Chinese Legislature Adopts Amendments to *Drug Administration Law*

China's top legislature, the Standing Committee of National People's Congress, recently approved the amendments (the "Amendments") to the *Drug Administration Law*. The Amendments, effective as of April 24, 2015, cover the following major changes to the original *Drug Administration Law*:

- Removing price control over drug products

  Article 55 of the previous *Drug Administration Law* stated that drug manufacturers, drug distributors and medical institutions must abide by the government pricing mechanism where the drug price was mandated or guided by the government. In addition, drug manufacturing companies should provide the government pricing authorities with genuine information with respect to the costs for drug production and distribution.

  The Amendments eliminated Article 55 of the original *Drug Administration Law*, which is believed to be a prelude to the upcoming drug pricing reform. China's pricing authority, the National Development and Reform Commission, is reportedly set to abandon its control over drug prices later this year. Drug prices will be determined through market competition (such as tendering or negotiation with local medical insurance authorities) in lieu of fixed price caps.

- Streamlining the licensing process for drug companies

  Article 7 and Article 14 of the previous *Drug Administration Law* required a drug manufacturer or a drug distributor to obtain a Drug Manufacturing License or a Drug Distribution License as a pre-approval for incorporation. Drug companies could not obtain their business licenses from the State Administration for Industry and Commerce or its local counterparts ("AIC") before successfully obtaining the operational permits.

  The Amendments removed the pre-approval requirement in order to simplify the business administration process for drug companies. Going forward, a drug manufacturers or distributors will be able to obtain business licenses before obtaining a Drug Manufacturing License or a Drug Distribution License.

  Relatedly, the Amendments also deleted Article 100 of the previous *Drug Administration Law* in connection with revocation of operational permits. In the event that a drug company's Drug Manufacturing License or Drug Distribution License is revoked, the CFDA will no longer inform the AIC to amend the business license of or de-register the drug company.

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

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