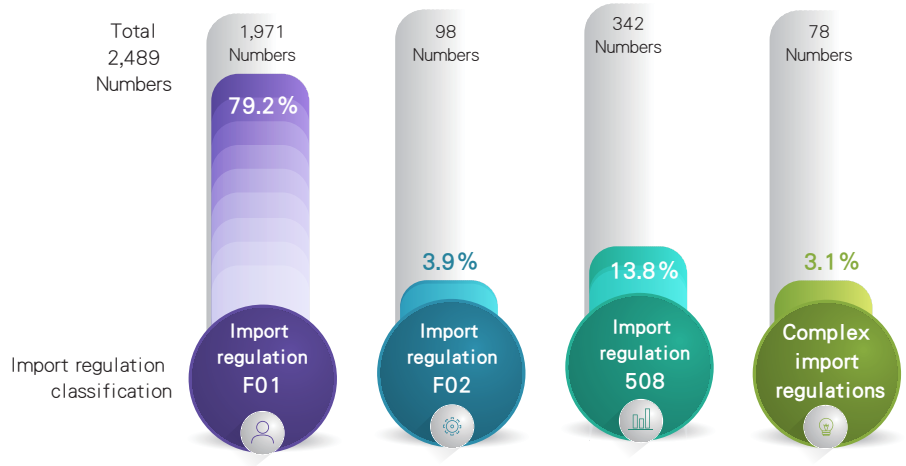


Figure 3-2 Statistics of import regulation numbers as of the end of 2016

(2) Border inspection

Food imports and related products must undergo and pass boarder inspections at harbors, ports and customs before the importation may proceed. Refer to Table 3 in Annex II for detailed inspection statistics. Figure 3-3 shows the distribution of import applications in 2016. The Port of Keelung received the largest number of applications (accounting for 54.49% of the total) in 2016. Approximately 675,000 batches of food import inspections were carried out, a figure that grew by 5.47% compared to 2015. Among these, about 52,000 batches (7.81% of the total) underwent random sampling and testing, and 1.74% were found to have failed to conform to the regulations. Nonconformities are mostly fresh, chilled, or frozen vegetables, food utensils, spices and medicated diet, with most nonconformities pertaining to residual agricultural chemicals or heat resistance tests. Such products were either returned or destroyed according to law preventing their sales in Taiwanese markets.

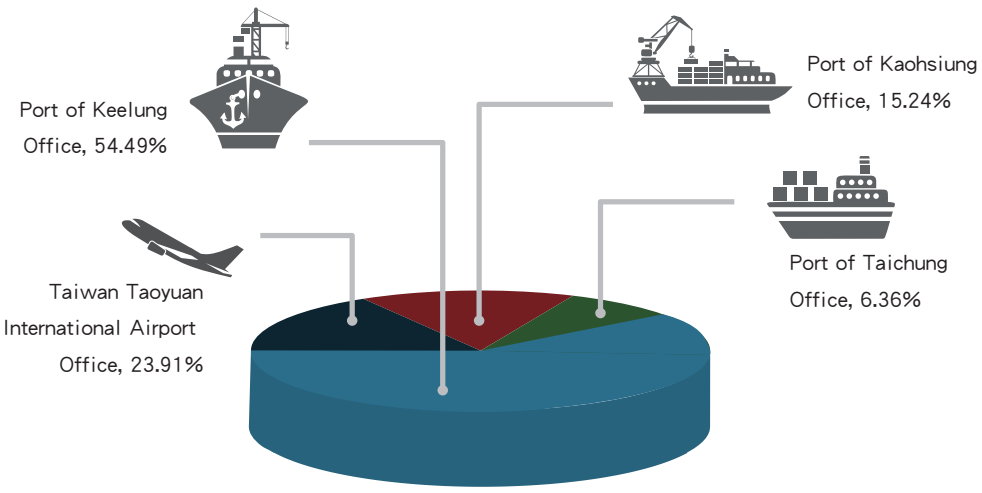
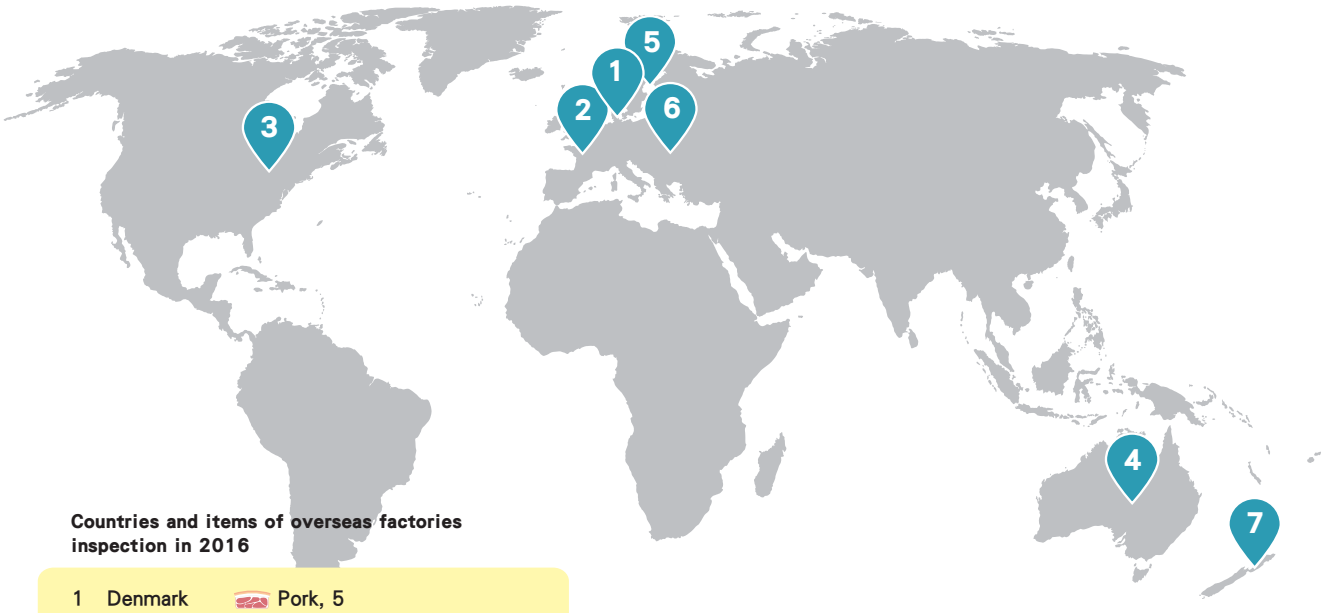


Figure 3-3 Distribution of inspections handled by TFDA offices at various ports in 2016

(3) Inspections of overseas factories

According to Article 35 Paragraph 1 of the *Food Safety Act*, systematic inspections may be implemented for the management and control of foods with higher risk of safety before import. In 2016, TFDA conducted on United States, the Netherlands, Paraguay, Belgium and Hungary on-site audits which apply for meat and meat products being imported to Taiwan. According to *Food Safety Act* Article 35 Paragraph 3, to effectively achieve source management of food products, TFDA designates personnel for field inspections on sanitation and safety management of the import food. In 2016, seven countries and their products were inspected (Figure 3-4).



Countries and items of overseas factories inspection in 2016

1	Denmark	Pork, 5
2	Netherlands	Pork, lard, 5
3	United States	Beef, 6 / Dairy products, 5
4	Australia	Dairy products, 5
5	Norway	Fishery products, 6
6	Hungary	Pork, 5
7	New Zealand	Dairy products, 5

Figure 3-4 Countries and items of overseas factories inspection in 2016

Section 2. Medicinal Products and Cosmetics Manufacturing Management

Current Status

To ensure the stable production and management of medicinal products and cosmetics are maintained, a source management system has been enforced in Taiwan to assist manufacturers in improving product quality. A systematic management to align with international GMP regulatory mechanisms for medicinal products and cosmetics were also employed to allow the industry to export their products to the international market. Controlled drugs are subject to the provisions of "*Controlled Drug Act*" and "Good Manufacturing Practice" for related matters to enhance manufacturing quality of controlled drugs and control the directions of the drugs.

Policies and Outcomes

1. Medicinal product manufacturing management

(1) Medicinal product management

A. Establish "Drug Master File (DMF) system" for active pharmaceutical ingredients import and self-use. From October 2009 to 2016, a total of 4,498 DMF applications are received, of which 3,038 have been approved while 1,460 are rejected. The approval rate is 67.5%.

B. Starting from January 1, 2016, medicinal products should use APIs which are in compliance with GMP, and the source data should be declared electronically. Until December 31, 2016, the declared rate has achieved up to 100%, besides the manufacturing or imports of drug products prohibited.

C. Promulgate GMP Standards for API on May 22, 2013(Pharmaceutical Inspection Co-operation Scheme: Good manufacturing practice, PIC/S GMP) has been fully implemented at the end of December, 2015. Until the end of December, 2016, a total of 245 items in 24 domestic API manufacturers have met GMP regulations for API. The total number of API import permit licenses for GMP reference are 1,531, accounting for 75.5% of total permit licenses.

(2) Complete compliance to the PIC/S GMP by modern pharmaceutical manufacturers

A. Taiwan formally became a member of the PIC/S organization since 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 in 2016.

B. Follow-up management for modern pharmaceutical manufacturers includes 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-market quality surveillances, and news events). Theme-based audits were also initiated to further verify the current status of quality management in modern pharmaceutical companies. On-site sampling and testing were conducted as part of the quality monitoring process to ensure that quality of medicinal products is maintained within the stated period of expiry.

C. At the end of December 2016, a total of 127 modern pharmaceutical manufacturers in Taiwan are compliant with PIC/S GMP standards (Table 3-1) and 936 overseas modern pharmaceutical manufacturers of imported medicinal products have been assessed as compliant. Also, by the end of December 2016, a total of 268 foreign modern pharmaceutical manufacturers have passed on-site inspections, ensuring a stable market supply of medicinal products of all dosage forms.

Table 3-1 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
2016	-	127	268

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

2. Controlled drug licenses and source management

(1) Controlled drugs-related license issuance and training

A. At the end of 2016, 15,413 institutions and companies with controlled drugs registration licenses, and a total of 52,757 professionals with controlled drugs prescription licenses had been approved (Refer to Table 4 in Annex II for detailed license statistics).

B. TFDA issued 95 “import permits”, 650 “permits for importing controlled drugs”, 198 “permits for exporting controlled drugs”, 435 “permits for manufacturing controlled drugs”, 42 “controlled drugs transportation licenses”, 416 “approval letter for medical/pharmaceutical education/research trial use”, a total of 1,836 copies in 2016.

C. To improve familiarity with laws and management practices related to controlled drugs amongst local health bureaus and related businesses, a total of 11 training courses of controlled drugs management laws were held in 2016.

(2) Supply of schedule 1 and 2 controlled drugs

A. 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$ 670,480,000 in 2016. Refer to Table 5 of Annex II for statistics for the revenue of Pharmaceutical Plant of controlled drugs.

B. For Schedule 1 and Schedule 2 controlled drugs with greater demands in medical institutions, the market is commissioned to domestic pharmaceutical manufacturers that have met GMP regulations, under the conditions that the said manufacturers must enforce safety and quality management measures aligned with those of Pharmaceutical Plant of Controlled Drugs.

C. To provide more diverse selection for pain management during treatment, TFDA developed new chemical entities (NCE), new administration paths and new dosage forms of opioids according to the needs of the medical institutions and patients. In 2016, 10/20mg long-lasting Oxycodone tablets, 5mg quick-acting capsules and 75μg/hr Fentanyl transdermal patch was imported for the first time to benefit patients suffering from severe pain.

(3) Continuing Improvement to Product Quality and Standards of Pharmaceutical Plant of Controlled Drugs

A. 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, and were rewarded for the next two years.

B. Post-market tracking studies were carried out for “Morphine Sulfate - 15 mg” to ensure product quality, safety, and therapeutic efficacy.

C. On-job-training for personnel was enhanced for PIC/S GMP, controlled drugs, and pharmaceutical affair management.

(4) Building new PIC/S GMP factories

To expand independent production capacities for Schedule 1 and Schedule 2 controlled drugs and improve product quality, TFDA initiated the “New Production Building Construction and Renovation Project for Pharmaceutical Plant of Controlled Drugs” since 2014. The new factory building was set for completion in 2017 and shall be used for production purposes after passing PIC/S GMP assessments.

3. Medical devices source management

(1) Manufacturer registration management

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. See Figure 3-5 for valid GMP registration letters for domestic medical device manufacturers and QSD registration letters for imported medical devices issued by the end of 2016.

(2) The inventory of medical device licenses with expired GMP/QSD registration letters

To ensure the quality of medical devices, a phased process for reviewing medical device licenses with expired GMP/QSD registration letters were completed in 2016. The review resulted in suspension of 112 medical device licenses relating to 58 pharmaceutical firms. These companies were notified to have their manufacturers re-

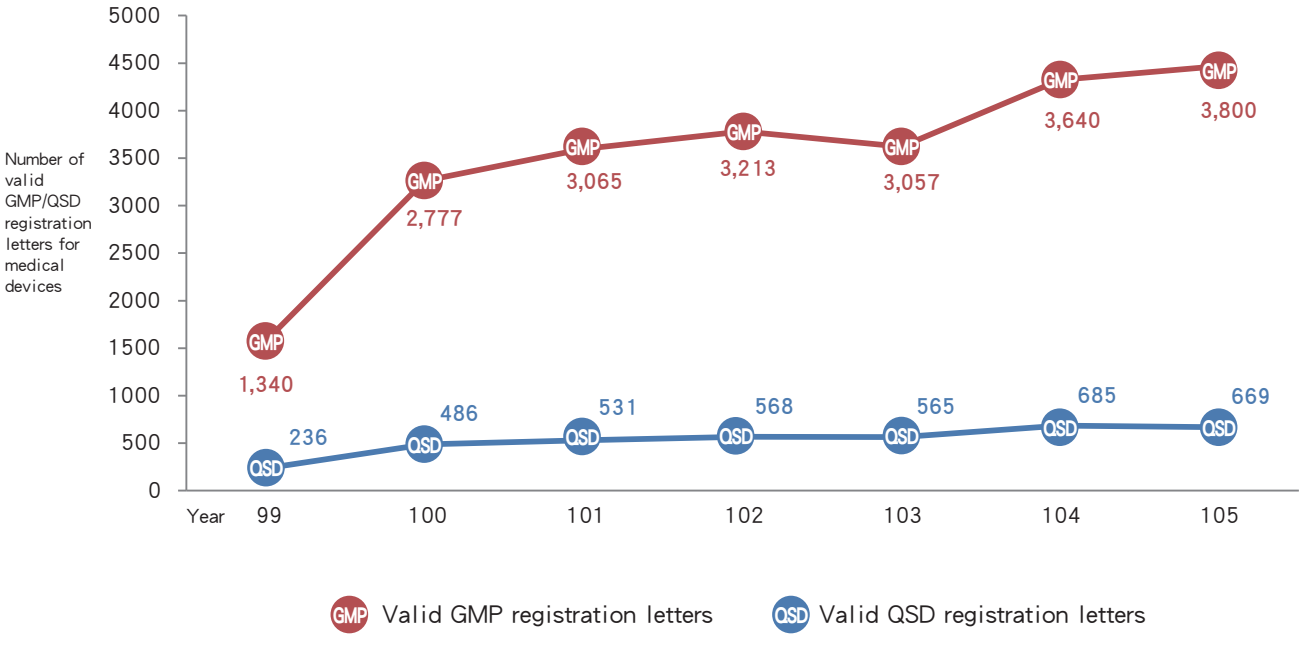


Figure 3-5 Number of valid GMP/QSD registration letters for medical devices

apply for medicament manufacturing licenses (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.

4. Cosmetics source management

Since 2008, TFDA and the Industrial Development Bureau (IDB) of the Ministry of Economic Affairs (MOEA) jointly promoted voluntary GMP validation mechanisms for cosmetic factories to improve manufacturing quality of the products. Cosmetics manufacturers are currently required to submit documented information to IDB and IDB then assembles an audit team to perform the audit. Manufacturers that pass the audit may then apply for a GMP certificate from TFDA. At the end of 2016, a total of 146 cosmetic manufacturers have voluntarily applied for GMP audits with IDB, of which 102 successfully passed the audit. In 2016 alone, 23 manufacturers applied and 16 successfully passed, for a qualification rate of 69.6% (Figure 3-6).

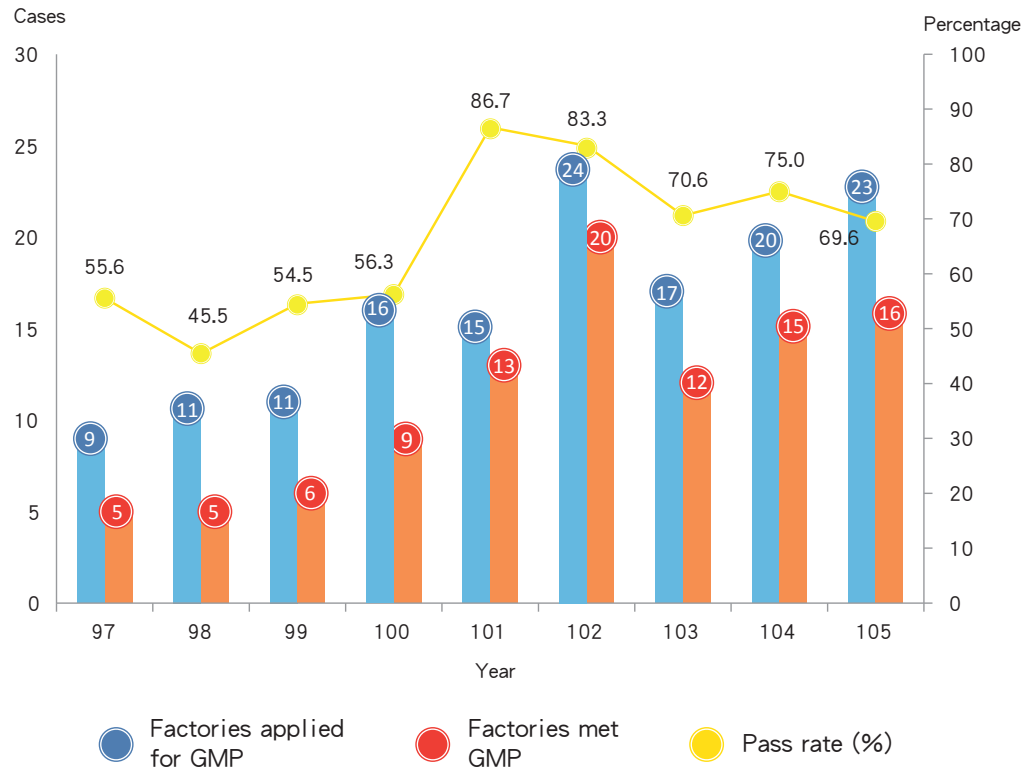


Figure 3-6 List of manufacturers that applied for and passed cosmetics GMP from 2008 to 2016

04

Distribution and Post-market Management

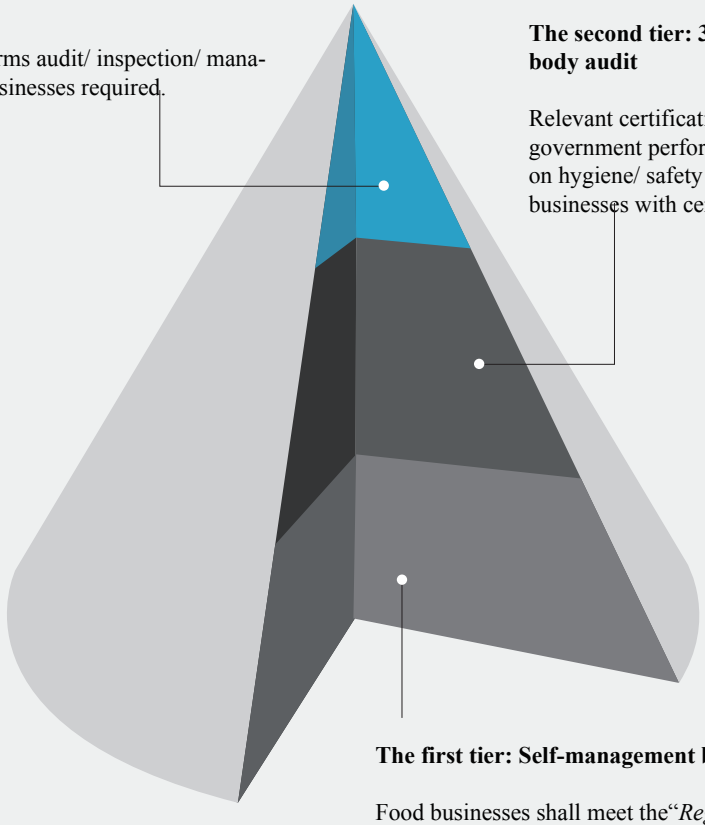
Three Tier Quality Control System for Food Safety

The third tier: The government inspection and test

Government performs audit/ inspection/ management on food businesses required.

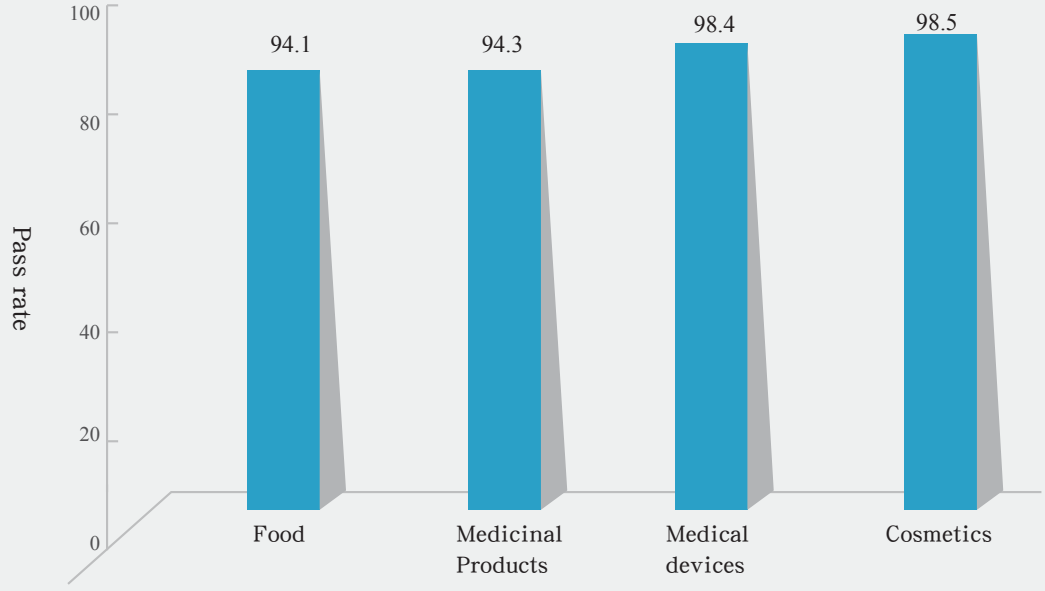
The second tier: 3rd party certification body audit

Relevant certification institutes accredited by government perform certification/ inspection on hygiene/ safety management for food businesses with certain scale/ class.



