

E-ALERT | Food & Drug

April 25, 2014

CHINA RESTRUCTURES ITS MEDICAL DEVICE REGULATORY SYSTEM

China is currently engaging in a comprehensive effort to restructure its medical device regulatory system. Since its reorganization in March 2013, the China Food and Drug Administration (CFDA) has issued numerous proposed rules and guidance documents related to, for example, device inspections, adverse event monitoring, gene-sequencing reagents and instruments, and innovative devices. This effort has reached a new peak with the State Council's adoption and promulgation of amendments that completely rewrite the core regulation governing devices, known as the Medical Device Supervision and Administration Regulation ([Medical Device Regulation](#) or MDR). The National People's Congress has enacted no statutes governing medical devices. Therefore, the MDR is currently the highest level of legislation in this area and sets the framework for all aspects of medical device regulation in China, including research and development, approval and registration, registration amendment and renewal, manufacturing, importation, distribution, device use in medical institutions, advertising and promotion, post-market surveillance, and penalties.

The MDR is implemented by a number of rules and guidance documents promulgated by CFDA, which CFDA also is in the process of revising and updating. Almost immediately after the final revised MDR (Revised MDR) was promulgated on March 31, 2014, CFDA released proposed implementing regulations on registration, manufacturing, distribution, and use of medical devices for public comment. This Alert discusses some of the important changes in the Revised MDR and the basic features of some of the current implementation efforts.

A Long-awaited Revision

The MDR has not been revised since its original promulgation in 2000 (2000 MDR). Since that time, the medical device market in China has grown significantly. As a result, CFDA has accrued a great deal of regulatory experience for the Revised MDR. In addition, the Revised MDR is the result of two rounds of comments on earlier drafts, [one](#) in 2007 and [one](#) in 2010.

The Revised MDR has nearly doubled in length, and covers a broad spectrum of medical device regulation. As a result, it deserves close study by any medical device company doing business in China. The Revised MDR will take effect on June 1, 2014. We summarize some of the key changes below.

Definition of Medical Device

The Revised MDR amends and expands the definition of "medical device." The definition from the 2000 MDR was based on the "purpose" for which the instrument, apparatus, appliance, material or other article was to be used. The 2000 MDR listed several purposes, including the prevention, diagnosis, monitoring, treatment or alleviation of disease, injury or disability, and the investigation, replacement or modification of the anatomy or of a physiological process, as well as the prevention of pregnancy.

The Revised MDR's definition still centers on the "purpose" of the device, and adds "life support or sustenance" as an intended purpose for a medical device. It also expands upon the earlier definition by adding *in vitro* diagnostic reagents and calibration products as types of medical devices. It also adds human sample testing to supply information for medical treatment or diagnosis as one of the purposes for medical devices.

For many years, CFDA has treated most *in vitro* diagnostic reagents as medical devices. It made this position explicit with the enactment of the Registration Measures on In Vitro Diagnostic Devices (Trial) (IVD Registration Measures) issued on April 19, 2007. Nevertheless, CFDA has not always included (and has sometimes excepted) device-type IVDs¹ in the rules, guidance and policy documents on medical devices.² This new definition raises the question of when IVDs and other medical devices will be treated similarly in the future.

Classification of Medical Devices

Currently, CFDA classifies devices into three risk-based categories: Class I devices for which safety and effectiveness can be ensured through routine administration; Class II devices for which further control is required to ensure safety and effectiveness; and Class III devices which are implanted into the human body, or used for life support or sustenance, or which pose potential risks to the human body, and therefore must be strictly controlled in respect to safety and effectiveness. Each class has different procedures and rules for manufacturing, distribution and post-market surveillance. CFDA publishes a Medical Device Classification Catalogue assigning classifications to different categories of medical devices.

Over the last year, CFDA has endeavored to streamline the classification process. One example of this is the creation of an online platform through which applicants may submit a petition for CFDA for determination of device classification, including whether the article is "class 0" (i.e., not a medical device). In addition, CFDA has recently published proposed revisions to the device classification catalogue, which not only set forth additional categories, but also set forth the [general principles](#) according to which CFDA and stakeholders can determine a device's classification.

The device classification provisions in the Revised MDR retain the three-class categorization system. The research and development, manufacturing, distribution, use and post-market surveillance rules are applied based on a device's classification in a similar way.

The Revised MDR, however, is more specific about how classification works, adopting some of the principles set forth in earlier classification catalogues for classifying a device. In assessing risk, CFDA will consider a device's intended purpose, structural characteristics, method of use, and other relevant factors. CFDA will continue to publish a Classification Catalogue, but as part of the publication process, the revised MDR now expressly requires that CFDA undertake consultations with industry, users and trade organizations. It must also reference international device classification practice.

