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CFDA ISSUES NEW RULES ON MEDICAL DEVICE RE-REGISTRATION, CLASSIFICATION, AND DISTRIBUTION

In December of 2013, the China Food and Drug Administration ("CFDA") released a final rule and two proposed rules governing medical device re-registration, classification, and distribution, bringing significant implications for the domestic and foreign medical device industry. These rules come at a time when CFDA is working on an amendment to the primary regulation governing medical devices in China, the Regulation for the Supervision and Administration of Medical Devices ("Medical Device Administrative Regulation"), which was enacted in 2000. Draft revisions of the Medical Device Administrative Regulation were released by the government for comment in 2007 and 2010, but it has not been finalized. The subjects covered in the recently issued rules discussed in this alert are likely to be considered in the revision of the Medical Device Administrative Regulation, and so, as explained below, they are a good window into future medical device regulatory changes in China.

The new final and proposed rules are:

- A final Notice on Matters Related to Medical Device Re-registration, issued on December 9, 2013 ("Re-registration Notice");
- A proposed Rule on Medical Device Classification, issued on December 24, 2013 ("Draft Classification Rule"); and
- A proposed Rule on Good Supply Practices for Medical Devices, issued on December 26, 2013 ("Draft GSP Rule").

Foreign and domestic medical device companies should monitor these developments and submit comments, where applicable. The following sections contain brief analysis of all three rules.

1. RE-REGISTRATION NOTICE

The Re-registration Notice reduces burdensome requirements in the application process for domestic and foreign manufacturers, when renewing or making major changes to an existing medical device license in China. The term "re-registration" for medical devices under Chinese laws does not mean that the applicant must go through the registration process from the very beginning. Instead, it should be interpreted, under Medical Device Registration Measures enacted in 2004 ("Registration Rule"), to refer to the process of renewing and making major substantive changes to existing medical device licenses. Such major substantive changes include a change of the manufacturing facility, a change in the indications, or a change in the specifications, structure, or composition of the device.[1] The Re-registration Notice does not apply to *in vitro* diagnostic devices. For areas where the Re-registration Notice does not contain relevant provisions, the Registration Rule shall continue to apply.

[1] By contrast, a minor change in an item on the license (or the registration form) will only entail an amendment to the license. Examples of minor changes are name changes or changes to the wording of the address of a manufacturing facility.

Based on the Registration Rule, if any of the changes noted above occur during the four-year term of the license, the license holder may need to apply for re-registration. Prior to issuance of the Re-registration Notice, license holders had to submit multiple application materials to CFDA when amending their licenses to reflect substantive changes. In some cases, the materials submitted could be related to aspects of the product or manufacturing that were not affected by the change.

The primary benefit of the Re-registration Notice for license holders is that, in most cases, they will only have to submit materials primarily related to the change they are making. For example, if a domestic license holder is changing the location of its domestic manufacturing facility, it will need to submit a declaration describing the change in location, and *inter alia*, reports on inspections of the new facility's quality control systems and a self-test report for products manufactured in the new facility.

Similarly, a foreign license holder must submit a declaration that the location of the facility has changed, "appropriate approval documentation" for the facility, and a self-testing report for the products manufactured at the new facility. In the context of both foreign and domestic license holders, a license holder does not need to re-submit the product standards, the testing report, or the package insert in connection with the re-registration process, with the caveat that in such instances, the license holder will continue to be bound by the originals after the change is approved.

The Re-registration Notice contains similarly modified requirements for other major changes, such as the indications of the device, its specifications, its standards, and its performance structure and composition. The Re-registration Notice specifies the circumstances under which a re-registration application should be submitted and provides a list of materials that should be submitted.

Also of great benefit in conserving license holder resources is an easier renewal process. Medical device licenses must be renewed six months prior to the expiration of the four-year license term. If there are no changes at the time of renewal to the products, product standards, and package insert, the license holder now only needs to submit a declaration to that effect, as well as a declaration that the device still complies with mandatory standards in China. In these circumstances, the manufacturer shall continue to be bound by the original product standards and testing report after renewal.