The first tier: Self-management by the business

Food businesses shall meet the"*Regulations on Good Hygiene Practice for Foods.*"TFDA has established regulations and implement such as food business registration management, mandatory conduct test, traceability system management and food safety monitoring plans for food businesses belonging to a category and scale.



Post-market quality surveillance

04 Distribution and Post-market Management

To control the quality of food, medicinal products, cosmetics and medical devices after being placed on the market, TFDA promotes food, medicinal products traceability system and Good Distribution Practice (GDP). In the meanwhile the businesses are asked to reinforce self-management and establish a comprehensive food and medicinal products monitoring system.

Section 1. Product Distribution Management

Current Status

TFDA actively constructs three-tier food quality control system, implements product traceability system, promotes GDP, optimizes and controls medicinal products directions and management, refines product manufacturing and distribution management strategies and reinforces businesses self-management to completely control the storage, transportation, distribution of food, medicinal products and cosmetics.

Policies and Outcomes

1. Safety and monitoring of food distribution

(1) Implement food traceability system

To enforce food traceability management system, TFDA announced to revise "*Food Businesses Shall Establish Traceability System of Food Products*" on October 4, 2016. Twenty-two categories of food manufacturers, importers or retailers were forcefully included in the scope of food traceability systems. 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://facebook.fda.gov.tw). Food businesses are required to use invoices based on the recognition of the treasury institutes, should also use electronic uniform invoices.

(2) Improving sanitation and risk control measures of food factories

According to Article 8, paragraph 1 of *Food Safety Act*, all food businesses, including personnel, operation sites, sanitation management of facilities and quality assurance system, shall meet *the Regulations on Good Hygienic Practice for Food* (GHP) to ensure the sanitation management of manufacturing, processing, distribution, packaging, transportation, storage, selling, import and export and reduce the possibility of food contamination. Seafood processing plants, meat processing plants, dairy product processing industry, box meal factory and food services within international tourist hotels shall meet the *Regulations on Food Safety Control System* (HACCP) . TFDA and local government will jointly conduct auditions (Figure 4-1) to implement control measures.

Figure 4-1 Number of compliance audits carried out according to the Food Safety Control System in 2016

(3) Three-tier food quality control system

The monitoring of food safety requires self-management by the businesses, the impartial third party independent test institute and governmental audition and sampling, the joint implementation of the three channels to establish the three-tier quality control system and safeguard food safety of the fellow citizens (Figure 4-2).

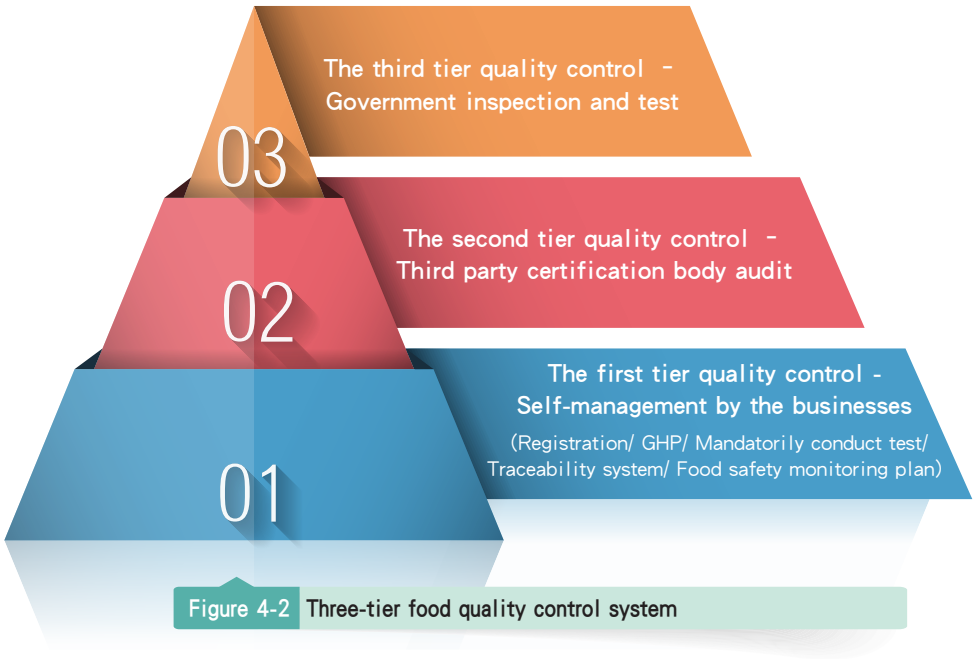


Figure 4-2 Three-tier food quality control system

A. The first tier quality control: Self-management by the businesses

On April 21, 2016, TFDA promulgated "*Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatoily Conduct Test and Meet the Minimum Testing Cycle and Other Relevant Matters*" and announced 17 categories of food businesses (including edible oils, processed meat products, processed dairy products, processed seafood products, food additives, special dietary foods, soybeans, corn, wheat, flour, starch, salts, sugar, soy sauce, tea leaves, pre-packaged tea drinks, and non-department store retailers of comprehensive commodities) that required enacted food safety monitoring plan. Additionally, edible oil importers and businesses of integrated commodity retail other than department stores are enacted mandatory conduct test since July 31, 2016.

B. The second tier quality control: Third party certification body audit

After revising *Food Safety Act* in 2015, the original commissioned certification body is replaced by accredited certification body. Moreover, inspections

announcements were released for canned food products, special nutrient foods, dairy products, and food additive industries. Ten manufacturing businesses involving capital more than NT$30 million dollars, including edible oil, sugar, salt, flour, starch and soy sauce industries, are also required for certification. By the end of 2016, 519 certification audits were carried out.

C. The third tier quality control: Audition capacities

(A) Auditing projects: Auditing projects summarzie local government, health bureaus audition and monitoring data, evaluate domestic and overseas food safety alert and forums, give a comprehensive interpretation and supervision over focused administrative projects, high-violator, high-risk, high-profile projects, and conduct project audition sampling jointly with local government and health bureaus. In 2016, 47 project were conducted.

(B) Inspection program of the Executive Yuan Joint Task Force for Food Safety: For essential food categories that have significant impacts on fellow citizens, 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. Three important joint audits were completed in 2016.

(C) Supervising food inspection responsibilities of local governments, health bureaus, and departments: In 2016, a total of 112,382 *Good Hygienic Practice* (GHP) audits for food products, 424,402 product labeling inspection, and 49,800 product sampling tests were carried out. Refer to Table 6 in Annex II for detailed local health bureaus food audition statistics.

2. Medicinal product trace and track

To effectively control medicinal products sources and distribution, *Pharmaceutical Affairs Act* added Article 6.1 on December 2, 2015 and authorized the establishment of " *Regulations governing the trace and track system for medicinal products*" based on *Pharmaceutical Affairs Act* added Article 6.1, paragraph 3 on September 6, 2016. The regulations clearly specify that medicinal product categories announced by the central health competent authorities, the license holders or distributors shall establish information system for tracing the source and tracking the flow of medicinal product. TFDA primarily plans to include three categories of medicinal products including plasma-derived preparations, vaccines and botulinum toxin into stage 1 advanced traceability scope.

3. Facilitate medicinal products GDP system

(1) PIC/S has promulgated GDP in 2014 and extended its requirements on medicinal products quality control from GMP to GDP. The main purpose was to prevent the storage, transportation and distribution process of medicinal products from affecting product quality.

(2) TFDA promotes medicinal products distribution management system since 2011 and opens for applying medicinal products GDP counseling visits. By the end of 2016, 590 pharmaceutical factories, distributors and logistics were inspected, and 107 companies with excellent performance, will continue receiving counseling inspections and training programs.

(3) On February 18, 2016, promulgate the implementation details and schedules for "*Good Manufacturing Practice (GMP)*: *Distribution*". Manufacturers and dealers with medicinal product permit licenses must comply with such standards completely by 2019.

4. Distribution management for controlled drugs

(1) TFDA has established "Controlled drugs management information system". Institutions or business with controlled drug registration licenses are required to record daily increase and decrease of stocks and inventory of controlled drugs truthfully and report the records regularly. The distribution is managed through auditions and inspections on upstream and downstream sources.

(2) To reinforce the management of controlled drugs, a total of 17,145 on-site inspections were conducted in 2016. There were 437 institutions been violating the regulations and the violation rate was 2.55% (Table 7 in Annex II for inspection statistics). A total of 351 institutions with higher consumption rate or increased consumption rate of hypnotics were inspected in projects of 2014. Of which, 59 were found violating and the violation rate was 16.81%.

(3) The top two violations are "incomplete documentation of controlled drug handbook" and "incomplete/ missing routine recording of inventory". Violators all received relevant penalties.

5. Medical devices and cosmetics distribution management

(1) To ensure the product quality established by the original manufacturers can be maintained during transportation and marketing period, TFDA promotes medical devices distribution management since 2014 and promulgates "*Medical Device GDP*" on June 18, 2015. Host 5 sessions of GDP training course in 2016, complete counseling inspections in 30 medical device distributors. Additionally, include related regulations in the draft of Act governing medical devices management advanced promulgated on December 5, 2016. In the future, medical devices GDP will be implemented in scheduled stages.

(2) To rapidly recognize medical devices on the market, quickly obtain product adverse events report and ensure uniformity of barcode formats of medical devices, TFDA announced "*Medical Device* UDI" on October 30, 2015 to provide businesses qualified medical device UDI barcode format regulations that comply with international standards and established the foundations of their automatic distribution management system. In 2016, through the implementation of programs, TFDA successfully introduced UDI into routine medical device inventory management in patient's surgical records of Division of Cardiovascular Surgery at Taipei Veterans General Hospital.

(3) To plan for revising *Statute for Control of Cosmetic Hygiene* and establishing "Cosmetic product notificaiton system", TFDA encourages industries actively register on the Notification Portal now. After the revision, TFDA will enforce industries to register on the portal to control cosmetics on the market.

(4) The establishment of Cosmetic Product Notification Portal is completed in 2013 (Figure 4-3). To help industries familiarize with the use and operations of the notification portal, TFDA organized 3 orientations and 25 training courses in 2016. A total of 1,326 companies and 2,041 cosmetic products were successfully registered online.

Figure 4-3 Cosmetic products notification portal

Section 2. Post-market Management

Current Status

To ensure post-market safety surveillance mechanisms of food, medicinal products and cosmetics, TFDA supervises the establishment of domestic and overseas safety alert reinforce reporting system, carrying out real-time measures, sampling tests high market risk influences on specific population and primary consumption items or high-profile domestic and foreign products. Additionally, TFDA refers monitoring results of last year or previous years and establishes monitoring plans to effectively reduce the incidence of damages.

Policies and Outcomes

1. Post-market product safety management

(1) Food

A. International alert monitoring

TFDA has designated personnel to monitor international susceptible food recycling alerts and issued real-time information to remind businesses of avoiding importing problematic products. In 2016, international alerts were monitored to publish a total of 102 food comsumer traffic light alerts on the Food and Drug Consumer Service Network (http://consumer.fda.gov.tw/) (Figure 4-4).

Figure 4-4 The main page of the Food and Drug Consumer Service Network

B. 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 2016, TFDA received a total of 192 reports of unintended reactions of health foods or food in capsule or tablet forms, and monitored a total of 1,590 food safety alerts.

C. Food poisoning statistics, prevention and control

There were 486 food poisoning outbreaks reported in 2016. The vehicles of food poisoning outbreaks included compound cooking food and others, aquatic products and its processed products, meats, eggs, dairy products and its processed products, confectionery and candies, vegetables, fruits and its processed products. Most frequent outbreaks were due to vehicles of compound cooking food and others (Table 8 in Annex II for detailed statistics). To raise awareness of food poisoning and prevent such outbreaks, TFDA established a specific webpage for prevention of food poisioning and published Annual Report for Food Poisoning and Prevention as a reference for relevant fields.

(2) Medicinal product quality management

A. The Reporting System of Medical Product Defects was established in 2004, allowing healthcare professionals and the public to report medicinal products with suspected defect. A total of 869 defective drug products were received in 2016, of which recalls were initiated for 8 medicinal products. Meanwhile, people can also use mobile device to report medicinal product defects .

B. Monitoring overseas medicinal products quality alerts on a daily basis to monitor imports whether recalled in other countries. A total of 646 products were monitored in 2016, among them, 4 medicinal products withdrew from overseas had been imported in Taiwan. TFDA already asked the companies to recall these products.

C. To ensure the quality of biologics, a total of 396 batches, 12,688,690 doses are sealed for tests (Table 9 in Annex II for detailed statistics).

(3) Medical devices and cosmetics

A. Medical devices and cosmetics ADR

To strengthen the practicality and convenience of reporting system, TFDA integrates the original system and establishes "Post-market Quality Management System for Food, Medicinal Products and Cosmetics". TFDA received 427 medical devices adverse reactions and 3,429 defective medical devices in 2016, which had been evaluated subsequently. A total of 58 cosmetics adverse events were revealed in 2016, of which 15 cases of adverse reactions and 43 cases of defective products, all have been informed to local health bureaus for related matters or companies to submit investigation reports. TFDA also continues follow-ups.

B. Online cosmetics safety surveillance

In 2016, a total of 160 cosmetic products purchased from four online shopping platforms such as PChome, momo, GoHappy and Yahoo, have passed quality tests. Thirty-four packaging/labeling violations have been found (the violation rate is 21.25%), cases of suspected product violations have been delivered to local health bureaus for processing (Table 4-1).

Table 4-1 Online cosmetics safety surveillance results

Cosmetics	Number of online shopping platforms	Inspection items					
		Quality test			Package labeling		
		Number of sampling	Number of nonconformity	Violation rate (%)	Inspected number	Number of nonconformity	Violation rate (%)
Components identification and quality surveillance of lotions	9	16	0	0	40	7	17.5
Components identification and quality surveillance of facial cleansers		16	0	0	40	6	15
Components identification and quality surveillance of nail polish		16	0	0	40	16	40
Components identification and quality surveillance of sunscreens		16	0	0	40	5	12.5
Total	9	64	0	0	160	34	21.25

C. Medical devices and cosmetics joint audit

To effectively supervise whether the labeling of medical devices and cosmetics on the market comply with approved regulations, a regular medical devices and cosmetics joint audit is carried out annually. In 2016, TFDA conducted joint audit on 6 categories, a total of 229 medical devices and cosmetics that are high-violation, high-risk, high-profile, and 61 violations were found (Table 4-2).

Table 4-2 Joint audit results of medical devices and cosmetics in 2016

Categories	Product name	Number of inspected counties/cities	Number of inspected stores/street vendors	Product labeling		
				Inspected number	Violations	Violation rate (%)
Medical devices	Non-sterile ultrasound gel	9	50	29	5	17.2
	(Dental) endosseous implant	9		41	18	43.9
	Static electric therapy apparatus	7	41	25	8	32
	Total	25	91	95	31	32.6
Cosmetics	Teeth whitening cosmetics	7	57	30	6	20
	Wet wipes containing moisturizing agents			65	13	20
	Perming agent			39	11	28.3
	Total	7	57	134	30	22.3

D. Post-market review of Class I medical devices

TFDA conducted a comprehensive review over three types of products with Class I medical devices licenses such as “Audiometer”, “Environmental Chamber for Storage of Platelet Concentrate” and “Cement Dispenser”. By the end of 2016, 78 licenses reviews have been completed. A total of 30 licenses were found to have stated functions that did not meet the scope identified in the original declaration, and thus have been revoked.

(4) Illegal drugs, food and cosmetics inspection

The “Joint Task Force of Anti-Counterfeit Drugs” is assembled on April 30, 2014 to take action against all the illegal drugs. In addition, monitor food, drugs, medical devices, and cosmetic advertisements and the results of 2016 are as follows:

A. Four hundred and sixty illegal drugs cases are inspected with penalty of NT$ 4.113 million dollars, and the violation rate was sharp dropped from 27.22% in 2002 to 1.22% in 2016 (Figure 4-5).

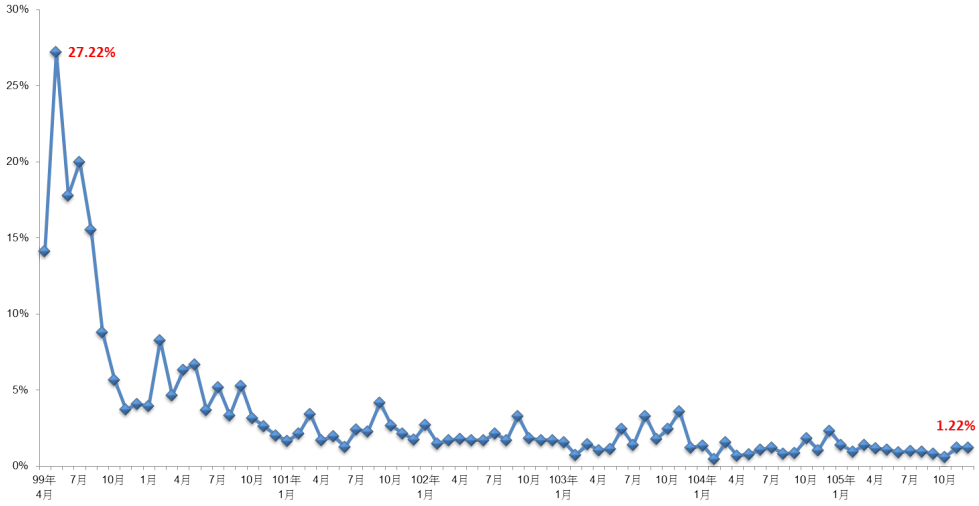


Figure 4-5 The violation rate of illegal drugs

B. A total of 8,139 cases of illegal advertisements for food, drugs, and cosmetics products were inspected by local health bureaus, with a total fine of NT$ 199,35.3 million. The percentage of illicit advertisements was dropped from 13.9% in 2010 to 4.85% in 2016 (Figure 4-6).

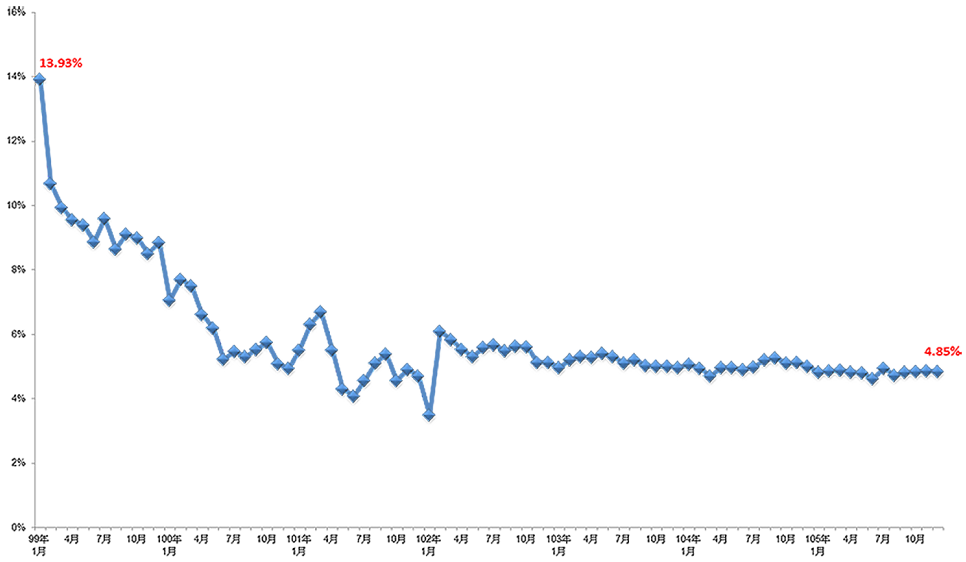


Figure 4-6 The percentage of food, drugs, medical devices and cosmetics of illicit advertisements

2. Post-market product quality surveillance

In 2016, a total of 14 PMS plans were implemented, including six for food products, one for medicinal product, five for medical devices, and two for cosmetics. Conforming rates for food products, drugs, medical devices and cosmetics were 94.1%, 94.3%, 98.4% and 98.5% respectively. Cases of nonconforming products were transferred to the responsible local health bureaus and departments to pursue subsequent legal actions as well as source control.

(1) TFDA has continued to carry out 6 post-marketing surveillance of heavy metal, mycotoxins, veterinary drugs, agricultural chemical residues, food adulteration, and genetically modified (GM) food. A total of 7,212 products were monitored, with a conforming rate of 94.1% (Table 4-3). Nonconformity products were sent for legal processing. TFDA also conducts source improvement through inter-departmental coordinating mechanisms. Refer to Table 10 in Annex II for detailed statistics.

(2) Select medicinal products based on risk assessment factors for quality surveillance. In 2016, TFDA selects medicinal products for cardiovascular drugs, antipyretic analgesics, antibiotic, a total of 88 samples were taken for testing and with conformity rate of 94.3% (Figure 4-7). Refer to Table 11 in Annex II for detailed statistics of medicinal products.

Table 4-3 Test results of food quality surveillance

Surveillance items and results	Number of sampling	Number of conformity	Number of nonconformity	Conformity rate (%)
Agricultural chemical residues	3,341	2,978	363	89.1
Veterinary drug residues	2,278	2,246	32	98.6
Mycotoxins	515	502	13	97.5
Heavy metals	601	598	3	99.5
Food adulteration	126	120	6	95.2
Genetically modified (GM) food	351	345	6	98.3
Total	7,212	6,789	423	94.1

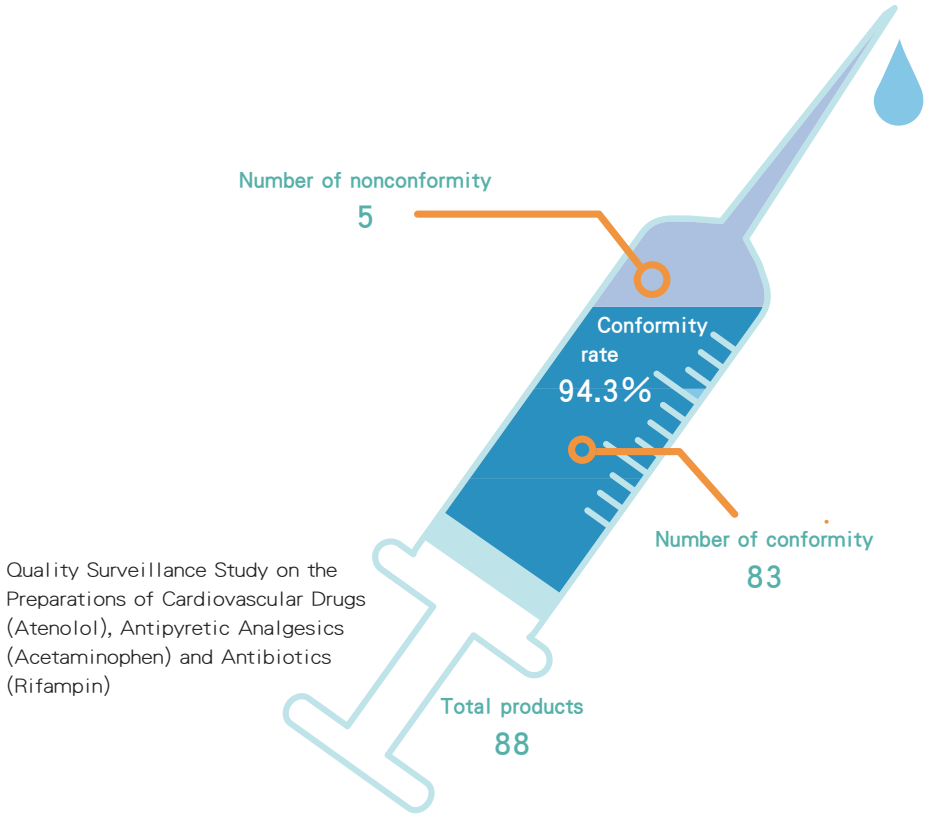


Figure 4-7 Test results of medicinal products surveillance

(3) According to adverse device reaction (ADR) reports and alert database every year, medical devices with high-risk and potential hazards will be taken into consideration for annual surveillance. In 2016, a total of 193 marketed medical devices are sampled for quality and package labeling inspection tests. Among them, 190 products are conformed with quality surveillance standards (conformity rate 98.4%) while 162 products are conformed with package labeling standards (conformity rate 83.8%) (Table 4-4).

