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# Taiwan Food and Drug Administration FDA

# 2015 Annual Report

Food and Drug Administration, Ministry of Health and Welfare
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FDA Taiwan Food and Drug Administration

# 2015 Annual Report

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## Supportive Systems

# Foreword

## A New Start for *Confidence in Food and Drugs Safety*

The safety and quality of food, drugs and cosmetic products are closely entwined with our lives and health. To initiate a chapter and era for food and drugs safety management and meet public expectations and *Confidence in Food and Drugs Safety,* the Taiwan Food and Drugs Administration (TFDA) has shouldered the crucial task of protecting public health and continued to build a comprehensive and robust food and drugs safety management system.

This annual report has been specifically compiled so that every reader will be able to gain an understanding of policy highlights and outcomes achieved in 2014. *Product management* has been selected as the main theme of this annual report, which describes the implementation of relevant regulations and policies governing food, medicinal products, controlled drugs, medical devices, and cosmetics. We have also established a *supportive system* to demonstrate the product quality assurance, factory management, logistics, monitoring, and border control. That includes risk assessment management, technology developed results, national laboratories, inspection network, international collaborations, risk communication, and consumer protection, hopefully, this annual report will promote public cognition about the current status of Taiwan's food and drugs management policies and business. Additionally, this annual report contains a series of major events and general statistical information for public reference and review.

## Management and Regulatory Improvements, Optimization of Review Service Capacity and Efficiency

To ensure the comprehensiveness of our country's food safety and sanitation management system, the TFDA twice revised food safety regulations in 2014. The *Act Governing Food Sanitation* was formally revised to the *Act Governing Food Safety and Sanitation* which adopts the protection of public food safety as its highest principle. Key amendments include thorough improvements to food business registration, traceability, and three-level quality control with self-management responsibilities, establishment of a Food Safety Office in the Executive Yuan, setting up a Food Safety Fund to increase resource utilization, and large increases in the fines and penalties against food adulteration and counterfeiting. 2014 is also marked as the first year of food business registration. Following promotional efforts of all county and city health bureaus as well as support shown by various food businesses, over 150,000 food businesses have been successfully registered nationwide as of 31 December 2014. TFDA continued its border inspection of food products as well as post-market surveillance of residual veterinary drugs and pesticides to thoroughly enforce and control food sanitation and safety.

TFDA also developed new food analysis and testing methods. In 2014, TFDA successfully developed the world's first testing and identification methods for *tainted animal contents in oils and fats* as well as *dimethyl yellow and diethyl yellow in food*. DNA barcode identification and inspection technology for commercial fish and exclusive molecular biology testing methods for Dory Fish were established as well. TFDA also strategically integrates resources from the private sector as well as all health bureaus for work specialization, 154 private laboratories and 21 health bureau laboratories have been certificated at the end of 2014 which can be able to carry out a total of 1,837 tests.

For improvements to the medicinal product review mechanism and advising of domestic pharmaceutical manufacturers on alignment to international standards, TFDA established the *Professional Consultation System for Pharmaceutical Projects* for new drug development in the country in 2014. A tangible result under the system was the development of Nemonoxacin, a new chemical entity independently developed and first approved in Taiwan with TFDA consultation. This achievement demonstrates

that the standards of the Taiwanese pharmaceutical sector are on par with those of developed nations and that new drug application and management systems in Taiwan are also aligned with those employed by countries with advanced pharmaceutical industries. To further improve Taiwan's medicinal product manufacturing quality and compliance to international standards, TFDA thoroughly implemented the PIC/S GMP standards starting in 31 December 2014. Under PIC/S, source management of medicinal products is strictly enforced to safeguard drug use safety amongst the general public.

TFDA also worked hard in creating an excellent, high-quality, and comprehensive clinical trial environment for medical devices with the successful signing of a multi-national medical device clinical trial cooperative program agreement between the top 5 medical institutions in Taiwan and leading international firms in 2014.

## Common Goals and Collaboration - International Participation and Building Consumer Confidence

In 2014, TFDA endeavor to participate in international harmonization organizations, signing three agreements related to food, medical device and cosmetics and memorandums of understanding (MOU) to promote bilateral activities and creating new international markets. To achieve the goals of cross-Strait partnership and exchange, TFDA continued to promote harmonization of regulations and standards employed by Taiwan and Mainland China under the terms of the *Cross-Strait Agreement on Medical and Health Cooperation and the Cross-Strait Rapid Reporting System.*

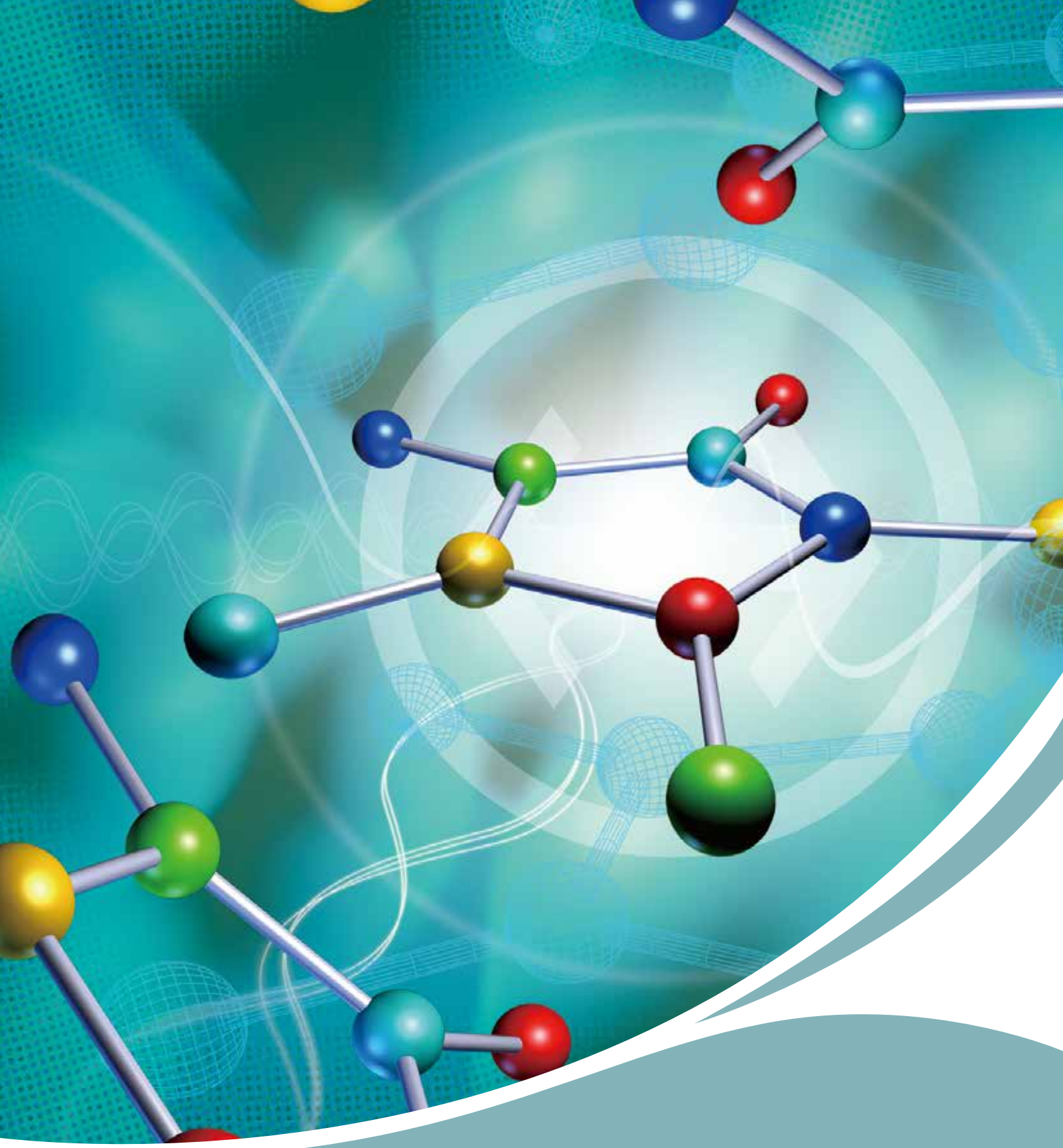
On the issues of consumer protection and risk communication, the core value adopted by TFDA is to create correct consumer knowledge and understanding. Potential safety and quality risk factors in food, medical products, and cosmetics are communicated through diverse and real-time channels, helping to quickly disseminate correct information to eliminate public doubts and concerns. In 2014, TFDA combined together the power with teachers and students in various schools as well as civil groups to promote correct knowledge on food safety and medication knowledge. Enthusiastic volunteers were also widely recruited to jointly safeguard food safety and transmit correct information.

## Commitments Towards a Homeland with Safe Food and Safe Drugs

To achieve the vision of *serving as a guardian of food and drug safety that the public can depend upon and creating a safe consumer environment for food and drugs*, and to prepare against increasingly diverse food and drug safety challenges in the future, TFDA has adopted the goals of enhancing legal basis and scientific research, strengthening import management, improving production quality, controlling product flows, and safeguarding consumers. Thus, a comprehensive food and drug safety management system is created to provide *Confidence in Food and Drugs Safety.*

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

Yu-Mei Chiang



# 1 Policy and Organization

Policy Objectives and Focus Areas

Organization Framework

Future Prospects

# 1 Policy and Organization

The safety, quality, and efficacy of food, drug and cosmetics are intimately related to public health. A competent authority with comprehensive product management capabilities must effectively control and manage marketed food, drug, and cosmetics, counter illegal drugs and violative foods, conduct product health risk assessment and management, and prevent abuse of controlled drugs. At the same time, in order to promote national biotechnology development, strengthen consumer protection, and align the country's laws to global food and drug safety management trends, the original Food and Drug Bureau was restructured to form the Taiwan Food and Drug Administration, Ministry of Health and Welfare ("TFDA") with the goals of strengthening food and drug safety management and establishing a unified regulatory mechanism.

## Section 1. Policy Objectives and Focus Areas

The TFDA takes reference from administrative guidelines of the Executive Yuan, implementation and development of related policies, and current social conditions to enhance food and drug regulations, strengthen management over manufacturing plants, raw materials, and imported products, effectively track product distribution, and establish transparency of product information to safeguard consumer safety and provide the general public with an environment that promotes *Safe Food* and *Safe Drug*.

### Administrative Objectives

1. Improve the comprehensiveness of management and risk assessment systems for food, drug, and cosmetics; strengthen the management of raw materials and sources of food, drug and audit the distribution of these products; rebuild the reputation of Made in Taiwan (MIT) food and drug.
2. Promote interministerial collaboration; prohibit illegal drugs and intentionally adulterated food products; strengthen controls over food and drug advertisements; achieve effective reduction in drug abuse.
3. Establish a medicinal product review mechanism aligned with international trends; simplify drug review procedures; achieve effective drug production management and safety monitoring; and provide the public with safe and effective drug.

### Administrative Highlights

#### 1. Amendments to Product Management Regulations;

(1) Enhance the legal context for modern product review and management;

(2) Enhance the legal context for food management;

(3) Develop medicinal product technologies and conduct regulatory science research.

### 2. Strengthen Product Manufacture Management

(1) Establish food business and product registration systems;

(2) Enhance product raw material management;

(3) Promote business compliance with good practice regulations or health guidelines.

### 3. Perfect Product Review Regulation

(1) Establish modernized food and medicinal product review systems.

(2) Strengthen medicine and cosmetics advertisement review mechanisms;

(3) Improve personnel professionalism and competence.

### 4. Strengthen Product Distribution Audit and Quality Monitoring

(1) Strengthen the monitoring of food production and distribution;

(2) Strengthen the management of imported foods;

(3) Strengthen the management and auditing of plants manufacturing drugs, medical devices, and cosmetics;

(4) Develop comprehensive product post-market surveillance investigation and research;

(5) Strengthen food products, drugs, and cosmetics distribution audits and quality monitoring;

(6) Strengthen and enhance auditing and management systems for illegal drugs and illicit advertisements.

### 5. Strengthen Laboratory Testing Capabilities

(1) Integrate central and local systems to establish a comprehensive inspection management system;

(2) Improve inspection technologies and laboratory network functions;

(3) Improve national laboratory functions.

### 6. Strengthen International Collaboration and Cross-Straits Exchanges

(1) Enhance international collaboration regulations to establish an internationally harmonized environment;

(2) Improve food and drugs testing to international standards.

### 7. Reinforce Risk Management

(1) Strengthen food safety risk assessment capabilities;

(2) Promote consumer education and risk communication;

(3) Enhance the consumer protection framework.

## Section 2. Organization Framework

The original Food and Drug Bureau was reformed into the new Taiwan Food and Drug Administration (TFDA) as part of the reorganization of the Ministry of Health and Welfare of 23 July 2013. The reformed TFDA continues to carry out its professional tasks and demonstrate its post-reorganization performance in order to ensure public safety and interests in the use of food products, medicinal products, medical devices, and cosmetics.

### Organization and Positions

1. TFDA is charged with the management food, drugs, controlled drugs, medical devices, and cosmetics ("products") as well as the formulation and implementation of policies and laws. TFDA is also responsible for carrying out product inspection and registration, reviews and audits, business production flow audits and consultation, test research and technological development, risk assessment and management, safety monitoring, investigation and handling of hazardous incidents, and implementation of consumer protection measures.
2. To implement the Biotechnology Take-Off Diamond Action Plan of the Executive Yuan, TFDA is also making improvements to its professional review capabilities, strengthening its technological assessments, and establishing early warning surveillance for adverse drug reactions (ADR). TFDA is also encouraging further integration of personnel and resources from partnering organizations such as the Center for Drug Evaluation and the Taiwan Drug Relief Foundation.

### Organization Framework

1. TFDA comprises Divisions of Food Safety, Medicinal Products, Medical Devices and Cosmetics, and Controlled Drugs. For product and regulatory planning and management as well as promotion of national policies, additional TFDA units were established, such as the Division of Risk Management, Division of Research & Analysis. Northern, Southern, and Central Administration Centers for managing product quality assurance, factory management, distribution, monitoring, and border controls have been established as well. TFDA has Division of Planning & Research Development for comprehensive integrated planning and five departmental units for supporting administration management including Office of Secretariat, Office of Personnel, Office of Accounting, Office of Service Ethics, and Office of Information Management. (Figure 1-1).
2. Due to changing social trends and wide-ranging product issues, TFDA has established a Factory for Controlled Drugs which shall formulate relevant actions according to the nature of its tasks and project requirements. Policies for product management must be based upon extremely specialized data. TFDA is actively working and forming close partnerships with professional consultation agencies such as Center for Drug Evaluation, Taiwan Drug Relief Foundation and so on.

3. At the merger of 2010, TFDA had a personnel headcount of 467 individuals. In 2011, the task of border inspections was handed over from the Ministry of Economic Affairs Bureau of Standards, Metrology and Inspection to TFDA, raising personnel headcount by 18 individuals to a total of 485. However, the headcount was reduced in 2012 to 484 to reduce redundant personnel. In 2013, in response to organizational restructuring and the need to carry out relevant businesses, the headcount was further increased to 527 individuals. In 2014, TFDA headcount was once again raised to 602 individuals after approval by the Executive Yuan.

Figure 1-1 Organization chart of, Food and Drug Administration, Ministry of Health and Welfare

## Section 3. Future Prospects

Trends in food products, medicinal products, and cosmetics safety management as well as medicinal product review and food safety management are closely related to industrial development. TFDA advancedly continues to revise laws and implement management future developments in order to strengthen production source controls, food hygiene laws, as well as food source, imported product, and raw materials management. TFDA also carries out border inspections and strengthen food safety monitoring in order to provide a safe food consumer environment for fellow citizens.

To provide medicinal products with the required safety and quality assurance, TFDA shall continue to enhance production quality and ensure proper management, strengthen the comprehensiveness of pharmaceutical regulations, establish medicinal product review systems aligned with those adopted worldwide, implement medicinal product source management, strengthen the suppression of illegal drugs and illicit advertisements, and enhance the management of controlled drugs.

To safeguard consumer drug consumption and cosmetics safety, TFDA shall achieve effective management of products and raw material distribution as well as strengthen post-market management of products such as by expanding quality monitoring plans and conducting multi-county (city) or agency joint audits, monitoring both domestic and international product warnings, recalls of nonconforming medicinal products and cosmetics, reports of adverse reactions, and conduct risk communication for consumer safety. Future efforts and directives of TFDA are follows:

1. Establish management regulations harmonized with global standards to promote biotechnology industry development.
2. Implement food additive source management and improve food production quality.
3. Establish a comprehensive medicinal product safety network to safeguard drug-use safety of citizens.
4. Expand market audit and quality monitoring to strengthen consumer protection.
5. Actively participate in international organizations to expand international food and drug partnerships and opportunities.

# 2 Food Management

Food Laws, Regulations, Standards and Product Reviews

Food Product Source Management

Food Product Safety Chain Monitoring

Food Safety and Sanitation Management

# 2 Food Management

To protect its core value of public health, the Administration takes reference from international norms and continues to amend and expand food-related laws and regulations, strengthen food source control and supervision of production flows, and raise hygiene awareness among food practitioners. In addition, to safeguard people's food safety, the Administration actively drives the registration of food businesses, retroactive traceability, and a three-tiered quality control system through its core programs entitled *Eight Food Safety and Hygiene Management Action Programs.* It is also building triangulated lines of defense by implementing the strengthening measures and amendments of the *Act Governing Food Safety and Sanitation* to rebuild the public confidence in food safety, restore in the market order, and to jointly create a *Good Food environment*.

## Section 1 Food Laws, Regulations, and Standards, and Product Reviews

### Current status

To strengthen food safety management, the Administration actively promotes amendments to the *Act Governing Food Safety and Sanitation* to create a more robust legal source for the country's food management system. As part of its comprehensive food safety management, the Administration regularly announces newly passed food-related sub-regulations and adopts relevant policies and measures. In addition, to protect the health and safety of consumers, the Administration carries out food safety management of food items of a special nature or which must undergo verification of their special effects. Also, at the front end, the Administration implements a product registration system to protect the public.

### Policies and Outcomes

1. The Ministry of Health and Welfare actively promoted the amendment of the *Act Governing Food Sanitation*, the amended text of which was promulgated on June 19, 2013. On February 5, 2014, the law's name was amended to *Act Governing Food Safety and Sanitation* to mark the government's commitment to food safety management. To complete the country's legislative and regulatory system of food safety and sanitation management, a Presidential Decree on December 10, 2014 promulgated the amendment of a number of articles of the *Act Governing Food Safety and Sanitation* to strengthen the overall law from various angles, effectively enhance food safety management performance, and provide consumers with a further improved mechanism. The amendments are shown in Table 2-1 below.
2. Important laws, regulations, and standards, either new or revised, related to the food management include: *Regulations for Application of Health Food Permit; Regulations Governing the Product Names and Labeling of Prepackaged Fresh Milk, Sterilized Milk, Flavored Milk, Milk Drink, and Milk Powder; Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification; Regulations Governing Food Allergen Labeling; Regulations on food safety control system; Regulations on Nutrition Labeling for Prepackaged Food Products; and Regulations for Systematic Inspection of Imported Food*. Further details are given in Appendix 1 Annex, Table 1.
3. With regards to registrations of specific food, licenses issued until the end of 2014 are shown in Table 2-2. In 2014, there were 2,478 applications for registrations of food additives. Among these, 2,274 cases were reviewed, and 1,696 cases (74.58%) were registered. For health foods, 41 permits were issued, of which 26 passed through the individual case review process, and 15 passed in through the standard specification review process. Also, 12 licenses for genetically modified foods were issued. Further detail is given in Appendix 1 Annex, Table 2.

Table 2-1 Amendments to the *Act Governing Food Safety and Sanitation* in 2014

| Date of amendment | Title of legislation | Summary of content |
|---|---|---|
| February 5th | *Act Governing Food Safety and Sanitation* | 1. The law's full title is amended to *Act Governing Food Safety and Sanitation*<br>2. Stipulate that food stuffs containing genetically modified food raw materials shall be registered for examination purposes<br>3. Stipulate that importing businesses shall establish a traceability system for tracing the source and tracking the flow of the genetically modified food raw material<br>4. Stipulate that specific food businesses shall test their raw materials, semi-products or end products on their own, or deliver them to other testing agency (institution), corporation, or organization for testing, to manage and control quality<br>5. Stipulate that the central competent authorities may establish a food safety protection fund.<br>6. Increase fines and penalties |
| December 10th | *Act Governing Food Safety and Sanitation* | 1. The Executive Yuan shall establish the Food Safety Board<br>2. Food businesses that are Exchange-Listed, OTC-Listed or by the central competent authority in a public announcement shall be equipped with laboratories<br>3. Proclaimed food businesses should use electronic uniform invoices<br>4. The food or food additive factory shall be independently established, which shall not engage in non-food manufacturing, processing, or preparation at the same address and the same factory<br>5. The tracing sources of the domestic certified agricultural products, and the production systems prescribed in a public announcement shall conspicuously indicate. In the event that a label only identifies the name of a domestic responsible vendor, the details of the manufacturer shall be submitted to the competent authorities of the jurisdiction<br>6. Food businesses import food additive combinations, they shall attach product ingredients report and official sanitary certificate issued by the export country<br>7. The police agency shall dispatch its personnel to assist the competent agency the in carrying out inspections of food-related businesses<br>8. Upper limit of fines for adulterated or counterfeited and other behavior was raised to TWD 200 million<br>9. The competent authorities are given the authority forfeited or retrieved of improper gains<br>10. Food business violates regulations and result in harms to consumers, they shall bear the responsibilities for compensation<br>11. The sources and purposes of the food safety protection fund have been expanded |

Table 2-2 Numbers of certificates issued till the end of 2014.

| Food categories to be inspected and registered | Total certificates issued<br>Number of approved certificates |
|---|---|
| Imported food in tablet or capsule forms | 8,201 |
| Domestic vitamin products in tablet or capsule forms | 1,607 |
| Food additives | 6,178 |
| Infant and follow-up formula | 193 |
| Formula for certain disease | 155 |
| Genetically modified (GM) food | 74 |
| Vacuum-packed ready-to-eat soybean foods | 134 |
| Health food | 288 |

## Section 2 Food Product Source Management

### Current Status

Food processing sanitation and safety control is a complex chain from raw material sourcing, production, post-harvest treatment, processing, manufacture, distribution, transport, sales, to consumer consumption. Food safety management should focus upon preventing the incidence of hazards and enact control measures that cover both the source of production as well as the consumer market. Source management legislation and systems shall thoroughly implement the spirit of self-management, strengthen the management of imported foods as well as food additives to prevent food hazards.

### Policies and Outcomes

#### 1. Strengthen Food Additives Management

(1) Establishing food additive classification harmonized with international standards: TFDA continues collecting international specifications from the United Nations Codex Alimentarius Commission (CAC) as well as the United States, European Union, and Japan to adjust and harmonize classifications of Taiwan's food additives with those used in international standards. In 2014, a total of 800 food additives have been in the positive list. Each additive has been provided with a scope of use and limit standards that should be complied with.

(2) *Three-Division* management strategy of food additive sources: Management of food additive sources shall be administered through intermenstrual cooperation between the Ministries of Health and Welfare, Ministry of Finance, and Ministry of Economic Affairs, using a *three-division strategy* as shown in Figure 2-1 to divide *importing by flow, manufacturing by district, and sales by industry* to prevent illegal chemical substances from coming into any food production chain.

Figure 2-1 Three-Division Management Strategy for food additives


(3) Food additive registration system: Set up a fadenbook (mandatory registration) data system for food additives (website: http://fadenbook.fda.gov.tw/). A total of eight seminars on the food additives registration system and system operation instructions for business owners were held in 2014. By the end of 2014, a total of 2,203 food additive manufacturers, importers, and local vendors have completed registration processes for a total of 102,053 items.

#### 2. Promote the *Food Safety Control System*

(1) To ensure food sanitation and safety, implement the Food Safety Control System for high-risk food businesses to prevent the incidence of food hazards, and provided support for local health authorities in implementing compliance audits (Table 2-3).

Table 2-3 Number of compliance audits carried out according to the Food Safety Control System in 2014.

| Product category | Businesses inspected |
|---|---|
| Aquatic products processing industry | 200 |
| Meat processing industry | 138 |
| Dairy products processing industry | 12 |
| Box meal factories | 191 |

(2) TFDA continued to encourage professionals with vocational certification to commit themselves to the food industry, and food businesses require enforcement of food safety control system (HACCP) shall establish a Food Safety HACCP team, where at least one of the team members must be a qualified professional with vocational certification in compliance to the rules prescribed by the *Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification,* in charge of food safety management to ensure the safety of food production processes.

## 3. Enhance Management of Edible Oil Businesses

TFDA management of edible oil businesses is directed by the *Eight Major Action Guidelines of Food Safety and Sanitation Management* as described in Figure 2-2. Under this scheme, TFDA is committed to establishing edible oil registration systems, traceability systems, and three-tier quality control, setting up management measures to acquire product supplier and source information from businesses, creating product and sales flow management, strengthening food business self-management, and ensuring that food businesses are responsible for food safety.

Figure 2-2 Registration system, traceability, and three-tier quality control for edible oil businesses

## 4. Management of Imported Foods

(1) Important import control measures

a. Imported foods and related products must apply for food import inspections at TFDA offices at the ports of entry in compliance with the *Act Governing Food Safety and Sanitation* and *Regulations of Inspection of Imported Foods and Related Products*. The foods may only be imported if they pass inspection. Nonconforming products must be either returned or destroyed by law. According to the provisions of paragraph 1 of Article 30 of the *Act Governing Food Safety and Sanitation*, there are about 324 CCC code for foods or related products that must file food import inspection applications in 2014.

b. In response to the illicit cooking oil incident of September 2014, TFDA has temporarily suspended import inspections for edible pork lard (oil) from Hong Kong as well as edible animal fats from Vietnam. Additionally, imported edible oils from Mainland China (including Hong Kong and Macau), imported edible animal oil from Australia, and plant oils from Vietnam must be furnished with an approved and documented proof of sanitation from their home country's competent authorities before import food inspections.

(2) Comprehensive New Management Measures for Separate Flow of Imported Oils

a. To strengthen Taiwan's management of imported oils and protect food sanitation and safety for the general public, new management measures that divide imported oils by flow came into force on 31 October 2014. Interministerial collaboration employed compound import regulations to carry out import flow management for 89 CCC code of oil imports listed in Chapters 15 and 38 of the Import and Export Commodity Classification of the Republic of China. During the importation process, importers must also fill the purpose, lot number and the information for traceability of the imported commodities in the blank next to the commodity name on the Declaration of Import.

b. Since 31 October 2014, where the aforementioned 89 CCC code of oil products and commodities have been imported for food purposes, the importer must apply for food imports inspections with TFDA. For feed purposes, the importer must implement feed imports inspection with the Executive Yuan Council of Agriculture. For industrial purposes, the importer must apply for industrial oil imports inspections. If the importer fails to provide the purpose of the imported commodity during import for inspections by the competent authority, the oil products and commodities may not be imported into Taiwan. Figure 2-3 shows the oil product flow distribution policy.

Figure 2-3 Flow distribution management policy for oil products

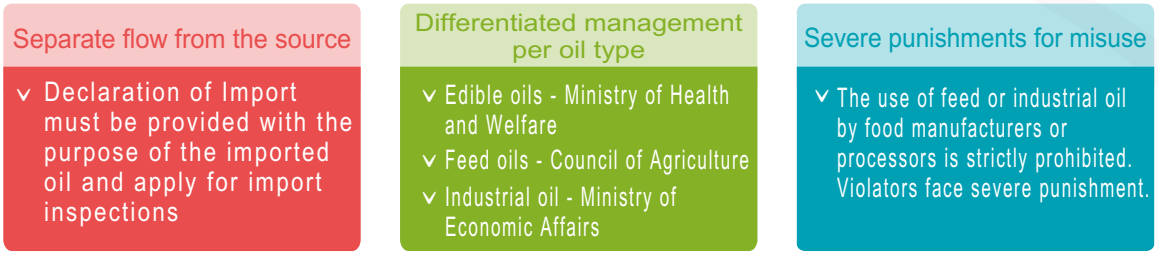
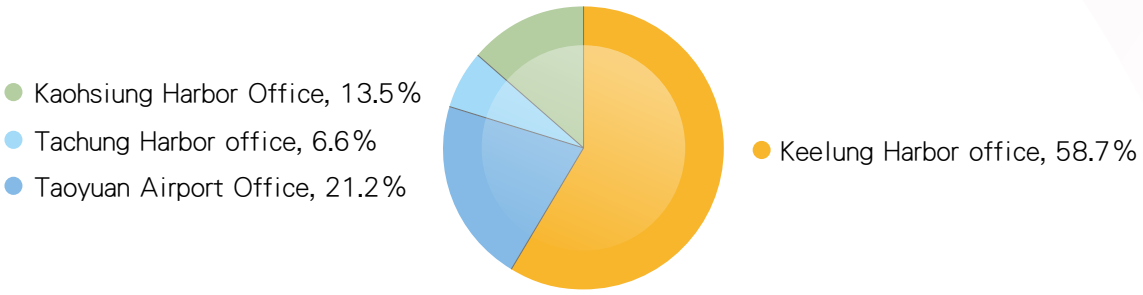


Figure 2-4 Border inspections handled by TFDA offices at Taiwan ports in 2014




(3) Imported Food and Related Product Inspections

a. Imported Foods and related products must undergo border inspection at the harbors and ports of entry. Only conforming food items may be imported. Refer to Appendix 1 Annex Table 3 for detailed inspection statistics. Figure 2-4 shows the border inspections handled by TFDA offices at various ports. A total of 616,286 batches of food were inspected, which was a 19.7% increase compared to 2013. A total of 48,704 batches (for 7.9% of the total) were subject to sampling inspection, with 1.36% of the sampled batches failing to pass the regulations. Most of the nonconformities occurred for fresh, cold, or frozen vegetables, fruits, and teas, with the main reason of nonconformity being failure to meet the limits imposed for levels of residual agricultural chemicals. Nonconforming products were either returned or destroyed, and none were released to the local market.

b. Following the Fukushima Daiichi nuclear disaster of Japan, TFDA has suspended food inspection applications from the five Japanese prefectures and cities of Fukushima, Ibaraki, Tochigi, Gunma, and Chiba. Strengthened radioactivity monitoring of various food items imported from Japan has been in force since 20 March 2011. A total of 63,972 cases were inspected by the end of 2014. Radiation inspection levels all met the relevant requirements.

c. *Three Controls and Five Verifications* control measures have been imposed on imported beef. Batch inspection was carried out for beef products imported from countries where the use of ractopamine is legal. Exporters who have repeatedly passed the inspections may obtain reduced inspection frequencies. In 2014, a total of 16,095 batches of beef products were inspected, of them 1,940 batches were selected to sampling inspection. Inspection ratio is 12.1%. All inspected batches met the requirements.

(4) Publishing the *2013 Annual Report on the Statistics of Imported Foods Management and Import Inspections*

Since 2011, TFDA analyzes its border inspection results of food items every year to generate an annual report to understand the causes of foods and related products import risks, product categories, and source countries. Annual statistics, investigations, and surveys are used to identify key focus areas for future management as well as areas in need of adjustment or improvement to construct a comprehensive food import management system and safeguard food health for the country's citizens.

(5) Inspection of Overseas Factories

To effectively achieve food management through source contral, the results of risk evaluation were referenced to carry out on-site inspection. A total of 4 countries and their products were inspected in 2014, including US for beef, Canada for pork, New Zealand for beef and mutton, and China for Eriochier sinensis. According to the provisions of Paragraph 2 of Article 35 of the *Act Governing Food Safety and Sanitation*, TFDA may perform systematic inspections on the food or related products with higher degree of risk.

Sources from Spain and France have been completed systematic inspections and the list of those meat products which processed by the establishments way approved by TFDA for export to Taiwan in 2014.

## Section 3 Food Product Safety Chain Monitoring

### Current status

To ensure that food products meet *Act Governing Food Safety and Sanitation*, TFDA has established a convenient inspection date system that provides correct and up-to-date information, allowing for extensive integration of information from central and local governments to achieve effective on-site inspection of registered food products as well as post-market surveillance of food products to jointly safeguard food supply chain for the general public.

### Policies and Outcomes

#### 1. On-site Inspection of Registered Foods

In 2014, on-site inspections were completed for manufacturers and vendors of health foods, domestic vitamin products in tablet or capsule forms, and food additives. Inspection results are shown in Table 2-4.

Table 2-4 Results of on-site inspection of registered foods in 2014

| Category | Number of inspections | Findings |
|---|---|---|
| Health food manufacturing plants | 26 | No major non-compliance was found. Defects were corrected before follow-up audits |
| Domestic vitamin products in tablet or capsule form manufacturing plants | 40 | No major non-compliance was found. Defects were corrected before follow-up audits |
| Food additives manufacturers and vendors | 73 | No major non-compliance was found. Defects were corrected before follow-up audits |

## 2. Establishing a Food and Drugs Audit and Combat Team

To ensure the safety of food products, drugs, and cosmetics, the *Food and Drugs Audit and Combat Team* was established in 1 July 2014 to strengthen the post-market surveillance system. The Team is tasked with the mission of ensuring food and drug safety and eliminating illegal products. By working together with central and local goverment, the team strengthens audit capacity and enhances overall audit competences to demonstrate their determination of *combating deliberately adulterated foods and illegal drugs*.

## 3. Post-Market Surveillance of Food Products

(1) TFDA manages the food product audit and monitoring system, and monitors various county and city governments in implementing routine audits and sampling inspections. Additionally, TFDA works with various local health departments in carrying out various audit and inspection projects to ensure food product sanitation, safety, and quality.

(2) Monitoring health bureaus in carrying out food product audits: In 2014, the health bureaus carried out a total of 135,000 Good Hygienic Practice (GHP) audits, 523,045 product label audits, and sample inspections of 41,085 product items. Appendix 1 Annex Table 4 provides detailed statistics of these health bureau food audits.

(3) Joint food product monitoring with health bureaus: In 2014, a total of 4,396 items were inspected. Any nonconformities found was handled according to law by the local health bureau. An interministerial coordination system has also been established to implement root cause improvements. Table 2-5 shows the results of the TFDA surveillance efforts. Appendix 1 Annex Table 5 provides detailed statistics on testing for residual pesticides and veterinary drugs in food products.

