ANTITRUST ENFORCEMENT IN THE PHARMACEUTICALS AND MEDICAL PRODUCTS INDUSTRY IN CHINA

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I. INTRODUCTION

Antitrust enforcement in the pharmaceuticals and medical products industry in China is part of a larger regulatory and policy framework that has developed in recent years to address specific industry issues. For example, in response to high drug prices, measures such as the "two-invoice" system[2] and centralized drug procurement processes[3] have been implemented. To address issues relating to the alleged poor quality of drugs manufactured in China, measures have been introduced that support the emergence of quality generic drugs.[4]

Against this regulatory backdrop, China's Anti-Monopoly Law ("AML") has also been used as another tool to deal with problems in the industry. The pharmaceuticals and medical products industry in China has seen high levels of antitrust enforcement activity from 2015 onwards. The State Council has also issued guidance in September 2018 indicating that China would strengthen antitrust enforcement against anticompetitive conduct and price increases that give rise to drug shortages.[5]

The AML has been used to address various types of anti-competitive conduct in the pharmaceuticals and medical products industry. One is unilateral conduct by dominant undertakings that abuse their dominance in various ways, including through excessive pricing, refusals to supply, and tying practices. It has also been used against horizontal coordination amongst competitors, for example, to divide the market or to fix prices. Anti-competitive vertical agreements involving resale price maintenance ("RPM") have also been caught. The following sections take stock of the cases to date, and highlight the most common antitrust issues that arise.

One key trend worth highlighting at the outset is that the enforcement action appears to be heavily focused on the supply of active pharmaceutical ingredients ("APIs") in China. The vast majority of cases highlighted below relate to API manufacturers, and is a reflection of the supply issues that plague this market, including the persistent shortages and price hikes in the supply of APIs experienced in the past few years. Part of the reason behind this may be the oligopolistic or monopolistic market structures that exist due to the limited number of players licensed to supply APIs in the market - many such cases involve abuses by the only manufacturer of a specific API or coordinated conduct amongst a small handful of API manufacturers. China's antitrust regulator ("SAMR") also reportedly indicated in 2019 that the supply of APIs would be an enforcement priority.

II. ABUSE OF DOMINANCE CASES

There have been seven abuse of dominance cases to date in the pharmaceuticals industry. Save for one, all these cases involve the supply of APIs. The following table summarizes the API cases, and also identifies the abusive conduct involved.

Year	Parties	API	Abusive Conduct
2015	• Chongqing Qingyang Pharmaceutical	Allopurinol	Refusal to supply
2016	• Chongqing Southwest No.2 Pharmaceutical Factory	Phenol	Refusal to supply
2017	• Wuhan Xinxing Jingying Medical	Methyl salicylate	Imposing unfair terms and conditions

2 The two-invoice system set out in the Notice on Implementation Guidelines for Promoting Two-invoice System for Pharmaceutical Procurement among Public Health Institutions limits the number of invoices that may be raised in the course of drug procurement to two – one from the supplier to the distributor and the other from the distributor to the public health institution. It is intended to reduce distribution costs by bringing down the number of parties involved in the procurement process.

3 In late 2018, China's Central Comprehensively Deepening Reforms Commission entrusted the Shanghai City Government to implement a centralized drug procurement program through which the government awards a contract to the lowest bidder with a guaranteed sales volume of 60-70 percent of the total market for a year. The program covers 11 major cities in China (i.e. Beijing, Tianjin, Shanghai, Chongqing, Shenyang, Dalian, Xiamen, Guangzhou, Shenzhen, Chengdu, and Xi'an, which constitutes around 30 percent of the China market).

4 For example, under the Opinions on Reforming and Improving the Policy for Supply Guarantee and Use of Generic Drugs implemented by China's State Council in 2018, public hospitals are required to list high quality generics in their formularies and purchase them through collective tenders; physicians at public hospitals are generally required to prescribe pharmaceuticals using their generic names instead of their brand names, and hospitals will be encouraged to fulfil the prescriptions with generics. Additionally, the government-funded Basic Medical Insurance will reimburse for high quality generics at the same rate as it would for the corresponding brand name drug. This reimbursement policy is designed to encourage medical institutions to switch to and dispense high quality generics.

