

The Application of the Anti-Monopoly Law to the Pharmaceutical Sector in China

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ABSTRACT

This article explores the application of China's Anti-Monopoly Law (“AML”) in force since 2008, to the Chinese pharmaceutical sector. Competition law issues affecting this industry are technical, complex and varied, and have been a priority in antitrust enforcement to date. While the general assessment of these problems by China's competition authorities greatly mirrors international practice, there are some unique traits that aim to deal with the specific local context. In this article, the authors consider and assess these peculiarities. It is organized as follows: Part 2 covers the basics of Chinese antitrust enforcement, including the authorities, governing rules, market definition and the interface of competition policy and industrial policy in the pharmaceutical sector. Part 3 discusses merger control issues in the pharmaceutical industry. Part 4 assesses anti-competitive agreements; Part 5 abuse of dominance and Part 6 administrative monopoly. Part 7 offers a conclusion.

1. INTRODUCTION

China's pharmaceutical industry continues to be one of the largest and most significant markets globally. In 2015, overall sales of drugs in China reached USD 108 billion, making it the second largest market in the world. It is expected that the size of the pharmaceutical market in China will grow to USD 167 billion by 2020, at a steady annual growth rate of 9.1 percent. Overall public and private healthcare spend is expected to increase significantly from USD 640 billion in 2015 to USD 1.1 trillion in 2020.¹ Given the importance and continued growth of its pharmaceutical market, China offers opportunities for both domestic and foreign players in the industry in terms of organic and inorganic growth through mergers and acquisitions (“M&A”) activity, strategic alliances and collaboration arrangements. However, in tandem with the rapid development of the pharmaceutical industry, there has also been a notable increase in the degree of scrutiny of business practices and transactions in the pharmaceutical sector by China's competition authorities.²

China's Anti-Monopoly Law (“AML”) came into effect in August 2008. In nine years,

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¹ US DEPARTMENT OF COMMERCE, INTERNATIONAL TRADE ADMINISTRATION, 2016 TOP MARKETS REPORT PHARMACEUTICALS COUNTRY CASE STUDY: CHINA, at 1.

² For the purpose of this article, “pharmaceutical product” may be understood to include medical device and biotechnology.

China has quickly established itself as one of the world's major competition regimes. In the context of merger control, as of 1 October 2016, out of twenty-seven transactions conditionally approved by the Ministry of Commerce ("MOFCOM"), four concerned the pharmaceutical sector: the acquisition of Wyeth by Pfizer (the "*Pfizer/Wyeth*" case),³ the acquisition of Alcon by Novartis (the "*Novartis/Alcon*" case),⁴ the acquisition of Gambro by Baxter (the "*Baxter/Gambro*" case)⁵ and the acquisition of Life Technology by Thermo Fisher (the "*Thermo Fisher/Life Technology*" case).⁶ In the context of antitrust enforcement, the pharmaceutical sector remains an antitrust enforcement target for the National Development and Reform Commission ("NDRC") and the State Administration for Industry and Commerce ("SAIC"). Notable examples include the investigations against Weifang Shuntong and Weifang Huaxin for the exclusive supply of active pharmaceutical ingredients ("APIs") for compound reserpine tablets (the "*Compound Reserpine APIs Exclusivity*" case);⁷ Chongqing Qingyang for abuse of dominance for allopurinol APIs (the "*Allopurinol APIs*" abuse case);⁸ Chongqing Qingyang, Chongqing Datong, The Place Pharmaceutical Jiangsu, Shanghai Xinyi and Shangqiu Huajie for price fixing and dividing the sales market for allopurinol tablets (the "*Allopurinol Tablets*" cartel case);⁹

³ See Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Pfizer's Acquisition of Wyeth (2009) No. 77, (the "MOFCOM Announcement on Pfizer/Wyeth"), 29 September 2009, available at <http://fldj.mofcom.gov.cn/article/ztxx/200909/20090906541443.shtml>.

⁴ See Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Novartis' Acquisition of Alcon (2010) No. 53, (the "MOFCOM Announcement on Novartis/Alcon"), 13 August 2010, available at <http://fldj.mofcom.gov.cn/article/ztxx/201008/20100807080639.shtml>.

⁵ See Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Baxter's Acquisition of Gambro (2013) No. 58, (the "MOFCOM Announcement on Baxter/Gambro"), 8 August 2013, available at <http://fldj.mofcom.gov.cn/article/ztxx/201308/20130800244176.shtml>.

⁶ See Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Thermo Fisher's Acquisition of Life Technology (2014) No. 3, (the "MOFCOM Announcement on Thermo Fisher/Life Technology"), 14 January 2014, available at <http://fldj.mofcom.gov.cn/article/ztxx/201401/20140100461603.shtml>.

⁷ On 15 November 2011, the NDRC imposed a total fine of RMB 7.03 million (USD 1.07 million) against Weifang Shuntong and Weifang Huaxin for the exclusive supply of a raw material used in hypertension drugs. See, Press Release, NDRC, Two Pharmaceutical Companies Were Penalized for Monopolizing Raw Materials Used in Hypertension Drugs (15 November 2011), available at http://jjs.ndrc.gov.cn/fjgld/201203/t20120306_465386.html.

⁸ On 28 October 2015, the Chongqing Administration for Industry and Commerce fined Chongqing Qingyang RMB 439,308.53 (USD 66,860) for illegally refusing to supply allopurinol API. See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2015) No. 15, 28 October 2015, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201512/t20151221_165120.html.

⁹ On 15 January 2016, the NDRC imposed a total fine of RMB 3,995,400 (USD 607,300) against Chongqing Qingyang, Chongqing Datong (an affiliated company of Chongqing Qingyang and responsible for distribution of allopurinol), The Place Pharmaceutical Jiangsu, Shanghai Xinyi and Shangqiu Huajie (the exclusive distributor of Shanghai Xinyi) for price fixing and dividing the sales market for allopurinol tablets. See Press Release, NDRC, NDRC Investigated Allopurinol Tablets Cartel Case (15 January 2016),

Huazhong Pharmaceutical, Shandong Xinyi and Changzhou Siyao for price fixing and jointly boycotting transactions for estazolam APIs and estazolam tablets (the “*Estazolam APIs/tablets*” cartel case);¹⁰ Chongqing Southwest for abuse of dominance for phenol APIs (the “Phenol APIs” abuse case);¹¹ and Medtronic for resale price maintenance for medical devices (the “Medtronic RPM” case).¹² It is also worth noting that, in May 2016, the NDRC started an industry-wide inquiry into pricing issues in the pharmaceutical sector. In addition, private claims in the pharmaceutical sector, such as Ruibang’s lawsuit against Johnson & Johnson (the “Johnson & Johnson/Ruibang” case),¹³ have also drawn attention from the public.

This article explores the application of China’s AML to the Chinese pharmaceutical sector. Competition law issues affecting this industry are technical, complex and varied, and have been a priority in antitrust enforcement to date. While the general assessment of these problems by China’s competition authorities largely mirrors international practice, there are some unique traits that aim to deal with the specific local context. In this article, we consider and assess these peculiarities. It is organized as follows: Part 2 covers the basics of Chinese antitrust enforcement, including the authorities, governing rules, market definition and the interface of competition policy and industrial policy in the pharmaceutical sector. Part 3 discusses merger control issues in the pharmaceutical industry. Part 4 assesses anti-competitive agreements; Part 5 covers abuse of dominance and Part 6 discusses administrative monopoly. Part 7 offers a conclusion.

available at http://jjs.ndrc.gov.cn/fjgld/201601/t20160128_772982.html.

¹⁰ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 5, 22 July 2016, *available at* http://jjs.ndrc.gov.cn/fjgld/201607/t20160727_812579.html; the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 6, 22 July 2016, *available at* http://jjs.ndrc.gov.cn/fjgld/201607/t20160727_812583.html; the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 7, 22 July 2016, *available at* http://jjs.ndrc.gov.cn/fjgld/201607/t20160727_812587.html.

¹¹ On 24 November 2016, the Chongqing Administration for Industry and Commerce fined Chongqing Southwest RMB 500,123.9 (USD 76,238, and the penalty imposed included an amount of RMB 482883.9 as “illegal gain” collected by the SAIC) for illegally refusing to supply phenol API. See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2016) No. 15, 24 November 2016, *available at* http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201612/t20161213_173318.html.

¹² On 5 December 2016, the NDRC imposed a total fine of RMB 118.52 million (USD 18.04 million) against Medtronic for entering into monopoly agreements to fix resale prices and set minimum resale price for medical devices. See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 8, 5 December 2016, *available at* http://jjs.ndrc.gov.cn/fjgld/201612/t20161209_829716.html.

¹³ On 11 August 2010, Ruibang, a distributor of Johnson & Johnson, claimed that Johnson & Johnson imposed unlawful minimum resale price maintenance (RPM) in a distribution agreement. In the first instance, the Shanghai First Intermediate Court dismissed the case on the grounds that there was insufficient evidence of anti-competitive effects. On 1 August 2013, the Shanghai High Court overturned the decision and determined that the RPM provisions restricted competition in the market and constituted a monopoly agreement. See Judicial Decision of Shanghai High Court, (2012) Hu Gao Min San [Zhi] Zhong Zi No. 63, *available at* http://www.hshfy.sh.cn/shfy/gweb/flws_view.jsp?pa=adGFoPaOoMjAxMqOpu6a438PxyP0o1qop1tXX1rXaNjO6xSZ3c3hoPTUPdcssz (last visited 14 March 2017).

2. FUNDAMENTALS

2.1 ENFORCEMENT AUTHORITIES

The State Council has set up the Anti-Monopoly Commission (“AMC”), which is a consultation and coordination body without substantive enforcement powers.¹⁴ The State Council has placed responsibility for the enforcement of the AML with the MOFCOM, the NDRC and the SAIC (individually an “enforcement authority”, and collectively the “enforcement authorities”). Merger review is administered by the MOFCOM, leaving the NDRC and the SAIC to concentrate on day-to-day operational antitrust issues (such as anti-competitive agreements and abuses of market dominance).¹⁵ Theoretically, the NDRC and the SAIC are responsible for different areas. The NDRC focuses on price-related conduct, such as price-fixing, while the SAIC is responsible for non-price-related conduct, such as market sharing, tying or refusal to supply.¹⁶ In practice, however, anti-competitive conduct does not always fall neatly into either price or non-price-related activities as there is often some overlap. Also, there is no official allocation of enforcement powers of specific industries (such as the pharmaceutical industry) between the NDRC and the SAIC. There is little guidance available publicly as to which authority will take the lead if and when conflicts arise over jurisdiction. The NDRC and the SAIC are understood to possess certain internal working rules that are designed to facilitate coordination between the authorities.

Merger review is administered centrally by the MOFCOM, and it does not delegate its power to enforce the AML to its local counterparts.¹⁷ However, both the NDRC and the SAIC may authorize their respective provincial level counterparts to enforce the AML within their respective administrative areas. The NDRC has generally authorized its provincial level counterparts (the “local DRCs”) to enforce the AML, while the SAIC may authorize its provincial level counterparts (the “local AICs”) to enforce the AML on a case-by-case basis. While such delegation of enforcement powers may create efficiencies, it does once again offer the potential for disparities in practice and policy between regions. This unique distinction between the spheres of competence of the NDRC and the SAIC, and the NDRC’s and the SAIC’s delegation of enforcement powers to their provincial level counterparts raise the risk of parallel investigations and inconsistent decision-making. This issue was highlighted in two recent cases. In 2015, the Chongqing Administration for Industry and Commerce (the “Chongqing AIC”) fined Chongqing

¹⁴The functions of the AMC mainly involve the formulation of competition policies and guidelines, the assessment of the overall status of market competition, and the coordination of enforcement activities. *See* AML, Art. 9.

¹⁵It is worth noting, however, that the MOFCOM is authorized to investigate breaches relating to anti-competitive agreements and abuse of market dominance relating to foreign trade activities pursuant to Article 32 of the Foreign Trade Law (effective as of 1 July 2004).

¹⁶In economic terms, there is little difference between an agreement to limit output and a price-fixing agreement. Similarly, supplying goods or services at excessively high prices is not materially different from a refusal to supply goods or services.

¹⁷However, the MOFCOM may ask its local counterparts to “assist” with the review of specific cases (*e.g.*, by conducting local market study or seeking comments from local market players).

Qingyang for abuse of dominance for allopurinol API in the *Allopurinol API* abuse case¹⁸ and then in 2016, the NDRC fined the same company for price fixing and dividing the sales market for allopurinol tablets in the *Allopurinol Tablets* cartel case.¹⁹ Therefore, market participants will need to be sensitive to such distinctions between the different authorities and adopt strategies to build relationships with the different levels of the enforcement authorities relevant to their businesses.

2.2 GOVERNING RULES

Since the AML came into effect, the State Council, the AMC and the enforcement authorities have issued a number of regulations and guidelines to enforce the AML. For example, the AMC adopted the Guidelines on the Definition of the Relevant Market.²⁰ The MOFCOM issued a variety of regulations and guidelines on procedure and substance to inform the merger control process, such as the Guidelines on Notification of Concentrations of Undertakings.²¹ The NDRC and the SAIC also issued regulations and guidelines to govern the enforcement of the conduct rules, including the Rules against Price-related Monopolies issued by the NDRC (“NDRC Price-related Monopolies Rules”),²² the Rules on the Prohibition of Monopoly Agreement (“SAIC Monopoly Agreement Rules”)²³ and the Rules on the Prohibition of Abuse of Dominant Market Positions (the “SAIC Abuse of Dominance Rules”)²⁴ issued by the SAIC.²⁵

In addition to the AML and its implementation rules, the enforcement authorities may employ other Chinese laws to challenge anti-competitive conduct by pharmaceutical companies.