Table 2-5 Post-market surveillance of food products in 2014

| Surveillance item | Result | | | |
|---|---|---|---|---|
| | Total | Conforming | Nonconforming | Conformity rate (%) |
| Pesticide residues in agricultural products from markets and packing firms | 2,528 | 2,205 | 323 | 87.22 |
| Veterinary drug residues in food products | 830 | 794 | 36 | 95.70 |
| Mycotoxin contents in commercial foodstuffs | 461 | 449 | 12 | 97.40 |
| Heavy metals (lead and cadmium) contents in marketed vegetables and fruits | 170 | 170 | 0 | 100 |
| Heavy metals (lead, cadmium, and mercury) contents in rice | 200 | 200 | 0 | 100 |
| Pesticide residues in rice | 207 | 207 | 0 | 100 |

(4) Joint food product audit and sampling inspection projects with health bureaus: Key administrative items, high-risk food products and food additives, and public concerns were targeted in these projects. TFDA supervised and worked jointly with health bureaus in carrying out a total of 18 audits and sampling inspection projects, including hot pot food services, food products sold online, soy sauce, rice vermicelli, cut vegetables, fruit and vegetable juices and dairy products, soybean product factories and manufacturers, edible oil manufacturers and packing plants, rice processors that produce packaged rice, Mid-Autumn Festival food products sold online, enoki mushrooms, preserved turnips, candied fruits, plastic baby milk bottles, preserved vegetables, poultry processing sites, labeling of egg products from poultry farms, concentration of effective chloride residues in ready-to-eat food products sold by convenience stores, and registration and inspection of food additive businesses.

(5) Food product safety joint inspection and enforcement team: food products that are considered daily necessities and significant impact health shall be audited at the original manufacturing site or production plants. In 2014, a total of nine audit projects were completed: holiday foods for Chinese New Year, rice, eggs, holiday foods for Dragon Boat Festival, meat processing plants, seafood processing plants, starch-derived foods, oil making factories.

## Section 4 Food Safety and Sanitation Management

### Current status

More and more people eat out or eat take-away. Sanitation of food service is a major issue of concern amongst these diners. Ingredient selection, utensil sanitation, environment cleanliness, and sanitation awareness of food service personnel are linked with each other. Hence, TFDA is implementing sanitation management in food service to control food safety and sanitation by improving sanitation and safety awareness and behaviors amongst food service personnel, actively providing guidance and encouragement for food service to conduct self-management, and communicating food sanitation and safety policies with the general public and food service.

### Policies and Outcomes

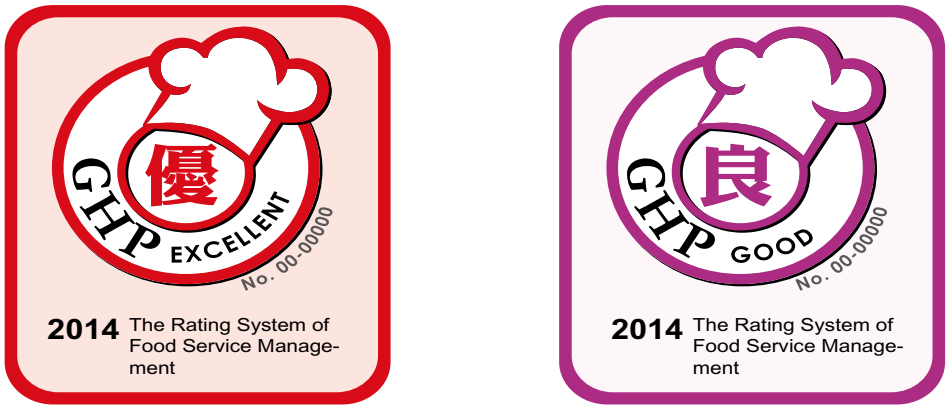
#### 1. Food Service Safety and Sanitation

(1) Statistics and Prevention of Food Poisoning

a. In 2014, a total of 480 foodborne disease outbreaks were reported, of which 186 outbreaks were confirmed with etiologic agent. Analysis revealed that schools and food service establishments were most likely to occurring foodborne disease and the main etiologic agent was bacteria. Foodborne disease tends to result from improper sanitation and safety concepts, such as cross-contamination of food processing, or improper storage conditions or environment. Appendix 1 Annex Table 6 provides detailed statistics on foodborne disease.

b. To raise awareness on foodborne disease and prevent it from happening, a webpage dedicated to prevention of foodborne disease has been established. TFDA is also collecting data from foodborne disease outbreaks and compiling them into the Annual Report on Foodborne Disease Outbreaks and Prevention which are then printed and distributed to target audiences for reference.

Figure 2-5 *Excellent and Good* logos awarded by the Rating System of Food Service Management




(2) Promoting The Regulations on Good Hygiene Practices for Food amongst Food Service

a. To improve sanitation and safety self-management capacities of domestic food service, TFDA actively promoted the rating system of food service management. Assessment results were used to divide food service into two rating levels of Excellent or Good with corresponding food service sanitation assessment certifications (logos), which have an effective period of two years (Figure 2-5). From 2010 to 2014, a total of 10,732 food services were assessed and certified. The rating system of food service management shall continue promoting to enhance domestic food service sanitation self-management capabilities.

b. TFDA is also providing food services with counseling on self-management eating environment sanitation and food service staff health. The *Food Ingredient Hazard Analysis Manual for Food Services* as well as *Uniform Interpretation Manual for the HACCP* have been amended accordingly and provided to local health departments for use.

## 2. Diverse Promotion of Food Sanitation and Safety Policies

Different types of media channels were used to constantly educate and improve awareness of food sanitation and safety amongst consumers. Industries, governments, and academia experts were invited to conferences and publish articles related to food safety issues to ensure the comprehensiveness of food sanitation and safety awareness programs.

(1) Education, Training, and Extension

In 2014, TFDA worked with various professional associations to hold food management policy implementation seminars in northern, central, and southern Taiwan, explaining statutory regulations, the registration and traceability system, source management of imported food products, and other major policies to both food businesses as well as local health bureau.

(2) Outcomes for the Promotion of Food Business Registration System

a. The Food Business Registration System is a key reform to Taiwan's *Act Governing Food Safety and Sanitation.*

(a) Article 8 of the *Act Governing Food Safety and Sanitation* stipulates that food businesses belonging to a category and scale designated by the central competent authority in a public announcement must be registered before they may commence their business operations. TFDA also promulgated the *Regulations Governing the Registration of Food Businesses* on 3 December 2013 to specify regulations governing business registration and management of registration.

(b) TFDA also promulgated on 24 April 2014 that food additive businesses must be registered as well. Starting on 1 May 2014, all food additive manufacturers, processors, or importers must be fully registered before they may begin production, processing, or importing. Starting on 1 October 2014, food additive businesses must be first registered before they may be allowed to sell their items.

(c) On 16 October 2014, TFDA promulgated *Regulations Governing the Category and Scale of Food Businesses May Commence Its Business Operation after Applying for Registration and Date of Implementation*, clearly requiring edible oil manufacturers or processors that have completed factory registration, as well as edible oil importers that have completed factory registration, business registration, or company registration, to complete registration at the Food Business Registration System before 31 October 2014. Other manufacturing and processing businesses, food service, import businesses, and retail businesses with factory registration, business registration, or company registration had to complete registration at the Food Business Registration System before 31 December 2014.

b. In 2014, promotional leaflets for food business registration regulations were printed and distributed. A toll-free service helpline and personnel support at local health bureaus were also made available for providing inquiry services. A total of 68 promotion and interpretation seminars as well as other package measures were also made available for food businesses. With the active promotion and support of food businesses, a total of 158,562 food businesses completed their registration by 31 December 2014. Local health departments are currently still promoting the Food Business Registration System.

# 3 Medicinal Products Management

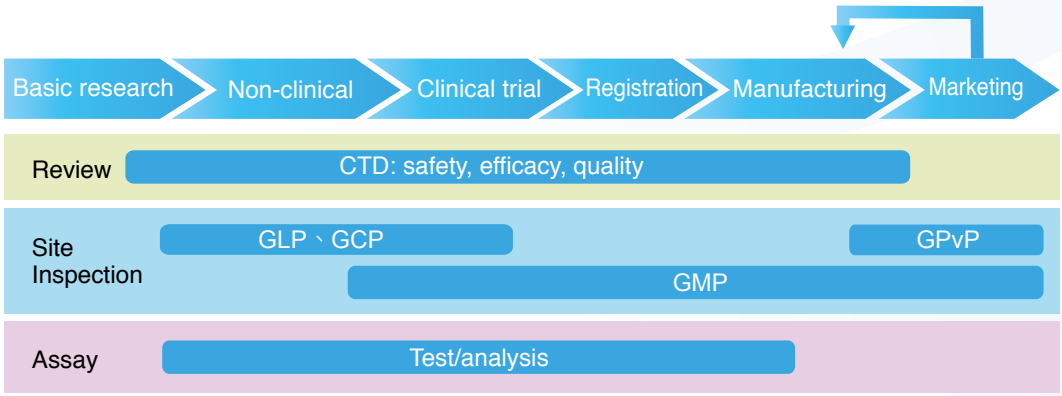
- Medicinal Product Regulations and Registration
- Medicinal Products Source Management
- Medicinal Products Quality Chain Monitoring
- Medicinal Products Safety Management

# 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.

The life cycle of medicinal products from research and development to market release includes basic research, non-clinical studies, clinical trials, registration, manufacturing, and marketing. Every phase of this life cycle must be compliant with various specifications ("GXP") via reviews, audits, and inspections, which forms a comprehensive medicinal product life cycle management framework (Figure 3-1). For example, CTD is used as the format for registration data, using stringent reviews as checkpoints to ensure the quality, safety, and efficacy of medicinal products. GLP and GCP inspections are carried out during Non-clinical study and clinical trail to ensure quality. Manufacturing processes are also audited for compliance to GMP. Where necessary, pre-marketing and post-marketing inspections and compliance with GPvP may be executed to achieve comprehensive drug life cycle requirements.

Figure 3-1 Medicinal product life cycle management framework




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

## Section 1 Medicinal Product Regulations and Registration

### Current status

Quality demands for post-market medicinal products prescribed by international laws become ever more stringent every year, especially for post-marketing registration change management and the release of emerging medicinal products (such as cellular and gene therapy products). Corresponding national law in Taiwan is still lacking in these areas. Hence, TFDA continued to revise and formulate relevant management specifications, at the same time reference global drug management trends and the management for medicinal products that are high-risk or consumed by a specific population. Medicinal product registration systems were established along with continuous revision of medicinal product management laws to ensure consistent quality and efficacy of the medicinal products.

## Policies and Outcomes

### 1. Comprehensive Regulation

Important revisions to medicinal product management regulations and standards in 2014 include advertisements for orally administered western medicine containing alcohol, regulations for registration of medicinal products, new drug applications (NDA), safety standards for non-clinical study of medicinal products, clinical trial applications for human cellular therapy products, advertisements for solutions containing codeine or caffeine, Good Clinical Practice for medicinal products, comparability exercise standards for biotechnology / biological drugs, and list of accepted specifications from the International Conference of Harmonization (ICH). For details, please refer to Appendix 1 Annex Table 7.

### 2. Registration of Medicinal Products

Medicinal product registration can be divided into active pharmaceutical ingredient (API) and its preparations. Preparations can be further divided into new drugs, biological products, generic drugs and orphan drugs. Where local clinical trials or bioavailability (BA) and bioequivalence (BE) studies are required as attachments for inspection and registration applications, the corresponding project plans and reports must be reviewed as well.

(1) Medicinal Product Inspection and Registration before Market Release

a. 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 medicinal product approval system.

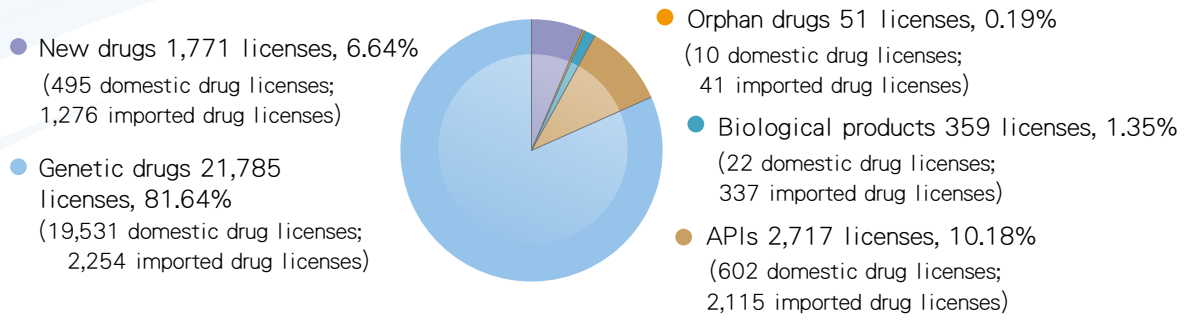
b. As of 2014, TFDA had issued a total of 26,683 pharmaceutical licenses, which included 2,717 (10%) active pharmaceutical ingredients and 23,966 (90%) pharmaceutical finished products (generic drugs, new drugs, biologics and orphan drugs) (Figure. 3-2). Statistical data on approved drug licenses issued every year are provided in Appendix 1 Annex Table 8.

(2) Clinical Trial Reviews

a. By revising the *Guidance for Investigational New Drug Applications* and the establishment of *Centralized Clinical Trail Ethics Review (central IRB)* mechanism, TFDA dedicates in accelerating the IND review process.

b. In 2014, TFDA received a total of 315 new IND applications and 2,486 IND amendments. The growth rate of submission is 1.2 times more than 2013.

Figure 3-2 Statistics on pharmaceutical (2014)



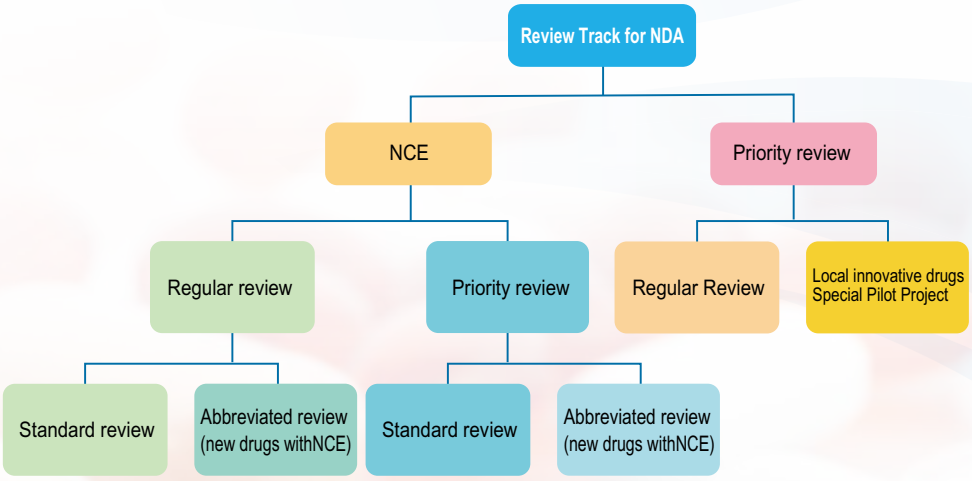
c. The conduction of clinical trials must follow the requirement *of Good Clinical Practice (GCP)*, which asks the welfare and the rights of testing subjects and maintain the data quality and integrity. TFDA also include the regular Contract Research Organization (CRO) inspections into GCT requirements and 3 CROs were inspected during year 2014.

d. *In vivo* bioavailability/bioequivalence and *in vivo* dissolution studies are important methods for demonstrating therapeutic equivalence between innovative and generic drugs. Until the end of 2014, there were 2,008 approved medicinal products had conducted BA/BE studies in Taiwan, and 1,895 of them were domestic products.

(3) Innovation of New Drug Review and Approval Mechamism

New drug application (NDA) review procedures and time controls were promulgated on 22 May 2014 in order to improve drug review transparency, strengthen review process, and shorten overall review time. TFDA has also referenced the review systems of Europe, the United States, Japan, and other advanced countries and promulgated the *Abbreviated Review Procedure for New Drug Applications*, the *Priority Review System for New Drug Applications*, and the *Pilot Program for Locally Developed New Drug Applications* (Figure 3-3) in order to accelerate the market release of new drugs and satisfy the treatment requirements of those with urgent medical needs. In 2014, a total of 135 NDAs were approved, which included 29 local drugs and 106 imported drugs, with an average new drug review length of 288 days which is better than some ICH memberships, like USA, Europen, Japan etc. For example, Taigexyn Capsule, the locally developed new chemical entity (NCE) of nemonoxacin, was the first approved by TFDA in the world. TFDA then provided consultation for post-market risk management plans.

Figure 3-3 Review track for NDA




**Priority review principles: NCE+ Serious Disease+ Unmet Medical Needs**

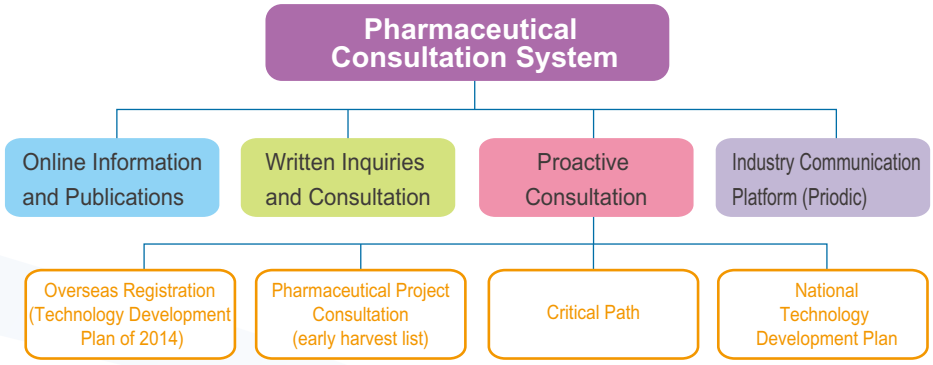
### 3. Promoting Pharmaceutical Projects Professional Consultation

(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 2014, TFDA helped 33 projects to meet R&D milestones, which comprise 3 new drug approvals, 2 new drug applications, 7 phase III clinical trials, 11 phase II 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.

Figure 3-4 Professional Consultation System for Pharmaceutical Projects

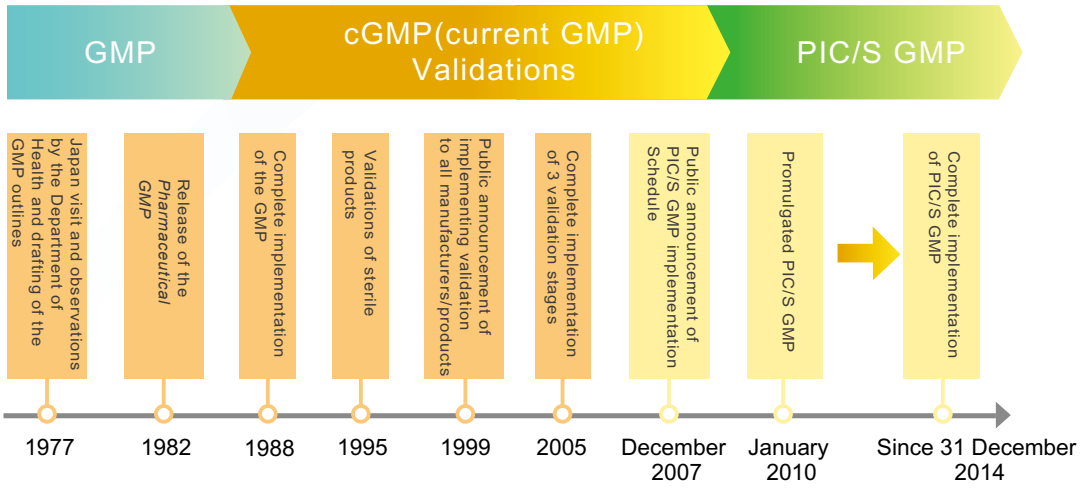



## Section 2 Medicinal Products Source Management

### Current Status

To improve medicinal product manufacturing quality and follow international standards, Taiwan has imposed increasingly stringent management aligned with international regulations over modern pharmaceutical dosage forms manufacturers. Since 1982, Taiwan has promogated Good Manufacturing Practice (GMP) regulation, then in 1995, promoted current Good Manufacturing Practice (cGMP) while developing dynamic cGMP management models aligned with global trends. Starting in 2007, Taiwan also began implementing the GMP standards of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). As of 31 December 2014, PIC/S GMP standards implementation to all modern pharmaceutical manufacturers has been completed, demonstrating that Taiwanese pharmaceutical manufacturing levels are now aligned to international standards, giving it access to global markets. The history on the implementation of GMP is illustrated in Figure 3-5.

Figure 3-5 History of implementing GMP amongst modern pharmaceutical manufacturers




An overview on the management scope of Taiwan's pharmaceutical GMP system shows that the system started from modern pharmaceutical manufacturers and gradually incorporated pharmaceutical distributors, medicinal gases manufacturers, and API manufacturers. In the future, pharmaceutical Good Distribution Practice (GDP) will also be promoted and implemented to ensure that quality management covers the entire pharmaceutical supply chain. To achieve medicinal products source management and safeguard public safety in drug use, TFDA must ensure conformance of PIC/S GMP amongst all modern pharmaceutical manufacturers, improve pharmaceutical quality management of the manufacturers, and strengthen internal and external supervision of the manufacturers.

## Policies and Outcomes

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

(1) Promotion of PIC/S GMP

a. In 1 January 2013, ahead of Japan and South Korea, Taiwan became an official member of PIC/S, demonstrating international acceptance of the regulations, adminstration systems, and inspection standards of pharmaceutical manufacturers in Taiwan. In 31 December 2014, TFDA has successfully ensured that all modern pharmaceutical manufacturers have successfully implemented the PIC/S GMP and fully comply with its requirements in order to continuously safeguard drug use safety of the general public.

b. To continuously enforce stringent monitoring of medicinal products manufacturing, in addition to conducting routine inspection of manufacturing sites every two-to-three years, unannounced on-site inspections will be carried out in response to special incidents (such as whistle-blowing events, post-market quality surveillance anomalies, and news events). For-cause inspection plans must be used to verify whether the manufacturing sites are carrying out continuous monitoring of medicinal product quality, by conducting on-site inspections and product sampling as part of the quality monitoring measures to ensure that medicinal products quality within shelf life are maintained.

c. There were a total of 98 domestic GMP-compliant modern pharmaceutical manufacturers at the end of December 2014, while 870 foreign manufacturers of imported pharmaceuticals have been assessed as compliant. From 2002 to the end of December 2014, a total of 246 foreign modern pharmaceutical manufacturers, coverd types of dosage forms, have passed on-site inspections, ensuring a stable market supply of medicinal products. Implementation results are shown in Table 3-1.

d. To improve the quality of medicinal gases and prevent the risks of cross-contamination of different gases, TFDA has provided consultation and promoted GMP and PIC/S GMP-compliance since 2002. Complete implementation of PIC/S GMP was achieved by 1 January 2014. By the end of 2014, a total of 34 medicinal gases manufacturers had complied with PIC/S GMP.

## 2. Source Management for Modern Pharmaceutical Manufacturers

a. The Drug Master File (DMF) system has been established to fortify the import management for imported and self-use active pharmaceutical ingredients (API). From October 2009 to the end of 2014, a total of 2,089 DMF applications were handled and closed, of which 1,441 cases were approved and 648 cases were rejected, representing an approval rate of 69%.

b. To strengthen the quality management of API manufacturers, the international PIC/S GMP Guide was adopted as a compliance standard on 22 May 2013. In order to ensure API manufacturing quality and improve global competitiveness of domestically manufactured APIs, a public announcement was made on 25 September 2013 to achieve complete implementation of API GMP by 31 December 2015. By the end of December 2014, a total of 21 domestic API manufacturers and 163 items was found to be GMP-compliant.

Table 3-1 GMP-compliance of assessed domestic and foreign pharmaceutical manufacturers

| Year | Number of GMP-compliant domestic modern pharmaceutical manufacturers | Number of PIC/S GMP-compliant domestic modern pharmaceutical manufacturers | Number of foreign pharmaceutical manufacturers found to be GMP-compliant 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 |
| 2014 | 98 | 98 | 246 |

**Note: The numbers of domestic and foreign pharmaceutical manufacturers that have passed the assessments are yearly accumulated figures.**

## Section3 Medicinal Products Quality Chain Monitoring

### Current Status

After a medicinal product is released to the market, there are still many uncertainties that may influence or even impact product quality. These uncertainties may include changes to production processes as well as transport and storage environments. Hence, TFDA is promoting the Good Distribution Practice (GDP) for medicinal products to ensure the quality of product storage, transport, and distribution processes. A comprehensive post-market quality chain monitoring system must be deployed, with measures such as establishing a reporting system, active monitoring of global medicinal product quality alerts, using risk assessments for selecting items, integrating the resources of local health bureaus, and implementing quality monitoring of medicinal products sold on the market. In order to prevent the sales of counterfeit or prohibited drugs through improper sales channels and other acts that seriously endanger public health and safety, one of the key work items of health agencies must be the suppression of illegal drugs and illicit advertisements.

### Policies and Outcomes

#### 1. Quality Monitoring of Medicinal Products

(1) Drug Product Defect Reporting System

Taiwan established a Reporting System of Medical Product Defects in 2004 to enable medical personnel and the general public to immediately report any medical products with suspected defects, allowing government agencies to take swift action. In 2014, a total of 845 medical product defect reports were received, of which 150 were classified as high-risk defects. A total of 14 medical product recalls was made as well.

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

Quality monitoring items have been selected in response to medicinal product management and policies, risk assessment factors, and requirements of county- and city-level health departments in order to safeguard medicinal product use quality and safety of the general public. In 2014, a total of 372 cases was sampled and inspected of which 365 cases were found to be compliant while seven were found to be nonconforming. The nonconforming products were officially handed over to the health bureaus or departments in charge of the original inspections while the responsible manufacturers were notified to conduct product recalls. Table 3-2 shows the monitoring results of the project. Detailed statistics on quality monitoring of released medicinal products are presented in Appendix 1 Annex Table 9.

Table 3-2 Medicinal Products quality monitoring and testing results in 2014

| Project title | Total cases | Conforming cases | Nonconforming cases | Conformity rate (%) |
|---|---|---|---|---|
| Surveillance on the quality of antidiabetic, NSAIDs , hypnotic and antibiotic preparations in Taiwan | 90 | 87 | 3[a] | 96.7 |
| Post-market surveillance of varicella and MMR live attenuated vaccines | 148 | 148 | 0 | 100.0 |
| Post-market quality surveillance and testing for foreign materials in Traditional Chinese Medicine preparations | 134 | 130 | 4[b] | 97.0 |
| Total | 372 | 365 | 7 | 98.1 |

**Note: a. One case of dissolution test result nonconformity of anti-diabetic medication and two cases of dissolution test result nonconformities for anti-inflammatory painkillers.**

**b. Two cases in nonconformities of total aerobic microbial counts and two cases of total ash.**

(3) Monitoring of Global Medicinal Product Quality Alerts

Global medicinal product quality (recall) alerts are monitored on a daily basis for immediate tracking and initiating recalls of medicinal products when necessary. In 2014, a total of 656 global medicinal product quality alerts was monitored. Of these, nine medicinal products had beenimported into Taiwan and were subsequently recalled. The manufacturers also provided continuous active notification of the incident and conducted relevant recalls.

(4) Biological Products Lot Release

381 batches of biological products lot releases have been implemented. A total of 12,616,466 doses was approved and released, while eight batches were blocked (for about 53,385 doses) due to transport temperature nonconformities.

(5) In 2014, illegal pharmaceutical additives to weight loss or virility products were monitored. A total of 109 capsules, tablets, and powdered foods were sampled from drugstores, pharmacies (drug stores), and distributors. Of these, two were found to have pharmaceutical contents. Another three were found to contain ingredients not indicated on the label. All these cases were transferred to the relevant county- or city-level health agencies for further handling.

## 2. Medicinal Product Distribution Management

(1) Medicinal product quality requirements of national health authorities from around the world have expanded from the traditional production-aspects characterized by the Good Manufacturing Practice (GMP) to the distribution aspects governed by the Good Distribution Practice (GDP). The main purpose of this expansion is to avoid storage, transport, and distribution processes from affecting medicinal product quality and ensure drug-use safety for consumers.

(2) Many countries and organizations around the world, including the World Health Organization (WHO), the European Union (EU), the United States, Singapore, Malaysia, Mainland China, Australia, Canada, and Japan have stipulated laws related to GDP for medicinal products to establish relevant regulation and management measures. Additionally, the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) also promulgated its own GDP Guide on 1 June 2014. All of these measures demonstrate the importance placed on the management of medicinal product distribution.

(3) To ensure the comprehensiveness of the medicinal product quality management system throughout the entire supply chain, TFDA promoted a medicinal product distribution management system in Taiwan since 2011, started from 2012, TFDA conducted GDP gap assessment visit to the companies applied for consultation. By the end of 2014, a total of 95 pharmaceutical manufacturers, agents, and logistics related companies for a total of 190 sites have undergone consultation visits, of which 78 companies were given the rating as “excellent” . During this period, TFDA also held training activities as information sessions, forums, technical seminars, and on-site demonstration, to improve distribution/transportation service providers' awareness and understabnding of the concepts of medicinal product quality management.

(4) Referenced from the details of PIC/S GDP for medicinal products, TFDA announced a draft of guidelines for Taiwan's GDP for medicinal products in order to provide businesses with GDP standards for reference purposes. In the future, TFDA will continue to promote legislation for GDP system to ensure the comprehensiveness of medicinal product supply chain management systems.

## 3. Suppression of Illegal Medicinal products, Food Products, and Cosmetics

(1) Integrating Resources Across Multiple Departments and Strengthening the Prohibition of Counterfeit and Inferior Drugs

On 22 March 2010, the Executive Yuan established a project for *Increasing the Suppression of Counterfeit and Inferior Drugs and Illegal Broadcasting Channels*. Relevant central government departments and agencies as well as local governments have established a *Joint Task Force for the Suppression of Counterfeit and Inferior Drugs* to audit counterfeit, illegal, and inferior drugs, food products adulterated with drugs, Traditional Chinese Medicine adulterated with drugs, and other types of illegal drugs, and have continued to monitor illegal advertisements of food products, medicinal products, and cosmetics. The following lists the outcome of the measures carried out so far:

a. Discovery of illegal medicinal products: A total of 1,500 audits were carried out on average every month. Discovery of illegal drugs was reduced from 27.22% in 2010 to 1.20% in 2014 as shown in Figure 3-6.

b. Advertisement violation rates: Violation rates of food products, medicinal products, and cosmetics advertisements decreased from 13.93% in 2010 to 4.97% in 2014 as shown in Figure 3-7.

Figure 3-6 2010-2014 Incedence of illegal drugs

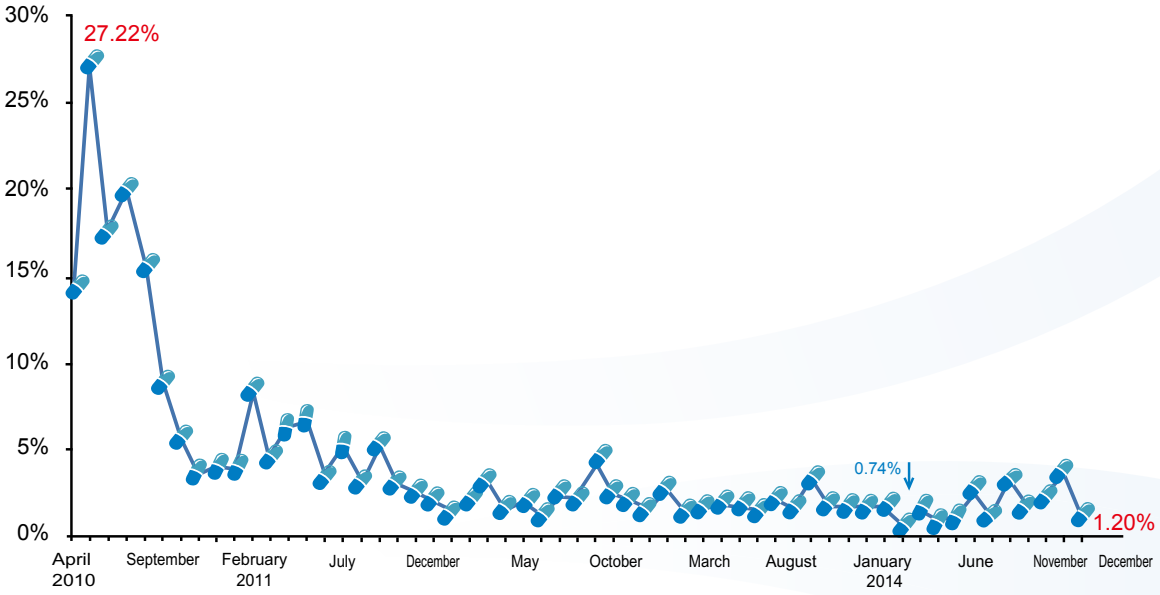
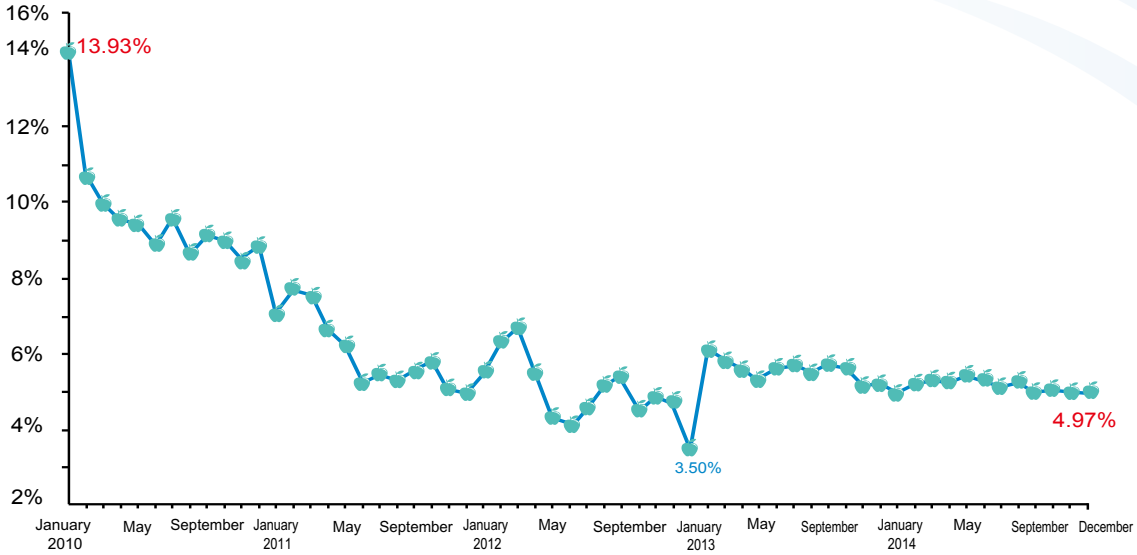



Figure 3-7 2010-2014 Food products and drugs advertisement violation rates from



(2) Continuing the Monitoring of Illegal Medicinal products, Food Products, and Cosmetics on the Market

a. In 2014, a total of 721 illegal medicinal products were found. A total of 508 cases were brought to justice, while administrative actions were imposed for 37 of these cases, with fines totaling TWD 865,000.

b. Measures such as interministerial collaboration, simplified procedures, and improved supervision of health agencies have been implemented. A total of 3,068 cases of illicit food product, medicinal products, and cosmetics advertisements were found in 2014, with fines totaling TWD 94.089 million.

c. Joint Audit Project of Illegal Medicinal products and Cosmetics

In addition to strengthened management of active pharmaceutical ingredients (APIs) produced by upstream pharmaceutical companies, improved auditing was also conducted for downstream sales and distribution channels. News reports were also aired at appropriate occasions to form effective deterrence against the sales channels of illegal businesses. In 2014, a total of five joint audit projects of illegal medicinal products and cosmetics were implemented (Table 3-3). A total of 142 violators were identified. Major violations included: sales of prescription medicine without prescription, provision of medicinal products by non-pharmacists, improper records for controlled drugs, retail display of prescription drugs, sales of orally administered drugs containing alcohol by non-pharmaceutical companies (such as betelnut stands, Internet cafes, and convenience stores), and retail display, dispensing, or supply of inferior drugs, with fines totaling TWD 2.118 million.

