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No. 650

The Regulations on Supervisory Management of Medical Devices have been revised and approved at the 39th Executive Meeting of the State Council on February 12, 2014. The revised Regulations on Supervisory Management of Medical Devices are hereby promulgated and should be put into force upon June 1, 2014.

Premier, Li Keqiang

March 7, 2014

Regulations on Supervisory Management of Medical Devices

(Promulgated as No. 276 Decree of the State Council of the People's Republic of China on January 4, 2000; revised and approved at the 39th Executive Meeting of the State Council on February 12, 2014)

Chapter I General Rules

Article 1 These Regulations are formulated in order to protect the safety and effectiveness of medical devices and safeguard the physical health and life safety of the public.

Article 2 Any unit or individual engaged in the research, manufacture, operation, use, supervisory management of medical devices within the territory of the People's Republic of China should abide by these Regulations.

Article 3 The State Food and Drug Administration should be responsible for the supervisory management of medical devices all over the country. Relevant departments under the State Council should be responsible for the work relating to the supervisory management of medical devices within their respective scopes of responsibility.

The food & drug supervision departments of various local people's governments above the county level should be responsible to supervise and manage the medical devices within their respective administrative regions. Relevant departments of various local people's governments above the county level should be responsible for the work relating to supervision and management of medical devices within their respective scopes of responsibility.

The Food and Drug Administration Department of the State Council should cooperate with relevant departments of the State Council to carry out and implement the planning for and policies on the medical devices industry.

Article 4 The State should carry out classified management for medical devices according to its potential risk.

The medical devices with lower risks are categorized as Class I medical devices; their safety and effectiveness can be guaranteed by implementing general management.

The medical devices with moderate risks are categorized as Class II medical devices; their safety and effectiveness can be guaranteed by implementing stricter management.

The medical devices with higher risks are categorized as Class III medical devices; their safety and effectiveness can be guaranteed by taking special measures and by stricter management.

When evaluating the risks of any medical devices, their intended use, structural feature, use method and other factors must be taken into account.

The Food and Drug Administration Department of the State Council should be responsible for formulating classification rules and classified catalogue for medical devices, and should, depending on the production, operation and application of medical devices, analyze and evaluate their risk changes in a timely manner and then adjusts the classified catalogue. When formulating and adjusting the classified catalogue, the opinions and suggestions from manufacturers, users and various medical devices associations should be taken into account sufficiently, while referring to international medical device classification practice. The classification catalogue of medical devices should be published to the society.

Article 5 The research and manufacture of medical devices should follow the principles of safety, effectiveness and cost conservation. The State encourages various manufacturers to research innovative medical devices and take full advantage of the role of market mechanism to promote popularization and application of new technologies in medical devices so as to boost the development of the medical devices industry.

Article 6 All medical devices and products should comply with the mandatory standards of the state for medical devices. If there is no mandatory national standards, the compulsory standards of medical devices industry should be executed.

The catalogue of single-use medical devices should be formulated, adjusted and publicized by the food & drug administration department of the State council together with the health and family planning departments of the State Council. Any medical devices whose safety and effectiveness can be guaranteed in case of reuse should not be listed in the catalogue of single-use medical devices. Any medical devices whose safety and effectiveness can be guaranteed in case of reuse after having their designs, production processes, disinfection & sterilization technologies improved should be deleted from the catalogue of single-use medical devices.

Article 7 Various industrial associations in the field of the medical device industry should strengthen self-discipline, promote the construction of a credit system, urge

enterprises to carry out various production and operation activities in compliance with laws and guide enterprises to be honest and trustworthy.

Chapter II Registration and Notification of Medical Devices

Article 8 Class I medical devices are for notification-based management and Class II and Class III are for registration-based management.

Article 9 When Class I medical devices are submitted for notification and Class II and Class III medical devices are submitted for applying for registration, the following information should be submitted:

- (I) Analysis on risks of the product;
- (II) Technical requirements for the product;
- (III) Test report of the product;
- (IV) Clinical evaluation data;
- (V) The Instructions for Use and the sample of product labels for the product;
- (VI) Quality Assurance System documents related to product research & development and manufacture;
- (VII) Other documents necessary to prove the safety and effectiveness of the medical device.

The registration applicant and the person to submit the medical device for notification should be responsible for the authenticity of all the documents submitted.

Article 10 For Class I medical devices, the person to submit the product for notification should submit all the required documents to the food & drug administration department of the local municipal-level people's government. The test report therein may be an internal test report of the applicant; the clinical evaluation data should not include the clinical trial report and may be the document that uses the data obtained from references or during clinical application of similar products to prove their safety and effectiveness.

An overseas manufacturing enterprise that exports Class I medical devices to China may have their documents required for notification and the official marketability certificates issued by state/local authority submitted by their representative office or legal representative in China to the Food and Drug Administration Department of the State Council.

If any items stated in any document submitted for notification change, the applicant should submit it to the original competent department for notification.

Article 11 When submitting Class II medical devices for registration application, the applicant should submit all the documents required for registration to the food and drug administration department of the local government of the province, autonomous region or municipality directly under the central government where the applicant is

located. The applicant to submit Class III medical devices for registration should submit the application documents to the Food & Drug Administration department of the State Council.

