Order from China Food and Drug Administration

No. 4

Regulation on Registration of Medical Device was approved by general meeting of State Food and Drug Administration on June 27, 2014, and is hereby published. This regulation will come into effect on October 1, 2014.

Director Zhang Yong

July 30, 2014

Regulation on Registration of Medical Device

Chapter 1 General

Clause 1 This regulation is established based on Regulation on Supervision and Administration of Medical Device to regulate registration and filing management of medical devices and to ensure safety and effectiveness of such medical devices.

Clause 2 Medical devices distributed and used in the territory of the People's Republic of China should complete application procedures for registration or filing according to this regulation.

Clause 3 Medical device registration refers to a process during which a food and drug administration authority performs a systematic evaluation on safety and effectiveness studies of medical devices to be marketed by the applicant and results of such studies based on registration application of the applicant through legal procedures to determine if the application should be approved.

Medical device filing refers to a process during which the medical device filing applicant submits filing documents to a food and drug administration authority, and the food and drug administration authority puts such documents on record for future reference.

Clause 4 Medical device registration and filing should follow the principles of openness, equity, and justice.

Clause 5 Class I medical devices should be subject to filing management, and Class II and Class III medical devices should be subject to registration management.

For filing of Class I domestic medical devices, the applicant should submit filing documents to corresponding municipal level food and drug administration authority.

Class II domestic medical devices should be reviewed by the food and drug administration authority in relevant province, autonomous region, or municipality, and a medical device registration certificate should be granted to approved devices.

Class II domestic medical devices should be reviewed by China Food and Drug

Administration, and a medical device registration certificate should be granted to approved devices.

For Class I imported medical devices, the applicant should submit filing documents to China Food and Drug Administration.

Class II and Class II imported medical devices should be reviewed by China Food and Drug Administration, and a medical device registration certificate should be granted to approved devices.

Registration and filing of medical devices at Hong Kong, Macau, and Taiwan should be the same as imported medical devices.

Clause 6 The medical device registration and filing applicants should take legal responsibilities for their products as they bring the products to the market in their own name.

Clause 7 Food and drug administration authorities should publish registration and filing information of medical devices in a timely manner according to relevant laws. The applicants can inquire the review progress and results. The review results should be made available to the public.

Clause 8 Research on innovative medical devices are encouraged by the government. A special review procedure has been established for innovative medical devices to facilitate promotion and application of new medical device technologies and speed up development of medical device industry.

Chapter 2 Basic requirements

Clause 9 The medical device registration and filing applicants should create a quality management system related to product development and production, and maintain effective operation of this system.

For registration of domestic medical devices subject to special review procedure for innovative medical devices, if samples are to be produced by other enterprises, such enterprises should be medical device manufacturers with corresponding production range. For registration of domestic medical devices not subject to special review procedure for innovative medical devices, production of the samples should not be entrusted to other enterprises.

Clause 10 The personnel dealing with medical device registration or filing affairs should have corresponding expertise, be familiar with laws, regulations, rules, and technical requirements for medical device registration or filing.

Clause 11 The registration and filing applicants should meet basic requirements for safety and effectiveness of medical devices, and ensure regulated development process as well as true, complete, and traceable data.

Clause 12 The registration or filing documents should be submitted in Chinese. Any translations from foreign literature should be accompanied by the original text. Any reference to unpublished documents should be accompanied by supporting documents showing such use is authorized by the owner.

The registration and filing applicants should be responsible for authenticity of the

submissions.

Clause 13 For registration or filing application for Any imported medical device, a marketing permission should have been obtained for such device in the country (region) where the registration or filing applicant is registered or where the device is produced.

If the product in question is not managed as a medical device in the country (region) where the registration or filing applicant is registered or where the device is produced, the registration or filing applicant should provide relevant supporting documents, including the marketing permission for such product in the country (region) where the registration or filing applicant is registered or where the device is produced

Clause 14 Foreign registration or filing applicants should complete the application procedures through its representative offices in China or a Chinese legal entity as its agent. Such offices or agents should assist the foreign applicants during relevant work.

In addition to handling of medical device registration or filing affairs, the agent should take the following responsibilities:

(1) Contact with corresponding food and drug administration authority and the foreign registration or filing applicant;

(2) Pass on relevant information such as relevant laws and technical requirements accurately to the registration or filing applicant;

(3) Collect information about adverse events of relevant medical devices in the market and deliver such information to the foreign registration or filing applicant while reporting it to corresponding food and drug administration authority;

(4) Assist with recall of marketed medical devices and report the case to corresponding food and drug administration authority;

(5) Take joint responsibilities related to product quality and after services.