Table 3-3 Results of joint audits for illegal medicince products and cosmetics

| Month of audit | Project audit items | Results |
|---|---|---|
| March | Medicinal product audit project (prescription medicine and pharmaceutical company licenses) | A total of 31 pharmacies, pharmaceutical companies, betelnut stands, or Internet cafes was audited. A total of 12 violators were found |
| April | Pharmacist audit project (prescription medicine and dispensing of controlled drugs) | A total of 618 pharmacies, drugstores, and clinics was audited. A total of 73 violators was found for a total of 75 violations |
| June | Orally Administered Western Medicine Containing Alcohol Audit Project | A total of 105 betelnut stands were audited, with 14 violations being the sales of orally administered drugs containing alcohol |
| August to September | Medicinal Product Audit Project (prescription medicine and inferior drugs) | A total of 173 pharmacies, clinics, and hospitals was audited. A total of 21 violators was found |
| October | Antibiotics Audit Project | A total of 41 pharmacies was audited. A total of 22 violators was found |

## Section 4 Medicinal Products Safety Management

### Current Status

Medicinal products with unknown or unexpected risks have been identified in recent years. This has given rise to urgency for enacting effective controls of post-market safety of medicinal products and establishing a comprehensive post-market safety surveillance system and legal context (Figure 3-8).

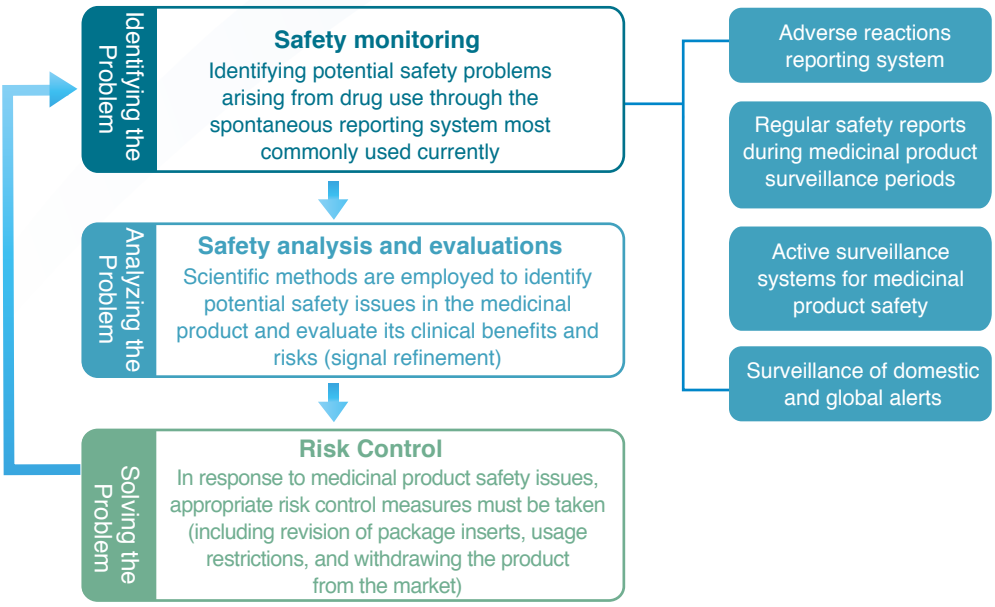
### Policies and Outcomes

#### 1. Strengthened Medicinal Product Safety Surveillance

(1) Adverse Drug Reaction Reporting System

The National Adverse Drug Reactions (ADRs) Reporting System was established in 1998. In 2014, a total of 11,399 cases were reported to this system.

Figure 3-8 Procedure for post-market safety controls for medicinal products




(2) New 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 collect safety information on drug used both domestically and abroad and provide periodic safety update reports. From 2004 to the end of 2014, a total of 291 new medicines are under new drug safety monitoring.

(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 167 drug safety alerts were monitored in 2014.

(4) Proactive Drug Safety Monitoring Mechanism

The proactive assessment 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 reevaluate drug safety. In 2014, there were 59 drugs re-evaluated, among them, 22 were required for risk management measures, including 21 safety labeling changes or restricted use, Chloramphenicol and ketoconazole oral dosage products were asked to be off the marketd due to its risk.

# 4 Controlled Drug Management

Controlled Drugs Regulations and Distribution Management

Management of Pharmaceutical Plant of Controlled Drugs

Controlled Drug Alerts and Monitoring

Controlled Drug Abuse Prevention

# 4 Controlled Drugs Management

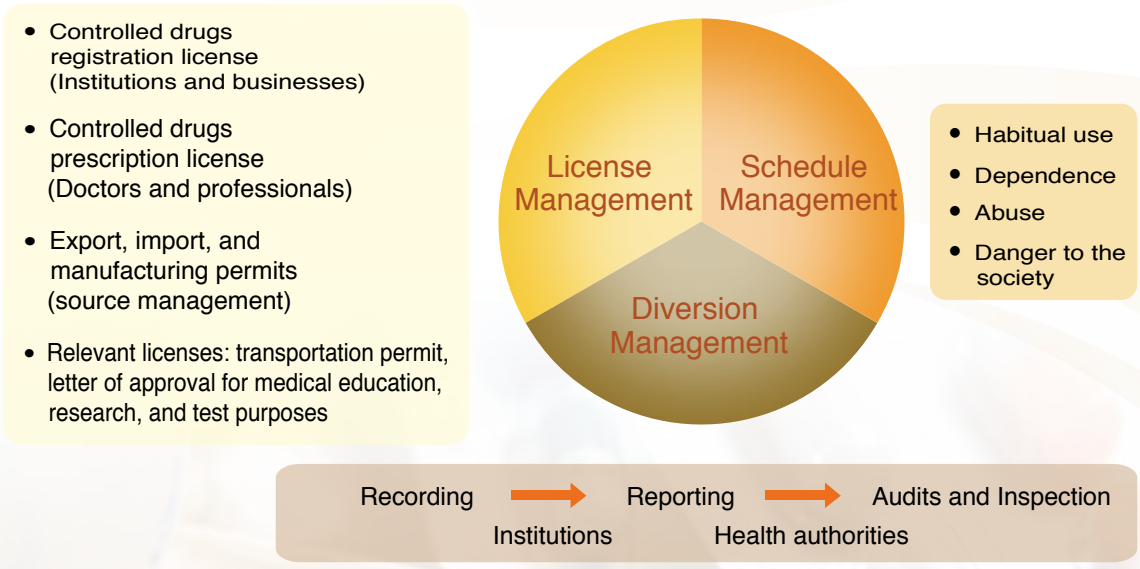
To strengthen management of controlled drugs used for medical and scientific purposes in Taiwan, TFDA has established regulations, certification, and distribution management of controlled drugs as well as management systems for early-warning monitoring and abuse prevention. Total-quality validation was also implemented for Factory of Controlled Drugs in order to improve the quality of medicinal products and to prevent abuse or illegal use of controlled drugs.

## Section 1. Controlled Drugs Regulations and Distribution Management

### Current Status

Drug abuse is a common problem around the world. Improper use of addictive controlled drugs or its illegal distribution makes such drugs as dangerous as illegal drugs. 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 control narcotic drugs, psychotropic substances and their preparations via the *Narcotics Hazard Prevention Act*. However, some of the drugs and substances may offer medical or scientific research value, and would hence be classified as a controlled drug. The *Controlled Drugs Act* is used as the legal reference, making use of license management, scheduling management, and diversion management (Figure 4-1) as the control framework to manage controlled drugs used for medical purposes or scientific research while preventing their abuse and illegal use.

Figure 4-1 Controlled drugs management framework



## Policies and Outcomes

### 1. Amendments to the Controlled Drugs Categories

Current categorization of controlled drugs reference the scheduling system of the United Nations as well as the management items used in developed countries. Controlled drugs are categorized into four schedules according to their habitual use, dependence, abuse, and danger to the society. Once the categorizations have been reviewed and approved by the *Ministry of Health and Welfare Controlled Drugs Review Committee*, they will then be submitted to the Executive Yuan to be publicly announced accordingly. Two board meetings were held to add 6 items to the list of controlled drugs (See Table 4-1) and annual statistic on quantities of all the schedules of controlled drugs in 2014. (See Table 4-2)

Table 4-1 A list of controlled drugs added in 2014 corresponding regulation schedule

| Regulation date | Regulation schedule | English name |
|---|---|---|
| 24 April | Schedule 2 (narcotic drugs) | Oripavine |
| 6 October | Schedule 2 | Benzylpiperazine; BZP |
| 24 April | Schedule 3 (narcotic drugs) | Noroxymorphone |
| 24 April | Schedule 3 | Fluoromethcathinone; 1-Fluorophenyl-2-methylaminopropan-1-one; FMC |
| 6 October | Schedule 3 | （1-（5-fluoropentyl）-1H-indol-3-yl）（2,2,3,3-tetramethylcyclopropyl）methanone; XLR-11 |
| 6 October | Schedule 3 | 2-（4-bromo-2,5-dimethoxyphenyl）-N-[（2-methoxyphenyl）methyl] ethanamine; 25B-NBOMe |

Table 4-2 Annual statistic on quantities of all the schedules of controlled drugs in 2014

| Schedule of Controlled Drugs | Schedule 1 | Schedule 2 | Schedule 3 | Schedule 4 | Schedule 4 Active Pharmaceutical Ingredients; API | Total |
|---|---|---|---|---|---|---|
| Number of items | 9 | 176 | 37 | 72 | 7 | 301 |

## 2. The Management for the Medical Purpose of Controlled Drugs

(1) The Ministry of Health and Welfare has set up a *Medical Purpose of Controlled Drugs Review Committee*. In 2014, the committee had reviewed 130 cases with the long term controlled drugs prescription due to non-cancer intractable pain to ensure all the narcotic prescriptions were not abused.

(2) When the health bureaus found any cases involved with improper controlled 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 2014, there are 20 violation cases regarding to the improper prescription.

## 3. Management of Controlled Drug Licenses

(1) As of the end of 2014, there were a total of 14,857 businesses with controlled drugs registration licenses and 49,059 individuals with prescription licenses for the use of controlled drugs. Appendix 1 Annex Table 10 provides detailed statistics on the licenses of controlled drugs.

(2) All the controlled drugs used for manufacturer, import and export vendors, health related researches and experimental purpose need license through certificate, agreement and approval documents. In 2014, a total of 1833 such licenses were issued.

## 4. Management of Controlled Drugs Audits

(1) TFDA has closely supervised all the health bureaus to reinforce the audit of controlled drugs. In 2014, there were 17,057 cases had onsite inspections, a total of 304 had violation. The violation rate of 1.78%. The most common violation cited during an inspection were *the improper or inaccurate records in the controlled drugs log* followed by *failure to declare controlled drug transactions on a regular basis*. All violations were penalized accordingly. Appendix 1 Annex Table 11 provides detailed statistics on controlled drugs audit results.

(2) In 2014, a special program- *Program for Strengthening Prescription Audits for the controlled drug Zolpidem* 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 302 facilities were inspected, 45 violating facilities were noted. The violation rate of 14.9%. All violations, which included 18 cases of medical malpractice, have been handled according to the relevant regulations.

## 5. Training for Controlled Drugs

Seminars on updates to laws and regulations and licensing procedures were given to local health agencies as well as central veterinarian authorities. In 2014, a total of three basic courses and one advanced course was held, attended by a total of 344 trainees.

## Section 2. Management of Pharmaceutical Plant of Controlled Drugs

### Current Status

According to the rules prescribed by the *Controlled Drugs Act*, the import, export, manufacturing, and sales of Schedule 1 and Schedule 2 controlled drugs shall be implemented by the Pharmaceutical Plant of Controlled Drugs of TFDA. Currently, the acquirement of Schedule 1 and Schedule 2 controlled drugs by the plant involves self-production, commissioned production, or imports from other countries.

### Policies and Outcomes

#### 1. Self-production, Commissioned Production, and Imports of Schedule 1 and Schedule 2 Controlled Drugs

(1) Every dosage form of controlled drugs independently produced by the Pharmaceutical Plant of Controlled Drugs is compliant with the PIC/S GMP regulations. A total of 10 items are self-produced, with each item adhering to drug-specific production control standards and process standards to ensure the quality and safe treatment of the drug. Appendix 1 Annex Table 12 provides detailed statistics on the sales of self-produced drugs.

(2) The quantity, types, and dosage forms of controlled drugs required by various medical institutions are increasing. The production of Schedule 1 and Schedule 2 controlled drugs with larger market requirements has been commissioned to GMP pharmaceutical manufacturers, who are required to maintain the same level of safety and quality management standards as the Factory for Controlled Drugs of TFDA. TFDA has also established production monitoring specifications and dispatches personnel to monitor production processes of the commissioned pharmaceutical manufacturers to ensure product quality and safety. Currently, the production of five items has been commissioned to private pharmaceutical manufacturers.

(3) To increase the number of options available for pain medication in Taiwan, an additional import item *Jurnista Prolonged-Release Tablets 8mg* was introduced in 2014. This product is a long-term pain relief medication that releases the new chemical entity (NCE) dihydromorphenone via an osmotic pump-controlled release system for prolonged and continuous control of pain to improve medication convenience and adherence of cancer patients.

#### 2. Personnel Training

To improve familiarity of Factory personnel with PIG/S GMP and controlled drugs related laws, a total of four training sessions for Factory personnel were held in 2014.

#### 3. New Factory Building and Renovation

The *Factory for Controlled Drugs New Building and Renovation Project* was initiated on 23 December 2014 in order to expand production capacities for Schedule 1 and Schedule 2 controlled drugs and improve production quality. The Project is expected to be completed by the end of 2017. Once the new factory building and renovations have been completed, production of controlled drugs shall no longer be outsourced to ensure complete self-production.

### 4. Morphine Sulfate Sustained Release Film Coated (FC) Tablets 30mg wins the SNQ Award

In 2014, identification barcodes for the smallest type of product packaging was updated from bottles to blister packs. The product *Morphine Sulfate Sustained Release Tablets 30mg* was subject to stringent and professional scientific validation and reviews conducted by the Symbol of National Quality (SNQ) committee and was formally named as a certified quality product for the pharmaceuticals / prescription medicine category in the *17th National Biotechnology & Medical Care Quality Award*.

## Section 3. Controlled Drug Alerts and Monitoring

### Current Status

Abuse of illegal drugs may severely affect mental and physical health, and the issue is becoming a growing challenge due to globalization and increasingly complex trends. Drug abuse also leads to other issues such as reduced quality of the working population, increase in drug-related crime, impact on economic development and public safety, and may even affect overall national competitiveness. To establish a healthy society protected from hazardous drugs, illegal drug control strategies must focus on prevention. Drug abuse reports must be actively compiled to establish robust early-warning systems and functions and eliminate the spread of illegal drugs.

### Policies and Outcomes

#### 1. Collecting and Compiling National Drug Abuse Information

(1) To understand the state of drug abuse, drug types, and trends in the country, TFDA has a drug abuse monitoring mechanism. Drug abuse information on the *Controlled Drug Abuse Reporting System* (http://dars.fda.gov.tw/) is compiled and analyzed on a monthly basis. Also, statistics such as drug abuse urine tests, non-urine tests of suspected drugs and controlled drugs cases, and discovery of illegal drugs in the Taiwan region are compiled to form the *Drug Abuse Case and Testing Statistics* to achieve the purposes of monitoring and understanding the current state and trends of drug abuse throughout the country.

(2) In 2014, a total of 17,896 cases of drug abuse were reported by medical institutions. Results of analysis are provided below:

a. The top-3 types of illegal drugs abused were heroin with 11,185 individual cases reported (62.5%), (meth) amphetamine with 4,858 cases (27.1%), and ketamine with 1,626 cases (9.1%).

b. Drug types and demographics analysis found that ketamine was the most common drug abused by those below 19 years of age. (Meth) amphetamine was the most common drug abused by those from 20 to 29 years of age, while heroin was the most common drug abused by those 30 years of age or above.

c. The top reasons for drug abuse were *dependence* (36.6%) followed by *stress relief* (15.5%).

## 2. The Results of National Drug Abuse Survey in 2014

a. To understand the current status and long-term trends of drug abuse in Taiwan, TFDA conducted the *National Drug Abuse Survey* in 2014. The main objectives of the survey was to achieve in-depth discussions on the behaviors, cause, frequency, source of substances, and substance use issues amongst drug abusers to assess the effectiveness of policies and provide a reference for formulating future directives.

b. Survey results indicated that lifetime prevalence for illegal drug use was 1.29% between the ages of 12 to 64 years. The top-3 types of illegal drugs used were amphetamine, ketamine, and cannabis. The age group between 18 to 44 years of age was most likely to commit drug abuse. The most commonly abused drug for those between 18 to 24 years of age was ketamine, while that for those between 35 to 44 years of age was amphetamine. The leading motivation for first-time drug abuse was *curiosity* (66.7%) followed by *relaxation / stress relief* (14.2%), *friends already using drugs* (13.0%), and *for recreation* (11.7%).

## 3. Establishment of Technology and Database for Drug Abuse

In response to the deteriorating drug abuse and addiction issues, TFDA continues to dedicate the developing new technology and establishing databases to achieve the prevention effectively and control of drug abuse. Important outcomes of 2014 are listed in Table 4-3.

Table 4-3 Major achievements of drug abuse assay technologies and database establishment

| Outcome | Benefits |
|---|---|
| Completed the synthesis of 13 standards and the establishment of standard spectrum database of $^{1}H$, $^{13}C$-NMR, FTIR, GC-MS, and HRMS | To meet the test demands, the Standards are extremely expensive or not commercially available in Taiwan |
| Optimized spectrum conditions for 203 standards (including amphetamine, cathinone, tryptamines, opioids, marjuana, synthetic cannabinoids, cocaine, benzodiazepine and its metabolic derivatives) as well as established secondary fragment mass spectrum database | To quickly screen the known or unknown abuse drugs to prevent drug abuse |
| Developed the pre-treatment and GC-MS instrument methods for nine items of synthetic cannabinoids such as JWH-018, JWH-122, JWH-250 and its metabolites in the urine | To accelerate drug abuse analysis time to track trends in drug abuse |

## Section 4. Controlled Drug Abuse Prevention

Drug abuse currently remains a major challenge to the field of medical and public health. Drug abuse and addiction problems have grown worse in recent years, posing a hazard against individual health while increasing crime and unemployment, severely impacting social and national stability and development. Hence, there is a need to strengthen measures that prevent drug abuse amongst the general public by developing effective preventive measures and intervention.

### Policies and Outcomes

#### 1. Promote Proper Use of Hypnotic Drugs amongst Physicians

A total of four seminars on controlled sedatives and sedative-hypnotic drugs were held in 2014 to advocate proper administration of hypnotic drugs by physicians. A total of 346 physicians attended the seminars to gain a better understanding of controlled sedative-hypnotic drugs and their proper usage, and reduce the risks of iatrogenic addiction resulting from improper drug use.

#### 2. Multi-agency Collaboration for the Prevention of Drug Abuse

(1) TFDA has jointly organized the *Integrated Promotion Program for Anti-Drug Education* with the Ministry of Justice and the Ministry of Education, and carried out the *2013- 2014 Anti-Drug Education Expo and Talent Training Program*. 9,124 individuals participated in the training while 15,808 individuals attended the Education Expo.

(2) TFDA has worked with the Health Promotion Administration of the Ministry of Health and Welfare for the *Integrated Promotion Program for Addictive Substance Prevention Education* to create micro-movies deterring tobacco, drugs, and betelnut abuse, the online game *titled Truth or Dare*! and addictive substance prevention for dommies, including *Dumb Things We Did That Year and Drug Myths You Must Know*. TFDA also collaborated a total of 57 corporations in the *Anti-Tobacco, Anti-Betelnuts*, and *Anti-Drug Healthy Corporation Campaign* to jointly establish a work environment free from drugs, tobacco, and betelnuts.

#### 3. Drug Abuse Prevention Seed Instructor Training

A total of seven Instructor Training Courses (including basic and advanced courses) were held in northern, central, and southern Taiwan in 2014, training a total of 442 seed instructors. TFDA also established 213 drug abuse prevention inquiry stations, with seed instructors providing education and community pharmacists offering inquiry services and other forms of public interaction in order to strengthen public awareness on the proper use of controlled drugs and the prevention of drug abuse.

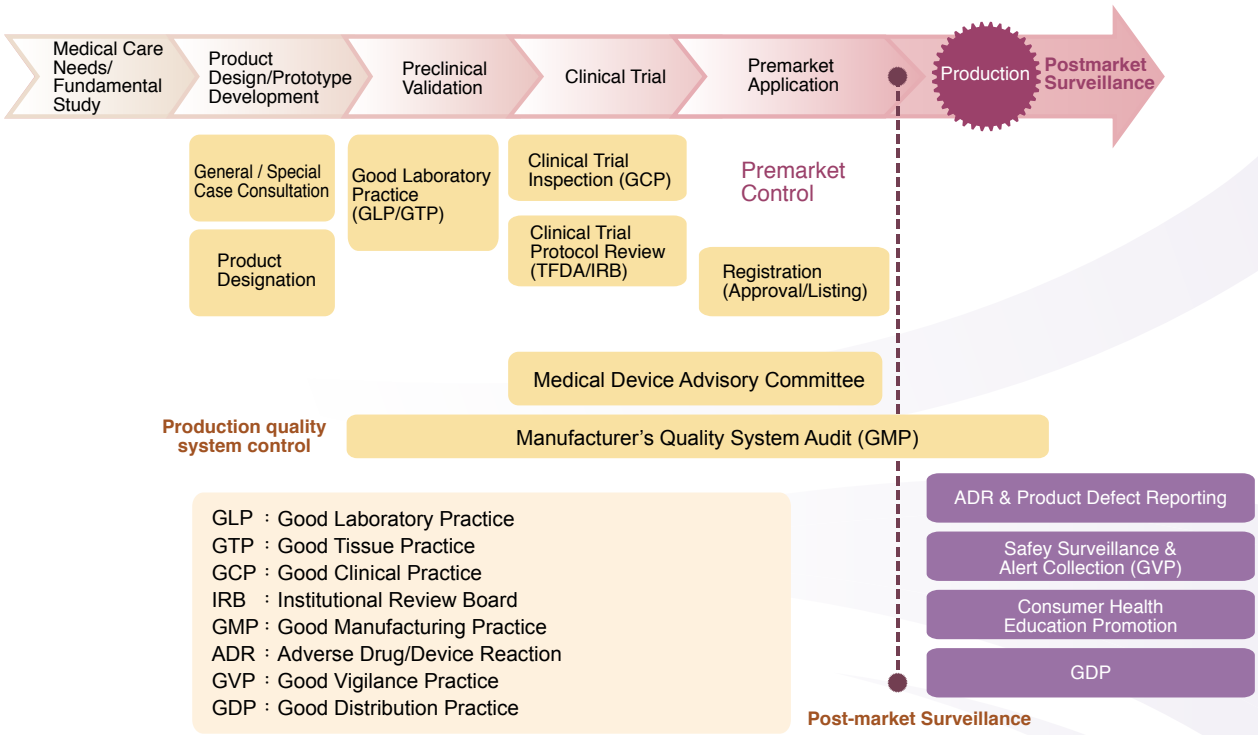
# 5 Medical Devices Management

- Medical Device Regulations and Product Review
- Medical Device Source Management
- Medical Device Quality Chain Monitoring
- Medical Device Safety Management

# 5 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 (Figure. 5-1) covering international regulatory harmonization, production source control, pre-market gatekeeping, post-market monitoring, supply chain management, and professional counseling service was established to effectively ensure the safety, effectiveness, and quality of medical devices, as well as to promote development of Taiwan's biotech and pharmaceutical industry, creating an environment beneficial for consumers, the industries, and the government.

Figure 5-1 Medical device total product life cycle management system




## Section 1 Medical Device Regulations and Product Review

### Current Status

The medical device industry is the one that requires highly strict regulatory requirements and management. A transparent, effective, and appropriate regulatory environment must be established in order to safeguard the safety of device usage for public and promote industrial development. To strengthen management over medical device safety, effectiveness, and quality before market release, management items for inspection and registration such as preclinical testing, clinical trials, and product inspection standards are reviewed accordingly. Medical device industries are also provided with regulatory inquiry and project consultation services for innovative research and development applications, providing a strong foundation for their business development.

## Policies and Outcomes

### 1. Harmonization with International Regulations and Standards

In 2014, amendments to medical device regulations and administrative directions include *Registration Requirements of Online Sales for Medical Devices by Pharmaceutical Firms, Regulations for Governing the Management of Medical Device, Regulations of Pharmaceutical Manufacturer Inspection, Application for medical device designation, Technical criteria for home-use blood sugar monitoring systems, Medical Device license transfer documents, Reference Guide for Nano-Medical Devices Identification*, *and Good Submission Practice (GSP) for the registration of medical devices*. Details are given in Appendix 1 Annex Table 13.

### 2. Medical Devices Review

(1) Classification of Medical Devices

Depending on the characteristics and the degree of risk of medical device, medical devices in Taiwan 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 2014, the number of valid medical device licenses was 37,798, including 23.6% for domestic products and 76.4% for imported products, respectively.

(2) Review Time and Quality for Medical Device

a. Comprehensive Revolution of the Medical Device Registration Mechanisms

Streamlined and priority review mechanisms were established according to the level of risk for medical device, and each of these two mechanisms can reduce review time. By the end of 2014, 1,002 medical device international standards and 90 medical device guidance documents announced by US FDA were recognized, and 46 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. Improving Review Time and Enhancing Review Capabilities

In 2014, a total of 5,218 medical device registration reviews were completed. The review time is equivalent to the level of global leading countries. The reviews included 113 cases of innovative medical devices with no similar items, which required an average review duration of about 178 days, a 13% reduction from the duration incurred in 2013. In 2014, TFDA also approved a world-leading total of six innovative medical devices (versus a total of one such device approved in 2013).

(3) Establishment of Quality Medical Device Clinical Trials Environment

In 2014, a total of 64 clinical trial applications were reviewed with an average review time of 38 days, a 30% reduction from 54 days in 2012. From 2012 to 2014, the number of multi-country and multi-center clinical trials for medical devices had increased from 1 to 5. High ranking medical device clinical trial professionals have also been dispatched to the United States, Europe, Japan, and other countries for training to support multi-country collaborative medical device research and development. Five major Taipei hospitals (Chang Gung, Wanfang, Taipei Medical University Hospital, Veterans General Hospital, and National Taiwan University Hospital) signed multi-country medical device clinical trial partnership programs with major international corporations (Sumitomo, Cook, Swissray, Siemens, and Medtronic) helping to convert Taiwan into an important hub for entering the Asia Pacific market and other emerging markets (Figure 5-2).

(4) Comprehensive Counseling Mechanism

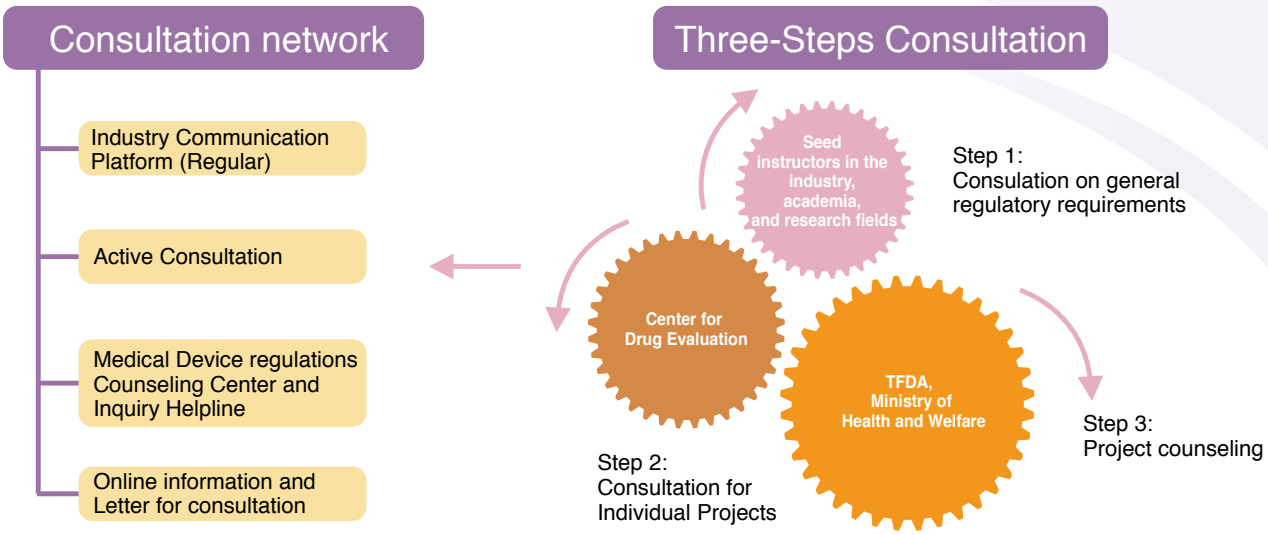
a. Establishing a Three-Step Consultation Network

In response to the rapid development of Taiwan's medical device industry, TFDA has encouraged the research and development of innovative medical devices. TFDA has thus established a

comprehensive regulatory consultation network and strengthened the seamless three-step counseling mechanism. TFDA is also actively identifying potential high-end innovative medical device industries to provide with relevant consultation as well (Figure 5-3).

Figure 5-2 Taiwan's five major hospitals signing the multi-country medical device clinical trial partnership program


Figure 5-3 Comprehensive consultation program for medical device industry



b. Outcomes of the Consulting Program

As of the end of 2014, TFDA has successfully assisted 13 domestically manufactured medical devices through to approval, 9 cases entering the clinical trial, and transferred 3 academic research and development outcomes to the industry, which included clinical trials for the world's first high-end treatment of cartilage defects, clinical trials for the first innovative negative pressure sleep apnea treatment device, and approval for the first domestically made one-step artificial dental implant.

c. Establishing a Regulatory Counseling Center

In collaboration with Center for Drug Evaluation (CDE), TFDA established the medical device regulations counseling center, which offered up to four dedicated inquiry service helplines starting in 2013 and an additional two voice mailboxes in 2014. A total of 16,276 inquiry calls were received.

d. Training Seed Regulatory Personnel

Personnel for providing consultation are from TFDA, the Center for Drug Evaluation, and 48 well-trained seed regulatory personnel. The namelist of the 48 trained personnel has also been published online for public access in order to expand the scope of services provided. It is hoped that the provision of comprehensive and local consultation will help local businesses overcome the legal barriers as early as possible.

## Section 2 Medical Devices Source Management

### Current Status

As of the end of 2014, Taiwan had a total of 1,290 registered medical device manufacturers. 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. Consistent systematization of management and alignment with international GMP for medical devices are carried out in order to support the international marketing of medical device industries. Also, in order to achieve the objectives of source management, existing quality systems of medical device manufacturers are reviewed using manufacturer site audits or quality system document checks (for importers). Manufacturers that satisfy Taiwan's GMP will be issued an approval letter of registration with a valid period of three years.

### Policies and Outcomes

#### 1. Systemic Oversight of Authorized Auditing Organizations

There are currently four authorized medical device GMP auditing organizations in Taiwan, including the Center for Measurement Standards of the Industrial Technology Research Institute (ITRI), Electronics Testing Center (ETC), Metal Industries Research & Development Centre (MIRDC), and Plastics Industry Development Center (PIDC). To improve TFDA's capabilities in assessing the certification agencies and to enhance global alignment of relevant systems, TFDA has commissioned a special program entitled *Enhancement of Assessment Capabilities of Authorized Auditing Organizations, Audit Standards, and Relevant Regulations for Auditing* to carry out *Headquarter Assessment and Witness Assessment* of the authorized auditing organizations to ensure audit quality. Training was also provided to the personnel of these four auditing organizations so that manufacturer auditing results would be based on identical and consistent standards.

#### 2. Registration Management of Medical Device Manufacturing Factories

Medical device importers should apply for registration letters to demonstrate 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

Table 5-1 Number of valid registrations for medical device GMP / QSD

| Year | Number of vaild 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 |
| 2014 | 565 | 3,057 |

apply for on-site inspections of overseas manufacturing factories. By the end of 2014, there were 565 valid registration letters for domestic medical device GMP, and 3,057 registration letters for imported medical device QSD (Table 5-1).