An overseas manufacturing enterprise that exports Class II and Class III medical devices to the territory of China should have their documents required for registration application and the marketability certificates issued by state/local authority submitted by their representative office or legal representative in China to the Food and Drug Administration Department of the State Council.

The product test report contained in the registration application documents for Class II and Class III medical devices should be the test report issued by a medical device test institution; the clinical evaluation document therein should include the clinical trial report, unless the medical devices are exempted from undergoing the clinical trial according to Article 17 of these Regulations.

Article 12 The Food and Drug Administration Department accepting the registration application should transfer the registration application documents to the technical evaluation institution within 3 working days upon acceptance. The technical evaluation institution should submit its evaluation opinions to the Food and Drug Administration Department.

Article 13 The Food and Drug Administration Department accepting the registration application should approve or disapprove the application within 20 working days upon receiving the evaluation opinion. For those complying with safety and effectiveness requirements, the registration should be approved and the Medical Device Registration Certificate should be issued; for those not complying with requirements, the registration should not be approved, but the disapproval reasons should be given in writing.

If the Food and Drug Administration Department of the State Council considers it necessary to check the Quality Assurance System during the process of examining and evaluating an imported medical device, the quality assurance system certification institution should be organized to check the Quality Assurance System.

Article 14 If the design, raw material, manufacturing technique, scope of application, method of application and other information of any registered Class II or III medical device have any substantial change and such change may impact the safety and effectiveness of the medical device, the applicant should apply to the original registration authority for changing the registered information; if there's no substantial changes or the change would not influence the safety and effectiveness, such changes should be reported to the original registration authority for notification.

Article 15 The validity period of a Medical Device Registration Certificate should be 5 years. If needing to extend the registration due to expiration of the validity period, an application for extending registration should be submitted to the original registration department within 6 months prior to expiration.

Except for any case mentioned in Clause 3 of this Article, the Food and Drug Administration Department accepting the application for registration extension should

approve or disapprove the application before the validity period of the original Medical Device Registration Certificate ends. Any failure in approving or disapproving such application within the specified period of time should be deemed as having been approved for extending registration.

In any of the following cases, the registration should not be allowed for extension:

- (I) The applicant fails in submitting the application for extending registration within the specified time limit;
- (II) The compulsory medical device standard has been revised but the medical device submitted for registration extension application does not meet the new requirements;
- (III) Any medical device to be used to cure unusual disease or respond to emergent public health event fails in meeting the requirements specified in the registration certificate within the specified period of time.

Article 16 For a medical device newly developed but having not been listed in the classification catalogue, the applicant may submit it directly for registration application in accordance with the provisions set forth in these Regulations for Class III medical devices, or may judge the product category according to the classification rules and then submit it for registration application or notification after its category is confirmed by the Food and Drug Administration Department of the State Council.

For those class III medical devices directly applying for registration, the Food and Drug Administration Department of the State Council should determine its category depending on its degree of risk, and should timely incorporate the medical device approved of registration into the classification catalogue. For those applying for category confirmation, the Food and Drug Administration Department of the State Council should determine the class of the medical device and notify the applicant within 20 working days after the application.

Article 17 For any Class I medical device submitted for notification, there is no need for a clinical trial. The clinical trial should be conducted when a Class II/III medical device is submitted for registration application. In any of the following cases, however, the clinical trial may be exempted:

- (I) The medical device is a product having definite working mechanism, finalized design and mature production processes, while there have been similar medical devices of similar specifications already applied clinically for many years without severe effect and its regular usage would not be changed;
- (II) The safety and effectiveness can be proven through non-clinical assessment;
- (III) The safety and effectiveness of the medical device can be proven through the analysis and evaluation by using the data obtained from the clinical trial of similar product or during clinical application.

The catalogue of medical devices exempted from clinical trial should be formulated, adjusted and published by the Food and Drug Administration Department of the State Council.

Article 18 The clinical trial for a medical device should be executed by a qualified clinical trial institute in compliance with the Specifications for Quality Control of Clinical Trial for Medical Devices and should be submitted for notification in the Food and Drug Administration Department of the people's government of the local province, autonomous region or municipality directly under the central government where the clinical trial proposer is located. The Food and Drug Administration Department accepting the application for clinical trial notification should notify the notification details to the Food and Drug Administration Department and health & family planning administration department at the same level where the clinical trial institution is located.

The conditions for qualification authentication of clinical trial institutes and the Specifications for Quality Control of Clinical Trials should be jointly formulated and published by the Food and Drug Administration Department of the State Council and the health & family planning department of the State Council. The Food and Drug Administration Department and the health & family planning department of the State Council should be jointly responsible for authenticating the clinical trial institute of medical devices and publicizing the list of qualified clinical trial institutions.

Article 19 Clinical trial of class III medical devices that has high risk to human body should be approved by the Food and Drug Administration Department of the State Council. The catalogue of Class III medical devices having relatively higher risks to human body should be formulated, adjusted and published by the Food and Drug Administration Department of the State Council.

When examining and approving a clinical trial, the Food and Drug Administration Department of the State Council should comprehensively analyze such conditions as equipment, professionals, etc. of the institution undertaking the clinical trial, the risk level of such medical device and implementation scheme of clinical trial, clinical benefits and risk analysis report and so on. Any institute approved to carry out a clinical trial should be reported to the clinical trial proposer, the Food and Drug Administration Department and the health & family planning administration department of the people's government of the province, autonomous region, and municipality directly under the central government where the clinical trial institution is located.

