

Notice on Printing and Distributing the *Management Measures for Monitoring and Re-evaluation of Medical Device Adverse Events (Trial)*

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To who concerned in provincial, autonomous region, and municipality-level Food and Drug Administrations (drug administrations), Health Departments/Bureaus, Health Bureau of Xinjiang Production & Construction Corps, National Institute for the Control of Pharmaceutical and Biological Products, Center for Drug Evaluation Center, Center for Medical Device Technology Evaluation, Certification Committee for Drugs of the State Food and Drug Administration (SFDA),

The Management Measures for Monitoring and Re-evaluation of Medical Devices Adverse Events (Trial) was formulated by the Ministry of Health and SFDA according to Regulation on Supervision and Administration of Medical Devices, in order to enhance the monitoring and re-evaluation of medical device adverse events. The Measures is hereby printed and distributed to you, please comply with them accordingly.

State Food and Drug Administration

Ministry of Health of the PRC

December 29, 2008

Management Measures for Monitoring and Re-evaluation of Medical Device Adverse Event

(Trial)

Chapter One General Provisions

1. The Measures is made to enhance the monitoring and re-evaluation of medical device adverse events according to the Regulation on Supervision and Administration of Medical Devices

2. The Measures is applicable to manufacturers, trading companies and user organizations of medical devices, technical institutions for monitoring medical device adverse events, food and drug administrations and other related departments.

3. The State encourages citizens, legal persons and other related social organizations to report medical device adverse events.

Chapter Two Responsibilities

4. The SFDA is responsible for nation-wide monitoring and re-evaluation of medical device adverse events. The details are as follows:

(1) Work together with the Ministry of Health to formulate regulations on monitoring and re-evaluation of medical device adverse events and supervise the implementation of the regulations;

(2) Organize and examine the monitoring and re-evaluation of medical device adverse events in manufacturers, trading companies and user organizations of medical devices, and work

work together with the Ministry of Health to examine the monitoring work of medical device adverse events in health institutions.

(3) Organize and give assistance in investigation and handling of the unexpected and mass adverse events such as severe injuries or death;

(4) Work together with Ministry of Health to determine and release the key monitoring varieties in medical device adverse events;

(5) Publicize the monitoring and re-evaluation results of nation-wide medical device adverse events;

(6) Based on the results above-mentioned, to take relevant measures according to the laws.

5. Provincial, autonomous region and municipality-level food and drug administrations are responsible for the monitoring and re-evaluation of medical device adverse events in their respective administrative regions. The details are as follows:

(1) Organize to examine the monitoring and re-evaluation of medical device adverse events of local manufacturers, trading companies and user organizations of medical devices, and work together with same-level competent health departments to examine the monitoring of medical device adverse events by local medical and health institutions.

(2) Work together with the same-level health competent departments to investigate and handle the unexpected and mass adverse events such as severe injuries or health

(3) Publish the monitoring and re-evaluation results of local medical device adverse events;

(4) Based on the results above-mentioned, to take relevant measures according to the laws.

6. Ministry of Health and local all-level competent health departments are responsible for the work related to implementation of monitoring of medical device adverse events by medical and health institutions. The details are as follows:

(1) Organize to examine the monitoring work of medical device adverse events by medical and health institutions;

(2) Supervise and examine medical device-related techniques and behaviors, and take relevant actions against the medical technique and behavior that result in severe consequence;

(3) Give assistance in the investigation of medical device adverse event arising in medical and health institutions;

(4) Take relevant actions against the medical devices with severe consequence.

7. State Drug Adverse Reaction Monitoring Center is responsible for the technical work of nation-wide monitoring and re-evaluation of medical device adverse events. The details are as follows:

(1) Collect, evaluate and feedback the information on monitoring of nation-wide medical device adverse events;

(2) Be responsible for the technical work related to re-evaluation of medical device;

(3) Provide technical guidance to provincial, autonomous region and municipality-level agencies for monitoring of medical device adverse events;

(4) Undertake the construction and maintenance of database and information network on nation-wide monitoring of medical device adverse events.