Chapter 3 Product technical requirements and registration inspection

Clause 15 The registration or filing applicant should prepare the product technical requirements for the medical device to be registered or filed. For Class I medical devices, such product technical requirements should be submitted to the food and drug administration authority by the applicant during application. For Class II and Class III medical devices, such product technical requirements should be approved by the food and drug administration authority during registration review.

Product technical requirements mainly include performance indicators and testing methods for made medical devices. The performance indicators refer to functional and safety indicators of made products that can be objectively determined and other indicators related to quality control.

Medical devices marketed in China should meet approved product technical requirements for registration or filing.

Clause 16 For registration application of Class II and Class II medical devices, a registration inspection is required. Relevant product should be inspected by a

recognized medical device inspection body according to product technical requirements.

Production of the samples for registration inspection should meet relevant requirements defined by the medical device quality management system. Clinical trials or registration application can only be initiated after the product has passed the registration inspection.

For filing of Class I medical devices, the applicant can submit a self-inspection report for the product.

Clause 17 For a registration inspection, the applicant should provide the inspection body with relevant technical data needed for the inspection, samples for inspection, and product technical requirements.

Clause 18 The medical device inspection body should be qualified for performing medical device inspection and conduct the inspection within the specified range. In addition, the inspection body should make a pre-evaluation on the product technical requirements submitted by the applicant. The pre-evaluation conclusions should be produced to the applicant together with the registration inspection report.

For medical devices not included in the inspection range of the medical device inspection body, the inspection should be made by a competent body designated by corresponding registration review authority.

Clause 19 The products inspected within the same registration unit should be able to represent safety and effectiveness of other products in the unit.

Chapter 4 Clinical evaluation

Clause 20 Clinical evaluation of a medical device refers to the process during which the registration or filing applicant confirms compliance of the product with intended use or applicable range through clinical literature, clinical experience data, and clinical trials.

Clause 21 Clinical evaluation documents refer to the documents resulting from clinical evaluations made by the registration or filing applicant.

In cases where clinical trials are required, the submitted clinical evaluation documents should include clinical trial protocol and clinical trial report.

Clause 22 Filing of Class I medical devices requires no clinical trials. Clinical trials are required for registration of Class II and Class III medical devices.

Clinical trials are not necessary in any of the following circumstances:

(1) A predicate medical device with explicit operation mechanism, well established design, and mature production process has been marketed and used for years without any serious adverse event and without any change of normal purpose;

(2) Safety and effectiveness of the device can be proven through non-clinical evaluation;

(3) Safety and effectiveness of the device can be proven through analysis and assessment made with data from clinical trials or clinical use of predicate medical

devices.

The catalogue of medical devices exempted from clinical trials should be prepared, adjusted, and published by China Food and Drug Administration. For products not included in this catalogue, if the safety and effectiveness of the medical devices can be proven through analysis and assessment made with data from clinical trials or clinical use of predicate medical devices, the applicant can describe the case during registration application and submit relevant supporting documents.

Clause 23 Clinical trials for medical devices should be performed by a qualified clinical trial organization according to the requirements defined in medical device clinical trial quality management regulations. Production of clinical trial samples should meet relevant requirements defined in the medical device quality management system.

Clause 24 Any clinical human tests with high risk to be performed for Class III medical devices should be approved by China Food and Drug Administration. The catalogue of Class III medical devices requiring clinical trial review should be prepared, adjusted, and published by China Food and Drug Administration.

Clause 25 Clinical trial review refers to the process during which China Food and Drug Administration performs an integrated analysis of risk level of the medical device requiring clinical trials, clinical trial protocol, and clinical benefit and risk comparison report based on the application to determine if the clinical trials should be approved.

Clause 26 If medical device clinical trial review is required, the applicant should submit application documents to China Food and Drug Administration according to relevant requirements.

Clause 27 After starting the procedure for handling a medical device clinical trial review application, China Food and Drug Administration should hand over the application documents to the medical device technical review organization within 3 working days.

The technical review organization should complete the technical review within 40 working days. China Food and Drug Administration should make the final decision within 20 working days after completion of technical review by granting the medical device clinical trial permission for approved application or delivering a written explanation indicating the reasons for denial.