Chapter III Production of Medical Devices

Article 20 Those to produce medical devices should meet the following requirements:

- (I) Have the production site, environment and conditions, production equipment and professionals appropriate to the production of the medical device;

- (II) Have the institution, or personnel and testing equipment available for quality inspection of the medical device produced;
- (III) Have the quality assurance system that can guarantee the quality of medical devices;
- (IV) Have after-sales service ability compatible with the manufactured medical device;
- (V) Meet the requirements set forth in product development and manufacturing process documents.

Article 21 An applicant engaged in production of Class I medical devices should submit a notification application to the food & drug administration department of the municipal-level government of the region where it is located and should submit all the certification documents meeting the requirements set forth in Article 20 of these Regulations.

Article 22 An applicant engaged in production of Class II and Class III medical devices should apply to the Food and Drug Administration Department of the people's government of the province, autonomous region and municipality directly under the central government where it is located for production permit and submit the certification documents meeting the requirements given in Article 20 of these Regulations.

The Food and Drug Administration Department accepting application should examine the application documents within 30 working days from the date of acceptance, conduct field inspection according to the requirements of the Specifications for Production Quality Assurance of Medical Devices. If the specified requirements are met, a production permit for medical devices should be approved and issued; if the requirements are not met, no permit will be issued and the reasons should be stated in writing..

The validity period of such Production Permit is 5 years. Those needing extension should have the extension formalities gone through according to relevant statutory provisions.

Article 23 The Specifications on Quality Assurance of Medical Devices should clearly define the design, development, conditions of manufacturing devices, purchase of raw material, process control, organization setting and manning of the enterprise and any other issues possible to impact safety and effectiveness of the medical device.

Article 24 The enterprise to manufacture medical devices should, in compliance with the Specifications for Quality Assurance of Medical Devices, establish and perfect its quality assurance system for medical devices and keep it effective; organize the production strictly according to the technical requirements submitted for registration or notification and ensure the medical device delivered meet the mandatory standards and the technical requirements submitted for registration and notification.

Medical device manufacturing enterprise should conduct regular self-test to the Quality Assurance System and submit the self-test report to the Food and Drug Administration Department of the people's government of the province, autonomous region and municipality directly under the central government where it is located.

Article 25 In the event that the production conditions of medical device manufacturing enterprise change and do not meet the requirements of the Quality Assurance System of medical device anymore, the medical device manufacturing enterprise should immediately taken rectification measures; if the safety and effectiveness of the medical device might be affected, the production activity should be immediately stopped and reported to the Food and Drug Administration Department of the people's government at the level of county where it is located.

Article 26 Medical devices should have a generic name. The generic name should conform to the naming rules for medical device formulated by the Food and Drug Administration Department of the State Council.

Article 27 Any medical devices should be accompanied with an Instructions for Use and appropriate labels. The content of such labels should be consistent with those submitted for registration or notification.

The instructions for use or labels of a medical device should indicate the following items:

- (a) Generic name, model and specification;
- (b) Name, registered address, production site and contact information of manufacturing enterprise;
- (c) Serial number required in the technical specification of the product;
- (d) Production date and service life or invalidation date;
- (e) The performance, main structure and scope of application of the medical device;
- (f) Contraindications, precautions and other required warning or caution information;
- (g) Instructions for Installation and Use or Schematic Diagrams
- (h) Maintenance method, special storage conditions and method;
- (i) Other contents that should be indicated as specified by the technical specifications of the medical device.

For Class II and Class III medical devices, the numbers of their Medical Device Registration Certificates and the name, address and contact information of the certificate holder of the medical device should be indicated as well.

As to any medical device to be used by the individual consumer, the special instructions for safe use should be given.

Article 28 For the medical device manufactured under entrustment, the entrusting party is responsible for the quality of the medical device. The entrusted party should be a medical device manufacturer that complies with these Regulations and possesses

relevant manufacture conditions. The entrusting party should strengthen the management on the manufacturing behavior of the entrusted party and ensure that the entrusted party implements the production according to statutory requirements.

The implantable medical device with higher risk should not be manufactured under entrustment. The catalogue of the medical device varieties prohibited for manufacture under entrustment should be formulated, adjusted and published by the Food and Drug Administration Department of the State Council.

Chapter IV Operation and Application of Medical Devices

Article 29 The enterprise engaged in operational activities of medical devices should possess the operation premises and storage conditions appropriate to the operation scale and scope as well as the Quality Assurance System and quality management organ or personnel appropriate to the medical device.

Article 30 The enterprise engaged in operation of Class II medical devices should submit a notification application to the Food and Drug Administration Department of the municipal people's government where it is located and submit the supporting certification documents complying with Article 29 of these Regulations.

Article 31 The enterprise engaged in operation of Class III medical devices should apply for a Medical Device Operation Permit from the Food and Drug Administration Department of the municipal people's government where it is located and submit the certification documents required in Article 29 of these Regulations.

The Food and Drug Administration Department accepting the application should check the application within 30 working days after receiving the application, and if necessary, organize a review. If meeting the specified requirements, an operation permit for medical devices shall be approved and issued. If not meeting the specified requirements, such permit shall not be approved, but the reasons should be given in writing.

