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Anti-Commercial Bribery Laws in China and Their Enforcement in the Pharmaceutical Industry

Lei Li, Sidley Austin LLP

Anti-commercial bribery laws have a huge impact on the daily business operation of companies in China. At present, relevant laws and regulations in China are very general and vague and, as a result, enforcement agencies at local levels have a great deal of discretion in determining what types of activities constitute commercial bribery, and what penalties will be imposed.

In recent years, enforcement authorities in China have been very active in pursuing commercial bribery cases and imposing fines, and the pharmaceutical industry has been a hot target. In enforcement actions, many marketing practices that are widely used and accepted in the pharmaceutical industry both in China and in other markets were determined to be commercial bribery, and this has resulted in huge disruption of pharmaceutical companies' operations in China.

Anti-commercial bribery investigations in China and investigations in the U.S. under the Foreign Corrupt Practices Act ("FCPA") bear certain similarities, and it is not impossible that enforcement agencies in the U.S. could look at a determination in China as the "clue" to pursue an FCPA investigation. This is particularly true for the pharmaceutical industry, because most hospitals in China are run by the government, and their managers and physicians are very likely to be considered "government officials" under the FCPA. Therefore, multinational companies with a presence in China, particularly pharmaceutical manufacturers, should implement a unified system to handle compliance risks under Chinese and U.S. laws.

Legal Framework for Commercial Bribery in China

Definition and Applicable Rules

At present, Chinese laws and regulations relating to commercial bribery are very much scattered, and there is no uniform definition of commercial bribery.

The *PRC Anti-Unfair Competition Law* ("AUCL") is the primary legal basis for administrative authorities to crack down on commercial bribery. It also provides for a private right of action for any person that is adversely affected by commercial bribery against any other person that gives commercial bribes. The AUCL prohibits business operators from "giving bribes in the form of property or other means for the purpose of selling or purchasing products."[1] This definition provides very little guidance in practice, without specifying the key elements for the determination of what constitutes commercial bribery.

The AUCL is enforced by the State Administration for Industry & Commerce ("SAIC") and its local offices ("Local AICs"). The SAIC promulgated the

Provisional Rules on Prohibition of Commercial Bribery Activities in 1996 ("SAIC Rules"), which defines commercial bribery as "an activity by which a business operator bribes the other party to the transaction, either an entity or an individual, in the form of property or other means for the purpose of selling or purchasing products."[2] This definition, in fact, has narrowed the definition of commercial bribery in the AUCL by limiting the recipient of commercial bribes to "the other party to the transaction."

In addition, the *PRC Criminal Law* imposes criminal sanctions for "giving employees of companies, enterprises or other entities property for the purpose of obtaining unjust benefits,"[3] if the circumstances of such conduct are serious. This provision is viewed as the definition of commercial bribery under the *PRC Criminal Law.*

A key question in determining what amounts to commercial bribery under the AUCL and the *PRC Criminal Law* is how "property" is defined. Generally speaking, the term "property" has very broad scope under Chinese law, and for the determination of commercial bribery by the SAIC, "property" means any cash and non-cash payments, including, but not limited to, property given to the other party to the transaction, disguised as marketing fees, publicity fees, sponsorship fees, R&D fees, labor service fees, consulting fees or commission fees, as well as reimbursement of various expenses, etc.[4] The term "other means" may include without limitation any interests other than property, such as domestic or overseas trips.[5] However, none of the laws or regulations gives any interpretation of the clause "for the purpose of" selling or purchasing products.

Totality Approach to Determination of Commercial Bribery

Anti-commercial bribery provisions in PRC laws and regulations are very general and vague, but several agency rules and guidance documents have shed light on how to make the determination in practice.

In 2007, an inter-agency commercial bribery supervisory body issued a guidance document,[6] explaining the distinctions between charitable donations and commercial bribery as follows:

1. Donations should: (i) comply with the relevant laws and regulations governing donation; (ii) be in express terms and be recorded in accounting books truthfully; (iii) not be associated with commercial transactions; (iv) not prejudice the legitimate interests of other business operators; and (v) be used for public interest.
2. In contrast, commercial bribery is intended to pursue business opportunities or preferential treatment through conferral of money or property.

