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01

Administrative Goals

Point 1



Enhance the management of the life cycle of food, medicine, medical devices, and cosmetic to maintain the hygiene, safety and quality and create a safe environment for consumption.

Point 3

Reinforce international harmonization of laws and regulations, develop inspection capacity, improve the illegal drugs inspection network; promote the communication and advocacy of food and drug safety to raise the public's awareness of hazards and improve the quality of consultation services provided by agencies.

Point 2

Strengthen source control management and traceability system, and implement audits and border inspections to improve the sound quality monitoring system.



Ch1 Organization and Policies

Taiwan Food and Drug Administration of the Ministry of Health and Welfare (TFDA) was founded on July 23, 2013, as part of the organizational reform in the Executive Yuan. To fulfill the Ministry of Health and Welfare's commitment of promoting the health and wellbeing of the public, TFDA takes "Safe and effective medicinal products, safe and healthy food." as its mission, under the vision of "Being a reliable guardian on food and medicinal product safety, creating a safe

food and medicinal consumer environment." (Figure 1-1) Upholding the core value of "total product life cycle management" of food, medicine, and cosmetics, through the source, production, and distribution management, TFDA continues to devote itself in establishing a comprehensive safety management system for food and drugs to ensure the safety and quality of food and drugs for consumers.



Figure1-1 TFDA's visions and missions



Section 1

Organizational Framework

Led by the Director-General, TFDA is composed of two Deputy Director-Generals, one Chief Secretary, and seven business units. Including: Division of Planning and Research Development, which is responsible for planning and management, technical planning management, international cooperation, legal system, consumer protection, etc.; Division of Food Safety, Division of Medicinal Products, Division of Medical Devices and Cosmetics, as well as Division of Controlled Drugs, are responsible for products management, policies, and relevant regulations of their managed products; Division of Quality Compliance and Management is responsible for laboratory management and authentication, manufacturers management and inspection of pharmaceutical and cosmetic products, and inspection of human organ bank; Division of Research and Analysis is responsible for the testing of food, medicinal products, and cosmetics, methodological development and evaluation, pharmacopeia editing and compilation; TFDA also sets 3 District Centers (North, Central, and South) which are responsible for laboratory testing of imported food, medicinal products, and cosmetics; as well as distribution examinations and inspections. In addition to the business divisions, we have also established five administrative units, including Office

of Secretariat, Office of Personnel, Office of Accounting, Office of Service Ethics, and Office of Information Management, to assist in administrative management (Figure 1-2). Also, TFDA has two Task Forces (i.e. Factory for Controlled Drugs and Decision Support Center) to provide professional information, getting professional assistances from consultation units such as Taiwan Drug Relief Foundation and the Center for Drug Evaluation, Taiwan.

Section 2

Administrative Goals

TFDA sets the administrative goals and focuses based on the administrative policies of Executive Yuan and administrative programs of MOHW along with the budget plans, current development highlights, and social needs on food, medicinal products, and cosmetics management in 2020.

- I. Enhance the management of the life cycle of food, medicine, medical devices, and cosmetic to maintain the hygiene, safety, and quality and create a safe environment for consumption.
- II. Strengthen source control management and traceability system, and implement audits and border inspections to improve the sound quality monitoring system.
- III. Reinforce international harmonization of laws and regulations, develop inspection capacity, improve the illegal drugs inspec-

