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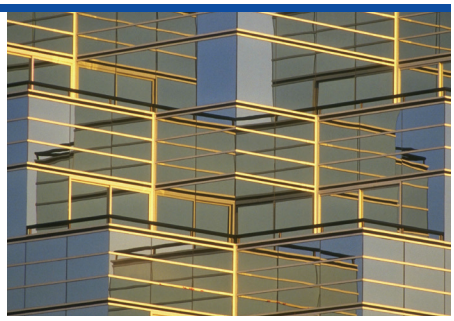
China Amends Regulations on Supervision and Management of Medical Devices; Prior Marketing Approval Requirement to Import Medical Devices Remains Unchanged



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On March 31, 2014, China Premier Mr.Li Kequiang signed Decree No. 650 on the amended *Regulations on Supervision and Management of Medical Devices* ("the amended regulations"), which update the original regulations[1] released in January 2000. In comparison to the original regulations, the amended regulations ease the supervision and management of low risk medical devices, establish a monitoring and recording system for distribution and usage stages, and increase penalties for violations and noncompliance. The amended regulations will enter into force on June 1, 2014.

The significant changes contained in the amended regulations are as follows:

- **Refining the definition of medical devices:** The amended regulations newly include in vitro diagnosis reagents and calibrators into the category of products defined as medical devices. They also expand the description of the purpose of medical devices by including: (a) "life support or maintenance"; and (b) "to collect information for diagnosis or treatment utilizing human sample testing."
- **Easing classification-based supervision and management of products:** By clarifying the three-class classification system based on potential health risk levels, the amended regulations ease supervision requirements of low risk medical devices:
  - Class-I devices,[2] whether imported or not, are no longer subject to registration procedures. Instead, such devices must be notified before the municipal offices of China's Food and Drug Administration (CFDA). However, Class-II and Class-III[3] devices are still subject to registration before CFDA's provincial offices and CFDA itself, respectively.

1 Order 276 "Regulation on Supervision and Administration of Medical Devices" dated January 4, 2000.

2 Class-I devices include scissors and blades for general surgery use, among others.

3 Class-II devices include medium-risk devices that affect health safety such as sphygmomanometers and condoms. Class-III devices include high-risk devices used to maintain or support vital functions, such as disposable syringes, contact lens, artificial joints, and anesthetic gas machines.

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- Under CFDA's direct supervision and management, ***imported medical devices are no longer subject to approval prior to their first importation in China***. However, the same CFDA classification-based management system described above applies. Notably, it is still necessary to submit prior marketing approval in the country of origin when filing records or applying to register any imported medical device before the CFDA, regardless of class.

- Though the amended regulations maintain clinical trials as a general requirement for registration of Class-II and Class-III devices, they waive the clinical trial requirement for certain Class-II and Class-III devices listed in a separate catalogue to be developed by CFDA. It remains uncertain at this time when the CFDA will release the catalogue.

- **Improving supervision of production, distribution, and usage stages:**

  - Producers of Class-I devices must still file records before the municipal CFDA offices, while producers of the other two categories of devices must apply before CFDA's provincial offices to obtain production licenses, which are valid for five years.

  - Distributors of Class-III devices are subject to a distribution licensing system under the amended regulations. Meanwhile, distributers of Class-II devices are only required to register with CFDA's municipal offices, while distributors of Class-I devices are free from the registration process.

  - Distributors and users of medical devices are required to establish inspection systems when purchasing such products. Wholesalers of Class-II and Class-III devices, as well as retailers of Class-III, are required to establish separate sales records.

  - The amended regulations also establish a monitoring mechanism regarding the adverse effects of medical devices, along with a recall and revaluation system for registered devices.

- **Increasing penalties for violations and noncompliance:** The amended regulations increase the penalty ranges and types of penalty measures. For example, medical device distributors who violate the registration and/or approval requirements may face a fine of up to 20 times the value of the goods sold and/or the suspension of licenses.

While the amended regulations are an improvement over the previous version, they still fall short of addressing certain key technical barriers to trade (TBT) raised by the United States and other trading partners with respect to prior marketing approval in the country of origin requirements for imported medical devices. This trade barrier was most recently highlighted in United States Trade Representative (USTR)'s 2014 Technical Barriers to Trade Report released on April 1, 2014 *(please refer to the W&C US Trade Report dated April 15, 2014)*. It is likely that the Chinese government will continue to encounter pressure from foreign medical device manufacturers to further revise the regulations to remove this trade irritant.

Click here for a copy of Decree 650 (in Chinese).

Please let us know if you have any questions.