State Council of the People's Republic of China Decree No. 650

No. 650

The *Regulation on the Administration of Medical Devices*, as revised and adopted at the 39th executive meeting of the State Council on February 12, 2014, is hereby promulgated and shall come into force on June 1, 2014.

Prime Minister Li Keqiang

March 7, 2014

The Regulation on the Administration of Medical Devices

(State Council of the People's Republic of China Decree No.276 Issued on January,4, 2000

Revised and adopted at the 39th executive meeting of the State Council on February 12, 2014)

Chapter 1 General Provisions

Article 1 This Regulation is formulated for the purposes of ensuring the safety and effectiveness of medical devices and guaranteeing human health and life safety.

Article 2 Whoever engages in the research and development, manufacturing, operation, use as well as administration of medical devices within the territory of the People's Republic of China shall abide by this Regulation.

Article 3 The food and drug administration department of the State Council shall be responsible for the administration of the medical devices nationwide. The relevant departments of the State Council shall be responsible for the administration with respect to medical devices within their respective functions.

The food and drug administration departments of the local people's governments at or above the county level shall be responsible for the administration of medical devices within their respective administrative regions. The relevant departments of the local people's governments at or above the county level shall be responsible for the administration with respect to medical devices within their respective functions.

The food and drug administrationadministrati of the State Council shall cooperate with the relevant departments of the State Council to implement the national plans and policies on the medical device industry.

Article 4 The state shall conduct the classification administration of medical devices according to their risk levels.

Medical devices of Class I mean the medical devices with low risks, of which safety and effectiveness can be ensured through routine administration.

Medical devices of Class II mean the medical devices with moderate risks, which shall be strictly controlled and administered to ensure their safety and effectiveness.

Medical devices of Class III mean the medical devices with relatively high risks, which shall be strictly controlled and administered through special measures to ensure their safety and effectiveness.

The evaluation of the risk levels of medical devices shall take consideration of the expected objectives, structural features, use methods and other factors of medical devices.

The food and drug administration department of the State Council shall be responsible for formulating the classification rules for and the classified catalogues of medical devices, and, according to the information on the manufacturing, operation and use of medical devices, timely analyzing and evaluating the risk changes of medical devices, and adjusting the classified catalogues; and shall formulate and adjust the classified catalogues, fully listen to the opinions of the manufacturing and operation enterprises, use entities and industry organizations of medical devices, and, conduct the classified practices by reference to those for international medical devices. The classified catalogues of medical devices shall be announced to the general public.

Article 5 The research and development of medical devices shall follow the principles of safety, effectiveness and economy. The state shall encourage the research and innovation of medical devices, and maximize the role of the market mechanism to promote the popularization and application of new technologies in medical devices, and drive the development of the medical device industry.

Article 6 The medical device products shall satisfy the national compulsory standards for medical devices, and, if no such standard is available, meet the compulsory industry standards for medical devices.

The catalogue of single-use medical devices shall be formulated, adjusted and published by the food and drug administration department of the State Council jointly with the administrative department of health and family planning of the State Council. The medical

devices of which safety and effectiveness can be ensured when being reused shall not be listed in the catalogue of single-use medical devices. The medical devices of which safety and effectiveness can be ensured when being reused due to the improvements in designs, manufacturing technologies, disinfection and sterilization technologies, etc. shall be removed from the catalogue of single-use medical devices.

Article 7 The medical device industry organizations shall strengthen the industry self-regulation, promote the construction of credit system, urge enterprises to conduct manufacturing and operation activities in accordance with the law, and guide enterprises to act in good faith.

Chapter 2 Registration and Filing of Medical Device Products

Article 8 The medical devices of Class I shall be subject to the product filing administration, and the medical devices of Class II and Class III shall be subject to the product registration administration.

Article 9 The following materials shall be submitted for the filing of the medical device products of Class I and the application for registration of the medical device products of Class II and Class III:

(1) Product risk analysis materials.

(2) Product technical requirements.

(3) Product inspection reports.

(4) Clinical evaluation materials.

(5) Sample manuscripts of product instructions and labels.

(6) Quality management system documents with respect to product research, development and manufacturing.

(7) Other materials required to prove the safety and effectiveness of the products.

Medical device registration applicants and the parties undergoing filing of medical devices shall be responsible for the authenticity of the materials submitted by them.

Article 10 For the filing of the medical device products of Class I, the parties undergoing filing of medical devices shall submit the filing materials to the food and drug administration departments of the local people's government at the districted city level. The product inspection reports thereof may be the self-inspection reports of the parties undergoing filing

of medical devices, and the clinical evaluation materials thereof exclude clinical trial reports, and may be the materials capable of proving the safety and effectiveness of the medical devices through literatures or the data obtained from the clinical application of similar products.

Where any overseas manufacturing enterprises export the medical devices of Class I to the territory of China, the representative offices established by them within the territory of China or the incorporated enterprises within the territory of China designed by them as agents shall submit to the food and drug administration department of the State Council the filing materials and the documents certifying the approval of the marketing of such medical devices by the competent departments in the countries (regions) where the parties undergoing filing of medical devices are located.

In case of any change of the matters as specified in the filing materials, the filing shall be modified at the original filing departments.

Article 11 To apply for the registration of the medical device products of Class II, registration applicants shall submit the registration application materials to the food and drug administration departments of the people's governments of the provinces, autonomous regions or municipality directly under the Central Government where such applicants are located. To apply for the registration of the medical device products of Class III, registration applicants shall submit the registration application materials to the food and drug administration department of the State Council.

