



Taiwan Food and Drug Administration Annual Report





2014 Annual Report

Food and Drug Administration

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Forward

Embarking on a New Era of Food and Drug Management

On January 1, 2010, The Department of Health of the Executive Yuan integrated the Bureau of Food Safety, the Bureau of Food and Drug Analysis, the Bureau of Pharmaceutical Affairs, and the Bureau of Controlled Drugs and formed the Taiwan Food and Drug Administration (TFDA). This was done in order to effectively integrate resources and promote administrative efficiency, so as to unify the management of food and drug safety. On July 23, 2013, in response to the reorganization of the central government, the Food and Drug Administration went through a status change to be affiliated under the Ministry of Health and Welfare. TFDA is committed to building a strong management system in order to achieve food and drug safety for the general public.

Stating our administrative activities and outcomes in the 2013 annual report, we have introduced the TFDA organization infrastructure and administration objectives related legislation and policy promotion for food, drugs and control drugs, medical devices and cosmetics. Six supporting systems are included to form a web-like network. Achievements in product quality assurance, factory operation and management, distribution, monitoring and border management are presented. Major events of the year, chronicles and statistics in 2013 are also listed for reference.

Management Innovation and Quality Service

On June 19, 2013, the “Act Governing Food Sanitation” was amended to fortify food safety management. Industry is being held responsible for more self-management. Also a product Food traceability system was established, as well as increased penal provisions. By the end of 2013, the TFDA had listed the permitted usage and limits for a total of 800 food additives. Since 2011, the TFDA had encouraged the food additive related companies to voluntarily register in the TFDA online information system. By the end of 2013, there were 669 companies registered with information on 27,712 food additive items, thus completing the food additives registry information system. Border inspection and post-market monitoring assisted in forming a comprehensive food safety control system. The TFDA continues to develop innovative analytical technology for the detection of hazardous substances in food, while the function is also useful for food related emergencies. The maleic anhydride testing method was developed and used in the modified starch incident in 2013. This is a leading discovery preceding the US, Europe and Japan. The TFDA also leads in developing a new high resolution liquid chromatography tandem mass spectrometry method to analyze copper chlorophyll in oil. This innovation was developed to meet the urgent demands for the adulterated olive oil incident in 2013. By the end of 2013, there were a total of 151 laboratories that have passed the requirements and received accreditation for testing a total of 1,192 items.

In order to safeguard national medication safety, an overhaul of the drug review mechanism has been performed. Taking for example the new drugs that went through the “priority review mechanism”, the approval time frame has been shortened more than 33% in 2013, ahead of the USA, Europe and Japan. In 2013, a new lung cancer target therapy medication, Afatinib, received approval from the TFDA ahead of other countries. In order to provide onsite counsels to industry, in September, 2013 we set up two TFDA medical equipment legal consulting offices,



one in northern Hsinchu and one in the Kaohsiung biomedical science park. Furthermore, for the convenience of the consumer, a new policy was passed to allow three additional items of Class two medical devices to be sold on websites, television channels and by mail order service after approval. In 2013 the TFDA had accomplished standards, guidelines and draft making with respect to a total of 516 drugs, cosmetics and medical devices.

The TFDA cooperates with the Executive Yuan in stopping the sale of illegal medication through radio advertisement. The confiscation rate of illegal drugs has decreased from 27.22% in 2010 to 1.71 % in 2013, and the non-compliance rate of advertisement dropped from 13.93% in 2010 to 5.14% in 2013.

In 2013, the TFDA had signed three memoranda of understanding on cooperation regarding food, drugs and cosmetics. Since January 1, 2013, the TFDA has become a member of the Pharmaceutical Inspection Co-operation Schemes (PIC/S), which allows the TFDA to access global pharmaceutical safety warning information promptly, and decreases the redundant rechecks for pharmaceutical plants. This helps in further boosting Taiwan pharmaceutical medication export value and thusly establishing a stronger network with the global market.

Five Safety Strategies for a Safe Environment in the Future

To become a reliable keeper of food and drug safety, and to establish a safe environment for the consumer, there are five strategic aspects that we have promised to uphold.

First, safeguard a stable management system through good legal framework and explicit implementation.

Second, safeguard products and raw materials importation.

Third, safeguard production through manufacture quality assurance management.

Fourth, safeguard the distribution of products and raw materials through management control.

Fifth, safeguard consumers through products safety management.

Through these five multiple layers of safety management strategies, we can achieve the ultimate goal of consumer safety protection.



Acting Director-General
Food and Drug administration,
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01

Policies and Organization

Administrative Objectives and Highlights

Organization Framework and Job Delegation

Future Prospects

Chapter 1 | Policies and Organization

The quality, safety and proficiency of the food, drug and cosmetics have profound relationship with our daily living. Our mission is to safeguard the national public health. To promote the growth of our manufacturing industries, to build up strong industry management teams, to emphasize the post market quality control, to reinforce the illegal drug and violation food suspension, to develop new national biotechnology, to ensure consumer's protection and to globalize the food and drug safety management are our goals. In pursuit of highly functional performance TFDA went through organization transformation to meet our goals .On July 23, 2013, the Taiwan Food and Drug Bureau was reformed as the Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA). A synchronized turnkey operation was established.

Section 1 Administration Objectives and Highlights

In accordance with the Executive Yuan's 2013 policy, the TFDA coordinates new, revised policies with current social concerns, as they maintain the high regulatory standards for food, drug and cosmetics management. TFDA stands strongly behind our commitment. We believe that a healthy environment will insure everyone enjoys the quality of good food and taking the medication without worry.

Policy Objectives

1. To fortify the food, drug, and cosmetic management by establishing a complete management system for a risk factor assessment mechanism, product sources and raw materials distribution and monitoring. The good MIT food and drug reputation was revalidated. Improve the management and risk assessment system of food, drugs and cosmetics, strengthen the raw materials management, source management and distribution inspection of food and drugs, rebuild the product credibility of MIT food and drugs.
2. To integrate collaboration with joint departments that effectively set up solid teams for drug abuse prevention by seizing illegal drugs and pulling improper food and drug advertisements.
3. To meet the dynamics rhythm of new global trends with meticulous but effective drug approval processes and mechanism, and secure product management and safety monitoring, until the goal to safeguard the drug safety and effectiveness for all the consumers has been fulfilled.

Highlights

1. Amendments for Products Management Regulations

- (1) To reach our goal by constant revision and addition of new up to date product audit management systems and regulations.
- (2) To reach our goal by constant revision and addition of new food management regulations.
- (3) To reach our goal by pursuing new pharmaceutical and scientific research and related amendment of the law.

2. Product Manufacture Management

- (1) To establish a good food manufacture and product audit and registration system.
- (2) To establish a solid raw material management.
- (3) To encourage manufacture to comply with Good Practice and Sanitary act guidelines.

3. Improve Product Review and Audit Management

- (1) To establish a solid food audit mechanism.
- (2) To establish a contemporary drug monitoring system.
- (3) To fortify drugs and cosmetics advertisement monitoring mechanism.
- (4) To enhance staff professional expertise.

4. To Reinforce Product Distribution Inspection and Quality Control Monitoring

- (1) To emphasize the distribution monitoring for food manufacturers.
- (2) To reinforce import food management.
- (3) To extend food quality and safety monitoring territory.
- (4) To emphasize pharmaceutical, medical equipment and cosmetics factories management and audit.
- (5) To develop a comprehensive product post-marketing surveillance investigation and research.
- (6) To strength the distribution inspection and quality control monitoring for drugs and cosmetics.
- (7) To reinforce inspection and improve management mechanism of illegal drugs and illicit (irregular) advertisements.

5. To Amplify Laboratory Testing Capacity and Research Momentum

- (1) To integrate central and local infrastructures for a comprehensive inspection management system.

- (2) To upgrade laboratory testing technology and to strengthen the laboratories' network functions.
- (3) To invigorate the capacity and function of the national laboratory.

6. To Accelerate International Cooperation and Cross-Strait Exchanges

- (1) To develop a harmonious global environment with abiding respect for the international cooperative regulations.
- (2) To promote contemporary food and drug testing.

7. To Reinforce Risk Management

- (1) To strengthen food safety risk assessment capabilities.
- (2) To promote consumer education and risk communication.
- (3) To fortify consumer protection infrastructure.

Section 2 Organization Framework and Job Delegation

In coordination with the Ministry of Health and Welfare organizational transformation, the Food and Drug Administration, Ministry and Welfare (TFDA) was formed on July 23, 2013, committed to provide professional service to each consumer and safeguard each individual's food, drugs, medical devices and cosmetics safety.

Organizational Duties

The TFDA is in charge of food, drugs, controlled drugs, medical equipment and cosmetics related management including relevant policy and regulation creation, drafting and enforcement. The TFDA carries the functions as the following: product registration and examination record keeping, audit and certificate issue, manufacturers chain monitoring and correlated training, product of laboratory testing, research and technological development, product of risk assessment and management comprehensive, product monitoring outbreaks investigation and resolution and promoting consumer protection.

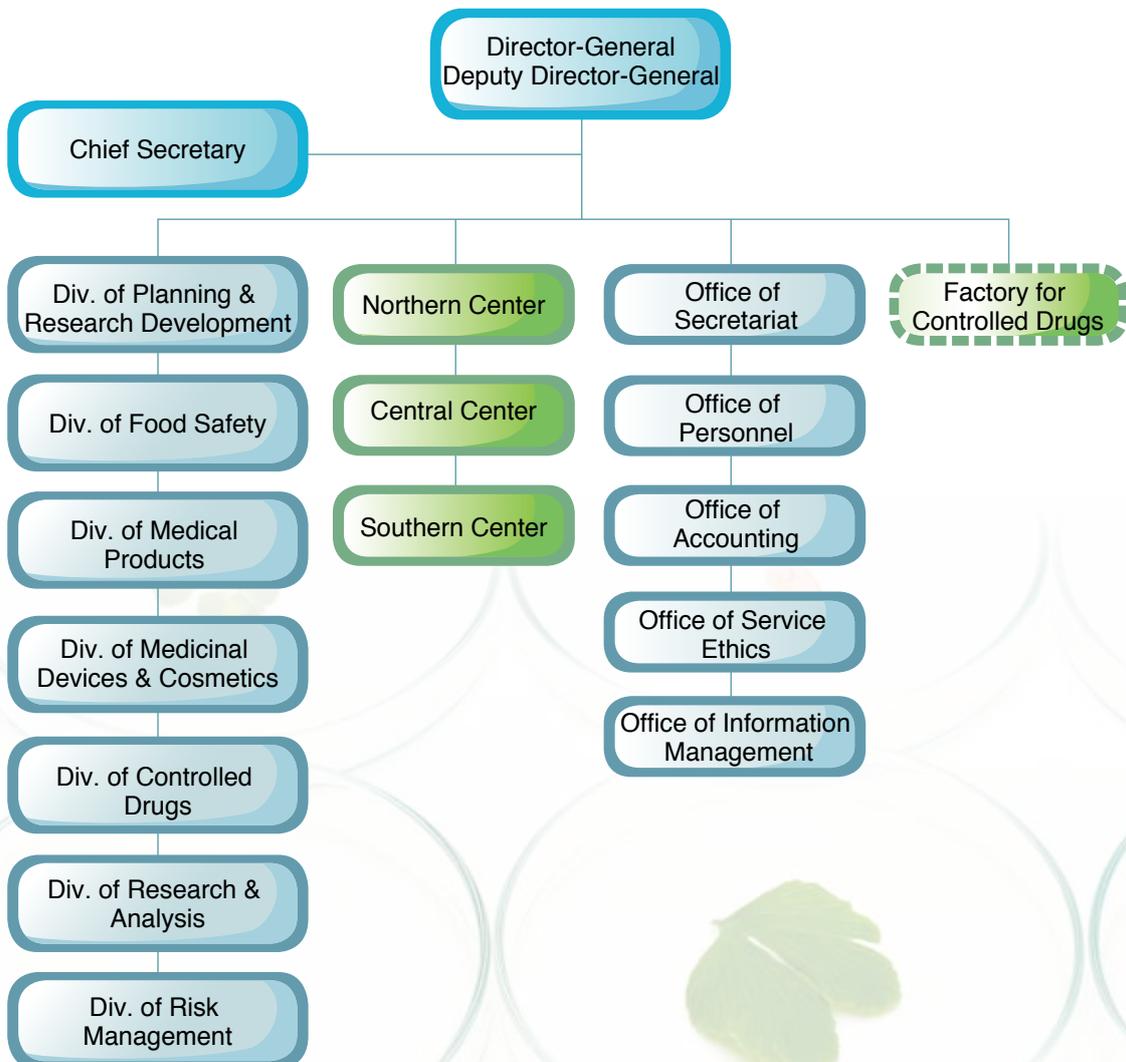
The TFDA

1. TFDA has different divisions - food, drug, medical devices & cosmetics and the controlled drugs promoting policy making and reinforcement. Risk management research and development are also included in our management realm. We have Center Regional Administration in northern, southern and central Taiwan, that are responsible for product quality control, risk factor management, distribution, monitoring and border control. Div. of Planning & Research Development is in charge of organizing planning and works closely with five subdivisions - the Office of

Secretariat, Personnel, Accounting, Service Ethics, and Information Management. We plan and build self-sufficient control drug manufacturing factory per needed. (Figure 1-1)

- The total number TFDA employees were 467 in 2010. In 2011, TFDA integrated 18 members from Bureau of Standards, Metrology and Inspection, the M.O.E.A. In 2013, The TFDA was expanded through organization reform, employment jumping to 527.

Fig. 1-1 Organization chart of ministry of health and welfare, food and drug administration



Section 3 Future Prospects

In order to create a consumer environment where the population can be confident in “Food” and “Drugs” are safe, in response to the trend in food and drug administration trends, the administration will use the “Five safes” actions as management objectives, through the all levels check in “Stability”, “Safe entry”, “Safe industry” and “Safe distribution”, achieve the ultimate goal of protecting the consumers’ “Safety”, descriptions of the five safes management are as follows:

1. To Secure the Gateway Control

Quality control for importing goods which includes the raw material based on rigid customs and border regulation.

2. To Secure the Management control

The risk factors management and classification system will promote quality and productivity of manufacturers. Moral ethnics are emphasized.

3. To Secure Persistent Management Control

The TFDA persistent works on advance innovation and renovation. We transform every challenge into a chance to grow. From a single product violation to a critical outbreak, we simultaneously revised our policy and management to meet the demand by developing new technology and renovating affiliated facilities. Persistent improvement has received global recognition.

4. To Secure the Effectiveness of Dynamic Management Control

Auditing and monitoring has contributed to information resources and manpower management, and food chain quality and safety controls.

5. To Secure Safety Controls

Promptly providing comprehensive information resources for consumers and opening new channels for communication will promote the awareness of the food safety concerns for everyone. As all the risk factors are revealed, consumer’s right will be protected. This is one of the TFDA’s ultimate goals.

There are 5 Solid Secure Actions to Affect Our Commitment

1. To keep update with the most current internationalized management regulations to invigorate the development of the biotechnology science and industry.
2. To reinforce the implement of food source management and to improve the quality of the food manufacturing.
3. To build up a solid Structure for drug safety network and to safeguard every consumer’s health and safety.
4. To extend market inspection and quality monitoring and to safeguard consumer benefits.
5. To actively involved in international organizations, to promote global food and drug cooperation and collaboration.



02

Food Management

- Food Laws and Regulations
- Food Product Source Management
- Food Product Safety Chain Monitoring
- Food Safety and Sanitation Management

Chapter 2 | Food Management

Food safety concerns public health and nation's image. Recent years, couple food - related incidents have placed a negative impact on our food industry. Credibility and reputation have been suffered dramatically. In order to restore and rebuild a healthy environment, TFDA works vigorously to establish a solid and contemporary management mechanism for risk factors, product source and distribution and monitoring system .TFDA stands behind the commitment to safeguard food safety for every individual.

Section 1 Food Laws and Regulations

Status

The “Act Governing Food Sanitation” was amended on June 19, 2013. On February 5, 2014 further amended as the “Act Governing Food Safety and Sanitation” to reinforce the self-management for food businesses, establish traceability system for tracing the source and tracking the flow, chart and impose harsh penalties in aid to achieve the goal to build a comprehensive food safety system.

Policy and Outcome

1. Establishing and Amending Food Sanitation Management Related Laws and Regulations

Comprehensive review of existing laws and regulations related to food safety and sanitation, through comprehensive amendments and additions to laws and regulations, improves food safety and sanitation system, as shown in Table 2-1.

2. Establishing and Amending the Relevant Regulations According to the Act

Research and analyze international regulations and standards trends, continue to improve our national applicable standards, until the end of 2013 the additions (revisions) for the following provisions: “Standards for Pesticide Residue Limits in Foods”. 349 kinds of pesticides, for 3,587 MRLs; “Standards for Veterinary Drug Residue Limits in Foods”.

124 kinds of veterinary drugs, 1,286 items residue tolerance; the cumulative total of published front list the Standards for Specification, Scope, Application and Limitation of Food Additives for 800 food additives; “Food Sanitation Standard” 37 items.

Table 2-1 Establishing and amending food sanitation management related laws and regulations in 2013

Date	Law/regulation name	Contents summary
June 19	Act Governing Food Sanitation	The total number was increased to 10 chapters and 60 provisions, where risk management for food safety, food import control, food testing, food examination and control are particularly regulated in their specific chapters. Health authorities are given more power and obligation. Reinforcing the responsibility of the food businesses and imposing harsh the fines and punishments for criminal violations are noted
October 2	Regulations Governing the Labeling of Prepackaged Beverages Claimed to Contain Fruit and/or Vegetable Juice	<ol style="list-style-type: none"> 1. Prepackaged beverages of which the packaging bears the names (product name included) and/or images (illustrations) of fruit and/or vegetable and sold for direct consumption. That shall be labeled explicitly declare the juice content percentage of fruit/vegetable on the front of the package 2. Nomenclature for Various Food Categories
November 19	Regulations Governing Traceability of Foods and Relevant Products	<ol style="list-style-type: none"> 1. Clearly specify the specification object for traceability system for food and related products and establish a record data range 2. Be able to effectively control the flow of irregular products in future food hygiene and safety incidents
November 20	Regulations Governing the Labeling of Prepackaged Frozen Food	<ol style="list-style-type: none"> 1. Prepackaged frozen food products being sold in the market shall be label with preservation methods and storage condition 2. In addition to comply with the foregoing provisions, prepackaged frozen food products may only serve after heating and cooking and being sold in the market shall be label with heating and cooking temperature and period
November 29	Regulations Governing the Labeling of Prepackaged Rice Thread	Prepackaged pure rice thread, rice thread, and mixed rice thread products sold in the market should bear a label indicating the rice content or similar information on the front-side of the product packaging
December 3	Regulations Governing the Registration of Food Businesses	Clearly stipulate the regulations governing the condition, procedure, and the matters to be registered for the application for registration and other matters to be complied. It will expedite the registration process and further enhance the capability of the authority regarding the license approval. In addition, it can be served as the audit references
December 5	Regulations Governing the Food Examination, Testing and Control Measures	To ensure all food and related products including food additives, food utensils, food containers, food packages and food detergents comply with the Act Governing Food Sanitation and to provide measures for the authority to perform inspection, sampling, testing and quality control management with consistency



3. Guidelines Setting for Manufacturing Procedures

Set operational guidelines for the industry to follow, control from the production source, in 2013 the “Guidelines for labeling of ready-to-eat fresh food” and the “Guidelines for reducing polycyclic aromatic hydrocarbons content in foods” were completed.

4. Review Management Mechanism for Registered Food

In accordance with the provisions of Act Governing Food Sanitation and the Health Food Control Act, one of the foods and food additives designated by the central competent authority in a public announcement shall be manufactured processed, or imported without filing product registration with and procuring a license from the central competent authority.

In 2013, totally 2, 193 licenses were issued for all categories, cumulatively were issued at the end of 2013 15,915 licenses, as shown in Table 2-2.

Table 2-2 Registration cases reviewed in 2013

Category	Licenses issued in 2013	Cumulative licenses issued at the end of 2013
Health Food	33	276
Genetically modified (GMO) soybean and corn	9	63
Food Additives	674	5,494
Imported Foods in Tablet or Capsule Form	1,134	8,157
Domestic Vitamin Products in Tablet or Capsule Form	265	1,411
Infant and follow-up formula	34	212
Formula for Certain Disease	37	178
Vacuum-Packed Ready to Eat Soybean Foods	7	124
Total	2,193	15,915



Section 2 Food Product Source Management

Status

The food safety management involves serial of intricate process. In accordance with TFDA regulations, food businesses are trained to be self-management and to establish a food safety management task force from raw materials to the final products. Emphasizing the risk management and reinforcing the import food and food additive management have lowered the incident rate.

Policy and Outcome

1. Promote “Food Safety Control System”

All the food businesses must meet the Regulation on Good Hygiene Practice (GHP) for Food”, while the Hazard Analysis and Critical Control Points (HACCP) continues to be implemented for high-risk food; in 2013, four categories, including seafood processing industry, meat processing industry, box meal factory and dairy product processing industry, have been announced and specified to be included in the scope of enforcement and implementation of HACCP compliance inspection work (Table 2-3).

Table 2-3 Number of cases that completed HACCP compliance audits in 2013

Product type	Period (years)	Numbers inspected	Issues completed in 2013
Seafood Processing industry	2004~2013	194	Implemented total of 102 cases of HACCP tracking and counseling
Meat Processing industry	2008~2013	222	Implemented at least 105 cases of HACCP tracking and counseling
Dairy product Processing industry)	2011~2013	50	Implemented GHP and HACCP on a total of 52 cases and 123 production lines
Box meal factory)	2013	195	Implementation HACCP and completion of the compliance audit, for a total of 188 cases



2. Imported Food and Related Product Inspections

- (1) All the Imported food and related products must be inspected at the border inspection and must comply with regulations to enter.
- (2) In 2013, imported food and related product inspections on borders were completed for a total of 514,710 batches, of which 38,460 were examined (7.47%). Approximately 1.45% failed to meet regulations and was either withdrawn or destroyed (Table 2-4).

Table 2-4 Common non compliant food products among border inspection applications

Rank	Product category	Inspection application batch number	Test batch number	Compliance batch number and failure rate (%)	Non compliant inspection items	Common food items	Country
1	Fruit	23,566	2,321	104 (4.48)	Pesticide residue	Strawberries, fresh peaches, satsuma mandarines, etc.	Japan, USA, etc.
2	Vegetables	21,209	1,647	60 (3.64)	Pesticide residue	Chili pepper and bell pepper fruits, pea pods, spinach, shiso leaves, asparagus	Mainland China, Japan, Thailand and USA, etc.
3	Tea	7,168	1,669	55 (3.30)	Pesticide residue	Green tea, black tea, macha, etc	Japan, Vietnam, etc.
4	Traditional Chinese medicines also used as food	2,147	565	37 (6.55)	Pesticide residue	Woffberry, snow fungus, haw flakes, etc	Mainland China, etc.
5	Crustacean fisheries	14,195	1,010	36 (3.56)	Heavy metals	Live mud crabs, lobsters, other crab species, etc.	Indonesia, Philippine, USA, etc.
6	Spices	2,285	250	36 (14.40)	Pesticide residue	Chili powder, Sichuan pepper powder, etc.	India, Thailand, Mainland China, etc.

- (3) After Japan's Fukushima nuclear disaster , import food inspection application from the counties of Fukushima, Ibaraki, Tochigi, Gunma, and Chiba have been temporarily suspended. From March 20, 2011, the radiation control of import food from Japan were reinforced. A total of 13,985 cases were tested in 2013 and found compliant.
- (4) Under the "Three Controls Five Verifications" import beef managing policy, in 2013, a total of 13,300 batches of beef products had applied for inspection of which 2,819 were tested.

3. Management of Food Additives

- (1) Establish internationally harmonized food additive categories

Continued to collect the Codex Alimentarius Commission (CAC) and specifications from the United States, European Union, Japan and other countries, reorganize Taiwan's food additives classification system, and give every food additive category a detailed definition and function presentation, at the same time review whether the classification for nutritional additives, sanitizing agents and others is appropriate, and assess if there is need to define another management mode.

- (2) Implement food additives source management

On June, 20, 2013, the third meeting for the Food Safety Collaborative Department conference reconfirmed the importance of teamwork. The Ministry of Health and Welfare, Ministry of Economic Affairs, and Ministry of Finance to work as a solid team to against cross contamination food additive and chemicals for non-food applications. We used three strategies for management. Involved import manufacturing and sale sectors.

- (3) Mandatory registration

- a. Food businesses belong to a category and scale designated by the central competent authority in a public announcement may commence its business operation only after applying for registration. Particularly, TFDA mandatorily reinforced the registration of food additive businesses engaging in the manufacture, import or sale of single substance or combination of substance of food additives. In the near future, other food businesses will be required to apply for mandatory.
- b. Starting from 2011, TFDA encouraged food additive businesses apply for voluntary registration. The website for Regulations Governing the Registration of Food Businesses Information System website [login URL: <http://fadenbook.fda.gov.tw/> (transliteration for "must register")] was established. By the end of 2013, there were 669 food additive businesses, importer and vendors signed in which involved a total of 27,712 product items.

Section 3 Food Product Safety Chain Monitoring

Status

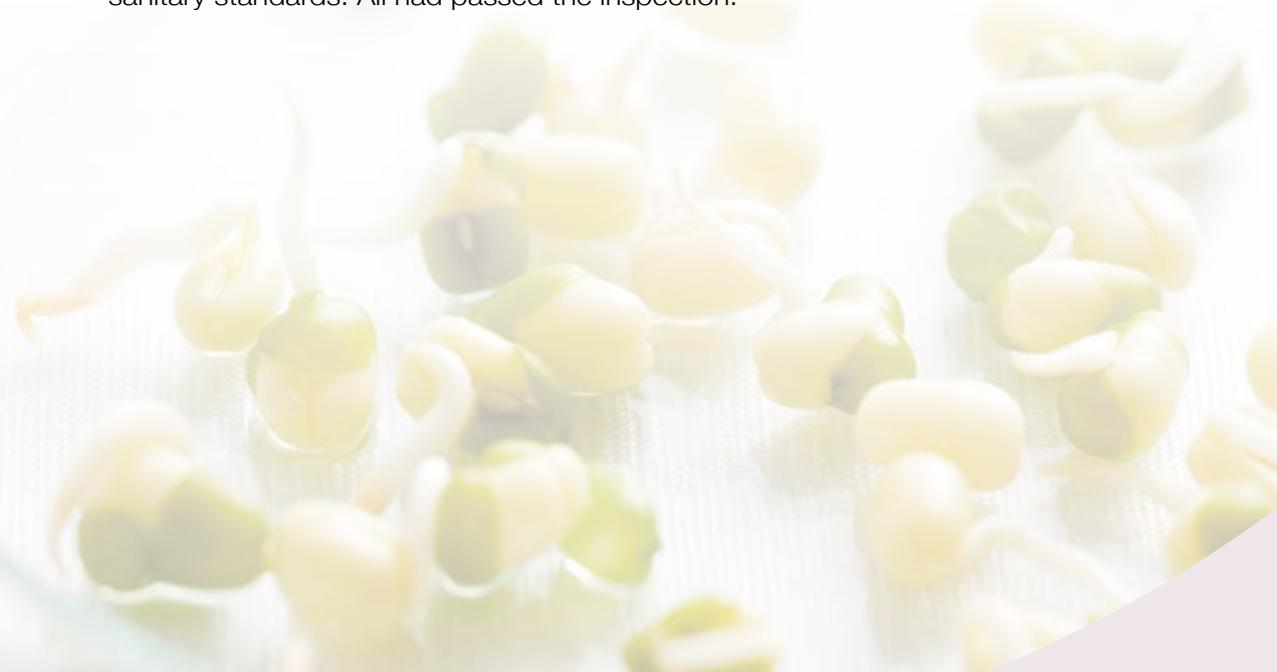
TFDA provides current informative resources for food compliance standards by building network between central and local authorities. Simultaneously updated information will strengthen the post marketing monitoring and keep inspection record current. Hence, every consumer's benefits will be safeguarded.

Policy and Outcome

1. The Interagency Team of Taiwan Government for Food Safety Inspection and Enforcement

In October of 2013, as the Executive Yuan food safety meeting, collaboration for food safety audit and inspection group was formed, involving the local and central authorities. The inspection focus on the food oil, dairy, rice, food for traditional festivals and important daily products. TFDA conducted inspections with focusing points from the food source or the food manufactures. The disqualified products information were disclosed and handled in accordance with regulations for maintaining public food safety.

