CLIFFORD
CHANCE

Briefing note
July 2011

# Greater China Healthcare and Life Sciences Bulletin: Summer 2011

Welcome to the Summer edition of our Greater China Healthcare and Life Sciences (HCLS) Bulletin.

The bulletin is a quarterly update prepared by Clifford Chance on recent developments in the healthcare and life sciences sector in Greater China. It contains articles written by Clifford Chance lawyers on topical issues as well as selected new laws and regulations.

## Recent developments

It is nearly three years since the adoption of the Anti-Monopoly Law (AML), and in that time China's enforcement authorities have increasingly focused on enforcement in the pharmaceutical sector.

In the area of merger control, nearly two-thirds of conditional clearance decisions have involved mergers between international pharmaceutical companies, while the largest number of conduct investigations by the NDRC have involved practices in the pharmaceutical sector.

Enforcement of the AML coincides with a changing competitive environment, as international companies look for growth opportunities through M&A activity or non-structural alliances in China, and domestic companies seek outbound opportunities through joint ventures or other partnerships.

In this issue, we therefore focus on antitrust issues, consider some of the challenges facing companies, and examine the enforcement trends in China.

This edition includes three industry insight articles and two further articles on key developments in the regulatory environment.

We hope you find the bulletin to be a useful resource. Please email any of our contacts with suggestions for future issues, ideas to improve the content of this bulletin.

***Industry insights***

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

In the first of two articles, we focus on the changing shape of merger reviews for pharmaceutical companies in China. A period of intense merger and acquisition activity in the sector is set to coincide with a time of change and more rigorous enforcement in the application of China's merger review system. We examine the implications for foreign pharmaceutical companies in the wake of the conditional clearance of the 2010 Novartis/Alcon merger and several recent policy pronouncements by China's enforcement authorities.

Read more on page 3

**Pharma companies and antitrust in China: Part two – anti-competitive behaviour, abuse of dominance, and the regulatory regime**

In the second of our two articles, we explore important new developments in the competition law regime that impact the way pharmaceutical companies can

## Contacts

If you would like to know more about the subjects covered in this publication or our services, please contact:

**China**
Emma Davies
Partner, Shanghai
Head of Asia Pacific Healthcare Practice
Tel: +86 21 2320 7215
Email: emma.davies@cliffordchance.com

Glen Ma
Partner, Shanghai
Head of China Healthcare Practice
Tel: +86 21 2320 7217
Email: glen.ma@cliffordchance.com

**Hong Kong**
Ling Ho
Partner, Hong Kong
Intellectual Property, Litigation and Dispute Resolution
Tel: +852 2826 3479
Email: ling.ho@cliffordchance.com

Wendy Wysong
Foreign Legal Consultant, Hong Kong/
Partner, Washington D.C.
Anti-Corruption, Litigation and Dispute Resolution
Tel: +852 2826 3460
Email: wendy.wysong@cliffordchance.com

Clifford Chance, 40th Floor, Bund Centre,
222 Yan An East Road, Shanghai 200002
China
www.cliffordchance.com

conduct their day-to-day business operations. We examine certain business practices that should be avoided, existing loopholes or grey areas in the regulatory regime, and the more onerous responsibilities imposed on pharmaceutical companies that are dominant in their system.

Read more on page 9

**Getting old in a new way: Foreign investment in China's retirement home sector**

With important demographic challenges looming, and as part of its overhaul of the nation's healthcare and social security systems, China's government recently announced that it would be launching initiatives to encourage overseas capital into the retirement home sector. We examine the regulatory system governing foreign investment in this area, and explore the current state of the market, where a number of foreign organisations are reported to have begun exploring opportunities in the sector, working alongside Chinese partners.

Read more on page 15

***Regulatory environment: Key developments***

**MOFCOM: Consolidating China's pharmaceutical distribution sector**

The Ministry of Commerce (MOFCOM) recently issued an outline of its plans for the development of the national drug distribution sector through to 2015, a further step towards the consolidation of China's historically fragmented pharmaceutical industry. Foreign investors in particular may be interested to note that MOFCOM has identified the investment of overseas capital and mergers and acquisitions as important elements of its strategy for the sector. MOFCOM has also encouraged Chinese pharmaceutical companies to embrace the "go out" policy and to invest overseas. We examine the implications of MOFCOM's publication.

Read more on page 22

**Bribing foreign public officials: China's new 'FCPA'**

The PRC Criminal Law has been amended with the introduction of an article creating a new offence of bribery of foreign public officials or officials of international public organisations. The PRC Criminal Law applies to any crime committed within Chinese territory or anywhere by a Chinese citizen or entity. This new anti-corruption legislation, in keeping with similar regimes such as the Foreign Corrupt Practices Act (FCPA) regime in the US, may have important implications for entities that deal with international public health organisations and services, and for Chinese entities doing healthcare-related business overseas. We discuss important elements to this change in the law.

Read more on page 23.

***Selected Greater China healthcare laws and regulations***

**State Council**

"Pilot Scheme regarding the Launch of Old-age Pension Insurance for Urban Residents" (″二〇一一年六月一日 – 国务院常务会决定启动城镇居民社会养老保险试点 (自2011年7月1日起实施)″), passed on 1 June 2011 and effective as of 1 July 2011.

The Pilot Scheme is being launched with a view to guaranteeing basic living standards for old-aged citizens. Under the Scheme, pension contributions will be paid by both urban residents and the Government. Those over the age of 16 (excluding students) are entitled to be enrolled in this pension system and citizens may begin to draw on the pension from the age of 60. The Pilot Scheme represents part of the Government's ongoing reforms aimed at strengthening China's social security system.

**Ministry of Commerce (MOFCOM)**

"Outline of the Development Plan for the National Drug Distribution Industry (2011-2015)" (″二〇一一年五月五日 – 商务部正式对外发布了《全国药品流通行业发展规划纲要（2011–2015）》″) , promulgated by MOFCOM on 5 May 2011.

Under the Outline, MOFCOM will take steps over the next five years to tighten controls over the proliferation of pharmaceutical enterprises, encourage mergers and acquisitions, establish storage mechanisms for essential herbal medicines, promote online sales, and attract further foreign investment in the sector. The Outline constitutes a further step in the Government's efforts to consolidate and reform the Chinese pharmaceutical industry.

**The People's Government of Shanghai Municipality**

"Notice of the People's Government of the Shanghai Municipality on Deepening Recent Major Plans for Implementing Medical and Health Reforms within the Shanghai Municipality", (″二〇一一年五月十四日 – 上海市人民政府关于印发上海市深化医药卫生体制改革近期重点实施方案的通知(沪府发[2011] 18号)″), promulgated on 14 May 2011.

The Shanghai Municipality has set out plans to: (1) enable all citizens to have access to basic public health services; (2) ensure effective provision of basic drugs at a reasonable price; and (3) explore new methods of providing community health services through reforms of the family doctor system. Practical steps contemplated include imposing an open tender system on the sourcing of pharmaceuticals (with a view to decreasing prices), and taking steps to improve the city's basic medical insurance system and eliminate discrepancies in the operation of the insurance system across Shanghai.

*For a more comprehensive list of regulatory changes from April–June 2011, please see page 25.*

CLIFFORD
CHANCE

Briefing note
July 2011

# 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



If you would like to know more about the subjects covered in this publication or our services, please contact:


Emma Davies
Partner, Shanghai
Head of Asia Pacific Healthcare Practice
Tel: +86 21 2320 7215
Email: emma.davies@cliffordchance.com

Glen Ma
Partner, Shanghai
Head of China Healthcare Practice
Tel: +86 21 2320 7217
Email: glen.ma@cliffordchance.com

Ninette Dodoo
Counsel, Beijing
Head of China Antitrust Practice
Tel: +86 10 6535 2256
Email: ninette.dodoo@cliffordchance.com

Bai Yong
Associate, Beijing
Tel: +86 10 6535 2286
Email: yong.bai@cliffordchance.com

Clifford Chance, 40th Floor, Bund Centre, 222 Yan An East Road, Shanghai 200002 China
www.cliffordchance.com




[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.

CLIFFORD
CHANCE

Briefing note
July 2011

# 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




If you would like to know more about the subjects covered in this publication or our services, please contact:

Glen Ma
Partner, Shanghai
Head of China Healthcare Practice
Tel: +86 21 2320 7217
Email: glen.ma@cliffordchance.com

Ninette Dodoo
Counsel, Beijing
Head of China Antitrust Practice
Tel: +86 10 6535 2256
Email: ninette.dodoo@cliffordchance.com

Bai Yong
Associate, Beijing
Tel: +86 10 6535 2286
Email: yong.bai@cliffordchance.com

Clifford Chance, 40th Floor, Bund Centre, 222 Yan An East Road, Shanghai 200002 China
www.cliffordchance.com




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.

