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Client briefing
Spring 2011

Greater China Healthcare and Life Sciences Bulletin - First Edition

Welcome to the Spring 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 on issues of topical interest as well as selected new laws and regulations.

Recent developments

In a recent meeting with SFDA officials, we asked about the current top priorities of the Chinese government for the HCLS sector. The following areas were highlighted:

- ***Strengthening price controls in the drugs industry***. As an example of this, in December last year, NDRC cut the retail price of 174 drugs produced by more than 60 pharmaceutical manufacturers, including, among others, Bristol-Myers Squibb, Eli Lilly, Merck & Co, Novartis, Pfizer and Roche.

- ***Large-scale consolidation of the distribution sector***. While obtaining a newly issued PRC drug distribution licence has been difficult for some time now, the authorities are becoming even less willing to issue new licences and suspending the processing of applications outright in some provinces (Zhejiang, for example). Recent announcements of acquisitions and growth in the distribution sector by larger State-owned players such as Sinopharm and Shanghai Pharma are consistent with the government's macro-economic plans for consolidation.

- ***Successfully implementing the recently published Chinese Pharmaceutical GMP system***. This is a key mandate for the SFDA in 2011. Encouraging the transition to the stricter requirements while not adversely impacting industry output, jobs and tax revenue will be a difficult balance, and a grace period until the end of 2015 is being granted for most drug producers to reach the required standard.

- ***Increasing competition in the hospital sector through private sector participation***. While limits on foreign investment into this sector are being relaxed (see our separate article in this edition), recent moves in the market such as those being made by mainland based Wuhan Asia Heart Hospital, suggest that the most aggressive investment will come from onshore private capital.

In this edition, we have included two articles in our Industry Insights section and five on what we see as key developments in the regulatory environment. Don't forget, we also include a link to a comprehensive round up of regulatory changes at the end of this bulletin.

We hope you find the Bulletin to be a useful resource. Please email any of our contacts listed here with suggestions as to how to improve the content of this bulletin or if you wish to unsubscribe.

Main content

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Industry Insights

Intellectual property – How to preserve your most valuable asset

Foreign companies doing business in China's life sciences sector are no different to local companies. However, they must pay special attention to the protection and enforcement regime in China of their intellectual property (IP), often their most valuable asset. This article provides an overview of key IP issues for life sciences companies in China.

To read more, see the Clifford Chance client briefing "Key IP Issues for Life Sciences Companies in China".

Co-promotion agreements

Co-promotion arrangements are a way of gaining access to one of the fastest growing pharmaceutical markets in the world. Joining forces with an experienced player in the Chinese market can be a key tool for market access. We highlight the main legal issues associated with such arrangements. (External Publication)

To read more, see the Global Reference Guide Biotech & Pharmaceuticals publication, written by Campbell Izzard and Daryl Fairbairn of Clifford Chance, "Co-promotion arrangements in China's pharmaceutical and biotech industries".

Regulatory environment – key developments

Chinese medical institutions – Door opens to private investment

Following the circulation in November 2010 of a policy directive designed to promote private sector investment in Chinese medical institutions, investors have been looking closely at whether these policies will be proactively implemented by local government. This article summarises the key elements of this policy directive and looks at what further steps have been taken to ensure their implementation.

To read more, see the Clifford Chance client briefing "Chinese Medical Institutions - Door opens to private investment".

NDRC – Pharmaceuticals head up price violations in 2010

The NDRC recently announced that almost one-third of all price-related violations investigated by NDRC in 2010 are related to the pharmaceutical sector. This article summarises the NDRC's latest enforcement policy and its impact.

To read more, see the Clifford Chance client briefing "NDRC announcement on pricing violations in the pharmaceutical sector in 2010".

The UK Bribery Act 2010: An end to mixing medicine with sweets?

The standard bearer for anti-corruption legislation for three decades, the US Foreign Corrupt Practices Act, has now been overtaken by the UK Bribery Act 2010, which has broader application, stricter sanctions and fewer defences. The Bribery Act, which comes into force on 1 July 2011, will mean that any company which carries on business in the UK will be at risk of prosecution where bribery is committed on its behalf anywhere in the world. This article considers how far the implications of the Bribery Act will extend to the life sciences sector, including what businesses with a UK presence should do in order to ensure compliance.

To read more, see the Clifford Chance client briefing "The UK Bribery Act 2010: An end to mixing medicine with sweets?".

FCPA probe of the pharmaceutical industry

Several major pharmaceutical companies have confirmed that they have received enquiries from the United States Department of Justice (DOJ) and Securities and Exchange Commission (SEC) regarding their sales and marketing practices in China, India, Russia, Brazil and other emerging markets.The practices at issue include gifts and entertainment, honoraria and the use of clinical trials.

This article reviews the industry-wide probe of the pharmaceutical industry under the US Foreign Corrupt Practices Act (FCPA), which US authorities launched in 2010.

To read more, see the Clifford Chance client briefing "FCPA Probe of the Pharmaceutical Industry".

Commercial bribery blacklist

This update considers the Chinese Ministry of Health's latest steps to tackle corrupt practices in the industry and its new ruling on the blacklisting of pharmaceutical enterprises found to have engaged in commercial bribery.

To read more, see the Clifford Chance client briefing "New rule on blacklisting of pharmaceutical enterprises engaging in commercial bribery".

Selected Greater China Healthcare Laws and Regulations

National Development and Reform Development (NDRC)

"NDRC Notice on Adjusting the Ceiling Retail Price of Certain Types of Drugs classified as (i) Anti-Microbial and (ii) relating to the Circulatory System" ("国家发展改革委关于调整部分抗微生物类和循环系统类药品最高零售价格的通知") (Fa Gai Jia Ge [2011]No. 440), promulgated on 2 March 2011 and effective as of 28 March 2011.

The purpose of the notice is to lower the retail price of certain types of drugs by prescribing ceiling prices and uniform pricing.

The General Office of the State Council

"Notice of the General Office of the State Council on Issuing the Pilot Work Arrangements for Public Hospital Reform in 2011" ("国务院办公厅关于印发 2011 年公立医院改革试点工作安排的通知") (Guo Ban Fa [2011]No. 10), promulgated on 28 February 2011.

The arrangements include key categories of reform for public hospitals , such as reforms to the relationship between public hospitals and government, prioritising the development of county level hospitals, and promoting non-publicly funded medical institutions.

Ministry of Health (MOH) and Ministry of Commerce (Mofcom)

"MOH Notice on Adjusting the Approval Limit for Sino-Foreign Equity and Cooperative Joint Venture Medical Institutions" ("二〇一一年一月二十五日 - 卫生部关于调整中外合资合作医疗机构审批权限的通知 (本通知自印发之日起施行"), promulgated on 25 January 2011 and effective as of the same date (Notice).

The MOH has issued this Notice to delegate the approval authority to local health bureau in relation to the establishment and changes in Sino-foreign equity and cooperative medical institutions. The Notice further implements the policies specified in the State Council's 3 December 2010 Opinion on Further Encouraging and Guiding Social Capital to Invest in Medical Institutions (关于进一步鼓励和引导社会资本举办医疗机构的意见).

For a more comprehensive list of regulatory changes from December 2010 to March 2011, click here.

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Ann practices 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.

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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.

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Key IP Issues for Life Sciences Companies in China

Introduction

Few can resist the attraction of China as an investment destination. With one of the fastest growing economies and the largest population in the world, China offers not only a potentially lucrative market but also a highly-educated workforce. For decades, foreign companies deployed sales and opened distribution channels in China to increase revenue. Later, foreign companies outsourced manufacturing and certain services to China to reduce costs. More recently, foreign companies are building research centers to tap into local talent. Foreign companies doing business in China's life sciences sector are no different than others when taking these measures. However, they must pay special attention to the protection and enforcement regime in China of intellectual property (IP), oftentimes their most valuable asset. This article provides an overview of key IP issues for life sciences companies in China.

1. IP Issues in Forming Local Operations

Historically, foreign companies preferred the use of wholly owned subsidiaries (WOFE) for conducting business in China. However, sometimes they would form joint ventures (JV) due to foreign ownership restrictions, to take advantage of a local partner's superior distribution channels or local market knowledge, or to bid on government projects. For example, foreign investment in the production of certain drugs and vaccines is classified as "restricted" under the *Catalogue of Industrial Guidance for Foreign Investment* (Amended 2007), and thus, subject to strict governmental examination and approval in China. Under these instances, the investment vehicle is likely limited to a JV under which a Chinese partner will hold majority interest.

The formation of a JV often involves the sharing of IP with the local partner. The JV documentation should clearly define the background IP contributed by each party, as well as stipulate the ownership and usage of later developed modifications, improvements, and new IP. The JV documentation also should provide audit rights over production and research sites and invention and accounting records. In addition, the JV documentation should include safeguards to deter improper use and disclosure of IP as well as to cap IP infringement liabilities.