Another document, jointly issued by the PRC Supreme People's Court and the PRC Supreme People's Procuratorate in 2008,[7] provides guidance on distinctions between commercial bribery and gifts, which reaffirms the methodology described above.

It is clear from the guidelines set forth in these documents that the plain reading of the laws and regulations should not be the sole basis for determining whether certain activities constitute commercial bribery. Instead, an analysis of the totality of the circumstances should be employed, with all relevant factors taken into account, particularly the intent of the payment, the circumstances of the activities, and the history of similar dealings.

If an enforcement authority alleges that a commercial practice that is commonly used and widely accepted in an industry is commercial bribery under a plain reading of the laws and regulations, the accused company may invoke the above documents as part of its defense, and use the totality analysis to prove its genuine, non-corrupt

intent. Commercial bribery risks associated with such practices may be significantly lessened if the enforcement authority accepts the totality approach. However, the totality approach guidelines are not binding, and it is possible that Local AICs would not strictly adhere to them in their enforcement actions.

Penalties for Violations

Companies or individuals engaged in commercial bribery may be subject to (1) administrative penalties; (2) criminal liability; and (3) civil liability.

Administrative Penalties

Upon a finding of commercial bribery by a Local AIC, the party giving the bribes may be subject to administrative penalties including (i) monetary fines ranging from RMB 10,000 to RMB 200,000 (approximately $1,500 to $30,000); (ii) confiscation of illegal proceeds (if any); and (iii) revocation of business licenses.[8] Notably, for administrative penalties, the amount of the fine in each penalty decision is generally determined based on the seriousness of the underlying conduct. The amount of the fine does not have to be in proportion to the amount of any illegal proceeds derived from the underlying conduct or the monetary value of the bribery. The amount of the fine is also to a large extent subject to the discretion of the Local AIC.

Criminal Liability

Unlike administrative penalties, criminally prosecuted commercial bribery is mainly based upon a prescribed threshold of monetary value.[9] Upon conviction, applicable criminal penalties include: (1) depending upon the monetary value of the bribery, imprisonment of up to 10 years for an individual briber or a directly-responsible employee of an institutional briber;[10] and (2) fines to institutional bribers.[11]

Civil Liability

Pursuant to the AUCL, the party giving commercial bribes may also be held liable for damages of a third party suffering losses as a result of the bribery. However, in practice, such civil damages are rarely sought.

Commercial Bribery in the Pharmaceutical Industry

Regulations and Penalties

Pharmaceutical industry has been the focus of commercial bribery enforcement actions in China. Pharmaceutical manufacturers and distributors must comply with not only general rules, but also industry-specific rules. In particular:

1. A pharmaceutical manufacturer, distributor or its representatives shall not offer "any property or other benefits" in any manner to the relevant personnel of health care institutions ("HCI") using its drugs, including personnel in charge of the HCI, drug procurement personnel, physicians, etc.,[12] with the intent to influence their drug purchasing decisions or prescription practice.[13] "Other benefits" may include in-kind articles and other items of monetary value, such as home furnishings, membership cards with monetary value, reimbursement of travel expenses, and shopping coupons.[14]
2. Pharmaceutical companies may be determined to have engaged in commercial bribery if they (i) give physicians kickbacks, commissions or other benefits; or (ii) pursue business opportunities or business interests through "inappropriate means" in the course of sales and marketing activities.[15]

3. Commercial bribery conducted by the employee of a drug manufacturer (e.g., medical representatives) or distributor for the purpose of selling or purchasing products for his/her employer shall be attributed to the drug manufacturer or distributor.
4. HCIs and physicians are considered to be business operators and are eligible as recipients of commercial bribes, and physicians may be subject to criminal charges for receiving commercial bribes.[16]

