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China Issues Draft Opinion on Anti-Bribery and Antitrust Requirements for Pharmaceutical Market Access

Proposal Includes Self-Reporting Requirements and Liability for Acts by Third Parties

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Anti-corruption

On April 13, 2020, China's National Healthcare Security Administration ("NHSA") released a draft opinion titled "Guiding Opinions on Establishment of a Drug Pricing and Procurement Creditworthiness System" (the "Draft Opinion"; Covington's translation is available here) setting forth proposed requirements for a creditworthiness evaluation and disciplinary system for companies that want to participate in centralized drug procurement and bidding activities. The changes would impose two main requirements on companies: (1) companies must submit a letter committing to not engage in bribery or market manipulation;[1] and (2) companies must proactively report violations of PRC anti-bribery and antitrust laws, such as the Anti-Unfair Competition Law and the Anti-Monopoly Law, to provincial healthcare security administrations and drug procurement agencies. In addition, companies must agree to bear responsibility for—and report violations by—their delegates and agents. Companies that fail to meet these requirements could lose access to China's public healthcare market in several ways, including bidding on drug procurement, selling products to public hospitals, and listing products online.

Background

The Draft Opinion is yet another step in China's healthcare reform in recent years. Since 2016, China has implemented several measures to reform its healthcare system and to ensure a steady supply of safe and effective drugs at lower prices.[2] Three key developments as part of this effort have been: (1) the adoption of the Two-Invoice System,[3] (2) the establishment of the NHSA, and (3) the implementation of centralized Volume-Based Procurement for off-patent drugs.

[1] The publicly available text of the Draft Opinion references the commitment letter as an appendix but does not include the full text of the letter.
[2] On December 27, 2016, the State Council released its 13th Five-Year Plan on Deepening Reform of the Medical and Healthcare System, which included reforming China's supply chain for pharmaceutical drugs as one of its goals.
[3] For additional information on the Two-Invoice System, see our client alert here.

The Two-Invoice System, introduced in January 2017, aims to reduce drug prices and corruption in multi-tier distribution chains by allowing at most two tax-valid invoices (also known as *fapiaos*) during the distribution chain from a drug manufacturer to the end user, essentially limiting the supply chain to one distributor. Some commentators have opined that while the Two-Invoice System reduced the number of middlemen in the pharmaceutical distribution chain, manufacturers may be driven to increase prices to account for the margins previously added on by the multiple layers of middlemen between manufacturers and end-customers. And some drug manufacturers have increased sales and marketing spend after the implementation of the Two-Invoice System, at least in part due to difficulty continuing the practice of spreading out the margins among different levels of distributors and sales agents, such as contract sales organizations.

The establishment of the NHSA in March 2018 consolidated the Chinese government's ability to regulate drug pricing (previously handled by the National Development and Reform Commission) and healthcare insurance payments (previously handled by the Ministry of Human Resources and Social Security) under one agency. Since its creation, the NHSA's mandate has been to eliminate waste and abuse of healthcare insurance funds and ensure fair and transparent pricing of drugs.

In November 2018, in an effort to address overinflated margins in drug pricing, the NHSA launched the Volume-Based Procurement pilot program in eleven major cities in China, in which pharmaceutical companies submitted bids for several off-patent drugs, with the winners gaining a guaranteed sale volume of the total market for that drug for a year. In September 2019, China expanded this pilot program nationwide.

As a result of these reforms, market authorization holders in China have had to adapt their business models and operational strategies, including product pricing and promotional spend, to respond to the government's three goals of maintaining drug safety, lowering drug prices, and reducing corruption in the life sciences sector.

Key Proposed Changes

The Draft Opinion sets forth several key requirements and suggestions that would affect drug manufacturers operating in China:

1. Requiring an anti-corruption and antitrust commitment letter related to the acts of both the company and its third-party representatives

In order for a pharmaceutical company to participate in centralized drug procurement opportunities, the Draft Opinion requires the company to submit a certification committing to the following: (i) not engage in commercial bribery, including providing improper benefits to personnel responsible for drug procurement at public hospitals, (ii) not engage in manipulating the market and drug prices, (iii) be jointly liable for commercial bribery and market manipulation by its service providers for the benefit of its products, and (iv) accept corresponding penalties imposed by healthcare security administrations. Companies failing to submit the certification will be barred by provincial drug procurement agencies from participating in activities related to sales of pharmaceutical products to public hospitals such as product listings and public tenders.

Notably, the commitment letter would hold manufacturers liable for acts of commercial bribery and market manipulation not only by their own employees, but also by their third-party representatives, such as service providers and agents.

