China Releases Fast Track Approval Process for Innovative Medical Devices

On February 7, 2014, the China Food and Drug Administration ("CFDA") promulgated a notice titled *The Fast Track Approval Process for Innovative Medical Device (Tentative)*, effective as of March 1, 2014. Unlike the draft notice issued in March 2013 which acknowledged only domestic medical device companies as qualified applicants, the official notice allows both domestic and foreign medical device manufacturers to benefit from the fast track approval process.

A medical device eligible for the fast track approval process must be "innovative," which is defined by the following criteria: (i) the core technology related to the product must be registered in China as an invention patent that the manufacturer owns or is licensed to use, or the patent claims covering the core technology have been published by the State IP Office; (ii) the product's working or functioning mechanism was first seen in China, its performance or safety improved significantly compared to similar products, and its technology is worldwide pioneering and has evident value in the clinical application; and (iii) the manufacturer has completed the early stage R&D and the product's basic design, the R&D activities are authentic and under control, and the R&D data is complete and traceable.

In addition to the relevant patent certificate/information, the applicant is required to submit the following to substantiate the notion of innovation: (i) a search report issued by an information or patent search institution; (ii) academic papers or articles published in core journals that can fully prove the clinical value of the product; (iii) analysis of the application of the same kind of product marketed in China and abroad (if any); and (iv) proof of the product's innovativeness and significant clinical value.

The eligibility for fast track approval will be initially assessed by the Provincial Food and Drug Administrations (with respect to domestic applications) or the CFDA (with respect to foreign applications) within 20 working days from the date of accepting the applications. Once the preliminary review is satisfactory, the submissions will be transferred to a special office under the Center for Medical Device Evaluation ("CMDE") for a final decision within 40 working days from the date of case acceptance. This special office will also be in charge of review and approval of such innovative medical devices.

Once an innovative medical device is qualified for the fast track approval process, the CFDA and the Provincial FDAs will prioritize such applications throughout the entire approval process, ranging from regulatory testing, technical reviews and quality management system inspections. In addition, the CFDA and the Provincial FDAs are required to appoint a dedicated liaison to respond to and guide the applicant in a timely manner. The final notice also creates an opportunity for the applicant to spontaneously request discussions with the CMDE on major technical issues, safety matters, clinical study protocol, and other issues, an opportunity which is currently not available.

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