Notice of Shanghai Food and Drug Administration to further strengthen the supervision and management of medical device enterprises

Shanghai food and medicine supervision drug flow〔2017〕#205

District and City Market Supervision and Administration Bureau:

In recent years, with the improvement of regulations and supervision of medical devise, the awareness of law and regulations in our city's IVD business enterprises continue to improve. But from the daily supervision, complaints reported, case investigation and related work, our bureau found that some medical equipment business enterprises still exist weak links in quality management, violations at individual business are still occurring. To further strengthen the city's IVD management aspects of the regulation, the relevant announcement are hereby notified:

1) Further strengthen supervision of the full process in IVD business enterprises

In accordance with the "who is responsible for approval, who is responsible" principle, the district market bureau should strengthen the medical device business enterprises permission, at the same time, to further strengthen the supervision after and strict implementation of territorial supervision responsibilities, enterprise regulations training, corporate legal and legal awareness and the implementation of corporate responsibility. Strengthen the daily supervision on enterprises with operating site and the storage divided in two jurisdictions, and carefully verify the actual operation of enterprises and storage and distribution situation. For enterprises that voluntarily cancel their business qualifications, verify whether the investigation has been settled and the disposal of unsafe products and prevent security risks. For enterprises to change the place of business and warehouses and medical equipment management quality management practices not in accordance with laws and regulations, investigation should be conducted thoroughly and consequences should be dealt with seriously.

2) Further strengthen the product information retrospective declaration of inspection work

To further strengthen the medical device product traceability, we should focus on supervision and management of three types of medical devices in accordance with the "Shanghai Medical Device Management Quality Management Regulations Implementation Rules" requirements, establish and improve the management of product management system, timely report the progress on "Shanghai medical equipment business enterprises Retrospective reporting system ". Enterprises should report complete product information, supplier information and sales unit

information to meet product traceability requirements. For those who do not report or omit the information, we should strengthen on-site inspection and verification, urge enterprises to report, if necessary, to take administrative interviews, publicity reminders and other related measures to ensure that three types of products retrospective declaration.

3) Further strengthen supervision and administration of problematic product recall

To strictly supervise the implementation of medical device enterprises ‘recall management system. For enterprises responsible for importing the medical equipment for overseas manufacturers, we shall supervise their taking principle responsibility of the investigation of reasons of defect, report and recall of the impact product, take the initiative to fulfill the recall obligation to the defective product, and conduct follow-up inspections, and supervise the effective implementation of the enterprise recall plan. To those who fail to perform their duties according to the regulations and the law, we shall, in accordance with the provisions of the State Administration of Food and Drug Administration "Administrative Measures for Recall of Medical Devices", strictly pursue the legal responsibility of the relevant enterprises.

4) Further strengthen supervision of the labeling and IFU of imported products

According to the "Medical Device Supervision and Management Regulations" and "medical device instructions and labeling management regulations", the use of imported medical device in China should be accompanied by manual and label in Chinese. Domestic medical device business enterprises shall not engage in labeling and other production and processing activities. During inspection, the market bureaus shall, stop the sale and use of imported medical devices that are not provided with Chinese instructions and labels, and report to the Municipal Food and Drug Administration. At the same time, we should pay close attention to the source of imported medical device. If any abnormal Chinese manual and the label or unauthorized labeling and processing of the Chinese label within China are found, we shall conduct in-depth investigation, tracing the source; any enterprise with illegal activities found will be punished severely.

Shanghai Food and Drug Administration

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