¹⁸ See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2015) No. 15, 28 October 2015, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201512/t20151221_165120.html.

¹⁹ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 1, 15 January 2016, available at http://jjs.ndrc.gov.cn/fjgld/201602/t20160202_774107.html.

²⁰ See the AMC, GUIDELINES ON THE DEFINITION OF THE RELEVANT MARKET, issued on 24 May 2009, available at http://www.gov.cn/zwhd/2009-07/07/content_1355288.htm.

²¹ See the ANTI-MONOPOLY BUREAU OF THE MOFCOM, GUIDELINES ON NOTIFICATION OF CONCENTRATIONS OF UNDERTAKINGS, issued on 5 January 2009 and amended on 6 June 2014, available at <http://fldj.mofcom.gov.cn/article/i/201406/20140600614679.shtml>.

²² See the NDRC, RULES AGAINST PRICE-RELATED MONOPOLIES, issued on 29 December 2010, available at http://jjs.ndrc.gov.cn/zcfg/201101/t20110104_389399.html. These are substantive rules which provide guidance as to what would constitute price-related abusive conduct.

²³ See the SAIC, RULES ON THE PROHIBITION OF MONOPOLY AGREEMENT, issued on 31 December 2010, available at http://www.saic.gov.cn/fldyfbzdjz/zcfg/zcfg/201101/t20110107_103378.html. These are substantive rules which provide guidance as to what would constitute non-price-related monopoly agreements.

²⁴ See the SAIC, RULES ON THE PROHIBITION OF ABUSE OF DOMINANT MARKET POSITIONS, issued on 31 December 2010, available at http://www.saic.gov.cn/fldyfbzdjz/zcfg/zcfg/201101/t20110107_103379.html. These are substantive rules which provide guidance as to what would constitute non-price-related abusive conduct.

²⁵ Due to the allocation of enforcement powers between the NDRC and the SAIC, there is considerable overlap between the implementation rules issued by the NDRC and the SAIC, respectively, but the implementations rules are not entirely consistent.

The NDRC also implements the Price Law,²⁶ and the SAIC also implements the Anti-Unfair Competition Law (“AUCL”).²⁷ Antitrust investigations may be initiated based on the evidence detected during the process of investigations initiated under these laws.²⁸ Moreover, the pharmaceutical sector is highly regulated in China. There are industry-specific laws and regulations that set out rules on the authorization, production, registration, importation, pricing and distribution of pharmaceutical products, such as the Pharmaceutical Administration Law²⁹ and the Administrative Rules on the Management and Registration of Pharmaceutical Products.³⁰ These sector-specific rules are not directly relevant to the application of the AML to the pharmaceutical sector, but the enforcement authorities may take into consideration the impact of these rules when they are enforcing the AML.

²⁶Price Law, promulgated by the Standing Committee of the National People’s Congress on 29 December 1997. The NDRC initiated a working group in late 2014 to oversee the Price Law amendments. The main objective of the proposed amendments is to resolve the relationship between the Price Law and the AML. One proposed solution is to make the Price Law supplementary to the AML when there is an antitrust-related issue, so that Chinese regulators can use Price Law to handle antitrust cases with little impact on the market while delegating cases with greater potential market influence to be dealt with under the AML.

²⁷The Anti-Unfair Competition Law was promulgated by the Standing Committee of the National People’s Congress on 2 September 1993. There are overlaps between the AML and the AUCL in several aspects. For example, tying and imposing unreasonable conditions can also be illegal under the AUCL, and the law applies even in the absence of dominance (*see* AUCL, Art. 12). Changes are expected in several areas of the AUCL, which are currently under public consultation. In particular, various antitrust provisions are proposed to be removed—such as those on administrative monopolies, predatory pricing and tying—that are already regulated under the AML.

²⁸For example, in practice, it is likely that evidence of anti-competitive conduct (such as anti-competitive agreements, anti-competitive tying or other abusive conduct) by pharmaceutical companies is gathered by local AICs when they are conducting commercial bribery investigations.

²⁹The Pharmaceutical Administration Law was promulgated by the Standing Committee of the National People’s Congress on 20 September 1984 and amended on 24 April 2015. According to the Pharmaceutical Administration Law, manufacturers have to obtain a Pharmaceutical Production License from the local Food and Drug Administration where that producer is located (“local FDA”, and “FDAs”). The setting up of pharmaceutical wholesale enterprises must be approved by the provincial-level FDAs, to be issued a Pharmaceutical Trade License. The establishment of pharmaceutical retail enterprises must be approved by local FDAs at or above county level, to be issued a Pharmaceutical Trade License. Pharmaceutical manufacturing enterprises must conduct manufacturing activities in accordance with the Good Manufacturing Practice of Pharmaceutical Products (“GMP”) stipulated by the China Food and Drug Administration (“CFDA”). Pharmaceutical trading enterprises must conduct trading activities in accordance with the Good Supply Practice of Pharmaceutical Products (“GSP”) stipulated by the CFDA.

³⁰The CFDA, ADMINISTRATIVE RULES ON THE MANAGEMENT AND REGISTRATION OF PHARMACEUTICAL PRODUCTS issued on 18 June 2007. According to the rules, a “Product Registration Number” or market authorization (for those produced in China) is required to market pharmaceuticals in China. Imported pharmaceutical products must be registered with the CFDA before entering into the Chinese market. The CFDA issues Import Pharmaceutical License for imported pharmaceutical products (including those imported from Hong Kong, Macau and Taiwan). The Administrative Rules on Importation of Pharmaceutical Products (issued by CFDA and China General Administration of Customs on 18 August 2003 and amended on 24 August 2012) states that a pharmaceutical product should be permitted to go through the custom clearance procedures only after it has been granted an Import Pharmaceutical License.

2.3 MARKET DEFINITION

Defining the relevant market is usually the starting point for the enforcement authorities to conduct their competition analysis. Like in other jurisdictions, definition of the relevant market is not an entirely objective matter, and may vary from one enforcement authority to another. The Guidelines on the Definition of the Relevant Market provides a framework for the enforcement authorities in terms of defining relevant markets. As a general principle, it is accepted by the enforcement authorities that when determining a relevant market, substitutability from both demand and supply sides is considered.³¹ However, the “substitutability analysis” in the Guidelines on the Definition of the Relevant Market only provides a framework for defining the relevant markets. In practice, the enforcement authorities may rely on other sources of reference, such as the case law in other jurisdictions (in particular in the EU), third-party industry reports, the company’s own view in internal documents and the views of industry experts.

Within the pharmaceutical industry, products are usually categorized based on different criteria—for example whether the products are prescription or over-the-counter (“OTC”) pharmaceuticals, whether the products are originator or generic pharmaceuticals, and/or by indication, *i.e.*, on the basis of the condition that the product is designed to treat. In practice, the enforcement authorities tend to define relevant markets narrowly. A few published precedents in the pharmaceutical sector may shed light on the approaches to market definition adopted by the enforcement authorities. For pharmaceutical products, the practice of the MOFCOM indicates that the relevant product market is usually defined according to the products’ therapeutic areas. The Anatomical Therapeutic Chemical (“ATC”) classification system is the most widely used, up-to-date, authoritative and well-recognized method in many countries around the world.³² The ATC classification system is devised by the European Pharmaceutical Marketing Research Association (“EphMRA”) and maintained by EphMRA and Intercontinental Medical Statistics (“IMS”).³³ The ATC is hierarchical and has 16 categories (A, B, C, D, etc.) each with up to four levels. The first level (ATC1) is the most general and the fourth level (ATC4) is the most detailed. At the third ATC level (ATC3), pharmaceuticals are grouped in terms of their therapeutic indication, *i.e.*, their intended use. In general, these groups of products generally have the same therapeutic indication. Therefore, the ATC3 level is generally used as the starting point for investigating and defining relevant product markets.³⁴ In the Pfizer/Wyeth decision, the MOFCOM expressly adopted the ATC3 classification system to categorize the pharmaceutical

³¹ See the GUIDELINES ON THE DEFINITION OF THE RELEVANT MARKET, 24 May 2009, *available at* http://www.gov.cn/zwhd/2009-07/07/content_1355288.htm.

³² For example, this is the approach expressly adopted by the European Commission.

³³ The ATC classification system has also been adopted by the World Health Organization (“WHO”). The classification system prepared by the WHO slightly differs from the EphMRA ATC system. Despite differences between the anatomical therapeutic classification methods adopted by EphMRA and WHO, the two organizations have been coordinating to address this discrepancy since 1991. Consequently, the anatomical therapeutic classification used by the WHO and EphMRA are now very similar.

³⁴ However, the ATC3 level is not in all cases an appropriate basis for the definition of product markets and it may appropriate to also carry out analyses at other ATC levels (such as the ATC4 level), or a mixture thereof, if the circumstances of a case show that sufficiently strong competitive constraints faced by the undertakings involved are situated at other levels and there are indications that the ATC3 class does not lead to a correct market definition.

products.³⁵

The NDRC's and the SAIC's practice, however, indicates that the relevant product market for the pharmaceutical products can be defined even more narrowly, for instance, at the level of a specific product. For example, in the *Allopurinol API* case, the Chongqing AIC conducted a detailed analysis into the pharmacology and prices of allopurinol tablets. The Chongqing AIC noted that allopurinol tablets are used to treat gout, a type of arthritis disease. There are several other drugs used in the treatment of gout, but the Chongqing AIC found them not to be sufficiently substitutable with allopurinol tablets due to the difference in the mode of action, the price and the reimbursement policy. Allopurinol API is an indispensable ingredient for the production of allopurinol tablets. As a result, the Chongqing AIC concluded that the allopurinol API market was the relevant market.³⁶ In the *Phenol APIs* case, the Chongqing AIC followed the same approach as that in the *Allopurinol API* case, but the Chongqing AIC further clarified that prescription and OTC pharmaceuticals should be defined as different relevant product markets. The Chongqing AIC noted that salicylic acid and phenol plasters is the only available OTC pharmaceutical to treat clavus and phenol API is an indispensable ingredient for the production of salicylic acid and phenol plasters. As a result, the Chongqing AIC concluded that the phenol API market was the relevant market.³⁷ In the *Allopurinol Tablets* cartel case, the NDRC did not conduct a detailed analysis on the definition of the relevant market, but focused its investigation and analysis on allopurinol tablets.³⁸ More recently, in the *Estazolam* cartel case, the NDRC expressly defined the relevant product markets as the markets for estazolam API and estazolam tablets.³⁹

For medical devices, the MOFCOM's practice indicates that the MOFCOM may divide markets along broad lines in the first instance to include the product/products treating the same diseases/injuries, and then segment markets further based on factors such as price, focus of treatment, suitable patients, and technical characteristics. For example, in the *Baxter/Gambro* case, the MOFCOM first identified the Continuous Renal Replacement Therapy ("CRRT") series products and haemodialysis dialyzer products as the overlaps between the parties. The MOFCOM noted that the CRRT series products are usually used to treat patients in ICUs suffering from life-

³⁵ See the MOFCOM Announcement on Pfizer/Wyeth.

³⁶ See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2015) No. 15, 28 October 2015, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201512/t20151221_165120.html.

³⁷ See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2016) No. 15, 24 November 2016, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201612/t20161213_173318.html.

³⁸ See the Administrative Penalty Decision of the NDRC (2016) No. 1, 15 January 2016, available at http://jjs.ndrc.gov.cn/fjgld/201602/t20160202_774107.html.

³⁹ See the Administrative Penalty Decision of the NDRC (2016) No. 5, 22 July 2016, available at http://jjs.ndrc.gov.cn/fjgld/201607/t20160727_812579.html; the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 6, 22 July 2016, available at http://jjs.ndrc.gov.cn/fjgld/201607/t20160727_812583.html; the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 6, 22 July 2016, available at http://jjs.ndrc.gov.cn/fjgld/201607/t20160727_812587.html.

threatening acute renal dysfunctions or injuries and the haemodialysis dialyzer products are mainly used for the treatment of conventional acute kidney injuries and chronic kidney diseases. The MOFCOM further noted that the CRRT series products comprise CRRT monitors, CRRT dialyzers, CRRT bloodlines, CRRT catheters and CRRT liquors and the haemodialysis dialyzer products comprise haemodialysis monitors, haemodialysis dialyzers, haemodialysis dialyzer bloodlines, haemodialysis catheters and haemodialysis liquors. The MOFCOM concluded that each of the CRRT series products and the haemodialysis dialyzer products constitute a separate relevant product market and in particular, focused its investigation on the CRRT monitors market, the CRRT dialyzers market, the CRRT bloodlines market and the haemodialysis dialyzers market.⁴⁰ In the Medtronic RPM case, the NDRC did not conduct a detailed analysis on the market definition, but it focused its investigation on specific medical devices.⁴¹ It is unclear whether the SAIC will adopt the same approach as there has not been case law published by the SAIC on how the product market is defined for medical devices.

With regard to the relevant geographic market, the enforcement authorities typically define the market for finished pharmaceutical products as national in scope, primarily due to the fact that pharmaceutical products are subject to strict national regulation, and specific national requirements in terms of product registration, pricing and distribution and, where applicable, reimbursement schemes.⁴²

2.4 INTERFACE OF COMPETITION POLICY WITH INDUSTRIAL POLICY

The AML expressly empowers the enforcement authorities to take into account non-competition factors when enforcing the AML, leaving room for the enforcement authorities to consider industrial policy when enforcing the AML. The interface of competition policy with industrial policy derives from Article 1 of the AML, which provides a multi-facet purpose of the AML, including preventing or ceasing anti-competitive conduct, promoting fair market competition, improving economic efficiency, protecting the legitimate rights and interests of consumers and the public, and promoting the healthy development of the socialist market economy.⁴³ In addition, Article 4 of the AML provides that the State shall formulate and implement competition rules appropriate to a socialist market economy and improve macroeconomic measures and establish a unified, open, competitive and orderly market system.⁴⁴ These provisions enable the enforcement authorities to weigh competition factors along with non-competition factors when they enforce the AML. After the text of the AML was finalized, Chinese legal authorities and government officials continued to make statements confirming that

⁴⁰ See MOFCOM Announcement on Baxter/Gambro.