Drug companies often collaborate with government institutions or universities in research efforts. When working with entities previously owned by or affiliated with the Chinese government or a university in China, one should carefully review the IP chain of title for completeness and any joint ownership issue. The Patent Law of the People's Republic of China (PRC) states that unless otherwise agreed upon, a joint owner can individually exploit or allow another to exploit a jointly owned patent by means of a general license; consent by all joint owners is required for other ways of exploitation (Article 15). Agreements should be drafted to ensure that commercial use of any jointly developed IP can be exclusive and will not be blocked by such default veto power.

Key Issues

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2. IP Issues in Manufacturing and Distribution

Companies that manufacture and distribute products or services through local agents in China must consider the risks of parallel import, counterfeiting, infringement and trade secret theft. In China, parallel import is not considered an act of patent infringement (see PRC Patent Law, Article 69.1), but may be considered an act of trademark infringement under specific circumstances based on recent case law. In *Michelin Group v. Tan Guoqiang and Ou Can* (2009), the Changsha Intermediate People's Court ruled that the importation of foreign-made tires without consent from the trademark owner and without a Chinese Compulsory Product Certification constitutes trademark infringement. In rendering its decision, the Court considered the possible adverse effects on the owner's reputation due to the quality and safety of the uncertified product.

Drug counterfeiting is a serious issue in China, despite government efforts such as the requirement of Good Manufacturing Practice (GMP) certification, a clamp down on false advertising, and criminal sanctions including the 2007 execution of the former director of the State Food and Drug Administration (SFDA). Xiaoyu Zheng, as head of the SFDA from 1998 to 2005, was convicted of taking bribes worth over RMB6 million (about US$850,000) from eight companies, for approving an antibiotic blamed for at least 10 deaths and other substandard medicines. The unusually harsh sentence reflects Beijing's desire to address corruption and ensure consumer health safety.

Companies should coordinate enforcement tactics with local agencies, and contemplate anti-counterfeiting labeling tools and public education. In a landmark move, Pfizer signed two memorandums of understanding with the Shanghai government in 2003 and 2004, respectively, and provided training and personnel to assist the local authorities in combating counterfeit drugs in the area. The efforts were considered successful, as Chinese officials later seized more than 600,000 counterfeit Viagra labels and more than 400,000 counterfeit Viagra tablets with an estimated value of US$4.3 million.

Drug manufacturing oftentimes involves processes that are better protected by trade secret instead of patents. To minimize theft of trade secrets, companies should monitor their physical parameters and cyber security, and ask employees to sign confidentiality and non-competition agreements. Companies should also track the career path of key employees, and monitor IP filings by these individuals. It is not uncommon for the head of R&D of a Chinese company to also be affiliated with local universities or the government, or even a competitor. Since the Chinese legal system offers limited recourse in trade secret infringement disputes, companies must take practical and preemptive steps to protect their trade secrets.

3. IP Issues in Innovation

Many pharmaceutical companies have established R&D centers in China of significant scale. For the reasons described above, companies must have an IP strategy in China. Unfortunately, many foreign companies do not procure IP protection in China until too late. In the meantime, their Chinese counterparts, in a quest for higher profits, have started to create IP and are not shy to exert their rights. For example, the French low-voltage electronics manufacturer Schneider battled for years with its top Chinese competitor Chint on multiple continents, but ended up losing and subsequently settling a patent infringement lawsuit initiated by Chint in China. While the number of patent applications filed by Chinese pharmaceutical companies is still very small compared to their global counterparts, there is no doubt that the Chinese will continue its investment in IP. Thus, life sciences companies should assess in advance the IP landscape of the target product by conducting clearance searches and address upfront any potential validity and infringement issues.

Importantly, foreign companies that intend to patent in China and exploit employee-generated inventions must consider the rights and remuneration granted under various Chinese laws. As an example, Rules 77 and 78 of the Implementing Regulations of the PRC Patent Law stipulate that absent agreement to the contrary or rules and regulations formulated according to law, within three (3) months after a patent is issued, the employee inventor would be entitled to at least RMB3,000 (about US$450) for each invention patent, or RMB1,000 (about US$150) for each utility model patent, and that during the term of the patent, the employee would be additionally entitled to at least 2% of the net profit generated by practicing the invention patent (at least 0.2% for utility model patents), or at least 10% of the net profit generated by licensing the patent. Equally unfamiliar to many is Article 326 of the PRC Contract Law, which stipulates that when a

service invention is transferred, the employee has the right of first refusal under the same conditions. As more Chinese employees participate in R&D efforts, their IP contribution will increase and need to be compensated accordingly.

Patent applications to be extended into China should be drafted in ways that comply with the PRC Patent Law. Foreign applicants are often surprised to find much narrower claims being granted in China than in the U.S. and Europe. For inventions that rely on genetic resources, the PRC Patent Law uniquely requires a patent applicant to disclose in the application the direct and original sources of the genetic resources (Article 26.5); the resulting patent can be held invalid if the acquisition or use of the genetic resources violate a law or regulation (Article 5.2). The PRC Patent Law also requires a patent application for an invention completed in China to be subject to security review or be first filed in China as a domestic or PCT application; failure to comply would result in loss of patent rights in China (Article 20).

4. IP Issues in Licensing and Technology Transfer Agreements

The import and export of technology into and out of China is heavily regulated. Some foreigner companies have the false impression that a transaction is exempted from Chinese law if a foreign governing law is selected. While a foreign judgment or ruling can be applied for recognition in China under certain circumstances, a Chinese court can and has refused to recognize judgments and rulings that contradict the basic principles of Chinese law or violate the national, social, and public interest of China. In order for an IP licensing or technology transfer agreement to be validly enforced in China, it must comply with China's Foreign Trade Law, Contract Law, Anti-Monopoly Law, and Patent Law, just to name a few.

The *Regulations of the People's Republic of China on Administration of the Import and Export of Technology*, effective from January 1, 2002 ("Regulations"), is the main legal framework that regulates technology import and export in China, including patent transfer, assignment of patent application rights, patent licenses, assignment of trade secrets, provision of technical services, and other means of technology transfer. In China, a technology can be classified as (i) a "prohibited" technology, which cannot be imported/exported; (ii) a "restricted" technology, which can be imported/exported only upon license approval; or (iii) an unrestricted technology, which can be freely imported/exported but the related contract must be registered with the relevant government authority. The government has published two catalogues that list technologies the import/export of which is prohibited or restricted; technologies not listed in the catalogues are freely tradable. Companies doing business in the life sciences sector should check the catalogues to determine whether the involved IP can be imported/exported, since several drug production processes and raw materials are considered prohibited or restricted technology in the catalogues.

For a technology import contract, the Regulations prohibit the inclusion of restrictive clauses that (1) require the licensee to accept supplementary conditions that are not absolutely necessary for the import of the technology, including the purchase of unnecessary technology, raw material, product, equipment or service, or to pay exploitation fees or to undertake obligations for expired or revoked patents; (2) restrict the licensee's right to improve technology or use the improved technology, or right to acquire similar or competitive technology from other sources; (3) unduly restrict the licensee's right to purchase raw material, part, product or equipment from certain channels or sources, or the quantity, variety, or sales price of the products made by the licensee; or (4) unduly restrict the export channels of products made through the use of the technology. The Regulations also require the licensor to be responsible for IP infringement due to use of the technology, as well as guarantee ownership or transfer right of the technology, and guarantee that the technology is complete, without error, effective and able to achieve the technological target agreed upon. Furthermore, the Regulations stipulate that an improvement made to the technology belongs to the improving party; the foreign licensor cannot require the licensee to assign or license the improvement to the licensor without compensation. While these mandates may seem counterintuitive to foreigners, they are consistent with the Chinese government's intent to trade market access for domestic technological progress. In fact, the subsequent chapter governing technology export contracts do not contain any of these provisions. Foreign companies should take note that the Chinese courts could void provisions or even entire agreement considered anti-competitive.

