LIFE SCIENCE IN THE CROSSHAIRS OF CHINA'S PUBLIC ANTITRUST ENFORCEMENT

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I. INTRODUCTION

2018 ended up being a relatively silent year in terms of China's public antitrust enforcement. Due to the internal institutional reform and consolidation of the three antitrust authorities, as well as the external intense relationship with the U.S., China's public antitrust enforcement enters into a transitional period. Nonetheless, life science as a sector closely pertinent to people's livelihood continues to be the enforcement priority of the new Chinese antitrust authority – the State Administration for Market Regulation ("SAMR"). In 2018, SAMR investigated and penalized various anti-competitive practices in the life science sector, including monopoly agreements, abuse of (collective) dominance, gun-jumping in merger transactions, and administrative monopoly. Indeed, during the past several years prior to 2018, China has already seen an increased antitrust enforcement targeted at the life science sector. In terms of legislation, the former antitrust authority, the National Development and Reform Commission ("NDRC") issued the *Price Behavior Guidelines on Operators of Active Pharmaceutical Ingredients and Drugs Prone to Shortages* ("API Guidelines"),[2] which is the first industry-specific pricing guideline since the implementation of China's *Anti-Monopoly Law* ("AML") in 2008. With Chinese antitrust authorities ramping up efforts on enforcement in the life science sector, more antitrust cases are expected to occur in the near future.

II. CHINA'S PUBLIC ANTITRUST ENFORCEMENT ENTERS INTO A TRANSITIONAL PERIOD

In March 2018, the State Council issued the *Plan on Deepening Reform of Party and State Institutions*, which established SAMR as a direct agency under the State Council for comprehensive market supervision. The institutional reform has brought significant changes to China's antitrust enforcement system. Also, the Sino-U.S. trade war has influenced the enforcement focus of the authorities.

A. SAMR is Now the Sole Antitrust Enforcement Authority at the Central Level

The Chinese government consolidated three antitrust enforcers, the NDRC which had regulated price-related conduct, the State Administration for Industry and Commerce ("SAIC") which had regulated non-price-related conduct, and the Ministry of Commerce which had regulated merger control ("MOFCOM"). After China's new antitrust regulator finalizes its agency integration, SAMR will have the power to investigate any monopolistic practice regardless of its type. However, this new authority has not completed adaption to the new situation in terms of substantive and procedural rules, as well as the staffing situation.

2 Only the Chinese version is available at http://www.ndrc.gov.cn/gzdt/201711/W020171123358187048047.pdf.

B. The Delegation of Enforcement Power from the Central Level to the Provincial Level

One of the adverse impacts of the institutional reform is that the authorized number of antitrust officials in SAMR has decreased from 61 to 41,[3] an approximately 30 percent decrease which has rendered the authority less capable of handling a large number of antitrust cases. As a cure, the *Notice on Antitrust Enforcement Authorization*[4] issued by SAMR in January 2019 authorizes provincial authorities to take charge of antitrust cases in its administrative jurisdiction on a regular basis. After unified authorization, general and prior authorization from a superior agency is not required by provincial authorities. With thousands of officials at the provincial level on the frontlines to take on monopolistic cases and issues, the delegation of authority is expected to generate much more enforcement cases than before at the provincial level.

C. SAMR's Lower Political Status Might Impede Its Progress Towards a Tough Work Style

SAMR is built on the basis of SAIC, which is a so-called direct agency under the State Council, ranking lower than MOFCOM and NDRC (both are classified as the constituent departments of the State Council). Before the consolidation, the NDRC generally took the lead in antitrust enforcement, including its tough enforcement against Qualcomm. As the SAMR is built upon SAIC, it therefore has an overall lower political status than before and its enforcement style might be more alike to the previous SAIC.

