



Anti-Bribery Battle in China's Healthcare Industry and the New Blacklisting Rules: A Treatment with Side Effects

Compliance and Ethics

Health Law





Introduction

According to the [2014 Corruption Perceptions Index](#) issued by Transparency International, which scored a country's perceived level of public sector corruption, the People's Republic of China (China or PRC) scored a 36 on a scale from 0 to 100 (100 means it is perceived as very clean), ranking China 100 out of 177 countries and territories. Corruption is one of the critical challenges multinationals face when doing business in China.

Since President Xi Jinping took office, China has undertaken a wide-reaching anti-corruption campaign. On the business side, pharmaceutical companies and the healthcare industry have been hit hard by the Chinese anti-corruption campaign, led by the corruption scandal of global healthcare company, GlaxoSmithKline plc (GSK). [GSK was fined](#) RMB 3 billion (approximately USD\$488,346,000) by the Chinese government due to "bribery of non-government officials" in a secret trial in Changsha City's Intermediate Court, Hunan Province on Sept. 19, 2014.

China's recent, proactive stance and restrictive rules targeting the pharmaceutical and medical

device industries signal that multinational pharmaceutical companies must comply with the PRC's domestic anti-corruption rules along with other relevant laws, such as the [US Foreign Corrupt Practices Act](#) (the FCPA) and [UK Bribery Act 2010](#) (the UK Bribery Act). This article will first introduce current Chinese regulations for combating anti-corruption in the healthcare industry. Next, it will focus on the PRC's current enforcement action in the healthcare sector after the implementation of three Circulars. Lastly, the article will provide some recommendations regarding China's anti-corruption and blacklisting regulations governing the healthcare industry such as: (1) expediting PRC's healthcare reform by allocating medical resources evenly, establishing more private hospitals, promoting private health insurances, and increasing doctors' income; and (2) adopting a discretionary blacklisting mechanism to provide more incentives for the non-complaint healthcare companies to comply.

Three circulars lead the anti-bribery battle in the Chinese healthcare sector PRC's National Health and Family Planning

Commission (NHFPC), formerly the Ministry of Health, issued three main Circulars (Circulars 49, 50 and 163) regarding anti-corruption and anti-bribery issues in the healthcare sector with an increasing emphasis on compliance in 2013 and 2014. Circular 49 listed nine prohibited acts for healthcare institutions and healthcare professionals. Circulars 50 and 163 revised the PRC's blacklisting rules for commercial bribery in the healthcare industry, regulating the procurement of medicine, medical devices and medical supplies.

Nine prohibitions (Circular 49)

NHFPC and PRC's State Administration of Traditional Chinese Medicine jointly published a notice, "Nine Prohibitions for Strengthening Ethical Conduct in the Healthcare Industry" (the Nine Prohibitions or Circular 49) on Dec. 26, 2013. Specifically, the Nine Prohibitions prohibits hospitals and doctors from the following actions:

- Linking medical professionals' salaries with the revenue received from prescribing medicines and physical examinations;
- Receiving commissions from prescribing medicines or referring patients to receive physical examinations or treatments;
- Charging higher fees beyond the national standard price cap for medical services and medicines;
- Receiving improper public donations;
- Participating in promotional activities for medicines, food and nutrition and issuing illegal advertisements;
- Providing data related to medicine and medical device usage for commercial purposes;
- Procuring, selling and using medicines, medical device and medical supplies through private channels; and
- Receiving improper benefits, kickbacks and entertainment from healthcare companies and their distributors and salespersons; and Receiving cash, securities and valuable gifts from patients.

If a healthcare institution violates any of the Nine Prohibitions, NHFPC's Administrative Department will issue a notice to publicly criticize its misconduct, request the non-complaint healthcare institution to provide remedial measures or lower the ranking of the non-complaint healthcare institution. If an administrative penalty is necessary, the non-complaint healthcare institution will be given a warning,

may be ordered to shut down, or can have its business license revoked.

