Foreword by the Director-General

The Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare was established to promote every citizen's health and the public welfare. Based on its mission of "Providing safe and effective medicines, safe and healthy food", TFDA aims to become a trusted guardian of food and medicine safety for the people, managing the policies for food, medicine, medical devices, and cosmetics which ensure that the people are guaranteed the safety and quality of food and medicine. In order to document relevant important policies and implementation, TFDA prepares an annual report that summarized various important policies, plans, and achievements in the previous year, publishing them domestically and internationally for reference.

In response to the COVID-19, which can cause severe acute respiratory infection, have ravaged the world since 2020, the government has established the Central Epidemic Command Center (referred to as the CECC) to facilitate cross-functional coordination. TFDA introduced advanced deployment measures such as making an inventory of drugs and medical devices, accelerating the reviews of emergency use authorizations, establishing project teams for consultation services, tracking the essential supplied for pandemic control, and assisting in the research, development, and introduction of pandemic control drugs and medical devices. Besides, in response to the imbalance in the supply and demand of masks during the pandemic, the CECC coordinated efforts between the public and private sectors to establish the Mask Rationing Plan and quickly solve problems to improve the self-defense capabilities against the pandemic for everyone.

During the joint fight against the pandemic, TFDA has achieved great results in refining various works. In terms of food safety management, TFDA has implemented several measures, including announcing comprehensive regulations, enhancing the supervision of manufacturing, sale, import, and export, and improving advanced inspection technologies and big data risk analysis capabilities, to reinforce the management from farm to table throughout the life cycle of food and build a complete food-based safety net.

In order to ensure the safety, efficacy and quality of drugs, TFDA not only implements product lifecycle management model and also actively collaborates with other parties around the world to improve drug risk assessment, quality control and digital management. TFDA also provides a regulatory environment which is harmonized with international standards. Meanwhile, TFDA actively establishes relative standards for regenerative medicine preparations to accelerate the development of the domestic industry to respond to the emerging biomedical tech-

nology nowadays.

In recent years, TFDA has continued to review and amend the relevant regulations of the *"Controlled Drugs Act"*, having prevented the abuse or illegal use of controlled drugs through inspections on the distribution of controlled drugs and advocacy anti-drug campaigns.

It is worth mentioning that the much-anticipated *"Medical Devices Act"* has been promulgated by the President on January 15, 2020. TFDA has also established 22 sub-regulations drafts, including categorization and classification of medical devices, issuance of medical device license, listing and registration, flow management, etc., to build a complete lifecycle management system for medical devices. In addition, after announcing the guidelines for inspection and registration of Artificial Intelligent-Based Software as a Medical Device, TFDA has worked closely with companies by providing consultation to promote the research and development of relevant medical devices in Taiwan.

Facing the COVID-19 pandemic, it has been difficult for countries to have face-to-face communications. However, using video-conferencing technology, TFDA has exchanged ideas with various international organizations on regulatory management and inspection techniques. In 2020, TFDA became an official member of the APEC RHSC Medical Devices Regulatory Science Center and a member of the International Cooperation on Cosmetics Regulation (ICCR). Through active participation in international activities, TFDA worked to ensure that domestic laws and regulations follow international standards and improve Taiwan's visibility in the international arena.

With the continuing emergence of novel substances and the impact of emerging technologies and new chemical substances, the hygiene and safety management of food and drug have become a complicated issue. TFDA will have adhered to ensure food and drug safety for the people by integrating cross-functional coordination, industry players, and consumers to expand public participation. Source management, effective supervision, and inspection technology are incorporated into the core values of consumer safety to establish a comprehensive safety net for food, medicine, medical devices, and cosmetics.

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

Shaw-Mei Wu