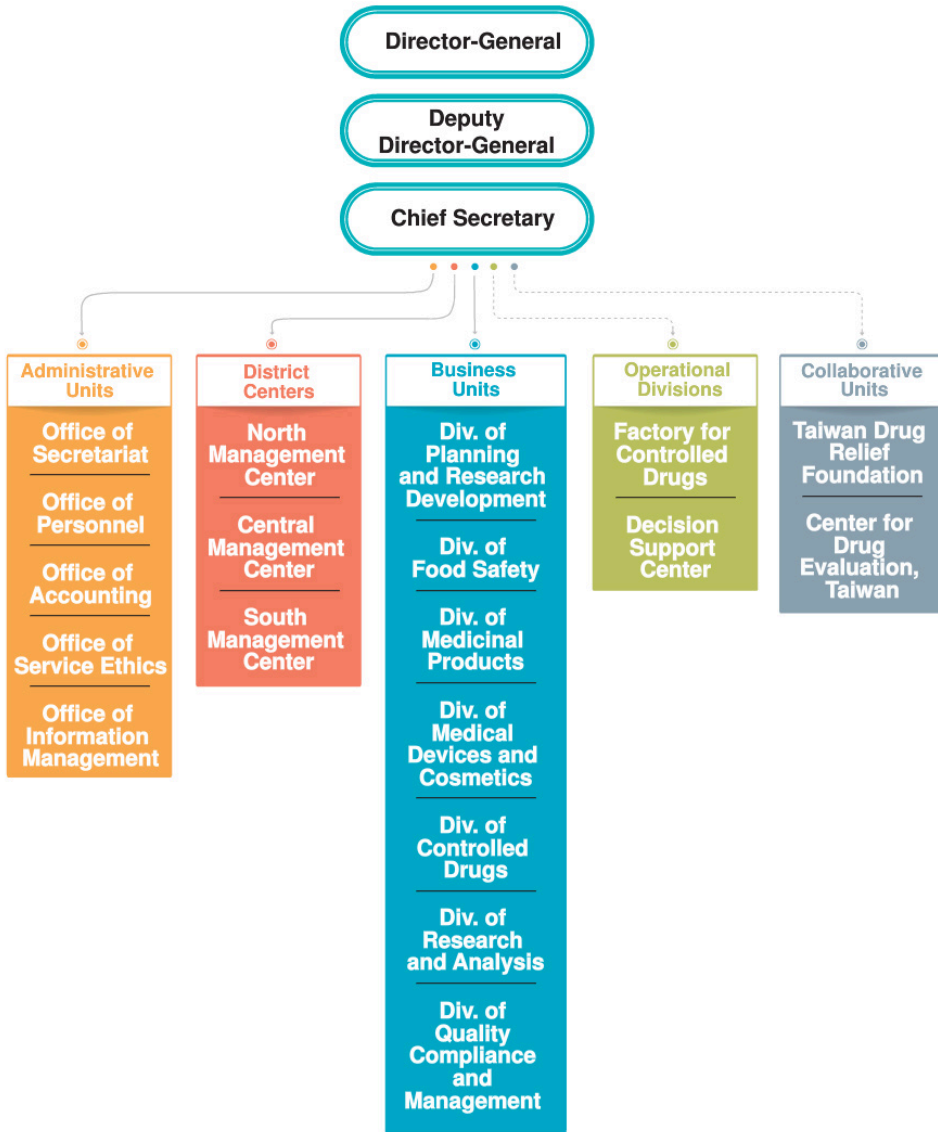


Figure1-2 The organization framework

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tion network; promote the communication and advocacy of food and drug safety to raise the public’s awareness of hazards, and improve the quality of consultation services provided by agencies.

Section 3

Food Management Overview

Enabling consumers to enjoy “Safe and Health Food” is the core value of a food management policy. As food safety issues

around the world continue to evolve, food management appears to become more diversified, innovative, and informative. TFDA adopts the “farm-to-table” management concept to ensure the hygiene and safety (Figure 1-3) of steps from the manufacturing of raw materials to sales channels and reinforces the implementation of the “Five-point Food Safety Policy” (Figure 1-4) to achieve food safety through government management and self-discipline of the industry and public participation.

