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What the new Drug Administration Law brings

The latest Drug Administration Law amendments introduce welcome changes such as relaxed permit requirements and free prices. Pharmaceutical companies should keep abreast of the drug pricing reform, and track review and approval changes in the pipeline

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China's Standing Committee of National People's Congress recently approved the second revision (Amendments) of the *PRC Law on the Administration of Pharmaceuticals* (Drug Administration Law), the core piece of legislation governing the pharmaceutical industry in China. The Amendments, effective as of April 24 2015, introduced several welcoming changes to the original Drug Administration Law, which has not seen substantive updates since 2001.

The first noteworthy change is that the Amendments removed the pre-approval requirement so as to simplify the business administration process for drug companies. Article 7 and Article 14 of the original Drug Administration Law required a drug manufacturer or distributor to obtain the Drug Manufacturing Permit or the Drug Distribution Permit (Operational Permits) as a pre-approval for incorporation. Drug companies could not obtain their business licenses from the State Administration for Industry and Commerce or its local counterparts (AIC) before successfully obtaining the Operational Permits. Pursuant to the Amendments, the drug manufacturers or distributors will be able to obtain business licenses before obtaining the Operational Permits.

This is part of the Chinese government's general initiative to "streamline administration and delegate power" (简政放权) and to issue industrial approvals after business registrations (先照后证). It allows drug manufacturing and distribution investors to prepare for and start up their businesses in the name of their newly incorporated legal entities. Although legally set up, these entities are still not able to engage in drug manufacturing and distribution until receiving approvals, or the Operational Permits, from the local counterparts of the China Food and Drug Administration (CFDA). From now on, applicants can first obtain business licenses from the relevant AICs, with a qualifier in the business scope stating that for any business activities subject to approvals, companies can only engage in these activities after approvals are obtained from the relevant authorities.

Relatedly, the Amendments also deleted Article 100 of the previous Drug Administration Law in connection with the revocation of the Operational Permits. In the event that a drug company's Drug Manufacturing Permit or Drug Distribution Permit is revoked, the CFDA will no longer inform the relevant AICs to amend the company's business license or to de-register the company.

Another significant change relates to the lift of the government's drug price controls. Article 55 of the original Drug Administration Law provided that drug manufacturers, distributors and medical institutions must abide by the state-run pricing mechanism where prices were mandated or guided by the government. In addition, drug manufacturers should provide the government pricing authorities with genuine information with respect to drug production and distribution costs.

The Amendments deleted Article 55, unveiling China's drug pricing reform to eliminate fixed price caps and to introduce a market-oriented mechanism. Two weeks later on May 4 2015, this change was further substantiated by the *Opinions on Promoting Pharmaceutical Price Reform* (Opinions) jointly released by China's central pricing authority, National Development and Reform Commission (NDRC), along with several other administrative bodies.

According to the Opinions, the NDRC aims to gradually establish a market-driven drug pricing system and minimise direct government intervention of drug pricing. Drug prices are to be determined through market competition such as tendering or negotiations with local medical insurance authorities. Specifically, the Opinions set forth five product-specific principles of the reform of the drug pricing system:

- **Drugs reimbursed by the Basic Medical Insurance (BMI) funds:** Prices will be established on the basis of reasonable medical reimbursement standards by the BMI administrations together with other authorities;
- **Patented drugs and drug products with exclusive sources of supply:** Prices will be determined through a transparent and multilateral negotiation mechanism;
- **Blood products not listed in China's National Reimbursable Drug List, immunisation and vaccines purchased by national centralised procurement, national free antiretroviral treatment for HIV and birth-control drugs and devices:** Prices will be determined by government procurement or negotiations;
- **Narcotic drugs and Type 1 psychotropic drugs:** The government will continue to set the maximum ex-factory and retail prices;
- **Drugs not in any of the above categories:** Prices will be set by the manufacturers based on the production costs as well as market demand and supply.

It is anticipated that the NDRC will allow the market to decide on drug pricing and increase the frequency of price surveillance in the future, most likely by monitoring prices and enforcement against unlawful pricing behaviour.

Since 2000, the Chinese government, especially the NDRC, has played a key role in the drug pricing system by setting the "government-guided prices" or maximum retail price.

This reform will undoubtedly be deemed the most significant change in the Chinese drug pricing system for years. According to an anonymous NDRC spokesman, although some drug prices may increase due to production costs or market demand, the NDRC expects that most drugs will not experience a rapid price increase.

Overall, the Drug Administration Law Amendments introduce welcoming changes and show the government's determination to foster the development of the pharmaceutical industry by lifting redundant administrative controls. Meanwhile, the Drug Administration Law is expected to further evolve in the coming years, as the CFDA is in the process of proposing another round of revisions to the Drug Administration Law for approval by the State Council and the National People's Congress. Potential policy changes on the CFDA's agenda include piloting a Marketing Authorisation Holder system to the current drug approval system, introducing a Drug Master File system to the review system for active pharmaceutical ingredients, drug excipients and packaging materials and further delegating review and approval authorities to the local FDAs. It is crucial that life science companies continue to monitor the proposed changes and assess the impact on their business models in order to maintain a competitive edge amid China's fast changing regulatory landscape.

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