(4) Based on risk levels and primary consumption items every year, cosmetic products will be selected for quality surveillance. In 2016, a total of 329 cosmetic products are sampled for post-marketing surveillance (e.g. preservatives and microorganisms). Among them, 324 products are conformed with quality surveillance standards (conformity rate 98.5%) while 285 products are conformed with package labeling standards (conformity rate 86.6%) (Table 4-4).

Table 4-4 Test results of medical devices and cosmetics in post-marketing surveillance

Categories	Name of Project	Total products	Inspection items			
			Quality		Package labeling	
			Conformity No.	Nonconformity No.	Conformity No.	Nonconformity No.
Medical devices	Sterility surveillance of the medical gauze and cotton balls	78	78	0	63	15
	Sterility surveillance of acupuncture needles	56	56	0	44	12
	A study investigating the detection capacity of a molecular diagnostic kit for high-risk HPV 16/18	11	11	0	9	2
	Post-marketing surveillance of color additives leaching test for color contact lenses	28	28	0	28	0
	Quality examination of medical gloves on the market	20	17	3	18	2
	Total number (%)	193 (100)	190 (98.4)	3 (1.6)	162 (83.9)	31 (16.1)
Cosmetics	Post-marketing surveillance study on preservatives of cosmetic products in Taiwan	152	150	2	111	41
	Annual microbiological survey of cosmetics in Taiwan's market	177	174	3	174	3
	Total number (%)	329 (100)	324 (98.5)	5 (1.5)	285 (86.6)	44 (13.4)

05

Testing Technology and Capability

Section 1. The Mission and Functions of National Laboratory

Section 2. Enhancing Local Testing Proficiency and Quality

Section 3. Private Laboratory Accreditation and Management System

National Laboratories

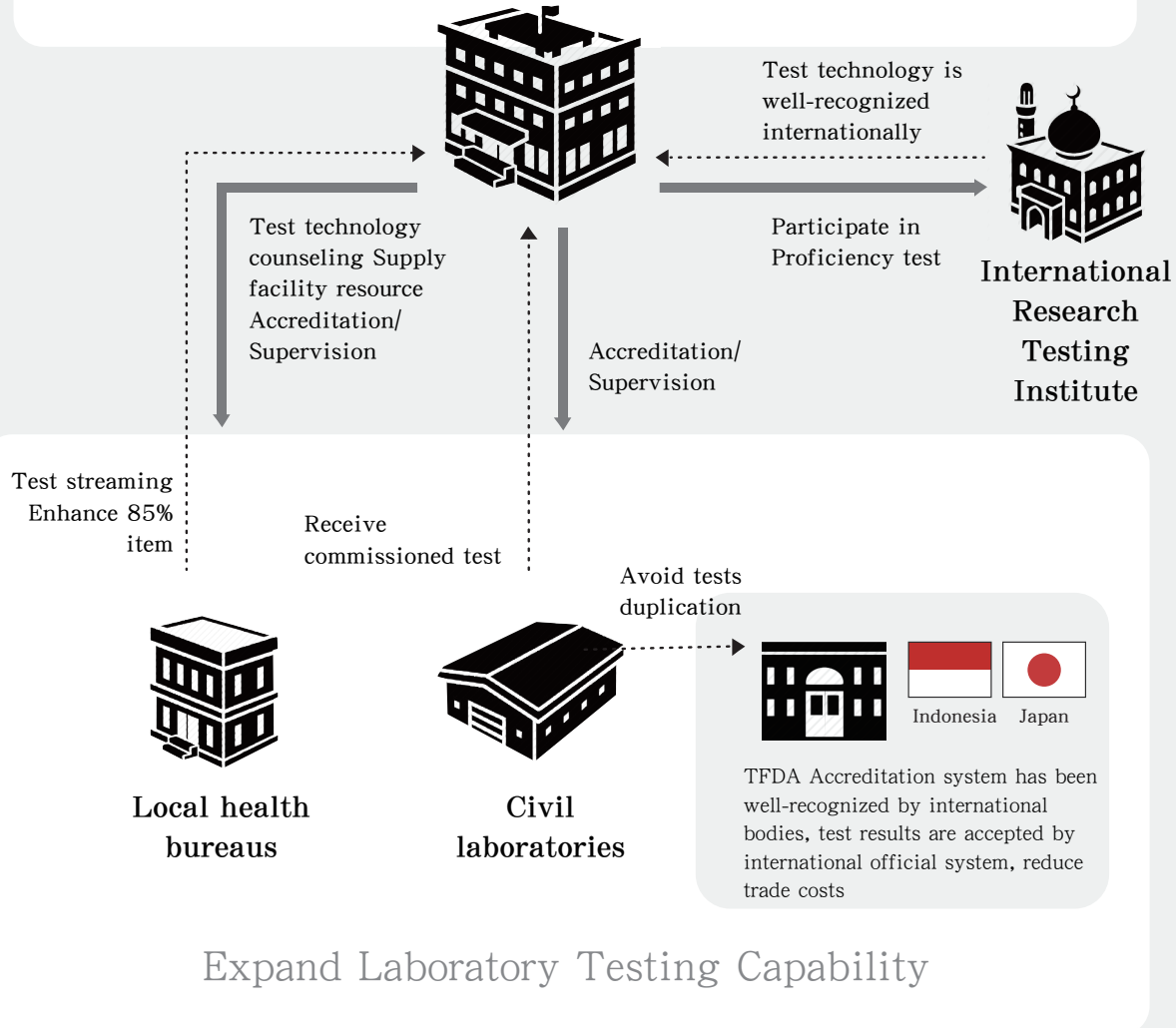
Testing technology development & strengthening

Discover high-risk, high-violation products:

- Firstly discover instant coffee packs submitted by the domestic police department containing drugs
- Firstly discover counterfeit botulinum preparations in the samples submitted by national custom

Identify consumer-cared events, relieve public concerns:

- Develop testing methods for oat product-containing pesticide residuel glyphosate, control the contents of glyphosates in oat product at boarder and domestic market in time
- Develop testing methods for oil-containing benzene, identify the contents of benzene in oils distributed on the market



Expand Laboratory Testing Capability

05 Testing Technology and Capability

The growing complexity and diversity of engineering technologies in food, medicinal products, medical devices and cosmetics make the managment and measurement of them more challenging than ever before. TFDA continues to advance laboratory testing capabilities and estibilish fast, reliable, and internationally harmonized methods to identify unknown substances, contingencies, and contaminants which may hurt product qualities and public health. TFDA also continues to strengthen test capacities and quality of local government health bureaus, constructs effective streaming system, encourages civil laboratory certifications to ensure the quality and reliability of commissioned tests, effectively use test resources and expand test capacities.

Section 1. The Mission and Functions of National Laboratory

Current Status

The National Laboratory is in charge of testing, formulating analytical 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. Test business

In 2016, 86,600 tests were carried out for 7,618 specimens. Details are described in the following:

(1) Collaborate with administrative management: Including test for product application permit registration, batch seal and tests for biologics, boarder examination for condoms

and tests for accidents. For example, the determination of glyphosate in oat products and benzene in oil products, false labeling of lutein in capsules or tablets or clarification of suspected carcinogens in drip bag coffee.

(2) Provide administrative assistance: Including tests delivered by the prosecution, police, investigation, justice or custom departments and technical support by local health bureaus. For example, food poisoning due to consumption of toxic mushrooms and suspension of flyblown chicken legs in lunch boxes for students in elementary schools.

2. The establishment and promotion of test methods

To respond to test requirements, TFDA establishes fast and reliable methods, details are described in the following:

(1) Add and revise 22 announced test methods for food products (a total of 205 items), including "Test method for food antioxidants – Multiple analysis" and "Test method for pesticide residues in avian and livestock food – Multiple analysis for residues"; 38 recommended test methods for food products (a total of 57 items), including "Test methods for veterinary drug residues in honey bees – Test for nitrofuran metabolites" and "Test methods for iodine contents in food products"; 8 recommended test methods for cosmetics (a total of 73 items), including "Test methods for hair dyes in cosmetics (II)" and "Diameter measurement of titanium dioxide microparticles in cosmetics".

(2) Establish "Guideline on Minimum Requirements for Biological Products (VI)" (Figure 5-1), including addition and revision of 9 items such as "Methylpentoses in Polysaccharide Vaccines" etc.," and the host of "Orientations of Guideline on Minimum Requirements for Biological Products", to facilitate mutual communications with businesses industry.

(3) Publish "Chinese Pharmacopoeia 8th ed." (Figure 5-2) to align with the regulations of three major pharmacopoeias in the world, namely USP, EP and JP. The Chinese pharmacopoeia (Ch.P.) includes the 1st self-developed and patented API (Nemonoxacin Malate) and additional 4 self-developed and produced API (Calcitriol, Docetaxel, Duloxetine, Gemcitabine hydrochloride). The inclusion of new drugs developed in Taiwan facilitates the transformation and upgrading of medical and pharmaceutical industries.

Figure 5-1 Test standards for biologics (VI)

Figure 5-2 Chinese pharmacopoeia 8th ed.

3. Strengthening the testing capacity of the national laboratory

On the topics of illegal additives, emergent GM products, emergent contaminants, adulteration products and unknown microorganisms, the testing capacities and technology of TFDA haven been greatly improved through purchasing equipment and the host of "International food adulteration test and Chinese herb misuse identification seminars" as well as more than 10 national conferences or advisory board meetings. Through technology communication and experience sharing, TFDA strengthens laboratory quality assurance operations and actively passes certifications to obtain the recognition of international institutes.

(1) Discovery of high-risk and high-violation products

A. Electronic cigarettes are currently illegal 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. In 2014, 395 specimens were tested, whereas the number was greatly increased to 2,134 in 2015 and further increased to 3,062 in 2016. From 2014 to 2016, a total of 5,591 tests for electronic cigarette specimens were completed and nicotine content was found in 74% of the specimens (Figure 5-3). The specimens that contain nicotine were transferred to the original authorities for subsequent handling.

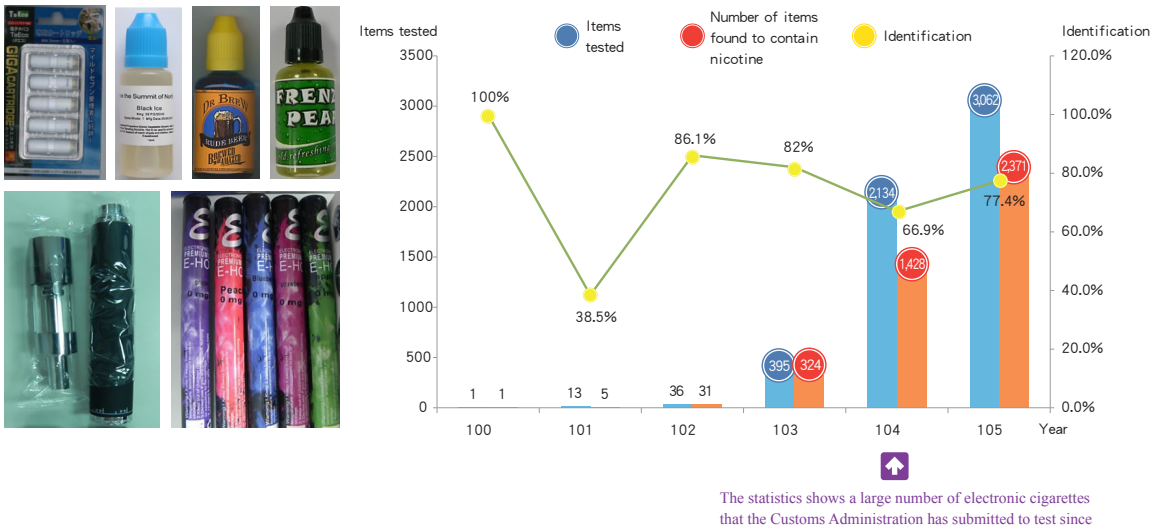


Figure 5-3 The appearance, diagram and detection rate of the e-cigarette

B. In the inspection of instant coffee packs submitted by Taipei City Police Department, it reveals that the samples contain not only the Schedule III drug Ketamine, but a suspicious un-identified component was also discovered. Through GC-MS analysis and compared the results to the Analytic Laboratory Urine and Drug Abuse Report System (UDARS), the component has been confirmed as synthetic 6-methoxy Methylone (Figure 5-4) which is inspected for the first time in Taiwan. The activity and toxicity of 6-methoxy Methylone still remain unknown at present; the misuse of such component may result in sever impacts on public health. TFDA announced the news promptly on October 12 to warn compatriots to be aware of it. Owing to the components identified as the analogue of Methylone and Mephedrone, it is speculated to act similar pharmacological properties as the Schedule II drugs Mephedrone and MDMA. In view of above, TFDA suggests Narcotics Review Committee, Ministry of Justice to include the component as narcotics to boost the strength of defense for anti-drug ties.

C. The botulinum toxin preparations submitted by Custom Administration, Ministry of Finance in March, 2016 were found without containing botulinum toxin type A. Because the appearance of the product is similar to the ones that have been approved, this is the first adulteration of botulinum toxin preparations found in Taiwan (Figure 5-5). TFDA issued the news immediately to remind fellow citizens. After being disclosed by social media, Taiwanese Dermatological Association and Consumers' Foundation, Chinese Taipei both held press conferences to educate the public about how to identify adulterate medicinal products to prevent fraud.

Figure 5-4 6-methoxy Methylone was found in the instant coffee packs and its chemical structure.

Figure 5-5 The differences between real and adulterate BTX preparations

(2) Clarify events consumers care about and relieve the doubts of the public

A. In May 2016, oat products from the US were found containing glyphosate, a type of pesticide. To be aware of glyphosate contents in oat products at boarder inspections and that have been distributed on the market, TFDA developed specific testing methods in a very short period to analyze 36 oat products imported from 8 countries (including the US and Australia). Ten products were found containing glyphosate with the level of 0.2-1.8 ppm, which had violated the regulations that prohibit the use of glyphosate in oat products in Taiwan. TFDA provided such test results to border inspection units for further handling and sanctions. TFDA also released the testing methods immediately to the public and all testing bodies for reference to expand national test capacities and thus achieve safeguard effective for public health.

B. In September 2016, Consumers' Foundation, Chinese Taipei acted as a whistleblower as carcinogenic matters, namely benzene, was detected in oil products on the market. The source of oil products and processing procedures were suspected involving illegal matters. TFDA promptly established analytical methods and tested 40 oil products. Of which 26 products were free of benzene detection. At the same time, 14 samples containing benzene with the level between 2.0-34.2 ng/g, which is still within the background value set by European Research Institute (≤100 ng/g)[note]. Based on the scientific evidence, TFDA issued test results of benzene levels in oil products on the market and successfully relieved the doubts and concerns about such products.

   Note: Opinion on certain aromatic hydrocarbons present in food (expressed on 20/1/1999). From http://ec.europa.eu/food/fs/sc/scf/out24_en.html.

C. In September 2016, a rumor was widespread online that a wet strength agent, polyamine-epichlorohydrin resin, PAE resin, was added in drip coffee packs to avoid breakage of coffee packs during immersion in hot water. Moreover, it is also claimed that the alcoholic and oily substances in coffee may expedite and dissolve the carcinogens of the wet strength agent into the coffee. To clarify such accusation, TFDA tests 9 drip coffee packs on the market. The results showed that the filter bags used in all 9 products are all made of PP non-woven fabric materials, which are all 3-MCPD-free. All samples were in accordance with the regulation of the material test and migration test, respectively. TFDA rapidly released test results to the public 3 days after the news with the support of scientific evidence.

D. To clarify the rumor of heavy metal releasing from BBQ nets, TFDA sampled 10 BBQ nets and plates on the market and simulated real BBQ situations with non-marinated and soy sauce-marinated pork tenderloin slices. The purpose was to investigate heavy metal transmission from various BBQ utensils and the differences of hazardous contents such as Benzopyrene as well as PAHs from scorched pork. In September 2016, TFDA held a press conference to announce test results. A press release entitled “Heavy metal from BBQ net? TFDA says: It’s just a rumor.” was also issued to inform the public that the concerns about heavy metal transferred from BBQ utensils shall be relieved based on the scientific evidence. However, scorched meat indeed increased the level of hazardous materials. Therefore, TFDA demonstrated safe BBQ approaches to protect public health.

(3) Develop new testing technology to detect illegal products

A. TFDA has developed a testing method to analyze lutein levels in capsules/tablets and subsequently tests 13 products on the market. The results showed that 6 products contain 80% lutein levels of the labeling, 3 of them even only contain 20% of the labeling, which have violated the regulations of *Food Safety Act*. TFDA thereby issued a press release in June 2016 to ask food businesses involving dietary supplement (in capsules/tablets) honestly publishing nutrition facts on the product labeling to protection company reputations and ensure the rights and interests of the consumers. Additionally, after the press release issued by TFDA, the prosecutor's office, Yunlin court actively tested related products and uncovered unscrupulous businesses changing product expiration dates and selling expired lutein products. The violator was prosecuted on July 12, 2016, and the unlawful benefits were all confiscated . The test results are helpful to investigation conducted by the prosecutor's office and enhance the awareness of food quality of the fellow citizens.

B. To respond to the requirements of management for adding illegal colorants, TFDA establishes a new generation of food colorant detection method using HPLC-MS, which enhances the testing accuracy and precision of current testing methods from 8 food colorants to 46 colorants in Taiwan and thus greatly improve the capacities as well as management efficiency of food testing in Taiwan. Such testing approach has been applied to boarder inspections since 2016. Among 84 suspicious or hard-to-test import candies and cookies specimens, 9 samples were found containing illegal colorants (e.g. Azorubine, Amaranth and Sulforhodamine B) in Taiwan, thus successfully prohibited the import of violation products.

(4) TFDA developed species identification methods by molecular biotechnology for the sake of effectively protecting public health and food safety

A. In December 2016, three people had symptoms of nausea, vomiting and abdominal pain after eating wild mushrooms. TFDA received the rest of wild mushrooms and conducted species identification developed by molecular biotechnology. The data indicated that these wild mushrooms were *Chlorophyllum molybdites* (Figure 5-6), which caused poisoning symptoms. TFDA then issued a press release to educate the public not to consume unknown mushrooms from the field.

B. Changhwa local health bureau reported a case of flyblown-like objects found in chicken legs in lunch boxes in an elementary school. By DNA identification

and CO I genetic sequencing, TFDA confirmed that these flyblown-like objects were flyblown of *Lucilia cuprina* (Figure 5-7). TFDA assisted Changhwa health bureaus to clarify the source of contamination and protect food safety by developing identification approaches for unknown samples.

C. Kaohsiung health bureau and Tainan prosecutor's office conducted joint inspection of the manufacturing factories of pork blood cake and found some suspicious products. TFDA received a total of 6 samples of raw materials and products for pork DNA identification because the products and samples appeared to be black and were suspected containing no porcine materials. After analysis using high resolution GC-MS and tandem UV detector, a suspicious peak was found in the non-target sample, which had been confirmed as Heme B. Heme B is a blood matrix, so the samples were sent for HPLC protein identification. The results showed that all 6 samples contained porcine hemoglobin, proteins and heme, which indicated that the products are made of porcine materials. Such testing technology can be used to determine the authenticity of raw materials to assure the consumers' right.

Figure 5-6 *Chlorophyllum molybdites*

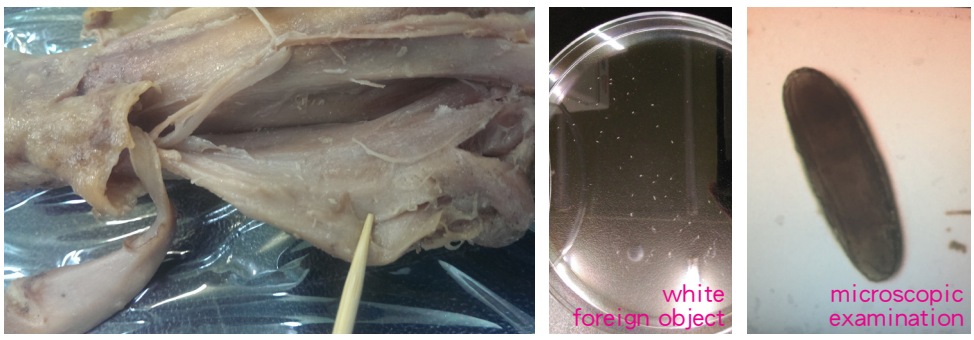


Figure 5-7 Chicken legs containing flyblowns

(5) 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 5-1).

Table 5-1 A list of international proficiency testing schemes that TFDA has participated in 2016

Organizer	Name of the proficiency test	Results
Central Science Laboratory (CSL, England)	Food Analysis Performance Assessment Scheme (FAPAS) proficiency tesitng program (15 items)	Satisfactory
US Department of Agriculture (USDA)	Testing for the presence of biotechnology events in corn and soybean	Satisfactory
ENERSOL Laboratory	Inter-laboratory Proficiency Trial of Male Condom Testing Laboratories	Satisfactory
National Institute for Biological Standards and Control (NIBSC)	Joint collaborative study of the 4th WHO International Standard for HBV Joint collaborative study o the 3rd WHO International Standard for HAV	Satisfactory
Collaborative Testing Services, Inc. (CTS)	Forensics testing proficiency tests	Satisfactory

(6) Publications

TFDA employed emerging technologies to establish new testing methods, and published 8 papers in international journals and published 77 reports or poster presentations in domestic and international conferences.

