Preface by the Director-General

To safeguard public health and well-being, the Taiwan Food and Drug Administration (TFDA) under the Ministry of Health and Welfare has always upheld the unwavering belief in "safe and effective medicinal products, safe and healthy food." From food and medicinal products to medical devices and cosmetics, TFDA maintains the highest standards of scrutiny at every stage to ensure that these type of products encountered in daily life meet stringent safety and quality requirements. In response to the rapid evolution of industrial structures and global trends, TFDA continues to strengthen regulatory frameworks and promote policy innovation. By integrating life cycle management with intelligent regulatory tools, TFDA strives to enhance its effectiveness and reinforce a trusted national safety network. To comprehensively document key policies and achievements each year, TFDA publishes an annual report that consolidates major highlights and program outcomes. This report serves as a valuable reference for both domestic and international stakeholders, showcasing Taiwan's steady progress in the safety management of food, medicinal products, medical devices, and cosmetics.

Looking back at 2024, food safety continued to be a topic of strong public concern. In the face of major incidents, TFDA consistently prioritized public health, promptly activated emergency response mechanisms, and mobilized cross-sector resources to strengthen inspection, investigation, and communication—reinforcing the nation's food safety defense line. Furthermore, TFDA also continued to demonstrate excellence in governance and international alignment. Key milestones included Taiwan's GMP regulatory system successfully passing the PIC/S reassessment, affirming its regulatory capability and alignment with international standards; participation in global pharmaceutical affairs for the first time as an associate member of ICMRA, expanding Taiwan's global dialogue and cooperation platform; role as Chair of the 18th ICCR, guiding Taiwan's cosmetics sector onto the global stage; and hosting the 2024 APEC Communication Platform for Analytical Technology of mRNA derived Medicinal Products Workshop and the Food Export and Market Experience Sharing Conference, further strengthening ties among industry, government, and academia, and elevating Taiwan's global competitiveness and presence in the international arena.

In food safety management, TFDA continues to adopt a full life cycle approach based on the "farm to table" principle, promoting the "Five-point 2.0 Food Safety Policy." Through rolling updates to regulations, strengthening risk forecasting, and the application of artificial intelligence to support border prediction and automated monitoring, TFDA reinforces the resilience and safety of the food supply chain. In response to public concerns over heavy metals, Sudan dyes, and foodborne illnesses, TFDA promptly revised standards and intensified inspections to ensure greater protection of food safety. Taiwan's food regulatory system has also been aligned with international standards.

TFDA has implemented the second-tier quality management certification for food businesses, helping domestic enterprises expand into overseas markets while establishing a transparent and traceable safety management framework—ensuring that the public can eat with peace of mind and confidence in food safety.

In pharmaceutical policy and regulation, the "Regenerative Medicinal Products Act" was officially promulgated, marking a major step forward in advancing regenerative medicine in Taiwan. Drug safety surveillance continues to be strengthened, with ongoing improvements in supply chain monitoring and steady implementation of digitalized management systems. TFDA has also clarified the regulatory distinction between human and veterinary drugs to enhance precision in oversight. TFDA actively participates in international organizations such as ICH and PIC/S, and regularly hosts international seminars and Taiwan-Japan pharmaceutical exchange meetings to foster regulatory trust and collaboration. Drug quality and supply resilience have improved in parallel. TFDA has optimized testing technologies to ensure pharmaceutical manufacturing complies with GMP standards, and has promoted certification for GDP distribution licenses to reinforce a strong and secure foundation for public medication safety.

In the management of controlled drugs and the prevention of drug abuse, TFDA regularly reviews and revises the scheduled items listed under the Controlled Drugs Act. The rational use of controlled drug prescriptions is audited to prevent inappropriate prescribing by physicians, and to strengthen inspection of controlled drug distribution. TFDA has also established an emergency department drug abuse surveillance mechanism and compiles the "Drug Abuse Case and Testing Statistics" report monthly. In addition, TFDA actively promotes the proper use of controlled drugs and drug abuse prevention through interministerial collaboration and diverse outreach efforts, including partnerships with civic organizations and engagement on social media platforms.

In response to the rapid advancement of medical device technology and ongoing industry innovation, TFDA continues to refine standards adoption, review processes, and post-market surveillance to enhance the overall efficiency of end-to-end product management. By aligning with international standards, TFDA consistently updates and announces relevant regulations, promotes Quality Management Systems (QMS), Good Distribution Practice (GDP), and the electronic submission system to improve review efficiency and information security. Ongoing industry consultation and guidance are provided to support the development and market entry of smart medical devices and emerging products. TFDA has also actively advanced international cooperation, hosting the APEC Medical Device Regulatory Science Center of Excellence Workshop, participating in GHWP, IMDRF, and MDSAP, as well as promoting Taiwan-EU technical collaboration program, in order to better align Taiwan's medical device sector with global regulatory systems. These efforts ensure the safety and quality of medical devices used by the public while helping the industry expand into international markets.

In cosmetics management, 2024 marked the full implementation of the new regulatory framework, including product notification, increased information transparency, and phased adoption of GMP to ensure oversight from manufacturing to end use. TFDA actively participates in international regulatory cooperation platforms such as the International Cooperation on Cosmetics Regulation (ICCR) to promote alignment with global standards. It also hosted international symposium on industry transformation and innovation to guide Taiwan's cosmetics sector toward sustainability and global integration. In testing and analysis, TFDA continues to optimize analytical methods and engage in technical exchanges with international laboratories to enhance testing capacity and global visibility, ensuring that the public has access to safe, high-quality cosmetic products.

Looking ahead, TFDA will continue to safeguard the safety of food, medicinal products, medical devices, and cosmetics for the entire population. TFDA will actively enhance risk management through smart technologies, optimize the Five-point 2.0 Food Safety Policy, promote regulatory harmonization with international standards, refine testing capabilities, and promote industrial upgrading. By integrating the strengths of government, industry, academia, and research institutions, TFDA will deepen source-level management and effective supervision, while expanding international cooperation to build a comprehensive safety network. In the face of emerging technologies and global challenges, TFDA remains committed to the belief: "Public-private collaboration, autonomous governance, innovation in practice, and creating a shared future for all." TFDA strives to create a safer, healthier, and more sustainable living environment for all.

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