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China's NMPA Proposes Implementing Regulations for the Drug Administration Law

China's National Medical Products Administration ("NMPA") recently announced a comprehensive draft amendment ("Draft Amendment") to the Implementation Regulation of the PRC Drug Administration Law ("DAL Implementing Regulations"). The NMPA is soliciting public comments on the Draft Amendment through June 9, 2022.

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The Draft Amendment introduced important changes to the regulatory framework and aimed to codify many regulatory initiatives implemented by the Chinese government since the promulgation of the current PRC Drug Administration Law ("DAL") in 2019, for example, patent linkage and regulatory data protection. The Draft Amendment also reflected the NMPA's new attempt to address issues of greater public concern, such as penalty guidelines for violations of the DAL.

The Draft Amendment, once approved and released by the State Council, will significantly impact the operations of pharmaceutical companies. We strongly encourage life sciences companies to submit comments before the deadline, and closely monitor the legislative progress.

Highlights of the Draft Implementing Rules are summarized below.

1. Extraterritorial reach of the DAL

The Draft Amendment proposes to extend the reach of DAL to offshore development and manufacturing activities of pharmaceutical companies to the extent that the pharmaceutical companies would like to obtain marketing authorizations for their drug products in China.

All of the overseas R&D activities and production activities concerning a drug to be marketed in China and/or already marketed in China should be carried out in compliance with the regulatory requirements specified in applicable Chinese laws, regulations, rules, standards and specifications. While the Chinese GCP and GMP are not fully harmonized with the international standards, this requirement may create additional compliance burden on international pharmaceutical companies.

2. IND and NDA approval assignment

The Draft Amendment outlines rules to change IND and NDA applicants. Specifically, the IND approval assignment must be approved by the CDE, and the CDE may issue a new CTA showing the new IND holder. However, the Draft Amendment does not specify the conditions and timeline for the CDE's approval. If a company wants to assign its NDA approval to another company, the assignment must cover all formulations of the relevant drug product.

It is worth noting that the CDE currently does not review or approve the IND approval assignment. Companies can agree on the assignment by contract, and the assignee only needs to update the sponsor information on the CDE's clinical study registry. The proposed change may raise the bar for IND approval assignment.

3. Possibility for cross-border contract manufacturing

The DAL is silent on the permissibility of cross-border contract manufacturing. In practice, the NMPA has been firmly holding the bifurcation of approval pathway. A PRC-domiciled marketing authorization holder (MAH) cannot contract a CMO outside of China; neither can a foreign MAH contract a CMO in China. The Draft Amendment reiterates this distinction with respect to clinical supply, but the same requirement does not seem to apply to commercial supply. We welcome this change as it will create possibilities for cross-border contract manufacturing.

4. Market exclusivity

The Draft Amendment introduces three types of market exclusivity, namely pediatric drug exclusivity, orphan drug exclusivity and generic drug exclusivity. During the exclusivity period, generic manufacturers will be prohibited from securing a marketing authorization.

A market exclusivity period of up to 12 months could be given to an innovative (i.e., first time in the world) pediatric drug or a pediatric drug with a new dosage form, specification, indication, dosing regimen or administration. Innovative orphan drugs could be entitled to a market exclusivity period of up to seven years. First-to-market generics could be entitled to a market exclusivity period of the shorter of the remaining patent term or 12 months.

5. Regulatory data protection

Patent linkage and regulatory data protection have been a major area of concern for R&D-based pharmaceutical companies. The latest amendment to the PRC Patent Law acknowledged patent linkage, and the Draft Amendment only restated the operating mechanism. The noteworthy point is on regulatory data protection, which was not included explicitly in the DAL.

The Draft Amendment provides a six-year period of exclusive right to marketing authorization holders and prohibits unauthorized use of undisclosed clinical data and other data for regulatory filings. In addition, the NMPA should not disclose such proprietary data in public unless for the interest of the public or when protective measures are in place to prevent unfair commercial use of such data.

We suggest further clarifying the scope and conditions of regulatory data protection. All data included in the IND and NDA applications should be within the scope of protection, and the NMPA should only be allowed to disclose such data for public interest and with comprehensive protective measures.

6. Sentencing guidelines for administrative penalties

The PRC Administrative Penalties Law stipulates that administrative penalties shall be educational in nature and be commensurate with the facts, nature and severity of the unlawful acts. To implement such principle, the Draft Amendment defines a set of sentencing guidelines for administrative penalties. Enforcement authorities should give more severe penalties to companies manufacturing or selling counterfeit or inferior drugs to pregnant women or children, manufacturing or selling counterfeit or inferior biologics, causing injuries with the counterfeit or inferior products, or with recurring violations. If a company has actively taken measures to reduce or eliminate drug safety risks caused by its violation or can prove that it has no fault with respect to committing such illegal activity, there is a chance that it may be given a reduced penalty, or even no penalty under the Draft Amendment.

These sentencing guidelines, once finalized, will provide greater predictability and defense for pharmaceutical companies and their executives.