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China Announces Amendments to Regulation on the Supervision and Administration of Medical Devices

On May 19, 2017, China's State Council promulgated the amendments to the 2014 Regulation on the Supervision and Administration of Medical Devices ("the Amendments"), which became effective immediately. The Amendments clarify issues related to device distributors' liabilities of selling non-conforming products, the use of large medical equipment, and revocation of clinical study site certification.

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The key changes proposed in the Amendments can be summarized as follows:

- **Device distributors can be exempted from penalties of selling non-conforming products if they fulfill the inspection obligations:** Under the original Article 66 of the 2014 Regulation on the Supervision and Administration of Medical Devices, a device distributor would be sanctioned by the local counterpart of China Food and Drug Administration ("CFDA") for selling any devices that do not meet with mandatory standards or product technical requirements. In practice, it is unreasonable to require a distributor to conduct quality inspections on the incoming devices to ensure compliance with this Article 66. The Amendments now clarify that the device distributors can be exempted from penalties if they fulfill the inspection obligations under the regulations and can identify the source of such devices.
- **Device study sites do not need to be pre-certified:** Medical institutions can conduct clinical studies if they complete record-filing with the local authorities. The criteria will be promulgated and announced by the CFDA and National Health and Family Planning Commission ("NHFPC").
- **Authorities can supervise the deployment of large medical equipment:** According to the Amendments, large medical equipment is defined as any large medical equipment that involves complicated technology, huge investment, high operating costs and huge impacts on medical costs. Large medical equipment is subject to catalogue management. The Amendments specify that local health authorities can penalize hospitals for failure to comply with the restrictions for using large medical equipment, such as excessive examination and excessive treatment. In the current administrative rules governing large medical equipment, health authorities are only authorized to issue an order to cease the use of the relevant equipment if the hospitals violate the use restrictions for large medical equipment. However, the Amendments provide that the local health authorities can impose a fine in the range of five to ten times of the illegal proceeds for any use of large medical equipment without a permit. In addition, providing false materials when applying for the large medical equipment permit will be subject to a fine of no more than 100,000 RMB.

If you would like to discuss the foregoing or any other related matter, please contact [Katherine Wang](#) or your usual Ropes & Gray advisor.