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China's SAMR Issues Guidance to Healthcare Companies on Preventing Commercial Bribery Risks

On January 14, 2025, China's State Administration for Market Regulation ("SAMR")[1] issued the Compliance Guidance for Healthcare Companies on Preventing Commercial Bribery Risks (the "Guidance"), which took effect immediately.[2] The Guidance outlines important changes regarding interactions with healthcare professionals ("HCPs") in China and describes compliance requirements in four key areas: (1) scope of responsibilities for medical representatives; (2) fee-for-service payments to HCPs; (3) sponsorships, grants, and donations; and (4) clinical trials. Healthcare companies[3] should evaluate their compliance policies in accordance with the Guidance to align internal requirements with SAMR's expectations, given SAMR's role as China's primary enforcer of commercial bribery laws directly impacting healthcare companies.

Background

SAMR published a draft version of the Guidance on October 11, 2024 for public comment.[4] The Guidance is SAMR's first comprehensive industry guidance aimed at preventing commercial bribery in the healthcare sector. The Guidance applies to both pharmaceutical and medical device companies involved in the research, development, manufacturing, and distribution of medical products.[5]

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[1] SAMR is China's main regulator for the conduct of private businesses in the marketplace and is the main enforcer of China's Anti-Unfair Competition Law which, among other things, addresses commercial bribery in the marketplace.

[2] See full text (Chinese) of the Guidance here.

[3] While the Chinese term used in the Guidance (医药) translates to "pharmaceutical," this summary uses the term "healthcare" because the Guidance states that it applies to both pharmaceutical and medical device/medical technology companies.

[4] See October 2024 draft version of the Guidance here.

[5] Guidance, Articles 3 and 4.

Key Takeaways

1. Scope of Medical Representatives' Responsibilities

The Guidance reiterates[6] several key prohibitions for healthcare companies and their medical representatives[7] when engaging in academic activities related to drugs and medical devices: (1) assigning sales responsibilities to medical representatives; (2) interfering with or influencing the proper use of medical products by HCPs; (3) seeking to collect or collecting prescription volumes; and (4) providing improper benefits to HCPs directly or indirectly in exchange for the prescription, recommendation, use, or procurement of medical products.[8]

While both the Medical Representative Record-Filing Administrative Measures[9] and the Guidance prohibit companies from assigning "sales responsibilities" to medical representatives, many healthcare companies in China continue to assign sales targets or KPIs to their sales personnel because they distinguish "sales responsibilities" (销售任务) from "sales targets" (销售目标). The former is more narrowly interpreted to refer to collecting accounts receivables and processing purchase and sales receipts, which aligns with multinational pharma companies' interpretation of "sales responsibilities" as described in the Medical Representative Record-Filing Administrative Measures issued by the National Medical Products Administration.[10] Even though SAMR did not clarify the meaning of "sales responsibilities" in the Guidance, local AMRs in China may scrutinize the practice of assigning sales targets to medical representatives, and AMRs may use such targets as a basis for or as a factor in their commercial bribery enforcement decisions.

2. Fee-for-Service Payments to HCPs

Unlike the position taken by the National Health Commission ("NHC")[11] that prohibited HCPs from accepting fee-for-service payments (e.g., speaker fees) directly from healthcare companies,[12] the Guidance allows healthcare companies to make fee-for-service payments directly to an HCP, provided that: (1) the services provided by the HCP are based on "authentic, reasonable, and legitimate business needs"; (2) the selection of the HCP is based on "professional knowledge, expertise, work experience, and other objective standards"; (3) the

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[6] Medical Representatives Record-filing Administrative Measures, Articles 12 and 13.

[7] This summary collectively refers to pharmaceutical medical representatives and medical device academic promotional personnel as "medical representatives."

[8] Guidance, Article 13.

[9] This includes both the Medical Representative Record-Filing Administrative Measures (Trial Implementation) issued in 2020 and the draft Medical Representative Administrative Measures issued by the National Medical Products Administration in November 2024 for public comment.