## Section 3 Medical Device Quality Chain Monitoring

### Current Status

Risk assessment mechanisms are used every year to target specified items. Resources from local health bureaus are integrated in order to conduct the product quality monitoring plan. Post-market quality surveillance is carried out by sampling marketed products offered in various drugstores, pharmacies, medical device vendors, manufacturers or agents and subject them to quality inspections.

### Policies and Outcomes

#### 1. Post-market Quality Surveillance of Medical Devices

Based on medical device management policy as well as items with higher nonconformities found during post-market surveillance program, and adverse medical device reaction (ADR) reports, or other risk assessment factors, TFDA carries out nationwide sampling inspections. In 2014, a total of 216 items were sampled and subjected to quality testing as well as package labeling checks. Of which, 205 items passed quality testing (qualified rate is 94.9%), and 129 items passed package labeling checks (qualified rate is 59.7%). Nonconforming products were officially reported to the local health bureau responsible for further administrative handling according to Pharmaceutical Affairs Act. Results of various quality surveillance projects are shown in Table 5-2.

#### 2. Joint Post-market Audit of Medical Devices

In order to effectively supervise the compliance of package labeling of marketed medical device products, TFDA has provided support to local health bureaus by conducting joint medical device audits. In 2014, a total of four medical device product categories were targeted for joint audits due to their high rates of violation, risks, public scrutiny, and public sentiment. A total of 140 items were audited, with 25 found to be nonconforming, a nonconforming rate of 17.9%. Major types of violations included labeling and package inserts that violate the *Pharmaceutical Affairs Act.* Every pharmaceutical company that committed package labeling violations for the medical devices has been handled according to law by the local health bureau that exercise jurisdiction over them (Table 5-3).

Table 5-2 Quality surveillance results of Medical Devices in 2014

| Project title | Total case no. | Surveillance issues | | | |
|---|---|---|---|---|---|
| | | Quality[a] | | Package labeling | |
| | | Conforming no. | Nonconforming no. | Conforming no. | Nonconforming no. |
| Survey on the quality of surgical gowns in Taiwan[b] | 8 | 4 | 3 | 8 | 0 |
| Survey on the quality of marketed medical masks in Taiwan | 25 | 21 | 4 | 25 | 0 |
| Hepatitis B surface antigen and antibody assay performance surveillance | 22 | 22 | 0 | 21 | 1 |
| Sterility surveillance for medical-use sterile phlegm removal device and tracheostomy tube | 83 | 80 | 3 | 26 | 57 |
| Sterility surveillance for catgut or absorbable suture | 69 | 69 | 0 | 40 | 29 |
| Sterility surveillance for urethral catheters | 9 | 9 | 0 | 9 | 0 |
| Total number (Percentage) | 216 (100) | 205 (94.9) | 10 (4.6) | 129 (59.7) | 87 (40.3) |

**Note:**

**a: For surgical gowns and marketed medical masks, passing criteria would depend on whether or not the item is capable of meeting the registered specifications.**

**b: There is one specimen that is not included within the scope of the quality surveillance criteria for surgical gown liquid protection.**

Table 5-3 Statistical analysis of joint audit results of medical devices in 2014

| Medical devices | Number of inspected counties /cities | Medical, aesthetic dental, and orthopedic clinics | Product labeling | | |
|---|---|---|---|---|---|
| | | | Inspected cases | Nonconforming cases | Nonconforming rate |
| Hyaluronic acid dermal fillers | 5 | 12 | 27 | 5 | 18.5 |
| Surgical sutures | 5 | 28 | 71 | 5 | 7.0 |
| Dental implants | 5 | 11 | 19 | 8 | 42.1 |
| Hyaluronic acid implants for joint cavities | 5 | 12 | 23 | 7 | 30.4 |
| Total | 5 | 40[a] | 140 | 25 | 17.9 |

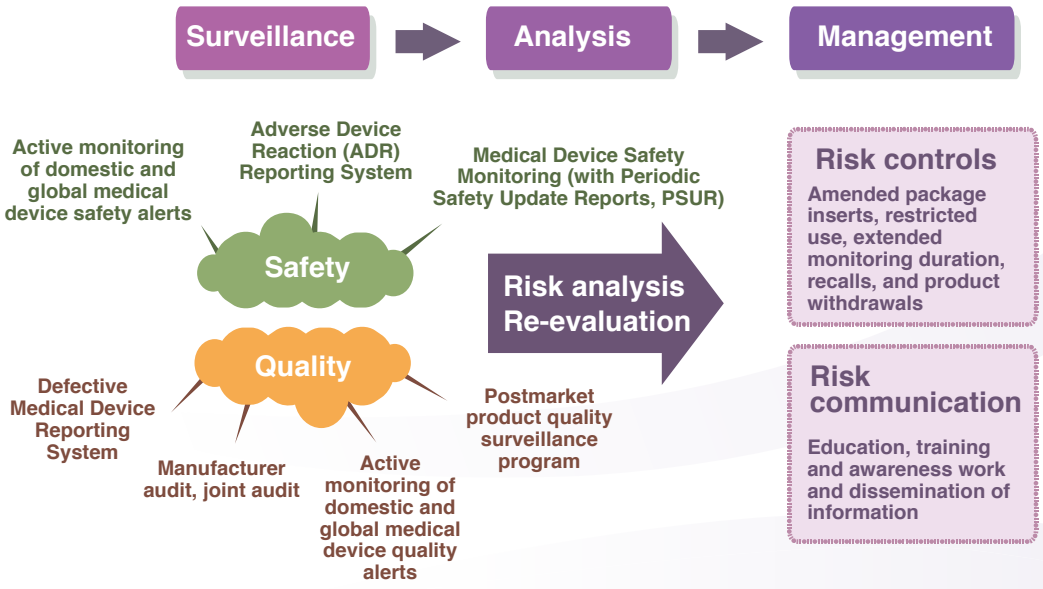
**Note: a: single clinic may undergo two or more product audits.**

## Section 4 Medical Device Safety Management

### Current Status

To establish a comprehensive safety surveillance mechanism and maintain post-market safety surveillance of medical devices, TFDA has established an adverse device reaction (ADR) reporting system, and been actively monitoring domestic and global medical device safety alerts, strengthening distribution management of marketed goods, and promoting awareness of relevant regulations and policies (Figure 5-4). The use of effective quality reporting systems allows for quick feedback, helps regulatory agencies to exercise effective medical device safety management, and may propose corrective and preventive measures to achieve a positive feedback cycle for excellent quality.

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




### Policies and Outcomes

#### 1. Strengthening Post-market Safety Monitoring of Medical Devices

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

a. In 2014, a total of 1,454 safety alerts were received from the Safety Alert Dissemination System (SADS) of the Asian Harmonization Working Party (AHWP).

b. In 2014, Taiwan's ADR Reporting System received a total of 1,401 cases of defective medical devices and 209 cases of adverse device reactions.

c. In 2014, a total of 3,058 domestic and global safety alerts were actively monitored. These include 1,293 product advisories and 1,765 recall notifications. TFDA flagged 93 of these alerts as potentially affecting the domestic public, and translated them into summaries for announcement.

(2) Joining the Global Vigilance Report Exchange System

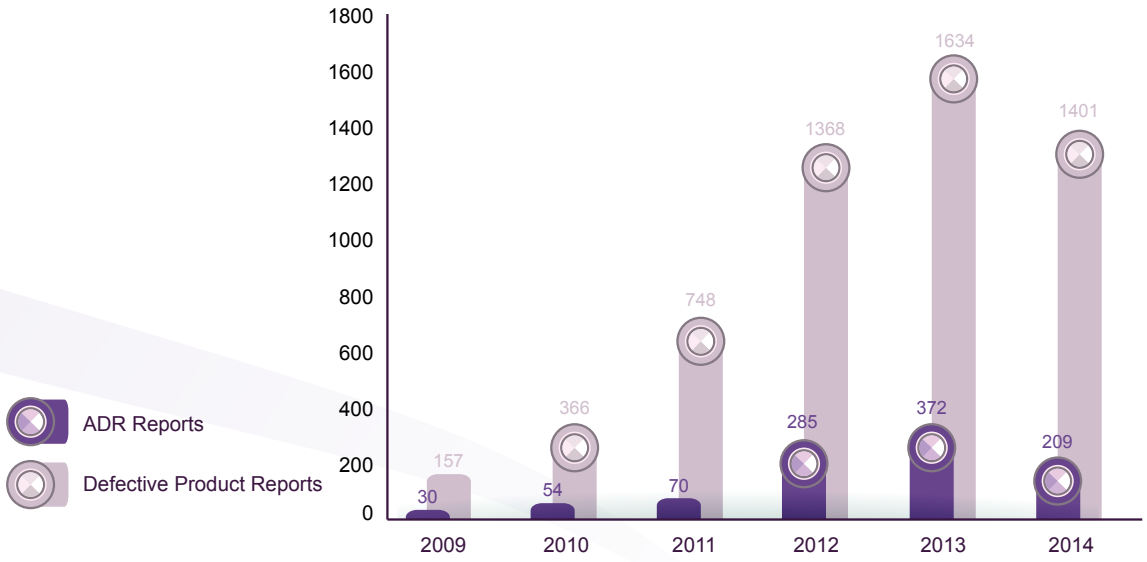
TFDA is a member of the National Competent Authority exchange program (NCAR) of the International Medical Device Regulators Forum (IMDRF) and receives recall notifications and safety

alerts issued by any member on a simultaneous basis. In 2014, a total of 331 global vigilance reports were received. After evaluation, 93 of these were found to affect domestic market and related firms were notified accordingly to take response measures.

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

TFDA has, through promotion and awareness seminars, continued to encourage medical institutions, manufacturers, and the general public to use the National ADR/Defective Product Reporting System to report adverse events in order to enable the detection of post-market quality and safety issues of medical devices and the implementation of risk management measures. The number of reported ADR rose from 30 cases in 2009 to 209 cases in 2014. Defective product reports rose from 157 to 1,401 cases over the same period (Figure 5-5).

Figure 5-5 Defective product / ADR reports of medical devices




## 2. Pharmaceutical Firm and Product Distribution Management

(1) Legalizing Online Sales for Class 1 and Some Class 2 Medical Devices

While ensuring public safety on the use of medical devices, TFDA has also been working to improve convenience in acquiring such devices. According to its 1 November 2012 public notice *Registration Requirements of Mail-Order Purchase for Medical Devices*, TFDA allows sales of Class 1 low-risk medical devices and stipulates that dealers must have a pharmaceutical firm license permit for the sales of medical devices as well as a physical business location and sales channel. Applications must be submitted to the local health bureau in charge. Once approved, the medical device may be marketed and sold through the Internet, television channels, and mail order. On 2 January 2014, TFDA publicly announced three other Class 2 medical devices that can be sold through mail or online, including condoms, tampons, and body fat meters for home use. Additionally, pharmaceutical firms are required to specify on mail-order purchasing channels about certain information, such as reading product instruction manuals carefully, regular calibration for products with measurement function, and information about the manufacturing date and expiry date of the product.

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

Pharmaceutical firms have many times incorrectly declared the identification scope in the affidavit for Class 1 medical devices. In order to safeguard medical device usage safety among consumers, the re-evaluation mechanism for Class 1 medical devices were initiated. A total of 84 permit re-evaluations were completed in 2014.

(3) Promoting Good Distribution Practice for Medical Devices

To ensure that medical device importers, dealers, and pharmacies are capable of maintaining product quality specified by the original manufacturer during transport and sales, TFDA announced the draft of Good Distribution Practice (GDP) for Medical Devices in December 2013. Subsequently in 2014, a reward program was established to commend those who have voluntarily implemented the GDP mechanism. TFDA organized three seminars and training sessions as well as one achievement and commendation meeting. TFDA also visited a total of 10 medical device vendors and provided GDP counseling to them.

## 3. Strengthening Awareness of Medical Device Regulations and Technologies

(1) Promoting Key Regulations and Technologies

To facilitate the promotion and implementation of key regulations, TFDA implemented a total of 25 promotional activities in 2014, including Essential Principles (EP) and Summary of Technical Documentation (STED) of medical device safety and performance to harmonize with global trends, drafting registration and technical guidances for *in vitro* diagnostic devices (IVD), holding academic conferences on international regulatory requirements for nano-medical devices, conducting safety and risk assessment education and awareness seminars on the application of nanotechnology in medical devices, implementing Good Submission Practice (GSP) for medical devices, and other key regulations.

(2) Strengthening Communication with Industry and Medical Institutions

To improve relevant personnel's competence in purchasing, acceptance verification, maintenance, and adequate perception of medical device ADR or defective product reporting system, TFDA held four seminars in 2014 on the appropriate selection and purchasing of medical devices in four city-level medical institutions in Taipei, Taichung, Tainan and Hualien.

(3) Establishing a Communication Platform for Industry Associations

In 2014, TFDA held two meetings for promoting communication with medical device industry associations. Through such platform, direct dialogue exchanges were carried out with the industry in order to achieve a mutually beneficial consensus over policies and facilitate the development and implementation of policies.

(4) Strengthening the Knowledge Capacity of Medical Device Regulations for Academic and Research Sectors

In order to ensure seamless integration of results from academic research institutions with industrial development and to reduce the gap between the academic field and actual needs of industry, TFDA has held three regulatory awareness seminars in medical engineering related conferences. The purpose of the seminars was to encourage academic research institutions to incorporate regulatory concepts related to medical devices during the early phases of research and development (R&D), reduce R&D time and cost, encourage commercialization of research results, and generate economic benefits.

# 6 Cosmetics Management

Cosmetics Regulations and Product Review

Cosmetics Source Management

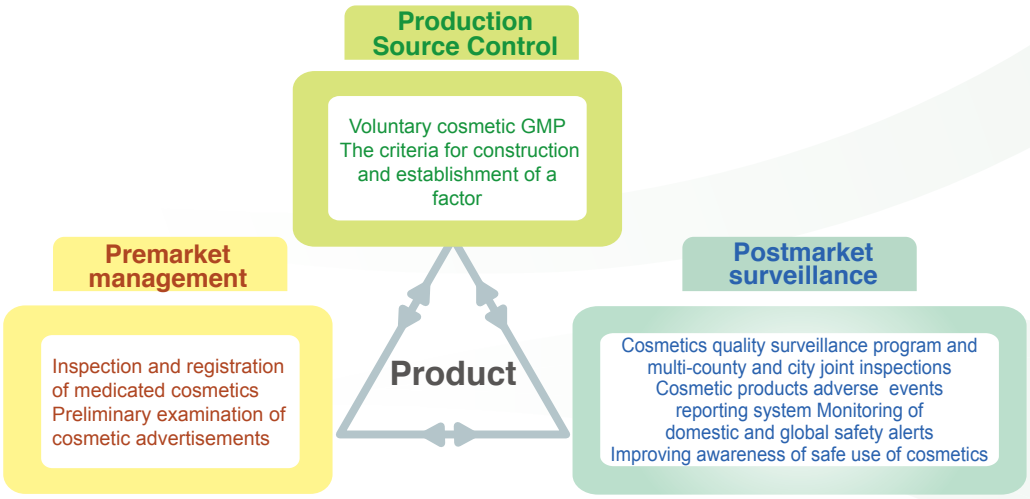
Cosmetics Quality Chain Monitoring

Cosmetics Safety Management

# 6 Cosmetics Management

Cosmetics have become indispensable in our daily lives, giving rise to public concerns on cosmetics quality and whether long-term use may threaten human health and safety. Current cosmetics management system is divided into three parts, namely production source control, premarket management, and post-market surveillance (Figure 6-1). Source control includes ensuring the compliance of manufacturers to the criteria for construction and establishment of a factory as well as encouraging Voluntary Cosmetics Good Manufacturing Practice (GMP) for cosmetics. Premarket management includes registration of medicated cosmetics and preliminary examination of cosmetic advertisements. Post-market surveillance focuses on implementing cosmetics quality surveillance projects, multi-county and city joint audits, establishing cosmetic products adverse events reporting system, regular monitoring of domestic and global cosmetic safety alerts, and strengthening consumer awareness for safe use of cosmetics. Together, these three parts will help create a comprehensive cosmetics quality and safety protection network.

Figure 6-1 Current cosmetic management framework




## Seciton 1 Cosmetics Regulations and Product Review

### Current Status

Rules prescribed by the current *Statute for Control of Cosmetic Hygiene* include premarket inspection registration systems for medicated cosmetics as well as application systems for cosmetic advertisements. Currently, approval for these items exceeds 90%. In recent years, the distribution of cosmetics in global markets has become more widespread and flexible. EU and ASEAN countries currently lack premarket review procedures for cosmetic products. To harmonize administrative regulations and hygiene standards of cosmetics with international regulations and to promote further development for the cosmetic industry, TFDA has referenced cosmetic regulations and management systems adopted in other countries with the aim of lifting requirements for premarket inspection and registration of cosmetics as well as preliminary examination of cosmetic advertisements. Currently, TFDA has planned to establish a premarket registration and product information file (PIF) system, implement GMP for cosmetics across the board, strengthen post-market surveillance and cosmetic company management to ensure the comprehensiveness of cosmetic management systems.

## Policies and Outcomes

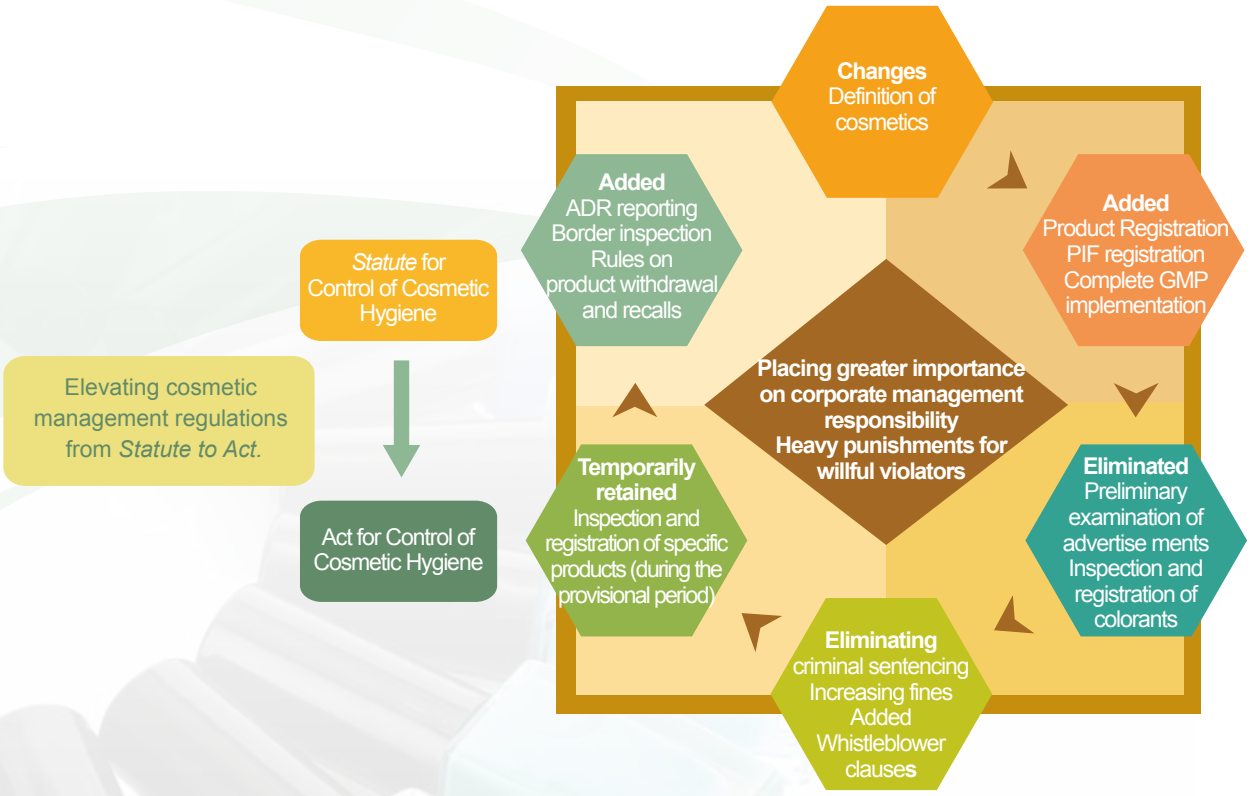
### 1. Creating the Legal Environment and Harmonization with International Standards

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

a. To establish a legal environment harmonized with global cosmetic management standards, TFDA is referencing international specifications to revise definitions for cosmetics and replace existing inspection and registration systems for medicated cosmetics and cosmetic colorants with the Product Information File (PIF) for the premarket product registration and management system. Source management will also be strengthened, with plans made for implementing border sample inspections and implementation of a GMP system for all relevant cosmetics. Cosmetic advertisement management models have also been revised to phase out the preliminary examination system of cosmetic advertisements. Minimum limits to fines have been added, and amounts the maximum limits of fines have been raised. New rules have also been introduced defining adverse reactions to cosmetics that must be reported as well as withdrawal or recalls of nonconforming cosmetics by cosmetic companies.

b. In 2014, revisions to the *Statute for Control of Cosmetic Hygiene* have been drafted. A total of four corporate impact forums, three cosmetics registration and system operation seminars, and three cosmetic GMP rules seminars were held to collect public opinions and improve awareness for the relevant policies.

Figure 6-2 Key revisions to the overall *Statute for Control of Cosmetic Hygiene*



(2) Adding Various Regulations and Hygiene Standards

Regulations from various countries are referenced to achieve harmonization of rules. Cosmetic regulations and hygiene standards added or revised in 2014 are listed in Table 6-1.

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

(1) Inspection and registration of medicated cosmetics

a. In 2014, TFDA handled a total of 1,900 cases of cosmetics inspection and registration applications, of which 1,661 cases were approved (Table 6-2).

Table 6-1 Regulations and hygiene standards associated with cosmetics added or revised in 2014

| Date | Regulation / standard name | Summary |
|---|---|---|
| 8 January | Amendments to *Regulations Governing Maximum Residual Amounts of Heavy Metals (Lead and Arsenic) as Impurities in Cosmetics"* | Residual lead or arsenic impurities in the final product should not exceed 10 ppm and 3 ppm respectively |
| 15 May | Amended *Guideline for the Use of Preservative Ingredient and Dosage Limit Requirement in Cosmetics* | Amended the usage limits and published additional reminders for the use of *Methylisothiazolinone* and *Mixture of 5-Chloro-2-methyl- isothiazol-3(2H)-one and 2-Methyl- isothiazol-3(2H)-one with magnesium chloride and magnesium nitrate* |
| 9 October | Amended the Management *Regulations Governing the Composition of Camphor, Menthol, and Methyl Salicylate in Cosmetics* | Removed the management regulation stipulating *cosmetics containing Camphor as an ingredient should label in its package insert or packaging that the product should not be used by those with glucose-6-phosphate dehydrogenase deficiency* |

Table 6-2 The number of approved cosmetics licenses issued from 2010 to 2014

| Year | Total applications | Licenses granted | Approval rate |
|---|---|---|---|
| 2010 | 1,594 | 1,437 | 90.2% |
| 2011 | 1,634 | 1,519 | 93.0% |
| 2012 | 1,721 | 1,482 | 86.1% |
| 2013 | 1,650 | 1,506 | 91.3% |
| 2014 | 1,900 | 1,661 | 87.4% |

b. TFDA approved and issued a total of 28,708 licenses in 2014, of which 6,219 licenses were granted to domestically made cosmetics while 22,489 licenses were granted to imported products (Figure 6-3).

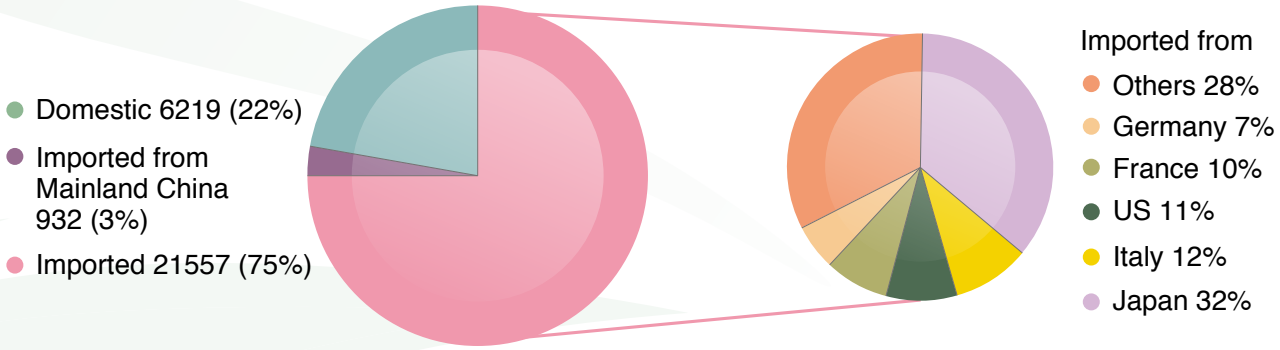
(2) Cosmetic Advertisement Examination

a. To help business owners'gain better understanding on the procedures for producing and applying for cosmetic advertisements, TFDA has promulgated the *Guidelines for Cosmetics Advertising and Rules for Application of Drugs and Cosmetics Advertising for reference and compliance. Additionally, TFDA has produced leaflets titled Tips for Identifying Legal Cosmetic Advertisements* to help consumers correctly identify legal advertisements.

b. To unify examination standards for cosmetic advertisements, TFDA has promulgated the *Cosmetics Advertising Act and Examination Manual* and an *Enumeration of Expressions that are Appropriate or Inappropriate to be Claimed for Cosmetics.* To ensure the comprehensiveness of rules governing the examination of cosmetic advertisements, TFDA is also using its cosmetic advertisement management consultation committee to investigate special cases and provide professional opinions.

c. In 2014, TFDA received a total of 1,449 applications for cosmetic advertisements, of which 1,286 were approved (88.7%).

Figure 6-3 Number of licenses granted for medicated cosmetics as of 2014



## Section 2 Cosmetics Source Management

### Current Status

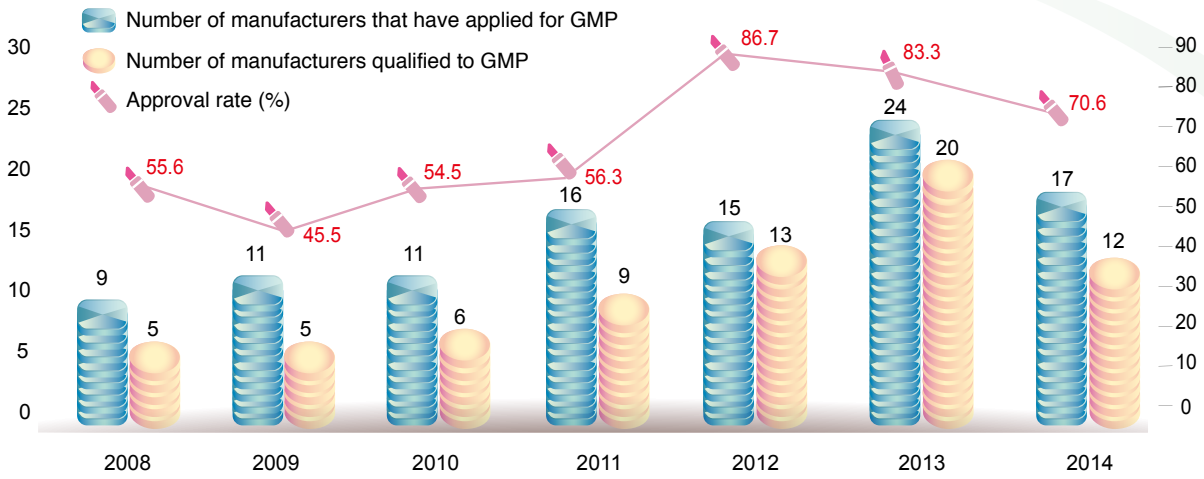
Since 2008, TFDA has been working with the Industrial Development Bureau (IDB) of the Ministry of Economic Affairs (MOEA) to promote voluntary compliance with GMP among cosmetics manufacturers in order to ensure the quality of manufactured products. Currently, cosmetics manufacturers are required to submit documented review information to the IDB. An audit team established by the IDB conducts the audit. Manufacturers who have passed the audit may then apply for a GMP certificate from TFDA. To conform with international GMP for cosmetics and greatly improve the manufacturing standards of the cosmetic industry in Taiwan, TFDA and the IDB have also amended the *Enforcement Focuses for Voluntary Compliance to GMP Standards* on 9 June 2014, and established Taiwan's national standard CNS 22716 as the reference for verifying the quality management system involved in order to align the management system to the international standard ISO 22716. Suppliers can refer to the state and requirements of actual production as well as dosage form or product to define the scope of their certificate applications. Cosmetic management strategies and measures between countries have also been referenced to amend the *Statute for Control of Cosmetic Hygiene* and establish a new section of *Cosmetics Product Notification Portal*. Business owners are encouraged to voluntarily register themselves at the system's portal. Once the revisions have been passed, registration will become mandatory in order to eliminate the need for pre-market registration, shorten the time-to-market for the products, and provide TFDA with full knowledge of all cosmetics currently being marketed for the purpose of providing consumers with effective protection.

### Policies and Outcomes

#### 1. Production Source Control

As of the end of 2014, a total of 103 cosmetics manufacturers have voluntarily applied for GMP audits with IDB, of which 70 manufacturers have passed the audit. A total of 17 manufacturers submitted their applications in 2014 with 12 passing the audits (approval rate of 70.6%) as shown in Figure 6-4. Certified product categories include skin toners, skin balms, essences, shampoo, face wash, shower foam, masks, lipsticks, chapsticks, lip gloss, pressed powder, and eye shadow.

Figure 6-4 A list on the number of cosmetic manufacturers that have applied for and passed GMP specifications from 2008 to 2014



### 2. Establishing the *Cosmetics Product Notification Portal*

TFDA is promoting the *Cosmetics Product Notification System* to align with international standards with countries like the United States as well as the EU and ASEAN member states which do not require premarket reviews. In 2013, TFDA established the Cosmetics Product Notification Portal, using pre-market registration to replace the pre-market inspection system, shorten products' time-to-market, and effectively manage products already released to the market. In 2014, a total of three training seminars were held while 1,102 products have been registered online by 138 cosmetic companies.

## Section 3 Cosmetics Quality Chain Monitoring

### Current Status

TFDA has a risk assessment system to select items for conducting national cosmetic quality monitoring and joint audit programs across multiple counties and cities for the purpose of strengthening post-market safety management of cosmetics.

### Policies and Outcomes

### 1. Quality Monitoring of Commecercially Available Cosmetics

In 2014, the quality monitoring program included quality inspections and labeling checks for a total of 520 items divided into four categories (Table 6-3), of which 492 items were found to conform to quality monitoring standards (94.6%) and 411 items were found to conform to product labeling requirements (79%). The 28 items that failed in quality monitoring standards and the 109 items whose packaging and labeling failed to display required ingredients as publicly announced by TFDA were transferred to the respective local health bureaus and dealt with in accordance with the law.

Table 6-3 Results of cosmetic monitoring in 2014

| Project title | Total cases | Items inspected | | | |
|---|---|---|---|---|---|
| | | Quality | | Package labeling | |
| | | Conforming cases | Nonconforming cases | Conforming cases | Nonconforming cases |
| Survey on Nonylphenol and Nonylphenol Polyethylene Glycol Ether of Marketed Cleaning Cosmetics in Taiwan | 80 | 79 | 1 | 74 | 6 |
| Microbiological Survey of marketed cosmetics in Taiwan | 149 | 143 | 6 | 112 | 37 |
| Survey on Whitening Ingredients and Alpha - Hydroxy Acids of Marketed Cosmetics in Taiwan Area | 137 | 137 | 0 | 114 | 23 |
| Survey on the Quality of Marketed Nail Polishes, Containing Essential Oils, Makeup Cosmetics in Taiwan | 154 | 133 | 21 | 111 | 43 |
| Total items (percentage) | 520 (100) | 492 (94.6) | 28 (5.4) | 411 (79.0) | 109 (21.0) |

## 2. Joint Audits of Marketed Cosmetics

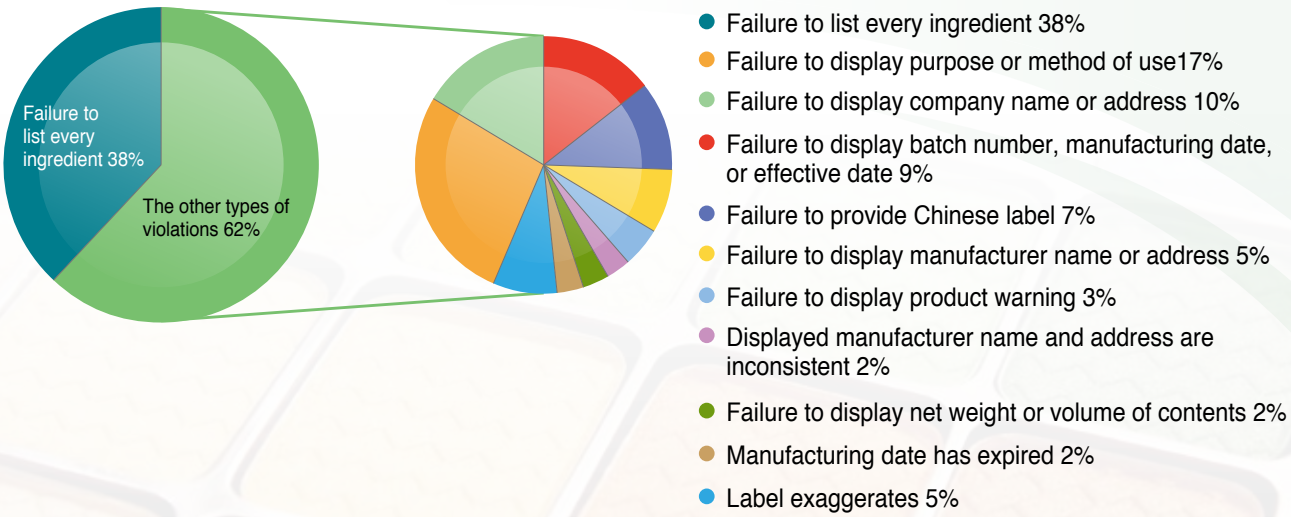
In 2014, a total of three joint audits were carried out for a total of 697 cosmetic products, of which 43 were found to be in violation of specified regulations (violation rate of 6.2%). Suspected violating products were handled according to law by the competent health agencies (Table 6-4). The leading type of violation was failure to list all ingredients; this accounted for 38% of all violations. The remaining 62% of the violations were, in descending order: failure to label purpose of use, failure to provide name of the manufacturer, and failure to provide address of the manufacturer.

