Pharmaceutical companies face severer antitrust compliance challenges – Commentary on the "Price Conduct Guidelines on Operators of Drugs prone to Shortages and APIs"

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Background

Four months after seeking comments, the National Development and Reform Commission ("**NDRC**") released "Price Conduct Guidelines on Operators of Drugs prone to Shortages and APIs[2]" ("**Guidelines**") on 16 November 2017. This is the first price-related anti-monopoly guidelines for a specific industry since the Anti-Monopoly Law was implemented. The Guidelines provide risk assessment warning and compliance guidance for pricing monopolistic behaviours involving both drugs prone to shortages and active pharmaceutical ingredients ("**APIs**"). For the first time, the Guidelines clarify that enforcement agencies use the "Prohibition plus Exemption" principle to identify pricing monopolistic agreements and refine the consideration of certain abusive activities (e.g. unfair pricing and refusal to deal). In addition, the Guidelines remove controversial provisions such as exclusive dealing that is included in the draft Guidelines. We recommend that the relevant pharmaceutical enterprises should conduct the anti-monopoly risk audit by reference to the Guidelines and adopt more strict compliance measures to identify and prevent the relevant legal risks.

Scope of application

The Guidelines define the concept of shortage drugs and APIs, that is, drugs that not being able to be supplied sufficiently in a certain area, including "Chinese herbal medicines, Chinese herbal decoction medicines, Chinese patent medicines, antibiotics, biochemical medicines, radiopharmaceuticals, serums, vaccines, blood products and Diagnostic drugs, etc., as well as chemical or natural raw materials used in the manufacture of pharmaceutical preparations." However, the Guidelines do not give a specific meaning of "not being able to supply sufficiently".

The Guidelines regulate not only producers of shortages drugs and APIs, but also natural persons, legal entities and other organizations engaged in the operation or services for shortages drugs and APIs, such as exclusive or non-exclusive distributors of APIs. Two API general distributors were penalized for abuse of dominance before the issuance of the Guidelines. The applicable scope of

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[2] The original text of "Price Conduct Guidelines on Operators of Drugs prone to Shortages and APIs" is available at http://jjs.ndrc.gov.cn/zcfg/201711/t20171122_867540.html

the Guidelines is consistent with previous practice which includes manufacturers, distributors, medical institutions, etc.

Horizontal Price Monopolistic Agreements

The Guidelines do not break through the form of monopolistic agreement set forth in the Anti-Monopoly Law, which includes agreements, decisions and concerted practice[3]. Such agreements can be reached by way of written, verbal, email, text messages, WeChat and other instant messages.

The Guidelines cover a wider range of horizontal agreements than the NDRC's Provisions on Anti-Price Monopoly implemented on 1 February 2011. The horizontal pricing monopolistic agreement in the Guidelines not only lists pricing-related behaviours but also refers to other types of monopolistic agreements that are not directly related to prices (e.g. output limit, market segmentation and boycott). Although these activities are not directly related to prices, the ultimate goal is to control prices and lead to price increases or price convergence. These provisions also further expand, refine, and thus increase the practicability of the provisions of the horizontal monopoly agreement under Article 13 of the Anti-Monopoly Law, which enables enterprises to carry out internal inspection.

"Prohibition plus Exemption" principle

Article 6 of the Guidelines clarify that the NDRC strictly complies with the "Prohibition plus Exemption" principle to investigate the price monopoly agreement in the enforcement, that is, the acts stipulated in Article 13, Article 14 of the Anti-Monopoly Law are expressly prohibited; however, business operators can apply for exemptions if the requirements of Article 15 of the Anti-Monopoly Law can be met. Due to the unclear provisions of the Anti-Monopoly Law and lack of implementing rules and guidelines before the issuance of the Guidelines, both academics and practitioners have argued about what principle should apply to monopoly agreements in China. These arguments mainly focus on whether "per se illegal" or “rule of reason” should be applied in analyzing and defining monopolistic agreements. For the first time, the Guidelines clarify that enforcement agencies should apply "Prohibition plus Exemption" approach to price monopolistic agreements, and the NDRC does not apply "per se illegal" to investigate monopoly agreements. However, it remains to be seen whether the courts will change their “rule of reason” approach which was used consistently in the trial of monopolistic agreement cases.

