China Reforms Its Review and Approval Systems for Drugs and Medical Devices

On August 18, 2015, China’s State Council issued an important document, the Opinions on Reforming Review and Approval Process for Drugs and Medical Devices (the RAP Opinions). The RAP Opinions require China Food and Drug Administration (CFDA) to finish its backlog of drug applications by the end of 2016 and to follow strictly its statutory review and approval timeline beginning in 2018. In addition, the RAP Opinions offer directions to reform the existing review and approval systems. The highlights are:

- The current drug classification system will be changed. “New drugs” will be defined as drugs not marketed anywhere in the world and further categorized into innovative new drugs and improved new drugs; “generic drugs” currently defined as “drugs having existing national standards” will be re-defined as “drugs having equivalent quality and efficacy with the originators’ drugs.”

- Innovative drugs will get expedited review and approval. Certain drugs will be entitled to a fast-track review and approval by CFDA, including (i) innovative drugs treating HIV, malignant tumors, severe infectious diseases and rare diseases; (ii) innovative drugs and pediatric drugs for which manufacturing is transferred to China; (iii) innovative drugs with advanced formulation techniques, innovative treatment methods or apparent treatment advantages; (iv) drugs responding to urgent clinical demand; and (iv) drugs developed under special national research and development programs of China.

- A market authorization holder (MAH) system will be implemented on a trial basis for drugs. Research and development institutions and research personnel may apply for drug approvals in their own names and when the approved technologies are transferred for manufacturing, the manufacturers will only be subject to CFDA’s on-site inspection and product testing, with no additional technical reviews.

- The clinical trial approval regime will be improved. Parallel clinical studies can be conducted in China for new drugs that have not been marketed in other countries, and approvals on clinical trials for innovative drugs will focus on clinical value and protection of study subjects.

- The current approval processes for drug packaging materials and excipients will be simplified. Packaging materials and excipients will be reviewed and approved together with the underlying drugs; a corresponding drug master file system is expected to be established.
• The current medical device review and approval system will also be reformed. Devices with core technologies covered by invention patents and with significant clinical value will be given review priority.

The RAP Opinions will likely reshape China’s existing review and approval systems, especially for drugs, which will significantly impact the regulatory strategies of innovative companies for the China market. CFDA is expected to develop detailed implementing regulations following the principles in the RAP Opinions and the national law and regulations on drugs are also expected to be amended accordingly. In particular, it remains to be seen how the currently-defined new drugs, especially those marketed in other countries, but not yet in China, will fit in the new drug classification system, and how CFDA will implement the MAH system in the near future.

If you have any questions regarding this Sidley Update, please contact the Sidley lawyer with whom you usually work, or

Chen Yang
Partner
+86.10.5905.5600
cyang@sidley.com

Ling Su
Strategic Advisor, Life Sciences
+86.21.2322.9327
ling.su@sidley.com

Sidley China Life Sciences Practice

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For further information on the China Life Sciences Practice, please contact:

Chen Yang
Partner
+86.10.5905.5600
cyang@sidley.com

Zhengyu Tang
Partner
+86.21.2322.9318
zytang@sidley.com

Yuet Ming Tham
Partner
+852.2509.7645
yuetming.tham@sidley.com

Joseph Chan
Partner
+86.21.2322.9328
joseph.chan@sidley.com

Lei Li
Partner
+86.10.5905.5505
lei.li@sidley.com

Wenseng “Wendy” Pan
Partner
+1.212.839.8544
wpan@sidley.com
Sidley Global Life Sciences Practice


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For further information on the Global Life Sciences Practice, please contact:

Scott Bass
+1.202.736.8684
+1.212.839.5613
sbass@sidley.com

James C. Stansel
+1.202.736.8092
jstansel@sidley.com

Paul E. Kalb, M.D.
+1.202.736.8050
pakalb@sidley.com

M. Patricia Thayer
+1.415.772.7469
+1.650.565.7569
pthayer@sidley.com

David J. Zampa
+1.312.853.4573
dzampa@sidley.com

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