⁴¹ See the Administrative Penalty Decision of the NDRC (2016) No. 8, 5 December 2016, *available at* http://jjs.ndrc.gov.cn/fjgld/201612/t20161209_829716.html.

⁴² The MOFCOM may, however, accept that the market for raw materials is wider than that for finished pharmaceutical products, and may define such a market as worldwide. In practice, even if the relevant geographic market is defined as China, the MOFCOM usually requests data and analyze the status of market competition at the global level as well.

⁴³ See AML, Art. 1.

⁴⁴ See AML, Art. 4.

the AML is designed at least in part to implement industrial policy and curb the influence of foreign companies.⁴⁵

2.5 ELEMENTS OF CHINA'S INDUSTRIAL POLICY IN PHARMACEUTICAL SECTOR

Until recently, one unique feature of the pharmaceutical sector, as well as a notable element of China's industrial policy in the pharmaceutical sector, has been price control.⁴⁶ On 4 May 2015, seven authorities of the Chinese central government jointly issued the Opinions on Promoting Reform in Pharmaceutical Pricing, which removed price controls for most pharmaceutical products from 1 June 2015.⁴⁷ Going forward, the price of the majority of pharmaceutical products would no longer be set by the NDRC but rather by the market. On the same day, the NDRC issued the Notice on Strengthening the Supervision of Pricing Activities in the Pharmaceutical Industry, to support the reform of the pricing mechanism for pharmaceutical products.⁴⁸ It is understood that the NDRC will devote more attention to, and strengthen the supervision of, pricing activities by pharmaceutical companies in the future.⁴⁹

The second element of China's industrial policy in the pharmaceutical sector is China's Five Year Plan, which serves as a roadmap for regulators and officials.⁵⁰ The current Five Year

⁴⁵ Examples of such statements are provided in the report, US CHAMBER OF COMMERCE, COMPETING INTERESTS IN CHINA'S COMPETITION LAW ENFORCEMENT: CHINA'S ANTI-MONOPOLY LAW APPLICATION AND THE ROLE OF INDUSTRIAL POLICY ("US Chamber Report"), 8 September 2014, *available at* https://www.uschamber.com/sites/default/files/aml_final_090814_final_locked.pdf.

⁴⁶ Previously, the NDRC (and the local DRCs) was the main authority to control the pricing of pharmaceuticals. There were two kinds of price controls: (1) fixed price: pharmaceutical products under the National Immunization Project and Family Planning Project were subject to fixed prices; and (2) maximum retail price set by the NDRC (or the local DRCs): there were three types of pharmaceutical products that were subject to the maximum retail price set by the government, namely, national essential pharmaceutical products, pharmaceutical products subject to reimbursement under the general national medical insurance scheme, and pharmaceutical products with strong market positions. A manufacturer may freely determine the price of its products as long as the price does not exceed the maximum retail price or fixed price set by the government.

⁴⁷ See the OPINIONS ON PROMOTING REFORM IN PHARMACEUTICAL PRICING, issued by the NDRC, the National Health and Family Planning Commission, the Ministry of Human Resources and Social Security, the Ministry of Industry and Information Technology, the Ministry of Finance, the MOFCOM, the China Food and Drug Administration, Fa Gai Jia Ge (2015) No. 904, 4 May 2015, *available at* http://www.sdpc.gov.cn/zcfb/zcfbtz/201505/t20150505_690664.html.

⁴⁸ See the NDRC, NOTICE ON STRENGTHENING THE SUPERVISION OF PRICING ACTIVITIES IN THE PHARMACEUTICAL INDUSTRY, Fa Gai Jia Jian (2015) No. 930, 4 May 2015, *available at* http://jjs.ndrc.gov.cn/zcfg/201505/t20150505_690681.html.

⁴⁹ For example, since the NOTICE ON STRENGTHENING THE SUPERVISION OF PRICING ACTIVITIES IN THE PHARMACEUTICAL INDUSTRY was issued on 4 May 2015, the NDRC and its local branches conducted two rounds of special six-month campaign to investigate illegal conduct in relation to pharmaceutical prices across the pharmaceutical and healthcare industry from 1 June 2015 to 1 December 2015, and 1 June 2016 to 1 December 2016, respectively.

⁵⁰ China has implemented Five Year Plans since 1953. The current Five Year Plan is China's thirteenth Five Year Plan, which is a blueprint for socio-economic development in China for 2016 to 2020 with

Plan is the thirteenth Five Year Plan, under which several areas within the pharmaceutical sector, such as innovative pharmaceutical products, high performance medical instruments, biotechnology and precision medical instruments, are categorized as strategic areas.⁵¹ Since the adoption of the thirteenth Five Year Plan, the State Council and government authorities will issue various rules and policies to implement the general strategies set out in the thirteenth Five Year Plan.⁵²

The third element of China's industrial policy in the pharmaceutical sector is the guidance of foreign investment. The Catalogue for the Guidance of Foreign Investment Industries ("Foreign Investment Catalogue") classifies foreign investment in various industries according to three categories: encouraged, restricted and prohibited.⁵³ Those that are not listed in the Foreign Investment Catalogue are understood to be permitted. Before the Foreign Investment Catalogue was amended in 2015, investments in the pharmaceutical sector could fall under any of these categories depending on the products involved. According to the 2015 Foreign Investment Catalogue, however, most of the restrictions previously imposed on the foreign investment in the pharmaceutical sector have been removed.

The fourth element of China's industrial policy in the pharmaceutical sector is the national security review system. The system and framework of China's national security review were introduced in 2011 when the State Council published its Notice on the Establishment of a Security Review System Regarding Mergers and Acquisitions of Domestic Enterprises by Foreign Investors.⁵⁴ The pharmaceutical sector has not been expressly listed as one of the sensitive industries that may be subject to national security review, but certain transactions in the pharmaceutical sector could attract national security review if there is a sufficient nexus with industries that are expressly subject to national security review.⁵⁵ In addition, although the

initiatives and reforms in certain strategic industries and geographic regions.

⁵¹ See the NDRC, OUTLINE OF CHINA'S THIRTEENTH FIVE YEAR PLAN, available at <http://www.ndrc.gov.cn/fzgggz/fzgh/ghwb/gjjh/201605/P020160516532684519514.pdf> (last visited 14 March 2017).

⁵² For example, it is reported that the NDRC and several authorities of the Chinese central government are jointly drafting the Plan of the Development of the Pharmaceutical Industry during the thirteenth Five Year Plan.

⁵³ The CATALOGUE FOR THE GUIDANCE OF FOREIGN INVESTMENT INDUSTRIES, issued by the MOFCOM and the NDRC, 10 April 2015, available at http://www.sdpc.gov.cn/zcfb/zcfbl/201503/t20150313_667332.html.

⁵⁴ See STATE COUNCIL, NOTICE ON THE ESTABLISHMENT OF A SECURITY REVIEW SYSTEM REGARDING MERGERS AND ACQUISITIONS OF DOMESTIC ENTERPRISES BY FOREIGN INVESTORS ("State Council Notice"), issued on 12 February 2011. The State Council Notice delineates the scope of national security review to cover (1) the acquisition of any stake by foreign investors in enterprises active in the military industry or related industries; and (2) acquisitions that may result in foreign investors acquiring actual control in the following sectors: key agricultural products, key energy resources, key infrastructure, key transportation services, key technologies and key equipment manufacturing.

⁵⁵ For example, in accordance with the requirements of national security review, China's State Administration of Foreign Exchange ("SAFE") issued an internal notice, which contained a list of sectors that will be subject to national security review. While the list has not been made available to the public, it is understood to include the manufacture of medical devices and equipment. Moreover, wholesale and retail

national security review is applied under the context of M&A transactions, it provides an indication on the “key industries” that may draw attention from the Chinese government more generally.

The last element of China’s industrial policy in the pharmaceutical sector, which is more relevant to M&A transactions, is the encouragement of consolidation in the pharmaceutical sector. As a general industrial policy, the Chinese government has signalled that it intends to encourage private investment and consolidation in key industries in China.⁵⁶ With respect to the pharmaceutical sector, on 9 October 2010, three authorities of the Chinese central government issued a notice to encourage mergers and consolidations between pharmaceutical companies.⁵⁷ These government initiatives are aimed at encouraging principally M&A activity between domestic pharmaceutical companies as well as outbound M&A activity. Due to the competing goals of the AML, industrial policy may also play an important role when the enforcement authorities enforce the AML in the pharmaceutical sector. Enforcement activities have raised concerns about how the enforcement authorities consider non-competition factors.⁵⁸

3. MERGER CONTROL

3.0 OVERVIEW

Under the AML, a “concentration” must be notified to MOFCOM if the turnover thresholds are met. There are no special rules that apply to the assessment of concentrations or the calculation of turnover in the pharmaceutical sector. In this section, we examine some key issues in merger control and their implications for pharmaceutical companies.

3.1 ASSESSMENT OF MERGERS

The substantive test for the MOFCOM’s assessment of a proposed transaction is whether

services (which may include chain drug stores) are also understood to be on the list.

⁵⁶On 6 September 2010, the State Council issued its OPINIONS ON PROMOTING ENTERPRISE MERGERS AND RESTRUCTURING according to which the Chinese Government will promote consolidation, trans-regional mergers and restructuring, overseas mergers and acquisitions, and investment cooperation among competitive enterprises by focusing on key industries, and relax restrictions on market access for private capital to the key industries. *See* STATE COUNCIL, OPINIONS OF THE STATE COUNCIL ON PROMOTING ENTERPRISE MERGER AND RESTRUCTURING, 6 September 2010, *available at* http://www.gov.cn/zwggk/2010-09/06/content_1696450.htm.

⁵⁷The GUIDING OPINIONS ON ACCELERATING THE STRUCTURAL RESTRUCTURING OF THE PHARMACEUTICAL INDUSTRY, issued by the Ministry of Industry and Information Technology, the Ministry of Health and the China Food and Drug Administration, 9 October 2010, *available at* <http://politics.people.com.cn/GB/1027/13177565.html>.

⁵⁸For example, it is believed that in the enforcement activities involving IT companies, the NDRC has considered the impact of the IT companies’ business activities on Chinese industrial policies such as innovation, patent creation and technology licensing. *See* the report provided by the US–CHINA BUSINESS COUNCIL ON COMPETITION POLICY AND ENFORCEMENT IN CHINA 18, (“USCBC Report”) (September 2014), *available at* http://uschina.org/sites/default/files/AML%202014%20Report%20FINAL_0.pdf. *See also* the US CHAMBER REPORT, at 56–67.

such transaction “has or may have the effect of eliminating or restricting competition in China”.⁵⁹ Unlike the “significant impediment to competition” or “substantial lessening of competition” tests applicable in other major jurisdictions, there is no express requirement that the impact of the notified transaction on competition be “significant” or “substantial” under the AML.

On 5 September 2011, the MOFCOM issued the Interim Rules on the Assessment of the Impact of Concentrations of Undertakings on Competition (“Competition Effects Rules”). The Competition Effects Rules reiterated the factors that the AML allows the MOFCOM to consider during its merger review including market shares, the degree of market concentration in the relevant market with reference to the Herfindahl-Hirschman Index (“HHI”), and the impact of the transaction on effective competition or consumers.⁶⁰ The Competition Effects Rules also indicate that the MOFCOM may take into account non-competition factors (such as social and public interest considerations) during its investigations.⁶¹

In the pharmaceutical sector, the MOFCOM’s review of transactions focuses on the analysis of specific areas of overlap between the parties’ activities—namely overlaps between parties’ in-market products but also sometimes overlaps between parties’ pipeline products. In practice, the MOFCOM usually pays close attention to the combined market shares resulting from the transactions. There are no safe harbours or benchmarks for determining whether a transaction may or may not raise competition concerns in China. The MOFCOM may raise red-flags in cases involving combined market shares in the twenty to thirty percent range, and the prospect for remedies is relatively high in cases involving combined market shares of fifty percent or more. Although the MOFCOM’s focus is on the impact of a transaction in China it may also carefully consider parties’ market shares at the global level.⁶²

As for the market share estimates, practice indicates that the MOFCOM’s preference is for market data from reliable independent third-party sources such as trade associations or information and database companies. In the pharmaceutical sector, the IMS database is frequently used as a reliable source of data for prescription drugs, and sources such as Euromonitor may prove a useful database for certain OTC products. However, it can sometimes be difficult to obtain reliable sources for market data. In the absence of such data, parties will need to consider carefully the available options for data collection and for market share estimates, including the methodology used for gathering the data, the assumptions made and the reliability of the data. Parties may need to take careful advice as to where to turn for the most reliable market data for particular products.

The fact that a transaction may not lead to a significant increment in post-merger market

⁵⁹The AML requires that the MOFCOM assess whether a notified transaction has or may have the effect of eliminating or restricting competition in China. *See* AML, Art. 27.

⁶⁰*See* the MOFCOM, INTERIM RULES ON THE ASSESSMENT OF THE IMPACT OF CONCENTRATIONS OF UNDERTAKINGS ON COMPETITION, 5 September 2011, *available at* <http://fldj.mofcom.gov.cn/article/zcfb/201109/20110907753173.shtml>.

⁶¹*See* the COMPETITION EFFECTS RULES, Arts. 9 and 12.

