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Amendment to Drug Administration Law

On August 26, 2019, the China's National People's Congress passed the amended Drug Administration Law (the **Amended DAL**) which will take effect on December 1. The new law brings in some changes while codifying many existing practices. We summarize in this article the key highlights, including intellectual property related rules, of the Amended DAL.

1. Redefine "counterfeit drugs"

The Amended DAL no longer considers an unapproved drug as a counterfeit drug simply because it has not obtained a Chinese marketing approval. Under the *Drug Administration Law of 2015* and previous DAL drafts, any unapproved drug is treated as a counterfeit drug even if the drug is lawfully approved in a foreign country. Such drug is now taken out of the scope of counterfeit drugs and separately regulated under article 124 of the Amended DAL.

This article 124 forbids manufacturing or importing any unapproved drug. A violator will face administrative penalties including the confiscation of property, forced suspension of business, a fine, revocation of licenses, debarment from engaging in drug business, and administrative detention. However, article 124 further provides that importing a small amount of unapproved drugs that have been approved overseas may only result in a reduced penalty or exemption from penalty. The new rule will make the enforcement against previously illegal imports more difficult.

Since article 141.2 of the *Criminal Law of the PRC* defers the definition of counterfeit drugs to the DAL, the Amended DAL may also affect the criminal charges against producing and selling counterfeit drugs.

2. Codify marketing authorization holder (the MAH) system

The MAH system will be implemented across the country after December 1. A MAH must be an enterprise or a research institution (article 30.1). A foreign company may apply to be a MAH if it appoints a domestic company to undertake its responsibility within the country. The appointed domestic company shall bear joint and several liabilities with the MAH (article 38). A marketing authorization is transferrable subject to the approval of the National Medical Products Administration (the **NMPA**) (article 40).

A MAH may contract out its manufacturing work of drugs except for blood products, narcotic drugs, psychotropic drugs, medical toxic drugs, and potential illicit drug precursors (article 32.4). It is worth noting that vaccine was taken out of the prohibited list of contract manufacturing compared with a previous DAL draft. Vaccines are regulated separately under the *Vaccine Administration Law*. A vaccine MAH is generally required to manufacture vaccines by itself and may only, with the NMPA's approval, contract out any portion that is beyond its manufacturing capacity (article 22.4 of the Vaccine Administration Law, effective from 1 December 2019).

3. Product liability

The Amended DAL introduces a "first liability system" similar to that of the *Food Safety Law of the PRC*. A patient who suffers damage due to drug quality problems has the choice of claiming compensation for such damage from the MAH, the manufacturer, the distributor or the medical institution. If any of the aforementioned entities receives such claim, it must pay the compensation first if deemed liable and then may seek indemnity from the other liable parties if appropriate (article 144.2).

Punitive damages against the manufacturer, distributor or drug-using institution of a counterfeit drug or a substandard drug are possible (article 144.3).

4. Patent linkage and data exclusivity absent

A pervious DAL draft proposed several rules that are friendly to innovative pharmaceutical companies. But those rules, including data exclusivity, patent linkage, and the acceptance of foreign clinical trial data for marketing authorization, are missing from the Amended DAL.

5. Other provisions

The Amended DAL brings in changes that aim to enhance the availability of medication to patients, to speed up the regulatory approval for new drugs, and to ease the administrative burden of participants in the drug industry. Some important provisions reflecting those aims are summarized in this section. Many of these rules have been promulgated by NMPA's regulations or draft regulations in the last few years.

Rules on marketing approval and clinical trials include:

- Pediatric drugs are eligible for fast-track approval (article 16.3). The approval processes for drugs with urgent clinical needs and shortages, and new drugs indicated for major contagious diseases and rare diseases are also given priority treatments (article 96).
- Applicants for clinical trials are given automatic approval after a waiting period of 60 working days if no objection is issued (article 19.1).
- Only registrations for conducting generic bioequivalent trials are required, without the need of express NMPA approval (article 19.1).
- Institutions that conduct clinical trials need to register with the NMPA instead of having to obtain licenses (article 19.2).
- Compassionate use of a drug under clinical trial may be possible within the clinical trial institution to treat patients who suffer from life-threatening diseases with no alternative therapy and who cannot enter a clinical trial (article 23).
- Conditional approval is possible for drugs treating life-threatening diseases with no alternative therapy or drugs urgently needed for a public health emergency (articles 26). The MAH must conduct follow-up research after launch to confirm that the benefit of the conditionally approved drug outweighs its risk (article 78).

Rules on manufacturing and distribution include:

- Manufacturers are required to abide by the rules of Good Manufacturing Practice (GMP) and distributors are required to abide by the rules of Good Supply Practice (GSP) (articles 43 and 53). The old requirement to obtain a GSP certificate or a GMP certificate is abolished.
- Medical institutions may apply for a "one-time" import of a small amount of unapproved drugs subject to the approval of the NMPA or a provincial government authorized by the State Council. The drugs can only be used within the medical institution for the approved purpose (article 65.1).
- The previous DAL draft forbids a MAH or a distributor from selling any prescription drug on a third-party online platform. But this restriction has disappeared in the Amended DAL. It is possible that online distribution of prescription drugs becomes real at a certain point in the future. However, there is not any detailed guidance at present.

The Amended DAL is available in Chinese at: link.

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