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China Life Sciences

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China's State Council Announces Reform on the Drug and Device Approval System

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China will launch new reforms of its current review and approval system for drugs and medical devices, announced by China's State Council, in its August 18, 2015, circular *Opinions Concerning the Reform of the Review and Approval System for Drugs and Medical Devices Issued by the State Council* (the "Opinions", Guo Fa Notice [2015] No.44). The Opinions describe (i) launching a pilot program of a market authorization holder ("MAH") system for drugs, (ii) allowing synchronous in-country clinical trials for new drugs that have not yet been marketed overseas, and (iii) adopting qualified clinical data obtained directly from multicenter clinical trials.

Overall, the reform emphasizes improving the efficiency of the review system, resolving the drug application backlog by the end of 2016, improving the quality of the generic drugs, encouraging the development of innovative drugs and creating a more transparent review and approval process.

Major reforms provided in the Opinions include:

- **Launching MAH Pilot Program for Drugs**: In the current legal framework, only drug manufacturers are qualified to obtain regulatory approvals. Under the proposed MAH pilot program, both R&D institutions and scientific research personnel can apply for approvals for new drugs. Furthermore, when R&D institutions and scientific research personnel transfer the new drug approval to a drug manufacturer, it will not be necessary to repeat the technical review process. Instead, an on-site inspection of the manufacturer's manufacturing process and product testing will be sufficient.
- **Improving Drug Clinical Trial Approvals**: Companies can arrange synchronous clinical trials in China for new drugs that have not yet been marketed overseas. Any qualified clinical data obtained from multicenter clinical trials can be used in the drug application.
- **Simplifying the Drug Approval Process**: The Opinions introduce new measures that will (i) simplify the drug technology transfer review process, (ii) change from an approval system to a filing system for bioequivalence studies of generic drugs, (iii) reject renewal applications for any approved drugs that were not marketed within the valid term of their approvals, and revoke such drug approvals upon expiration.
- **Introducing New Classifications and Definitions for Drugs**: Currently, drugs are classified as (i) new drugs and (ii) generic drugs. The Opinions confirm that new drugs will be further classified into innovative drugs and improved forms of new drugs. Furthermore, the Opinions provide new definitions for (i) new drugs, meaning drugs that have not yet been marketed anywhere in the world (a more restricted term than the current definition, which includes drugs marketed outside China but not yet in China); and (ii) generic drugs, meaning drugs consistent with the originator drug in quality and efficacy.
- **Accelerating the Approval Process for Innovative Drugs**: The Opinions permit more types of new drugs to have access to accelerated reviews and approvals. In addition to innovative drugs and new drugs that address urgent clinical needs (e.g., AIDS, malicious tumors, critical contagious diseases, rare diseases), the following types of drugs will benefit from the fast-track reviews and approvals: (i) drugs sponsored by national science and technology grants, (ii) innovative drugs and pediatric drugs whose manufacturing is

localized in China, and (iii) innovative drugs using modern formulation technology, applying innovative treatment measures, or having apparent treatment advantages. Applicants need to make a commitment that the in-market price of their innovative drugs will be no higher than that in the country of origin or in any comparable markets around China.

- **Reforming the Approval Process for Medical Devices**: Any innovative medical device applications with patented core technology and significant clinical value will be reviewed on an accelerated basis. The regulatory body will timely amend the domestic technical standards for medical devices and adopt more international standards. In addition, the CFDA will delegate provincial level FDAs to lead the reviews and approvals concerning mature, safe and controllable devices.

Since the Opinions set forth only general principles of the reforms, more detailed implementation measures are expected from the China Food and Drug Administration ("CFDA"), which has apparently already begun drafting some measures (e.g., the MAH pilot program, the fast-track review channel for innovative drugs).

To achieve the aforementioned tasks, the Opinions propose (i) accelerating amendment of the current legislation, i.e., the Drug Administration Law and its Implementing Measures, as well as the Drug Registration Rules; (ii) adjusting and increasing the registration fees for drugs and devices every five years; (iii) considering hiring more examiners or experts to handle technical reviews; and (iv) establishing a joint task force amongst the relevant government agencies to guide the reform.

The Opinions represent a strong determination of China's central leadership to reform the drug and device review and approval mechanism. Life sciences companies should closely monitor the implementation initiatives published by the China FDA and incorporate these changes into their business strategies 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.