



# ALL EYES ON ANTITRUST ENFORCEMENT IN CHINA'S PHARMACEUTICAL INDUSTRY



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## I. INTRODUCTION

August 1, 2016 marks the eighth anniversary of the entry into effect of China's Anti-Monopoly Law (“AML”). Enforcement of the law has gone through various phases, with the peak – at least in terms of press coverage – during 2014, culminating in the *Qualcomm* decision by the National Development and Reform Commission (“NDRC”) in February 2015.<sup>2</sup>

Since the *Qualcomm* decision Chinese antitrust enforcement has been less headline-grabbing and, generally speaking, lower profile. However, in the past months, press reports have picked up again, as some sectors have been publicly identified as targets for antitrust enforcement action. One of these sectors is life sciences, in particular pharmaceuticals.

The main driver behind the intensified antitrust scrutiny in the pharmaceutical sector was, likely, the liberalization of drug pricing in June 2015.<sup>3</sup> Before that, it was the government that decided the prices – or at least price ranges – of most of the commonly used drugs in China, especially those covered by the national health insurance scheme. This often meant price caps (ex-factory and retail) for the drugs. However, the far-reaching policy reform in June

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<sup>1</sup> Hogan Lovells, Beijing.

<sup>2</sup> National Development and Reform Commission, [2015] Administrative Penalty Decision No. 1, February 9, 2015, see [http://jjs.ndrc.gov.cn/fjgld/201503/t20150302\\_666170.html](http://jjs.ndrc.gov.cn/fjgld/201503/t20150302_666170.html).

<sup>3</sup> Opinions on Pushing Forward the Pharmaceutical Pricing Reform, Fa Gai Jia Ge [2015] No. 904, May 4, 2015, see [http://www.sdpc.gov.cn/zcfb/zcfbtz/201505/t20150505\\_690664.html](http://www.sdpc.gov.cn/zcfb/zcfbtz/201505/t20150505_690664.html).



2015 abolished the old pricing system, allowing most drug prices to be decided by the market.

Already when announcing the drug price reform in June 2015, NDRC – which, apart from antitrust enforcement powers, was also in charge of setting drug prices or price ranges – announced that it would use antitrust as a tool to prevent price collusion and manipulation, abuses of dominance to impose excessive prices and other negative outcomes following the reform: “enhancing the supervision of market prices for drugs is a key measure to maintain the price order in the drug market and to ensure a smooth drug price reform.”<sup>4</sup>

But beyond this particular announcement, NDRC and the two other authorities empowered to enforce the AML – the Ministry of Commerce (“MOFCOM”) and the State Administration for Industry and Commerce (“SAIC”) – have made clear through case practice that pharmaceuticals are a key target for antitrust enforcement action. Indeed, the recent enforcement cases in China's pharmaceutical sector cover all three antitrust authorities, and all types of anti-competitive conduct.

The AML targets three types of conduct which most other antitrust regimes in the world also sanction: restrictive agreements, abuse of dominance and anti-competitive mergers. Unlike many other regimes, the AML also prohibits so-called “administrative monopolies,” a term used to describe government conduct with anti-competitive effects. Below, we will look at pharmaceuticals antitrust cases for each of these four types.

## II. RESTRICTIVE AGREEMENTS AND ABUSE OF DOMINANCE – THE QINGYANG SAGA

In the past months, there were two *Qingyang* cases – one investigation against cartel conduct and one against abuse of dominance, one by NDRC and one by a SAIC branch.

Both NDRC and a local SAIC branch targeted Qingyang, a manufacturer of both allopurinol active ingredients and allopurinol drugs for the treatment of gout (a type of arthritis disease). In November 2015 and in February 2016 respectively, SAIC's local office in Chongqing and NDRC each punished Qingyang for engaging in antitrust infringements concerning the same products.

In the case investigated by SAIC's Chongqing office, the key allegation was that Qingyang had committed an abuse of dominance, more specifically a refusal to deal.<sup>5</sup> The facts were as follows.

For the production of allopurinol active ingredients a manufacturer needs to go through a series of government approval processes, including environmental impact assessment, certification of safe production, and drug production qualification, etc. At the time of the abusive conduct, Qingyang was the only company with valid government licenses to manufacture allopurinol active ingredients, which in turn were deemed indispensable for

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<sup>4</sup> NDRC Notice on Strengthening the Supervision of Pricing Conduct in the Pharmaceutical Market, Fa Gai Jia Jian [2015] No. 930, May 4, 2015, see [http://www.sdpc.gov.cn/gzdt/201505/t20150505\\_690683.html](http://www.sdpc.gov.cn/gzdt/201505/t20150505_690683.html).