D. SAMR has Reshuffled Officials to Handle Antitrust Cases

SAMR has integrated and reshuffled the officials coming from the three previous antitrust enforcement authorities to conduct antitrust enforcement. At the highest level of SAMR's leadership, the general director Mr. Wu Zhenguo came from the previous merger control authority MOFCOM, and the other four vice general directors come from MOFCOM, NDRC, SAIC, and the General Administration of Quality Supervision Inspection and Quarantine ("GAQSIQ"), respectively. At the level of daily enforcement, SAMR has allocated officials coming from the previous NDRC, SAIC, and MOFCOM into different enforcement divisions under the anti-monopoly bureau. The integration of antitrust officials will sharpen SAMR's antitrust enforcement capabilities and terminate the past chaos status of conflicting enforcement styles. In addition, SAMR's efficiency of antitrust enforcement has also been enhanced after the institutional reform. According to a study of an antitrust intelligence-gathering third party, there has been an outstanding improvement in the duration of SAMR's review of simple procedure merger cases, with the average duration reduced from 17 days in 2Q2018 to 15.57 days in 4Q2018.

E. SAMR has Declared to Adopt a Competitive Neutrality Doctrine and will Continue focusing on the Life Science Sector

In the past decade, there has been a long-held belief in the international business community that China's antitrust authorities apply the AML in a discriminatory way against multinational companies ("MNCs"), with the amount of enforcement higher and the gravity of penalty heavier than that of its domestic companies. In November 2018, the minister of SAMR announced that China will apply the competitive neutrality doctrine to create and maintain a level playing field among domestic companies, state-owned companies, and private companies,[5] which reflects SAMR's determination to provide a fairer competition environment for all kinds of companies, including the MNCs. As demonstrated from the four cases publicly investigated and penalized by SAMR, SAMR enhanced its enforcement against domestic company and will likely take a more prudent attitude in handling cases involving MNCs. The four cases addressed by SAMR are the *Chlorpheniramine Maleate API* case (2018),[6] the *Glacial Acetic Acid* case (2018),[7] the *Tally* case (2018),[8] and the *Tugboat* case (2018),[9] all of them are against domestic companies.

3 Currently, SAMR has around 50 antitrust officials, exceeding the authorized number.

4 http://samr.saic.gov.cn/xw/yw/wjfb/201901/t20190103_279720.html.

5 http://www.chinanews.com/wap/detail/zw/gn/2018/11-06/8669434.shtml.

6 http://samr.saic.gov.cn/gg/201901/t20190118_280436.html.

7 http://samr.saic.gov.cn/gg/201812/t20181224_278969.html.

8 http://samr.saic.gov.cn/gg/201807/t20180720_275163.html.

9 http://samr.saic.gov.cn/gg/201806/t20180625_274741.html.

As to the industries facing enforcement, the SAMR has always paid enormous attention to those industries closely relevant to the people's livelihood, with the life science industry being a top priority in recent years. According to the speech given by the minister of SAMR Mr. Zhang Mao in the first national market supervision annual meeting, the life science industry will continue to be a focus of China's antitrust regulation in 2019.[10]

III. HIGH-PROFILE ANTITRUST CASES IN THE LIFE SCIENCE SECTOR

A. Tacit Collusion has Fallen under the Radar of the Chinese Authorities

In the last few years, China's antitrust authorities have investigated a cluster of horizontal antitrust cases relating to API and finished drug products. One major feature among these cases demonstrates that the companies were penalized for reaching collusion without any written agreement. In the *Allopurinol* case (2015),[11] NDRC penalized five manufacturers of both allopurinol APIs and allopurinol drugs. Allopurinol is used for the treatment of hyperuricemia and gout. The manufacturers were fined for reaching horizontal agreements on price-fixing and allocation of sales market. In terms of price collusion, the NDRC found that the allopurinol manufacturers organized several meetings to discuss the price for sale and bidding, and to allocate the market to each manufacturer. In the *Estazolam* case (2016),[12] the NDRC issued another penalty decision on price-fixing of Estazolam API and tablets, marking the first antitrust case on concerted practices in China. Estazolam is a type of psychotropic drugs used to treat patient with anxieties by its sedative, hypnotic, and anti-anxiety effects. The investigation showed that the three Estazolam manufacturers had reached horizontal agreements to jointly boycott other Estazolam tablet manufacturers while ceasing to supply API to the downstream tablet market in order to increase prices of the tablets manufactured by themselves. The Changzhou company was a follower of the other two companies on joint boycott and price-fixing. In terms of collusion, the NDRC found that the Changzhou company had reached a meeting of minds with the other two companies for the reasons that (1) it had participated in the meeting; and (2) it had neither clearly opposed the cartel proposal nor reported the meeting to China's antitrust authorities. It was also found by the NDRC that the Changzhou company, jointly with the other companies, had simultaneously increased the price to the same level. This case demonstrates that to apply the rule of concerted practice, the NDRC will consider information exchange and parallel conducts. After the institutional reshuffle, the SAMR rendered the case involving the issue of horizontal agreement in the *Glacial Acetic Acid* case (2018). Glacial acetic acid is for the treatment of renal failure and uremia. The agreement reached in this case was likely to be a hub and spoke cartel. At first, the Jiangxi company in the downstream market communicated with three glacial acetic acid manufacturers to raise prices separately by telephone. Then, the Jiangxi company held several meetings with two of the three glacial acetic acid manufacturers. The SAMR concluded that the three manufacturers had exchanged price information with each other and had concluded and implemented the price increase agreement.