Clause 28 If any supplemental documents need to be provided by the applicant during the technical review, the technical review organization should notify the applicant of all required content through a single notice. The applicant should submit the supplemental documents according to the notice within 1 year. The technical review organization should complete the technical review within 40 working days after receiving the supplemental documents. The time for the applicant to prepare the supplemental documents is not counted in the review time frame.

If an applicant fails to submit the supplemental documents before the deadline, the technical review organization should terminate the technical review and give suggestions about denying the application. In this case, China Food and Drug Administration will make a final decision of denial after reviewing the case.

Clause 29 In any of the following circumstances, China Food and Drug Administration should cancel a already granted medical device clinical trial permission:

(1) The clinical trial application documents are false;

(2) New studies show that an approved clinical trial application has ethical or scientific issues;

(3) Other situations requiring cancellation.

Clause 30 The medical device clinical trials should be carried out within 3 years after approval. If they are not carried out before the deadline, the granted permission will become invalid automatically. In this case, a new application is required for further clinical trials.

Chapter 5 Product registration

Clause 31 During medical device registration application, the applicant should submit application documents to relevant food and drug administration authority according to relevant requirements.

Clause 32 After receiving a application, the food and drug administration authority should perform formal review on the documents and take one or more of the following steps depending on actual circumstances:

(1) Start handling the application if it is within its working range and the application documents are complete and compliant with the formal review requirements;

(2) If the application documents contain errors that can be corrected on the site, the applicant should be allowed to make the correction on the site;

(3) If the application documents are not complete or not compliant with formal review requirement, the applicant should be notified of all supplemental content through a single notice within 5 working days. If the notice is not delivered within this time limit, the application should be handled from the date when the application documents received;

(4) If the application is not within its working range, it should notify the applicant that the application will not be handled.

When a decision is made by the food and drug administration authority on whether to handle the medical device registration application, it should produce a dated notice affixed with the seal of the authority indicating whether the application will be handled.

Clause 33 The food and drug administration authority handling the registration application should hand over the application documents to the technical review organization within 3 working days from the date when the handling procedure is started.

The technical review organization should complete the technical review work in 60 working days for Class II medical device registration, or 90 working days for Class III medical device registration.

If a review by foreign experts is required, or if a joint review with a drug review organization for a combined drug and device product is required, the time required for organizing such reviews should not be counted in the review time frame. The technical review organization should notify the applicant of required time in written.

Clause 34 During product technical review, the food and drug administration authority can retrieve original investigation data, and organize quality system audit related to product development and production on the applicant.

Quality management system audit for registration of Class II and Class III domestic medical devices should be carried out by food and drug administration authority of corresponding province, autonomous region, or municipality. The quality management system audit for registration of Class III domestic medical devices should be instructed by, and, if necessary, participated by China Food and Drug Administration. The drug administration authority of corresponding province, autonomous region, or municipality should complete the system audit within 30 working days according to relevant requirements.

During a technical review for Class II or Class III domestic medical devices, if the technical review authority under China Food and Drug Administration believe it's necessary to carry out a quality system audit, it should instruct the quality system inspection technical organization under China Food and Drug Administration to initiate the audit according to relevant requirements and participate in such audit if necessary.

The quality management system audit time should not be counted in the review time frame.

Clause 35 If any supplemental documents should be provided by the applicant during the technical review, the technical review organization should notify the applicant of all supplemental content through a single notice. The applicant should provide all supplemental documents in one single submission within 1 year. The technical review organization should complete the technical review within 60 working days after receiving the supplemental documents. The time for the applicant to prepare the supplemental documents is not counted in the review time frame.

If the applicant has any doubt about the notice concerning supplemental content, it can put forward written suggestions to the corresponding technical review organization to indicate the reason and provide relevant supporting documents.

If an applicant fails to submit the supplemental documents before the deadline, the technical review organization should terminate the technical review and give suggestions about denying the application. In this case, corresponding food and drug administration authority will make a decision of denial after reviewing the case.

Clause 36 The food and drug administration authority handling the registration application should make the final decision within 20 working days after completion of the technical review. For devices meeting safety and effectiveness requirements, the application will be approved. A medical device registration certificate will be granted within 10 working days after the decision is made, and the approved product technical requirements will be sent to the applicant as attachments. If the application is denied, a written notice should be delivered indicating the reasons and reminding the applicant of the right of applying for re-examination or administrative reconsideration or initiating administrative proceedings.

