BAKER & McKENZIE

Client Alert

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China's New Rules on Bribery Blacklisting of Healthcare Companies and Ethics of Healthcare Professionals

1. The New Rules

On 25 December 2013, the People's Republic of China National Health and Family Planning Commission ("**NHFPC**") issued the *Regulations on Establishing a Commercial Bribery Blacklist for the Purchase and Sale of Medicines* ("**2013 Blacklist Regulations**"),[1] effective from 1 March 2014 and replacing the earlier 2007 blacklist regulations. The 2013 Blacklist Regulations have 15 articles, five new, and ten substantially modified from the 2007 regulations. The aim is to combat corruption in the healthcare sector by (i) promoting implementation of a commercial bribery blacklist ("**Blacklist**"); (ii) subjecting blacklisted enterprises and individuals to nationwide exposure by publishing a Blacklist on the NHFPC's website; and (iii) further restricting blacklisted enterprises and individuals by means such as procurement-related penalties in other provinces and a nationwide ban for repeat offenders.

The NHFPC also issued its *Nine Prohibitions to Strengthen Ethical Conduct in the Healthcare Industry* ("**Nine Prohibitions**")[2] on 26 December 2013, effective the same day. The Nine Prohibitions re-emphasize restrictions imposed on healthcare professionals ("**HCPs**") and healthcare institutions, and highlight high-risk areas such as offering improper donations, subsidies, travel and entertainment.

2. The 2013 Blacklist Regulations

2.1 What is to be Blacklisted

The scope of the companies potentially subject to the Blacklist is broad. It includes manufacturers, distributors of medicines, medical devices and medical consumables or spare parts, their respective agents who risk, as a result of committing commercial bribery in selling their products, procurement bans or being otherwise disadvantaged in bidding and procurement, as well as reputational loss.

1 http://www.nhfpc.gov.cn/fzs/s3577/201312/ef92cb05dee341a18fff7b3e00eb1156.shtml

2 http://www.nhfpc.gov.cn/jcj/s3577/201312/09bd7a8be8f8420d91997a0041aa868e.shtml

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The 2013 Blacklist Regulations lists the following four specific situations (and one catch-all provision) where an enterprise or individual can be listed on the provincial Blacklist:

(a) a court convicts them of bribery (whether or not criminal penalties were imposed);

(b) the bribery is relatively minor and the procuratorate decides not to prosecute;

(c) the disciplinary and supervisory authorities have investigated and taken measures according to laws;

(d) the financial, administration for industry and commerce, food and drug administration or other such authorities impose administrative penalties; or

(e) other circumstances stipulated by relevant laws, regulations or rules.

2.2 Nationwide exposure of violations

The provincial health administrations will publish their Blacklists on their websites, and submit their local records to the NHFPC within one month of publication. The NHFPC will then publish the local records on its website, thus giving nationwide exposure to commercial bribery and compounding the commercial and reputational loss for companies put on provincial Blacklists.

2.3 Nationwide ban for repeat offenders

An enterprise or individual put on a provincial Blacklist two or more times within any five-year period will be blacklisted nationally for two years. During those two years no public medical institution or healthcare institution that receives public funding in China may purchase any medicine, medical devices, medical consumables or spare parts from the blacklisted enterprise or individual.

2.4 Procurement-related penalties in other provinces

An enterprise or agent put on a provincial Blacklist is blacklisted within that province for two years. If they bid on a procurement project in another province, the other province may factor in the blacklisting and reduce the bidding enterprise or agent's procurement score accordingly.

2.5 Mandatory requirement for stand-alone non-corruption agreements

In addition to purchase contracts, enterprises and individuals must now sign stand-alone Integrity Agreements with hospitals and healthcare institutions. These agreements must state the sales representatives' names, include an express statement that they prohibit commercial bribery, and further provide that if commercial

bribery is committed, the enterprises and individuals will be put on the Blacklist.

2.6 Detailed company information to be exposed

The Blacklist will publish these items: name of enterprise or individual, business address, name and title of legal representative or responsible person, basis of the illegality, related court judgments or written administrative penalty decisions and blacklisting start and end dates.

3. The Nine Prohibitions

The Nine Prohibitions provide the following restrictions:

3.1 Healthcare institutions may not link an HCP's compensation to revenue generated from sale of medicine or medical examinations.

3.2 Healthcare institutions may not give HCPs commissions for prescriptions, and HCPs may not accept commissions for introducing patients to other institutions for examinations, treatment or purchase of medicine.