The Revised MDR also clarifies the procedure for classifying a new type of device. Specifically, for a new medical device that does not fit under a category recognized in the Classification Catalogue, the Revised MDR states that applicants may follow the registration procedures for Class III devices or make their own determination and then petition the Agency for a classification determination.

¹ The majority of IVDs are regulated as medical devices (i.e., device-type IVDs). However, China does regulate some IVDs, such as blood donor screening reagents, as drugs. Drug Administration Law Implementing Regulations, art. 39 (CFDA No. 360 2002).

² For example, CFDA issued a [2013 Re-registration Notice](#) that applied to medical devices generally, but not *in vitro* diagnostic devices.

Device Registration

A medical device “registration” is an approval obtained from CFDA or one of the local (provincial or a lower level) food and drug regulatory authorities to market a specific device. The Revised MDR simplifies the pre-market approval and registration process for lower-risk medical devices, and adds rights for registration holders.

Notably, the Revised MDR eliminates the pre-marketing registration requirement for Class I devices. Now Class I devices need only undergo a “filing” procedure with a municipal regulator (i.e., below the provincial level). Class II and Class III devices must still be registered through a licensing procedure.

In some ways, the “filing” procedures are substantially similar to licensing procedures in terms of rigor and application material requirements. For example, the Revised MDR specifies that for both pre-marketing registrations and filings, applicants must provide device risk analysis material, device technology requirements, testing reports, clinical evaluation reports, product insert and labeling samples, quality control information, and materials needed to prove the device’s safety and efficacy. There are, however, some significant differences. For example, for Class I devices, the testing reports can be the filer’s own testing reports. By contrast, for Class II and III devices, they must be a testing reports from a government-accredited medical device testing laboratory.

Another significant development is that the Revised MDR no longer requires that a domestic manufacturer obtain a “manufacturing license” – discussed below – prior to applying for registration for its product. This means that so long as a domestic manufacturer has developed the necessary quality control systems, it can apply for product registration. The manufacturer need not wait to have its manufacturing facilities completed. The [purpose](#) of this change is to promote domestic research and innovation in the medical device field.

Under the Revised MDR, import manufacturers may follow the general registration and filing procedures applicable to domestic devices, with certain exceptions. For example, applicants must file (for Class I devices) or register (for Class II or III devices) with CFDA, instead of with provincial or municipal regulators. Import manufacturers must still provide a certificate proving that the medical device is allowed to be marketed in its country of origin or manufacture. If CFDA determines during the technical review process that it needs to audit the quality control system of the manufacturing facility, it will organize such an audit by a medical device testing institution.

The Revised MDR expands the medical device registration certificate’s validity period from four years to five years. This means that manufacturers will now need to start the renewal process four years and six months after their license is issued, i.e., six months prior to the date of expiration. The Revised MDR is silent on how this provision will apply to registrations that are currently undergoing the renewal process. Registrations will also no longer be automatically revoked after a production stoppage of two years or more.

The criteria for submitting amendments to device registrations have been simplified. Currently, amendments are required for any changes in model, specifications, location of the manufacturing facility, product standards, product performance, structure and composition, and scope of use.³ Now an amendment to a registration need only be submitted during the device license term if a change occurs that affects the safety and efficacy of the device. With certain exceptions, if the amendment to a registration application is not approved prior to expiration of the registration (i.e., the license itself), the application will be considered approved.

³ As we stated in an earlier [alert](#), CFDA has previously reduced the burdensome requirements in the re-registration process for renewing or making major changes to an existing medical device license in China.

The Revised MDR introduces a provision on fees for medical device registrations. The schedule of fees will be set by CFDA's Finance and Pricing Department. It is unclear whether the reference to fees is merely administrative or if the fees are meant to supplement agency resources to lead to faster approval times.

Clinical Trials

Significant clarifications and changes have been made in the area of clinical trials. Class I devices do not require China-based (sometimes referred to as local clinical trials) prior to registration. In contrast, most Class II and Class III devices must successfully undergo clinical trials before registration and approval for marketing. The Revised MDR clarifies which Class II and Class III devices may be exempt from the clinical trial requirement. Specifically, it sets forth three circumstances in which the clinical trial requirement is waived for lower-risk Class II and Class III devices.

Class II and Class III devices will be exempt under the following three circumstances, which CFDA will determine: (1) devices for which there exists an already-marketed equivalent in terms of manufacturing, design, and operating mechanism, with a good safety record; (2) devices for which safety and effectiveness may be proven using non-clinical data; and (3) devices for which clinical trial data already exists. CFDA will publish a catalogue of the Class II and III devices exempted under these provisions, and CFDA has already issued a [proposed catalogue](#) for public comment.