Where any overseas manufacturing enterprises export the medical devices of Class II and III to the territory of China, the representative offices established by them within the territory of China or the incorporated enterprises within the territory of China designed by them as agents shall submit to the food and drug administration department of the State Council the registration application materials and the documents certifying the approval of the marketing of such medical devices by the competent departments in the countries (regions) where the registration applicants are located

The product inspection reports amid the application materials for the registration of the medical device products of Class II and Class III shall be the inspection reports issued by the medical device inspection institutions. Clinical evaluation materials shall include clinical trial reports, but exclude the reports on the medical devices exempt from clinical trials in accordance with the provisions of Article 17 of this Regulation.

Article 12 The food and drug administration departments accepting registration applications shall, within three working days from the dates of acceptance of applications, transfer the registration application materials to technical review institutions. Technical review institutions shall, after completing the technical review, submit the review opinions to food and drug administration departments.

Article 13 The food and drug administration departments accepting registration applications shall make decisions within 20 working days from the dates when the review opinions are received. The medical devices which meet the safety and effectiveness requirements shall be approved to be registered, and the medical device registration certificates shall be issued thereto, and for those failing to meet the requirements, the registration applications thereof shall be denied and the reasons therefor shall be given in writing.

Where the food and drug administration department of the State Council deems that it is necessary to verify the quality management system when organizing a technical review on any imported medical devices, it shall authorize a technical institution for quality management system inspection to conduct the verification of the quality management system.

Article 14 In case of any substantial change of the designs, raw materials, manufacturing technologies, scopes of application and application methods, etc., of the registered medical device products of Class II or Class III, which may affect the safety and effectiveness of such medical devices, the registrants shall apply to the original registration departments for undergoing the formalities for registration modification. In case of any non-substantial change thereof, which do not affect the safety and effectiveness of such medical devices, the information on the change shall be reported to the original registration departments for filing.

Article 15 A medical device registration certificate shall be valid for five years. If the registration of a medical device registration certificate needs to be renewed upon the expiration of its validity period, an application for registration renewal shall be filed with the original registration department six months before the validity period expires.

Except for the circumstances as prescribed in Paragraph 3 of this Article, the food and drug administration department receiving the registration renewal application shall make a decision on whether to approve the renewal thereof prior to the expiration of the medical device registration certificate. The failure to make such a decision within a prescribed time limit shall be deemed as the approval of the renewal.

The registration shall not be renewed under any of the following circumstances:

(1) The registrant fails to file a registration renewal application within a prescribed time limit.

(2) The compulsory standards for medical devices have been revised, and the medical devices subject to the application for registration renewal fail to meet the new requirements.

(3) The matters as specified in the medical device registration certificate fails to be completed within a prescribed time limit with respect to the medical devices used for treating rare diseases or urgently needed to respond to public health emergencies.

Article 16 For the newly researched and developed medical devices which have not been listed in the classified categories, applicants may directly apply for the product registration in accordance with the provisions of this Regulation on the registration of the medical device products of Class III, or may, according to the classification rules, determine the product categories, and apply for the product registration or filing in accordance with the provisions of this Regulation after applying for the category confirmation to the food and drug administration department of the State Council.

For any direct applications for the registration of the medical device products of Class III, the food and drug administration department of the State Council shall determine the categories according to the risk levels, and timely incorporate the medical devices approved to be registered into the classified catalogues. Where any application categories have been confirmed, the food and drug administration department of the State Council shall, within 20 working days from the dates of acceptance of applications, determine the categories of such medical devices and inform the applicants of the determination results.

Article 17 Clinical trials are not required for the filing of the medical devices of Class I, but necessary for the application for the registration of the medical devices of Class II and Class III. However, medical devices may be exempt from clinical trials under any of the following circumstances:

(1) The same categories of the marketed medical devices with clear and definite working mechanisms, finalized designs and mature manufacturing technologies have been put into clinical application for years, with no record of severely adverse event and with their general purposes unchanged.

(2) The safety and effectiveness of such medical devices can be proved through non-clinical evaluation.

(3) The safety and effectiveness of such medical devices can be proved through the analysis

and evaluation of the data obtained from the clinical trials or clinical application of the same categories of medical devices.

The catalogue of the medical devices exempt from clinical trials shall be formulated, adjusted and published by the food and drug administration department of the State Council.

Article 18 The clinical trials of medical devices shall be conducted in qualified clinical trial institutions in accordance with the requirements of the quality management norms for the clinical trials of medical devices, and be reported for filing to the food and drug administration departments of the people's governments of the provinces, autonomous regions or municipalities directly under the Central Government where the clinical trial presenters are located. Food and drug administration departments accepting the clinical trial filing shall notify the filing information to food and drug administration departments and administrative departments of health and family planning at the same level in the places where the clinical trial institutions are located.

The qualification accreditation conditions of medical device clinical trial institutions and the clinical trial quality management norms shall be formulated and published by the food and drug administration department of the State Council jointly with the administrative department of health and family planning of the State Council. The medical device clinical trial institutions shall be determined and published by the food and drug administration department of the State Council jointly with the administrative department of health and family planning of the State Council.

Article 19 The medical devices of Class III which may pose relatively high risks to human bodies according to the clinical trials thereof shall be approved by the food and drug administration department of the State Council. The catalogue of the medical devices of Class III which may pose relatively high risks to human bodies according to the clinical trials thereof shall be formulated, adjusted and published by the food and drug administration department of the State Council.

The food and drug administration department of the State Council shall, when approving clinical trials, conduct a comprehensive analysis on the devices, professionals and other conditions of the institutions planning to undertake the medical device clinical trials, the risk levels of such medical devices, the implementation plans for the clinical trials, and clinical benefit and risk comparison and analysis reports, etc.. Where any clinical trial is approved, a notification shall be given to the clinical trial presenter and the food and drug administration

department and the administrative department of health and family planning of the people's government of the province, autonomous region or municipality directly under the Central Government where the clinical trial institution is located.

