Order of China Food and Drug Administration

No. 29

Measures for the Administration of Medical Device Recalls ("the Measures" for short) were already deliberated and approved in administration meeting of China Food and Drug Administration (CFDA) on January 5, 2017. The Measures are hereby released and put into force since May 1, 2017.

Director: Bi Jingquan

January 25, 2017

Measures for the Administration of Medical Device Recalls

Chapter 1 General Rules

Article 1 The Measures are hereby established according to *Regulation on the Supervision and Administration of Medical Devices* in order to strengthen supervision and management of medical devices, control defective medical device products, eliminate potential safety hazards of medical devices, ensure safety and effectiveness of medical devices and safeguard human health and life safety.

Article 2 The Measures apply to recalls of medical devices already marketed within the territory of the People's Republic of China as well as supervision and management of these recalls.

Article 3 Medical device recall mentioned herein refers to a behavior of a medical device producing enterprise that adopts warning, inspection, repair, relabeling, instruction manual modification and perfection, software upgrading, replacement, withdrawal and destroying against defective products of certain category, model or batch number already sold in the market according to stipulated procedure.

Medical device producing enterprise mentioned above refers to domestic medical device product registrant or recorder, or authorized agent of overseas manufacturer of imported medical devices within the territory of China.

Article 4 Defective medical device products mentioned herein include:

(1) Products with unreasonable risks that possibly endanger human health and life safety existing during normal use;

(2) Products not comply within mandatory standards and technical requirements of registered or filed products;

(3) Products with unreasonably risks possibly existing due to incompliance with relevant medical device production, operation and quality management provisions;

(4) Other products requiring recalls

Article 5 A medical device producing enterprise is the subject of control and elimination of product defects and it shall initiatively recall defective products.

Article 6 Medical device producing enterprises shall establish and perfect medical device recall system, collect information related to safety of medical devices, investigate and evaluate medical devices with possible defects and timely recall defective products according to stipulations set out herein.

The authorized agent of overseas manufacturer of imported medical devices within the territory of China as mentioned above shall timely report relevant information regarding implementation of recalls of medical devices only overseas to China Food and Drug Administration; if a recall is implemented within the territory of China, the authorized agent within the territory of China shall organize the implementation of such recall according to stipulations set out herein.

Medical device operating enterprises and using units shall assist medical device producing enterprises in investigating and evaluating defective products, initiatively coordinate producing enterprises to perform recall obligation, timely pass on and feedback information on medical device recalls based on recall plan and control and recycle the defective products.

Article 7 If medical device operating enterprises and using units find out that the medical devices they operate and use are possibly defective products, they shall timely suspend selling or using of such medical devices, timely inform medical device producing enterprises or suppliers, and report to local food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government; if the using units are medical organizations, they shall also report to local health administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government.

After food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where medical device operating enterprises and using units are located, they shall timely notify food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where medical device producing enterprises are located for general information.

Article 8 Food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where producing enterprise recalling medical devices are located are responsible for supervising and managing recalls of medical devices. Food and drug supervision and administration departments of other provinces, autonomous regions and municipalities directly under the Central Government shall properly coordinate and assist relevant work of medical device recalls within their administrative regions.

CFDA is responsible for supervising the management work of national medical device recalls.

Article 9 CFDA and food and drug supervision and administration departments of provinces, autonomous regions and municipalities directly under the Central Government shall follow medical device recall information notification and disclosure system, take effective approaches to disclose information concerning defective products

and recalls to society as well as notify relevant information to health administration departments in same level for general information when necessary.

Chapter 2 Investigation and Evaluation of Medical Device Defects

Article 10 Medical device producing enterprises shall establish and perfect medical device quality management system and medical device adverse event monitoring system as stipulated, collect and record information concerning quality complaints and adverse events of medical devices, analyze information collected, and investigate and evaluate defects possibly existing in medical devices.

Medical device operating enterprises and using units shall coordinate with medical device producing enterprises to launch investigation concerning defects of relevant medical devices and provide relevant materials.