The Revised MDR eliminates the requirement that an applicant apply for approval from CFDA or a provincial regulator, depending on the circumstances, before conducting a clinical trial for all devices except for high-risk Class III devices, which will require approval from the national CFDA itself before any clinical trial may be initiated. The Revised Regulation does not provide a definition or criteria for how to determine what is a high-risk Class III device that requires a clinical trial application. However, the Revised MDR states that CFDA will publish a catalogue of high-risk III devices, which may provide guidance as to the qualifying standards.

Manufacturing

The Revised MDR retains the requirement that manufacturers of Class II and Class III devices obtain a manufacturing license, which is no longer required prior to registration. However, the MDR now makes it explicit that manufacturers will have to provide application materials and documentation evidencing a sufficient quality control system, the ability to provide post-marketing services, and a product development and manufacturing documentation process. All device manufacturers must comply with medical device [Good Manufacturing Practices](#), which CFDA promulgated in 2009.

The Revised MDR explicitly permits contract manufacturing of most medical devices except for high-risk implantable devices. CFDA will publish a catalogue of devices that may not be manufactured according to a contract manufacturing arrangement.

Distribution

The Revised MDR has simplified the notification and licensure requirements for entities distributing Class I and II devices. Class I device distributors will no longer have a filing requirement. Distributors of Class II devices no longer need to obtain a distribution license (a sometimes lengthy procedure), but may go through a less cumbersome "filing" procedure with the municipal level food and drug regulatory authority. Distributors of Class III devices must still obtain a distribution license.

The Revised MDR adds significant sales recordkeeping requirements for wholesalers of Class II and Class III devices, as well as retailers of Class III devices. These wholesalers and retailers will be expected to keep records of the name, model, specifications, and quantity of the medical devices sold, their production batch/lot number, shelf-life, sale date, manufacturer name, supplier name and contact information, and applicable licensing numbers. The CFDA has [proposed](#) Good Supply Practices for medical devices, but that proposal has not yet been adopted.

Labeling and Advertising

The Revised MDR adds some content requirements for the package insert and labeling, which are currently set forth in the [Provisions](#) on the Administration of Manuals, Labels and Package Marks of Medical Devices. The Revised MDR now specifies that the product insert and label must include, among other things: (1) the common name, model and specifications; (2) name, address and contact information of the manufacturer; (3) date of manufacture and expiration date; (4) product performance, composition and scope of use; (5) contraindications and other alerts; and (6) special storage instructions. For imported medical devices, the product insert and label must be in Chinese.

Standards for advertising have become more stringent. The Revised MDR retains the pre-approval requirement for medical device advertising, but specifies additional standards for approval and imposes additional duties on the publisher or broadcaster of the advertisement. The 2000 MDR sets a general standard for medical device advertising that requires that the content of the advertisement be based on the approved labeling. The Revised MDR also requires that it be true, and not contain false, exaggerated, or misleading content. The Revised MDR also adds a requirement for the broadcaster or publisher of the advertisement to examine the approval document from CFDA, the document's validity and whether the advertisement conforms with its approval.

Medical Institution Use

The Revised MDR adds recordkeeping and reporting requirements for medical institutions, a term which includes both private and public hospitals and clinics that use medical devices. Medical institutions must record identifying information relating to Class III devices to ensure traceability in the case of adverse events. If a medical institution encounters an unexpected adverse event, it will be expected to stop the use of the device, and notify the manufacturer or other institution responsible for the quality control of the device. The Revised MDR also allows for the transfer of used medical devices between medical institutions if the devices are safe, effective, not expired, and otherwise meet specifications.

Adverse Event Monitoring, Device Reevaluation, and Recalls

CFDA has adopted various rules with respect to adverse event monitoring, device reevaluation ([AE Measures](#)) and recalls ([Recall Measures](#)). The Revised MDR incorporates these rules, in some cases with stricter obligations.

For example, the Revised MDR now explicitly requires that medical device manufacturers, distributors and medical institution users monitor for and report adverse events. This requirement had been previously set forth in the 2008 [Trial Measures](#) on Medical Device Adverse Event Monitoring and Re-evaluation. The Revised MDR also contains directives to the National Center for ADR Monitoring and CFDA to improve their monitoring and review of adverse events, and as appropriate, to stop production, marketing, import or use of the unsafe medical devices.

The Revised MDR imposes more stringent reevaluation requirements on CFDA. The AE Measures require CFDA to reevaluate a medical device that has caused serious injury or death. However, the Revised MDR requires that CFDA and provincial food and drug regulatory authorities reevaluate a device if there is a known change to the safety or efficacy of a device based on advances in scientific research, an adverse event investigation shows a potential defect, or CFDA has reevaluated other requirements.