B. Monopolistic Practices in Indirect Vertical Relationships are also Forbidden

Two notable penalty decisions rendered by China's enforcement authorities on vertical agreement cases in the life science industry in the last few years are the *Medtronic* case (2016) addressed by the NDRC and the *Smith & Nephew* case (2017, addressed by the Shanghai Price Bureau.

The highlight of these two cases is that both relate to manufacturers setting the resale prices at all distribution levels. According to Article 14 of the AML, a vertical agreement can only be concluded by an undertaking with its primary distributor. Yet in these two cases, the enforcement authorities, when determining the illegality of the manufactures' practices, took into consideration the resale price maintenance ("RPM") imposed on secondary distributors. For example, in the *Smith & Nephew* case, Shanghai Price Bureau analyzed the RPM on secondary distributor as "strengthened the implementation effect of the monopolistic agreement," and that such practice "precluded and restricted the price competition among secondary distributors."

Vertical agreements are generally regarded as having less of an anticompetitive effect than horizontal agreements or abuse of dominant position. At present, only retail price fixing and minimum retail price setting are expressly prohibited by Chinese antitrust law, yet with the reform of the antitrust authorities, new regulations on vertical agreement as well as other monopolistic practices are in the pipeline and likely to provide guidance on the determination of other vertical agreement.

10 http://samr.saic.gov.cn/xw/yw/zj/201812/t20181227_279356.html.

11 http://www.ndrc.gov.cn/xwzx/xwfb/201601/t20160128_772977.html.

12 http://www.ndrc.gov.cn/xwzx/xwfb/201607/t20160728_812719.html.

C. Chinese Authorities have no Hesitation in Condemning Controversial Abusive Practices

The philosophy of abuse regulation has been wandering between the protection of private rights and the preservation of social equality ever since the introduction of antitrust law. Differing from some jurisdictions, especially the U.S., Chinese authorities are vigilant against big companies damaging market competition, and will often find practices which might not be forbidden in other jurisdictions to be illegal as an abuse of dominance. In the recent legislation and enforcement cases, the issues of unfairly high price and collective dominance, which are highly controversial in other jurisdictions, were further examined by the Chinese enforcement authorities.

1. Unfair High Pricing

Unfair high pricing, or excessive pricing, is often addressed in Chinese antitrust laws and enforcement. The previous NDRC published the *Provisions on Anti-Price Monopoly*[13] in 2010, in which it defined unfairly high price by comparison with the price of other sellers and the normal extent of price increases and production costs. In the next year, the NDRC first discussed the issue in the life science industry in the *Compound Reserpine API* case (2011).[14] In the public notice, it described the illegal practice as "an abrupt price increase from less than 200 RMB per kg to 300-1350 RMB per kg," but failed to ascertain the analysis of its illegality. Under the API Guidelines, other elements are considered in determining unfairly high price, including the previous price in the market and the price of other geographic markets. In the *Chlorpheniramine Maleate API* case (2018), the SAMR compared the product price with its cost (which is reflected in the purchased price and the imported price). Without referring to the other elements, the SAMR found that the product price is unfairly high as it was 3-4 times its cost.

