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China Life Sciences

October 10, 2017

China's Central Government Unveils Final Policy for Drug and Device Regulatory Reform

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Based on the CFDA's policy proposals published in May 2017, China's central government announced its final policy for drug and device regulatory reform on October 8, 2017 ("Final Policy"). The Final Policy reiterates the importance of creating an innovative-conducive regulatory system and incorporates the CFDA's main proposals to deregulate the conduct of clinical studies, to accelerate drug and device approvals, and to reinforce the responsibility of Marketing Authorization Holders.

In addition, the Final Policy attempts to strike a balance between the potentially conflicting interest of innovative and generic drug manufacturers. For example, the Final Policy modifies certain initiatives concerning the exclusivity entitlement of innovative drugs in the CFDA's draft. Compared with the CFDA's proposals, the Final Policy removes procedural details of the patent linkage system and the specific number of years of regulatory data protection for eligible drugs. The Final Policy seems to have intentionally left these details for further elaboration in the implementing measures to be issued by the CFDA and other related government authorities, e.g., the State IP Office.

Last but not least, the Final Policy introduces a few new initiatives that were not included in the original CFDA's proposals. It announces a pilot program to grant compensatory patent term extensions to selective new drugs under defined conditions. Meanwhile, it also calls for the CFDA's actions to promote early launch of generic drugs, biosimilars, and follow-on drug-device combination products to improve accessibility and reduce the health care burden.

Highlights of the Final Policy include the following:

1. Deregulating the conduct of clinical studies: The Final Policy upholds the CFDA's proposal to simplify the qualification process for clinical study sites and the ethics committee approval process. According to the Final Policy, companies need to secure the relevant ethics committee approvals before applying for the Clinical Trial Authorization. Nevertheless, the Final Policy neither explicitly sets a time limit for the Clinical Trial Authorization process (a time limit of 60 working days was previously provided in the CFDA's proposals), nor explicitly allows foreign companies to conduct Phase 1 studies in China.

2. Accelerating the drug and device approval process: The Final Policy upholds the CFDA's proposal for conditional approvals for urgently needed therapies and orphan drugs, as well as market access benefits for new drugs. A rare disease catalogue and a rare disease patient registration system will be set up, and applicants of new products treating rare diseases may be eligible for reduced trials. Innovative drugs and devices funded by China's national R&D research grants will be eligible for priority reviews.

3. Promoting drug innovation and the growth of generics: The Final Policy re-affirms the CFDA's proposals to establish a patent linkage system and to enhance regulatory data protection. However, the Final Policy removes the procedural details pertaining to both mechanisms. Generic manufacturers are required to notify patent holders of their applications for marketing authorizations in order to allow their timely filing of patent litigation claims. The CFDA/CDE's review of the generic applications does not automatically stay during the patent disputes. China's unique patent linkage system may not be able to sufficiently protect patent holders

in its implementation, because the China Orange Book has not been formally announced, and follow-on applicants will not be motivated to voluntarily notify the parent holders.

4. Strengthening the administration and supervision throughout product life cycles: The Marketing Authorization Holder system will be rolled out nationwide for both drugs and devices, allowing research-focused individuals and organizations to become license holders. However, the Marketing Authorization Holders will be held ultimately responsible for pre-approval and post-approval compliance obligations, as well as for the activities of their contracted research organizations, manufacturers and distributors. The CFDA and local FDAs will continue to ensure GCP, GMP, and GSP compliance through rigorous inspections. The Marketing Authorization Holders also need to register their medical representatives with local FDAs in order to detail physicians.

5. Enhancing technical review infrastructure: The Final Policy upholds the CFDA's proposal for a multi-disciplinary technical review system and reinforces the CFDA and Center for Drug Evaluation ("CDE") officials' confidentiality undertakings during the technical review process. Technical review conclusions will be made public for transparency and better oversight (except for company confidential information). The Final Policy accepts the CFDA's proposals for allowing CTA applicants' pre-submission consultation meetings with the CDE, but it removes procedural details therefrom. It also declares that the authority for technical reviews concerning Class 2 medical devices will be gradually consolidated by the Center for Medical Device Evaluation.

The Final Policy will likely reshape the competitive dynamics in China's life sciences industry. R&D-based pharmaceutical and medical device manufacturers should carefully study the Final Policy, monitor the follow-on implementation measures to be issued, and analyze their impacts on business operations in China.

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