November 12, 2015

Recent Regulatory and Legislative Changes

The Chinese central government has taken several important steps in reforming the drug approval system in China, which could have far-reaching implications for pharmaceutical companies in China as well as foreign companies that are interested in commercializing their products in China.

On August 9, 2015, China's State Council issued the Opinions on Reforming the Review and Approval Process for Drugs and Medical Devices (the "State Council Opinion"). One of the Key reforms mentioned in the State Council Opinion, is the launch of a pilot program ("the "Pilot Program") of a market authorization holder ("MAH") system for drugs.

On November 4, 2015, the Standing Committee of China's National People's Congress issued a decision to authorize the State Council to carry out the Pilot Program in ten provinces/municipalities, which provided the legal basis for the State Council Opinion.

On November 6, 2015, the China Food and Drug Administration ("CFDA") issued the draft Pilot Plan on Marketing Authorization Holder System ("Pilot Plan") for comments.

We have summarized the relevant features of the Pilot Program and assess the implications for foreign drug companies doing business in China.

Pilot Drug Marketing Authorization Holder System

Under the current Chinese drug approval system, applicants who seek approval for commercializing drugs that are manufactured in China must own a manufacturing facility that is capable of producing the drugs in accordance with GMPs. This requirement has resulted in unnecessary buildup of drug manufacturing capacities and has prevented research and development organizations or personnel from enjoying the economic benefits from commercialization of the drugs they develop. Many companies do not have the financial resources to build a drug manufacturing facility and are therefore forced to transfer their products to a larger manufacturing company for commercialization.

Under the Pilot Program, in addition to drug manufacturers, research and development organizations and Chinese scientific research personnel working in the pilot cities or provinces could be a MAH.

In order to address the potential risks associated with the MAH system, MAHs are required to provide guarantee or purchase insurance to cover the potential product liabilities. In addition, MAHs are required to have a quality management system, the ability to release and recall the products, and risk control and emergency handling capabilities.

The Pilot Program will be implemented in ten provinces and municipalities, including Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong and Sichuan.

The Pilot Program is three years long, beginning on December 1, 2015. Narcotic drugs, psychotic drugs, medicinal toxic drugs, radioactive drugs, preventive biologics and blood plasma products are not included in the Pilot Program.

Implications of for Foreign Drug Companies

As of today, most foreign drug developers have chosen to seek approval of their drugs as "imported drugs" and have them manufactured outside of China, rather than pursuing approval as domestic drugs and have them manufactured in China. There are many reasons foreign drug makers choose the imported drug approval pathway, one of the main reasons being the requirement for drug developers to own a manufacturing facility in order to obtain approval to commercialize the products. Often, small and mid-size foreign drug companies do not have the financial resources to build manufacturing facilities in China even if they decide to commercialize the products themselves, and large pharmaceutical companies typically have global supply strategies and would not just build a manufacturing facility in China for the sake of seeking regulatory approval in China.

There are certain benefits associated with local manufacturing in China, including market access, cost savings, etc. The implementation of the MAH system will provide foreign drug developers with the option of seeking approval of their drugs as domestic drugs rather than imported drugs by entrusting a qualified third party to manufacture the drugs in China.

Before foreign drug companies could really avail themselves of the MAH system and pursue domestic approval path for their products, there must be some high quality contract manufacturing organizations that could be entrusted with the manufacturing of the drugs, ideally not only just for the China market but also for the worldwide market. However, it should be noted that it is not entirely clear whether drug development companies are eligible to become MAH under the Pilot Program as the term "research and development organizations" is not defined in the relevant regulations.

What to Expect Next

Judging from the short time gap between the issuance of the decision by the National People's Congress and the issuance of the draft Pilot Plan by the CFDA (i.e., two days), we expect the MAH system to be implemented in the 10 pilot provinces/municipalities very soon. Drug companies should closely monitor the issuance of the final Pilot Plan and the complementary regulations to be issued by local government agencies and evaluate the impact on their business operations and strategies in China.

Key Contacts

Christina Zhang Shanghai	