[10] Medical Representatives Record-filing Administrative Measures, Article 13.

[11] The NHC is the main cabinet-level department in China responsible for national healthcare policies in China. The NHC does not have direct enforcement power over private companies.

[12] See https://www.163.com/dy/article/IS669F1M0532C8QK.html.

HCP's service complies with their medical institutions' internal rules; (4) the amount of the fee-for-service payment reflects fair market value; (5) healthcare companies are advised to implement a cap on the payment amount and frequency when engaging HCPs for services; (6) healthcare companies should retain records of the fee-for-service arrangement; and (7) speaker fees must be made via bank transfers.[13] The Guidance prohibits paying speaker fees in cash or cash equivalents and prohibits using fee-for-service opportunities to reward or induce product prescription or procurement.[14]

Notably, the recommendation to implement caps on the frequency and total amount of fee-for-service payments to HCPs was not widely discussed in previous government and industry guidelines.[15] While most multinational pharma companies have implemented overall caps on HCP fee-for-service arrangements,[16] the practice is somewhat less well-established in the medical device industry.

Unlike the NHC, the SAMR has direct enforcement authority over the activities of healthcare companies. SAMR's explicit recognition that companies can legitimately engage and directly pay HCPs for their services provides helpful clarity to companies in an environment of heightened scrutiny of commercial bribery issues.

3. Sponsorships, Grants, and Donations

The Guidance is also prohibits direct sponsorships and grants to HCPs for attending third-party medical conferences.[17] Since the start of China's anti-corruption campaign in the healthcare industry in 2023, some enforcement authorities have viewed as improper companies providing direct support to HCPs, either by selecting which HCPs will receive or benefit from the support, or by giving sponsorships to medical associations while knowing the identities of the HCPs who will benefit from the sponsorships. The Guidance formalizes this position by prohibiting direct sponsorships and grants to HCPs.[18]

This prohibition will impact the healthcare companies that continue to provide direct support to HCPs to attend third-party medical conferences. The current RDPAC Code of Practice,[19] for

[13] Guidance, Article 18.

[14] Guidance, Article 19.

[15] The 2022 RDPAC Code requires member companies to establish caps on service fees to be paid to HCPs.

[16] Covington's China Pharma Anti-Corruption Compliance Survey in 2024 included questions on this topic.

[17] Guidance, Article 31 and 34.

[18] Guidance, Article 31(1) and 34(2).

[19] RDPAC Code of Practice (2022). RDPAC is the largest industry association of multinational R&D-based pharmaceutical companies in China. RDPAC publishes a code of practice regarding compliance requirements and standards that are mandatory for all member companies.

instance, permits direct support[20] to HCPs for their participation in medical interaction programs, although it requires companies to limit the direct support an HCP may receive from a company to "a reasonable frequency" and limits the total number of HCPs who can receive direct support for a medical interaction program.[21] While the prohibition in the Guidance may impact how some multinational pharma companies approach sponsorships and grants, most medical device companies may not be directly affected because AdvaMed China required member companies to phase out direct sponsorship of HCPs by January 1, 2018.[22]

Due to the prohibition in the Guidance against providing direct sponsorships and grants to HCPs, it appears that healthcare companies in China will also not be allowed to make fee-for-service payments to HCPs directly for speaking at third-party events (i.e., meetings organized by medical associations). The current consensus among multinational pharma companies is that, going forward, medical associations should pay HCPs for speaking at meetings organized by medical associations.

