News

Regulation of Medical Devices in Taiwan Moves from A to A+ 【Date：2017-07-07】

Taiwan’s medical device regulatory system is actually at the global forefront. Back in 1970s, Taiwan was one of the few countries in the world that regulated medical devices. In 1993, the Pharmaceutical Affairs Act was enacted to facilitate the creation of a congenial environment for the development of Taiwan’s medical device industry. To date, the Pharmaceutical Affairs Act continues to play an important role in the regulation of medical devices in Taiwan. However, as time passes and countries around the world have put into effect laws and regulations specifically for regulating medical devices, experts in Taiwan expressed their opinions that regulations on management of medical devices ought to be separated from the Pharmaceutical Affairs Act. Hence, the Taiwan Food and Drug Administration (TFDA) has initiated an arduous task of drafting the Medical Devices Act.

Medical devices are closely related to our lives. From incubators that keep newborn babies warm to contact lenses which are used among the youth, or from first-aid bandages for treating minor cuts to reading glasses used by the elderly, these are all considered to be “medical devices.” To ensure the safety, effectiveness and quality of medical devices, TFDA categorizes medical devices into three classes according to their risk level: Class I (low risk), Class II (medium risk), and Class III (high risk). At the same time, TFDA regulates medical devices by auditing quality management system of manufacturers, performing pre-market assessment, and conducting post-market surveillance to protect consumers.

“What are the differences between the new Act from the present Act?” The proposed new regulation further implements the classification system of medical devices, since applications of certain kinds of Class I medical devices will be changed to electronic listing and applicants will be required to annually report their devices through an annual declaration system. Moreover, the new Act strengthens the management of medical device manufacturers. In addition to defining medical device manufacturers according to manufacturing phases, legal entities that design and place devices on the market under their names are also incorporated into manufacturers. On the other hand, legal entities that lease medical devices and service or

repair medical devices are incorporated into medical device dealers. To keep updated information about devices on the market, manufacturers will have to establish a management mechanism to track medical devices and TFDA will also require Good Distribution Practice (GDP) for medical devices. It is anticipated that the new Act will help improve the medical device regulation into a sound system for life cycle management of medical devices and promote development of the medical device industry. Presently, TFDA has completed the procedures of draft announcement in Taiwan and notification to WTO for collecting comments. It is expected that the draft would be sent to the Executive Yuan for review by the end of 2017. As the competent authority for regulating medical devices, TFDA will continue to promote various reforms that are globally harmonized, as well as to establish a reasonable and transparent review system and a better regulatory environment. In the meantime, TFDA will also strive to promote relevant biotech industry, enhance international cooperation, and provide consultation assistance related to regulations. It is hoped that these would help industry connect to the world and that medical device industry could become an important force to boost the economic growth, such that Taiwan’s consumers, industry, and government are all benefited.

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