Chinese FDA to Launch a Quality Consistency Evaluation for Generic Drugs

Chinese State Food and Drug Administration ("SFDA") issued a draft *Work Plan for Quality Consistency Evaluation for Generic Drugs* ("Work Plan") on November 22 for public comments through December 6. As part of the *12th Five-Year Plan for Drug Safety*, the Work Plan aims at elimination of generic drugs which fail the quality consistency evaluation in order to enhance the overall quality standards of generic drugs.

The Quality Consistency Evaluation will focus on consistency of composition and clinical efficacy between the test and reference products. SFDA intends to pilot the Quality Consistency Evaluation on the solid oral dosage forms of essential drugs which have been applied widely in the patient population, with a large sales volume, produced by multiple manufacturers and that can be compared to a specific reference product.

To carry out the Quality Consistency Evaluation, SFDA will form a Project Office to designate a list of test products and drug control institutes responsible for the conduct of the Quality Consistency Evaluation each year. The Project Office will also be in charge of the formulation and publication of the evaluation methods/specifications and the reference products, which will most likely be the originator's products. Manufacturers of generic drugs are expected to conduct the Quality Consistency Evaluation on test products against the reference products based on the SFDA-published evaluation methods and submit the evaluation results as well as samples of the test products to the provincial FDAs where the manufacturers are located. The provincial FDAs shall subsequently organize an on-site inspection of the manufacturing facilities and collect three batches of the test products produced therefrom for verification testing by the designated drug control institutes. The evaluation results and verification testing results will be forwarded by the provincial FDAs to the Project Office for an expert panel review. Failure to obtain a satisfactory opinion from the expert panel will subject the test products to be withdrawn from the market.

Quality consistency can be established based on conformity with quality specifications set by the reference products and in-vitro in-vivo correlation. Specifically concerning solid oral dosage forms, SFDA would introduce dissolution profile comparisons to evaluate quality consistency between the test and reference products.

Multinational pharmaceutical companies are advised to closely monitor the implementation of the Quality Consistency Evaluation, especially if they are qualified as the originators and can position their branded generics or off-patent drugs as reference products. Reference products will most likely be entitled to preferential treatment during price-setting and tendering processes.

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