ROPES & GRAY ALERT

Government Enforcement ▪ China Life Sciences ▪ Global Health Care Compliance

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Shanghai Tightens Industry Interactions with HCPs

In August 2017, multiple departments of Shanghai government,[1] led by Shanghai's Health and Family Planning Commission ("Shanghai HFPC"), jointly issued a series of administrative rules[2] (collectively, "Recent Shanghai Rules") to tighten the interactions of pharmaceutical and medical device companies with health care professionals ("HCPs") working in Shanghai hospitals and to crack down on commercial bribery in the course of sale and procurement of medical products.

The Recent Shanghai Rules echoed and reinforced the existing mechanisms in two earlier rules issued by China's central government in late 2013 to combat corruption in the health care sector, *i.e.*, the *Regulations on the Establishment of Commercial Bribery Records for the Purchase and Sale of Medicines* (also known as the "2013 Blacklisting Rules"), and the *Nine Prohibitions for Strengthening Ethical Conduct in the Healthcare Industry* (also known as the "2013 Nine Prohibitions"). However, the Recent Shanghai Rules also went further than these earlier rules and considerably expanded the scope of activities subject to restrictions.

1. Mandating Registration of Medical Representatives

China's State Council first proposed registering medical representatives ("MRs") of pharmaceutical companies in February 2017 and assigned China's Food and Drug Administration ("CFDA") the task of setting up an MR registration system. In August, the Shanghai FDA became the first local FDA to announce the draft implementing measures and solicited public comments on them. The Shanghai draft measures defined MRs as professionals who engage in communication and feedback of drug product-related information on behalf of pharmaceutical manufacturers, as well as general agents of imported drugs in China and Marketing Authorization Holders.[3] An MR is allowed to engage in academic promotion and technical consultancy work when interacting with HCPs, but is forbidden to carry out the sale of drugs. Once registered in the online database administered by the Shanghai FDA, a certificate will be issued to the MR, so that he or she can interact with HCPs within the permitted range and following the prescribed procedures. Identities of registered MRs will be published and any misconduct by the MRs will also be recorded in the MR registration system.

The Shanghai MR registration measures caused extensive debate among industry stakeholders. The MR definition did not cover those individuals with similar functions but employed by non-drug manufacturers, such as drug distributors and third-party service providers of manufacturers and distributors (*e.g.*, contract sales organizations, or "CSOs"). The definition also did not expressly cover medical device manufacturers, leaving it vague as to whether medical device MRs also need to be registered in order to legally function. The distinction between the permitted

[1] These included, among others, the Shanghai HFPC, the Shanghai Human Resources and Social Security Bureau, the Shanghai Medical Insurance Office, and the Shanghai Food and Drug Administration.

[2] Three rules were issued: (i) *Opinion on Strengthening the Mechanism to Crack Down on Kickbacks in Sale of Medical Products*; (ii) *Administrative Provisions on Management of Commercial Bribery Records in Purchase and Sale of Medical Products*; (iii) *Administrative Regulations on Reception of Medical Product Manufacturers and Distributors by Shanghai Medical and Healthcare Institutions*. One draft rule was announced for public comments: *Provisional Measures for Implementing a Registration System of Shanghai Medical Representatives*.

[3] "Marketing Authorization Holders" typically refers to pharmaceutical companies which own the regulatory approvals for their drugs but do not manufacture these drugs. Details of the Marketing Authorization Holder pilot initiative can be found in our China Life Sciences Alert dated June 15, 2016.

"academic promotion" and the forbidden "commercial promotion /selling" activities is also not clear. The Shanghai FDA is currently evaluating comments from the industry and is likely to clarify these issues in the upcoming final version of the MR registration measures.

2. Imposing Stringent Control over Hospital Visits and On-site Interactions with HCPs

In addition to pioneering with the MR registration system, Shanghai also created a set of procedures for Shanghai-based medical institutions to follow when receiving pharmaceutical and device company representatives at hospitals, including manufacturers and distributors of drugs, medical equipment and consumables (collectively, "Medical Products"), as well as agents and employees of these companies (collectively "Industry Representatives"). For the purpose of these rules, the broader Industry Representatives, not just MRs, need to abide by the stipulated procedures when conducting on-site visits at hospitals.