The valid period of medical device registration certificates is 5 years.

Clause 37 Medical device registration items include licensing items and registration items. The licensing items include product name, model, specification, structure and composition, applicable range, product technical requirements, production address of imported medical devices, etc. Registration items include registrant name and address, agent name and address, and registration items include registrant name and address, agent name and address, address of domestic medical device manufacturer, etc.

Clause 38 For a medical device urgently needed for treating rare diseases or handling public health events, the responsible food and drug administration authority can request the applicant to complete further work after market entry during approval of the medical device, and record such request in the medical device registration certificate.

Clause 39 After start of a registration application handling procedure, the responsible food and drug administration authority should deny the registration request in any of the following circumstances and inform the applicant of the decision:

(1) The studies carried out by the applicant on the safety and effectiveness of the medical device to be marketed and the results fail to prove safety and effectiveness of the product;

(2) The registration application documents contain false information;

(3) The registration application documents are confusing and contradictory;

(4) The topics of the registration application documents apparently deviate from the application items;

(5) Other cases forbidding registration.

Clause 40 After start of a registration application handling procedure, the applicant can revoke the registration application and relevant documents from the responsible food and drug administration authority before the final decision is made by the authority. In this case, the applicant should explain the reason for revocation.

Clause 41 After start of a registration application handling procedure, if evidence shows that the registration application documents may contain false information, the responsible food and drug administration authority can suspend the review and check authenticity of the information before deciding to resume the review or deny the application.

Clause 42 If an applicant contests the denial decision made by the responsible food and drug administration authority, it may, within 20 working days after receiving such decision, file a re-examination application at the said food and drug administration authority. Coverage of the re-examination application is limited to the original application items and documents.

Clause 43 After receiving a re-examination application, the responsible food and drug administration authority should make the re-examination decision within 30 working days and inform the applicant of the result in written form. If the original decision is affirmed, the authority will not handle further re-examination application from the applicant.

Clause 44 If an applicant contests the denial decision made by the responsible food and drug administration authority, and has applied for an administrative reconsideration or bring an administrative suit, the responsible food and drug administration authority will not handle further re-examination application from the applicant.

Clause 45 If a medical device registration certificate is lost, the registrant should immediately publish a lost property notice on the media designated by the original issuing authority. The registrant can apply for a re-issued certificate at the original issuing authority 30 days after the said publication, and the original issuing authority should re-issue the certificate within 20 working days.

Clause 46 If a medical device registration application directly involves major interest relation between the applicant and other people, the responsible food and drug administration authority should let the applicant and such stakeholders know that they have the right to apply for hearings based on relevant laws, regulations, and other rules of China Food and Drug Administration. During review of a medical device registration application, if the responsible food and drug administration authority believes that the application concerns major licensing issues related to public interest, it should announce it to the public and hold a hearing.

Clause 47 For newly developed medical devices that have not been included in the classification catalogue, the applicant can directly apply for Class III medical device product registration, or determine the product type based on classification rules and obtain confirmation from China Food and Drug Administration before applying for registration or filing.

If an applicant directly applies for Class III medical device registration, China Food and Drug Administration will determine the class based on its risk level. If a domestic medical device is judged as Class II, China Food and Drug Administration will hand over the application documents to the food and drug administration authority in the province, autonomous region, or municipality where the application is located for further review. If a domestic medical device is judged as Class I, China Food and Drug Administration will hand over the application documents to the food and drug administration authority in the city where the application is located for filing.

Clause 48 Any patent right dispute arising out of a registration application review or after approval should be settled according to relevant laws and regulations.

Chapter 6 Registration change

Clause 49 For a registered Class II or Class II medical device, if any change occurs to the contents of the medical device registration certificate or its attachments, the applicant should apply for registration change at the original registration authority, and submit application documents according to relevant requirements.

If any change occurs to product name, model, specification, structure and composition, applicable range, product technical requirements, or production address of an imported medical device, the registrant should apply for modification to licensing items at the original registration authority.

If any change occurs to registrant name and address or agent name or address, the

registrant should apply for modification to licensing items at the original registration authority. If any change occurs to production address of an imported medical device, the registrant should complete registration item modification after corresponding production license is modified.

