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ALERT

China Life Sciences

March 14, 2016

China FDA Launches a New Classification System for Registration of Chemical Drugs

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China FDA formally launched a new classification system for chemical drugs, with the release of the *Reform Scheme of the Classification System for Registration of Chemical Drugs* ("Reform Scheme") on March 4, 2016.[1] The Reform Scheme is an important part of the general reform of the drug and device approval system initiated by China's State Council in late 2015.[2] The Reform Scheme's new classification of small molecule drugs differs considerably from the old classification under the *Drug Registration Rules* ("DRR").

The Reform Scheme redefines "new drugs" and "generics." Under the old classification of the DRR, the term "new drugs" referred to drugs never marketed in China, even if they had been marketed outside of China. Under the new classification, "new drugs" now refers only to (i) new chemical entities that have never been marketed anywhere in the world, or (ii) improved new forms of known chemical entities that have never been marketed anywhere in the world. Domestic drugs that have been marketed outside of China, even if they have not been marketed in China, are now considered generic.

Imported drugs now fall into a separate Class 5 and continue to follow the existing registration pathway under the DRR. Below is an overview of the new classification system.

Classification	Definition / Scope	Regulatory Exclusivity Period
Class 1 New drugs	Innovative drugs that contain new chemical entities with clinical value and have never been marketed anywhere in the world.	5 years
Class 2 New Drugs	Improved and new forms of drugs based on known chemical entities (such as improved chemical structure, new administration route, and new indication) that have apparent clinical advantages and have never been marketed anywhere in the world.	3-4 years
Class 3 Generic	Domestic drugs (i) referencing originator drugs that are marketed outside of China, but not in China yet, and (ii) consistent with the originator drugs in quality and efficacy.	0
Class 4 Generic	Domestic drugs (i) referencing originator drugs that are already marketed in China, and (ii) consistent with the originator drugs in quality and efficacy.	0
Class 5 Imported Drugs	Imported drugs that seek to be marketed in China, including both the originator's drugs and non-originator's drugs.	0

[1] The initial draft of the Reform Scheme was announced for public comments on November 6, 2015.
[2] See our Alerts dated August 21, 2015 and November 19, 2015.

China FDA considers this reclassification to be in line with other major countries' drug regulatory philosophy.

While no significant changes are expected for the registration pathway of imported drugs, the new classification system is likely to impact China's domestic drug manufacturers in the following ways:

- They will have more incentives to develop Class 1 new drugs, which may receive an expedited review and a more favorable standing in post-approval tendering and reimbursement.
- They will more actively pursue Class 2 new drugs, focusing on new and improved drug forms with clear clinical value. The new drug status will also allow Class 2 drugs some regulatory exclusivity-period protection.
- They will have more incentives to be the first to bring good quality Class 3 generics onto the Chinese market. Under the Reform Scheme, Class 3 drugs are not entitled to any regulatory exclusivity-period protection. Nevertheless, applicants will only need to conduct bioequivalence studies against the originator drugs, instead of having to obtain a Clinical Trial Authorization and to conduct full-scale clinical trials as new drugs. This will allow Class 3 drugs to go to market in a much shorter time in order to compensate for the loss of regulatory exclusivity available for new drugs.

The ongoing drug approval reform may transform the competitive landscape of pharmaceutical companies in China. Currently, the government demonstrates a clear resolution to foster indigenous innovation and improve the quality of domestic players. It is important for firms to stay informed of the changing policies and adapt their market-entry strategies accordingly.

If you would like to discuss the foregoing or any other related matter, please contact Katherine Wang or your usual Ropes & Gray advisor.