Still, there are circumstances under which a major change requires a license holder to start the registration process again, from the very beginning. The Re-registration Notice cites two such circumstances: (1) if there is a change in the "basic principles" underlying the product; and (2) if there is a "significant" change in the indications, structure, design, performance, function, and materials of a device that necessitates a re-evaluation of its safety and effectiveness. Unfortunately, the Re-registration Notice does not provide further background on what constitutes a basic-principle or significant change.

Finally, the Registration Rule requires that a "quality tracking report" accompany all re-registration applications. The Re-registration Notice provides that this quality tracking report must contain an analysis of any suspected adverse events, their causes, and an explanation of their "influence" on the safety and effectiveness of the device.

The Re-registration Notice became effective on January 1, 2014. Domestic and foreign manufacturers of medical devices in China should be aware of it when applying for amendments or renewals to their licenses.

2. DRAFT CLASSIFICATION RULE

In 2000, China enacted the Medical Device Classification Rule (the "2000 Classification Rule"). Pursuant to that rule, CFDA classifies all medical devices based on the level of risk of harm to humans, i.e., Class I, II, and III. A device's classification impacts that device in several ways, including the type of licensure process and post-marketing surveillance requirements applicable to that device. China also classifies medical devices by other features, e.g., active, inactive, and IVD.

The Draft Classification Rule is a long-expected update to the 2000 Classification Rule. Whenever a domestic or foreign manufacturer intends to register a new device for the purpose of sales in China, the 2000 Classification Rule provides a reference for determining which class the device falls under in order to prepare the appropriate registration application. CFDA and its local counterparts may also consult the 2000 Classification Rule to determine the classification of a new device.[2] The Draft Classification Rule contains revisions that account for legislative and technological developments since the 2000 Classification Rule.

Notably, the Draft Classification Rule no longer contains a definition of the term "medical device." The drafters explain that this change is intended to accommodate a new definition of medical device that will be included in the revised Medical Device Administrative Regulation. The Draft Classification Rule also incorporates the general classification rules provided under the revised draft of the Medical Device Administration Regulation and specifies that devices are categorized as Class I, II, and III based on their risk levels. A device's risk and, therefore, its class is determined by considering the device's expected purposes, structural features, forms of use, and status of use.

The Draft Classification Rule makes it clear that for medical devices listed under China's 2002 Medical Device Classification Catalogue (the "Catalogue"), their class shall be determined according to the Catalogue. The Catalogue is produced by CFDA and sets out 43 device categories on the basis of the uses of devices. For those devices not listed in the Catalogue, the provincial FDA in the locality of the domestic manufacturer or the location of domestic agent of the foreign manufacturer may propose a class of such devices based on the Draft Classification Rule and submit the proposal to CFDA for approval. CFDA will update the Catalogue with newly classified devices once it has approved them.

Devices outside the Catalogue are classified based on a Classification Determination Table, which is an attachment to the 2000 Classification Rule. When special situations that are not addressed by the table arise, the 2000 Classification Rule sets forth rules (or basic principles) on how to handle those issues. The Draft Classification Rule has not only updated the table, but it has also updated these basic principles:

- First, for a kit containing multiple devices, its class will be that of the highest classified individual device in the kit.
- Second, the classification of device accessories shall be determined by their influence on the effectiveness and safety of the devices with which they are intended to be used.
- Third, a piece of standalone software for function control of a particular device shall be deemed to be in the same class as the device it serves.
- Finally, if the risk level of a particular device is likely to be impacted by any change occurring to such device, such device shall be re-classified. This updated principle of re-classification is

[2] As mentioned below, before consulting the 2000 Classification Rule, manufacturers and authorities might read through Medical Device Classification Catalogue. If such device falls under any category and sub-category of the catalogue, its classification will be clearly set out beside the name of relevant sub-category.

broader than the current principle in the 2000 Classification Rule, which only applies when the device's use purpose and method of function are changed.