The Guidance generally retains the requirements from Measures for the Administration of Public Welfare Donations Accepted by Health Institutions regarding charitable donations.[23] For example, donations must be voluntary, documented in writing, and cannot be used to disguise profit-making activities or benefit specific individuals or departments.[24]

4. Addressing Bribery Risks in Clinical Trial Activities

While not breaking significant new ground, the Guidance includes a section that specifically addresses the corruption risks from clinical trial activities, perhaps signaling future increased scrutiny from enforcement authorities in this space. Consistent with Good Clinical Practice for Drugs,[25] the Guidance requires healthcare companies to enter into written agreements with researchers, clinical institutions, and other parties involved in clinical studies, as well as to retain relevant clinical trial records.[26] Notably, if healthcare companies outsource clinical trial work to external vendors, the Guidance requires companies to include anti-bribery provisions in clinical trial agreements with vendors and requires that companies carefully review costs associated with the trials (e.g., pass-through expenses) before reimbursing the vendor.[27]

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[20] The 2022 RDPAC Code uses the term "support" instead of "sponsorship" (as was used in previous versions of the RDPAC Code) to refer to travel, meals, accommodation expenses, and registration fees paid by member companies for HCPs to attend medical interaction programs.

[21] RDPAC Code of Practice 2022, Section 7.2.

[22] Code of Ethics on Interactions with Health Care Professionals in China (effective July 1, 2024), Section IV.II.F. AdvaMed China is the largest industry association for multinational medical device companies in China. AdvaMed China publishes a compliance code that is mandatory for member companies.

[23] Measures for the Administration of Public Welfare Donations Accepted by Health Institutions, Article 6, 16, and 20.

[24] Guidance, Articles 26, 27(4), 28(1), and (3).

[25] Good Clinical Practice for Drugs, Articles 7, 32, and 40.

[26] Guidance, Article 39(1) and (4).

[27] Guidance, Article 39(3).

5. Other Areas of Note

The Guidance addresses several other potential areas of elevated risk for healthcare companies, including meals/hospitality, the use of rebates/discounts, and the provision of free medical equipment.

For instance, the Guidance requires that companies determine the scope and standards for business hospitality and limit such to "reasonable and proportionate" expenses.[28] This standard aligns with existing industry guidance, such as the 2024 AdvaMed Code of Ethics on Interactions with Health Care Professionals, which requires that meals and refreshments be "modest in value and subordinate in time and focus to the training and/or educational purpose of the meeting"[29] and the RDPAC Code of Practice, which has long capped meals with HCPs at RMB 300 (about USD 40) per person per meal.

The Guidance also addresses the provision of rebates and discounts to counterparties in a transaction. It further clarifies the concepts of "discounts" and "commissions," which are permissible under the PRC Anti-Unfair Competition Law,[30] provided that the discounts and commissions are transparent and truthfully recorded.[31]

Under the Guidance, it is also permissible to lease medical equipment to hospitals free of charge, provided that the lease of equipment fulfills a legitimate business purpose,[32] the lease period and volume of equipment are appropriate, the lease agreement is documented in a written contract specifying equipment ownership, and equipment leases are not provided in exchange for business opportunities or competitive advantages. The Guidance prohibits linking medical equipment leases with sale of medical devices, consumables, drugs, or services and prohibits using equipment leases to interfere with government procurement.

Looking Forward

Although the Guidance is not a binding law or regulation, it offers valuable insight for healthcare companies into the compliance expectations and the enforcement priorities of China's main enforcement authority for commercial bribery and provides detailed guidelines for healthcare companies on how to refine internal compliance policies to align with SAMR's expectations.[33] Healthcare companies are also advised to review their business activities in light of the Guidance to mitigate against potential anti-corruption compliance risks. We also expect that industry associations may update their compliance guidelines in the near future to align industry codes with the requirements in the Guidance, such as the prohibition of direct HCP sponsorships and grants.

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[28] Guidance, Article 15.

[29] 2024 AdvaMed Code of Ethics on Interactions with Health Care Professionals in China, Section III.3.C.

[30] Anti-Unfair Competition Law, Article 7.

[31] Guidance, Article 23.

[32] Such as for demonstration purposes or trial use.

[33] Guidance, Article 3.

If you have any questions concerning the material discussed in this client alert, please contact the China-focused members of our Anti-Corruption/FCPA practice:

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