⁶²The MOFCOM considered the parties’ market shares both in China and at the global level in the *Novartis/Alcon* case, the *Baxter/Gambro* case, and the *Thermo Fisher/Life Technology* case.

shares is not necessarily relevant. In the *Novartis/Alcon* case, the MOFCOM determined that the parties' combined global market share in ophthalmic anti-inflammatory and anti-infective compounds was over fifty-five percent, and that their combined share in China was over sixty percent. Novartis reportedly added less than one percent to the existing high share held by Alcon but, nevertheless the MOFCOM imposed a remedy—albeit behavioral.⁶³ Similarly, in the *Baxter/Gambro* case, the MOFCOM determined that the parties' combined global market share in CRRT monitors, CRRT bloodlines, CRRT dialyzers was sixty-four percent, fifty-nine percent and sixty-two percent, respectively, and that their combined share in China was fifty-seven percent, eighty-four percent and seventy-nine percent, respectively. The high combined market shares were mainly due to the existing high share held by Gambro but, nevertheless the MOFCOM requested Baxter to divest its CRRT business globally.⁶⁴

Several of the MOFCOM's decisions in the pharmaceutical sector reflect the increased sophistication in its competitive assessment of mergers. The *Pfizer/Wyeth* case was the first time that the MOFCOM publicly noted its reliance on HHI to assess the impact of a transaction in the relevant market.⁶⁵ In the *Novartis/Alcon* case, the MOFCOM raised possible coordination issues for the first time as a basis for imposing a remedy. Specifically, the MOFCOM raised the issue that the merged entity could coordinate its behaviour with Hydron to restrict competition. The decision noted that the merged Novartis/Alcon entity would be the second largest company in China for contact lenses care products. Prior to the transaction, Novartis had already appointed Hydron as its exclusive distributor for one of its subsidiaries. Hydron was the largest producer and distributor in China.⁶⁶ the MOFCOM considered the coordination concerns again in the *Baxter/Gambro* case, and noted that coordination concerns arose where Baxter had an agreement for Nipro to manufacture haemodialysis dialyzers for Baxter. Both Baxter and Gambro produced and sold the product. Nipro also sold the same product.⁶⁷ In the *Thermo Fisher/Life Technology* case, the MOFCOM engaged independent third party consultant to conduct an economic analysis on the competition issues and for the first time, applied the "estimated price increase test" as a specific tool for the economic analysis.⁶⁸

3.2 REMEDIES

Unlike the EU, the AML allows the MOFCOM not only to "eliminate", but also to "mitigate" competition concerns when imposing remedies. Therefore, the MOFCOM tends to be more flexible in negotiating or imposing remedies. To the extent remedies are required, the MOFCOM does not necessarily follow the remedies imposed in other jurisdictions on the same transaction and may require remedies that are not commonly used in other jurisdictions. In addition, early imposition of remedies on the transaction in other jurisdictions does not necessarily mean that the MOFCOM review process may be expedited. On 4 December 2014, the

⁶³ See MOFCOM Announcement on Novartis/Alcon.

⁶⁴ See MOFCOM Announcement on Baxter/Gambro.

⁶⁵ See MOFCOM Announcement on Pfizer/Wyeth.

⁶⁶ See MOFCOM Announcement on Novartis/Alcon.

⁶⁷ See MOFCOM Announcement on Baxter/Gambro.

⁶⁸ See MOFCOM Announcement on Thermo Fisher/Life Technology.

MOFCOM issued its Rules on Imposing Conditions on Concentrations of Undertakings (for Trial Implementation) (“Remedies Rules”), which came into effect on 5 January 2015.⁶⁹ The Remedies Rules reflect the MOFCOM’s preference for structural remedies, such as asset and/or business disposals. The *Pfizer/Wyeth* case was the first time that the MOFCOM required a substantive structural remedy consisting of the divestment of a product portfolio, including licensing rights to relevant IP and related tangible and intangible rights.⁷⁰ In the *Baxter/Gambro* case, the MOFCOM required the divestment of Baxter’s CRRT business globally.⁷¹ In the *Thermo Fisher/Life Technologies* case, the MOFCOM required the divestment of certain business lines as well as a majority stake in a Chinese company.⁷² MOFCOM’s stated requirements for suitable purchasers of a to-be-divested asset/business are generally in line with the EU and US approaches. In practice, however, the MOFCOM might prefer to approve Chinese buyers due to concerns not related to competition policy (e.g., on an industrial policy basis).⁷³

At the same time, the MOFCOM’s practice indicates that it appears more receptive to non-structural remedies than the competition authorities in other jurisdictions. For example, the *Novartis/Alcon* case demonstrated the MOFCOM’s willingness to accept certain behavioral and quasi-structural remedies—in this case a commitment not to re-enter a particular market for a period of five years and the termination of an existing exclusive distribution agreement in another market.⁷⁴ Similarly, in the *Baxter/Gambro* case, the MOFCOM required Baxter to terminate its Original Equipment Manufacturer (“OEM”) agreement with Nipro in China by 31 March 2016.⁷⁵ In the *Thermo Fisher/Life Technologies* case, the MOFCOM required Thermo Fisher, for the subsequent ten years, to commit to certain designated supply arrangements for certain products at the option of the relevant third parties. The MOFCOM also required Thermo Fisher, for the subsequent ten years, to decrease the list price in China for certain products by one percent per year and not to decrease the percentage discount from the list price available to distributors in China.⁷⁶

Remedies imposed in merger cases in the China context are broadly consistent with international practice, but certain remedies may be unique to China. For example, similar to the European Commission’s decision in the same case, the MOFCOM required divestment of certain animal health products in approving the *Pfizer/Wyeth* case. However, in China, the larger of the

⁶⁹ See the MOFCOM, RULES ON IMPOSING CONDITIONS ON CONCENTRATIONS OF UNDERTAKINGS (FOR TRIAL IMPLEMENTATION), 4 December 2014, available at <http://www.mofcom.gov.cn/article/b/c/201412/20141200835207.shtml>.

⁷⁰ See MOFCOM Announcement on Pfizer/Wyeth.

⁷¹ See MOFCOM Announcement on Baxter/Gambro.

⁷² See MOFCOM Announcement on Thermo Fisher/Life Technology.

⁷³ For example, in the *Pfizer/Wyeth* case, the buyer of the divested business was a Chinese company; in *Panasonic/Sanyo*, the buyer of the divested business was also a Chinese company and was reported to be a company that raised concerns during the MOFCOM’s review and paid an “exceptionally low” price for the divested business.

⁷⁴ See MOFCOM Announcement on Novartis/Alcon.

⁷⁵ See MOFCOM Announcement on Baxter/Gambro.

⁷⁶ See MOFCOM Announcement on Thermo Fisher/Life Technology.

relevant overlapping products was required to be divested.⁷⁷ In the *Novartis/Alcon* case, the requirement that Novartis commit not to re-enter a particular market in China for five years also seems unique, especially given the combined market shares involved in the jurisdiction (including the modest post-merger increments in the market share) and Novartis' stated intention to withdraw from the market concerned.⁷⁸ In the *Thermo Fisher/Life Technologies* case, the requirement that Thermo Fisher commit to supply products and to decrease price with a specific percentage for a period of ten years in China also seems unique to China.⁷⁹

It is also worth noting that the MOFCOM has imposed "hold-separate" remedies in several cases, requiring the buyer to ring fence part of the target's operations which conduct business in China.⁸⁰ The conditions in these cases are far-reaching and give the MOFCOM discretion to postpone integration further if deemed necessary. Thus far, such unique hold-separate remedies have not been imposed in any case in the pharmaceutical sector. However, the MOFCOM is reviewing the effectiveness of the hold-separate remedies and if they are found to be effective, the MOFCOM may continue to use such remedies. Therefore, it is possible that such hold-separate remedies may be imposed when the MOFCOM reviews cases in the pharmaceutical sector in the future.

3.3 IMPACT ON TRANSACTION TIMETABLE

Given the burdensome information requirements and the increased sophistication in the MOFCOM's review, it is perhaps not surprising that the review process is noticeably longer in cases involving the pharmaceutical sector. The MOFCOM's review period consists of three phases—an initial review period of thirty days, a second phase of up to ninety days and an

⁷⁷ See MOFCOM Announcement on Pfizer/Wyeth.

⁷⁸ See MOFCOM Announcement on Novartis/Alcon.

⁷⁹ See MOFCOM Announcement on Thermo Fisher/Life Technology.

⁸⁰ For example, in Seagate's acquisition of Samsung's hard disk drive business, Western Digital's acquisition of Hitachi Global Storage Technologies, Marubeni's acquisition of Gavilon and MediaTek's acquisition of MStar, MOFCOM imposed hold-separate obligations that allowed the parties to proceed with the transaction, but froze integration for a period specified by the MOFCOM. See Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Seagate's Acquisition of Samsung's Hard Disk Drive Business (2011) No. 90, 12 December 2011 (the "MOFCOM Announcement on Seagate/Samsung"), available at <http://fldj.mofcom.gov.cn/article/ztxx/201112/20111207874274.shtml>; Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Western Digital's Acquisition of Hitachi Global Storage Technologies (2012) No. 9, 2 March 2012 (the "MOFCOM Announcement on Western Digital/Hitachi"), available at <http://fldj.mofcom.gov.cn/article/ztxx/201203/20120307993758.shtml>; Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of Marubeni's Acquisition of Gavilon (2013) No. 22, 22 April 2013 (the "MOFCOM Announcement on Marubeni/Gavilon"), available at <http://fldj.mofcom.gov.cn/article/ztxx/201304/20130400100376.shtml>; Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Conditional Approval of MediaTek's Acquisition of MStar (2013) No. 61, 26 August 2013 (the "MOFCOM Announcement on MediaTek/MStar"), available at <http://fldj.mofcom.gov.cn/article/ztxx/201308/20130800269821.shtml>.

extended third phase of up to sixty days. Second-phase reviews are routine in the pharmaceutical sector, in particular in cases that raise substantive competition concerns. It is possible that a high-profile case may enter the extended third phase review if the MOFCOM is unable to complete its review process earlier. The above-mentioned aspects relating to the MOFCOM's practice in negotiating and imposing remedies inevitably make the process of review more complex and longer in cases involving remedies. Out of the four conditionally approved transactions in the pharmaceutical sector as of October 2016, all cases entered the second-phase review and two cases entered into the extended third phase review.⁸¹

It is also possible that the notification may need to be withdrawn and re-filed if there are considerable delays in the review process, and the MOFCOM is unlikely to be able to complete its review within the statutory review period.⁸² Up to date, there has not been any case in the pharmaceutical sector in which the notification was withdrawn and re-filed. Additionally, it should be noted that after a notification is made to the MOFCOM, it has the discretion to accept the notification only after it deems the notification to be complete. The clock on the initial review phase only starts to run after the MOFCOM formally accepts the notification.⁸³ In practice, it can take several weeks to months for a notification to be declared complete, depending on the MOFCOM's priorities, deal complexity, the parties' responsiveness to the MOFCOM's information requests, and possible complaints from stakeholders. As there are usually industry policy concerns in transactions in the pharmaceutical sector, the MOFCOM tends to consult widely during its review and may seek the opinion of government authorities and interested third parties, including relevant trade associations as well as customers, suppliers and competitors. Based on experience, the involvement of and consultation with key stakeholders may significantly delay the MOFCOM's review process.

Pharmaceutical companies should bear in mind that the MOFCOM clearance process may have a significant impact on closing timetables, given the prospect of a lengthy pre-notification period and the increased likelihood of the MOFCOM opening a second-phase investigation. It is important to engage with the MOFCOM early in the process in order to agree on market definition and relevant data sources, identify possible competition concerns, and establish a realistic timetable. Additionally, one of the challenges posed by China's lengthy merger review process is coordination with other merger control procedures in cross-border transactions. Companies will need to think carefully whether to launch the China process first or whether to

⁸¹The *Baxter/Gambro* case and the *Thermo Fisher/Life Technologies* case entered the extended third phase. The *Baxter/Gambro* case was notified on 31 December 2012 and cleared on 8 August 2013 after a third phase review. In the *Thermo Fisher/Life Technologies* case, the parties notified the transaction on 3 July 2013 and the transaction was conditionally approved on 14 January 2014 after a third phase review.

⁸²For example, in five out of the twenty-seven conditionally approved transactions, namely, Western Digital's acquisition of Hitachi Global Storage Technologies, Glencore's acquisition of Xstrata, Marubeni's acquisition of Gavilon, MediaTek's acquisition of MStar, and NXP's acquisition of Freescale, the parties withdrew and re-filed their transactions and as a result, the whole review process for these transactions took more than 180 calendar days from the date on which the transaction was declared complete.

⁸³See MOFCOM ANTI-MONOPOLY BUREAU, GUIDANCE TO THE ANTI-MONOPOLY REVIEW OF CONCENTRATION OF UNDERTAKINGS, 11 March 2010, available at <http://fldj.mofcom.gov.cn/article/xgxz/200902/20090206034057.shtml>.

dovetail the China process and the other merger review procedures. In practice, the decision will often depend on which countries trigger a notification obligation.

3.4 SIMPLIFIED PROCEDURE AND ENFORCEMENT AGAINST FAILURE TO NOTIFY

Since April 2014, the MOFCOM has started to operate a simplified procedure for qualifying simple cases.⁸⁴ There are six types of situations that qualify for simplified procedure including where the combined market share of all parties to the concentration is less than fifteen percent in horizontal transactions; those where the market share in relation to each market relevant to the merger is less than twenty-five percent in vertical or conglomerate transactions; those for joint ventures established outside of China which do not engage in economic activities in China; those for acquisitions of foreign entities which do not engage in economic activities in China; and those by which joint ventures, which are jointly controlled by two or more parties, become controlled by one or more parties.⁸⁵ Although the MOFCOM has not given any formal guidance as to the duration of the review of simple mergers, MOFCOM has an unofficial target thirty calendar day review period (first-phase review) for qualifying simple cases.