The validity period of a Medical Device Operation Permit is 5 years. If it is required for extension prior to expiration, the validity period extension formalities should be gone through according to relevant statutory provisions.

Article 32 When purchasing a medical device, the enterprise to operate or use the medical device should check and verify the qualification of the supplier and the conformity certificate of the medical device. An enterprise engaged in wholesale of Class II/III medical devices or in retail of Class III medical devices should establish a sales recording system.

The items to be recorded should include:

- (a) Name, specification, model, specification and quantity of medical devices;
- (b) Production lot number, period of validity, and sales date of medical device;
- (c) Name of manufacturing enterprise;

(d) Name, address and contact information of the supplier or purchaser;

(e) No. of relevant licensing documents.

The incoming inspection & test records and the sales records of medical devices should be authentic and be stored according to the time limit stipulated by the Food and Drug Administration Department of the State Council. The state encourages to adopt advanced technologies and measures to record.

Article 33 The medical devices should be transported and stored in compliance with their Instructions for Use and labels; in the event that there are special requirements for temperature, humidity and other environmental conditions, some appropriate measures should be taken to guarantee the safety and effectiveness of medical devices.

Article 34 Medical device users should have the storage place and conditions compatible with the variety and quantity of medical devices in use.

Medical device users should strengthen technical training for operating persons so as for them to use the medical device in accordance with the Instructions for Use, technical operation standard and other requirements.

Article 35 Medical device users should use any reusable medical device according to the Sterilization and Management Regulations for medical devices formulated by the health and family planning administration department of the State Council.

Any single-use medical device should not be reused. Any used single-use medical device should be destroyed and recorded according to relevant provisions of the state.

Article 36 The user of a medical device should examine, inspect, calibrate and maintain the medical device at regular intervals according to the Instructions for Use and record the results and make timely analysis and evaluation so as to ensure the medical device is in good state and guarantee the application quality. An archive should be created for any medical device with long service life, recording relevant matters including use, maintenance, transfer, valid service life, etc.. The storage time of such records should not be less than 5 years after the expiration of the specified service life of the medical device.

Article 37 The user of a medical device should properly preserve the original documents of any purchased Class III medical device and ensure the traceability of the information.

The user of large-scale medical device, implantable and interventional medical device should record the name, key technical parameters and necessary information closely related to application quality and safety into the case history or other relevant files.

Article 38 If it is found that any medical device has any potential safety hazards, the medical device user should immediately stop the use, and notify the manufacturing enterprise or other institutions responsible for its quality to conduct inspection and maintenance; the medical device that still can't meet usage safety standard should no longer be used.

Article 39 The Food and Drug Administration Department and the health & family planning administration department should supervise and administer the quality of the medical device in use and the application behavior in various application nodes respectively depending on their respective duties.

Article 40 Any medical device operator or user shall not trade or use any medical device not legally registered or without conformity certificate or is expired, invalid or obsolete.

Article 41 In the event that any medical device in use is to be transferred between medical device users, the transferor should guarantee the safety and effectiveness of the medical device to be transferred. Any expired, invalid, out-of-date or unqualified medical device shall not be transferred.

Article 42 Any medical device to be imported must be the one that has been registered or submitted for notification in accordance with Chapter II of these Regulations.

Any imported medical device should have Chinese Instructions for Use and labels. The instructions for use and labels should meet the requirements set forth in these Regulations and relevant compulsory standard, while specifying the country of origin, name, address and contact information of the agent. Any medical device without Chinese instructions for use and labels or with instructions for use and labels not meeting the requirements of this article shall not be imported.

Article 43 The entry and exit inspection and quarantine institution should inspect and test any imported medical device according to laws; those being proven unqualified shall not be imported.

The Food and Drug Administration Department of the State Council should timely report the registration and notification information of the imported medical device to the entry and exit inspection and quarantine department of the state. The entry and exit inspection and quarantine institution at the location where the import port is located should immediately report the customs clearance conditions to the Food and Drug Administration Department of the municipal people's government of the region where it is located.

Article 44 Enterprises exporting medical devices should ensure that the medical device to be exported meet the requirements of the importation country (region).

Article 45 Any advertisement of any medical device must be authentic and legitimate but should not contain any false, exaggerated or misleading contents.

The advertisement of medical device should be subject to the examination and approval of the Food and Drug Administration Department of the people's government of the province, autonomous region, or municipality directly under the central government where the medical device manufacturing enterprise or medical device agent is located, and obtain the approval document for medical device advertising. The advertisement publishers publishing the advertisement of medical device should check the approval document for advertising and verify its authenticity

in advance; the advertisement publishers should not release medical device advertisement that has not obtained approval document or the authenticity of the approval document has not be verified or the contents of the advertisement is inconsistent with the approval document. The Food and Drug Administration Department of the people's government of the province, autonomous region, or municipality directly under the central government should publish and update the catalogue of the approved medical device advertisements and the contents of the approved advertisements.

The medical device that have been instructed to stop manufacturing, sales and use by the Food and Drug Administration Department of the people's government above the provincial level should not have the medical device advertisement published in the suspension period.

The administrative measures for examination and approval of medical device advertisements shall be formulated by the Food & Drug Administration department of the State Council jointly with the Industrial and Commercial Administration department of the State Council.

Chapter V Treatment of Adverse Events and

Recall of Medical Device

Article 46 The State shall establish the medical device related adverse event monitoring system to collect, analyze, evaluate, and control medical device related adverse events.