CLIFFORD
CHANCE

Briefing note
July 2011

# Getting old in a new way: Foreign investment in China's retirement sector

## Introduction

China is currently carrying out the most far-reaching reform of its healthcare services since the period of 'opening up' began in the 1980s.

Most attention is usually given to the government's initiatives to expand medical insurance, the quality of rural medical care, and the range of medicines eligible for reimbursement by the State and their affordability.

However, a key element of the reform package has also been the effort to liberalise foreign investment in medical institutions.[1] Alongside investment in hospitals, the government has targeted retirement homes as a priority for the investment of private capital.

In the face of a potential demographic crisis, the fact that the government is encouraging investment in this area should not be a surprise. It is well-documented that China's population is rapidly ageing, a trend that will only gather pace as parents who had children under the one child policy (introduced in 1979) begin to retire. According to some estimates, a fifth of Shanghai's population is already aged over 60, with the number predicted to rise to 29% by 2030.[2]

This demographic trend has created a social phenomenon: today's families are sometimes referred to as suffering from the "four, two, one" problem – with a couple stuck in the middle, looking after one child and four aged parents, with no siblings to share the burden.[3]

While there remains a strong culture of caring for older relations at home, the erosion of this tradition is being accelerated by the twin modern pressures of a younger urban population moving away from home and pursuing increasingly demanding careers. The proportion of older people living in retirement communities has historically been low in China, but in the coming years many families may feel this is an option they will be obliged to explore.

This article charts the government's recent initiatives to encourage foreign investment in China's retirement homes. It provides an overview of the regulatory system governing both foreign investment in this area and the key ongoing compliance obligations of retirement homes.

It also discusses the state of the market, observing that recent growth in the sector has been led by domestic private sector investment, with a number of foreign organisations reported to have begun exploring opportunities in the sector in recent months, generally working alongside Chinese partners.

## Key issues




If you would like to know more about the subjects covered in this publication or our services, please contact:

Emma Davies
Partner, Shanghai
Head of Asia Pacific Healthcare Practice
Tel: +86 21 2320 7215
Email: emma.davies@cliffordchance.com

Campbell Izzard
Senior Associate, Shanghai
Tel: +86 21 2320 7235
Email: campbell.izzard@cliffordchance.com

Clifford Chance, 40th Floor, Bund Centre,
222 Yan An East Road, Shanghai 200002
China
www.cliffordchance.com




[1] See Clifford Chance's Client Briefing of March 2011 – 'Chinese Medical Institutions – Door opens to private investment.'

[2] Financial Times, 29 April 2011.

[3] "四二一"家庭，路在何方?' ('"Four two one" families – where is this taking us?'), Yunnan Daily, 5 April 2008, http://www.yndaily.com/html/20080405/news_99_16443.html

## Regulatory analysis

At the national level, China has yet to form a comprehensive legal framework governing retirement homes. Most legislation regulating retirement homes has been promulgated by local government.

*Foreign investment*

"Service institutions for the elderly" are categorised as "encouraged" in China's 2007 Catalogue of Industries for Guiding Foreign Investment (外商投资产业指导目录) (Foreign Investment Catalogue), demonstrating the government's desire to encourage foreign investment in the social welfare sector. One implication of this designation is a potentially less time-consuming and more supportive approvals process.

Despite the lack of national legislation specifically regulating retirement homes, two laws (The Tentative Measures for Administration of Social Welfare Institutions (Tentative Measures)[4] and the Standards of Social Welfare Institutions for the Elderly (Standards)[5]) have general applicability to retirement homes – this is because the concept of 'social welfare institutions' covers all those institutions that provide care services to the elderly, including retirement homes.

*Investment in new retirement home projects*

The Tentative Measures require foreign investors to set up a retirement home in the form of an equity or contractual joint venture with a Chinese party. While no specific limit on the proportion of foreign ownership is imposed by law, this does not mean that super-majority stakes by foreign investors will necessarily be permitted. Close consultation with government departments, including the Bureau of Civil Affairs, should be maintained prior to submitting an approval application to prevent push back on the foreign party's shareholding ratio during the application process, which would inevitably result in delays.

The establishment of a foreign-invested retirement home must also be approved by the Foreign Trade and Economic department of MOFCOM at the provincial level[6].

Where services provided by a retirement home include a high-level of medical treatment such as diagnostic and therapeutic activity, the home may be classified as a 'medical institution' in addition to being designated a 'service institution for the elderly'. Medical institutions are subject to a range of additional investment criteria, details of which are contained in our Client Briefing of March 2011 – 'Chinese Medical Institutions – Door opens to private [embed a link] investment'.

Detailed procedures and regulatory requirements for the establishment of a new retirement home will be provided by the local authorities and will vary from region to region.

*Acquisitions of existing retirement homes by foreign investors*

An acquisition of an existing Chinese-owned retirement home by a foreign investor would be subject to the usual government approvals process for foreign acquisitions. Approval will need to be sought from MOFCOM and/or its local counterparts depending on the size of the investment and will involve the submission of documents, including the equity purchase agreement, shareholders' agreement and articles of association, to the approval authority. Moreover, the requirements applicable to establishment of a new foreign-invested retirement home would also apply so the post-acquisition company would need to be established as a joint venture with a Chinese party.

*Policy initiatives and incentives*

The government has recently stated that it intends to unveil a package of national-level policies to encourage foreign investment in retirement homes. In March 2011, Vice Minister of Civil Affairs Dou Yupei announced that China would seek to encourage overseas investment in this area and alluded to upcoming preferential policies for all retirement homes in the use of land, water and power, and tax breaks. Until now, such incentives have largely been enjoyed exclusively by 'non-profit' and State-owned homes.[8]

For now, details of these new incentives remain unclear. Existing policies do afford some tax incentives to overseas investors – for example, care services for the aged provided by retirement homes are exempt from business taxes.[9] However, until the new reforms take effect, other incentives are available only to non-profit institutions.

Various reports have suggested that recent examples of private investment in the sector by Chinese entities have

[4] See Tentative Measures for Administration of Social Welfare Institution (社会福利机构管理暂行办法) issued by the Ministry of Civil Affairs on 30 December 1999.

[5] See Standards of Social Welfare Institution for the Elderly (老年人社会福利机构基本规范) issued by the Ministry of Civil Affairs on 6 February 2001.

[6] Note that the Tentative Measures set out the procedures for establishment of a social welfare institution. Since the Tentative Measures generally apply to all social welfare institutions, if there exist local regulations specifically applicable to retirement homes, an investor shall comply with the procedures set out in local regulations based on the Chinese legal principle that "special law shall be superior to general law". The local regulatory environment is discussed below.

[7] Elizabeth/Sue – please would it be possible to embed a link here to the relevant article from the Spring edition?

[8] Xinhua, 8 March 2011, http://www.china.org.cn/china/NPC_CPPCC_2011/2011-03/08/content_22086639.htm

[9] See the Opinion on Pushing Forward the Home-based Care Services (关于全面推进居家养老服务工作的意见) issued by the State Administration of Taxation on 29 January 2008.

generally been classified as 'non-profit'. As few details of the structure of such investments are available, it remains a matter for speculation whether these non-profit institutions are scrupulously philanthropic and rolling all profits back into the business.

From the point of view of foreign investors, it is important to be aware that until the reforms proposed by Dou Yupei are implemented, they may not enjoy the same government incentives generally afforded to their competitors.

From our own government consultations, it appears that foreign-invested retirement homes are unlikely to be assessed as "non-profit" irrespective of their fundamental purpose. The implication of this is that until the current regulatory regime is amended further, foreign invested homes would be ineligible for the same package of incentives in areas such as land use, tax, water and power enjoyed by the majority of their Chinese competitors, which are likely to continue to classify themselves as "non-profit".

*Local legislation regulating retirement homes*

In recent years, several large cities have formulated local regulations to encourage investment in retirement homes, including Beijing, Shanghai and Tianjin. We will use Shanghai as an example to illustrate the broader regulations of foreign investment in retirement homes in China.

*Procedures for establishment of a new retirement home*

On 8 June 1998, Shanghai Municipal People's Government promulgated Shanghai Municipal Administrative Measures of Retirement Homes (the Shanghai Administrative Measures)[10] which provide detailed procedures and requirements for the establishment of retirement homes by both domestic and foreign investors.