TDFA actively collects and refers to

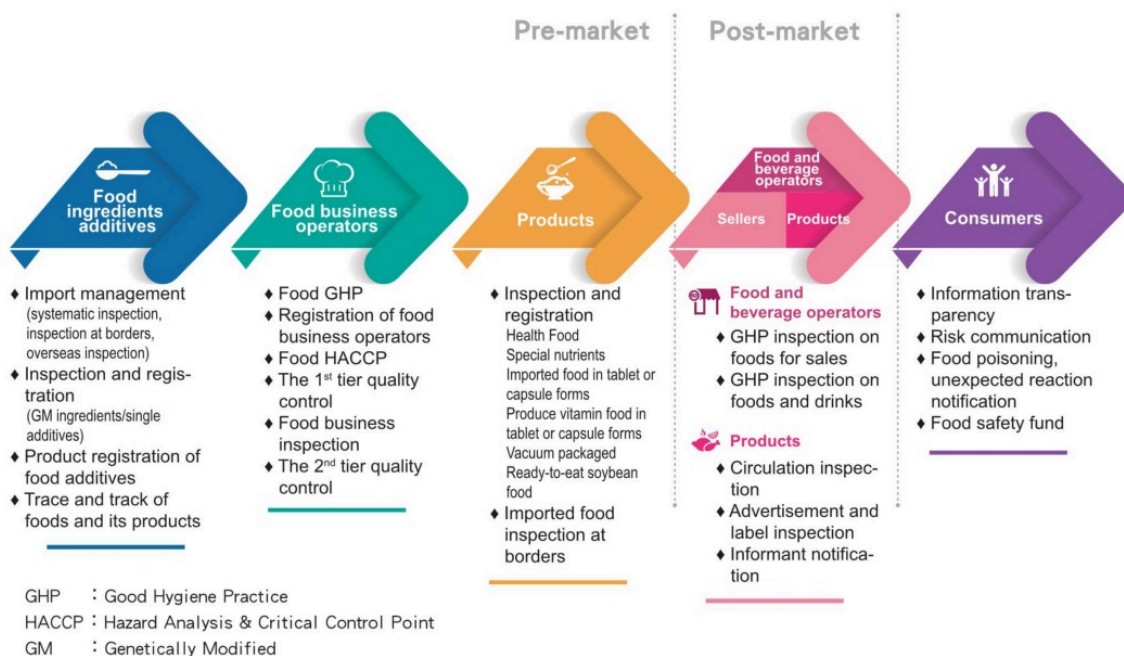


Figure 1-3 Food management structure

international food management regulations, continuously updates regulations relevant to the “Act Governing Food Safety and Sanitation” to strengthen inspection capabilities and capacity, and actively develops new food inspection methods. In addition to continuously improving source management of food imports, the Agency establishes a central-local collaboration practice to conduct specialized inspections, random inspections, and post-market monitoring of food. It uses big data to improve risk management and early warning detection efficiency, ensuring food hygiene, safety, and quality.

Section 4

Overview of Drug and Controlled Drug Management

I. Medicinal products management framework

Different from general consumer goods, medicines can only be sold on the market after obtaining marketing authorizations issued by the central health authority. In terms of the life cycle management of medicinal products, product development, preclinical



Figure1-4 Five-Point Food Safety Policy

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trials, clinical trials, marketing application, manufacturing to marketing, and various good operating practices, etc., must be followed. To ensure the safety of the public, TFDA continues to reinforce the quality management policy throughout the drug life-cycle (Figure 1-5) through harmonization with international regulatory standards, digital drug management, standardization of quality and safety supervision, ban and inspection of illegal drugs, drug business operators and product circulation management, etc. All of these measures are ensuring the safety, efficacy and quality of drugs, so that those in need can obtain the medicines in a

timely manner. These measures would also facilitate the development of biotechnology industry in Taiwan and create a win-win situation among patients, pharmaceutical industries and the government.

II. Controlled drug management framework

Controlled drugs refer to addictive narcotic drugs, psychotropic drugs, and other drugs that require regulations and may only be used for medical and scientific purposes. If used improperly or illegally, they can easily cause health hazards to the people.

