China Introduces Major Changes to Medical Device Regulations

On March 31, 2014, China's State Council released the amended *Regulations on the Supervision and Administration of Medical Devices* (the "Regulations"), effective as of June 1, 2014. A series of implementing rules are expected to be further released by the CFDA in coming months.

This long-anticipated amendment will significantly change China's device regulatory regime on the following aspects:

- A risk-based administration

The Regulations classify medical devices into Class 1, 2, or 3 based on product risk profiles. The China Food and Drug Administration ("CFDA") can dynamically adjust the classification based upon changes in the risk profiles.

The marketing authorization process varies by product risk profiles. Unlike Class 2 or 3 devices, Class 1 devices do not require prior approvals by the CFDA or its local counterparts; a prior filing for record with the relevant municipal FDA is sufficient. Similarly, prior approvals are not mandatory for the distribution of Class 1 and 2 devices. Distributors of Class 3 devices can apply for approvals from municipal FDAs, rather than provincial FDAs as currently required.

- Encouraging device innovation

The Regulations introduce several measures to foster device R&D. Clinical trial authorizations will no longer be mandatory for Class 2 devices, and will only be required for certain high-risk Class 3 devices. Class 2 and 3 devices with proven safety records in clinics or through non-clinical methods can be exempt from clinical studies. Furthermore, the amended Regulations allow companies to apply for marketing authorizations without first obtaining the device manufacturing permit, provided that the relevant GMP requirements are fully in compliance during product design and development processes. This change will help R&D-based device companies save substantial investments in manufacturing facilities.

- Raising the bar for device GMP and GSP compliance

Device manufacturers must establish and operate GMP-compliant facilities, and periodically report self-evaluation results to the relevant provincial FDAs. Device distributors, on the other hand, must establish a GSP-compliant system to inspect and accept product deliveries as well as the relevant permits and licenses supplied by manufacturers. It will be mandatory for wholesalers of Class 2 and 3 devices as well as retailers of Class 3 devices to maintain complete sales records.

- Strengthening post-market supervision

A dedicated chapter was added to the amended Regulations governing the monitoring of device adverse events, product re-evaluation, and product recalls. The amended Regulations require the local FDAs to continuously scrutinize device companies on their post-market compliance, and exercise investigational

powers when appropriate, e.g., to seize relevant contracts, accounting books, and illegal medical devices. In serious cases, local FDAs can shut down premises used for illegal production and distribution.

- Escalated penalties for non-compliance

Sanctions for non-compliance will be considerably stricter under the amended Regulations. For example, penalties for unlicensed manufacturing (distribution) or manufacturing (distribution) of unlicensed products will be as high as 20 times the value of devices concerned. Device companies will also be barred from applying or renewing the relevant licenses or permits for five years.

Device companies are encouraged to carefully evaluate impacts of the amended Regulations on their operations in China and incorporate new statutory requirements in their market entry strategies.

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