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Briefing note
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Pharma companies and antitrust in China: Part one - merger clearance

Introduction

Historically, companies doing business in China's pharmaceutical sector have tended to overlook competition law as a key concern in terms of transaction timetables – but no longer.

In the wake of the adoption in 2008 of China's Anti-monopoly Law (AML) and increased enforcement of the law by China's antitrust agencies in the sector, pharmaceutical companies are beginning to pay special attention to the competition regime in China.

Enforcement of the AML may have a significant impact on transaction closing timetables, and is likely to call into question a variety of commercial practices. Antitrust issues are already having an impact on both foreign and domestic market participants, and an understanding of the antitrust regime is becoming necessary for pharmaceutical companies to operate effectively in China.

In the first of two articles on the impact on pharmaceutical companies of China's antitrust regime, we focus on the changing shape of merger control review.

According to a report published by IMS Health, China is expected to become the world's third-largest prescription drug market in 2011 and the second largest by 2020.[1] Many foreign pharmaceutical companies are targeting China as a key platform for growth at a time of upheaval across the global industry, and almost all the major international players include the acquisition of Chinese companies towards the top of their list of methods for securing rapid growth in the region.

A period of intense M&A activity is set to coincide with evolving and potentially more intrusive enforcement of China's merger review system. We examine the implications of these market trends for pharmaceutical companies.

Antitrust issues in merger reviews

The State Council has placed responsibility for the enforcement of the AML with the Ministry of Commerce (MOFCOM), the National Development and Reform Commission (NDRC) and the State Administration for Industry and Commerce (SAIC).

Merger review is administered by MOFCOM, leaving the two other agencies to concentrate on day-to-day operational antitrust issues (such as cartels, anti-competitive agreements and abuses of market dominance).

Much of the enforcement activity in China has focused on merger control since the AML came into force in August 2008. As at the time of publication, MOFCOM had vetoed one transaction (Coca-Cola Company's proposed acquisition of China Huiyuan Juice Group Limited),[2] and imposed conditions on a further

Key issues

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[1] See, http://www.imshealth.com/imshealth/Global/Content/IMS%20in%20the%20News/Documents/PharmaVoice,%20February,%20Pharmerging-China,%20Mandy%20Chui.pdf.

[2] See, http://fldj.mofcom.gov.cn/aarticle/ztxx/200903/20090306108494.html.

seven, two of which were in the pharmaceutical sector. On 29 September 2009, MOFCOM cleared the acquisition of Wyeth Inc. (Wyeth) by Pfizer Inc. (Pfizer) subject to conditions,[3] and on 13 August 2010, MOFCOM cleared the acquisition of Alcon Inc. (Alcon) by Novartis AG (Novartis) subject to conditions.[4]

Market definition

MOFCOM's review of transactions in the pharmaceutical sector 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.

For example, in the Pfizer/Wyeth decision, MOFCOM identified an overlap in the narrowly defined animal health market of swine myscoplasma hyponeumniae vaccines as the main cause for concern. In the Novartis/Alcon decision, MOFCOM identified competition concerns in the market for ophthalmic anti-inflammatory and anti-infective compounds and the market for contact lens care products.

Definition of the relevant market is MOFCOM's starting point in conducting competition analysis, and markets tend to be defined narrowly:

- In the case of human health medicines, MOFCOM's practice indicates that relevant product markets are usually defined according to the products' therapeutic areas. Traditionally, categories at the third level of the Anatomical Therapeutic Chemical classification system (ATC-3) developed by the European Pharmaceutical Marketing Research Association (EphMRA) and maintained by EphMRA and Intercontinental Medical Statistics (IMS) provide a useful starting point for market definition.[5] The WHO has also adopted the ATC classification system, although minor differences exist between the two classification systems in terms of classification of certain drugs. It will usually suffice to explain the classification system used for data collection. For Chinese traditional medicines, it may be necessary to consider alternative methods of classification in order to determine the precise areas of overlap between products. For animal health products, MOFCOM may divide markets along broad areas in the first instance (for example medicinal food additives, biologicals (including vaccines), pharmaceuticals (including, inter alia, anti-microbials and antibiotics), nutritional feed additives and hygiene products), and then segment markets further based on, for example, the animal species, the specific disease or condition targeted, mode of action, dosage, etc.

- With regard to the relevant geographic market, MOFCOM is usually of the view that the market for finished pharmaceutical products should be regarded 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. 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.

It can sometimes be difficult to obtain reliable sources for market data, including market share estimates. It is thus advisable for parties to identify appropriate databases for data gathering for the purpose of the notification. Parties should also engage with relevant trade associations at an early stage to request data if this information is available.

The IMS database is a hospital-sales-based database, and is frequently used as a reliable source of data for prescription drugs. However, Euromonitor may prove a more useful database for certain OTC products. Practice indicates that MOFCOM's preference is for market data from reliable independent third-party sources. 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.

