China Intensifies Antitrust Enforcement in the Pharmaceutical Industry:

NDRC Issues Ruling in its First Concerted Practice Case

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Introduction

Since the implementation of the Anti-Monopoly Law (the "**AML**") in August 2008, those industries particularly affecting the populous' quality of life have been the major focus of the antitrust authorities' enforcement agenda. Targeted industries include those such as automobile, consumer goods, insurance, construction materials, tourism, tobacco, telecoms and public utilities, etc. In particular, the National Development and Reform Commission (the "**NDRC**") has launched several rounds of "antitrust storms" upon the auto industry, which attracted wide attention in recent years. In the meantime, enforcement upon the pharmaceutical industry has been relatively light, even though it is a critical sector affecting quality of life. In spite of some discussion and various rumors, neither the NDRC nor the State Administration for Industry and Commerce of the PRC (the "SAIC") had penalized any pharmaceutical enterprises over the past few years. However, during a single month period in the beginning of 2016, both the SAIC and the NDRC respectively published penalty decisions against pharmaceutical companies, i.e. the Chongqing Qingyang Pharmaceutical Monopoly case[2] and the Allopurinol Drug Cartel case[3]. The nearly parallel actions evidence an accelerated enforcement targeting the pharmaceutical industry.

The end of July in 2016 witnessed another serious jolt to the pharmaceutical industry. The NDRC published the penalty decision on Huazhong Pharmaceutical Company Limited ("**Huazhong Pharmaceutical**"), Shandong Xinyi Pharmaceutical Co., Ltd ("**Shandong Xinyi**") and Changzhou Siyao Pharmaceutical Co., Ltd ("**Changzhou Siyao**"), which collusively reached and implemented monopoly agreements. The three companies were imposed fines totaling over RMB 2.6 million. Two types of monopoly behaviors in upstream and downstream markets were identified in this case. The three companies reached and implemented monopoly agreements on the joint boycott of transactions in estazolam active pharmaceutical ingredients (APIs) market, as well as another monopoly agreement on

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[2] The original Chinese notice issued by the SAIC is available at: http://www.saic.gov.cn/zwgk/gggs/jzzf/201512/t20151222_165152.html
[3] The original Chinese notice issued by the NDRC is available at: http://jjs.ndrc.gov.cn/gzdt/201607/t20160727_812589.html

collusively increasing and fixing prices in the estazolam active pharmaceutical tablets market. It is worth noting that this case marks the first occasion where Chinese antitrust authorities identified a cartel reached by way of concerted conduct. Meanwhile, this case is the second joint boycott case following the Guangdong Panyu Animation and Gaming Monopoly case.[4] Furthermore, this case indicates that antitrust authorities are increasing law enforcement efforts upon the pharmaceutical industry and demonstrates how the NDRC has become more mature and professional in handling complicated cases.

Monopolistic Conduct and Assertion of Concerted Conduct

Estazolam has sedative, hypnotic, and antianxiety effects. It is listed as a nervous system drug in the Class II psychotropic drug under the national basic drug catalog and also the national low-priced drug catalog. China has implemented rigid regulations on market entry standards and manufacturing of Class II psychotropic drugs, and has granted only four companies a license to manufacture estazolam APIs. Of those four companies, only three actually manufacture estazolam APIs, i.e. Huazhong Pharmaceutical, Shandong Xinyi and Changzhou Siyao. These three companies also manufacture estazolam tablets. The NDRC alleged that between September and October 2014, the three companies met in Zhengzhou City of Henan Province to discuss business arrangements (the "Zhengzhou Meeting") related to estazolam APIs and tablets. At the Zhengzhou Meeting, the three companies reached a consensus on two matters: (1) each company should use estazolam APIs for internal purposes only; and (2) act concertedly to raise prices of estazolam tablets. Shortly after that, the three companies gradually ceased API supply to other tablet manufacturers and raised estazolam tablet prices.

According to Article 13(2) of the AML, monopoly agreements include agreements, decisions and other concerted conducts designed to eliminate or restrict competition. In this case, Huazhong Pharmaceutical communicated with Shandong Xinyi through meetings, phone calls and text messages to effectuate the cessation of supply and the price hike. These actions constituted the offending monopoly agreement. Changzhou Siyao did not actively participate in the conspiracy. However, it did not object to the collusion and later followed the lead of the other two companies. Such conduct constituted a concerted practice. This case marks the first time in eight years of AML enforcement that the antitrust authorities rendered a decision leveling a penalty for monopolistic concerted practice. Two provisions guide the determination of what might constitute concerted practice. The NDRC follows its Article 6 of the *Provisions on Anti-Price Monopoly*. SAIC, of course, analyzes concerted practice under its Article 3 of the *Provisions for Administrative Authorities for Industry and Commerce on Prohibiting the Conclusion of Monopoly Agreements*. NDRC's Article 6 and SAIC's Article 3

[4] The original Chinese notice issued by the SAIC is available at: http://www.saic.gov.cn/zwgk/gggs/jzzf/201512/t20151208_164680.html

differ in nuanced ways. Overall, however, they both each consider the following major factors in analyzing whether concerted practice occurred: uniformity, exchange of information, reasonable explanation, market structure and market changes, etc.

