China Releases New Essential Drug List

China's Ministry of Health released the new essential drug list (the "2012 EDL") on March 15, 2013, effective as of May 1, 2013. Essential drugs are those which meet basic health care demands in suitable dosage forms with reasonable prices and a guaranteed supply. Essential drugs shall be made available at all grass roots health care services providers and will be fully reimbursed by the Basic Medical Insurance. By rolling out the 2012 EDL, the government aims to meet the basic clinical needs, reinforce the collective tendering and procurement process for essential drugs, and contain health care costs. Compared with the previous version issued in 2009 (the "2009 EDL"), highlights of the 2012 EDL are:

- The 2012 EDL has expanded from 307 to 502 products, including 317 chemical drugs/biological products and 203 traditional Chinese medicines (TCMs). The types of dosage forms are increased from 780 to 850 in the 2012 EDL, while the drug specifications are reduced from 2,600 to 1,400. Some of blockbuster products from notable multinational pharmaceutical companies are included in the 2012 EDL, such as Plavix (Sanofi/BMS), Glucobay (Bayer), Norvasc (Pfizer) and Diovan (Novartis).
- The 2012 EDL also expands its coverage of diseases. Specialty drugs, such as oncology drugs and drugs for blood diseases, including Taxol produced by BMS, are listed in the 2012 EDL. For the first time, human insulin products are included as well, e.g., Humulin from Novo Nordisk and Novolin from Eli Lilly.
- Nearly 200 drugs in the 2012 EDL can be used for pediatric purposes, including all pediatric vaccines currently in the Chinese national immunization plan. An example is Methotrexate from Pfizer, which is used for childhood leukemia.

Multinational pharmaceutical companies may expect higher sales volume and wider geographic coverage once their products are listed in the EDL. However, while all essential drugs are subject to mandatory collective tendering and procurement in order to be supplied to public hospitals, it will likely be more challenging for multinational companies to defend their premium prices.

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