If a healthcare professional violates any of the Nine Prohibitions, his or her employer should criticize his or her improper conduct or link the misconduct to his or her performance evaluation by demotion, suspension or dismissal. If the violation is serious, NHFPC's Administrative Department will (1) suspend the practice of the non-compliant healthcare professional and the NHFPC's local counterparts at the provincial level will publicize the decision within its jurisdiction; or (2) revoke the healthcare professional's license and NHFPC will publicize the decision in its online system nationwide.

Circulars 50

NHFPC issued Circular 50 on Dec. 25, 2013, which came into effect on March 1, 2014. The purpose of Circular 50 is to regulate the procurement of medicine, medical devices and medical supplies for healthcare institutions, prohibiting illegal dealings and combating commercial bribery. NHFPC's local counterparts are required to establish their own commercial bribery records (Commercial Bribery Records), a list of companies and their distributors that manufacture and distribute medicine, medical devices and medical supplies that provided improper property or benefits to the healthcare professionals.

Causes of being blacklisted

Circular 50 lists several causes from which medicine manufacturers and distributors can be blacklisted and added into the Commercial Bribery Records:

- The healthcare company and distributor have been convicted of a bribery crime by a People's Court.
- Although charged with a bribery crime, a People's Court exonerated the healthcare company and distributor from any criminal punishment because the crime is minor and punishment is not required.
- A People's Procuratorate* decided not to prosecute the healthcare company and distributor because the bribery crime is minor.
- A disciplinary inspection and supervision authority initiated an investigation for bribery against the healthcare company and distributor and made a decision in accordance with law.
- A government agency (e.g., Treasury, the Administration for Industry and Commerce, and the Food and Drug Administration, etc.) made an administrative decision to punish the healthcare company and distributor for bribery.
- Catch-all provision: other circumstances provided by laws, rules and regulations.

* A People's Procuratorate is responsible for prosecuting criminal cases in China.

When a company is blacklisted, NHFPC's local counterparts will provide a written notice to the healthcare company and distributor before listing them in the Commercial Bribery Records. The healthcare company is entitled to provide a statement or defense and request a hearing.

Period of debarment

At the provincial level, all public medical institutions or government-funded medical institutions in a given province will not procure any medicines, medical devices and medical supplies from any healthcare company and distributor for two years if such healthcare company and distributor was

listed in that province's Commercial Bribery Records. Although the one-time violator can technically still participate in government procurements in other provinces where it was not backlisted, the one-time violator will lose points when public medical institutions in other provinces evaluate their bids and discover that they were blacklisted in another province. If a healthcare company and its distributor have been listed in the Commercial Bribery Records two or more times within five years, public medical institutions nationwide will not procure any medicine, medical devices and medical supplies from such a frequent violator.

Circulars 163

On February 26, 2014, NHFPC published Circular 163 implementing Circular 50's rules. Circular 163 specifies the job responsibilities of the divisions under NHFPC, sets up deadlines for NHFPC's local counterparts to revise their system for Commercial Bribery Records, and establishes a reporting system and timeline for the municipal level, provincial level and national level.

A sample integrity contract was attached in Circular 163, prohibiting healthcare institutions and healthcare professionals from the following activities: accepting any form of kickbacks, receiving entertainment arranged and paid for by a healthcare company, soliciting cash, securities or valuable gifts, and providing information regarding specific medicines usages to any healthcare company and distributor. The sample integrity contract also prohibits a healthcare company and its distributors from the following: (1) influencing healthcare institutions to purchase their medicines and medical products by offering kickbacks or lavish meals; (2) providing sightseeing or lavish meals and accommodations that exceed the standard budget; (3) promoting medical products in the hospital's examination room or recovery room; and (4) visiting team leaders, division heads or relevant healthcare professions at home and providing commissions.

