

# 2024 Director-General's Foreword

## *The Director Preface*



For the sake of people's health and quality of life, Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA) has remained dedicated to its mission of "Safe and effective medicinal products, safe and healthy food." TFDA not only supervises and manages products in the four major categories of foods, pharmaceuticals, medical devices, and cosmetics, but also ensures their safety and effectiveness, and continues to promote important relevant policies and regulations. By advancing food and drug safety improvement plans and safeguarding the safety and quality of food, drugs, medical devices, and cosmetics, TFDA is an important promoter of people's health and well-being. To record its important policies and administrative accomplishments, TFDA publishes annual reports summarizing the achievements of the previous year's major policies, plans, and administrative efforts, which provide a reference for domestic and foreign readers.

Covid-19 restrictions were gradually lifted in 2023. While the Covid pandemic caused incalculable harm, it also increased the public's attention and sensitivity to health and safety. Responding to needs of the post-pandemic era, TFDA has continued to assiduously safeguard the sanitation, safety, and quality of foods, medicinal products, medical devices, and cosmetics throughout each stage of the product

life cycle. TFDA also utilizes AI technology to enhance control of products at customs, monitor product distribution, inspection and consulting assistance to create a reassuring consumer environment. In addition, TFDA provides a high-quality network of consultation services and adjustable review mechanisms to protect the public's right to effective medication. We also strive to harmonize regulations with their international counterparts, are working to develop smart food and drug testing and inspection techniques, and use innovative communication strategies to provide citizens more correct knowledge concerning food, drugs, medical devices, and cosmetic safety.

In the area of food safety management, TFDA has actively gathered and consulted international food management standards and techniques, performed the rolling review and revision of regulations associated with the *Act Governing Food Safety and Sanitation*, and developed new food testing methods. At the same time, we have instituted horizontal and vertical communication and cooperation mechanisms with local and central authorities to facilitate border inspections, food audits, and aftermarket monitoring and testing. Furthermore, we apply big data analysis to boost the effectiveness of risk management and warning detection, which safeguards the hygiene, safety, and quality of food.



In the area of pharmaceutical management, TFDA actively participates in international activities, and stays abreast of pharmaceutical review and inspection trends. We have implemented a patent linkage system, are continuously updating regulations and standards in light of the domestic pharmaceutical industry's state of development, and are steadily improving Taiwan's pharmaceutical management regulatory environment. We have announced the *Regulations for Application and Review Committee Deliberation Process of Drug Injury Relief*. We are steadily improving pharmaceutical quality testing methods, ensuring that pharmaceutical manufacturers comply with GMP Regulations, and implement pharmaceutical businesses to obtain pharmaceutical GDP distribution permits; as of the end of 2023, a cumulative total of 1,010 firms had obtained such permits, ensuring that the public can obtain safe, high-quality medications.

Responding to drug abuse detection and control needs, TFDA has added new items to the list of controlled drugs and active pharmaceutical ingredients (APIs), established drug abuse monitoring mechanisms, and engaged in technology sharing with investigative and interdiction agencies. As a participant in joint efforts to prevent drug abuse, we are working in collaboration with Non-Governmental organizations (NGOs), indigenous communities, online media, and other ministries to conduct drug abuse prevent education. We held 382 of the "Fun in Preventing Drug Abuse" touring awareness sessions in 2023, in which we cooperated with 11 private organizations to prevent drug abuse through fun educational activities.

In the area of medical device management, we established classified management regulations consistent with international norms, strengthened medical device pre-marketing review and management, and expanded the functions of the medical device digital management system. This has accelerated the marketing of innovative and intelligent medical devices, and we are also ensuring that the manufacture and distribution of medical devices complies with quality management system (QMS) and GDP standards. We have made the QMS review process more transparent, which has yielded a win-win outcome for the public, industry, and medical device management. TFDA actively participates in the conferences of international organizations, promotes the harmonization of medical device regulations in the Asia-Pacific region. Participation in the Medical Device Single Audit Program (MDSAP) and the establishment of the Technical Cooperation Program (TCP) with the EU help promote greater alignment of audit resources, streamlining the review of regulatory requirements. This has boosted the international competitiveness of Taiwan's medical device industry.

In the area of cosmetic management, to respond to changes in the cosmetic management system and increase management flexibility, TFDA has accelerated the implementation of the new management system for specific purpose cosmetics, and is promoting the use of the product information file (PIF) system for cosmetic products. We are also continuing to hold GMP-related activities intended to help manufacturers of specific purpose cosmetics meet GMP requirements as quickly as possible after July 1, 2024. Our active participation in the activities of international organizations has facilitated the exchange of cosmetics testing technologies, and enabled TFDA to stay current with international trends in cosmetic management.

TFDA had numerous international breakthroughs and successes in 2023, including the following notable achievements: TFDA became an affiliate member of the International Medical Device Regulators Forum (IMDRF), and is continuing to share its management system knowledge and methods through IMDRF participation; Taiwan was successfully included on the list of third countries able to export active pharmaceutical ingredients (APIs) to the EU, which will shorten the time needed to apply for the export of APIs to Europe; TFDA cooperated with the Asia-Pacific Self-medication Industry (APSMI) Association in holding an international pharmaceutical conference, which promoted friendly interchange with other countries. These positive results are continuing to broaden and deepen Taiwan's international influence and industrial competitiveness.

TFDA bears a crucial public mission as the trusted guardian of food and drug safety. We consistently uphold our sacred duty to maintain people's health in our management of food, drugs, medical devices, and cosmetics. We rely on forward-thinking perspectives to constantly improve ourselves and prepare ourselves to tackle future challenges. At the same time, we also organize resources from different sectors and cooperate with international partners to establish a comprehensive safety network. We are striving to upgrade our testing technology, strengthen source management, and maintain effective supervision to ensure the safety and quality of food, drugs, medical devices, and cosmetics. TFDA will continue to take determined steps to create a safe consumer environment for food, drugs, medical devices, and cosmetics, and to protect the public's health and safety.

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