8. Provincial, autonomous region, municipality-level technical agencies for monitoring of medical device adverse events are responsible for the technical work of monitoring and re-evaluation of medical device adverse events in their respective administrative regions. The details are as follows:

- (1) Collect, evaluate, feedback and report the information on monitoring of local medical device adverse events;
- (2) Be responsible for the technical work of re-evaluation of domestic medical devices Category I, II approved by local food and drug administration.

Chapter Three Reporting of Adverse Event

9. Manufacturers, trading companies and user organizations of medical devices shall establish management system for monitoring of medical device adverse events, and appoint relevant agency as well as provide full-time (part-time) personnel to monitor their own medical device adverse event.

Manufacturers, trading companies and user organizations of medical devices shall establish and maintain records on monitoring of medical device adverse events. The records shall be maintained until 2 years after the operating period of medical device, and the shelf life of the records shall be not less than 5 years.

Records on monitoring of medical device adverse events shall include the contents of Appendix 1~3 of the Measures, and the documentations produced during discovery, report, evaluation and control of adverse events.

10. Manufacturers of medical devices shall take initiative to collect from their trading companies and user organizations all the suspicious medical device adverse events resulted by their products, and the trading companies and user organizations shall give relevant assistance.

The enterprises that manufacture medical devices Category II, III shall establish relevant system to ensure the traceability of their products.

11. Manufacturers and trading companies of medical devices shall report adverse events incurred by the medical devices they produce or trade, and the adverse events result in or may result in severe injuries or death.

The user organizations shall report the adverse events incurred by the medical devices they use, and the adverse events result in or may result in severe injuries or death.

Reporting of medical device adverse events shall follow the principle of “be suspicious and be reported” .

12. In case manufacturer, trading company and user organization of medical devices discover or know the medical device adverse event required to be reported, they shall fill in the *Report Form of Suspicious Medical Device Adverse Event* ([Appendix 1](#)) and report the event to the provincial, autonomous region and municipality-level technical agencies for monitoring of medical device adverse events, in which, the event resulting in death shall be reported within 5 working days after discovery or knowing, and the event causing severe injuries,

possibly causing severe injuries or death shall be reported within 15 working days after discovery or knowing.

The trading company and user organization of medical devices shall inform related manufacturer of medical devices of the event while reporting to provincial, autonomous region and municipality-level technical agencies for monitoring of medical device adverse events.

The manufacturer, trading company and user organization of medical devices may bypass the intermediate leadership when reporting adverse event if necessary, but they shall inform the bypassed local provincial, autonomous region and municipality-level technical agency for monitoring of medical device adverse events in time.

13. In case individual discover the medical device adverse event that results in or may results in severe injuries or death, he/she may report the event to local provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse events or report to the county-level or above food and drug administration.

Upon receiving report from individual of medical device adverse event, the county-level or above food and drug administrations shall notify local provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse events.

14. Upon receiving the report of adverse event, the provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse events shall notify in time the counterpart technical agency where the related manufacturer of medical device is located. Upon receiving the notification, the counterpart technical agency shall urge the

manufacturer of medical devices in its jurisdiction to record, investigate, analyze, evaluate, handle and report the adverse event.

15. Within 20 working days after first report, the manufacturer of medical devices shall fill in the *Supplementary Report Form of Medical Device Adverse Event* ([Appendix 2](#)) and report the event to local provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse event.

In case any condition arises beyond the first report and the supplementary report above-mentioned or the manufacturer of medical devices takes further action, the manufacturer of medical devices shall promptly submit related supplementary information to local provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse events.

For the purpose of protection of public safety and health or clarification of the special problems in the report of medical device adverse event, provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse events shall notify in writing the manufacturer of medical devices to submit related supplementary information. The written notification shall contain the specific requirements, reason and deadline for the supplementary information.