In December, 2013, we had performed inspection for the dairy products with the collaboration with Council of Agriculture under the Executive Yuan, Ministry of Economic Affairs and local health bureaus, a total of 17 dairy manufacturers including 20 factories were inspected with pinpointing sources of fresh milk, food additives, labeling and the environment and sanitary conditions of the factories. 20 cases of raw milk and 46 cases of dairy products were tested for veterinary drug residues and dairy sanitary standards. All had passed the inspection.



2. On-Site Inspection of Registered Foods

In 2013, a total of 140 on-site inspections were performed in factories and vendors with no major violation; inspection results are as shown in Table 2-5.

Table 2-5 On-site inspection of registered foods

Category	Number of checks	Check results
Health food manufacturing plants	20	No major non-compliance has occurred, defects in Good Manufacturing Practice operational specifications for health food plants were corrected during a second review.
Domestic vitamins in tablet and capsules form manufacturing plants	40	No major non-compliance has occurred, defects in GHP were corrected during a second review.
Food additives manufacturing and vendors	80	No major non-compliance has occurred, defects in GHP were corrected during a second review.

3. Post-Market Surveillance of Food Products

- (1) Planning for food inspection mechanism and surveillance system, supervising the implementation of inspection and sampling test of marketed foods by local health authorities, to ensure food safety and quality.
- (2) Under the collaboration program, TFDA and local Health Bureaus had conducted inspections which covered various categories from food labeling, food sampling test, high risk food manufacturer, daylily farmers and wholesaler, campus and hotel food's inspection and special projects of starch, soy sauce and food oil on food safety incidences.
- (3) Collaborating with local Health Bureaus to perform post-market food surveillance plan, through strengthening checks on food in order to meet health standards. A total of 4,051 cases were surveyed in 2013, results are shown in Table 2-6.

4. Continue the Expansion of the Function of "PMDS, Product Management Distribution System"

- (1) To enhance the efficiency on food distribution audit, and strengthen the post-market management, PMDS express query system and related digital handheld processor query system will be continually expanded and integrated with the current information system to establish prompt and friendly PMDS inquiry service environment.
- (2) Providing the capability of the first line inspectors to access quickly the current



Table 2-6 Post-market food surveillance results in 2013

Surveillance item	Results			
	Total	Conform	No conform	(%)Conformity rate
Monitoring of pesticide residues in agricultural products from markets and packing firms	2,340	2,080	260	88.89
Determination of veterinary drug residues in foods	736	703	33	95.51
Heavy metals (Cadmium, Mercury and Lead) surveillance in rice	202	202	0	100.0
Mycotoxin surveillance in commercial foodstuffs	421	412	9	97.86
Monitoring of heavy metal contents in fruits and vegetables from markets	151	151	0	100.0
Pesticides residues surveillance in rice	201	201	0	100.0

Note: cases noncompliant after inspection are all investigated and processed by local health authorities according to the law

information across the borderline of local county and enhance the effectiveness of post-market management. Strengthening the collection of risk information through studies vertically and horizontally and adoption of quick responding policy to solve the problem from the source end.

- (3) The operations of the following systems as “Food Sanitation Database System”, “Food Poisoning Database System”, “Food Registration Database System”, “Imported Food Border Inspection Automated Database System”, “Food Safety Control System Database”, “International Food Safety Rapid Notification System” and the “ROC chef Certificates Information Management System” were integrated. Moreover, the “Health Foods plant inspection” and “On-site audit for imported food declaration and discharge” functions were established. The details about planning the “Overseas source factory inspection for imported food” function were initiated.
- (4) In 2013, the system functions were continued to expand. 6 new auditing capacities were added (Table 2-7). The digital connection with the Infectious Disease Announce System of Center for Disease Control (CDC) promotes the accomplishment for local health bureaus. A well-built network had enhanced the prompt information accessibility and accuracy.

Table 2-7 Newly added 2013 check function

No.	New function
1	Food additives factories inspection
2	Factory inspection for domestic capsule and tablet form food factories
3	Audit on marketing specifications for infant formula and complementary food formula for older infants
4	Audit on special nutritional food for patients
5	Labeling audit on imported capsule and tablet form foods
6	Overseas source audit for imported food

Section 4 Food Safety and Sanitation Management

Status

Restaurant sanitary management involved from raw materials' selection, utensils hygiene, environment cleanliness and staff hygiene concept training. All above are closely related. Therefore, emphasizing the hygiene and safety training for food servers, educating and encouraging the owners to build up a self-management program and inspiring the participation of professional technicians will promote the restaurant owner to effectively follow the HACCP regulations.

Policy Outcome

1. Food Service Management

(1) Managing food service hygiene awards

- a. The food service hygiene rating system has been built since 2010. It was a team effort and designed by the local health authorities and professional scholars. The on-site inspection is based on four aspects including "personnel, ingredients, environment and utensils". After the on-site assessments, all the food service businesses qualified with GHP regulations will be classified either as "excellent" or as "good" ratings.
- b. To encourage all the restaurants to meet the compliance of GHP and to continue to monitor a self-motivated sanitation management, local Health Bureaus will announce and disclose the rating results, and reward the excellent and good rating food service businesses with the "food hygiene rating assessment "excellent" or "good" marks".
- c. In 2013, in order to amplify the promotion of sanitary rating assessment for breakfast bars, movies named as the "Hygiene Operational Guidelines Video for Breakfast

staff” was produced to demonstrate and to emphasize the importance of self-motivated sanitary management. In 2013, a total of 3,456 food service businesses passed the food service rating assessment from local Health Bureaus, of which 1,958 owners had shared their concerns toward self-motivated management.

- (2) It is mandatory for the entire 189 box meal factory to follow the regulations of HACCP. TFDA encourages all the restaurant owners to meet the HACCP’s compliance. In 2013, consulting services were provided for the central kitchen workers and owners. Voluntary HACCP assessment program in food service industry is operated to encourage all the food service businesses to meet the HACCP regulations and to pass the certification requirements.
- (3) ROC Chef certificate informatics system
 - a. TFDA has established a new version of “ROC chef certificates informatics system” and provided chefs with trainings. In 2013 restaurant hygiene education was added into the training program which also offering HACCP training. And the credentials can be credited through high school and college continues education programs. There are eight continuing educations and seminars held in December of 2013.
 - b. At the end of 2013, a total of 235 facilities become our program’s providers. In order to protect the personal information and privacy, each login requires each individual’s digital citizen certificate. We feel honor that our system was awarded as the 7th outstanding MOICA application award in 2013.
 - c. A total of 2,000 restaurant sanitary training workshops were held under our program from 2011 to 2013, while the attendance rate is more than 180,000 people. TFDA continues to revise and to update our programs and encourages food and restaurant workers to attend all the continuing educations.
- (4) Since 2009, TFDA has held “FDA outstanding chef commendations” meeting annually. We believe that education will keep the chefs updated with all the current sanitary information and put health concept first while they handle all the food-related process. In 2013, a total of 63 chefs have been commended for their outstanding performance. 8 hours of continuing educations is required annually in order to renew the license.
- (5) Promotion of food technologist (certification)
 - a. In 2013, the Ministry of Health and Welfare, recommended the Ministry of Examination Yuan to set up the “Senior examinations of professional and technical personnel for Food technologist” as a specialty license test. In order to promote food businesses to comply with HACCP regulations and to build up competent specialists for every profession.

- b. From 2011 to 2013, a total of 935 food technologists had passed the license tests, and from 1990 to 2013 a total of 1,520 food technologists were employed by the food industry.
- c. TFDA has hosted outreach and training programs for food technologist and encourage them to contribute their professional expertise to the food industry. In addition, hiring food technologist in the food industry will help the owner updated with HACCP regulations and improve the operation quality.

(6) Foodborne outbreak

a. Foodborne outbreak

In 2013, there were 409 outbreaks of foodborne cases, while vehicles of 71 cases are identified. Schools and cafeteria hold the high rate from the statistical analysis (Fig. 2-1).The most common etiology is bacteria contamination (Fig. 2-2). The major reason was improper food handling due to poor hygiene conception cross-contamination during food process and improper food storage condition and environment (for statistics on food outbreak please refer to Appendix I annex table 1).

b. Foodborne outbreak prevention

TFDA has set up a special foodborne outbreak website for public education purpose. Furthermore, TFDA had collected all the relevant statistic data and information and published the “Annual report of foodborne outbreak” report. All the information is open for the public.

Fig. 2-1 2013 Percentage of foodborne outbreaks-associated locations

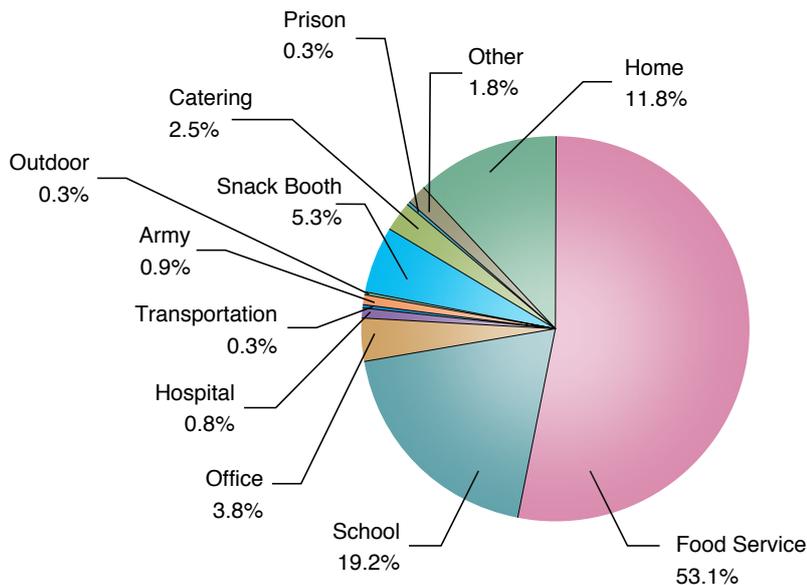
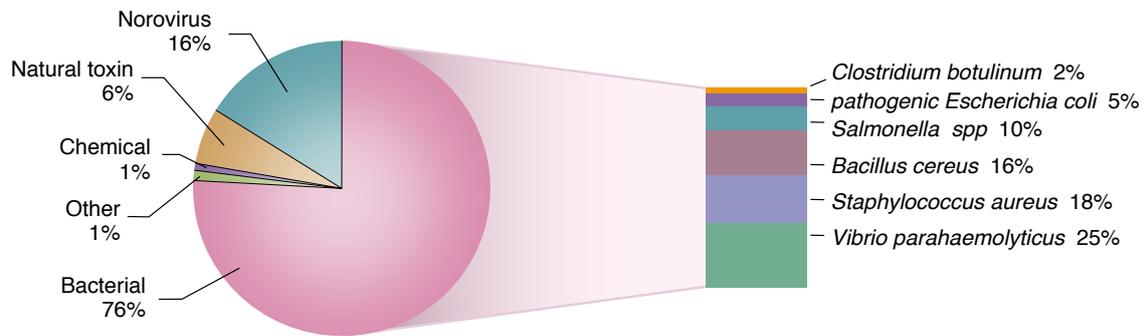


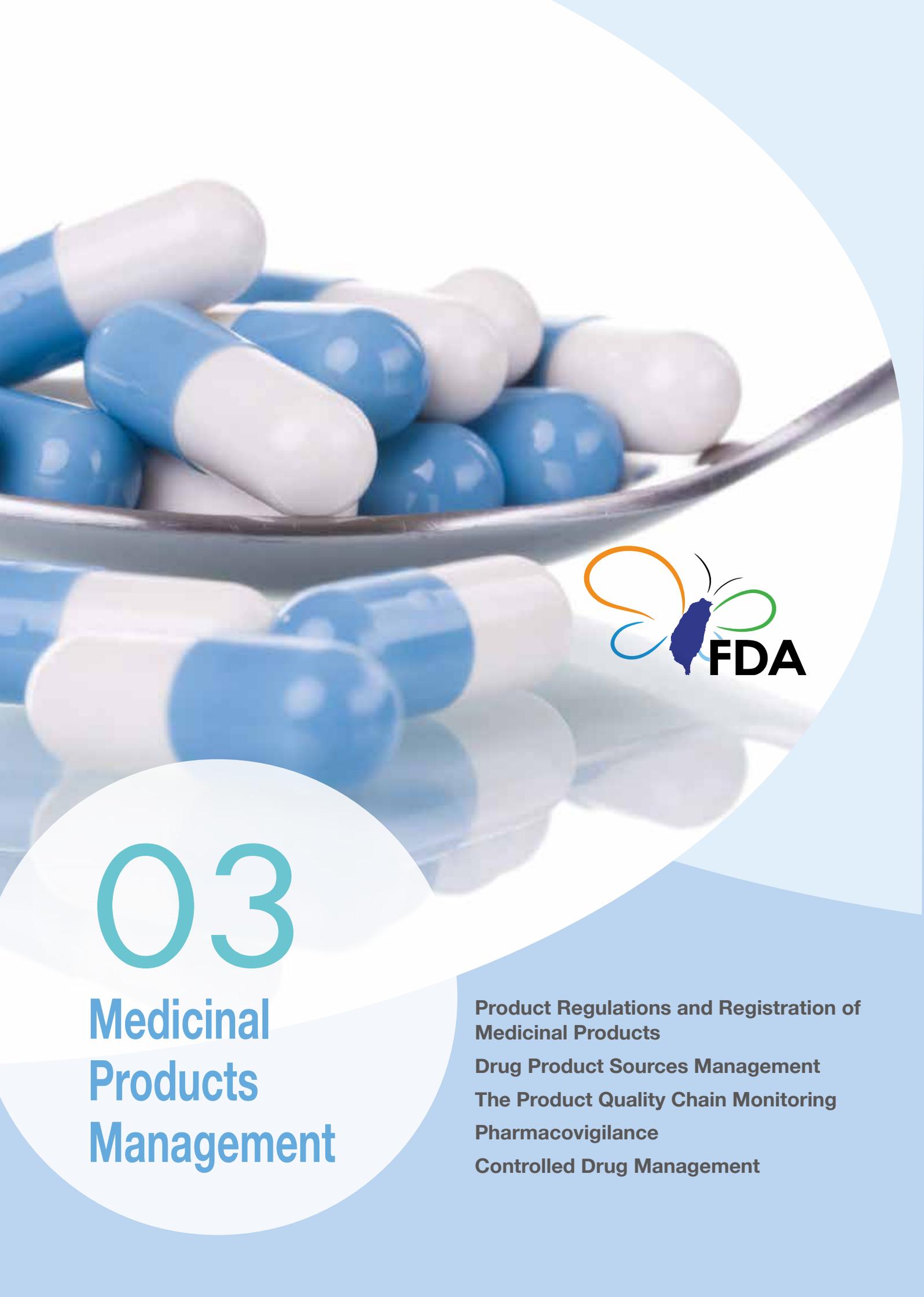
Fig. 2-2 Percentage of foodborne outbreaks cases etiology agents in 2010-2013



2. Food Safety and Sanitary Education and Counseling Services

- (1) In order to highlight the importance of the “Regulations Governing the Registration of Food Businesses”, TFDA has hosted 20 seminars all over the country, and invite food-related businesses (including food manufactures, importers, food service businesses, food additive businesses and plastic food utensil container and packaging businesses) to participate and to support the implementation.
- (2) To improve the professional skills of inspectors, in 2013, TFDA had reinforced the “Expanded food quality and safety surveillance plan” which provided 11 different kinds of training programs (24 classes with a total of 477 participants), through basic training, on-site visits and inspections, the professional expertise was sharpened.
- (3) In order to enhance the foodborne outbreak investigation and case handling capability for the health bureau authorities, TFDA had hosted the “Foodborne outbreak investigations practices basic and advanced classes” in 2013, with 2 different classes and 72 participants.





03

Medicinal Products Management

Product Regulations and Registration of Medicinal Products

Drug Product Sources Management

The Product Quality Chain Monitoring

Pharmacovigilance

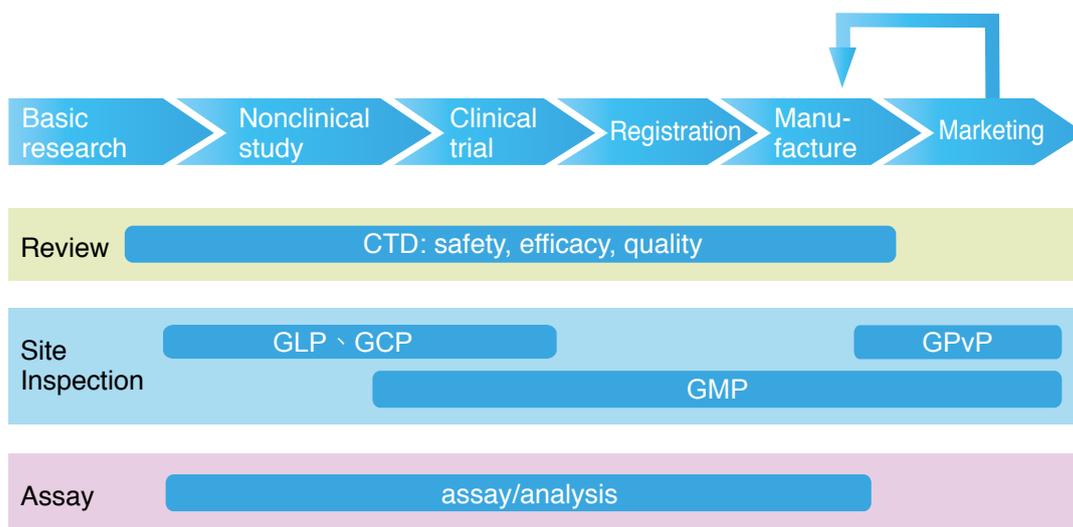
Controlled Drug Management

Chapter 3 | Medicinal Products Management

Different from consumer goods, medicinal products are highly regulated. In order to ensure public health, the regulations of medicinal products need to be harmonized with international standards, as well as simplified and integrated in review process. The source and distribution of medicinal products (including active pharmaceutical ingredients) have to be regulated. Post-marketing surveillance is conducted to ensure the quality and safety of medicinal products. In addition, investigation of illegal drugs and controlled drug managements are taken to protect public safety.

Moreover, a product lifecycle management system is established, including pre-marketing approval and post-marketing surveillance system. The requirements of pharmaceutical registration include development information, results of nonclinical studies, clinical trials, stability tests, and chemical manufacture control documents with common technical dossier. Inspections of GXP and post-marketing monitoring are also executed to achieve comprehensive drug life cycle requirements (Fig. 3-1).

Fig. 3-1 Drug life cycle



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

- Polices and Organization
- Food Management
- Medicinal Products Management
- Medical Devices Management
- Cosmetics Management
- Risk Assessment and Risk Management
- The National Laboratory
- Laboratory Network
- Research Outcomes
- International Cooperation and Cross-Strait Exchanges
- Consumer Protection and Advocacy
- Major Events
- Appendix

Section 1 Product Regulations and Registration of Medicinal Products

Policy and Outcome

1. Comprehensive Standardized Regulation

Table 3-1 Revisions and additions to regulations governing the management of pharmaceutical affairs, 2013

Publication date	Regulation/specification	Summary
January 31	Regulations for Bioavailability and Bioequivalence Studies	Amendments of article 15, 17 and 21, which included the cross-over design of BA/BE studies, the data exclusion criteria, and the description of using basket/paddle methods during dissolution tests
February 23	Guidance for Investigational New Drug Applications	Any new drug clinical trial application must fulfill the current requirement.
March 11	Revision for the set up standard for new pharmaceutical manufacturing factory, Amendment for Standards for Medicament Factory Establishments and Pharmaceutical Good Manufacturing Practice Regulations	Combine Part 3 for "Good Manufacturing Practices for Pharmaceuticals" and Part 4 as "Good Manufacturing Practices for Medical Devices" of the set up standard for new pharmaceutical manufacturing factory, and then transferred without modification to under the Part 2 and 3 sections for "the Pharmaceutical Good Manufacturing Practice Regulations"
April 17	Guideline for Review and Approval of Botanical Drug Products	The application and approval guidelines for the botanical new drug products. A separate regulation was issued to meet the distinctive properties of the botanical drug products
April 18	Guideline for Review and Approval of new chemical entities which have been approved for over 10 years in the 10 advanced countries	This guideline lists the requirement of technical document for marketing approval of drugs which have been approved in the 10 advanced countries for over 10 years, including new chemical entity drug in Taiwan. There are plenty clinical information for those drugs, the publicly available information is accepted to substitute for partial submission document
May 22	Announcement the Part 2, titled as "Guide to Good Manufacturing Practice for Medicinal Products (Part II)"	Provide GMP reference for manufacturers of Active Pharmaceutical Ingredients, in Chinese and English for the "Good Drug Manufacturers Guidelines"
May 29	Guideline for the Nonclinical Pharmacology/Toxicology Studies for Medicinal Products Applications	Removing outdated standards for physiological values of laboratory animals and specific pathogen-free experimental animals



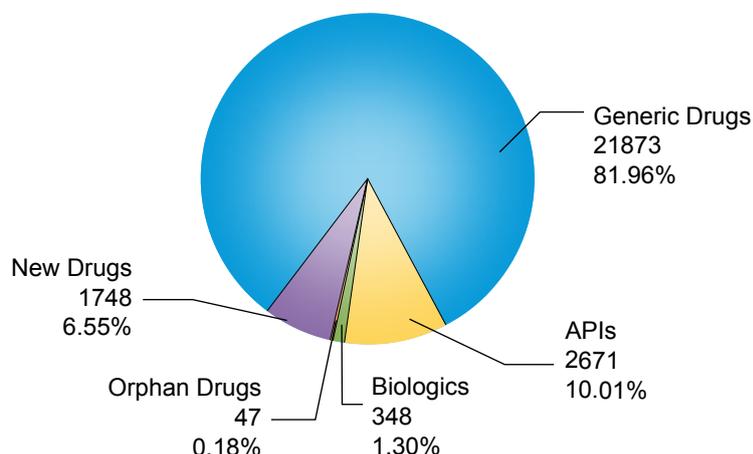
Publication date	Regulation/specification	Summary
June 25	Amendment for the Article 21 in the “Pharmaceutical Good Manufacturing Practice Regulations”	Excluding living animals for Pyrogen Tests is reinforced for Medical esthetic concerns
July 26	Regulations for Registration of Medicinal Products	Amendments for the articles 10, 46 and 70. Revise the rule for the pyrogen tests preferred nonliving animal descriptions, and the bioequivalence data requirements of immediate/modified-release formulations for post-market changes
July 30	Revise Article 3 of “Pharmaceutical Good Manufacturing Practice Regulations”	<ol style="list-style-type: none"> 1. In coordination with the revision of Article 57 of the Pharmaceutical Affairs Act, the added storage and distribution should be conform to the provision of this guideline 2. Also, stipulate that operations and regulations of manufacturing with reference to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S)
August 14	Regulation for Accelerated Approval of New Medicinal Products	Created a mechanism for the express purpose of meeting pressing medical treatment needs of citizens. Used empirical evidence to select surrogate endpoints which could reduce the R&D timetable of medicinal products and allow products to reach market earlier
September 4	Guideline for Review and Approval of Biosimilar Monoclonal Antibodies	A new guideline for the biological similarity monoclonal antibody drugs for the experimental and technical information requirements for approval
September 25	The announcement regarding the method and time frame on good manufacturing practice for “the manufacturers of Active Pharmaceutical Ingredients”	Set up the full GMP compliant regulations and schedule in regards of the domestic manufacturing and importing production plants of western drug APIs

- Polices and Organization
- Food Management
- Medical Products Management
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2. Registration of Medicinal Products

- (1) TFDA follows the global standard that stresses on the importance of the Safety, Efficacy and Quality, and TFDA also implements the “Common Technical Document (CTD)” for drug approval system.
- (2) As of 2013, TFDA had issued a total of 26,687 pharmaceutical licenses, which included 2,671 (10%) active pharmaceutical ingredients and 24,016 (90%) pharmaceutical finished products (generic drugs, new drugs, biologics and orphan drugs).(Fig. 3-2)

Fig. 3-2 Statistics on pharmaceutical licenses (2013)



3. Clinical Trial and Management

- (1) By revising the “Guidance for Investigational New Drug Applications” and the establishment of “Centralized Clinical Trial Ethics Review (central IRB)” mechanism, TFDA dedicates in accelerating the IND review process.
- (2) In 2013, TFDA received a total of 258 new IND applications and 1,958 IND amendments. The growth rate of submission is 1.4 times more than 2012.
- (3) The conduction of clinical trials should follow the requirement of “Good Clinical Practice (GCP)”, maintain the data integrity and quality base on the welfare of subjects. TFDA reinforced GCP inspection by initiating the inspection on clinical trial conducting 3 contract research organizations (CRO) since 2013.
- (4) In vivo bioavailability/bioequivalence and in vitro dissolution studies are important methods for demonstrating therapeutic equivalence between patent and generic drugs. Until the end of 2013, there were 1,980 approved medicinal products had conducted BA/BE studies in Taiwan, and 1,495 of them were domestic products.

4. Innovation of New Drug Review and Approval Mechanism

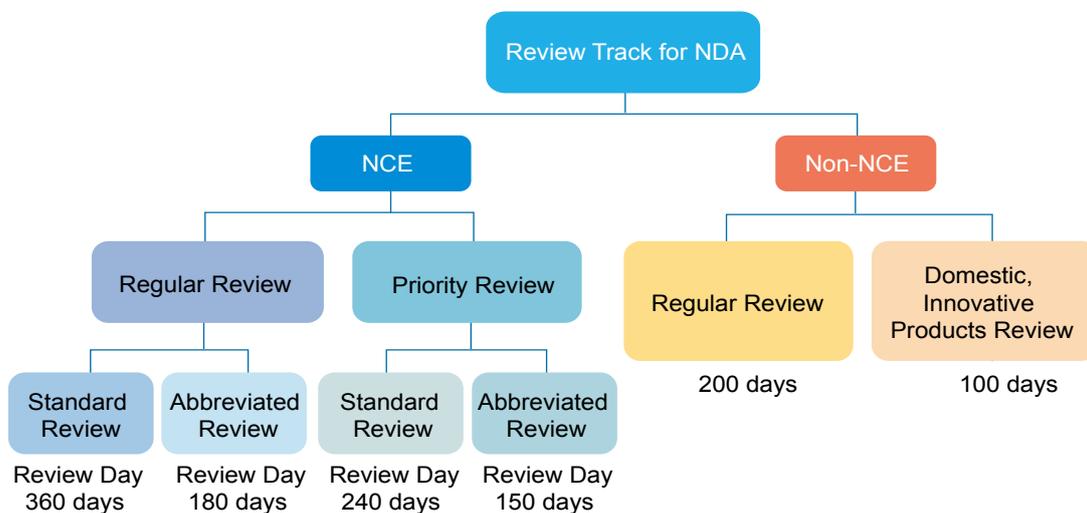
(1) Integrating and simplifying the review mechanism

An integrated, simplified and transparent review system was built to expedite the review process (Fig. 3-3). In 2013, a total of 157 new drug applications were reviewed, which include 26 items were made in Taiwan and 131 imported items. A total of 122 items were approved.

(2) Innovation of new drug review mechanism

For the purposes of expedition for the approval and review process and prioritizing the approval process, TFDA built up “abbreviated review system”, “priority review system” and “domestic innovative products evaluation program” for new drug applications, which individually cut down by “one-half”, “one-third” and “one-half” review time. (Fig. 3-3). In 2013, the average time of priority review system was 228 days, which is better than some ICH memberships, like USA, European and Japan etc. For example, Afatinib, the biomarker targeting lung cancer medication, was the first approved by TFDA in the world.

Fig. 3-3 Review track for NDA



NCE: New Chemical Entity

Priority Review NCE+ Serious Disease+ Unmet Medical Needs

Abbreviated Review NCE+US FDA & EMA Approved + No Ethnic Difference & Same Indication

5. Promoting Pharmaceutical Project Professional Consultation

(1) Under the Executive Yuan’s “Taiwan Biotech Industrialization Take-off Action Plan”, TFDA emphasized the importance of professional consultation. A pharmaceutical consultation mechanism is built to work with all the manufacturers in Taiwan.

- (2) By complying with four indexes, Innovative, Contributive, Effective and Satisfactory stages as screening criterion, TFDA expedites the process to support manufacturers to successfully complete clinical trials until the final drug approval.
- (3) In 2013, TFDA helped 27 projects to meet R&D milestones, which comprise 2 new drug approvals, 3 new drug applications, 7 each of phase II and phase III clinical trials, and 4 phase I clinical trials. Furthermore, TFDA conducted more than 18 consulting meetings, offering customized advices suited to their current product development and research status.