Clause 50 If an application for modified registration items meets all requirements, the responsible food and drug administration authority should issue the medical device registration modification certificate within 10 working days. If the documents submitted for such application are incomplete or fail to meet formal review requirements, the responsible food and drug administration authority should request the applicant to supplement all required information through a single notice.

Clause 51 For modifications to licensing items, the technical review organization should focus on review of changes, and evaluate safety and effectiveness of the product after modification.

The food and drug administration authority handling application for modification to licensing items should organize a technical review within the time frame defined in Chapter 5 of this regulation.

Clause 52 The medical device registration modification certificate should be used in combination with original medical device registration certificate, and should have the same valid period as the latter. After the registration modification certificate is obtained, the registrant should revise the product technical requirements, user instructions, and labels by itself based on the modification.

Clause 53 For licensing item modification handling and approval procedures not defined in this chapter, relevant rules in Chapter 5 should apply.

Chapter Renewed registration

Clause 54 If a renewed registration is needed for a medical device registration certificate upon expiry, the applicant should file an application at the responsible food and drug administration authority 6 months before such expiry, and submit application documents according to relevant requirements.

After receiving the application for a renewed registration, the responsible food and drug administration authority should approve the renewal before expiry of the medical device registration certificate except for the cases defined in Clause 55 of this regulation. If the authority fails to approve it before the expiry, the application should be seen as approved.

Clause 55 Renewed registration should not be approved in any of the following circumstances:

(1) The registrant fails to file an application for renewal before the deadline;

(2) The compulsory medical device standards have been revised, and the medical device in question fails to meet new requirements;

(3) For a medical device urgently needed for treating rare diseases or handling public health events, the registrant fails to complete the procedures defined in the medical device registration certificate by the registration authority during approval.

Clause 56 For medical device renewed registration handling and approval procedures not defined in this chapter, relevant rules in Chapter 5 should apply.

Chapter 8 Product filing

Clause 57 Product filing is required for Class I medical devices prior to production.

Clause 58 During filing application for a medical device, the applicant should submit filing documents according to Clause 9 of Regulation on Supervision and Administration of Medical Device.

The responsible food and drug administration authority should approve the filing application immediately if the filing documents meet defined requirements. If the filing documents are incomplete or fail to meet defined format, the authority should notify the applicant of all required supplemental documents through a single notice, and approve the filing after all such documents are provided by the applicant.

For filed medical devices, the responsible food and drug administration authority should prepare filing certificates according to relevant requirements, and publish the information contained in the filing forms on its website.

Clause 59 If any change occurs to the content in the filing form or technical requirements for a filed medical device, the filer should submit a description about the change and relevant supporting documents to the original filing authority for modification. If the filing documents meet formal requirements, the responsible food and drug administration authority should publish the change and put the modified documents on record.

Clause 60 In case of any change to the class of a filed medical device, the filer should actively propose cancellation of the original filing documents at the responsible food and drug administration authority. If the medical device is changed to Class II or Class III, a registration application is required according to this regulation.

Chapter 9 Supervision and management

Clause 61 China Food and Drug Administration is responsible for supervision and management or registration and filing of medical devices across the nation, and providing supervision and instructions for local food and drug administration authorities during medical device registration and filing work.

Clause 62 The food and drug administration authorities on province, autonomous region, and municipality level are responsible for supervision and management or registration and filing of medical devices in their respective regions, organization of supervisory review, and timely reporting of relevant information to China Food and Drug Administration.

Clause 63 The food and drug administration authorities on province, autonomous region, and municipality level should perform daily supervision and management on registration and filing of imported medical device agents in their respective regions.

Clause 64 The municipal food and drug administration authorities in cities with

administrative districts should inspect the filing work regularly, and report relevant information to corresponding food and drug administration authorities on province, autonomous region, and municipality level.

Clause 65 If a medical device needs to be cancelled according to laws or regulations, or if an registrant applies for cancellation of registration for a medical device before expiry, the responsible food and drug administration authority should cancel the registration according to laws and disclose the cancellation to the public.

Clause 66 If a registered medical device is changed to a lower class, the medical device registration certificate will remain valid in its valid period. If any renewal is needed, the registrant should apply for renewed registration or filing at the responsible food and drug administration authority based on the new class 6 months before expiry of the medical device registration certificate.