Article 47 Any enterprise to operate and use any medical device should monitor any adverse event to arise from production, operation or application of the medical device. Any adverse event if found or any suspected adverse event should be reported to the medical device related adverse event monitoring institute in accordance with the provisions of the Food and Drug Administration Department of the State Council.

Any organization and/or individual is entitled to report to the Food and Drug Administration Department or the adverse event monitoring institution if finding any medical device adverse event or suspected adverse event.

Article 48 The Food and Drug Administration Department of the State Council should strengthen the construction of medical device related adverse events monitoring network.

The Monitoring Institute for Adverse Events of Medical Devices should make more efforts to monitor medical device related adverse events, and take initiative to collect the information on adverse events; timely conduct verification, investigation, analysis and evaluation in a timely manner when finding any adverse event or receiving any adverse event report, and submit appropriate settlement suggestions to the Food and Drug Administration Department and the health & family planning administration department.

The medical device related adverse event monitoring institute should publicize their contact information to facilitate medical device manufacturers and users to report any medical device related adverse event.

Article 49 The Food and Drug Administration Departments should, in a timely manner, take appropriate control measures according to the results of the evaluation on the medical device adverse events, including releasing warning information and ordering to stop production, selling, importing or application.

The Food and Drug Administration Department of the people's government above the provincial level should, jointly with the health & family control planning departments and other organizations at the same level, organize the investigation and settlement of any medical device related adverse events that cause sudden, serious injury or death affecting a large of people in a timely manner, and strengthen the monitoring for similar medical devices.

Article 50 Medical device manufacturers, operators and and users should assist the medical device related adverse event monitoring institutes and the Food and Drug Administration Department in investigating any adverse events.

Article 51 In any of the following circumstances, the Food and Drug Administration Department of the people's government above the provincial level should organize a re-evaluation for registered medical devices:

- (a) In the event that there is any change on safety or effectiveness of medical device due to the development of scientific research;
- (b) In the event that the monitoring and analysis results on medical device related adverse events show that the medical device possibly has potential safety hazards;
- (c) In any other case that needs re-evaluation as stipulated by the Food and Drug Administration Department of the State Council.

In the event that the re-evaluation results show that the safety and effectiveness of a registered medical device cannot be guaranteed, the Medical Device Registration Certificate should be cancelled by the original certificate issuing department, which should be then made known to the public. Any medical device with the Medical Device Registration Certificate being cancelled should not be manufactured or imported, sold and used.

Article 52 If it is found that the medical device manufactured does not comply with the compulsory standard and the technical requirements for registered or archived products, or have other defects, the medical device manufacturer should immediately stop the manufacturing, notify relevant manufacturers, operators and consumers to stop the use and operations, and recall the sold medical device, take appropriate remedy, destruction or other measures, record relevant information, publish relevant information and report the recall and treatment details to the Food and Drug Administration Department and the health & family planning administration department.

If any medical device operator finds that the medical device is in any of the aforesaid cases, they should immediately stop the operation, notify relevant manufacturers, operators, users and consumers and record the operation termination and notification details. If the medical device manufacturer thinks that the medical device belongs to the medical devices that need to be recalled according to the above article, it should be recalled immediately.

If any medical device manufacturer and operator fails in recalling or stopping the operation of the medical device mentioned in this article, the Food and Drug Administration Department may order them to recall or stop operation.

Chapter VI Supervision and Inspection

Article 53 The Food and Drug Administration Department should strengthen the supervision and inspection for registration, notification, manufacturing, operating and application activities of medical devices, especially supervising and inspecting the following items:

- (a) Whether the medical device manufacturer has organized the manufacturing according to the technical requirements of the product submitted for registration or notification;
- (b) Whether the Quality Assurance System of the medical device manufacturer is kept effective;
- (c) Whether the manufacturing and operation conditions of the medical device manufacturer meets the statutory requirements continuously.

Article 54 During supervision and inspection, the Food and Drug Administration Department shall have the following rights:

- (a) Access the site for inspection and sampling;
- (b) Browse, reproduce, seal up, and detain relevant contracts, bills, account books and other relevant documents;
- (c) Seal up and detain any medical device not complying with statutory requirements, any illegally used parts, fittings or raw materials and any tools or equipment used for illegal production;
- (d) Close down any premises to be used for any illegal production or operation activities in connection with medical devices specified in this article.

To conduct any supervision and inspection, the Food and Drug Administration Department should first show their qualification certificate and should keep the commercial secrets of the inspected enterprises confidential.

Associated organizations and/or individuals should offer assistance and cooperation to the Food and Drug Administration Department during such supervision and inspection but should not conceal any relevant information.

Article 55 If there is any hazard to human body or there is evidence proving that it is possible to do harm to human health, the Food and Drug Administration Department may take emergent control measures such as suspending production, importation, operation or application.

Article 56 The Food and Drug Administration Department should strengthen regular or irregular sampling inspection on all the medical devices manufactured, operated, and used by medical device manufacturers and operators and users. No inspection fee or other expense shall be charged for such sampling inspection but all the expenses arising thereof shall be disbursed from the financial budget of the government at the same level.

The food & drug administration department of a people's government above the provincial level should, depending on the sampling inspection results, publicize an announcement on quality of relevant medical devices.

