China Unveils Detailed Rules to Implement the Core Device Regulation

The amended *Regulation for the Supervision and Administration of Medical Devices* (the "Regulation," also known as the State Council Order No. 650), which came into force on June 1, 2014, set the new framework for China's device regulatory regime. On August 1, 2014, the China Food and Drug Administration (the "CFDA") unveiled five rules to implement this core Regulation (the "Implementing Rules"). The Implementing Rules cover several key aspects of regulating medical devices, including marketing authorization, package inserts and labelling requirements, manufacturing, distribution, and separate rules for IVD products. The most noteworthy updates include the following:

- Contract manufacturing of prototypes and commercial supplies is only available for innovative devices.

  According to the Regulation, companies may apply for marketing authorizations (or product registrations) without first obtaining device manufacturing permits.

  The Implementing Rules clarify that a company will still need a manufacturing permit to commercialize the product license if its product is not an innovative device designated for fast track approval by the CFDA. Only license owners of CFDA-designated innovative devices can completely outsource manufacturing of both the initial prototype and the final commercial supplies, with the exception of certain high-risk implantable devices. In the event where the product in question is a non-innovative device, the license owner must manufacture a prototype in its own capacity, build its own manufacturing facilities and obtain a device manufacturing permit before it can use a contract manufacturer for the unmet manufacturing demands.

- Clinical trial waiver is possible if safety and efficacy can be demonstrated through analysis of clinical data of the same type of products.

  The Regulation generally requires companies to conduct clinical trials for the registration of Class II and III devices unless certain prerequisites are met. It also provides that a "waiver catalogue" will be issued by the CFDA to list all the exempted devices. It left open whether a product not on the "waiver catalogue" can be waived from clinical trials.

  Now the Implementing Rules clarify that for products not on the "waiver catalogue," an applicant can still apply for trial waiver on a case-by-case basis. To obtain a waiver, an applicant must demonstrate the safety and efficacy of a device through data derived from clinical trials or clinical uses of the same type of product.

  For certain high-risk Class III devices, the Regulation also requires clinical trial authorizations ("CTA") before conducting clinical trials. The Implementing Rules further specify that the technical review of a CTA should be completed within 40 working days of submission, and the trials should be initiated within three years of the issuance of a CTA.

- Mandatory QMS/GMP on-site inspections will be arranged before product registration and manufacturing authorization.

  The Regulation generally requires that companies comply with the relevant quality management requirements during product design and development. It is not clear whether an actual inspection over the

applicant's quality management system (QMS/ GMP) would be conducted by the provincial FDAs during the product registration stage.

The Implementing Rules clarify that during the technical review of a domestic product, the relevant provincial FDA is responsible for organizing a QMS/GMP inspection of the applicant, to be completed within 30 working days. This additional step could potentially prolong the device registration process. It is speculated that a later QMS/GMP inspection prior to the grant of the manufacturing permit may take less time.

As for import products, overseas QMS/GMP inspections can also be carried out by the CFDA over foreign applicants when deemed necessary during the technical review.

- License amendment for non-substantive changes and license renewal are simplified.

  The Implementing Rules divide a product license amendment into an amendment of either "approved items" or "registered items." Changes to "approved items" — such as product name, model, specifications, structure and composition, scope of use, and product technical standards — will require technical reviews and longer lead time. Changes to "registered items," on the other hand, such as the name and address of the applicant, can be granted within 10 working days of submission.
  In any case, a product license is now valid for five years and renewal cannot be rejected except on explicit statutory grounds. If a renewal application is neither approved nor rejected on the date of license expiry, renewal is deemed automatic.

Device companies are encouraged to carefully review the Implementing Rules in conjunction with the Regulation and assess the potential impact on their market access and regulatory compliance in China. Meanwhile, the CFDA is contemplating more ancillary device rules, including a new version of device classification, a new GSP and an updated GMP in the coming months and stakeholders should continue to monitor the progress.

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

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