16. The manufacturer of medical devices Category II, III shall summarize and analyze the monitoring of medical device adverse events of last year before end of each January, fill in the *Annual Summary of Medical Device Adverse Events* ([Appendix 3](#)), and report to local

al provincial, autonomous region, or municipality-level technical agency for monitoring of medical device adverse events.

The trading company, user organization of medical devices and the manufacturer of medical devices Category I shall summarize the monitoring of medical device adverse events of last year before end of each January, and maintain the records for future check.

17. Provincial, autonomous region, and municipality-level technical agencies for monitoring of medical device adverse events shall investigate, verify, analyze, evaluate the report of medical device adverse events, and make report according to requirements:

(1) Upon receiving the first report of the event causing death, to promptly report to provincial, autonomous region, or municipality-level food and drug administration and State Center for Monitoring of Drug Adverse Reaction, and at the same time, report to the provincial, autonomous region or municipality-level health administration.

(2) Upon receiving the first report of the event causing death, within 5 working days, to indicate preliminary analysis in the Report Form of Suspicious Medical Device Adverse Event, report to provincial, autonomous region or municipality-level food and drug administration and State Center for Monitoring of Drug Adverse Reaction, and make a copy to provincial, autonomous region, or municipality-level health administration; upon receiving the supplementary report and related supplementary information on the event causing death, within 15 working days, fill out analysis or supplementary opinions in the Supplementary Report of Medical Device Adverse Events, report to provincial, autonomous region or municipality-level food and drug administration and State Center for Monitoring of Drug Adverse Reaction, an

d make a copy to provincial, autonomous region, or municipality-level health administration

(3) Upon receiving the first report of the event causing severe injuries, possibly causing severe injuries or death, within 15 working days, to write preliminary analysis in the Report Form of Medical Device Adverse Event, and report to State Center for Monitoring of Drug Adverse Reaction; upon receiving the supplementary report and related supplementary on the event causing severe injuries, possibly causing severe injuries or death, within 20 working days, to write analysis or supplementary opinions in the Supplementary Report of Medical Device Adverse Event, and report to State Center for Monitoring of Drug Adverse Reaction.

(4) Make summary and give analytical suggestions for the received report of the event causing or possibly causing severe injuries or death, and quarterly report to provincial, autonomous region, or municipality-level food and drug administration and State Center for Monitoring of Drug Adverse Reaction, and make a copy to provincial, autonomous region or municipality-level health administration.

(5) Upon receiving the annual summary from the manufacturer of medical devices Category II, III, within 30 working days, to give analytical opinions, and report to State Center for Monitoring of Drug Adverse Reaction; make summary and give analytical opinions before end of each February, and report to provincial, autonomous region or municipality food and drug administration.

18. Upon receiving the report from provincial, autonomous region or municipality-level technical agency for monitoring of medical device adverse events, State Center for Monitoring of Drug Adverse Reaction shall further analyze, evaluate the report, conduct investigation and verification if necessary, and make report according to following requirements:

(1) Upon receiving the first report of the event causing death, to promptly report to State Food and Drug Administration(SFDA), give preliminary analytical suggestions within 5 working days, sent the suggestions to the SFDA and make a copy to the Ministry of Health; upon receiving the supplementary report and other related information on the event causing death, within 15 working days, give analytical suggestions, sent the suggestions to the SFDA, and make a copy to the Ministry of Health.

(2) Make summary and give analytical suggestions for the received report of the event causing or possibly causing severe injuries or death, quarterly sent to the SFDA, and make a copy to the Ministry of Health.

(3) Upon receiving the annual summary, to make summary and give analytical suggestions before end of each March, sent to the SFDA and make a copy to the Ministry of Health.

19. During investigation, verification, analysis and evaluation of the report of adverse events, technical agencies for monitoring of medical device adverse events shall promptly report the progress of verification and examination in case verification by experts or examination by medical device testing agency is necessary.

The technical agency for monitoring of medical device adverse event shall give associative opinions and analyze possible reason for the event.