According to the “Controlled Drugs

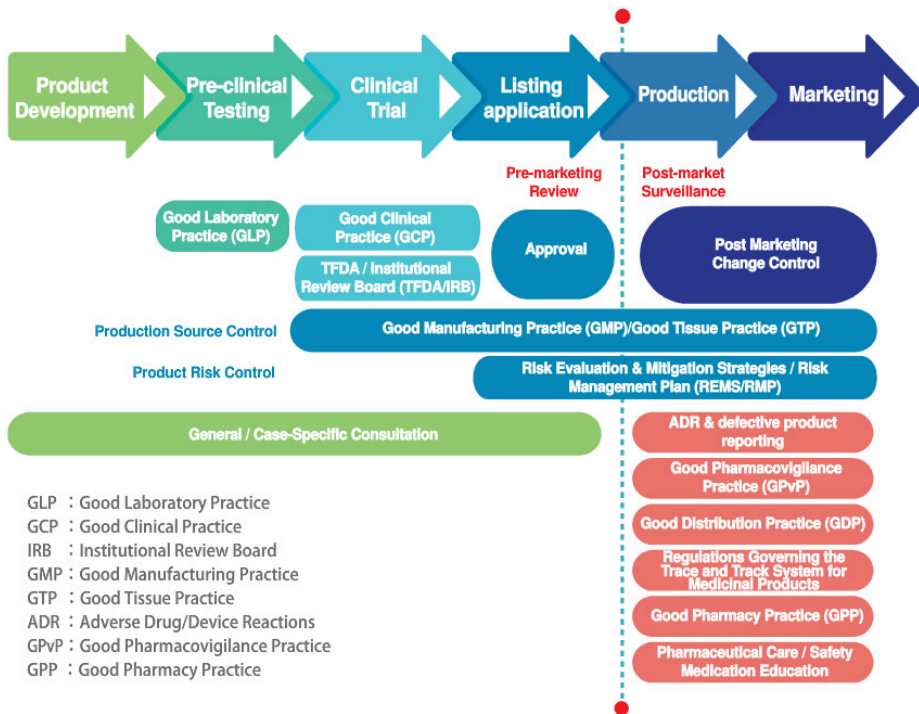


Figure1-5 Life cycle management structure of drugs



Act”, controlled drugs are categorized into four categories: their potential for habitual use, dependence, abuse, and danger to society. The source management of various types of users (such as institutions, industry operators, physicians, dentists, veterinarians, or paraveterinary workers) is conducted through certifications such as controlled drug registration certificate, use license, and export, import, and manufacturing agreement. The flow management is also strengthened, requiring users to register and declare the income, expense, and balance of controlled drugs in ledgers, to prevent the use or abuse of controlled drugs. Its management structure is shown in Figure 1-6.

Section 5

Overview of Medical Devices and Cosmetics Management

I. Medical devices management framework

Following technological advancement and increasing demand for technological medical and health devices, the medical device industry has become one of the most promising industries in the biotechnology sector in Taiwan. In response to the booming development of domestic medical device industry, TFDA has established a quality

