
China Competition Authority Initiates Drug Pricing Investigation

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*On May 22, 2015, the National Development and Reform Commission (the NDRC) of China promulgated a notice (the **Pricing Investigation Notice**) announcing that it would carry out a nationwide drug pricing investigation on pharmaceutical companies and related institutions. The investigation was formally launched on June 1, 2016 and will last until October 31, 2016, with the aim to regulate pricing-related monopoly or unfair competition activities in drug and bulk medicine markets in China.*

Background

As one of the three government authorities enforcing the Anti-Monopoly Law of China, the NDRC is responsible for regulating pricing-related monopoly activities. As early as April 6, 2016, Premier Li Keqiang delivered a speech at an executive meeting of the State Council and mentioned that Chinese medical reform had entered a critical stage and that reducing drug prices should be seen as a key point of this reform. The premier emphasized accelerating the establishment of a drug price tracking mechanism for making drug prices transparent. As one of the implementation efforts, in January 2016, the NDRC imposed fines in the total amount of around RMB 4 million (approximately USD \$600,000) on five Chinese domestic pharmaceutical manufacturers and sales companies for entering into and enforcing monopoly agreements fixing prices and allocation of markets for allopurinol, a drug used in treating gout and kidney disease. Also, from early May 2016, the NDRC has engaged in interviews and discussions with foreign-invested and domestic pharmaceutical companies to collect relevant information on whether these companies had violated laws and regulations regarding pricing competition.

Main Focus of the Investigation

According to the Pricing Investigation Notice, the targets of the investigation include manufacturers of bulk medicine and drugs, medical institutions, disease prevention and control centers, blood banks, procurement platforms and industry associations. The focus of this investigation will be on abnormal

fluctuations of pricing for bulk medicine and various types of drugs. The NDRC will focus on seven types of illegal conduct, including:

- (i) execution and enforcement of monopoly agreements by and among drug manufacturers, operators and/or industry associations;
- (ii) abuse of dominant market position by drug manufacturers and distributors to raise drug prices or bulk medicine prices;
- (iii) price fraud and misleading presentation of prices by drug retailers;
- (iv) violation by hospital institutions of zero-profit policies and markup percentages policies for certain drugs whose prices are set by the government;
- (v) violation of the ceiling prices set by the government for certain drugs;
- (vi) violation of policies regarding clear price tags and price disclosure; and
- (vii) other illegal conduct prohibited by the Price Law and Anti-Monopoly Law of China.

It is reported that frequently the prices of imported drugs are unreasonably higher than the prices of domestic drugs. There is public suspicion (which the authorities probably share) that those higher prices are due to pricing monopoly or other pricing and marketing strategies that may violate fair competition rules. It is anticipated that the NDRC might conduct stricter supervision over imported drugs to maintain the price of imported drugs at reasonable levels.

Information Required to be Disclosed to the NDRC for the Investigation

Based on our experience, we expect the NDRC will require multinational and domestic pharmaceutical companies to submit various types of materials and information to assist its investigation, such as:

- (i) basic information regarding the company, including but not limited to registration information, the company's affiliates, the company's organization, shareholder relationships, and information regarding substantial shareholders, legal representative as well as ultimate controller (if any);
- (ii) amount of sales in the global market and in the Chinese market from 2013 to 2015;
- (iii) amount of sales and sales volume in the global market and in the Chinese market for the company's top 10 products (the **Bestselling Products**) in the global market from 2013 to 2015; and the same data for the top 10 products in the Chinese market;
- (iv) main competitors of the company, and their market share in relevant markets;
- (v) information regarding price fluctuations for the Bestselling Products in the Chinese market from 2013 to 2015;
- (vi) detailed description of the company's sales model, business policy and sales target in China, including a list of distributors; and

- (vii) information regarding distribution agreements, distribution models, price comparison of Bestselling Products in Chinese market and other markets, patent status in China and other information the company wants to clarify or explain.

We anticipate that more pharmaceutical companies may be investigated and requested to prepare responses to the NDRC's inquiries during the investigation. We suggest that multinational pharmaceutical companies carefully review their existing operations, marketing and distribution strategies and pricing policies in China with the help of their legal departments and external counsel to mitigate any risks, and try to obtain details and accurate records of their drug supply chains and distribution pricing. In the meantime, we will closely monitor this investigation and provide follow-up advice as it proceeds.

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If you have any questions about the content of this Alert, please contact the Pillsbury attorney with whom you regularly work, or the authors below.

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