Article 57 The State should implement a uniform qualification authentication system for medical device inspection institutions. Only the inspection institution recognized by the Food and Drug Administration Department of the State Council together with relevant national certification and accreditation departments can carry out the inspection of medical devices.

If the Food and Drug Administration Department needs to inspect any medical device in the law enforcement course, it should entrust a qualified medical device inspection institution and pay relevant expenses.

If having any disagreement on the inspection results, the inspected enterprise may select a qualified medical device inspection institution to conduct a re-inspection within 7 working days upon receiving the inspection results. The medical device inspection institution undertaking the re-inspection work should give the reinspection results within the time limit specified by the Food and Drug Administration Department of the State Council. The re-inspection results shall be final.

Article 58 If any medical device possibly contains any hazardous substance or its design, raw materials or production process is changed without authorization so that there is any potential safety hazards, but the medical device cannot be correctly inspected according to the inspection items and inspection methods specified by national standard and industry standard, the medical device inspection institution may use appropriate supplementary inspection items and methods for inspection. The inspection results obtained by using supplementary inspection items and methods, if approved by the food & drug administration department of the state council, may be used as the basis for the Food and Drug Administration Department to judge the quality of medical device.

Article 59 The Food and Drug Administration Department of the people's government at the municipal or county level with districts should strengthen the supervision and inspection of medical device advertisements. Any medical device advertisement not being approved or with the content modified without authorization should be reported to the Food and Drug Administration Department of the people's

government of the local province, autonomous region or municipality directly under the central government, while being publicized to the public.

Industrial and commercial administration departments should supervise and check any medical device advertising activities according to the relevant laws and administrative rules on advertisements and investigate and punish any illegal acts. If any illegal advertising act pertaining to medical devices is found, the food and drug administration department should immediately put forward punishment suggestions and submit it to the local industrial and commercial administration department at the same level according to relevant procedures.

Article 60 The Food and Drug Administration Department of the State Council shall set up a uniform medical device supervision and management information platform. The Food and Drug Administration Department should use the platform to release the daily supervision and management information relating to licensing, notification, sampling inspection and illegal acts in connection with medical devices in a timely manner. However, no business secret of the party concerned should be disclosed.

The Food and Drug Administration Department should establish a credit system for registration applicants, notification applicants, manufacturers, operators and users of medical devices and conduct more frequent supervision and inspection to those of bad credit records.

Article 61 The Food and Drug Administration Department and other similar departments should publicize their contact information to accept consultation, complaint and reporting. The Food and Drug Administration Department should make timely reply after receiving any consultation, complaint or reporting relating to medical device supervision and inspection and should make timely verification, treatment and reply. The consultation, complaint and reporting details and the reply, verification and treatment should be recorded and stored.

If the information reported against illegal or incorrect research, development, production, operation and application of any medical device is proven true, the food the drug administration department and other relevant departments should reward the informer.

Article 62 The Food and Drug Administration Department of the State Council should publicly solicit opinions when formulating, adjusting and modifying the catalogue specified in these Regulations and provisions relating to medical device administration, while listening to the opinions of experts, medical device manufacturers and operators, users, consumers, and relevant associations by way of hearing, discussion, etc.

Chapter VII Legal Responsibility

Article 63 In any of the following circumstances, the Food and Drug Administration Department of the people's government above the level of county should confiscate any illicit incomes, the medical device illegally manufactured and

operated, and such articles as the tools, equipment, and raw materials used for illegal manufacturing and operation; in case the value of the medical device illegally manufactured and operated is less than RMB 10,000, a penalty higher than RMB 50,000 but lower than RMB 100,000 should be imposed additionally; in case the value of the medical device illegally manufactured and operated is above RMB 10,000, a penalty at more than 10 times but less than 20 times of the value of the goods should be imposed additionally; in cases of gross violation, any medical device permit application from the person and enterprise concerned shall be rejected within the next 5 years:

(a) Manufacture and operate Class II and Class III medical devices without obtaining the Medical Device Registration Certificate;

(b) Engage in the manufacturing activities of Class II and Class III medical device without authorization;

(c) Engage in the operating activities of Class III medical devices without authorization;

If committing the acts specified in Item (a) in the previous article and the case is of gross violation, the Medical Device Manufacturing Permit and the Medical Device Operating Permit should be revoked by the original issuing authority.

Article 64 If any Medical Device Registration Certificate, Medical Device Manufacturing Permit, operation permit or advertisement permit is obtained by providing false information or taking other deception means, it shall be revoked by the original issuing authority, while a penalty above RMB 50,000 but less than RMB 100,000 should be imposed and no application for medical device related license or permit submitted by the person and enterprise concerned shall be accepted within 5 years.

In case of falsifying, altering, buying and selling, leasing, and borrowing relevant medical device licensing certificate, the original issuing authority should confiscate or cancel the certificate involved and confiscate the illegal incomes; for illegal income of less than RMB 10,000, a penalty above RMB 10,000 but less than RMB 30,000 should be imposed additionally; for illegal income of more than RMB 10,000, a penalty at more than 3 times and less than 5 times should be imposed additionally; for those acts that violate public security regulations should be given a public security punishment by the public security organ.

