2023 Foreword by the Director-General

Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA), for the sake of protecting people's health and creating a safe living environment, with "Safe and effective medicinal products, safe and healthy food" as its mission, manages the quality and safety of food, medicinal products, medical devices and cosmetics that people are exposed to on a daily basis and continues to promote various important policies, laws and regulations and advance in food and drug safety reforms, solutions and measures while fulfilling its crucial mission to defend and protect national health. In order to document relevant important policies, achievements, and performance, TFDA prepares annual reports summarizing various important policies, plans and implementation achievements of the previous year and publishes them domestically and internationally for reference.

In 2022, people's lives were still affected by COVID-19. TFDA accelerates support for the industry to quickly devote themselves to the fight against the pandemic. Besides the reduced time required to prepare and produce standard products and real-time preparation and production of viral nucleic acid standards for mainstream strain, auditing of commercially available self-test kits took place; applicable regulations governing random border inspections of medical devices were amended; random border inspections were increased; and test methods were prepared and made known to the public. All were meant to protect the efficacy of in-vitro diagnostic test kits used by our people and to boost individuals' capability of protecting themselves against the pandemic throughout the nation.

As far as food safety management is concerned, in order to ensure control over the process from production to distribution of food and to identify potential risk items, TFDA worked with other ministries and departments and the prosecution, police, and investigation authorities, to reinforce food auditing and other multiple supervisory mechanisms, adjusted the inspection methods and items on a rolling basis reflective of domestic and international information, boosted the production random inspection rate and advanced in subsequent label management; all are meant to protect the rights of consumers. Meanwhile, smart technologies such as big data analysis have been applied to help with risk management. Cross-checking, comparison, contrast and analysis of linked cloud food data are applied to keeping track of potentially risky businesses. Meanwhile, applicable laws and regulations are proactively revised and food

management regulations are improved to continue safeguarding people's health.

In pharmaceutical administration, TFDA continues to advance in e-management of the reviews of medicinal products. Besides the reporting system that has been established, safety and quality information on domestic and international medicinal products are being monitored. Meanwhile, commercial product quality monitoring and manufacturer audits are conducted in order to strengthen the mechanism available for the trace and track management of medicinal products and risk control over the quality and safety of medicinal products. In addition, assistance was given to related pharmaceutical businesses in helping them familiarize themselves with and consolidate Good Distribution Practice (GDP) requirements. As of the end of 2022, 940 pharmaceutical dealers had obtained their GDP permits. Distribution management over medicinal products has been gradually enforced to protect medication safety.

In addition, TFDA is proactively reflecting upon and amending applicable requirements in the "*Controlled Drugs Act*". Every year, a controlled drug audit project plan is formulated to strengthen the inspection of the prescription rationality of controlled drugs and to prevent iatrogenic addiction or abuse. Meanwhile, TFDA works with non-governmental organizations and other ministries and departments in promoting the prevention of and education on substance abuse in diversified ways by reaching out to workplaces, communities, aboriginal tribes, and online populations. TFDA collaborated with 12 NGOs in total throughout 2022 and held a meme creation campaign to communicate to people how to prevent substance abuse.

The "Medical Device Quality Management Application Platform" set up by TFDA was officially launched on January 1, 2022. Medical device businesses can apply for inspections and track the status of an application quickly through the e-platform. Moreover, TFDA has actively taken part in international organizations in an effort to (1) help domestic medical device businesses enhance their international competitiveness; (2) improve and optimize laws and regulations and related support mechanisms concerning medical devices; (3) encourage multi-lateral cooperation on to create win-win situations for all parties.

In order to increase the familiarity of cosmetic businesses with the applicable requirements and to successfully establish production information files, the amendment of the "Guidelines on the Establishment of Cosmetic Product Information File" was announced in 2022. Moreover, in order to protect children's health and avoid mistaking cosmetics for food, the amendment of the "Guidelines for Safety of Children Cosmetics" was announced; this would protect the health and safety of children in the use of cosmetics.

What is worth mentioning is that 2022 marked the 10th anniversary of the Joint meeting between Taiwan and Japan, the 40th anniversary of Good Manufacturing Practice (GMP) for medicinal products, and the 10th year of accession to PIC/S. Both Taiwan and Japan realize the importance of international collaboration and hence are prepared to embark on action items and the development blueprint for the coming 10 to 15 years. Meanwhile, TFDA will continue to work with the industry and boost the professionalism of the pharmaceutical industry concurrently internationally with solid GMP as its cornerstone so that the general public gets access to pharmaceutical products of the same quality as advanced countries.

Given overall environmental changes, health, and safety concerning food, drugs, medicine, and cosmetics will constantly be met with stern tests and challenges. For the sake of fulfilling its mission as a "guardian of the public to ensure food and drug safety," TFDA will cope with challenges in the future with a forward-thinking approach by integrating ministries/departments, businesses, and consumers and also connecting and working with international counterparts in a joint effort to build a comprehensive safety protection network for the four major types of products in our country.

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