4. Important outcomes of food and medicinal product test technology during 2016

In recent years, with the rapid development of food and medicinal products-related manufacturing process and technology, the significant increment of samples pending for testing, and to protect the safety of food and medication of the public, TFDA actively develops and establishes testing methods to effectively control food chemistry and biological areas, biologics and merging biotechnology products, medicinal products, medical devices as well as cosmetics. Refer to Table 12 in Annex II for detailed program outcomes.

Section 2. Enhancing Local Testing Proficiency and Quality

Current Status

To enhance testing capacities of local government and health bureaus, all local health bureaus in Taiwan had joined the "nation-wide Regional Joint Testing Specialization System of Health Bureaus and Departments" since 2010. TFDA also continues purchasing precision instruments and equipment to enhance test technology and capacity of local government and health bureaus.

Policies and Outcomes

Enhance local testing capacities and quality

Integrate testing resources, provide reimbursement, supervise inspections to effectively enhance local testing efficiency and quality and construct a food safety laboratory network.

(1) Subsidizing instruments and equipment, and enhancing capacity of the Lab testing Network

TFDA provided support for acquiring precision instruments and standard samples for local health bureaus. 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 85% after the subsidies. When compared with 2015, additional "Independent Tests" introduced in 2016 included tests for "food adulteration", "Bormate in packed drinking water" and "Food poisoning-related bacteria".

(3) Laboratory accreditation

To ensure laboratory testing quality of local health bureaus, TFDA accredited 755 laboratory test items in 22 health bureaus and departments throughout Taiwan by 2016.

Section 3. Private Laboratory Accreditation and Management System

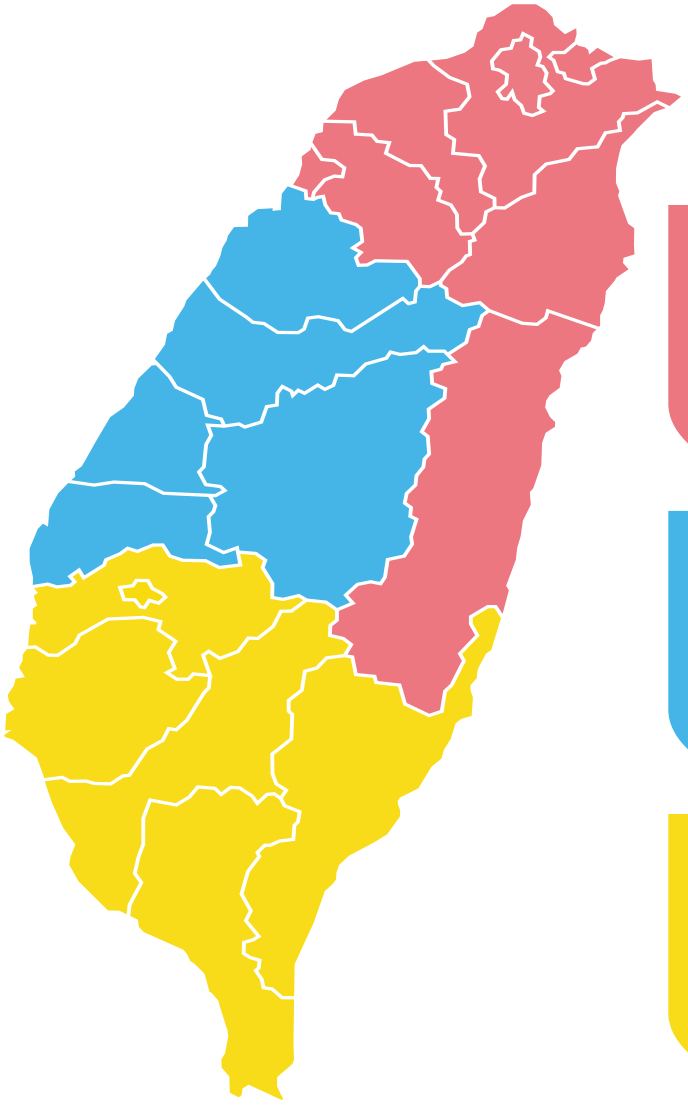
Current Status

TFDA continues strengthening private laboratory accreditations and publishes a list of accredited laboratories that may be referred 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. Additionally, to protect public health, TFDA strengthens the management over food factories from the source and establishes food safety and sanitation management certifications for food businesses.

Policies and Outcomes

1. Accreditation of food, medicinal products and cosmetics laboratories

To effectively leverage testing resources of private laboratories, ensure the quality and credibility of commissioned testing activities, and expand testing capacities, TFDA implemented a proactive and free accreditation program for private laboratories. The scope of TFDA laboratory accreditation include tests for food, medicinal products, cosmetics, urine tests for identifying drug abuse, and Good Laboratory Practice (GLP) for non-clinical studies. As of the end of 2016, 175 laboratories throughout Taiwan were accredited (144 private laboratories and 31 government laboratories), including 81 food testing laboratories, 34 medicinal product and cosmetic testing laboratories, 14 urine testing laboratories for identifying drug abuse, and 15 GLP laboratories (Figures 5-8 and 5-9). As for regional distribution, there were 89, 34, and 52 accredited laboratories in northern, central, and southern Taiwan respectively. 1,478 tests items were accredited, of which 1,046 were related to food, 379 related to medicinal products and cosmetics, 9 related to urine tests for identifying drug abuse, and 44 GLP-related tests items (Figure 5-10). The accreditation program helped to establish laboratories with adequate testing capacity and credibility able to meet testing requirements for emergencies and sudden events.



North District 89

TFDA : Div. of Research & Analysis, North Management Center (a total of 7 factories)

Local health bureaus : North District Joint Testing System (a total of 10 counties/cities)

Accredited laboratories : 35 food businesses, 18 medicinal products/cosmetics, 6 drug abuse urine, 13 GLP(a total of 72 factories)

Central District 34

TFDA : Central Management Center (a total of 1 factory)

Local health bureaus : Central District Joint Testing System (a total of 5 counties/cities)

Accredited laboratories : 18 food businesses, 5 medicinal products/cosmetics, 3 drug abuse urine, 2 GLP (a total of 28 factories)

South District 52

TFDA : South Management Center (a total of 1 factory)

Local health bureaus : South District Joint Testing System (a total of 7 counties/cities)

Accredited laboratories : 28 food businesses, 11 medicinal products/cosmetics, 5 drug abuse urine (a total of 44 factories)

Figure 5-8 Distribution of TFDA-accredited laboratories

(1) Expanding testing capacities of laboratories

A. Accreditation programs for food laboratories as well as medicinal products 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 2016, the numbers of accredited laboratories and tests increased to 115 laboratories and 1,425 tests items respectively, with 53, 23, and 39 laboratories in northern, central, and southern Taiwan respectively. 81 of those were food testing laboratories while 34 were medicinal product and cosmetic testing laboratories (Figure 5-9 and 5-10).

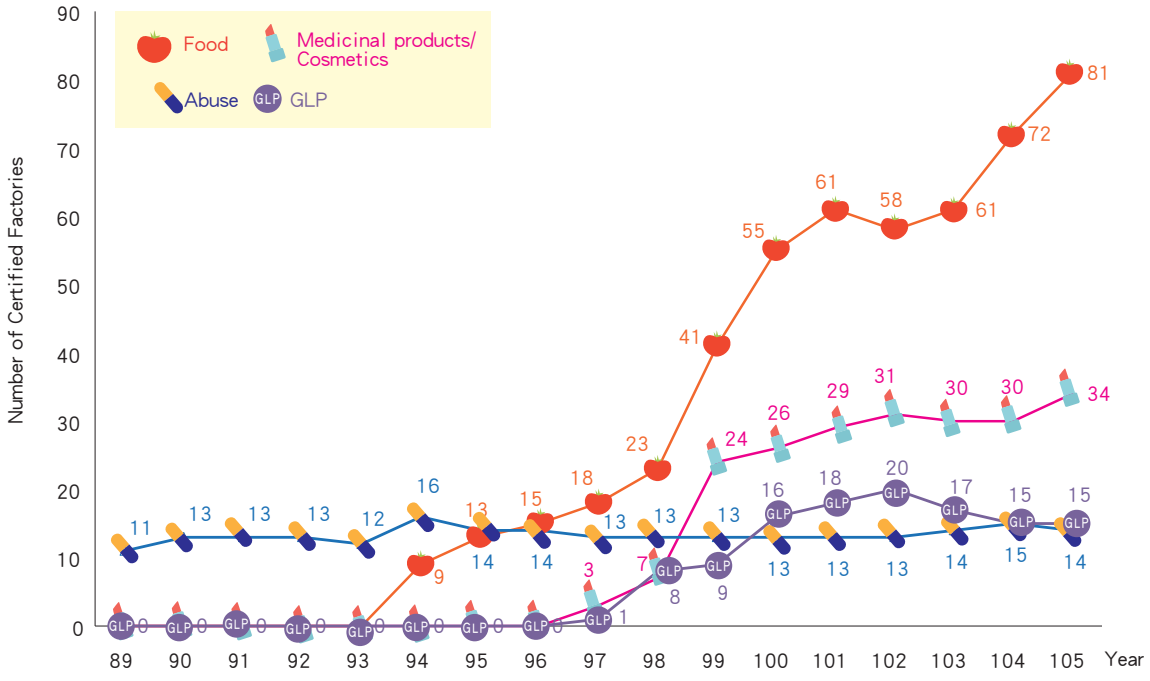


Figure 5-9 Number of TFDA-accredited laboratories of all years

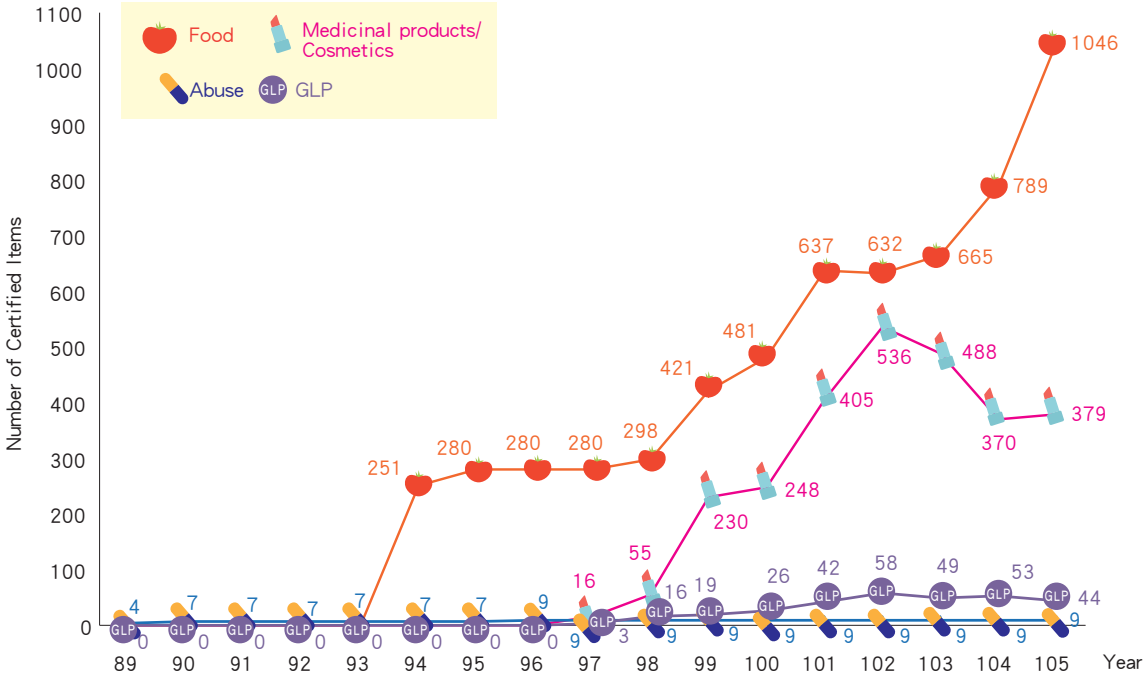


Figure 5-10 Number of TFDA- accredited tests of all years

(2) Enhancing monitoring and supervision systems

A. Regular and unannounced audits

To effectively monitor and manage accredited test laboratories and establish a system for assessing the truthfulness of test data, in 2016, TFDA audited 147 accredited test laboratories, of which 112 of the audits were first-time audits, expansion of test items, change of test items, permit extension, and surveillance audits, while 26 of the audits were unannounced.

B. Implementing proficiency testing

TFDA regularly publishes the results of proficiency testing of accredited laboratories. In 2016, 25 proficiency tests were carried out, including 17 food tests and 8 medicinal product and cosmetic tests. TFDA also organized 8 “Laboratory Accreditation Tests Using Double-Blind Samples” in order to verify the truthfulness of testing data. As the results of proficiency tests of accredited laboratories, the satisfaction rate of food is 80% when medicinal products and cosmetics is up to 90%. Additionally, testing laboratories that were accredited for “food aflatoxin” by TFDA in 2016 must participate in the international proficiency test which are announced and assigned by TFDA in 2017.

(3) Exemption from repeated testing

A. Japan

In September 2016, the 5 testing laboratories for the list of Class B public testing agencies of exporting countries of the Ministry of Health, Labor and Welfare in Japan, TFDA asked for quantitative LOD data for pesticide tests to confirm their conformity of Japanese Government Standards, 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.

B. Indonesia

According to Indonesia "Department of Agriculture Regulation No. 4", 103 products with Fresh Food of Plant Origin are required to present test reports issued by Department of Agriculture, Indonesia before product import. Testing items include pesticide residues, heavy metals, aflatoxin, Ochratoxin, *Salmonella enteric*, *Escherichia coli*, etc. The scope of products includes fruits, vegetables, corn products, nuts, beans and tea leaves. The regulation is effective starting from February 17, 2016. Three certified testing laboratories recommended by TFDA received the certification of Department of Agriculture, Indonesia on November 18, 2016 and successfully achieved exemption from border inspection to accelerate customs clearance and reduce commercial costs for food companies.

(4) Introducing accelerated accreditation tests

On February 1, 2016, 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 laboratories to apply for accreditation. In 2016, two laboratories and two test items successfully completed accelerated accreditation, providing an additional option and reference for border inspection tests and commissioned testing for business requirements.

(5) Expanded tests

To collaborate with administrative highlights, new tests added in 2016 include: material test, tests for heavy metals in canned food, sweeteners, pesticide residue (Apo-Haloperidol Tablet), corn and corn products-derived fumonisins B1 and B2, qualitative test for GM soy beans and nicotine in electronic cigarette, all of which have been accredited.

2. Accreditation of urine testing laboratories for identifying drug abuse

(1) As of the end of 2016, TFDA accredited 14 urine testing laboratories for identifying drug abuse, of which 5, 3, 5, and 1 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 in 2016. Four round of routine proficiency tests of 56 accredited institutions were carried out as well. As of the NCRs of on-site inspections and proficiency tests, the accredited testing institutes must complete the improvement.

(3) In 2016, 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: When the requirements of urine tests for emerging drug abuse proposed by Ministry of Justice, TFDA may investigate the willingness of accredited testing institutes and conduct on-site inspection based on the regulations of Article 24 in the "*Act governing certifications of testing and medical institutes for drug abuse urine tests.*" After confirmation TFDA will list the institutes as one of the recommended (not accredited) laboratories and the list is available on the official website of TFDA.

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 2016, TFDA completed GLP audits and consultations for 12 laboratories and accredited 15 GLP laboratories and 44 tests items, of which 13 and 2 laboratories were in northern and central Taiwan respectively.

(3) Considering animal welfare and 3R principles (replacement, reduction and refinement), TFDA added new accredited replacement items and met the future international trends.

(4) In 2016, TFDA implemented auditor training and business management seminars, and introduced the latest information from other countries to establish consistent auditing standards as well as trends in the industry.

4. The second tier (Third party certification systems)

(1) According to the *Act Governing Food Safety and Sanitation* Article 5, paragraph 5 and 6, 3rd party certification system (2nd tier quality control) refers to food businesses of a certain scale and category must have their sanitation and safety management systems certified by a certification body (CB) accredited by the central competent authority; Health and Safety Management System means that the food business needs to comply with Good Hygiene Practice for Food (GHP) and Food Safety Control System(HACCP).

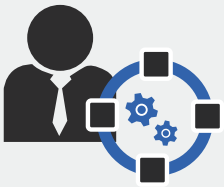
(2) TFDA promulgated "*Act governing food businesses safety and sanitation management as well as the management of commissioned validations*" on November 7, 2014 that food businesses categories and scales within the scope of central competent authorities announcement must receive mandatory on-site inspections conducted by 3rd party certification body. TFDA promulgated "*Accreditation of Certification Body and Sanitation and Safety Control of Food Businesses of Certification Regulations*", "SOPs of food safety and sanitation management accreditation system" and "SOPs of food safety and sanitation management certification body system" on May 13, 2016 to complete 2nd tier quality control system.

(3) Starting from 2014, TFDA required food businesses with announced capital over NT$ 30,000,000 dollars, including edible oil manufacturers, canned food, special nutrients, dairy, food additives businesses and 10 food categories (including sugar, salt, flour, starch, soy sauce) with capital more than NT$ 30,000,000 dollars for certifications. A total of 519 businesses completed certifications by the end of 2016.

06

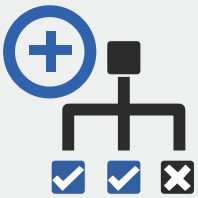
Early Warning, Monitoring and Risk Management

Early Warning Monitoring and Risk Management



Plans

Collect information and make risk-management plans



Strategies

Passive Surveillance
Active Surveillance

Methods

Monitoring:

Passive

- Reporting system
- Safety report during new drug surveillance period

Active

- Domestic/International product alerts monitoring
- Regular/Periodic factory inspection
- Data application of interdepartmental food IT system

RISK

Re-Review

Analysis
Re-evaluation

- Drug safety re-evaluation
- Drug active surveillance
- Oil traceability analysis
- Import food risk analysis

Control Outcomes

Risk control:

- 20 medicinal products have adopted risk control measures, e.g. NSAID anti-inflammatory drugs to control cardiovascular risks, the 3rd-4th generation of contraceptives to control thrombotic risks, bisphosphonates to control osteonecrosis of jaw and atypical fracture risks
- 35 medical devices have taken risk control measures, e.g. becoming prioritized factory inspection or GMP/QSD review documents, prolong monitoring, supply data, becoming safety surveillance target
- Use data exploration and statistical analysis to screen high-risk food

Risk communication:

- Issue 12 drug risk communication letters
- 4 newsletters of medicinal product safety

Control Measures

- Amend package insert
- Restrict the use
- Implement risk management plan
- Recall
- Withdraw from the market
- Strengthen audition and monitoring

06 Early Warning, Monitoring and Risk Management

With the development of big data technology, active monitoring mechanisms on food and medicinal products, and crisis management mechanism, the concept of risk management and emergency response are applied into TFDA's operation to prevent from occurrence of emergencies and reduce the possible impact of hazards.

Section 1. Big Data Analysis and Early Warning Mechanism for Food Safety

Current Status

Food and Drug Decision Support Center (refer to as "DSC" below) under TFDA was established on September 2, 2015. Its establishment is aimed at collecting public opinions both nationally and internationally, to identify risks by using big data analysis, and to help decision making for other departments concerned. The DSC consists of three dedicated groups. They are (a) a public opinion monitoring group to monitor media and social networking news in Taiwan and overseas; (b) a system integration group to integrate data from multiple source systems and monitor data safety from internal and external agencies; and (c) a data analysis group to predict potential risks and trends based on data mining technology and statistical methods.

Policies and Outcomes

1. Integrate data from multiagency Make plans before actions

(1) TFDA system integration

The "Core-Foodcloud" of DSC integrates the Five-Must information systems of TFDA, namely the Automated Management System for Border Inspections (Must-Declare), the Product Distribution Management System (Must-Test), the Food Business

Registration System (Must-Register; also refer to "Fadenbook"), the Inspection System (Must-Inspect), and the Traceability System (Must-Trace; also refer to "Ftracebook"). And the analytical results are graphically visualized with several monitoring dashboards, see Figure 6-1.

Figure 6-1 Real-time monitoring dashboards displayed at Food and Drug Decision Support Center

(2) Multiagency system integration

DSC also integrates food-related data with other government agencies, such as Environmental Protection Administration (EPA), Council of Agriculture (COA),Ministry of Economic Affairs (MOEA), Ministry of Finance (MOF), and Ministry of Education (MOE); and forms a network of "Pan-Foodcloud", see Figure 6-2. As at March 31, 2017, DSC has already established 26 major categories, with a total of 102 dashboards and statistical indicators, and connected 16 systems within 6 relevant agencies. The total amount of connecting data is approximately 34.76 million, while the connecting firms/ industries are approximately 1.8 million.

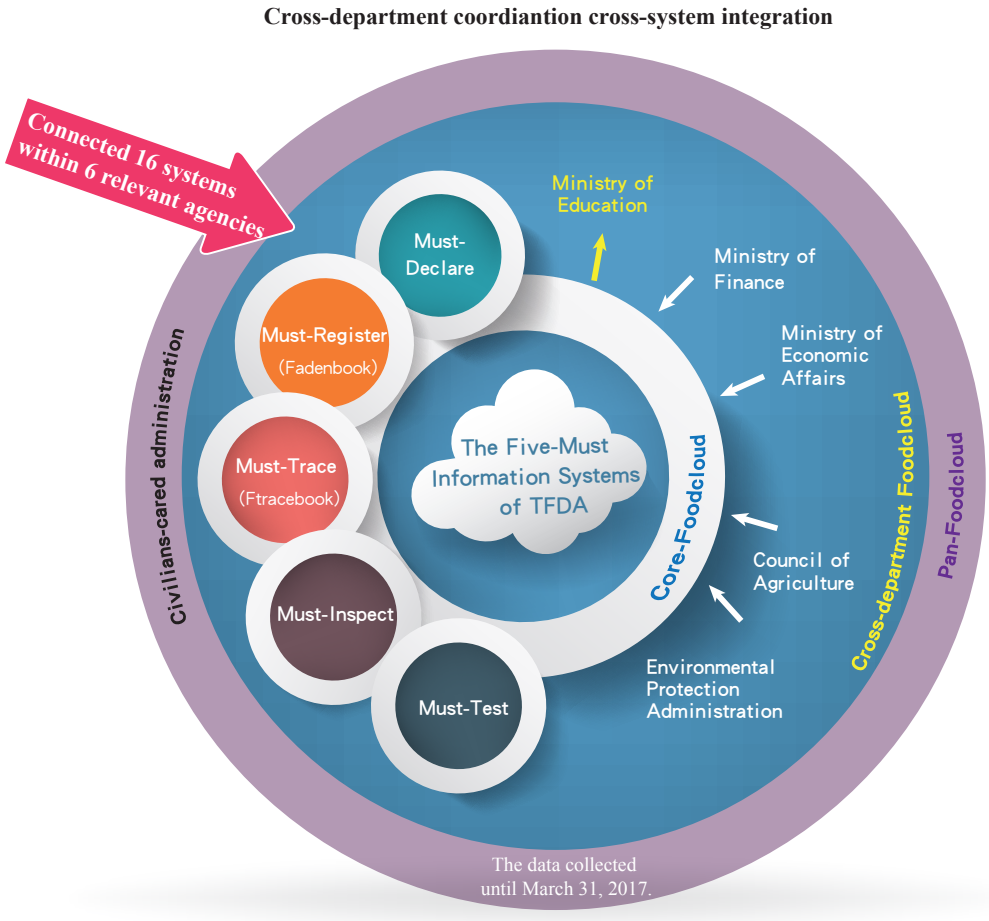


Figure 6-2 Foodcloud framework

2. Establish risk prediction models Monitor real-time operating system

(1) Analyzing the use or destination of oil products

By means of the system integration process, DSC can easily trace the source and suppliers of food (current targets are industrial oil, feed oil and waste cooking oil) through the transaction records, and conduct automatic risk surveillance through different modules. Meanwhile, it proposes lists of the high-risk industries, and reports them to other enforcement agencies as a reference of prioritized inspection.

