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Briefing note
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Pharma companies and antitrust in China: Part two – anti-competitive behaviour, abuse of dominance and enforcement trends

China's pharmaceutical industry has been growing at an average rate of 20% per year by production value over the past decade, nearly doubling every four years.

As a result, China offers opportunities for many players in terms of organic and inorganic growth through M&A activity, strategic alliances and collaboration arrangements.

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 by China's competition authorities.

In this second of two articles exploring the impact of China's antitrust regime on the pharmaceutical industry, we consider in more detail how the day-to-day operations of pharmaceutical companies are affected by China's competition regime, and highlight certain commercial practices that may attract the attention of the enforcement authorities.

Enforcement authorities – who is responsible for what?

Enforcement of China's Anti-Monopoly Law (AML) is split between three agencies.

The Ministry of Commerce (MOFCOM) is responsible for merger control. We have examined the role of MOFCOM in Part I of our series on pharmaceutical companies and antitrust, 'Merger Clearance'. [Link to Article 1]

The National Development and Reform Commission (the NDRC) and the State Administration for Industry and Commerce (SAIC) share responsibility for anti-competitive agreements, abuse of market dominance, and abuse of administrative power.

Theoretically, the NDRC and SAIC are responsible for different areas. The NDRC focuses on price-related conduct, such as price-fixing, while SAIC is responsible for non-price-related conduct, such as market sharing, tying or refusal to supply.

In practice, however, anti-competitive conduct does not always fall neatly into either price or non-price-related activities – there is often some overlap. This unique distinction between the spheres of competence of the NDRC and SAIC raises the risk of parallel investigations and inconsistent decision-making.

There is little guidance available publicly as to which authority will take the lead if and when conflicts arise over jurisdiction.

Key issues

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1 See, http://www.reuters.com/article/2008/01/09/idUS123158+09-Jan-2008+BW20080109.

2 The NDRC and SAIC's respective enforcement of the applicable rules on abuse of administrative power is not addressed in this article.

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

NDRC and SAIC are understood to possess certain internal working rules that are designed to facilitate coordination between the authorities. It remains to be seen how such rules will apply in practice, since the rules have not been made public.

Both SAIC and NDRC envisage delegating enforcement of the AML to local authorities. For example, NDRC generally delegates power to authorities at the provincial level to enable them to handle cases within their respective administrative areas.

While such delegation of enforcement powers may create efficiencies, it does once again offer the potential for disparities in practice and policy between regions. Market participants will need to be sensitive to such distinctions between the authority of different regulators and adopt strategies to build relationships with the different levels of the enforcement authorities relevant to their businesses.

In recent months, both NDRC and SAIC have adopted important new implementing rules that complement the AML's existing provisions on anti-competitive practices. These rules may call into question certain commercial practices that until now have been permissible (and indeed common) in China's pharmaceutical sector. They also grant NDRC and SAIC considerable discretion in enforcing the AML.

Overall, there are clear signs that both agencies have become more active in their efforts to censure anti-competitive conduct, and market participants will need to give careful thought to whether their existing business practices will withstand heightened regulatory scrutiny.

Types of anti-competitive behavior and evolving enforcement trends

In line with international practice, the implementing rules of both NDRC and SAIC pay particular attention to forms of cooperation between competitors – ranging from price-fixing and market-sharing cartels to certain kinds of collaboration agreements.

Moreover, the types of behaviour targeted for scrutiny may be relevant to every stage of the pharmaceutical business cycle, including supply chain and distribution networks, collaboration arrangements, and pricing.

Broadly, the focus of the enforcement authorities is divided between two areas:

- Anti-competitive agreements:
  - o price-related conduct: examples include price fixing (including, in certain circumstances, parallel pricing) and resale price maintenance; and
  - o non-price related conduct: examples include tying, refusals to supply, and the sharing of markets and/or customers.

- Abuse of market dominance: This area addresses the special position and responsibilities of dominant entities. In China, dominance 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.

Dominance is presumed where an undertaking has a market share of 50%, and where two undertakings together hold two-thirds of the market, or three undertakings hold three-quarters of the market . Behaviour such as market sharing, unlawful tying and imposing unreasonable terms is particularly likely to attract the attention of the enforcement authorities.
We consider each of these areas in more detail below.

(i) Price-related conduct

Price-fixing by competitors is expressly prohibited under Chinese competition law.

