

## Chinese FDA Imposes Mandatory Electronic Barcoding on Imported Drugs

The State Food and Drug Administration (“SFDA”) issued a Notice on Relevant Issues Concerning Imposing Electronic Barcoding on Imported Drugs (“Notice”) on January 29, 2013 with immediate effect. Pursuant to the Notice, manufacturers of imported narcotics, psychotropic drugs, blood products, vaccines, injectables made by Traditional Chinese Medicines (“TCM”), and drugs listed on the national or provincial Essential Drug Lists (“EDL”) must affix electronic barcodes to the external packages of the imported drugs at the offshore manufacturing facilities indicated on the respective import drug licenses. If the imported drugs are approved for domestic re-packaging in China, the affixture of electronic barcodes can be completed by the licensed re-packaging entity. Photos or packaging samples demonstrating proper affixture of electronic barcodes must be included in the submission for import registration with the local FDA at the port of entry. Imported drugs subject to the Notice will be denied import registration if they do not bear the electronic barcodes by January 1, 2014.

Manufacturers of imported drugs subject to the Notice can appoint a pharmaceutical manufacturer, a pharmaceutical distributor or its affiliates in China to act as the local agent to coordinate electronic barcoding. Such local agent shall file for a record with the Administrative Services Center of the SFDA and will be responsible for applying for electronic barcodes, entering relevant information in the SFDA’s database and managing product recalls on behalf of manufacturers. Changes in relation to the local agents or termination of the appointment shall be reported within five working days with the SFDA’s Administrative Services Center.

It is anticipated that the SFDA will further roll out the implementation of electronic barcoding to cover all domestically produced and imported pharmaceutical products by 2015. Multinational pharmaceutical companies supplying products to China are advised to consider impacts on their manufacturing activities and prepare in advance.

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