China Food and Drug Administration Creates a Prioritized Drug Review and Approval Pathway

On February 24, 2016, the China Food and Drug Administration (CFDA) published Opinions on Implementing a Prioritized Review System to Avoid Drug Review Backlogs (the Opinions). This is a significant reform measure which introduces a “prioritized” review and approval pathway for certain drug applications, including -

- Registration applications for drugs with “apparent clinical value,” such as (i) innovative drugs not marketed anywhere in the world; (ii) innovative drugs for which manufacturing is transferred to China; and (iii) drugs with advanced formulation technologies, innovative treatment methods and “apparent” treatment advantages;

- Clinical trial applications for generic drugs that are submitted three years prior to expiration of the relevant patents or manufacturing applications for generic drugs that are submitted one year prior to expiration of the relevant patents;

- Clinical trial applications for new drugs that are under parallel clinical trial applications in the U.S. and the EU and have been approved for clinical trials there;

- Registration applications for drugs that are under parallel application in the EU and the U.S. with the same production line and have passed on-site inspections by those agencies;

- Registration applications for new drugs developed under special national scientific research and development programs;

- Registration applications for drugs for preventing or treating HIV, tuberculosis, viral hepatitis, rare diseases, malignant tumors, pediatric drugs and drugs for diseases specifically affecting seniors;

- Registration applications for drugs with urgent clinical demand and supply shortages. A detailed list of such drugs will be proposed by China’s National Health and Family Planning Commission and the Ministry of Industry and Information Technology; and

- Registration applications for foreign pediatric drugs that have been approved in the U.S., the EU and surrounding regions of China, supported with clinical data developed in those countries and regions.

To implement this system, CFDA’s Center for Drug Evaluation (CDE) will establish a communication mechanism through both consultation meetings and an online platform. Companies may, once the relevant
applications have been filed and moved to CDE, submit a separate application through the online platform requesting prioritized review. The prioritized review process will include (i) definitive timelines for the start of technical review, sample testing, on-site inspection, review conclusion and approval decision-making; and (ii) meetings with the reviewer to exchange information, discuss study data, as well as to seek regulatory guidance for the product development. Companies conducting clinical trials may, after completion of Phase I and II trials, discuss with the reviewer the study results and its Phase III study plan, and may move to Phase III trials without any further approval if they agree upon the Phase III plan with the reviewer. For drugs targeting life-threatening diseases with no currently available effective treatment, companies may, through consultation with the CDE reviewer and based on early phase clinical data, obtain a conditional approval of the drug before completion of Phase III confirmatory trials.

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

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Sidley China Life Sciences Practice

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