5 Suggestions for Improving the National Essential Medicines System, State Council Notice (2018) No. 88

2017	• Zhejiang Second Pharma Tianjin • Handewei Pharmaceutica	Isoniazid	Excessive pricing Refusal to supply
2018	• Hunan Er-Kang Medical Operation • Henan Jiushi Pharmaceutical	Chlorpheniramine maleate	Excessive pricing Tying Refusal to supply
2019	• Nantong Jinghua Pharmaceutical (investigation suspended following commitments)	Phenobarbital	Refusal to supply

A. Refusal to Supply

The most common type of abusive conduct relates to refusal to supply. Article 17(3) of the AML prohibits dominant undertakings from refusing to trade with counterparties without a justified reason. Refusals to supply can take many forms beyond an outright refusal, including making false claims of lack of stock, and requiring downstream manufacturers pay excessive deposits (see e.g. the *Hunan Er-Kang* case). Article 9 of NDRC's Price Behavior Guidelines for Operators of Active Pharmaceutical Ingredients and Drugs Prone to Shortages ("Drug Pricing Guidelines") also indicates that charging excessive prices may amount to a constructive refusal to supply.

The *Chongqing Qingyang Pharmaceutica* case is a classic example of how dominant undertakings can benefit from a refusal to supply when they are active in both the upstream and downstream markets. In that case, the infringing undertaking was dominant in the upstream manufacturing of allopurinol API, and was also active in selling allopurinol tablets downstream. It restricted the supply of its allopurinol API to foreclose its competitors in downstream markets for allopurinol tablets, and at one point increased its downstream market share by 47 percent.

However, having a downstream market presence is not a necessary element for finding an abusive refusal to supply. In several other cases (e.g. the *Hunan Er-Kang* case, and the *Chongqing Southwest No.2* case) the Chinese regulator found a refusal to supply notwithstanding the dominant undertakings' lack of economic activity downstream. By artificially creating a shortage downstream, the dominant undertakings benefitted by charging higher API prices to the downstream manufacturers that it supplied.

A separate observation is that, at times, the regulator may not pursue API suppliers for a refusal to supply. For example, in the *Wuhan Xinxing Jingying Medical* case, even though the only two manufacturers of methyl salicylate API entered into an exclusive agreement with a distributor and thereafter refused to supply others directly, the regulator pursued a case against the distributor rather than the manufacturers, for imposing unreasonable trading conditions on counterparties when the distributor resold the API products to its customers.

B. Excessive Pricing

Excessive pricing infringements are also a common infringement amongst the cases involving the supply of APIs. Under Article 17(1) of the AML, dominant undertakings are prohibited from selling products at unfairly high prices. Article 8 of the Drug Pricing Guidelines notes that excessive prices can be determined by:

(1) comparing it with the prices of the same type of drugs sold by other undertakings;

(2) where the market is stable and where costs are not significantly affected, examining whether price increases exceed the usual range;

(3) examining whether increases in drug prices are significantly higher than the increases in costs ("Cost Plus Approach"); or

(4) comparing price differences in the same geographic market over time ("Price Across Time Approach"), or comparing the price differences between different geographic markets during the same period of time.

In practice, SAMR appears to have adopted the Cost Plus Approach when determining that excessive prices were charged in the *Hunan Er-Kang* case. Specifically, the dominant undertaking increased prices of chlorpheniramine maleate API by three to four times the average cost of procuring the products, even though the latter costs were stable. By charging downstream manufacturers RMB 2940/KG, while its average purchase cost was RMB 860/KG, SAMR held that the dominant undertaking's price increase "obviously exceeded the normal range…[which was] obviously unfair."

In *Zhejiang Second Pharma* case, SAMR appeared to adopt the Price Across Time Approach. In finding that there was excessive pricing, SAMR focused on price differences in the same market over time and held that compared to the preceding year, one dominant undertaking had increased its API prices by 3.52 times while another had increased prices by 19 times.

It appears that the threshold for finding an excessive pricing infringement is lower in China compared to various other major competition law jurisdictions. For example, while it is possible to compare the price of the same product over time to determine excessive pricing under the AML, the UK Competition Appeal Tribunal in *Flynn Pharma*[6] did not consider the Price Across Time Approach as a sufficient stand-alone ground for finding an excessive pricing infringement. In particular, it highlighted that many factors affect the "before" price that may render it artificially low and unrepresentative of normal competitive conditions.