3.3 Healthcare institutions may not overcharge patients.

3.4 Healthcare institutions, industry associations and research associations may not accept illegal or unreasonable donations. Donations must be:

(a) handled by their financial departments, and be used according to the donor agreement for non-profit activities (that is not to benefit employees);

(b) accepted by the legal entity, not departments within it or individuals;

(c) not conditioned on buying products or services or linked to other conditions that might affect fair competition, and not for overseas tourism (or tourism-in-disguise).

3.5 Healthcare institutions and HCPs may not illegally advertise, participate in promotions for medicine, food, healthcare products, etc., or disclose patients' or customers' personal data and medical information.

3.6 HCPs may not collate prescription statistics for commercial purposes or facilitate medical sales personnel doing so.

3.7 HCPs may not illegally buy, sell, or use medicine, medical devices or consumables without strictly following the relevant compliance policies on procurement, acceptance, safekeeping and supply.

3.8 HCPs may not accept kickbacks in any form from enterprises or individuals, or participate in entertainment arranged, organised or paid for by healthcare enterprises and individuals and held in commercial entertainment venues.

3.9 HCPs may not accept financial benefits from patients or their relatives, including "red packets", payment vouchers and valuable gifts.

Violations may be punished by the healthcare institutions or healthcare administration authorities. Serious violations may be criminally prosecuted.

4. Practical implications

4.1 2013 Blacklist Regulations: greater supply side exposure; uncertain implementation

Blacklisted manufacturers, distributors and agents will face purchase bans, disadvantages in bidding and procurement, and reputational loss. But it is still uncertain how the 2013 Blacklist Regulations will be implemented.

The first attempt to establish a commercial bribery blacklist system was under the 2007 regulations, but their enforcement has been uneven. Not many health administration authorities have published Blacklists. First, the local government authorities are concerned about loss of tax revenue and job opportunities. Second, due to lack of coordination between the authorities who have information and infrastructure for information sharing, building up the Blacklists has relied largely on healthcare administration authorities pro-actively approaching or consulting sources such as courts, procuratorates or whistle-blower reports. Thus, the scope of the Blacklists is relatively limited and mainly focused on criminal violations.

The 2013 Blacklist Regulations may make a difference in 2014. The goal of establishing a nationwide Blacklist may pressure local health administration authorities to build up or improve their Blacklists as soon as possible. In addition, given the active enforcement against commercial bribery in the healthcare sector in 2013, NHFPC and its counterparts may make further efforts to coordinate with other authorities to improve their Blacklists in the near future. However, since the 2013 Blacklist Regulations were issued by NHFPC itself, rather than jointly with other authorities such as the State Administration for Industry and Commerce, the Supreme People's Court and the Supreme People's Procuratorate, the extent to which the implementation of the Blacklists can be improved is still uncertain.

4.2 Integrity Agreements: additional liability for pharma and medical device companies

Requiring pharma and medical device companies to sign a compliance statement is already common practice. Now the 2013 Blacklist Regulation explicitly makes it mandatory, which will

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unavoidably increase pharma and medical device companies' potential liability for several reasons. First, disclosing the names of its sales representatives in the Integrity Agreement may make it more difficult for a company to argue that any commercial bribery was the act of an individual carried out without the company's knowledge. Second, the explicit acknowledgement that being blacklisted is a consequence of commercial bribery will make it more difficult for the companies to challenge its appropriateness. Third, in practice, the Integrity Agreement templates are usually prepared by the healthcare institutions with broad and vague terms which the healthcare institutions are generally unwilling to substantially change. As a result, these Integrity Agreements may expose pharma and medical device companies to much broader liability and more disputes.

4.3 Nine Prohibitions: more demand side scrutiny

The Nine Prohibitions seek to reduce demand for unlawful income or benefits by disciplining HCPs and healthcare institutions. As a result, healthcare institutions will be expected to strengthen their internal compliance polices and controls and give more training to HCPs, and HCPs will be expected to be more prudent when interacting with the medical manufacturers, distributors and agents.

Accordingly, pharma and medical device companies may need to take various measures to strengthen compliance, such as:

(a) revising their compliance policies to ensure the restrictions under the Prohibitions are adequately and sufficiently covered;

(b) involving legal and compliance teams when structuring sensitive arrangements such as overseas training, donations, consulting; and

(c) providing tailored trainings on the Nine Prohibitions to sales representatives, marketing managers or others who frequently interact with HCPs or healthcare institutions.