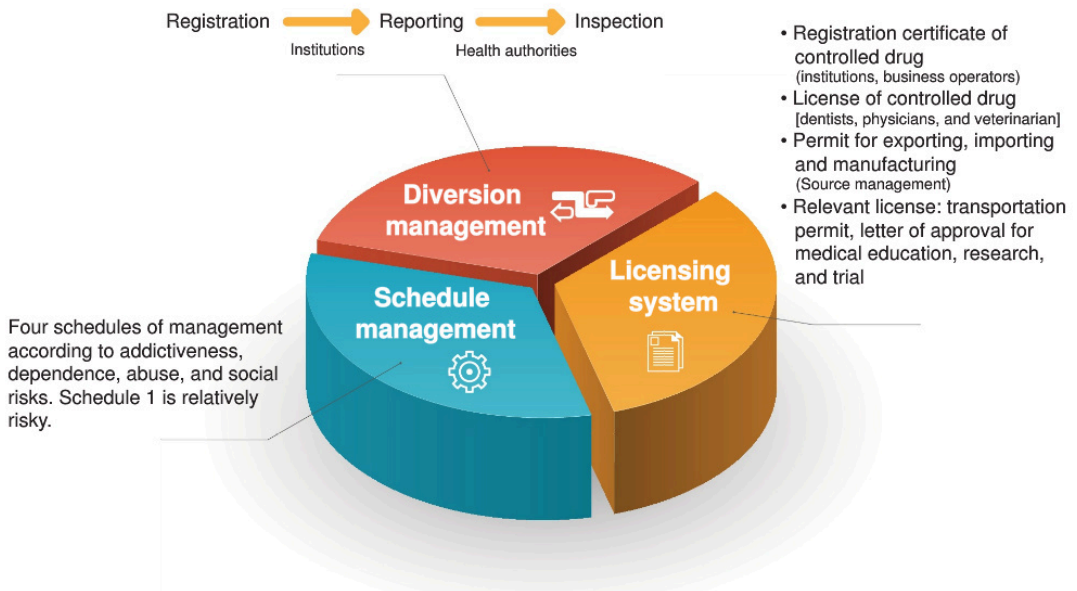


Figure1-6 Management structure of controlled drugs

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lifecycle management system for medical devices covering various aspects, including internationalization of regulatory management, flow control, pre-market inspections, post-market monitoring, management of medical device firms, and product circulation management (Figure 1-7). The system can effectively control the safety, efficacy, and quality of medical devices ; at the same time, it can continue to facilitate the development of the biotechnology and the pharmaceutical industry, so to create a win-win situation for

consumers, business operators, and the government.

II. Cosmetics Management framework

The current cosmetics management system includes three parts: production source control, pre-market management and post-market surveillance (Figure 1-8). The production source control includes ensuring that manufacturers comply with the Establishment Standards for Cosmetics Manufac-

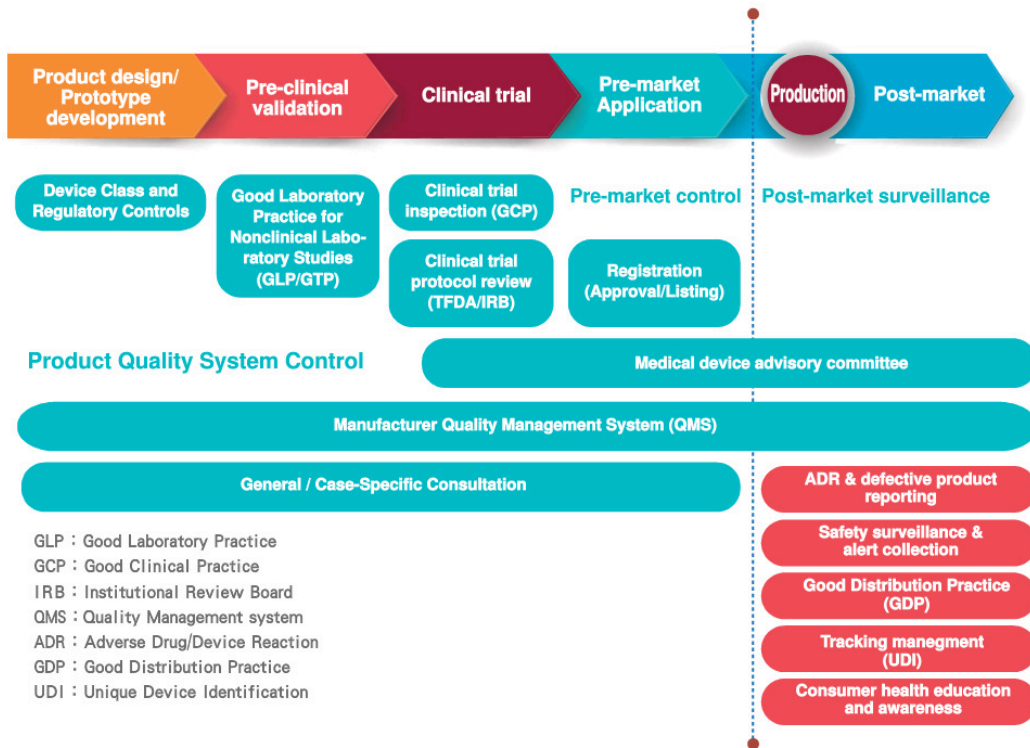


Figure 1-7 Full life-cycle management structure for medical devices



tory and promotion of Good Manufacturing Practices (GMP); the pre-marketing management includes notification of cosmetic products and establishment of product information file to replace the registration of specific purpose cosmetics during 5-year transition period; post-market surveillance focus on the quality monitoring plan and inspections of the cosmetic products across counties and cities, the establishment of product adverse event reporting system for cosmetics, regular monitor of the safety alert for domestic and global cosmetics, and strengthening consumer awareness of safe cosmetics use to create a comprehensive cosmetics quality and safety protection network.