Section 2 Drug Product Sources Management

Status

In 1982, TFDA had promoted “Good Manufacturing Practice, GMP”. In 1995, TFDA reinforced “current Good Manufacturing Practices, cGMP”, and simultaneously correspondent with the dynamics of the global regulations. Furthermore, in 2007 we announced the GMP standard of the “Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Schemes, PIC/S”. We set up December 31, 2014 as a due date to complete the implementation. Ultimately, the made in Taiwan manufacturers will be globally recognized and promoted in the international markets.

Besides pharmaceutical manufacturers, manufacturers of medicinal gases and active pharmaceutical ingredients were also included in the management of GMP for medicinal products. TFDA had constantly promoted Good Distribution Practice, GDP, guidelines to encompass the quality management of the whole supply chain with fortified infrastructure and supervision. TFDA devotes to safeguarding the public with rigorous and comprehensive GMP/GDP management.

Policy and Outcome

1. Complete the Complying Process of PIC/S GMP for All the Pharmaceutical Manufacturers

- (1) Promotion of PIC/S GMP
 - a. Every 2 to 4 years, TFDA will conduct a follow-up GMP inspection to reinforce the supervision of the quality management of medicinal products.
 - b. TFDA had set December 31, 2014 as a due date for all the pharmaceutical manufacturers to meet the requirements of PIC/S GMP. Furthermore, TFDA had made an announcement that any pharmaceutical manufacturer noncompliant with PIC/S GMP after the time limit will be forced to cease the manufacturing of medicinal products (Table 3-2).



Table 3-2 Status of GMP compliance of domestic and foreign pharmaceutical manufacturers

Year	No. of domestic western pharmaceutical manufacturers compliant with GMP	No. of domestic western pharmaceutical manufacturers compliant with PIC/S GMP	No. of foreign western pharmaceutical manufacturers compliant with GMP after on-site inspection
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

c. A total of 57 domestic pharmaceutical manufacturers had complied with PIC/S GMP Guide by the end of December 2013. This positive impact promotes the cooperation among international pharmaceutical trading business and contact manufacturing. The export of the medicinal products had increased double in recent four years.

(2) The implementation of PIC/S GMP for the medicinal gases manufacturers

a. TFDA had helped the medicinal gases manufacturers to meet the requirements of PIC/S GMP Guide since 2002. The scope covered the fields of materials supply, production control, quality control, quality management system as well as the prevention of cross contamination to assure the quality of medicinal gases.

b. A total of 28 medicinal gases manufacturers had met the requirements of PIC/S GMP Guide on December 31, 2013, the due date of the implementation of PIC/S GMP on medicinal gases manufacturers.

2. Product Sources Management for Pharmaceutical Manufacturers

(1) “Drug Master File (DMF)” polity was established to fortify the active pharmaceutical ingredients (API) management. From October 2009 to the end of 2013, the total number of DMF applications were 1,455; 871 of them were approved (59.86 % approved).

(2) TFDA had adopted PIC/S GMP Guide for active pharmaceutical ingredients. Furthermore, on September 25, 2013, TFDA had announced API manufacturers should comply with PIC/S GMP Guide by December 31, 2015. By the end of December, 2013, there were 146 API items compliant with PIC/S GMP Guide which were manufactured by 21 API manufacturers.

- (3) On May, 22, 2013, TFDA made an announcement regarding to the adoption of PIC/S GMP Guide for the active pharmaceutical ingredients manufacturers. Moreover, TFDA had promoted the use of GMP raw materials and API DMF system. Fortifying the management of product sources will safeguard the quality of medication.

Section 3 The Product Quality Chain Monitoring

Status

Many uncertain factors, such as drug manufacturing changes, transportation and storage environmental impact, may affect the quality of drugs. So the drug good distribution practice (GDP) is promoted to ensure the drugs in storage, transport and distribution process, which quality and packaging integrity are still maintained. Establishing smooth post-marketing quality chain includes the establishment of a reporting system, active monitoring global drug product recalls and alerts, risk assessment mechanism to select items, integration of the local health office resources, and implementation of drug quality monitoring. In addition, cracking down illegal drugs and advertisement is one of important projects.

Policy and Outcome

1. Quality Control and Monitoring of Medicinal Products

- (1) Medicinal products quality defects reporting system

The reporting system of quality defects for medicinal products was established in 2004. In 2013, a total of 831 quality defects were reported, including 144 high risk quality defects reports, and 18 cases were recalled.

- (2) Outcomes for the post market surveillance

In accordance with the health drug acts, random testing were conducted by the health bureau under the concerns for the high risks factor to promote the quality control. In 2013, a total of 343 random testing were performed which including 6 violation and 56 nonviolent items. The violated items were sent back to the manufacturers under the reinforcement of the local health bureaus (Table 3-3).

- (3) Monitoring global drug product recalls and alerts

Foreign drug recalls information announced by other competent authorities are monitored daily to prevent the recalled batches of the product from being distributed in Taiwan. In year 2013, there were total of 702 recalls and alerts monitored, and 3 imported drug products were identified defective and voluntarily recalled by market authorization holder.



Table 3-3 Results of drug quality monitoring tests in 2013

Project name	Total cases	Conforming cases	Nonconforming cases	Not determined
Surveillance on the quality of anticoagulant, corticosteroid and aAntibiotic preparations in Taiwan	85	84	1 ^a	
Investigation of microbial limit for rectal drug	88	32		56 ^b
Post-market surveillance of rotavirus vaccine in Taiwan	26	26		
Investigation on the contaminations in Chinese herbal preparations	144	139	5 ^c	
Total	343	281	6	56

Note:

- a: failed specimen was a steroid preparation which dissolution test failed to meet specifications**
- b: not determined specimen had pending original specifications, therefore test results were not judged, and provided only for background checks and reference**
- c: failed specimens were 2 cases of total aerobic microbial counts, 1 case of aflatoxin content, 1 case of total ash and acid insoluble ash and 1 case of a total ash that failed to meet specifications**

(4) Lot release for biological products

In 2013, 389 lots of biological products were applied for batch release in Taiwan. Among them, 377 lots (12,510,000 doses) were released, but 12 lots (about 135,436 doses) were rejected due to the failed test or the cold chain failure during transportation.

2. Drug Distribution Management

(1) Promote the Good Distribution Practice (GDP): Internationally, the quality management of medicinal products is including the whole medicinal product life cycle. In addition to implementing GMP in pharmaceutical manufacturers countries have started to conduct GDP. To ensure the quality of medicinal products during the distribution process from pharmaceutical manufacturers to pharmacies, the TFDA has initiated program to promote the GDP in medicinal products progressively since 2011. By collecting the information related to the GDP system and also the regulations from the PIC/S members, and the TFDA arranged a series of training activities to promote the concept of GDP to the companies connected in the supply chain. The training programs included forums, workshops and also conferences. Furthermore, the TFDA conducted the gap assessment visits to assist the manufacturers and wholesale distributors in implementing GDP. From 2012-2013, the TFDA conducted the GDP gap assessment visits to assist 35 wholesale distributors and 20 PIC/S GMP medicament factories and praised 48 foresaid companies.



Picture of celebration ceremony of GDP gap assessment visits in 2013

(2) In the future, the TFDA will offer a platform between the government and the industries to have a more intimate understanding. The TFDA would like to know the approaching challenge of implementing GDP, and have both the manufacturers and distributors adequately understand the requirements of the GDP guidelines. The TFDA plans that the PIC/S GMP pharmaceutical manufacturers implement GDP in priority. On the supplier side, the pharmaceutical manufacturers need to encourage their wholesale distributors to meet the GDP.

3. Illegal Drugs Inspection

To safeguard the public health for using drugs, TFDA continues to rigidly reinforce the inspection for sales of illegal drugs and counterfeit drugs.

(1) Integration and reinforcements

In March 2010, the Executive Yuan convened all the government authorities and worked out a unique program as “enforcement of anti-counterfeit drugs and illegal broadcasting station” to take action against all then illegal and counterfeit drugs. The results are as follows:

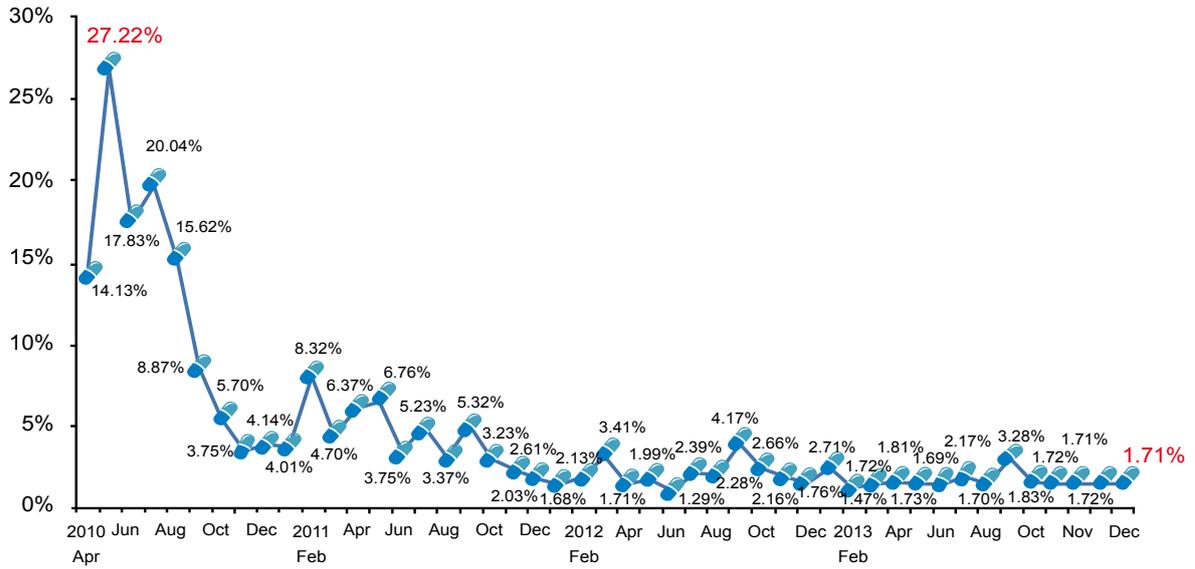
a. The illegal violation rate among the inspections

Because the local health bureaus performed more than 1,500 inspections each month, the illegal violation rate was sharp dropped from 27.22% (2010) to 1.71% (2013)(Fig. 3-4).

b. After the program starting, the total number of the confiscating illegal drug tablets was raised from 18,370,000 to 1,451,900,000 tablets.



Fig. 3-4 2010-2013 Incidence of Illegal Drugs



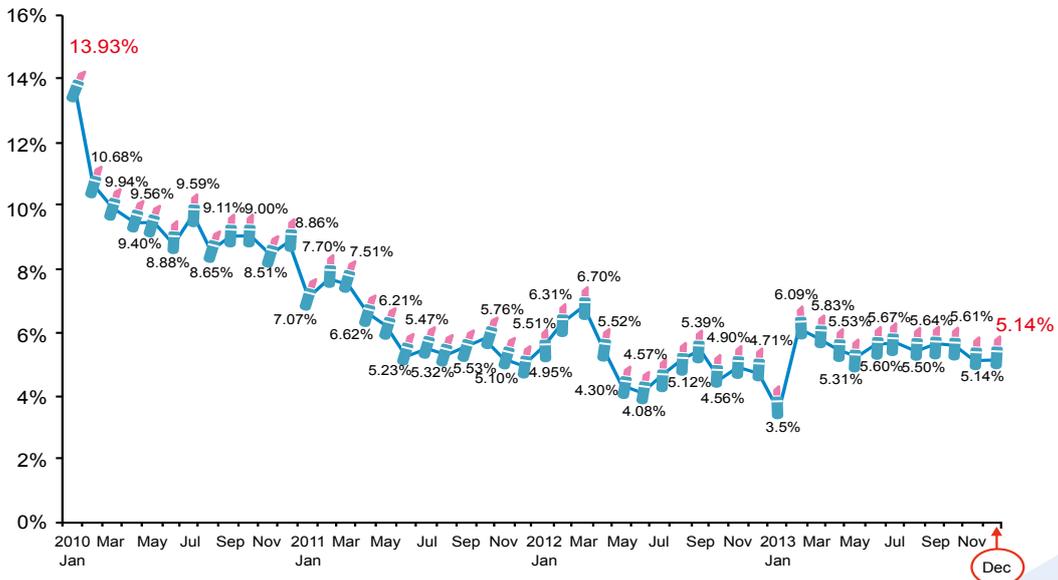
c. The illegal violation rate

In 2013, the 24.8% drug violation was food containing undeclared medicine. This kind of violation was 48.4 % involved sex medication and 34.9% involved diet medication.

d. The improper advertising violation

The violation rate of food, drugs and cosmetics advertisements was dropped from 13.9% (2010) to 5.14 % (2013). It has successfully blocked the misleading information to the public (Fig. 3-5).

Fig. 3-5 2010-2013 Food, Drugs, Medical Devices and Cosmetic incidence of illegal advertisements



(2) Constant monitoring illegal food and drugs in market

To stop sales of illegal food and drugs in market, TFDA enhances upstream raw material and source management by the integration of the government authorities, and also increases inspection numbers for downstream stores. In addition, TFDA emphasized education programs through all the media. To prevent illegal food and drugs advertisements spreading, TFDA and Department of Chinese Medicine and Pharmacy monitored and reported all regarding to the food, drugs, medical devices and cosmetic violation advertisement. Once there is a violation, the case will be transferred to the local health bureau and referee to the local court district attorney. The results are as follows:

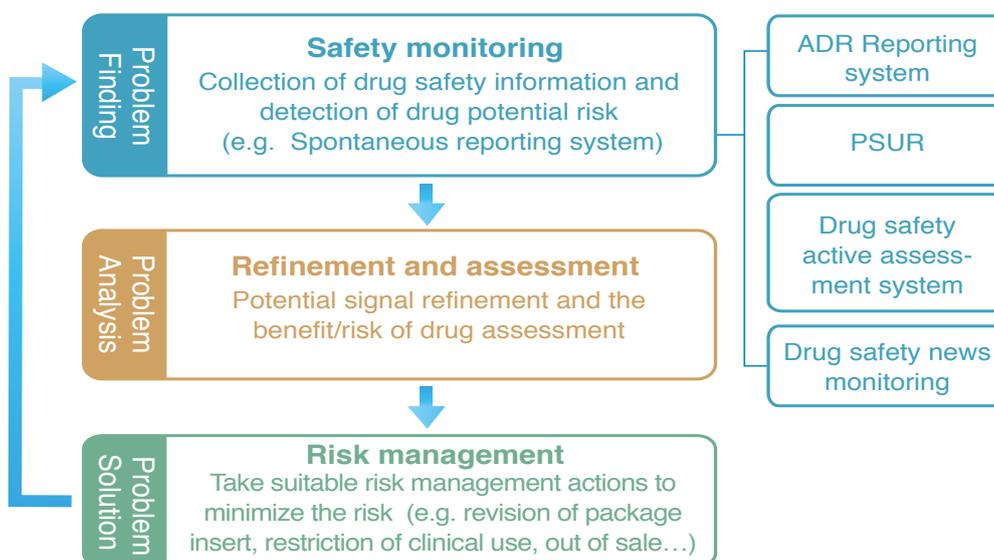
- a. In 2013, there were 881 violation cases, while 844 cases were sent to legal agents. These violations had a total fine of NT\$645,000. The local health bureaus had provided consulting education program to validate the importance.
- b. In 2013, there were 6,815 cases and a total fine of NT\$152,656,000 involved the advertisements violation by integration of government authorities, simplification of inspection process, and the regulation reinforcement.

Section 4 Pharmacovigilance

Status

In recent years, numbers of drugs have been discovered for having unknown or unexpected side effects (risks) after marketed. In order to enhance patient safety, Taiwan Food and Drug Administration keep improving drug safety monitoring mechanisms and regulatory environment (Fig. 3-6).

Fig. 3-6 Post-marketing safety surveillance



Policy and Outcome

1. To Fortify the Drug’s Safety Monitoring System

(1) Adverse drug reactions (ADRs) reporting system

“The National Adverse Drug Reactions (ADRs) Reporting System” was established in 1998. In 2013, a total of 10,667 cases were reported to this system.

(2) Drug safety monitoring

“Regulations Governing Safety Monitoring of Medicines” was announced in 2004, and “safety monitoring period” is required for new drugs. During the period of drug safety monitoring, license holders shall voluntarily provide safety information on drug used both domestically and abroad. From 2004 to the end of 2013, a total of 284 new medicines are under new drug safety monitoring. On November 21st, 2013, “Regulations Governing Safety Monitoring of Medicines” was amended; the drug risk management plan and the post-marketing clinical trials were also added into the regulation.

(3) Monitoring domestic and global drug safety alerts

The ADR center and TFDA monitor domestic and international drug safety alerts, for issue warnings to healthcare professional and the public. A total of 291 drug safety alerts were received in 2013.

(4) Proactive monitoring of drug safety

The proactive monitoring of drug safety mechanism was established since 2010. Such mechanisms actively analyze the post-market drug safety of high-risk drugs by using national health insurance data as reference for drug safety re-evaluation or planning of risk management.

2. Re-Evaluation of Drug Safety and Risk Management

For drugs with safety concerns, domestic and global data were collected to re-evaluate drug safety. In 2013, there were 64 drugs re-evaluated, among them, 26 were required for risk management measures, including 22 safety labeling changes or restricted use, 2 drugs were required to implement “Risk Management Plan (RMP)” and 3 were off the market, including calcitonin nasal spray, meprobamate and chloramphenicol oral dosage products.

Section 5 Controlled Drug Management

Status

To strengthen drug regulation for medical and scientific purposes, the TFDA referred to the United Nations' Single Convention on Narcotic Drugs, Convention on Psychotropic Substances and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substance to implement the "Controlled Drugs Act". The management mechanism includes the License Management, Scheduling Management and Diversion Management. These systems aimed to prevent abuse and illegal use of controlled drugs.

Policy and Outcome

1. New Amendments

The Ministry of Health and Welfare has set up a Controlled Drugs Review Committee to determine the categorization of controlled drugs. In 2013, two board meetings were held to add 8 more items to the list of controlled drugs (See Table 3-4) and annual statistic on quantities of all the schedules of controlled drugs in 2013. (See Table 3-5):

Table 3-4 The revision of the Schedules and Items of controlled drugs in 2013

Regulated date	Regulated Schedule	Item
April 18	Schedule 2 (Narcotics)	Tapentadol
October 21	Schedule 2	Chloromethamphetamine (CMA)
October 21	Schedule 2	Fluoromethamphetamine (FMA)
April 18	Schedule 3	JWH-122 \ (4-methyl-1-naphthyl)-(1-pentylindol-3-yl) methanone
April 18	Schedule 3	AM-2201 \ 1-[(5-fluoropentyl)-1H-indol-3-yl]-(naphthalen-1-yl)-methanone
October 21	Schedule 3	4-Methylethcathinone (4-MEC)
October 21	Schedule 3	Phenazepam
October 21	Schedule 3	Chloroamphetamine (CA) (Revision)

Table 3-5 Annual statistics on quantities of all the schedules of controlled drugs in 2013

Controlled drug schedule	schedule 1	schedule 2	schedule 3	schedule 4	schedule 4 APIs	Total
Quantity	9	174	33	72	7	295

2. The Management for the Medical Purpose of Controlled Drugs

The Ministry of Health and Welfare has set up a Medical Purpose of Controlled Drugs Review Committee. In 2013, the committee had reviewed 159 cases with the long term controlled drugs prescription due to non-cancer intractable pain to ensure all the narcotic prescriptions were not abused. When the health bureaus found any cases involved with improper control drug prescriptions will be sent to the committee for review. The resolved solutions varied, from correction, consulting to penalizing, per the severity of the each individual case. In 2013, there are 11 violation cases regarding to the improper proscription.

3. Control Drug License Management

Till the end of 2013, there are total of 14,477 "Controlled Drugs Registration License" owned by the facilities, and 47,384 "Controlled Drugs Prescription License" owned by the individuals. All the control drug used for manufacturer, import and export vendors, health related researches and experimental purpose need license through certificate, agreement and approval documents. In 2013, a total of 1952 were issued.

4. Control Drug Audit Management

- (1) TFDA has closely supervised all the health authorities to reinforce the audit of controlled drugs. In 2013, there were 16,197 cases had onsite inspections, a total of 211 had violation. The violation rate was 1.3%. The most common violations cited during an inspection were the improper and incomplete documentation of drug transactions, including the amount of controlled substances dispensed, discarded, and received. All violations were subject to applicable laws.
- (2) In 2013, a special program - the Audit of Zolpidem Prescription, was conducted to improve the proper prescribing of Zolpidem. TFDA conducted a data analysis and the high out-of-pocket costs related to the prescribing of Zolpidem were examined. A total of 352 facilities were inspected, 50 violating facilities were noted. The violation rate was 14.20%, all was resolved per regulation. Defendant were sentenced to pay a fine or to a prison sentence. Among the 50 violating facilities, 15 facilities involved the malpractice issue.

5. Training and Education Programs

The TFDA provide training program to the local health officers veteran while updating and Renewing license are required. There were two basic and one advanced continue education programs were held in 2013 with a total of 325 individuals attending record. To improve the participants to master the control drugs relating regulations. In 2013, TFDA also held four training conferences for the medical researchers with a total of 484 individual's participants. These seminars strengthen the understanding of all the process involved control drug management and regulations.



04

Medical Devices Management

Medical Device Regulations and Product Review

Medical Devices Source Control

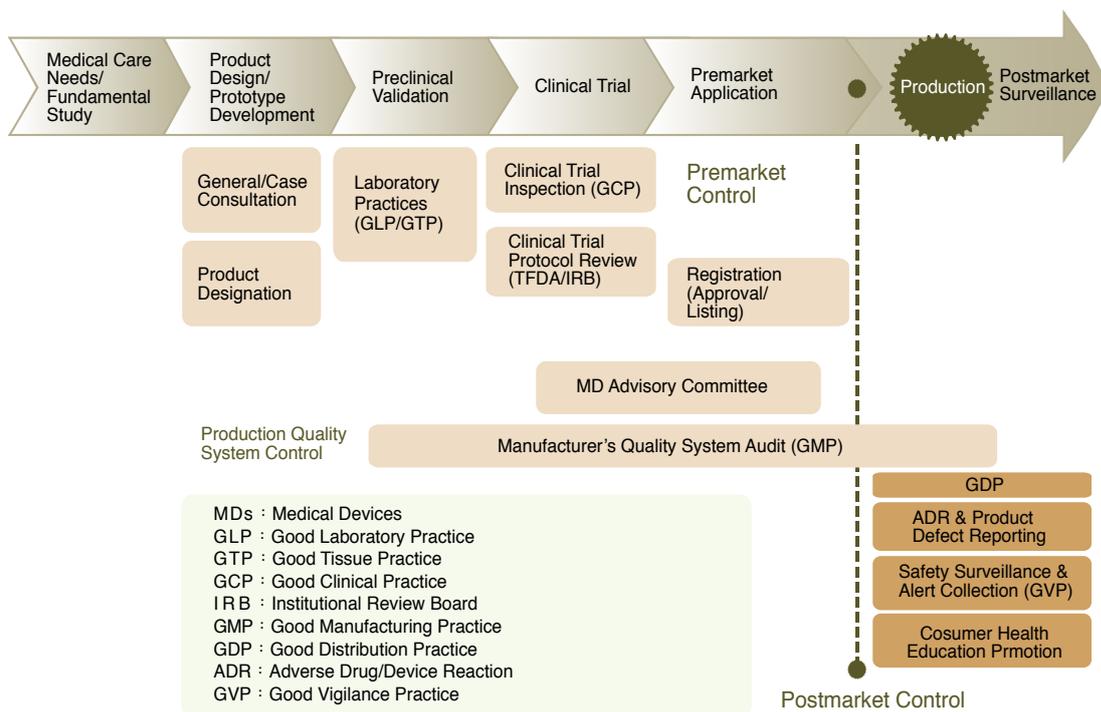
Post-Market Quality Surveillance of Medical Devices

Medical Device Safety Management

Chapter 4 | Medical Devices Management

Medical device industry is an emerging industry that carries lots of potential to be developed in a broad array of dynamic and versatile medical fields. Facing with the vividness and quality management of domestic medical device industry and the core emphasis on consumer protection, a total product life cycle regulatory system (Fig. 4-1) covering international regulatory harmonization, production quality system control, pre-market control, post-market control, supply chain control, and professional counseling service was established to effectively ensure the safety, effectiveness, and quality of medical devices.

Fig. 4-1 Medical device total product life cycle regulation



Section 1 Medical Device Regulations and Product Review

Status

For marketing application cases of Taiwan-developed innovative products, TFDA provides regulatory advices and counseling services. These services provide important niches to assist industrial development.



Policy and Outcome

1. Harmonization with International Regulations and Standards

In 2013, a total of 8 medical device regulatory amendments and related announcements were made as follows (Table 4-1):

Table 4-1 Update and amendments of medical device regulations and related announcements

Date	Regulation/Standard name	Content summary
March 11	Publish the "Pharmaceutical Good Manufacturing Practice Regulations" and revise the "Standards for Medicament Factory Establishments"	Adopt ISO 13485:2003 version. Medical device manufacturers are comprehensively required to be in compliance with the medical device Good Manufacturing Practices (GMP)
March 14	Revise the "Food and Drug Administration, Ministry of Health and Welfare Key Principles for Medical Device Consultation"	To increase the willingness of multinational companies to conduct clinical trials for medical devices in Taiwan, multinational multicenter clinical trials (MCT) programs for medical devices become qualified for application of regulatory project counseling
April 2	Announce the recognition of 90 US FDA medical device product standards	Assist medical device manufacturers to prepare inspection and registration application documents and the reference for medical device regulation
April 30	Amend "Guidelines for Registration of in Vitro Diagnostic Medical Device" Article 7	Relaxation of provisions related to the number of test specimen for human immunodeficiency virus (HIV) in vitro diagnostic reagents for HIV-1 subtype O, revision of international standards for hepatitis B surface antigen (HBsAg), HIV-1 antigen and Anti-HBs analytical sensitivity
May 1	Announce the joining of the Notified Bodies of European Union and the TFDA-Authorized Medical Device GMP Auditing Organizations to the second generation Taiwan and Europe medical devices factory inspection report exchange of Technical Cooperation Programme version 2.0 (TCP II)	To strengthen Taiwan and Europe's mutually beneficial cooperation, TFDA published the 11 EU AIMD / MDD / IVDD Notified Body Partners and the 4 ROC TFDA Authorized Medical Device GMP Auditing Organizations newly added to the TCP II list (new member: PIDC)
May 8	Revise the Pharmaceutical Affairs Act, Article 13 – Definition of medical devices	Add "regulating fertility", "do not achieve its primary intended function by pharmacological, immunological or metabolic means in or on the human body", "software" and "reagent for in vitro use" into the scope of medical devices, to enhance harmonization with international regulations
May 15	Regulations for the Inspection and Examination of Imported Medicaments	Provide the legal basis for conducting random checks and testing of medical devices before permission of import, in order to establish the mechanism for random border inspections and punishments
June 10	Publish the "Scope and types of medical devices which pharmacies may retail"	Publish the revised Article 19, Paragraph 2 of the "Pharmaceutical Affairs Act". Pharmacies may also have retail business for a certain class of medical devices. Paragraph 3 of the same Article authorizes central health authorities to set scope and types for the certain classes of medical devices



2. Medical Devices Product Review

(1) Classification of medical devices

Depending on the characteristics and the degree of risk of medical device, medical devices are divided into 17 categories (more than 6,200 variety of items) and three classes including Class 1 (low risk), Class 2 (moderate risk) and Class 3 (high risk). Up to the end of 2013, the number of valid medical device licenses was 35,792.