If a registered medical device is changed to a higher class, the registrant should apply for registration at the responsible food and drug administration authority based on the new class according to Chapter 5 of this regulation. China Food and Drug Administration should define the deadline for completing such procedures in the class adjustment notice.

Clause 67 If any food and drug administration authorities on province, autonomous region, and municipality level violates this regulation during handling of a medical device registration, China Food and Drug Administration will deliver a notice to demand correction before a deadline. If the authority fails to make proper correction before the deadline, China Food and Drug Administration can make a public announcement directly to cancel the corresponding medical device registration certificate.

Clause 68 The food and drug administration authorities, relevant technical organizations and their personnel should be obliged to keep confidential the trial data and technical secrets submitted by the registration or filing applicants.

Chapter Legal responsibilities

Clause 69 Any applicant who obtains a medical device registration certificate by providing false information or through other deception means will receive punishment according to Clause 64.1 of Regulation on Supervision and Administration of Medical Device.

Any applicant who provides false information during filing will receive punishment according to Clause 65.2 of Regulation on Supervision and Administration of Medical Device.

Clause 70 Any person who counterfeits, alters, buy or sell, lease, or lend a medical device registration certificate will receive punishment according to Clause 64.2 of Regulation on Supervision and Administration of Medical Device.

Clause 71 Any person failing to complete filing modification procedures for Class I medical device or registration modification procedures for Class II or Class III medical device according to this regulation will receive punishment according to provisions concerning absence of filing in Regulation on Supervision and Administration of Medical Device.

Clause 72 Any person failing to complete medical device registration licensing item modification procedures will receive punishment according to provisions concerning absence of medical device registration certificate in Regulation on Supervision and Administration of Medical Device.

Clause 73 If an applicant fails to conduct clinical trials according to Regulation on Supervision and Administration of Medical Device and this regulation, the responsible food and drug administration authority on county or higher level will demand correction and impose fines less than 30000 RMB. In serious cases, the clinical trials should be stopped immediately, and granted clinical trial approval should be withdrawn.

Chapter 11 Supplementary provisions

Clause 74 In general, grouping of medical device registration or filing units is based on product technical principles, structure and compositions, performance indicators, and applicable range.

Clause 75 The composite parts recorded in the Structure and Compositions field of a medical device registration certificate, if used for the original registered product for the purpose of consumable replacement, after service, or repair, can be sold separately.

Clause 76 The format of medical device registration certificates should be defined by China Food and Drug Administration centrally.

Format of registration certificates:

×1 device registration ×2××××3×4××5××××6. Where:

×1 refers to the abbreviation of the region where the registration authority is located:

"State" for Class III domestic medical devices and Class II and Class III imported medical devices;

The abbreviation of the province, autonomous region, or municipality where the registration authority is located for Class II domestic medical devices;

×2 refers to the registration type:

“Permit” for domestic medical devices;

“Import” for imported medical devices;

“License” for medical devices at Hong Kong, Macau, and Taiwan;

××××3 refers to the initial registration year;

×4 refers to the product administration class;

××5 refers to product type code;

××××6 refers to the serial number for initial registration.

For a renewed registration, ××××3 and ××××6 will remain unchanged. For an adjustment of product administration class, renumbering is required.

Clause 77 Format of a filing certificate number for Class I medical device:

×1 device filing ××××2××××3 number.

Where:

×1 refers to the abbreviation of the region where the filing authority is located:

"State" for Class I imported medical devices;

The abbreviation of the province, autonomous region, or municipality where the filing authority is located plus the abbreviation for municipal administration region (only if administration districts are contained in the region) for Class I domestic medical devices;

××××2 refers to the filing year;

××××3 refers to the serial number during filing.

Clause 78 Registration and filing of in-vitro diagnosis agents managed as medical devices should follow Regulation on In-vitro Diagnosis Agent Registration Management.

Clause 79 Medical device emergent review procedures and special review procedures for innovative medical devices should be established by China Food and Drug Administration separately.

Clause 80 According to work needs, China Food and Drug Administration can entrust specific medical device registration tasks to food and drug administration authorities on province, autonomous region, or municipality, or technical organizations, or relevant social organizations.

Clause 81 The standards for charges collectable during medical device product registration should be in line with rules established by financial and pricing offices of the State Council.

Clause 82 The regulation comes in to force on October 1, 2014. The Regulation on Registration of Medical Device (former No. 16 order of China Food and Drug Administration) issued on August 9, 2004 will be annulled on the very same day.