China Expects Major Changes in Drug Registration and Contract Manufacturing Rules

The China Food and Drug Administration ("CFDA") recently announced several draft rules, most notably, the Draft Amendment of the Provisions for Drug Registration (also known as the Drug Registration Rules, DRR) and the Draft Administrative Regulations on the Review and Approval of Drug Contract Manufacturing ("Draft Contract Manufacturing Rules), which will significant impact the pharmaceutical industry. The CFDA is soliciting public comments on both Rules through early December, 2013.

1. **Highlights of the Draft Amendment of the DRR**

- **IND Approval (also known as Clinical Trial Authorization) will be transferrable.** IND Approval can be transferred from one entity to another throughout all phases of clinical studies concerning new drugs. An IND holder is also allowed to change the manufacturing process, product specification, and manufacturing location of the study drugs by filing a supplementary application to the CFDA before entering into Phase 3 of the study.
- **Generic applications can be submitted and reviewed at anytime during the patent term of the pioneer drug.** Provided that the generic manufacturer submits a non-infringing statement on patents relevant to the drug under review, the CFDA will not act as a gatekeeper to suspend the regulatory approval process if the manufacturer of the pioneer drug argues for a patent infringement by the generic manufacturer.
- **Administrative exclusivity for new drugs during the monitoring period will be restricted.** Under the current DRR, the first to market manufacturer of locally produced new drugs will have a period of up to 5 years of administrative exclusivity (also known as the new drug monitoring period). Submissions made by other manufacturers concerning the same active pharmaceutical ingredient as the new drugs during the administrative exclusivity period can be continued only if there are ongoing clinical studies on those drugs in question. Under the Draft Amendment, the follow-on submissions will continue to be reviewed by the CFDA as long as their IND applications are filed before the start of the administrative exclusivity period.

2. **Highlights of the Draft Contract Manufacturing Rules**

- **The authority to review and approve contract manufacturing will be delegated by the CFDA to its provincial counterparts ("PFDAs").** In principle, the PFDA where the outsourcing manufacturer is located will be responsible for the review and approval of contract manufacturing. In the event that the outsourcing manufacturer and the contract manufacturer are located in different provinces, a pre-approval from the PFDA where the contract manufacturer is located is also needed.
- **The CFDA will prohibit more categories of drugs from contract manufacturing.** In addition to vaccines and blood products, narcotic drugs, psychotropic drugs, pharmaceutical precursor chemicals and their drug preparations, biological products, biochemical multi-component drugs, TCM injections, and drug substances will also be prohibited from contract manufacturing.
- **On-site inspection by the PFDA will be mandatory.** In addition to paper-based review, the appropriate PFDA will conduct on-site inspection to examine the contract manufacturer's

manufacturing conditions, technology level, quality management, and the consistency of product standards with those of the outsourcing manufacturer.

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