Article 11 Medical device producing enterprises shall timely report information of medical device adverse events collected to drug supervision and administration department as stipulated. The food and drug supervision and administration may analyze and investigate information of medical device adverse events or defects possibly existing. Medical device producing enterprises, operating enterprises and using units shall coordinate.

Article 12 Main contents of evaluation of defective medical devices include:

(1) If the products comply with mandatory standards and technical requirements of registered or filed products;

(2) If fault or injury occurs during use of medical devices;

(3) If injury would be caused under existing service environment and if scientific literatures, researches and relevant tests or verifications are available to explain the reasons of injury;

(4) Range of region involved in the injury and characteristics of groups of people;

(5) Degree of injury caused to human health;

(6) Probability of occurrence of injury;

(7) Short-term and long-term consequences of injury occurring;

(8) Other factors possibly causing injury to human body.

Article 13 Medical device recalls can be classified as follows according to severity of defects of medical devices:

(1) Level-1 recall: The use of such medical devices possibly or already causes serious health hazards;

(2) Level-2 recall: The use of such medical devices possibly or already causes temporary or reversible health hazards;

(3) Level-3 recall: The use of such medical devices results in relatively small possibility of hazard but recall is still needed.

Medical device producing enterprises shall determine recall levels as the case may and scientifically design recall plans and organize implementation of such plans according to recall levels and selling and using conditions of medical devices.

Chapter 3 Voluntary Recall

Article 14 If medical device producing enterprises confirm the existence of defects in medical devices after conducting investigation and evaluation according to requirements of Article 10 and Article 12 of the Measures, they shall immediately decide and implement recalls as well as release product recall information to society.

If level-1 recall is implemented, announcement of medical device recall shall be released in the website of CFDA and major media of the central government; if level-2 or level-3 recall is implemented, announcement of medical device recall be released in the websites of food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government. The recall announcement released in websites of food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government shall be linked with the website of CFDA.

Article 15 If medical device producing enterprises make decisions on medical device recalls, they shall inform relevant medical device operating enterprises, using units or users within 1 day for level-1 recall, within 3 days for level-2 recall and within 7 days for level-3 recall respectively.

Notice of recall shall include the following contents:

(1) Basic information of medical device recalled such as name, model and batch number;

(2) Cause of recall;

(3) Requirements of recall: Immediate suspension of selling and using this product and forwarding notice of recall to relevant operating enterprises or using units, etc.;

(4) Methods for handling of medical devices recalled

Article 16 Upon making decisions on medical device recalls, medical device producing enterprises shall immediately submit a report of medical device recall event to local food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government as well as food and drug supervision and administration departments approving registration or filing of such medical products. Also, the medical device producing enterprises shall submit investigation and evaluation report and recall plan to local food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government as well as food and drug supervision and administration departments approving registration or filing of such medical products for filing within 5 working days.

Food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where the medical device producing enterprises are located shall report relevant conditions of recalls to CFDA within 1 working day after receipt the report of medical device recall event mentioned above.

Article 17 Investigation and evaluation report shall include the following contents:

(1) Specific conditions of medical devices recalled, including basic information concerning name, model and batch number;

(2) Cause for implementation of recall;

(3) Investigation and evaluation results;

(4) Recall classification

The recall plan shall include the following contents:

(1) Production and selling conditions of medical devices and quantity of recall proposed;

(2) Specific contents of recall measures including organization, scope and time limit of implementation of recall;

(3) Announcing approaches and scope of information on recall;

(4) Expected effect of recall;

(5) Handling measures after medical device recalls

Article 18 Food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where the medical device producing enterprises are located may evaluate recall plans submitted by the producing enterprises. If they think measures adopted by medical device producing enterprises cannot effectively eliminate defects or control product risks, they shall request the producing enterprises to adopt more effective measures such as improvement of recall class, expansion of recall scope, shortening of recall time or change of recalled products. The medical device producing enterprises shall modify recall plans and organize the implementation of such modified plans according to requirements of food and drug supervision and administration departments.

Article 19 If medical device producing enterprises change recall plans reported, they shall timely report to local food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government for filing.