Under these rules, medical institutions shall collect from all visiting companies information related to the company, the relevant products, and the visiting employees. They must also keep ledger files of such information. Industry Representatives are allowed to interact with HCPs only within designated areas of the hospitals and are prohibited from carrying out any activities in "key areas of diagnosis and treatment," such as inpatient and outpatient departments, emergency departments, medical examination departments, medical equipment departments, pharmacy departments and IT management departments.

Hospitals are required to administer proper internal procedures for receiving Industry Representatives and must strictly follow several "rules of thumb," *i.e.*, "reception only at specified time, specified venue, by specified persons, and followed by meeting records." All visits by Industry Representatives need to be requested beforehand and meeting details need to be decided in advance. In principle, the receiving persons from the hospitals shall consist of the staff from both the medical administrative division and the relevant clinical departments, with at least two receiving persons present together from each hospital.

Hospitals are required to keep records of Industry Representatives so as to keep track of their integrity and compliance status, and to record any irregularities or misconduct during their visits to the hospital. If any Industry Representative enters the "key areas of diagnosis and treatment" to engage in drug selling or collation of prescription statistics, upon three accumulated violations, the relevant manufacturers or distributors will be blacklisted from supplying the hospital in question and the Industry Representative's misconduct will be reported to Shanghai's municipal HFPC, FDA and the centralized procurement office. If any manufacturers or distributors are found to be blacklisted by several public hospitals, the municipal authorities will likely disqualify them from participating in collective tenders.

Meanwhile, hospitals found to have seriously violated the requirements in interacting with Industry Representatives will receive merit deductions in their periodic review by the HFPC. The responsible HCPs and hospital management personnel will also receive disciplinary warnings or actions, including, among others, possible suspension of the physician's prescription right for three to six months.

3. Strictly Enforcing the Records-Keeping Requirement under Commercial Bribery Laws and Reiterating Blacklisting Consequences

Since the introduction of the central government's *2013 Blacklisting Rules*, the majority of the provincial blacklists appear to have been only sporadically maintained. To actively maintain records of commercial bribery cases and to effectively blacklist relevant stakeholders, the Recent Shanghai Rules reinforced the level-by-level violation reporting mechanism and set strict time limits on the duty to report.

Reportable commercial bribery violations are determined according to the same criteria laid out in the *2013 Blacklisting Rules*, including minor to serious bribery cases in the health care sector being prosecuted or investigated

by the relevant authorities. Once becoming aware of a bribery case, hospitals must report them to their supervisory governmental agency (the district level HFPC or other applicable agencies) within five working days, detailing the names of involved companies and individuals. The district level supervisory agencies shall investigate and verify the facts and names related to the violation, upon completion of which they shall further report the violations to the Shanghai HFPC within five working days. The Shanghai HFPC, within 15 working days of receiving the report, shall investigate and verify the violations according to the *2013 Blacklisting Rules*.

Once bribery cases are confirmed, the records will be published online on the Shanghai HFPC's website, including information such as the company's name, business address, legal representatives or persons in charge, directly responsible persons, facts of the violation and relevant judicial decisions and penalties imposed. Within one month of publicizing the records at the Shanghai provincial level, the case information will be further reported to the National HFPC for broader dissemination.

Recent Shanghai Rules reiterated the serious consequences of blacklisting as set forth in the *2013 Blacklisting Rules*. Blacklisted companies or individuals are subject to debarment from Shanghai's centralized procurement office and cannot supply Shanghai public hospitals for two years. Companies or individuals blacklisted in provinces other than Shanghai are subject to a credit points deduction in tendering to Shanghai's centralized procurement. If they are blacklisted two or more times within five years in other provinces, they are similarly subject to debarment from Shanghai's centralized procurement office and cannot supply Shanghai public hospitals for two years. Recent Shanghai Rules also made it clear, however, that if a company is blacklisted, its subsidiaries or parents as independent legal entities are not implicated or considered blacklisted.

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The regulatory developments in the Recent Shanghai Rules evidence a continued emphasis by PRC authorities on curbing bribery and corruption in the health care sector from both the supply and demand sides. Other provinces are likely to model themselves on the Recent Shanghai Rules and adopt similar measures. The wider implementation of these measures may pose significantly higher compliance requirements and risks for companies operating in China's health care sector. Facing China's evolving health care anti-corruption landscape, companies are advised to closely monitor further developments and update their company policies and controls to mitigate potential risks.