<sup>5</sup> Adrian Emch, *Effects Analysis in Abuse of Dominance Cases in China – Is Qihoo 360 v. Tencent a Game-Changer?*, Competition Law International 11, 28 (2016).



the production of allopurinol drugs.

For this and other reasons, the SAIC Chongqing office held that Qingyang had a 100 percent share in the relevant market upstream, the market for allopurinol active ingredients. From October 2013 to March 2014, Qingyang was found to have refused to supply allopurinol active ingredients to its competitors in the allopurinol drug market downstream. During these six months, Qingyang was the only downstream producer with access to allopurinol active ingredients. Not surprisingly, Qingyang's share in the allopurinol drug market rose from 10 percent to close to 60 percent, within just six months.

SAIC's Chongqing branch also made a quite detailed examination of the actual effects of Qingyang's conduct, finding that the conduct had caused significant harm to the market, the industry and customers. The authority found that prices for allopurinol active ingredients had increased from 240/kg to 535/kg, and were passed on to end customers purchasing allopurinol drugs.<sup>6</sup>

Following its investigation, SAIC's Chongqing office imposed a fine of close to RMB 440,000 (around USD \$66'000) on Qingyang.

In the NDRC case, Qingyang was fined for a price fixing and market allocation cartel.<sup>7</sup> The conduct underlying the NDRC investigation started right after the refusal to deal sanctioned by SAIC's Chongqing bureau.

After the six-month period during which Qingyang had cut off supplies for rival allopurinol drug makers and gained a share of close to 60 percent in the downstream allopurinol drug market, it restarted supplies of allopurinol active ingredients to some of its competitors. However, according to the NDRC decision, these renewed supplies were not unconditional: in April 2014, Qingyang and three others competitors downstream reached an agreement to increase the prices of allopurinol drugs, and to allocate spheres of influence by dividing up several of China's provinces among them. NDRC also found Qingyang to have threatened the other cartelists with cutting supplies of active ingredients again in case of non-compliance with the agreement.

This cartel lasted for about six months too, and the four cartelists were fined in total around RMB 4 million (around USD \$600,000).

In May 2016, NDRC's Jiangsu branch reported actions taken against a similar price fixing cartel at the local level.<sup>8</sup> That case also involved a chemical ingredient for the production of drugs. Six companies were found to have held "industry alliance" meetings to fix minimum sales prices. NDRC fined those companies lightly, taking into account the relatively short period of infringement and the limited negative effects on the market.

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<sup>6</sup> Chongqing Administration for Industry and Commerce, Administrative Penalty Decision, [2015] Yu Gong Shang Jing Chu Zi No. 15, October 28, 2015, see

[http://www.saic.gov.cn/zwgk/gggs/jzf/cjd/201512/t20151221\\_165120.html](http://www.saic.gov.cn/zwgk/gggs/jzf/cjd/201512/t20151221_165120.html).

<sup>7</sup> NDRC press release, *NDRC investigated and punished allopurinol drug monopoly agreement case*, January 28, 2016, see [http://www.ndrc.gov.cn/gzdt/201601/t20160128\\_772979.html](http://www.ndrc.gov.cn/gzdt/201601/t20160128_772979.html).

<sup>8</sup> Jiangsu China press release, *Six companies fined for violating the Anti-Monopoly Law*, May 25, 2016, see <http://jsnews.jschina.com.cn/system/2016/05/25/028773762.shtml>.



### III. ANTI-COMPETITIVE MERGERS – CARROT AND STICK

Like in many other jurisdictions, a filing is compulsory in China if a transaction qualifies as a reportable transaction (called “concentration between business operators” in China) and the revenue thresholds are met. Before filing and clearance, the transaction cannot be implemented.

Since mid-2014, MOFCOM operates a streamlined filing regime for transactions deemed “simple cases.” Compared to standard cases, “simple case” filings require less information to be submitted to MOFCOM, and are generally cleared faster – in most cases, within phase 1 of the procedure. Today, around 70 percent of transactions are filed as “simple cases.” Over the past months, several pharmaceutical deals have gone through the “simple case” procedure, for example Furen Medicines Group's acquisition of equity in Kaifeng Pharmaceutical.<sup>9</sup>

At the same time as making it easier for some transactions under the “simple case” regime, MOFCOM has started cracking down harder on reportable transactions that were not filed, in breach of the law.<sup>10</sup> Over the past few months, MOFCOM has published several decisions where it sanctioned companies for breach of the AML's merger control rules. Two of these decisions were addressed to pharmaceutical companies.