(2) Review time for medical devices

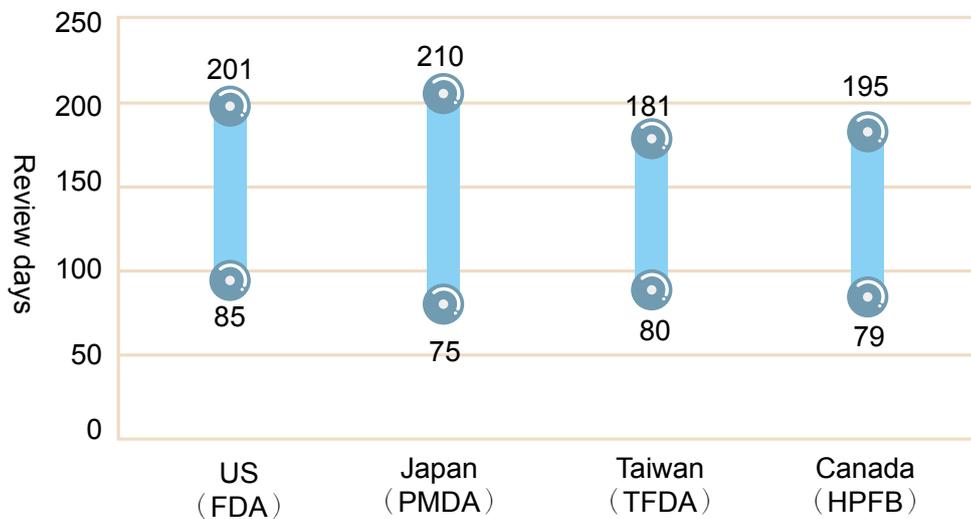
a. The comprehensive revolution of the medical device registration mechanisms

Streamlined and priority review mechanisms were established according to the level of risk, and each of these two mechanisms can reduce review time respectively by 80% and 50%. By the end of 2013, 1,002 medical device international standards and 90 medical device guidance documents announced by US FDA were recognized, and 37 domestic preclinical testing guidance documents were announced to provide direction for the medical device industry and improve the consistency and transparency of the medical device registration.

b. The review time is equivalent to the level of global leading countries

In 2013, reviews of 5,294 cases of medical device registration were completed, including 91 cases without similar medical devices marketed in Taiwan. The review time is equivalent to the level of global leading countries (Fig. 4-2).

Fig. 4-2 Comparison of the review time for medical device registration in Taiwan with other countries



(3) Establish quality medical device clinical trial environment

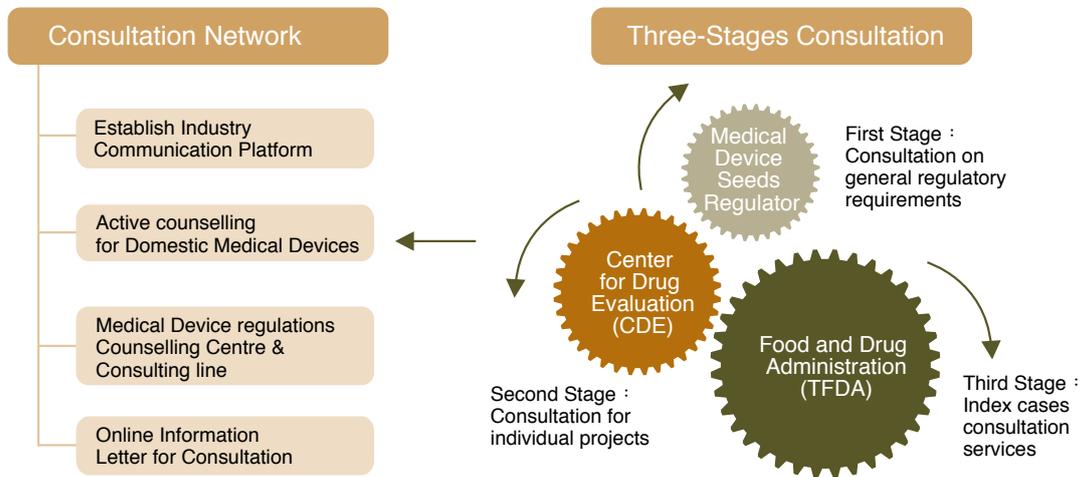
In 2013, 68 clinical trial application case reviews were completed. From 2012 to 2013, the number of multi-country multi-center clinical trials (MCT) had increased from 1 to 6. Three medical device Good Clinical Practice (GCP) inspections were completed with the involvement of foreign experts. In order to train seeded personnel for conducting clinical trials, 10 physicians were selected and sent to Europe, United States, Japan and other countries to learn clinical trials for medical device.

(4) Comprehensive consultation program

a. Build a 3-step consultation network

In response to the rapid development of domestic medical device industry, the TFDA has established a comprehensive regulatory consultation network which strengthened the three-stage counseling mechanism. Furthermore, a regulatory counselling center was established in consolidation with the capacity of third party providing counselling service (Fig. 4-3). In 2013, TFDA expanded telephone service lines to four lines. A total of 11,802 calls were received.

Fig. 4-3 Comprehensive consultation program for medical device industry



b. Outcomes for consulting program

By the end of 2013, TFDA has successfully assisted 11 cases through to approval, 7 cases entering clinical trials and 2 technology transfers into the industry. Some examples include the global first clinical trial of an advanced treatment for repairing cartilage defect, the clinical trial of an innovative negative-pressure designed sleep apnea therapeutic device, and the marketing approval for domestic first one-stage dental implants. By the end of 2013, there are still 8 consultation cases ongoing.

c. Train seeded regulatory personnel

In collaboration with the Center for Drug Evaluation (CDE) and the 37 seeded regulatory personnel, TFDA began on-site consultation in the Hsinchu Biomedical Science Park and the Lujhu Kaohsiung Biomedical Park to help industry overcome regulatory obstacles.

Section 2 Medical Devices Source Control

Status

Ensuring sustained stable production and management to meet the needs or specifications of the original design is an important quality assurance for medical devices. The implementation of quality management for medical device manufacturing is an effective measure for source control.

Policy and Outcome

1. The Internationalized GMP Regulation for Medical Devices

(1) The alignment of GMP with global regulatory requirements

On March 11, 2013, the “Pharmaceutical Good Manufacturing Practice Regulations” was announced and the “Standards for Medicament Factory Establishments” was amended. The 2003 version of ISO 13485 was thereby adopted for implementation. It was set forth that “Class 1 medical devices that are non-sterile or without a measuring function” and “medical devices for use in clinical trials” must comply with the GMP requirements. This fully incorporated self-compliance of medical device GMP and promoted the quality of domestic manufacturing factories to a higher level.

(2) Signing of Technical Cooperation Programme between authorized auditing organizations of Taiwan and European Union

In 2013, the signing of “Technical Cooperation Programme, TCP II” was completed between 4 TFDA authorized auditing organizations and 11 EU notified bodies. Both sides would recognize the mutual acceptance of audit reports, which effectively reduced duplicate inspections of the quality system for 18 manufacturers and enhanced the pace of medical device entrance into the global market.

2. Systemic Oversight of Authorized Auditing Organizations

Currently, there are 4 R.O.C. medical device GMP authorized auditing organizations, including Center for Measurement Standards of Industrial Technology Research Institute, Electronics Testing Center, Metal Industries Research & Development Centre, and Plastics Industry Development Center. In order to facilitate the global alignment of medical device GMP auditing system, TFDA conducted “headquarter assessment” and “witness assessment” on authorized auditing organizations to ensure the quality of audit.

3. Registration Management of Medical Device Manufacturing Factories

Medical device importers may apply for registration letters proving the compliance of overseas manufacturing factories with the regulation of R.O.C. Quality System Documentation (QSD). The audit inspections for domestic manufacturers are primarily conducted on-site. Importers may apply for on-site inspections of overseas manufacturing factories. By the end of 2013, there were 568 valid registration letters for domestic medical device GMP, and 3,231 registration letters for imported medical device QSD (Table 4-2).

Table 4-2 Number of valid registrations for medical device GMP/QSD

Year	Valid registration letters for medical device GMP/QSD	
	Valid GMP registration letters	Valid QSD registration letters
2010	236	1,340
2011	486	2,777
2012	531	3,065
2013	568	3,213

Section 3 Post-Market Quality Surveillance of Medical Devices

Status

For post-market quality and performance surveillance of medical devices, specific items were chosen on the basis of risk factor evaluation each year. TFDA integrated the resources from the local health bureaus to implement the surveillance program in order to monitor the quality and performance of post-market medical devices.

Policy and Outcome

1. Post-Market Quality and Performance Surveillance of Medical Devices

(1) Risk factor evaluation for the medical devices under surveillance

The surveillance items are chosen based on the risk factors such as medical device post-market adverse event reports and surveillance reports for defective items. National samplings are performed for the specific items. The test results provide a complete quality assessment of the products and prevent possible harm caused by poor quality of medical devices, and can be used as reference for future policy making on product quality management.

(2) Results for the post-market quality and performance surveillance

In 2013, a total of 199 samples were inspected for quality performance and package labeling. There were 174 samples passing the quality performance qualification and the qualification rate was 93.5%. There were 191 samples passing the package labeling qualification and the qualification rate was 96%. The devices which failed the inspection were sent to the local health bureaus to deal with in accordance with the law. The results of the surveillance are shown in Table 4-3.

Table 4-3 Post-market quality and performance surveillance results of medical devices for 2013

Project name	Total case no.	Surveillance issues			
		Quality testing		Packaging and labeling	
		Conforming no.	Nonconforming no.	Conforming no.	Nonconforming no.
Investigating fluorescence in cotton, gauze, and medical cotton swab in Taiwan	26	26	0	26	0
Survey of marketed daily wear contact lenses in Taiwan	30	30	0	30	0
Survey of di(2-ethylhexyl)phthalate (DEHP) in polyvinyl chloride (PVC) medical devices in Taiwan	26	26	0	23	3
Survey on persulfate of marketed denture cleansers in Taiwan	14	14	0	9	5
Survey on the quality of marketed contact Lens care products in Taiwan	23	23	0	23	0
Sterility testing of urinary catheters in Taiwan: A survey report	80	67	13	80	0
Total medical devices no. (percentage)	199 (100%)	186 (93.5%)	13 (6.5%)	191 (96%)	8 (4%)

2. Post-Market Medical Device Joint Inspections

To effectively monitor the compliance of medical device package labeling with the requirements, TFDA proposes to integrate the inspection resources more closely with local health bureaus. TFDA conducted medical device joint inspections in collaboration with the local health bureaus. The medical devices found violating the requirements for package labeling were sent to the local health bureaus to deal with in accordance with the law. The results of the joint inspections are shown in Table 4-4.

Table 4-4 The statistical analysis for joint inspections on medical devices in 2013

Product type	Inspected counties no.	Inspected shops/street vendors	Product labeling		
			Inspected cases	Violations	Violation rate (%)
Color contact lens	6	49	142	19	13.3%
Wound dressings	6	49	330	21	6.3%
Surgical masks	6	49	155	19	12.2%
Condoms	7	26	256	2	0.7%
Powered heating pads	7	26	32	0	0%
PVC medical devices containing DEHP	7	13	18	0	0%
Total of medical devices	13*	75*	933	61	6.5%

Note: *Because of different implementation times, some counties and shops/street vendors were inspected twice

Section 4 Medical Device Safety Management

Status

To improve safety surveillance, TFDA has set up the medical device adverse event/defective product reporting system, continues to conduct medical devices post-marketing surveillance, proactively monitors global medical device safety alerts, promotes the Good Distribution Practice, and disseminate regulatory policies.

Policy and Outcome

1. Strengthening Medical Device Post-Marketing Safety Monitoring

(1) Monitor global medical devices safety alerts proactively

In 2013, a total of 3,737 medical device safety alerts were processed, including 1,985 product warnings and 1,752 recall requests. The TFDA flagged 127 safety warnings which were related to domestic safety and asked for extra attention.

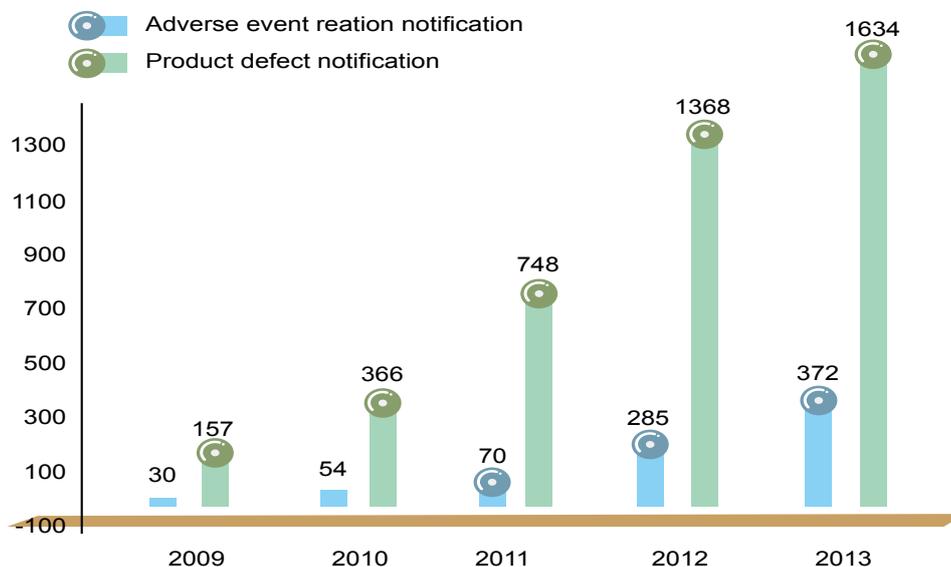
(2) Join the National Competent Authority Report exchange program (NCAR).

The TFDA is a member of the NCAR of the International Medical Device Regulators Forum (IMDRF). We receive the recall notifications and safety warnings from the member states. In 2013, 399 global warning reports were received.

(3) Increase reports of medical device adverse reactions and defective products

The TFDA encouraged manufacturers and the public to report medical device adverse reactions and defective products via the medical device reporting system. From 2009 to 2013, reports of adverse reactions increased from 30 to 372 and defective products increased from 157 to 1634 (Fig.4-4).

Fig. 4-4 Defective products/adverse reactions reporting for medical devices



2. Manufacturer and Product Distribution Oversight

(1) Legalize online sales for Class 1 Medical Devices

For easier access to medical devices while protecting consumer safety, since November 1, 2012, dealers of drugs or medical devices may sell Class 1 medical devices online and the requirements for their registration were announced. The sales of class 1 low risk medical devices online, on television and mail order were opened.

(2) Legalize online sales for part of the Class 2 medical devices

For convenient access to home use medical devices, in 2013, opening the sales of three Class 2 medical devices, including home use condoms, tampons and body fat meter through mail or on line with product descriptions was announced.

(3) The promotion of Good Distribution Practice (GDP)

In December 2013, TFDA announced the draft on GDP emphasizing quality control for the distribution process and regulatory oversight of vendors.

3. Strengthening Promotion of Medical Device Regulations and Policies

(1) Important policy advocacy

For promotion and implementation of important policies, in 2013, TFDA sponsored a total of 30 conferences to promote the important policies.

(2) Strengthening communication with industry and medical institutions

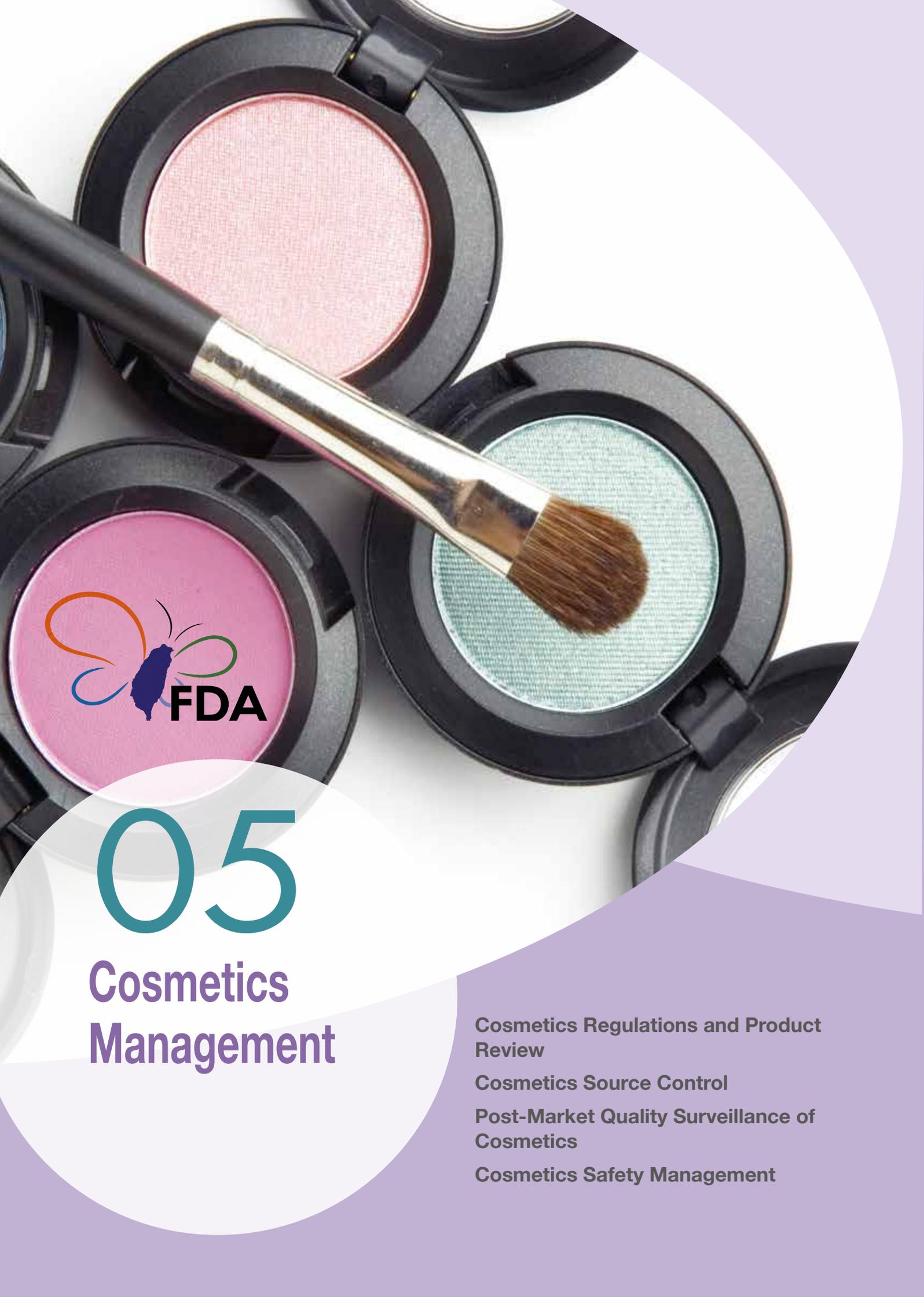
The TFDA conducted 2 conferences, "2013 Medical Device Industry Trends and Regulatory Forum", to hear feedbacks from industry, and consider incorporating them into future policies.

(3) Establishing a communication platform for industry associations

Through the platform of non-scheduled meetings with medical device industry associations, TFDA can communicate through direct dialogue with the industry. It promotes mutual cooperation and consensus in policies, and facilitates the promotion and implementation of policies.



2013 Medical Device Industry Trends and Regulatory Forum



05

Cosmetics Management

Cosmetics Regulations and Product Review

Cosmetics Source Control

Post-Market Quality Surveillance of Cosmetics

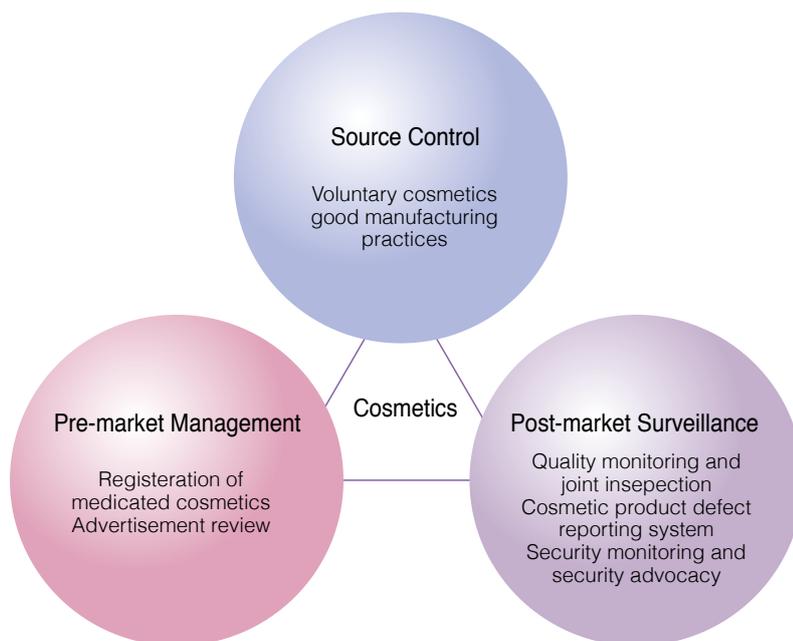
Cosmetics Safety Management

Chapter 5 | Cosmetics Management

Cosmetics have become essential goods in daily life. The stability, quality, and safety to human health for long-term use have become public focus. The concerns on cosmetic quality and safety have also induced the attention of the management of cosmetic quality and safety in every country.

The current management infrastructure is divided into three elements: source control, premarket management and post market surveillance (Fig. 5-1). The measure for source control is the voluntary cosmetic GMP. The pre-market management includes the pre-market registration of medicated cosmetics and color additives as well as the pre-market cosmetics advertisement review. The post-market surveillance is implemented by the quality monitoring program and cross-county joint inspection. Cosmetic product defect reporting system is built. Consumer advocacy for safe use of cosmetics is also strengthened to construct a comprehensive cosmetics quality and safety network.

Fig. 5-1 Current cosmetic management framework



- Polices and Organization
- Food Management
- Medicinal Products Management
- Medical Devices Management
- Cosmetics Management
- Risk Assessment and Risk Management
- The National Laboratory
- Laboratory Network
- Research Outcomes
- International Cooperation and Cross-Strait Exchanges
- Consumer Protection and Advocacy
- Major Events
- Appendix

Section 1 Cosmetics Regulations and Product Review

Status

In accordance with the provision of the current statute for the control of cosmetics hygiene, pre-market approval & registration are required for medicated cosmetic and pre-authorization is required for cosmetics advertisement. However in recent years the global cosmetic market continues to gain increasingly active circulation. In order to harmonize our cosmetic regulations with the rest of the world and promote the development of the cosmetic industry in our country, we have referred relevant cosmetic regulations from various countries. In the future, we will aim to abolish the medicated cosmetics pre-market registration system and cosmetics advertisement pre-authorization system.

Policy and Outcome

1. Create a Regulatory Environment in Compliance with International Norms

- (1) Draft of amendment to the statute for the control of cosmetics hygiene
 - a. Referring to international norms, we are planning to amend the definition of cosmetics and abolish the pre-market registration system for medicated cosmetics and color additives. Instead, we will ask to establish a Product Information File (PIF), and adopt the pre-market notification system. To enhance source management, we have implemented sample testing system at the border and determine the feasibility of full implementation of the cosmetic GMP system. Furthermore, we plan to remove the penalty system and replace it with administrative fines, add to the lower limit and raise the upper limit of the fines. Moreover, we have added the rules for adverse reactions reporting from cosmetic use, and product removal from the retailer shelves.
 - b. For the Draft Amendment to the Statute for the Control of Cosmetics Hygiene in 2013, we held three seminars and one hearing. Additionally, three seminars for Cosmetics Product Notification portal and PIF, and three seminars for the GMP regulations for cosmetics were held, for the purposes of achieving policy advocacy, strengthening communication and collecting public opinions.
- (2) Revision of administrative regulations and health standards

To harmonize our cosmetics regulations with the rest of the world, we revised the administrative regulations and health standards, as shown in Table 5-1



Table 5-1 Revisions of the administrative regulations and health standards in 2013

Date	Summary
March 26	Enumeration of Expressions that are Appropriate or Inappropriate to be Claimed for Cosmetics
April 30	Announcement of Priority Review Program for Cosmetics Compliant with Voluntary Cosmetics Good Manufacturing Practices and priority registration review program for those who have obtained Taiwan's official documents
May 28	Amendment of Regulation on the pH Value and Warning Statement of Cosmetics Containing Alpha Hydroxy Acids and Other Related Ingredients
June 27	Amendment of Regulation on Residue Limits for Free Formaldehyde in Cosmetics
August 27	Amendment of Regulation Governing the use and the Dosage Limit of Urea Ingredient in Cosmetics
September 17	Regulations Forbidding the Use of Rhododendrol Ingredient in Cosmetics
December 31	Amendment of Guideline for the Use of Preservative Ingredient and Dosage Limit Requirement in Cosmetics

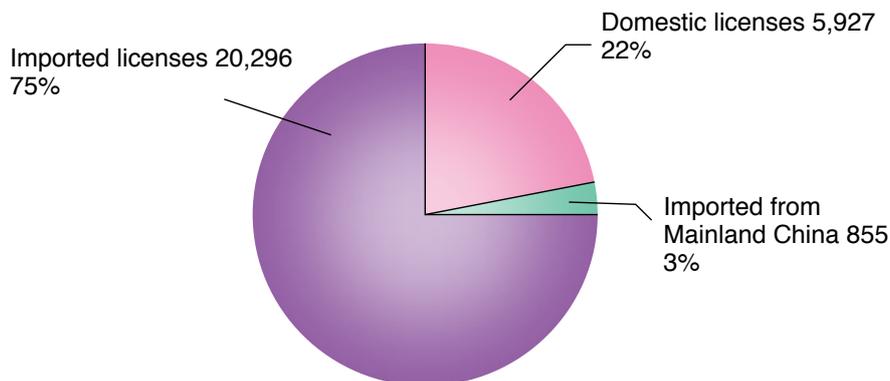
2. Pre-Market Approval & Registration and Advertising Examination for Cosmetics

- (1) Pre-market approval & registration for cosmetics
 - a. In 2013, total number of review for medicated cosmetics approval & registration were 1,650 (including prioritized review cases). 1,506 of them were approved (as shown in Table 5-2).

Table 5-2 Number of approved licenses during years 2010-2013

Year	Total Number of Applications	Total Number of License Granted
2010	1,594	1,437
2011	1,634	1,519
2012	1,721	1,482
2013	1,650	1,506

Fig. 5-2 Total number of medicated cosmetic licenses granted until year 2013



b. Until year 2013, total number of medicated cosmetic licenses issued by the Bureau were 27,078, including a total number of 5,927 and 21,151 licenses for domestic products and imported products, respectively (as shown in Fig. 5-2)

(2) Advertising examination for cosmetics

- a. In order to unify the examination standards for the review authorities, we set up "Cosmetics Advertising Act and Examination Manual", "Guideline for Cosmetics Advertising" and "Rules for Application of Drugs and Cosmetics Advertising", for vendors to follow as guidelines of advertising examination.
- b. We regularly hold meetings with health authorities to deal with advertising examination and improve quality of examination, in order to achieve examination consistency.
- c. We hold training programs on reviews to strengthen the principle of consensus. In addition, the Cosmetics Advisory Councils, which have already been established, study special cases and draft the complete advertisement regulations for cosmetics; meanwhile, also assist TFDA to amend "Enumeration of Expressions that are Appropriate or Inappropriate to be Claimed for Cosmetics".
- d. In 2013, a total of 1,261 cosmetic advertisements were examined, and 1,192 of them were approved.

Section 2 Cosmetics Source Control

Status

Since 2008, we have worked alongside with the Industrial Development Bureau, Ministry of Economic Affairs; to promote the program designed for cosmetics manufacturers

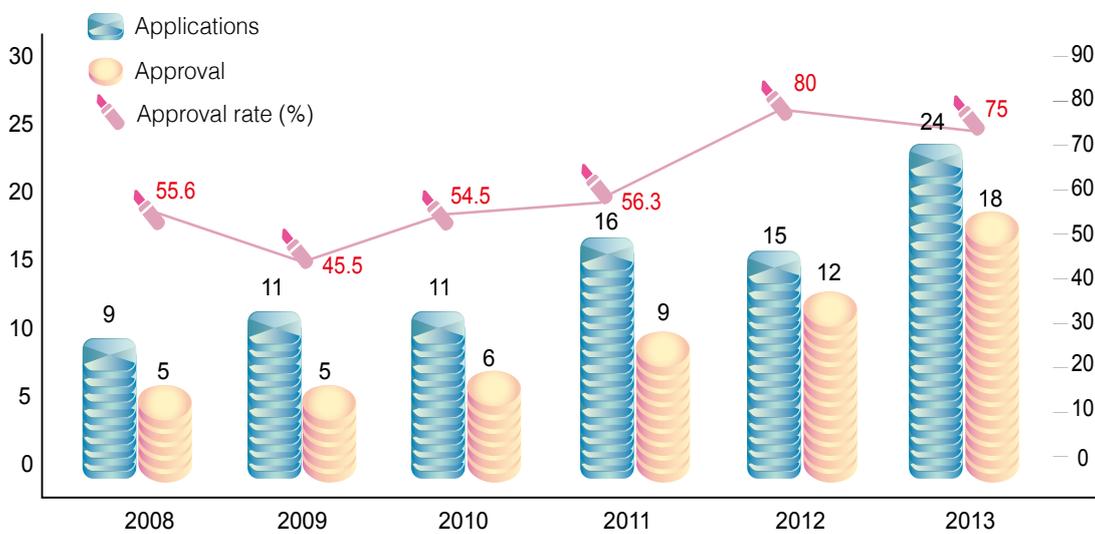
to ensure compliance with voluntary cosmetics GMP, and to conform to international norms and standards. Referring to the international cosmetics management policy, we propose the “Cosmetics Product Notification Portal”. With the exemption of the pre-market approval & registration when implementing this new system, we aim to shorten time to the market and improve competitiveness of the products.

