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Pros and Cons of Drug Price Renegotiation

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Second-round price negotiation of drugs following centralized procurement ("**Price Renegotiation**") was bound to be controversial from its inception.

From the opponents' point of view, Price Renegotiation has no merit: it reduces the credibility of provincial bid invitations, violates the *Bidding Law*, breeds corruption and unhealthy practices within medical institutions, adds to sales costs and expenses, and reduces profit margins for drug manufacturers, gives rise to inconsistent regional purchase prices, creates disorderly market competition, and results in a decreased quantity of drugs.

From the supporters' point of view, the benefits of Price Renegotiation far outweigh any drawbacks: it solves the problem of widespread drug price cuts, restores market bargaining power to both hospitals pharmaceutical companies, brings transparency to drug purchase discounts offered to medical institutions, reduces the opportunity for doctors to collect kickbacks, efficiently solves the chronic problem of commercial bribery, lightens financial burdens of local governments, and promotes the reform of centralized drug procurement ("**Centralized Procurement**").

Centralized Procurement is Responsible for the "Problem" of Price Renegotiation

From 1993 to around 2000, Henan, Liaoning, Sichuan, Zhejiang, Shandong, Fujian and other provinces carried out independent exploratory work regarding Centralized Procurement. On November 12, 2001, the promulgation of *Working Procedures on Centralized Bidding and Procurement of Drugs by Medical Institutions (Trial Implementation)* ("**Document No. 308**") marked the formation of Centralized Procurement at the national level. On September 23, 2004, six ministerial level governmental departments promulgated the *Certain Provisions on Further Regularizing the Centralized Bidding and Procurement of Drugs by Medical Institutions* ("Document No. 320"), which improved the organizational units in charge of Centralized Procurement at the provincial level. On January 17, 2009, six ministerial level governmental

departments jointly promulgated the *Opinions on Further Regularizing Centralized Procurement of Drugs by Medical Institutions*, and the system design using provincial online Centralized Procurement as a model came into effect. On February 9, 2015, the General Office of the State Council promulgated *Guidance on Improving Centralized Procurement of Drugs by Public Hospitals* ("**Document No. 7**"), and the Centralized Procurement model was adopted that provinces and medical system reform pilot cities interact from two levels.

The policy aims of Centralized Procurement are to "consolidate the orderly distribution of drugs, standardize drug prices, redress unhealthy tendencies found in medical purchases and sales, lighten the burden of medical expenses on the public," and another primary goal is also to decrease drug prices. However, Centralized Procurement at the national level inevitably weakens the independent drug procurement rights of regional governments and hospitals, which gives rise to the issue of Price Renegotiation.

On April 14, 2012, the General Office of the State Council promulgated a notice, *"Deepening Reform of the Medical and Health Care System, Main 2012 Working Arrangements,"* which stated that the reform of public hospitals would result in the cancellation the drug price markups. Prohibiting drug price markups reduced the income streams for public hospitals from three to two, namely service charges and government subsidies. The remaining income streams for public hospitals were not enough to offset the loss of income derived from drug price markups since service charges did not keep pace with expenses and government subsidies were in short supply. The income of hospitals decreased and the issue of Price Renegotiation became even more severe.

Attitudes of Ministries Vary; Local Authorities Lack Coordination

Price Renegotiation involves multiple government authorities, including the State Council's Office for Rectifying Malpractice (supervisory authority), the National Health and Family Planning Commission ("**NHFPC**"), the Development and Reform Commission (the Administration of Commodity Prices), the Administration for Industry and Commerce, the Food and Drug Administration, and the Administration of Finance, among others.

At the ministerial level, the NHFPC is the most adamant opponent against Price Renegotiation. Since 2004, the NHFPC has repeatedly stated its opposition to Price Renegotiation in a series of regulatory documents and notices. The attitude of the National Development and Reform Commission ("**NDRC**") is relatively vague. On November 21, 2013, the NDRC declared its support for Price Renegotiation in a symposium about drug prices. However, it is noteworthy that the NDRC is also a co-signer of several documents prohibiting Price Renegotiation issued by multiple ministries from 2004 to 2010.

At the local level, the attitudes of local governments differ widely. According to rough estimates, about 16 provinces prohibit Price Renegotiation in written documents while 3 provinces

permitted it. Other provinces have not issued any specific opinions. However, even in the provinces that expressly prohibit Price Renegotiation, there also exist some flexible approaches at the municipal level. And the local governments mostly acquiesce to Price Renegotiation from the local financial perspective.

Pharmaceutical companies are most disadvantaged by Price Renegotiation and are always in opposition to it. Price Renegotiation not only increases the burden on pharmaceutical companies, reduces profit margins, disrupts sales strategies, but also subjects companies to possible administrative punishment. Public hospitals generally seek to initiate various forms of Price Renegotiation in order to realize profits under the existing procurement system while facing pressure from the NHFPC.

Issues in Applying Price Renegotiation Laws

Price Renegotiation participants, the public hospitals and pharmaceutical companies, are most concerned about regulatory prohibitions on Price Renegotiation and the potential administrative penalty risks that apply to undertaking such transactions. Price Renegotiation is prohibited by a series of regulatory documents promulgated by the General Office of the State Council, the NHFPC and other ministries, and local government regulations promulgated by different provinces. However, according to relevant stipulations of the *PRC Legislative Law* and the *Law on Administrative Penalties of the PRC*, these regulatory documents and local government regulations cannot not give rise to any administrative penalties without legal or State Council regulatory authorization. Therefore, there must be some form of authorization for Price Renegotiation prohibition penalties.