Conclusion

China is becoming a cradle for drug discovery and development. Over the last three decades, many pharmaceutical companies have formed local operations to distribute and manufacture drug products and services, and established research centers in China. In May 2006, AstraZeneca announced plans to invest US$100 million in R&D in China over a

period of three years beginning with oncology research. In June 2007, Eli Lilly & Co announced the establishment of Lilly Asia Venture Capital Fund to target China-based startups in life sciences sector. In July 2008, Bayer HealthCare acquired the Western over-the-counter cough and cold portfolio of Topsun Science and Technology Qidong Gaitianli Pharmaceutical Co. Ltd. for US$158 million. In March 2009, Eli Lilly unveiled an over US$40 million investment for expanding its facility in Suzhou, Jiangsu Province. In May 2009, GlaxoSmithKline signed a cooperation agreement with Chinese vaccine manufacturer, Shenzhen Neptunus Interlong Bio-Technique (NIBT), to form a joint venture to develop and manufacture influenza vaccines for China, Macau and Hong Kong. Other pharmaceutical giants also have commitments to add research capabilities in China. For example, Roche is building a fifth research centre in Shanghai, whereas Pfizer is building a global R&D centre for radiation biology and drug development in Wuhan, capital of central China's Hubei Province, to support the company's clinical drug development projects.

Life sciences companies depend on robust IP strategies to sustain its research and clinical work and subsequent commercial efforts. As more IP is generated in or licensed into China, life sciences companies cannot avoid Chinese IP laws. The Chinese government has a strong interest in ensuring the sustainability of its economy. As such, Chinese laws can differ from foreign laws in many important aspects, and heavily influence how companies compete on the basis of IP in China. As a result of all of these trends, it has become ever more important to both understand Chinese IP laws and to use them to one's advantage to maximize the protection they can offer to a multinational's IP that is either generated or used in this country.

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ASIA PACIFIC

Co-promotion arrangements in China's pharmaceutical and biotech industries

by Daryl Fairbairn and Campbell Izzard | Clifford Chance

THE PHARMACEUTICAL AND biotech industries have a rich and creative history with strategic collaborative arrangements. The benefits of partnering are many, including sharing of risk throughout the product development cycle, obtaining capital infusions, and gaining access to regulatory or marketing experience. Outside of developed western markets, collaborating can also mean access to new markets, or better access for those companies without a sufficient local sales force presence. Below we address the legal highlights associated with co-promotion arrangements in China, in particular as a tool for gaining access to this pharmaceutical market of increasing global importance.

In a co-promotion relationship, exploited in the US and Europe for many years, two or more companies typically combine their sales and marketing resources to sell the same product under a single brand. These arrangements can see responsibilities allocated between the parties in a number of different ways, depending on their expertise and tolerance for risk – from fully sharing all sales, marketing and promotional activities on the one hand, to provision of only promotional services on the other.

Co-promotion in China

One important reason for entering into a co-promotion arrangement in China is to gain access, or increased access, to one of the fastest growing pharmaceutical markets in the world. Joining forces with an experienced player in the Chinese market can provide a tool for market access, as a factual matter as well as from a reimbursement perspective. Through such a relationship a pharmaceutical product can be better marketed throughout China with a focus on successfully listing the product on the country's drug reimbursement lists.

While listing at a provincial level will be effective in generating sales to varying degrees, listing on the National Reimbursement Drug List when it is expected to be next revised in 2014 will ensure significant product sales. That said, government efforts to control drug prices will be an important factor in analysing the full benefit of listing on the National Reimbursement Drug List.

Negotiation focal points

The commercial framework for co-promotion agreements can also vary significantly. Some agree-

ments have very detailed and complex pricing structures, while others instead provide general principles with a detailed governance structure to allow the parties to agree more complex commercial details during the course of the collaboration. Some allocate risk and reward by requiring upfront payments, while others will maintain a compensatory arrangement based on other commercial factors, for example, volume.

Co-promotion agreements in respect of products can involve a lengthy relationship between the parties. This is important to allow the parties time to market the product to its full potential thereby recovering expenses incurred while recruiting, training and dedicating sales forces to promote the product while sales are lower. As a result, negotiation of termination rights which accurately reflect the underlying collaborative principles is essential. Termination rights can be purposely limited or, if more appropriate, sunset payments can be agreed in recognition of the continuing higher sales generated by the collaboration well after the legal agreement is terminated. What all forms of co-promotion agreements share in common is their complexity.

Ensuring competition compliance

In most jurisdictions, when entering into strategic collaborative arrangements competing companies should be mindful of competition concerns, and pharmaceutical co-promotion agreements in China are no exception. Some contractual structures, however, will be seen to raise fewer concerns than others. Relative to co-promotion, co-marketing agreements for example can be seen to increase competition by introducing a new product into a market that may not have otherwise been available. The fact that co-marketing agreements are typically structured to permit two companies to sell the same product under two different brand names has the tendency to increase competition in the marketplace. Co-promotion arrangements are potentially more sensitive and each form of potential arrangement should be vetted by competition counsel to account for sensitivities.

Looking forward

While there are only a handful of co-promotion arrangements involving MNC pharmaceutical products currently in China, they provide an excellent way for co-promotion partners to fill gaps in their products portfolios and market authorisation holders to enhance market access. As no specific regulatory approval is required to implement a co-promotion arrangement, they can be entered into in as short a period of time as it takes the parties to negotiate and agree terms. With the revision of the National Reimbursement Drug List expected in around three to four years time, we would not be surprised to see this form of collaborative arrangement grow in popularity in what will soon be the world's third largest pharmaceutical market. ■

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Chinese Medical Institutions - Door opens to private investment

On 26 November 2010, the State Council published a notice entitled "*Opinions on Further Encouraging and Guiding Social Capital to Fund Medical Institutions*" ("**MI Notice**", in Chinese, 关于进一步鼓励和引导社会资本举办医疗机构的意见)[1] further implementing the Chinese government's plan to diversify ownership within the Chinese hospital system. Certification as a 'medical institution' ("**MIs**") is required to establish any organisation which engages in medical treatment or diagnosis (including hospitals, clinics, nursing homes and clinical testing centres) and is issued by the PRC Health Bureau at county level or above.

The MI Notice is a directive to Chinese local government to implement the policies guidance it contains. Consequently, the full impact of the MI Notice will only be known once local level regulations are released. A number of industry insiders however, have noted that both local regulators and investors of private capital (referred to in the MI Notice as 'social capital') alike have been keenly awaiting this preliminary green light to private investment in MIs.

At present, state-run Chinese medical institutions ("**MIs**") are the dominant force in providing medical services to the Chinese public. Primarily because of regulatory constraints, privately funded (both foreign and domestic) MIs have played only a limited role in the national healthcare system accounting for around five to six per cent of total hospital beds. In addition, foreign investment has been restricted such that a Chinese partner must maintain a minimum of 30 per cent ownership in any MI.

The MI Notice forms a key part of changes to the regulatory and policy framework to allow ownership diversification in the Chinese hospital system to take place. This note briefly sets out the recent background to the release of the MI Notice and highlights the key regulatory and policy developments contained therein.

I. Background

On 17 March 2009, the State Council and Communist Party of China jointly issued the *Circular on Furthering Reform of the Healthcare System* (the "**2009 Circular**"). The *2009 Circular* embraces a complex set of policies on the Chinese healthcare system, affecting the regulation of social security policies, establishment of MIs, supply of basic drugs to the public, the administration of the healthcare sector generally, private investment into the healthcare sector and pharmaceutical pricing policy amongst other areas. In respect of MIs, the *2009 Circular* explicitly stated that the Chinese government would encourage private capital investment into the hospital system.

Key Issues

"Restricted" status removed

Equal treatment

Preference for private capital

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Following the issuance of the *2009 Circular*, the State Council promulgated the *Key Implementing Measures on Reform of Healthcare System from 2009 to 2011* (the "**Implementing Measures**") on 18 March 2009. The *Implementing Measures* outlined five central issues to be prioritised during the healthcare system's reformation process over this two year period; reforming State-run hospitals by utilizing private capital is key among these. In 2011, the national policy maker further issued a circular specifying the establishment of pilot programs to reform State-run MIs.[1]

Neither the *2009 Circular* nor the *Implementing Measures* set out detail on how private capital would be introduced to MIs. While the MI Notice contains only limited detail on this process itself, its promulgation has addressed for the first time, for example, the removal of regulatory obstacles which have restricted foreign and private capital from greater investment in MIs.

I. Policy highlights

The MI Notice is divided into three sections, including (i) relaxing market entry thresholds for private capital, (ii) further improving the business operating environment for privately-funded MIs, and (iii) promoting compliance by, and management of, privately-funded MIs. The 24 paragraphs constituting the *MI Notice* introduce a comprehensive range of policies, if implemented, providing a more flexible regulatory environment for privately-funded MIs. The more significant of these policies are highlighted below.

a. Lower market entry threshold for private capital (including foreign investment)

The MI Notice re-categorises the establishment of privately funded MIs as "permitted" as opposed to "restricted" as categorised in the *Guidance Catalogue for Foreign Investment*. However, the MI Notice reiterates that any foreign-invested MI ("**FIMI**") must take the form of a Sino-foreign joint venture and that wholly foreign owned MIs will be permitted on a pilot basis with restrictions on the permitted level of foreign investment to be gradually removed. Furthermore, investment originating from Hong Kong, Macau and Taiwan will be entitled to preferential policy support under the MI Notice when establishing a FIMI.