Chapter 3 Manufacturing of medical devices

Article 20 An enterprise engaging in the manufacturing of medical devices shall meet the following conditions:

(1) Having the manufacturing site, environmental conditions, manufacturing equipment and professional technicians adaptive to the medical devices produced by it;

(2) Having the institution or full-time inspection personnel and the inspection equipment for the quality inspection of the medical devices produced by it.

(3) Having the management system able to ensure the quality of medical devices.

(4) Having the after-sales service abilities adaptive to the medical devices produced by it.

(5) Meeting the requirements as prescribed in the manufacturing research and development and manufacturing process documents.

Article 21 The enterprises engaging in the manufacturing of the medical devices of Class I shall report themselves to the drug administration departments of the local people's governments at the districted city level for filing and submit the materials certifying their compliance with the conditions as prescribed in Article 20 of this Regulation.

Article 22 The enterprises engaging in the manufacturing of the medical devices of Class II and Class III shall apply for manufacturing licenses to the food and drug administration departments of the local people's governments of the provinces, autonomous regions or municipalities directly under the Central Government, and submit the materials certifying their compliance with the conditions as prescribed in Article 20 of this Regulation and the registration certificates of the medical devices produced by them.

The food and drug administration departments accepting manufacturing licenses shall review the application materials within 30 working days from the dates of acceptance of applications, and conduct verification in accordance with the requirements of the quality management norms for the manufacturing of medical devices. For those meeting the conditions as prescribed, permission shall be granted, and the medical device manufacturing licenses shall be issued thereto, and for those failing to meet the conditions, no permission shall be granted, and the reasons therefor shall be given in writing.

A medical device manufacturing license shall be valid for five years. If a medical device manufacturing license needs to be renewed upon the expiration of its validity period, the renewal formalities shall be handled in accordance with the relevant legal provisions on administrative licensing.

Article 23 The quality management norms for the manufacturing of medical devices shall explicitly specify the design and development of medical devices, manufacturing equipment conditions, raw material purchase, manufacturing process control, institutional setup and staffing of the enterprises and other matters which may affect the safety and effectiveness of medical devices.

Article 24 The medical device manufacturing enterprises shall, in accordance with the requirements of the quality management norms for the manufacturing of medical devices manufacturing, establish and improve the quality management systems adaptive to the medical devices produced by them and ensure the effective operation of such medical devices; and shall organize manufacturing in strict accordance with the technical requirements for the products subject to registration or filing to ensure the medical devices leaving factory meet the compulsory standards and the technical requirements for the products subject to registration or filing.

Medical device manufacturing enterprises shall conduct self-inspection on the operation of the quality management system on a regular basis, and submit the self-inspection reports to the food and drug administration departments of the local people's governments of provinces, autonomous regions or municipalities directly under the Central Government.

Article 25 Where the manufacturing conditions of medical device manufacturing enterprises change and no longer meet the requirements for the medical device quality management system, medical device manufacturing enterprises shall immediately take rectification measures, and, if the safety and effectiveness of such medical devices may be affected, immediately stop the manufacturing thereof, and report to the food and drug administration departments of the local people's governments at the county level.

Article 26 The medical devices shall have generic names. Generic names shall comply with the naming rules for medical devices formulated by the food and drug administration department of the State Council.

Article 27 The medical devices shall be attached with instructions and labels. The contents of instructions and labels shall keep consistent with the relevant contents subject to registration

or filing.

The instruction and label of a medical device shall indicate the following items:

(1) Generic name, model and specification.

(2) The name and domicile, manufacturing address and contact information of the manufacturing enterprise.

(3) The serial number of product technical requirements.

(4) Manufacturing date and service life or expiration date.

(5) Product's performance, main structure and scope of application.

(6) Contraindications, matters for attention, and other warnings or tips.

(7) Instructions for installation and use and the drawings thereof.

(8) Product maintenance methods, and special storage conditions and methods.

(9) Other contents that shall be indicated as prescribed in the manufacturing technical requirements.

The serial numbers of medical device registration certificates and medical device registrants' names, addresses and contact information shall also be indicated in the instructions and labels of medical devices of Class II and Class III.

The medical devices used by consumers themselves shall also include the special instructions for safe use.

Article 28 In the case of the commissioned manufacturing of medical devices, the commissioning parties shall be responsible for the quality of the medical devices to be produced upon commission. The commissioned parties shall be the medical device manufacturing enterprises which comply with the provisions of this Regulation and meet the corresponding manufacturing conditions. The commissioning parties shall strengthen the administration of the manufacturing of the commissioned parties to ensure the latter produce medical devices in accordance with the statutory requirements.

The implantable medical devices with high risks may not be produced through commission. The specific catalogues shall be formulated, adjusted and published by the food and drug administration department of the State Council.

Chapter 4 Operation and Use of Medical Devices

Article 29 An enterprise engaging in the operation of medical devices shall have the business premises and storage conditions adaptive to its scale and scope of operation, and the quality management system and quality management organization or personnel adaptive to the medical devices operated by it.

Article 30 An enterprise engaging in the operation of the medical devices of Class II shall report itself to the food and drug administration department of the local people's government at the districted city level for filing, and submit the certification materials on its compliance with the conditions as prescribed in Article 29 of this Regulation.

Article 31 An enterprise engaging in the operation of medical devices of Class III shall report itself to the food and drug administration department of the local people's government at the districted city level for filing, and submit the certification materials on its compliance with the conditions as prescribed in Article 29 of this Regulation.

The food and drug administration department accepting an operation permit application shall conduct the examination thereof within 30 working days from the date when such application is accepted, and organize the verification when necessary. Where the application meets the prescribed conditions, the permission shall be granted, and the medical device operation permit shall be issued; otherwise, no permission shall be granted, and the reasons therefor shall be given in writing.

