Amended Drug Administration Law of China: Changes and Consequences for the Pharmaceutical Industry

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On August 26, 2019, the Standing Committee of the National People's Congress passed the Amended Drug Administration Law (the Amended Law) in China, effective from December 1, 2019. Compared with amendments passed during the last ten years, the Amended Law contains several significant changes.

Key Takeaways

- The Amended Law serves as the legal basis for regulatory agencies to develop regulations to support the Law's reforms.
- The Amended Law abolishes the certification requirements of good clinical practice (GCP), good supply practice (GSP), and good manufacturing practice (GMP); as a result, clinical institutions, drug distributors, and drug manufacturers will no longer be subject to compulsory certification.
- The Amended Law significantly increases administrative penalties, specifically monetary penalties, for manufacturing and selling counterfeit drugs and other violations.

The below highlights are most relevant to multinational pharmaceutical companies with Chinese operations.

1. Codification of Reform Actions: The Amended Law codifies a number of reform actions and policies that have been implemented or contemplated by the Chinese government, including the Marketing Authorization Holder (MAH) system; 60-working-day silent approval for clinical trials; extended use of investigational drugs to non-study subjects; and priority review and conditional approval for innovative drugs, orphan drugs, or drugs with urgent medical demands. It provides the legal basis for regulatory agencies, particularly the National Medical Products Administration (NMPA), to develop more regulations to support these reform actions.

2. The MAH System: Endorsed by the Amended Law, the MAH system will be implemented nationwide, presumably after completion of the current pilot program in selected regions of China. The MAH system allows separation of the product license holders from the actual manufacturers, except for certain high-risk products such as vaccines. The MAH will become transferrable subject to NMPA approval.

The MAH system will provide more flexibility for companies to arrange their research, development, and manufacturing activities in China; transferability of the MAH will offer an alternative venue for local business development, especially for the acquisition of local products.

Furthermore, the Amended Law creates a new concept under the MAH system with intent to further regulate foreign companies importing drugs into China. A foreign MAH will be required to engage a local agent to perform its responsibilities under the Amended Law, with joint liability. While the fundamental consideration for creating this concept is to allow regulatory agencies to hold foreign MAHs accountable when things go wrong, it remains to be seen how the scope of such joint liabilities will be defined, especially when local agents are not in the relevant product's distribution chain.

3. Abolishment of GCP, GSP, and GMP Certification: The Amended Law abolishes the certification requirements of good clinical practice (GCP), good supply practice (GSP), and good

manufacturing practice (GMP), and as a result, clinical institutions, drug distributors, and drug manufacturers will no longer be subject to compulsory certification. China may see more GSP and GMP inspections of drug distributors and manufacturers by the national and local NMPA to ensure their ongoing compliance, but it is not entirely clear how clinical trial institutions will ensure self-compliance with GCP requirements and whether the NMPA would conduct inspections on these institutions on the same level as GSP and GMP inspections.

4. Online Sales of Prescription Drugs: The Amended Law lifts the current restrictions on online sales of prescription drugs. Except for vaccines, blood products, and other high-risk drugs under special control, prescription drugs may be sold online by MAHs, drug distributors, and third-party eCommerce portals. It is widely believed that NMPA will soon develop regulations for implementing such online sales, and it remains to be seen whether the existing GSP requirements must be further revised or clarified to ensure quality control on the last-mile delivery of prescription drugs to individual consumers.

5. Revisions to Counterfeit Drugs and Inferior Drugs Definitions: After more than ten years of research and debate, the Amended Law revises the definitions of counterfeit drugs and inferior drugs and eliminates the concepts of "deemed counterfeit drugs" and "deemed inferior drugs." A counterfeit drug is now defined more narrowly to include (i) a drug that contains ingredients not in compliance with the national drug standards; (ii) a nondrug passing off for a drug or one drug passing off for another drug; (iii) a deteriorated drug; or (iv) a drug labeled with unapproved indications. In contrast, the definition of an inferior drug is expanded to include (i) drugs with noncompliant quantity of ingredients; (ii) drugs with a noncompliant shelf life or batch number; (iii) drugs with unauthorized excipients; or (iv) drugs that are otherwise not in compliance with applicable national standards.

The Law also creates a few new concepts to address circumstances that were formally dealt with as counterfeit drugs or inferior drugs. These new concepts include, for example, "unapproved drugs" and "drugs with unapproved or noncompliant labels." For companies with legitimate operations, deviation from the existing legitimate product approval will not necessarily make that product a counterfeit drug, which may help reduce risk exposure, especially to criminal implications as well as to reputational damages, for these companies.

Although manufacturing or selling unapproved drugs may be subject to significant penalties, the Amended Law also allows for importation under limited circumstances of certain unapproved drugs that have been legally marketed in another country; this also requires further definition and clarification.

6. Increased Penalties: The Amended Law significantly increases the level of administrative penalties, especially monetary penalties, for various violations. For example, manufacturing and selling counterfeit drugs, inferior drugs or unapproved drugs, and/or making unauthorized changes to the approved manufacturing process for a product may give rise to a monetary penalty between 15 to 30 times the product's value. Notably, for penalties that are calculated based on product values, the Amended Law provides a baseline of RMB 100,000 (approximately US $14,000).

In addition, various data integrity violations, failure to timely conduct product recalls, failure to timely report adverse events, violation of GCP, GSP, and GMP, bribery in the course of purchasing and selling, and related violations will also be subject to increased penalties.

The Amended Law explicitly imposes personal liability on individuals responsible for certain corporate violations. Relevant individuals to be held personally liable include legal representatives

and other personnel considered directly responsible. In addition to monetary penalties, their liability includes debarment for five years, ten years, or even permanently.