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SIDLEY UPDATE

China Reforms Its Chemical Drug Classification System

On March 4, 2016, China Food and Drug Administration (CFDA) issued the *Work Plan for Reforming Chemical Drugs Registration Classification System* (the New Classification), which took effect on the same day.

The New Classification changes the current chemical drug classification system and sets forth new registration requirements for applicants. Under the New Classification, chemical drugs are classified into five categories:

1. Category I: Innovative new drugs not marketed anywhere in the world. Innovative drug is defined as a chemical compound with new and clearly defined structure, pharmacological property(ies) and apparent clinical value.
2. Category II: Improved new drugs not marketed anywhere in the world. This category includes: changes in an existing drug to optimize its structure (such as enantiomer, ester, salt, clathrate or chelate), new dosage form, new formulation and process, new route of administration, new combination or new indication.
3. Category III: Generic drugs, with equivalent quality and efficacy to the originator's drugs, that are marketed in other countries, but not yet in China. The active ingredient, dosage form, strength(s), indication, route of administration and dosing regimen of the generic drug must be the same as those of the originator's drug. The New Classification further defines the originator's drug as the drug that was first approved in the world, supported with complete and sufficient safety and efficacy data for marketing approval.
4. Category IV: Generic drugs, with equivalent quality and efficacy to the originator's drugs, that are already marketed in China.
5. Category V: Drugs that have been marketed in other countries, but not yet in China.

Drug applications under the New Classification will continue to follow the existing procedures defined by the CFDA. Specifically, Category I and Category II drug applications shall comply with the New Drug application process; Category III and Category IV drug applications shall comply with the Generic Drug application process; and Category V drug applications shall comply with the Imported Drug application process. Accordingly, only the new Categories I and II drugs are subjected to a monitoring period of three to five years, which is a de facto market exclusivity.

Several changes in the New Classification will have a significant impact on both multinational and domestic pharmaceutical companies with regard to their product development strategy and practice in China. For example, "new drug" eligibility is limited to those drugs that are not marketed anywhere in the world, as opposed

to “not marketed in China” in the previous definition. This change may incentivize multinational companies wishing to bring innovative drugs to China to start their product development in China earlier in the process than before in order to realize marketing advantages. For domestic companies to market a generic drug, they are now required to demonstrate the equivalent quality and efficacy against the originator’s product, regardless of whether the originator’s drug is marketed in China. This requirement represents a challenge to many local generic drug companies.

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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