Under the Shanghai Administrative Measures, a foreign investor is not allowed to set up a retirement home in Shanghai in the form of a wholly foreign-owned enterprise, which means it must find a reliable domestic partner. The procedures for establishment of a new foreign-invested retirement home as stipulated by the Shanghai Administrative Measures are:[11]

(a) certain application documents must be submitted to the Shanghai Ministry of Commerce (MOFCOM);

(b) Shanghai MOFCOM, in consultation with the Shanghai Municipal Civil Affairs Bureau, will decide within 30 days whether to approve the application. If the application is approved, Shanghai MOFCOM will issue a 'Foreign-invested Enterprise Certificate of Approval', and the bureau will issue a 'Retirement Home Certificate of Approval';

(c) having received such approvals, the investors may start construction. It should be noted that the 'Retirement Home Certificate of Approval' will be valid for either one or two years, depending on the scale of the proposed development. If the applicant fails to complete construction within the prescribed period, it will then be required to re-apply for approvals from the bureau and Shanghai MOFCOM; and

(d) once construction is completed, the applicant must apply to the Shanghai Municipal Civil Affairs Bureau for final acceptance and inspection. The bureau will conduct an inspection and issue its acceptance within 30 days upon receipt of the application. If the inspection is passed, the bureau will issue a 'Retirement Home Practicing Certificate'. If the inspection is not successful, the bureau will give the applicant written notification of its views as to how the project should be improved.

*Requirements for establishment of a retirement home*

Under the Shanghai Administrative Measures, new retirement homes must meet certain standards, which include that the home must have disability friendly facilities, qualified nursing and medical staff, and be established with sufficient capital for its operations.[12]

Such criteria are specific and limited in scope compared with the regulatory regimes in Western jurisdictions. The capital requirements for foreign invested homes will vary from project to project, with foreign investors expected to demonstrate that any particular project will have capital proportionate to its needs.

*Regulatory gaps – comparison with the US and UK*

Investors with experience of this sector in Western jurisdictions may be surprised to note the absence of a comprehensive national-level regulatory regime governing the ongoing management and organisation of retirement homes in China.

For example, the 1972 Moss Amendments to the United States Social Security Act oblige retirement homes that wish to qualify for reimbursement via the Medicaid programme to meet a broad range of minimum standards. The legislation specifies detailed requirements as to privacy, cleanliness, lighting,

[10] See Shanghai Municipal Administrative Measures of Retirement Homes (上海市养老机构管理办法) issued by Shanghai Municipal People's Government on 8 June 1998,

[11] See the website of Shanghai MOFCOM: http://wz.investment.gov.cn/SFI/guide/yanglaojigou.html?name=%C9%E7%BB%E1%B8%A3%C0%FB%BB%FA%B9%B9

[12] Pursuant to the Detailed Rules Regarding the Establishment of Retirement Homes in Shanghai (上海市养老机构设置细则) issued by Shanghai Civil Affairs on 19 February 1999. Other requirements include that: the retirement home shall be in line with the municipal plan in Shanghai; there shall be a fixed service place with at least 50 beds; the building design shall be in line with the architectural and design criteria for retirement homes, among others.

bedding, furniture, safety and many more issues.

In the United Kingdom, a dedicated regulator, the Care Quality Commission, has powers under statute to supervise retirement homes in areas such as the level of care provided, the quality of management, safety, and infection control.

China does not possess an equivalent national regulator focused specifically on this sector and regulatory standards are imposed by various local authorities.

## Recent market activity

*Demographic burden: Private sector meeting the challenge*

The Ministry of Civil Affairs recently announced that there were currently only 2.3 million beds in nursing homes across China, set against a population of 170 million (and rising) Chinese aged over 60. Vice-Minister Dou Yupei has stated that, while the government aims to double the number of beds by 2015, even were this target to be achieved there will still be a ratio of only 30 beds to every 1,000 retirement age citizens, compared to between 50 and 70 beds to every 1,000 in developed countries.[13]

A recent study in the Journal of the American Geriatrics Society[14] identified the rapid growth in retirement home development that has accompanied China's economic rise and the emergence of its demographic challenges. Examining the provision of elderly care in the wealthy eastern China cities of Beijing, Nanjing and Tianjin, it notes that more than half of the retirement homes in these cities had been built since 2000. In Tianjin, of 136 retirement homes, only 11 existed before 1990, against 84 built since 2000.[15] While the overall density of such homes compared with the retirement age population remains low, there has clearly been a rapid expansion over the past decade.

The study also emphasises the extent to which the recent growth of the industry has been led by the private sector. Its research of the industry in Nanjing found that 77% of the retirement homes built since 2000 were privately owned.[16] The average home in Nanjing drew 79.3% of its revenue from private paying residents as opposed to government funding, with recently established homes relying on private payments to an even greater degree.

In China, there remains no comprehensive national health insurance package for older people, so 'private payment' means exactly that. The study found that 61% of residents in Nanjing homes were funding their stay out of their pensions, with only 16% of residents being supported by some form of public welfare payment.

*Industry participants*

The most high profile participant in the industry is Cherish Yearn (亲和源), a private non-profit Chinese-owned entity. Its owners invested approximately RMB600 million (c.US$93 milion) to establish its flag-ship facility south of central Shanghai in 2008.

When completed, the site will hold 838 suites across 12 multi-storey buildings – a departure from the bungalow model seen in the West, reflecting the premium on efficient land use in China. Buildings are wheel-chair accessible and connected by a network of covered runways forming "all weather communities".[17]

Its website states that it provides nursing treatment, free monthly check-ups by doctors, broadband internet, and a 'University for the Elderly'. House-keeping is provided by the US outsourcing group Aramark, and catering by the French firm Sodexo.

Unsurprisingly, all this comes at a price – at a reported minimum US$67,000 for membership along with an annual fee of US$3,600[18], membership would be well outside the reach of most elderly Chinese – although within the means of many families based in and around relatively affluent Shanghai. As of January 2011, 300 of the 500 completed units had been occupied.[19]

A number of foreign investors have recently announced intentions to enter the market, although there remain few details yet of established foreign-backed projects. A conference in Beijing in May 2011, 'Retirement World Living', featured delegates from a number of foreign investors, including the Hong Kong-based asset manager Ajia Partners and Kerry Properties, as well as numerous mainland China investors.[20] Other news of foreign investment plans include:

- In January, NYSE-listed retirement home developer Emeritus Corporation announced that it had entered into a memorandum of understanding with asset managers Columbia Pacific Advisors "to begin exploring the potential to develop senior housing in China".[21]

[13] Vice Minister of Civil Affairs Dou Yupei, quoted in China.org.cn, 19 May 2011

[14] Feng Zhanlian and others, 'An Industry in the Making – the Emergence of Institutional Elder Care in China', Journal of the American Geriatrics Society, Volume 59, Issue 4, pages 738–744, April 2011

[15] Ibid., p.741

[16] Ibid., p.742

[17] Cherish Yearn website, http://www.qinheyuan.com/ylss1_e.htm

[18] National Real Estate Investor, 'US Developers Eye Tempting Opportunities in China', 25 April 2011

[19] Reuters, 'Aging China offers silver lining for investors', 14 January 2011

[20] South China Morning Post, 27 May 2011

[21] Emeritus Corporation press release, 27 January 2011

- In April, CSRA, a subsidiary of the large US retirement home developer Life Care Services, announced an agreement with a company based in Guangdong province to "develop and manage senior living communities across China". CSRA stated that it has begun work on developments in Beijing and Guangzhou, although it has not revealed details of the projects or scale of investment.[22]

- In February, TransGlobal Assets of Nevada entered into a joint venture with a Chinese partner to develop a large retirement home in Shandong province. The project will require US$230 million in financing, and TransGlobal stated that it was in negotiations with possible financing partners.[23]

Earlier reports of (smaller) overseas investments include the establishment by American Chinese investors of the Sunset Wellbeing Centre in Jiangsu Province in 2007 with a US$10 million investment,[24] a complex with a capacity of 1,500 residents, and the 2009 founding of the Golden Phoenix Retirement Home in Suzhou by Hong Kong investors with an investment of US$30 million.[25]

Despite this apparent recent upsurge of interest, foreign investors seeking to enter the market should keep in mind the examples of earlier troubled ventures. Germany's Augustinum Group announced plans in 2006 for a high-end retirement home in Shanghai, working in partnership with a local real estate developer and itself investing a reported US$117 million.[26] Reports now suggest that due to difficulties over land leasing rights and government policy, the project never got off the ground, and Augustinum has since said that it never made any investment in China.[27]

An earlier high profile example was that of Holiday Retirement Corp., a large US developer of independent living homes. It built a retirement home in Shanghai in 1998, but the project never opened and has since been converted into a hotel.[28]

## Conclusion

China's demographic challenges, and the government's enthusiasm for the sector, are such that more investment in retirement home living is inevitable, with private sector investors likely to continue to lead the way.