Policy and Outcome

1. Source Control

Since 2008, more and more manufacturers have applied and been approved for voluntary cosmetic GMP authentication (as shown in Fig. 5-3). In the future, we will continue to promote GMP, to enhance the international competitiveness of the cosmetics in our country.

Fig. 5-3 List of applications and approval for cosmetic product good manufacturing practices (GMP) from 2008 to 2013



2. Establishment of Cosmetics Product Notification Portal

In order to implement the “Cosmetics Product Notification Portal”, we referred to specifications of notification portal worldwide, considered the needs of our country and industry, and designed the “Cosmetics Product Notification Portal” (shown in Table 5-3).

Table 5-3 Progress of cosmetics product notification portal in 2013

Time	Progress
March to August	Established the "Cosmetics Product Notification Portal"
September to October	Invited cosmetics vendors for system testing and debugging
November	Held three seminars for the "Cosmetics Product Notification Portal"
December	Completed the establishment of the "Cosmetics Product Notification Portal"

Section 3 Post-Market Quality Surveillance of Cosmetics

Status

TFDA chooses particular items by risk assessment annually for cosmetic quality programs, and conducts annual joint inspection programs for cosmetics to meet our public mission of safeguarding the safety of post market cosmetics.

Policy and Outcome

1. Cosmetic Quality Monitoring

In 2013, two quality monitoring programs were performed. Products in violation of the regulations were sent to the local health authorities, and further legal actions were taken (Table 5-4).

2. Joint Inspection of Commercial Cosmetics

In 2013, we jointly inspected three kinds of cosmetic products (as shown in Table 5-5). Products in violation of the regulations were submitted to the local health authorities, and further legal actions were taken.

Table 5-4 Results of cosmetic quality monitoring in 2013

Title of project	Total		Passed		Failed	
	Test	Label	Test	Label	Test	Label
Survey on methanol and phthalate esters of marketed cosmetics perfume and hair sprays in Taiwan	50	50	47	39	3*	11
Microbiological survey of marketed cosmetics in Taiwan	50	50	50	49	0	1
Subtotal	100	100	97	88	3	12
Total	200		185		15	

*:The samples that failed the test were a hairspray and a polish remover, with methanol content above the maximum residue limit of 0.2%. Another hair spray contained phthalate esters above the maximum residue limit of 100 ppm.



Table 5-5 Statistical analysis of joint inspection on commercially available products in 2013

Product category	Number of counties inspected	Number of stores / stalls inspected	Product labeling		Quality testing	
			Number of samples inspected	Number of samples In violation	Number of samples tested	Number of samples failed
Body wash	9	81	1,425	46	18	3
Shampoo					29	1
Hand cleanser					13	1

Section 4 Cosmetics Safety Management

The TFDA set up the cosmetic product defect reporting system in 2008 and promoted reporting in 2009. The number of reported cases is increasing year by year because of consumer awareness. As more new products are developed and more news regarding misuse of products are released recently, our major concern is how to monitor the consumer risk factors by sharing the current news and resources, and blocking the misleading reports.

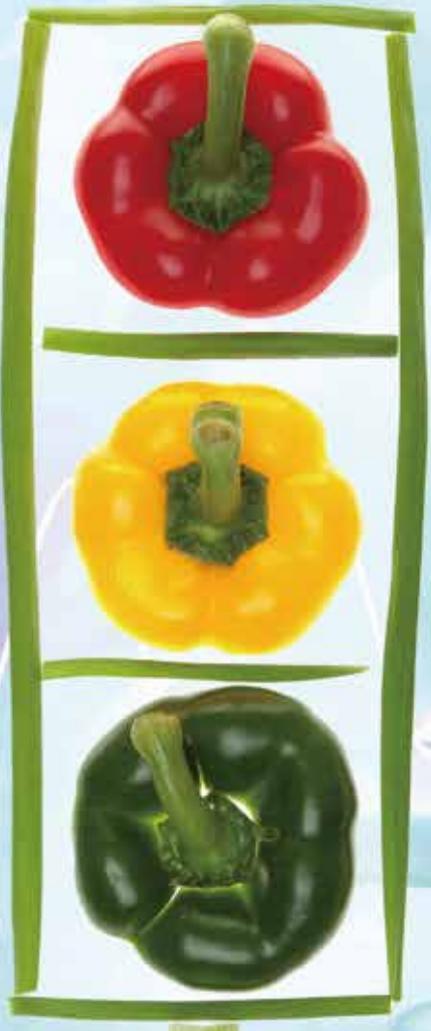
Policy and Outcome

1. Cosmetic Product Defect Reporting System

- (1) The reported cases grew from 6 in 2009 to 87 in 2013.
- (2) In 2013, TFDA called two conferences and printed brochures to give to the public to increase understanding of the cosmetic product defect reporting system (established by TFDA) and to enhance reporting rate.
- (3) TFDA is actively involved in the collection of the latest global safety and recall information, and monitors domestic consumer information and websites. In 2013, 327 domestic and international warnings were overseen. There were 52 consumer news items from “The Consumer’s Red and Green Signs for cosmetics safety”.

2. Cosmetics Safety Advocacy

- (1) The following websites, “The Taiwan Food Drug Administration”, “Cosmetic Product Defect Reporting System”, “The Consumer’s Red and Green Signs for cosmetics safety”, “The TFDA Cosmetics Blog for Safe Usage” , and “Cosmetics safety education programs in Youtube” are good platforms for the dissemination of safety information.
- (2) By multiple advocacy pathways, TFDA provides consumers with information on how to make the right choice on purchasing and using cosmetics.



06

Risk Assessment and Risk Management

Risk Assessment
Risk Management and Emergency
Response Mechanism

Chapter 6 | Risk Assessment and Risk Management

Risk assessment for food additives, pesticide residue concentration, veterinary drug residues, heavy metals, pathogenic microorganisms, GMO food, adulterated food, and allergens in food ingredients are major concerns in food safety and sustainability control. Most of the contingencies of life - what we eat, what pollutants are present in the natural and manufacturing environment, and how often we emphasize regulations will affect the operations of food manufacturers. Social and scientific influences are often applied for both imported and exported food management, particularly since joining the "World Trade Organization (WTO)".

Risk monitoring plays an important role in food, drugs, medical devices and cosmetics safety control. Quality control by means of high standard post-marketing surveillance, intensive follow-up of high risk products and awareness of information from public opinion and possible hazards are all critical. TFDA emphasizes immediate action towards all sources of crisis. Our priorities are to minimize risk factors and to predict and prevent outbreaks.

Section 1 Risk Assessment

Status

In accordance with the WHO and UN's food control in developing countries, TFDA is devoted to implementing a more scientific based policy, to include food risk factor evaluation and testing guidelines and make them available for global demands.

Policy and Outcome

1. Conference Meeting and Policy Reinforcement

On June 19, 2013, an amendment to the "Act Governing Food Safety and Sanitation" Article 4, Chapter II, "The central competent authority shall assemble experts and scholars specialized in food safety and risk assessment, as well as non-governmental organizations, to form a food safety risk assessment advisory committee. The regulations governing the formation, proceedings, procedures, scope and other matters to be complied with for the advisory committee shall be prescribed by the central competent authority." In 2011, the "Food Safety Risk Assessment Advisory Committee" was created. In 2013, TFDA invited the leaders of local communities and societies to become part of the policy making team.

2. Food Safety Risk Assessment Policy

After the Food Safety Risk Assessment Advisory Committee was established, the working guidelines for food safety risk analysis and the draft for risk factor evaluation for chemical ingredients in food were reviewed in 2013.

3. Promoting Risk Factor Evaluations

(1) Training programs and continued education

In order to enhance the professional criteria for risk factor training, TFDA conducted the JIFSAN training program (from the University of Maryland) and invited Dr. Mary A. Fox from John Hopkins University, Dr. Margret Ann Miller from the U. S. FDA and Dr. Andy Hwang from the Eastern Research Center, U. S. Department of Agriculture to Taiwan for a conference. Five related training programs were provided for 497 participants.

(2) The guidance documents about risk assessment principles and methods for both veterinary drug residues and microbiological hazards in food were drafted with reference to international regulations. The formal guidelines regarding principles and veterinary drug residues and microbiological hazard in food were drafted with reference to the current international regulations.

(3) Build a current national food intake database and exposure assessment resource links

In 2013, a data collection for national food consumption and nutrition analysis was carried out. Furthermore, a national database was established with emphasis risk factors for food hazards. This data base is open to new data entry. Exposure risk analysis was also discussed in detail.

4. Residue Concentrations of Dioxin and Remaining Pesticides were Investigated

(1) From researches about Dioxin risk assessment, the Lifetime Average Daily Dose (LADD) has met the requirements of the Tolerable Daily Intake (TDI) and the European Scientific Committee on Food (SCF)'s suggestions on Tolerable Weekly Intake.

(2) Total Diet Study

a. A Total Diet study was conducted in order to understand the basic food sample database and to then promote these health concepts to the public.

b. In 2013, the TDS food sample database for pesticide residue has been established and obtained the detective data of 251 pesticides in 200 representative foods. The risk of dietary exposure evaluation in each representative food were acceptable in three populations.

Section 2 Risk Management and Emergency Response Mechanism

Status

TFDA continues to promote risk management and emergency response mechanisms, and has established several risk management and emergency response teams in order to reduce the possibility and impact of the occurrence of risks and emergency events.

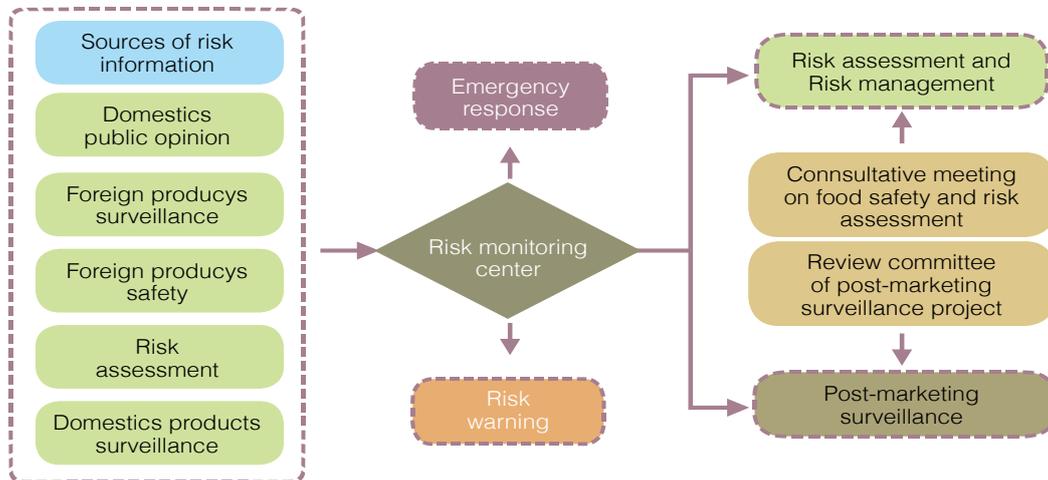
Policy and Outcome

1. Promotion of Organizational Risk Management Mechanism

(1) Risk Management Education and Training Programs

In 2013 there were two education conferences with 135 participants, with emphasis on the concepts of risk management and emergency response.

Fig. 6-1 Risk monitoring workflow



(2) Risk monitoring

Risk monitoring center conducted emergency operating procedures according to TFDA's risk monitoring flow chart (Fig. 6-1). If necessary, the center would report the alert notification to all related business sectors. In 2013, 4,731 news articles, 266 magazine articles and 1,869 international information on product recalls and safety alerts were collected and analyzed.

(3) Risk Factors Management

When the Ministry of Welfare and Health was formed, TFDA invited all the supervisory authorities to join the promotion team. They then organized a conference during which they revealed the ten major risk factors in 2013, along with a listing of desired outcomes and executive process details. All followed the guidelines of risk factor management and bonding among varied departments was promoted.

2. A Relevant and Dynamic Response towards Emergencies

(1) Practical stimulation training

In response to all outbreaks, a practical stimulation training was conducted to hone the staff's emergency preparedness skills. In 2013, a simulated scenario about corn starch contaminated with T-2 toxin was performed in order to strengthen the participants' ability to handle crisis. Audit committees were invited to evaluate the results and were encouraged to provide feedback and suggestions.

(2) Conducting emergency operations

According to the "Emergency handbook" in coordination with the flow charts (as previously stated), related emergency mechanisms were reviewed and practiced under the daily job report. Every step was listed in detail, including the major authorities. Furthermore, related websites, data analysis, and daily supervision programs were set up. TFDA carefully reviewed all incidences of neglect in order to prevent the same things from happening again.





07

The National Laboratory

Mission of the National Laboratory
Laboratory Function Enhancement

Chapter 7 | The National Laboratory

The technologies, functions, and categories of foods, medicines, medical devices and cosmetics had being grown at high speed. In order to catch up the trend, TFDA had taken all the contemporary sciences and technologies to boost up laboratory testing capacity and efficacy by setting all the trustworthy guidelines and enhancing surveillances for the outbreaks.

Section 1 Mission of the National Laboratory

Status

National Laboratory dominates all testing laboratories in medicines, foods, and cosmetics analysis which constantly works hard toward the new analytical method setting, research investigation, and local/district collaboration.

Policy and Outcome

1. Improve Inspection Capabilities

- (1) In 2013, TFDA purchased 19 new cutting edge instruments. The instructions in detail for all instruments were well written and available to the public.
- (2) Five conferences related to non-target and unknowns screening were held in 2013. The new and old concepts associated with chromatography, optical spectroscopy, mass spectrometry, NMR, and X-ray diffraction were delivered to total 266 participants.

2. Inspection and Testing Functions

- (1) Basic testing: Registration testing of medical equipment, health food, special nutrition supplements, food additives, lot release testing for biologics, and testing of emergency events. Almost four thousand items were conducted a year.
- (2) Cooperative Testing: Inspection or service testing for the related authorities, testing for food poisoning outbreak, testing for adulterant and illegal drugs of food and Chinese medicines. The results shown 392 items out of 2,566 tests were violated.
- (3) Collaborative Testing: Contract or assistance of testing for illegal drugs, medicines, and controlled drug, adulterant in Chinese medicine and food products. A total of 4,460 tests were conducted, while 3,499 items were violated.

3. The Development and Promotion of New Testing Methods

- (1) In 2013, 46 official analytical methods for foods were published. In addition, 61 and 9 recommended analytical methods for foods and cosmetics were published, respectively.
- (2) Developments of testing method for gossypol and copper chlorophyll in edible oils, and maleic acid modified starch in food products.
- (3) In 2013, six conferences related to methodology and one open forum on minimum requirement for biologics were hosted by the TFDA.

4. Standard, Preparation and Supply

In 2013, the new HCV genotype 2 national standard was prepared and assigned a unitage by the collaborative study.

Section 2 Laboratory Function Enhancement

Status

It take initiatives to develop fast and precise testing methods for the timely resolution of critical outbreaks .By identifying the problem, causal factors will be clear out and prevented from recurring. Thus, the consumer's anxiety and concerns may be relieved by providing scientific information and strategies through the public media.

Policy and Outcome

1. Incident of the Contamination of Dicyandiamide (DCD) in Imported New Zealand Powdered Milk

- (1) DCD is an approved nitrification inhibitor for increasing the efficiency of grass fertilizer in New Zealand.
- (2) January 24, 2013, the New Zealand authority made an announcement regarding to the trace residue of DCD found in their dairy products. TFDA responded to the DCD residue in milk as soon as the news announced.
- (3) TFDA conducted surveillances and reported 1 out of 12 cases of New Zealand powdered milk contained DCD. The residue level is below 0.06 mg/kg which is considered as no health risk concern.

2. Maleic Anhydride Modified Starch Incident

- (1) In May 2013, TFDA received a report from the Chiayi station, Investigation Bureau of the Ministry of Justice regarding a suspected ingredient of illegal maleic anhydride modified starch in foods. The illegal starch was used to increase chewy sensation of tapioca balls, flat noodles, and taro balls according to the manufactures.

- (2) TFDA started a serial of investigation and developed a new analysis method for maleic anhydride and maleic acid residue in foods. 155 domestic and imported food products were tested. 5 suspected products were found of maleic acid. The violations were confirmed by tracing back the raw material in the factories.

3. Event of Unapproved Genetically Modified (GM) Wheat Found in USA

- (1) May 24, 2013, the U.S. Department of Agriculture (USDA) announced that Roundup Ready GM specific gene was detected in wheat samples from an Oregon field, which was identified as the unapproved GM wheat event MON71800 developed by Monsanto. The announcement had attracted international attention. After information received, TFDA requested further explanation and investigation report from U.S. government.
- (2) TFDA conducted GM wheat investigations of relevant food products and raw materials from border by specific detection methods immediately. All testing results showed no contamination of GM wheat in Taiwan.

4. Copper Chlorophyll Adulterated Oils Incident

- (1) October 16, 2013, the Changhua County Health Bureau and the Department's Central District Administration Center found and reported an incident of illegal Copper Chlorophyll contamination in products labeled 100 % Olive oil. The adulterated oil products were made by the Chang Chi Foodstuff Factory Co., Ltd.
- (2) TFDA investigated the confiscated oil products and successfully developed a testing method for Copper Chlorophyll in edible oils.
- (3) TFDA invited experts and scholars to review and validate the developed testing method. Then, surveillances were started.



5. Business Week's Milk Blunder Incident

- (1) In November 2013, an article from Business Week distorted the fact of chemical residues in milk regarding the contaminations of antibiotics, plasticizers, estrogens and sedatives.
- (2) TFDA immediately conducted serials of investigations relevant to the article concerns. Followed by the standard of international recognized regulation, all the above test in results were negative involved with 9 different plasticizing testings, hormones, antidepressants, analgesics and 86 "veterinary drug residues" testings.

6. The Doubt of the Accuracy of Infrared Ear Thermometer

In 2007 to 2010, TFDA had surveyed the accuracy and specification for the infrared ear thermometer. The testing for compliance of the maximum permissible error within ambient operating range was implemented according to EN 12470-5: 2003 standard. The results show that 70% products do not meet the requirement. In 2013, there were related news reports about the accuracy issues for the infrared ear thermometer.

In 2013, TFDA had conducted on-site audit of products manufacturing and quality control, and performed accuracy test for infrared ear thermometer according to each registration information. The results were shown that 3 items did not correspond to the specification. The test reports were sent to local health authorities for further conduction.

7. The Doubts of the Color Additive Fall off in Marketed Daily wear Contact Lenses

- (1) In August 2013, the legislator held a press conference because 13 brands of color additive fell off in cosmetic contact lenses. Besides, the local health authorities had also received consumer complains for color additive falling off.
- (2) According to guidance for pre-clinical testing of soft contact lenses, color contact lenses may use 31 different kinds of color dye approved by U.S. FDA and color additive extraction test should be passed.
- (3) In 2013, 30 samples were collected and examined with each product's original registration data or the test methods established by TFDA. The results showed that no color additives were extracted from these samples.

8. The Heavy Metal, Cadmium was found in Shiseido Anessa Sunscreen Products in Mainland China

- (1) TFDA had announced that the heavy metals such as arsenic, lead, cadmium, mercury were prohibited from using in cosmetics. The maximum residual limit of the heavy metal, cadmium is 20 ppm.

- (2) In 2013, a batch of Shiseido sunscreen imported from Japan to China had been intercepted during entry inspection and quarantine and been found to contain cadmium. The news aroused much fear in Taiwan. TFDA had immediately collaborated with local health authorities to execute toxic heavy metals test for marketed sunscreen products. The results revealed that all products had met hygienic standard for cosmetics in Taiwan.

9. The Acrylamide and Clobetasol Propionate Were Found in China's Facial Masks

In 2013, the China Food and Drug Administration found the masks contained acrylamide and clobetasol propionate. The Taiwan Food and Drug Administration (TFDA) had immediately collaborated with local health authorities to execute chemical test for marketed facial masks. The results showed that all products had met hygienic standard for cosmetics, and allay fears in public.

10. The Doubts of Overdose Triclosan which is Used in Cleaning Products

- (1) Triclosan is an antimicrobial commonly found in liquid hand soap, shampoos, body cleanser, anti-acne products and many other household items. According to TFDA announcement, the maximum limit of Triclosan is 0.3%, and used as antimicrobial.
- (2) TFDA had conducted routine inspections for Triclosan in order to monitor and make sure all the products followed the hygiene regulations for recent years. In 2013, news reported that the Triclosan was over in marketed cleaning products. TFDA took prompt action and started immediate inspection for marketed cleaning products. The results showed that all products had met hygienic standard for cosmetics.



08

Laboratory Network

**Strengthening the Testing
Capability and Quality of Local
Health Bureau Laboratories
Laboratory Accreditation and
Management
Mobilization for Emergency**

Chapter 8 | Laboratory Network

In order to raise local laboratories testing capacity, TFDA works vigorously to enhance the testing ability and quality of local health bureau laboratories, and builds efficient integrated laboratory testing systems; meanwhile, TFDA also performs private laboratory accreditation. So far the accreditation region includes food, drug and cosmetics, drug abuse urine testing and non-clinical Good Laboratory Practice (GLP) testing. Besides, TFDA mobilizes integrated laboratory testing systems for emergency testing demands, and announces list of laboratories. Thus laboratories can help manufactures perform self-sufficient managing procedure.

Section 1 Strengthening the Testing Capability and Quality of Local Health Bureau Laboratories

Status

In order to enhance the testing capacities of local health bureau laboratories, regional integrated laboratory testing systems of local health bureaus were promoted since 2006. TFDA also coordinated authorized testing items of each local health bureau, and all of the local health bureau joined the testing systems in 2010. In 2012 integrated laboratory testing systems of municipal health bureaus were also built. Besides, TFDA subsidizes equipment for local health bureau, and raises the testing technique and capacities annually.

Policy and Outcome

Integration of the resources with the collaboration of the local health bureaus and the supervising authorities boosts the quality and effectiveness of the laboratory function, and further promotes the establishment for the National Food Safety Laboratory Network.

1. Subsidizes for New Equipment to Strengthen the Testing Network Capacities

After the implementation of regional integrated laboratory testing systems of local health bureaus, every local health bureaus are responsible for authorized test items. With practicing skills and plenty of equipment, test efficiency and quality have relatively increased.

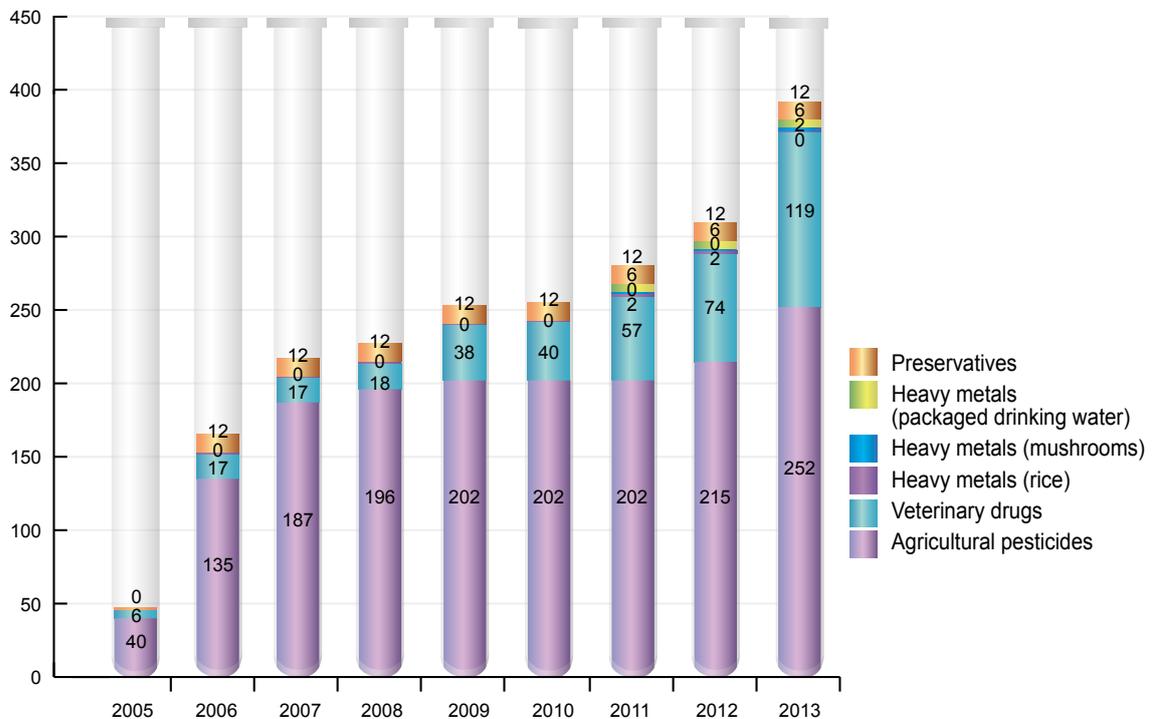
2. Results of Joint Regional Division

The implementation ratio of local self-test ability, starting from 2010 onwards, have been increasing year by year from the 35% average implementation before the subsidies, and in 2013 has already increased to about 70%. Newly added “Self-test items” include agricultural pesticides (252 items), veterinary drugs (119 items), heavy metals (11 items), mycotoxins (3 items), western drugs mixed to food (135 items), and others. After implementation of the joint division from 2005 to 2013, test items have increased gradually, improving the food testing capacities (Fig. 8-1).

3. Laboratory Accreditation

To ensure the testing quality of local health bureaus, until 2013, a total of 19 health bureaus laboratories have been accredited by TFDA, and counseling for health bureaus outside Taiwan Island to establish the authorized testing items has also been completed.