In practice, the simplified procedure has been working extremely well with the large majority of the qualifying simple cases unconditionally approved within the first-phase review period. Since the simplified procedure was adopted, transactions in the pharmaceutical sector have also benefited from the simplified procedure. Recent examples include China Resources Sanjiu's acquisition of Kunming Shenghuo Pharmaceutical, Hony Capital Fund's acquisition of Zhejiang Guangsha Medical Technology, Furen Medicines Group's acquisition of Kaifeng Pharmaceutical,⁸⁶ LBX Pharmacy Chain's acquisition of Lanzhou Huirentang Pharmaceutical,⁸⁷ the joint venture between Ajinomoto and Eisai, Cardinal Health's acquisition of Guizhou Yibai Pharmaceutical and Astorg Asset Management and Goldman Sachs' acquisition of HRA Pharma.⁸⁸

⁸⁴ On 12 February 2014, the MOFCOM officially published the INTERIM REGULATIONS ON STANDARDS EMPLOYED FOR SIMPLE CASES OF CONCENTRATIONS OF UNDERTAKINGS ("Simple Mergers Regulations"), available at <http://fldj.mofcom.gov.cn/article/ztxx/201402/20140200487001.shtml>. On 18 April 2014, the MOFCOM set out procedural rules for notifying simple mergers in its GUIDANCE OPINIONS (INTERIM) ON THE NOTIFICATION FOR SIMPLE CASES OF CONCENTRATIONS, available at <http://fldj.mofcom.gov.cn/article/xgxz/201404/20140400555353.shtml>.

⁸⁵ See the SIMPLE MERGERS REGULATIONS, Art. 2.

⁸⁶ The *China Resources Sanjiu/Kunming Shenghuo Pharmaceutical* case was unconditionally approved on 31 August 2016; the *Hony Capital Fund/Zhejiang Guangsha Medical Technology* case was unconditionally approved on 25 August 2016; and the *Furen Medicines/Kaifeng Pharmaceutical* case was unconditionally approved on 19 July 2016. See the MOFCOM List of Unconditionally Approved Case in the Third Quarter of 2016, 10 October 2016, available at <http://fldj.mofcom.gov.cn/article/zcfb/201610/20161001405824.shtml>.

⁸⁷ The *LBX Pharmacy Chain/Lanzhou Huirentang Pharmaceutical* case was unconditionally approved on 17 May 2016. See the MOFCOM List of Unconditionally Approved Case in the Second Quarter of 2016, 5 July 2016, available at <http://fldj.mofcom.gov.cn/article/zcfb/201607/20160701353023.shtml>.

⁸⁸ The *Ajinomoto/Eisai* case was unconditionally approved on 3 March 2016; the *Cardinal Health/Guizhou Yibai Pharmaceutical* case was unconditionally approved on 3 March 2016; and the *Astorg Asset*

At the same time as making the process for simple transactions easier under the simplified procedure, the MOFCOM has intensified enforcement against transactions that meet the notification thresholds but were either not notified or were implemented prior to clearance (“gun-jumping”). On 30 December 2011, the MOFCOM issued Provisional Measures on Investigating Concentrations of Undertakings Which Fail to be Notified, which came into effect on 1 February 2012.⁸⁹ Since 1 May 2014, the MOFCOM has started to implement a “name and shame” mechanism, under which the MOFCOM will publicly announce its decisions on penalizing parties who have failed to notify their transactions. Up to now, the MOFCOM has published eight decisions imposing fines on a number of Chinese and foreign companies for gun-jumping.⁹⁰ Two of these decisions were addressed to pharmaceutical companies.

The first case concerned Fosun Pharmaceutical Group’s acquisition of sixty-five percent in Suzhou Erye Pharmaceuticals (the “*Fosun/Erye*” case). Fosun Pharmaceutical Group requested consultation with the MOFCOM, but during the consultation period, the company acquired thirty-five percent stake (of the total sixty-five percent stake to be acquired) of the target. The MOFCOM found the thirty-five percent stake acquisition to give rise to an acquisition of control and imposed a fine of RMB 200,000 on Fosun Pharmaceutical Group.⁹¹ The second case concerned Dade Holdings’ acquisition of fifty percent stake in Jilin Sichang Pharmaceutical (the “*Dade/Sichang*” case). Dade Holdings acquired the fifty percent stake in the target in two steps: nineteen percent stake were acquired in 2011 and the other thirty-one percent in 2015. The MOFCOM found the second step to amount to an acquisition of control, but Dade Holdings had already implemented the second step, registering the increased stake in the business license. The MOFCOM imposed a fine of RMB 150,000 on Dade Holdings, taking into account the fact that Dade Holdings submitted the notification on its own initiative after implementing the second step.⁹² Both the *Fosun/Erye* case and the *Dade/Sichang* case appear to have had a clear China nexus (*i.e.*, a Chinese target company) and the fines were imposed despite neither transaction ultimately being found to restrict competition. These two cases in the pharmaceutical sector follow the general trend that the MOFCOM has stepped up the enforcement against gun-jumping, but with two out of thirteen published decisions on gun-jumping, they clearly indicate that the pharmaceutical sector has attracted more attention from the MOFCOM compared to other sectors.

Management/Goldman Sachs/HRA Pharma case was unconditionally approved on 29 January 2016. See the MOFCOM List of Unconditionally Approved Case in the First Quarter of 2016, 6 April 2016, available at <http://fldj.mofcom.gov.cn/article/zcfb/201604/20160401290524.shtml>.

⁸⁹ See MOFCOM, PROVISIONAL MEASURES ON INVESTIGATING CONCENTRATIONS OF UNDERTAKINGS WHICH FAIL TO BE NOTIFIED, 30 December 2011, available at <http://fldj.mofcom.gov.cn/article/zcfb/201201/20120107921682.shtml>.

⁹⁰ It was reported that the MOFCOM has so far initiated investigations into sixty-two cases of failure to file, of which thirty-eight cases were closed and eight penalty decisions were published on the MOFCOM’s website. See PaRR, *China’s Three Antitrust Agencies Report Growing Enforcement in 2015*, ABA ASIA FORUM, (6 June 2016).

⁹¹ See Administrative Penalty Decision of the Ministry of Commerce, Shang Fa Han (2015) No. 669, 16 September 2015, available at <http://fldj.mofcom.gov.cn/article/ztxx/201509/20150901124896.shtml>.

⁹² See Administrative Penalty Decision of the Ministry of Commerce, Shang Fa Han (2016) No. 173, 21 April 2016, available at <http://fldj.mofcom.gov.cn/article/ztxx/201605/20160501311079.shtml>.

4. ANTI-COMPETITIVE AGREEMENTS

4.0 OVERVIEW

In the following three parts of this article, the impact of China's antitrust enforcement regime on the pharmaceutical industry is explored. Specifically, consideration will be given to how the day-to-day operations of pharmaceutical companies are affected by China's competition law provisions, to identifying certain commercial practices in the pharmaceutical sector that have attracted careful scrutiny from the NDRC and the SAIC, and to highlighting some of the more recent cases in the sector. Broadly, the focus of the NDRC and the SAIC is divided into three areas: anti-competitive agreements, abuse of market dominance and abuse of administrative power. In this specific part, the focus is on exploring anti-competitive agreements.

4.1 AGREEMENT, DECISION OR CONCERTED ACTION

Article 13 of the AML defines monopoly agreement as any agreement, decision or concerted action that eliminates or restricts competition.⁹³ Proving the existence of an agreement is not always straightforward. The anti-competitive agreement does not have to be in written form, legally binding or actually enforced.⁹⁴ Either direct or circumstantial evidence may be used to prove the existence of an agreement. In practice, it may be rare that there is direct evidence of an express agreement, so most often the NDRC and the SAIC may need to rely on circumstantial evidence to find the existence of an agreement. In the *Allopurinol Tablets* cartel case, the NDRC relied on a set of direct and circumstantial evidence to determine that the companies reached an agreement to increase the price of allopurinol tablets and allocate the market between them. Such evidence included the distribution agreements, minutes of meetings, interview notes, sales record, and financial data.⁹⁵

An express agreement will definitely show concerted action, but a formal agreement is not necessary to establish concerted action. Allegations of concerted action are frequently based on a pattern of uniform conduct. Concerted action is quite conventional in other jurisdictions, but was unusual in China until the *Estazolam APIs/tablets* cartel case. In the *Estazolam APIs/tablets* cartel case, although the NDRC did not use the word, the "agreement" to increase the prices of the tablet form estazolam is described more in terms of a concerted action. The NDRC seemed to concede there was no agreement as to increasing prices, but that one company signalled an appropriate price point and others followed. The NDRC found that between September and October 2014, Huazhong Pharmaceutical, Shandong Xinyi and Changzhou Siyao met in Zhengzhou City to discuss business arrangements related to estazolam APIs and tablets. The companies did not reach any agreement on detailed price-fixing, but Huazhong Pharmaceutical proposed raising prices for estazolam tablets and the other two companies did not object. Relevant sales data showed that from October 2015 onwards, prices of Huazhong

⁹³ See AML, Art. 13.

⁹⁴ AML, Art. 46 provides that "if the agreement has been concluded but has not been implemented, a fine of up to RMB 500,000 may be imposed on the undertakings concerned."

⁹⁵ See, for example, the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 1, 15 January 2016, available at http://jjs.ndrc.gov.cn/fjgld/201602/t20160202_774107.html.

Pharmaceutical's estazolam tablets increased, and the other two companies increased prices for their products around the same time. The NDRC found that the increased price was the target price proposed by Huazhong Pharmaceutical at the Zhengzhou meeting.⁹⁶

The reference to decisions in the definition of monopoly agreement is often relevant to the actions of trade associations. Trade associations have attracted scrutiny from both the NDRC and the SAIC. The AML expressly prohibits trade associations from adopting anti-competitive rules, encouraging anti-competitive agreements between members or implementing decisions designed to eliminate or restrict competition.⁹⁷ To date, there are no reported cases in China of investigations into the practices of trade associations in the pharmaceutical sector. Nevertheless, there have been a number of examples of enforcement on the practices of trade associations. Both the NDRC and the SAIC have carried out investigations into cartels instigated by trade associations.⁹⁸ In the *Vitamin C* litigation in the US, the alleged anti-competitive practices arose from certain decision-making practices by one of China's trade associations in the pharmaceutical sector.⁹⁹

⁹⁶ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 5, 22 July 2016; the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 6, 22 July 2016; and the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 7, 22 July 2016.

⁹⁷ For example, Art. 9 of the Rules on the Prohibition of Monopoly Agreements prohibits a trade association from encouraging or facilitating prohibited anti-competitive agreements between its members such as by: (1) formulating or promulgating charters, rules, decisions, notices and standards that eliminate or restrict competition; and (2) convening, organizing or encouraging undertakings in the industry to enter into agreements, resolutions, minutes or memoranda that eliminate or restrict competition. Similarly, Article 9 of the Rules on Price-related Monopoly Agreements prohibits trade associations from: (1) formulating rules, decisions or notices that eliminate or restrict competition in terms of price; (2) organizing undertakings to enter into price-related monopoly agreements prohibited by these Rules; and (3) taking any other measures that encourage undertakings to enter into or implement price-related monopoly agreements.

⁹⁸ For example, on 4 January 2011, the NDRC fined the Zhejiang Fuyang Paper Making Industry Association for facilitating its members in relation to engaging in monopoly acts, in breach of both the AML and the Price Law. See the NDRC News Release, Zhejiang Fuyang Paper Making Industry Association was Fined for Reaching Price-fix Agreement (4 January 2011), available at http://www.sdpc.gov.cn/fzgggz/jggj/zhd/201101/t20110104_389454.html. On 26 January 2011, the Jiangsu Administration for Industry and Commerce fined the Concrete Committee of the Construction Materials and Construction Machinery Industry Association of Lianyungang City and sixteen concrete manufacturers for, *inter alia*, market sharing in breach of the AML. See the SAIC News Release, AIC Closed its First Administrative Monopoly Case (26 January 2011), available at http://www.saic.gov.cn/ywdt/gsyw/dfd/xxb/201101/t20110126_103772.html. More recently, on 16 August 2016, the Hubei Administration for Industry and Commerce announced its decision to fine the provincial insurance industry association RMB 200,000 for facilitating its members to enter into anti-competitive agreements. See the Administrative Penalty Decision of the Hubei Administration for Industry and Commerce, E Gong Shang Chu Zi (2016) No. 201, 6 May 2016, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201608/t20160816_170434.html.

⁹⁹ The trade association concerned was the China Chamber of Commerce for Import & Export of Medicines & Health Products. See *In re Vitamin C Antitrust Litigation*, 584 F. Supp. 2d 546. (E.D.N.Y 2008).