Article 65 In case of failure in submitting the product for notification according to the provisions of these Regulations, the Food and Drug Administration Department of the people's government above the county level should order the applicant to correct within specified time limit; for those do not make corrections within the time limit, the unrecorded organizations and product names shall be publicized to the society, and a penalty below RMB 10,000 should be imposed additionally.

In case of providing false materials when applying for notification, the Food and Drug Administration Department of the people's government above the level of county should publicize the applicant and its product names to the society; in serious cases,

the persons responsible shall be prohibited from engaging in medical device manufacturing and operation activities within the next 5 years.

Article 66 In any of the following circumstances, the Food and Drug Administration Department of the people's government above the level of county should instruct the applicant to make correction and confiscate their medical devices illegally manufactured, operated or used; in case the value of the medical device illegally manufactured, operated or used is less than RMB 10,000, a penalty above RMB 20,000 but less than RMB 50,000 should be imposed additionally; in case that the value of goods is more than RMB 10,000, a penalty more than 5 times but less than 10 times of the value of the goods should be imposed additionally; in case of gross violation, the medical device manufacturing and operating enterprises should be instructed to suspend production or business until the Medical Device Registration Certificate, the Medical Device Manufacturing Permit and the Medical Device Operation Permit are revoked by the original issuing authority:

- (a) Manufacture, operate and use any medical devices that do not comply with the compulsory standard, or does not comply with technical requirements already submitted for registration or notification;
- (b) The medical device manufacturing enterprise fails to organize production according to the technical requirements submitted for registration or notification, or fails in establishing the Quality Assurance System and keeping it in effective operation according to the provisions of these Regulations;
- (c) Operate and use the medical device without conformity certificate, or is expired, invalid and obsolete, or use any medical device that have not been lawfully registered;
- (d) Refuse to recall or suspend operation even after the Food and Drug Administration Department instructs them to implement recall or suspend operation according to the provisions of these Regulations;
- (e) Entrust any enterprises that do not meet the requirements of these Regulations to manufacture any medical device, or fail in managing the manufacturing behaviors of the entrusted party.

Article 67 In any of the following circumstances, the Food and Drug Administration Department of the people's government above the level of county shall instruct the medical device manufacturing and operating enterprises to make correction and impose them a penalty above RMB 10,000 but less than RMB 30,000 additionally; in case of gross violation, the medical device manufacturing and operating enterprises should be instructed to suspend production or business until the Medical Device Registration Certificate, the Medical Device Manufacturing Permit and the Medical Device Operation Permit are revoked by the original issuing authority:

- (a) The Medical device manufacturing enterprise's manufacture conditions have changed and no longer meet the requirement of Quality Assurance System for medical devices, and/or the enterprise has not make the rectification, stop the production or submit the required report as required in these Regulations;

- (b) Manufacture and operate any medical device with instructions for use and labels not complying with these Regulations;
- (c) Fail in transporting or storing any medical device according to these Regulations;
- (d) Transfer expired, invalid, obsolete and/or any unqualified medical devices.

Article 68 In any of the following circumstances, the Food and Drug Administration Department and the health & family planning administration department of the people's government above the level of county shall instruct them to make correction and give warning; for those that refuse to make corrections, a penalty above RMB 5,000 but less than RMB 20,000 should be imposed additionally; in case of gross violation, the medical device manufacturing and operating enterprises should be instructed to suspend production and business until the Medical Device Manufacturing Permit and the Medical Device Operation Permit are revoked by the original issuing authority:

- (a) Medical device manufacturing enterprise fails in submitting the self-test report of their Quality Assurance System as required;
- (b) The Medical device operating enterprises and users fail in establishing and implementing incoming inspecting and recording system for medical devices according to these Regulations;
- (c) Enterprises engaged in wholesale of Class II and Class III medical devices or retail of Class III medical devices fail in establishing and executing a sales recording system according to these Regulations;
- (d) For reusable medical devices, the medical device user fails in conducting sterilization and management according to these Regulations;
- (e) The medical device user reuses any single-use medical devices or fails in destroying any single-use medical device according to these Regulations;
- (f) The medical device user fails in examining, inspecting, calibrating and maintaining any medical device at regular intervals according to the Instructions for Use or fails in recording these operations or conducting analysis and evaluation in time to ensure that such medical devices are in good state;
- (g) The medical device users fails in correctly safekeeping the raw documents of any Class III medical device after purchase, or fails in recording the information of any large medical device, implantable or interventional medical devices into relevant case history or other related records.
- (h) The medical device manufacturer, operator or user fails in stopping using or fails in notifying relevant organization or individual for troubleshooting or repairing any medical device of potential safety hazardous or continues to use any medical device not complying the safety standard after repair.
- (i) The manufacturer, operator or use of any medical device fails in monitoring any adverse events of any medical device, fails in reporting any adverse event or fails in offering assistance for any medical device related adverse event monitoring

organization or food & drug administration department for investigation of adverse event according to these Regulations.

Article 69 Any organization or individual conducting the clinical trial for any medical device that violates these Regulations shall be instructed to make correction or immediately stop clinical trial by the Food and Drug Administration Department of the people's government above the level of county and a penalty above RMB 10,000 but less than RMB 50,000 should be imposed additionally; in case of gross violation, the person(s) in charge and other persons responsible should be demoted, dismissed or expelled; the qualification of the medical device clinical trial institution undertaking the clinical trial shall be revoked by the original issuing authority and any application for qualification authentication shall not be accepted within 5 years.