As another example, while a Cost Plus Approach may be sufficient to find an excessive pricing infringement under the AML, the UK Competition Appeal Tribunal in *Flynn Pharma* was cautious about solely looking at the amount of mark-up above cost applied by the dominant undertaking to determine excessiveness, especially if there were other methods available that suggested different results. The UK Competition Appeal Tribunal therefore rejected the regulator's assessment that anything above a reasonable rate of return on sales of 6 percent above cost for the sale of phenytoin sodium capsules was evidence of excessive pricing. More generally, even if prices were significantly above costs, competition law in the EU and the UK still requires the regulator to show that prices bear no reasonable relation to the economic value of the product. This element is not required for excessive pricing cases under the AML.

C. Tying

A third type of abusive conduct involves tying. In the *Hunan Er-Kang* case, for example, the dominant chlorpheniramine API manufacturers required downstream customers to purchase medicinal cane sugar, starch capsules and other medical supplements together with chlorpheniramine API. The medical supplements were unrelated to and ordinarily purchased separately from chlorpheniramine API according to customer needs. The tying conduct deprived downstream customers of their right to independent choice, and unfairly extended the manufacturers' dominance in the chlorpheniramine API market to the market for the supply of the various medical supplements.

III. ANTI-COMPETITIVE AGREEMENTS

The AML has also been used against anti-competitive agreements between competitors and anticompetitive vertical agreements containing RPM restrictions.

A. Horizontal Anti-competitive Agreements

Article 13 of the AML prohibits undertakings from entering into agreements with competitors to eliminate or restrict competition in the market. There are four recent AML cases in the pharmaceuticals and medical products industry involving an infringement of Article 13, and all relate to the supply of APIs:

Year	Parties	API	Abusive Conduct
2011	• Shandong Shuntong • Shandong Huaxin	Compound reserpine	Refusal to supply
2016	• Chongqing Qingyang Pharmaceutical • The Place Pharmaceutical Jiangsu, • Shanghai Xinyi United Medicinal Herbs • Shangqiu Huajie Pharmaceutical	Allopurinol	Price fixing and market sharing
2017	• Huazhong Pharmaceutical • Shandong Xinyi Pharmaceutical • Changzhou Siyao Pharmacy	Estazolam API and tablets	Price fixing and joint boycott

6 *Flynn Pharma and Flynn Pharma (Holdings) v. Competition and Markets Authority* [2018] CAT 11. This case is currently on appeal to the Court of Appeal of England and Wales.

2018	• Chengdu Huayi Pharmaceutical Excipients Manufacturing • Sichuan Jinshan Pharmaceutical • Taishan Xinning Pharmaceutical	Acetic Acid	Price fixing and information exchange

The above cases tend to fall within the mold of typical cartel behavior. For example, in *Huazhong Pharmaceutical* case, the infringing parties were found to have agreed amongst themselves to use all their manufactured estazolam API for captive use instead of supplying it downstream, and to fix the price of their downstream estazolam tablets. In the *Chengdu Huayi* case, the parties were found to have shared commercially sensitive information regarding acid market conditions and production volumes, which eventually culminated in an agreement to increase the product prices.

A further observation is that Allopurional API manufacture Chongqing Qingyang Pharmaceutical had been subject to back-to-back infringement findings within the period of a few months by both the Chongqing AIC and the NDRC because different agencies had different enforcement responsibilities. The Chongqing AIC was responsible for non-price related AML infringements and investigated the abuse of dominance conduct; NDRC was responsible for price related AML infringements and investigated the price-fixing conduct. Given that these split responsibilities have now been consolidated under SAMR, future investigations of AML infringements are likely to proceed on a unified basis.

B. Vertical Anti-competitive Agreements

Article 14 of the AML prohibits undertakings from fixing resale prices or setting minimum resale prices (i.e. RPM practices), which ordinarily arises in the context of a vertical agreement between parties at different levels of the supply chain (e.g. manufacturer-distributor). There have been two cases to date involving RPM conduct in the medical products industry:

Year	Parties	API	Abusive Conduct
2016	• Smith & Nephew Medical (Shanghai) Limited • Shandong Huaxin	Over-the counter (OTC) CICA-CARE silicone gel sheets for scar treatment	RPM
2016	• Medtronic (Shanghai) Management	Medical equipment for cardiovascular diseases, restorative therapies, and diabetes	RPM

Both cases involve fairly standard RPM conduct, i.e. imposing resale prices on downstream distributors. In the *Medtronic* case, for example, Medtronic was fined for setting fixed and minimum resale prices for its distributors and e-commerce firms in China, and also restricting the latter from selling directly to end-customers. Among other things, it enforced resale prices by refusing to supply to non-adhering entities, revoking discount rights, imposing fines, and reducing trade credits.