In sanctioning price-related anticompetitive behaviour, NDRC effectively has a choice of two legislative tools: the AML and China's Price Law. Recent action by NDRC in other sectors has shown that it is increasingly willing to make use of the AML, and the consumer goods and retail sector in particular has seen the NDRC bring action under the AML over price cartels and tying.

When it comes to the pharmaceutical sector, NDRC has continued to prefer the Price Law, which is likely due to a combination of several factors. Liability under the Price Law is strict and does not require determination of relevant markets, neither does it require the regulator to demonstrate anti-competitive effects resulting from the alleged behaviour.

NDRC, as China's economic planning agency, has an established history of applying the Price Law. This may mean that NDRC is more confident that it will obtain effective results when it brings a claim under the Price Law. Additionally, there are certain commercial practices that are caught by the Price Law (such as, for example, deceitful or misleading pricing, fabricating or diffusing information about price increases, bidding up prices and pushing up product prices to an excessively high level), which are not covered by the AML.

[4] In the case of the NDRC: Rules on Price-related Monopoly and Procedural Rules on the Administrative Enforcement of Price-related Monopoly. See, http://jjs.ndrc.gov.cn/zcfg/t20110104_389399.html, http://jjs.ndrc.gov.cn/zcfg/t20110104_389401.html.
In the case of SAIC: Rules on the Prohibition of Monopoly Agreements, the Rules on the Prohibition of Abuse of Dominant Market Positions, and Rules on the Abuses of Administrative Power. See, http://www.saic.gov.cn/fldyfbzdjz/zcfg/zcfg/201101/t20110107_103378.html, http://www.saic.gov.cn/fldyfbzdjz/zcfg/zcfg/201101/t20110107_103379.html, http://www.saic.gov.cn/fldyfbzdjz/zcfg/zcfg/201101/t20110107_103380.html.

[5] The presumption does not apply to an undertaking with a market share of less than 10%.

Over the past year, certain practices in the pharmaceutical sector have attracted careful scrutiny from NDRC. According to a notice it published in February 2011, in 2010 NDRC carried out more investigations into violations of the Price Law within the pharmaceutical sector than in any other sector.

The main price-related infringements identified were price fraud, collusion between pharmaceutical companies and healthcare providers during bidding procedures, and high and/or excessive pricing – all of which behaviours are caught under the Price Law but not necessarily by the AML.

The prices of the vast majority of prescription drugs that are reimbursed under the national insurance system are controlled by the government. This means that when it comes to drugs sold under the reimbursement drug lists, there is theoretically little scope for price fixing and accordingly less risk of enforcement action relating to such medication.

Market participants should be aware, however, that the government is acutely sensitive to the ultimate cost of drugs to the public, and any anti-competitive behaviour which is likely to impact consumer prices may be dealt with severely. Examples might include unlawful tying or distribution models that result in increased costs for China's drug reimbursement scheme.

The recent example of NDRC's decision to fine Unilever for briefing the media on upcoming price rises of its consumer products demonstrates how the enforcement authorities may adopt a wide interpretation of their powers to support their policy goal of containing China's price inflation.

(ii) Non-price related conduct

Certain common practices and important business activities in the pharmaceutical sector may also attract the particular attention of the enforcement authorities.

- 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 looser, non-structural form of collaboration. For example, a co-promotion agreement can be structured with or without a structural dimension but offer the same or similar benefits to the parties. A structural collaboration arrangement has certain merits in that it offers, inter alia, legal certainty if a notification to MOFCOM is required for prior approval. However, the perceived merits of legal certainty will need to be carefully weighed against the additional compliance burdens of such an arrangement – transaction costs associated with obtaining any necessary M&A approvals, drug registrations, dealing with corporate governance issues and navigating China's merger control process.

Outside structural constructs, collaboration agreements can give rise to enforcement action if not carefully considered and planned. In China, collaboration agreements are not regarded as unlawful if they generate efficiencies, competition is not eliminated altogether or significantly restricted, and consumers benefit. Each case will turn on its specific circumstances. Nevertheless, sufficient safeguards should be adopted to ensure that commercially sensitive information is carefully ring-fenced, and careful consideration is given to the appropriateness of market or customer allocation.

Parties will also need to examine the choice of partner to determine whether to enter into the agreement in the first place. 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.