Under the Draft Classification Rule, *in vitro* diagnostics is an independent category based on expected purposes and structural features. This new categorization is consistent with China's Registration Measures on *In Vitro* Diagnostic Devices (Trial) issued on April 19, 2007, which treat IVDs as medical devices but also dictate separate processes for research and development and registration.

In accordance with technological developments since 2000, the Draft Classification Rule adds new items under the categories of active and inactive devices. For example, "ordinary medical dressing" and "functional medical dressing" have replaced "medical dressing" under the inactive device category, and "active implantable device" and "standalone software" have been added to the active device category.

Foreign and domestic device manufacturers should continue to monitor for the issuance of the final version of the Draft Classification Rule.

3. DRAFT GSP RULE

Good Supply Practices ("GSP") have been adopted by regulators in many countries. GSP refers to a set of standards for the quality management of the distribution process for drugs and medical devices that aims to minimize the risks and ensure the product quality during this process. The issuance of the Draft Medical Device GSP Rule is a landmark event in device regulation in China.

Until now, China has not adopted any GSP standards for medical devices. In contrast, the GSP standards for drugs have been in place since 2000 and were just revised last year. The lack of GSP standards for medical devices has caused a number of problems, such as: (1) failure of distribution companies to meet the temperature control requirements, included in the specifications for an individual device, during the storage and transportation process; (2) illegal termination of lease contracts for required office and warehouse space, upon receipt of distribution licenses, to reduce operating costs; and (3) failure to keep a record of purchase and sale activities, which makes it impossible to track defective devices.

The Draft GSP Rule is intended to establish basic standards to remedy these and other problems. In that respect, the Draft GSP Rule sets out the fundamental requirements for quality management of medical device distribution. Some of the requirements proposed by the Draft GSP Rule include:

- Corporate officers are primarily responsible for the overall quality of the company's distribution activities, but there must also be specialized quality control personnel.
- Qualification requirements for employees with key roles in quality management, inspections, and sales of implantable devices.[3]
- Companies are required to keep complete and accurate records of procurement, inspection, storage, sales, inventory management, return and replacement, temperature and humidity, inspections, and disposal of nonconforming products for varying lengths of time depending on their classifications.
- Distribution enterprises must have separate offices and warehouses that are suitable to their business scale and scope. Such companies may not place warehouses in residential buildings

[3] In order "to give consideration to small and medium size enterprises," the Draft GSP Rule does not propose minimum numbers of employees who must be qualified in any given role.

or military barracks. It should be noted, however, that there is no minimum square footage requirement for offices or warehouses because local FDAs have already imposed various requirements in this regard.

- Companies engaged in wholesaling of Class III devices are required to install a computer information system to serve the distribution business, whereas distributors of Class I and Class II devices are simply *encouraged* to set up such system.

The remainder of the Draft GSP Rule sets forth practice standards for 10 key steps of the distribution process: (1) procurement, (2) receipt, (3) inspection and acceptance, (4) stock in, (5) storage, (6) periodic checks, (7) sales, (8) stock out, (9) transportation, and (10) after-sale services. The Draft GSP Rule does not apply to online sales.

The biggest open question remains enforcement. The Draft GSP Rule itself does not specify how it will be enforced. It does not make clear, for example, whether companies must apply for a device GSP certification after receiving the required license to distribute medical devices or whether GSP compliance will be incorporated as a step in the device distribution license application process. It is also unclear whether and what type of administrative liability will be imposed if a company fails to comply with the Draft GSP Rule. The measures governing medical device distribution licenses are silent on this point.

CFDA is seeking public comments on the Draft GSP Rule until January 20, 2014. Companies that distribute medical devices in China should consider submitting comments before the close of comment period.

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