China Clarifies Fast Track Approval Eligibility for Novel Biologics

The Chinese State Food and Drug Administration ("SFDA") created a fast track review and approval process for novel drugs in its Drug Registration Rules issued in 2007. The fast track approval process is available for (1) active ingredients and their finished formulations derived from plants, animals or minerals, which have never received any market authorization in the world or newly discovered crude drugs or their finished formulations; (2) chemically active pharmaceutical ingredients and their finished formulations or biologics which have not received any market authorization in the world; (3) new drugs which are used to treat AIDS, malignant tumors, or rare diseases and have obvious clinical advantages; or (4) new drugs used to treat diseases for which no effective treatment is available. In 2009, SFDA further promulgated the administrative measures on fast track reviews and approvals to define the procedure and document requirements ("2009 Administrative Measures"). The statutory timeline for the technical review of a fast track IND filing can be reduced from 90 days to 80 days and that of a fast track NDA filing can be reduced from 150 days to 120 days.

The Drug Registration Rules and the 2009 Administrative Measures did not provide sufficient clarity on how to determine the novelty of a specific biologic drug given the structural complexity of biologics. The Center for Drug Evaluation ("CDE"), an administrative body under SFDA responsible for technical reviews during regulatory approval process, issued an opinion on March 11 to clarify the conditions for fast track approvals for novel biologics. These conditions include the following:

- The product derives from a major new drug R&D project funded by the Chinese government and the applicant is the first domestic developer of the product in question.
- The product has not received any market authorization in the world and is accepted for fast track approval based on CDE's internal evaluation.
- For a product which has been approved outside China but not yet received market authorization in China, CDE will determine its eligibility based on clinical demands in China through an internal evaluation or by an expert panel.

Products whose NDA or IND filings do not meet the above conditions will typically be subject to the regular review and approval process, unless they are urgently demanded by clinical needs or are intended for critical diseases, e.g. AIDS or MDR-TB.

Biologics manufacturers should carefully evaluate the eligibility of their products in order to take advantage of the fast track approval process.

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