Anti-corruption enforcement in healthcare industries in China

Circulars 50 and 163

As of October 27, 2014, 26 provinces in China have enacted local ordinances implementing Circular 50 and Circular 163. As part of its duties under the Circulars, NHFPC will monitor and inspect the enforcement of these local rules. For example, NHFPC's local counterparts in Chongqing City (Chongqing's NHFPC), a major city in Southwest China, blacklisted a Chinese medical device company called "Chongqiong Weixin Medical Device Limited Company" (Weixin Medical) from Oct. 16, 2014, to Oct. 16, 2016. NHFPC's website also reprinted the decision to blacklist Weixin Medical. According to the notice regarding the first blacklisting record of commercial bribery in the purchase and sale of medicines, issued by Chongqing's NHFPC, Liu Kai, the general manager of Weixin Medical, bribed Wang Yi, the former division head of the Equipment Division of the Thirteenth People's Hospital of Chongqing, with RMB 135,000 (approximately USD \$21,981.40). Weixin Medical is a small company incorporated in Chongqing City, where it focuses on the distribution and wholesale of medical and surgical devices.

Nine prohibitions (Circular 49)

At the local level, several provinces and municipals have published relevant opinions and notices, implementing the Nine Prohibitions. Some provinces have formed leadership groups and committees to oversee and monitor the enforcement of the Nine Prohibitions. As of Aug. 26, 2014, NHFPC's local counterparts in Hubei Province has [dealt with 333 cases](#) regarding violation of the Nine

Prohibitions, involving 455 non-compliant persons.

In addition, some provinces and municipalities have started anti-corruption enforcement actions. For example, in an opinion issued by NHFPC's local counterparts in Hangzhou City, Zhejiang Province (Hangzhou's NHFPC), Hangzhou's NHFPC is combating corruption in the healthcare industry by requesting that local hospitals conduct internal investigations to see if any healthcare professionals have received kickbacks or properties from healthcare companies and distributors through procurements or through seminars or academic conferences. Multinational pharmaceutical companies such as AstraZeneca PLC, Novo Nordisk and Eli Lilly have also been expressly criticized in the opinion. Moreover, SAIC staff visited the regional office of Roche Holding AG in Hangzhou in May 2014. Although the purpose of this visit is not clear, it seems the PRC government is putting more pressure on pharmaceutical companies, closely monitoring any non-complaint activities.

Suggestions to improve the anti-bribery reforms and blacklisting rules for healthcare industry in China

Expediting the healthcare reform in China

Although China's healthcare reform started in 2009, its progress has been slow and patients still face challenges obtaining medical services due to factors such as an uneven allocation of medical resources, high medicine prices and low salaries for doctors. Below are several options for the PRC government and its hospitals to expedite healthcare reform.

First, medical resources should be allocated to small towns, suburban areas, and rural areas and not only major metropolitan areas. During the past decades, the Chinese government, at all levels, has placed too much emphasis on economic development and financial growth, while neglecting the social services and public health. Local governments have built many large medical centers and provide more medical resources in response to the great number of patients in big cities. However, rural areas did not get the same attention as major cities did and lacked funds to purchase medical equipment and build hospitals. The government should invest and build more medical centers and specialized hospitals in rural and suburban areas so that patients can access to high-quality hospitals wherever they live.

Second, the government should facilitate the establishment of more private hospitals to relieve the difficulty of seeing a doctor in a few hospitals. Private pharmacies or pharmacy chains should also be promoted so that the price of medicine can be more transparent and the patients will have more options to choose their pharmacies. Public hospitals in China are permitted to "charge a 15 percent mark-up on the price of medicines," which is a loophole abused by some doctors to overprescribe medicines or provide unnecessary tests and treatment. Additionally, since public hospitals are government-run, they have a significant monopoly in the marketplace, protecting them from outside competition. If there are more private hospitals in China, patients will have more options and be able to choose the doctors they want to see and the hospitals they want to go. Public hospitals might also have more incentives to improve its service through competition with private hospitals.

In addition, doctor's income and benefits should be increased to match their education and experience. [Doctors in China have been severally underpaid](#), which leads some of them to earn "extra money" through kickbacks and illegal commissions by prescribing drugs that are more expensive, overprescribing drugs, and requesting unnecessary physical checks and imaging services, etc.