4.2 AGREEMENTS THAT ARE EXPRESSLY PROHIBITED UNDER THE AML

Articles 13 and 14 of the AML provide a list of anti-competitive agreements, which covers both price-related and non-price related anti-competitive agreements. Examples of price-related anti-competitive agreements include price fixing and resale price maintenance (“RPM”) and examples of non-price related anti-competitive agreements include limiting production or sales volumes, dividing sales or procurement markets, restricting the purchase of new technology or new products, and concerted refusals to deal.¹⁰⁰ Article 15 of the AML allows companies to justify anti-competitive agreements under Articles 13 and 14. To benefit from Article 15, the companies concerned must meet all of the following conditions: (i) the agreement concerned must have a qualifying purpose; (ii) the agreement concerned must not substantially restrict competition in the relevant market; and (iii) consumers will receive a fair share of the resulting benefits.¹⁰¹

As of December 2016, several pharmaceutical companies have been investigated by the NDRC for participating in anti-competitive agreements. However, to date, there is no public record that an anti-competitive agreement has been successfully benefitted from Article 15 of the AML. In the *Allopurinol Tablets* cartel case, the NDRC found that the three allopurinol tablet manufacturers and two distributors held four meetings from April 2014 to September 2015 in order to reach and implement agreements to increase the price of allopurinol tablets. Additionally, the three allopurinol tablet manufacturers agreed to divide the sales market for allopurinol tablets by limiting their respective tendering activities to within the sales area allocated to each manufacturer.¹⁰² The *Estazolam APIs/tablets* cartel case concerned an agreement between the only three producers of estazolam API not to supply other manufacturers of estazolam tablets and to increase the price of the tablets they themselves sold.¹⁰³ In the *Medtronic RPM* case, the NDRC expressly mentioned that Medtronic did not argue that any restriction in competition might be offset by the countervailing benefits listed in Article 15 of the AML.¹⁰⁴

RPM has been a key focus of the NDRC’s enforcement in recent years.¹⁰⁵ The *Medtronic*

¹⁰⁰ See AML, Arts. 13 and 14.

¹⁰¹ See AML, Art. 15. Examples of the “qualifying purpose” include: (1) to update technology, research and develop products; (2) to improve product quality, reduce cost, improve efficiency and implement standardization; (3) to enhance the competitiveness of small and medium-sized enterprises; (4) to protect public interests; (5) to mitigate economic recession; or (6) to protect legitimate interests in international trade and foreign economic cooperation.

¹⁰² See Press Release, NDRC, NDRC Investigated Allopurinol Tablets Cartel Case, *available at* http://jjs.ndrc.gov.cn/fjgld/201601/t20160128_772982.html (last visited 17 April 2017).

¹⁰³ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 5, 22 July 2016; the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 6, 22 July 2016; and the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 7, 22 July 2016.

¹⁰⁴ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 8, 5 December 2016, *available at* http://jjs.ndrc.gov.cn/fjgld/201612/t20161209_829716.html.

¹⁰⁵ For example, in February 2013, the Guizhou DRC imposed a fine of RMB 247 million on Kweichow Moutai and the Sichuan DRC imposed a fine of RMB 202 million on Wuliangye Group for RPM; in

RPM case is the first case on RPM in the pharmaceutical sector. The NDRC's decision concerns conduct which looked like conventional RPM—for example, getting distributors to stick to the price lists determined by Medtronic through a combination of incentives and penalties. The decision also refers to fixed margins and approvals for bid prices.¹⁰⁶ Considering that pharmaceutical companies usually adopt the distribution business model in the sale of their pharmaceutical products, pharmaceutical companies must be aware that RPM remains to be a key focus of the NDRC's enforcement and distributors must be able to freely set their resale price.

One issue worth noting in the area of RPM is the potential different approaches between the NDRC and the courts.¹⁰⁷ In practice, the NDRC takes a “prohibition plus exemption” approach to analyze monopoly agreements, under which the monopoly agreements listed in Articles 13 and 14 are presumed to be anti-competitive and the companies being investigated have the burden of proving that the agreements can be justified under Article 15.¹⁰⁸ In the *Johnson & Johnson/Ruibang* case, however, the Shanghai High Court held that the RPM is not presumed to be anti-competitive and the anti-competitive effect of the challenged RPM must be analyzed before it is ruled to be illegal. In particular, the Shanghai High Court adopted a “four-element” analytical framework: competition in the relevant market, the defendant's market power, the defendant's intent to enforce the RPM, and the competitive effects.¹⁰⁹ Although the NDRC's case law indicated that the approaches taken by the NDRC and the local DRCs were not necessarily consistent and that in certain cases the NDRC also conducted an analysis on the anti-competitive effect of the challenged RPM,¹¹⁰ there still seems to be more divergence than

August 2013, the NDRC announced that it imposed a total fine of RMB 668.73 million on six infant formula manufacturers for RPM; in May 2014, the NDRC announced that it imposed a total fine of RMB 19 million on seven eyeglasses manufactures for RPM; in September 2014, the Shanghai DRC imposed a fine of RMB 31.7 million on Chrysler and the Hubei DRC imposed a fine of RMB 248 million on Audi for RPM; in April 2015, the Jiangsu DRC imposed a fine of RMB 350 million on Mercedes-Benz for RPM; and in September 2015, the Guangdong DRC imposed a find of RMB 123.3 million on Dongfeng-Nissan for RPM.

¹⁰⁶ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 8, 5 December 2016, available at http://jjs.ndrc.gov.cn/fjgld/201612/t20161209_829716.html.

¹⁰⁷ As explained above, the the NDRC focuses on price-related conduct, while the SAIC is responsible for non-price-related conduct. Therefore, the SAIC is theoretically not involved in RPM-related cases.

¹⁰⁸ The former Director-General of the NDRC's Price Supervision and Anti-Monopoly Bureau indicated that the legal principle towards vertical monopoly agreement is “prohibition plus exemption”. He further pointed out that this approach also applies to horizontal monopoly agreement. See K. Xu, *The Application of the Leniency Program to Vertical Agreement*, CHINA ECONOMIC HERALD, available at <http://www.ceh.com.cn/xwpd/2013/10/255896.shtml> (last visited 17 April 2017).

¹⁰⁹ See Judicial Decision of Shanghai High Court, (2012) Hu Gao Min San [Zhi] Zhong Zi, No. 63, available at http://www.hshfy.sh.cn/shfy/gweb/flws_view.jsp?pa=adGFoPaOoMjAxMqOpu6a438PxyP0o1qop1tXX1rXaNjO6xSZ3c3hoPTUPdcssz.

¹¹⁰ For example, in the investigation against Kweichou Moutai, the Guizhou DRC did not elaborate on the reasons behind the decision. At the same time, however, in the investigation against Wuliangye Group, the Sichuan DRC conducted an analysis on the inter-brand and intra-brand competition and the interest of consumers.

convergence between the administrative enforcement and the private litigation of RPM.¹¹¹

4.3 AGREEMENTS THAT ARE NOT EXPRESSLY PROHIBITED UNDER THE AML

4.3.0

Assessment of agreements that are not expressly prohibited under the AML presents special challenges. Both Article 13 and Article 14 of the AML empower the enforcement authorities to enforce against other agreements determined by the enforcement authorities to be anti-competitive. Certain common practices and important business activities in the pharmaceutical sector may also attract particular attention from the enforcement authorities.

4.3.1 Collaboration agreements

Examples of collaboration agreements include strategic alliances, co-promotion agreements, and research and development agreements. These are increasingly common in the pharmaceutical sector in China and often form important parts of market participants' business strategies. Collaboration agreements in China can take different forms ranging from transactions with structural dimension, which require assessment under the merger control rules, to agreements that offer a loose-knit, non-structural form of collaboration. For example, a co-promotion agreement can be structured with or without a structural dimension but still offer the same or similar benefits to the parties. A structural co-promotion agreement might include the creation of a joint venture with a corporate identity and the necessary resources, including financing, assets and personnel, to conduct business in the relevant market. However, there is no express requirement under the AML or its implementation rules that a joint venture needs to be incorporated as a legal entity in order to constitute a notifiable concentration.¹¹² The fact that activities are organized contractually is not in and of itself an obstacle to creating a notifiable joint venture, provided it brings about a structural change to the activities of its parents on the relevant markets in the same way as an incorporated legal entity.¹¹³

¹¹¹For example, there is a significant divergence as to whether the structure of the AML's application to RPM should follow strictly the "prohibition plus exemption" approach; whether there is a need to define the relevant market and to evaluate the competitiveness of the market; whether it is necessary to analyze the intent of the defendant to conduct RPM and to balance the anti-competitive and pro-competitive effects. See S. Jiang and D.D. Sokol, *Resale Price Maintenance in China: An Economic Perspective*, 3 JOURNAL OF ANTITRUST ENFORCEMENT Suppl. 1, i132 (2015).

¹¹²The AML provides that a concentration may arise through contract although it does not indicate the specific circumstances in which this can occur.

¹¹³With its prohibition of the establishment of the network center by Maersk, MSC and CMA CGM (the "P3 Alliance"), the MOFCOM had set a precedent to guide undertakings on what types of alliance arrangements must be filed to the MOFCOM for merger review. The proposed P3 Alliance was structured as a limited liability partnership. In its decision, the MOFCOM identified the P3 Alliance as a "tight joint operation" as the parties to the proposed P3 Alliance would integrate all their capacity through establishing a network center. The differences between such "tight joint operation" and a traditional loose-knit shipping alliance were rooted in the cooperation form, operational procedure, and cost allocation. See Public Announcement of the Ministry of Commerce on the Antitrust Review Decision on the Prohibition of the

A structural collaboration arrangement has certain merits in that it offers, *inter alia*, legal certainty if a notification to the MOFCOM is required for prior approval.¹¹⁴ However, the perceived merits of legal certainty will need to be carefully weighed against the additional compliance burdens of such an arrangement, including: the transaction costs associated with obtaining any necessary M&A approvals; drug registrations; dealing with corporate governance issues; and navigating China's merger control process. Non-structural form of collaboration can give rise to enforcement action if they are not carefully considered and planned. In China, collaboration agreements are not presumed to be anti-competitive. Neither the SAIC nor the NDRC have made any special pronouncements on collaboration agreements in the pharmaceutical sector. Nevertheless, there is a potential for violation of the AML to the extent that any such agreement includes, for example, territorial or customer allocation, allows for exchange of commercially sensitive information, adopts exclusive dealing spanning several years, or fixes minimum sales targets. Therefore, sufficient safeguards should be adopted to ensure that commercially sensitive information is cautiously ring-fenced, and careful consideration is given to the appropriateness of market or customer allocation. In particular, the competition risk profile is heightened in cases where the pharmaceutical companies involved in a given collaboration agreement compete head-to-head and are each other's closest competitors in the market concerned by the agreement.

4.3.2 Supply and distribution agreements

Article 14 of the AML expressly prohibits supply and distribution agreements that fix the price of commodities for resale to a third party, or restrict the minimum price of commodities for resale to a third party. These are the most problematic category of anti-competitive restrictions, and it is the NDRC that has the competence to prohibit such price-related anti-competitive agreements.¹¹⁵ With respect to what other types of provisions in a supply or distribution agreement would be considered anti-competitive, the AML and the implementation rules are far less clear on the point.¹¹⁶

In the pharmaceutical sector, a case that is worth noting on this issue is the *Compound Reserpine APIs* exclusivity case. The case concerned the exclusive supply of a raw material used in a hypertension drug. The raw material is manufactured in China by only two companies. Two pharmaceutical companies, Weifang Shuntong Pharmaceutical Co. Ltd. ("Shuntong") and Weifang Huaxin Pharmaceutical Trading Co. Ltd. ("Huaxin") benefitted from the exclusive supply from the two raw material manufacturers. Following grant of exclusive supply, Shuntong and Huaxin increased the price of the raw material. This case was pursued by the NDRC, which

Establishment of the Network Center by Maersk, MSC and CMA CGM (2014) No. 46, 17 June 2014, available at <http://fldj.mofcom.gov.cn/article/ztxx/201406/20140600628586.shtml>.

¹¹⁴Note, however, that the conduct of the structural entity that emerges following the transaction remains subject to the AML provisions that govern anti-competitive conduct.

¹¹⁵See S. Marco Colino, *Distribution Agreements under China's Anti-Monopoly Law and the Hong Kong Competition Ordinance*, 1 CHINA ANTITRUST LAW JOURNAL 67 (2017).

¹¹⁶In fact, the SAIC's earlier draft of the Monopoly Agreement Rules identified a number of non-price-related vertical agreements that could be caught by the AML. However, such provisions were deleted when the SAIC Monopoly Agreement Rules were officially issued.

the exclusivity supply and the increase in the price of the raw material led to significant increase in prices of the drug.¹¹⁷ In the *Medtronic RPM* case, it is worth noting that there are a number of references to restrictions on cross-territory sales and/or resale to individual consumers and a prohibition on distributors selling competing products.¹¹⁸ The extent to which a supplier can allocate customers or territories to its distributors is uncertain under the AML and unfortunately the *Medtronic RPM* case does nothing to clarify the position other than to suggest such restrictions can be unlawful—at least insofar as such conduct would exacerbate the effects of RPM. The SAIC, which is responsible for non-price-related conduct, may be expected to provide more guidance on these issues in the future.

4.3.3 Cooperation with generics manufacturers

One area that has been of particular sensitivity to enforcement authorities in other jurisdictions has been anti-competitive agreements between pioneer pharmaceutical manufacturers and generics manufacturers.¹¹⁹ As is well known, many multinational pharmaceutical companies are facing a “patent cliff”, with intellectual property rights (“IPR”) protection on a range of key drugs reaching the end of their exclusivity periods. Furthermore, despite significant research and development investments, the number of new drugs being brought into the market has experienced a steady decline. A priority for enforcement authorities in other jurisdictions has thus been to ensure that originator drug companies do not attempt to mitigate this situation by striking deals with generics manufacturers to delay the arrival on the market of competing generic products, or engage in practices that block or delay the development of competing originator drugs.

Problematic practices in this regard may include: agreements between originator drug manufacturers and generic drug manufacturers that delay or intend to delay generic drug competition; accords which serve to keep prices high; payments made by originator drug manufacturers in exchange for delayed entry; or commercial arrangements that result in higher

¹¹⁷ See, Press Release, NDRC, Two Pharmaceutical Companies Were Penalized for Monopolizing Raw Materials Used in Hypertension Drugs (15 November 2011), available at http://jjs.ndrc.gov.cn/fjgld/201203/t20120306_465386.html.