A medical device operation permit shall be valid for five years. If a medical device operation permit needs to be renewed upon the expiration of its validity period, the renewal formalities shall be handled in accordance with the relevant legal provisions on administrative licensing.

Article 32 Where a medical device operation enterprise or use entity is to purchase any medical devices, it shall examine the qualification of the suppliers of goods and the compliance certification documents of the medical devices, and establish the purchase check and inspection recording system. An operation enterprise engaging in the wholesale of the medical devices of Class II and Class III and in the retail of the medical devices of Class III shall also establish the sales recording system.

The recorded items shall include:

(1) Name, model, specification and the quantity of the medical devices;

(2) The batch numbers, validity periods and sales dates of the medical devices;

(3) The name of manufacturer;

(4) The names, addresses and contact information of suppliers or purchasers;

(5) Relevant license certification document numbers, etc.

The purchase check and inspection records and sales records shall be authentic, and be preserved for a period as prescribed by the food and drug administration department of the State Council. The state shall encourage the recording by means of advanced technologies.

Article 33 The transportation and storage of medical devices shall comply with the requirements as indicated on the medical device instructions and labels. Where there are any special requirements for temperature, humidity and other environmental conditions, the corresponding measures shall be taken to ensure the safety and effectiveness of the medical devices.

Article 34 The units using the medical devices shall have the storage places and conditions adaptive to the varieties and quantities of the medical devices in use.

The units using the medical devices shall strengthen the technical training of staff members, and use medical devices in accordance with the product instructions, technical operation rules and other requirements.

Article 35 The units using the medical devices shall dispose of the reused medical devices in accordance with the disinfection and management provisions formulated by the administrative department of health and family planning of the State Council.

The single-use medical devices may not be reused, and the used ones shall be destroyed and recorded in accordance with the relevant provisions of the state.

Article 36 For the medical devices which need to be inspected, tested, calibrated, maintained and preservedby units using the medical devices on a regular basis, the inspection, testing, calibration, maintenance and preservation thereof shall be conducted and recorded in accordance with the requirements of product instructions, and analysis and evaluation shall be conducted in a timely manner to ensure the medical devices work in good condition and guarantee the use quality. Use archives shall be established for each large medical device with long service life to record the use, maintenance, transfer, actually used time and other matters concerning the device. Such records shall be kept for at a minimum five years after the prescribed service life of the medical devices expires.

Article 37 Units using the medical devices shall properly keep the source materials on the purchase of the medical devices of Class III, and ensure the information traceability.

Where large medical devices as well as implantation and intervention medical devices are used, the names, key technical parameters and other information of medical devices as well as the necessary information closely related to the use quality safety shall be recorded in medical history and other relevant records.

Article 38 Where any potential safety hazards of the medical devices in use are discovered, the entities using the medical devices shall immediately stop using such medical devices, and notify the manufacturing enterprises or other institutions in charge of product quality for overhaul. Were the medical devices still fail to meet the use safety standards after being overhauled, such medical devices may not be used any more.

Article 39 The food and drug administration departments and administrative departments of health and family planning shall, according to their respective responsibilities, respectively supervise and administer the quality of the medical devices in use and the use of medical devices.

Article 40 The medical device operation enterprises and use entities may not operate and use the medical devices which have not been registered according to law, have no product compliance certificate, and have been expired, invalid and eliminated.

Article 41 Where the medical devices in use are transferred among units using the medical devices, the transferors shall ensure the safety and effectiveness of the medical devices transferred, and shall not transfer expired, invalid or eliminated medical devices, or the medical devices unqualified upon inspection.

Article 42 The imported medical devices shall be the medical devices which have been subject to registration or filing in accordance with the provisions of Chapter II of this Regulation.

The imported medical devices shall have Chinese instructions and Chinese labels. Instructions and labels shall satisfy the provisions of this Regulation and the requirements of the relevant compulsory standards, and specify in the instructions the places of origin of the medical devices as well as the names, addresses and contact information of the agents. Those without Chinese instructions and Chinese labels or Chinese instructions or Chinese labels of which fail to comply with the provisions of this Article shall not be imported.

Article 43 The entry-exit inspection and quarantine institutions shall inspect the imported medical devices in accordance with the law. The medical devices unqualified upon inspection shall not be imported.

The food and drug administration department of the State Council shall notify the information on the registration and filing of the imported medical devices to the entry-exit inspection and quarantine department of the state in a timely manner. The entry-exit inspection and quarantine institutions in the locations of import ports shall timely notify the information on the customs clearance of medical devices to the food and drug administration departments of the local people's government at the districted city level.

Article 44 The enterprises exporting medical devices shall ensure the medical devices exported by them meet the requirements of import countries (regions).

Article 45 The medical device advertisements shall be authentic and legitimate, and may not contain any false, exaggerated or misleading content.

The medical device advertisements shall be examined and approved by the food and drug administration departments of the people's governments of the provinces, autonomous regions or municipalities directly under the Central Government where the medical device manufacturing enterprises or agents of import medical devices are located, and obtain the approval documents for medical device advertisements. The advertisement publishers which publish the medical device advertisements shall verify beforehand the approval documents for the advertisements and the authenticity thereof, and may not publish the medical device advertisements which have not obtained approval documents, of which approval documents have not been verified to be authentic, or of which contents are inconsistent with those of the approval documents. The food and drug administration departments of the people's governments of provinces, autonomous regions or municipalities directly under the Central Government shall publicize and timely update the catalogues of the approved medical device advertisements and the approved advertisement contents.

No advertisement involving the medical devices of which manufacturing, marketing, import or use is ordered to be suspended by the food and drug administration departments of the people's governments of provinces, autonomous regions or municipalities directly under the Central Government may be published during the period of suspension.

