Cooley

China Food and Drug Administration Offers Guidance on Clinical Trial Exemptions for Medical Devices

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Eligible medical devices for clinical trial exemptions

The "Administrative Measures for the Registration of Medical Device" (Registration Measures) was issued by the China Food and Drug Administration (CFDA) and became effective on October 1, 2014. According to the Registration Measures, Class II and Class III devices meeting the following criteria are exempt from clinical trial requirement：devices that have been sold and used for years without record of serious adverse events; devices that can be proven safe and efficacious by evaluation of non-clinical data; and devices that can be proven safe and efficacious by evaluation of clinical data of medical devices of the same type.

The CFDA is entrusted to compile and publish catalogues of medical devices that are exempt from clinical trials (Exemption Catalogues). The first batch of exempt Class II and Class III devices was published by the CFDA on August 21, 2014 and included more than 500 devices. The second batch was published by the CFDA for comment on December 14, 2015 and included an additional 300 devices.

The Exemption Catalogues are not intended to be exhaustive lists of medical devices that are exempt from clinical trials. The Registration Measures make it clear that even if a device is not listed in the Exemption Catalogues, if it can be proven safe and efficacious by evaluation of clinical data of medical devices of the same type, the applicant is able to provide an explanation and submit the supporting data at the time of registration application.

Further guidance on seeking clinical trial exemptions

On May 19, 2015, the CFDA issued the Technical Guiding Principles on the Clinical Evaluation of Medical Devices (Guiding Principles) to provide further guidance on how applicants can obtain clinical trial exemptions for eligible medical devices.

According to the Guiding Principles, if a medical device is listed in the Exemption Catalogues, the applicant needs to demonstrate that its device is "equivalent" to the listed device. The applicant could accomplish this by submitting data comparing its device to the description of the device listed in the Exemption Catalogues and by comparing its device to a device of the same type that has been registered in China.

If a medical device is not listed in the Exemption Catalogues, the applicant could get around the clinical trial requirement by proving that its device is safe and efficacious through comparisons with a medical device of the same type that has been registered in China and is substantially equivalent to the device under registration in terms of fundamental principle, structure, manufacturing materials, and other aspects.

To prove that the medical device under registration is substantially equivalent to a registered medical device of the same type, the applicant is required to compare both the similarities and the differences between the medical device under registration and the

medical device of the same type, and confirm that any difference between the two devices does not have any adverse effects on the safety and efficacy of the product being registered. Both clinical trial data and clinical application data within or outside of China could be used to support the analysis and clinical data could include clinical literature data and clinical experience data.

Although the Registration Measures mention that medical devices can be exempt from the clinical trial requirement if they can be proven to be safe and efficacious through non-clinical evaluations, the Guiding Principles make no mention of exemption through this approach.

Status and challenges

The regulations on clinical trial exemptions are relatively new. There have not been many applications submitted for exemptions. Therefore, it is not clear how useful these regulations are to companies that are trying to bring medical devices that are similar to those already on the Chinese market to China and hope to expedite the registration process in reliance on clinical trial exemptions. For applicants that are trying to seek an exemption for devices that are not listed in the Exemption Catalogues, the biggest challenge likely to be obtaining the data for medical devices of the same type.