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Significant Revisions to China's Regulations on the Supervision and Administration of Medical Devices (State Council Order No. 650)

China's State Council released its new Administrative Regulation on the Supervision and Administration of Medical Devices March 7, 2014, which will be effective June 1, 2014 (the "New Regulation").

The State Council Legislative Affairs Office worked more than six years revising the predecessor of the New Regulation (the "Old Regulation"), which had been effective since 2000. The revisions are intended to establish a more efficient and scientific regulatory regime for supervision and administration of medical devices. The New Regulation addresses research and development, clinical trials, product approvals, manufacturing, business operations, sales, and advertising. Generally, the New Regulation moderates the oversight of low-risk medical devices and strengthens the supervision on high-risk devices. The New Regulation, summarized below, will have a significant impact on all medical device enterprises.

Major Changes

A. Medical Devices Registration and Filing Requirements

- All Category I medical devices, including those manufactured in foreign countries, can enter the market through a filing with CFDA or its local counterpart. CFDA intends that the filing procedure should be more efficient compared with the more burdensome registration procedure. Upcoming guidelines and agency implementation will be important to achieve any efficiencies.
- Under the Old Regulation, a material change in a registered device required a new registration as a new device. By comparison, under the New Regulation, a material change only requires a change in registration. Generally, a material change in a registered medical device is when the device's safety and/or efficacy might be affected by any change in its

design, raw material, manufacturing procedure, etc. In practice, CFDA's local counterparts have wide discretion in determining what changes constitute material changes.

- An immaterial/minor change in a registered medical device is no longer subject to the approval by the original registration authority; filing such change with the authority is sufficient.
- The term of a medical device registration is five years instead of four, and the registration can be extended through renewal, instead of re-registration.

B. Changes in Regulation of Clinical Trials

- Under the New Regulation, clinical trial reports shall be issued by a qualified clinical trial institution. The New Regulation does not address whether clinical trial reports issued in foreign countries are acceptable for foreign manufactured devices. The 2004 Administrative Measures on Registration of Medical Devices allowed foreign clinical data for the majority of imported medical devices and there has been considerable debate on this issue. If only Chinese local clinical trial reports are acceptable in the future, it may cause significant delay and added expenses in the registration process for foreign manufacturers, and possibly for specific classes of devices. More guidance is expected in upcoming implementing rules.
- Under the New Regulation, a clinical trial of low-risk medical devices no longer requires the approval of CFDA or its counterparts, but a filing is required. Certain Category III medical devices that involve very high risks must still obtain the necessary approvals.
- Clinical trials for certain Category II and Category III medical devices that have a proven record of safety can be exempted in accordance with the New Regulation.

C. New Changes for Distributors

- Distributors of Category II medical devices may file with CFDA's counterparts at the municipal level instead of obtaining a permit as required by the Old Regulation. Implementing rules, here also, may make it more clear if filing will be easier.
- Distributors and other sellers of medical devices are required to verify and inspect the qualifications of their manufacturers or providers, as well as the certificates of conformity of the devices they will purchase.
- Wholesalers of Category II medical devices and all Category III medical devices sellers (wholesalers and retailers) shall also establish a system to maintain their sales records.

D. Changes for Manufacturers

- The New Regulation specifically stipulates that medical device enterprises

shall comply with good manufacturing procedures (GMPs) for manufacturing, operating conditions and quality control systems. Manufacturing enterprises must conduct self-inspections on a regular basis and submit self-inspection reports to CFDA's counterparts at the municipal level. CFDA and its counterparts can make regular and random inspections to check on compliance.

- An enterprise that intends to manufacture Category II and/or Category III medical devices may apply for registration of its medical device first and then apply for its manufacturing license. Under the Old Regulation, it had to first obtain its manufacturing license. Under the Old Regulation, before an enterprise was issued a medical device registration certificate, it had to establish qualified manufacturing facilities in order to be qualified for obtaining a manufacturing license. Under the New Regulation, the enterprise can first get its medical device registered, and then proceed to obtain the manufacturing license. This may provide for a speedier overall process, and possibly with lower expenses for the manufacturer.
- The New Regulation stipulates what information must be included in the specifications and labels of medical devices. Medical devices manufactured in foreign countries must have their Chinese labels attached before they are imported into China.
- The New Regulation contains a section on monitoring adverse incidents, re evaluating registered medical devices, and recalling defective medical devices. Every medical device enterprise must now establish an adverse incidents monitoring system to monitor and report adverse incidents.

E. Increased Legal Penalties and Liabilities

- The New Regulation increases liabilities and penalties for manufacturers. The Old Regulation imposed fines for certain serious violations based on two to five times of the illegal proceeds. Under the New Regulation, however, it would be five to 10 times (or even 10 to 20 times) of the value of the involved medical devices.
- Further, the New Regulation clarifies that the fine will be calculated based on the value of the medical devices concerned in its illegal activities, and manufacturing costs and other expenses incurred will not be deducted for the purpose of calculating the fine.
- Every failure to comply with the new requirements imposes significant new penalties. For instance, the New Regulation presents punishment for deceptive advertising on medical devices; and punishment for forgery, alteration, purchase, sale, and lease of any medical device certificates or permits.

Other Important Provisions

Other changes include:

- The New Regulation redefines the scope of “medical devices.” It now includes vitro diagnostic reagents and calibrators. It also adds the following to the description of the purpose of medical devices: (i) for life support or maintenance; and (ii) to provide information for medical treatment or diagnosis through human sample testing.
- The requirement that Category III medical devices shall be subject to the China Compulsory Certification is removed.
- The New Regulation repeats and emphasizes the major liabilities of manufacturing enterprises to recall defective medical devices that are stipulated in the Administrative Measures on Recall of Medical Devices (2011).

CFDA is developing a number of important guidelines that will implement many of these changes. These should clarify what manufacturers and distributors need to do to comply with the New Regulation.

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