ROPES & GRAY ALERT

China Life Sciences

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China Announces a Detailed Pilot Plan for the Marketing Authorization Holder System for Drugs in Selected Regions

Attorneys
Katherine Wang

China's State Council announced on May 26, 2016, a detailed pilot plan for the Marketing Authorization Holder System ("MAH") for drugs in 10 provinces[1] in China (the "Plan"). The three-year pilot program[2] was initiated in November 2015 by the Standing Committee of the National People's Congress as an important reform measure to encourage drug innovation.[3] According to the Plan, domestic drug research and development ("R&D") institutions and individuals in the piloted regions are eligible to apply for and hold drug product licenses. Eligible parties can now commercialize their drug assets without having to become drug manufacturers themselves. As marketing authorization holders, they can completely outsource the actual manufacturing to contract manufacturing organizations.

Specifically, the following drugs are eligible for the piloting program: (1) new drugs approved after the implementation of the Plan; (2) generic drugs approved as category 3 or 4 drugs under the new classification system of chemical drugs;[4] (3) previously approved generics that have passed the equivalence assessments against originator drugs; and (4) previously approved drugs whose licenses were held by drug manufacturers originally located within the piloted regions, but have been moved out of the piloted regions due to corporate mergers or other reasons. Narcotic, psychopathic, toxic, radioactive, biological prophylactic, or blood products are excluded from the pilot program.

To be eligible as marketing authorization holders, R&D companies must be incorporated in the piloted regions, and R&D individuals must be Chinese citizens working in the piloted regions. Both R&D companies and individuals must have the capability to assume drug quality and safety-related liabilities through providing guarantees or through purchase of insurances.

The marketing authorization holders may engage contract manufacturers for manufacturing, provided that the contract manufacturers are licensed and GMP-certified, and are also located within the piloted regions. The marketing authorization holder and the engaged contract manufacturer can be located in two different provinces within the piloted regions, in which case the Plan requires the local FDAs of their respective provinces to exercise joint supervision.

Marketing authorization holders may apply to transfer the marketing authorization to another eligible holder, or to change the designated contract manufacturer. Such change applications can be submitted both when the drug license application in question is pending and after the drug is approved. Applications first must be submitted to relevant provincial FDAs, who will relay the applications to the CFDA for final review and approval.

The Plan requires the MAH holders to establish their quality assurance and pharmacovigilance systems to ensure post-market drug safety and quality. Patients who suffer physical injuries caused by the quality of approved drugs

[1] Cities include Beijing City, Tianjin City, Hebei Province, Shanghai City, Jiangsu Province, Zhejiang Province, Fujian Province, Shandong Province, Guangdong Province, and Sichuan Province.
[2] The pilot program ends on November 4, 2018, according to the Plan. The Plan has yet to announce whether or not MAH will be formally implemented nationwide after the three-year pilot.
[3] See details on the overall drug approval reform policy introduced by the Standing Committee of the National People's Congress in our Alert dated November 19, 2015.
[4] See details on the new classification system of chemical drugs in our Alert dated March 14, 2016.

can choose to seek compensation either from the marketing authorization holders, or the drug manufacturers, or the drug distributors.

The MAH system demonstrates China's strong momentum to unleash innovation in the pharmaceutical sector. Both local and foreign players should consider leveraging the regulatory flexibility of the pilot program to acquire or spin off assets and to utilize contract manufacturing arrangements. Contract manufacturers are also advised to revisit potential opportunities in the Chinese market.

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