The review methods for medical device advertisements shall be formulated by the food and drug administration department of the State Council jointly with the administrative department for industry and commerce of the State Council.

Chapter 5 Handling of Adverse Events and Recall of Medical Devices

Article 46 The state shall establish the medical device adverse event monitoring system to

collect, analyze, evaluate and control medical device adverse events in a timely manner.

Article 47 The medical equipment manufacturing and operation enterprises and use entities shall monitor the adverse events of the medical devices produced, operated or used by them, and shall, when finding any medical device adverse events and suspicious adverse events, report to adverse event monitoring technology institutions in accordance with the provisions of the food and drug administration department of the State Council.

Any entity or individual which discovers any medical device adverse event or suspicious adverse event shall be entitled to report to the food and drug administration department or the medical device adverse event monitoring technology institution.

Article 48 The food and drug administration department of the State Council shall strengthen the construction of the medical device adverse event monitoring information network.

Medical device adverse event monitoring technology institutions shall strengthen the information monitoring of medical device adverse events, and take the initiative to collect the information on adverse events; and shall, if finding any adverse events or receiving any adverse event reports, conduct verification, investigation and analysis in a timely manner, evaluate such adverse events, and give suggestions on handling such events to food and drug administration departments and the administrative departments of health and family planning.

Medical device adverse event monitoring technology institutions shall publish the contact information to facilitate the report of medical device adverse events by the medical device manufacturing and operation enterprises and use entities, etc.

Article 49 The food and drug administration departments shall, according to the evaluation results of the medical device adverse events, timely release the warning information, order to suspend the manufacturing, sale, import and use of medical devices or take other control measures.

The food and drug administration departments of the people's governments at or above the provincial level shall, jointly with the administrative departments of health and family planning at the same level and the relevant departments, timely organize the investigation and handling of the medical device adverse events which trigger sudden or mass serious injuries or deaths, and organize the intensified monitoring of the similar medical devices.

Article 50 The medical device manufacturing and operation enterprises and use entities shall cooperate with the investigation of the medical device adverse events conducted by medical

device adverse event monitoring technology institutions and food and drug administration departments.

Article 51 Under any of the following circumstances, the food and drug administration departments of the people's governments at or above the provincial level shall organize the re-evaluation of the registered medical devices.

(1) There are cognitional changes concerning the safety and effectiveness of medical devices according to the development of scientific research.

(2) The results of the monitoring and evaluation of medical device adverse events show that the medical devices may have defects.

(3) Other circumstances under which re-evaluation is needed as prescribed by the food and drug administration department of the State Council.

Where the re-evaluation results show that the safety and effectiveness of the registered medical devices cannot be ensured, the original certificate issuing departments shall cancel the medical device registration certificates and announce them to the general public. The medical devices with their medical device registration certificates being cancelled shall not be produced, imported, operated or used.

Article 52 Where any medical device manufacturing enterprises discover that the medical devices produced by them fail to comply with the compulsory standards or the technical requirements for the products subject to registration and filing, or have any other defects, the manufacturing thereof shall be ceased immediately, and the relevant manufacturing and operation enterprises, use entities and consumers shall be notified to stop operation and use thereof, recall the medical devices which have been marketed, take re-medical and destruction and other measures, record relevant circumstances, release relevant information, and report the information on the recall and handling of medical devices to food and drug administration departments and administrative departments of health and family planning.

Where any medical device operation enterprises discover that the medical devices operated by them fall under any of the circumstances as prescribed in the preceding paragraph, the operation thereof shall be ceased immediately, and the relevant manufacturing and operation enterprises, use entities and consumers shall be notified, and the information on the cessation of operation and use thereof shall be recorded.

The medical devices which are considered by medical device manufacturing enterprises

necessary to be recalled according to the provisions of the preceding paragraph shall be recalled immediately.

Where any medical device manufacturing and operation enterprises fail to recall the medical devices or cease the operation thereof in accordance with the provisions of this Regulation, food and drug administration departments may order the enterprises to recall the medical devices or cease the operation thereof.

Chapter 6 Supervision and Inspection

Article 53 The food and drug administration departments shall strengthen the supervision and inspection of the registration, filing, manufacturing, operation and use of medical devices, and put focus on supervising and inspecting the following matters:

(1) Whether medical device manufacturing enterprises organize manufacturing in accordance with the technical requirements for the products subject to registration or filing.

(2) Whether the quality management systems of medical device manufacturing enterprises keep operating effectively.

(3) Whether the manufacturing and operation conditions of medical device manufacturing and operation enterprises consistently comply with the statutory requirements.

Article 54 Food and drug administration departments shall have the following functions in the process of supervision and inspection:

(1) Implementing inspection and taking samples on site.

(2) Consulting, duplicating, sealing up or seizing the relevant contracts, bills, account books and other relevant materials.

(3) Sealing up or seizing the medical devices which fail to comply with statutory requirements, the spare and accessory parts and raw materials used in violation of laws, and the tools and equipment used for the illegal manufacturing of medical devices.

(4) Sealing up the places where the manufacturing and operation of medical devices are conducted in violation of the provisions of this Article.

Food and drug administration departments shall produce law enforcement certificates in the process of implementing supervision and inspection, and keep confidential the trade secrets of the inspected entities.

Relevant entities and individuals shall cooperate with the supervision and inspection

conducted by food and drug administration departments, and may not conceal the relevant information.

Article 55 Where the medical devices may cause injuries to people or may endanger human health as proved by evidences, food and drug administration departments may take the emergency control measures suspending the manufacturing, import, operation or use thereof.