The sector is likely to continue to attract foreign investors from the Asia Pacific region and the US, where there is a tradition of private sector participation in retirement home provision. Investors from Hong Kong, Taiwan and Singapore may feel particularly well placed to understand the sensitivities of provision of elderly care in a Chinese cultural context.

Foreign investors will find that a reliable local partner that can provide insight into the local governmental environment and market may prove invaluable. Given the importance of land ownership issues to the sector, foreign market entrants may choose to focus their efforts on working with Chinese real estate developers, who are likely to be comparatively familiar with the relevant regulatory framework.

Until the new subsidy regime proposed by the Ministry of Civil Affairs becomes embedded in national law or policy, foreign investors will need to discuss carefully any applicable policy support with the local government. It may be possible (as in other sectors) for investors to negotiate a subsidies package with local authorities, which could be set out in a broad memorandum of understanding between both sides.

[22] CRSA press release, 12 April 2011

[23] TimeShare Holdings, Inc., (now TransGlobal Assets) press release, 25 February 2011.

[24] 福利到商业：外资养老院机会('From welfare to business: foreign investment's retirement home opportunity'), 3 March 2008, http://finance.sina.com.cn/g/20080303/15304572949.shtml

[25] 州成立首家外商投资养老院 ('First foreign invested retirement home set up in the region') , 13 July 2009, http://hi.baidu.com/%D5%C5%C0%DA%B5%C4%B2%A9%BF%CD/blog/item/06e7d831094b0412ebc4af2b.html

[26] Shanghai Daily, 7 June 2006.

[27] 'Growing old in China: the business of growing grey', 4 April 2011, http://www.bbc.co.uk/news/mobile/business-12573049

[28] Wall Street Journal, 'Housing Operators Put Focus on China', 9 March 2011.

CLIFFORD
CHANCE

Briefing note
July 2011

# MOFCOM: Consolidating China's pharmaceutical distribution sector

China's Ministry of Commerce (MOFCOM) has outlined its plans for the development of the pharmaceutical sector from 2011 to 2015, focusing on the distribution of drugs.[1]

The outline expands on various themes relating to the consolidation of the pharmaceutical industry that were identified in China's 12th Five Year Plan.

## Current status of the pharmaceutical distribution sector

Figures in the outline show that, by the end of 2009, there were over 13,000 pharmaceutical wholesalers, 2,149 pharmaceutical chain-store enterprises with over 135,000 branded pharmacies, and more than 253,000 independently operated pharmacies in China.

By the end of 2009, merger and restructuring activity among pharmaceutical distributors started to increase, as did consolidation in the market. Sales revenue from the top 100 pharmaceutical wholesalers by that time accounted for 70% of nationwide pharmaceutical sales.

However, in comparison to other major pharmaceutical markets, the degree of consolidation in the pharmaceutical distribution sector in China is still low and problems remain due to a variety of reasons identified in the outline, including local-level protectionism resulting in low cross-region expansion, a low threshold for market entry (contributing to a proliferation of small, low-quality operators), an absence of industry planning and administration, and inadequate law enforcement and supervision.

## Objectives

Specific objectives for the successful consolidation of the industry are set out in the outline. These include:

(i) the creation of between one to three large nationwide pharmaceutical groups, each with annual sales of over RMB100 billion; and 20 regional pharmaceutical companies with annual sales of over RMB10 billion;

(ii) by 2015 the sales revenue of the top 100 pharmaceutical wholesalers should account for more than 85% of total nationwide sales revenue and sales from the top 100 pharmaceuticals retailers should account for 60% of nationwide sales; and

(iii) by 2015 branded chain-store pharmacies should account for over two-thirds of all retailers.

Unsurprisingly, the three market leaders, (Sinopharm, Shanghai Pharma and China Resources) have been actively embracing the central government's policy of consolidation. Each has recently carried

[1] "Outline of the Development Plan for the National Pharmaceutical Distribution Industry (2011-2015)" ("全国药品流通行业发展规划纲要（2011-2015）"), promulgated by MOFCOM on 5 May 2011. The announcement is available in Chinese at: http://www.mofcom.gov.cn/aarticle/ae/ai/201105/20110507534948.html

## Key issues

Consolidation of the pharmaceutical sector

Encouragement of foreign investment

If you would like to know more about the subjects covered in this publication or our services, please contact:

Emma Davies
Partner, Shanghai
Head of Asia Pacific Healthcare Practice
Tel: +86 21 2320 7215
Email: emma.davies@cliffordchance.com

Campbell Izzard
Senior Associate, Shanghai
Tel: +86 21 2320 7235
Email: campbell.izzard@cliffordchance.com

Karen Xu
Associate, Shanghai
Tel: +86 21 2320 7278
Email: karen.xu@cliffordchance.com

Clifford Chance, 40th Floor, Bund Centre,
222 Yan An East Road, Shanghai 200002
China
www.cliffordchance.com

out a number of acquisitions of smaller rivals and stated that they are seeking further opportunities for strategic investment, such as opportunities to acquire distributors with niche market focuses and pharmaceutical companies with particularly attractive product portfolios and research and development capabilities. They have also started the integration of various parts of their own businesses, such as centralising procurement and sales and marketing.

Meanwhile, media reports suggest that companies in the next tier below these national champions, such as Nanjing Pharmaceutical, Zhejiang International Group and Jointown Pharmaceutical Group, are also poised to undertake further acquisitions/restructurings and may receive central government backing in the form of financing and tax breaks.

## Implementation strategy

MOFCOM has proposed a number of key steps in order to achieve the ambitious objectives contained in the outline. These include:

*Increase domestic market concentration*

Pharmaceutical distribution companies are to be encouraged to expand and improve their corporate strength through M&A activity as well as financial and strategic equity investment. Pharmaceutical distributors with competitive strength, sound corporate governance and good standing will be encouraged to develop their networks nationally in China. This is with a view to encouraging the development of a pharmaceutical distribution system consisting of national and regional players encompassing both urban and rural areas. Conversely, small and middle-sized pharmaceutical distributors will be encouraged to merge with their larger rivals.

*Foreign investment*

Foreign investors in particular may be interested to note that MOFCOM has identified the investment of overseas capital and M&A activity as important to implementing its strategy for the sector. The outline states that MOFCOM is seeking to improve both the "volume and standard" of foreign investment, implying that steps will be taken to improve the foreign direct investment framework in this sector, and specifically refers to the need to protect the legal rights of foreign investors.

*Outbound investment*

Encouraging leading domestic players to "go global" is a key tenet of the outline, whether by M&A activity or by listing offshore. This is with a view to establishing international procurement and marketing networks and to compete internationally.

*Supporting legal framework*

It is implicit in the outline that a series of laws, regulations and policies will be amended or promulgated to support the integration of the pharmaceutical distribution sector, including amending or repealing policies preventing the reform and development of the industry or impeding fair competition, and improving market-oriented mechanisms.

Other policies that the outline suggests may be implemented in the future include: technological reform and innovation; improvement of infrastructure; improvement of the financing environment, and implementation of financing methods of greater sophistication.

Local government is also encouraged to implement preferential policies in terms of land, finance and dedicated funds to support the development of the industry.

## Conclusion

While the outline focuses on broad national-level policies and is largely aspirational in content, a recent example of the way in which local governments are implementing reforms on the ground has been seen in Shanghai. There, the municipal government has released details of its city-wide healthcare reforms. These include measures to provide basic drugs at a reasonable price, and impose an open tender system on the sourcing of pharmaceuticals.[2]

China's 12th Five Year Plan identified consolidation and restructuring of the pharmaceutical industry as a key element of its contemplated reforms to the healthcare sector. Although the language of the outline lacks detail, we would expect further tangible support for the consolidation of the sector to follow in the near future.

[2] "Notice of the People's Government of the Shanghai Municipality on Deepening Recent Major Plans for Implementing Medical and Health Reforms within the Shanghai Municipality", (″二〇一一年五月十四日 – 上海市人民政府关于印发上海市深化医药卫生体制改革近期重点实施方案的通知（ 沪府发[2011] 18号)″), promulgated on 14 May 2011.

CLIFFORD
CHANCE

Briefing note
July 2011

# Bribing foreign public officials – a new offence in China

## Eighth amendment to the Criminal Law

The Standing Committee of the National People's Congress promulgated the Eighth Amendment to the Criminal Law of the People's Republic of China on 25 February 2011, which will take effect on 1 May 2011.

Among others, this amendment adds a second paragraph into Article 164 of the PRC Criminal Law creating a new offence of bribery of foreign public officials or officials of international public organisations.

## Text of the amendment

Article 29 of the Amendment adds a second paragraph to Article 164 of the PRC Criminal Law which reads as follows:
"Providing property to any foreign public official or official of an international public organization for the purpose of seeking improper commercial benefit shall be subject to the penalty provided by the preceding paragraph."