Section 6

Future Perspective

With the trends of global trade and the development of technology, the discovery of novel substances, and the impact of emerging technologies and new chemicals, the safety and sanitary issues of food and medicinal products gradually become critical. In view of the importance of food and drug safety and the expectations from the public, TFDA integrates different departments and businesses, and expand the participation of the public to construct a safe protection network for food, medical products, and cosmetics. Future important administrative

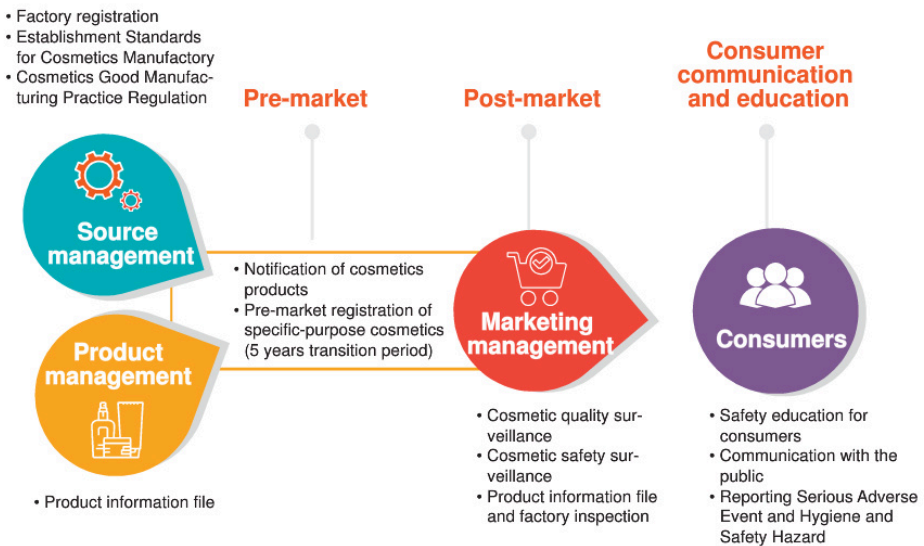


Figure 1-8 Cosmetic Hygiene and Safety Management Framework

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plans include:

- I. Implementation of the forward-looking “Food Safety Construction Plan,” which includes the construction plan for a modernized food and drug national laboratory and educational training building, the program to strengthen health department’s food safety audition and inspection capacity, the program to strengthen central competent authority’s food safety, safe drug use and illegal drug inspection capacity, and the program to improve the capacity and standardization of emerging infectious disease drugs and food-borne pathogen testing research, to build a modern national food safety laboratory complying with international standards, purchase high-precision inspection equipment, comprehensively improve the efficiency of food safety testing and research and development, further strengthen the management capacity of local and central governments agencies.
- II. Implement “Five-Point Food Safety Policy” reform plan, continue to expand the food safety management resources, combining business self-management and public participation to maximize the effectiveness of limited resources by executing

these management strategies, the three-tier product quality management, and market inspection will be practically carried out. In addition, the big data approach for food will be adopted to plan the risk strategies to enhance the domestic food management capacity.

- III. Improve the comprehensiveness of medicinal products legal environment, strengthen drug supply chain control and the GMP/GDP management, build a management system for regenerative medicine, implement precision medicine pilot programs, expand diversified pharmaceutical services, and improve international coordination of medical regulations.
- IV. Promote various regulations of the “*Medical Devices Act*” and the “*Cosmetic Hygiene and Safety Act*”, and accelerate the integration with international regulations. In response to the development of innovative medical devices and cosmetics, establish forward-looking and flexible management regulations. Reinforce consumer protection, and improve post-market surveillance to promote the development of domestic medical devices and cosmetics industries.