Article 56 Food and drug administration departments shall strengthen the spot check and inspection of the medical devices produced, operated and used by the medical device manufacturing and operation enterprises and use entities. No inspection fees or any other fees may be charged for the spot check and inspection, and the fees required shall be incorporated into the government budget at the same level.

The food and drug administration departments of the people's governments at or above the provincial level shall timely release the medical equipment quality announcements according to the spot check and inspection conclusions.

Article 57 The qualification accreditation of medical device inspection institutions shall be administered unifiedly in accordance with the relevant provisions of the state. Only the inspection institutions accredited by the administration department certified and accredited by the State Council jointly with the food and drug administration department of the State Council may conduct the inspection of medical devices.

Where food and drug administration departments need to inspect medical devices in the process of law enforcement, they shall authorize the qualified medical device inspection institutions to conduct inspection, and pay relevant expenses.

The parties concerned which have raised any objection to the inspection conclusions may, within seven working days from the receipt of the inspection conclusions, select the qualified medical device inspection institutions for re-inspection. The medical device inspection institutions undertaking the re-inspection shall draw the re-inspection conclusions within the time limit as prescribed by the food and drug administration department of the State Council. A re-inspection conclusion shall be the final inspection conclusion.

Article 58 For the medical devices which may contain hazardous substance, the designs, raw materials and manufacturing technologies of which are altered without permission or have hidden safety risks, which cannot be inspected according to the inspection items and inspection methods as prescribed by the state standards and industry standards for medical devices, medical device inspection institutions may supplement the inspection items and

inspection methods for inspection, and the inspection conclusions drawn by the supplemented inspection items and inspection methods may be taken as the bases for food and drug administration departments to accredit the quality of medical devices as approved by the food and drug administration department of the State Council.

Article 59 The food and drug administration departments of the people's governments at the districted city level and at the county level shall strengthen the supervision and inspection of the medical device advertisements, and, if finding any medical device advertisements which have not been approved or tampered the approved advertisements, report to the food and drug administration departments of the local people's governments of provinces, autonomous regions or municipalities directly under the Central Government, and the latter shall announce them to the general public.

The administrative departments for industry and commerce shall, in accordance with the laws and administrative regulations on advertising management, supervise and inspect the medical device advertisements, and investigate and punish illegal acts. Food and drug administration departments shall, if finding any illegal publishing of medical device advertisements, provide handling suggestions, and turn them over to the local administrative departments for industry and commerce at the same level in accordance with the relevant procedures.

Article 60 The food and drug administration department of the State Council shall establish a unified medical device administration information platform. The food and drug administration departments shall, through the information platform, timely publish the routine administration information on medical device licensing, filing, spot check and, the inspection and investigation and punishment of violations of laws, etc. in accordance with the law, but may not divulge the trade secretes of the parties concerned.

The food and drug administration departments shall establish credit archives for medical device registrants, the parties undergoing filing of medical devices, and medical device manufacturing and operation enterprise and use entities, and increase the frequency of supervision and inspection on the enterprises that have bad credit records.

Article 61 The food and drug administration and other departments shall publicize the contact information of their own entities, and accept consultation, complaints and tip-offs. Food and drug administration and other departments shall give timely replies after receiving the consultations concerning the administration of medical devices; and shall record and keep the information on consultations, complaints and tip-offs, and on the reply, verification and

handling thereof.

After any tip-offs on the research and development, manufacturing, operation or use of medical devices are verified to be true, the food and drug administration and other departments shall reward the informers.

Article 62 To formulate, adjust and modify the catalogues as prescribed by this Regulation and the norms concerning the medical device administration, the food and drug administration department of the State Council shall solicit public opinions, and listen to the opinions from experts, medical device operation and operation enterprises and use entities, consumers and relevant organizations, etc. by such means as hearings and demonstration meetings.

Chapter 7 Legal Responsibilities

Article 63 Under any of the following circumstances, the food and drug administration departments of the people's governments at or above the county level shall confiscate the illegal gains, the medical devices produced or operated in violation of laws, and the tools, equipment, raw materials and other articles used for illegal manufacturing and operation; and shall impose a fine of more than 50,000 yuan but less than 100,000 yuan if the amount of the value of the medical devices produced or operated in violation of laws is less than 10,000 yuan, or impose a fine of more than ten times but less than 20 times the amount of the value if the amount of the value of the medical devices is 10,000 yuan or more, and, if the circumstances are serious, refuse to accept the medical device licensing applications filed by the relevant persons in charge and enterprises within five years:

(1) Manufacturing and operating the medical devices of Class II and Class III which have not obtained medical device registration certificates.

(2) Engaging in the manufacturing of medical devices of Class II and Class III without permission.

(3) Engaging in the operation of the medical devices of Class III without permission.

Under any of the circumstances as prescribed in Item (1) the preceding paragraph, if the circumstance is serious, the original certificate issuing department shall revoke its medical device manufacturing license or the medical device operation permit.

Article 64 Where any false materials are provided or the medical device registration certificates, medical device manufacturing licenses, medical device operation permits,

advertisement approval documents and other licenses are obtained by other fraudulent means, the original certificate issuing departments shall revoke the licenses that have been obtained, and impose a fine of more than 50,000 yuan but less than 100,000 yuan, and shall not accept the medical device licensing applications filed by the relevant persons in charge and enterprises within five years.

Where the relevant medical device licenses are forged, altered, traded, leased or lent, the original certificate issuing departments shall confiscate or revoke such licenses, and confiscate the illegal gains. If the illegal gains are less than 10,000 yuan, a fine of more than 10,000 yuan but less than 30,000 yuan shall be imposed; or if the illegal gains are more than 10,000 yuan, a fine of more than three times but less than five times the illegal gains shall be imposed. Where any violation constitutes the violation of public security administration, the competent public security organ shall impose a public security administration punishment in accordance with the law.