2. Collective Dominance

Although the term "collective dominance" is not clearly construed in Chinese antitrust laws, Article 19 of the AML, which hints at the concept, is used to interpret it. Article 19 provides that if two undertakings collectively have a market share of more than 2/3, or three of more than 3/4, and none of them has a market share of less than 1/10, then these undertakings are presumed to have a dominant market position. China's antitrust authorities have applied Article 19 on collective dominance in two cases in the life science industry. The NDRC first applied this rule in the *Isoniazide API* case (2017), in which two undertakings were determined to have collective dominance based on its combined and individual market shares exceeding 2/3 and 1/10 without further explanation. In the second case on *Chlorpheniramine Maleate API* (2018), the two undertakings were determined by the SAMR to have collective dominance. In addition to the market share assumption, the sales and purchase relationship, the strategic cooperation agreement, and the coordinated practices between them were considered by the SAMR.

D. Chinese Authorities are Vigilant in Merger Filings Concerning the Life Science Industry

The life science industry has experienced a huge wave of mergers and acquisitions activity in the past several years in China. The reasons for this trend are numerous. First, M&A has traditionally been an important source of innovation and portfolio realignment for life science companies. Second, with the Chinese laws and regulations on the life science industry becoming increasingly stringent, companies, especially small start-up companies, turn to M&A to survive. Also, the healthcare reform in China has removed pricing control of most drugs,[15] and has thus opened up the life science market and attracted large capital inflows. Given the circumstance, the SAMR has adopted a vigilant attitude towards merger review of life science companies. Before January 23, 2019, among the 39 conditionally cleared transactions, six of them were related to life science companies: The acquisition of Wyeth by Pfizer (2009), the acquisition of Alcon by Novartis (2010), the acquisition of Gambro by Baxter (2013), the acquisition of Life Technology by Thermo Fisher Scientific (2013), the acquisition of St Jude by Abbott (2016), and the merger of Becton Dickinson and Bard (2017). Once a merger transaction is deemed anti-competitive, the filing undertakings can propose remedies to offset the anti-competitive effect. In the six conditionally cleared transactions, both structural and behavioral remedies were applied. Structural remedies usually take the form of business divestures, i.e. the divesture of Baxter's global continual renal replacement therapy business in the *Baxter/Gambro* case. Behavioral remedies varied in different cases, such as termination of sales and distribution agreement in the *Novartis/Alcon* case, and price reduction in the *Thermo Fisher/Life Technology* case. In addition, the undertakings were fined for failing to file before the execution of the merger transaction in five transactions, with the fines ranging from 150,000 to 400,000 RMB. These observations from the above cases

13 http://www.gov.cn/flfg/2011-01/04/content_1777969.htm.

14 http://jjs.ndrc.gov.cn/fjgld/201203/t20120306_465386.html.

15 In May 2015, NDRC issued *Notice on Issuing the Opinions on Pushing Forward the Pharmaceutical Pricing Reform*, which removed the government pricing control for all drugs except for narcotics and type I psychotropic drugs. http://www.ndrc.gov.cn/zcfb/zcfbtz/201505/t20150505_690664.html.

demonstrate that the Chinese authorities are determined to tackle life science antitrust problems. With the fast development of the investigation techniques and enforcement abilities of the authorities, companies conducting covert or indirect monopolistic practices are now difficult to escape from investigation. Practices which did not attract much attention, such as covert exchange of competitive information or maintaining retail price for indirect dealers, are also highly risky. What's worth special attention is that for practices which may be legal in other jurisdictions might be defined as illegal abuse of dominance in China. With Chinese antitrust authorities making great efforts in the enforcement of all types of monopolistic practices, the supervision on life science industry is becoming increasingly stringent.