RPM practices have been treated as *per se* illegal by the Chinese antitrust regulator in practice. The Supreme People's Court of China held in *Yutai v. Hainan Provincial Price Bureau* (2019) that once the regulator finds the existence of RPM practices involving fixed or minimum prices, a rebuttable presumption arises that the conduct infringes the AML without having to show anti-competitive effects. This would be the case even if the agreement had not been implemented. Importantly, the approach differs in a civil litigation case, where private claimants are required to show actual losses suffered, which necessitates some examination of effects.

Separately, Article 5 of the Drug Pricing Guidelines expressly prohibits imposing fixed or minimum resale prices for API or drugs that are subject to shortages. If there is evidence to show that the API or drug suppliers are able to exert control over the resale prices charged by third parties and third-party platforms, this would also amount to an infringement.

C. AML Related Court Litigation

The key private enforcement case in the pharmaceuticals and medical products industry is the Shanghai High People's Court decision in *Rainbow v. Johnson & Joh*nson (2013). In that case, Beijing Ruibang Yonghe Science and Technology Trade Company ("Rainbow") had an arrangement to distribute Johnson & Johnson's ("J&J") staplers and sutures to certain hospitals in Beijing, which included a minimum resale price restriction.

Rainbow subsequently acquired the right to distribute to another Beijing hospital by submitting bid prices that were lower than J&J's minimum resale prices. On discovering this, J&J refused to supply its products to Rainbow, and eventually declined to renew its distributorship. Rainbow brought an action against J&J for illegally imposing RPM in breach of Article 14 of the AML. Apart from its significance in clarifying the court's approach to RPM in private enforcement cases,[7] this case demonstrates how private enforcement of the AML has been used as an effective tool in commercial disputes in the medical products sector: J&J was ultimately made to compensate Rainbow for losses amounting to RMB 530,000 for illegal RPM conduct, although this was substantially less than the RMB 14.4 million that Rainbow had asked for in damages.

Apart from private lawsuits, it is noteworthy that market players have sought to pressure the antitrust regulator to take enforcement action against local government agencies for abuse of administrative power (so-called "administrative monopoly" conduct). For example, Guangzhou Pui's Pharmaceutical Factory (Berthelot) in 2018 requested SAMR to investigate the Shenzhen Health and Family Planning Commission for allowing only one group purchasing organization (Shenzhen Quanyaowang Pharmaceutical) to service local hospitals and pharmaceutical manufacturers, on the grounds of abuse of administrative power under Article 32 of the AML. The Beijing Higher People's Court ultimately upheld the lower court's finding that SAMR had no obligation to investigate. While the Beijing Higher People's Court recognized that complainants affected by the complained antimonopoly conduct could challenge the regulator's performance of its duties, the plaintiff in this case was not directly impacted by SAMR's enforcement action (or lack thereof).

Significantly, this development potentially opens the way in the future for private complainants directly affected by anticompetitive conduct to compel SAMR to carry out investigations. Already, there have been several reports in the past year that pharmaceuticals industry players and industry associations have met with SAMR and called for action against anticompetitive conduct by API manufacturers.[8] The possibility of challenging SAMR can have real effects on future enforcement action, and may present an alternative strategy for private parties looking to take action against anticompetitive conduct.

IV. CONCLUSION

Ever since the AML came into effect, China has seen a high level of antitrust enforcement activity in the pharmaceuticals and medical products industry, particularly from 2015 onwards. AML enforcement sits alongside other regulations and policy initiatives to address problems within the industry, in particular, relating to the shortage and high prices of APIs, and RPM practices for certain medical products. At the same time, private parties have also begun to wield the AML as a means to address commercial disputes by bringing private actions, or potentially by challenging a regulator's decision not to commence investigations. AML enforcement is expected to continue to play a significant role in the pharmaceuticals and medical products industry going forward, and it would be prudent for industry players to navigate the regulatory pitfalls when running their businesses.

7 See e.g. Fei Deng, Su Sun, *Rainbow v. Johnson & Johnson: RPM Litigation in China*, Distribution Vol. 18 No. 1 (March 2014).

8 Among others, the Zhejiang Pharmaceutical Industry Association reportedly called for action against API price hikes in September 2019, while the China Pharmaceutical Industry Association reportedly organized a meeting with SAMR in August 2018 to share concerns about API price hikes and shortages.

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