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Drug Procurement GPOs: Antitrust Law Compliance Matters

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The drug market in China has long been subject to both market competition and administrative control. While the government leaves drug prices to market fundamentals in principle, it also actively intervenes in the case of market failures, which includes adjusting the market structure to regulate drug prices.

Administrative intervention is a double-edged sword. Due to the first-line reviewing officers lack of experience with the recently implemented fair competition review system, the relevant regulatory departments need to make a full analysis and assessment before intervening in the market. The competition law enforcement agencies should also closely monitor the regulatory departments' abuse of administrative power and assist in establishing proper enforcement principles in influential cases. For example, the National Development and Reform Commission ("**NDRC**") recently played a very positive role in the standardization of the drug group purchasing organization ("**GPO**") reforms in Shenzhen.

Shenzhen Municipal Health and Family Planning Commission ("SMHFPC") launched GPO reforms, aiming to reduce drug procurement costs and curb commercial bribery and other illegal acts during the drug procurement and sales process. However, the Commission permitted only one GPO to provide drug group purchasing services. In this case, the company Quanyaowang was chosen to become the exclusive GPO after several rounds of selection. As a result, Quanyaowang came to dominate the Shenzhen drug market and excluded market competition. Although Quanyaowang was chosen through a competitive selection process, SMHFPC created administrative barriers in the relevant market that established Quanyaowang as a true monopolist.

We are unclear as to whether SMHFPC imposed certain restrictions on Quanyaowang's conduct and, if so, whether those restrictions would have prohibited Quanyaowang from abusing its market dominant position. However, it was quite possible that the expected benefits from the reforms were marginalized or even overtaken by Quanyaowang's monopoly

profits. Even if the relevant authority regulated the excess monopoly profits, the resulting rent-seeking issues would act to seriously affect market efficiency, weaken drug manufacturer participation and ultimately harm the interests of consumers. The illegality of Quanyaowang's conduct was clearer, since it not only excluded competitors from the relevant market, but also did not improve market efficiency.

NDRC ordered a series of rectification measures which preserved the basic GPO model implemented in Shenzhen and also added a supplemental drug procurement platform. These measures are expected to alleviate insufficient market competition to some degree. Whether these measures can ensure the full competition in the market, however, remains to be observed and assessed by the relevant departments.

Competition law enforcement agencies convey their thoughts on law enforcement through the cases that they handle and decide. The findings from these cases will serve as a frame of reference for the relevant regulatory departments when developing the drug price reform policies.

Case Summary

On April 7, 2017, NDRC published its conclusions relating to an investigation of SMHFPC's suspected abuse of administrative power with the purpose of excluding and limiting market competition. NDRC found that SMHFPC had committed an abuse of administrative power with the purpose of excluding and restricting competition in violation of Articles 8 and 32 of the *Anti-monopoly Law*. SMHFPC committed to undertake measures to rectify these violations.

On July 1, 2016, SMHFPC issued the *Circular of SMHFPC on Promulgation of a Pilot Program for Promoting Public Hospitals Drug Group Purchasing Reforms in Shenzhen* (Shen Wei Ji Fa [2016] No.63), which represented the formal implementation a GPO pilot program in Shenzhen. The GPO model in Shenzhen essentially required public hospitals citywide to select a number of commonly used clinical drugs and to engage in group procurement. One pharmaceutical enterprise, Quanyaowang, was selected and was responsible as the GPO for centralizing the citywide public hospitals' quantities of drugs and limiting procurement prices. Quanyaowang also cooperated with the public hospitals and other drug manufacturers in the municipality to establish a drug procurement and distribution coordination system, which was expected to significantly reduce drug prices, promote the reasonable use of clinical drugs, reduce medical industry malpractice and enhance drug supply capacity. Shenzhen officially commenced the GPO pilot program citywide on July 1, 2016, which was to conclude in June 2017.

The GPO pilot program caused controversy from its inception. Based on reports from business and industry association, NDRC and its counterparts in Guangdong Province jointly launched investigations of SMHFPC for abusing its administrative powers in excluding competition during the implementation of the GPO pilot program reforms. Upon investigating,

NDRC found that SMHFPC had engaged in three forms of conduct that acted to exclude or restrict competition during the GPO pilot program.

a. Only one enterprise was permitted to provide GPO services. The GPO is responsible for procuring the required drugs on behalf of the hospitals and for providing group services. Before the reforms, all operators that met state qualifications and were able to provide the relevant services could serve as a GPO. However, the GPO pilot program provided that only one enterprise could be chosen to provide the drug GPO services, to the exclusion of all other qualified enterprises that were willing to provide such services. As a result, there was only one operator without any competition in the Shenzhen GPO market.

b. The Shenzhen public hospitals and drug manufacturers were limited to using Quanyaowang's services. First, all Shenzhen public hospitals could only purchase drugs through Quanyaowang, and could not select other qualified GPOs nor procure drugs themselves through the provincial centralized drug procurement platform. Second, the drug manufacturers were limited to only selling drugs to public hospitals through Quanyaowang that were contained in a drug catalogue, and drug sales through the provincial drug procurement platform were prohibited. These restrictions undermined the normal competitive order of the pharmaceutical market.

c. Drug distributors were only to be designated by Quanyaowang, which violated the relevant provisions of the *Guidance of General Office of the State Council on the Improvement of Public Hospitals Centralized Drug Procurement* (Guo Ban Fa [2015] No.7), which stipulates that drug manufacturers may independently choose their own distributors.

SMHFPC, as the administrative authority in charge of public health and family planning issues in Shenzhen, has decision-making power and management authority over the relevant matters within the city. SMHFPC exercised its administrative powers to promote the GPO pilot program. However, SMHFPC's exercise of its administrative power must be reasonable and conform to the *Anti-monopoly Law* and the *Opinions on the Establishment of Fair Competition Review System in the Development of Market System* (Guo Fa [2016] No. 34).

SMHFPC's actions in this case clearly exceeded "reasonable limits" and constituted an abuse of administrative power with the effect of excluding and restricting competition. These actions were found to be in violation of Article 8 of *Anti-monopoly Law*, which stipulates that "administrative organs and organizations authorized by laws or regulations to perform the function of administering public affairs may not abuse their administrative power to exclude or restrict competition." SMHFPC was also found to have violated Article 32 of the *Anti-monopoly Law*, which provides that "administrative organs … may not abuse administrative power to limit, or limit in disguised form, units or individuals to deal in, purchase or use products from designated operators."

Based upon the NDRC findings, SMHFPC committed to take the following three rectification measures:

a. Ensure the autonomy of public hospitals to procure drugs. Subject to drug centralized procurement principles, public hospitals will have the right to either entrust the designated GPO (i.e., Quanyaowang) to purchase drugs or to procure drugs by themselves through the provincial drug procurement platform.

b. Ensure the independent right of drug manufacturers to choose drug distributors. SMHFPC will revise and improve the GPO drug procurement distribution system so as to allow drug manufacturers to independently choose distributors.

c. Ensure the autonomy of drug manufacturers. SMHFPC will allow drug manufacturers to sell drugs contained in the catalogue to public hospitals either through the designated GPO (i.e., Quanyaowang) or through another procurement platform.

In addition, SMHFPC also undertook to revise and improve the relevant policies during the GPO pilot program period in order to comply with the *Anti-monopoly Law* and *Opinions on the Establishment of Fair Competition Review System in the Development of Market System* (Guo Fa [2016] No. 34). The relevant policies will be revised to allow qualified GPOs to enter the relevant market and ensure that the GPO program can develop in an orderly way.

● Important Announcement

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