## Definition of foreign public officials

The term "foreign public official" is not defined under the PRC Criminal Law. In a recent interview on the amendment, the officials in the Congress responsible for the drafting of this amendment confirmed that it was adopted to implement the United Nations Convention Against Corruption ratified by China in 2005.

According to this Convention, "foreign public official" refers to any person holding a legislative, executive, administrative or judicial office of a foreign country, whether appointed or elected, and any person performing a public function, including for a public agency or public enterprise or providing a public service under the law of a foreign country. Similarly, the term "official of an international public organization" is not defined by the Amendment.

Under Article 2 of the United Nations Convention Against Corruption, this term refers to any international civil servant or any person who is authorised by such an organisation to act on behalf of that organisation.

## Improper commercial benefits

The amended provision does not define what an "improper commercial benefit" is but one may refer to the opinions provided by the Supreme People's Court and the Supreme People's Procuratorate on the provisions relating to the commercial bribery for guidance.

However, it is noteworthy that the pre-existing Article 164 prohibits bribery of non-State officials in order to seek "improper benefits" while the amended provision is limited to bribery seeking "improper commercial benefits." The specific reasons for this difference is unclear.

Another point worth attention is that the extortion exception applicable to the crime of bribing State officials under Article 389 is not mentioned in the

## Key issues



If you would like to know more about the subjects covered in this publication or our services, please contact:


Wendy Wysong
Foreign Legal Consultant, Hong Kong/
Partner, Washington D.C.
Anti-Corruption, Litigation and
Dispute Resolution
Tel: +852 2826 3460
Email: wendy.wysong@cliffordchance.com

Clifford Chance, 40th Floor, Bund Centre,
222 Yan An East Road, Shanghai 200002
China
www.cliffordchance.com

amended provision. Under Article 389, if any property is provided to a State official under extortion and no improper benefit is provided in return, it does not constitute a bribery crime. It is unclear at this stage whether this exception will be added to the amended provision in the future.

## Property

Again, the amended provision does not define the notion of property. However, this notion, which is also used in the definition of commercial bribery and bribery of domestic public officials, should most probably be understood to include any cash, physical assets or financial benefits that can be calculated in monetary terms, such as house renovation, membership cards or gift cards in which a cash amount is deposited or expenses of tours, etc.

## Extraterritorial jurisdiction

The PRC Criminal Law applies to any crime (i) committed within the Chinese territory (a crime is deemed to have been committed within Chinese territory when either its act or result – eg, receiving an improper commercial benefit – takes place in China) or (ii) committed anywhere by a Chinese citizen or entity.

In the latter case, however, if the value of the bribe is "relatively large" but not "significant", and therefore subject to penalties less than three years of imprisonment, the bribery may be exempted from prosecution.

## Clifford Chance's Asia Pacific anti-corruption group

Clifford Chance's on-the-ground anti-corruption team in Asia Pacific combines litigation and M&A specialists. Our team advises on a range of issues including upstream (risk management and front-line compliance, advisory, M&A due diligence, in-house training workshops) and downstream (investigations, crisis management, advising on remedial actions and defence work) legal support.

Our team boasts Wendy Wysong, a specialist in white collar crime and ex-US federal prosecutor, with expertise on the US Foreign Corrupt Practices Act, export controls, and economic sanctions. Wendy has added a regional office in Hong Kong to her regular desk in Washington DC.

On-the-ground anti-corruption lawyers with local Hong Kong and PRC capabilities backed by US expertise mean our offering is second to none. In addition, we have strong resources among our global network with very recognised capabilities in the US (FCPA practitioners), London (UK Bribery Act) and Europe and are able to manage the multinational and complex anti-corruption enforcement risks.

CLIFFORD
CHANCE

Briefing note
July 2011

## Greater China Healthcare and Life Sciences Bulletin

# Selected regulatory changes April – June 2011

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年三月二十八日– 国家食品药品监督管理局办公室关于征求《药物Ⅰ期临床试验管理指导原则（征求意见稿）》等意见的函 （食药监注函[2011]39号）请于2011年4月30日前将修改意见反馈我司

Letter from the General Office of the SFDA on Soliciting Opinions on "Guiding Principles for the Administration of the First Stage Clinical Drug Testing (Consultation Draft)" , issued on 28 March 2011. Deadline for Submission: 30 April 2011.

**Ministry of Health (MOH)**

二〇一一年三月二十四日 – 卫生部关于印发《医疗卫生机构医学装备管理办法》的通知（本办法自发布之日起施行）

"Notice on Issuing the 'Measures for the Administration of Medical Equipment of Medical Institutions'", promulgated by MOH on 24 March 2011 and effective as of the same date.

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年三月二十三日– 国家食品药品监督管理局办公室关于开展部分高风险医疗器械生产企业生产质量管理体系专项检查的通知（食药监办械[2011]46号）

"Notice of the General Office of the SFDA on Developing a Special Inspection for the Administrative System of Production Quality of Enterprises Producing Certain High Risk Medical Equipment", promulgated on 23 March 2011.

**The Fourth Plenary Session of the 11th NPC**

2011年3月14日第十一届全国人民代表大会第四次会议批准 《中华人民共和国国民经济和社会发展第十二个五年规划纲要》

"The 12th Five-year Economic and Social Development Plan of the PRC", passed by the NPC on 14 March 2011.

国家发展改革委 **(National Development and Reform Commission)**、监察部 **(Ministry of Supervision)** 、国务院纠风办 **(The Office for Rectifying Malpractice of the State Council)**、卫生部 **(Ministry of Health)**、国家中医药管理局 **(State Administration of Traditional Chinese Medicine)**、解放军总后勤部 **(The General Logistics Department of the Chinese People's Liberation Army)**

二〇一一年三月十四日 – 关于开展全国医药卫生服务价格大检查的通知（发改价检［2011］501号）

"Notice on Launching a Comprehensive Nationwide Inspection of Prices of Healthcare and Hygienic Services", jointly promulgated on 14 March 2011.

**Ministry of Health (MOH), State Administration of Traditional Chinese Medicine (SDTCM) and the General Logistics Department of the MOH**

二〇一一年一月三十日– 卫生部、国家中医药管理局、总后勤部卫生部关于印发《医疗机构药事管理规定》的通知（卫医政发[2011]11号）（本规定自2011年3月1日起施行）

Notice on Issuing the 'Provisions for the Administration of Pharmaceutical of Medical Institutions', jointly promulgated on 30 January 2011 and effective as of 1 March 2011.

**Ministry of Health (MOH)**

二〇一一年四月十一日 – 卫生部关于在全国医疗卫生系统开展“三好一满意”活动的通知 （卫医政发[2011] 30号）

"MOH Notice on Launching the 'Three excellencies and One satisfaction' Program in Medical and Hygiene System throughout China", promulgated on 11 April 2011.

**Ministry of Health (MOH), Ministry of Civil Affairs (MCA) and Ministry of Finance (MOF)**

二〇一一年四月六日 – 卫生部、民政部、财政部关于做好2011年新型农村合作医疗有关工作的通知（卫农卫发[2011] 27号）

"Notice Requiring Proper Implementation of Relevant Task Concerning the New Type of Cooperative Medical Care Initiatives in Rural Areas in 2011", jointly promulgated by MOH, MCA and MOF on 6 April 2011.

**National Development and Reform Commission (NDRC) and Ministry of Health (MOH)**

二〇一一年三月三十日 – 国家发展改革委、卫生部关于开展按病种收费方式改革试点有关问题的通知 （发改价格[2011]674号）

"Notice on Relevant Issues Concerning the Launching of Pilot Reform Program to Charge Fees by Type of Diseases", jointly promulgated by NDRC and MOH on 30 March 2011.

**State Food and Drug Administration (SFDA)**

二〇一一年三月二十四日– 国家食品药品监督管理局关于公布第二十三批允许发布处方药广告的医学药学专业刊物名单的通知 （国食药监稽[2011]135号）

"SFDA Notice on Promulgating the 23rd List of Medical and Pharmaceutical Journals on Which Advertisements on Prescription Drugs Can be Placed ", promulgated on 24 March 2011.

**State Council**

二〇一一年三月十九日– 国务院关于落实《政府工作报告》重点工作部门分工的意见 （国发〔2011〕7号）

"Opinions on Implementing the Division of Work among Government Departments for Key Tasks under the 'Government Work Report' ", promulgated by State Council on 19 March 2011.

**Ministry of Health (MOH)**

二〇一一年三月三日 – 卫生部关于印发《全国慢性病预防控制工作规范》（试行）的通知 （卫疾控发 [2011] 18号）

"MOH Notice on Regulating the Task for Chronic Diseases Prevention and Control throughout China (Trial Implementation)", promulgated on 3 March 2011.