Authority / Factors	SAIC	NDRC
Uniformity in Acts	Whether there is uniformity in the market acts committed by business operators	There is consistency in the price adjustment activities of business operators
Exchange of Information	Whether there has been communication of intention or exchange of information between business operators	There has been communication of intention between business operators
Reasonable Explanation	Whether business operators are able to give any reasonable explanations for their concerted practice	——
Other Factors	Market structure, competition, market changes and industry situation.	Market structure and market changes.

(Table1: Detailed stipulations on assertion of concerted conducts)

The following text elaborates the specific criteria the NDRC uses to assess whether a concerted practice occurred under the facts presented.

Uniformity in Acts

The uniformity in acts committed by the companies is mainly reflected by the following circumstances: (1) the timing of the respective price hikes of the three companies were basically consistent with each other; (2) the margin of price increase of the three companies were basically consistent with each other; and (3) the three companies refused to supply estazolam APIs to the downstream tablets manufacturers during the same period of time.

Exchange of Information

The three companies discussed the suspension of supply and the price increases of estazolam tablets at the Zhengzhou Meeting. Even they had not agreed on a precise rate increase, the other two companies did not expressly object to Huazhong Pharmaceutical's proposal. After

the Zhengzhou Meeting, HuaZhong Pharmaceutical and Shandong Xinyi actively communicated with each other on price changes through meetings, phone calls, and text messages. The NDRC alleged that Changzhou Siyao attended the Zhengzhou Meeting and did not clearly object to the proposal for collusion. It also failed to voluntarily and independently report the cartel to the antitrust authorities. Such behavior constituted an exchange of information with the other two companies. Thus it can be seen that avoiding active involvement will not exculpate the accused. In fact, any tacit approval may be presumed to constitute an exchange of information which will in turn comprise significant evidence of concerted conduct.

Absence of Reasonable Explanations

Changzhou Siyao's defense was that the suspension of supply was a result of its limited capacity and was accomplished to protect its own demand for manufacture of the tablets. Also, Changzhou Siyao claimed that its decision to raise the price of estazolam tablets was based on three neutral factors. Changzhou Siyao stated it relied on data it collected from the market, national policy and the overall competition in the market. However, the NDRC rejected these defenses, due in no small part to the tacit understanding and coordination between the two other companies.

Market Structure and Changes

The NDRC concludes that the estazolam APIs market is a typical oligopolistic market. China has implemented rigid controls which inhibit the market entry of the manufacture of estazolam APIs. Only three companies manufacture estazolam APIs long-term. It is difficult for other companies to access to this market. Meanwhile, the estazolam APIs are a key ingredient in manufacturing estazolam tablets. The tablets manufacturers are highly dependent on the ingredient manufacturers and can only purchase APIs from estazolam API enterprises. The three investigated companies were easily able to reach a tacit understanding regarding the estazolam APIs market. Moreover, fourteen estazolam tablets manufacturing companies were forced to cease the production after the collusive suspension of estazolam APIs supply by the three companies in 2015. The competition in the supply of estazolam tablets deteriorated rapidly. Therefore, the NDRC concluded that the joint refusal of the three estazolam API companies to supply facilitated further collusive price hikes.

In conclusion, the NDRC concluded that Huazhong Pharmaceutical, Shandong Xinyi, and Changzhou Siyao had reached and implemented monopoly agreements as to the joint boycott of supply in the estazolam APIs market. Such behavior forced out other estazolam tablets manufacturers. It also severely eliminated and restricted competition in the estazolam tablets market. Meanwhile, the behavior of reaching and implementing the horizontal agreements on

raising price of estazolam tablets directly caused substantial price hike from the beginning of 2015. Such collusion harmed the interests of consumers.

Penalties and strict standards of leniency programme

The NDRC imposed different penalties on the three companies based on the nature, degree, duration of their respective behaviors, as well as based on their roles, their degree of cooperation, and any other meritorious performance in this case.

Company	**Grounds for mitigation of penalty**	**Amount of fine (RMB)**	**Fine as % of 2015 turnover in the estazolam tablets market**
Huazhong Pharmaceutical	Played a leading role as the organizer in reaching and implementing the agreements; more serious offender ; and no grounds for a reduction in penalty	157.1829 1,571,829	7%
Shandong Xinyi	Participated in unlawful practices, but actively co-operated with the NDRC; this constituted meritorious conduct	54.7563 547,563	2.5%
Changzhou Siyao	Acted merely as a follower; fewer violations; actively rectified its behavior	48.4431 484,431	3%

(Table2: Detailed penalties in the estazolam case)

