China Tightens Supervision and Enforcement in the Medical Device Sector

On March 13, 2014, the China Food and Drug Administration (the "CFDA") announced an action plan titled "*Rectifications of Five Common Types of Noncompliance Concerning Medical Devices*" (the "Five Rectifications Campaign"). A five-month enforcement campaign will be launched to implement this plan.

The "Five Rectifications Campaign" is being initiated by the Department of Medical Device Supervision under the CFDA. This department was newly created after the CFDA's organizational restructure in May 2013, signaling the agency's intention to strengthen post-market supervision. The "Five Rectifications Campaign" aims to address prevalent and serious acts of misconduct. It will also help the CFDA define a baseline of compliance for the imminent promulgation of the amended *Regulations for the Supervision and Administration of Medical Devices*.

Specifically, the following types of noncompliance are deemed high priorities for rectification:

- Fraud and misrepresentation relating to product registration: The enforcement will focus on the integrity of clinical trial data and the truthfulness of the sample production process in relation to initial registrations of Class 2 and 3 devices.
- Noncompliance relating to product manufacturing: The enforcement will focus on failures to properly sterilize disposable devices (such as IV sets or bladder catheters), and failures to properly examine dialysis concentrate and solutions before product release.
- Noncompliance relating to product distribution: The enforcement will focus on the sale of unlicensed Class 2 and 3 devices in the name of user experience programs, and violations in relation to the storage and transportation of IVD reagents.
- Noncompliance relating to product promotion: The enforcement will focus on illegal advertising of physiotherapeutic devices, unapproved device advertisements, exaggeration of product efficacy, and off-label promotion.
- Use of unregistered products: The enforcement will focus on the clinical use of unregistered IVD products at hospitals.

The CFDA urges provincial FDAs to impose maximum penalties on companies found committing any of the five types of noncompliance, and to revoke their licenses to operate. Provincial FDAs will also demand that companies cease immediate sale and order the companies to recall products for disposal.

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