While neither SAIC nor NDRC has made any special pronouncements on collaboration agreements in the sector, market participants should prepare themselves for the eventuality that the enforcement authorities will turn to this area in the future. 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 information exchange of commercially sensitive information, adopts exclusive dealing spanning several years, or fixes minimum sales targets.

6 The notice is available in Chinese at http://jjs.ndrc.gov.cn/gzdt/t20110216_395182.htm.

7 The NDRC's statement (in Chinese) on the Unilever matter is available at http://www.ndrc.gov.cn/xwfb/t20110506_410543.htm, and media coverage can be found at http://business.globaltimes.cn/industries/2011-05/659816.html.

8 A structural co-promotion agreement might include the creation of a joint venture with corporate identify and the necessary resources, including finances, assets and personnel, to conduct business in the relevant market.

9 The conduct of the structural entity that emerges following the transaction remains subject to the AML provisions that govern anti-competitive conduct.

■ Supply and distribution agreements

For China's enforcement authorities, not all agreements are born equal. The SAIC has indicated that it will tend to focus its efforts on agreements between competitors (i.e. so-called "horizontal" agreements), as opposed to "vertical" arrangements with suppliers and distributors. Moreover, it has indicated that it will adopt a "rule of reason" approach when considering commercial practices, meaning that only unreasonable restrictions will likely be considered illegal.

The AML expressly prohibits supply and distribution agreements to the extent that these include price-fixing and/or resale price maintenance. These are the most problematic category of vertical agreements, and it is NDRC that has the competence to prohibit such agreements (as the restrictions are price-related).

The AML is far less clear as to what other types of provisions in a supply or distribution agreement would be considered anti-competitive and SAIC's implementing rules are silent on the point. There are earlier precedents, however, where certain types of tying practices between a customer and dominant supplier have been investigated by regulators.

■ 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.

As is well known, many multinational pharmaceutical companies are facing a "patent cliff", with intellectual property protection on a range of key drugs reaching the end of exclusivity periods. Furthermore, despite significant R&D investments, the number of new drugs brought to market has experienced 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 producers that delay or intend to delay generic drug competition in order, which serve to keep prices high, payments made by originator drug manufacturers in exchange for delayed entry, or commercial arrangements that result in higher costs for the national reimbursement scheme. Some of these issues have drawn special attention from enforcement authorities in other jurisdictions such as US and EU.

While the Chinese enforcement authorities have yet to focus specifically on this area, we anticipate increased attention in the future in China as increasing numbers of originator drug companies partner with Chinese generics producers and enter into collaboration arrangements, settle eventual patent disputes, and M&A activity intensifies in the industry.

■ Trade associations

Trade associations have also attracted scrutiny from both the SAIC and (to a greater extent) the NDRC. The AML expressly prohibits trade associations from adopting anti-competitive rules, encouraging anti-competitive agreements between members or from implement decisions designed, for example, to exclude particular companies.

There are no reported cases in China of investigations into the practices of trade associations and/or their members in the pharmaceutical sector. Nevertheless, there has been increased focus by the enforcement authorities on the practices of trade associations. In recent months, the NDRC and SAIC have carried out investigations into cartels instigated by trade associations. In the US, there is pending antitrust litigation against an alleged cartel involving certain Chinese companies active in the production and sale of Vitamin C. The alleged anti-competitive practices arose from certain

[10] In fact, SAIC's draft rules on anti-competitive practices identified a number of practices unrelated to price that could be caught by the AML.

[11] See, for example, the prepared statement of the Federal Trade Commission on "Competition in the Pharmaceutical Marketplace: Antitrust Implications of Patent Settlements" before the Committee on the Judiciary United States Senate, May 24, 2001. More recently, 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 pharma sector in the EU, including so-called "pay-for-delay" patent settlements. In April 2011, the European Commission opened a formal investigation to examine whether a patent settlement agreement infringed the EU competition rules by hindering the entry of the generic drug, Modafinil, in the EEA. The agreement was part of the settlement of patent infringement disputes between Cephalon, a US-based pharmaceutical company, and Teva, an Israel-based generic drug producer under which Teva undertook not to sell its generic Modafinil products in the EEA before October 2012.

[12] See, Article 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.

decision-making practices (which appear to have since been abandoned) by one of China's pharma-related trade associations, the China Chamber of Commerce for Import & Export of Medicines & Health Products.