(2) Analyzing the risks of imported food

As for border control on food items, DSC conducts a long-term data analysis on 6 high-risk categories, i.e. tea, fresh and frozen fruits, frozen vegetables, frozen aquatic products, spices and sauces, and establish 5 risk indicators, including declared import quantities, declared net weight, sampling rate, non-conformity rate and annual growth rate of non-conformity rate, and effectively achieve the purpose of real-time monitoring.

(3) Analyzing Japanese radiation monitoring data of food of Ministry of Health, Labour and Welfare

Given the concern about radiation contamination of Japanese food, DSC analyzed nearly 1.52 million radiation monitoring data from April, 2012 to December, 2016, released by Ministry of Health, Labour and Welfare, Japan, in order to figure out the radiation testing results on distribution and non-distribution products.

3. Grasp the trends and respond actively

As the food-related emergency happens, DSC will usually be necessary to initiate “war” mode to protect public health by containing and controlling the distribution of affected food products. For example, some companies in Taiwan have been accused of passing off catfish as cod in 2015, and the issue has been reported to DSC who have since found out that the 2nd quarter is the peak season of imports of Vietnamese catfish, and alerted other enforcement agencies to conduct field examination of the top 5 importers until this incident has been effectively curbed. Another example is the imported fish sauce could not be brought into compliance with TFDA Import Alert in 2016, as a result of that, DSC used “declared net weight”, “sampling rate” and “non-conformity rate” as risk factors to screen several high-risk importers and reported them to the enforcement agencies. Moreover, another incident regarding the adulteration of expiration date of

seasonings has occurred in 2016. Since then, DSC analyzed 6 types of seasonings, and established analytical modules to find out the abnormal products with too-long or too-short validity period, and alerted other enforcement agencies.

4. Enhance cross-disciplinary cooperation and provide backup support

DSC recruits talents in various professional fields, such as information technology, food science, medical laboratory science, public health, pharmaceutical sciences, biomedical sciences, etc. Besides, to enhance everyone's knowledge and skills in data analysis, DSC also provides regular training courses open to all staff in TFDA, and invites experts or scholars in related fields to share their experiences.

Section 2. Active Monitoring System for Medicinal Product Safety

Current Status

To eliminate potential risks and achieve effective early warning, the feedback of an alert system (e.g. medicinal products, medical devices and cosmetics ADR system, controlled drugs abuse reporting system), control international alerts, collect data and uses scientific evidence to prevent in advance and construct safety monitoring system for medicinal products.

Policies and Outcomes

1. Active monitoring system for medicinal product safety

Although the efficacy, safety and quality of medicinal products have been confirmed preliminarily before marketing, unexpected risks still may occur after marketing. Therefore, the establishment of a complete post-marketing surveillance system and laws for medicinal products (Figure 6-3) is required.

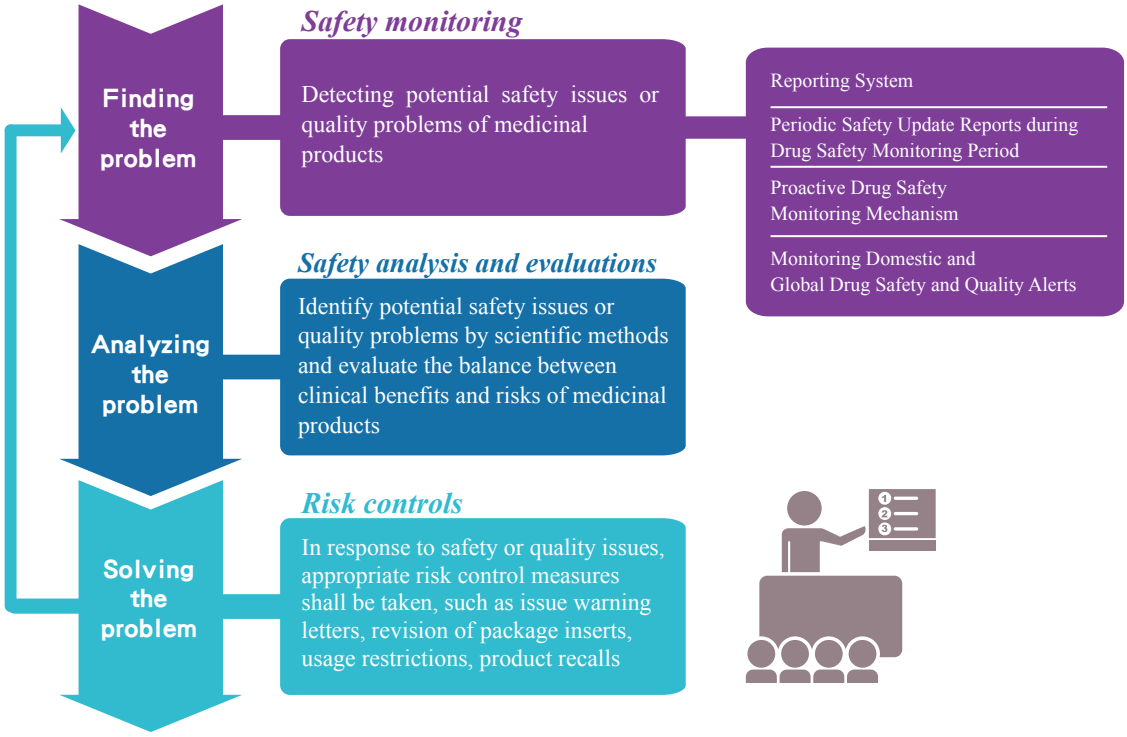


Figure 6-3 Post-market control process of medicinal products

(1) Risk recognition and information collection

A. Reporting system

A number of reporting systems for advers drug (ADR), medicinal product defects and therapeutic inequivalence have been established in Taiwan. A total of 14,102ADR cases,869 defective drug products and 52 therapeutic inequivalence cases were reported in 2016. Additionally, the reporting system also established mobile device reporting for medicinal product defects and therapeutic inequivalence in August 2016 to make it more user-friendly.

B. Monitoring of global alerts

Medicinal product safety or quality alerts around the world are monitored on a daily basis. A total of 131 medicinal products safety alerts and 646 quality alerts were monitored in 2016.

C. New drug safety surveillance

The drug license holder of new drugs must submit periodic safety update reports during the preliminary period after approval. A total of 474 medicinal products are under new drug monitoring at the end of 2016.Additionally, the format of the

report has been revised on Jan 13, 2016 to comply with the international standard.

D. Routine and for-cause inspections

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 evaluation mechanisms and controls

A. Re-evaluation of medicinal product safety

New drugs pass monitoring period, death reports 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 and suggest risk management measures such as issue a warning letter, revision of package inserts, usage restrictions if necessary. In 2016, a total of 54 medicinal products were re-evaluated, of which risk management measures were initiated for 20 medicinal products.

B. Medicinal product quality survey

(A) In response to quality defects reports of medicinal products, the companies will be requested to submit investigation report and corrective and preventive actions (CAPA) plans to TFDA according to GMP regulations and initiate drug recall where necessary. In 2016, a total of 110 serious quality defects were monitored, of which 8 medicinal products were recalled.

(B) For the medicinal product recall mechanism, 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-market sampling results failed to meet the specifications, where factory inspection identified quality issues, or where companies have initiated product recalls voluntarily. In 2016, a total of 301 medicinal products were recalled due to quality problem.

C. 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 11

medicinal products in 2016.

D. 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 bisphosphonates medications, third-and fourth-generation combined oral contraceptives, anti-epileptic drugs that contain carbamazepine, TNF-alpha blockers and acne medication with cyproterone acetate and ethinyloestradiol.

E. Risk communication

In 2016, a total of 301 domestic medicinal products recalls, 26 global drug quality alerts, 12 risk communication letters and 4 newsletters of medicinal product safety were announced to remind the public and medical staffs of the safety or quality alerts of medicinal products.

(3) Training of risk assessment professionals

In 2016, TFDA held a total of 15 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 in order to promote reporting of ADRs. Moreover, 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.

2. Controlled drug alert monitoring and abuse prevention

Drug abuse is becoming an increasingly global and complex challenge. TFDA summarizes and analyzes national drug abuse trends, provides cross-departmental database integration of drugs and drug abuse reporting system and big data of drug abuse analysis as references for drug abuse control strategies.

(1) Collecting and compiling national drug abuse information

A. Statistics

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

B. Report data

TFDA established the "Controlled Drug Abuse Reporting System" that compiles epidemiological analyses and report data every month:

(A) In 2016, a total of 22,412 drug abuse cases were reported by medical institutions. The top 3 drug abuse categories were heroin with 14,036 individuals (62.6%), (meth) amphetamine with 6,587 individuals (29.4%), and ketamine with 2,904 individuals (13.0%).

(B) Demographics of the reported cases were analyzed, the drug abuse cases by gender consists of male and is mostly distributed in between 40~49 years of age (32.9%) and between 30~39 years of age (31.6%). Among the drug categories used by all age groups, ketamine was the most common drug abused by those below 29 years of age, heroin was the most common drug abused by those between 30~69 years of age . Individuals aged over 70 years (inclusive) primarily abused zolpidem.

(C) Analyses for the most common sites of 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 main reasons of drug abuse were "dependence (37.5%)", followed by "stress relief (16.3%)".

(2) Integrating the Cross-departmental narcotics and drug abuse reporting system database

A. 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 is to use big data analytics to clarify the three major aspects of drug abuse, namely "Narcotics User Profile", "Effective Treatment Model" and "Narcotics Production and Marketing Course", an accurate understanding of drug related data and analysis. The information be used as a reference to propose various preventive strategies.

B. As of December 2016, a total of 20 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 6-4) to provide government to implement in the statutory tasks.

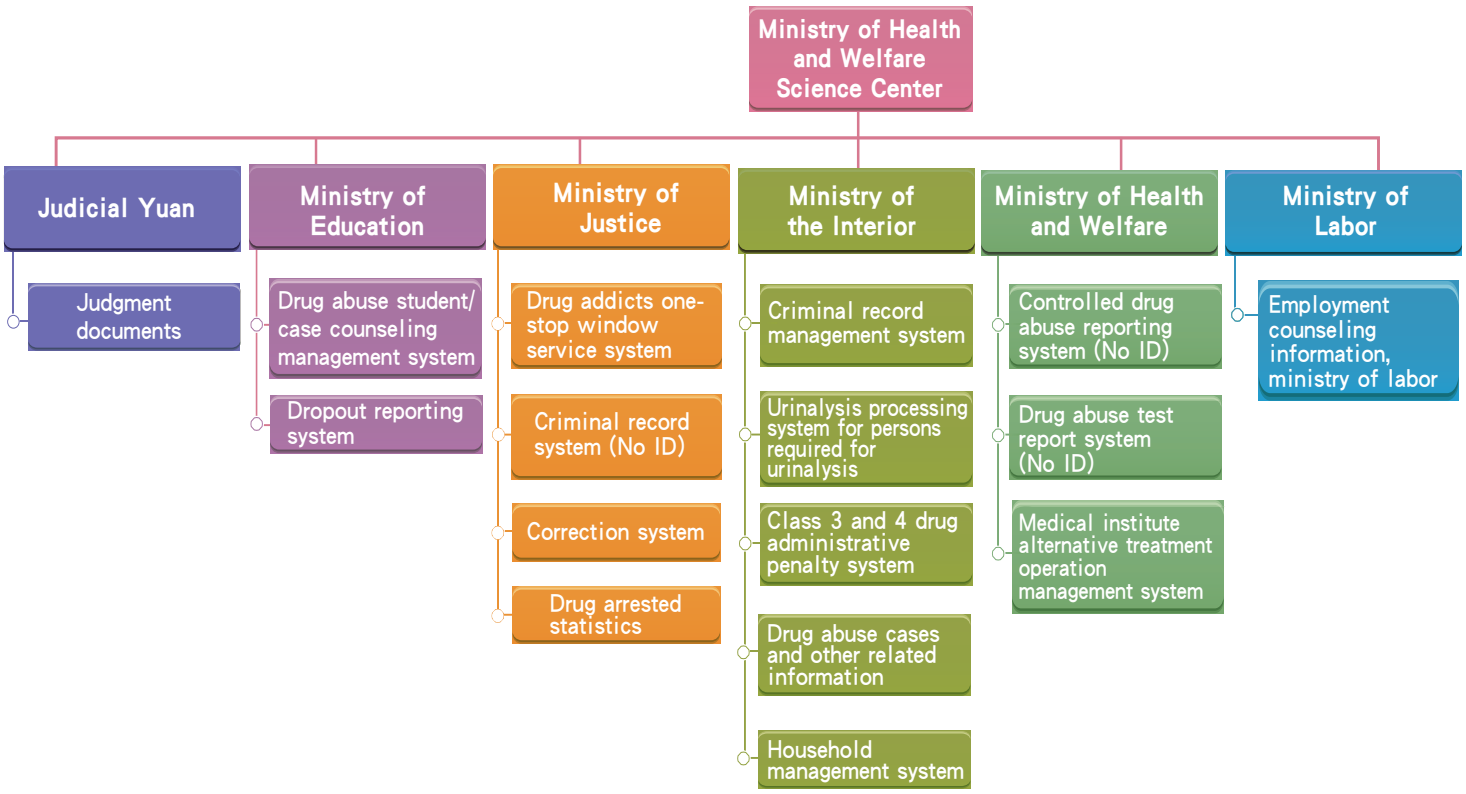


Figure 6-4 Integration of narcotics and drug abuse reporting system database from multiple departments

3. Medical devices and cosmetics post-market safety surveillance mechanisms

To establish a comprehensive post-market safety and quality surveillance of medical devices and cosmetics, TFDA use these measures, like receiving customer's feedback, actively collecting national and international alert information and so on to achieve goals of real-time handling, CAPA, risk control and risk communication (as Figure 6-5 Post-marketing risk control mechanisms of medical devices).

Figure 6-5 Post-market risk control mechanisms of medical devices

(1) Medical devices and cosmetics risk recognition and data collection

A. Actively monitor alerts

(A) In 2016, TFDA actively collect 2,044 national and international medical device safety alerts and selected 80 alerts which closely relevant to fellow citizen's health for further translate and promulgate.

(B) In 2016, TFDA monitored 192 updated national and international cosmetics recall and safety alerts, passed them to health bureaus and cosmetics associations through e-mails, and issued 165 food must-know alerts to the consumers.

B. ADR

(A) Through "Post-market Quality Management System for Food, Medicinal products, and Cosmetics", in 2016, TFDA received 427 medical devices ADR and 3,429 defective medical devices, which had been standardized and evaluated subsequently.

(B) A total of 58 cosmetics adverse events, of which 15 cases of adverse reactions and 43 cases of defective produsts were received in 2016, all have been informed to local health bureaus for related matters or companies to submit investigation reports. TFDA also continues follow-ups.

C. Risk evaluation mechanisms and control of medical devices and cosmetics

(A) Convene 3 medical devices safety advisory board meetings in 2016 to evaluate and review 17 applications and promulgate dermal implants within the identification scope of "I.0007 Hyaluronic acid implants" on December 2, 2016 for overall safety surveillance. By the end of December 31, 2016, 2 major categories of medical devices that are within the identification scope, including "drug eluting cardiac stents", shall be completely enrolled for safety surveillance.

(B) For defective medical devices reports, TFDA classifies based on risk and hazardous levels and informs companies with permits to investigate the causes of quality abnormalities of medical devices in accordance with GMP regulations. In 2016, among 35 medical devices required for prioritized factory inspections or GMP/QSD document reviews, 3 of them were asked to amend package inserts, 5 of them were asked to prolong surveillance

period, 3 of them were asked to supply related documents and 2 of them were asked to be enrolled for safety surveillance.

(C) In 2016, TFDA convened 3 cosmetics hygiene management advisory board meetings to discuss 9 themes and assist TFDA revise "Table of cosmetics types and scopes", establish "Safety guidelines of cosmetics for children use", "Technical Guidelines for Cosmetics UVA Sunscreen Performance Tests (Human Subject Test)" and "Technical Guidelines for Cosmetics Sunscreen Performance Tests (Human Subject Test)"

D. Cultivate talents for risk assessments

(A) To help medical institution staffs effectively control the causes of medical device defects and their application experience and understand correct handling approaches, processes and provisions, TFDA hosts 8 educational training course and 2 safety seminars in 2016. TFDA also hosts "Competitions simulating the handling of medical device defects" and implements trial "Accreditation reward systems of ADRs in medical institutes".

(B) Through project counseling seed hospitals to establish nosocomial medical device ADR system, the number of participating seed hospitals has increased to 32 by the end of 2016.

(C) To enhance the professional knowledge and capacities of cosmetics management in staffs of health competent authorities, TFDA held 2 seminars in 2016. Additionally, to strengthen the awareness of Cosmetics ADR (PAE) reporting system in general consumers and thus increase reporting rates, TFDA organized 4 cosmetics ADR (PAE) seminars and practices in northern, central and southern Taiwan in 2016. At the same time, through biotechnological beauty and cosmetics exhibitions, country-tour of minibus and the distribution of small gifts by local health bureaus, TFDA promotes "Post-market Quality Management System for Food, Medicinal products and Cosmetics" to enhance the reporting rate of cosmetic ADR(PAE).

Section 3. Crisis Management Mechanism

Current Status

Courses were held in 2016 to help TFDA staff members improve their familiarity with risk management and crisis management concepts to respond to and handle emergencies. Public opinions and information were reviewed on a daily basis. Regular post-marketing surveillance was also conducted to maintain the safety of goods sold on the market for the general public. Corresponding response mechanisms 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. Risk management

(1) Education and training

In 2016, a total of two training sessions of risk management and crisis management training for 201 attendants were held (Figure 6-6). The risk management and crisis handling taskforce group is responsible for major risk in individual units in 2016 and follow-up their implementation of “new response policies” on quarterly basis.

Figure 6-6 Risk management and crisis management training

(2) Review meeting

The 2016 review meetings of risk management and crisis management taskforce group were held on January 10, 2017 to review risk items listed by various departments and agencies. And major public incidents, legislator inquiries, and past items mentioned in the given year are referenced to determine the major risk items for 2017.

2. The development of emergency responsiveness

(1) Response to emergency incidents

To respond to "Public Hearing of Importing Japanese Food", TFDA initiates three levels of emergency responses on November 11, 2016, and establishes an emergency response center composed of the following taskforces: "Information Communication Group", "Business Handling Group", "Administration Support Group", "Laboratory Technology Group", "Caring and Assistance Group", "Staff Operation Group" as well as "IT Support Group" for discussion. And the completion of After Action Report(AAR) is released for staffs to learn about the handling of similar incidents.

(2) Practices of responsiveness

On August 19, 2016, TFDA invited other departments concerned of TFDA to participate in exercise of pesticide residues in tea leaf-based beverages. The background was set as an incident of a popular top-seller handmade tea-leaf-based beverage. Through validating all SOPs and strengthening the roles and responsibilities of all units corresponding to such incident, the emergency handling and responsiveness of all TFDA units will be improved. In the meantime, seed staffs are also trained to respond to all emergencies to avoid the recurrence of similar incidents.

(3) Revising documents related to crisis management

TFDA completed the revision of "Management Manual for the Handling of Food-related Incidents by Central Government Agencies" in the first half of 2016 as the reference for Food Emergency Response Center; in the second half of 2016, TFDA implemented document verification and rolling revisions on 8 "Emergency Response Manuals" and relevant documents to correspond to the exercise for "Emergency Response to Food Incidents" and taskforce meeting resolutions.

07

International Cooperation and Cross-strait Exchanges

International Collaboration

Involvement of international organizations

Official Member

APEC

The "Good Registration Management" roadmap and "Good Submission Practice Guideline" jointly submitted by Taiwan and Japan have been endorsed by RHSC.

AHWP

As one of the founding members, Taiwan has been the Chair of AHWP WG2-Pre-market: IVDD Work Group for a long while, and developed four IVD-related international guidance documents endorsed by AHWP 2016.

Observer

ICCR

For the first time attended ICCR as an observer and obtained first-hand information on the current status and trends of international cosmetics regulations.

EDQM

Attended 2016, The 1st European Pharmacopoeia Advisory Committee as an observer of EDQM, observed the process, focuses and operation of establishing European Pharmacopoeia.

ICH

TFDA attend ICH as observer to discuss and develop the international guidelines for pharmaceuticals review, which could promote regulatory harmonization

Bilateral consultation

Poland

Signed "Memorandum of Understanding on Cooperation Concerning Pharmaceutical Products and Medical Devices between Taiwan and Poland" to facilitate medical and pharmaceutical industry development.

Japan

Completed joint reviews of dental implant cases, established the foundation of mutual trust on pre-market review through the 4th Joint Conference of Taiwan and Japan on Medical Products Regulation.

European Union

For the first time attended "The 1st Europe cosmetics testing technology symposium" and "The 13th meeting of the Laboratory Network of Official Cosmetics Control Laboratories", to establish communication channels for exchanging international cosmetics management regulations, standards and testing methods.

Indonesia

Recommended 3 national food certification laboratories to Indonesia Government, where had also been recognized by Indonesia Government. Assist domestic food businesses in exporting products to Indonesia.

Participation and hosting of large-scale international symposiums

AOAC

TFDA gave a lecture in "Taiwan Section Business Meeting" at 130th AOAC Annual Meeting to present the competence of Taiwan on analyses.

APMP

TFDA was invited to present articles at "Grain Products Safety Measurement and Standards Symposium" hosted by APMP to present TFDA previous research outcomes in fungi toxin area

Food Conference

Hosted the 8th AOAC Internal, Taiwan Section Annual Meeting, expressing the capability of testing in analytical area and establishing communication channels with international experts.

Medicinal Product Conference

Hosted "2016 Asia-Pacific Good Registration Management Practice Scientific Excellence Center Preliminary Symposium" and trained seed trainers of Good Registration Management Practices from 15 APEC economic members.

Medical Device Conference

Hosted "2016 International Medical Devices PIC/S and Implementation Symposium", and exchanged opinions about management regulations, pre-market review process, post-market surveillance and UDI printing practice.