Fig. 8-1 Gradual increase of test items after implementation of the joint division from 2005 to 2013

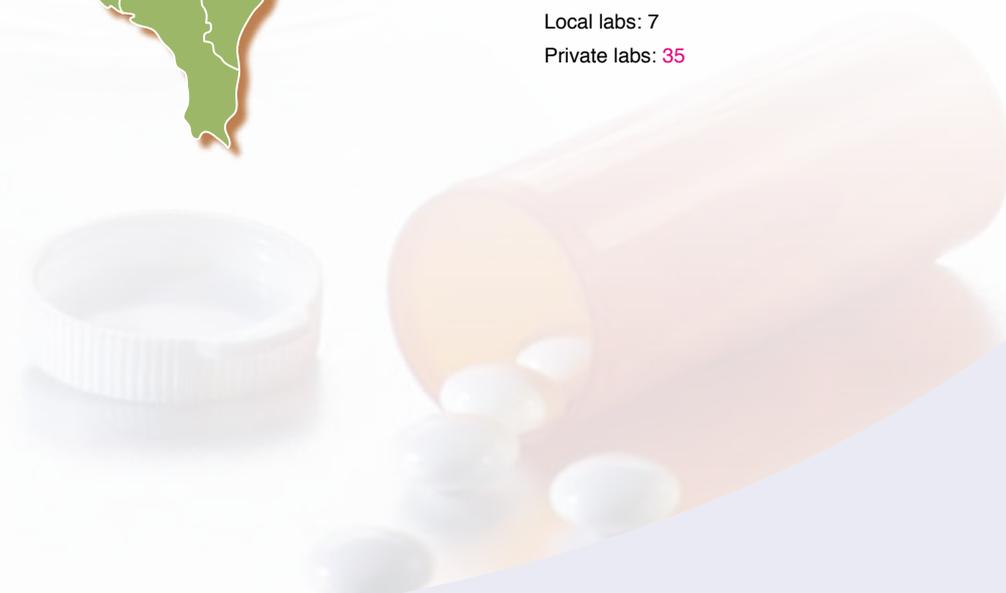
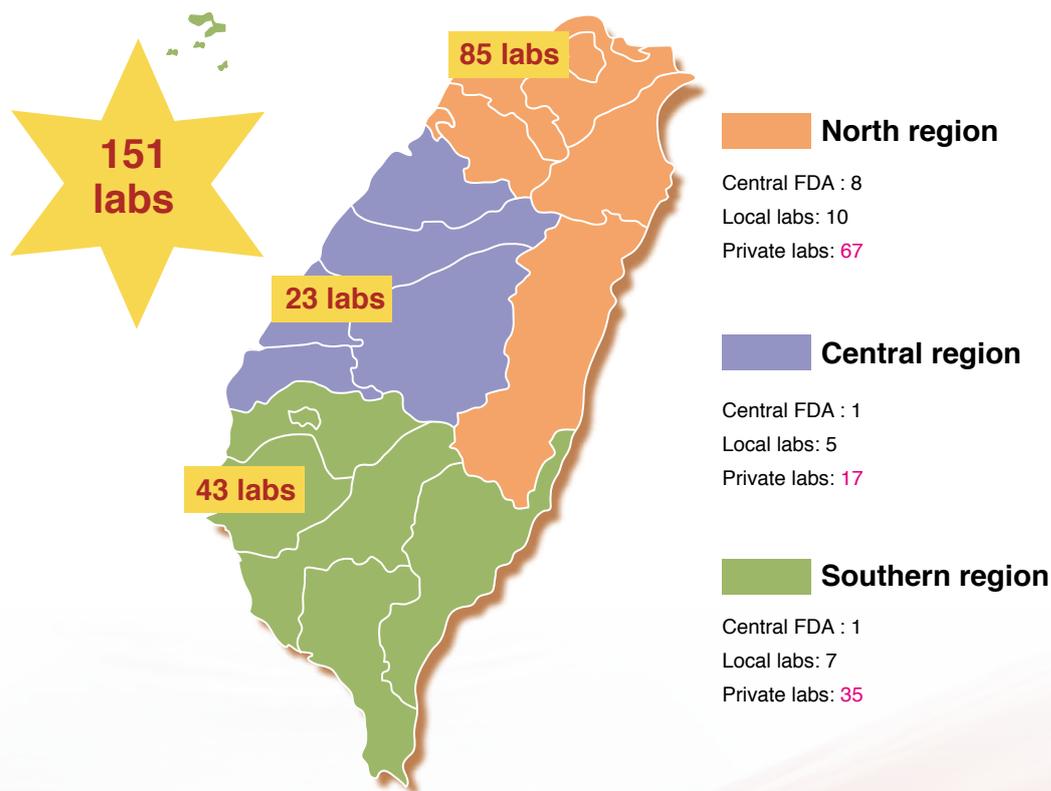


Section 2 Laboratory Accreditation and Management

Status

TFDA has been actively organizing free of charge accreditation for private laboratories in order to (1) effectively utilize testing resources of private laboratories, (2) ensure the quality and credibility of the commissioned tests, and (3) expand the testing forces. Currently TFDA accreditation scope includes (1) food, (2) drug and cosmetics, (3) drug abuse urine testing and (4) non-clinical GLP testing, and provides laboratories with testing capacities and credibility. Besides, those laboratories can meet emergency testing demands. Accreditation status is as shown in Fig. 8-2, the number of accredited items is 1,192.

Fig. 8-2 Numbers and distribution status of TFDA accredited laboratories



Policy and Outcome

1. Food, Drug and Cosmetics Laboratory Accreditation

(1) Expand the laboratory's capacities

In 2010 TFDA accelerated and expanded the accreditation action program for food, drug and cosmetics laboratories, number of accredited laboratories and items doubled from the 36 laboratories and 353 items in 2009, to the 86 laboratories and 1,125 items of end of 2013, of which 44 laboratories are in northern region, 13 in central region and 29 in southern region. There are 57 accredited for food, and 29 accredited for drug and cosmetics (Fig. 8-3 and 8-4).

Fig. 8-3 Laboratories accredited by TFDA over the years

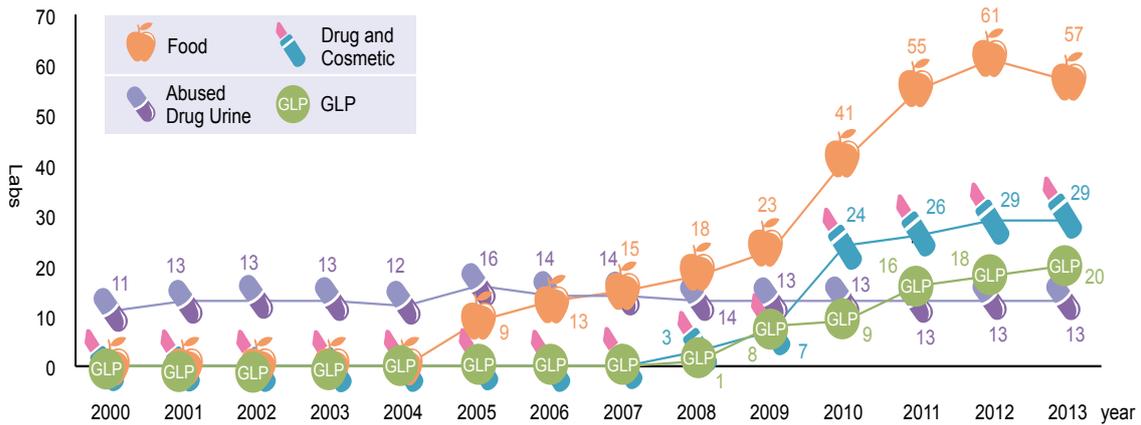
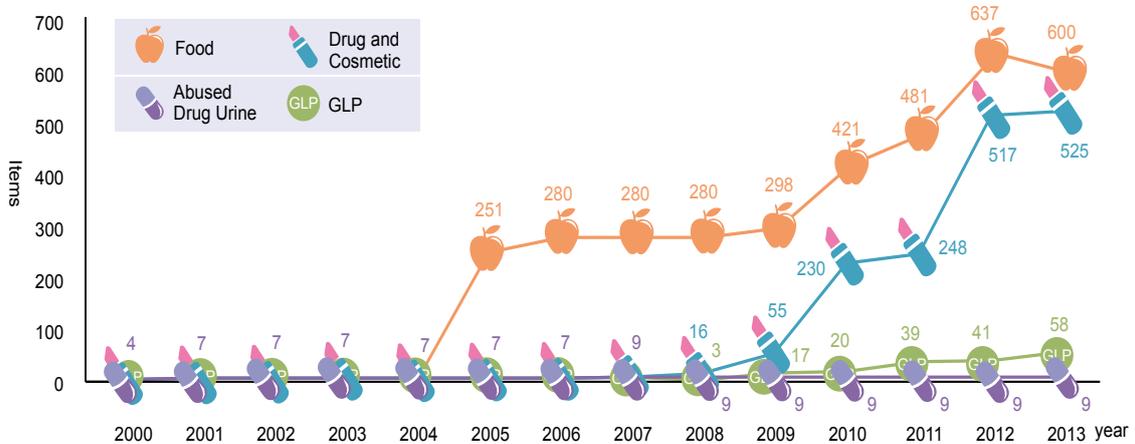


Fig. 8-4 Items number accredited by TFDA over the years



(2) The Fortification of the Managing Mechanism

a. Supervisory audit and irregular audit

In 2013 143 accredited laboratories were audited, including first time, items addition, changes and extensions, 93 laboratories underwent supervisory audit and 50 laboratories submitted to irregular audits.

b. Organizing proficiency tests

In 2013 added items and increased the frequency of proficiency tests, increasing frequency to 29 from the original 20, including 22 for food and 7 for drug and cosmetics. TFDA also organized 2 sessions of the “Laboratory accreditation test using double-blind samples”, in order to audit the authenticity of test data. In addition, TFDA encourages laboratories to participate in overseas proficiency tests to ensure the quality and self-management capabilities of accredited laboratories.

(3) Avoid duplication of testing

In January 2013 TFDA recommended five laboratories to being registered in the Class B list of common inspection agency system from exporting countries, Ministry of Health, Labour and Welfare, Japan, and to promote the exempting of importing sampling and testing operations of food imported from Taiwan to Japan, to speed up customs clearance and reduce test costs.

(4) Constant Amendments for Policy and Regulations related to the Accreditation Issuing

On July 23, 2013,TFDA announced the amendment of the “Operating procedures for food and drug and cosmetics laboratory accreditation”, “Standards for laboratory quality management” and another 5 accreditation related operating procedures and standards, in order to strengthen supervision and management of the accredited laboratory.

2. Accreditation for Drug Abuse Urine Testing Laboratories

- (1) By the end of 2013 a total of 13 institutions have been accredited for drug abuse urine testing, with 5 located in the north, 2 in the center, 5 in the south and 1 in the east.
- (2) To ensure the test quality of those accredited institutions, 13 regular inspections and 7 irregular inspections were performed in 2013, and 4 time quarterly routine proficiency tests were also performed, for a total of 52 institutions.

3. Non-Clinical Good Laboratory Practices (GLP) Accreditation

- (1) TFDA Implements the “Non-clinical Good Laboratory Practices (GLP)”, and establishes the laboratory accreditation review panel for the GLP field. In 2013 10 laboratories have applied and completed the GLP audit and counseling, and laboratories accredited for GLP by TFDA have increased to 20, with 15 located in the north, 3 in the center, and 2 in the south, with a total of 58 items accredited.

- (2) TFDA organized GLP annual audit personnel training and education course in 2013, and introduced the latest international information in real-time so that audit standards are conforming internationally.

Section 3 Mobilization for Emergency

Status

In response to emergency testing demands, TFDA mobilizes private laboratories with relevant testing equipment and capability to participate in the testing work, and through emergency response mechanism assists self-management inspection of commercial products and industry. To regulate the published private laboratories, as well as to ensure their test quality, on August 4, 2011 the “Operational directives in response to mobilizing private laboratories in emergency operations” was set up to be followed when facing relevant operations for a large number of required tests.

Policy and Outcome

1. In Response to Emergencies, TFDA Formulates the Participation and Testing Process for Accredited Private Laboratories.

2. Achievements of Emergency Inspection Mobilization

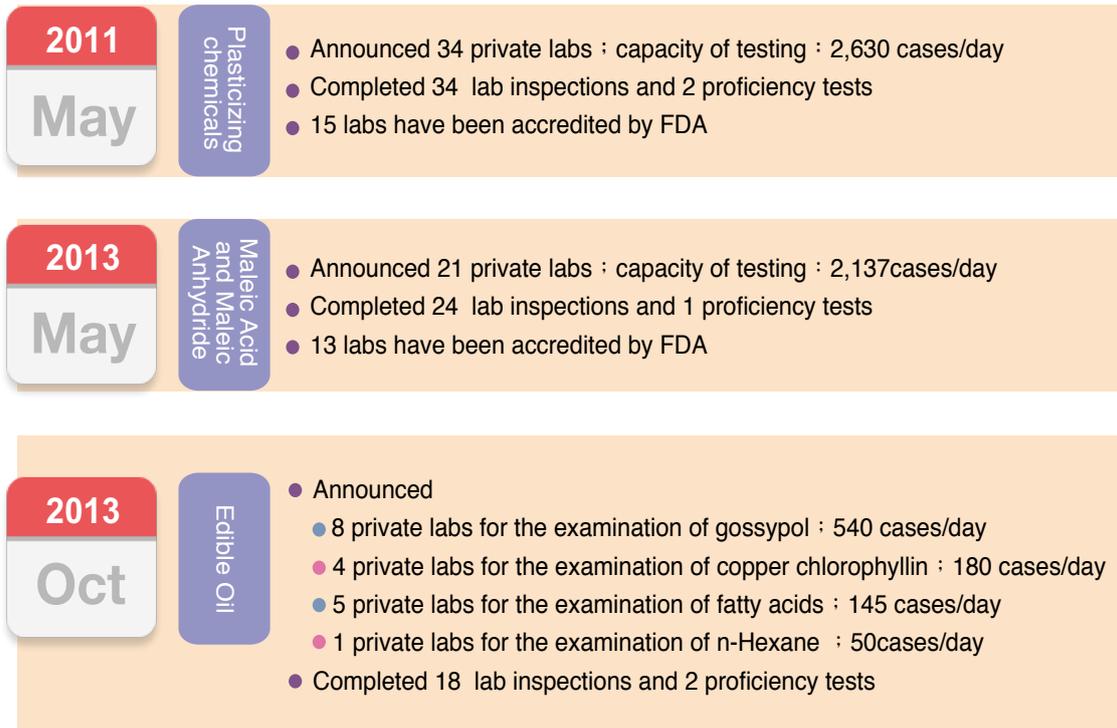
- (1) Laboratory list and inspection force

In response to the large number of test requirements, the “National Inspection Resource Database” which was set up by TFDA has investigated whether private laboratories possessing testing instruments were willing to participate and their testing capacities. The private laboratory mobilization achievements, such as plasticizers, maleic anhydride chemically modified starch and oil incidents, in response to emergencies in 2011-2013 as shown in Fig. 8-5.

- (2) Quality control of laboratory testing management

In response to emergencies, TFDA published list of laboratories, in addition to reviewing document, on-site inspection and proficiency tests were also organized and implemented. If the results of on-site inspection or proficiency tests are not satisfactory during the corrective period, if necessary, “Outside sample acceptance by laboratory for the test will be stopped”.

Fig. 8-5 Achievements for private laboratories mobilization in response to emergencies in 2011-2013





09

**Research
Outcomes**

Food Safety Control Research

**Medical Products Safety Quality
Research**

**Substance Dependence Integrated
Research**

**Nanotechnology Product Policy and
Management Research**

**Agricultural Biotechnology and
Genetically Modified Organisms
(GMOs) Research**

Chapter 9 | Research Outcomes

The Taiwan Food and Drug Administration (TFDA) safeguards food, drugs, cosmetics and medical devices safety for the public. Our mission is to promote life quality for a better future. The comprehensive regulatory policies shall be built on the solid basis of research on regulations, safety risk, and analysis technology to promote the harmonization of the domestic and international regulatory system, improve the linkage between laws and audit reinforcement, and look for the balance between “the maintenance of use safety” and “the promotion of technology development for better life quality.”

Section 1 Food Safety Control Research

States

The food safety management system is served as an important criterion for national and public health, and therefore, 70 research projects have been conducted and the outcomes are used for policy references in order to build the “safe” environment for food consumption.

Policy and Outcome

1. Product Source Management

Food chain involves serials of intricate complexity, while its various steps are closely correlated with each other. Every single step has an impact with the others, Good start brings promising result, Product source management is the critical initial step to promote the effective food safety management. Important outcomes are shown as in Table 9-1.

2. Food Distribution Monitoring and Management

In 2013, the TFDA monitored a total of 4,051 food items while the qualification rate was 92.4% to actively detect the defect rate in the market. Retrograde study data analysis was performed to prevent future food source contamination and to implement the comprehensive food safety system from production to consumption.

3. Enhancement of Risk Factor Evaluation for Food Safety

Food safety incidents have been frequently known in the recent years. In order to the effectiveness towards crisis management, the TFDA emphasizes prevention with early detection that promotes better results, particularly in high risk food factors or relevant ones. The important outcomes are shown as in Table 9-2.

4. Improvement of Test Technology and Lab Network Function

In order to quickly and effectively to safeguard food safety, the TFDA actively develops and builds important methods as shown in Table 9-3.

Table 9-1 Important outcomes of food product source management in 2013

Field	Outcome	Effectiveness
Food additives	Completed the compiling of "Food Additives Manual for Producers" and "Food Additives Auditing Manual for Health Agencies" and sent to relevant food producers and health stations of each city and county	Strengthened the correct awareness of food producers and health agencies respectively towards food additives and product manufacturing and sales control and management as well as auditing
Imported food	Completed statistic and analysis of the structural changes of origin countries, types, volume, and trading amounts of imported food to Taiwan in 2012	Provided reference for management polices of food safety management and information for negotiations
Risks of the catering industry	1. Advised 13 catering providers to introduce good hygiene practices (GHP) 2. Completed the compiling of the manuals of "Guidelines of GHP for Ready-to-eat Food" and "Operational Guidelines for Operators Engaged in Cutting of Fruit and Vegetables"	1. Established operational standards and control points and conditions of production process of ready-to-eat food, cooked food, and drink for improvement and the increase of product yield rate 2. Manuals can be used as the GHP reference for relevant producers
Health food management	Planned to enact the amendment draft of "Points Governing the Extension, Registration Change, Transfer and Re-issuing of Health food Permit"	Provided as the reference for future amendment of governing points to fully enhance the effectiveness and completeness of relevant rules and regulations of health food in Taiwan

Table 9-2 Important outcomes of food safety risk evaluation in 2013

Field	Outcome	Effectiveness
Maintenance and updating of risk databanks	The databanks built and updated include: 1. National food consumption databank 2. Taiwan food nutrition contents databank 3. The e-databank of health food	The establishment of databanks helps to promote the implementation of food traceability system, improve the responsive and handling mechanism for food safety incidents, and provided the reference for relevant policies made by the TFDA
Types of risk factors for food evaluation include: 1. Mold and bacillus cereus of rice ingredients and rice 2. Environmental hormones-PBDEs and hexa-BBs 3. Organic tin of aquatic products 4. Total amounts and types of as contained in grains 5. Chemical residuals in herb plant food 6. Nitrofurans contained in dairy and relevant products 7. Dioxin contained in tea and fresh vegetables 8. Acrylamide contained in baby food and breakfast cereal food 9. Stainless steel made food containers and utensils 10. Tests of milk bottles sold in the market 11. Triclosan, CH ₂ O, and ,4 dioxane contained in food detergent	Completed in total of 1,477 risk factors for food safety	The data has been used for local risk evaluation, particularly for the benefits of risk evaluation such as the identification of hazards and the description of hazard description



Table 9-3 Important outcomes of food test technology in 2013

Field	Outcome	Effectiveness
Types of test methods amended: 1. Tests for chemical residuals and animal drugs contained in food 2. Tests of genetically modified foods, Nutraceuticals & Functional Foods 3. Tests of illegally added, unknown substances, heavy metals, and natural toxicants contained in food 4. Tests of endocrine disturbance and other pollutants 5. Tests of foodborne pathogenic microorganisms	1. Added 13 official analytical methods for foods 2. Amended 33 official analytical methods for foods 3. Added 61 recommended analytical methods for foods	Practically applied to daily life to improve the relevant energy and quality of food safety in Taiwan
Special events: 1. Starch made from maleic anhydride 2. Copper Chlorophyll in cooking oil	The advanced countries have not established analytical methods, and the TFDA led others to establish test methods	Practically applied by health agencies at the local level to develop test methods to audit sources and relevant products

Section 2 Medical Products Safety Quality Research

States

In response to the dynamic changes in the drug and medical device industries, the management systems are required to be as versatile as possible in order to meet the security assurance and complication prevention purpose. Hence, researches on 71 different themes have been conducted for the building of more comprehensive management systems to achieve policy objectives to protect the public physical and psychological safety. Important outcomes are described below:

Policy and Outcome

1. Scientific Researches on the Technology Development and Legal Aspects of Medical Products

The TFDA works on the safety of drugs and medical devices to complete the legal system and assist the promotion of the R&D energy for the industry to link up academic researches and clinical practices and to strengthen the R&D chain of medical products. Important outcomes are shown as in Table 9-4.

2. Upgrade the Nation’s Laboratory Function from Drug and Cosmetics Technology Guidelines and Safety Evaluation Perspective

Important outcomes of technology inspection and safety evaluation of composition and drug safety are shown as in Table 9-5.

Table 9-4 Important outcomes of drug technology in 2013

Outcome	Effectiveness
Completed the enactment of standards/specification/draft of 516 items of drugs, medical devices, and cosmetics	For the TFDA and the industry to evaluate and control quality of products before and after launched to the market for the benefit to improve the quality biotechnology industry and to serve as the reference of managerial policies
Established "Center for Pharmaceutical Science" on March 25, 2013	Improved drug safety and effectiveness for the promotion of the development of medical industry in Taiwan
Screened the relevant technology services and evaluation of 1,262 items of drugs	Assisted safety evaluation operation of drug products to safeguard national health and the rights of clinical subjects for the benefit to adopt the responsive and counter measures
Organized 115 academic events (including conferences, seminars, seminars, and training sections)	<ol style="list-style-type: none"> Promoted academic exchanges and meanwhile collect various opinions for the full consideration of the legal environment of the drug act in Taiwan Through the cooperation and linkage of regional resources, the promotion of safe drug use education has been jointly launched to increase the knowledge and competence of safe drug use in the daily life

Table 9-5 Important outcomes for upgrading the nation's laboratory function

Field	Outcome	Effectiveness
Biological drugs and new advanced biologic	<ol style="list-style-type: none"> Established the animal attack model of EV71 vaccine potency test and PCV tests for live attenuated vaccines Established HCV genotype 2 national standard and sennoside B standard 	<ol style="list-style-type: none"> Provided for the EV71 vaccine development in Taiwan and strengthened the abilities to detect virus contaminations in live attenuated vaccines to ensure vaccine safety for the public Served as the reference for pre-market and post-market quality evaluation of relevant products for the benefit of development of the biotechnology
Management of chinese medicine	<ol style="list-style-type: none"> Built identification and preparation methods for various confusing herbs including Tianma and Fangjii Established test methods for Cinnamon and Agastache 	Practically applied to herbal materials and Chinese medicinal preparations tests and solved the difficulty to analyze complicated ingredients of agents to improve Chinese medicine test technology and quality
Drug quality	Completed the development of analytical methods for antibiotics contained in drugs in total of 17 ingredients	Practically applied to the regular test operations to quickly and accurately screen additives and to safeguard the public drug use safety
Medical devices and cosmetics	Respectively established <ol style="list-style-type: none"> Test methods for the 7 banned dyes and 10 Corticosteroids in cosmetics Orthopedics Implants - mechanical test methods for interspinous device Test methods for the oxygen permeability of contact lenses Test methods for water tightness and tensile strength of surgical gloves 	Practically applied to the regular test operations to ensure safety effectiveness of products and to safeguard the public drug use safety

3. Synchronization of Global Regulations and Promotion of International Cooperation

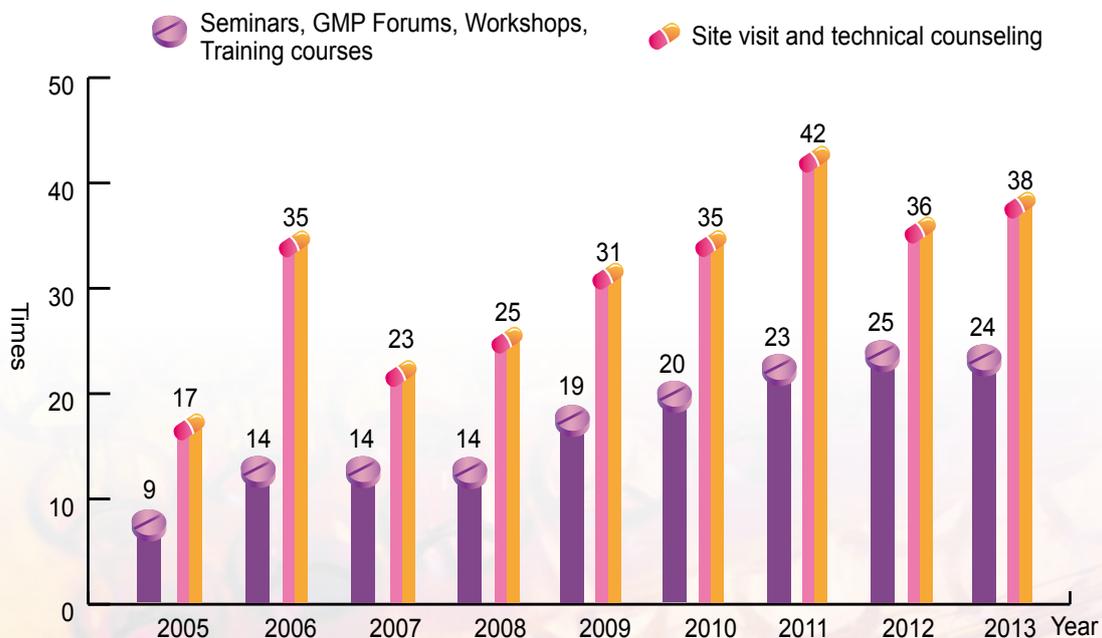
In 2013, the TFDA successfully increased global cooperation with different countries as well as the environmental building. In December, 2013, the TFDA joined The European Directorate for the Quality of Medicine and Healthcare (EDQM) and served as a pharmaceutical observer.

4. Research Enhances the Source Management and Manufacturing Quality

To enhance the development of Taiwanese biotechnology and pharmaceutical industry, the TFDA promote the domestic GMP management system actively.

In 2013, the TFDA provided a program of consulting visits for 38 pharmaceutical manufacturers and helped them to accelerate the implementation of PIC/S GMP. The TFDA also held 24 conferences to assist pharmaceutical manufacturers in training (Fig. 9-1). In order to prevent infectious diseases contamination or cross-contamination by human tissue and cell, TFDA conducted 15 GTP inspections of somatic cell therapy, and inspected 29 human tissue banks in 2013.

Fig. 9-1 Guide the domestic pharmaceutical manufacturers number of times through the years (2005-2013)



Section 3 Substance Dependence Integrated Research

States

Drug abuse is a universal challenge in the medical and public health fields. Hence, 19 research projects were conducted for the purpose of the control of drug management, the monitoring of the drug abuse and analysis of the prevention and intervention of the drug abuse mechanism.

Policy and Outcome

1. Comprehensive Control for Drug Classification and Management

In 2013, 5 seminars regarding sedatives sleeping pills and narcotics were held including one national on-line seminar and one seminar each for the northern, central, southern and east parts of Taiwan. In total of 1,292 medical doctors participated to share the updated knowledge highlighted the awareness for the risk and complication for control drug prescriptions. Ultimately, it will minimize the addiction risk from prescribed medication.

2. The Prevention and Intervention for Families, Communities and High Risk Groups' Drug Abuse Issues

The TFDA has built 6 anti-drug educational resource centers in the northern, central and southern districts of Taiwan to promote anti-drug education and developed two promotion strategies: "The Four Anti-Drug Actions" and "The Five Signature Notes Taking Sedative Sleeping Pills When Necessary" as well as prepared 10 educational brochures on how to prevent drug abuse to share the concepts of prevention with the communities.

3. Epidemiological Studies on Emerging Abused Drug

In 2013, a survey of knowledge, attitude and practice for new residents about drug abuse was conducted, the results found as follows can be used for management policy planning as a reference in the future.

- (1) For the knowledge and motivation of using illicit drugs, men are higher than women. Women living in the cities have higher proportions of using illicit drugs than those living in the countryside. 90% of women show no interest in illegal drugs.
- (2) MDMA, amphetamine, heroin, marijuana, and ketamine are the most heard illicit drugs.
- (3) Less than 10 % of the participants had heard family or friends who used illicit drugs before.
- (4) Educational background, gender, nationality, tobacco and alcohol use, and social support have associated with drug abuse.
- (5) The majority did not pay attention to anti-drug advocacy and treatment, however, the better ways for enhancing their awareness of drug are to provide television-based video or posters.



4. Establishment of Technology and Database for Drug Abuse

In response to the deteriorating drug abuse and addiction issues, TFDA continues to dedicate the developing new technology and establishing database to achieve the prevention effectively and control of drug abuse. Important outcomes are shown as in Table 9-6.

Table 9-6 Important outcomes for the establishment of test technology and data for drug abuse prevention and control in 2013

Outcome	Effectiveness
Completed the synthesis of 12 standard items and the establishment of standard spectrum database of H ¹ , C ¹³ -NMR, FTIR, GC-MS and HRMS	To meet the test demands, which the synthetic standards are not commercially available for abused drugs in Taiwan
Completed the optical spectrum conditions of 191 standard items (including amphetamine, cathinone, tryptamines, opium, marijuana, active substances of marijuana, cocaine, and benzodiazepines) as well as secondary fragment mass spectrometry database	To prevent and control drug abuse, quickly screening known and unknown abused drugs
Completed the discussion on optimal ionization conditions and spectrum linkage conditions of 35 substances contained in urine	Speeded up the time effectiveness of abused drugs and commanded the trend of drug abuse
Development the pre-treatment method and GS/MS instrument spectrum test methods for synthetic cathinones in urine	Provide as the reference method for the private labs to command the prevalent trend of synthetic cathinones

Section 4 Nanotechnology Product Policy and Management Research

States

Nanotechnology is the new 21st Century trend. The TFDA sets policies for nanotechnology research and application guidelines including all the correlated byproduct manufacture, risk factor evaluation and monitoring system management to assure the product safety and quality control.

Policy and Outcome

1. Establishment of Exceptional Rule and Regulation Management for Nano Biomedical Products

- (1) In 2013, 8 nanotechnology byproduct conferences were held including 2 for the nanotechnology drug policy, 3 for nanotechnology medical equipment policy, risk factors and experts, 1 for professional experts in nanotechnology cosmetics, and 2

for the education and management of nano-scale food to build the dialogues and communication channel for the industry, the government, academia, and the research institutions in order to achieve the goals of exchanges and building consensus.