[3] For the analysis of concerted practice, see Michael Gu’s article dated 22 August 2016,“China Intensifies Pharmaceutical Antitrust Enforcement: NDRC Rules in First-ever Concerted Practice Case”: http://www.anjielaw.com/uploads/soft/170215/1-1F215111447.pdf

How to identify dominant market position

In addition to strictly complying with the criteria of market dominant position in the Anti-Monopoly Law, the Guidelines also emphasize that "market share is a key element in measuring market power of operators." Moreover, according to Guidelines, "to assess the market share can take into account the actual production capacity of operators, potential capacity, intellectual property and other factors." This is the first time that enforcement agency clearly stipulates that market share can take into account the "potential production capacity". It undoubtedly sets a higher red line and more stringent compliance requirements for the shortage drugs and APIs operators with high market shares.

It is also noteworthy that the Guidelines set out the dominant position in the form of substantive control of other operators. Article 7 of the Guidelines stipulates that "enforcement agencies shall consider the circumstances in which there is evidence that the operator exercises substantive control over the relevant enterprises to obtain dominant position." The Guidelines do not elaborate on "substantive control." In practice, requiring APIs or shortage drugs suppliers to supply exclusively and accepting their prices and thus controlling its production and sales by way of underwriting agreements or exclusive agency agreement may be considered as a substantive control.

In addition, the Guideline follows the relevant provisions under the Anti-Monopoly Law that "presumed to have a dominant position." The principle of presumption is confirmed by the NDRC in the Second Pharma Co. Ltd and Handewei Pharmaceutical Co. Ltd abuse of dominance case which was penalized by NDRC on 28 July 2017[4]. In this case, the market share of Zhejiang Second Pharma Co. Ltd. and Tianjin Handewei Pharmaceutical Co. Ltd. exceeded two-thirds in the isoniazid APIs, and the relevant market share of each company has never fallen below one-tenth. In the penalty decision, the NDRC also analyzed the reliance degree of other operators, entry barriers to identify the two companies held a dominant position.

Typical Abuse of Dominance

The Guidelines elaborate on five specific types of abuse of dominance, namely, unfair pricing, refusal to deal, restrictive transaction, charging unjustified fees and differential treatment. Due to the length of the article, this article focuses on the analysis of unfair pricing, refusal to deal and other activities which tend to cause controversy in practice.

[4] Notice of the Penalty Decision of Second Pharma Co. Ltd and Handewei Pharmaceutical Co. Ltd abuse of dominance case, see the website of NDRC: http://jjs.ndrc.gov.cn/fjgld/201708/t20170815_857737.html; http://jjs.ndrc.gov.cn/fjgld/201708/t20170815_857735.html

1. Identification on Unfairly High Prices

Abuse of market dominance in the way of unfairly high selling price or unfairly low purchasing price is a risking area for APIs operators. In the Second Pharma Co. Ltd and Handewei Pharmaceutical Co. Ltd abuse of dominance case, the APIs manufactures were penalized precisely because of sale of the isoniazid APIs on unfairly high prices. According to the Anti-Monopoly Law, the determination of an unfairly high prices does not need to consider whether there is a "justifiable reason" and can be directly determined by the act itself. However, in the Provisions on Anti-Price Monopoly, the NDRC specifies the factors that should be considered in determining unfairly high prices. To some extent, it can be deemed as a valid reason for acts such as cost changes and level of price increases. The Guidelines follow the identified factors under the Anti-Price Monopoly Regulation and expand it to set out several criteria for determining whether the medicine price is rising fairly or not. The considering factors for unfairly high pricing sales (unfairly low price purchases) in the Provisions on Anti-Price Monopoly and the Guidelines both include prices of competitors over the same period, rising costs, or decreasing costs. The Guidelines contain a new provision that compare the historical prices in the same area and prices in different regions of the same period.