The first case concerned Fosun Pharmaceutical Group's acquisition of 65 percent in Suzhou Erye Pharmaceuticals.<sup>11</sup> In September 2015, MOFCOM published its decision sanctioning Fosun Pharmaceutical Group for violation of the AML. In that transaction, the buyer was a large Chinese private company, and the target a former state-owned antibiotics manufacturer in Southern China.

Fosun Pharmaceutical Group requested consultation with MOFCOM about the transaction. However, during the consultation period, the company completed part of the transaction by acquiring 35 percent shares of the target (of a total of 65 percent shares to be acquired). MOFCOM found the 35 percent stake acquisition to give rise to the acquisition of a “controlling right,” without further explaining the details of its reasoning.

MOFCOM fined Fosun Pharmaceutical Group RMB 200,000 (around USD \$30,000). Later on, it appeared that Fosun Pharmaceutical Group re-filed the remaining 30 percent share acquisition with MOFCOM,<sup>12</sup> which was unconditionally cleared following a “simple case” procedure.

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<sup>9</sup> *Furen Medicines Group/Kaifeng Pharmaceutical*, MOFCOM Simple Case Public Notice, June 20, 2016, see <http://fldj.mofcom.gov.cn/article/jyzjzjyajs/201606/20160601342147.shtml>.

<sup>10</sup> Adrian Emch & Jiaming Zhang, *Chinese Competition Law—the Year 2015 in Review*, Global Competition Litigation Review 30, 34 (2016).

<sup>11</sup> *Fosun Pharmaceutical Group/ Suzhou Erye Pharmaceuticals*, MOFCOM Administrative Penalty Decision, Shang Fa Han [2015] No. 669, September 16, 2015, see <http://fldj.mofcom.gov.cn/article/ztxx/201509/20150901124896.shtml>.

<sup>12</sup> *Shanghai Fosun Pharmaceutical Development and Fosun Industrial (Hong Kong)/Suzhou Erye Pharmaceuticals*, MOFCOM Simple Case Public Notice, June 24, 2015, see <http://fldj.mofcom.gov.cn/article/jyzjzjyajs/201506/20150601021728.shtml>.



The second case is Dade Holdings' acquisition of 50 percent of shares in Jilin Sichang Pharmaceutical.<sup>13</sup> In that case, Dade Holdings split the acquisition into two steps: 19 percent of shares in the target were acquired in 2011, and the remaining 31 percent in 2015.

Here, MOFCOM considered the second step to amount to an acquisition of a “controlling right,” triggering the merger filing obligation. Yet Dade Holdings’ had already implemented the second step of the transaction, registering the increased shareholding in the target’s business license. MOFCOM held that this conduct breached the AML’s merger control provisions. As Dade Holdings on its own motion submitted a merger filing after closing, MOFCOM imposed a (relatively low) fine of RMB 150,000 (around USD \$23,000).

Both cases shed light on the MOFCOM’s recent practice of getting tougher on companies attempting to evade their merger filing obligations. These two pharmaceutical cases follow this general trend although, with two out of seven recent failure to file decisions, they are represented prominently compared to other sectors.

Like for most other sectors, there have not been a significant number of MOFCOM interventions in terms of substantive antitrust analysis in pharmaceutical mergers in the past few months. The last public decision imposing remedies in a pharmaceutical merger was *Thermo Fisher Scientific/Life Technologies*, back in January 2014.<sup>14</sup>

#### IV. “ADMINISTRATIVE MONOPOLIES” – ENFORCEMENT BROUGHT TO A NEW LEVEL?

“Administrative monopoly” is the popular term for abuse of administrative powers to restrict competition.

Since the AML's entry into force, its “administrative monopoly” provisions have only been sporadically used. However, in the past few months, we have seen a tick-up of enforcement actions against “administrative monopolies,” and the pharmaceutical sector was disproportionately represented in those actions.

The first action took place in Bengbu, a city in Anhui Province. In April and May 2015, a local healthcare authority in Bengbu issued several notices laying out rules for collective tenders for around 90 local hospitals. In these notices, the local authority designated the specific producers of 30 types of drugs, even though there were alternative producers in the market. In addition, the authority set different requirements for local companies and non-local companies to be admitted to the tender processes.