Article 65 Where any entities fail to carry out formalities for filing in accordance with the provisions of this Regulation, the food and drug administration departments of the people's governments at or above the county level shall order them to make corrections within a prescribed time limit. If they fail to make corrections within the prescribed time limit, the entities which fail to carry out formalities for filing and the names of such products shall be announced to the general public, and a fine of less than 10,000 yuan may be imposed.

If any entities provide any false materials when undergoing the filing, the food and drug administration departments of the people's governments at or above the county level shall announce to the general public the filing entities and the names of their products. If the circumstances are serious, the directly responsible persons shall not engage in medical device manufacturing and operation activities within five years.

Article 66 Under any of the following circumstances, the food and drug administration department of a people's government at or above the county level shall order the violator to make corrections, and confiscate the medical devices produced, operated or used in violation of laws; and impose a fine of more than 20,000 yuan but less than 50,000 yuan if the amount of the value of the medical devices produced, operated or used in violation of laws is less than 10,000 yuan, or impose a fine of more than five times but less than 10 times the amount of the value if the amount of the value of the medical devices produced, operated or used in violation of laws is more than 10,000 yuan, and, if the circumstances are serious, order it to

suspend manufacturing or operation until the original certificate issuing department revokes its medical device registration certificate, medical device manufacturing license and medical device operation permit:

(1) An enterprise produces, operates or uses the medical devices which fail to meet the compulsory standards or fail to comply with the technical requirements for the products which have been subject to registration or filing.

(2) A medical device manufacturing enterprise fails to organize manufacturing in accordance with the technical requirements for the products which have been subject to registration or filing, or fails to establish the quality management system and maintain the effective operation thereof in accordance with the provisions of this Regulation.

(3) An enterprise operates or uses the medical devices which have no product compliance certificate or have been expired, invalid or eliminated, or uses the medical devices which have not been registered in accordance with the law.

(4) An enterprise still refuses to recall or stop the operation of medical devices after a food and drug administration department orders it to do so in accordance with the provisions of this Regulation.

(5) An enterprise authorizes an enterprise which fails to satisfy the conditions as prescribed in this Regulation, or fails to administer the manufacturing of the authorized party.

Article 67 Under any of the following circumstances, the food and drug administration department of a people's government at or above the county level shall order the violator to make corrections, and impose a fine of more than 10,000 yuan but less than 30,000; and shall, if the circumstances are serious, order it to suspend manufacturing and operation until the original certificate issuing department revokes its medical device manufacturing license and medical device operation permit:

(1) A medical device manufacturing enterprise fails to make corrections, stop manufacturing or report in accordance with the provisions of this Regulation when its manufacturing conditions change and no longer comply with the medical device quality management system requirements.

(2) An enterprise produces and operates the medical devices of which instructions and labels fail to comply with the provisions of this Regulation.

(3) An enterprise fails to transport or store medical devices in accordance with the

requirements for the instructions and labels of the medical devices.

(4) An enterprise transfers the medical devices in use which have been expired, invalid or eliminated or unqualified upon inspection.

Article 68 Under any of the following circumstances, the food and drug administration department and the administrative department of health and family planning of the people's government at or above the county level shall order the violator to make corrections according to their respective responsibilities and give it a warning; and impose a fine of more than 5,000 yuan but less than 20,000 yuan if it refuses to make corrections, or, if the circumstances are serous, order it to suspend manufacturing and operation until the original certificate issuing department revokes its medical device manufacturing license and medical device operation permit:

(1) A medical device manufacturing enterprise fails to submit the self-examination report of the quality management system as required.

(2) A medical device operation enterprise or the unit using it fails to establish and implement the purchase check and inspection recording system in accordance with the provisions of this Regulation.

(3) An enterprise engaging in the wholesale of the medical devices of Class II and Class III or in the retail of the medical devices of Class III fails to establish and implement the sale recording system in accordance with the provisions of this Regulation.

(4) A unit using the medical device fails to dispose of the reused medical devices in accordance with the provisions on disinfection and management.

(5) A unit using the medical device reuses any single-use medical devices, or fails to destroy the used single-use medical devices as required.

(6) A unit using the medical device fails to inspect, test, calibrate, maintain, preserve and record the medical devices which need to be inspected, tested, calibrated, maintained and preserved on a regular basis in accordance with the requirements of the product instructions, or fails to conduct timely analysis or evaluation to ensure the medical devices work in good condition.

(7) A unit using the medical device fails to properly keep the source materials on the purchase of the medical devices of Class III, or fails to record as required the information on large medical devices and implantation and intervention medical devices in medical history

and other relevant records.

(8) A unit using the medical device fails to immediately stop using or issue a notice of overhauling the medical devices after it finds that such medical devices have any potential safety hazard, or continues using the medical devices which fail to meet the use safety standards after being overhauled.

(9) A medical device manufacturing and operation enterprise or use entity fails to conduct the medical device adverse event monitoring in accordance with the provisions of this Regulation, fails to report any adverse event as required, or fails to support the adverse event investigation conducted by a medical device adverse event monitoring technology institution and a food and drug administration department.

Article 69 Where an enterprise conducts the medical device clinical trials in violation of the provisions of this Regulation, the food and drug administration department of the people's government at or above the county level shall order it to make corrections or immediately stop the clinical trials, and may impose a fine of less than 50,000 yuan thereon; or, where any serious consequences are caused, take the disciplinary actions of demotion, removal from office or expulsion against the directly responsible persons in charge and other directly responsible persons in accordance with the law. If the enterprise is a qualified medical device clinical trial institution, the competent department which grants it the qualification shall cancel its qualification of being a medical device clinical trial institution, and may not accept any qualification accreditation applications filed by it within five years.

