



国家市场监督管理总局

State Administration for Market Regulation

Update on the Anti-monopoly Enforcement in China's Pharmaceutical Sector

March 31, 2022



I. Strengthening the regulation and enforcement, and cracking down on monopoly behaviors

- **The market concentration ratios of some APIs and preparations are high**
- **High entry barriers of markets in the pharmaceutical sector**
- **Some business operators disregard the law and make profits through monopoly behaviors**

- **Monopoly behaviors occur from time to time in the pharmaceutical sector**
- **Unreasonable increase in drug prices**
- **Drug supply shortage**



I. Strengthening the regulation and enforcement, and cracking down on monopoly behaviors

- Since the establishment, the SAMR has investigated and handled a total of 10 monopoly cases in the pharmaceutical sector, with a total penalty amount of over 1.3 billion yuan
- In 2021, the SAMR investigated and handled 6 monopoly cases in the pharmaceutical sector, with a total penalty amount of 950million yuan
 - 3cases regarding monopoly agreement and3cases regarding abuse of dominant market position
 - imposed a fine of 100.7 million yuan on Simcere Pharmaceutical Group for abusing its dominant market position
 - imposed a fine of 764 million yuan on Yangtze River Pharmaceutical Group for reaching and implementing vertical monopoly agreements
 - Guided the Tianjin, Jiangsu,Henan and Shanghai's market regulation authorities to legally impose administrative penalties on production and distribution enterprises of **Fluocinonide** and **Camphor** APIs for reaching and implementing horizontal monopoly agreements, and on distribution enterprises of **Phenol** and **Pralidoxime Chloride** APIs for abusing their dominant market position.



I. Strengthening the regulation and enforcement, and cracking down on monopoly behaviors

➤ The case of Sincere Pharmaceutical Group abusing its dominant market position

- Batroxobin is a fibrin pro-coagulant protease contained in the venom of the Bothrops atrox. Batroxobin API is mainly used for the production of Batroxobin injection. Batroxobin injection is mainly used for the treatment of acute cerebral infarction, improving ischemic symptoms caused by various occlusive vascular diseases and improving peripheral and microcirculatory disorders.
- Globally, there is only one manufacturer of Batroxobin API - DSM, Switzerland. In April 2019, Sincere Pharmaceutical, through its subsidiary, entered into a Cooperation and Supply Agreement with DSM, which provides for the exclusive supply of Batroxobin API in China, and Sincere Pharmaceutical obtained the entire supply of Batroxobin API in China.
- Sincere Pharmaceutical refused to supply APIs to downstream preparations enterprises without justifiable reasons, which violates Article 17 of the Anti-Monopoly Law and constitutes an abuse of dominant market position due to refusing to deal with the counterparties without justifiable reasons.
- In January 2021, the SAMR issued an administrative penalty decision against Sincere Pharmaceutical, requiring it to stop the illegal act and imposing a fine of 2% of its sales for the year 2019, totaling RMB 100.7 million.



I. Strengthening the regulation and enforcement, and cracking down on monopoly behaviors

➤ The case of Yangtze River Pharmaceutical Group reaching and implementing vertical monopoly agreements

- In August 2019, the SAMR received a report that Yangtze River Pharmaceutical (Group) Co., Ltd. had limited the minimum sales price of drugs such as LanQin Oral Solution and Bailiemian Capsules by sending price adjustment letters and other means, which was suspected of reaching and implementing monopoly agreements. The SAMR attached great importance to this case, and after verifying that the report was basically true, a formal investigation was opened in November 2019.
- According to the investigation, Yangtze River Pharmaceutical reached agreements with downstream enterprises such as drug wholesalers and retail pharmacies to fix the resale prices of drugs and limit the minimum resale prices of drugs nationwide by **signing cooperation agreements, sending price adjustment letters and verbal notifications** between 2015 and 2019.
- At the same time, Yangtze River Pharmaceutical ensured the implementation of those agreements by **formulating implementation rules, strengthening assessment and supervision, punishing distributors who sold drugs at low prices, and commissioning intermediaries to monitor the prices of drugs sold online.**
- Yangtze River Pharmaceutical violated Article 14 of the Anti-Monopoly Law, which prohibits business operators from agreeing with counterparties to fix the prices of goods for resale to third parties. In 2021, the SAMR imposed a fine of 3% of its sales for the year 2018, totaling 764 million yuan, on Yangtze River Pharmaceutical.