2. Requiring timely self-disclosure of violations related to commercial bribery and market manipulation

The Draft Opinion requires a pharmaceutical company to voluntarily report to healthcare security administrations and drug procurement agencies violations of PRC anti-corruption or antitrust laws[4] by the company itself or by its third-party representatives within 10 business days of receiving an adverse administrative or court decision. A company does not need to be officially indicted or penalized to trigger this reporting obligation; an official ruling by a government agency that a violation occurred is sufficient.

If the self-reporting obligation is triggered, a company is required to report at least the following: (1) the products and monetary amount at issue; (2) cause of action and judgment; (3) organizations and individuals involved in the case; and (4) details regarding any kickbacks related to drug sales. Any failure to report or omissions in reporting will negatively impact a company's eligibility to participate in the public procurement program. The Draft Opinion also describes the establishment of an information-sharing system among government agencies to verify the information self-reported by companies.[5]

3. Encouraging remedial actions by violators

The Draft Opinion encourages pharmaceutical companies to timely rectify their wrongdoings before agencies impose formal disciplinary measures by actively taking remedial actions, such as terminating guilty employees and business partners, issuing public statements of apology, adjusting the inflated drug prices, and returning unjust enrichment to authorities. The Draft Opinion states that the provincial drug procurement agencies should notify a pharmaceutical company and give at least three months for the company to remediate the issues. The Draft Opinion also states that, for companies with serious or especially serious credibility damage, remedial actions must include reducing inflated margins and returning improper gains in order to improve their creditworthiness rating—literally translated, "dishonesty" rating—and be eligible for a more lenient penalty.

4. Encouraging whistleblowing of bribery violations

The Draft Opinion encourages the public to report commercial bribery and market manipulation-related misconduct by pharmaceutical companies to the regulatory authorities. The Draft Opinion states that when whistleblowers provide necessary evidence to substantiate misconduct related to bribery and market manipulation, the provincial healthcare security administrations and drug procurement agencies should cross-check the evidence against the self-disclosure provided by pharmaceutical companies and refer the case to law enforcement authorities if appropriate.

Proposed Penalties

The Draft Opinion sets forth a disciplinary system of how agencies should rate misconduct, the misconduct's negative effect on the pharmaceutical companies' creditworthiness, and

[4] The relevant laws include the Drug Administration Law, Pricing Law, Anti-Monopoly Law, and Anti-Unfair Competition Law.

[5] The Draft Opinion does not clarify whether the information sharing and creditworthiness tracking overlaps with China's Social Credit System (see our blog post here), although we assume that those systems will eventually be linked in some way.

the resulting penalties that could be imposed by provincial level healthcare security administrations through drug procurement agencies.

The Draft Opinion states that the healthcare security administrations and drug procurement agencies should evaluate the misconduct disclosed by companies and other government agencies based on several factors, such as the nature of the misconduct, the facts of the case, the timing of the misconduct, and the impact of the misconduct. The government then provides a rating of the creditworthiness damage to the company: "average," "moderate," "serious," or "especially serious."

The Draft Opinion lists the proposed penalties associated with the different ratings:

- A company that suffers "average" creditworthiness damage will receive a written warning from the provincial drug procurement agency.

- A company that suffers "moderate" creditworthiness damage will receive a written warning from the provincial drug procurement agency and a warning about the company will be automatically displayed when public medical institutions order products from the company.

- A company that suffers "serious" creditworthiness damage will receive the same penalties as a company that suffered moderate creditworthiness damage, plus the company's eligibility to list its products for procurement, tender eligibility, and distribution rights *for the product at issue* will be suspended. The length of the suspension will depend on the company's remedial actions and resulting changes to the company's creditworthiness rating.

- A company that suffers "especially serious" creditworthiness damage will be subject to same penalties as a company that suffered serious creditworthiness damage, and in addition, the company's eligibility to list its products for procurement, tender eligibility, and distribution rights for *all of its products* will be suspended. The length of the suspension will depend on the company's remedial actions and resulting changes to the company's creditworthiness rating. The company will also be subject to investigations by provincial healthcare security administrations related to the defrauding of healthcare security funds, and the company's improper gains from the misconduct will be confiscated.

If a company's actions result in two or more especially serious creditworthiness damage incidents within five years, or if a company receives an especially serious creditworthiness damage rating in three or more provinces within three years, the NHSA will notify all provincial healthcare security administrations, and the company's nationwide eligibility for listing products for procurement, tender eligibility, and distribution rights will be suspended. The NHSA will also officially notify health agencies, market regulation agencies, tax authorities, and securities authorities of the company's misconduct.

Observations and Recommendations

➢ **Extension of Efforts to Reduce Costs and Blacklist Companies Engaging in Bribery**

The Draft Opinion is an extension of various efforts dating back to 2007 to formally punish through blacklisting pharmaceutical companies that bribe doctors (see an alert from 2013 here). While bribery in the healthcare sector continues to be a significant

problem, some commentators have speculated that the Draft Opinions are another tool for the government to push pharmaceutical companies, particularly innovative ones, to further lower drug prices.