Discretionary blacklisting rule will provide more incentive for non-complaint healthcare companies to comply

Healthcare companies will have more incentives to comply with the anti-corruption rules if blacklisting is not automatic upon the occurrence of the corrupt conduct. The reason why Chinese regulators should be careful about using the mandatory blacklisting mechanism is due to the severe consequences of debarment. First, if blacklisted, a one-time violator will be ineligible from all future contracts with the public medical institutions in a given province for two years while a frequent violator will be debarred for five years nationwide. Debarring the entire company for one individual's fault is a harsh punishment since it will also affect the thousands of the employees of the non-complaint companies. Second, it is [extremely difficult](#) for a blacklisted company to survive since the chances for a debarred company to engage in a new contract with local government are slim. For the Weixin Medical case mentioned above, according to Xinhuanet, the office of Weixin Medical was empty and its employees were also not reachable, a signal of the company's shutdown, which is merely a month after Weixin Medical was blacklisted. Third, collateral costs from being blacklisted are high, including reputational damages, future lawsuits, and financial loss. Blacklisting can cut off the revenue and other financial resources of a blacklisted company, leading to the end of its business. Moreover, blacklisted corporations are unlikely to spend money or put efforts to improve their compliance program since "their government revenue streams are cut off."

Conclusion

It is a positive sign that Chinese regulators are combatting bribery and corruption both inside the government and in the business world. Besides the current statutes and regulations governing anti-bribery, Chinese regulators probably will pass more rules and actively take enforcement actions against bribery. Due to its lucrativeness, frequent interaction with the government and healthcare professionals' relative low income, the healthcare industry has been and will continue to be scrutinized hard during the anti-bribery campaign. The NHFPC needs to provide detailed and further guidance and implementation in terms of the textual interpretation and the actual enforcement of China's anti-bribery and corruption laws. The enforcement agencies will encounter challenges such as due process and process fairness when blacklisting a non-complaint healthcare company and/or its distributors.

Expediting the on-going healthcare reform in China will be the key to solving the bribery challenges in the healthcare industry. Specifically, the government should allocate the medical resources more evenly in the cities, suburban and rural areas, encourage the establishment of private hospitals and pharmacies, promote private insurance plans to relieve the burden of patients, hospitals and government, and increase doctors' salaries to match their education and experience. The Chinese regulators should also reconsider the blacklisting models, learning the mature US suspension and debarment regulations and developing into a discretionary mechanism when adjudicate misconduct of non-complaint companies. A discretionary mechanism will provide more incentives for a rule-breaking company to cooperate with the government agency, remediate its misconduct and implement a better internal compliance program.

Further Reading

Notice of the National Health and Family Planning Commission and State Administration of Traditional Chinese Medicine on the Printing and Distributing of the "Nine Prohibitions for

Strengthening Ethical Conduct in the Healthcare Industry,” [hereinafter Nine Prohibitions or Circular 49].

Notice of the National Health and Family Planning Commission on Issuing the Provisions on the Establishment of Commercial Bribery Records in the Purchase and Sale of Medicines [hereinafter Circular 50].

Notice of the General Office of the National Health and Family Planning Commission on Enforcement of Commercial Bribery Records in the Purchase and Sale of Medicines [hereinafter Circular 163].

26 Provinces Enact Local Ordinances Implementing Commercial Bribery Records in the Purchase and Sale of Medicines (promulgated by the St. Nat'l Health & Family Planning Comm'n, Oct. 27, 2014).

Opinion Issued by Hongzhou City's NHFPC Regarding Further Combating Corruption, Development of Risk Control, and Special Action Against Kickbacks in Healthcare Industry.