II. Delineating the red line and improving the system and rules

➤ **Anti-monopoly Guidelines on the API Sector**

- Adopted by the plenary session of the Anti-Monopoly Commission under the State Council and released for implementation on November 15.
- Establishing the regulatory rules in the API sector which are in line with the current anti-monopoly practice requirements, based on the current development status, market competition and business behavior characteristics of the field of APIs in China, as well as the in-depth summary of the anti-monopoly enforcement experience in the field of APIs since the implementation of the Anti-monopoly Law.
- With 6 chapters and 29 articles closely linked to the Anti-monopoly Law, which address the prominent monopoly problems in the field of APIs, clarify the basic principles, ideas and methods of anti-monopoly regulation, and refine the criteria for determining monopoly behaviors.
- The Guidelines mainly provide for five aspects, namely **General Provisions, Monopoly Agreements, Abuse of Dominant Market Position, Concentration of Business Operators, and Abuse of Administrative Power to Exclude and Restrict Competition.**

General Provisions	<ul style="list-style-type: none"> • Clarifying the objectives and rationale of the Guidelines and defining the relevant underlying concepts • Regulatory Principles: Protecting fair market competition, legally conducting scientific and efficient regulation, focusing on protecting consumers’ interests, and continuously strengthening legal deterrence • Explaining the idea of how to define relevant product markets and relevant geographical markets
Monopoly Agreements	<ul style="list-style-type: none"> • Analyzing the basic ideas of anti-monopoly enforcement on monopoly agreements, clarifying the forms of monopoly agreements, and providing specific explanations for other collusions • Listing the common ways in which business operators reach or implement monopoly agreements as well as enforcement considerations • Clarifying that the implementation of territorial restrictions or customer restrictions by the API business operators on their counterparties may constitute vertical monopoly agreement behaviors • Refining the analysis ideas for business operators conducting collusion • Specifying the forms of hub-and-spoke arrangements • Exemption and leniency policies • Regulating the behaviors of industrial associations
Abuse of dominant market position	<ul style="list-style-type: none"> • Clarifying the basic ideas of the anti-monopoly enforcement on abuse of dominant market position, and clarifying the factors for determination whether or presumption that a business operator has a dominant market position • Clarifying the calculation method for market share • Refining the common manifestations of abuse of dominant market position • Addressing price increases by monopoly, control of sales and supply cut-offs, requirements to buy preparations back and other common monopoly behaviors in the field of APIs • Ideas and considerations for determination of joint abuse of dominant market position
Concentration of Business Operators	<ul style="list-style-type: none"> • it is clearly stipulated that, for some API varieties with relatively small market size, if the annual turnover of the business operators in the market do not reach the notification threshold, but there is evidence showing that the concentration conducted by the business operators has or may have the effect of excluding or restricting competition, the anti-monopoly enforcement agency of the State Council shall conduct an investigation in accordance with the law • In the event of the above-mentioned concentration of business operators, the business operators in the field of APIs are encouraged to negotiate with the anti-monopoly enforcement agency as early as possible before conducting the concentration
Abuse of Administrative power to Exclude and Restrict Competition	<ul style="list-style-type: none"> • Refining the manifestations in the API sector of the abuse of administrative power to exclude and restrict competition, such as restricting transaction, impeding the free circulation of commodities, restricting bidding activities, restricting investment in or establishment of branches, forcing business operators to engage in monopoly behaviors, formulating provisions excluding or restricting competition • Specifying that the fair competition review shall be conducted for the regulations, regulatory documents as well as other policies and measures related to the economic activities of market players in the field of APIs



II. Delineating the red line and improving the system and rules

➤ Draft amendments to the Anti-monopoly Law

- Hub-and-spoke arrangements

Article 18 The business operator shall not organize other operators to reach monopoly agreements or provide substantial assistance to other business operators to reach monopoly agreements.

- The "safe harbor" rule

Article 19 If the business operators can prove that their market share in the relevant market is lower than the threshold set by the anti-monopoly enforcement agency of the State Council, the provisions of Article 16, Article 17, Article 18 of this Law shall not apply, unless there is evidence that the business operators have reached agreements to exclude or restrict competition.



III. Strengthening collaborative advocacy to promote the benign development of the industry

- Focusing on communication and coordination with authorities of health, drug regulation, health insurance, taxation and other authorities to enhance synergy and cooperation in terms of clue acquisition, information sharing, data query, result notification and effect transmission
- Focusing on supervising pharmaceutical companies to carry out self-examination and rectification of their own business practices, timely eliminating and mitigating the consequences of damage caused by violations of the law, and effectively restoring the competition order of the market
- Through strict enforcement, constituting an effective deterrent, to let the whole industry clearly understand the serious consequences of monopoly violations, as well as doing a good job in publicizing and explaining typical monopoly cases in the pharmaceutical field and related legal provisions and giving full play to the warning and guiding effect of the cases, to further improve pharmaceutical enterprises' compliance awareness of the competition law



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Thank you!

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