Table 6-4 Statistical analysis of joint audits of cosmetics in 2014

| Cosmetics | Number of inspected counties /cities | Number of stores/ street vendors audited | Product labeling | | |
|---|---|---|---|---|---|
| | | | Audited Items | Violative Items | Violation rate (%) |
| Nail polish | 9 | 87 | 277 | 19 | 6.9 |
| Cosmetics containing essential oil | 9 | 87 | 183 | 9 | 4.9 |
| Lipsticks | 9 | 87 | 237 | 15 | 6.3 |
| Total | 9 | 87[a] | 697 | 43 | 6.2 |

**Note: a : For each audited store/street vendor, checks for all three categories were performed.**

Figure 6-5 Statistical analysis of joint audits of cosmetics and the type of violations listed of 2014



## Section 4 Cosmetics Safety Management

### Current Status

TFDA established the Cosmetic Product Defect Reporting System in 2008, which was renamed Cosmetic Products Adverse Events Reporting System in 2014. Significant promotional efforts have been made since 2009 to help increase cosmetics safety awareness among consumers, leading to annually increasing numbers of defective product reports. Public announcements, hygiene standards, and relevant information are released every year. Key administrative focuses also include improvements to risk communication and interaction with cosmetic companies as well as accelerating transmission of cosmetics safety information.

### Policies and Outcomes

#### 1. Cosmetic Products Adverse Events (PAE) Reporting System (originally Cosmetic Product Defect Reporting System)

(1) The number of cosmetic PAEs reported has risen from six cases in 2009 to 105 cases in 2014 (Figure 6-6). According to statistics of PAE categories (partial defects or adverse reaction that include two or more defect types) of 2014, 89 items associated with labeling issues, 18 with appearance abnormalities, eight with defective packaging, and one with an expiration problem. The remaining 15 items were categorized as "other" (Figure 6-7).

(2) In 2014, a total of three awareness-raising meetings for the Cosmetic Products Adverse Events Reporting System have been held. Documentation and operation manuals for the Reporting System were also created and distributed as part of the promotion program to improve public understanding and encourage the public to report cosmetic PAEs.

(3) TFDA also constantly collects the latest news on cosmetic recalls and safety-related information around the world, and monitors information on domestic online shopping reports, webpages on medical hygiene, beauty and health, and medical news. In 2014, a total of 407 domestic and global alerts were monitored and 62 consumer Red and Green Light alerts were issued.

#### 2. Promoting Cosmetics Safety

TFDA has attended 2 seminars regarding cosmetic research and development and quality surveillance, which were held by Taiwan Testing and Quality Assurance Association (TTQAA) and The Beauty Business Trade Association of Taipei to introduce current management specifications for cosmetics and trends of future legal revisions so that cosmetic businesses are provided with the correct concepts of cosmetic selection and purchases.

Figure 6-6 Analysis of the cosmetic PAE reports in past years

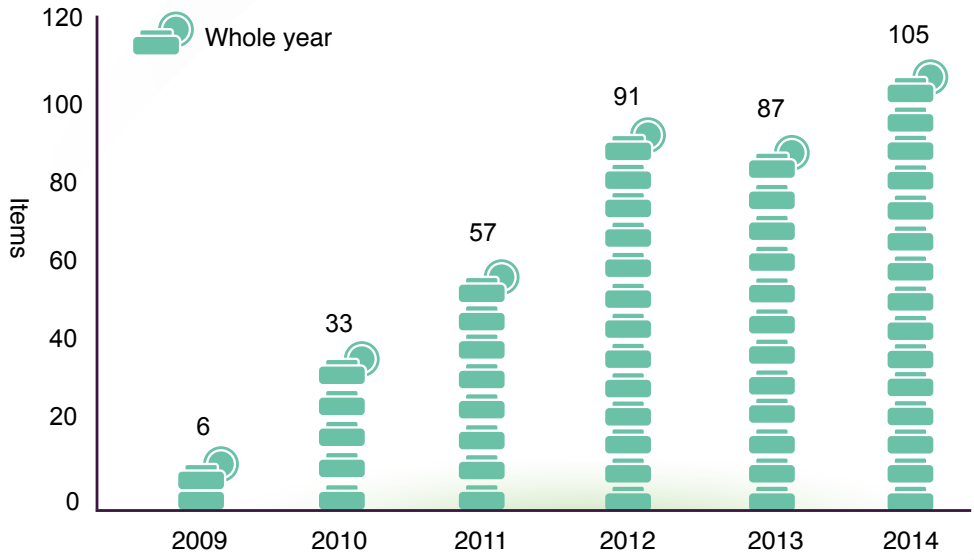
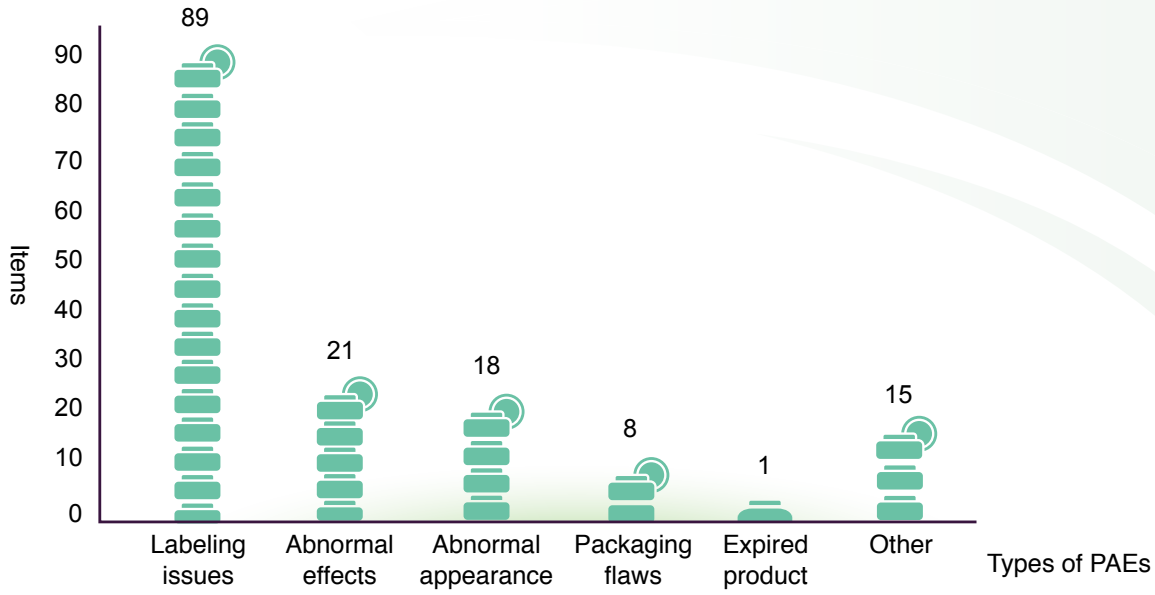



Figure 6-7 Statistics on cosmetic PAE categories of 2014



# 7 Risk Assessment Management and Research Outcomes

Risk Assessment

Risk Management and Emergency Response Mechanism

Research Outcomes

# 7 Risk Assessment Management and Research Outcomes

To ensure the safety and quality of food products, medicine, and cosmetics as well as to achieve preventive or early detection of potential product risks, TFDA runs risk management systems. It uses risk assessment as the basis for formulating policies and management measures, and incorporates risk management and crisis handling in its operations to reduce the impact of risks that do materialize. Additionally, administrative policies are also be driven by advances in food and medicinal product technologies. TFDA promotes various kinds of technological research and employing the results of this research to provide the empirical basis for establishing first-rate food and drug policies as well as technical specifications for innovative tests.

## Section 1 Risk Assessment

### Current Status

Risk assessments play critical roles in the safety and risk management of food products, medicinal products, and cosmetics. Investigations and reporting systems such as food dioxin inspections, medicinal product quality inspections, and medical device and cosmetic adverse reaction reporting systems are employed to build risk databases. Specialized or consultation team meetings are convened in order to assess risk levels and propose risk management strategies such as amendments to medicinal product package inserts, establishment of recall systems, and stipulation of relevant laws. Post-market surveys shall then be used to assess overall benefits of these risk management measures to ensure the health and safety of citizens in this country.

### Policies and Outcomes

To make better control over risks as well as identify potential risk factors, various channels are employed to collect information on food, medicinal products, medical devices, cosmetics and other fields within the purview of TFDA, in order to build the database. The potential risk database was then be analyzed and assessed by the consultation or relevant methods for the risk regulation, by means of it, preventive and improvement measures for these risks are proposed. Additionally, to fortify the risk concepts and sensitivity of our staff, the training programs are held regularly for better risk management.

### 1. Food Safety Risk Assessments

(1) Risk Identification and Data Collection

a. Establishment of the National Food Consumption Database and Risk Assessment Information

In 2014, TFDA continued to build upon the National Food Consumption Database established in 2013 to collect, update and revise dietary information of citizens in the country. Food intake calculation results were released on the National Food Consumption Database website for public access and download. TFDA also provided raw data to those who need to perform exposure assessments. Additionally, the electronic newsletters of the National Health Research Institute, the Nutrition Society of Taiwan, and the Taiwan Dietitian Association to inform researchers of the National Food Consumption Database.

b. Background value surveys for risk factors in food and total diet study risk assessments

(a) Investigation and risk assessments of dioxin levels in food

In 2014, the risk assessment was performed for dietary dioxin levels of residents in the Southern Taiwan. Content surveys and exposure risk assessments were performed for 17 types of polychlorinated dibenzodioxins / dibenzofurans (PCDDs / PCDFs) and 12 types of dioxin-like polychlorinated biphenyls (PCBs) to estimate life-time average daily doses (LADD). Results indicate that LADD of residents in Southern Taiwan are lower than both the tolerable daily intake (TDI) of World Health Organization (WHO) and the tolerable weekly intake (TWI) of Scientific Committee on Food (SCF) of Europe.

(b) Total Diet Study

A total diet study (TDS) was carried out to ensure food safety of fellow citizens and established a basic food sample database. Supporting samples of special hazardous substances targeted in the year were also procured and tested for the risk assessment. For 2014, TFDA continued to build and expand Taiwan's TDS food sample database for pesticide residue established in the previous year (2013), expanding the database to include 250 representative food products and testing data for 252 types of pesticide residues to improve the comprehensiveness of TDS and risk assessments for residual pesticides. Risks for each type of pesticide were estimated according to the dietary intake of the 250 representative foods among three demographic groups, with estimated results indicating that the risks are acceptable.

c. Unintended Reaction Reporting for Food Products

In 2008, TFDA has established the *National Reporting System for Unintended Reactions of Health Food and Food in Capsule or Tablet Forms* to collect post-market safety information from the general public on any unintended reactions. TFDA consultation committee assessed the cases reported and product safety to carry out relevant measures at once to minimize potential hazards and contain the scope of impact. From 2008 to 2014, a total of 150 cases of unintended reactions were reported for health food and food in capsule or tablet forms. A total of 1,134 food safety information were also monitored accordingly.

d. Monitoring International Food Safety Alerts

Dedicated TFDA personnel monitored food recall alerts from around the world on a daily basis and disseminated relevant information to prevent imports of recalled foods infected with potential risk. In 2014, a total of 267 food consumer Red and Green Lights alerts were published on the Food and Drug Consumer Knowledge Services Network (http://consumer.fda.gov.tw/).

(2) Risk Assessment Mechanism and Control

a. Food Product Risk Factor Analysis

In 2014, food risk factor analyses for a total of 3,518 samples were completed, including background surveys for hazardous substances in food, sanitation standards for commercially available food products, and compliance surveys for product labels. Information on the *Food and Drug Consumer Knowledge Services Network* has been transferred and linked with the *Health Risk Assessment Database for Food Safety*. From 2009 to 2014, a total of 890 risk assessment data was recorded, of which 50 and 100 risk assessment items were added and updated in 2014.

b. Convening Specialized Consultant Meetings to Assess and Propose Control Measures

(a) Bovine Spongiform Encephalopathy Expert Committee Consultation

In addition to meat product reviews, imported beef and beef products are required to go through food safety and risk assessments for Bovine Spongiform Encephalopathy (BSE) as well as reviews conducted by the BSE expert committee of TFDA. Any country that has experienced BSE outbreaks and intends to export beef and beef products to Taiwan must submit an application that includes epidemiological surveys and monitoring data of BSE cases that have occurred in the country as well as preventive measures, risk assessments, and other information for review. Other review procedures such as risk assessments and on-site review are also conducted to ensure the safety of the country's beef products. The expert committee must ensure the complete safety of the products and complete risk communication before allowing the import of the said products. A total of 4 BSE expert consultation meetings were convened in 2014.

(b) Food Sanitation, Safety and Nutrition Advisory Committee

The Food Sanitation, Safety and Nutrition Advisory Committee is composed of professionals and academics from various fields providing consultation and recommendations for food sanitation, safety and nutrition policies, surveys and research projects, various standards, scientific and technological exchanges, and handling of major cases with reference value for revising administrative and regulatory regulations. A total of one Food Sanitation, Safety and Nutrition Advisory Committee was convened in 2014.

(3) Training Risk Assessment Professionals

From 2011 to 2014, TFDA offered training courses from the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) , established by the US FDA and the University of Maryland. Professionals and academics from Taiwan and other countries were also invited to provide lectures to gradually improve the technological capacity for improving Taiwan's food risk assessment technology and alignment with international standards. In 2014, two food safety risk assessment professionals from other countries were invited to Taiwan for academic exchange, namely Dr. Lihan Huang of the United States Department of Agriculture's Eastern Research Center and Dr. Jørgen Schlundt from the National Food Institute of the Technical University of Denmark TFDA also held a total of five training courses on food safety and risk assessment principles and methods which were attended by 802 individuals. Two conferences were also held to exchange information with overseas academicians.

## 2. Medicinal Product Safety Risk Assessments

(1) Risk Identification and Data Collection

a. Adverse Drug Reactions (ADRs) Reporting System

*The National Adverse Drug Reactions (ADRs) Reporting System* and *The National Drug Product Defect Reporting System were* established in 1998 and 2004 respectively. In 2014, a total of 11,399 ADR reports and 845 defective product reports.

b. Monitoring International Alerts

Domestic and global medicinal product safety or quality alerts are monitored on a daily basis to initiate investigations at once where necessary. In 2014, a total of 167 medicinal product safety alerts and 656 medicinal product quality alerts were monitored.

c. New Drug Safety Monitoring

For new drugs, periodic safety update reports (PSUR) must be submitted during the early stages of market release to monitor new drug's safety profile. As of the end of 2014, a total of 291 new medicines are under new drug safety monitoring.

d. Post-market Surveillance Plan

Commercially avalaible medicinal products are selected for sampling analysis according to the risk levels involved. In 2014, a total of 90 medicinal products with suspect therapeutic effectiveness such as soporific drugs containing Zolpidem, diabetes medication containing Metformin, and painkillers containing Piroxicam were sampled for testing. Of these, three medicinal products failed the test. The responsible pharmaceutical companies were ordered to recall the products and make improvements within a specified period.

(2) Risk Assessment Mechanism and Control

a. Re-evaluation of Drug Safety and Risk Management

(a) Medicinal Product Safety Consultation Team

A Medicinal Product Safety Advisory Committee was established to assess severe cases reported such as deaths, new drugs passed monitoring period, global medicinal product alerts, and other medicinal products with safety signal. The Medicinal Product Safety Advisory Committee helps clarify new safety concerns of medicinal products, assesses the balance of clinical benefits and risks, and suggests risk management measures such as label changes, restricts the clinical use, or request the sponsor to implement risk management plans. When the risks of a medicinal product outweigh its clinical benefits, the product may be withdrawn from the market (by terminating the drug permit license).

(b) Re-evaluation of Drug Safety and Risk Management

In 2014, a total of eight Medicinal Product Safety Advisory meetings were held to re-evaluate the safety of 59 medicinal products. Of these, 22 products were subject to risk management measures, including 21 revisions of the product label or restricted clinical use as well as the requirement for implementing risk management plans for two medicinal products, and termination of drug permit licenses for orally administered antibiotics containing Chloramphenicol and Ketoconazole as the risks outweigh the clinical benefits.

b. Medicinal Product Quality Inspections

Investigations and corrective actions were implemented for defective drug product reports. For defective products with high levels of concern or high frequency, the responsible pharmaceutical company must submit an investigation report for the causes of abnormal quality as well as preventive and corrective actions. Where necessary, drug recalls must be required out as well. Under the medicinal product recall mechanism, pharmaceutical companies must follow the Regulations for Medicament Recall and carry out recalls in the following situations: defective product evaluation results; the product is imported and is being recalled in other countries; post-market sampling results fail to meet specifications; on-site inspections have identified quality concerns; or the pharmaceutical company voluntarily initiates a recall. Companies involved are required to correct quality abnormalities within the limited time as necessary. In 2014, a total of 150 defective products were monitored. Among these, 11 medicinal products had to be recalled after evaluation, while 86 medicinal products had to be recalled due to quality concerns.

c. Regular and For Cause Inspection

Inspections were carried out regularly at manufacturing plants. For cause inspections were also carried out where there are major quality concerns for the medicinal product.

d. Communicating Medicinal Product Risks

Medicinal product safety or quality alerts are publicly announced where necessary to remind the general public and medical staff. In 2014, a total of nine press articles, 12 medicinal product safety information and risk communication forms, recall information for 105 medicinal products, and four Drug Safety Newsletters (on quarterly journals) were released.

e. Promoting Medicinal Product Risk Management amongst Pharmaceutical Companies

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

(3) Training Risk Assessment Professionals

TFDA continued to provide training, seminars, and public announcements for medical staff, pharmaceutical companies, and the general public on the topics of adverse reaction reporting, defective product reporting, post-market surveillance and risk management for medicinal products. In 2014, a total of nine seminars were held in order to improve understanding of medicinal product management, compliance with reporting requirements amongst medical workers, and raise awareness on the responsibilities for conducting post-market safety and quality surveillance and risk management amongst pharmaceutical companies.

## 3. Medical Device Safety and Risk Assessments

(1) Risk Identification and Data Collection

a. Monitoring of Medical Device Alerts

In 2014, TFDA conducted continuous monitoring of medical device safety and quality incidents posted on various official health websites on a daily basis. Information acquired from the monitoring was also used to initiate domestic investigation. In 2014, a total of 3,058 alert-related operations were monitored and filed accordingly.

b. Medical Device Adverse Reaction/Defect Report

In 2014, TFDA continuous received adverse reaction and defective product reports for medical devices. These cases were then standardized for further analysis and evaluation. In 2014, a total of 209 domestic adverse reaction reports, 544 global adverse reaction reports, 1,401 defective product reports, 181 clinical trial adverse reaction/defective product reports, and 102 periodic safety reports were handled by TFDA.

c. Post-market Surveillance of Medical Devices

TFDA refers to the *Operation Directions for Product Post-market Surveillance*, promulgated on 15 April 2010, as well as adverse incident reports and alerts when deciding whether or not to include potentially hazardous and high risk medical devices in the annual quality surveillance. In 2014, a total of 207 products were inspected, of which 11 products were found to be nonconforming (a nonconformity rate of 5.3%). All these products have been transferred to the responsible health bureaus for subsequent investigations and penalties.

(2) Risk Assessment Mechanism and Control

a. Medical Device Safety Assessments

To effectively monitor the medical devices used in clinic, establishment of a comprehensive medical device risk management policy is necessary.Post-market safety assessments was initiated when receiving the aforementioned adverse reaction reports, defective product reports, expiration of surveillance periods, safety alerts, or safety concerns found for medical devices. Relevant domestic and global medical device safety information is also collected. A Medical Device Safety Evaluation Consultation Committee conducts risk assessment of the safety and effectiveness in clinical use for marketed medical devices, and formulates risk control measures such as revision of package inserts, conducting unannounced site visits, extending safety monitoring periods of medical devices, or disseminating risk information from medical device evaluations. TFDA held two safety evaluation consultation committee meetings in 2014.

b. Quality Surveys for Medical Devices

The risk level of defective medical devices is classified according to their hazard levels. According to which, companies holding license permits are reminded every quarter to abide by the Good Manufacturing Practice (GMP) for medical devices, conduct root causes analysis for quality nonconformities, and submit preventive and corrective actions.

c. Risk Management for Medical Devices

In 2014, TFDA initiated measures for medical devices of safety and quality concern based on the results of medical device safety evaluations and quality inspections. A total of 11 medical devices were prioritized for site visits and GMP/QSD document reviews. Among these, the monitoring period was extended for one medical device, revisions to the package inserts were asked for two medical devices, while additional information was requested for five medical devices. Regarding medical device safety and quality alerts, a total of 93 medical device alerts were published on relevant websites in 2014. Abstracts and summaries were also emailed to the contact windows of hospitals to improve risk awareness of medical staff and personnel as well as to enhance domestic communication of medical device usage safety.

(3) Training for Risk Assessment Professionals

TFDA has continued to hold seminars on the Medical Device ADR Reporting System for medical institutions, manufacturers, and general public while advocating relevant management rules related to the *Regulations for the Reporting of Serious Adverse Reactions of Medicaments.* A total of four such seminars was held in 2014 which were attended by about 300 individuals. The seminars provided instructions on the means of operating the reporting system to improve user willingness to report adverse reactions as well as increase the number of reports.

## 4. Cosmetic Safety and Risk Assessments

(1) Risk Identification and Data Collection

a. Evaluation of Cosmetic Adverse Reaction/Defective Product Reports

Since the establishment of the Cosmetic Products Adverse Events Reporting System in 2008, TFDA has continuously analyzed and evaluated adverse events of cosmetics that are released to the market every year. A total of 105 adverse events were received in 2014, of which 89 (about 85%) involved labeling issues (including incomplete labeling, untruthful labeling, and lack of labeling) followed by illegal ingredients or other active ingredients, abnormal appearance, packaging defects, expiration, and other issues.

b. Monitoring of Cosmetic Alerts

TFDA continues to actively collect global news on cosmetic recalls and safety-related information while monitoring information on domestic online purchases and webpages on medical hygiene, beauty and health, and medical news. In 2014, a total of 407 domestic and global alerts were monitored while 62 consumer Red and Green Light alerts were issued.

c. Post-market Surveillance of Cosmetic Products

TFDA has carried out post-market surveillance that includes quality inspections and joint audits of commercially available cosmetics (whitening, cleansing, nail polish, and lipstick). A total of 520 items were randomly sampled to undergo quality testing (conforming rate of 93%) while 697 items underwent labeling checks (conforming rate of 93.8%). Nonconforming products have been transferred to the responsible local health bureau and handled according to the relevant laws.

(2) Risk Assessment Mechanism and Control

a. Cosmetic Hygiene Management Consultation Committee

Since 1996, TFDA has held annual meetings of the Cosmetic Hygiene Management Consultation Committee to discuss cosmetic management policies, quality, safety, and safe technologies, to serve as reference for policy development in addition to scientific literature and international management regulations.

b. Stipulating Quality and Safety Related Regulations for Cosmetics

Based on scientific evidence, specialized literature, international cosmetics management specifications as well as recommendations from Cosmetic Hygiene Management Consultation Committee members, TFDA publicly announced a total of 182 standards for medicated cosmetics, 300 types of illegal ingredients, and 100 types of restricted ingredients such as preservatives, bacteriostatic agents, astringents, and whitening agents by the end of 2014. Targeted demographics and applicable body parts are also referenced when formulating maximum microbial contents within the cosmetics. Both medicated cosmetics and general cosmetics must satisfy all pertinent hygiene standards.

c. Advocating Cosmetic PAE Reports

In 2014, a total of three promotion meetings was held for the Cosmetic Products Adverse Events Reporting System. Awareness-raising meetings were held and reporting system instruction manuals were disseminated to strengthen public understanding of the Cosmetic PAE Reporting System and improve reporting rates.

(3) Training for Risk Assessment Professionals

To strengthen the awareness of industry firms about what should be performed in a cosmetic safety assessment, TFDA held the "2014 EU cosmetics Product Information File (PIF) and Safety Assessment" conference in 2014. The main theme of its content program on safety assessment was the Cosmetic Product Safety Report (CPSR), which was divided into safety information (product composition, physiochemical properties, microbial content, impurities, toxicological properties of the ingredients, and ingredient exposure) and objective evaluations (assessment factors that impact product safety such as hazardous characteristics of the ingredients as well as local and systemic exposure assessments).

## Section 2 Risk Management and Emergency Response Mechanism

### Current Status

To ensure adequate response to sudden emergencies, TFDA has continued to organize relevant educational courses in order to improve risk management and emergency response concepts amongst fellow colleagues. Information and news are collected and surveyed on a daily basis. Post-market surveillance is also used regularly to ensure the safety of marketed products amongst the general public. In case of emergencies, a response mechanism is also in place to quickly handle and contain issues to prevent escalation. Daily surveillance and report of the emergency track progress in those cases. Once the incident ends, improvement measures are formulated in order to improve risk handling capabilities.

### Policies and Outcomes

#### 1. Promotion and Control of the Organizational Risk Management Mechanism

(1) Education and Training for Risk Management and Emergency Response Mechanism

TFDA holds risk management and emergency response training courses every year, using actual incidents in TFDA as lesson materials to strengthen overall concepts for risk identification and emergency prevention amongst fellow colleagues. TFDA held four such training courses in 2014 which were attended 258 individuals.

(2) Relevant Unit Management Assessment for Risk Management and Emergency Response

In order to follow up on the progress of risk management and emergency response plans of 2014, TFDA regularly submits the management plans to the supervising task force in the Ministry of Health and Welfare, in accordance with the *Guidelines for Risk Management and Emergency Response of the Ministry of Health and Welfare.*

(3) Management Review Meetings for Risk Management and Emergency Response

Management review meetings are held regularly on an annual basis to review risks listed by each unit. Major public incidents, legislator inquiries, and past items mentioned in the given year are referenced to determine the major risk items for 2015.

#### 2. Enhance Emergency Response and Handling

(1) Responding to Emergencies

a. To report emergencies, initiate corresponding responses, and handle major emergencies, TFDA has formulated the *Emergency Response Manual* and relevant documents. Figure 7-1 details TFDA's procedures for handling emergencies.

Figure 7-1 Emergency incident handling workflow of the Food and Drugs Administration

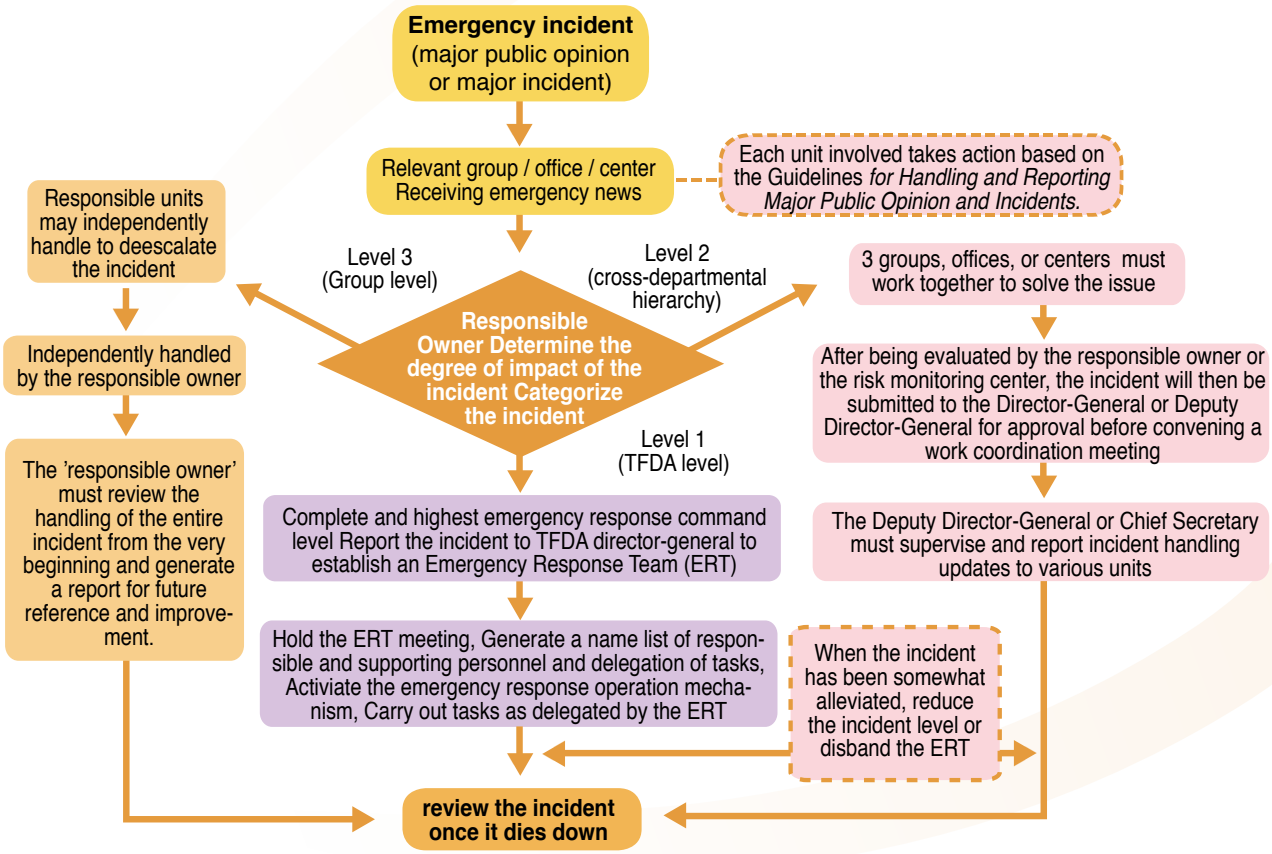
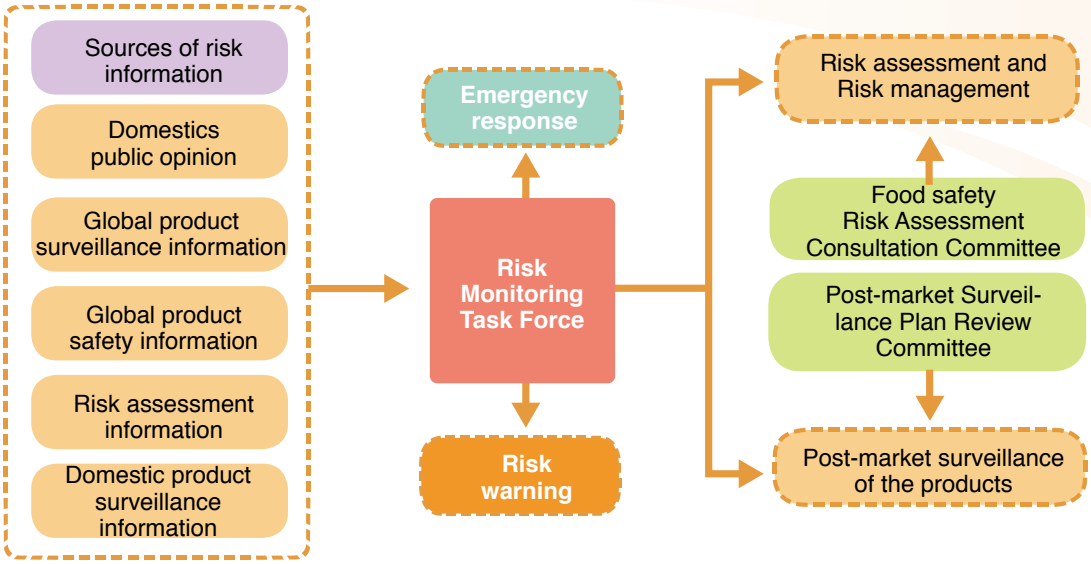



Figure 7-2 Risk control workflow



b. Major emergencies of 2014 included the *Tainted Cooking Oil Incident and Illegal Use of Dimethyl Yellow*. Emergency response mechanisms were activated to deal with these emergencies. In addition to daily surveillance and analysis of public opinion, establishing a dedicated website zone for these incidents, formulating Q&A, and submitting *daily work reports* to supervising agencies, TFDA also carried out internal evaluations and improvements and composed a post-incident report for future reference.

(2) Revising Emergency Response Documents

To strengthen the effectiveness and improve the cycle-time of crisis handling by TFDA, relevant document revisions were made in 2014, as follows:

a. To strengthen the ability of TFDA in handling public opinions and the incident itself, the spokesperson system described in the Emergency *Response Manual* has been amended to report emergencies and carry out relevant responses.

b. To ensure information review and quality of news media publications,the *Guidelines to Press Release Operations* have been revised accordingly. All agencies publishing food-related press articles must notify the health bureau of their jurisdiction via *Taiwan's International Food Safety Authority Network* (TIFSAN) one hour before the release of the articles.

c. To improve the reporting efficiency for incidents that gave rise to major public opinions and discussions, the *Guidelines for Handling and Reporting Major Public Controversies and Incidents* have been revised. Major public controversies and preliminary handling must be immediately communicated to superiors via instant messaging to ensure that the latest information are communicated comprehensively.

d. To improve major incident response effectiveness, amendments have been made to *Response Checklist for Class 1 Emergencies*. Checklist items have been added as a result of the handling of cooking oil product adulteration as well as illegal adding of copper chlorophyll.

## 3. Public Opinion Monitoring and Post-market Surveillance Mechanism

(1) Monitoring of Public Opinion

a. Following its risk monitoring workflow (Figure 7-2), TFDA has monitored public opinions related to TFDA work since 2010. Relevant public opinions reflected in domestic printed and electronic media are monitored on a daily basis to quickly assess the state of media publications and to compile and analyze developments of public opinions and their level of impact. Relevant information is then communicated to superiors and responsible units via cellphone text messaging or emails to facilitate comprehensive information control, allowing the TFDA to describe the incident to the media and general public. Also, press releases are issued when necessary to provide correct information and prevent unnecessary public panic.

b. In 2014, a total of 4,946 news prints, 281 public feedback and opinion articles on magazines, and 470 press articles were compiled, while a total of 2,833 international food and drug safety information have been monitored accordingly.