IV. TREND OF CHINA'S ANTITRUST ENFORCEMENT IN THE LIFE SCIENCE SECTOR FROM THE PERSPECTIVE OF A PRACTITIONER

With the latest legislation and enforcement developments, China's antitrust enforcement in the life science sector has become increasing complex and difficult to handle. Based on the foregoing study on the antitrust practice in the life science sector, several conspicuous trends may be worth noting:

A. Sectors Pertinent to People's Livelihood, Primarily the Life Science Sector, is the Priority of China's Antitrust Enforcement

The life science sector is closely connected with people's daily life and the Chinese government has attached great importance to it. Since 2018, the Chinese Premier Mr. Li Keqiang has strongly urged the price deduction of expensive imported drugs.[16] As a consequence, the multinational pharmaceutical giant Pfizer has volunteered to decrease the prices of all 20 of its imported drugs.[17] Under this regime, life science has become an increasingly important enforcement focus of China's antitrust enforcement authorities. In the *Glacial Acetic Acid* case (2018), the SAMR fined the API companies up to 12.83 million RMB for price fixing, which is the biggest fine in API cases during the last ten years. Enforcement in the life science sector can always raise a wave of discussion and attract large public and media attention, and the massive coverage of heavy penalties can effectively deter future monopolistic practices. It is expected that more antitrust enforcement in the life science sector will take place in 2019.

B. China's Antitrust Authorities May Tighten Its Scrutiny on Pay-for-Delay Agreements

In recent years, the U.S. and EU have penalized certain pay-for-delay agreements. So far, China has seen no enforcement or litigation concerning pay-for-delay agreements. This may be because China, as one of the biggest producers of generic drugs, fundamentally refuses to enter into any pay-for-delay agreements. Also, it might not be practical if the originator life science company needed to negotiate the terms and make a payment with every generic drug manufacturer.

In December 2018, China's National Health Commission issued the *Notice on the Work Plan of Accelerating the Supply Guarantee and Utility Policy of Generic Drugs*,[18] which strengthened that antitrust enforcement efforts should be made in the field of generic drugs. China's antitrust authorities therefore might take a more stringent attitude against pay-for-delay agreements when such matters occur, especially if they lead to excessively high drug prices.

C. The Institutional Reform May Break Out on Generic Drugs Antitrust Enforcement

Worldwide, a number of antitrust matters arise out of generic drugs, including product hopping, forced switching, the aforementioned pay-for-delay agreement, etc. Such practices have been penalized in the U.S. and EU, but the prohibition on them is not expressly provided in the AML. These matters have stirred heated discussions, but no enforcement has been made in China. As China has always tried to regulate the high price of drugs, especially imported drugs, to an affordable level, China's antitrust authorities are likely to take opposing attitudes towards any drug-related practice with any anti-competitive effect. While the institutional reform erases the enforcement limitation of enforcement authorities, SAMR might pay much more attention to the anti-competitive effects of a practice than before, and new types of monopolistic practices might be defined.

16 http://www.gov.cn/guowuyuan/2018-04/13/content_5282287.htm.

17 http://hbyphcjgw.hbwsjs.gov.cn/new/show4452.html.

18 http://www.nhfpc.gov.cn/tigs/s7848/201812/831103872660468 6a9e91832c81584b4.shtml.

D. More Follow-on Damage Actions might be Carried Out in 2019

Follow-on actions are private enforcement where the victims of anticompetitive behavior rely on the penalty decisions issued by antitrust authorities to bring actions for damages against the investigated companies. The follow-on actions have more possibility to win a case than other antitrust civil actions brought without penalty decisions, for the plaintiffs' burden of proof will be greatly reduced by relying on the fact and legal analysis of the penalty decisions. Due to the lack of discovery procedure of evidence, plaintiffs in an antitrust lawsuit bear an enormous burden of proof and as a result it is extremely difficult for them to win in any type of antitrust lawsuit. In China, the civil proceeding legislation practically stifles the development of private antitrust enforcement. Although the Supreme People's Court of China ("SPC") has released a judicial interpretation on antitrust civil lawsuits which reduced plaintiffs' burden of proof to a certain extent, the heavy burden of proving the existence of antitrust conduct and its anti-competitive effect still lies upon antitrust plaintiffs. It is reported that the SPC has been working on drafting a legal interpretation of the AML to reasonably reduce the plaintiff's burden of proof. Under such circumstance, a large amount of follow-on damage actions, including public interest litigation, are presumed to occur in 2019.

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