Before the Guidelines are released, enforcement agencies actually already considered factors such as cost, changes in market supply and demand and prices over the same period when investigating and dealing with unfair high pricing sales. According to the published cases, the criteria for selling products at unfairly high prices include the situation of "sharp price hike" and "price multiplied by x times the previous year". When determining the unfairly high prices, enforcement agencies would compare the current price with the previous price in the same period of time and focus on the degree of price increase. Meanwhile, enforcement agencies would also take into account factors that led to price increases, such as rising production costs, changes in market supply and demand and other factors. In the Second Pharma Co. Ltd and Handewei Pharmaceutical Co. Ltd abuse of dominance case, the highest selling price of isoniazid APIs was 19 times as the highest selling price of the previous year, and "neither company failed to give any evidence to justify substantial price increases of APIs due to the rising cost and the market supply and demand changes ", therefore the NDRC concluded that the two companies selling goods in unfairly high prices was in violation of the Anti-Monopoly Law. The Guidelines give a clearer way of determination and supervision of the price hiking of operators.

2. Removal of illegality identification of exclusive dealings in Guidelines (Draft for Comments)

Article 9 of the Guidelines (Draft for Comments) stipulates that operators shall not abuse their market dominance to implement exclusive dealings and control prices. In practice, the exclusive dealings are usually shown as “underwriting agreement”, “exclusive agency agreement”, “exclusive sales agreement” and so on. During the public consultation period of the Guidelines (Draft for Comments), the authors expressed the concerns over the provision on prohibiting “exclusive dealings” and recommended that this provision shall be deleted[5]. Exclusive dealing is not illegal by its nature, and laws should not forbid undertakings with market dominance to choose their own nation-wide or regional general agent or distributor and conduct their business by way of exclusive distribution. The authors believe that the real possible violation of the antitrust law is to manipulate prices and disrupt competition after obtaining a monopoly position by way of exclusive dealings, which is not essentially different from controlling prices through other means. A separate listing of the rules prohibiting exclusive dealings is a bit more “superfluous” and can easily lead to an improper interpretation, thus affecting the normal business practices of enterprises who adopt exclusive dealing modes. The Guidelines eventually remove the rules on “exclusive dealings” and focus on price manipulation conducted by dominant market players by way of exclusive dealing.

3. Refusal to deal emphasizes the competitive impact on downstream markets

According to the Guidelines, operators of drugs prone to shortages and APIs with market dominance shall not refuse to deal with the counterparty in a disguised form without justifiable reasons by means of setting unfairly high sale price, or unfairly low purchasing price. Compared with the Guidelines (Draft for Comments), the Guidelines clarify that the impact of refusal to deal on downstream market competition can be considered when analyzing whether there is justified reason for refusal to deal, that is, considering that "the existing production capacity of undertakings cannot satisfy market supply, or the product must be provided for its own production use, and its supply or own production use do not seriously exclude the downstream market competition."

After the introduction of the Guidelines (Draft for Comments), the authors submitted a proposal to the NDRC and recommend the enforcement agency clarifying the constitutional elements of refusal to deal and specifying that undertakings competing both in the upstream and downstream businesses as one of the constitutional elements of refusal to deal by undertakings[6]. According to

[5] For the analysis of “exclusive dealings”, see Michael Gu and Sihui Sun's article dated 29 August 2017, "Drug Operators ' Attention - Price Conduct Guidelines on Operators of Drugs Prone to Shortages and APIs" (Draft for Comments) Put Forward Stringent Compliance Requirements ": http://www.anjielaw.com/uploads/soft/170830/1-1FS0094545.pdf

[6] For the analysis of "refusal to deal," see Michael Gu and Sihui Sun's article published on 29 August 2017, "Drug Operators ' Attention - Price Conduct Guidelines on Operators of Drugs prone to Shortages and APIs" (Draft for Comments) put forward stringent compliance requirements ": http://www.anjielaw.com/uploads/soft/170830/1-1FS0094545.pdf

the prevailing antitrust theory, an operator's purpose of refusal to deal is not to seek profit from the counterparty of the transaction, but to force them out of the market by refusing to deal so that the counterparty cannot obtain the basic conditions or raw materials essential to production and operation, by which the undertaking can achieve the purpose of squeezing out competitors as well as controlling and influencing the relevant market[7]. Therefore, in the field of APIs, refusals to deal under the sense of typical antitrust law should generally meet the following conditions: an undertaking with dominance in APIs market also participates in the competition of downstream market, that is, the market of preparations. In order to enhance or consolidate its competitiveness in the field of preparation products, the operator leverages its market power in the APIs market to the downstream preparation market by means of ceasing the supply to competitors in the downstream market and blocking off the APIs for its own use, by which it may restrain the competition in preparations market.