(iii) Dominant entities

In the case of anti-competitive practices involving dominant companies, it remains uncertain whether NDRC or SAIC will embark on a vigorous enforcement of the AML, and if so, how they will enforce the rules.

The challenge for the enforcement authorities is, firstly, to establish dominance, and then to demonstrate unlawful conduct. It may not be difficult for enforcement authorities to demonstrate dominance in the pharmaceutical sector. This is likely to be the case especially 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.

As for establishing whether conduct is unlawful, based on recent developments in other sectors it is likely that the focus of the enforcement authorities would be on whether a given practice is objectively justified. Problematic conduct includes refusal to deal, exclusive or restrictive dealing, tying and imposing unreasonable terms and discrimination. The NDRC and SAIC implementing rules provide (limited) guidance on possible justifications, and both regulators have indicated that each case will turn on the specific circumstances of the case. Pharmaceutical companies with dominant market positions are well advised to pay close attention to their activities in China and to take advice where necessary.

While the SAIC has been the least active of China's three competition authorities since the introduction of the AML, upcoming provisions as to the way intellectual property rights (IPRs) are dealt with under the AML may be set to change this situation.

Strong IPRs are important in the pharmaceutical sector and senior officials of SAIC have indicated in public that, in principle, a company cannot be presumed to be dominant only because it owns intellectual property rights. In addition, certain practices involving the use of intellectual property rights can only be an infringement in exceptional circumstances. However, SAIC's implementing rules indicate that abusive commercial practices stemming from the exercise of intellectual property rights can be sanctioned.

It is well known that SAIC has for some time been giving attention to how to improve enforcement in this area, and has been closely following enforcement actions in the US and EU, where the interaction between intellectual property and antitrust is an area of some sensitivity and has been the subject of some decisions with far-reaching implications. The SAIC's guidelines will be closely scrutinised to see whether China will lean closer to the US or to the EU approach. The guidelines will need to be carefully analysed when released so that market players can understand their obligations in this highly sensitive area.

Penalties

Breach of the provisions of the AML carries serious consequences, with the possibility of fines of up to 10% of turnover. It remains unclear whether such an amount will be limited to sales in China or would be calculated as a proportion of global turnover – regardless, it is clear that such fines have the potential to have a severe impact. The AML grants the ability for some level of immunity from prosecution to be given to entities which "blow the whistle" on anti-competitive agreements and cooperate with the authorities in subsequent investigations.

Conclusion

China's competition regime in the area of anti-competitive behavior or conduct is still undeveloped, particularly compared with recent progress made by MOFCOM's anti-monopoly bureau in the area of merger clearance.

Despite this, there are signs that NDRC and SAIC are gearing themselves up to take stronger enforcement action under the AML in the future. Given the Chinese government's current pre-occupation with rising price inflation, it remains the

[13] For example, on 4 January 2011, 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, http://jjs.ndrc.gov.cn/gzdt/t20110104_389453.htm. On 26 January 2011, the Jiangsu Administration for Industry & Commerce fined the Concrete Committee of the Construction Materials and Construction Machinery Industry Association of Lianyungang City and 16 concrete manufacturers for, inter alia, market sharing in breach of the AML. See, http://www.saic.gov.cn/ywdt/gsyw/dfdt/xxb/201101/t20110126_103772.html.

[14] In re Vitamin C Antitrust Litigation, 584 F. Supp. 2d 546. (E.D.N.Y 2008).

[15] For reference, see our article 'Merger Clearance' for an overview of MOFCOM's current approach to market definition in the pharmaceutical sector.

[16] It is unclear whether the guidelines will address patent filing or drug registration strategies as a possible basis for competition concerns. In the EU, for example, the European Commission successfully defended its abuse of dominance case against Astra Zeneca for the misuse of regulatory procedures before the General Court of the European Union in Luxembourg. See, European Commission Decision of 15 June 2005 (Case COMP/A. 37.507/F3 – AstraZeneca), and Case T-321/05 AstraZeneca v. Commission.

case that price-related anti-competitive behavior, particularly in the consumer goods sector, is likely to be their initial focus.

However, we anticipate that over the short to medium term, we will also see more examples of enforcement under the AML in the pharmaceutical sector, particularly given the rising level of consolidation in the sector.