Cosmetics Symposium

Hosted "2016 International Symposium on Cosmetic Regulation" to help domestic cosmetic industry understand relevant product regulatory status and future trends.

07 International Cooperation and Cross-strait Exchanges

International politics, economic and trade and medical health would mutually influence each other. One of the key strategies of the government's administration would be to align with international standards. Through international and cross-strait collaborations and exchanges, TFDA exchanges significant information, align with international standards and promote collaboration and development in the pharmaceutical and health industries and related provisions.

Section 1. International Cooperation and Communication

Current Status

To improve the international visibility of Taiwan's food, medicinal products, medical devices, and cosmetic product quality and industries, TFDA actively participates in international harmonization organizations, hosts conferences on international regulations, and establishes platforms for bilateral partnerships to align with international standards.

Policies and Outcomes

1. Participate in international organizations and events

(1) Food

TFDA attended the Asia-Pacific Economic Cooperation (APEC) Sub-Committee on Standards and Conformance (SCSC) meeting from August 17 to 23, 2016. TFDA also attended the 67th routine meetings of WTO/SPS and the Expert Workshop on Harmonization of Pesticide Maximum Residue Limits (MRLs) to actively exchange food safety standards and activities with other members from October 22 to 30, 2016.

(2) Medicinal products

TFDA has long-term participated in Regulatory Harmonization Steering Committee (RHSC) of Life Science Innovation Forum (LSIF) under Asia-Pacific Economic Cooperation (APEC). In February 2016, the APEC Regulatory Harmonization Steering Committee (RHSC) endorsed the Roadmap to promote Good Registration Management jointly proposed by Taiwanese and Japanese Governments and "Good Registration Management Center of Excellence Pilot workshop" in Taiwan. The "Good Submission Practice (GSubP) Guideline for Applications" developed by Asia Partnership Conference of Pharmaceutical Associations (APAC) in cooperation with TFDA was endorsed by the RHSC as one of the APEC guidelines in April 2016.

(3) Medical devices

A. Taiwan is one of the founding members of the Asian Harmonization Working Party (AHWP). TFDA official has long-term served as the Chair of In Vitro Diagnostic Devices Work Group (WG2 - Premarket: IVDD) for the AHWP technical committee and led the development of in vitro diagnostic medical devices (IVDs) international guidance documents endorsed as AHWP official documents. During 2016, TFDA completed 4 AHWP endorsed guidances. Moreover, the International Standard Organization / Technical Committee 212 (ISO/TC 212) also agreed on having a TFDA staff person to become member of the expert committee of work group 3 for TFDA to continue participating in the establishment of relevant standards.

B. Attend the 9th "International Medical Device Regulators Forum (IMDRF)" annual meeting in Brasilia, Brazil from March 5 to 12, 2016 and a workshop on medical software by "Global Diagnostic Imaging, Healthcare IT & Radiation Therapy Trade Association (DITTA)" to remain updated on the latest regulatory trends.

C. Attend "The 21st Asian Harmonization Working Party (AHWP) Annual Meeting" in the Philippines from November 20 to 26, 2016 to participate in important decision making, give an update on the latest progress and future plans in IVDD Work Group (led by Taiwan) and discuss matters with regulatory representatives from New Southbound countries.

(4) Cosmetics

TFDA attended "International Cooperation on Cosmetics Regulation (ICCR)" (Figure 7-1) on behalf of Taiwan between July 12-14, 2016 for the first time and served as the 10th Meeting Observer to further understand current status and trends of international cosmetics regulations and to enhance the international visibility of its cosmetics management .

Figure 7-1 International Cooperation on Cosmetics Regulation (ICCR)

(5) Controlled drugs

A. Attend " National Prescription Drug Abuse and Heroin Summit" from March 21 to April 2, 2016 to observe US experience in drug abuse prevention.

B. Attend "The 47th American Addictive Drug Association Annual Meeting" between April 12-19, 2016 and discuss addiction medicine, overdose prevention and marijuana-related issues with experts from the US and Canada as the reference for establish our policies.

C. Attend "The 8th Global Pain Management Association" between May 19-25, 2016 to discuss pain management, clinical/technical training and international collaboration issues with global experts and scholars.

2. Multi-channel communications about international tests

(1) Food area

A. The 130th AOAC Annual Meeting was held in Dallas, USA during September 18-21, 2016. A total of more than one thousand experts and scholars attended the meeting. TFDA presented articles as well as 3 posters relating to fight against food adulterations, and addressed a keynote speech during organizer-arranged section "Taiwan Section Business Meeting" to exhibit the competitiveness of testing technology in Taiwan and establish communication channel with international experts.

B. Asia Pacific Metrology Programme (APMP) is one of the five APEC district expert organizations. The duty of the program is to promote the development, collaboration and freedom of trade between individual Asian-Pacific Economic Bodies. The organization hosts a "Seminar for grain products safety measurements and standards" to discuss and exchange opinions and comments relating fungi toxins and heavy metals. TFDA was invited to orally present the research outcomes in fungi toxin studies (Figure 7-2).

Figure 7-2 Seminar for grain products safety measurements and standards

(2) Medicinal product areas

A. TFDA attended the 1st EP Committee Meeting from March 15 to 16, 2016 (Figure 7-3) as Observer of European Directorate for the Quality of Medicines & Healthcare, Council of European (hereinafter referred to as EDQM) to learn about the preparation process, highlights and operation model of EP and exchange opinions on medicinal product quality requirements and testing technology with representatives from different countries.

B. TFDA attended "2016 23rd blood-borne pathogen screening and monitoring seminar" jointly hosted by International Plasma Fractionation Association (IPFA) and Paul Ehrlich-Institut (PEI) between May 23-28, 2016, and "2016 Standard blood-borne pathogen genetic amplification seminar" hosted by NUBSC between June 5-10, 2016 to improve the knowledge about blood-borne pathogen

Figure 7-3 2016 The 1st European Pharmacopoeia (EP) Committee Meeting

testing, the preparation of international viral standards of blood-borne pathogens by NIBSC and the most updated technology in nucleic acid amplification techniques and genetic sequencing analysis.

(3) Cosmetics area

Attending Global Summit on Regulatory Science (GSRS) hosted by US FDA between September 5-11, 2016. The theme was the standards and applications of nanotechnology. TFDA oral presented 2 articles on the meeting and communicated with international experts.

3. Bilateral activities (including signing related agreements and Memorandum of Understanding (MOU))

(1) Taiwan and Poland signed "TAIWAN-POLAND Medicinal Products and Medical Devices Memorandum of Understanding (MOU)" on January 14, 2016 and successfully expanded our international collaborations. The MOU allows both parties exchanging information regarding medicinal products and medical device pre-marketing management and clinical trials, so industry may have provision harmonization, improved efficiency and predictable benefits; in the meanwhile, the public may access to safe and good quality medicinal products.

(2) Attend Taiwan-EU Economic and Trade Consultation Pharma Working Group Meeting on April 27 and October 12, 2016, so both sides exchanged opinions about strengthening medical devices and cosmetics laws, administrative legal entities and bilateral collaborations.

(3) TFDA firstly designates a staff to attend "The 1st Europe cosmetics testing technology symposium" and "The 13th meeting of the Laboratory Network of Official Cosmetics Control Laboratories" hosted by the European Network of Official Cosmetics Control Laboratories (OCCLs) between June 14-19, 2016. Attend "The 5th European Union post-marketing surveillance platform meeting of cosmetic product analysis" and "The 14th European Network of Official Cosmetics Control Laboratories" hosted by the OCCLs between December 4-9 to establish communication channels for exchanging international cosmetics management regulations, standards and testing methods.

(4) TFDA attended Nation Institution of Infection Disease (NIID) in Japan from June 26 to July 9, 2016 to demonstrate critical technology of novel virus-inactivation tests and the Plaque reduction neutralization test (PRNT) of JapENnc.

Figure 7-5 The 4th Joint Conference of Taiwan and Japan on Medical Products Regulation in 2016

(5) TFDA attended the 10th TIFA meeting held in Washington D.C. on October 4, 2016 to give explanations of its future cosmetics management, labeling and plans to the U.S. delegation. Both sides also discussed marketing procedures of medical devices.

(6) Attend the 4th Joint Conference of Taiwan and Japan on Medical Products Regulation (Figure 7-5) between December 7-8, 2016 to discuss topics related to pharmacenticals and medical devices regulations, health insurance, and the outcomes of working groups. As for medical devices, both sides agreed to establish a medical device information sharing group. As for pharmaceuticals, representatives from the government and industry of Taiwan requested Japanese Government to revise bioequivalence guidelines in the meeting.

(7) TFDA has recommended 3 accredited domestic food testing laboratories to Indonesian Government, which has been recognized by Department of Agriculture, Indonesia on November 8, 2016. Such laboratories are permitted to issue test reports of 103 fresh plant origin products. During exporting products, if domestic food businesses attach reports issued by one of the above laboratories, the products may directly pass custom inspection in Indonesia in order to reduce trade obstacles and ensure product quality.

4. Organize large-scale international seminars

(1) TFDA and European Chamber of Commerce Taiwan jointly organized “2016 EU-Taiwan International food trade seminar” and “2016 Taiwan and European food safety management seminar” on March 9, 2016. TFDA addressed two speeches on

the seminar, which were: "The Regulations and Implementation of the Systematic Inspection for Import Food According to *Act Governing Food Safety and Sanitation* in Taiwan" and "Introduction of Taiwan food traceability system".

(2) Host "International seminar for food adulteration and Chinese herb misuse" on March 29, 2016 and invite experts from the US and UK to Taiwan sharing their opinions regarding such hot topic among international society. Such seminar greatly improves national identification technology, non-specific target analysis and Chinese herbal medicinal products.

(3) Host "International seminar for processing aids" on July 29, 2016 and invite experts and industry representatives from New Zealand, EU, USA, China, Japan and Taiwan sharing their opinions regarding laws, management and industrial application of processing aids, and the most updated management regulations as well as experience.

(4) Host "International seminar for import food safety management" between September 29-30, 2016 and invite food safety officials from Austria, Hungary and Japan sharing their food management system and boarder inspection measures.

(5) Host "2016 International Symposium on Cosmetic Regulation" on August 2, 2016 and invite government officials and experts from EU, Association of Southeast Asian Nations (ASEAN), USA, Japan and China to assist representatives of Taiwan's government, industry and academic sectors in understanding the current regulatory status and future trends of related products.

(6) Organize "International Conference on Medical Device Regulations for Implementation" in Taiwan on August 25, 2016. TFDA invited experts from EU, Canada and USA to address relevant regulation and future perspectives as well as Unique Device Identification (UDI). Additionally, experiences on pre-marketing review process, post-marketing surveillance and UDI printing and labeling practices were exchanged (Figure 7-6).

Figure 7-6 International Conference on Medical Device Regulations for Implementation

Figure 7-7 2016 APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop

(7) Host "2016 International seminar for plastic food utensils, containers and packaging management policies" on October 13, 2016 to invite scholars and experts from Germany, UK and Japan sharing their opinions about risk assessment on food contact materials, the management of suppliers, the promotion of self-certification system. Representatives from relevant governmental departments, associations also attended such seminar to facilitate multi-channel communications.

(8) TFDA scheduled a "2016 Global Health Forum in Taiwan-Session 9" with MOHW between October 23-24, 2016: Drug Accessibility and Quality Management, and invited the former Officials from Department of Health, the Philippines, Dr. Kenneth Y. Hartigan-Go, M.D. as well as Mr. Naoyuki Yasuda, Minister of International Department, PMDA, Japan, as speakers. Additionally, Chung-Hua Institution for Economic Research and Div. of International Collaboration, MOHW jointly organized "APEC International seminar for medical products trade and regulatory laws" and invited APEC officials from Indonesia, Vietnam, Malaysia, Thailand, the Philippines sharing their experience in management.

(9) Host "APEC Good Registration Management Regulatory Science Center of Excellence Pilot Workshop" in Taiwan between November 15-17, 2016 and invite experts from USA, Japan, Taiwan, Singapore and UK to share their experience in practice. Seed trainers for Good Registration Management 15 APEC economic bodies are also trained at the seminar (Figure 7-7).

Section 2. Cross-strait Communication

Current Status

Since the "Cross-Strait Food Safety Agreement" singed in 2008, TFDA plans to establish "Cross-strait collaboration plans for expanding food safety management" based

on the professions of academic/research fields or civil groups to promote cross-strait business cooperation in food safety. Through cross-strait department leaders/experts routine meetings, the organization of conferences or seminars, visiting food-related institutes and businesses, TFDA facilitates cross-strait collaboration in food safety surveillance and reaches consensus for management.

As of medicinal products, "Cross-Strait Cooperation Agreement on Medicine and Public Health Affairs" was signed by Taiwan and China in 2010. TFDA thereby established "The Working Group on Safety Administration and Research and Development of Medicinal Products" and set four taskforces (i.e. medicinal products and cosmetics, medical devices, health food and testing methods) to discuss bilateral cooperation mechanisms, construct systemic work frame platform, assure product quality and safety management, handle significant safety incidents relating to medicinal products and coordinate standards and regulations. TFDA also implemented clinical trial collaboration projects to learn implementation outcomes from each other, and fully use bilateral medicinal products management and research capacity to develop safe and effective medicinal products for the public.

Policies and Outcomes

1. Systemic meetings

(1) Food

In 2016, TFDA hosted several cross-strait food safety seminars in Taiwan and invited representatives from food associations and businesses to participate, including "Seminars for Food safety risk evaluation: The meaning of scientific, operational regulations and food safety protection in Taiwan", "Seminar for cross-strait online trading – food safety management regulations and practice", "2016 International seminar for microorganisms and food safety management", "Round table seminar for cross-strait microorganism standards and testing" and "Seminar for the application of big data in food safety management".

(2) Medicinal products

TFDA and China Food and Drug Administration promulgated "Cross-strait clinical trial center collaboration – reduce test duplication on April 25, 2016 based on " "Cross-Strait Cooperation Agreement on Medicine and Public Health Affaris": a total of 8 clinical trial centers, including National Taiwan University Hospital, Taipei Veterans General Hospital, Chang Gung Medical Foundation - Linkou branch, Tri-Service General Hospital, Peking Union Medical College Hospital, Peking University First Hospital, Shanghai Fudan University Zhongshan Hospital, Shanghai Jiao Tong University Ruijin

Hospital, complied with Good Clinical Practice (GCP) and can be the reference for bilateral medicinal product registration.

2. Border control information notification

(1) 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. 890 cases were reported by both parties in 2016. In 2016, 72 nonconforming food exported from Taiwan to China were reported majorly due to different standards of microorganism in food hygiene between the two parties. The rest factors included different boarder sampling rate between the two parties and China included nonconformity products but not involving food safety issues. In 2016, 118 incidents of food exported from China to Taiwan that failed to conform to Taiwan's regulations were reported, and most of them have beyond scope pesticide residues.

(2) With regard to previous nonconformity products, those exported from China to Taiwan all have been returned or destroyed. For those exported from Taiwan to China that failed to conform to Taiwan's regulations of 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

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 2016, in total, both sides made 28 notifications on food additive standards and 12 notification on food safety and sanitation standards.

4. Others – cross-strait drug prevention

TFDA attended "the 2nd cross-strait drug abuse and drug prevention seminar" in August 2016. During this seminar, TFDA exchanged business and information with experts in relevant fields, achieve consensus, fully use bilateral management sources to enhance anti-drug efficacy.

08

Information Transparency and Diverse Communication

Information Transparency and Communication Diversity

Interactive Promotion

Promoting Food Sanitation and Safety
- Food safety information stores
- Food safety-related exhibition

Promoting Awareness of Safe Drug Use
- Community pharmacy drug use inquiry
- Promoting safe drug use

Advocating Safe Selection of Medical Devices and Cosmetics
- Propaganda minibus
- Lectures and press conference
- Online quizzes with prizes

Propaganda of Controlled Drugs Abuse Prevention
- Anti-drug abuse education and advocation
- Addictive substances prevention and education

Website

Official Website
- TFDA Rumor Buster
- TFDA Articles
- Electronic Newspaper
  *Food and medicinal products weekly report
  *Controlled drugs newsletter
- Safe drug use interactive e-learning website

Social Media
- TFDA facebook
- Sleep very well
- Safety use of cosmetics

Official website

TFDA facebook

Helpline

1919 National Food Safety hotline
1919

Medical device counseling helpline
02-8170-6008

Cosmetics inquiry hotline
02-2521-7350

Publications

Diverse and professional publications such as Journal of Food and Drug Analysis[Note] and Annual Report of Food and Drug Research

JFDA

Note: The Journal of Food and Drug Analysis (JFDA) was funded in 1993, which rates as Grade A or Excellent Journal by Ministry of Science and Technology (MOST) for several times. JFDA now has been included by many international databases, including BIOSIS Previews, EMBASE (Excerpta Medica), Abstracts of Chinese Medicines, Chemical Abstracts, International Food Information Service (FSTA) and ISI Products: Research Alert, Biochemistry & Biophysics Citation Index and Science Citation Index Expanded. JFDA has also been included in the well-recognized journal evaluation tool - Journal Citation Report (JCR) since 1998, in SCI Expanded since 2003 and in PubMed/Medline of National Library of Medicine (NLM) since 2014.

JFDA is a quarterly publication journal, which publishes in January, April, July and October. In JCR data published in 2016, the impact factor of JFDA in food, medicinal products, medical devices, cosmetics, Chinese herb tests/analyses area was 3.048.

08 Information Transparency and Diverse Communication

TFDA establishes novel health education and policy promotion models based on new media habits to pass on food safety and risk training and policies.

Section 1. The Provision of Real-time Consumer Information

Current Status

TFDA uses the official website (http://www.fda.gov.tw) and various online platforms accessible to consumers to provide information about food, drugs, medical devices and cosmetics.

Policies and Outcomes

1. In 2016, “TFDA Articles” is established based on three major topics including “safe dine out, safe drugs and transparency of medical devices and cosmetics”. In addition, “Rumor buster” (Figure 8-1) and “TFDA Advisory” also open online submission function for the pubic to submit answers. From April 2016 to date, a total of 400 articles have been published. The accumulative page view has reached up to 182,744 times.
2. “TFDA Facebook” not only releases the most updated food and drug information, but organizes games such as “I want you, drug-use Talent” to accumulate up to 56,000 fans. TFDA also posts “Sleep very well Facebook” to introduce interesting and practical daily living information and news to help the public learn about controlled drugs properly.
3. “TFDA Rumor Buster” (Figure 8-1) clarifies all fasified rumors online relating to food, drugs, medical devices and cosmetics. A total of 254 articles have been published to date, the page view has reached up to 1,350,000 times. Additionally, more than 1,050 news reports have been forwarded by the mass media.

Figure 8-1 TFDA Articles and "Rumor Buster"

4. Establish “Safe drug use interactive e-learning website” for the public to download food safety materials. In 2016, a total of 301 domestic medicinal products recalls, 26 food must-know news, 12 “risk communication table of medicinal product safety”, and 4 newsletters of medicinal product safety were posted to pass along medicinal products safety or quality alerts to the public and medical staffs.
5. Release real-time national and international news and news the public care about through “Food & Drug Consumer Newsletter ” and “controlled drug newsletter”.
6. In 2016, TFDA publishes several books relating to medicinal products and food such as “Chinese Pharmacopoeia 8th ed.”, “TFDA Annual Report (Chinese and English version)”, “Journal of Food and Drug Analysis (JFDA), volume 24”, “Testing standards for biologics VI”, “Dug abuse prevention guidelines” and “Manual of food additive traceability” for the public to read (refer to Annex III for List of publications).
7. Set medical device counseling helpline (02)8170-6008 and cosmetics regulatory helpline (02) 2521-7350.

Section 2. Diverse Channels Available for Interactive Communication

Current Status

Help the consumers to learn basic risks of medicinal products and current government policies as well as regulations through systemic risk communication.

Policies and Outcomes

1. 1919 National food safety hotline

1919 National Food Safety Hotline is the first cross-departmental single-counter public convenience service hotline. Existing food-related inquiry hotline from four public agencies including TFDA, Consumer Protection Committee, Council of Agriculture, and Ministry of Economic Affairs were integrated. The 1919 Hotline provided five services: (1) receiving complaints of food products, (2) providing food-related consultation, (3) acquiring support for consumer issues, (4) providing consultations to small and medium-sized enterprises (SMEs), and (5) providing consultation on fresh farm product. Since the initiation of 1919 hotline from December 4, 2015, to December 2016, the service capacity was about 20,000 telephone calls and the satisfaction rate was up to 80%.

2. Training program for food sanitation volunteers

Combine civil sources and volunteers to help the government safeguard food safety. In 2016, food sanitation volunteers completed 37,394 inspections of food labeling and 38,371 hours of food advertisement surveillance. Additionally, TFDA invites professionals with food safety backgrounds and experience in food safety management (e.g. dietitian, food technologist) to serve as food sanitation volunteers promoting food safety on working places, campus and communities. The outcomes are significant.

3. Food safety and sanitation propaganda

(1) Prepare 3 articles about food processing and publish on children scientific magazines (e.g. “Youth Newton”), print “awesome food safety science” brochures and release electronic books to local health bureaus and schools as food safety education materials.

(2) Organize 4 food safety-related exhibitions (e.g. International food exhibition, Taiwan cuisine exhibition) and interesting games based on the theme "safe store" to interact with the public and increase the participation of the public in food safety policies.

(3) Considering the popularity of advertisements on TV, radio, magazines, light box advertising and bus, TFDA uses traditional social media to transmit proper food safety information and knowledge, including new food labeling regulation, food businesses registration, food poisoning prevention, the awareness of food safety in arrival area at the airport. Moreover, TFDA publishes a total of 7 articles, a series of food safety topics, namely "Knowledge on dining table" at the 1st week of every month since April 2016.

(4) Establish "Food safety information store" and related events

A. TFDA promulgated "Food safety information store" on August 23, 2016. Through mobile phone advertisement and online search engine "Banner", the platform has been reviewed for 3,000,000 times. Moreover, in 2016 September to October, TFDA organized "food safety information store – online quiz with prize". A total of 27,688 participants joined the activity.

B. "Food safety information store" is accessible from the front page of TFDA official website. The mobile version is also available. More food and illegal businesses information will be uploaded to the platform. "Food safety information store" has 8 categories (Figure 8-2).

4. Medical devices and cosmetics proper use propaganda

(1) Use "Propaganda minibus" to organize 3 activities. Because of the cute appearance of the propaganda minibus, about 900 participants joined the 3x3 squares game to learn about proper use of medical devices.

(2) Organize medical device lectures and invite experts and doctors to elaborate proper use of "Hydrophilic Wound Dressing", "Orthokeratology Contact Lens" and "Medical Support Stocking" through simple and understandable languages.