¹¹⁸ See the Administrative Penalty Decision of the National Development and Reform Commission (2016) No. 8, 5 December 2016, available at http://jjs.ndrc.gov.cn/fjgld/201612/t20161209_829716.html.

¹¹⁹ For example, see *Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements Before the S. Committee on the Judiciary*, (statement of the US Department of Justice on 24 May 2001), available at <https://www.justice.gov/atr/competition-pharmaceutical-marketplace-antitrust-implications-patent-settlements>. In the EU, the European Commission launched a sector inquiry into pharmaceuticals in 2008. It examined the reasons why fewer new medicines were being brought to market and why generic entry seemed to be delayed in some cases. Preliminary results were published in November 2008 with a final report in July 2009. The inquiry highlighted certain shortcomings in the pharmaceutical sector in the EU, including pay-for-delay patent settlements. On 8 September 2016, the European General Court upheld the European Commission’s *Lundbeck* decision and ruled for the first time that pharmaceutical pay-for-delay agreements breach the EU antitrust rules. See Press Release, European Commission, Commission Welcomes General Court Judgments Upholding its Lundbeck Decision in First Pharma Pay-for-delay Case (8 December 2016), available at http://europa.eu/rapid/press-release_MEMO-16-2994_en.htm.

costs for national reimbursement schemes. These arrangements are frequently referred to as pay-for-delay agreements. Some of the issues raised by these practices have drawn special attention from enforcement authorities in other jurisdictions such as the US and the EU.¹²⁰ While the Chinese enforcement authorities have yet to focus on this controversial area, in the light of the developments elsewhere it is reasonable to expect that it will attract increased attention in a not too distant future.

5. ABUSE OF DOMINANCE

5.1 THE NOTION OF DOMINANCE

Abuse of dominance addresses the special position and responsibilities of dominant companies. In the case of anti-competitive practices involving dominant companies, the challenge for the enforcement authorities is, firstly, to establish dominance, and then to demonstrate unlawful conduct. In China, the term dominant market position is defined as a market position where an undertaking has the ability to control price, quantity and other trading terms such as quality, or to restrict or foreclose market entry.¹²¹ The reference to “other trading conditions” includes factors other than “the price or quantity of commodities, which may have a material effect on trade, including, amongst others, the quality of commodities, payment conditions, methods of delivery and post-sales services”.¹²² The issues which will be taken into account in determining whether an undertaking is dominant include market share, the ability to control the sales market or the procurement market for raw materials, financial and technical strength, the extent of reliance by other undertakings on the undertaking and barriers to entry.¹²³

There are market share thresholds that can lead to a presumption of dominance. Dominance is presumed where an undertaking has a market share of fifty percent, and where two undertakings hold two thirds of the market, or where three undertakings hold three-quarters of the market. Conversely, there is a rebuttable presumption that an undertaking is not dominant if its market share is below ten percent. In addition, where an undertaking that has been presumed to be dominant can prove that it is not dominant, it shall not be determined as having a dominant market position.¹²⁴ The holding of IPRs is one of the multiple factors that may help to determine dominance, but an undertaking shall not be presumed to have a dominant market position in the relevant market merely on the basis of holding IPRs.¹²⁵ It may not be difficult for the enforcement authorities to demonstrate dominance in the pharmaceutical sector: it may be easily determined for patent-protected drugs and generic drugs if the market shares held are significant.

¹²⁰On pay-for-delay practices in the EU and the US, see S. Marco Colino, N. Dunne, K. Fournier, S. Pais and D. Ritzmann, *The Lundbeck Case and the Concept of Potential Competition*, CONCURRENCES REVIEW (forthcoming Issue 2, 2017).

¹²¹See AML, Art. 17.

¹²²See the SAIC ABUSE OF DOMINANCE RULES, Art. 3.

¹²³See AML, Art. 18.

¹²⁴See AML, Art. 19.

¹²⁵See Art. 6, (*Rules on the Prohibition of Abuses of IPRs for the Purposes of Eliminating or Restricting Competition*).

This is likely to be the case in niche markets where only a small number of companies are active, whether international or domestic, and also in cases where the enforcement authorities were minded to define markets along provincial lines or price bands, or to distinguish between originator and generic drugs. All of these factors would make for narrow market definitions.¹²⁶

In the context of antitrust litigation in China, however, proving dominance has been a difficult task and the plaintiffs who have attempted to enforce the dominance provision have been overwhelmingly unsuccessful. There has not been any leading case specifically dealing with pharmaceuticals on this issue, but cases in other sectors may shed light on the difficulty for plaintiffs to prove that a defendant is dominant. For example, in *Qihoo 360 v. Tencent*, the Supreme People’s Court ruled that even though Tencent held an eighty percent share of the market for instant messaging services, there was insufficient evidence to indicate that Tencent held a dominant market position as Tencent had limited power to control prices, quality, quantity or restrictions on trading terms.¹²⁷

5.2 ABUSIVE CONDUCT

The AML prohibits undertakings from abusing a dominant market position by selling at unfairly high prices or purchasing at unfairly low prices, selling below cost, refusals to deal, exclusive dealing, tying or imposing unreasonable conditions, or price discrimination.¹²⁸ The concept of abuse is an objective one, which refers to conduct by a dominant company which seriously and unjustifiably distorts competition or leads to weakening of competition on the relevant market. As for establishing whether a given conduct is abusive, the focus of the enforcement authorities would be on whether the given conduct is objectively justified. There is no exact equivalent of Article 15 AML, which provides an exemption for conduct falling under Article 13 and Article 14. However, the concept of “objective justification” has some similarities. Another point worth emphasizing is that abusive conduct must be conducted by undertakings with a dominant market position, which means dominant companies have “special responsibility”: conduct which is permitted when dominance does not exist can be an abuse when engaged in by a dominant company.

5.3 TYPES OF ABUSIVE CONDUCT

5.3.0

Some types of abusive conduct are particularly relevant in the pharmaceutical sector in the context of China. These include excessive pricing and refusal to deal. Both of these practices are examined below.

5.3.1 Excessive pricing

The AML prohibits undertakings from abusing a dominant market position by selling at

¹²⁶For reference, see our discussion on market definition in the pharmaceutical sector in Part 2.3.

¹²⁷See the Supreme People’s Court’s judgment, (2013) Min San Zhong Zi No. 4, available at <http://www.court.gov.cn/xwzx/yw/201410/P020141016368497539811.docx> (last visited 17 April 2017).

¹²⁸See AML, Art. 17.

unfairly high prices or purchasing at unfairly low prices.¹²⁹ In a comparative context, charging high prices does not violate US antitrust law in and of itself.¹³⁰ It is also rarely challenged in the EU.¹³¹ China is one of the very few authorities to actually have pursued excessive pricing cases in recent years. In China, excessive pricing has even been one of the key focuses of the NDRC's enforcement practice to date. In particular, in the Notice on Strengthening the Supervision of Pricing Activities in the Pharmaceutical Industry, abuse of dominance through excessive pricing was expressly listed as an unlawful activity which would be subject to careful scrutiny.¹³² Therefore, excessive pricing is likely to be a key concern for the NDRC in the pharmaceutical sector.

In practice, it can be extremely difficult to determine to what extent prices are “unfairly high” and to what extent the prices are “fair”. The NDRC Price-related Monopolies Rules provide some guidance on the factors that shall be considered when determining “unfairly high prices” or “unfairly low prices”: (i) whether the sale price is obviously higher than the price at which other undertakings sell the same commodity, or whether the purchase price is obviously lower than the price at which other undertakings purchase the same commodity; (ii) where the cost remains stable, whether a rise in the sale price or a reduction to the purchase price exceeds the normal range; and (iii) whether the range of price increase on resale is obviously higher than the rate of increase in cost; or whether the range of price reduction in purchase obviously higher than the rate of reduction in the cost of the trading counterparty.¹³³ As there has been only limited guidance on what constitute “unfairly high prices” or “unfairly low prices”, the NDRC enjoys significant discretion when determining whether and when prices are unfairly high or low. Although the NDRC stated it will pay special attention to excessive pricing in the pharmaceutical sector, there has not been any leading case in the pharmaceutical sector in which the NDRC challenged a pharmaceutical company on the basis of excessive pricing. However, based on the case law of the NDRC in other sectors, pharmaceutical companies should be aware of several characteristics manifested in the NDRC's enforcement against excessive pricing.

First, the NDRC is particularly concerned over prices being higher in China than elsewhere.¹³⁴ Therefore, it seems that the NDRC is particularly concerned over “discriminatorily

¹²⁹ See AML, Art. 17.

¹³⁰ See United States submission to the Organisation for Economic Co-operation and Development (“OECD”), DAF/COMP/WP2/WD (2011) 65, available at <http://www.justice.gov/atr/public/international/278823.pdf> (last visited 17 April 2017).

¹³¹ Cases with an excessive pricing component have been a rarity in the UK and EU competition enforcement in line with the Court of Appeal in *Attheraces Limited v. The British Horseracing Board Limited*: “... the law on abuse of dominant position is about distortion of competition and safeguarding the interests of consumers in the relevant market. It is not a law against suppliers making ‘excessive profits’ by selling their products to other producers at prices yielding more than a reasonable return on the cost of production, *i.e.*, at more than what the judge described as the ‘competitive price level’.”

¹³² See NDRC, NOTICE ON STRENGTHENING THE SUPERVISION OF PRICING ACTIVITIES IN THE PHARMACEUTICAL INDUSTRY, Fa Gai Jia Jian (2015) No. 930, available at http://jjs.ndrc.gov.cn/zcfg/201505/t20150505_690681.html.

¹³³ See NDRC PRICE-RELATED MONOPOLIES RULES, Art. 11.

¹³⁴ It is worth noting that the NDRC is considering drafting a set of regulation to establish a price

excessive pricing” in China. This has been reflected in the Qualcomm investigation, in which the NDRC found that the royalty rates Qualcomm charged to Chinese licensees were not only excessive, but were also higher than that charged to licensees in other jurisdictions.¹³⁵ Therefore, pharmaceutical companies, in particular multinationals, should review the prices of their products in different jurisdictions and if the prices in China are higher than those in other jurisdictions, have a consistent way to explain this. Second, it can be extremely difficult to negotiate with the NDRC on what is a fair price. In practice, NDRC is acutely sensitive to the final sales price of pharmaceutical products and may focus on “low prices” rather than “competitive prices”. Third, the NDRC may adopt various benchmark and methodology in assessing whether prices are “high”, including direct comparison of prices in different jurisdictions, direct comparison of prices over the past few years, direct comparison of prices with other competitors and cost/margin analysis.¹³⁶ Fourth, there is a broader question of whether the NDRC’s role as price regulator can change quickly. Reform is happening, but it is unlikely to change the position on the ground for many years. For example, in the Qualcomm investigation, Qualcomm made a commitment to use a specific royalty rate of sixty-five percent of the net selling price of the device as “agreed by the NDRC”. Pharmaceutical companies may still find themselves to be in a position to negotiate specific prices or price levels with the NDRC or the local DRCs, particularly considering that prior to the pharmaceutical price reform in June 2015, the NDRC and the local DRCs were in charge of setting the prices or price ranges of pharmaceutical products.

5.3.2 Refusal to deal

The AML prohibits undertakings from abusing a dominant market position by refusing to deal with trading counterparties without justification.¹³⁷ The SAIC Abuse of Dominance Rules set forth the specific types of activities that may be regarded as refusing to deal from the SAIC’s perspective, including reducing the existing business volume, delaying or suspending on-going business, refusing to engage in new businesses, setting restrictive conditions to make it difficult to

monitoring system of pharmaceutical products, under which for a product sold in/imported to China, the NDRC intends to request price information on the product in the UK, the Netherlands, France, Canada, Australia, Brazil, South Africa, Japan, Korea, Hong Kong, Macau and Taiwan as well. This clearly indicates that the NDRC is interested in understanding whether and why prices in China are higher than those in other jurisdictions.

¹³⁵In the *Qualcomm* investigation, the NDRC identified the following abusive conduct when Qualcomm charged license fees to Chinese licensees which led to excessive pricing: (i) Qualcomm failed to provide its patent list to Chinese customers during negotiations, included expired patents in its patent portfolio and charged for the expired patents; (ii) Qualcomm required Chinese companies to cross license their patents to Qualcomm free of charge, and without deducting the value of the cross licensed patent from the Qualcomm licensing fee; and (iii) Qualcomm’s patent licensing fee was calculated on the basis of the wholesale net selling price of the mobile phone. See Press Release, the NDRC, NDRC Ordered Qualcomm to Rectify Its Monopolistic Conduct and Imposed a Fine of RMB 6 Billion on Qualcomm (10 February 2015), available at http://jjs.ndrc.gov.cn/gzdt/201502/t20150210_663872.html.

¹³⁶See X. Xinyu, *Lessons Learned from the Antitrust Enforcement in the Pharmaceutical Sector in the UK (I): An Analysis of the Pfizer Case*, in PRICE SUPERVISION AND ANTI-MONOPOLY IN CHINA (Vol. 5, 2016); also see Y. Zeng, *On the Methodology of Determining Unfair Prices in the Antitrust Enforcement*, in PRICE SUPERVISION AND ANTI-MONOPOLY IN CHINA (Vol. 10, 2016).