**Department of Drug Safety & Inspection of the State Food and Drug Administration (SFDA)**

二〇一一年四月二十五日 – 国家食品药品监督管理局药品安全监管司关于征求《药品生产质量管理规范认证管理办法》和《药品生产质量管理规范检查员聘用及考评办法（暂行）》意见的函 （食药监安函[2011]60号） 请于2011年5月15日前将意见反馈我司。

Letter from the Department of Drug Safety & Inspection of the SFDA on Soliciting Opinions on "Administrative Measures on Regulating the Accreditation Administration of the Good Manufacturing Practice (GMP) for Pharmaceutical Products" and "Measures for the Evaluation and Regulation of Recruiting Inspector for the Good Manufacturing Practice (GMP) for Pharmaceutical Products (Interim Implementation)" , issued on 25 April 2011. Deadline for Submission : 15 May 2011.

**State Food and Drug Administration (SFDA)**

二〇一一年四月二十五日 – 国家食品药品监督管理局发布2010年药品不良反应报告

"Report on Adverse Drug Reaction in 2010", promulgated on 25 April 2011.

**The Informatization Office of the Leading Group under Ministry of Health (MOH)**

二〇一一年四月二十二日 – 卫生部信息化工作领导小组办公室《卫生综合管理信息平台建设指南（试行）》 （卫办综函[2011] 350 号文）

"Guide on Establishing Information Platform for the Comprehensive Management of Medical Healthcare (Trial Implementation)", promulgated on 22 April 2011.

**Department of Food Permit and Control of the State Food and Drug Administration (SFDA)**

二〇一一年四月二十日 – 国家食品药品监督管理局食品许可司关于征求《保健食品技术审评要点（征求意见稿）》意见的函 （食药监许函[2011]145号） 请于2011年4月27日前将修改意见反馈我司。
Letter from the Department of Food Permit and Control of the SFDA on Soliciting Opinions on " Main Points on Technical Review of Health Products (Consultation Draft)", issued on 20 April 2011. Deadline for Submission : 27 April 2011.

**The General Office of the Ministry of Health (MOH)**

二〇一一年四月十九日 – 卫生部办公厅关于统一使用医疗质量安全事件信息报告系统的通知 （卫办医管函[2011] 337号）（自2011年5月1日起施行）

"Notice of the General Office of the MOH on Using an Unified Information Reporting System on Medical Quality and Safety Matters", promulgated on 19 April 2011 and effective as of 1 May 2011.

**Ministry of Health (MOH)**

二〇一一年四月十八日 – 卫生部关于印发《三级综合医院评审标准（2011年版）》的通知 （卫医管发[2011] 33号）

"Notice of the Accreditation Standards for Tertiary General Hospitals (2011 Version)", promulgated on 18 April 2011.

**Ministry of Health (MOH)**

二〇一一年四月十八日 – 卫生部关于《卫生行政执法文书规范（修订稿）》公开征求意见的通知 （ 卫生行政执法文书规范(修订稿）） 意见收集截至日期为：5月5日。

"MOH Notice on Soliciting Opinions on "Standards for Administrative Law Enforcement Documentation of Medical and Health (Amended Draft)", issued on 18 April 2011. Deadline for submission : 5 May 2011.

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年四月八日 – 国家食品药品监督管理局办公室《关于关于加强维生素C原料药生产许可管理的通知》（食药监办安[2011] 57号）

"Notice on Strengthening the Administration of Permit Manufacture of Vitamin C as an Active Pharmaceutical Ingredient", promulgated on 8 April 2011.

**The General Office of the Ministry of Health (MOH)**

二〇一一年四月七日 – 卫生部办公厅关于做好2011年医改新闻宣传工作的通知

"Notice on Getting Good Results from News and Publicity Efforts for 2001 Medical Reform", promulgated on 7 April 2011.

**Ministry of Finance (MOF)**

二〇一一年四月六日 – 财政部关于印发《新旧医院会计制度有关衔接问题的处理规定》的通知 （财会[2011] 5号）

"Provisions of the MOF on Addressing the Transitional Issues from New to Old Hospital Accounting Standards", promulgated on 6 April 2011.

**Ministry of Finance (MOF)**

二〇一一年四月二日 – 财政部关于印发《基层医疗卫生机构新旧会计制度有关衔接问题的处理规定》的通知 （财会[2011] 6号）

"Provisions of the MOF on Addressing the Transitional Issues from New to Old Hospital Accounting Standards at Basic Medical and Health Institutions", promulgated on 2 April 2011.

**Ministry of Health (MOH)**

二〇一一年二月十二日 –卫生部关于印发《医药卫生中长期人才发展规划（2011–2020年）》的通知（卫人发[2011] 15号）

"MOH Notice on Issuing the Plan for Medium to Long-term Talent Development for the Medical and Health Profession (2011-2020)", promulgated on 12 February 2011.

**Shanghai Municipal Health Bureau**

二〇一一年四月十四日 – 上海市卫生局关于印发《2011年上海市中医药工作要点》通知

"Notice of the Shanghai Municipal Health Bureau on Issuing the Main Tasks of Traditional Chinese Medicine in Shanghai in 2011", promulgated on 14 April 2011.

**Shanghai Municipal Health Bureau, Shanghai Municipal Human Resources and Social Security Bureau, Shanghai Municipal Medical Insurance Bureau, Shanghai Municipal Development and Reform Commission, Shanghai Municipal Food & Drug Administration and Shanghai Shenkang Hospital Development Center ("Six authorities")**

二〇一一年四月十一日 – 上海市卫生局、上海市人力资源和社会保障局、上海市医疗保险办公室、上海市发展和改革委员会、上海市食品药品监督管理局、上海申康医院发展中心《关于进一步改善本市医疗服务、切实缓解群众看病就医突出问题的若干意见》

"Several Opinions on Further Improving Medical Services and Alleviating Problems with the Public Seeking Treatment in Shanghai Municipality", jointly promulgated by the six authorities on 11 April 2011.

**Shanghai Municipal Price Bureau, Shanghai Municipal Supervision Bureau, The General Office for Rectifying Malpractice of Shanghai Municipal, Shanghai Municipal Health Bureau ("Four authorities")**

二〇一一年四月十日 – 上海市物价局、上海市监察局、上海市纠正行业不正之风办公室、上海市卫生局《关于开展本市医药卫生服务价格大检查的通知 》（沪价检[2011] 001号）

"Notice on Launching Massive Inspection on Medical and Health Services and their Prices in Shanghai Municipality", jointly promulgated by the four authorities on 10 April 2011.

**Ministry of Commerce (MOFCOM)**

二〇一一年五月五日 – 商务部正式对外发布了《全国药品流通行业发展规划纲要（2011–2015）》

"An Outline of the Development Plan of the National Drug Circulation Industry (2011-2015)", promulgated by Mofcom on 5 May 2011.

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年五月三日 – 国家食品药品监督管理局办公室关于进一步做好中药材质量监管工作的通知 （食药监办安[2011]64号）

"Notice of the General Office of the SFDA on Further Improving the Quality Supervision of Traditional Chinese Medicines ", promulgated on 3 May 2011.

**State Food and Drug Administration (SFDA)**

二〇一一年五月三日 – 国家食品药品监督管理局关于深入开展基本药物生产和质量监督检查工作的通知 （国食药监安[2011]196号）

"SFDA Notice on Conducting Thorough Supervision and Inspection of the Production and Quality of Essential Drugs", promulgated on 3 May 2011.

**State Food and Drug Administration (SFDA)**

二〇一一年五月十七日 – 国家食品药品监督管理局关于印发保健食品技术审评要点的通知 （国食药监许[2011]210号） （自发布之日起施行）

"SFDA Notice on Issuing the Key Points on Technical Review of Health Products", promulgated on 17 May 2011 and effective as of the same date.

**Ministry of Health (MOH)**

二〇一一年五月四日 – 卫生部关于保健食品中使用食品添加剂问题的复函 （卫监督函[2011] 110号）

"Reply Letter by MOH on the Issues Regarding the Use of Food Additives in Health Products", replied on 4 May 2011. Ministry of Health (MOH), Ministry of Public Security (MPS), Ministry of Industry and Information Technology (MIIT), State Administration for Industry & Commerce (SAIC), State Food and Drug Administration (SFDA) and State Administration of Traditional Chinese Medicine (SDTCM) ("Six Authorities")

二〇一一年四月二十七日 – 卫生部、公安部、工业和信息化部、工商总局、食品药品监管局、中医药局关于印发药品安全专项整治工作检查评估实施方案的通知（国食药监办[2011]195号）

"Notice on the Implementation Plan for the Examination and Evaluation of the Special Rectification Work of Drug Safety", jointly promulgated by the six authorities on 27 April 2011.