Assessment of mergers

Both the Pfizer/Wyeth decision and the Novartis/Alcon decision point to increased sophistication in MOFCOM's assessment of horizontal mergers. The Pfizer/Wyeth decision was the first time that MOFCOM publicly noted its reliance on HHI indices – the Herfindhal-Hirschman Index that measures the concentration of a market – to assess the impact of a transaction in a relevant market. In Novartis/Alcon, MOFCOM raised possible coordination issues for the first time as a basis for imposing a remedy to secure the approval of a transaction.

Notifications made during the past three years in this sector indicate that MOFCOM usually consults a wide range of parties, including other government agencies, trade associations, competitors and customers, before making a decision – with a consequent impact on the

[3] See, http://fldj.mofcom.gov.cn/aarticle/ztxx/200909/20090906541443.html.

[4] See, http://fldj.mofcom.gov.cn/aarticle/ztxx/201008/20100807080639.html.

[5] This approach was adopted by MOFCOM in the Pfizer/Wyeth transaction.

duration of the review process. MOFCOM may also conduct site visits and public hearings if it deems this necessary during the review process.

There are no safe harbours or benchmarks for determining whether a transaction may or may not raise competition concerns in China. Although MOFCOM's focus is on the impact of a transaction in China it may also carefully consider parties' market shares at the global level.

MOFCOM's analysis of M&A transactions is based on a prospective assessment of future market conditions. In practice, MOFCOM may raise red-flags in cases involving combined market shares in the 25-30% range, and the prospect for remedies is relatively high in cases involving combined market shares in the 50% range.

The fact that a transaction may not lead to a significant increment in post-merger market shares is not necessarily relevant, as the Novartis/Alcon case demonstrates. In Novartis/Alcon, MOFCOM determined that the parties' combined global market share in ophthalmic anti-inflammatory and anti-infective compounds was over 55%, and that their combined share in China was over 60%. Novartis reportedly added less than 1% to the existing high share held by Alcon but, nevertheless MOFCOM imposed a remedy – albeit behavioural.

In June 2011, MOFCOM published for public comment a draft of its Interim Provisions on the Assessment of the Effects of Concentrations of Undertakings on Competition (Draft Interim Provisions). The Draft Interim Provisions begin by highlighting the factors that the AML allows MOFCOM to consider during its merger review:[6]

(1) market shares and the market position of the undertakings involved in the concentration in the relevant market, including their ability to exercise control over that market;

(2) concentration levels in the relevant market;

(3) effects of the concentration on market entry and development of technologies;

(4) effects of the concentration on consumers and other relevant undertakings;

(5) effects of the concentration on national economic development; and

(6) other factors that may have effects on competition in the market.

The Draft Interim Provisions also indicate that MOFCOM will focus its analysis of horizontal mergers based on internationally accepted norms, namely unilateral effects and coordinated effects (which means in layman's terms whether the combined firm will have the ability to increase prices unilaterally or whether the remaining suppliers in the particular market will coordinate prices), and based on questions of foreclosure in the case of vertical mergers.

The Draft Interim Provisions are intended to increase transparency and predictability in MOFCOM's review procedures, and they do note that transactions may offer various benefits to competition at the same time as they raise competition issues. Certain factors such as "national economic development" leave the door open for possible consideration of non-competition factors during the merger review process but no specific guidance is provided on the meaning of "national economic development". The Draft Interim Provisions also note that the public interest may be taken into account.[7]

Remedies

On 5 July 2010, MOFCOM published Interim Provisions on Implementing Asset or Business Divestitures in Concentrations of Undertakings (Provisions on Remedies). These Provisions on Remedies focus on procedures for structural remedies even though MOFCOM has shown in practice a willingness to accept both quasi-structural and behavioural remedies.

The Pfizer/Wyeth decision was the first time that 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. The Novartis/Alcon decision demonstrated MOFCOM's willingness to accept certain behavioural 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. 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 EU, MOFCOM required divestment of certain animal health products in approving the Pfizer/Wyeth transaction. However, in China, the larger of the relevant overlapping products was required to be divested. The requirement that Novartis commit not to re-enter a particular market for five years in China also seems unique to the China context especially given the combined market shares involved in China (including the modest post-merger increments in market share) and Novartis'

6 These factors are cited in MOFCOM's Pfizer/Wyeth and Novartis/Alcon decisions.

7 Interim Provisions on the Assessment of the Effects of Concentrations of Undertakings on Competition. This is available in Chinese at http://fldj.mofcom.gov.cn/aarticle/zcfb/201106/20110607585023.html

stated intention to withdraw from the market concerned.