¹³⁷See AML, Art. 17.

continue to conduct business, or refusing to give access on reasonable terms to essential facilities for production and operation activities. According to the SAIC Abuse of Dominance Rules, when determining “essential facilities” a comprehensive analysis should all be conducted with several factors to be considered, including the feasibility of investing in or developing and constructing such facilities, the trading counterparty’s reliance on the facilities to effectively conduct production and operational activities, the likelihood that the undertaking may provide access to the facilities and the possible effects on the undertaking’s own production or operational activities arriving from providing access to the facilities.¹³⁸ The justifications that may be considered by the SAIC include: (i) whether the refusal to deal is based on ordinary operations and efficiency of the undertaking; and (ii) the impact of the refusal to deal on economic efficiency, social and public interests and economic development.¹³⁹

The NDRC Price-related Monopolies Rules also set forth the specific measures that may be regarded as refusing to deal from the NDRC’s perspective: if an undertaking with dominant market position sets an excessively high sale price or an excessively low purchase price, it can be regarded as refusing to deal.¹⁴⁰ The justifications that may be considered by the NDRC include: (i) the trading counterparty has a very poor credit record, or its operations are in a state of continuous deterioration, which may expose the deal to material commercial risks; and (ii) the trading counterparty is able to purchase the same or substitutable commodities from other undertakings at a reasonable price, or is able to sell the commodity to other undertakings at a reasonable price.¹⁴¹

In the pharmaceutical sector, refusal to supply an indispensable input used for the production of a specific pharmaceutical product may be regarded as a specific type of refusal to deal. The *Allopurinol APIs* abuse case is the first published decision by the SAIC or the Local AICs finding a refusal to deal in breach of the AML. In the *Allopurinol APIs* abuse case, Chongqing Qingyang had entered into an exclusive distribution agreement with Hunan Xiangbaihe, but they subsequently refused to supply allopurinol APIs, an indispensable input used for the production of allopurinol tablets, to Hunan Xiangbaihe or any other companies from October 2013 to March 2014. At the same time, however, Chongqing Qingyang ramped up its own production of allopurinol tablets, increasing its market share from ten percent to close to sixty percent. The Chongqing AIC found that Chongqing Qingyang had a dominant market position and that the company had abused that position in the upstream market (allopurinol APIs) to exclude competition in the downstream market (allopurinol tablets), which resulted in significant increases in the price of allopurinol APIs as well as allopurinol tablets. The Chongqing AIC concluded that the refusal to supply could not be justified after examining several factors including the purpose for executing the exclusive agreement and the purposes and effects of the refusal to supply. The Chongqing AIC specifically noted that the refusal to deal was not “commercially reasonable” based on Chongqing Qingyang’s ordinary operations and efficiency and had the purpose of maximizing its monopoly profits. The Chongqing AIC also analyzed the

¹³⁸ See SAIC ABUSE OF DOMINANCE RULES, Art. 4.

¹³⁹ See SAIC ABUSE OF DOMINANCE RULES, Art. 8.

¹⁴⁰ See NDRC PRICE-RELATED MONOPOLIES RULES, Art. 13.

¹⁴¹ See NDRC PRICE-RELATED MONOPOLIES RULES, Art. 13.

actual effects of the abusive conduct, and held that Chongqing Qingyang's abusive conduct caused significant harm to the market and customers.¹⁴²

In the *Phenol APIs* abuse case, the Chongqing AIC for the second time found a refusal to deal in breach of the AML. Chongqing Southwest had entered into a general agency agreement with Shangqiu Xinxianfeng in February 2014 and refused to supply phenol APIs to any company from February to April 2014. From May to December 2014, Chongqing Southwest only supplied phenol APIs to Shangqiu Xinxianfeng and five other companies which had never conducted business with Chongqing Southwest before May 2014. During this period, Chongqing Southwest refused to supply phenol APIs to a large number of companies even though these companies requested Chongqing Southwest to supply phenol APIs. Chongqing Southwest explained that it refused to supply phenol APIs because: (i) there were companies that used industrial or expired phenol APIs to produce salicylic acid and phenol plasters since 2013 which caused the sales volume of phenol APIs to decrease, and Chongqing Southwest needed a company to “clean up the market”; (ii) Chongqing Southwest's sales team was too small to handle a large number of customers; and (iii) Chongqing Southwest had resumed normal supply of phenol APIs since August 2014. The Chongqing AIC rejected each of the reasons submitted by Chongqing Southwest. The Chongqing AIC further found that Chongqing Southwest and Shangqiu Xinxianfeng agreed to increase price and sales volume in their general agency agreement and noted that the refusal to deal was with the purpose of maximizing its monopoly profits. The Chongqing AIC also analyzed the actual effects of the abusive conduct, and held that Chongqing Southwest's abusive conduct caused significant harm to the market and the customers.¹⁴³

Refusal to deal is a controversial issue in antitrust enforcement, not least in the pharmaceutical industry. The question of whether the raw material manufacturers have the obligation, or may be forced, to supply the raw materials to their competitors can be particularly difficult and uncertain. In addition, the application of the “essential facilities” doctrine referred to in the SAIC Abuse of Dominance Rules may be challenging. The essential facilities doctrine itself is controversial and not at all generally accepted. For example, in the EU, the essential facilities doctrine would apply only in situations involving a natural monopoly.¹⁴⁴ It remains to be seen whether the *Allopurinol APIs* case may lead to a more frequent use of the AML's refusal to deal provision by the enforcement authorities.

¹⁴²See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2015) No. 15, 28 October 2015, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201512/t20151221_165120.html.

¹⁴³See the Administrative Penalty Decision of Chongqing Administration for Industry and Commerce (2016) No. 15, 24 November 2016, available at http://www.saic.gov.cn/zwgk/gggs/jzzf/cfjd/201612/t20161213_173318.html.

¹⁴⁴The European Commission in its Article 102 Exclusionary Guidance Paper refers only to “natural monopoly” cases when discussing refusal to grant access to an essential facility. See Guidance on the Commission's Enforcement Priorities in Applying Article 82 of the EC Treaty to Abusive Exclusionary Conduct by Dominant Undertakings, 2009 O.J. (C 45) 7, paragraph 78 and footnote 52.

6. ADMINISTRATIVE MONOPOLY

6.0 OVERVIEW

Unlike many other antitrust laws in different jurisdictions, the AML also prohibits so-called “administrative monopoly”, which refers to the abuse of administrative powers by administrative authorities and organizations to eliminate or restrict competition. In this part of the paper, the application of the administrative monopoly provisions to the pharmaceutical sector is briefly discussed. As a related issue, the recently established “fair competition review system” is also subject to analysis.

6.1 ABUSE OF ADMINISTRATIVE POWERS

Under the AML, it is an infringement of competition rules for an administrative authority or organization empowered by laws and regulations to administer public affairs to eliminate or restrict competition by abusing their administrative power.¹⁴⁵ Specifically, the AML prohibits the following behavior by the administrative authorities or organizations: restricting an entity or individual from operating; purchasing or using commodities provided by undertakings that they designate; hindering the free circulation of commodities across regions; eliminating or restricting non-local undertakings from participating in local bidding activities; restricting the investment or the establishment of branches of non-local undertakings in the local market; coercing any undertaking to engage in monopolistic conduct, and formulating regulations that eliminate or restrict competition.¹⁴⁶

The AML, however, does not empower the NDRC nor the SAIC to directly impose penalties on the administrative authorities or organizations that abused their administrative powers and violated the administrative monopoly provisions of the AML. In practice, the NDRC or the SAIC can only issue a recommendation letter to the administrative authorities that supervise the infringing administrative authorities or organizations, requesting rectification measures to be taken. Recently, there has been an uptick of enforcement against the abuse of administrative powers. Both enforcers have targeted the abuse of administrative powers as a key area in their work plan and heightened their scrutiny of abuse of administrative powers.¹⁴⁷

¹⁴⁵ See AML, Art. 8.

¹⁴⁶ See AML, Arts. 32–37.

¹⁴⁷ As for the NDRC, “enforcement against abuse of administrative powers” has been listed as one of the key areas of the NDRC’s work in 2016. See the PRICE SUPERVISION AND ANTI-MONOPOLY BUREAU, KEY WORK OF THE PRICE SUPERVISION AND ANTI-MONOPOLY BUREAU IN 2016, in PRICE SUPERVISION AND ANTI-MONOPOLY IN CHINA (Vol. 2, 2016); see also H. Zhang (Director-General of the Price Supervision and Anti-Monopoly Bureau of the NDRC), *Overview of the Work in 2015 and the Arrangement of the Work in 2016 for the Price Supervision and Anti-Monopoly Bureau of NDRC*, in PRICE SUPERVISION AND ANTI-MONOPOLY IN CHINA (Vol. 3, 2016). As for the SAIC, the SAIC announced in April 2016 that it would conduct a nationwide campaign from April to October 2016 to crack down on abuse of administrative powers in the public sector. See Press Release, the SAIC, Public Announcement of the Administration for Industry and Commerce on Typical Issues regarding Restricting Competition and Conducting Monopolistic Behavior by the Public Enterprises (11 April 2016), available at http://www.saic.gov.cn/fldyfbzdjz/gzdt/201604/t20160411_167855.html.

In August 2015, the NDRC issued a recommendation letter and requested the Bengbu Municipal Health and Family Planning Commission (the “Bengbu MHFPC”) in Anhui Province to remedy its abuse of administrative power conduct. The conduct in question concerned designating suppliers of pharmaceutical products in its procurement activities and setting different eligibility criteria in biddings to exclude non-local bidders. More specifically, in April and May 2015, the Bengbu MHFPC issued several notices under which the Bengbu MHFPC designated specific manufacturers of certain pharmaceutical products, even though there were alternative manufacturers in the market. In addition, the Bengbu MHFPC set different requirements for local bidders and non-local bidders.¹⁴⁸ The NDRC found that the Bengbu MHFPC had abused its administrative powers to restrict non-local bidders’ participation in the bids in violation of the AML. This was followed by two similar cases later in 2015, where the NDRC investigated the Sichuan and Zhejiang healthcare regulators for local protectionism in the pharmaceutical procurement. In response to the investigations, the infringing healthcare regulators in both cases agreed to correct their behaviour.¹⁴⁹

6.2 THE FAIR COMPETITION REVIEW SYSTEM

On 1 June 2016, the State Council issued Opinions on the Establishment of the Fair Competition Review System in the Market System, establishing the “fair competition review system”.¹⁵⁰ The objective of the fair competition review system is to regulate administrative monopolies, to minimize unfair laws and regulations that support administrative monopolies, and to treat foreign and domestic companies fairly. The fair competition review system applies to all sectors. Under the system, each administrative authority or organization empowered by laws and regulations to administer public affairs is required to conduct a “self-review” when formulating new rules or policies to ensure that they do not give rise to anti-competitive effects. It still remains to be seen, however, how such a self-review mechanism will work in practice. The system may be used to further tackle administrative monopoly under the AML and may also mean more enforcement activities against administrative monopoly. The pharmaceutical sector may continue to be an enforcement target for the NDRC or the SAIC.

7. CONCLUSION

The pharmaceutical sector is a priority for antitrust enforcement in China. As explained in the paper, all three AML enforcement authorities: the MOFCOM, the NDRC and the SAIC, have been involved in dealing with antitrust issues in the pharmaceutical sector, and all types of antitrust issues: merger control, anti-competitive agreements, abuse of dominance and even

¹⁴⁸See News Release, the NDRC, NDRC Recommends Bengbu Healthcare Regulator to Correct Their Abuse of Administrative Powers (17 August 2015), *available at* http://www.sdpc.gov.cn/gzdt/201508/t20150826_748741.html.

¹⁴⁹See News Release, the NDRC, Sichuan and Zhejiang Healthcare Regulators Corrected Their Abuse of Administrative Power (2 November 2015), *available at* http://www.sdpc.gov.cn/gzdt/201511/t20151102_757334.html.

¹⁵⁰See OPINIONS OF THE STATE COUNCIL ON THE ESTABLISHMENT OF THE FAIR COMPETITION REVIEW SYSTEM IN THE MARKET SYSTEM, (2016) Guo Fa No. 34, 1 June 2016, *available at* http://www.gov.cn/zhengce/content/2016-06/14/content_5082066.htm.

administrative monopoly have been targeted through antitrust enforcement. There is probably no other sector that has seen the same level of antitrust scrutiny in China.

Antitrust issues in the pharmaceutical sector are extremely challenging. The evolving antitrust rules and their interaction with industrial policy make these issues increasingly complicated and difficult to navigate. In addition, as the enforcement authorities are not obliged to publish their decisions in detail, the publicly available information provides little or no information or substantive discussion as to the approaches taken by the enforcement authorities. Therefore, the manner in which the antitrust rules in the pharmaceutical sector will be enforced is still somewhat uncertain. Importantly, such scrutiny is likely to continue. The pharmaceutical sector still draws attention from the enforcement authorities and the general public. For instance, since the outset of the pricing reform in the pharmaceutical sector in 1 June 2015, the NDRC and the local DRCs conducted two special six-month campaigns to investigate illegal conduct in relation to prices across the pharmaceutical sector. In May 2016, the NDRC also started an industry-wide inquiry into pricing issues in the pharmaceutical sector and several pharmaceutical and medical device companies have been officially investigated. The industry-wide inquiry is still on-going and more companies may be investigated.

Market participants should be aware that the Chinese government is acutely sensitive to the final cost of pharmaceutical products to the public, and any anti-competitive conduct which is likely to impact the prices of pharmaceutical products may be dealt with severely. Based on the guidance issued by the enforcement authorities and the recent case law, key issues that may specifically attract the attention of the enforcement authorities are RPM, price collusion, price-fixing, abuse of dominance through excessive pricing, and refusal to deal. At the product level, products that may be particularly sensitive are pharmaceuticals included in the Medical Insurance Catalogue, patent pharmaceuticals, proprietary pharmaceuticals, pharmaceuticals with large sales volumes and which are frequently used in clinical application, and pharmaceuticals which attract wide social attention.