In the event that a medical device clinical trial institution issues a false report, its qualification as clinical trial institution shall be revoked by the competent authority previously awarding the qualification and any application for qualification authentication submitted later shall not be accepted within 10 years; the Food and Drug Administration Department of the people's government above the level of county may impose a penalty above RMB 50,000 but less than RMB 100,000 additionally; any illegal income arising thereof shall be confiscated; the person(s) in charge and other persons directly responsible for it should be punished by dismissal or removal.

Article 70 In case that any medical device inspection institution issues a false test report, the competent authority previously awarding the qualification shall revoke the inspection qualification of this institution and shall not accept their application for qualification identification within 10 years; a penalty above RMB 50,000 but less than RMB 100,00 should be imposed additionally; any illegal income arising thereof shall be confiscated; the person(s) in charge and other persons directly responsible should be punished by removal or dismissal; the person(s) if dismissed shall be not allowed for engaging in medical device inspection works again within 10 years from the date of dismissal.

Article 71 Those who violate these Regulations to release any medical device advertisement without approval, or release any medical device advertisement without verifying the authenticity of the approval document in advance, or release medical device advertisement with contents inconsistent with the approval document, should be punished by the industrial and commercial administration department according to the advertising laws and administrative laws and Regulations.

In case of modifying the contents of the medical device advertisement approved, the approval document for the medical device advertisement should be revoked by the original issuing authority and any future application for advertisement should not be accepted within 2 years.

In case of publishing false medical device advertisement, the Food and Drug Administration Department of the people's government above the level of province should decide to suspend the sales of the medical device and make it known to the society; for those that still sell the medical device, the Food and Drug Administration

Department of the people's government above the level of county should confiscate the medical device illegally sold and impose a penalty above RMB 20,000 but less than RMB 50,000 additionally.

Article 72 In the event that any medical device inspection & evaluation institution or any medical device related adverse events monitoring institution fails in performing their duties according to these Regulations and results in serious errors, the Food and Drug Administration Department of the people's government above the level of county shall instruct them for corrections, issue notice of criticism and give warning; in case of grave consequence, the person(s) in charge and other persons directly responsible should be demoted, dismissed or expelled.

Article 73 The Food and Drug Administration Department and its staff should exercise their administrative punishment rights strictly in accordance with the types and severity of punishments specified in these Regulations and depending on the nature and severity of any illegal act. The specific measures shall be formulated by the Food and Drug Administration Department of the State Council.

Article 74 In case that any provisions of these Regulations are violated and the Food and Drug Administration Department of the people's government above the level of county or other relevant competent department fails in performing their responsibilities as specified in these Regulations or abuses any power, neglect its duties, and commits irregularities, the person(s) in charge and other direct responsible persons shall be punished by the supervisory organ or the office in charge of appointment and removal shall give him a warning, demerit recording punishment or a severe demerit recording punishment; in case of serious consequences, a punishment such as demotion, dismissal or removal should be imposed.

Article 75 If violation of any provisions of these Regulations constitutes a crime, a criminal sanction shall be imposed according to laws; if causing any health, property or other losses, the person violating these Regulations shall bear the responsibility for compensation.

Chapter VIII Supplementary Provisions

Article 76 The terms used in these Regulations should have the following meanings:

The medical device cited in these Regulations means instruments, equipment, apparatus, in vitro diagnostic reagents and calibrators, materials and other similar or related articles to be directly or indirectly used for human body, including necessary computer software, whose effects are achieved mainly by physical means instead of pharmacological, metabolic or immunological means or merely play a subsidiary role by such means and whose purpose mainly is for:

- (a) Diagnosis, prevention, monitoring, treatment, and relief of disease;
- (b) Diagnosis, monitoring, treatment, relief and functional compensation of injury;

- (c) Examination, substitution, adjustment or support of physiologic structure or physiologic process;
- (d) Support or sustainment of life;
- (e) Gestation control;
- (f) Provide information for medical treatment or diagnosis through examination on samples from human body.

Medical device user refers to the unit or individual that uses medical device to provide such technical services as medical treatment to others, including medical institutions that have obtained the Medical Institution Practicing License, family planning related technical service institutions that have obtained the Family Planning Related Technical Service Institution Practicing License, and blood station, single plasma station, rehabilitation supporting device fitting institution, etc. that do not need to obtain Medical Institution Practicing License.

Article 77 Appropriate expenses may be charged for registration of medical devices. The specific charging items and criteria shall be worked out by the competent financial department and/or pricing department of the State Council according to relevant regulations of the State.

Article 78 The administrative measures for non-profitting contraceptive medical devices and the administrative measures for medical device used to respond to sudden public health events shall be formulated by the Food and Drug Administration Department of the State Council together with the health & family planning administration department of the State Council.

The administrative measures for medical devices in connection with Chinese Traditional Medicine shall be formulated jointly by the Food and Drug Administration Department and the Chinese medicine administration department of the State Council according to these Regulations; the scope and administrative measures for auxiliary rehabilitation devices shall be formulated by the Food and Drug Administration Department and the Civil Administration Department of the State Council jointly according to these Regulations.

Article 79 The administrative measures for military medical device should be organized and implemented by military health administration department according to these Regulations and relevant military Regulations.

Article 80 These Regulations shall take effect on June 1, 2014.