January 14, 2019

China Aims to Introduce Routine Drug and Device Overseas Inspections

Attorneys
Katherine Wang

China's drug and device regulator recently announced a set of rules signaling increased scrutiny of foreign drug and device companies. On December 26, 2018, the National Medical Products Administration (the "NMPA") released the Regulations for Drug and Device Overseas Inspection (the "Regulations"). The Regulations set out a working procedure for the NMPA to verify whether foreign drug and device companies' R&D and manufacturing activities adhere to applicable PRC statutory requirements and standards. Drugs and devices that are approved or intended for marketing in China will be subject to the Regulations.

History of Overseas Inspections

In recent years, the NMPA began to regulate the entire life cycle of imported drug and device products. In 2011, the NMPA started overseas inspections of drug companies. As of December 2018, it had inspected 131 drug products produced in 25 countries. In 2015, the NMPA started overseas inspections of device companies and so far, it has inspected 90 device products produced in 13 countries. Experiences derived from past inspections enabled the NMPA to formalize a set of working procedures in the Regulations.

When Would a Foreign Manufacturer Be Inspected?

The Regulations echo the NMPA's risk-based regulatory approach. The selection of companies inspected largely depends on the company and its product's overall risk level. The NMPA generally considers red flags such as concerns expressed by the CDE,[1] CMDE[2] or foreign regulators, past violations, adverse events and quality complaints. The NMPA may also conduct random checks on foreign manufacturers.

What Is the Inspection Scope?

The NMPA's inspections look to verify authenticity, reliability and compliance of R&D and manufacturing activities. The NMPA usually focuses on (i) consistency of actual manufacturing process with the processes registered with the NMPA, and (ii) China GMP compliance. During on-site inspections, foreign manufacturers must provide the NMPA inspection team full access to all relevant premises and documents, including real-time manufacturing processes of the product in question. As needed, the NMPA may also extend its inspections to R&D partners and third-party vendors, such as suppliers of API, excipients or packaging materials. Foreign manufacturers should coordinate with their partners and vendors to enable these extended inspections. Any foreign manufacturers that do not cooperate with the inspection team will receive a failure notice from the NMPA.

What Are Possible Inspection Results?

The NMPA's inspection results include (i) "pass," (ii) "corrective action," and (iii) "fail." Penalties include corrective actions, warning letters, suspension of import and sales, product recall and rejection of product license renewal. In practice, most manufacturers have been required to take corrective actions in order to close deficiencies. For severe deficiencies, the NMPA would order manufacturers to suspend importation and sales of their products in China. Since the end of 2018, the NMPA has banned importation of 19 drug products and two devices that were affiliated with severe deficiencies.

[1] "CDE" stands for "Center for Drug Evaluation," which is part of the NMPA and in charge of drug product review.
[2] "CMDE" stands for "Center for Medical Device Evaluation," which is part of the NMPA and in charge of medical device review.

Implications for Foreign Manufacturers

The Chinese regulator has shifted its regulatory philosophy from stringent pre-approval supervision to rigorous post-approval enforcement. While domestic drug and device manufacturers have been frequently inspected by the NMPA and its provincial counterparts, foreign manufacturers experienced a much lower frequency of inspections to date. The announcement of the Regulations signals the NMPA's desire to treat foreign and domestic companies equally. We advise that drug and device companies intending to market or commercialize their products in China carefully study the statutory requirements and standards, perform internal audits on the relevant facilities, and identify and close potential gaps as soon as possible to mitigate enforcement risks.

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