One highlight of this case is that the NDRC took a strict approach in applying leniency. During the investigation, Shandong Xinyi voluntarily admitted the basic fact of the Zhengzhou Meeting and the contents of the oral agreements. However, the NDRC refused to apply leniency because Shandong Xinyi's confession was overdue, volunteered only after the NDRC had uncovered key evidence. Instead, the NDRC imposed a lighter punishment on Shandong Xinyi according to Article 27(1) of the *Law of the PRC on Administrative Penalty*, which stipulates that "A party shall be given a lighter or mitigated administrative penalty if it has performed meritorious deeds when working in coordination with administrative organs during their investigation into violations of law". In accordance with the currently valid *Regulation on Procedures for Enforcement of Administrative Law on Anti-Price Monopoly*

promulgated by the NDRC, the first three undertakings to take the initiative to report the relevant information of the monopoly agreements and submit material evidence are entitled to the leniency, i.e. being awarded a reduction in penalty or an exemption. The regulation does not elaborate on the precise time necessary for voluntary reporting in the context of leniency, whether before or after the initiation of the investigation launched by the NDRC. Moreover, according to previous precedent, some companies received lighter punishment after voluntary confession following the initiation of the investigation (e.g. Zhenjiang Automobile Insurance case[5]). According to the *Guidelines for Application of the Leniency Programme to Cases of Horizontal Monopoly Agreements (Draft for Comments)* ("**Guidelines for Application of the Leniency Programme**") promulgated by the NDRC, the undertaking involved in the monopoly agreements still have the opportunity to apply for leniency even after the initiation of the investigation. Article 6 of the Guidelines for Application of the Leniency Programme stipulates that where a law enforcement authority has commenced investigation procedures, the evidence provided by the undertakings themselves shall be of significant value to the final findings (i.e. evidence that has a greater probative force or has supplementary probative value in proving the ways of reaching and implementing the monopoly agreements), which sets a high standard of evidence for the purpose of application of leniency. This case reflects that the NDRC gradually applies a more rigorous standard in leniency compared with the prior and more flexible leniency program. The Guidelines for Application of the Leniency Programme has not yet come into effect, however, the policy applied in this case is consistent with the principles in the Guidelines.

Conclusion

The pharmaceutical industry is a significant field affecting both health and safety and quality of life. According to media reports, the NDRC has issued two rounds of industry inquiries to pharmaceutical manufacturers, medical device manufacturers, and their distributors. This case is a new beginning for antitrust enforcement in the pharmaceutical industry. The NDRC is expected to crack down on more monopolistic cases and the expectation is that the new wave of antitrust storm would be stronger than that which afflicted the auto industry. According to the *Notice of Launching Special Inspection on Price of Drugs throughout the Country* promulgated by the NDRC in May 2016, the NDRC will focus on the active ingredient and the drugs of having abnormal fluctuations in prices. The NDRC aims at maintaining fair competition in the pharmaceutical market, protecting the legitimate rights and interests of patients, and regulating the prices of drugs.

[5] The original Chinese notice issued by the NDRC is available at: http://jjs.ndrc.gov.cn/gzdt/201409/t20140902_624513.html

According to our observation and analysis, the investigations initiated by the NDRC have the following targets: (1) the involvement of all variety of types of companies, including multinational, state-owned and private enterprises; (2) various illegal conduct, including refusing to enter into transactions, unfairly high prices, and tie-in sales by abuse of dominant market position, collusive price fixing and market allocation under the horizontal agreements and the resale price maintenance under the vertical agreements. Moreover, some hidden collusive behaviors (e.g. the concerted conduct in this case) and more complex behaviors (e.g. Pay for Delay) are also under the strict scrutiny of the NDRC; and (3) an increasing intensity of punishment. The authority may even impose record fines.

In order to prepare and respond to this round of pharmaceutical antitrust investigation, pharmaceutical and medical device enterprises are recommended to strengthen antitrust compliance construction, particularly in the following respects:

1. Conducting internal antitrust review, engage antitrust professionals to assist in carrying out internal audits, and evaluating potential antitrust risks;
2. Providing updated antitrust training to senior managers and employees (particularly those in sales and marketing departments) to strengthen their awareness of antitrust compliance;
3. Conducting antitrust review of business policies, marketing materials and other internal strategic documents from the antitrust compliance perspective; and
4. Paying close attention to the concerted conduct in this case and taking caution towards any exchange of information with competitors. Avoid discussions with your competitors concerning the exchange of sensitive information, including the price, production, and capacity, even during meetings organized by industry associations. When it comes to such sensitive topics, participants are to clearly raise objections against the proposal and demand, if necessary, that its objections and contrary views are recorded in the minutes of the meeting. Any ambiguous attitude could lead the company towards an unfavorable outcome such as that experienced by Changzhou Siyao; and
5. Seeking professional advice to make rectification plans as soon as possible under circumstances where any suspected violation is found. After a careful assessment of business benefits and legal risks, the company is advised to prepare a voluntarily report to the enforcement authority and ideally become eligible for leniency under the leniency program.