NDRC intervened, finding that the authority had abusively used its administrative powers to restrict non-local bidders’ participation in the tenders, in violation of the AML.<sup>15</sup>

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<sup>13</sup> *Dade Holdings/Jilin Sichang Pharmaceutical*, MOFCOM Administrative Penalty Decision, Shang Fa Han [2016] No. 173, April 21, 2016, see <http://fldj.mofcom.gov.cn/article/ztxx/201605/20160501311079.shtml>.

<sup>14</sup> *Thermo Fisher Scientific/Life Technologies*, [2014] MOFCOM Public Announcement No. 3, January 14, 2014, see <http://fldj.mofcom.gov.cn/article/ztxx/201401/20140100461603.shtml>.

<sup>15</sup> National Development and Reform Commission [2015] Fa Gai Ban Jia Jian No.2175, August 17, 2015, see [http://jjs.ndrc.gov.cn/fjgld/201508/t20150826\\_748682.html](http://jjs.ndrc.gov.cn/fjgld/201508/t20150826_748682.html).



The AML does not empower NDRC to directly impose sanction on government bodies held to infringe the “administrative monopoly” provisions, and hence NDRC only issued a “recommendation letter” to the provincial government overseeing the Bengbu healthcare authority, requesting rectification measures to be taken. Interestingly, although nothing in the AML compels it to do so, NDRC published its “recommendation letter,” a move that could be interpreted as a warning to other government bodies.

Shortly after, NDRC took two actions in Sichuan and Zhejiang Provinces against very similar government activities in the healthcare area.<sup>16</sup> This string of cases shows NDRC’s determination to tackle local protectionism in tendering processes at provincial level in the pharmaceutical sector.

In June 2016, the State Council issued a notice establishing the so-called “fair competition review system.”<sup>17</sup> This system works somewhat like an “advocacy” type of mechanism, in a decentralized way. Each government body (and entity with a public policy mandate) is required to conduct a self-review when formulating new business-related rules or policies, in order to check whether they may give rise to anti-competitive effects.

The main driver behind this development may have been NDRC’s antitrust bureau, and one of its objectives may have been to establish a new with “more teeth” to tackle “administrative monopolies” than the current AML regime allows. This new system – starting to take effect from July 1, 2016 – applies to all sectors. However, given NDRC’s cases in Anhui, Sichuan and Zhejiang Provinces, the pharmaceutical industry may continue to be a prime candidate for enforcement action.

## V. CONCLUSIONS

In this paper, we have discussed a wide range of recent antitrust enforcement actions in the pharmaceutical sector in China over the past months. All three AML enforcement bodies have been involved, and all types of anti-competitive conduct have been targeted.

The multiple actions described above put the pharmaceutical sector very clearly into the spotlight. Very few other sectors – perhaps none, except the automobile industry – have seen the same level of antitrust enforcement activism in recent months.

Furthermore, there does not seem to be an end in sight to this activism. The authorities have publicly vowed to focus on the healthcare sector, and are clearly keeping up with that promise. For example, in June 2016, NDRC launched a new round of nationwide pricing probes against pharmaceutical companies, hospitals, procurement agencies and

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<sup>16</sup> NDRC press release, *Sichuan, Zhejiang Province’s Health and Family Planning Commissions promptly correct the conduct eliminating or restricting competition in violation of the Anti-Monopoly Law in the process of collective procurement of drugs*, November 2, 2015, see [http://www.sdpc.gov.cn/gzdt/201511/t20151102\\_757334.html](http://www.sdpc.gov.cn/gzdt/201511/t20151102_757334.html).

<sup>17</sup> Opinions of State Council on Establishing the Fair Competition Review System in the Market System, [2016] Guo Fa No. 34, June 1, 2016, see [http://www.gov.cn/zhengce/content/2016-06/14/content\\_5082066.htm](http://www.gov.cn/zhengce/content/2016-06/14/content_5082066.htm).



industry associations.<sup>18</sup> Recent press reports indicate that NDRC may have kicked off an inquiry against a number of pharmaceutical and medical device companies in Shanghai, and that the scope of that investigation may be relatively broad. Hence, there is a lot of potential for further news on antitrust actions in China's pharmaceutical industry.

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<sup>18</sup> NDRC Notice on Conducting Drug Price Specific Inspections across the Nation, Fa Gai Jia Jian[2016] No.1101, May 22, 2016, see [http://www.ndrc.gov.cn/zcfb/zcfbtz/201605/t20160527\\_805108.html](http://www.ndrc.gov.cn/zcfb/zcfbtz/201605/t20160527_805108.html).