- (2) In 2013, there were 11 proposals of management and evaluation assessment (including drafts) and recommendations were proposed which cover current updates for sectors of global nanotechnology such as new information of product management, application and safety concerns.

2. The Potential for Bio-Nanotechnology to Grow

As nano technology advances rapidly, the TFDA continuously enacts effective test methods for nano related products. In 2013, test methods completed and the effectiveness are shown below (Table 9-7).

Table 9-7 Relevant specification (drafts) of nano material products proposed by the TFDA

Type of product	Name of management specification	Test method (draft) and effectiveness
Nano drugs	<ol style="list-style-type: none"> 1. Checklist for chemical, manufacturing and control and management Technology Information of Nano drugs (proposed) 2. Technology information list for new liposome drugs and agents, new dosage, and unit amount attached as required for the inspection and registration of generic drugs (proposed) 3. CMC screening standards for liposome drugs 	Established methods to measure the particle diameters of drug ingredients after nano processed and practically applied to the discussion on the grinding conditions of nano Chinese herb medicine
Nano medical devices	<ol style="list-style-type: none"> 1. Points to consider for identification of application of nanotechnology in medical devices 2. Draft template of EP/STED for dental composites 3. Precautions for biological evaluation of medical devices containing nano-materials 	<ol style="list-style-type: none"> 1. Nano anti-bacteria safety evaluation guidelines (draft) 2. Nano dental filling resin safety evaluation guidelines (draft)
Nano cosmetics	<ol style="list-style-type: none"> 1. Rules governing the requirements for submitting technology, safety, and stability data for reviews of cosmetics containing nano-materials 2. Recommendations for attaching the table of physical and chemical properties and the table of biological safety evaluation with the submission of cosmetics containing nano-ingredients 	Establish analytical methods of the Zinc oxide and Titanium dioxide nanoparticles in cosmetics, and using the above method to characterize the commercial compact powder
Nano food	<ol style="list-style-type: none"> 1. Guidance on the safety assessment of nano-scale food) 2. Nano-scale food packaging materials safety assessment method (draft) 	<ol style="list-style-type: none"> 1. Test methods for particle diameters of nano calcium and nano pearl powder (draft) 2. Food utensils, containers, and package test methods- Tests of plastics contained with nano silver (draft)

Section 5 Agricultural Biotechnology and Genetically Modified Organisms (GMOs) Research

States

In order to educate the public on Genetic Modified food (GMO) food, six projects of classified researches were organized for product sector (involving animals, plants and microorganisms), policy sector (involving document collecting and policy making), and professional training programs (involving communication and consultation).

Policy and Outcome

1. Enhancement of GMO Management to Improve Health and Safety

The “Methods for GMO Food Safety Evaluation” was originally published in 2007 and then revised on September 9, 2010. For the purpose of assurance of GMO food safety, further revision as “Keynotes for Methods GMO Food Safety Evaluation” was published in 2013.

2. Aim of Development and Contribution from Innovative Biotechnology

In 2013, “Guidelines for GMO Allergens inducing Factors Evaluation and Laboratory Operation Handbook” was published. It augments the newly published “Methods for GMO Food Safety Evaluation (the revised edition)” and can serve in the current collection for all global standard regulation and evaluation for the GMO allergen inducing factors issues.

3. Enhance the Administration Effectiveness with Continuous Professional Talent Trainings

Since 2009 to 2014, continued education and professional consulting services are held annually, which covers the basic GMO knowledge to current technology discussion. By sharing and updating all professional knowledge and technology, the skill to unleash the potential for future technology development and knowledge advance is reassured.



10

**International
Cooperation
and Cross-Strait
Exchanges**

**International Cooperation and
Exchange
Globalization of Laboratory Testing
Cross-Strait Exchanges**

Chapter 10 | International Cooperation and Cross-Strait Exchanges

Through a variety of international cooperation and exchanges, TFDA has been able to access relevant information, to improve operational measures, to increase business results and accelerate the integration with international standards, and to achieve the purpose of regulatory harmonization.

Section 1 International Cooperation and Exchange

Status

On January 1, 2013, TFDA has formally joined the Pharmaceutical Inspection Convention and Co-operation Scheme (PIC/S). As an active member, TFDA is actively involved in leadership exchange meetings in Europe, America, Japan and other countries. TFDA has signed agreements and memorandum, built cooperation platforms to enhance our international reputation, and through participation in international regulatory harmonizing organization, TFDA has built a complete data bank for the international regulatory information and maintained compliance with international standards.

Policy and Outcome

1. Participation in International Organizations and Activities

(1) PIC/S committee meeting and expert circles

On September 9-14, 2013, TFDA hosted “The 20th PIC/S Expert Circle Meeting on Human Blood, Tissues and Cells” in Taipei, 50 officials from 29 health authorities of 22 different countries attended the conference. TFDA was elected as Deputy Chair of sub-committee on Compliance and member for couple more sub-committees. Strong bonding with PIC/S was established and leadership of TFDA was recognized.



The 20th PIC/S Expert Circle Meeting on Human Blood, Tissues and Cells



A nice visit with the European Directorate for the Quality of Medicines & HealthCare, the Council of Europe (EDQM)

- (2) Reached a consensus on cooperation with the European Directorate for the Quality Control for Medicines & HealthCare, the Council of Europe (EDQM)

On May 31, 2013, TFDA delegation visited EDQM and reached a consensus for 6 cooperation projects including the “Establishment of Confidential Agreement”, “Establishing joint inspection programs in the field of GMP inspection on manufacturing of APIs in Taiwan”, “CEP training programs in Taiwan”, “Participating in EP Biological Standardisation Programme (BSP)” and “Endeavoring for becoming an observer of the European Pharmacopoeia”.

- (3) Role as an observer of the European Pharmacopoeia

Since TFDA has formally become an official observer of the European Pharmacopoeia in December 2013, TFDA takes part in all the meetings and is actively involved in the decision making process. TFDA has also attended all the training programs.

2. Signing of Agreements and Memorandums (MOU)

Three international cooperation agreements and MOUs were reached in 2013, including Austria, Belgium and Japan as shown in Table 10-1.

3. Regulations Harmonization

- (1) Food Standards exchange and integration

In 2013, TFDA participated in the APEC Sub Committee on Standards and Conformance (SCSC) meetings on January 27-28. TFDA participated in the Food Safety Cooperation Forum (FSCF) under the SCSC Committee on April 13 and further participated in WTO-related seminars and conferences on October 14-17.

- (2) Participation in international conferences on drug policy

a. On November 27-28, 2013, TFDA conducted an international symposium for the International Pharmaceutical Federation (FIP) and hosted the SIG Regulatory Science Workshop as “Harmonization of Bridging Studies among Asia-Pacific



Table 10-1 Signed food and drug related agreements and MOUs, 2013

Document name	Signed country	Effective date	Document contents
Memorandum of Understanding on Cooperation Concerning Safety information of Medical Products	Austria	July 9, 2013	Information exchange on medical products, including policies, practices, standards, manufacturing quality, laboratory testing, pre-market assessment, post-marketing vigilance/ surveillance, inspection reports, market compliance and requirements for the regulation of medical products
Memorandum of Understanding on Cooperation Concerning Food Safety	Belgium	October 25, 2013	Information exchange, international risk assessment programs and secondment
Arrangement for the establishment of the Framework of the cooperation on the medical products regulation	Japan	November 5, 2013	1. Establishing sub-group(s) under the Framework for sharing experiences in the implementation of medical products regulation 2. Strengthening cooperation under the Framework through such activities as conducting seminars and workshops and inviting experts to the Framework when necessary

Region”. This symposium was the first drug relevant bridging studies seminar held in the Asia Pacific region, ever since the FIP implemented international norms ICH E5 was established 20 years ago. Representatives of regulatory authorities and experts from 11 different countries and international famous and distinguished scholars had joined the conference. The AAPS president’s and FIP chairman’s speeches had attracted nearly 400 guests from different sectors of industry, government and science research community.

b. On November 29, 2013, TFDA conducted an international conference for the APEC Symposium, the subject of the meeting is “Establishing a Regional Infrastructure to Facilitate the Accessibility of Orphan Drugs”. 300 participants from industry, government and science research sectors had made the presentations for the global rare drug management. The conference has successfully promoted the global synergy for rare drug regulations.

c. In 2013, TFDA has participated 7 Asia-Pacific region meetings for the International Pharmaceutical Affairs-related activities, another 7 of ICH-related activities, 4 more international pharmaceutical affairs-related conferences and 14 telephone conferences and meetings.

(3) Leadership for medical device regulatory harmonization

a. TFDA was elected as Vice-Chair of the Asia Harmonization Working Party (AHWP) and as Chair of the organization's Work Group for In Vitro Diagnostic Devices (WG1a-IVDD) technical committee in 2011.



The AHWP WG1a-PAHWP-LSHTM Joint Conference on International IVD Medical Devices Regulations

After that, three documents were published regarding the international guidelines for in vitro diagnosis medical devices. These documents were published by a Taiwan-championed work group, named as WG1a. The documents later were endorsed by the AHWP and became official AHWP documents. Research funds from the Bill & Melinda Gates Foundation were received to host an international IVD medical devices meeting in 2013.

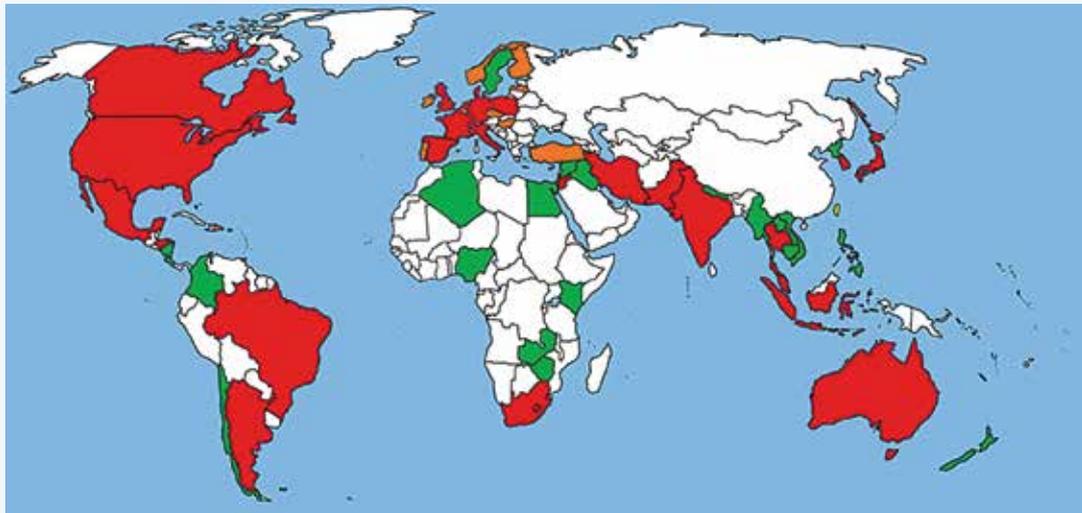
- b. In 2013, TFDA continued to participate in the APEC Life Science Innovation Forum Planning Group (LSIF-PG) meetings and Regulatory Harmonization Steering Committee (LSIF-RHSC) meeting. TFDA championed two priority work areas, including “Good Review Practice” (GRevP) and Combination Products in RHSC.

- (4) The cosmetic regulations will be amended to align with the international trends. Taiwan government is working on amending cosmetic regulations in order to harmonize with the international regulations and keep the communication channels open for the industry.

4. Vertical Alliance on Drug Abuse Prevention

In accordance with the provisions of international conventions, TFDA rigidly follows the written instruction for all the import and export control drugs required documents. International cooperation was emphasized. Safeguarding the distribution of legitimate controlled drugs is our mission. In 2013, 21 out of the

Fig. 10-1 Countries cooperated with TFDA with notification on international distribution of controlled drugs



■ Red represents countries with both import and export cases.
 ■ Green represents countries with export cases.
 ■ Orange represents countries with import cases.
 ■ White represents countries with neither import nor export cases.

total 41 exported countries have made a request to TFDA for the actual import quantity report, while 22 out of 52 imported countries have responded to the TFDA’s request and provided the actual export quantity report (Fig. 10-1), showing that Taiwan has become an important partner in the international distribution management of controlled drugs.

Section 2 Globalization of Laboratory Testing

Status

TFDA has worked closely with global top notch research facilities and sharpened our skills and knowledge with the cutting edge technology. In addition, TFDA hosted international conferences to share our experience. The momentum of our laboratory testing capacity grows through above experiences.

Policy and Outcome

1. Food Sector Industry

- (1) Enhancing cooperation with the United States Food and Drug Administration (FDA)
 - a. From 2011 to 2012, TFDA had sent our staffs to the FDA Food Safety and Nutrition Division (CFSAN) for one-year joint research project, and further invited the CFSAN pesticide inspection team leader Dr. Jon Wong to Taiwan, for academic exchange on food inspection technology.

- b. In 2013, U.S. FDA kindly provided instant technology support to our emergent requests twice. The first time is in the early 2013, the outbreak of dicyandiamide (DCD) in the New Zealand milk powder. The second time is at the end of 2013, the outbreak of edible oils in which copper chlorophyll may be adulterated.
- (2) Constantly participation in the “Association of Official Analytical Communities (AOAC)”
In recent years, TFDA has attended the annual meeting, oral and poster presentations were made in the international conferences.

2. Drug Sector Industry

- (1) In 2013, TFDA was invited to participate in the international collaborative study to calibrate “The 3rd WHO International Standard for B19V for NAT-based assays” and “The 2nd WHO International Standard for HAV for NAT-based assays”.



The “2013 International Conference on New Technologies of Vaccine Control and Development” Symposium

- (2) TFDA hosted an international symposium from May 29 to May 31, 2013, for the “2013 International Conference on New Technologies of Vaccine Control and Development”, and invited speakers from France, Belgium, Japan, Vietnam and Taiwan, The topics included “The Epidemiology of Zoonotic Diseases”, “New Vaccines R & D”, “The Quality Inspection Methods”, “The Quality Bioanalysis and Biomedicine”, “The Vaccine Quality Control System in Taiwan and Bioinformatics”, and “The Computational Medicine Management. The international conference promoted global knowledge connecting and technology exchange. Strong bonding was built among authorities, research facilities, and manufactures.
- (3) In 2013, TFDA prepared the national standard for Hepatitis C virus Genotype 2 for international collaborative study. Ten different laboratories including official laboratories manufactures and clinical trial facilities from 6 different countries such as United States, Britain, Germany, Japan, Switzerland and Taiwan were participated for the calibration analysis of the HCV.

- (4) In June 2013, TFDA was invited to “The 7th Asian World Vaccine Congress” conference. A keynote speech, titled as “Advancing Regulatory Convergence with international standards in Asia.” was delivered.
- (5) In May 2013, TFDA joined the internship for the “Drug Dissolution Theory and Methodology training”, as part of the USP training program.
- (6) In September, 2013, the National Pharmaceutical Control Bureau (NPCB), Ministry of Health, Malaysia, dispatched three officers to TFDA for a three-weeks training, the program related to the vaccine quality control testing, document reviewing, and inspecting.

3. Medical Devices Sector Industry

In September 2013, TFDA visited the Terumo medical device, Mitutoyo instrument manufacturing factories and Japan International verification unit JFE Techno-Research (JFE-TEC) for knowledge sharing. Scientists and technology researches from Taiwan and Japan discussed the concepts for medical device related measurement and verification.

Section 3 Cross-Strait Exchanges

Ever since “Cross-strait Agreement on food safety” signed on November 4, 2008, TFDA and its Mainland counterparts have convened “expert meeting of competent authorities” and “Import and Export Food Safety Meeting” each year to emphasize and exchange major concerns in food safety standards and risk communication. With regards to the medical products, another agreement, named “Cross-strait Agreement on medical and health cooperation”, was met on December 21, 2010, and on the basis of this Agreement, TFDA and CFDA have built up a working group to promote cooperation on product management, research and development.

TFDA and its Mainland counterparts designated contact points for different five categories including food, medicines, medical devices, health food and cosmetics in accordance with the agreements and established a communication platform and rapid notification mechanism. Furthermore, TFDA also entrusted Center for Drug Evaluation (CDE) with pilot programs for cross-strait cooperation on review procedures.

In 2013, TFDA continued unremitting technical exchange and comparison on laws and regulations between cross-strait. In order to accelerate the listing progress of Taiwanese products, TFDA successfully facilitated CFDA to establish a single consultation window for Taiwan manufacture’s inquiries. TFDA plans to focus cooperation on simplifying the approval process in the early next year.





1 1

Consumer Protection and Advocacy

Providing Immediate Information to
Consumer

Consumer Communication and
Advocacy

Chapter 11 | Consumer Protection and Advocacy

Couple food related incident happened in the last few years. It had dramatically placed negative impact on our nation. The reputation of the food industry was suffered and the growth of our economy was slow down from the controversy consequences. In respond to the emergency, TFDA had taken immediate actions and worked vigilantly for restoration. We emphasize consumer advocacy, customer service and professional training. Furthermore, TFDA had used all the incidents as examples to enhance the communication channels among consumers, media and TFDA.

Using all the cutting edge technology and professional knowledge, TFDA works hard to lead the public out of the misleading information and overwhelming worry. Sharing all the current professional information through consumer advocacy has promoted the bonding. A trustworthy relationship is rebuilt. Safeguarding the food, drug and cosmetics safety for every consumer is our goal.

Section 1 Providing Immediate Information to Consumer

Status

TFDA has set up websites like the “Food and Drug Administration” website for providing real-time information (<http://www.fda.gov.tw/>) and the “Food and Drug Consumer Knowledge Services Network” (<http://consumer.fda.gov.tw/>) to provide the integrated information for food, drugs and cosmetics relevant inquiries. In addition, through publishing articles in books, journals, media and internet, we had provided consumers with updated information and public health education.

Policy Outcome

1. Constantly updating the “Food and Drug Administration”, “Food and Drug Consumer Knowledge Services Network” and relevant website, TFDA strives to provide the public with most instantaneous public health information. Education advocacy programs and inquiry services are available for all the public.
2. We have set up current information centers for public inquiry. Several food safety issues were discussed and highlighted in the current news section.
3. The “Real-time drug safety information monitoring and delivery platform” was established to monitor domestic and foreign drug safety and quality alerts, and to announce the alerts to the public in time.

4. To improve the public competence of using medicines appropriately. TFDA constantly updates the “Drug safety education interactive learning website”. There were 203,701 website visitors until the end 2013.
5. The drug safety and quality alerts are published constantly. A total of 63 drug recall messages, 29 drug consumer messages, and 24 “Risk communication letter” were issued in 2013.
6. The dedicated website of advocacy materials for medical devices was set up allowing consumers to quickly obtain information regarding safe selection, purchase, and use of medical devices. The statistical results on domestic and foreign safety monitoring for medical devices and cosmetics in 2013 are as shown in Table 11-1.

Table 11-1 Statistical results on domestic and foreign safety monitoring for medical devices and cosmetics in 2013

Item Category	Medical devices (cases)	Cosmetics (cases)
Safety alerts	1,985	62
Recall notification	1,752	265
Excerpt published	127	52

7. The Facebook fan page and blog of TFDA cosmetics safety were set up to provide real time information to the public.
8. We encourage all the medical facilities to join the “Bulletin on controlled drugs abuse” program. A routine report was made in regular bases, from the analysis of the “Statistical data on drug abuse cases and tests” data bank, were served as the reference for domestic anti-drug departments. The “Controlled drugs newsletter” is published quarterly.
9. The “Ketamine hazard zone” was built in the “Anti-drug resources pavilion”, and TFDA has set up “Safe sleep Facebook fan page”.
10. The “Online application and diversified convenient payment platform system” was built to provide the public and industry convenient online application, payment method and download for forms and relevant information.
11. In 2013, TFDA had published more than 20 different kinds of food and drug-related publications. The “Journal of Food and Drug Analysis” and the “Annual Report of Food and Drug Research” were published. The information listed above has helped consumers to make the right selection. Every consumer has the right to understand all the revealed facts.



The Food and Drug Administration's website



Journal of Food and Drug Analysis

Section 2 Consumer Communication and Advocacy

Status

Sharing all the professional information regarding the monitoring mechanism for food and drug safety control and building risk communication to consumers through media is our goal. It has enhanced the diversified communication channels. And that will be good reference for consumers to make any further decision.

Education advocacy is a long-term commitment. Good information contributes to make good decision. A variety of communication channels were built as following. (Table 11-2) How to let public media be the advocacy to support our advocacy programs and health concepts are our goals.

Table 11-2 List of health advocacy outreach activities from the FDA in 2013

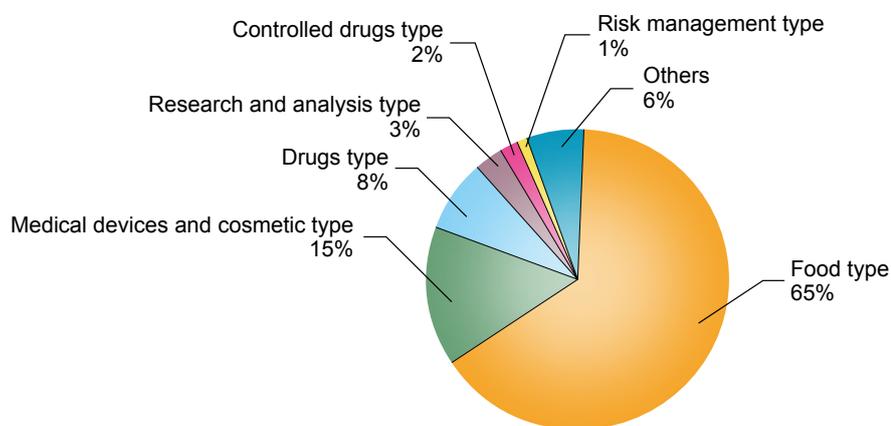
Classification Subject	Exhibitions / events (sessions)	Press conference (sessions)	Radio invited to visit (times)	Advocacy films / advertising (no.)	Radio advertising (no.)	Advocacy goods (unit) / print ads (no.)	Expert / department authored articles (no.)	Press release (no.)
Food	28	36	26	4	3	3	65	142
Drug	1	3	14	3	0	7	5	48
Medical devices	1	2	10	2	1	6	0	54
Cosmetics	0	2	8	4	1	6	24	
Controlled drugs	0	2	13	11	4	30	0	23
Illegal advertising illegal drugs	2	2	3	1	0	4	0	9
Total	32	47	74	25	9	56	94	276

Policy and Outcome

1. Diversified Advisory Services

(1) The call center number is (02) 2787-8200. In 2013, we had received 43,557 phone calls and 65% is inquiring regarding the food related issues (Fig. 11-1).

Fig. 11-1 Proportion of cases notified from call centre in 2013



(2) In the director's e-mailbox, we have received public citation and case petitions. A total of 10,617 cases were received in 2013. More than 50 % were food related issues. And all was resolved within five working days.

2. Consumer Risk Factor Concepts Advocacy

- (1) Holding forums and activities through meetings and conferences will promote risk factor education. It has brought up the community awareness.
- (2) TFDA has hosted legal conferences regarding the consumer protection. By proving advocacy programs, it will promote the understanding and prioritize the questions needed to be asked while any concerns come up. We had invited local communities and social groups "Health and safety risk concepts" workshops.
- (3) In response to food safety incident on edible oils, the "Adulterated and illegal copper chlorophyll added oils incident" forum was held to promote the communication with consumers. We emphasizes communication and by providing public health education.

3. Food Safety and Health Advocacy

(1) TFDA had established food sanitary volunteering programs to amplify the post market investigation by on site visiting and instant feedback. We emphasize safe food advocates. Seminars as "National Food Hygiene Volunteering Education and Training"

were held. A total of 814 volunteers were trained. Famous chef Ajishi was invited and endorsed “National Food Hygiene Volunteers Rallying Press conference”.

- (2) TFDA continues to update and to upgrade our informatics system. Further, TFDA has collaborated all the ministries, food management related facilities & departments. Through all the media and news magazines, we shared the most current food safety information and advocate the “Act Governing Food Safety and Sanitation”. In 2013, special websites were built based on current events when the “Maleic Anhydride Modified Starch” and “Adulterated and illegally added copper chlorophyll oils” incidents happened.
- (3) TFDA has conducted programs like the “Seeds planting for elementary school teachers to cultivate right food safety concepts to our young generations”. We have provided trainings regarding food poisoning prevention, proper food storage and all the food safety and risk factors concepts.
- (4) Through activities such as the International Food Fair, vegetarian food Fair, Taichung International Tea, Coffee and Bakery Show (TCFB Taichung), TFDA added fun into our advocacy programs, By interactive games and simple charts, we shared food and safety policies, prevention of food poisoning, and proper food storage information with the demonstration. And we also shared the consumer tips about how to choose the package food items. All the food incidents were used as examples for consumer advocacy.

4. Drug Safety Advocacy and Pharmacist Care Services

- (1) TFDA has produced the public health video to advertise the importance of drug safety. The content of the video is in coordination with the "Executive Plan for Counterfeit Drugs Joint Banning Group, Executive Yuan". In the advocacy film "The illegal drug prevention – father and daughter story”, we emphasize that the public should never take any medicine without knowing it’s source and manufacturers.
- (2) On September 25, the official "Drug Safety Day", a press conference for the topic of using drug correctly was held, and how to take analgesics appropriately was emphasized in this press conference (Fig. 11-4). On September 28, TFDA conducted a hiking activity named as the "Use Drug Correctly, Make Health Better". It was focus on the issue of analgesics use and promoted the five core capabilities and the “5-Yes and 5- No” principle of using drug correctly.
- (3) There are 112 educational centers of using drug correctly, 22 certified data banks of drug resources and manufacturers, and 473 community-based drug counseling stations in medical institutions nationwide. Also, TFDA constructed 1,321 educational sessions to promote the concept of drug safety.

- (4) In 2013, “The drug safety manual for Taiwan new residents” was translated into 4 different kinds of languages: Chinese, English, Indonesian and Vietnamese. Besides, TFDA hosted several numbers of educational seminars of drug safety for the new residents the physical or mental disabled, and their care keepers. Moreover, 60 seed teachers for spreading the concept of drug safety were well-trained in order to effectively promote the concept of using drug safely and correctly.
- (5) According to the year 2013 national survey of drug use behaviors and habits, 18.1% of the public does not realize that different analgesics inhibit the different kinds of pain. Hereafter, TFDA has produced several public health advocacy films, posters and pamphlets to educate the public about the concepts and behaviors of using drug correctly.
- (6) Pharmaceutical care services
- a. In 2013, TFDA hosted 3 home-based pharmaceutical care and 6 software training courses for pharmacists. A total of 354 qualified pharmacists were involved in the development of pharmaceutical care services.
 - b. In 2013, 6 local Health Bureaus were chosen to conduct the local pharmaceutical care and home-based care services. The total number of 744 issues of drug medication was detected. Regarding the community-based care, the service assisted 401 cases and revealed 428 questions of drug medication. Above all, each question resolved can save NT\$ 446 on the drug expenditures.

5. Drug Abuse Prevention

- (1) Drug abuse monitoring and early warning
- We have used diverse media for public health education to strengthen the drug abuse prevention network. In 2013, there were 19,535 drug abuse cases reported from medical institutions. The analyzed results were as follows:
- a. The top three most abused drugs were heroin (13,458 cases, 68.9%), (meth) amphetamines (4,704 cases, 24.1%) and ketamine (1,421 cases, 7.3%).
 - b. In 2013, 6 Department of Health in various countries were chosen to participate in the promotion program of the local pharmaceutical care service and home-based care service. The total number of 744 issues of drug medication was detected. Regarding the community-based care, the service assisted 401 cases and revealed 428 questions of drug medication. Above all, each question resolved can save NT\$ 446 on the drug expenditures.
 - c. Two major causes of drug abuse are “drug dependence” (44.7%), and “peer pressure” (15.9%).
- (2) Drug abuse prevention advocacy
- a. TFDA has worked with 34 non-government organizations to conduct drug abuse prevention events including public health crosstalk, dance, drama activities and lectures .In 2013, 790 advocacy activities were constructed by TFDA.

- b. Digitalized all the education resources will increase public awareness of drug-abuse. TFDA set up databank and digital anti-drug abuse resources and make it available for the public. TFDA have provided all the current drug related science information and people education materials.
- c. The film “Say No to Ketamine - toilet life story”, “Using Ketamine is a game we cannot afford” had showed in more than 700 cinemas and the short anti-drug film, “Take Ketamine, Diapers for Life” had played in the TVs in the Taipei MRT platforms.
- d. TFDA has set up 6 anti-drug educational resources centers all over the country. Posters, newsletters and brochures were made for the “Four ways to reverse drugs' damage”, “Five capabilities to correctly use sedative hypnotics” programs. Public health education is reinforced.