A pilot program has since been launched in Shanghai, Fujian, Guangdong, Hainan and Chongqing allowing qualified Hong Kong and Macau investors to open wholly-owned MIs in these locations.[2] Under the program, Taiwanese investors can apply to establish wholly-owned MIs in Shanghai, Jiangsu, Fujian, Guangdong and Hainan.[3] There has not been any indication yet when investors from outside these regions will be permitted to establish wholly-owned MIs.

The *MI Notice* explicitly states that priority should be given to private capital in reallocating or developing additional healthcare resources. Such a statement implies that greater priority would be given to the establishment of a privately-funded MI where existing MIs are insufficient to meet local demand for healthcare. Further, the MI Notice cautiously encourages the use of private investment in restructuring public hospitals, stating that qualified non-public MIs will be considered for such projects in pilot regions at first instance.

The level of government office required to approve a project is important in any early analysis of a China investment project's approvability and potential timeline. The *MI Notice* specifies that the authority to approve the establishment of Sino-foreign MIs is to be delegated to the provincial counterparts of the Ministry of Health and the Ministry of Commerce. As an indication of the momentum behind implementation of the policies articulated in the

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[1] *See* the *Notice on the Arrangement of Pilot Reform Program of State-run Hospitals in 2011* (i.e., 2011 年公立医院改革试点工作安排), issued by the State Council's Office on 28 February 2011.

[2] Details on the implementation of this program are set out in the *Interim Administrative Rules on the Establishment of Wholly Foreign Owned Hospitals in Mainland by Hong Kong and Macao Investors* (香港和澳门服务提供者在内地设立独资医院管理暂行办法), which was jointly promulgated by the Ministry of Health and Ministry of Commerce on 22 December 2010.

[3] Details on the implementation of this program are set out in the *Interim Administrative Rules on the Establishment of Wholly Foreign Owned Hospitals in Mainland by Taiwan Investors* (台湾服务提供者在大陆设立独资医院管理暂行办法), which was jointly promulgated by the Ministry of Health and Ministry of Commerce on 22 December 2010.

MI Notice, the MOH issued the *Notice on Adjusting the Limit of Authority for Examining and Approving Sino-Foreign Equity and Cooperative Joint Venture Medical Institutions* on 25 January 2011 (effective as of the same date) (the "**MOH Notice**"), a move flagged in the *MI Notice*.

The MOH Notice expands on the approvals process for Sino-Foreign or Cooperative Joint Venture medical institutions explaining that such institutions will be subject to a "preliminary examination" (初审) by the city-level health authorities, before applying for approval to the provincial counterpart of the MOH. As indicated in the MI Notice and further clarified in the MOH Notice, it would appear that there is no longer any need to apply to the national Ministry of Health for approval. After obtaining provincial-level approval, such institutions will also need to obtain approval from the corresponding department of the Ministry of Commerce.

b. The regulatory and business operation environment improved for privately funded MIs

In addition to creating a framework for removing restrictions on MIs' access to private capital, the *MI Notice* aims to create a more level playing field for both State-funded and privately-funded MIs. Specifically, the *MI Notice* requires that the income tax holidays and governmental subsidies available for State-funded MIs should be equally applicable to their privately-funded but non-profit equivalents. Further, the for-profit but privately-funded MIs should be exempt from business tax, though these MIs would still be subject to enterprise income tax.

The *MI Notice* commits to recognizing qualified privately-funded MIs as service providers under the State-run medical insurance plans. In the context of current reforms to the Chinese medical insurance system, this ensures that privately-funded MIs will not automatically miss out on those relying on reimbursement under one of the medical insurance plans.

Historically, many medical practitioners in China have been dis-incentivised from joining privately-funded MIs as the more prestigious positions (both academically and professionally) are found at larger State-funded hospitals. The *MI Notice* stresses that medical practitioners employed by privately-funded MIs will be entitled to the same academic and professional recognition as their peers working at State-run hospitals in an effort to lay the groundwork to address this issue.

c. Regulatory compliance of privately-funded MIs to be closely monitored

The third section of the *MI Notice* focuses on emphasising that privately-funded MIs should be effectively regulated and monitored, undoubtedly a key government concern when considering the partial privatisation of the MI sector. For example, the local MOH is specifically required to evaluate privately-funded MIs under its medical quality control appraisal scheme. In addition, privately-funded MIs are encouraged to engage domestic or even overseas management companies to source MI management services reflecting a desire to utilise professional expertise to improve operation of the expanding sector.

II. Conclusion

Undoubtedly, the *MI Notice* represents a milestone in the progress of China's healthcare reforms delivering a clear message that the Chinese government has officially opened the door to private investment in the MI sector. Despite this positive sign, how aggressively local governments, particularly in key markets such as Beijing and Shanghai, implement the MI Notice will only be known once more detailed implementing rules are issued although early indications are positive.

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Client briefing
March 2011

NDRC announcement on pricing violations in the pharmaceutical sector in 2010

China's pricing regulator, the National Development and Reform Commission ("NDRC"), recently published an announcement (the "NDRC Announcement") ranking the pharmaceutical sector as the worst offender for pricing violations in 2010 and signalled that it would put increased emphasis on enforcing pricing regulations[1].

Background

Since the mid 1990s, China has steadily introduced and updated a framework to govern the pricing of drugs. Currently, NDRC and its provincial offices are responsible for setting or providing guidelines for the price of all drugs available for reimbursement under China's national basic medical insurance scheme and certain other specific drugs, such as anaesthetics and vaccines. Under the current regime, NDRC is responsible for establishing ceiling retail prices for price controlled drugs and, increasingly, certain permitted margins between manufacturer and distributor, and distributor and dispenser[2].

Drug prices are coming under increasing pressure from the government as it implements the goals of its healthcare reform launched in 2009. Notably, in December last year, NDRC cut the retail price of 174 drugs produced by more than 60 pharmaceutical manufacturers, including, among others, Bristol-Myers Squibb, Eli Lilly, Merck & Co, Novartis, Pfizer and Roche.

Pricing violations – the pharmaceuticals sector

According to the NDRC Announcement, from a total of around 47,000 price-related violations investigated by NDRC last year, 15,304 violations related to drugs, accounting for around a third of all total violations. As a result, RMB 53.2 million was refunded to patients and illegal earnings of RMB 180 million were confiscated.

In its announcement, the NDRC notes several common forms of price related violations including the false reporting of drug purchase prices, violating permitted or falsifying actual margins, over-prescribing drugs for the purposes of increasing revenue, and price collusion between drug companies and medical institutions during the bidding process.

Key Issues

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[1] The announcement is available in Chinese at: http://jjs.ndrc.gov.cn/gzdt/t20110216_395182.htm.

[2] Article 13 of the Circular on Releasing the Opinions on Reforming the Pricing Mechanisms of Drug and Medical Service（关于印发改革药品和医疗服务价格形成机制的意见的通知）jointly issued by NDRC, Ministry of Health and Ministry of Human Resources and Social Security on and effective from 9 November 2009.

Legal consequences

The issuance of the NDRC Announcement indicates more emphasis will be put on identifying price related violations and enforcing sanctions within the pharmaceutical sector. Linked with stronger enforcement, the State Council also recently raised the upper limit for price violation penalties from RMB 500,000 to RMB 2 million[3].

Anyone that fails to comply with the government's pricing rules can be ordered to rectify the situation, turn over the profit gained from the violation itself and can be subject to a fine of up to five times the illegal gains. If no illegal gains are involved, a penalty of up to RMB 2 million and/or temporary suspension of business is also possible.

[3] Article 6 of the *Decision of the State Council on Amendments to the Rules on Administrative Sanctions against Price-related Violation of Laws* (国务院关于修改《价格违法行为行政处罚规定》的决定) issued by the State Council on and effective from 4 December 2010.

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Client briefing
March 2011

The UK Bribery Act 2010: An end to mixing medicine with sweets?

The standard bearer for anti-corruption legislation for three decades, the US Foreign Corrupt Practices Act (the "FCPA") has now been overtaken by the UK Bribery Act 2010 (the "Bribery Act") which has broader application, stricter sanctions and fewer defences. A clean sweep some might say? Time for a closer, somewhat medical, examination.

This briefing considers: How far the implications of the Bribery Act will extend to the Life Sciences sector, including (i) interactions with healthcare professionals, (ii) public procurement tendering, AND (iii) what businesses with a UK presence should do, in order to ensure compliance.

