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Research Note

Current development in medical devices postmarket surveillance in Taiwan

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The Taiwan Food and Drug Administration, Ministry of Health and Welfare (hereinafter referred to as the "TFDA") ensures consistent and improved management of medical device safety. Medical devices usually refer to any equipment, software, or material intended to be used in the diagnosis, prevention, monitoring, or treatment of diseases or injuries [1]. Because of the increasing complexity of medical devices and the variability of usage environments, the concept of "total product life cycle" has been introduced during the product development phase [2]. Besides the strict regulatory framework to ensure the safety of both patients and health care providers, sustained monitoring and information collection are also crucial tasks to evaluate the safety and risk of marketed medical devices. Postmarket surveillance of medical devices includes reporting of adverse reactions and obligatory periodic safety update report for high-risk medical devices in the monitoring stage. All the current efforts on postmarket surveillance in Taiwan are aimed at implementing effective risk management and assessment controls and improving the protection for our citizens.

Two online reporting systems are being established for sustained monitoring and collecting the safety information on marketed medical devices, namely, Adverse Events of Medical Device Reporting System and Defective Product Reporting System. In 1988, a nationwide reporting system of adverse drug reaction was set up. This network included one national center and four regional centers located in northern, central, southern, and eastern Taiwan. In 2001, the Adverse Events of Medical Device Reporting System was integrated into this system. To further harmonize data processing and enhance operational efficiency, the reporting network was subsequently centralized to establish the National Adverse Drug/Device Reaction (ADR) Reporting Center in 2005. In the same year, an online reporting system for medical product defect was also established. The defects may be attributed to manufacture, transportation, storage, distribution, and/or handling of the product, with the distinction that a product defect may or may not result in an adverse event (e.g., improper labeling). For the purpose of ensuring the quality of medical devices and preventing end users from possible hazards, voluntary reporting is encouraged when a product defect is found prior to use.

Reports on adverse events of medical devices or defective products are routinely collected from all the regions of Taiwan daily. Manufacturers, licensed agents, health care providers, or end users all can report problems related to the medical devices freely through the website. The total numbers of both adverse events and defective product reporting from 2003 to 2013 are indicated in Fig. 1. The steady increasing trend of adverse events reporting with the passing years may be related to the increasing complexity of medical devices and the variability of usage environments. The numbers of

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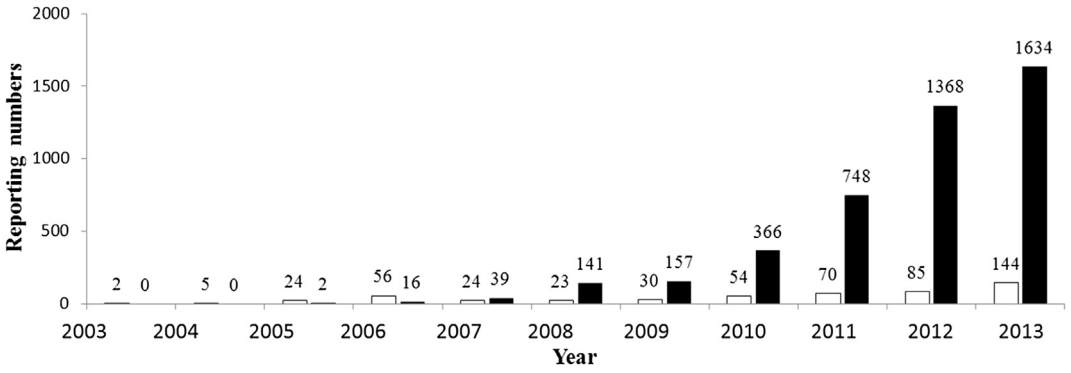

Fig. 1 – Reporting numbers of adverse events (open bars) and defective products (closed bars) for the period between 2003 and 2013.

defective product reporting, by contrast, showed a dramatic growth since 2010. This result implied that the continual promotion and education could be an efficient way to encourage voluntary reporting of defective products.

All the reports of adverse event or product problem were first registered into the database of the National ADR Reporting Center, which is operated under the Taiwan Drug Relief Foundation. National Taiwan University, the TFDA's commissioned agency, would subsequently review and preliminarily evaluate the safety data. As an example, 144 adverse event reports for medical devices were received in 2013. Of the 106 reports that have been evaluated currently, about 8.7% (9 reports) were "severe" adverse events and 81.5% percent (84 reports) were "moderate/mild" adverse events. Furthermore, 1481 valid defective product reports received from January 1, 2013, to October 31, 2013, were classified and assessed according to the Device Problem Code [3]. The five most common types of device defects were "1250: Fluid Leak" (214 reports, 12.7%), "2944: Foreign Material Present in Device" (210 reports, 12.4%), "2588: Defective Item" (150 reports, 8.9%), "1506: Product Quality Issue" (125 reports, 7.4%), and "1104: Detachment of Device Component" (121 reports, 7.2%). Further findings indicated that disposable products, such as administration set, syringe, gauze/sponge, and absorbent fiber, were the most commonly reported cases. These results indicated that the reporting tendency with regard to defective products would be strongly dependent on the usage frequency of the products and also on the specific characteristics of the device defects.

The proper measures undertaken are notifying the manufacturer to take appropriate action, such as product correction, sales restriction, or market withdrawal, and also performing audit inspection. The Safety Evaluation Advisory Committee, which consists of 15 panelists including scientific, engineering, and clinical experts, will also propose recommendations for the TFDA to consider possible regulatory action.

The TFDA actively and routinely monitors overseas information related to medical device alert and recall from websites of foreign competent authority, such as the FDA, the Medicines and Healthcare products Regulatory Agency (UK), the Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices; Germany), the Swissmedic, the Health Canada, the Therapeutic Goods Administration (Australia), and the Pharmaceuticals Medical Devices Agency (Japan), to respond accordingly and promptly. Furthermore, cooperative agreements with the United States, European Union, Switzerland, Australia, and Liechtenstein have been established since 1998. Such international cooperation helps to mutually exchange medical device vigilance reports and audit reports. Furthermore, the TFDA has also applied to join the Safety Alert Dissemination System of Asian Harmonization Working Party in 2010. The agency received a total of 5619 safety alerts, recall notices, or any issues of concern (both domestic and international) between 2010 and 2012. Of these, 580 reports were translated and disseminated. In addition, with participation in the global National Competent Authority Report (NCAR) program in 2010, the TFDA could further exchange information related to recall notifications, safety alerts, hazard alerts, product notifications, and other product advisories. Up to December 2013, 1047 reports on defective medical devices and recall notices have been received from the NCAR Secretariat.

Bearing the responsibility as a gatekeeper of the quality of medical devices, the TFDA will unceasingly work hard on improving all kinds of measures to provide our citizens with a better quality of life.

Conflicts of interest

All contributing authors declare no conflicts of interest.

REFERENCES

[1] WHO. Medical device regulations: global overview and guiding principles, vol. 24. Geneva, Switzerland: WHO; 2003.
[2] Axendia Inc. & Cambashi Inc. Total product lifecycle management for medical devices: lowering costs while increasing quality. Cambridge, UK: Cambashi; 2009. p. 1–36.
[3] U.S. FDA. The device problem code hierarchy. Washington, DC: U.S. FDA. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/EventProblemCodes/ucm134761.htm. (Last Updated: 02/12/2014).