**Ministry of Health (MOH)**

二〇一一年四月十四日 – 卫生部关于印发《综合医院康复医学科建设与管理指南》的通知 （卫医政发[2011] 31号）（自发布之日起施行）

"MOH Notice on Issuing the Guide to the Administration and Establishment of Rehabilitation Departments in General Hospitals", promulgated on 14 April 2011 and effective as of the same date.

**Shanghai Municipal Development and Reform Commission**

二〇一一年四月二十六日 – 上海市发展改革委关于进一步下放外商投资项目核准权限的若干意见 （沪发改外资[2011] 022号）

"Several Opinions on Further Delegating the Authority for Approving Foreign-invested Projects to Authorities at Lower Level ", promulgated by Shanghai Municipal Development and Reform Commission on 26 April 2011.

**Shanghai Municipal Development and Reform Commission and Science and Technology Commission of Shanghai Municipality**

二〇一一年四月二十九日 – 上海市发展和改革委员会、上海市科学技术委员会关于发布《上海市生物医药创新产品价格管理办法》的通知 （沪发改价费[2011] 004号）（自2011年5月1日起正式执行）

"Measures for the Administration of the Prices of Innovative Biochemical Products in Shanghai Municipality", jointly promulgated by Shanghai Municipal Development and Reform Commission and Science and Technology Commission of Shanghai Municipality on 29 April 2011 and effective as of 1 May 2011.

**State Council Executive Meeting**

二〇一一年六月一日 – 国务院常务会决定启动城镇居民社会养老保险试点 （自2011年7月1日起实施）

"Pilot Scheme on Launching Old-age Pension Insurance for Urban Residents", passed on 1 June 2011 and effective as of 1 July 2011.

**General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)**

二〇一一年五月三十一日– 国家质量监督检验检疫总局《关于进一步加强进口台湾食品、食品添加剂及相关产品检验监管的公告》（2011年第79号公告）（自2011年6月1日起实施）
附：暂停进口台 湾的食品及食品添加剂生产企业名单（5月31日）

"Announcement of the AQSIQ on Further Strengthening the Inspection and Supervision of Food, Food Additives and Relevant Food Products Imported from Taiwan", promulgated on 31 May 2011 and effective as of 1 June 2011.
Appendix : List of Taiwanese Production Enterprises Temporarily Banned from Exporting Their Food Additives and Food Products to China (as of 31 May 2011).

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年五月二十六日 – 国家食品药品监督管理局办公室关于进口生物制品按《中国药典》（2010年版）进行生产工艺变更有关事宜的通知 （食药监办注[2011] 77号）

"SFDA Notice on Relevant Matters on Changing the Production Technology of Imported Biological Products Based on 'Chinese Pharmacopoeia' (2010 Version)", promulgated on 26 May 2011.

**Department of Food Permit and Control of the State Food and Drug Administration (SFDA)**

二〇一一年五月二十六日 – 国家食品药品监督管理局食品许可司关于再次征求《保健食品说明书标签管理规定（征求意见稿）》意见的函 （食药监许函[2011]209号） （修改意见于2011年6月3日前反馈）

"Letter from Department of Food Permit and Control of the SFDA on Re-soliciting Public Opinions on the "Administrative Regulations on Specification Labels for Health Products (Consultation Draft)", issued on 26 May 2011. Deadline for Submission : 3 June 2011.

**Ministry of Health (MOH)**

二〇一一年五月二十三日 – 卫生部关于印发《食品相关产品新品种申报与受理规定》的通知 （卫监督发[2011] 49号）

MOH Notice on Issuing the Regulations on the Declaration and Acceptance of New Types of Food-related Products", promulgated on 23 May 2011.

**State Food and Drug Administration (SFDA), Ministry of Industry and Information Technology (MIIT), Ministry of Public Security (MPS) and State Administration for Industry & Commerce (SAIC)**

二〇一一年五月十八日 – 国家食品药品监督管理局、工业和信息化部、公安部、国家工商行政管理总局 关于进一步严厉打击利用互联网发布虚假药品信息非

法销售药品的通知（国食药监稽[2011]222号）

"Notice on Further Severely Cracking Down on the Release of False Information on Drugs and Illegal Sales of Drugs via Internet", jointly promulgated by SFDA, MIIT, MPS and SAIC on 18 May 2011.

**Department of Drug Registration under State Food and Drug Administration (SFDA)**

二〇一一年五月十七日 – 国家食品药品监督管理局药品注册司关于征求非处方药技术评价相关技术指导原则意见的通知（食药监注函[2011]63号）（请于2011年6月20日前反馈）

"SFDA Notice on Soliciting Public Comments on the Principles for the Relevant Technical Guidance for Assessment of OTC Drugs", issued on 17 May 2011. Deadline for Submission : 20 June 2011.

**State Food and Drug Administration (SFDA)**

二〇一一年五月十五日 – 国家食品药品监督管理局关于加强尼美舒利口服制剂使用管理的通知（国食药监安[2011]209号）[调整临床使用：“尼美舒利”修改说明书]

"SFDA Notice on Strengthening the Administrative Measures on the Use of Nimesulide Oral Preparation", promulgated on 15 May 2011.

**Ministry of Human Resources and Social Security (MOHRSS)**

二〇一一年五月十二日 – 人力资源和社会保障部关于公开征求《实施〈中华人民共和国社会保险法〉若干规定》（征求意见稿）意见的通知（请于2011年5月20日前反馈）

"MOHRSS Notice on Soliciting Public Opinions on the 'Several Provisions on the Implementation of the 'Social Insurance Law of the PRC' (Consultation Draft)' ", issued on 12 May 2011. Deadline for submission : 20 May 2011.

**Ministry of Health (MOH)**

二〇一一年五月四日– 《药品不良反应报告和监测管理办法》（中华人民共和国卫生部令81号）（自2011年7月1日起施行）

"MOH Order No 81 – Administrative Measures on the Report and Supervision of Adverse Drug Reactions", promulgated on 4 May 2011 and effective as of 1 July 2011.

**Ministry of Health (MOH) and Ministry of Finance (MOF)**

二〇一一年五月三日 – 卫生部、财政部关于做好2011年基本公共卫生服务项目工作的通知

"Notice on Proper Handling of Basic Public Health Service Projects in 2011", jointly promulgated on 3 May 2011.

**Ministry of Health (MOH)**

二〇一一年四月二十五日 – 卫生部关于印发《国家基本公共卫生服务规范（2011年版）》的通知

"MOH Notice on Issuing the Regulations on National Basic Public Health Services (2011 Version)", promulgated on 25 April 2011.

**The People's Government of Shanghai Municipality**

二〇一一年五月十四日 – 上海市人民政府关于印发上海市深化医药卫生体制改革近期重点实施方案的通知（ 沪府发[2011] 18号）

"Notice of the People's Government of Shanghai Municipality on Deepening Recent Major Plan for Implementing Medical and Health Reform in Shanghai Municipality", promulgated on 14 May 2011.

**Ministry of Civil Affairs (MCA)**

二〇一一年六月十六日 – 民政部发布2010年社会服务发展统计报告

"Statistical Report of the MCA on the Development of Social Services in 2010", promulgated on 16 June 2011.

**Ministry of Human Resources and Social Security (MOHRSS)**

二〇一一年六月十日 – 人力资源和社会保障部关于公开征求《在中国境内就业的外国人参加社会保险暂行办法（征求意见稿）》意见的通知（修改意见及理由于2011年6月17日前反馈）

The MOHRSS is Soliciting Public Opinions on the "Interim Measures for Foreigners Employed in China to Participate in Social Insurance (Consultation Draft)", issued on 10 June 2011.
Deadline for submission : 17 June 2011.

**Legislative Affairs Office of the State Council**

二〇一一年六月十日 – 国务院法制办公室关于《精神卫生法（草案）》公开征求意见的通知（修改意见于2011年6月17日前反馈）（全文）

Legislative Affairs Office of the State Council is Soliciting Public Opinions on "Mental Health Law (Consultation Draft)", issued on 10 June 2011. Deadline for Submission : 17 June 2011.

**Ministry of Human Resources and Social Security (MOHRSS)**

二〇一一年六月十日 – 人力资源和社会保障部关于《社会保险个人权益记录管理办法（征求意见稿）》公开征求意见的通知 （修改意见及理由于2011年6月17日前反馈）

The MOHRSS is soliciting Public Opinions on the "Administrative Measures for Individual Equity Records Relating to Social Insurance (Consultation Draft)", issued on 10 June 2011. Deadline for submission : 17 June 2011.