20. In case of discovering unexpected and mass medical device adverse events, the manufacturer, trading company and user organization of medical devices shall promptly report th

e event to local provincial, autonomous region, or municipality-level food and drug administration, health administration and technical agency for monitoring of medical device adverse events, and fill in and sent the Report Form of Suspicious Medical Device Adverse Event within 24 hours. The manufacturer, trading company and user organization of the medical devices shall bypass intermediate leadership if necessary during reporting, but inform in time the bypassed local provincial, autonomous region, or municipality-level food and drug administration, health administration and technical agency for monitoring of medical device adverse events.

21. Upon knowing there happened unexpected and mass medical device adverse event, the provincial, autonomous region, or municipality-level food and drug administration shall promptly work together with same-level health administration to conduct investigation, verification and handling of the event, and report to the SFDA, Ministry of Health and State Center for Monitoring of Drug Adverse Reaction.

SFDA may work together with the Ministry of Health to directly organize or coordinate investigation, verification and handling of the unexpected and mass medical device adverse event according to the hazard degree of the event or regulations on emergency management.

22. The technical agency for monitoring of medical device adverse events shall feedback relevant information to the organization or individual who reports the medical device adverse event.

Chapter Four Re-evaluation

23. Manufacturer of medical devices shall, based on the technique structure and quality system of medical devices, establish the condition for initiating re-evaluation of medical device, procedure and method for evaluation of medical device.

Manufacturer of medical devices shall analyze the adverse event of its products without delay and conduct re-evaluation of medical devices.

Manufacturer of medical devices shall know the potential safety hazard of its medical devices through retrospective study of product design, self-examination result of quality system, periodic risk analysis of product and relevant study literature on safety risk of medical devices, and conduct re-evaluation of medical devices.

24. During re-evaluation of medical devices, manufacturer of medical devices shall re-evaluate the technical data and contents such as analysis report of safety risk, product technical report, applicable product standard and instruction, clinical testing report, label, manual, etc. in original medical device registration materials, based on the effective information on product safety and operational experience acquired after the product is marketed.

25. Manufacturer of medical devices shall make plan for re-evaluation, and report the plan for re-evaluation, progress of implementation and re-evaluation results according to following requirements:

(1) Manufacturer of domestic medical devices Category III and the manufacturer of foreign medical devices report to the SFDA; the manufacturer of domestic medical devices Category I, II report to local provincial, autonomous region or municipality-level food and drug

administration.

(2) Manufacturer of medical devices shall submit the plan for re-evaluation and result report of the re-evaluation within 30 working days respectively before and after the implementation of the plan for re-evaluation.

(3) In case the implementation period of the plan for re-evaluation is more than one year, the manufacturer of medical devices shall report annual progress of the implementation.

26. Manufacturer of medical devices shall, based on the conclusion of re-evaluation, fulfill registration procedures if necessary according to relevant regulations on registration of medical devices.

In case the manufacturer of medical devices applies for cancellation of registration certificate of medical device based on the conclusion of re-evaluation, the original authority that issued the certificate shall report the cancellation level-by-level to the SFDA within 30 working days after completing cancellation formalities.

27. SFDA and provincial, autonomous region, municipality-level food and drug administrations are responsible to supervise and examine the re-evaluation of manufacturer of medical devices, and organize to conduct re-evaluation of medical devices if necessary.

SFDA is responsible to conduct re-evaluation of domestic and foreign medical devices, and provincial, autonomous region, municipality-level food and drug administrations are responsible to conduct re-evaluation of the medical devices Category I, II approved to be marketed in their administrative regions.

28. For the medical devices that have caused severe injuries or death, and pose threat to the safety and health of the public, the SFDA and provincial, autonomous region, municipality-level food and drug administrations shall work together with same-level health administrations, to directly organize technical agencies for monitoring of medical devices adverse events, manufacturers of medical devices, user organizations and related technical institutions, scientific research institutions and relevant experts to carry out re-evaluation.

29. In case food and drug administration organizes to conduct re-evaluation of medical devices, the same-level technical agency for monitoring of medical device adverse events shall draw up plan for the re-evaluation, implement the plan and make re-evaluation report.