In Chongqing Qingyang Pharmaceutical Co., Ltd. ("Chongqing Qingyang")'s abuse of market dominance case[8], Chongqing Qingyang implemented such a typical refusal to deal. On the contrary, the identification in Chongqing Southwest No.2 Pharmaceutical Factory Co., Ltd.'s refusal to deal case[9] was slightly far-fetched. Although in that case Chongqing Southwest No.2 Pharmaceutical Factory Co., Ltd. exteriorly refused to supply, which was in line with the characteristics of refusal to deal, however, since it only produced raw materials and did not produce preparations, it did not compete with downstream enterprises at all. Therefore, its actual purpose of refusing to deal was not to eliminate competition. It is debatable to identify such behaviour as abuse of market dominance.

At present, there is no specific explanation for refusal to deal under the framework of China's antitrust law. Its constitutional elements can only refer to the general constitutional elements of abuse of market dominance, namely: (1) the operator has market dominant position; (2) the operator has abused its dominant position; (3) such abusive behaviour is without justifiable reason; (4) such abusive behaviour would eliminate or restrict market. Similarly, based on the prevailing antitrust theory, the interpretation of justifiable reason refers to the consideration of the pursuit of legitimate commercial interests. For example, due to restrictions on supply capacity or purchasing power, it is difficult for undertakings to deal with counterparties in the transaction, and so forth[10].

[7] Knowledge of Antitrust Law of the People's Republic of China, State Council Anti-Monopoly Commission, People's Publishing House in 2012, page 127.

[8] Notice of the Penalty Decision of Chongqing Qingyang Pharmaceutical Co., Ltd. ("Chongqing Qingyang")'s Abuse of Market Dominance, see the website of State Administration For Industry and Commerce: http://www.saic.gov.cn/fldyfbzdjz/jzzfgg/201703/t20170309_232277.html

[9] Notice of the Penalty Decision of Chongqing Southwest No.2 Pharmaceutical Factory Co., Ltd.'s Refusal to Deal, see the website of State Administration For Industry and Commerce: http://www.saic.gov.cn/fldyfbzdjz/jzzfgg/201703/t20170309_232291.html

[10] Knowledge of Antitrust Law of the People's Republic of China, State Council Anti-Monopoly Commission, People's Publishing House 2012, page 128.

It is a welcome development that the Guidelines for the first time recognize the competition impact on the downstream markets as a justified consideration. The authors further suggest that operators are involved in the competition in both upstream and downstream be clearly included as one of the key elements of refusal to deal by undertakings in the relevant implementation rules of Anti-Monopoly Law.

Conclusion

In view of the peculiar or more common price monopoly and price violation behaviours found in the production and circulation market of APIs discovered in law enforcement, the Guidelines strengthen the price supervision mechanism of the API market and clearly regulates the market pricing behaviour of shortage medicines and APIs, as well as provides a practical guidance for the pricing behaviour of relevant pharmaceutical companies. The Guidelines explain in great detail about what cannot be done by way of enumeration, which provides the undertakings with a standard for self-assessment and puts more stringent compliance requirements on the operators. In addition to price monopoly-related behaviour, the Guidelines also provides for other behaviours that disrupt market prices, such as prohibiting operators from “fabricating and disseminating information about price hikes”, “hoarding drugs prone to shortages and APIs with tight market supply and fluctuating prices in a large quantity”, “forcing up prices by other means”, “using false or misleading prices to deceive consumers”, “not implementing government fixed prices”, “violating the clearly marking prices”, and so on. The promulgation of the Guidelines will help to promote the regulation of market pricing behaviour of drugs prone to shortages and APIs, establish a fair market environment for the purchase and sale of medicines and protect the interests of consumers. Operators shall conduct internal inspection on their pricing behaviour and related business models to prevent potential legal risks by reference to the Guidelines.

In addition, principle of “Prohibition plus Exemption” and market definition, factors to identify refusal to deal and unfair pricing, as well as the concept of "substantial control" reflected in the Guidelines will all pose new challenges to the antitrust compliance of pharmaceutical enterprises. In practice, the determination of monopolistic behaviour in other industries may also refer to these provisions in the Guidelines.