Chinese FDA Released Guidelines for Rx-OTC Switch

The State Food and Drug Administration ("SFDA") recently announced a set of technical guidelines for switching prescription drugs to over-the-counter drugs ("Rx-OTC Switch Guidelines"). The Rx-OTC Switch Guidelines include the Tentative Evaluation Guidelines for Rx-OTC Switch, the Principles for Defining the Indications of OTC Drugs, the Evaluation Guidelines for Traditional Chinese Medicines ("TCM") with Toxic Ingredients to be switched to OTC Drugs, the Principles for Defining Class B OTC Drugs, the Indications of OTC Drugs (TCM Section), and the Indications of OTC Drugs (Chemical Drugs Section).

A prescription drug is qualified for OTC evaluation if it meets the following basic requirements:

- Its formulation or active pharmaceutical ingredient must be approved by SFDA and be widely applied in patients over a long period of time;
- There is sufficient research on its formulation or active pharmaceutical ingredient with precise results and satisfactory safety data;
- There are statutory quality specifications for its formulation or active pharmaceutical ingredient and a proven quality profile thereof;
- The method of use, dosage and treatment course are precise and the efficacy can be ascertained;
- The indication is listed in SFDA's approved scope of OTC indications, typically common diseases or symptoms, recurring diseases or chronic diseases;
- The instructions for clinical application are clear if intended for pediatric diseases or pregnant women; and
- The route of administration, dosage form, dosage, specification, timing of administration, storage, packaging, label and insert sheets are suitable for self medication.

OTC evaluation is comprised of safety evaluation and efficacy evaluation. The safety evaluation focuses on (i) safety of the pharmaceutical product when it is regulated as a prescription drug, e.g., analysis of the pharmacology and toxicology data, adverse drug reactions, likelihood for drug dependence, in-vivo tolerance and interaction with foods, (ii) safety of the pharmaceutical product under the circumstances of self diagnosis and self medication, and (iii) safety of the pharmaceutical product in the event of abuse or misuse. The efficacy evaluation focuses on whether a majority of the target patient population would benefit from the pharmaceutical product for cure and symptom relief provided sufficient instructions for use and warning.

OTC drugs with higher safety will be classified as Class B OTC drugs and can be purchased by consumers at ordinary retailers, e.g. supermarkets or department stores, without seeking guidance from healthcare professionals for administration, compared to Class A OTC drugs which would require guidance from healthcare professionals for administration and are available only at retail pharmacies. OTC drugs which meet the following criteria will be regulated as Class B OTC drugs:

- Those applied to minor ailments/symptoms or used as nutritional supplements;
- Those with higher safety, i.e., marketed in China for over ten years, widely applied in patients, with precise research on safety of its active pharmaceutical ingredients and adverse drug reactions, stable quality, and very unlikely to be abused or misused by consumers.

Pediatric OTC drugs other than vitamins or minerals, chemical OTC drugs containing antibiotics or hormones, OTC drugs with an ADR occurrence rate exceeding 0.01 percent, compound OTCs containing traditional Chinese medicines, or adjuvants will not be qualified as Class B OTC drugs.

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