An additional important agency regulation that may affect commercial bribery determinations is the *Provisional Rules on Administration of Receipt of Donations and Sponsorships by Health Care Institutions* ("Donation Rules"), promulgated by the PRC Ministry of Health ("MOH").[17] The Donation Rules set forth the requirements concerning the receipt and use of donations and sponsorships by HCIs, including:

1. Donations and sponsorships must be received in the name of the HCI, not an internal department of the HCI;
2. Donations and sponsorships must be paid or delivered to the finance department of the HCI, and may not be used without being recorded in the accounting books; and
3. Donation or sponsorship plans must be reviewed and approved by the internal audit department and the financial department of the HCI to ensure that the payments are legitimate.

On their face, violations of the Donation Rules by HCIs will only result in disciplinary penalties on HCIs, without subjecting the donors, usually pharmaceutical companies, to commercial bribery charges. However, in practice, Local AICs often look at the Donation Rules when considering commercial briberies, and the donations and sponsorships that fail to comply with the Donation Rules are likely to be prosecuted as commercial bribery.

If found to have engaged in commercial bribery, in addition to other generally applicable penalties, drug manufacturers and distributors will be put on a blacklist by provincial health authorities. As a result, no HCIs within that province would be allowed to purchase any drug or device from this manufacturer or distributor for a period of two years.[18] In a recent notice, the MOH further requires provincial health authorities to disqualify blacklisted drug manufacturers from submitting bids in centralized drug procurement programs.[19] This blacklist system has been set up and enforced by health authorities in some provinces, and the MOH requires it to be set up in all provinces of China by the end of 2010.

Enforcement Realities

Marketing, promotion and distribution activities of drug companies have huge commercial bribery risks in China. Some practices are clear bribery, such as "prescription fees" paid to physicians for prescribing drugs, "formula fees" paid to physicians or pharmacists for information on the prescription amount of competitor's drugs, etc. However, because of the broad, vague definition of commercial bribery in PRC laws and regulations, and the lack of clear enforcement guidelines, enforcement authorities, especially Local AICs, have a great deal of discretion in their enforcement actions. The enforcement practices vary greatly from province to province, city to city, and even case to case within the same local authority. Some enforcement actions may have been pursued based on penalty-collecting motivations, rather than based on solid legal grounds.

As a result, marketing practices that are widely used and accepted in the pharmaceutical industry are sometimes targeted by Local AICs as commercial bribery. Indeed, commercial bribery determinations have been made and fines have been levied against donations and grants, sponsorships, payment of

speaker fees, etc. This has resulted in huge risks to multinational drug companies' operations in China, and fines in these cases range from hundreds of thousands RMB to over one million RMB. In the future, a prohibition against participating in centralized drug procurement programs may result in even more serious damages than simple fines.

Under the Chinese legal system, if a company disagrees with a commercial bribery determination by the Local AIC, it may file an administrative review application with a higher-level AIC, or the government at the same level as the Local AIC. It also may file an administrative suit with competent courts, either after going through the administrative review proceedings and not receiving a satisfactory result, or directly, without going through the administrative review proceedings. However, in practice, it is very difficult to have a Local AIC's commercial bribery determination reversed, either through administrative review or through court proceedings.

Commercial Bribery Investigations in China and the FCPA

Anti-commercial bribery investigations in China and investigations in the United States under the FCPA are initiated and conducted under two different laws, in two different jurisdictions. In theory, a commercial bribery determination in China would not automatically trigger an FCPA investigation in the United States, and we have not seen any FCPA investigations triggered by an investigation in China. However, we cannot exclude the possibility that enforcement agencies in the United States could look at a reported commercial bribery determination in China as the "clue" to pursue an FCPA investigation. In fact, most commercial bribes in the pharmaceutical industry in China are very likely to constitute prohibited corrupt payments under the FCPA, because over 70% of hospitals in China are public hospitals run by the government,[20] and therefore managers and physicians at these hospitals are very likely to be considered "foreign officials" under the FCPA.[21]Therefore, it is strongly advisable that multinational companies with a presence in China, particularly pharmaceutical manufacturers, consider FCPA compliance and China anti-commercial bribery compliance together, and implement a single system to handle compliance risks under U.S. and Chinese laws.

