April 10, 2013

The China State Food and Drug Administration (SFDA) began to solicit public comments on the draft Special Procedures for Examination and Approval of Innovative Medical Devices (Special Procedures) on March 20, 2013. The Special Procedures were designed to streamline and increase the efficiency of the examination and approval process for medical devices and further support the development of innovative medical devices industry in China.

The Special Procedures would grant qualified innovative medical devices priorities in multiple procedures in the medical device registration process, on the condition that the standards will not be lowered and the registration procedures will not be reduced.

Under the Special Procedures, innovative medical devices must meet certain eligibility requirements to be granted priority status, including an IP requirement, innovation requirement, development stage requirement and localization requirement. Specifically, (i) the applicant must be either the owner or licensee of Chinese invention patents covering the core technology; (ii) the product is superior to other products on the market and innovative, and has significant clinical application value; and (iii) the product has gone past early development stage. Furthermore, the applicant must be a legal entity established in China and have a Medical Devices Manufacturing License; the product must be manufactured in China.

In order for a medical device to be approved under the Special Procedures, the applicant shall file a special examination and approval application with the local counterpart of SFDA at the provincial level (Local FDA). The applicant must get its application dossier ready and submit such to the Local FDA, which includes an application form and supporting documents to prove its eligibility under the Special Procedures. For example, with respect to the innovation requirement, the applicant must provide: (i) a patent search report issued by an information or patent search institution at a national level; (ii) academic papers published in core journals that can fully prove the clinical application value of the product; (iii) description of the product's innovativeness and significant clinical application value; and (iv) analysis of the application of the same kind of products marketed in China and abroad, etc. The Local FDA will conduct a preliminary review and then submit the application together with its preliminary opinion to the SFDA for final approval.

Upon approval by the SFDA of its eligibility under the Special Procedures, the innovative medial device will enjoy first priority in going through the following formalities with relevant authorities or institutions: quality control system assessment, medical device registration testing, technical evaluation, and final examination and approval by the SFDA after the technical evaluation.

In addition to giving first priority to innovative medical devices regarding the registration procedures, both the SFDA and Local FDAs are required to communicate with and provide guidance to the applicant, to deal with technical problems and speed up the registration process. The communication mechanism provided under these Special Procedures is similar to the communication mechanism for new drug registration set forth under the Administrative Provisions on Special Examination and Approval of the Registration of New Drugs issued by SFDA on January 7, 2009.

The Special Procedures illustrate the government's strong support for the innovation of the medical devices industry. However, the provisions are fairly vague, and it is not clear whether faster approvals will be obtained under these Special Procedures. For example, there is no designated review channel for innovative medical devices, and there is no statutory timeline for completing priority reviews. Given the high eligibility requirements and burdensome documentation requirements under the Special Procedures, applicants may not be incentivized to avail themselves of the Special Procedures. From this perspective, the utility of the new examination and approval mechanism still remains to be seen.