Article 20 Medical device producing enterprises shall submit Report of Implementation Conditions of Recall Plan to local food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government according to recall plan during implementation of recall on a regular basis to report implementation conditions of recall plan.

Article 21 Medical device producing enterprises shall keep detailed records on handling of medical devices recalled and report to food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where medical device producing enterprises are located. These records shall be preserved for 5 years after registration certificates of medical devices expire. The handling records on recalls of first-category medical devices shall be preserved for 5 years. If product defects can be eliminated by means of warning, inspection, repair, relabeling, instruction manual modification and perfection, software upgrading, replacement and destroying, the abovementioned behaviors can be completed in places where products are located. If the medical devices shall be destroyed, they shall be destroyed under the supervision of food and drug supervision and administration department.

Article 22 After finishing recall, medical device producing enterprises shall evaluate recall effect and submit medical device recall summary report to local food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government within 10 working days after completion of recall.

Article 23 Food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government where medical device producing enterprises are located shall review the summary report within 10 days since the date when the report is received as well as evaluate recall effect; if it is concluded that the recall hasn't effectively eliminated product defects or controlled product risks, the producing enterprises shall be requested in writing to recall again. The medical device producing enterprises shall recall again according to the requirements of food and drug supervision and administration departments.

Chapter 4 Mandatory Recall

Article 24 If food and drug supervision and administration departments regard that the medical device producing enterprises fail to initiatively recall defective medical device products as they are supposed to after investigation and evaluation, they shall order the medical device producing enterprises to recall medical devices.

Decision on mandatory recall can be made by either food and drug supervision and administration departments of relevant provinces, autonomous regions and municipalities directly under the Central Government or food and drug supervision and administration department approving registration or filing of such medical devices. Food and drug supervision and administration departments making this decision shall release information on mandatory recall to society in their websites.

The medical device producing enterprises shall recall the medical devices according to requirements of food and drug supervision and administration departments as well as release product recall information to society according to stipulations set out in Paragraph 2 of Article 14 in the Measures.

Food and drug supervision and administration departments shall request medical device producing enterprises, operating enterprises and using units to immediately suspend selling or using of such medical devices, and inform the users to immediately suspend the use of such defective medical devices when necessary.

Article 25 After making a decision on mandatory recall, food and drug supervision and administration departments shall deliver notice of mandatory recall to medical device producing enterprises. The notice shall include the following contents:

(1) Specific conditions of recalled medical devices, including basic information such as name, model and batch number;

(2) Cause for implementation of recall;

(3) Results of investigation and evaluation;

(4) Recall requirements, including scope, time limit, etc.

Article 26 After receiving notice of mandatory recall, medical device producing enterprises shall inform medical device operating enterprises, using units or users, establish and submit a recall plan, and organize the implementation of the recall plan according to stipulations set out in Article 15 and Article 16 of the Measures.

Article 27 Medical device producing enterprises shall report relevant conditions of medical device recalls to food and drug supervision and administration department and conduct subsequent handling of medical devices recalled according to stipulations set out in Article 19, Article 20, Article 21 and Article 22 of the Measures.

Food and drug supervision and administration departments shall review medical device recall summary reports submitted by medical device producing enterprises according to stipulations set out in Article 23 of the Measures as well as evaluate recall effect and inform health administration departments in the same level when necessary. If it is regarded that the recall is not thorough after review and evaluation, and defects are not effectively eliminated and product risks are not controlled, food and drug supervision and administration departments shall request medical device producing enterprises to recall again in writing, while the medical device producing enterprises shall recall again according to requirements of the food and drug supervision and administration departments.

Chapter 5 Legal Responsibilities

Article 28 If medical device producing enterprises cause existence of defects of medical devices marketed due to violations of laws, regulations and rules, administrative punishment shall be imposed according to law, but these producing enterprises already adopt recall measures to initiatively eliminate or lighten hazardous consequences, the punishment will be imposed by food and drug supervision and administration departments in a lenient way or lightened in accordance with *Law of the People's Republic Of China on Administrative Penalty*; if law violating behaviors are minor and timely corrected without hazardous consequences, no punishment will be imposed.