Key Issues

Anti-Corruption Surgery

Enacted in April 2010, the Bribery Act is due to come into force on 1 July 2011. The Act replaces the Prevention of Corruption Acts 1889-1916 and fragmented bribery offences which exist at common law. It tracks, but unquestionably increases the burden already imposed by, the FCPA and also brings the UK into full compliance with the Organisation for Economic Cooperation and Development Convention on Combating Bribery of Foreign Public Officials in International Business Transactions ("OECD Convention").

- The Bribery Act introduces four much broader offences which are set to impact both the public *and* private sector:
- Bribing (active bribery) - Section 1
- Being bribed (passive bribery) - Section 2
- Bribery of foreign public officials - Section 6
- Failure of commercial organisations to prevent bribery (the "corporate offence") - Section 7

At the top of a long list of possible civil and criminal sanctions, offenders now face the prospect of a ten year maximum prison sentence, with "consenting or conniving" senior corporate officers also facing prosecution and the potential for the same prison term, as a consequence of bribes made or received by a body corporate.

In the absence of the facilitation payment for governmental action exception and the bona fide expenses defence available under the FCPA, *only* those businesses who can demonstrate the operation of "adequate procedures" will be able to sleep easier knowing that they have mitigated the corporate risks of an employee, or third party, breaching this new legislation. Even then, explaining why a bribe has occurred despite "adequate procedures" being in place, would likely raise serious reputational issues.

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The Bribery Act is all-embracing in scope and its extra-territorial reach will undoubtedly prompt many nervous businesses to re-think their compliance strategy; not least in the Life Sciences sector where anti-corruption measures are vital to protect the public interest, and to police interactions with healthcare professionals ("HCPs") and bidding for public procurement tenders.

From an industry perspective, corruption risks are very firmly in the spotlight. The UK authorities have already signalled to the pharmaceutical industry that it is under close scrutiny. It is also a topic of significant media interest, albeit that the financial services industry seems currently to have supplanted big pharma as public enemy number one. In particular, the 2010 Dougall case[1], involving a criminal prosecution for the £4.5 million pound bribery of Greek surgeons to encourage them to use orthopaedic products, demonstrated the appetite of the UK authorities to pursue corrupt practices in the sector. Notwithstanding that the Court of Appeal's decision in that case suggested that self reporting of corruption and co-operation on the part of the offender may influence sentencing, it gives little comfort that there will not be a flow of criminal prosecutions under the new Bribery Act.

Over-Hospitable HCP Interactions and Tenuous NHS Procurement Tenders

A UK Life Sciences company operating in full compliance with the ABPI Code[2], ABHI Code[3] and/or the Public Procurement Contract Regulations[4], might be forgiven for thinking that *its* HCP interactions and NHS procurement tenders could be nothing but law abiding, particularly in relation to anti-corruption legislation. This is not necessarily the case under the Bribery Act.

The recent amendments to the ABPI Code (which mostly come into effect from 1 May 2011), in particular, introduce more stringent requirements in the context of promotional aids, the documentation of joint working with the NHS and the provision of donations, grants and/or sponsorship by industry. These highlight industry concerns about existing practices permitted pursuant to the existing ABPI Code potentially giving rise to offences under the Bribery Act.

The Primary Offences: (1) Bribing & (2) Being Bribed

Deliberately broad, these active and passive offences are designed as a catch all. The central elements of these offences comprise the linked concepts of "an advantage" and "improper performance."

An "advantage" under the Bribery Act can be financial or otherwise; this is consistent with the existing industry codes which prohibit supplying lavish hospitality or valuable branded freebees to doctors. Perhaps one example of a less obvious advantage is where an HCP[5] acting in a consultancy capacity is paid for ten hours work, but in fact only works six hours. The HCP, omitting to do the four hours work for which he has been remunerated, would be given "an advantage," which could lead to both individual and pharmaceutical company being accountable, when the arrangement is intended to "induce" or "reward" the HCP's improper performance of his duties (or where acceptance would itself constitute improper performance) . It does not matter whether the advantage is offered directly or through a third party.

The Primary Offences are characterised by conduct with a limited role for intent. Further, no acts of bribery are actually required. In an industry context, if a doctor attends a steering committee meeting and solicits or is offered luxurious "spa" hotel hospitality, this would arguably constitute an offence, even if the hospitality is not actually provided and the advantage does not occur.

Likewise, conduct amounting to "improper performance" under the Bribery Act can arise out of an act *or an omission.*

[1] R v Dougall [2010] EWCA Crim 1048
[2] The Association of the British Pharmaceutical Industry (the UK's pharmaceutical industry trade association – ABPI) Code of Practice 2011, incorporates the principles concerning interactions with health care professionals from Directive 2001/83/EC

[3] The Association of British HealthCare Industries (the ABHI – the largest devices trade association in the UK), issued the ABHI Code of Practice in 2009 (valid as from 1 February 2010) which provides guidance in part, on HCP interactions relating to medical devices

[4] The Public Procurement Contract Regulations 2006 SI 2006 No.5, (as amended), set out the procedures to be followed at each stage of the procurement process leading to the award of contracts for works, services and supplies by contracting authorities
[5] Whether or not the consultant is a public official for these purposes does not matter because the Bribery Act applies equally to the improper performance of duties to an employer in the private sector.

In applying the reasonableness test in identifying corrupt activity, it is clear that inviting a senior hospital manager to a lavish lunch for no justifiable purpose gives rise to risk, but the *omission* of an individual might be a little less clear cut. An omission could encompass an HCP being influenced in the conduct of his clinical research on behalf of his primary care trust so as to exclude consideration of a competitor product.

Indirect bribes are also caught under the Bribery Act. Thus, a medical devices company offering a senior managerial position to the son of an important doctor at a hospital that subsequently awards a lucrative contract, would almost certainly be exposed to risk. It follows that the making of a list of interested parties, both within and outside of a Life Sciences organisation would be a prudent risk mitigant.

A further difficult area is that of public procurement tenders and the controversial issue of value added goods or services. The UK procurement regulations[6] prohibit contracting authorities from imposing requirements on the operator which are "incidental and unconnected" to the public procurement contracts. Accordingly, tenders which offer products which are "incidental and unconnected" to the subject of the public procurement contract risk breach of the Regulations and UK bribery laws. Notwithstanding that, perhaps because of confusion around the concept of incidental and unconnected, the practice of public authorities transparently seeking value added goods or services is not uncommon in the procurement sphere. A public official leveraging better value for money from a private supplier does not of itself seem inherently wrong. The difficulty under the Bribery Act is that the official is seeking an advantage (even though it is not personal) which would result in an improper performance of duties on contract award, if the value added element is incidental and unconnected to the subject matter of the tender. A tender document soliciting value added extras and a response offering them may well, therefore, give rise to a criminal offence, even if the contract is not awarded.

Offence 3: Bribing a foreign official

The Bribery Act prohibits bribing a foreign public official ("FPO"). Again, under this offence, the wide definition of "active" bribery is all embracing. A mere "intention to influence" in order to obtain or retain business or an "advantage" in the conduct of business, is sufficient. Unlike the Primary Offences described above, no element of improper performance is necessary.

HCPs and FPOs have long been considered one and the same in some European countries, but the definition under the Bribery Act of an FPO as "an individual who holds a legislative, administrative or judicial position" or "exercises a public function" makes it unclear as to whether or not a foreign HCP would necessarily fall within the scope of an FPO. Assuming that this is the case, the provisions of the Bribery Act would suggest that offering an FPO a two hour inter-country business flight to and from a technology centre for consultancy services related to a new medical device, could well be classed as an "intention to influence", even if the offer was turned down. In practice, the decision whether or not to prosecute may well involve consideration of any element of impropriety but, nonetheless, the uncertainty is far from satisfactory.

With the facilitation payment exemption unavailable to UK businesses, defences to this third offence are limited, albeit that the Bribery Act permits advantages which are permitted in written law. This will require companies to seek advice on local law and could well make the life of a compliance policy draftsman very difficult in seeking to impose a consistent global policy and avoid the risks inherent in local exceptions. In practice, businesses may well be cautious and adopt a conservative line of taking a highest common denominator approach.

The upshot is that companies will have little choice but to seek local legal advice in circumstances in which it is contemplated that a benefit or advantage of any kind is to be provided to a FPO.

Offence 4: Failing to prevent bribery at a corporate level

This strict liability offence is arguably the most far reaching under the Bribery Act. UK commercial organisations will be exposed to prosecution, where *a person associated with the organisation* bribes another person intending to obtain or retain business or to obtain or retain an advantage for the organisation. This wide definition in principle includes agents, consultants and contingent-workers who provide services to the organisation. Further, it also potentially ecompasses the conduct of joint-venture or consortia partners when that entity intends to secure a benefit for the organisation. Bribery by *any* person who performs services on behalf of an organisation can place the organisation at risk, including in respect of activities overseas. From an industry perspective, the practice of outsourcing the organisation of HCP

[6] The Public Contracts Regulations 2006 SI 2006 No.5, Regulation 30 (as amended)

scientific meetings to UK or international meeting planners or CROs, without strict compliance parameters, could be very perilous indeed.