(2) Post-market Surveillance

a. To monitor post-market quality and safety of the products, TFDA has continued to implement post-market surveillance. Marketed products that pose higher risks, that are likely to impact the health of specific demographics, that are considered essential consumer items, or items of domestic or global concern were sampled and tested. Previous or past survey results and other factors were also referenced to develop the surveillance plan.

b. A total of 24 programs were included in the 2014 post-market surveillance plan, including 12 food products, 3 medicinal products, 4 medical devices, and 2 cosmetics. Nonconforming rates of food products were 7.8%, while medical devices, cosmetics, and medicinal products had a combined nonforming rate of 3.4% in 2014. Nonconforming products face administrative penalties and other relevant measures as enforced by the competent health authority. TFDA also offers consultation to support manufacturer improvements and safeguard consumer safety.

## Section 3. Research Outcomes

### Current Status

In 2014, TFDA carried out a total of seven technological key projects: the *Food Safety Control Research*, the *Medicinal Product Safety and Quality Improvement Project,* the *Quality and Safety Risk Management System that Integrates Traditional Chinese Medicine and Pharmaceutical Products, Prospective Topics on Genetically Modified Foods and Enhancing Risk Analysis Capabilities,* the *Project for the Integration and Improvement of Food-borne Disease and Pathogen Monitoring and Protection Network,* the *Integrated Project for Addictive Substances - A Study on the Management of Controlled Drugs and Prevention of Drug Abuse,* and the *Study on Regulatory Management of Sciences for Nanotechnology Biomedical Products.* The purpose of this technological research, to provide a scientific basis for food and drugs management policies, was use to help TFDA update the latest trends in research developments.

### Policies and Outcomes

Results of the seven technological key research projects were as follows:

#### 1. Food Safety Control Technology Project

(1) To continuously improve upon the inadequacies of current management systems, and to strengthen relevant management policies and standards, a total of six management specifications and 32 management references or internal management recommendations have been formulated, which include standard specification review systems of health food, recommendation for health food review mechanism and related regulations, and management specifications for the labels of marketed food products to achieve source management.

(2) In response to food safety issues during 2014, TFDA developed the world's first testing and identification methods for tainted animal contents in oils and fats as well as dimethyl yellow and diethyl yellow in food. DNA barcode identification and inspection technology for commercial fish were developed as well, such as the specific molecular biology testing method for Dory Fish (*Zeus faber*).

(3) A total of 4,314 samples have been tested for medication employed for animal rearing and aquacultural species, residual pesticides in retail and packaged farm products, heavy metal contents, mycotoxin hazards in food, and special nutrient products to achieve early detection of food products manufacturers' noncompliance with current food labeling specifications. Administrative investigations, improvements, or recalls must also be implemented to improve the sanitation and safety of food products in the market.

## 2. Medicinal Product Safety and Quality Improvement Project

(1) To improve medicinal product safety and quality, research results were referenced to formulate 20 clauses related to pharmaceutical affairs such as contents of package inserts of medicinal products, drafts for the amendments of the *Pharmaceutical Affairs Act and the Regulations for registration of Medicinal Products*, drafts for *in vitro* diagnostic device (IVD) package inserts and clinical evaluation review standards, and inspection standards for biomedical products. A total of 45 medicinal product safety re-evaluations have also been carried out in response to key global medicinal product safety issues.

(2) Emerging technologies have also been employed to research, develop, and establish testing methods for medicated cosmetics. A total of 15 research reports on test techniques have been completed accordingly. Additionally, 10 recommended testing methods for cosmetics were developed and publicized on TFDA website to provide a basis for testing methods for marketed cosmetics as well as a reference for vendors and labs.

(3) Active monitoring of medicinal product safety is also used for early detection of medicinal product safety signals to clarify the correlation between risks and drugs, improve risk-benefit ratios for medicinal products, reduce improper use, and prevent the incidence of adverse reactions.

## 3. Quality and Safety Risk Management System that Integrates Traditional Chinese Medicine and Pharmaceutical Products

(1) Phase 1 Traditional Chinese Medicine (TCM) and pharmaceutical product ADR reporting systems have been integrated to establish a single reporting channel that improves the ease of reporting incidents by both medical personnel and the general public while also improving management efficiency of cases reported.

(2) In response to PIC/S and relevant laws as well as international harmonization, two regulatory science recommendation reports for generic drugs were completed (on pharmacokinetics/pharmacodynamics and chemical manufacturing and controls) to serve as a basis for future regulatory revisions or consultation and improve market release efficiency of the products.

(3) The drug permit license system has been employed to filter through the 23,608 permits on the system, generate a list of missing medicinal products, formulate the *Medicinal Product Deficiency Allocations and Comprehensive Treatment System Project* for reducing the incidence of medication gaps to make sure medication accessible for the patients' rights.

### 4. Prospective Topics on Genetically Modified Foods and Enhancing Risk Analysis Capabilities

TFDA has added 100 items of risk assessment information which have been published them on TFDA website for public perusal in order to enhance Taiwan's capacity for implementing food safety risk assessments and management capacities of genetically modified (GMO) food products. Besides, public health risk assessments have also been carried out for the intake of food products containing GMO soybeans. The National Food Consumption Database has also been updated with relevant food classification and food coding system. Risk communication and information transmission of GMO food safety assessment topics were alsoin progress at the same time to generate knowledge economy and value.

### 5. Project for the Integration and Improvement of Food-Borne Disease and Pathogen Monitoring and Protection Network

To improve food product safety and management efficiency and ensure public food safety, examining, monitoring of important foodborne pathogens and food sources are carried out to assess the contamination of high-risk pathogens in food products and to strengthen management of origin and self-management of food businesses. Continuous monitoring is also used to evaluate the effectiveness of surveillance to prevent food contamination by medium-to-high-risk pathogens.

### 6. Integrated Project for Addictive Substances - A Study on the Management of Controlled Drugs and Prevention of Drug Abuse

(1) *The Amended Draft for the Controlled Drugs Act* was completed and submitted for legislative revision and reference. Drug abuse information from various departments and agencies was compiled and analyzed to study relevant risk factors of drug abusing demographics in the Taiwan region and to provide the country with empirical data for preventing drug abuse amongst high-risk populations.

(2) In case of emergency, rapid data comparisons can be made. Optimized mass spectroscopy parameters for standard sample testing and analysis methods for 203 types of controlled drugs and emerging drugs of abuse were developed as well. Additionally, medicinal product information for 258 types of emerging drugs of abuse or products that generate toxic metabolites (or contain controlled ingredients) have been established, offering instant access to reference data.

### 7. A Study on Regulatory Management of Science for Nanotechnology Biomedical Products

(1) Relevant management specifications and risk assessment and management information from around the world on nano-food and nano-medicinal products were collected to formulate a total of four regulatory drafts for nano-foods and two regulatory drafts for nano-medicinal products, providing a reference basis for formulating national nano-product management specifications in the future.

(2) TFDA testing capabilities for nano-plastics and composite materials as well as nano-medicinal products were established to address potential future needs for monitoring the quality of commercial food containers and nano-medicinal products.


# 8 National Laboratory and Testing Network

Mission of the National Laboratory

Strengthening the Testing Capability of National and Local Laboratories

Comprehensive Private Laboratory Accreditation and Management System

Comprehensive Mobilization for Emergency Testing

# 8 National Laboratory and Testing Network

The growing complexity and diversity of engineering technologies in food, medicinal products, medical devices and cosmetics make the managment and measurement of them more challenging than ever before. TFDA continues to advance laboratory testing capabilities and estibilish fast, reliable, and internationally harmonized methods in order to determin untargets, contingencies, and contaminants which may hurt product qualities and public health. TFDA persistently strengthen the testing capacity and quality of local health bureaus, and develop an efficient network of specialized test locations, to improve local testing capabilities. Private laboratories were also accredited in order to support testing required by government agencies, consumer associations, and manufacturers which need internal quality control and export requirements. In response to product safety contingencies, the laboratory network is mobilized to implement emergency inspections. Through the emergency response mechanism, TFDA announces a list of private laboratories to the public for reference use, and helps the manufacturers to perform voluntary management and testing from the source.

## Section 1 Mission of the National Laboratory

### Current Status

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

### Policies and Outcomes

#### 1. Improve Analysis Capabilities

(1) A total of four precision instruments and equipment were procured, namely the MALDI-TOF mass spectrometer for microbial identification, a gas chromatograph equipped with tandem mass spectrometer, a pyrolysis analyzer, and an elemental analyzer equipped with tandem isotope ratio mass spectrometer. Technical documents were also composed for use by various fields.

(2) TFDA held three unknown material identification training sessions which were attended by 221 individuals. Course contents included applications of chromatography / mass spectroscopy in food testing, techniques and practical applications of organic spectroscopy, and practical analytical techniques for determining the authenticity of honey and its products.

#### 2. Analysis Mission

(1) Basic Testing: Registration testing for medical devices, cosmetics, health food, special nutrition supplements, and food additives; lot release for biologics (detailed statistics are provided in Appendix 1 Annex Table 14); as well as testing for emergency eventing. A total of 3,460 tests have been carried out.

(2) Cooperative Testing: TFDA provides testing support for the local health bureaus to test the auditing and sampling specimens which the agency is incapable of testing independently, consumer complaints, and complex food poisoning incidents. These include tests for cosmetics, illegal medical products, and testing for the presence of pharmaceutical adulterants in prescription Chinese herbal medicines or food products. A total of 2,275 tests were carried out, which identified 501 nonconformities or tested positive for pharmaceutical ingredients.

(3) Collaborative Testing: Providing support for paid or commissioned tests as well as testing for forensic purposes for illegal medical products, controlled drug and narcotics, and pharmaceutical adulterants in prescriptive Chinese herbal medicines and food products. A total of 3,053 tests were carried out, of which 2,572 cases tested positive for pharmaceuticals, drug misuse, or other nonconformities.

## 3. Formulating and Promoting Testing Methods

(1) In 2014, 18 official analytical methods for food items were published. In addition, 60 and 10 recommended analytical methods for food products and cosmetics were published, respectively.

(2) In response to food safety and adulteration incidents, the *Method of Test for Polyaromatic Hydrocarbons in Oils and Fats,* the *Method of Test for Acrylamide in Oils and Fats,* the *Method of Test for Dimethyl Yellow and Diethyl Yellow in Food, the Method of Test for Animal-Derived Ingredients in Tainted Oils and Fats - Qualitative Test of Swine, Chicken, Bovine, Ovine and Fish Ingredient,* the *Method of Test for Animal-derived Ingredients in Food - Qualitative Test of Zeus faber Ingredient, and the Method of Test for Animal-derived Ingredient in Food - Qualitative Test of Pangasianodon hypophthalmus Ingredent* have been developed accordingly.

(3) Development of rapid screening programs of food contaminants. A state of art high resolution mass spectrometer supported with the concept of massive database is utilized to develop appropriat testing method for simultaneous detection of preservatives, colorants, food additives, and other complex residues in foods. Analytical methods were also developed to identify adulterants in honey by element analysis and isotope ratio mass spectrometers.

(4) A total of three conferences entitled *Food Hygiene Analysis, International Food Analysis,* and the third *Cross-Strait Technical Exchange and Conference for Medicinal Product Testing* were held.

(5) Issue the *Minimum Requirements for Biological Products IV* and held the *Minimum requirement for biological products Workshop* to promote bidirectional exchange between the industry and the competent authorities.

## 4. Preparation and Supply of the Standard

997 vials of candidate standard and 988 vials of working standard of the HBV genotype C DNA were prepared to establish the national standards which can be provided to the manufacturers and blood centers for the development and quality control of the molecular diagnostics to advance the biotechnology industry.

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

### Current Status

To develop rapid and accurate testing methods to clearify the contingencies, propose response strategies, to eliminate public concerns through the press and media. Continue to enhance instrument and equipment testing techniques and standards. Strengthen laboratory quality assurance and actively seek accreditation and international recognition. Additionally, the testing capacities of the local health bureaus have been improved. In 2010, every health agency throughout the country has been included in the *Regional Joint Specialized Testing System of Health Bureaus* to implement specialization. TFDA also continued to subsidy precision instruments in order to strengthen testing resources, techniques and capacities of the health bureaus.

### Policies and Outcomes

#### 1. Advancement of the Testing Capability of the National Laboratory

(1) Forensic Science Testing Certified to ISO/IEC 17025 and Aligned with Global Standards

a. The controlled drugs laboratory of the TFDA has been accredited the ISO/IEC 17025 forensic science testing certification, demonstrating that testing standards and techniques are compliant to international specifications and standards, which assists to improve the credibility of testing results from the laboratory.

b. To attain higher quality, the certification award ceremony was held at TFDA (Figure 8-1). The Director of the Board of the Taiwan Accreditation Foundation (TAF) attended the ceremony to award the certificate personally. Other distinguished guests were invited to attend it, which included representatives from the Chemical Forensics Division of the Ministry of Justice Investigation Bureau (MJIB), the National Police Agency of the Ministry of Justice, and the Criminal Examinations Center of the Military Police Command and so on.

Figure 8-1 Award ceremony of the ISO/IEC 17025 forensic science testing certification

(2) *Preparation and Supply of Biological Standards* were awarded with the *Symbol of National Quality (SNQ) Award* and the *2014 National Biotechnology & Medical Care Quality Award*

a. To support pre- and post-market quality management of *in vitro* diagnostic device (IVD) in Taiwan, TFDA prepared the biological standards with highly professional and strict technology. Leading international laboratories were also invited to participate in the collaborative study to ensure the quality and credibility are aligned with those of the World Health Organization (WHO).

b. To promote the development of biomedical industry and the quality of clinical diagnostics, there were some standards available in TFDA and continually provided to the blood centers, medical institutions, and biotechnology companies for testing methods verification and *in vitro* diagnostic reagent development.

c. TFDA continually prepared the novel national biological standards with innovative and strict attitude to assist the biomedical industry of Taiwan in global recognition. Consequently, TFDA has garnered recognitions that include certification from the Institute for Biotechnology and Medicine Industry (IBMI), acquired the Symbol of National Quality (SNQ) for biotech services in the field of biotechnology, and won the Silver Award from the most prestigious *National Biotechnology & Medical Care Quality Award* (Figure 8-2 and Figure 8-3).

Figure 8-2 Award ceremony for the 17th *National Biotechnology & Medical Care Quality Award*

Figure 8-3 Receiving the Symbol of National Quality (SNQ) award

(3) Tainted Oil Incident

In September 2014, it was found that Chang Guann Co., Ltd. made use of gutter oil to manufacture and sell lard oil. TFDA immediately activated its emergency response mechanism and quickly developed the *Method of Test for Polyaromatic Hydrocarbons in Oils and Fats, the Method of Test for Acrylamide in Oils and Fats, and the Method of Test for Animal-Derived Ingredients in Tainted Oils and Fats - Qualitative Test of Swine, Chicken, Bovine, Ovine and Fish Ingredient*, and began carrying out a series of tests for acidic values, total polar compounds, polyaromatic hydrocarbons, and animal-derived ingredients for over 308 raw oil, semi-finished oil products, and completed products.

(4) Use of Dimethyl Yellow in Soy Products

a. When Hong Kong released the news for the *presence of Dimethyl Yellow in dried tofu products exported by Te Chang Food's to Hong Kong*, TFDA immediately identified the presence of Dimethyl Yellow in the black pepper flavored dried tofu manufactured by the company. Further checks were performed for raw materials and upstream suppliers and it was found that the root cause lied in the illegal use of Dimethyl Yellow chemical dye in oily tofu skins manufactured by Chiu Yuan Enterprise and a food additive combination named *Chien Hsin soy emulsifier* manufactured by Chien Hsin Enterprise.

b. Further study on the adulteration, a additionally suspect dye was found in the Chien Hsin soy emulsifier. The unknown compound was further separated, purified, and identified as Diethyl Yellow for the first time of presence in food. TFDA intermediately released *the Method of Test for Dimethyl Yellow and Diethyl Yellow* for public reference. Out of 172 sample items taken for testing, a total of 85 (49.4%) tested positive for illegal use of Dimethyl Yellow and/or Diethyl Yellow. Inspection results were forwarded to the relevant authorities and inspection units for handling.

(5) Adulteration of Commercially Available Pork with Beef and Mutton

a. The Kaohsiung District Prosecutors Office found meat companies adding mutton suet to pork or cheap minced beef, and even added water in order to sell these adulterated meat as mutton to hot pot restaurants, stir fry restaurants, and night market vendors to gain illicit profits.

b. Health bureaus from both New Taipei City and Kaohsiung City conducted joint investigations and acquired a total of 46 samples of beef and mutton products from upstream and downstream producers. TFDA then employed specific test for bovine, ovine, and swine ingredients. Results indicated that six beef and mutton products contained swine ingredients, and evidenced that these products contain pork-derived adulterants. TFDA proclaimed specific test for bovine, ovine, and swine ingredients were effective in determining the authenticity of marketed meat products, safeguarding dietary rights and interests of the public and assisting investigations of District Prosecutors Office.

(6) Food Poisoning Outbreak from Accidental Consumption of Gupoyu (night-scented lily, *Alocasia odora*)

a. Accidental consumption of poisonous plants shaped like the taro led to a food poisoning incident with symptoms that included oral paralysis and throat pain after ingesting the poison.

b. Leftover of the suspected sample *yam rice* could no longer be used to discern the identity of the food ingredients. Molecular biology testing techniques were thus employed by TFDA to identify the plant species present in the sample and evidenced the etilogy of the poisonous plant *Alocasia odora.*

c. TFDA has developed and employs rapid species identification methods to effectively support and clarify the causes for food poisoning. Press releases were also published to remind the public and prevent accidental consumption of poisonous plants.

(7) High Aloin Contents of L'amour Health Food Capsules

a. As a result of concerns and feedback from consumers on the product, the Taipei Investigation Office of the Ministry of Justice Investigation Bureau (MJIB) sending the encapsulated products to TFDA in early July 2014, to determine the safety of the aloin.

b. Aloin contents were tested for the aloe vera plant (aloe vera gel, aloe vera skin, and total leaf), semi-finished aloe extracts from L'amour, and capsule products sold on the market that contain aloe extracts (freeze-dried powder for aloe juice). Results were then submitted to the relevant administrative agency for handling.

(8) News on Formaldehyde Contents in Electronic Cigarettes

a. In November 2014, the media reported formaldehyde and acetaldehyde contents in the vapors of electronic cigarettes. Carcinogen levels of these vapors would be several times higher than ordinary cigarettes.

b. TFDA therefore analyzed a total of 31 samples of electronic cigarette replenishment fluid (shown in Figure 8-4), of which seven contained nicotine, 28 contained acetaldehyde and 31 contained formaldehyde. A press release was issued to explain the 2014 test results for nicotine contents in electronic cigarettes, its impacts to health, and related laws and regulations.

Figure 8-4 Visual appearance of an electronic cigarette specimen


(9) Detection of *Pseudomonas aeruginosa* and Preservatives in Shower Foam

a. In July 2014, the Consumer Protection Committee of the Executive Yuan conducted microbial content and labeling inspections for shower foam, shampoo, and other products from 16 hotels and inns. Results showed that seven hotels and inns failed to comply with the regulations, including labeling violations as well as one case of aerobic plate count exceeding limits and the presence of *Pseudomonas aeruginosa*.

b. To strengthen the hygiene management of sanitation products in the hospitality industry, TFDA notified local health bureaus to conduct sample testing. Test results showed that aerobic plate count from three products exceeded the *Permitted Standards for Microbial Content in Cosmetics* proclaimed by TFDA. These three products were transferred to the responsible health bureaus to conduct recalls and scrapping within a specified deadline.

c. The 402nd issue of the consumer report published in October 2014 included an article entitled *46% of Shower Foam Tested Positive for Preservatives*. TFDA immediately requested local health bureaus to collect samples of the marketed products.

d. Test results showed that preservative contents are compliant to the *Standards on Preservative Contents, Usage, and Limits for Cosmetics.* Products with nonconforming labels were transferred to the responsible health bureaus for handling.

(10) Type A Botulinum Toxin Preparations Imported Without Permit

a. The demand for medical beauty is growing tremendously in Taiwan. Illegal imports of Type A botulinum toxin preparations are common place. Thus, TFDA continued to assist the Justice authority to identify whether preparations contain type A botulinum toxin.

b. To eliminate illegal imports of botulinum toxin preparations and other biological medication, TFDA held a press conference entitled *Beauty Reminders: Three Simple Tips to Identify Legal Botox Preparations* to provide the public with simple steps to recognize the legal drugs.

### 2. Strengthening Local Testing Capability and Quality

Local testing efficiency and quality were improved through integrating testing resources, providing subsidies to local health bureaus, and conducting supervision and performance assessments in order to establish a comprehensive national food safety laboratory network.

(1) Subsidizing Instruments and Equipment and Strengthening Testing Network Capabilities

Subsidies have been provided to various health bureaus in procuring high-precision instruments and standard samples. Test resources and special regional requirements of each local health agency were referenced in order to establish testing specializations in the northern, central, southern, and municipal regions as part of the *Joint Testing Division System for Health Bureaus*, helping to improve the specialization of test categories of each health bureau as well as testing efficiency and quality.

(2) Outcomes of Joint Regional Division

According to the *Central and Regional Specialization of Food Hygiene Tests*, independent testing ratio in local health bureaus was about 35% prior to the subsidies. After subsidies, independent testing capability rose to an average of 75%. Since 2013, additional *independent testing capabilities* have also been expanded in 2014 for pesticides (from 252 items to 311 items), animal medication (from 119 items to 122 items), and pharmaceutical adulterants in food products (from 135 items to 214 items).

(3) Laboratory Accreditation

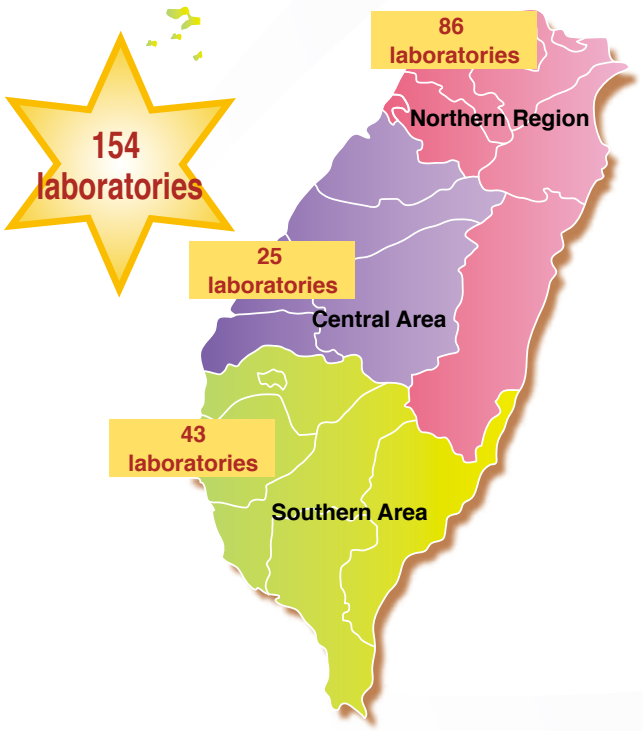
To ensure the testing quality of local health bureaus, a total of 21 health bureau laboratories and 626 tests were accredited by the TFDA laboratory accreditation system by the end of 2014.

## Section 3 Comprehensive Private Laboratory Accreditation and Management System

### Current Status

To effectively utilize testing resources of private laboratories, to ensure the quality and credibility of commissioned tests, and to expand testing capacity, the TFDA offers free accreditation services for private laboratories. Currently, the scope of laboratory accreditation conducted by TFDA includes food, drugs and cosmetics, urine tests for drug abuse, and GLP for non-clinical studies. As of the end of 2014, a total of 154 labs was accredited around the country (122 private labs and 32 public labs), of which 61 were food testing laboratories, 30 were drugs and cosmetics laboratories, 14 were drug abuse urine testing laboratories, and 17 were GLP (Figures 8-5 and 8-6). Regionally, there are 86, 25, and 43 accredited laboratories in northern, central, and southern Taiwan respectively. A total of 1,211 tests items have been accredited as well, of which 655 were food product tests, 488 were drugs and cosmetics tests, 9 were drug abuse urine tests and 56 were for GLP tests (Figure 8-7). These accreditations ensured that there are sufficient laboratories with the necessary testing capability and reliability to meet emergency testing requirements.

Figure 8-5 TFDA lab monitoring network and distribution of accredited laboratories




## Northern Region

Central TFDA: Research Testing Section and Northern Management Center (total of 8 laboratories)
Local health bureau: Northern Joint Testing Division System (total of 10 counties and cities)
Accredited laboratories: 28 food testing laboratories, 20 drugs and cosmetics testing laboratories, 6 drug abuse urine testing laboratories, and 14 GLP laboratorieslaboratories (total of 68 laboratories)

## Central Area

Central TFDA: Central Management Center (1 laboratory)
Local health bureau: Central Joint Testing Division System (total of 5 counties and cities)
Accredited laboratories: 10 food testing laboratories, 3 drugs and cosmetics testing laboratories, 3 drug abuse urine testing laboratories, and 3 GL Plaboratories (total of 19 laboratories)

## Southern Area

Central TFDA: South Management Center (1 laboratory)
Local health bureau: Southern Joint Testing Division System (total of 7 counties and cities)
Accredited laboratories: 23 food testing laboratories, 7 drugs and cosmetics testing laboratories, 5 drug abuse urine testing laboratories, and 0 GLP laboratories (total of 35 laboratories)

Figure 8-6 Number of accredited TFDA laboratories over time

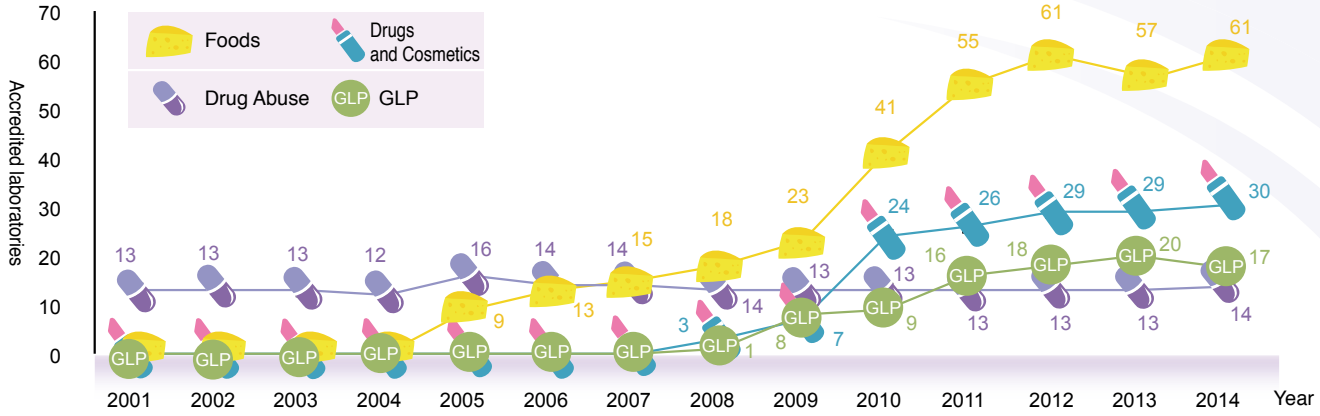
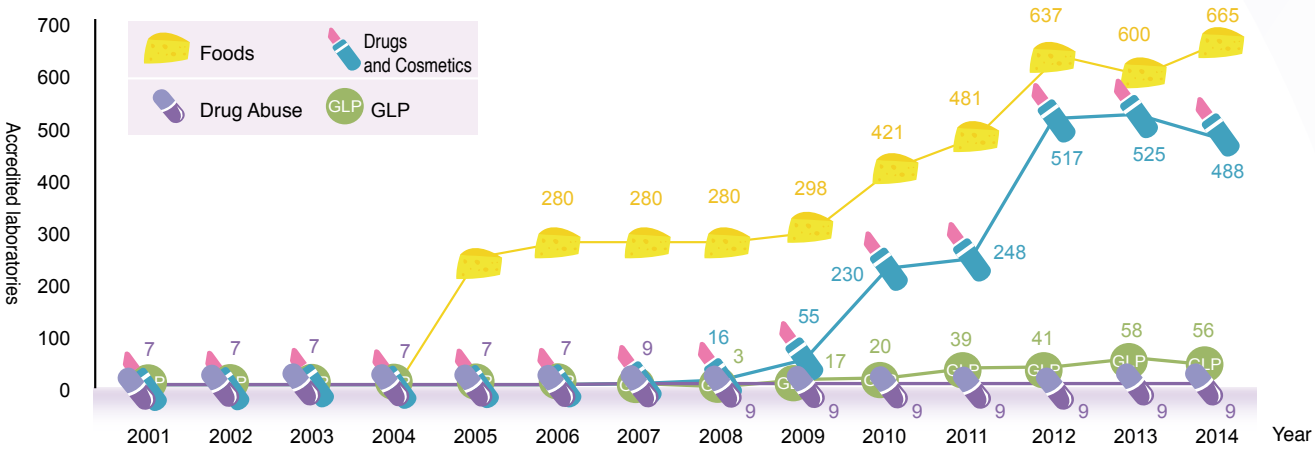


Figure 8-7 Number of accredited tests over time




## Policies and Outcomes

### 1. Accreditation for Food as well as Drugs and Cosmetics Laboratories

(1) Expanding Laboratory Testing Capabilities

a. Accreditation systems for food laboratories and drugs and cosmetics laboratories were initiated in 2004 and 2008 respectively. In 2010, laboratory accreditation action plans were further expanded and accelerated to quickly increase testing capabilities through continued implementation of border inspections of food and Traditional Chinese Medicine (TCM) products, establishment of standard limits for TCM, and accreditation of test items outsourced by administrative processes.

b. The number of accredited laboratories and tests increased from 36 laboratories and 353 tests in 2009 to 91 laboratories and 1,153 tests in 2014. These laboratories included 61 accredited food testing laboratories and 30 accredited drugs and cosmetics testing laboratories with 48, 13, and 30 laboratories in northern, central, and southern Taiwan respectively.

(2) Strengthened Supervision and Management Systems

a. Regular and Unannounced Audits

To effectively supervise and manage accredited laboratories and to establish a system for verifying the reliability of test data, TFDA performed a total of 108 audits, of which 88 were first-time audits, audits for increases or changes in testing scope, extension audits, and surveillance audits as well as 20 unannounced audits.

b. Organizing Proficiency Tests

Proficiency test results of various accredited laboratories are publicly released on a regular basis. In 2014, a total of 26 proficiency tests (20 for food and 6 for drugs and cosmetics) were held. Of which, 2 laboratories had their accreditation revoked for failure to meet proficiency test standards. A total of 4 *Laboratory Accreditation Test Using Double-Blind Samples* were also used to verify the correctness of test data.

(3) Avoid Duplication of Testing

In December 2014, TFDA selected a total of four laboratories and recommended them to register at the Japanese Ministry of Health, Labor and Welfare for Class B Public Testing Agency for Exporting Countries to successfully exempt Taiwan's food exports to Japan from sampling test operations at customs, accelerate customs procedures, reduce testing fees, and help lower trading costs for business owners.

(4) Encouraging Academic Laboratories to Participate in Food testing

TFDA organized four training sessions for international laboratory specifications (ISO/IEC 17025) as well as six testing technique training sessions which were attended by 344 individuals. Since July 2014, consultation committee members have completed 90 sessions of on-site laboratory consultation with double-blind sample testing to improve national testing quality and capacities for food safety and hygiene. A total of 35 public and private academic laboratories received these consultation services which were geographically distributed with 16, 11, and 8 laboratories in northern, central, and southern Taiwan respectively.

(5) Continued Revisions to Laws and Regulations Governing Laboratory Accreditation

In 19 August 2014, TFDA promulgated the *Regulations Governing Accreditation and Outsourced Accreditation Management of Food Testing Institutions* and the *Regulations Governing Accreditation and Outsourced Accreditation Management of Pharmaceutical Testing Institutions.* In September of the same year, the *List of Tests Not Requiring Measurement Uncertainty Assessment Reports for Food Testing Institutions Applying for Quantitative Test Accreditation* strengthened the supervision and management of accredited laboratories.

## 2. Accreditation for Drug Abuse Urine Testing Laboratories

(1) In 2014, a total of 14 drug abuse urine testing laboratories were accredited, with five located in northern Taiwan, three in central Taiwan, five in southern Taiwan, and one in eastern Taiwan. Accreditation for drug abuse urine tests covered nine drug ingredients, namely morphine, codeine, methamphetamine, amphetamine, MDMA, MDA, cannabis metabolites, ketamine and norketamine.

(2) To ensure the quality of drug abuse urine testing, TFDA conducted 13 routine on-site assessments of accredited drug abuse urine testing laboratories, seven unannounced audits, and four sessions of routine quarterly proficiency test for 52 institutions.

(3) In 2014, TFDA convened the *Drug Abuse Urine Testing Institution Accreditation Review Committee and On-Site Assessment Committee Meeting*, and the Conference for Drug Abuse Testing Techniques. Main resolutions included: delaying additional and extension audits payment systems; one institution was accredited; in the event that the testing institution needs to add a branch institution or office for temporary storage of remaining urine samples, the said institution must first submit an application to TFDA for review and verification before completing the registration.

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

(1) *Good Laboratory Practice (GLP) for non-clinical studies* is implemented in order to improve the correctness and reliability of test data. The scope of GLP accreditation of TFDA includes the fields of medicinal products, medical devices, health foods, and cosmetics, and covers various non-clinical safety tests related to biological systems at various product research and development phases in the aforementioned fields.

(2) In 2014, TFDA conducted and offered eight GLP audits and consultation, reaching a total of 17 GLP-accredited laboratories with 14 in northern Taiwan and three in central Taiwan. Of these, 56 testing items were accredited accordingly.

(3) In 2014, auditor training and business owner management seminars were also held in order to introduce the latest information from other countries, align audit standards with international specifications, and help business owners and relevant personnel understand GLP specifications and industrial trends.