The main laws and regulations relating to Price Renegotiation include the *PRC Bidding Law* and its implementing regulations, the *PRC Government Procurement Law* and its implementing regulations, the *PRC Anti-unfair Competition Law*, the *PRC Price Law*, the *PRC Pharmaceutical Administration Law*, and the *PRC Law on Administrative Penalties*. Currently, it remains controversial whether the *PRC Bidding Law* is applicable to Centralized Procurement and Price Renegotiation. The reason for this controversy is that it is ultimately the medical institutions which act as the final signatories and purchasers under Centralized Procurement, although the provincial and municipal Centralized Procurement centers and other platforms engage in the bidding and procurement process. Therefore, this case does not involve a conventional bidding arrangement since the tenderee and the purchaser are not the same. In addition, after the case *Shenyang Aojina Pharmaceutical Co., Ltd v. Shandong Finance Bureau* was heard by the Shandong Jinan Intermediate People's Court in March, 2015, a controversy also arose as to whether the *PRC Government Procurement Law* is applicable to Centralized Procurement of drugs.

Another law which cannot be ignored is the *PRC Anti-monopoly Law*. Based on legal interpretation, we may question whether the relevant Centralized Procurement ministerial regulations and local government normative documents and regulations enable administrative monopolies in violation of the *PRC Anti-monopoly Law* by prohibiting Price Renegotiation. Additionally, in practice, the local NHFPC and/or the medical groups organize(s) public hospitals within a particular region, and the hospitals can use their collective market position to force pharmaceutical companies to conduct Price Renegotiation after the companies win bids through Centralized Procurement. Such activity may constitute an abuse of dominant market position in violation of the *PRC Anti-monopoly Law*.

Potential Legal Risks

Based on the cases collected so far, no pharmaceutical company has been punished as a result of engaging in Price Renegotiation. In most circumstances, it was the medical institutions which were punished because they were involved in compliance issues related to commercial bribery or other anti-unfair competition activity during the Price Renegotiation. In other words, the medical institutions received administrative punishment for unrelated matters when engaging in Price Renegotiation and were not punished by the NHFPC, despite the NHFPC's express opposition to Price Renegotiation.

As for legal risks, pharmaceutical companies cannot be exempt from all liabilities if they are punished as a result of conducting commercial bribery. In practice, precedent shows that both parties conducting commercial bribery will be subject to administrative punishment. In addition, we cannot completely exclude the risks of criminal prosecution. In commercial bribery cases, it is difficult to prove that such bribery was not aimed at obtaining illegal interests or competitive advantage.

The NHFPC, however, cannot directly create any administrative penalties without legal or State Council regulatory authorization. Therefore, the NHFPC's administrative penalties for engaging in Price Renegotiation require a legal basis from laws such as the *PRC Government Procurement Law*, the *PRC Price Law* or the *PRC Anti-unfair Competition Law*. In addition, it should be noted that the NHFPC is directly in charge of medical institutions rather than pharmaceutical companies, based on the functional divisions between different government departments. Therefore, the NHFPC regulations are mainly seen as targeting medical institutions.

Furthermore, if the *PRC Government Procurement Law* is applicable to Centralized Procurement, medical institutions and pharmaceutical companies have to consider the potential risks posed by *the PRC Government Procurement Law* and the *Administrative Measures on Tenders and Invitations to Bid in Government Procurement of Goods and Services* in case that purchasers and suppliers substantively change the bidding results.

Strategies for Pharmaceutical Companies

In this article, we have mainly discussed the possible strategies and issues which pharmaceutical companies need to pay attention to when engaging in Price Renegotiation. We welcome pharmaceutical companies with specific Price Renegotiation issues to discuss with those issues with us for more targeted case analysis and discussion. We also recommend pharmaceutical companies to re-examine their existing contracts and business models from the following aspects:

a. Be clear about the policy environment and regulatory attitudes in different jurisdictions. Centralized Procurement of drugs is the responsibility of local governments. Therefore, it is crucial for pharmaceutical companies to clarify policy orientations and regulatory attitudes of local governments. We recommend pharmaceutical companies to consult local government authorities and refer to relevant laws and regulations in order to better understand local policies and regulatory attitudes and evaluate potential risks. Meanwhile, we recommend pharmaceutical companies to pay special attention to informal methods of Price Renegotiation and to evaluate different levels of potential risk.

b. Optimization of business models and processes. For instance, when doing business with distributors, pharmaceutical companies should engage in risk prevention and conduct a review of business practices such as processing documents, communication methods, issuing invoices, and distributors' codes of conduct.

c. Complete internal checks and recordkeeping. As for transactions involving Price Renegotiation, we recommend that pharmaceutical companies establish an internal check and recordkeeping system to record the transaction process which can be used as a basis of evidence or defense in any possible subsequent investigations.

d. As pharmaceutical companies are faced with more and more pressure to engage in Price Renegotiation, it is worth considering that Price Renegotiation may be involved with administrative monopoly or abuse of market dominant position. It is of interest to the pharmaceutical industry to discuss how the *Anti-monopoly Law* can be used against as a tool to protect the rights of pharmaceutical companies.

Important Announcement

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