Further, in principle, this offence captures the conduct of foreign companies that carry on business or parts of a business in the UK, even if the conduct occurs overseas. There is currently no clear guidance as to what constitutes carrying on business in the UK. At this stage, industry can only turn towards the final statutory guidance issued by the UK government on 30 March 2011. The guidance indicates that the issue is a matter for the Courts to determine but suggests that a UK listing or a UK subsidiary would not of itself be sufficient to constitute carrying on business. The guidance refers to the "common sense" concept of a "demonstrable business presence". Ultimately, there is the sense that this issue will be a matter that will be decided in the courts.

It remains to be seen whether a conviction for this offence will lead to an automatic disbarment from public procurement contracts. Even though prosecutional guidance suggests that this may not be the case, it is unclear whether EU member states would agree. The Government has promised to clarify this issue before the Bribery Act comes into force.

The only defence for a company to criminal liability under this offence is if it can show adequate means within the organisation to prevent bribery but this begs the question, is it really possible to prove that adequate measures are in place, if a bribe has occurred in any event?

In evaluating adequate procedures, the guidance discloses six principles for bribery prevention:

1. Proportionate procedures;
2. Top level commitment;
3. Risk assessment;
4. Due diligence;
5. Communication (including training); and
6. Monitoring and review.

This guidance and its helpful examples (some of which are specific to the Life Sciences industry) are only illustrative and are not intended to be a failsafe. Having said that, three potential "safe harbours" are identified: first, that an FPO's hospitality or expenditure will not be interpreted as an advantage where the cost of such would have been absorbed by the FPO's government in any event; second, that "offset" arrangements (described as a situation where some kind of additional investment is offered or required as part of an organisation's tender), which are permitted or required by local law, are acceptable; and third, it is contemplated that "reasonable and proportionate" hospitality which "seek to improve the image of a commercial organisation, better to present products and services, or establish cordial relations" are permissible.

The third of these exceptions in the draft guidance gives rise to particular difficulty. How will this exception be applied in practice and how will it align with industry codes? This is likely to give rise to a period of considerable uncertainty. The recent revision to the ABPI Code seems intended to ensure industry compliance but may well require at least pharmaceutical companies to go beyond what is contemplated under the Bribery Act in practice. It remains to be seen how the device sector will react.

Risk Mitigation

Taking into account the government guidance, Dougall and the existing industry codes which will now sit side by side with the Bribery Act, Life Science businesses should give further thought to the management of risk.

Identifying key areas of risk and tailoring guidance, training, due diligence and monitoring specifically to it, will go a long way towards filling any compliance gaps that arises as a consequence of the Bribery Act. For example, business might analyse the activities and procedures of: medical sales members who have regular contact with HCPs at marketing events and congresses; managers who liaise with potential clinical trial sites and staff in the midst of a new study for a drug or medical device; administrative staff organising scientific meetings on behalf of their managers who arrange

travel, accommodation and subsistence; finance staff involved in setting honoraria parameters for HCP consultancy interactions; and contracts staff who are involved in NHS procurement tenders. The list goes on but businesses should have measures in place to prevent and detect bribery in these areas, at the very least.

A Healthy Prognosis?

This determined piece of legislation will raise the compliance bar and, at a minimum, act as a deterrent. It remains to be seen how the Bribery Act will be applied to the sector in practice, but, if it is enforced vigorously (and active Serious Fraud Office bribery investigations in the sector suggest this will happen), it should help to generate a level playing field for industry participants and promote reward for competitive advantage based on the underlying quality of the product or services.

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Client Memorandum
August 2010

FCPA Probe of the Pharmaceutical Industry

Several major pharmaceutical companies confirmed last week that they have received inquiries from the United States Department of Justice ("DOJ") and Securities and Exchange Commission ("SEC") regarding their sales and marketing practices in China, India, Russia, Brazil and other emerging markets.[1] The practices at issue include gifts and entertainment, honoraria, and the use of clinical trials.

These inquiries are part of an industry-wide probe of the pharmaceutical industry under the U.S. Foreign Corrupt Practices Act ("FCPA"), which U.S. authorities had first signalled last year.

Background

The DOJ announced its industry-wide probe of the pharmaceutical industry in a series of speeches in late 2009 and 2010. In a November 2009 speech, the Assistant Attorney General of the Criminal Division of the DOJ, Lanny Breuer, stated that the pharmaceutical industry is a focus of his division's FCPA enforcement activity. Mr. Breuer noted that:

> *"The depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates, in our view, a significant risk that corrupt payments will infect the process. Our remarkable FCPA unit and our terrific health care fraud unit will be working together to investigate FCPA violations in the pharmaceutical industry in an effort to maximize our ability to effect ively enforce the law in this high-risk area."* [2]

In another speech Mr. Breuer further explained that:

"Our focus and resolve in the FCPA area will not abate, and we will be intensely focused on rooting out foreign bribery in [the pharmaceutical] industry. That will mean investigation and, if warranted, prosecution of corporations to be sure, but also investigation and prosecution of senior executives. Effect ive deterrence requires no less. Indeed, we firmly believe that for our enforcement efforts to have real deterrent effect, culpable individuals must be prosecuted and go to jail where the facts and the law warrant. [3]

Key Issues

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[1] Stephanie Kirchgaessner, *U.S. Probes Corruption in Big Pharma,* Financial Times, August 12, 2010 (available at http://www.ft.com/cms/s/0/9a8e8f90-a63e-1 1 df-8767-00144feabdc0.html).

[2] Lanny A. Breuer, *Prepared Address to 22nd Annual Forum on the Foreign Corrupt Practices Act,* Nov. 17, 2009 (available at http://www.justice.gov/criminal/pr/speeches-testimony/documents/1 1-1 7-09aagbreuer-remarks-fcpa.pdf).

[3] Lanny A. Breuer, *Prepared Keynote Address to the Tenth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum,* Nov. 12, 2009 (available at http://www.justice.gov/criminal/pr/speeches-testimony/documents/1 1-1 2-09breuerpharmaspeech.pdf).

As evidence that the DOJ's probe of the pharmaceutical industry is progressing in an aggressive manner, the Financial Times recently reported that several major pharmaceutical companies including GlaxoSmithKline, Pfizer, Bristol-Myers Squibb, Merck and Eli Lilly, among others, have been contacted by the DOJ and the Securities and Exchange Commission.[4]

Among other things, the article points out that the DOJ is particularly interested in corrupt payments that may have had the effect of influencing the reliability or integrity of data from clinical trial conducted outside of the United States.

General Overview of the FCPA

The FCPA applies to U.S. persons and companies, stockholders, officers, directors, employees, or agents acting on behalf of U.S. companies, and to "issuers" of U.S. securities. Foreign subsidiaries of U.S. companies may be subject to the FCPA, or may subject their parent companies to liability under the FCPA, in several circumstances. The FCPA has two sets of provisions, the anti-bribery provisions and the books-and-records provisions.

Anti-Bribery provisions

The anti-bribery provisions make it illegal to use the "instrumentalities of U.S. commerce" — such as the mails, phone lines, or internet — or to take any act while within the U.S. in furtherance of a corrupt payment or offer to pay anything of value to a "foreign official," directly or indirectly, to influence his official actions or to induce him to use his influence to assist the company. The FCPA also prohibits knowingly engaging in the prohibited conduct through a third party, such as a consultant, contractor, or joint venture partner.

Foreign officials include "any officer or employee of a foreign government or any department, agency, or instrumentality thereof, or of a public international organization, or any person acting in an official capacity for or on behalf of any such government or department, agency, or instrumentality, or for or on behalf of any such public international organization."

For the pharmaceutical industry, the DOJ has made clear that foreign officials include, for instance, doctors, pharmacists, lab technicians and other health care professionals who work for government-owned or controlled hospitals. The DOJ has further stated in this regard that "it is entirely possible, under certain circumstances and in certain countries, that nearly every aspect of the approval, manufacture, import, export, pricing, sale and marketing of a drug product in a foreign country will involve a 'foreign official' within the meaning of the FCPA."