## Section 4 Comprehensive Mobilization for Emergency Testing

### Current Status

TFDA formulated the *Principles for Mobilizing Private Laboratories in Response to Emergencies*. To meet testing requirements arising from emergencies, private laboratories with the relevant testing equipment and capabilities may be mobilized to participate in testing work, allowing the emergency response system to serve as the basis for post-market testing of products as well as self management and testing by business owners.

### Policies and Outcomes

#### 1. Selection Principles for the List of Accredited Laboratories

Laboratories accredited for *specified tests and methods* or other accredited laboratories certified by the Environmental Protection Administration (EPA) or Taiwan Accreditation Foundation (TAF). *National Inspection Resource Database* of the TFDA is also used to survey private agencies equipped with these testing instruments and invite these agencies to help carry out the specified tests.

#### 2. Verifying Laboratory Testing Capabilities and Public Release of the List of Accredited Laboratories

TFDA has provided laboratories with testing methods as the basis so that the laboratories would only need to refer to the standard operation procedures (SOP) and maintain quality assurance documents and relevant test records. Applicant laboratories that have been verified to have the necessary testing techniques and independent quality control capacities are included in the list of accredited laboratories, which is publicly released by the TFDA for reference by those intending to commission testing services.

## 3. Outcomes of Emergency Testing Mobilization

(1) List of Laboratories and Testing Capabilities

Given the large demand for testing, the TFDA has surveyed the *National Inspection Resource Database* to identify private institutions with the necessary testing instruments and capacity to participate in emergency testing. In response to emergency incidents from 2013 to 2014 such as maleic anhydride modified starch, tainted oil, adulterated lard, and Dimethyl Yellow, private laboratories have been mobilized to provide testing services. Figure 8-8 shows the results of such mobilization.

(2) Quality Management of Laboratory Testing

As a result of emergencies, testing quality of the laboratories publicly listed by the TFDA is managed via documentation and data reviews, on-site audits, and proficiency testing in order to thoroughly assess the testing capabilities of the laboratories. Any laboratory that fails to pass on-site audits or proficiency testing is *prohibited from receiving samples for the specified tests.*

Figure 8-8 Private laboratory mobilization outcomes in response to emergency incidents in 2014

**2014 September — Tainted Lard incident**

- Private laboratories publicly announced: 4 laboratories ; private laboratories test capabilities: 90 cases/day
- 4 laboratory audits completed. 1 benzopyrene test proficiency test was carried out.

**2014 December — Dimethyl Yellow and Diethyl Yellow Event**

- Private laboratories publicly announced: 10 laboratories ; private laboratories test capabilities: 425 cases/day
- 10 laboratory audits completed. 1 Dimethyl Yellow and Diethyl Yellow test proficiency test was carried out.

# 9 International Cooperation and Cross-Strait Exchange

# 9 International Cooperation and Cross-Strait Exchange

Information exchange and technical collaboration between countries are growing increasingly important. Since international politics, economy, and trade are closely intertwined, governments regard understanding of global trends and developments and aligning with international standards as a key administrative strategy. TFDA is making use of various international cooperation and exchange programs to achieve objectives of regulatory harmonization by acquiring relevant information, improving operational measures, improving work efficiency, and accelerating international alignment.

## Section 1. International Cooperation and Exchange

### Current Status

To improve the international visibility of Taiwan's food, medicinal product, medical device, and cosmetic industries, TFDA participates in international regulatory harmonization organizations, hosts international regulatory conferences, and builds bilateral cooperation platforms in order to collect regulatory information, amend relevant regulations according to the principles of international regulatory harmonization, and to promote alignment of Taiwan's regulations with international standards.

### Policies and Outcomes

#### 1. Participation in International Organizations and Activities to Promote Regulatory Harmonization

(1) Food Products

TFDA participated in the APEC Sub-Committee on Standards and Conformance (SCSC) held on 18-19 January and 11-12 August 2014, exchanging the information of food safety standards with other member economies. From 5-8 May, TFDA also participated in a food allergen conference under the SCSC. TFDA also attended a WTO conference and meetings on 13-17 October to strengthen exchange and integration of food standards of other members, improve transparency in food labeling regulations, and enhance the sharing of food safety information.

(2) Medicinal Products and Controlled Drugs

a. Taiwan has been an official member of *The International Generic Drug Regulators Pilot* (IGDRP) since its establishment in 2012, helping to promote exchanges between generic drug regulatory agencies to achieve efficient use of resources as well as regulatory harmonization. TFDA also successfully hosted the Sixth IGDRP Conference in 2014, inviting 40 members from 12 countries including Japan, Australia, Canada, Switzerland, Singapore, and Korea (Figure 9-1). The *Joint Review Task Force* was established during the meeting in order to jointly review generic drug registrations with the EU, Canada, Australia, Switzerland, and other countries

Figure 9-1 The 6th IGDRP conference


Participation of this taskforce will improve the international credibility of Taiwan's *generic drug review system.*

b. Since 2011, TFDA has been serving as the champion to lead the APEC 2020 Roadmap for Good Review Practices on Medical Products for the APEC Regulatory Harmonization Steering Committee (RHSC). From 2013 to 2014, TFDA was also part of the Good Review Practices Working Group. APEC RHSC cooperated with the World Health Organization (WHO) to formulate and draft the Good Review Practices Guidelines for Regulatory Authorities to improve international consensus and efficiency of review practices. The draft was adopted by the WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2014 and finalized by the WHO Executive Board in May 2015.

c. TFDA also attended the 2014 annual meeting of the International Society of Addiction Medicine held in the Japanese city of Yokohama from 1-7 October 2014 as well as the 142nd Annual Meeting and Exposition of the American Public Health Association held in the US city of New Orleans from 14-22 November 2014 in order to understand differences in the mode of abuse of prescription medicine between the United States and Taiwan and to share systems used in Taiwan for monitoring the flow of legal prescription medicine to illegal use.

d. TFDA is also participating in the activities of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S), the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), the

International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), as well as other international pharmaceutical organizations and conferences.

(3) Medical Devices

Taiwan is one of the founding member of the *Asian Harmonization Working Party* (AHWP). During 2013 to 2014 TFDA served as the Vice-Chair of the AHWP as well as the Chair of the *in vitro* diagnostic device (IVDD) work group (WG2-Premarket: IVDD) under the technical committee. A total of five international guidances for IVDD led by TFDA have been accepted as formal documents of the AHWP organization.

## 2. Bilateral Activities (including of relevant agreements and memorandum assessment)

(1) Under the common objectives and understanding of *providing the public with high-quality and safe medicinal products*, TFDA and the European Directorate for the Quality of Medicines & Healthcare (EDQM, Council of Europe) have both signed a *Confidentiality Agreement* on 12 May 2014 (Figure 9-2) to share non-public information regarding the quality and manufacture of Substances for Pharmaceutical Use, i.e. Active Pharmaceutical Ingredients (API) and Excipients that are used in the manufacture of medicinal products.Such measures will help integrate resources of both signatories and ensure the safety and quality of pharmaceutical substances.

TFDA also held the first joint symposium of TFDA and EDQM on 12-13 May 2014. EDQM Director Dr. Susanne Keitel was invited as a speaker to share the latest trends and regulations for API management in Europe, providing technical advice and consultation to Taiwan pharmaceutical

Figure 9-2 Signing of the *Confidentiality Agreement between the Taiwan Food and Drug Administration of Ministry of Health and Welfare and the European Directorate for the Quality of Medicines and HealthCare of the Council of Europe*

manufacturers regarding application for the Certificate of suitability to the monographs of the European Pharmacopoeia (CEP). It is hoped that these activities will make Taiwan's pharmaceutical industries more competitive, and build an environment that is beneficial for the general public, the industry, and the government (Figure 9-3).

(2) According to *the Arrangement between Taiwan and Japan for* the *Framework of Cooperation on the Medical Products Regulation* signed on 5 November 2013, Japan hosted the *2nd Joint Conference of Taiwan and Japan on Medical Products* Regulation on 31 October and 1 November 2014 in Tokyo (Figure 9-4). Open sessions and closed door meetings on the areas of pharmaceuticals, national health insurance, and medical devices were convened to strengthen bilateral exchanges and regulatory convergence between Taiwan and Japan. Cooperation details were also discussed. On the topic of pharmaceutical products, both parties have established their respective working groups to cooperate on five topics including new drugs and generic drugs review, management of OTC drugs, and cooperation

Figure 9-3 Hosting the joint symposium of TFDA and EDQM in Taipei


Figure 9-4 The Second Joint Conference of Taiwan and Japan on Medical Products Regulation

in GCP inspections. Contact persons have been established and regular meetings will be hosted for discussion of future cooperation directions.

(3) TFDA signed the *Memorandum of Understanding on Cooperation in the regulation of Health Product* with the Food and Drug Administration Philippines (FDAP) remotely through foreign representative offices of both countries on 12 September 2014. The purposes of this Memorandum are to establish a bilateral channel of communication for exchanging documents and information on food, medicinal products, medical devices, and cosmetics, explore possible avenues of collaboration, and formulate suitable joint monitoring and supervisory activities to establish a basis of collaboration for both countries.

## 3. Hosting Large International Conferences

(1) The *2014 EU-TW Food Safety Seminar* was held in Taiwan during 4-5 June 2014. Officials from the European Commission, experts and representatives from EU member states, and industrial representatives of companies in Taiwan and EU were invited, the seminar covers market supervision, product labeling, consumer protection, and other monitoring measures currently employed in both Taiwan and Europe as well as communication mechanisms used by the EU when dealing with food safety crises. The purpose of this Conference was to encourage relevant agencies and groups in Taiwan to comply with international standards (Codex Alimentarius) and best practices By using thorough and in-depth exchanges and discussions amongst industry, government, and academia, it is expected to further achieve international harmonization of food safety regulation and standards, encourage the Taiwanese food industry to upgrade, and guarantee the welfare of fellow consumers.

(2) The *Conference on International IVD Medical Devices Regulations* was organized by TFDA and held on 2 September 2014. Officials of authorities in charge of *in vitro* diagnostic (IVD) medical devices as well as industry experts were invited from five countries, namely the United States, the United Kingdom, China, Australia, and Indonesia. In addition to helping manufacturers in Taiwan gain access to the latest regulations and information from around the world, the conference also provided a platform for communicating relevant regulations to help the development of Taiwan's IVD medical device industry.

(3) The *2014 International Symposium of Cosmetics Regulation and Nanotechnology* Management was organized by TFDA and held on 15-16 September 2014. Experts and academics from the United States, EU, Japan, ASEAN, Mainland China, and Taiwan were invited to share the latest developments and practical experiences on regulations governing nanomaterial content in cosmetics, to further understanding on the latest management systems and future management trends for cosmetics containing nanomaterials from around the world.

(4) The *2014 International Symposium on Cosmetic Regulations* was organized by TFDA and held on 1 October 2014. Experts and academicians from the EU, Malaysia, the United States, Japan, and Mainland China were invited to introduce topics on cosmetic management, and directions for future regulatory revisions in Taiwan. The Symposium also helped improve understanding of cosmetic management regulations, content and product safety assessments, and the latest developments in alternatives to animal testing of cosmetics in various countries.

## Section 2. Globalization of Laboratory Testing

### 1. Food Field

(1) The *2014 International Conference on Food Testing Technology* was held on 30 October 2014. Experts from the Swiss Official Food Control Authority and Eurofins of France were invited to share their experiences and research outcomes on testing for adulterants in fruit juices, spices, and other food products. About 200 people from county and local health bureaus, private laboratories, universities and colleges, and other relevant testing institutions attended this Conference.

(2) In September 2014, TFDA attended the chemical expert work group meeting of the International Olive Conference (IOC) held at Madrid, Spain, as a special guest to discuss the copper chlorophyll testing method developed by Taiwan.

### 2. Medicinal Product Field

(1) In 2014, TFDA was invited to participate in the collaborative study of *Fifth WHO International Standard for HCV for NAT-based assays.*

(2) In October 2014, TFDA attended the 50th anniversary conference of the EDQM, and joined the poster exhibition with posters entitled *Reference Standards for Biologics and in vitro diagnostics in Taiwan* and *Trends in the Pharmaceutical Adulterants in Dietary Supplements in Taiwan*. TFDA also visited the laboratories of EDQM to gain information on the updates in the EU pharmacopoeia and Official Medicinal Control Laboratory Network. This information will help to align Taiwan's medicinal products testing specifications and methods with the intenartional trends as well as strength international collaboration for the standards establishment.

(3) TFDA traveled to Maryland in the United States to attend the *17th Annual Conference on Vaccine Research* organized by the National Foundation for Infectious Diseases (NFID) held at the end of April 2014 to understand the latest information and trends in the development of emerging vaccines, management and safety assessments of adjuvant vaccines, and current status of research for new influenza vaccine being carried out in Europe, the United States, and other developed countries.

(4) The National Pharmaceutical Control Bureau (NPCB) of the Ministry of Health of Malaysia dispatched two officials to TFDA in October 2014 for the two purposes of acquiring practical experiences on medicinal products testing and management and carrying out bilateral exchange between the two countries.

### 3. Medical Devices Field

In November 2014, TFDA visited Covidien's surgical-use medical device manufacturing plant as well as Johnson & Johnson's contact lens manufacturing plant in the United States to study quality testing and verification technologies for medical devices.

### 4. Cosmetics Field

In September 2014, TFDA was invited to attend the *International Conference for Regulatory Harmonization for Cosmetics and Cosmetic Nanotechnology Management* to offer a presentation titled *Achievements in Cosmetics Research and Analysis in Taiwan.*

## Section 3. Cross-Strait Exchange

### Current Status

Since the signing of the *Cross-strait Agreement on Food Safety* on 4 November 2008, TFDA has held an *Expert Meeting of Competent Authorities* as well as *Cross-Strait Food Safety Agreement - Import and Export Food Safety Meeting* with representatives from Mainland China in order to exchange information on topics related to food standards and risk communication. For medical and medicinal products, the *Cross-Strait Cooperation Agreement on Medicine and Public Health Cooperation* was signed on 21 December 2010. Under this Agreement, the TFDA established a Pharmaceutical Safety Management and R&D Working Group, and four Sub Working Groups for Pharmaceuticals and Cosmetics; Medical Devices; Health Foods; and Testing and Verification. The Agency also discussed bilateral cooperation mechanisms and established a platform for bilateral institutional collaboration on pharmaceutical safety (Figure 9-5); improved cooperation on quality and safety management, mechanisms for assistance with handling major pharmaceutical safety incidents, and coordination to promote standards. It also realized ad-hoc collaboration in clinical trials, to explore how to gradually adopt the implementation outcome of the other side, to make full use of the pharmaceutical management and R&D capabilities on both sides, strengthen the quality and safety of pharmaceuticals, and shorten the development process, so that the public has earlier access to safe and effective pharmaceuticals in order to protect the health of people on both sides of the Strait.

Figure 9-5 Structured platform for medicinal products established by Taiwan and Mainland China

## Policies and Outcomes

### 1. Institutionalization of Meetings

(1) Food Products

According to the Cross-strait Agreement on Food Safety, TFDA has held two meetings with experts from competent authorities of Mainland China in 2014:

a. The *Eighth Expert Meeting of Cross-Strait Food Safety Competent Authorities* was held in Kaohsiung, Taiwan with the National Health and Family Planning Commission of the Mainland China on 19 May 2014 to discuss topics that include the implementation status of agreement clauses, management progress and measures for plasticizers, and key revisions made to food safety regulations on both sides. Both sides agreed to use the platform of the Expert Meeting of Cross-Strait Food Safety Competent Authorities, and continue to exchange the latest versions of amended laws and regulations, in order to strengthen the standards of food safety management on both sides of the Strait.

b. The *Fifth Import and Export Food Safety Meeting for the Cross-Strait Food Safety* Agreement was held in Taichung, Taiwan during 9-10 July 2014 with the General Administration of Quality Supervision, Inspection and Quarantine of Mainland China (AQSIQ) to discuss various topics that included *improved cross-Strait notification for food safety incidents and nonconforming product identified at the borders, cross-Strait food safety management systems, management of imported aquacultural products from Taiwan, and testing and monitoring of vegetable oils.* Both sides agreed to continue their collaboration on regarding food safety border management systems, and promote mechanisms for real-time information exchange and recognition.

(2) Medicinal Products

After entering into the *Cross-Strait Cooperation Agreement on Medicine and Public Health Cooperation* in 2014 (Figure 9-6), Medical and Medicinal Products Safety Management and Research and Development Work Group has conducted eight exchange and work meetings (Table 9-1) as well as section meetings and communications on non-critical topics to simplify meeting procedures.

Figure 9-6 2014 Cross-Strait High-level Meeting for Medical and Medicinal Product Safety Management and Research and Development Work Group

Table 9-1 List of cross-strait meetings and exchanges on medicinal products in 2014

| Date | Location | Title of medicinal products meetings and exchange activities |
|---|---|---|
| September 2014 | Taipei, Taiwan | Drug Safety Management and R&D working Group |
| September 2014 | Taipei, Taiwan | Drug Safety Management and R&D working Group - Medical Device (Machinery) Sub-Working Group Meeting |
| October 2014 | Taipei, Taiwan | Drug Safety Management and R&D working Group - Drugs and Cosmetics Sub-Working Group Meeting |
| November 2014 | Fuzhou, Fujian Province, Mainland China | Third Cross-Strait Technical Exchange and Conference for Medicinal Product Testing |
| November 2014 | Fuzhou, Fujian Province, Mainland China | Drug Safety Management and R&D working Group - Inspection and Testing Sub-Working Group Meeting |
| December 2014 | Harbin, Heilongjiang Province, Mainland China | Fourth Cross-Strait Conference for Collaborative Medical and Medicinal Products Research and Development Collaboration |
| December 2014 | Harbin, Heilongjiang Province, Mainland China | 2014 Cross-Strait High-level Meeting for Medical and Medicinal Product Safety Management and Research and Development Work Group |
| December 2014 | Harbin, Heilongjiang Province, Mainland China | 2014 Cross-Strait Drug Safety Management and R&D working Group - Drugs and Cosmetics Sub-Working Group Meeting and Health (Healthcare) Food Products Sub-Working Group Meeting |

## 2. Establishing Rapid Reporting Systems to Ensure Food, Medical, and Medicinal Product Safety

(1) To ensure that both Taiwan and Mainland China are able to receive timely notification in the event of food, medicinal product, and cosmetic incidents, a quick notification system has been established by both parties. Contact window communication and enhanced safety management measures were employed in order to quickly eliminate doubts for the general public in both Taiwan and Mainland China.

(2) In 2014, Mainland China authorities notified Taiwan of 667 nonconforming food products exported from Taiwan to Mainland China, of which 535 cases were found to conform to the regulations of Taiwan (with the violations resulting from differences in standards of both countries) and 132 cases were found to have violated the regulations of Taiwan. Causes of nonconformities, in descending order of incidence, were 141 cases of labeling issues, 122 cases of microbial content, 43 cases of colorants, 37 cases of preservatives, 28 cases of imports without inspection and quarantine permit for access, 26 cases of heavy metals, 13 cases of sweeteners, nine cases of bleach, one case of animal medication, one case of pesticide, one case of mycotoxin, and 245 cases for other causes. The 132 cases of violation were reported to the competent health bureau following the *Procedure for Handling Food Product Exports from Taiwan Determined to be Nonconforming*. Food exporters were provided with consultation to encourage compliance to regulations of other countries. Actions were taken against the violating cases as well.

(3) In 2014, a total of 49 nonconforming imported food from Mainland China was reported. The causes of the nonconformities, in descending order of incidence, were 31 cases of pesticides, six cases of preservatives, five cases of animal medication, four cases of heavy metals, one case of other causes, one case of antioxidants, and one case of melamine.

### 3. Harmonization of Regulations and Standards

(1) Through their liaison windows, Taiwan and Mainland China announced revisions of food additive standards and the food safety and sanitation standards. Both sides made 21 announcements on the food additive standards and 2 announcements on the food safety and sanitation standards in 2014.

(2) The comparison of differences between the technical requirements in the *Pharmaceutical Affairs Act* of Taiwan and the newly revised Medical *Device Supervision Regulation* of Mainland China as well as five specific medical device standards for infrared lamps and clinical electronic thermometers was completed in 2014.

(3) TFDA held a *Seminar on Regulations Governing Cosmetic Exports to Mainland China and Actual Case Studies* on 4 January 2014. Personnel from the China Food and Drug Administration (CFDA) were invited to Taiwan in order to introduce regulatory policies and provide instructions on permit application for Taiwan business firms.

(4) TFDA also organized a *Cross-Strait Conference on the Management of Food Nutrition Labels* in Taiwan on 20 May 2014. Experts from competent authorities discussed and exchanged ideas on nutrition labeling regulations to achieve mutual understanding, these are taken as references for establishing relevant regulations in the future.

(5) Personnel from CFDA were invited to Taiwan for the joint Good Clinical Practice (GCP) inspection exchange program from 20-23 May 2014, and visited Taiwan's clinical trial centers to gain a deeper understanding of clinical trial institution management and GCP inspection systems from both sides. Differences of GCP regulations and inspection practices between both sides, and the future possibile collaborations in DCP inspections were disscussed.

(6) In 2014, names and technical terms in the appendix/general provisions of pharmacopoeias in both Taiwan and Mainland China were compared. Priorities included comparisons and harmonization of testing methods and standards for common tests in order to establish the feasibility of simplifying or exempting pharmaceutical testing in both Taiwan and Mainland China.

(7) The Third *Cross-Strait Technical Exchange and Conference for Medicinal Product Testing* was held in Fuzhou, Mainland China from 4-6 November 2014 (Figure 9-7) to present and discuss testing techniques for medicinal products, medical devices, health foods, and cosmetics. The purpose of the conference was to encourage mutual acceptance and recognition of future testing capabilities.

### 4. Cooperation on Research and Development

(1) Accelerating Time-to-Market for Products Made in Taiwan

a. Since 2012, TFDA has continuously requested the CFDA to authorize provincial and city-level drug administration agencies to review medical devices already approved for market sales in Taiwan. The *promotion of CFDA authorization of provincial and city-level drug administration agencies to review medical devices* from Taiwan remained listed as a key topic for future implementation.

b. After the July 2012 exchang on administrative regulations of cosmetic products, both Taiwan and Mainland China immediately exchanged comparative study results to discuss collaboration of testing agencies on both sides of the Strait with the hopes of accelerating the acquisition of test permits of cosmetics made in Taiwan and reduce the time-to-market of such products in Mainland China.

(2) Collaborations in Clinical Trials of Pharmaceuticals

In 2014, medicinal product management departments in both Taiwan and Mainland China finalized the *Cross-Strait Pharmaceutical Clinical Trial Cooperation Program*. A pharmaceutical clinical trial task force was established to accelerate collaboration between Taiwan and Mainland China in clinical trials for pharmaceuticals and to achieve the objective of minimizing duplicarion of trials.

(3) Developing Joint Inquiry and Review Programs

Open solicitations for a *Cross-Strait Joint Medicinal Product Research and Development Pilot* and a *Cross-Strait Joint Medical Device Research and Development Pilot* were implemented to establish a collaborative framework model for reviewing medicinal products and medical devices of Taiwan and Mainland China.

(4) Hosting the *Cross-Strait Conference on Medicinal Product Research and Development Collaboration*

The Fourth *Cross-Strait Conference for Medicinal Product Research and Development Collaboration* was held in Harbin, Mainland China, on 8 December 2014. Topics such as collaboration strategy for medicinal product research and development (R&D), establishment of collaborative platforms for clinical trial centers, simultaneous cross-Strait clinical trials, and *in vitro* diagnostic (IVD) medical device R&D were discussed. Relevant experiences were exchanged as well.

(5) Organizing the 2014 Cross-Strait High-level Meeting for Medical and Medicinal Product Safety Management and Research and Development Work Groups.

2014 Cross-Strait High-level Meeting for Medical and Medicinal Product Safety Management and Research and Development Work Groups was held on 10 December 2014 in Harbin, Mainland China, where both sides confirmed the achievement of 2014 and finalized the work plan for 2015.

Figure 9-7 The Third *Cross-Strait Technical Exchange and Conference for Medicinal Product Testing*


# 10 Risk Communication and Consumer Protection

Providing Consumers with Immediate Information

Consumer Communication and Advocacy

# 10 Risk Communication and Consumer Protection

For protecting consumers, TFDA continued to promote *Risk Assessment and Risk Management*, which can understand potential safety and quality risks of food, drugs, and cosmetics in advance. How to immediately transmit correct risk information to comsumers with effective channels is a keystone to protect consumers. In order to prevent public panic from inadequate or incorrect information, effective strategies of risk communication between consumers and TFDA have to be establishmented to strengthen consumer and media communication. After effective communication, the work of TFDA can be seen, and public understanding, trust, and confidence can be improved.

## Section 1 Providing Consumers with Immediate Information

### Current Status

Internet is the fastest information dissemination channel. TFDA has built its official website (http://www.fda.gov.tw) and the *Food and Drug Consumer Service Network* (http://consumer.fda.gov.tw/) to provide domestic information of food , drugs, and cosmetics. In both websites, the search and query functions help consumers find the information they need.

### Policies and Outcomes

#### 1. Services Provided by the Official Website

(1) TFDA website includes a food sanitation and safety awareness area that allows public download of and access to promotional materials, multimedia promotion, food product library, and other special sections. Focus topic areas, a news area, consumer Red and Green Lights, safe food and medicine, and other real-time information provision systems provide the needed information and news.

(2) A professional section and a children's section have been added to the *Food and Drug Consumer Service Network,* providing more diverse and convenient knowledge services to satisfy public needs and requirements (Figure 10-1).

Figure 10-1 Knowledge Service Website for Food and Drug Consumers

(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. A total of 103 domestic medicinal product recall alerts, 36 consumers red and green light information, and 12 *Risk Communication letters* were released.

(4) TFDA established the drug safety *Education leraning Website* to provide educational materials and lesson plans on correct drug usage. The website was browsed by more than 400,000 visitors.

(5) The *Food, Drugs and Cosmetics Advertisement Violation Inquiry System* provides a quick and instant audit implementation system that helps disseminate correct information amongst the general public.

### 2. Use of Facebook Fan Group

(1) The *Shiyong Wanjia* (practical health tips about food) Facebook Group has been established, with posts that describe interesting and practical lifestyle tips coupled with the latest events for the purpose of public education and awareness.

(2) Other resources such as *Anti-Drug Resource Library* and the Facebook fan group of safe and peaceful sleep were also established to strengthen the benefits of drug abuse prevention advocacy.

(3) The *TFDA Safe Cosmetics Use* Facebook Group and Blog were established. The *TFDA Select Cosmetics and Beauty Atelier and Cosmetics True or False Quiz with Prizes* were also released on the Internet.

### 3. Providing Relevant Information Channels

(1) Various digital press articles on food and drugs (such as the Food & Drug Consumer Newsletter) are available for public subscription. These publications provide immediate coverage of the latest news in Taiwan and other countries as well as information on public concerns.

(2) Internet activities such as the *Incredible Medical Device Superman Development Program* were organized, using games such as *limited time classification competitions and medical device quizzes* to help the public gain knowledge about medical devices.

(3) In 2014, a total of 20 food and drug publications were released, including the *Taiwan Food and Drug Administration Annual Report* (Chinese and English versions), *Medical Device GMP, a Cross-Generation Driver for Quality: 1989~2014, Minimum Requirements for Biological Products IV*, and *Manual for the Food Additives Traceability System*, providing the general public with a diverse selection of reading materials to satisfy their right to access information (refer to Appendix 2 for the list of publications).

## Section 2 Consumer Communication and Advocacy

### Current Status

The purpose of consumer communication is to improve consumer understanding of basic risks involved in food and drugs. Systematic risk communication will help consumers gain an understanding of current government policies as well as correct food product safety information. TFDA has strengthened public and media communication and awareness programs on topics related to food safety, correct use of medical products, and cosmetics management. Diverse communication channels were employed in order to establish correct knowledge and risk concepts amongst the public.

### Policies and Outcomes

#### 1. Diverse Inquiry and Communication Services

(1) To integrate inquiry, petition, and whistle-blowing services, TFDA has established an inquiry service helpline for (02)2787-8200 with five lines. A total of 41,027 calls were received in 2014, with food-related issues being the leading category (57.8%).

(2) The senior official email box is another channel of communication. In 2014, the Ministry of Health and Welfare and other supervisoring agencies transferred a total of 2,808 cases to TFDA. Another 9,383 cases were also received via the TFDA mail box for a total of 12,191 cases.

(3) TFDA also operates a (02) 8170-6008 medical device consultation helpline and (02) 2787-8097 cosmetics inquiry helpline, which received a total of 16,276 and 9,000 inquiries respectively in 2014. TFDA used these inquiries to advance correct consumer knowledge on safe purchases of medical devices and cosmetics.

(4) To publicize relevant policies, TFDA worked with broadcasting and interviewing programs to create the 55-episode special report series. The series were broadcast to help provide consumers with correct information.

#### 2. Advocating Consumer Risk Concepts and Knowledge

(1) In 2014, TFDA held 25 *Consumer Protection and Risk Education Seminars* that distribution channel operators and employees were invited to and offered instructions on proper approaches to handling disputes and reducing public concerns on food safety.

(2) A total of 1,248 retail personnel participated in these *Consumer Protection and Risk Education Seminars*. Attendants also took a pre-seminar and post-seminar assessment. Understanding of *fines about misleading advertisements* was rose from 58.1% to 75.2% after the seminar. Business owner's knowledge of regulations about the *product recall* was rose to 90%. However, the proportion of course attendants who correctly answered *procedure for mediating consumer disputes and prevention of food safety issues* were rather low (28.1% and 35.6% respectively), indicating that these two topics require further learning and understanding.

(3) If there are consumer disputes on food that cannot be successfully mediated, the consumer can dial the *National Consumer Service Helpline 1950* to report the issue.

### 3. Food Safety Defense League

(1) To establish the Food Safety Defense League, food and nutrition science departments of major universities in Taiwan were invited to set up 5 League Centers and 13 Seed Institutions. Specialized teams were established during this period to create *Food Safety and Sanitation* education manual and lesson materials. These information and resources were used to construct network platforms and Facebook groups for the league to create a short video entitled *Food Safety for the Whole Family* to educate the public on food safety.

(2) The League also conducted tours in major universities and colleges throughout the country to provide seminars for *Food Safety Defense League* seed instructors, training a total of 960 students from food and nutritional science departments as qualified seed instructors. 129 of these seed instructors visited junior high and elementary schools to promote food safety and sanitation education, providing lessons to a total of 13,944 individuals. On 10 December 2013, the League held a press conference on the promotion outcomes. Members of the League shared project results with the general public in order to demonstrate the League's determination in safeguarding food safety and the effectiveness of their measures.

### 4. Training Program for Food Sanitation Volunteers

(1) The *Training Program for Food Sanitation Volunteers* was initiated in 2013. Spirited individuals concerned with food safety issues were recruited and undergo basic training for food safety knowledge and competences so that they may play a part in upholding food safety throughout the country.

(2) In 2014, a total of 1,500 individuals were recruited as Food Sanitation Volunteers. When major food safety incidents occurred, these Volunteers would visit communities to promote correct food safety concepts and awareness amongst the general public. At other times, the Volunteers will help health agency personnel in the districts to promote food safety and health information, with 7,151 individuals benefiting from such promotion programs.

### 5. Advocating Food Safety and Sanitation

(1) TFDA organized 9 special media interviews related to the *Tainted Oil Incident* to strengthen the awareness for correct use and selection of oil products and eliminate uncertainties among the public. A total of 3 printed advertisements, titled *Six Measures for Strengthening Food Safety - Defense, Six Measures for Strengthening Food Safety - Cracking Down Intentional Adulteration*, and *Five New Family Safeguards for Food Safety*, were also created to communicate correct food safety information.

(2) Implementing *Elementary School Food Sanitation and Safety Promotion Program*: Creative drama competitions were organized. Exciting drama performances by school groups were used to help promote and internalize food sanitation and safety concepts.

(3) In 2014, TFDA organized promotional activities for food safety education at Food Taipei, the international food expo, the Kaohsiung Food Show, the Mid-Autumn Festival Charity Souvenir Sales Promotion Tour, the Southern Taiwan Biotechnology Expo, the Lifestyles & Regimen Exhibition, and other food-related public exhibitions to strengthen public awareness and knowledge on health food logos and food service sanitation ratings and assessments.

(4) TFDA also continued to promote food sanitation and safety in radios, TV, and printed media. A total of 18 articles entitled *Gastronomic Science* were published on UDN News, allowing readers to analyze food safety from a scientific perspective. Media broadcasting was released in 64,312 documents or exposures to reach about 20 million individuals.

(5) In response to amendments to the *Act Governing Food Safety and Sanitation*, multiple promotion and interpretation seminars were held to clarify key amendments. Promotional posters were also printed and uploaded for public download and access.

## 6. Management of Standard Contract Terms

(1) Based on Paragraph 1, Article 17 of the *Consumer Protection Act*, TFDA made amendments to three standard contracts related to food and food services, namely *Mandatory and Prohibitory Provisions of Standard Contract for Goods (Service) Coupons of Food Service, Reservation and Catering (Bando) Service Standard Form Contract Template*, as well as *Mandatory and Prohibitory Provisions of Standard Contract for Mail Order Purchase of Food or Food Service*. Seminars were held to help communicate these changes to help business owners uphold principles of trust and obligations for protecting the consumers' rights.

(2) In accordance with the regulation, food and food service must fully disclose relevant information so that consumers are able to discern the contents of the products and determine the extent of their rights. One may also dial 1950 the national consumer service helpline in the case of disputes or ask for assistance from local consumer protection officials or health bureaus.

(3) TFDA also created a *Standard Contract Template for Slimming and Beauty Services* as a reference for both business owners and consumers. Business owners must follow the amendments to the *Mandatory and Optional Items to be Included in Standard Contract Terms for Slimming and Beauty Products (Services) Coupons* and the *Mandatory and Optional Items to be Included in Standard Contract Terms for Slimming and Beauty Products* made on 15 August 2014 when establishing contractual terms to ensure compliance to consumer protection regulations and safeguard consumer rights.