Impact on transaction timetable

Pharmaceutical companies should continue to bear in mind that MOFCOM clearance may have a significant impact on closing timetables, given the prospect of a lengthy pre-notification period and the increased likelihood of MOFCOM opening a second-phase investigation.

MOFCOM's review period consists of three phases – an initial review period of 30 days, a second phase of up to 90 days and an extended third phase of up to 60 days. Cases rarely enter into the extended third phase period but second-phase reviews are (increasingly) routine even in cases that raise little or no substantive competition concerns.

To date, MOFCOM has handled more than 240 notifications, the vast majority of which have been cleared without conditions. However, only approximately 60% of these cases were completed during MOFCOM's initial 30-day review period.

In Pfizer/Wyeth, the transaction was notified on 9 June 2009 and cleared on 29 September 2009 after second phase investigations, including a public hearing. In Novartis/Alcon, MOFCOM received the parties' notification on 20 April 2010 and cleared the transaction on 13 August 2010 following second phase investigations.

It is important to engage with MOFCOM early in the process in order to agree market definition and relevant data sources, identify possible competition concerns, and establish a realistic timetable. The additional challenge 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 dovetail the China process and the other merger review procedures. In practice, the decision will often depend on which countries trigger a notification obligation.

Policy developments

In terms of policy developments in China, the Chinese government has signaled that it intends to encourage private investment and consolidation in key industries in China.[8] With respect to the pharmaceutical sector, three Chinese central government authorities together issued a notice to encourage mergers and consolidations between pharmaceutical companies on 9 November 2010.[9] These government initiatives are aimed at encouraging principally M&A activity between domestic pharmaceutical companies as well as outbound M&A activity.

For outbound M&A, given that the vast majority of outbound Chinese pharmaceutical investors are State owned enterprises (SOE) and are ultimately owned by a State organ, whether at central or local level, one of the possible challenges for such companies will be whether each SOE will be treated by foreign competition authorities (such as the European Commission in the EU or Foreign Trade Commission in the US), as independent for merger review purposes – for example, in the pharmaceutical context, whether SOEs owned by SASAC at central or local level will be considered as acting as one or different entities. If they are treated as acting as one, the difficulty in obtaining clearance in a timely fashion from the overseas competition authorities may be increased multiple-fold.

In a separate interesting development, the State Council published a Circular in February 2011 under which MOFCOM would effectively become the gatekeeper for the new national security review system. Under the envisaged national security review system, MOFCOM will determine whether applications for national security review should be forwarded for further scrutiny by a joint ministerial panel consisting of MOFCOM, NDRC and other relevant government agencies with responsibility for the industry concerned.[10] The Circular applies to the acquisition of Chinese entities or assets by foreign companies.

The publication of the Circular followed a statement by the Minister of MOFCOM, Mr. Chen Deming, in December 2010 that, from 2011, MOFCOM would streamline review of foreign direct investment, merger control and national security issues in order to protect the security of domestic industries.

Although not an express target for national security review according to the Circular, it is conceivable that certain transactions in the pharmaceutical sector could attract national security review if there is sufficient nexus with industries that are expressly covered by the Circular – for example transactions involving milk-based nutritional products where a key agricultural product would be concerned. [11]

In accordance with the requirements of national security review, China's State Administration of Foreign Exchange (SAFE) issued an internal notice to update

[8] On 6 September 2010, the State Council issued its Opinions on Promoting Enterprise Mergers and Restructuring according to which the Chinese Government will promote consolidation, transregional 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. The Notice in Chinese is available at: http://www.gov.cn/zwgk/2010-09/06/content_1696450.htm.

[9] The three Chinese central government authorities are the Ministry of Industry and Information Technology, the State Food and Drug Administration and the Ministry of Health. The Notice in Chinese is available at: http://www.miit.gov.cn/n11293472/n11293832/n11293907/n11368223/13476011.html.

[10] Circular of the General Office of the State Council on the Establishment of a Security Review System – Guobanfa (2011) No.6, available in Chinese at http://www.gov.cn/zwgk/2011-02/12/content_1802467.htm.

its internal foreign investment approval statistics system (SAFE Internal Notice). The SAFE Internal Notice is understood to contain 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 services (which may include chain drug stores) are also understood to be on the list. The manufacture or distribution of pharmaceutical products are not expressly mentioned.

Conclusion

The growing web of merger control rules for inbound and outbound China M&A, and their interaction with national security and foreign investment approvals regimes in China and overseas, promises to increase the complexity of obtaining clearance for China-related acquistions in the pharmaceutical sector.

Foreign and Chinese companies alike should ensure their deal timelines and government relations stralegies recognise these hurdles.

[11] The sectors implicated by the Circular are military and related activities and key sectors, including key agricultural products, key energy/natural resources, key infrastructure and transportation services, key technologies, and key equipment manufacturing activities. In the case of key sectors, national security is triggered if the foreign investor acquires actual control.