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CFDA Seeks to Remove Some Barriers to Foreign Drug Entry into China

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Food, Drugs, and Devices

On March 17, 2017, the China Food and Drug Administration ("CFDA") released a notice to seek public comments on four proposed adjustments to China's drug registration requirements ("Proposed Adjustments") that will remove some barriers to applications for clinical trials and drug registrations of imported drugs (drugs that are manufactured outside of China). The Proposed Adjustments could substantially impact the strategies for bringing imported drugs to China. Imported drug manufacturers should understand the potential impact of the Proposed Adjustments, consider submitting comments, and closely monitor future developments in this area. Comments are due on April 20, 2017.

The Proposed Adjustments are based on a blueprint for reform of the drug approval system that was introduced in State Council's Opinion on Reform of the Drug and Medical Device Approval Process ("Document 44"), and intended to (1) encourage innovative drug development in parallel with clinical trials abroad; (2) reduce the delay between the marketing authorization of drugs abroad and in China; and (3) meet the clinical needs for new drugs in China.

This Alert explains the four Proposed Adjustments and adds some context and analysis.

- **Adjustment Number 1**: The Proposed Adjustments would eliminate the requirement that an imported drug must wait until in Phase II or Phase III clinical study or receiving marketing authorization abroad before it may begin an international multi-center trial ("IMCT") in China. This adjustment could substantially reduce development delays for many companies.
- **Adjustment Number 2**: This proposal would change the "three application, three approval" system. This change would allow the applicant of an imported drug to directly apply for a marketing authorization upon the completion of its IMCT in China.

  This change would essentially reinstate the previous "two-application, two approval" system. Prior to 2013, imported drug manufacturers that wanted to conduct an IMCT with a China site were required to submit only two applications: (1) an application for the IMCT, and (2) an application for marketing authorization together with a request to waive the requirement of a local trial. Since late 2013, however, the CFDA has required an additional application—i.e., an application for waiver of a local clinical trial. This application must to be submitted after the completion of IMCT and before the application for the marketing authorization. This added cycle has significantly increased the time to obtain marketing authorization in China.

- **Adjustment Number 3**: This proposed change would eliminate the requirement that an imported drug be approved outside China before China will grant marketing authorization in the case of an "imported new chemical drug or innovative therapeutic biologic." The current system requires that an imported drug must be approved abroad and that the applicant submit evidence of that approval in the form of a certificate of pharmaceutical product before CFDA will permit marketing in China. Thus, the only choices are to wait until foreign approval or move manufacturing to China.

  This Proposed Adjustment would eliminate the delay or the need to move manufacturing to China for a drug that qualifies under the criteria above. The current drug classifications of chemical drugs define a new drug as "has not been approved in China or abroad." The Proposed Adjustment, however, has not defined or otherwise explained what constitutes an "imported new chemical drug or innovative therapeutic biologic." Therefore, the scope of this Proposed Adjustment will require clarification.

- **Adjustment Number 4**: This adjustment would permit CFDA to grant marketing authorization to any pending application currently seeking waiver of a local trial after completion of an IMCT, provided that the application otherwise meets all of the approval requirements. This Proposed Adjustment appears to make these pending applications eligible for Adjustment Number Two described above.

Although the Proposed Adjustments address timing issues, they do not address the closely related issue of the lack of regulatory protections. Specifically, the Proposed Adjustments do not propose any adjustments to provide patent linkage and data exclusivity protections to further encourage drug innovation.

For example, the classification of chemical drugs established in 2016 permits the submission and approval of a generic drug application even before the foreign reference drug has come to the China market. In other words, if the foreign reference drug does not have patent coverage in China, a generic drug manufacturer can file an abbreviated application under Class 3 in the registration categories for chemical drugs, rely on a "foreign reference product," and submit only bioavailability and bioequivalence data, before the innovative reference drug manufacturer has submitted any data to CFDA. This pathway allows CFDA to approve a generic drug without having the opportunity to evaluate the safety and efficacy data of the reference drug. This type of approval is arguably problematic because of the lack of direct access to the full data package. The establishment of a data exclusivity system could prevent such a result.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Food, Drugs, and Devices practice:

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