If medical device producing enterprises recall medical devices, other legal responsibilities that shall be undertaken by these enterprises according to law will not be exempted.

Article 29 If medical device producing enterprises violate stipulations set out in Article 24 of the Measures and refuse to recall medical devices, the matter will be handled according to stipulations set out in *Regulation on the Supervision and Administration of Medical Devices*.

Article 30 If medical device producing enterprises have any of the following circumstances, they will be warned and ordered to correct within a certain time limit; if they fail to correct within the said time limit, a penalty involving an amount below RMB 30,000 Yuan will be imposed:

(1) Violate stipulations set out in Article 14 of the Measures and fail to timely release product recall information to society as required;

(2) Violate stipulations set out in Article 15 of the Measures and fail to inform medical device operating enterprises, using units or users of decision on medical device recalls within stipulated time limit;

(3) Violate stipulations set out in Article 18, Article 23 and Paragraph 2 of Article 27 of the Measures and fail to adopt corrective measures or recall medical devices again according to requirements of food and drug supervision and administration department;

(4) Violate stipulations set out in Article 21 of the Measures and fail to record handling of medical devices recalled in detail or report to food and drug supervision and administration department.

Article 31 If medical device producing enterprises have any of the following circumstances, they will be warned and ordered to correct within a certain time limit; if they fail to correct within the said time limit, a penalty involving an amount below RMB 30,000 Yuan will be imposed:

(1) Fail to establish a medical device recall system according to provisions of the Measures;

(2) Refuse to assist the food and drug supervision and administration department in launching relevant investigations;

(3) Fail to submit report of medical device recall events, investigation and evaluation report and recall plan, implementation conditions of medical device recall plan and summarization report according to stipulations set out herein;

(4) Change recall plan but fails to submit the changed recall plan to food and drug supervision and administration department for filing.

Article 32 If medical device operating enterprises and using units violate stipulations in Paragraph 1 of Article 7 of the Measures, they will be ordered to stop selling or using defective medical devices and penalty involving an amount above RMB 5,000 Yuan and below RMB 30,000 Yuan will be imposed; if a serious consequence is caused, the original issuing department will cancel their *Medical Device Operating Enterprise License*.

Article 33 If medical device producing enterprises and using units refuse to coordinate with investigation of defects of relevant medical devices and assist the medical device producing enterprises in recalling medical devices, they will be warned and ordered to correct; if they refuse to correct, a penalty involving an amount below RMB 30,000 Yuan will be imposed.

Article 34 If food and drug supervision and administration departments and their staff do not perform the duties of medical device supervision and administration or abuse authority and misconduct in office and any of the following conditions occurs, the supervisory authority or appointment and dismissal authority will criticize and educate persons who are directly in charge and other direct responsible persons, or impose punishments such as warning, recording of a demerit or recording of a serious demerit according to law; if serious consequences are caused, the responsible persons will be demoted, dismissed or fired:

(1) Fail to release recall information to society as stipulated;

(2) Fail to report to relevant department or inform relevant recall information as stipulated;

(3) Fail to take mandatory recall measures when supposed to;

(4) Violate stipulations set out in Article 23 and Paragraph 2 of Article 27 of the Measures and fail to supervise and urge medical device producing enterprises to effectively implement recalls.

Chapter 6 Supplementary Provisions

Article 35 If medical devices recalled are already implanted in human body, medical device producing enterprises shall negotiate with medical organizations and patients and put forward opinions on handling of patients and plan measures to take according to different causes of recall.

Article 36 If medical devices recalled cause damages to patients, the patients may request compensation from medical device producing enterprises as well as medical device operating enterprises and using units. If patients request compensation from medical device operating enterprises, and using units and medical device operating enterprises and using units compensate, the patients will have the right to demand compensation from responsible producing enterprises.

Article 37 The Measures are put into force since May 1, 2017. *Measures for the Administration of Medical Device Recalls (Trial)* (Order of Ministry of Health No. 82) put into force since July 1, 2011 are canceled simultaneously.