Books and Records Provisions

The books and records provisions of the FCPA require U.S. issuers[5], which include non-U.S. companies that issue stock or ADRs on a U.S. exchange, to adopt internal controls that ensure accurate financial records with respect to any payments. These provisions apply to the foreign subsidiaries of the U.S. issuers to the extent that the subsidiaries' books and records are consolidated with their parents. Among other things, the books and records provisions require U.S. issuers to ensure: (1) that books, records and accounts are kept in reasonable detail to accurately and fairly reflect transactions and dispositions of assets, and (2) that a system of internal accounting controls is devised to: (a) provide reasonable assurances that transactions are executed in accordance with management's authorization; (b) ensure that assets are recorded as necessary to permit preparation of financial statements and to maintain accountability for assets; (c) limit access to assets to management's authorization; and (d) make certain that recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

FCPA cases against U.S. issuers typically include alleged violations of one or more of the accounting provisions on the ground that the accused company misreported or failed to record illicit transactions in the company's books. Common types of violations include failures to record transactions, for example, "off-the-book" transactions, and falsified or mischaracterized expenses, for example, illicit payments characterized as "training" or "consulting" expenses.

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[4] Kirchgaessner at Note 1.

[5] A U.S. issuer includes any company that either has a class of securities registered pursuant to section 12 of the Securities Exchange Act of 1934 ("Exchange Act") or that is required to file reports with the SEC pursuant to section 15(d) of the Exchange Act

Other Developments

Pharmaceutical companies should also be aware of two key recent developments, which may dramatically impact their positions with respect to the FCPA:

- As a result of recent legislation, potential violations of certain laws are at greater risk of disclosure by whistleblowers. The Dodd-Frank Wall Street Reform and Consumer Protection Act signed into law by President Obama last month contains in Section 922[6] a new whistleblower incentive program that would reward certain whistleblowers with between 10% and 30% of the total sum collected in a successful SEC enforcement action for which the whistleblower provided "original information." This would include enforcement actions for the violation of the FCPA accounting provisions and ancillary actions by the DOJ.

- SEC's Director of Enforcement has new power to issue formal orders of investigation. Under a new rule effective as of August 16, 2010, the SEC's Enforcement Division has the power to issue formal orders of investigation, which include subpoena power. Under the new rule, the Enforcement Division will be able to issue subpoenas for all of its cases, including those under the FCPA. The time and difficulty of issuing a subpoena will also be reduced.[7]

Next Steps

We expect that the DOJ and SEC will issue additional information requests to multinational pharmaceutical companies and medical device manufacturers, including non-U.S. companies. Accordingly, we recommend that companies prepare to receive such an inquiry, including by ensuring that the relevant persons within the company are aware of whom to notify if an inquiry arrives.

In this regard, any company that receives a subpoena as part of the current probe should carefully consider how the information provided to the U.S. authorities will impact their position under the FCPA. Relevant first steps to consider include:

1. Assess the jurisdictional reach of the subpoena and the impact of local law on the production of documents, and ensuring that the company has instituted an appropriate document retention and production procedure for its response to the subpoena;

2. Ensure that the company understands the legal implications of the information contained in the documents that are turned over to the U.S. authorities, including whether the documents subject the company to legal enforcement risk under applicable anti-corruption laws; and

3. Identify any tangential effects that may result from disclosing the information to the U.S. authorities.

Given the renewed focus of U.S. enforcement authorities on the industry and the new legislative developments that increase the risk that FCPA issues will be identified by U.S. authorities, in advance of receiving a subpoena, companies should take internal steps to confirm that they are properly managing their anti-corruption legal risk. This can include both a gap analysis of their existing systems and controls, as well as targeted internal reviews of their higher risk businesses and jurisdictions of operation.

6 Pub. Law. 111-203, § 922 (modifying the Securities Exchange Act of 1934 (15 U.S.C. 78a et. seq) by adding a new Sec. 21f).

7 Securities Exchange Commission, *Delegation of Authority to the Director of Its Division of Enforcement,* 75 Fed. Reg. 49820 (August 16, 2010) (codified at 17 C.F.R. 200.30-4).

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Client briefing
18 October 2010

New rule on blacklisting of pharmaceutical enterprises engaging in commercial bribery

On 21 June 2010, the Ministry of Health of China (MOH) issued a Notice on Further Crackdown on Commercial Bribery in Purchase and Sale of Pharmaceutical Products (Notice), which is another step taken by the Chinese government to tackle commercial bribery practices in the pharmaceutical industry.

In particular, the Notice requires the establishment by each local health authority at provincial level of a system to record any commercial bribery violation committed in its jurisdiction in connection with the purchase and sale of pharmaceutical products. In addition, companies having engaged in commercial bribery violations should be placed on a publicly available "blacklist".

The blacklist system was introduced for the first time by a rule issued by the MOH in 2007 (i.e. Provisions on Maintaining Records on Commercial Bribery in Purchase and Sale of Pharmaceutical Products dated 19 January 2007 (Provisions)). Under the Provisions, pharmaceutical manufacturers and distributors (as well as their agents) should be placed on to the blacklist published on the website of the relevant health authorities if they are found to have provided any property or other benefits to the management personnel, drug purchasing staff and/or medical staff of the concerned hospitals, and such activities are identified as crimes of bribery by competent courts, handled as bribery cases by relevant discipline inspection and supervision authorities or punished by other competent authorities.

Both the Provisions and Notice provide that, where a pharmaceutical manufacturer or distributor is blacklisted in a province, hospitals of that province should be prohibited from purchasing any drug, medical device or medical consumables from it for two years. The Notice further clarifies that such pharmaceutical manufacturer or distributor should also be banned from submitting bids in drug centralized procurement programs in the province for two years. The Provisions and Notice imply that the blacklisted status of a company in one province does not affect its sale of products and participation in the centralized drug procurement in the other provinces.

Since the implementation of the 2007 rule, various local health authorities have already established blacklists. For example, it is reported that, in Fujian Province, 36 enterprises have been placed on the blacklist. The Notice now emphasises that this blacklist system must be in place in all the provinces by 2010. Following such requirement, it is expected that the local governments will more vigorously implement the blacklisting rules.

Key Issues

Local Health Authorities to Record Incidents of Bribery

Provincial-level Blacklist of Companies that Bribe Medical Staff

Blacklisted Companies Excluded from Sales to Hospitals for Two Years

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Greater China Healthcare and Life Sciences Bulletin

Selected regulatory changes December 2010 – March 2011

Ministry of Health (MOH) and Ministry of Commerce (Mofcom)

"Notice on the Interim Administrative Measures for Establishment of Wholly Owned Hospitals by Taiwanese Service Providers in Mainland China" 二〇一〇年十月二十二日 - 卫生部、商务部关于印发《台湾服务提供者在大陆设立独资医院管理暂行办法》的通知 (卫医政发〔2010〕110 号) (自 2011 年 1 月 1 日起施行), jointly promulgated by MOH and Mofcom on 22 December 2010 and effective as of 1 January 2011.

Ministry of Health (MOH) and Ministry of Commerce (Mofcom)

"Notice on Implementing the Relevant Matters Under Supplement VII to the Mainland and Hong Kong Closer Economic Partnership Arrangement (CEPA)" 二〇一〇年十二月十四日 - 卫生部、商务部关于落实内地与香港澳门更紧密经贸关系安排补充协议七有关事项的通知 (卫医政发〔2010〕105 号) (自 2011 年 1 月 1 日起施行), jointly promulgated by MOH and Mofcom on 14 December 2010 and effective as of 1 January 2011.

Ministry of Health (MOH)

"MOH Notice on the Interim Provisions on the Administration of Short-term Practice by Medical Specialists of Hong Kong Special Administrative Region and Macao Special Administrative Region in Mainland China", 二〇一〇年十二月十六日 - 卫生部关于印发《香港和澳门特别行政区医疗专业技术人员在内地短期执业管理暂行规定》的通知 (卫医政发〔2010〕106 号)(自 2011 年 1 月 1 日起施行), promulgated on 16 December 2010 and effective as of 1 January 2011.

ARATS - Association for Relations Across the Taiwan Strait (Mainland China) and SEF - Straits Exchange Foundation (Taiwan)

"The Cross-strait Medical and Healthcare Cooperation Agreement" 海峡两岸关系协会、财团法人海峡交流基金会于二零一零年十二月二十一日在台北签署《海峡两岸医药卫生合作协议》 signed between ARATS and SER on 21 December 2010 in Taipei and effective as of the next day from receipt of the notice from each other confirming they have completed the relevant post-agreement procedures.

Ministry of Health (MOH) and Ministry of Commerce (Mofcom)

"Notice on the Interim Administrative Measures for Establishment of Wholly Owned Hospitals by Hong Kong and Macao Service Providers in Mainland China" 二〇一〇年十二月二十二日 - 卫生部、商务部关于印发《香港和澳门服务提供者在内地设立独资医院管理暂行办法》的通知 (卫医政发〔2010〕109 号) (自 2011 年 1 月 1 日起施行), jointly promulgated by MOH and Mofcom on 22 December 2010 and effective as of 1 January 2011.