(3) Organize press conferences such as "Online medical device auction and procurement know-how", "Know your subcutaneous hyaluronic acid implant", "Early diagnosis and early intervention through "Dengue fever rapid screen"", "Low frequency electric therapy apparatus therapeutic device, your pain killer", "learn about osteoporosis using bone densitometer". A total of 385 news were released.

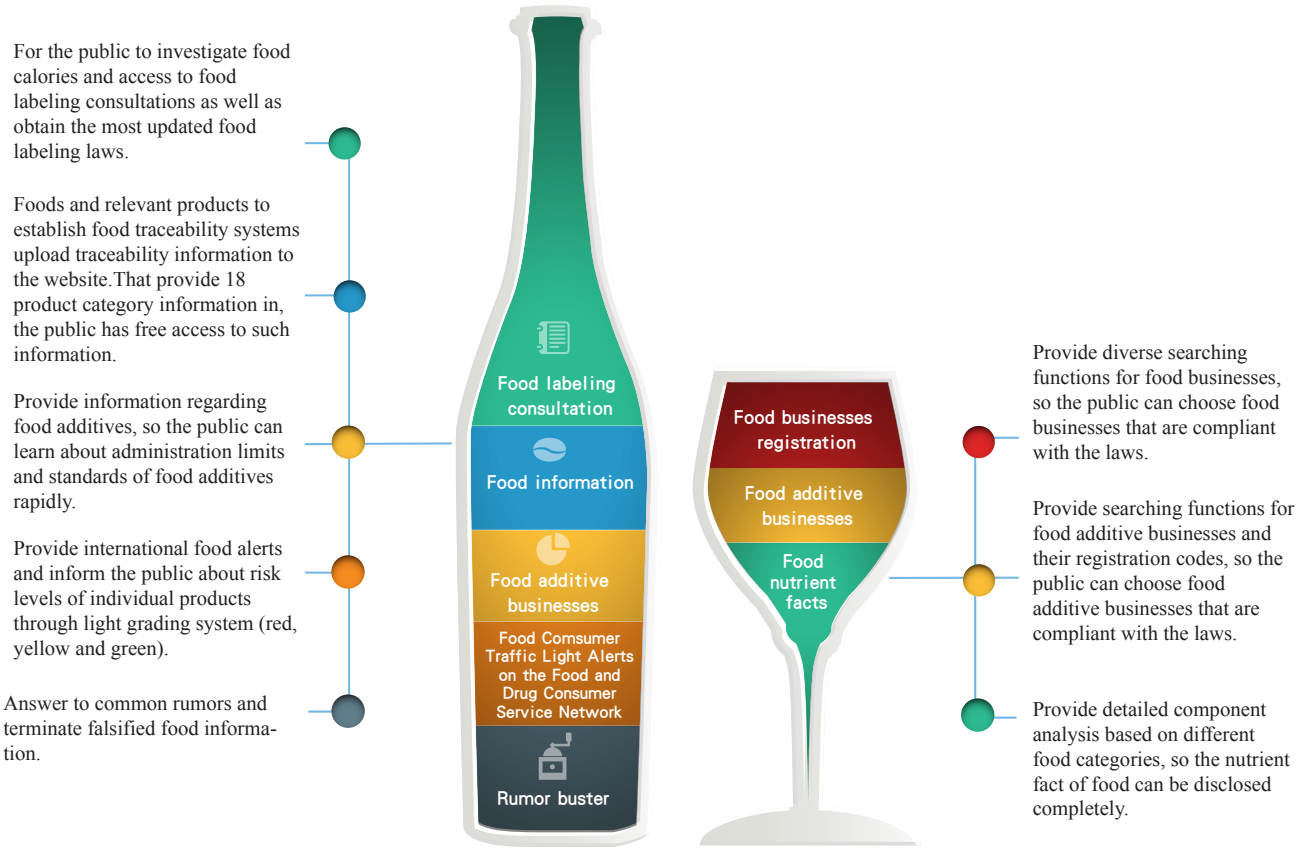


Figure 8-2 Introduction of 8 categories in "Food safety information store"

(4) Organize "Medical device knowledge testing", the online quiz with prize, plus interesting Q&A about medical devices to pass proper knowledge on medical devices.

(5) Propagate proper usage of cosmetics through 3 press conferences, including "Can cosmetics keep your skin white?", "Myths of using whitening cosmetics! ", "Usage safety of hair dye" and "Make up your knowledge propaganda minibus".

(6) Host 7 "propaganda minibus" sessions using a cat-resemble minibus to draw public attention and enrolled almost a thousand participants through quick Q&A and "Monopoly" games.

5. Promoting awareness for safe drug use

(1) Establish 22 resource centers for drug use, 465 community drug use inguiry stations and worked with 114 resource centers for drug use and seed schools across 20 counties and cities. A total of 11,987 people participated in the online quiz “Reading the label and knowing three types of drug”.

(2) Prepare a all-in-one “You must know about domestic generic drugs”, release the information on TFDA website, use colloquial wordings to introduce generic drugs, distribute the flyer “know your generic drug” and “the descriptions of quality management in generic drugs”, elaborate that the quality of generic drugs are well-controlled. Additionally, post “myth buster of generic drugs” on Food & Drug Consumer Newsletter, Pacific daily news, Yam and Taiwan Times to elaborate the quality of generic drugs (Figure 8-3).

Figure 8-3 How to understand "OTC drugs" labeling and flyers of "know your generic drugs"

6. Propaganda of controlled drugs abuse prevention

(1) Cross-departmental collaboration for drug abuse prevention

A. Establish “Anti-drug education and publicity plans” jointly with MOJ and MOE, and implement “”Go to communities” Anti-drug teacher community tour advocacy programs” together with anti-drug prevention and control centers in different counties/cities. A total of 17 counties/cities responded to this program and a total of 644 anti-drug lectures were held in 2016.

B. Promote “Addictive substance prevention and education integration program” together with the HPA, with the collation with 17 counties/cities and 72 enterprises, to implemented anti-smoking, anti-betel nuts and anti-drug programs in staffs work in 9 workplaces such as entertainment, hotels and religious groups.

(2) Anti-drug propaganda with civil groups

TFDA worked with 33 NGOs to support independent initiatives advocating drug abuse prevention within communities by using the educational and entertaining methods, such as magic, talk shows, drama, community lectures, competition and large scale events to interact with people. (Figure 8-4)

Figure 8-4 The tour of drama "Love everywhere, fight against drugs together" and talk show "SECRETS about drug"

(3) Diverse propaganda

A. Host “Song of anti-drug compose competition” and invite innovative song creation submission. A total of 113 songs were submitted. TFDA arranged the winner to present their works with the public.

B. Organize “Reversing Drug Abuse, Say Hello to Healthy Lives" innovative slogan competitions and board games competitions. A total of 1,221 slogans and 35 board games were submitted for the competition.

C. In 2016, add three new anti-drug posters (“Say no to emerging drugs”, “reveal the harm of emerging drugs” and “do not allow (meth) amphetamines controlling your life”), as well as English posters “You're young, so don't put yourself in danger!”, “Party, but without drugs”; and translate 4 flyer contents (“ Notice on carrying drugs in and out of the Republic of China”, “ Take Ketamine now, Wear Diapers for a lifetime”, “ Do Not Abuse Sleeping Pills” and “ Reveal Narcotics in Disguise”) into other 4 languages (i.e. English, Thai, Indonesian and Vietnamese) (Figure 8-5). At the same time, produce propaganda video tapes “Night lives” (Taiwanese version) regarding proper use of sedatives and hypnotics and 2 anti-drug videos.

D. Broadcast drug abuse prevention and proper use sedatives and hypnotics information through station light box, outdoor LED wall, newspaper, magazines, radio, YouTube, McDonald’s TV wall, mobile phone advertisement and flyers.

Figure 8-5 Propaganda flyers in foreign languages

09

Organization Introduction and Future Perspectives

Organization Framework

Director-General

Deputy Director-General

Chief Secretary

Business Unit

- Div. of Planning & Research Development Div. of Food Safety
- Div. of Medicinal Products Div. of Medical Devices & Cosmetics
- Div. of Controlled Drugs Div. of Research & Analysis
- Div. of Risk Management

District Center

- North Management Center
- Central Management Center
- South Management Center

Administrative Unit

- Office of Secretariat Office of Personnel Office of Service Ethics Office of Accounting Office of Information Management

Task Force

- Controlled Drugs Manufacturer Decision Support Center

Collaborative Unit

- Center for Drug Evaluation, Taiwan
- Taiwan Drug Relief Foundation

2016 Administrative Objectives

To strengthen food and medicinal products safety and safeguard public health

Total product life cycle quality management

Promote total product life cycle quality management of food, medicinal products 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 medicinal products.

Prohibition of illegal products

Promote cross-departmental collaboration for the prohibition of illegal medicinal products, 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 medicinal products.

Based upon risk assessment

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.

09 Organization Introduction and Future Perspectives

To effectively control food, medicinal products and cosmetics on the market, prohibit illegal matters, prevent and control drug abuse and align with international management standards. Food and Drug Bureau, Department of Health was recognized as Food and Drug Administration, Ministry of Health and Welfare on July 23, 2013.

Based on the administrative policies of Executive Yuan, TFDA aims to strengthen the control of food and medicinal products sources, production and distribution, the directions of raw materials and import products to achieve product transparency, protect consumer's safety and provide an environment of "safe drug and healthy food" for the consumers (Figure 9-1).

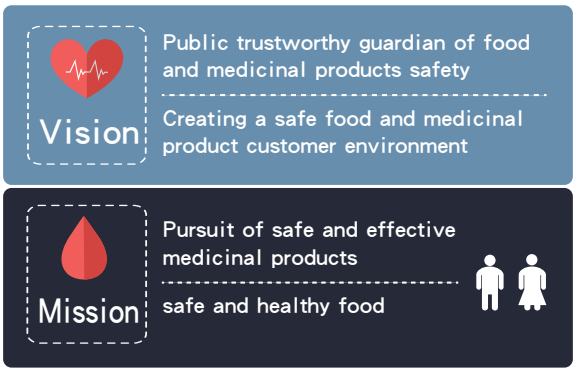


Figure 9-1 TFDA visions and missions

Section 1. Organization Framework

(1) TFDA comprises seven business units: The div. of planning & research development is responsible for the overall planning of the entire organization. Divisions of Food Safety, Division of Medicinal Products, Division of Medical Devices & Cosmetics as well as Division of Controlled Drugs are products and relevant provision management units. 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: Office of the Secretariat, Office of Personnel, Office of Service Ethics, Office of Accounting, and Office of Information Management (Figure 9-2).

(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 2, 2015 in order to acquire adequate information on food and drugs in Taiwan. This Center use big data analysis techniques to assess the risks and trends of food and drugs development in Taiwan and other countries, implement source management, and safeguard the health of the entire population.

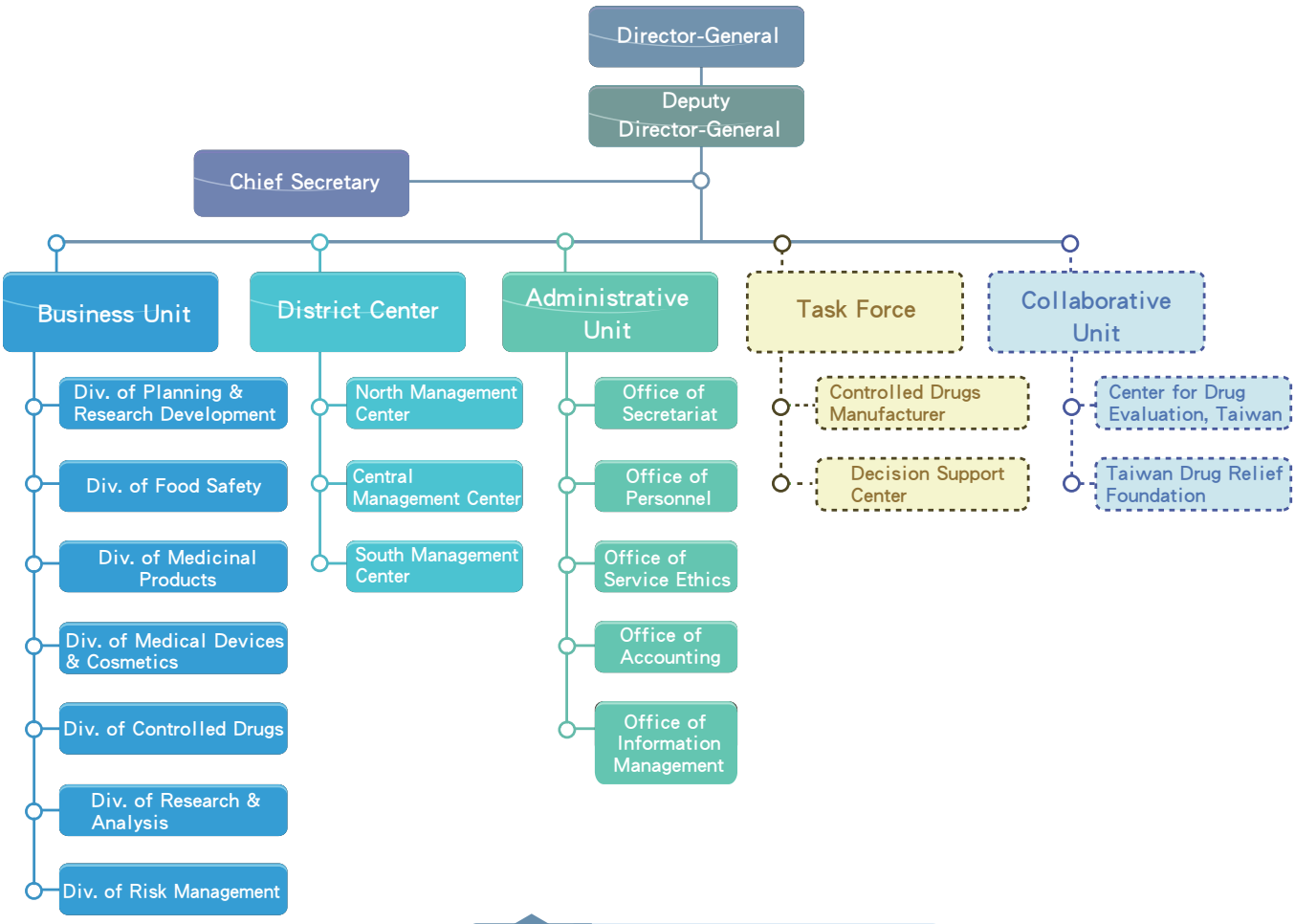


Figure 9-2 Organization framework

Section 2. Business Perspectives

1. Administrative goals

(1) Promote total product life cycle quality management of food, medicinal products 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 Integrate central and local monitoring and work specialization systems to safeguard the rights and interests of fellow citizens relating to food and drugs.

(3) Based on the results of risk assessment, 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.

2. Administrative highlights

(1) Promote Food and Drugs Management Capacity, Implement Source Management and Safeguard Consumer Safety:

A. Amendments for Product Management Regulations.
B. Strengthen Management of Product Manufacturing.
C. Comprehensive Product Review Management.
D. Strengthen Product Distribution Audits and Quality Monitoring.
E. Strengthen Laboratory Testing Capabilities.
F. Strengthen International Collaboration and Cross-Straits Exchanges.
G. Reinforce Risk Management.

(2) Enhance and Strengthen the 5 Circles of Cross-Departmental Food Safety Policies and Actions (Figure 9-3).

A. 1st Circle: Source management and establishment of a regulatory authority for toxic compounds.
B. 2nd Circle: Re-establish production management.
C. 3rd Circle: Conduct 10 times more market inspections to improve safety 10 fold.
D. 4th Circle: Increase the legal penalties for manufacturers that intentionally adulterate their products.
E. 5th Circle: Total monitoring of food safety.

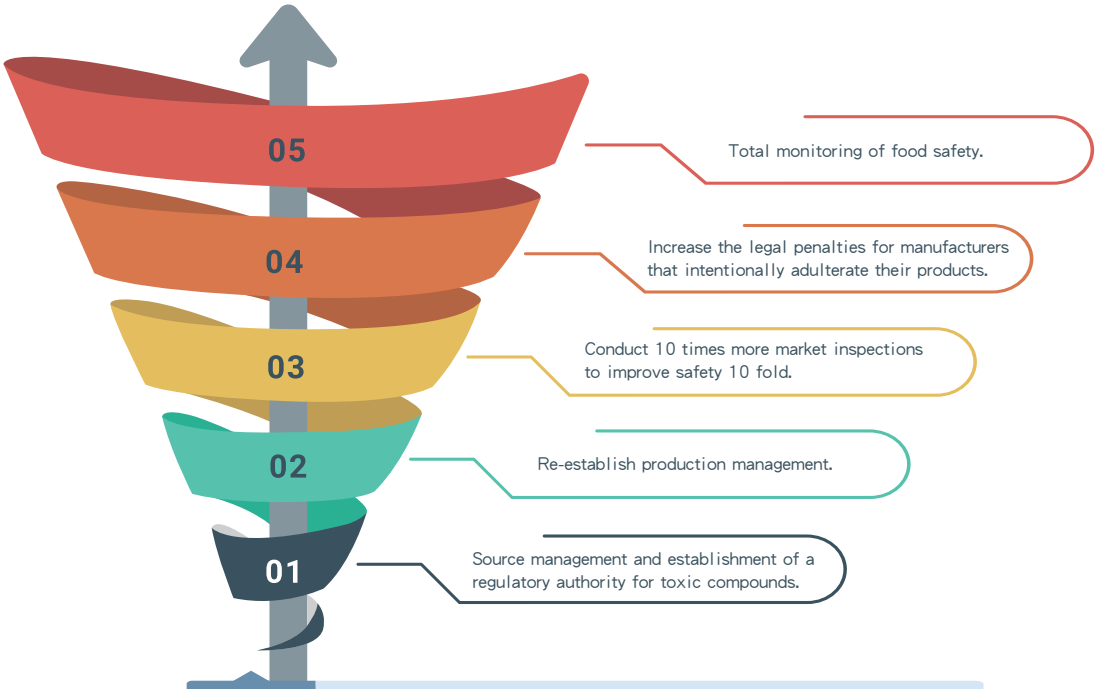


Figure 9-3 5 Circles of Cross-Departmental Food Safety Policies and Actions.

(3) Continue developing the biotechnology and pharmaceutical industries:

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

B. Establish and harmonize legal environments for medical drugs trade and commerce.

3. Future perspectives

With the trends of global trade and the development of technology, problems relating to food safety and sanitation become more and more complicated. Therefore, management with higher perspectives is required to establish several control gates. In the meanwhile, inter-departmental streaming can enhance the responsibility of management among businesses to ensure the safety of products and protect the rights and interests of the consumers.

It is the government's duty to protect the safety of food and medicinal products. TFDA integrates different departments and businesses and expand the participation of the public to construct a safe protection network for agriculture and food industry, establish an excellent "safe medication and healthy food" environment.

10

Annex

Annex I. Summary of Great Events

Time	Summary
January 1	Establish "*Act governing the management of food advertisements and promotions of food not suitable for long-term use of children*"
January 8	Establish "The complex import regulation containing F01 in "Import commodity classification of Republic of China"
	Revise "Import regulations containing 508 in Import commodity classification of Republic of China"
	The abolition of regulations governing 77 commodities on the "List of Commodities Subject to Export/Import Restriction"
January 12	Revise " Import regulations for commodities containing F01 and F02 category list Import commodity classification of Republic of China"
January 18	Revise "Standards for atomic dust or safe radiation contamination tolerance in food" and change to "Standards for atomic dust or radiation contamination tolerance in food"
January 21	Revise partial articles of "*Regulations for Application of Health Food Permit*"; the new application for health food registration has two-stage reviews, i.e. initial and secondary reviews.
	Establish "Guidelines for Assignment of Combination Products"
February 1	Revise " Import regulations for commodities containing "F01" and "F02" category list Import commodity classification of Republic of China"
February 4	Revise "Standards for vegetables, fruits and plants heavy metals limitations"
February 17	Establish "Hygienic standards for processing aids"
	Revise Table 1 of Article 2 and Table 2 of Article 3 in the "Application scope, limitation, specifications and standards for food additives"
February 19	Establish "Cosmetics must not contain Estradiol, Estrone and Ethinyl estradiol"
March 1	Revise "*Regulations for Implementation of Outer Box and Package Insert Format of Western Over-the-Counter Drugs*"
March 4	Establish the "General names of food additives"
March 8	Establish the "Food additives shall significantly label registration number of product"
March 9	Revise "The Complex Import Regulation Containing F01 in Import Commodity Classification of Republic of China"
March 11	Establish "*Act governing certification and validation of food sanitation and safety management system*"
March 18	Revise "Standards for pesticide residue limits in avian and livestock products" and change to "Standards for pesticide residue limits in animal products"; revise "Standards for pesticide residue tolerance"
March 23	Revise *"Import Regulations Containing "508" in Import commodity Classification of Republic of China*"
	Establish "Hygienic standards for edible bovine and sheep fat"
April 1	Establish "Baby wipes" are subject to management as cosmetics
April 6	Revise part of the articles in the "*Review standards for medicinal products registration*", which the primary amendments focusing on strengthening quality management of the main API

Time	Summary
April 6	Establish “Operational Directions for Law Suits Reimbursement by Food Safety Protection Foundation, Ministry of Health and Welfare”
April 15	Revise “Fees for registration review and certification issuance of food and food additives” and change to “Fees for registration review, related matters and certification issuance of food and food additives”
April 18	Revise “Food utensils, containers or packaging items required for labeling” and promulgate “*Regulations related to food utensils, containers or packaging labeling*”
April 21	Revise “*Food Businesses Shall Mandatorily Conduct Tests and Meet the Minimum Testing Cycle and Other Relevant Matters*” and change to “*Food Businesses Shall Enact Food Safety Monitoring Plan and Mandatorily Conduct Test and Meet the Minimum Testing Cycle and Other Relevant Matters*”
April 22	Revise “The Instruction of the Import Regulation F02"
	Establish “Application limitations of edible hydrogenated oils”
April 25	Revise “*Efficacy Assessment Method of Health Food for Protecting the Liver (Chemically Induced Liver Damage)*" ,and rename the Method as "*Efficacy Assessment Method of Health Food for Protecting the Liver*”
April 29	Revise “Hygienic standards for material gum arabic” and change to “Specifications for material gum arabic”
May 6	Revise “Medicinal products suitable for rare disorders prevention and control as well as *Pharmaceutical Affairs Act*”, add “”Taliglucerase alfa” (Injection; 200U/vial), which the indication is “Type 1 Gaucher's Disease”
	Establish “Operational Directions for Donations to Food Safety Protection Foundation, Ministry of Health and Welfre”
May 7	Host “2016 Medical and pharmaceutical products conference for business and trade provisions: The updated reformation and perspectives in pharmaceutical administration”
May 9	Revise Table 1 of Article 3 and Table 5 of Article 6 in the “*Standards for Pesticide Residue tolerance*”, add and revise 6 pesticide residue tolerances in 40 vegetables, fruits and corn products.
May 10	Revise “*Specific Food from Japan Must Submit Certificate of Radiation Test before They Enter the Food Inspection Application”*
May 19	Establish “Regulations for recovering unjust benefits of food businesses based on the *Food Safety Act* Article 49.2,” to recover unjust benefits from the businesses
June 3	Actively participate in the “2016 National Anti-drug Meeting” hosted by Ministry of Justice and assist in activity planning and preparations
June 6	Host “Management regulations and Practice Seminar of Online Food Trade between Taiwan and China”
June 15	Establish the “*Regulations on Fluorine Labeling for Prepackaged Food Grade Salt Products*”
June 24	Establish the “*Regulations Governing the Product Names and Labeling of Chocolate”*