- **Importance of Third-Party Management and Oversight**

  Unlike the PRC Anti-Unfair Competition Law, which provides that a company can avoid liability for commercial bribery by an employee if the company can prove that the employee's actions are unrelated to gaining a competitive advantage for the business operator, the Draft Opinion appears to make pharmaceutical companies directly liable for commercial bribery and market manipulation committed by their employees as well as their third-party distributors and sales agents. As currently drafted, the Draft Opinion does not contain any clarifications, exemptions, or safe harbors.

  Similar to guidance from U.S. regulators that third-party management is a critical component of an effective corporate compliance program,[6] the Draft Opinion demonstrates that PRC regulators are also pushing pharmaceutical companies operating in China to enhance their management and oversight of third-party distributors and sales agents. The Draft Opinion arguably pushes pharmaceutical companies harder on this point by linking the conduct of third-party business partners with the company's eligibility to participate in public procurement, which comprises the vast majority of China's pharmaceutical market.

- **Changing Calculus of Self-Disclosure and the Importance of Responding Carefully to Government Inquiries and Implementing Timely Remediation**

  The Draft Opinion's requirement that pharmaceutical companies self-disclose misconduct related to bribery and market manipulation or risk damaging their creditworthiness rating may change the calculus of self-reporting violations to the Chinese government, which to date has been exceedingly rare. For companies subject to legal regimes outside of China, such as the U.S. Foreign Corrupt Practices Act, companies may also need to consider the impact a voluntary disclosure in China might have on a decision to self-report to governments outside of China.[7]

  The Draft Opinion also underscores the importance of having a policy on how to respond to government inquiries. For example, it appears that companies would not be obligated to self-report if the misconduct is not related to commercial bribery or market manipulation, or does not otherwise violate the Drug Administration Law, the Pricing Law, the Anti-Monopoly Law, or the Anti-Unfair Competition Law. Further, the Draft Opinion lists several ways that a company could repair its creditworthiness rating for public procurement and appears to limit the relevant time period for misconduct that could affect a company's creditworthiness rating to the past three years. The Draft Opinion specifically notes that companies should terminate involved employees and third parties, which could be commercially difficult for companies that consolidate significant business in a single distributor or contract sales organization.

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[6] *See* U.S. Department of Justice, Criminal Division Guidance Document: *Evaluation of Corporate Compliance Programs* (2019); U.S. Department of Justice and U.S. Securities and Exchange Commission, *A Resource Guide to the FCPA* (2012).

[7] A decision to disclose to a government outside of China could be further complicated in some cases by China's International Criminal Judicial Assistance Law (see our blog posts here and here).

It remains to be seen how the requirements under the Draft Opinion will be implemented in practice and what additional implementing guidance will be issued. But we expect to see an uptick in disclosures and proactive remediation by companies if the NHSA mandates disclosure of misconduct and provides avenues for companies to remediate and mitigate the damages from the disclosure.

- **Additional Clarification Needed on Information Sharing and Remediation**

  The Draft Opinion leaves unanswered a number of important questions regarding how the proposed changes would be implemented. In addition to the apparent strict liability for misconduct of third parties discussed above, it remains to be seen how the NHSA would factor in a company's existing compliance program and a company's efforts to remediate improper behavior when making deciding how to penalize a company. The NHSA's approach on this issue could greatly affect how pharmaceutical companies address misconduct internally, self-report, and respond to anti-bribery and antitrust-related inquiries from regulators.

- **Potential Impact on Medical Device Companies**

  The Draft Opinion on its face applies only to pharmaceutical companies. However, changes as part of China's healthcare reform in recent years that first impact pharmaceutical companies—e.g., the Two-Invoice System, significant downward price pressure, heightened focus on anti-bribery efforts—have eventually applied to companies manufacturing medical devices, medical consumables, and diagnostic products.

Conclusion and Looking Forward

The publicly available text references that the NHSA has already sought internal comments from provincial-level healthcare security administrations. It is unclear when a final version of the Draft Opinion may be released.

The Draft Opinion demonstrates that China is continuing its efforts to lower drug prices, reduce inflated margins, and eliminate bribery and corruption in the pharmaceutical sector. The targeted guidance in the Draft Opinion related to bribery and market manipulation shows that the Chinese government views eliminating this type of misconduct as vital to ensuring a stable and secure healthcare system. Assuming that the Draft Opinion is promulgated in materially similar form as drafted, it will be critical for pharmaceutical companies to assess the risks posed by their third-party representatives and re-evaluate how to identify and remediate anti-corruption and antitrust issues both within the company and at its business partners.

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