Ministry of Health (MOH)

"MOH on Publication of the Standards for Delivery of Quality Nursing Services by Hospitals (Trial Implementation)" 二〇一〇年十二月二十二日 - 卫生部印发医院实施优质护理服务工作标准(试行) (卫医政发〔2010〕108 号) , promulgated on 22 December 2010.

State Ethnic Affairs Commission (SEAC)

"SEAC Notice on Publication of the Action Plan for Implementing a Major National Medical Campaign for the Near Term (2010-2012)" 二〇一〇年十二月二十二日 - 国家民族事务委员会关于印发全国民族医药近期重点工作实施方案（2010 - 2012 年）的通知 , promulgated on 22 December 2010.

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

"Notice on Hospital Financial System" 二〇一〇年十二月二十八日 - 财政部 卫生部关于印发《医院财务制度》的通知 (财社[2010]306 号) (本制度自 2011 年 7 月 1 日起在公立医院改革国家联系试点城市执行，自 2012 年 1 月 1 日起在全国执行), jointly promulgated by MOF and MOH on 28 December 2010 and effective as of 1 July 2011 for Public Hospitals in Certain Trial Cities and 1 January 2012 for the Whole Nation.

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

"Financial System for Basic Medical and Health Institutions" 二〇一〇年十二月二十八日 - 财政部 卫生部关于印发《基层医疗卫生机构财务制度》的通知 (财社[2010]307 号) (自 2011 年 7 月 1 日起执行), jointly promulgated by MOF and MOH on 28 December 2010 and effective as of 1 July 2011.

Ministry of Finance (MOF)

"MOF Notice on Accounting System for Basic Medical and Health Institutions" 二〇一〇年十二月二十九日 - 财政部关于印发《基层医疗卫生机构会计制度》的通知 (财会[2010]26 号) (自 2011 年 7 月 1 日起执行), promulgated on 29 December 2010 and effective as of 1 July 2011.

Ministry of Finance (MOF)

"MOF Notice on Hospital Accounting System" 二〇一〇年十二月三十一日 - 财政部关于印发《医院会计制度》的通知 (财会[2010]27 号) (本制度自 2011 年 7 月 1 日起在公立医院改革国家联系试点城市执行，自 2012 年 1 月 1 日起在全国执行), promulgated on 31 December 2010 and effective as of 1 July 2011 for Public Hospitals in Certain Trial Cities and 1 January 2012 for the Whole Nation.

State Food and Drug Administration (SFDA)

"SFDA Notice on the Publication of Summary Report on Advertisements of Illegal Drugs, Medical Devices and Health Products (Issue No. 4 of 2010)" 二〇一一年一月五日 - 国家食品药品监督管理局关于发布 2010 年第 4 期违法药品、医疗器械、保健食品广告公告汇总的通知 (国食药监稽[2011]3 号), promulgated on 5 January 2011.

Ministry of Health (MOH)

"MOH Guiding Opinion on Establishing Social Stability Risk Assessment Mechanism for Major Issues of the Medical System (Trial Implementation)" 二〇一一年一月五日 -卫生部关于建立卫生系统重大事项社会稳定风险评估机制的指导意见（试行）(卫办发[2011] 2 号), promulgated on 5 January 2011.

State Food and Drug Administration (SFDA), Ministry of Health (MOH) and State Administration of Traditional Chinese Medicine (SATCM)

"Notice on Strengthening the Supervision and Administration of Decoction Pieces in Traditional Chinese Medicine" 二〇一一年一月五日 - 国家食品药品监督管理局、中华人民共和国卫生部、国家中医药管理局关于加强中药饮片监督管理的通知 (国食药监安[2011]25 号), jointly promulgated on 5 January 2011.

The Chinese Institute of Certified Public Accountants (CICPA)

"CICPA Notice on the Guidance on Auditing Hospital Financial Reports" 二〇一一年一月十四日 - 中国注册会计师协会关于印发《医院财务报表审计指引》的通知 (会协[2011]3 号)(自 2011 年 7 月 1 日施行), promulgated on 14 January 2011 and effective as of 1 July 2011.

The General Office of Ministry of Health (MOH)

"Notice on the Issue of the Quality Management and Control Indicators of Class III Comprehensive Hospitals (2011 version)" 二〇一一年一月十四日 - 卫生部办公厅关于印发《三级综合医院医疗质量管理与控制指标（2011年版）》的通知 (卫办医政函[2011] 54 号), promulgated on 14 January 2011.

Ministry of Health (MOH)

MOH Order No. 79 - "Regulation for the Administration of the Quality Production of Pharmaceuticals (2010 Amended Version)" 二〇一一年一月十七日 - 中华人民共和国卫生部令第 79 号《药品生产质量管理规范（2010 年修订）》(自 2011 年 3 月 1 日起施行), promulgated on 17 January 2011 and effective as of 1 March 2011.

Ministry of Health (MOH)

"MOH Notice on Adjusting the Limit of Authority for Examining and Approving Sino-Foreign Equity and Cooperative Joint Venture Medical Institutions" 二〇一一年一月二十五日 - 卫生部关于调整中外合资合作医疗机构审批权限的通知 (本通知自印发之日起施行), promulgated on 25 January 2011 and effective as of the same date.

State Food and Drug Administration (SFDA)

"SFDA Notice on Relevant Questions Concerning the Implementation of the 'Regulations on the Administration of the Quality Production of Medical Devices (Trial Implementation)' and the Documents Relating thereto" 二零一一年一月二十七日 - 国家食品药品监督管理局关于实施《医疗器械生产质量管理规范（试行）》及其配套文件有关问题的通知 (国食药监械[2011]54 号), promulgated on 27 January 2011.

The People's Government of Shanghai Municipality

Shanghai Government Order No. 60 - "Administrative Measures of Shanghai Municipality on Supervision of the Basic Medical Insurance" 二〇一一年一月三十日 - 上海市基本医疗保险监督管理办法 (市政府令第 60 号) (自 2011 年 5 月 1 日起施行), promulgated on 30 January 2011 and effective as of 1 May 2011.

The General Office of the State Council

"Notice of the General Office of the State Council on Establishing a Security Review System for Mergers and Acquisitions of Chinese Enterprises by Foreign Investors" 二〇一一年二月三日 - 国务院办公厅关于建立外国投资者并购境内企业安全审查制度的通知 (国办发[2011] 6 号) (自本通知发布之日起 30 日后实施), promulgated on 3 February 2011 and effective 30 days from the date of promulgation of this Notice.

See Clifford Chance's Client Briefing - February 2011 - China Launches National Security Review System for Foreign M&A

The General Office of the State Council

"Notice of the General Office of the State Council on Issuing the Major Work Arrangements in 2011 for the Reform of Medical, Pharmaceutical and Hygiene System in Five Key Projects" 二〇一一年二月十三日 - 国务院办公厅关于印发医药卫生体制五项重点改革 2011 年度主要工作安排的通知 (国办发[2011] 8 号), promulgated on 13 February 2011.

Ministry of Health (MOH)

"MOH Announcement 2011 No.5 on Promulgating the Catalogue of Prevailing Valid and Effective Rules and Regulations of the Departments" 二〇一一年二月二十一日 -卫生部关于公布现行有效部门规章目录的公告 (2011年第 5 号), issued on 21 February 2011.

The General Office of the State Council

"Notice of the General Office of the State Council on Issuing the Pilot Work Arrangements for Public Hospital Reform in 2011" 二〇一一年二月二十八日- 国务院办公厅关于印发 2011 年公立医院改革试点工作安排的通知 (国办发[2011]10 号) promulgated on 28 February 2011.

National Development and Reform Development (NDRC)

"NDRC Notice on Adjusting the Ceiling Retail Price of Certain Types of Drugs classified as (i) Anti-Microbial and (ii) relating to the Circulatory System" 二〇一一年三月二日 - 国家发展改革委关于调整部分抗微生物类和循环系统类药品最高零售价格的通知 (发改价格[2011]440 号)(自 2011 年 3 月 28 日起执行), promulgated on 2 March 2011 and effective as of 28 March 2011.

Ministry of Commerce (Mofcom)

"Interim Provisions of MOFCOM on Issues Regarding the Implementation of the Security Reviews System of Mergers and Acquisitions of Chinese Enterprises by Foreign Investors" 二〇一一年三月四日 - 商务部实施外国投资者并购境内企业安全审查制度有关事项的暂行规定 (商务部公告 2011 年第 8 号)(自 2011 年 3 月 5 日起实施,有效期至 2011 年 8 月 31 日), promulgated on 4 March 2011 and effective as of 5 March 2011 which shall continue to be effective until 31 August 2011.