Time	Summary
June 29	Revise Table 1 in Article 2 and Table 2 in Article 3 of “Application scopes, limits, specifications and standards of food additives”, add nutritional additive KF and NaF in small-packed (≤1000g) salt for family use, and establish application limits as well as specifications and standards
July 4 to July 8	Participate in the “2016 PIC/S Official Committee Meeting and Annual Conference” hosted by PIC/S at Manchester, UK
July 11	Establish “Regulation for Drug Shortage Management”
	Host “International provisions and clinical performance evaluation conference for *In vitro* diagnostic medical devices”
July 14	Release and revise Table 1 in Article 3 and Table 5 in Article 6 of “Standards for pesticide residue tolerance”, revise the contents , add and revise 59 pesticide residue tolerance in 376 vegetables, fruits and corn products, and add jackfruit in the category of big berries
July 15	Promulgate “List of Legally Permitted Cosmetic Colorants” and abolish “Regulations for the use of new legal cosmetics coloring list”
August 1	Revise “*Expedited Review Process for New Drug Registration*”
August 2	Host “2016 International Symposium on Cosmetics Regulation”
	Revise “*Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China*”
August 9	Revise the tables in Article 2 of the “ Regulations Governing the Allocation and Purchase Limitation of Schedule I and II Controlled Drugs”
August 23	A grand open of “food safety information platform”, including information such as “theme issues”, “food labeling consultation platform”, “food businesses registration platform”, “food information”, “the purposes of food additives” and “myth buster”
September 6	Revise part of the regulations in the "list of examples of proper and inadequate sentences examples of cosmetics claimed effects" and change to “Enumeration of expressions that are appropriate or inappropriate to be claimed for cosmetics"
September 6	Establish “*Regulations governing the trace and track system for medicinal products* ”
September 8	Establish “*Act governing specific medicinal product project approval for manufacturing and import*”
September 22	Revise “Standardized package insert of topical dermal preparations containing Diclofenac”
	Promulgate “Good Hygienic Practice Guidelines for food manufacturers of anka products”
	Host the ceremony of “2016 Innovation Award for Medical Devices” and encourage physicians investing in basic development
September 25	Host an activity to promote the idea of “Read the label of three types of medicinal products” on Safe Medication Day (September 25)
October 4	Promulgate “Revisions of Chinese package insert of medicinal products containing nifedipine”

Time	Summary
October 5	List of Article 102 of *Pharmaceutical Affairs Act* remote areas where practicing pharmaceutical personnel are not available
October 6	Revise "*Import Regulations for Commodities Containing F01 and F02 Category List Import Commodity Classification of Republic of China*"
October 12	Promulgate "Regulations for Chinese package insert amendments on dose forms of systemic administration (oral intake, injections and suppositories) of NSAIDs (except aspirin) prescriptions"
October 14	Establish "Guidelines of Cosmetics for Safe Children Use"
October 19	TFDA food cloud was rewarded of 4 star certificate of the Euro Cloud Star Audit (ECSA), Secretary-General of TFDA attended the ceremony for certification
October 24	Host the conference of "2016 Global health forum in Taiwan – Medicinal Product Accessibility and Quality Management"
	Host the conference of "APEC Seminar on the International Cooperation Experiences in Addressing Trade and Regulatory Issues of Medical Products"
October 26	Revise Table 1 in Article 3 and Table 5 in Article 6 of "*Standards for Pesticide Residue Tolerance*", add and revise pesticide residue tolerance of 14 pesticides in 85 vegetables, fruits and corn products
November 1	Revise "*Import Regulations Containing 508 in Import Commodity Classification of Republic of China*"
November 8	Establish "Technical Guidelines for Cosmetics UVA Sunscreen Performance Tests (Human Subject Test)" and "Technical Guidelines for Cosmetics Sunscreen Performance Tests (Human Subject Test)"
November 10	Host the international conference "2016 International Conference on TPP/RCEP, Medical Products and Food Safety"
November 16	Promulgate "Regulations for package insert outer box format of Over-the-counter drugs – Staged (in years) schedules and measures"
November 23	Promulgate "Revision of Chinese Package Insert of Corticosteroid Injections"
November 30	Host 2016 "Seminars of ASEAN Medicinal Products Provisions"
December 6	Establish "*Pharmaceutical Affairs Act* Article 2.2 - List of essential medicinal products "
December 12	Revise Article 3, Table 1 of "*Standards for Pesticide Residue Tolerance*", add and revise 8 pesticide residue tolerances in 25 vegetables and fruits, and define pesticide residue of Metolachlor.
December 14	Revise "*The Food Businesses Which Import Food and Genetically Modified Food Raw Materials Shall Keep the Relevant Records, Documents and Electronic Files or Databases of the Imported Products*"
	Host the wrap-up presentation of "Improvement of Food Distributors Management" during 2016
December 19	Revise "*Regulations of Labeling Requirements for Special Dietary Food for Patients*", and rename the regulations as "Regulations Governing the Labeling of Formula for Certain Disease"
December 26	Revise part of the regulations for "*GMP (Part I. General Principles) and (Part II. API)*"

Annex II. Important Outcomes and Statistics

Table 1. Statistics of permits for health food and genetically modified (GM) food

Heath 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
2007	24	-	24	111	3	17
2008	33	-	33	144	2	19
2009	26	6	32	176	18	37
2010	16	4	20	196	3	40
2011	17	6	23	219	13	53
2012	22	8	30	249	9	62
2013	14	13	27	276	10	72
2014	26	15	41	317	12	84
2015	22	5	27	344	32	116
2016	25	7	32	376	11	127

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 2016, 376 permits were issued for health foods, including 312 permits for Type 1 approvals and 64 permits for Type 2 approvals. 37 of the permits were voided (include termination as a result of permit expiration, revocation of the permit, or permit merging). As of the end of 2016, the number of approved permits issued is 339.

Note 3: As of December 2016, 127 permits were issued for GM foods, of which 9 permits were for products no longer in production or were not extended. As of the end of 2016, the number of approved permits issued is 118.

Table 2. Statistics of approved medicinal products 2007-2016

Year	Generic drugs			Active pharmaceutical ingredients			Novel drug			Biologics			Orphan drugs			Total
	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	Produced in Taiwan	Import	Sum	
2007	422	32	454	6	115	121	22	47	69	0	16	16	0	0	0	660
2008	383	44	427	13	59	72	18	76	94	1	25	26	2	2	4	623
2009	449	47	496	5	91	96	24	56	80	0	17	17	0	2	2	691
2010	323	41	364	15	69	84	11	77	88	2	14	16	0	0	0	552
2011	220	52	272	20	172	192	17	46	63	1	24	25	0	2	2	554
2012	256	60	316	8	203	211	20	42	62	2	25	27	0	9	9	625
2013	247	51	298	7	105	112	23	14	37	0	1	1	0	3	3	451
2014	263	122	385	24	80	104	28	62	90	1	11	12	1	2	3	594
2015	175	86	264	18	81	99	27	90	117	0	35	35	3	5	8	520
2016	202	84	286	48	191	239	12	141	153	0	16	16	1	3	4	682

Table 3. Statistics of imported food inspection

Year	Number of registered lots	Total net weight(x 10k tons)	Number of inspected lots	Growth rate (%)	Testing rate (%)	Number of non-compliant lots
2011	420,602	717.7	29,801	-	7.1	289
2012	461,665	754. 5	38,793	9.8	8.4	467
2013	514,710	713.3	38,460	11.5	7.5	557
2014	616,286	796.6	48,704	19.7	7.9	664
2015	640,003	900.5	50,149	3.9	7.8	953
2016	674,991	882.9	52,722	5.5	7.8	915

Note : Growth rate refers to the increased percentage of registered and inspected number of the year compared to previous year.

Table 4. Statistics of controlled drug licenses

Year	Item	
	Controlled drugs registration licenses (institutions and companies)	Controlled drugs prescription license (persons)
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
2016	15,413	52,757

Table 5. Business statistics of controlled drug manufacturers

(Unit: thousand dollars)

Year	Total income	Income from selling	Revenue Remittance to the National Treasury
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
2016	701,254	670,480	100,000

Table 6. Audition statistics of food inspection carried out by local government health bureaus and departments

Year	Labeling inspection			Sampling tests			Inspection of Good Hygienic Practice(GHP)				
	Number of inspection	Number of compliant items	Compli-ance rate (%)	Number of sampling	Number of compliant items	Compli-ance rate (%)	Number of inspection	Number of consulation request of corrections within a deadine	Number of penalty	Number of businesses forced to close	Number of businesses brought to justice
2008	795,119	778,931	98.0	43,545	40,916	94.0	143,779	34,177	65	81	6
2009	874,959	857,355	98.0	38,770	36,158	93.3	150,675	32,463	92	18	6
2010	796,758	781,645	98.1	38,056	35,394	93.0	136,456	28,967	131	5	3
2011	806,324	796,795	98.8	42,372	40,132	94.7	117,420	35,013	6	12	0
2012	683,956	676,930	99.0	41,956	39,998	95.3	118,681	49,587	75	13	0
2013	635,121	628,266	98.9	40,898	38,608	94.4	123,476	51,324	31	21	0
2014	523,045	517,051	98.9	41,085	39,206	95.4	130,005	61,066	38	143	2
2015	340,347	338,200	99.4	47,078	44,916	95.4	119,927	54,979	82	11	0
2016	424,402	422,085	99.5	49,800	47,726	95.8	112,382	52,151	3	13	0

Table 7. Statistics for controlled drugs inspection

Year	Items		
	Number of inspection	Number of violations	Violation rate (%)
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
2016	17,145	437	2.55

Table 8. Statistics of food outbreaks

Year	Number of outbreaks	Food poisoning cases		Number of outbreaks by vehicles					
		Number of cases	Death toll	Aquatic products and its processed products	Meats, eggs dairy products and its processed products	Cereal, vegetables, fruits and its processed products	Confectionery and candies	Compound cooking food and others	Vehicle unidentified (Integrated)
2007	248	3,231	0	4	6	7	0	13	218
2008	272	2,924	0	10	3	2	2	19	236
2009	351	4,642	0	4	2	3	4	43	296
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338
2014	480	4,504	0	18	12	6	3	60	381
2015	632	6,235	0	17	3	7	1	53	551
2016	486	5,260	0	18	3	2	3	56	404

Table 9. Lot release of biologics

Year	Vaccines and toxoids				Blood preparations		Antitoxin and antiserum products				Other biologics		Annual summary	
	Domestic products		Import		Import		Domestic products		Import		Import			
	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose	lot amount	dose
2007	67	6,134,626	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
2013	64	4,149,722	161	7,201,090	134	988,939	4	5,512	1	20	25	166,494	389	12,511,777
2014	72	3,705,462	155	7,607,454	121	962,552	6	8,440	0	0	27	332,558	381	12,616,466
2015	123	5,808,339	163	7,548,124	146	1,137,717	3	3,234	0	0	22	226,082	457	14,723,496
2016	58	4,122,437	152	6,773,750	146	1,363,462	9	6,078	2	19	29	422,944	396	12,688,690

Table 10. Statistical analysis of the surveillance of pesticide residues, veterinary drug residues, fungi toxins and heavy metals in food

Year	Monitoring of Agricultural chemical residues		Veterinary drugs		Monitoring of Mycotoxins		Monitoring of heavy metals	
	Total cases	Conformity rate (%)	Total cases	Conformity rate (%)	Total cases	Conformity rate (%)	Total cases	Conformity rate (%)
2007	1,761	95.9	359	94.4	-	-	-	-
2008	1,765	88.2	252	92.1	-	-	-	-
2009	1,894	89.6	266	95.1	-	-	-	-
2010	2,051	90.5	330	98.2	-	-	161	100.0
2011	2,110	89.0	481	90.9	-	-	162	100.0
2012	2,363	89.8	572	93.0	356	96.1	410	100.0
2013	2,340	88.9	861	95.5	421	97.9	472	99.2
2014	2,528	87.2	830	95.7	461	97.4	801	99.4
2015	3,087	88.7	1,745*	98.2	512	94.3	601	99.0
2016	3,341	89.1	2,278*	98.6	515	97.5	601	99.5

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

Table 11. Statistics of post-market quality surveillance in medicinal products

Year	Medicinal products		Biologics		Chinese medicine*		Annual summary	
	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)	Number	Non-conformity rate (%)
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	0	0			212	0
2016	88	5.7					88	5.7

*The background values of heavy metals, pesticide residue and aflatoxin in Chinese Medicine are presented as "-".

Table 12. Important outcomes of food and drug testing technology in 2016

Category	Outcomes	Benefits
Food chemistry and biology	1. Complete establishing testing methods for inorganic arsenic in algae and heavy metals such as Methylmercury in aquatic animals, animal components in tuna species, natural toxins such as gibberellins in corn products, labeling conformity of heat-resistant plastic containers/packaging materials, nitrofuran metabolites in honey, multi-residue pesticides in poultry and livestock products (60 items) and radionuclide components 2. Complete adding and revising testing methods for food additives such as antioxidants and Ferrous ammonium phosphate 3. Establish 4 tests for new GM food categories and publish 2 recommended tests for GM food 4. Establish 6 test methods for Streptococcus pyogenes and probiotics	Announced 60 testing methods, including a total of 262 items in 2016 to enhance laboratory testing capacity and protect food quality and safety in Taiwan
Medicinal products	1. Complete establishing analytical methods for 12 types antibiotics (69 items), such as β-lactams 2. Establish analytical methods for cardiovascular drugs, mirror isomers and impurities 3. Complete established 13 standards and spectrum database 4. Use UPLC-Q-LIT and GC-MS to establish analytical methods for 20 synethic cannabinoids and 20 synthetic cathinones in urine respectively 5. Establish 55 LC-Q-TOF protocols for drug abuse testing and complete 600 urine sample analyses 6. Establish identification methods for Artemisiae scopariae Herba materials and analytical approaches as well as LC-MS for tonic Chinese medicinal preparations	1. Applied to clinical practices such as medicinal products routine tests, clinical determinations for drug abuse and criminal identification 2. Establish standards and spectrum database for comparing test results and meet the techniques for drug abuse 3. Apply to Chinese medicines identification, testing and quality management
Biologics and advanced biotechnology medicinal products	1. Establish the 2nd generation of HCV genotype 1 viral nucleic acid standard candidates and working standard candidates 2. Establish initial sandwich ELISA analysis for quantifying the antigen loads in EV71 vaccines 3. Establish ELISA analysis for detecting the contents of E protein in JapENnc vaccines 4. Establish the analytical platform of Neutralization Test for Rabies Virus Fluorescent Antibody Virus 5. Use LC-Q-TOF to establish testing methods and database of advanced protein medicinal products such as growth hormones and Herceptin	1. Establish national standards for the development and quality control of molecular diagnostic preparations 2. Applicable to EV71 vaccine potency evaluation *in vitro* vaccine potency tests 3. Establish quality assessment on domestic inactived JapENnc vaccines to replace traditional potency test using animal challenging models 4. For potency test of domestic human rabies vaccines 5. For post-market product quality surveillance
Medical devices and cosmetics	1. Establish testing method for the safety of stair-climbing device 2. Establish thermal safety assessment method for medical thermal pad 3. Establish emission rate testing method for infrared medical device 4. Perform safety assessment of mobility device such as medical wood stick 5. Establish testing methods for 25 forbidden components of hair dye and 14 forbidden pigments of cosmetics 6. Establish testing method for *in vitro* degradation of subcutaneous hyaluronic acid implants 7. Establish testing method for nanoparticles in cosmetics such as TiO_2 8. Perform "Comparison research of international cosmetic products containing nanoparticles"	The results can be applied to post market surveillance to ensure the safety and performance of medical and cosmetic products

Annex III. Publications in 2016

No.	GPN	Title	Responsible Section	Category	Date of publication
1	1010500189	Manual for Food Businesses Registration (manufacturing and processing industry)	Division of Food Safety	Books	105/1
2	1010501809	Manual for Establishing Traceability Management System of Food Services in International Tourist hotels	Division of Food Safety	Books	105/8
3	1010502002	2014 National Survey on Substance Use in Taiwan	Division of Controlled Drugs	Books	105/10
4	1010502228	2016 User's Guide for Drug Abuse Prevention	Division of Controlled Drugs	Books	105/10
5	1010502425	Chinese Pharmacopoeia 8th ed.	Division of Research & Analysis	Books	105/12
6	1010502703	Manual of Food Labeling Regulations	Division of Food Safety	Books	105/12
7	1010502791	User's Guide for Establishing Hygienic Management System for Food Suppliers	Division of Food Safety	Books	105/12
8	1010503051	Manual of food additives	Division of Food Safety	Books	105/12
9	1010503125	Manual of domestic vitamin products in tablet or capsule form	Division of Food Safety	Books	105/12
10	1010503133	Manual of hygienic management and practice on flour, starch and the upstream as well as downstream relevant industries	Division of Food Safety	Books	105/12
11	1010503134	User's Guide for GHP in brewing and fermentation industries	Division of Food Safety	Books	105/12
12	1010503147	Manual of audition, management and practice on low-acidity and acid cane food manufacturers	Division of Food Safety	Books	105/12
13	1010503170	Test standards for biologics VI	Division of Research & Analysis	Books	105/12
14	1010503179	Manual of food additive traceability system	Division of Food Safety	Books	105/12
15	2010301353	TFDA Annual Report	Division of Planning & Research Development	Series (journal)	105
16	2010302286	TFDA Annual Report (English version)	Division of Planning & Research Development	Series (journal)	105
17	2008200056	Journal of Food and Drug Analysis (JFDA)	Division of Planning & Research Development	Series (journal)	105
18	4909405233	Food & Drug Consumer Newsletter	Division of Risk Management	Series(weekly)	105

Annex IV. List of Websites

No.	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” 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 to make inquiries about these, check progress on their inquiries as well as download food QR-CODE.
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 and Medicinal Products Business Registration Platform	https://fadenbook.fda.gov.tw	A digital data system that enables government agencies to achieve effective control over food businesses.
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 Certificate Information System	https://chef.fda.gov.tw	Provides educational and HACCP resources for food sanitation, an online course area, and registration services that can be used for learning purposes.
9	Post-market Quality Management System for Food, Medicinal Products, and Cosmetics	https://qms.fda.gov.tw	This system provides the public, medical staffs and companies an integrated single portal for reporting defective products for medicinal products, adverse incidents of medical devices, unintended reactions of health food products, and adverse incidents of cosmetics to facilitate reporting system.
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.

No.	Name of the website	Website	Website summary
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.
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	To real-time control drug abuse in Taiwan, prevent abuse exaggeration, the system 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, medicinal products, cosmetics, and urine testing (for drug abuse) agencies to apply for accreditation.
17	Searching System of Approved Advertisement for medicinal products, medical devices and Cosmetics	http://adms.fda.gov.tw/adms/PUBLIC/PQuery.asp	Allows the public to inquire information on approved advertisements for medicinal products, medical devices, and cosmetics.
18	Illegal Advertisement Query System	http://pmds.fda.gov.tw/illegalad/	Quickly publishes results of illegal advertisement audits on food, medicinal products cosmetics 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	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 to facilitate the transparency of TFDA operation.

No.	Name of the website	Website	Website summary
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	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.
24	Online Application System of Human Organ Bank	https://htb.fda.gov.tw	This system provides online applications for human organs to ensure the integrity of submitted documents and facilitate application efficiency as well as provision conformity.
25	Cosmetic Product Notification Portal	https://cos.fda.gov.tw	To align cosmetic management with international standards, TFDA encourages manufacturers or importers to register their products through “Cosmetic Product Notification Portal” to facilitate the control of products on the market by the government.
26	TFDA News	http://fda-article.consumer.fda.gov.tw	“TFDA News” provides the most updated, the most accurate food and drug safety information and articles based on three themes “Safe dine out, safe medication and safe medical devices & cosmetics” to help the public obtain the most accurate and practical daily living knowledge.
27	Food sanitation and safety management certification and validation system	https://facs.fda.gov.tw	The system primarily assists the implementation of 2nd tier food quality control and enhances the efficiency of validation management through randomly designating validation institutes, controlling validation process and the presentation of results.
28	Information Platform for the Supply of Medicinal Products	https://dsms.fda.gov.tw	The system provides pharmaceutical companies and medical institutes in Taiwan to report shortage of medicinal products to facilitate real-time assessment and handling, reduce the influences caused by the shortage of medicinal products and protect the rights of the public.
29	Material Transfer Supporting System for	https://mrdss.fda.gov.tw/Web/	The system provides hospitals, pharmaceutical manufacturers and retailers, and human organ
30	Laboratory Information Management System	https://lims.fda.gov.tw	For the laboratories of local government and health bureaus to manage test processes through electronic systems.

2017 Taiwan Food and Drug Administration Annual Report

Publisher	Show-Mei Wu
Editor-in-Chief	Shiow-Ing Wu
Editorial Board	Der-Yuan Wang, Shu-Fen Wang, Yu-Roo Chu, Jo-Feng Chi, Meng-Hsiu Wu, King-Fu Lin, Chien-Liang Lin, Hsin-Chen Chen, Ruenn-Lan Feng, Su-Hsiang Tseng, Meir-Chyun Tzou, Wei-Chih Cheng, Fang-Ming Liu, Lan-Hui Chih, Fwu-Chyn Hsueh, Shi-Wern Chien, Chia-Hung Chien, Jen-Ting Wei, Hsueh-Yung Tai (arranged in stroke order)
Executive Secretary	I-Chen Yang
Executive Editor	Shu-Hwa Lian
Publishing Authority	Taiwan Food and Drug Administration, Ministry of Health and Welfare
Address	No.161-2, Kunyang St., Nangang Dist., Taipei City 11561, Taiwan (R.O.C.)
Website	http://www.fda.gov.tw
TEL	+886-2-2787-8000
Date of Publication	2017/12
Date of Initial Issue	2014/11
Publishing Frequency	Annual Report
Design & Printing	Linking Publishing
TEL	+886-2-8692-5588
Cover Price	NTD$250
Sales Center	Government Publications Bookstore, Sung Chiang Branch 1F, No.209, Sung Chiang Rd., Taipei City +886-2-2518-0207 Wu-Nan Bookstore No.6, Zhongshan Rd., Taichung City +886-4-2226-0330
ISSN	2313-5093
GPN	2010301353
Copyright	Taiwan Food and Drug Administration, Ministry of Health and Welfare

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