China Solicits Comments on Post-Market Study Guidelines

The Center for Drug Evaluation ("CDE") in China recently published the draft *Guidelines for the Administration of Post-Market Studies on Chemical Drugs and Therapeutic Biologics* ("Draft Guidelines") for public comments through November 21, 2013. The Draft Guidelines mainly apply to post-market studies required by the China Food and Drug Administration ("CFDA") as a pre-requisite for the new drug authorization ("NDA") in China. Post-market studies of OTC drugs or generic drugs are not subject to the Draft Guidelines. The Draft Guidelines also recognize post-market studies initiated at the discretion of the marketing authorization holder or any third party and may apply *mutatis mutandis* to these discretionary post-market studies.

The format of post-market studies can include clinical studies, surveys (e.g., observational/ epidemiological studies), animal studies or lab tests, each of which is further elaborated in the draft *Technical Guidance for Post-market Studies on Chemical Drugs and Therapeutic Biologics*. The relevant department at the CFDA (i.e., CDE or the Center for Drug Re-evaluation, CDR) will propose a list of possible post-market studies expected from the marketing authorization holder before issuing the NDA, as well as identify the mandatory/discretionary studies. The marketing authorization holder is encouraged to discuss the design and conduct of these post-market studies with the relevant department at the CFDA and propose an implementation schedule. A final proposal for the study design and conduct shall be submitted to the relevant department at the CFDA for review and confirmation by the marketing authorization holder upon receipt of a formal notice on post-market studies.

Upon receipt of written confirmation by the relevant department at the CFDA on the soundness of the study protocol and completion of registration in the online clinical study registry, the marketing authorization holder is allowed to initiate the post-market studies. Any material change in the study protocol will need to be reviewed and confirmed by the relevant department at the CFDA. The marketing authorization holder will also need to submit regular progress reports to the relevant department at the CFDA during the course of the post-market studies. The results of post-market studies will be evaluated concurrently by the marketing authorization holder and the relevant department at the CFDA to ascertain any impact on the marketing authorization.

R&D-based biopharmaceutical companies are advised to carefully review the Draft Guidelines and modify their internal policies and processes governing the initiation and implementation of post-market studies accordingly.

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