China SFDA Creates New Regulatory Pathways for Transfer of Drug Licenses

To accelerate GMP compliance by domestic pharmaceutical companies, the Chinese State Food and Drug Administration ("SFDA") published a notice on February 22, 2013 (the "Notice") clarifying the regulatory pathways for technology transfer, which implies new avenues for the transfer of drug product licenses.

The Technology Transfer Rules issued by the SFDA in 2009 (the "Transfer Rules") permit the transfer of pharmaceutical manufacturing technology in two cases: i) where the transferor and the transferee are affiliates or ii) where the transferor has an import license for the product and the transferee applies to manufacture the product locally based on the transferor's technology. The provincial FDA, where the transferee is located, is the appropriate authority to receive an application for technology transfer, but the technical review is performed by the Center for Drug Evaluation ("CDE") under SFDA. After the technology transfer is approved by the SFDA, the transferee will obtain the product license in its name for the product manufactured in reliance on the transferor's technology.

The Notice introduced two key changes to the Transfer Rules to the extent that the product in question is not a biological product. The technology transfer involving biological products must comply with the 2009 Transfer Rules.

- The scope of applicability of the Transfer Rules has been expanded to include a scenario under which a drug manufacturer is permitted to transfer manufacturing technologies of all specifications under the same dosage form to another drug manufacturer incorporated in China with the new GMP certification if the transferor decides not to upgrade its manufacturing facilities in full or in part. Under this scenario, the transferor and transferee do not have to be affiliates and the transferee may acquire selected product manufacturing technologies as assets, rather than acquire equity of the transferor in order to be the license holder of the products concerned.

- The authority of technical reviews is delegated to provincial FDAs by the CDE. Provincial FDAs need to build the necessary capabilities, as well as infrastructure, and seek SFDA approval before engaging in the technical reviews. This delegation of authority is expected to significantly expedite the approval process for technology transfer.

These changes can create more favorable options for acquisitions in China and would help further consolidate the industry. Multinational pharmaceutical companies may consider re-shaping their localization strategy in China, especially in the areas of branded generics.

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