

Legal Commentary



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Branded Drug Pricing Mechanism Reform and the Elimination of Monopoly Profits

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In October 2015, the CPC Central Committee and the State Council issued *Several Opinions* on *Advancing Pricing Mechanism Reform*. As the Opinions clearly state, China will generally lift price controls over all goods and services in competitive sectors by 2017. In the pharmaceutical field, pricing mechanism reform has always been both widely watched and controversial. In May 2015, seven ministries jointly issued *Opinions on Promoting Drug Pricing Reform*, abolishing the separate pricing mechanism for branded drugs. This started a new round of drug pricing reform.

Branded drugs were granted the privilege of separate pricing in 2010, pursuant to provisions issued by the former State Planning Commission. The price of branded drugs is much higher than that of generic drugs, which is called "Super National Treatment." However, is separate pricing the only reason for the substantial difference in price? The answer may be "no." Admittedly, there is still a gap between the quality and efficacy of some generic drugs and branded drugs. Besides this, it is noteworthy that doctors have no incentive to choose reasonably priced generic drugs since they do not need to pay for medicines, and choosing generic drugs may also expose doctors to the risk of patient complaints. Thus, the development of generic drugs has been impeded and the pharmaceutical manufacturers have had to lower the generic drug prices close to the cost of production in order to survive in the market.

To solve this pricing problem in the pharmaceutical field, a series of measures have been taken:

On the supply side, State Food and Drug Administration initiated a project to research methods of evaluating the quality and efficacy equivalence of generic drugs. Once implemented, most of the generic drugs of poor quality and efficacy will be eliminated and the high-quality generic drugs will be more accepted since they have been proven qualified.

On the demand side, the General Office of the State Council issued guidance to implement comprehensive trial reforms in urban public hospitals. One of the reforms is to eliminate hospital commissions for selling drugs. These measures can cut off the profit chain between hospitals and drug prices to a certain extent. Another reform is the introduction of a centralized purchasing mechanism, which is conducive to further splitting the profit chain, thus improving the situation on the demand side.

Overseas experience shows that patent drug manufacturers may avoid or reduce the huge profit losses caused by the patent cliff by way of "product hopping." This refers to when the patent for an older drug is going to expire, the drug manufacturer may take soft or hard measures to force consumers to switch to a new patent drug before a generic version of the older patent drug becomes available. Patent drug manufacturers may force product hopping on consumers by leveraging their market dominance, which may impede generic competition and violate competition laws. Although there has not yet been a product hopping case reported in China, product hopping may likely emerge once the price reform succeeds and generic drugs gain more competitive advantage in the China market. The PRC Anti-monopoly Law needs to be prepared to meet the challenges posed by product hopping. Two of the most prominent challenges for regulatory authorities may be proving market dominance, and the methodology of viewing the product hopping behavior as a whole rather than in parts.

• Important Announcement

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