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China FDA Solicits Comments on Priority Review Designation Procedure for Devices

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The China Food and Drug Administration ("CFDA") recently proposed a draft circular to address the priority review designation issue for medical devices, namely the *Circular Regarding Soliciting Comments Regarding Priority Review Designation Procedure for Medical Devices* (CFDA Circular [2016] No.40, the "Circular"). The Circular, which is now open to public comments through July 20, 2016, proposes the qualifying criteria, process, and features of priority review.

Prior to being marketed in China, any Class II and Class III device must go through a detailed technical review process conducted by the Center for Device Evaluation under the CFDA or at the provincial level ("CMDE"). The priority review designation discussed in the Circular may offer the device applicant a shorter review timeline for the application.

According to the Circular, an applicant with a Class II device (limited to imported application) or a Class III device (both domestic and imported application) can request priority review when submitting the device application, if the device (i) has been enrolled in the *National Science and Technology Major Project* or *National Key Research and Development Plan*, or (ii) meets any of the following conditions:

- can diagnose or treat rare diseases, and has outstanding advantages in clinical practice;
- can diagnose or treat malignant tumors, and has outstanding advantages in clinical practice;
- can diagnose or treat specific and frequently occurring diseases in the elderly, and where there is no effective way to diagnose or cure for such disease;
- can diagnose or treat specific and frequently occurring diseases in children, and where there is no effective way to diagnose or cure for such disease; or
- can address an urgent clinical need and the same type of device has not yet been marketed in China.

The CMDE will assess whether a device is eligible for priority review, and decide the priority review designation before the technical review process begins. For any application that has passed the initial eligibility review, a third party may submit an opposition to challenge the initial eligibility review result during the public notification period. A device application that does not receive a priority review designation will follow the standard review process.

A device application that receives "priority review" designation will be eligible to take advantage of several features intended to expedite the review process. Notably, the device applicant may enjoy frequent interactions with the CMDE.

In some cases, the CFDA may exercise its discretion to determine whether a device application qualifies for priority review based on an expert panel's opinion, not just when priority review is requested by the applicant.

The CFDA has already developed two expedited approval processes for devices, including (i) an accelerated approval for devices applicable to emergency public health incidents, and (ii) fast track approval for innovative

devices. Therefore, the release of the Circular reflects CFDA's determination to introduce new approaches to improve the device review time. Device companies are advised to monitor the changes recommended in this Circular.

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