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# **Regulatory Provisions for Medical Device Adverse Events Monitoring and Reevaluation (Tentative)**

REG.NO: SFDA 2008766 Issued on December 29, 2008

## **Chapter 1 General Provisions**

Clause1. These provisions are constituted in accordance with *Regulations on the Supervision and Administration of Medical Devices*, in order to enforce the monitoring and reevaluation of medical device adverse events.

Clause2. These provisions are applicable to medical device manufacturers, distributors and user facilities, medical device AE monitoring technical facilities, food and drug administrations, as well as other related administrations in charge.

Clause3. Citizens, legal persons and other related social organizations are encouraged to report medical device adverse events.

## **Chapter 2 Administrative Responsibilities**

Clause4 State Food and Drug Administration are responsible for monitoring and reevaluating medical device adverse events all over China, and take the following responsibilities:

4.1 Together with Ministry of Health to constitute the regulations on medical device adverse events monitoring and reevaluation, and supervise their implementation;

4.2 Together with Ministry of Health to organize the inspection of the progress in medical device adverse event monitoring and reevaluation implemented by manufacturers, distributors and user facilities of medical devices, and organize the inspection of the progress in medical device adverse event monitoring in health institutions;

4.3 Together with Ministry of Health to organize and coordinate the investigation and handling of the abrupt and group adverse events related to serious injury or death;

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4.4 Together with Ministry of Health to determine and announce specific devices which should be paid more attention in adverse events monitoring;

4.5 To notify the results of medical device adverse event monitoring and reevaluation in China;

4.6 To take regulatory actions based on related regulations, according to the results of medical device adverse event monitoring and reevaluation.

Clause5 The provincial food and drug administrations are responsible for the monitoring and reevaluation of medical device adverse events within their local districts and take following responsibilities:

5.1 To organize the inspection of the progress in medical device adverse event monitoring and reevaluation conducted by manufacturers, distributors and user facilities in their local districts, and cooperate with the health administrations of the same level to inspect the progress in medical device adverse event monitoring in the local health facilities;

5.2 To cooperate with the health administrations of the same level to investigate and handle the abrupt and group adverse events that cause serious injury and death;

5.3 To report the results of medical device adverse event monitoring and reevaluation in their local districts;

5.4 To take regulatory actions based on related regulations, according to the results of medical device adverse event monitoring and reevaluation.

Clause6. Ministry of Health and its local administrations of all levels are responsible for related administration of medical device adverse event monitoring in health facilities, and take the following responsibilities:

6.1 To organizing the inspection of the progress in medical device adverse event monitoring in health facilities;

6.2 To supervise and inspect the medical technology and actions related to medical devices, and taking administrative actions on the medical technology and actions which result in serious results;

6.3 To coordinate the investigation on medical device adverse events taking place in health facilities;

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