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***Lei Li** is an associate in Sidley Austin's Beijing office, focusing on M&A and private equity transactions and compliance and enforcement matters in the pharmaceutical industry. Before his relocation to Beijing, he worked in the firm's New York office for three years. Prior to joining the firm, Mr. Li worked in the Ministry of Commerce of the People's Republic of China for eight years. He can be reached at 010 6505 5359 or **lei.li**@sidley.com.*

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1 Article 8, AUCL, passed September 2, 1993, effective December 1, 1993.

2 Article 2, SAIC Rules, passed and effective November 15, 1996.

3 Article 164, the PRC Criminal Law.

4 Article 2, SAIC Rules.

5 Article 3, SAIC Rules.

6 *The Opinions on Correctly Handling the Policy Boundaries in Crackdown on Commercial Bribery,* the Central Leadership Group on Crackdown of Commercial Bribery, May 28, 2007.

7 *The Opinions on Application of Law in Handling Criminal Cases Involving Commercial Bribery,* the PRC

Supreme People's Court and the PRC Supreme People's Procuratorate, November 20, 2008.

[8] For drug manufacturers or distributors, the administrative penalty may include the revocation of pharmaceutical manufacturing or distribution licenses.

[9] *The Rules on Thresholds for Prosecution of Bribe-Related Crimes,* PRC Supreme People's Procuratorate, December 2000. Any serious misconduct in which a company, enterprise, agency, institution or organization gives bribes in exchange for inappropriate benefits, or gives kickbacks or commissions to government officials in violation of the provisions of the state shall be criminally prosecuted where (1) the amount of the bribe is more than RMB 200,000 (approximately $30,000); or (2) the amount of bribe is between RMB 100,000 and RMB 200,000 (approximately $15,000 and $30,000), but involves any of the following circumstances: (i) illegal benefits are being pursued; (ii) bribes are given to more than three recipients; (iii) bribes are given to Communist Party leaders, government leaders, judicial officials or law-enforcement officers; or (iv) severe damage is caused to national or social interests. Practically, these monetary thresholds do not need to be met with each individual bribe, but can be the aggregate amount offered by the giving party over a certain period of time.

[10] The *PRC Criminal Law*, Article 164.

[11] The *PRC Criminal Law*, Article 164, Article 393.

[12] Article 59 of the *PRC Law for Drug Administration* (the PRC National People's Congress, February 28, 2001).

[13] Article 85 of the *Implementation Rules of the PRC Law for Drug Administration* (the PRC State Council, August 4, 2002).

[14] *See supra* note 6.

[15] Section 3 of the *Opinions of SFDA in Implementing Special Enforcement Programs against Commercial Bribery* (May 24, 2006).

[16] *See supra* note 7.

[17] Issued by the MOH and effective April 6, 2007. Article 2 of the MOH Donation Rules defines "donations and sponsorships" broadly as "support and assistance in the form of funds, goods, etc., that are provided voluntarily and free-of-charge by individuals, legal persons or other entities to health care institutions."

[18] *MOH Rules for Retention of Commercial Bribery Black Marks in Pharmaceutical Sales & Purchase Activities,* January 19, 2007.

[19] *MOH Notice on Further Crackdown on Commercial Bribery in Purchase and Sale of Pharmaceutical Products*, June 21, 2010.

[20] As of November, 2009, there were 19,822 hospitals in China, 14,086 of which were public hospitals operated by the government, accounting for 71% of all hospitals. *See Gazette on the Development of China's Health Care System in 2009*, MOH; available at http://www.moh.gov.cn/publicfiles/business/htmlfiles/mohwsbwstjxxzx/s8208/201001/45652.htm. Moreover, almost all large hospitals are public hospitals run by the government.

[21] "The term 'foreign official' means 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." 15 U.S.C. § 78dd-1(f)(1).