Provisions on recalls are now included. The 2000 MDR did not mention recalls, although CFDA later adopted rules on medical device recalls. However, the Revised MDR provides that if manufacturers discover that their devices do not meet mandatory standards, the manufacturers should stop production, notify distributors, medical institution users and other consumers, recall the products and report the recall to CFDA and the National Health and Family Planning Commission. The Revised MDR also provides that if the manufacturer does not do so voluntarily, CFDA may order a recall or terminate the device's distribution.

Supervision and Inspection

The Revised MDR significantly expands the chapter on CFDA's ability to supervise and inspect the operations of device manufacturers and distributors. The chapter on supervision and inspection explains three focus points: (1) manufacturer compliance with the technical requirements set forth in registration or filing documents; (2) effectiveness of quality control systems; and (3) a somewhat vague requirement that the circumstances surrounding manufacturing and distribution ensure compliance with legal requirements.

The Revised MDR expands the authority that CFDA has to detain product, review records, and close facilities. Specifically, CFDA has more power to consult, copy, seize, and detain contracts, invoices, account books and related materials; to detain illegal medical devices, raw and semi-finished materials, and instruments and equipment in which the illegal medical devices are used; and to shut down manufacturing and distribution sites where acts prohibited under the MDR occur.

Enforcement

The Revised MDR significantly increases penalties for prohibited acts. For example, fines for various activities constituting illegal manufacturing and distribution have increased from up to five times the amount of the proceeds earned from the illegal activities to up to 20 times that amount. Fines for other prohibited acts have also been increased throughout the Revised MDR.

CFDA will also now impose a five-year moratorium on granting licenses for parties who manufacture or distribute unregistered Class II or Class III devices; manufacture Class II or Class III devices without a production license; or distribute a Class III device without a distribution license. The more severe penalty of license revocation for "serious cases" of misconduct of this type remains.

Medical device manufacturers and distributors should carefully review the new penalties. CFDA has decreed that it will impose the highest penalty allowed by law for certain violations discovered during the [Five Rectifications Campaign](#), which is described in fuller detail [here](#). That campaign, which cracks down on certain types of prohibited acts in the device space, will still be ongoing when the Revised MDR takes effect in June of 2014. The Five Rectifications Campaign runs until August 2014.

Regulatory Transparency

The Revised MDR is also consistent with CFDA's approach to transparency in publishing draft legislation and soliciting comments. Recently adopted CFDA rules require that the Agency seek public input on its rules and guidance documents. Under the Revised MDR, CFDA must set a hearing, expert meeting or otherwise solicit the opinions of experts, industry, medical institution users, and consumers and other interested persons on rulemakings and policy matters.

CFDA typically publishes its rules for public comment, giving stakeholders up to 30 days to submit their input. This practice sets a tight timeline for the significant changes that are taking place in this area. Stakeholders have been given a month to comment on a number of new rules implementing different parts of the Revised MDR.

New Implementing Rules

Within days of the promulgation of the Revised MDR, CFDA released a number of proposed drafts of implementing rules and some of the "catalogues" required under specific provisions. For example, CFDA issued proposed implementing [rules](#) for the new licensure and filing schemes that the Revised MDR sets forth for manufacturers of different classes of devices. It also issued similar proposed [rules](#) to implement the new regime for distribution licenses and filings. In addition, CFDA released a [rule](#) governing "classification" of manufacturers for purposes of surveillance and monitoring. Under these rules, manufacturers will be broken into categories depending on the devices they manufacture and their compliance history. Manufacturers with more violations will be monitored more closely.

Another major piece of implementing legislation that stakeholders will want to review carefully is the proposed [rules](#) governing medical device registration (and filings). These proposed rules set forth more detail about the particular application requirements for domestic and imported medical devices in different classes. CFDA also released another highly detailed set of proposed [rules](#) for registration of *in vitro* diagnostic reagents, which similarly set forth the requirements for the research and development and registration and filing processes.

Accompanying these proposed rules on registration were new proposed [rules](#) on labeling and package inserts, and two proposed [catalogues](#) to implement the exemptions from the clinical trial requirement for certain Class II and Class III devices. Comments on all of these proposed rules and catalogues are due on April 30, 2014.

Industry should continue to monitor for proposed and final rules in this area, as well as the cancellation of older rules by CFDA and provincial food and drug regulatory authorities. On April 11, 2014, CFDA issued a [notice](#) on the implementation of the Revised MDR that, *inter alia*, calls for provincial authorities to amend or cancel any of their rules that are not in conformity with the Revised MDR.

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