Based on the conclusion of re-evaluation, original authorities that approved registration of the medical device may order the manufacturer of the medical device to modify label and manual of the medical device, and may determine to cancel the registration certificate of the medical device without safety and effectiveness assured.

The SFDA may determine to reject medical device based on the conclusion of re-evaluation.

30. Before determining cancellation of registration certificate of medical device, the SFDA, and provincial, autonomous region, municipality-level food and drug administrations shall inform the manufacturer of the medical device that it enjoys the right of applying for a hearing.

Before determining rejection of medical device, SFDA shall announce the rejection to the public, and hold hearing according to the hearing regulations of the SFDA.

Chapter Five Control

31. After reporting of medical device adverse event according to the Measures, the trading company and user organization of medical device shall assist the manufacturer and competent department in investigating the reported event, provide related materials and take necessary control actions.

32. Based on the hazard degree of the medical device adverse event, manufacturer of the medical event shall take control measures such as warning, inspection, repair, re-labeling, modifying user's manual, upgrading software, replacement, recall, destruction, etc. as necessary.

33. In case the control measures taken by the manufacturer of medical device are not effective enough to prevent the medical device from posing threat to the safety and health of the public with regard to the adverse event arising, the SFDA may take measures including warning, announcement, suspension of marketing, suspension of use, order of recall for both domestic and foreign medical devices, and the provincial, autonomous region, municipality-level food and drug administrations may take the same measures for the medical device Category I, II approved to be marketed in their administrative regions.

34. SFDA shall periodically or specially make public the results of monitoring and re-evaluation of medical device adverse events, and publicize the control measures taken for related medical devices.

Chapter Six Supplementary Provisions

35. The terms in the Measures are defined as follows:

Medical device adverse event means various harmful events that happen to the qualified and listed medical device in normal operation and cause or possibly cause injuries to human health.

Monitoring of medical device adverse events means the procedure of discovering, reporting, evaluating and controlling of medical device adverse events.

Re-evaluation of medical device means to re-evaluate the safety and effectiveness of the listed medical devices and take relevant measures.

Severe injury refers to one of followings:

(1) Life – threatening;

(2) Resulting in permanent injury or damage to the function and structure of human body.

(3) Relevant medical measures are necessary to avoid the permanent injury or damage above-mentioned.

Medical and health institutions refer to the medical institution and other the health institution affiliated to competent health authorities, which are granted with Business License of Medical Institution in accordance with the Regulations on Administration of Medical Institutions.

36. The manufacturer of the medical devices that can be sold in both China and foreign countries, shall report its product-related adverse event that happens in foreign countries and causes or may cause severe injuries or death as well as the control measures to State Center for Monitoring of Drug Adverse Event and SFDA within 15 days after discovery of the event.

37. The harmful events that happen to the medical devices during clinical testing and cause or may cause injury to human body, shall be reported according to the Regulations on Clinical Testing of Medical Devices and relevant requirements of SFDA.

38. The requirements for manufacturer of medical devices specified in the Measures are applicable to the agency in China of foreign manufacturer of medical devices, including the representative office or appointed corporate entity in China of foreign manufacturer of medical devices.

The requirements for Taiwan, Hongkong and Macao manufacturers of medical devices are the same as that for foreign manufacturer of medical devices.

39. The contents and statistical information of the report of medical device adverse event are the basis for enhancing supervision and management of medical devices and conducting

re-evaluation of medical devices, but not the basis for solving medical dispute, medical law suit and medical device quality accident.

The medical accident or medical device quality problem shall be separately solved according to relevant laws and regulations.

40. In case food and drug administration and its staff violate regulation, delay reporting of adverse event, fail to take measures to control the recurring of severe medical device adverse event and cause severe consequence during the monitoring of medical device adverse event, they shall be imposed administrative sanctions according to regulation.

41. The forms and computer software related to reporting of medical device adverse events shall be compiled by SFDA.

42. The right to interpret the Measures shall be vested in the SFDA and Ministry of Health.

43. The Measures come into effective as of the day it's issued.