Where any medical device clinical trial institution issues a false report, the competent department which grants it the qualification shall cancel its qualification of being a medical device clinical trial institution, and may not accept its qualification accreditation applications within ten years, and the food and drug administration department of the people's government at or above the county level shall impose a fine of more than 50,000 yuan but less than 100,000 yuan thereon. If it obtains any illegal gains, the illegal gains shall be confiscated, and the directly responsible persons in charge and other directly responsible persons shall be removed from office or expelled in accordance with the law.

Article 70 Where any medical device inspection institution issues a false report, the competent department which grants it the qualification shall cancel its qualification of being a medical device inspection institution, and may not accept its qualification accreditation applications within ten years; and shall impose a fine of more than 50,000 yuan but less than

100,000 yuan thereon. If it obtains any illegal gains, the illegal gains shall be confiscated, and the directly responsible persons in charge and other directly responsible persons shall be removed from office or expelled in accordance with the law. Those subject to the disciplinary action of being expelled may not engage in the medical device inspection within ten years from the dates when the decisions on disciplinary action are made.

Article 71 Where any enterprise, in violation of this Regulation, publishes any medical device advertisement which fails to obtain an approval document, or publishes any medical device advertisement without verifying the authenticity of the approval document thereof beforehand, or the content of any advertisement publish by it is inconsistent with that as specified in the approval document, the administrative department for industry and commerce shall punish the enterprise in accordance with the relevant laws and administrative regulations on advertising management.

Where any enterprise tampers any content of an approved medical device advertisement, the original certificate issuing department shall revoke the approval document for this medical device advertisement, and may not accept the advertising approval applications filed by the enterprise within two years.

Where any false medical device advertisements are published, the food and drug administration departments of the people's governments at or above the provincial level shall make the decision on suspending the sale of such medical devices, and announce them to the general public. Where such medical devices are still for sale, the food and drug administration departments of the people's governments at or above the county level shall confiscate the medical devices illegally sold, and impose a fine of more than 20,000 yuan but less than 50,000 yuan.

Article 72 Where any medical device technical review institution or medical device adverse event monitoring technology institution fails to perform its duties in accordance with the provisions of this Regulation, which causes any gross fault in the review and monitoring work, the food and drug administration department of the people's governments at or above the county level shall order it to make corrections, circulate a notice of criticism of it and give it a warning. If serious consequences are caused, the disciplinary action of demotion, removal from office or expulsion shall be taken against the directly responsible persons in charge and other directly responsible persons in accordance with the law.

Article 73 The food and drug administration departments and their staff members shall, in

strict accordance with the categories and extents of punishments as set forth by this Regulation, exercise the power to impose administrative punishments in light of the natures and specific circumstances of the violations of laws. The specific measures shall be formulated by the food and drug administration department of the State Council.

Article 74 If the food and drug administration department of a people's government at or above the county level or any other department fails to perform the duties of administration of medical devices, or abuses its power, neglects its duties, practices favoritism or makes falsification, the supervisory organ or appointment and removal organ shall impose such disciplinary action as giving a warning, recording a demerit or recording a serious demerit on the directly responsible persons in charge and other directly responsible persons; and, if serious consequences are caused, impose disciplinary actions of demotion, removal from office or expulsion.

Article 75 If any violation of this Regulation constitutes a crime, the criminal liabilities shall be investigated in accordance with law. Whoever causes personal injury, property or other damages shall be liable for compensation in accordance with the law.

Chapter 8 Bylaws

Article76. The meanings of following terms in this regulation:

Medical devices means the instruments, equipment, appliances, in vitro diagnostic reagents and calibrators, materials and other similar or relevant articles directly or indirectly applied to human bodies, including the computer software required thereby. Their efficacies are achieved primarily by physical or other means rather than by pharmacological, immunological or metabolic means, though the pharmacological, immunological or metabolic means might be resorted to bring about certain supplementary effect. Their purposes are as follows:

(1) Diagnosis, prevention, monitoring, treatment or mitigation of diseases.

(2) Diagnosis, monitoring, treatment or mitigation of injuries or the functional compensation thereof.

(3) Inspection, replacement, adjustment or support of the physical structures or physiological processes.

(4) Life support or sustaining.

(5) Pregnancy control.

(6) Provision of information for medical or diagnostic purposes by inspecting the samples of human bodies.

Units using the medical devices means the institutions which provide medical treatment and other technical services for others by using medical devices, including the medical institutions which have obtained the practice licenses of medical institutions, the family planning technical service institutions which have obtained the practice licenses of family planning technical service institutions, as well as the blood stations, blood plasma collection stations, and rehabilitation assistance device adaptive institutions, etc.

Article 77 Fees may be collected for the registration of medical device products. The specific charging items and charging rates shall be formulated separately by the financial department and the price administrative department of the State Council in accordance with the relevant provisions of the state.

Article 78 The measures for the administration of non-profit medical devices for contraception and the measures for the administration of the medical devices researched and developed by medical and health institutions to respond to public health emergencies shall be formulated by the food and drug administration department of the State Council jointly with the administrative department of health and family planning of the State Council.

The measures for the administration of the medical devices for Chinese traditional medical treatment shall be formulated by the food and drug administration department of the State Council jointly with the administrative department of traditional Chinese medicines of the State Council in accordance with the provisions of this Regulation. The scope of rehabilitation assistance medical devices and the administrative measures therefor shall be formulated by the food and drug administration department of the State Council jointly with the civil affairs department of the State Council in accordance with the provisions of this Regulation.

Article 79 The administration of the use of military medical devices shall be organized and implemented by the health administrative departments of the army in accordance with the relevant provisions of this Regulation and of the army.

Article 80 This regulation shall take effect on June 1, 2014.