China Enhances Regulatory Oversight of Medical Device Studies and Vigilance

The China Food and Drug Administration ("CFDA") recently introduced two important initiatives concerning medical devices.

1. The *Tentative Rules on the Review and Approval of Medical Device Clinical Studies (Draft)* was announced for public comments until October 31, 2013. The CFDA intends to impose a pre-approval requirement for certain high risk Class 3 medical devices listed in the *Catalogue of Class 3 Medical Devices subject to Clinical Trial Authorization* ("CTA Catalogue"). The proposed CTA Catalogue includes 15 types of high risk implants, such as implantable pacemakers/defibrillators, implantable blood pumps, nano orthopedic implants, 3D-printed orthopedic implants, prosthetic heart valves and oral bone filling material containing drugs or biologics. Manufacturers of these high risk implants will need to apply for the CTA with the CFDA and the statutory timeline for approval is 95 days in total. In addition, a supplementary CTA application is mandatory in the events of (1) substantive changes in the study protocol, informed consent or other documents which may compromise the rights, safety and health of study subjects, the scientific merits of the study, data quality, study objectives, or end points; or (2) resuming a study previously suspended or terminated as required by the Medical Device GCP. The statutory timeline for the supplementary CTA is also 95 days.

2. The *Guiding Opinion on Further Improving the Infrastructure for the Monitoring of Medical Device Adverse Events* was issued on October 8, 2013 to define a 3-year work plan for the expansion of a monitoring network and upgrade of the technical evaluation capabilities. Local FDAs are expected to assign dedicated people to provide technical support for better evaluation and risk assessment of medical device adverse events, and form a coordination mechanism with the local health authorities to raise awareness of proactive monitoring of adverse events at healthcare institutions. The CFDA plans to establish a monitoring network comprised of all Class 3 medical device manufacturers and the majority of Class 3 medical device distributors as well as Class 3 and Class 2 hospitals by the end of 2015.

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