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年六月八日 – 国家食品药品监督管理局办公室关于对台湾地区生产的保健食品开展监督检查及抽验的紧急通知（食药监办稽[2011]83号） 附件：产品名单

"Emergency Notice on Carrying out Inspection and Sample Testing on Health Products Produced in Taiwan Region ", promulgated on 8 June 2011. Appendix : Product List

**State Council**

二〇一一年六月七日 – 国务院关于开展城镇居民社会养老保险试点的指导意见（国发〔2011〕18号）(2011年7月1日启动试点工作)

"Directive Opinion on Launching Pilot Scheme of Old-age Insurance for Urban Residents", promulgated by State Council on 7 June 2011 and Launching the Pilot Scheme on 1 July 2011.

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年六月三日 – 国家食品药品监督管理局办公室关于暂停生产销售有关保健食品的紧急通知（食药监办许[2011]82号）

"Emergency Notice on Temporary Ban on the Production and Sales of Certain Health Products", issued on 3 June 2011.

**Ministry of Industry and Information Technology (MIIT)**

二〇一一年六月三日 – 工业和信息化部关于在食品药品行业开展“讲诚信 保质量 树新风”活动的通知（工信部消费[2011]276号）

"MIIT Notice on Launching the Activity 'Treasure Integrity, Ensure High Quality and Foster New Trends' in the Food and Drug Industries" promulgated on 3 June 2011.

**The General Office of the State Food and Drug Administration (SFDA)**

二〇一一年六月二日 – 国家食品药品监督管理局办公室关于印发药品安全专项整治检查评估工作指导意见的通知（食药监办[2011]80号）

"Notice of the General Office of the SFDA on Issuing the Guiding Opinion on the Special Rectification, Examination and Evaluation for Drug Safety", promulgated on 2 June 2011.

**Ministry of Human Resources and Social Security (MOHRSS)**

二〇一一年五月三十一日 – 人力资源和社会保障部关于进一步推进医疗保险付费方式改革的意见 （人社部发〔2011〕63号 ）

"Opinions on Further Promoting the Reform on Payment Terms in Medical Insurance" , promulgated by MOHRSS on 31 May 2011.

**Ministry of Health (MOH)**

二〇一一年五月三十一日 – 卫生部关于进一步做好非公立医疗机构设置审批和管理工作的通知（卫医政发〔2011〕54号）

"Notice of the MOH on Further Proper Handling the Administration and Approval Work of Establishing Non-Public Medical Institutions", promulgated on 31 May 2011.

**State Council**

二〇一一年五月二十八日 – 国务院批转发展改革委关于2011年深化经济体制改革重点工作意见的通知（国发〔2011〕15号）

"Notice of the State Council on Forwarding the Opinion of the NDRC on Deepening the Key Tasks of Economic System Reform in 2011", promulgated by State Council on 28 May 2011.

**State Administration of Traditional Chinese Medicine (SATCM)**

二〇一一年五月二十七日 –国家中医药管理局关于印发《中西医结合医院工作指南（2011年版）》的通知（国中医药医政发〔2011〕31号）

"SATCM Notice on the Working Guide to Hospitals Practising Integrated Traditional Chinese and Western Medicine (2011 Version)", promulgated on 27 May 2011.

**Ministry of Human Resources and Social Security (MOHRSS)**

二〇一一年五月二十四日 – 关于普遍开展城镇居民基本医疗保险门诊统筹有关问题的意见（人社部发〔2011〕59号）

"Opinions on Relevant Questions Regarding Co-ordination Work for Out-Patient Consultation in Connection with Basic Medical Insurance for Urban Residents", promulgated by MOHRSS on 24 May 2011.

**Ministry of Health (MOH)**

二〇一一年五月二十日 –《医疗器械召回管理办法（试行）》（卫生部令第82号）(自2011年7月1日起施行)

"MOH Order No. 82 - Administrative Measures on Recalls of Medical Devices (For Trial Implementation)", promulgated on 20 May, 2011 and effective as of 1 July 2011.

**Shanghai Food and Drug Administration**

二〇一一年六月七日 – 上海市食品药品监管局关于严厉打击食品非法添加和滥用食品添加剂专项工作中有关事宜通知（食药监药注〔2011〕415号）

"Notice of the Shanghai Food and Drug Administration on Relevant Issues of the Special Work Regarding Severely Cracking Down Illegal Use and Misuse of Food Additives", promulgated on 7 June 2011.

**Shanghai Food and Drug Administration**

二〇一一年六月一日 – 上海市食品药品监督管理局关于开展医疗机构经营使用未经注册药品和医疗器械行为自查自纠的通知（沪食药监稽查〔2011〕399号）

"Notice of the Shanghai Food and Drug Administration on Launching Self-examination and Self-correction Regarding Operation and Use of Unregistered Drugs and Medical Devices in Medical Institutions", promulgated on 1 June 2011.

## Shanghai

**Emma Davies**
Tel: +86 21 2320 2722

Emma leads the mainland China corporate practice of Clifford Chance and the healthcare and life sciences group in Asia Pacific. She is bilingual in Mandarin and English and has spent over 15 years in Asia advising businesses on their investments in China. In addition to advising on various cross-border acquisitions and divestments for pharmaceutical and medical device companies and clients, she has assisted clients in executing collaborative agreements to co-commercialise products, including co-promote and distribution agreements between foreign life science companies in the China market.

**Ann Chen**
Tel: +86 21 2320 7212

Ann practises intellectual property law with an emphasis on global patent strategy. She counsels biotechnology, pharmaceutical and other life sciences clients, helping them obtain, protect and enforce their IP rights in China and abroad. Ann is familiar with many technical areas including molecular biology, cancer therapeutics, vaccines, gene therapy, transgenic plants and animals, nutritional supplements, herbal extracts, drug formulation and delivery, diagnostic kits, and medical devices. She is admitted in New York and the US Patent and Trademark Office.

**Glen Ma**
Tel: +86 21 2320 7217

Glen is a partner in Clifford Chance's Shanghai office and advises pharmaceutical and life science clients in a wide range of commercial and corporate matters. Glen has acted for pharmaceutical, nutritionals, animal health, OTC and CRO businesses in assisting them to implement their China and ex-China expansion and restructuring strategies. Glen qualified in the PRC in 2000 and was admitted to the New York State Bar in 2008.

**Campbell Izzard**
Tel: +86 21 2320 7235

Campbell is based in Clifford Chance's Shanghai office and has over nine years' experience in corporate and commercial law specialising in inbound M&A in the Chinese pharmaceutical and life sciences sectors. Campbell's recent transactions have included greenfield joint ventures, acquisitions, divestments, restructurings and marketing collaborations for a range of global industry leaders. Campbell was admitted in New Zealand in 2002, New South Wales in 2005, and is fluent in Mandarin.

## Shanghai

**Karen Xu**
Tel: +86 21 2320 7288

Karen is an associate in the Shanghai office. Her practice encompasses a broad range of transactions, including foreign direct investment projects and cross-border mergers and acquisitions in China. She is experienced in transactional and regulatory compliance work for large pharmaceutical manufacturers and medical devices companies.

## Beijing

**Ninette Dodoo**
Tel: +86 10 6535 2256

Ninette is a counsel in Clifford Chance's Antitrust Group and Head of Clifford Chance's Antitrust practice in China and the Asia Pacific region. She has more than 10 years' experience in advising major corporations on antitrust, foreign investment and regulatory matters across a range of industries. She is a member of Clifford Chance's Healthcare and Life Sciences group and is admitted in England and Wales, and Brussels. She advised on the Pfizer/Wyeth merger in China.

## Hong Kong

**Ling Ho**
Tel: +852 28263479

Ling is a partner in Clifford Chance's Hong Kong office, where she heads the Intellectual Property group in Asia and acts as Co-Head of Clifford Chance's Litigation and Dispute Resolution practice in China. Ling is admitted in both Hong Kong and England and Wales. A key focus of Ling's practice is contentious and non-contentious intellectual property matters in Asia Pacific as well as general dispute resolution in China relating to the healthcare and life science industry.

**Wendy Wysong**
Tel: +852 2826 3460

Wendy is a foreign legal consultant/partner in the Litigation and Dispute Resolution practice, working from both the Washington D.C. and Hong Kong offices. Her practice focuses on compliance and enforcement of international laws, including the US Foreign Corrupt Practices Act. She advises multinational corporations on their compliance programmes, as part of a global compliance team spanning the Clifford Chance network, to ensure compliance with all relevant jurisdictions' laws. Her work includes resolving complex licensing issues, internal compliance investigations, and representation before government agencies and in courts.

Wendy counsels clients based on her unique experience and insight as a former prosecutor and regulator. She is the former Deputy Assistant Secretary for Export Enforcement and Acting Assistant Secretary at the Bureau of Industry and Security, US Department of Commerce.