6. Advocacy for the Safe Selection of Medical Devices and Cosmetics

- (1) TFDA conducted the press conferences on “carefully recognizing the product license and reading the labeling will facilitate your selection of medical devices with ease”, “With the right wound dressing, wound care is fast and good!” product educational films and posters on “Medical devices protect your life”, “Love your family, take care of yourself, and choose legal medical devices”, “Medical devices protect your whole life” and “How to correctly select and purchase medical devices” to public and broadcast in various media.
- (2) FDA hosted press conferences for “Masked” men “Masked” women look here ~ facial treatment quintet, letting you be well-rounded! and “Magic hair care, so you have a way - safely select and use hair cosmetics”.
- (3) The animated movie for “Proper purchase and safe use of cosmetics” was played outdoors in Ximending. And an “Internet Quiz Contest” was conducted. These activities promoted consumers’ knowledge for proper purchase and safe use of cosmetics.



The press conference of 925 Drug Safety Day for analgesics taken correctly



12

Major Events

**Illegal Starch Manufacturing
Contamination Incident**

**Illegal Cooking Oil Adulteration and
Copper Chlorophyll Tainting Incident**

**The 2013 Act Governing Food
Sanitation Amendment**

**Integrating into PIC/S as the Official
Participating Authority**

Chapter 12 | Major Events

Section 1 Illegal Starch Manufacturing Contamination Incident

1. Causes of Incident

In 2013, unscrupulous food suppliers disregarded Taiwan citizens' health and national reputation by illegally producing food starch chemically modified by maleic acid, a substance banned as a food additive. It was widely used in many commonly consumed foods, including flat rice noodles, Taiwanese meatballs, oo-lian, tapioca balls, soy bean curd, starch jelly, taro cake/balls, sweet potato cake/balls, green bean vermicelli, sweet rice balls, fish paste, and pork paste, etc.

2. Timeline of Incident

Table 12-1 In 2013, Illegal starch manufacturing contamination incident timeline and descriptions

Case stage	Description
Brewing period	<ol style="list-style-type: none"> 1. Initiate Research and Discussions: On February 4th, it was rumored that maleic acid was present in processed foods. As a part of initial findings, the committee suspected suppliers were using unapproved maleic anhydride to manufacture chemically modified food starches 2. Establish Testing Techniques: On March 15th, the international collection process of information was initiated to develop test methodology
Investigation period	March 18 th - April 22 th : Commenced random testing of commercially available powder products such as starch, corn flour, tapioca starch, tapioca balls, taro balls, flat rice noodles, Oo-lian, and other related products, with 5 cases of maleic acid detection of 74 random samples tested
Trace and track period	<ol style="list-style-type: none"> 1. Trace and track investigation: Since April 10th, the Bureau of Health and Investigation have jointly inspected and confirmed violations by four end-product manufacturers and four starch manufacturers 2. Testing: During the investigation and trace and track periods, a total of 137 tests were performed 3. Press release was issued on May 13th
Comprehensive inspection period	May 14 th to 26 th : A large-scale law enforcement action was launched to reinforce the inspections of starch factories, dealers, and additive manufacturing plants
Launch "0527 Food Safety Case Investigation" project	<ol style="list-style-type: none"> 1. Launch complete-coverage, comprehensive inspections. 2. Demand Proof of Product Safety Affidavits or Certificates to be posted by all producers from eight major product manufacturing categories 3. Supervise and counsel starch producers 4. Increase informer cash rewards 5. Accelerate food sanctions legislation

3. Proactive Action Items

This Administration will immediately launch joint investigations with all local Health Bureaus to enforce inspections of all starch raw material manufacturers in their jurisdictions and trace and track the illegal products and raw material flow. Products that have been verified as illegal will be prohibited from sales, removed from shelves, recalled and returned to the upstream distributors or manufacturers, and destroyed under the supervision of the local Health Bureau immediately.

(1) Provide product safety affidavit or certificate

Starting from June 1st, 2013, all starch-category raw material suppliers were required to provide Product Safety Affidavits or Certificates to all vendors carrying starch-containing products. By June 20th, the Administration had confirmed and controlled the sources of the illegal upstream product manufacturing, and from that day on, vendors of starch products no longer needed to post raw materials Product Safety Affidavits or Certificates for starch products. However, they could still voluntarily post the affidavits or certificates, and any transgressions are still punishable by law.

(2) Process transparency

The reported results from all local city and county Health Bureaus have been collected, scrutinized, and published on the Administration's website. In the time leading up to June 30th, an estimated 571.63 tons of illegal products were recovered and confiscated. Except for a small portion (approximately 2.27%) sequestered by the prosecutors, the confiscated products have been destroyed. The involved suppliers that have been cracked down include one wholesaler and three distributors of "maleic anhydride", and nine manufacturers and 71 retailers of maleic anhydride-based starch.

4. Comprehensive Review of Regulations and Policies

Food safety incidents have repeatedly demonstrated that suppliers and manufacturers are incapable of self-management at the sources. Therefore, to curb the recurrence of illegalities from suppliers and manufacturers, comprehensive new laws will impose heavier penalties for all types of violations and increase fines for irregularities and criminal liabilities in order to give health agencies more authority and responsibilities and increase the liabilities of the food industry in order to establish and improve the food safety management system and consumer peace of mind.

Section 2 Illegal Cooking Oil Adulteration and Copper Chlorophyll Tainting Incident

1. Causes of Incident

- (1) In October 2013 an incident of adulterated oil and illegal addition of sodium copper chlorophyllin occurred. People in Taiwan commonly used olive oil for cooking, and



Taiwan has a high dependence on imported olive oil; unscrupulous businesses attempting to reduce product costs and meet market demands, committed such acts as illegal adulteration, false labeling, illegally using additives, etc.

- (2) According to Taiwan’s “Standards for Specification, Scope, Applications, and Limitation of Food Additives” provisions, if manufacturers intend to add copper chlorophyllin or sodium copper chlorophyllin in the production of foodstuff, the quantity added must be measured in accordance with the provisions on scope and limitations. Commercially available oil must be in compliance with the “Edible Fats Sanitation Standards,” and additives used must also meet the “Standards for Specification, Scope, Applications, and Limitation of Food Additives”.

2. Timeline of Incident

Table 12-2 Description and timeline of edible oil false labeling and illegal addition of copper chlorophyll incident

Case stage	Description
Reporting & tracing period	<ol style="list-style-type: none"> 1. Reports from citizen informants received: Testing results of the olive oil products provided by the informants showed fatty acid composition similar to CNS standards specifications but not quite identical, leading to the re-examination of products in order to verify whether there were illegalities 2. Inspections and random testing: Performed repeated inspections at factories, and sample testing of products, requested that businesses provide import declarations, blending and quality control records, and other evidence, but businesses deliberately evaded cooperation, leading to a lack of empirical proof. Since there were still doubts, further searches and investigations were performed jointly with prosecutors to seize specific evidence of violations
Investigation period	Initiate searches: Local Health Bureaus moved this case to the Prosecution for assistance. After the Prosecution collected the data, joint searches were launched by central and local health units on October 16 th , 2013
Comprehensive inspection period	<ol style="list-style-type: none"> 1. Heightened inspections: on October 17th, 2013, Health Bureaus from all counties were requested to heighten inspections on manufacturers and packaging plants of oils labeled “100%” edible 2. Released information on companies in violation and their products, imposed severe punishments according to the law, and requested all Health Bureaus to assist to supervise product recalls and product off-shelf operations 3. Statements about oil sanitation and safety, food additives and labels must be in compliance with the relevant provisions of the 2013 Food Sanction Management Act
Safe oil action	<p>On October 24th, 2013, Oil Safety Action was initiated:</p> <ol style="list-style-type: none"> 1. Confiscated illegal profits from businesses with major violations 2. Started comprehensive inspections, and mobilized all Health Bureaus nationwide for expanded inspections on retail products labeled as edible oil starting November 1st 3. Heighten border inspection of oil products 4. Demand edible fat industry to produce affidavits before October 31st, to ensure that raw materials and additives in their products are in line with what is shown on the labels

3. Proactive Action Items

(1) Launch “Oil Safety Action”

To protect the public rights on food consumption, the Ministry of Health and Welfare reinstated “thorough investigations and heavy fines” and also started the “Oil Safety Action” to continue investigations in conjunction with local Health Bureaus. And

Table 12-3 Analysis of unscrupulous manufacturers according to violation types

Violation type	Violations to the 2013 food sanction management Act	Penalties (provisions of violations)	Product handling
False labeling	Article 28 False Labeling	Fines between NT\$40,000 and NT\$200,000 (under Article 45)	Product corrections within deadline (According to Subparagraph 3, Paragraph 1 of Article 52)
Illegal addition of copper chlorophyll	Article 18 Provisions on Usage	Fines between NT\$30,000 and NT\$30,000,000 (under Article 47)	Products confiscation and destruction (According to Subparagraph 2, Paragraph 1 of Article 52)
Severe circumstances related to adulterated oil products	Article 15 “adulterating or falsifying”	1. 3 years imprisonment or a fine of not more than NT\$ 8,000,000 shall be imposed (under Article 49) 2. If not prosecuted, maximum fine can be set at NT\$150,000,000, or within the scope of their resulting profits (under Article 44)	Product confiscation and destruction (According to Subparagraph 1, Paragraph 1 of Article 52)
Business owners' refusal to provide information	Article 47 refusal to provide information or information is inaccurate	1. Fines between NT\$30,000 and NT\$3,000,000 (under Article 47) 2. For severe circumstances, the enterprises may be ordered to closing, and/or revoking all or part of registrations.	Suspend operations (According to Subparagraph 4, Paragraph 1 of Article 41)

inspections will continue to be conducted on oil manufacturers to track the flow of products and raw materials. Once products are verified to be illegal, product sales will be discontinued, products will be taken off-shelf and returned to the upstream retailers or manufacturers within the deadline, and product destruction is to be supervised by health authorities immediately. From November 1st, all 22 counties' Health Bureaus will begin the inspections on the labeling of raw materials and additives on edible oil products.

(2) Process transparency

This Ministry will supervise and control inspection operations and scrutinize, report, and publish results collected from all Health Bureaus regularly on the Food and Drug Administration's website (<http://www.fda.gov.tw/>) in a themed area titled "Adulterated Oil and Illegal Addition of Copper Chlorophyllin Incident Section." Information will be made public on the website to ease the populace. Unscrupulous vendors will be punished according to the June 19th, 2013 "Act Governing Food Sanitation". Violations are as shown in Table 12-3.

Section 3 The 2013 Act Governing Food Sanitation Amendment

1. Course of Amendment in 2013

- (1) The amendment draft to the 2013 Act Governing Food Sanitation was reviewed and passed by the Social Welfare and Environmental Sanitation Committee of the Legislative Branch on January 10th, 2013 on May 31th 2013 respectively.
- (2) On June 19th, 2013, the amended 2013 Act Governing Food Sanitation was promulgated, with the original seven chapters increased to 10 and the total number of provisions increased from the original 40 to 60. Special chapters on risk management for food safety, food import control, and food testing special chapters were added to explicitly regulate the food industry and to encourage self- management and a sense of responsibility, establish traceability system for sources and tracking the product flow, and add more comprehensive and heavy penalties, etc.

2. June 19, 2013: Authorization and Tasks from Act Governing Food Sanitation

Table 12-4 Main authorities and tasks given to health authorities by the 2013 act governing food sanitation

New additions by amendment	Amended section / clause	Content
I. Add special chapter of risk management for food safety	Section 2	The competent authority, in regards of emerging contaminants, amended the law to authorize health authorities, based on risk assessment or results of epidemiological survey of major food safety incidents are to announce the necessary governing measures in regards to significant or sudden food safety incidents, such as limiting or prohibiting imports and inspection. In addition, health authorities, based on scientific preventive principles, should be authorized to establish a food sanitation and safety monitoring system, and in the event of incidents endangering food sanitation and safety, they should issue warnings or adopt the necessary governing measures
II. Strengthen food businesses management	Article 7	Stipulate businesses self-management responsibilities
	Article 8	Enforce the rule that businesses can only begin to operate after registration
	Article 9	Establish a traceability system for tracing the sources and tracking the flow
	Article 12	Employ personnel with specialized professional or technical certificates
II. Strengthen food businesses management	Article 22 and Article 23	Require labels to state names of additive ingredients, not only functional names. Authorize the central competent authority to require labeling with main ingredients and their percentages
III. Strengthen the governing of food imports	Article 30	Import Custom Incentives Based on risk management principles, import custom incentives may be implemented for businesses with good import records to encourage continued self- management disciplines
	Article 33	Food Importer Liabilities To prevent the bound foodstuff in custody from being placed on the market by businesses, an imported food custody and money bond system has been put in place
	Article 35	Implementation of Source Management The competent authority has been authorized to implement systematic inspection before importation and send inspectors overseas for on-site inspections, reinforcement of management, and control of high-risk products

3. Develop Draft Amendments to Certain Provisions

As there were many instances of food act violation in 2013, this Ministry has developed a draft for the amendment of certain provisions in The 2013 Act Governing Food Sanitation, in addition to again amending the law to increase fines and criminal liabilities and adding the relevant mechanisms, including the inclusion of the concept of three levels of quality control in foods and the establishment of law and updating the source of food safety protection fund, in order to strengthen the food safety management and protection of consumer's rights.

Section 4 Integrating into PIC/S as the Official Participating Authority

1. Introduction to the PIC/S Organization

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) is an official international organization comprising of 46 regulatory authorities in the field of Good Manufacturing Practice (GMP) of medicinal products from all over the world. It leads the international development, implementation and maintenance of harmonized GMP standards and quality systems of inspectorates and other international affairs. The TFDA has been accepted as an official participating authority starting on January 1st, 2013.

2. Admission History

The TFDA submitted for PIC/S membership in 2010 and underwent a series of rigorous assessment by PIC/S, which included 89 indicators under 11 components in total. The accession procedures included dossier assessment and on-site visit. The Pharmaceutical Affair Act had been amended to specify that all pharmaceutical manufacturers engaged in the manufacture of medicinal products in Taiwan must be in compliance with PIC/S GMP.

3. After an Arduous Journey, We Successfully Became a PIC/S Member

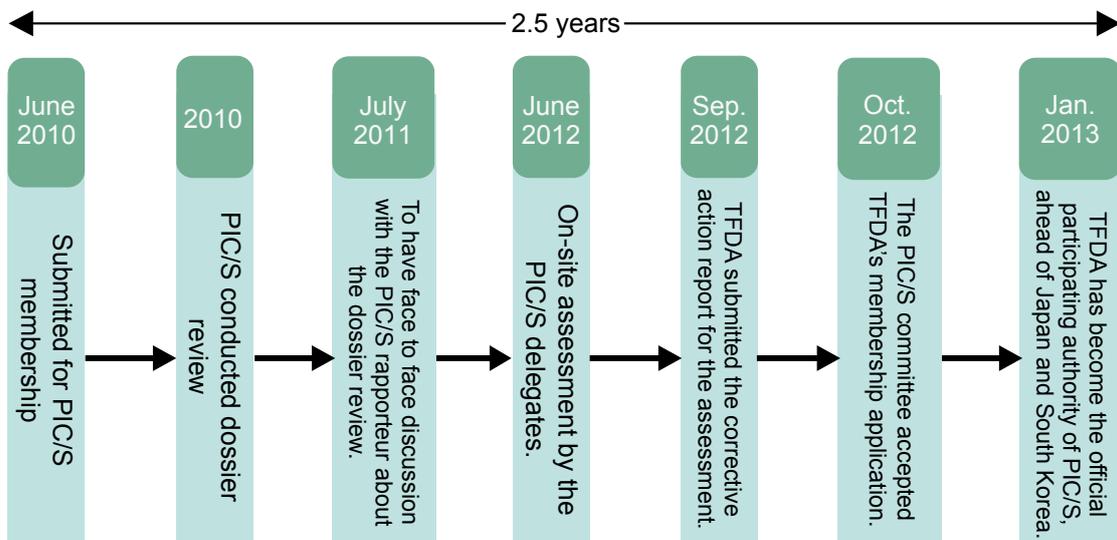
After 2 years and 6 months' efforts (Figure 12-1), on October 2nd, 2012 in Kiev, Ukraine, during the 35th PIC/S Committee meeting, all members approved our membership application. On January 1st, 2013 we became a full PIC/S member, ahead of Japan and South Korea, proving that Taiwan's pharmaceutical GMP

regulations, management systems and inspection standards have already gained international recognition and our domestic pharmaceutical quality is keeping pace with that of advanced countries.

4. Membership Benefits

After becoming an official member of PIC/S, Taiwan will not only be listed on the PIC/S Rapid Alert System; our international image has also been significantly enhanced, and our GMP inspection report can be recognized globally, in addition to avoiding duplicated inspections, and leveraging the inspection resources. Domestic

Fig. 12-1 PIC/S Admission timing





Taiwan became official PIC/S member here pictured with PIC/S chairwoman Ms. Helena Baião

manufacturers engaged in the manufacture of medicinal products that have authorized by MOHW based on PIC/S GMP inspection keep attracting manufacturing contracts from large international pharmaceutical companies, while increasing the value of exports of Western medicine. In addition, through the PIC/S platform, we can continue to strengthen our partnerships with other PIC/S members to assist domestic drug sales and marketing worldwide, allowing MIT drugs to “leap” onto the international stage.



Appendix

Appendix 1 Annual Statistics
Appendix 2 Website Links

Appendix 1 Annual Statistics

Annex table 1 Foodborne outbreaks statistics 2003-2013

Year	No. of Out-break cases	Number of poison cases		Food type of poisoning cause					
		No. of Patients	No. of deaths	Seafood and seafood products	Meat, eggs, milk and related products	Cereal, fruits, vegetables and related products	Confectionery	Compound cooking food (including meal boxes) and others	Unidentified vehicles
2003	251	5,283	0	8	0	5	0	15	224
2004	274	3,992	0	6	0	8	2	17	242
2005	247	3,530	1	7	5	4	0	18	213
2006	265	4,401	0	7	7	6	1	20	226
2007	248	3,231	0	4	6	7	0	13	218
2008	272	2,924	0	10	3	2	2	19	236
2009	351	4,642	0	4	2	3	4	43	296
2010	503	6,880	1	12	2	10	4	56	420
2011	426	5,819	1	23	5	9	1	73	315
2012	527	5,701	0	19	8	9	2	66	423
2013	409	3,890	0	10	7	9	1	22	338

Unit: case

Note: The total number has excluded the duplicate to get the correct summary.

Annex table 2 Health food and GMO food certificate statistics

Year	Issued health food license (Type 1+2)				Issued GMO food license	
	Type 1	Type 2	Licenses issued per year	Cumulative licenses issued per year	Licenses issued per year	Cumulative licenses issued per year
2003	11	-	11	40	6	9
2004	12	-	12	52	2	11
2005	23	-	23	52	1	12
2006	12	-	12	87	2	14
2007	24	-	24	111	3	17
2008	33	-	33	144	2	19
2009	26	6	32	176	18	37
2010	16	4	20	196	3	40
2011	17	6	23	219	13	53
2012	22	8	30	249	9	62
2013	14	13	27	276	10	72

Note 1: Health foods certified by the MOHW are classified in two types.

Type 1 (individual case review): manufacturer shall provide all the testing certificates relevant to food safety and health care effect .The license number is Wei Bu Chien Shi Tzu no. Axxxxx.

Type 2 (standard specification review): From December. 31, 2007, products shall comply with the standard specifications established by the MOHW. The license number is Wei Bu Chien Shi Tzu no. xxxxx.

Note 2: Till November 2013, a total of 276 licenses were issued including 239 type 1 licenses and 37 type 2 licenses; 27 licenses were invalid including expired, suspended, and combined licenses.

Annex table 3 Import food inspection statistics

Year	Inspected batches	Total net weight	Tested batches	Test percentage	Noncompliant batches
2011	420,601	717.7	29,800	7.09	288
2012	461,665	754.4	38,793	8.40	467
2013	514,710	713.3	38,460	7.47	557

Annex table 4 Annual statistics on pharmaceutical licenses

Year	Generic drugs			API			New drugs			Biologics			Orphan drugs			Total
	Do-mes-tic	Im-por-ted	Sub-total	Do-mes-tic	Im-por-ted	Sub-total	Do-mes-tic	Im-por-ted	Sub-total	Do-mes-tic	Im-por-ted	Sub-total	Do-mes-tic	Im-por-ted	Sub-total	
2003	315	71	386	30	126	156	40	98	138	0	26	26	0	3	3	709
2004	303	64	367	15	153	168	56	58	114	0	10	10	1	2	3	662
2005	369	47	416	8	132	140	18	43	61	0	14	14	2	6	8	639
2006	367	55	422	15	99	114	18	65	83	0	13	13	1	4	5	637
2007	422	32	454	6	115	121	22	47	69	0	16	16	0	0	0	660
2008	383	44	427	13	59	72	18	76	94	1	25	26	2	2	4	623
2009	449	47	496	5	91	96	24	56	80	0	17	17	0	2	2	691
2010	323	41	364	15	69	84	11	77	88	2	14	16	0	0	0	552
2011	220	52	272	20	172	192	17	46	63	1	24	25	0	2	2	554
2012	256	60	316	8	203	211	20	42	62	2	25	27	0	9	9	625
2013	247	51	298	7	105	112	23	14	37	0	1	1	0	3	3	451

Annex table 5 Lot release for biologics certificate statistics

Year	Vaccines and toxoids				Blood products		Antitoxins and antisera				Other biologics		Annual total	
	Domestic		Imported		Imported		Domestic		Imported		Domestic			
	Lots	Dose	Lots	Dose	Lots	Dose	Lots	Dose	Lots	Dose	Lots	Dose	Lots	Dose
2006	48	4,737,601	123	7,484,332	144	964,500	2	2,840	0	0	11	123,532	328	13,312,805
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

Annex table 6 Controlled drug permit and license statistics

Year	Item	
	Controlled drugs registration license	Controlled drugs prescription license
2004	12,011	33,052
2005	12,294	34,642
2006	12,302	36,112
2007	12,360	37,792
2008	12,465	39,467
2009	12,830	41,157
2010	13,266	42,619
2011	13,745	44,469
2012	14,149	45,844
2013	14,477	47,384

Annex table 7 Controlled drug audit statistics

Year	Item		
	No. of Audits	No. of Violations	Violation rate(%)
2004	15,681	182	1.16
2005	18,164	186	1.02
2006	16,629	306	1.84
2007	16,451	232	1.41
2008	16,241	270	1.66
2009	16,355	245	1.50
2010	15,154	196	1.29
2011	15,270	147	0.96
2012	16,214	202	1.25
2013	16,197	211	1.30

Annex table 8 Self-manufactured controlled drugs and sale statistics

Unit: Thousand NT\$

Year	Total income	Sales income	Delivered to Treasury
2001	323,087	301,924	153,841
2002	342,325	329,065	137,676
2003	371,757	368,132	116,600
2004	403,701	401,055	131,648
2005	423,671	419,829	128,771
2006	431,369	426,393	123,385
2007	436,341	433,122	107,105
2008	477,133	470,627	101,441
2009	507,794	505,340	138,473
2010	484,762	483,169	145,956
2011	491,524	489,523	116,414
2012	494,672	491,909	120,000
2013	513,092	510,119	120,000

Annex table 9 Post market drug quality monitoring statistics

Year	Pharmaceuticals		Biologics		Chinese medicine*		Annual total	
	Cases	Unqualified rate	Cases	Unqualified rate	Cases	Unqualified rate	Cases	Unqualified rate
2004	562	0	340	0.59	800	-	1,702	0.22
2005	439	0.46	324	0	800	-	1,563	0.26
2006	484	3.31	137	0	860	-	1,481	2.58
2007	295	2.37	0	0	480	-	775	2.37
2008	164	16.46	0	0	1,000	-	1,164	16.46
2009	180	1.11	0	0	720	-	900	1.11
2010	198	3.03	0	0	660	-	858	3.03
2011	230	8.70	23	0	664	3.13	917	6.94
2012	83	3.61	108	4.63	629	4.70	820	4.41
2013	85	1.18	114	0	544	3.47	743	1.75

* "-" Background values for investigation

Unusual ingredients found in concentrated Chinese medicine formulation .In 2011 , two out of 64 of post market product failed the qualification test.

unqualified rate ($2 \times 100 / 64 = 3.13\%$), in 2012 were 149,

unqualified cases were 7, unqualified rate ($7 \times 100 / 149 = 4.70\%$), in 2012 were 144, unqualified cases were 5, unqualified rate ($5 \times 100 / 144 = 3.47\%$).

Annex table 10 Residue pesticides and veterinary drugs in food

Year	Monitoring of pesticide residues in agricultural products from markets and packing firms				Determination of veterinary drug residues in foods			
	Case no.	Conforming cases	Non-conforming cases	Conformity rate(%)	Case no.	Conforming cases	Non-conforming cases	Conformity rate(%)
2004	1,276	1,268	8	99.4	-	-	-	-
2005	1,638	1,632	6	99.6	-	-	-	-
2006	1,605	1,589	16	99.0	-	-	-	-
2007	1,761	1,689	72	95.9	-	-	-	-
2008	1,765	1,557	208	88.2	-	-	-	-
2009	1,894	1,696	198	89.5	-	-	-	-
2010	2,051	1,856	195	90.5	330	324	6	98.2
2011	2,110	1,878	232	89.0	481	437	44	90.9
2012	2,363	2,121	242	89.8	572	532	40	93.0
2013	2,340	2,080	260	88.9	736	703	33	95.5

Annex table 11 Local health bureau auditing statistics

Year	Label inspection			Specimen testing			Food good hygiene practices (GHP) inspection				
	Label case no.	Non-conforming no.	Conformity rate (%)	Testing cases	Non-conforming no.	Conformity rate (%)	Inspection no.	Counseling/Deadline to improve no.	Fined cases no.	Business cessation no.	No. of cases referred to the courts
2008	795,119	16,188	97.96	43,545	2,629	93.96	143,779	34,177	65	81	6
2009	874,959	17,474	98.00	38,770	2,650	93.16	150,675	32,463	92	18	6
2010	796,758	15,140	98.10	38,056	2,493	93.45	136,456	28,967	131	5	3
2011	806,324	9,529	98.82	42,372	2,240	94.71	117,420	35,013	6	12	0
2012	683,956	7,027	98.97	41,956	1,958	95.33	118,681	49,587	75	13	0
2013	661,619	34,058	94.85	40,844	2,289	94.40	123,476	51,324	31	21	0

Appendix 2 Website Links

No.	Website name	Website
1	Taiwan Food and Drug Administration	http://www.fda.gov.tw
2	Food and drug consumer service network	https://consumer.fda.gov.tw
3	Online application with diversified and versatile platform	https://oaps.fda.gov.tw
4	Import food information system	https://ifi.fda.gov.tw
5	Product management distribution system	https://pmds.fda.gov.tw
6	Food Businesses registration platform	https://fadenbook.fda.gov.tw
7	ROC chef certificates informatics system	https://chef.fda.gov.tw
8	Overseas inspection system	https://ffis.fda.gov.tw
9	Post market quality management system for food ,drug and cosmetics management system	https://qms.fda.gov.tw
10	Electronic common technical document (eCTD) operating system	https://ectd.fda.gov.tw/ectd/index.aspx
11	Drug Information network	http://plan-consumer.fda.gov.tw/medication
12	Proactive monitoring of drug safety platform	https://sentinel.fda.gov.tw/
13	Drug safety monitoring	http://medwatch.fda.gov.tw
14	National drug therapeutic in equivalence reporting system	http://dtirs.fda.gov.tw
15	National adverse drug reactions (ADRs) reporting system	https://adr.fda.gov.tw
16	National medical product defective reporting system	http://recall.fda.gov.tw
17	National cosmetic defect product reporting system	http://cosmetic-recall.fda.gov.tw
18	Dietary supplement non-expected reporting system	http://hf.fda.gov.tw
19	Controlled drugs management information System	https://cdmis.fda.gov.tw
20	Surveillance system of drug abuse and addiction treatment	https://dars.fda.gov.tw
21	Analytical laboratory drug abuse reporting system	https://udars.fda.gov.tw
22	National substance use survey	http://nsus.fda.gov.tw
23	Laboratory accreditation network	https://lams.fda.gov.tw
24	Drug and cosmetics advertising management system	https://adms.fda.gov.tw/adms
25	Illegal advertising inquiry system	http://illegal-ad.fda.gov.tw
26	JFDA online journal system	http://jfda.fda.gov.tw
27	Online learning system	https://elearn.fda.gov.tw

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