## 7. Promoting Medicinal Product Usage Safety and Pharmacist Care Services

(1) To improve public knowledge on drug usage, TFDA focused on the theme of Common Drugs - *Antacids in 2014. Press conference entitled Stomach medicine only works if used right* was held on 25 September, revealing the result of public drug use behavior surveys for antacids. On 28 September, TFDA hosted a 925 Drug Use Safety Day and Health Education Promotion Event. *Health Defense - Press Conference on National Schoolchildren Medicinal Use Survey and Award Presentation*

Figure 10-2 *Stomach medicine only works if used rigth* press conference

*for Outstanding Educators for Medicinal Use* was also held on 3 December to release the results of schoolchildren medicnal use survy (Figures 10-2 to 10-3).

Figure 10-3 925 Drug Use Safety Day and Health Promotion Event


(2) To create a supportive environment for proper use of medicinal products, TFDA established 22 health education resource centers for safe medicine, and 520 community-based drug counseling stations in medical institutions nationwide. TFDA works with 112 correct drug use centers and seed schools across 18 counties and cities to help promote education for proper drug use. Up to 2014, the resource centers had hosted 1,941 educational sessions and offered consulting services to 20,380 visitors, which helped to strengthen public knowledge and competence in drug safety.

(3) *The drug safety manual for Taiwan new residents* was translated into 6 languages (Chinese, English, Thai, Cambodian, Vietnamese, and Indonesian). Besides, TFDA held eight educational seminars on drug safety for new residents in four counties and cities. A total of 60 seeded instructors were trained in order to further disseminate and improve the concept of safe medication amongst the new resident population.

(4) TFDA uses the variety of marketing strategies to enforce the consumer's capacity of proper drug use, using posters such as *Tourists Be Aware! Medicinal Products are NOT Souvenirs!*, advocacy films such as *Proper Use of Antacids*, as well as pamphlets and posters such as *proper use of orally administered liquid agents containing alcohol*, and *proper use of cold syrup and antacids* to educate the public the concepts of proper drug use.

(5) Pharmaceutical Care Services: TDFA had held training courses on community-based pharmaceutical care, training of instructors for pharmaceutical care services, and training of backend managers for pharmaceutical care services in 2014. A total of 568 qualified pharmacists were involved in the development of home and community-based pharmaceutical care services. In 574 home-based care services, multiple drug medication issues were found. The responsible pharmacists thus provided education on correct drug administering methods and concepts on seeking medical aid. For community- based care, the service assisted 1,384 cases and revealed 1,483 questions of drug medication. Above all, each question resolved can save an average NTD 65.4 on the drug expenditures.

## 8. Promoting Drug Abuse Prevention

(1) TFDA has designed and produced posters entitled Four Ways to Reverse Drugs' Damage and *Five Defensive Techniques against Drugs* as well as promotional pamphlets and leaflets on Reveal Narcotics in Disguise. *Correct use of Sedatives and Sleeping Pills* posters as well as 30-second promotional short videos on *Correct Use of Sleeping Pills*. TFDA also published *2014 Drug Abuse Prevention Guidelines* and *2014 Anti-Drug Report* to improve public awareness of the hazards of drug abuse.

(2) Newspapers, magazines, movie theaters, broadcasts, gas stations, and computer desktops in Internet cafes were also provided with promotional materials to promote public awareness of controlled drugs and drug abuse.

(3) TFDA also worked together with 44 Non-Governmental Organizations to promote voluntary community-level drug abuse prevention. A total of 1,094 promotional activities were held, reaching 365,116 individuals.

(4) An anti-drug micro-movie competition titled *Reversing Drug Damages for a Healthier Life and Mind* was organized and attracted submissions from 220 groups and associations. TFDA also made a DVD entitled *Healthy Mind and Drug-Free Lifestyle - An Anthology of 2014 Anti-Drug Promotional Videos* used by health bureaus (centers), medical institutions, and private associations.

(5) All 711 movie theaters throughout Taiwan were asked to air the short-video *Drug Abuse will Finish You Off* which reached 5 million individuals. Taipei BEST RADIO was also commissioned to air the 30-second segment entitled *Correct Use of Sleeping Pills* to teach the general public on the correct methods of using sleeping pills.

## 9. Promoting Safe Selection and Use of Medical Devices and Cosmetics

(1) A total of five health education and awareness press conferences were held on medical devices such as sphygmomanometers, infrared lamps, artificial knees, blood glucose meters, and tympanic thermometers. Media exposure amounted to 102 press articles, helping to improve public understanding of medical devices.

(2) TFDA also held a health education promotion conference entitled *Let's Learn About the Three Correct Steps for Summer Beauty.* Media exposure amounted to 32 press articles, helping to successfully market the concepts on correct selection of cosmetics while promoting policy implementation outcomes of the TFDA.

(3) TFDA also held a conference entitled *Correct Selection and Safe Use of Cosmetics* and promoted the need to *Know the Rules when selecting cosmetics, Read the Label* when reading product labeling, and follow the product usage instructions and warnings to ensure Use It Right in order to promote correct selection and understanding of cosmetics.

# Appendix

Significant Accomplishments and Statistics

Publications of 2014

Website Links

# Appendix 1. Significant Accomplishments and Statistics

## Annex Table 1. Amendments and revisions to food product regulations in 2014

| Date | Regulation / standard name | Summary |
|---|---|---|
| 28 January | *Regulations for Application of Health Food Permit* | Additional regulations on a product applying for a new registration application within 6 months of the expiration of original permit |
| 11 February | *Regulations for Systematic Inspection of Imported Food* | Clearly specifies the scope, procedures and relevant items of systematic inspection |
| 19 February | *Regulations Governing the Product Names and Labeling of Prepackaged Fresh Milk, Sterilized Milk, Flavored Milk, Milk Drink, and Milk Products* | 1. Product names and labeling of commercially available prepackaged fresh milk, sterilized milk, flavored milk, milk drink, milk powder, formula milk powder, and other milk products<br>2. Formula milk powder is required to indicate the percentage of actual milk powder content |
| 24 February | *Regulations on Placement and Management of Food Businesses Employment of Professionals with Vocational or Technical Certification* | Food businesses designated by the central competent authority in a public announcement to require enforcement of food safety control system (HACCP) shall place at least one professional with vocational certification, responsible for food safety control. And catering and bakery businesses designated by the central competent authority in a public announcement shall have a certain percentage of professionals with technical certification |
| 3 March | *Regulations Governing the Labeling of Packaged Beverages Claimed to Contain Fruit and/or Vegetable Juice* | The promulgation and enforcement date of the regulations was moved forward to 1 July 2014 |
| 7 March | *Regulations Governing Food Allergen Labeling* | Clearly states the requirements to provide conspicuous labeling on prepackaged food products that contain shrimp, crab, mango, peanuts, milk, egg, and products thereof |
| 11 March | *Regulations on Food Safety Control System (HACCP)* | 1. Clearly specifies the scope and implementation details of the Food Safety Control System<br>2. Clearly states that at least one person of HACCP team shall be professional with vocational certification and conduct at least one internal audit once a year |
| 24 March | *Regulations Governing the Management of Infant and Follow-up Formula Advertisement and Sales Promotion* | TFDA has formulated the Regulations Governing the Management of Infant and Follow-up Formula Advertisement and Sales Promotion in order to restrict infant and follow-up formula advertisement and sales promotion activities and prevent these activities from influencing breastfeeding choices |
| 15 April | *Regulations on Nutrition Labeling for Prepackaged Food Products* | 1. Sugar content has been included as a mandatory labeling item<br>2. Nutrition labeling format must include the five main food groups and indicate any of the two following units:<br>(1)Per serving and per 100 g / mL<br>(2)Per serving and recommended daily percentage value (%)<br>3. Amended Recommended Daily Intake (RDI) value for caloric content and various nutrients, and additional RDI values for infants 1-3 years of age and pregnant women |

| Date | Regulation / standard name | Summary |
|---|---|---|
| 17 April | *The direction of the Hygienic examination of the Carcasses, Viscera and Meat Cuts in transport* | Clearly specifies the scope, procedures, and relevant items for the hygienic examination of carcasses, viscera, and meat cuts |
| 9 May | *Catering of international tourist hotel shall conform to the regulations on food safety control system* | At least one catering in international tourist hotels is required to implement Food Safety Control Systems |
| 20 May | *Regulations Governing the Labeling of Flavoring Ingredients in Food Additive Products* | 1. Clearly labeling of spice content in food additives<br>2. Ingredients other than spices must be labeled according to their respective names |
| 10 June | *Regulations on Prepackaged Food Products Exempted from the Nutrition Labeling* | Clearly states the types of packaged foods that do not require nutrition labeling |
| 19 June | *Regulations Governing Items of Food Utensils, Food Containers or Packaging Shall Be Labeled* | 1. Clearly states the labeling that must be provided for specified plastic food utensils, containers, and packaging as well as the enforcement date of the specifications<br>2. Integrates the food utensils, food containers, or packaging that must be labeled according to law, and clearly states the eight items including product name, material name, and tolerable temperature that must be indicated in the label by the product manufacturer |
| 11 August | Box meal factory shall conform to the *Regulations on Food Safety Control Systems* | Changes were made to the legal basis and title according to the promulgation of the *Food Safety Control System* |
| 21 August | *Food Businesses shall mandatorily conduct tests and meet the minimum testing cycle and other relevant matters* | Clearly specifies the food business category, scale, test frequency, and items of mandatoily conduct test |
| 2 September | *The importation of products that are not intended for sale and whose value and quantity are consistent with the public announcement of the central competent authority may be exempt from applying for inspection* | TFDA formulated customs clearance codes for products can be exempt from applying import inspection, and clearly states the conditions of these products |
| | *The Fishery Products from fishing belonging to Republic of China and identified domestic by Fishery Administration, Council of Agriculture, may be exempt from applying for inspection special code DH000000000004.* | TFDA formulated customs clearance codes for products can be exempt from applying import inspection, and clearly states the conditions of these products |
| 3 September | *Regulations Governing the Establishment of the Advisory Committee on Genetically Modified Foods* | Clearly states the organization, meeting, procedures, scopes, and rules and regulations of the Advisory Committee on Genetically Modified Foods |
| 16 October | *Regulations Governing the Category and Scale of Food Businesses May Commence Its Business Operation after Applying for Registration and Date of Implementation* | Clearly states that factory registration, business registration, and company registration by food manufacturer, processing, food service, import, and retail businesses shall complete registration before 31 December 2014 |

| Date | Regulation / standard name | Summary |
|---|---|---|
| 24 October | *Edible oil manufacturers shall do tests and meet the minimum testing cycle and other relevant matters* | Clearly specifies the business scale, test frequency, and items of mandatorily conduct test for edible oil |
| 27 October | *Food Businesses that shall Establish Traceability Systems for Food and Other Relevant Products* | Clearly specifies the food business category, scale and enforcement date |
| 7 November | *Certification of Sanitation and Safety Control of Food Businesses and Commission of Certification Regulations* | Food businesses must follow Paragraph 6, Article 8 of the Act Governing Food Safety and Sanitation and conduct compliance audits to verify their sanitation and safety management systems. Businesses publicly announced as the intended target of the audits must also be verified by the central competent agency or a commissioned party |
| | *Regulations on Good Hygiene Practice for Food (GHP)* | Clearly states the personnel, operation sites, sanitation management of facilities and quality assurance system of food businesses.The regulation documented in the form of articles based upon standard regulations provided by the central competent agency to ensure compliance to the legal system |
| 20 November | *Regulations Governing Advertisement and Promotion of Food Products Not Suitable for Long-term Consumption by Children* | Based on Paragraph 3, Article 28 of the *Act Governing Food Safety and Sanitation*, TFDA formulated the *Regulations Governing Advertisement and Promotion of Food Products Not Suitable for Long-term Consumption by Children* to protect children from unhealthy food and carry out the balanced diets for them |
| | *Food Businesses Required the Certification of Sanitation and Safety Management* | According to Article 2 of the *Certification of Sanitation and Safety Control of Food Businesses and Commission of Certification Regulations*, canned food manufacturer must accept sanitation and safety management verification |
| | *Food Businesses Required to Accept Sanitation and Safety Management Verification as well as Verification Details and Items* | According to Article 2 of the *Certification of Sanitation and Safety Control of Food Businesses and Commission of Certification Regulations*, any edible oil and fat manufacturer with a paid-in-capital of TWD 30 million must accept sanitation and safety management verification |

| Date | Regulation / standard name | Summary |
|---|---|---|
| 15 December | *Regulations Governing the Labeling of Restructured Meat Products* | Restructured meat provided by packaged or bulk food product manufacturers or vendors directly serving prepared foods and beverages must indicate in a conspicuous manner the word restructured or similar terms |
| 22 December | *Labelling Requirements for Prepackaged Food, Food Additives, and Unpackaged Foods Containing Ingredients of Genetically Modified Organisms (GMOs)* | 1. Prepackaged food, food additives, and unpackaged food containing genetically modified food material must be labeled with the terms *GMO* or *contains GMO*<br>2. Final products that no longer contain transgenetic fragments or transgenic proteins are exempt from labeling the product with *GMO* or *contains GMO*<br>3. The maximum level for unintentional content of GMO in non-GM food ingredients is 3% |
| 26 December | *Health Care Effects Specified in the Health Food Control Act* | TFDA formulated the Health Care *Effects Specified in the Health Food Control Act* which contain the following: liver protection, anti-fatigue, modulation of blood lipids, modulation of blood sugar, modulation of immunity, bone health protection, maintaining dental health, aging delay, enhancing iron absorption, improvement to gastrointestinal function, support blood pressure modulation, reducing body fat formation, help modulate allergic constitution, and other similar texts and phrases describing effects |
| January to December | *Standards for Pesticide Residue Limits in Foods, Standards for Veterinary Drug Residue Limits in Foods, Standards for Specification, Scope, Application and Limitation of Food Additives,* and food sanitation standards | Total items formulated: 4,355 MRLs for 354 pesticides; 1,389 MRLs for 135 veterinary drugs; scopes, limits, and specifications of usage for 800 types of food additives; and 36 food sanitation standards |

## Annex Table 2. Statistics of health food and GM food licenses

| Health food license issued (Type 1 and Type 2) | | | | | GM food license issued | |
|---|---|---|---|---|---|---|
| Year | Type 1 | Type 2 | Year Licenses issued | Cumulative licenses issued in the year | Year Licenses issued | Cumulative licenses issued |
| 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 |
| 2014 | 26 | 15 | 41 | 317 | 12 | 84 |

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

**Type 1 (individual case review): Manufacturers must provide testing certificates that demonstrate food safety and health care effects. The license number must be *Wei Bu Chien Shi Tzu* No. Axxxxx**

**Type 2 (standard specification review): Product must comply with standard specifications formulated by the MOHW. The license number must be *Wei Bu Chien Shi Kui Tzu* No. xxxxxx**

**Note 2: As of December 2014, a total of 317 approved licenses for health food had been issued, of which 265 are Type 1 and 52 are Type 2, while 29 licenses had become invalid (expired, suspended, or merged with other licenses). A total of six licenses were also issued for changed formulas.**

**Note 3: As of December 2014, a total of 84 licenses were issued for GM food, which included 10 licenses where production has stopped or permit extensions have not been submitted.**

## Annex Table 3. Import food inspection statistics

| Year | Inspected batches | Total net weight (x 10,000 tons) | Examined batches | Test ratio (%) | Nonconforming of Examined batches |
|---|---|---|---|---|---|
| 2011 | 420,602 | 717.7 | 29,801 | 7.09 | 289 |
| 2012 | 461,665 | 754.5 | 38,793 | 8.40 | 467 |
| 2013 | 514,710 | 713.3 | 38,460 | 7.47 | 557 |
| 2014 | 616,286 | 796.6 | 48,704 | 7.90 | 664 |

## Annex Table 4. Statistics of health bureau food audits

| Year | Labeling audits | | | Sampling tests | | | Good Hygienic Practice (GHP) for food | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Labels Cases | Nonconforming cases | Conformity rate (%) | Cases sampled | Nonconforming cases | Conformity rate (%) | Site audits performed | Sites advised / improvement within deadline requested | Sites fined | Sites suspended | Sites transferred to court |
| 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 | 7,026 | 98.97 | 41,956 | 1,958 | 95.33 | 118,681 | 49,587 | 75 | 13 | 0 |
| 2013 | 635,121 | 6,855 | 98.92 | 40,898 | 2,290 | 94.40 | 123,476 | 51,324 | 31 | 21 | 0 |
| 2014 | 523,045 | 5,994 | 98.85 | 41,085 | 1,879 | 95.43 | 130,005 | 61,066 | 38 | 143 | 2 |

**Note: There was a mistake in the statistics of 2013 resulting from changes to calculation methods used by the health bureaus. Corrections have been made by removing the number of double audits for the same items.**

## Annex Table 5. Statistics on testing for residual pesticides and veterinary drugs in food products

| Year | Monitoring pesticide residues in agricultural products from markets and packing firms | | | | Testing for residual veterinary drugs in food products | | | |
|---|---|---|---|---|---|---|---|---|
| | Total cases | Conforming | Nonconforming | Conformity rate (%) | Total cases | Conforming | Nonconforming | Conformity rate (%) |
| 2005 | 1,638 | 1,632 | 6 | 99.63 | 256 | 225 | 31 | 87.89 |
| 2006 | 1,605 | 1,589 | 16 | 99.00 | 197 | 173 | 24 | 87.82 |
| 2007 | 1,761 | 1,689 | 72 | 95.91 | 359 | 339 | 20 | 94.43 |
| 2008 | 1,765 | 1,557 | 208 | 88.22 | 252 | 232 | 20 | 92.06 |
| 2009 | 1,894 | 1,696 | 198 | 89.55 | 266 | 253 | 13 | 95.11 |
| 2010 | 2,051 | 1,856 | 195 | 90.49 | 330 | 324 | 6 | 98.18 |
| 2011 | 2,110 | 1,878 | 232 | 89.00 | 481 | 437 | 44 | 90.85 |
| 2012 | 2,363 | 2,121 | 242 | 89.76 | 572 | 532 | 40 | 93.01 |
| 2013 | 2,340 | 2,080 | 260 | 88.89 | 736 | 703 | 33 | 95.52 |
| 2014 | 2,528 | 2,205 | 323 | 87.22 | 830 | 794 | 36 | 95.70 |

## Annex Table 6. Statistics on cases of food poisoning

| Year | Outbreaks | Foodborne disease outbreaks incidence | | Vehicles identified in foodborne disease outbreaks | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Cases | deaths cases | Seafood produce and its processed products | Meat, eggs, and dairy and their processed products | Cereals, vegetables, and fruits and their processed products | Confectionery and candies | Compound cooking food and others | Unknown causes of vehicles |
| 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 |
| 2014 | 480 | 4,504 | 0 | 18 | 12 | 6 | 3 | 60 | 381 |

**Note: Total cases of vehicles responsible for foodborne disease outbreaks must be deducted to prevent double-counting of values.**

## Annex Table 7. Status of amendments of pharmaceutical affairs regulations in 2014

| Date | Regulation / standard name | Summary |
|---|---|---|
| 22 January | *Regulations Governing Warnings in Advertisements for Orally Administered western medicine Containing Alcohol or Chinese Medicinal Liquors* | Advertisement regulations for orally administered western medicine containing alcohols (including amino acids and multi-vitamin nutrient supplements) were amended accordingly to prevent excessive consumption and workplace accidents amongst the workers |
| 14 February | *Regulations for Registration of Medicinal Products* | Added definitions for biosimilar and categorized such pharmaceutical products as a genetically engineered drug according to their characteristics. Amended Attachment 6 Information Documents to be Attached for the Registration of Biopharmaceuticals in Article 41 |
| 21 February | *Regulations Governing Medicament Manufacturer Inspection* | Revised a number of articles in the Regulations Governing Medicament Manufacturer Inspection according to the amended Good Manufacturing Practices for Pharmaceuticals and Regulations for the Issuance of Medicinal Products and Medical Devices Manufacturing Licenses and Evidentiary Documents for Good Manufacturing Practices |
| 25 March | *PIC/S: Guide to Good Manufacturing Practice for Medicinal Products (Part 1, Annexes)* | Promulgated amendments to a number of articles in the *PIC/S Good Manufacturing Guidelines for Pharmaceuticals (Part 1, Annexes)*. The title of the specifications was also changed to *PIC/S: Guide to Good Manufacturing Practice for Medicinal Products (Part 1, Annexes)* |
| 2 April | *Penalty Standards for Violating the Good Manufacturing Practices for Pharmaceuticals* | Stipulation of Penalty Standards for Violating the Good Manufacturing Practices for Pharmaceuticals |
| 7 May | *Regulations for Registration of Medicinal Products* | Article 73 was amended, requiring all locally produced pharmaceuticals to attach the entire prescription content when applying for extensions |
| 23 May | *Regulations for Administration Document Attachments for New Drug Application and Communication Channels Provided by TFDA* | Specification contents were revised to include *risk assessments for delayed ventricular repolarization time, toxicological kinetics testing*, and *immunotoxicity testing* guidelines and relevant segments, and added Chapter V for *Specifications for Non-Clinical Study of New Anti-Cancer Drugs* |
| 7 July | *Guidelines for the Nonclinical Pharmacology/Toxicology Studies for Medicinal Products Applications (Revision 5)* | Specification contents were revised to include *risk assessments for delayed ventricular repolarization time, toxicological kinetics testing*, and *immunotoxicity testing* guidelines and relevant segments, and added Chapter V for *Specifications for Non-Clinical Study of New Anti-Cancer Drugs* |
| 17 September | *Clinical Trial Application Procedures and Review Standards for Human Cell Therapy Products* | Defined and explained relevant information and contents required when applying for clinical trials of human cell therapy products in order to provide a reference for Principal Investigators preparing application information for clinical trials |
| 25 September | *Regulations Governing Warnings in Advertisements for Orally Administered Liquid Agents and Syrups Containing Codeine or Caffeine* | Formulated regulations on warnings that must be displayed in relevant advertisements to prevent excessive or long-term consumption of the specified pharmaceuticals as well as subsequent addiction or dependence |

| Date | Regulation / standard name | Summary |
|---|---|---|
| 23 October | *Guidance for Industry: Good Clinical Practice* | Amended the competent authority of Article 2 to the Ministry of Health and Welfare |
| 2 December | *Comparative Testing Standards for Biotechnological / Biopharmaceutical Products* | This standard was formulated to provide a basis and reference for businesses when changing manufacturing processes for biotechnological / biopharmaceutical products |
| 12 December | *Priority Review System for New Drug Applications / Accelerated Approval Mechanism for New Drug Applications* | Amended the definition of new drugs in Article 7 of the *Pharmaceutical Affairs Act* (new compositions, new therapeutic compounds, or new method of administration) in order to accelerate drug research and development as well as time-to-market |
| 22 December | *A List of Adopted ICH Guidelines* | A list of the adopted guidelines from the *International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)* was formulated in order to provide a reference for business owners when preparing technical information for submission |

## Annex Table 8. Annual statistics on the number of approved drug permit licenses

| Year | Genetic drugs | | | APIs | | | NCE | | | Biological products | | | Orphan drugs | | | Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Domestic | Imported | Subtotal | Domestic | Imported | Subtotal | Domestic | Imported | Subtotal | Domestic | Imported | Subtotal | Domestic | Imported | Subtotal | |
| 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 |
| 2014 | 263 | 122 | 385 | 24 | 80 | 104 | 28 | 62 | 90 | 1 | 11 | 12 | 1 | 2 | 3 | 594 |

## Annex Table 9. Statistics on post-market quality surveillance of drugs

| Year | Medicinal Product | | Biologics | | Traditional Chinese Medicine | | Annual total | |
|---|---|---|---|---|---|---|---|---|
| | Cases | Nonconforming rate (%) | Cases | Nonconforming rate (%) | Cases | Nonconforming rate (%) | Cases | Nonconforming rate (%) |
| 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 |
| 2014 | 90 | 3.33 | 148 | 0 | 134 | 2.99 | 372 | 1.88 |

**Note: "-" refers to a background value survey**

## Annex Table 10. Statistics on controlled drugs licenses

| Year | Item | |
|---|---|---|
| | Controlled drugs registration licenses (licenses issued) | Controlled drugs prescription licenses (individuals) |
| 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 | 14,511 | 47,391 |
| 2014 | 14,857 | 49,059 |

## Annex Table 11. Statistics on controlled drug audits

| Year | Item | | |
|---|---|---|---|
| | Number of audits | Number of violations | Violation rate (%) |
| 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 |
| 2014 | 17,057 | 304 | 1.78 |

## Annex Table 12. Statistics on independent production and sales of controlled drugs

**(Unit: 1000 New Taiwan Dollar)**

| Year | Total income | Sales income | Submitted to National Treasury |
|---|---|---|---|
| 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 |
| 2014 | 533,320 | 527,940 | 120,000 |

## Annex Table 13. Status of the amendments and revisions to relevant regulations governing medical devices in 2014

| Date | Regulation / standard title | Summary |
|---|---|---|
| 2 January | Revised the draft of the first point promulgated in the *Registration Requirements of Mail-Order Purchases of Medical Devices by Pharmaceutical Companies* | A total of three Class 2 medical devices, namely body fat analyzers, condoms, and tampons can now be purchased through mail-order. Stronger requirements have been imposed upon the pharmaceutical companies to provide consumer reminders to read product manuals prior to use and the responsibilities of the companies in providing regular calibration |
| 7 January | Promulgated amendments to Articles 4 and 8 as well as Attachment 1 of Article 3 of *Regulations for Governing the Management of Medical Device* | As of 11 March 2014, medical device manufacturers must demonstrate compliance to Good Manufacturing Practice (GMP) for medical devices. Where necessary, amendments have also been made to achieve the goal of international harmonization |
| 21 February | Promulgated the revisions to a number of articles in the *Regulations of Medicament Manufacturer Inspection* | The TFDA signed an Exchange of Letters on the Technical Cooperation with Liechtenstein which would simplify medical device GMP applications and shorten the time-to-market for the country's medical device manufacturers |
| 25 February | Promulgated the revisions to the *Medical Device Application Form for Designation Inquiry* | Product function and purpose columns have been added, allowing business firms to voluntarily ascertain the expected function and purpose of product before submitting medical device designation inquiry applications and facilitating the determination of product characteristics |
| 20 May | Promulgated new technical standards for *Household Blood Sugar Monitoring Systems* and nine other *in vitro* diagnostic devices | To strengthen management of *in vitro* diagnostic devices (IVD), TFDA established technical guidances for nine IVDs, namely *household blood sugar monitoring systems, pregnancy test agents, IVD calibration specimens, IVD agents for drug abuse, IVD devices for glycated hemoglobin, C-reactive protein test reagents, rheumatoid factor test systems, extrinsic coagulation test instruments*, and *tumor-associated antigen test systems*, providing manufacturers with a reference when conducting product research and development and when preparing application and registration documents and information |
| 29 August | Released the new version of the *Transfer Document* | Amendments were made to the format of the T*ransfer Document* that must be attached when registering transfers of medical device license permits. The text that originally allowed the original authorizes to commission the recipient as an agent to register the transfer at TFDA has been deleted in order to comply with current regulations |
| 5 September | Promulgated revisions to *Regulation for Registration of Medical Devices* | (1) Clearly stated that pre-clinical testing and the original manufacturer's quality control documents must include safety and functional test data, and that the responsible testing lab must comply with relevant operational practice.<br>(2) Clearly stated that Class 3 medical devices must comply with the requirements prescribed in the *Essential Principles and Summary of Technical Documentation for Medical Device Safety and Functions* |
| 22 September | Promulgated amendments to Attachment 1 of Article 3 and Attachment 2 of Article 4 in the *Regulations for Governing the Management of Medical Devices* | To achieve the goal of international harmonization the amendments of to Taiwan's medical device regulation items are timely made, among which is the revision to medical device category, type, and item of a stair climber |
| 22 October | Promulgated the *Reference Guide for Nano-Medical Devices Identification* | Provides a reference for businesses researching and developing nano-medical devices |
| 19 December | Promulgated *Good Submission Practice for Medical Device Registration* | Provide support for manufacturers in establishing capabilities for internal preparations of registration documents for medical devices and improve the quality of submitted documents, thereby enhances case approval rate and efficiency |

## Annex Table 14. Statistics for lot release for biologics

| Year | Vaccines and toxoids | | | | Blood products | | Antitoxins and antiserums | | | | Other biologics | | Annual total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Domestic | | Imported | | Imported | | Domestic | | Imported | | Imported | | | |
| | 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 |
| 2014 | 72 | 3,705,462 | 155 | 7,607,454 | 121 | 962,552 | 6 | 8,440 | 0 | 0 | 27 | 332,558 | 381 | 12,616,466 |

## Appendix 2. Publications of 2014

| S/N | GPN | Title | Responsible unit | Publication date |
|---|---|---|---|---|
| 1 | 1010300341 | 2014 Compilation of Drug Abuse Testing Methods | Division of Research & Analysis | March 2014 |
| 2 | 1010300907 | 2014 Anti-Drug Report | Division of Controlled Drugs | May 2014 |
| 3 | 1010301031 | Sanitary Operation Reference Manual for Operators Fresh cut Vegetables and Fruits | Division of Food Safety | May 2014 |
| 4 | 1010301525 | 2014 Drug Abuse Prevention Guidelines | Division of Controlled Drugs | July 2014 |
| 5 | 1010203773 | Correctly Choice Food Materials and Food Additives Reference Manual for Small-sized Bakeries | Division of Food Safety | July 2014 |
| 6 | 1010301691 | Anti-Drug Report 2014 | Division of Controlled Drugs | September 2014 |
| 7 | 1010303009 | Q Boy's and Q Girl's Kaleidoscope of Food Safety | Division of Food Safety | December 2014 |
| 8 | 1010303094 | 2014 Substance Abuse: Prevention, Hazards, and Cessation of Substance Abuse | Division of Controlled Drugs | December 2014 |
| 9 | 1010303173 | Medical Device GMP, a Cross-Generation Driver for Quality: 1989~2014 | Division of Medical Devices & Cosmetics | December 2014 |
| 10 | 1010303220 | Promotional Manual for Registration of Food Businesses | Division of Food Safety | December 2014 |
| 11 | 1010303221 | Manual for Registration Audit of Food Businesses | Division of Food Safety | December 2014 |
| 12 | 1010303232 | Minimum Requirements For Biological Products IV | Division of Research & Analysis | December 2014 |
| 13 | 1010303234 | Manual of Domestic Vitamin products in Tablet or Capsule Forms | Division of Food Safety | December 2014 |
| 14 | 1010303235 | Audit Manual for Food Additives | Division of Food Safety | December 2014 |
| 15 | 1010303236 | Manual of Food Additives | Division of Food Safety | December 2014 |
| 16 | 1010303276 | Manual for Food Additives Traceability Systems | Division of Food Safety | December 2014 |
| 17 | 1010303291 | Sanitary and Safety Operations Reference Manual for Personnel Supplying Raw Food Products | Division of Food Safety | December 2014 |
| 18 | 2010002894 | Annual Report of foodborne outbreaks (2013) | Division of Food Safety | December 2014 |
| 19 | 2010103850 | 2013 Imported Food Management and Import Inspection Statistic Report | Division of Food Safety | December 2014 |
| 20 | 4510302869 | Healthy Mind and Drug-Free Lifestyle | Division of Controlled Drugs | December 2014 |
| 21 | 2010301353 | 2014 Taiwan Food and Drug Administration Annual Report (Chinese version) | Division of Planning & Research Development | November 2014 |
| 22 | 2010302286 | 2014 Taiwan Food and Drug Administration Annual Report (English version) | Division of Planning & Research Development | December 2014 |
| 23 | 2009902762 | Annual Report of Food and Drug Research, Issue 5 | Division of Planning & Research Development | December 2014 |
| 24 | 2008200056 | Journal of Food and Drug Analysis, Issue 22 | Division of Planning & Research Development | March, June, September, December, 2014 |
| 25 | 4909405233 | Food & Drug Consumer Newsletter | Division of Risk Management | January to December, 2014 |

## Appendix 3. Website Links

| S/N | Website name in English | Website address |
|---|---|---|
| 1 | Taiwan Food and Drugs Administration | http://www.fda.gov.tw |
| 2 | Food and Drug Consumer Service Network | https://consumer.fda.gov.tw |
| 3 | Online Application and Public Service Platform | https://oaps.fda.gov.tw |
| 4 | Imported Food Information System | https://ifi.fda.gov.tw |
| 5 | Product Management Distribution System | https://pmds.fda.gov.tw |
| 6 | Food Business Registration Platform | https://fadenbook.fda.gov.tw |
| 7 | Taiwan's International Food Safety Authority Network | https://tifsan.fda.gov.tw |
| 8 | ROC Chef Certificates Information System | https://chef.fda.gov.tw |
| 9 | Post-market Quality Management System of Medical Products, Food Products, and Cosmetics | https://qms.fda.gov.tw |
| 10 | Drug Registration Review and Online Application Platform | https://e-sub.fda.gov.tw/dohclient |
| 11 | Medication Information Network | http://plan-consumer.fda.gov.tw/medication |
| 12 | Active Drug Safety Monitoring Platform | https://sentinel.fda.gov.tw |
| 13 | Taiwan National Adverse Drug Reactions Reporting System | https://adr.fda.gov.tw |
| 14 | National reporting System for Unintended Reactions of Health Food and Food in Capsule or Tablet Forms | http://hf.fda.gov.tw |
| 15 | Controlled Drugs Management Information System | https://cdmis.fda.gov.tw |
| 16 | Drug Abuse Reporting System | https://dars.fda.gov.tw |
| 17 | Urine Test for Drug Abuse Reporting System | https://udars.fda.gov.tw |
| 18 | Laboratory Accreditation Management System | https://lams.fda.gov.tw |
| 19 | Advertisement for Drugs and Cosmetics Management System | https://adms.fda.gov.tw/adms |
| 20 | Illegal Advertisement Query System | http://illegal-ad.fda.gov.tw |
| 21 | JFDA Journal Online System | http://jfda.fda.gov.tw |
| 22 | e-Learning System | https://elearn.fda.gov.tw |
| 23 | Director-General's Mail Box | https://faq.fda.gov.tw/message/default.aspx |
| 24 | FDA Open Data Platform | http://data.fda.gov.tw |
| 25 | Food Traceability and Management Information System | http://ftracebook.fda.gov.tw |

**Note: The level of public access for the website services and online services be determined by the registration certificate and system authorization controls.**

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