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China's Legislature Passes the New Drug Administration Law

Attorneys
Katherine Wang

After almost two years of extensive review and deliberation, the Chinese legislature finally passed the new Drug Administration Law ("DAL") on August 26, 2019, which will go into effect on December 1, 2019.

Noteworthy Differences from the Most Recent Draft

The final version of the DAL remains largely consistent with the second draft issued in April 2019[1] though there are a few noteworthy differences. First, the final version of the new DAL takes a more lenient approach to online sale of prescription drugs. Except for certain high-risk pharmaceutical products,[2] online sale of prescription drugs is not entirely prohibited, but it must satisfy separate regulations to be issued by the National Medical Products Administration ("NMPA"). The new DAL also revises the definition of counterfeit drugs. Counterfeit drugs typically refer to drugs that are contaminated, contain no or incorrect active ingredients, or have the right active ingredients but at the wrong dose. The current DAL treats unapproved drugs as counterfeit drugs, which deviates from the common understanding. The new DAL focuses the definition on active ingredients and claims, rather than regulatory approvals. While importing and selling unapproved drugs in large quantities is still illegal, these acts would be not deemed equivalent to importing and selling counterfeit drugs, which is a criminal offense. Last but not least, the new DAL requires foreign pharmaceutical companies to appoint a legal agent in China. The legal agent will need to assume the same regulatory obligations and liability as the foreign marketing authorization holder.

Rewarding Innovation and Deterring Misconduct

The new DAL codifies many of the major reform initiatives implemented by the Chinese government since 2015. The Marketing Authorization Holder (MAH) system, compassionate use, conditional approvals, and priority review/approval for pediatric and orphan drugs are representative examples. The new DAL also signals a clear shift from stringent pre-approval supervision to active post-approval enforcement. For example, pharmaceutical manufacturers and distributors (including retailers) must be certified every five years for GMP and GSP compliance under the current DAL. The new DAL replaces the static certification system with a dynamic inspection system. Pharmaceutical manufacturers and distributors need to be prepared for fly-in inspections at an increased frequency. The NMPA will expand its inspection force to more effectively supervise the operations of pharmaceutical companies, both at home and abroad, as well as their vendors and suppliers. Failure to comply with the statutory obligations will result in more severe penalties, both in the scale of fines and in the forms of sanctions. For example, falsification of regulatory approvals and regulatory dossiers will result in increased fines (from up to three to 15 times the illegal proceeds). The legal representative and main responsible persons of the company will face new sanctions, including 10 years of debarment and detention by the police.

Unresolved Questions

The new DAL does not provide sufficient clarity to a few critical issues. First, patent linkage and regulatory data protection have been an area of concern for R&D-based pharmaceutical companies. Although both the State Council and the NMPA have promoted these mechanisms in previous policies, they are not included in the new DAL. It is unclear whether the Chinese government will continue to advance these mechanisms and include procedural details in the PRC Patent Law as well as the Implementing Regulations of the DAL.

Another interesting question is whether the MAH system will provide more flexibility in structuring cross-border transactions. Under the current DAL, imported and domestic drugs are subject to two different regulatory pathways.

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[1] See Ropes & Gray Alert dated May 15, 2019 for more details.

[2] Vaccines, blood products, anesthetics, psychotics, medical toxins, radioactive drugs, and precursor chemicals.

Historically, regulatory approvals for imported drugs would be issued to the foreign marketing authorization holders, yet regulatory approvals for domestic drugs would be issued to the actual manufacturers in China. Under the new DAL, the MAH system applies equally to imported and domestic drugs. Subject to the NMPA's approval, marketing authorizations can be transferred from one company to another without changing contract manufacturers. These changes could potentially result in a convergence of the bifurcated pathways and enable Chinese MAHs to work with overseas CMOs. Likewise, foreign MAHs may also choose to work with CMOs in China and restructure their supply chains. If such theses become true, foreign companies will more likely transact with Chinese companies to divest their product portfolios or localize the production of their assets in China. The new DAL is silent on whether the MAH system will retrospectively benefit products approved under the current regulatory regime. We hope the upcoming Drug Registration Rules will provide more information about the regulatory approval pathways and the transfer of marketing authorizations and legacy regulatory approvals under the new DAL.

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