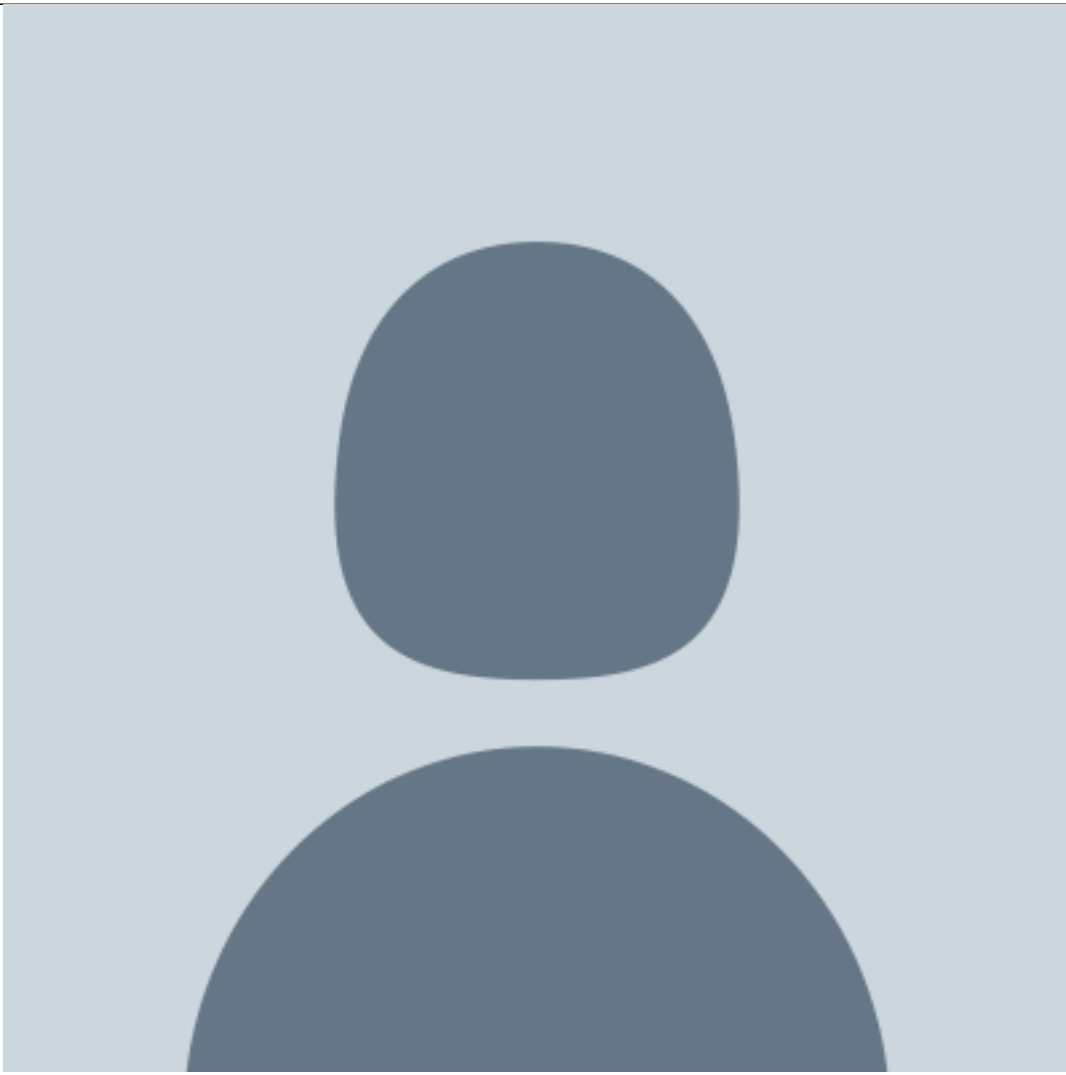
Notice of the General Office of the State Council on Printing and Distributing the Key Arrangements for Deepening Reform of the System of Pharmaceuticals and Healthcare in 2012.

Circular 50, Art. 7.

Tillipman, *supra* note 17, at 53-55.

Id. at 55.

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Association of Corporate Counsel