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Chinese Pharmaceutical, Biotech, and Medical Device Industry Associations Issue First Comprehensive Compliance Guidelines

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Anti-corruption / Life Sciences

In late March 2021, five prominent Chinese pharmaceutical, biotech, and medical device associations released the *Pharmaceutical Industry Compliance Management Practices* (医药行业合规管理规范, the "Compliance Standards"), the first comprehensive compliance guidelines tailored for life sciences companies operating in China. (Despite the title, the Compliance Standards apply to all life sciences companies, not only pharma companies.) The anti-bribery/anti-corruption section of the Compliance Standards provides detailed guidance that, with a few exceptions, aligns with the requirements from codes of conduct issued by industry associations for multinational life sciences companies, such as the RDPAC Code of Practice[1] and the AdvaMed Code of Ethics on Interactions with Health Care Professionals in China ("AdvaMed China Code").[2] The Compliance Standards provide life sciences companies in China with a high-level compliance framework across different enforcement areas.

The Compliance Standards are not binding, and while the document does not have explicit endorsement by the Chinese government, the breadth of involvement across state-affiliated trade associations suggests that the Compliance Standards may be used as industry expectations in China and, potentially, a standard against which future enforcement may be measured.

Multinational life sciences companies that have anti-bribery/anti-corruption programs that comply with the RDPAC Code of Practice and AdvaMed China Code should not need to significantly revamp their compliance programs or make broad changes as a result of the Compliance Standards. The Compliance Standards also serve as a useful reference and benchmark for both nascent and established compliance programs in China.

[1] RDPAC is the China Association of Enterprises with Foreign Investment R&D-Based Pharmaceutical Association Committee, an industry association of multinational pharmaceutical companies in China with R&D capabilities. RDPAC released the most recent version of its Code of Practice in 2019.

[2] The Advanced Medical Technology Association in China is an industry association of leading global medical device companies in China. AdvaMed released the most recent version of its Code of Ethics on Interactions with Healthcare Professionals in China in 2016, effective January 1, 2017.

Background

Trade associations for multinational companies operating in China in the pharmaceutical and medical device industries have had existing codes of practice as early as 2006.[3] More recently, five key Chinese pharmaceutical and medical device associations,[4] supported by external vendors, collaborated to draft the Compliance Standards. The Compliance Standards were implemented on February 26, 2021, and were released to the public on March 25, 2021.

The Compliance Standards serve as a non-binding reference guide for the member companies of the five Chinese pharmaceutical and medical device associations, which encompass hundreds of multinational and China-based biopharmaceutical, biotech, and medical device companies. While the Compliance Standards are non-binding and lack any mechanism or procedure to adjudicate disputes among companies or issue sanctions against companies for violations, they provide a base standard and useful compliance framework for pharmaceutical and medical device companies operating in China.

Key Takeaways

1. Scope of the Compliance Standards

Unlike the RDPAC Code of Practice and the AdvaMed China Code, which focus on anti-bribery and anti-corruption issues during promotional activities and interactions with healthcare professionals ("HCPs"), the Compliance Standards are much broader in scope and cover other compliance topics such as anti-monopoly, centralized procurement, data privacy and network security, adverse events, environment/health/safety, and tax and financial compliance.[5] The Compliance Standards open with a section on general compliance principles that apply to all areas of compliance, and include eight annexes on specific enforcement areas (such as commercial bribery).

The broad scope of the Compliance Standards appears to reflect the shift towards an integrated compliance approach that leverages tools such as risk assessments, early detection of emerging risks, and back-end testing to address compliance risks across different areas, instead of focusing compliance efforts solely on one specific area, such as anti-corruption.

This summary focuses only on anti-bribery and anti-corruption compliance under the Compliance Standards.

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[3] The RDPAC Code of Practice 2006.

[4] China Pharmaceutical Industry Association (中国化学制药工业协会)，China Association of Traditional Chinese Medicine (中国中药协会)，China Biochemical Pharmaceutical Industry Association (中国生化制药工业协会)，China Association for Vaccines (中国疫苗行业协会)，and China Association for Medical Devices Industry (中国医疗器械行业协会).

[5] The Compliance Standards cover eight areas of compliance: (1) anti-commercial bribery; (2) anti-monopoly; (3) finance and taxes; (4) product promotion; (5) centralized procurement; (6) environment, health, and safety; (7) adverse event reporting; and (8) data compliance and network security.

2. General Compliance Principles

The first twenty pages of the Compliance Standards set out the general principles of effective compliance programs, including a list of applicable national and local compliance standards in China, definitions of commonly used compliance terms, compliance management framework and responsibilities, compliance risk analysis and evaluation, compliance training, disciplinary actions for compliance violations, and procedures for whistleblower complaints and conducting compliance investigations.

The Compliance Standards state that effective compliance management is based on five main elements: (1) establishing a compliance management structure; (2) establishing a compliance management scope; (3) establishing and refining a compliance management system; (4) establishing a culture of compliance; and (5) establishing a mechanism for maintaining and ensuring compliance.

Experienced compliance professionals are likely already familiar with the general principles set out under the Compliance Standards. Similar to the Evaluation of Corporate Compliance Programs (updated June 2020)[6] and the FCPA Resource Guide (updated July 2020),[7] the Compliance Standards emphasize the need to continuously improve compliance programs through periodic testing and review. While the five major elements under the Compliance Standards are grouped and described differently from the hallmarks of an effective compliance program under the FCPA Resource Guide, the substantive requirements in the section on general compliance principles capture most of those hallmarks, such as "commitment by senior and middle management," "training and communications," "risk assessment," "incentives and disciplinary measures, and "continuous improvement, periodic testing, and review." We have prepared a chart comparing the Compliance Standards against the RDPAC Code, AdvaMed China Code, and other such codes, which is available upon request.

Further, because the Compliance Standards provide only high-level guidance, a company seeking to establish a robust compliance program will need to consult additional resources to develop tailored and nuanced compliance policies that address the key risks facing the company while being mindful of the company's resources and business realities.

3. Substantive Guidance Related to Anti-Bribery/Anti-Corruption Compliance

Annex A (Anti-Commercial Bribery Compliance) and Annex D (Product Promotion Compliance) provide detailed guidance that addresses the common risk areas in the sale and promotion of pharmaceutical products and medical devices in China.

(1) Government Officials and HCPs

The Compliance Standards broadly define "government officials" to include officials or employees of any government, government branches, governmental institutions (including state-owned enterprises), public officials or employees who work for organizations that have administrative management authorities under laws and regulations, officials and employees

[6] U.S. Department of Justice (DOJ), Criminal Division Guidance Document: *Evaluation of Corporate Compliance Programs* (June 2020).
[7] *A Resource Guide to the U.S. Foreign Corrupt Practices Act, Second Edition* ("FCPA Resource Guide").

who work for public international organizations, officials of political parties, candidates for political offices, or anyone representing or acting on behalf of the above individuals.[8]

Notably, the Compliance Standards do not include HCPs in the definition of government officials, which, in our experience, is generally consistent with the approach taken by most China-based companies. In contrast, the majority of multinational life sciences companies' compliance policies for their China operations define HCPs who work for public healthcare organizations as government officials, to reflect the position taken by U.S. regulators in FCPA settlements involving life science companies. While both multinational and China-based life sciences companies generally subject government officials and HCPs to similar (and generally more stringent) requirements regarding gifts, meals, fee-for-service arrangements, and other transfers of value, there are different requirements under PRC laws, regulations, and rules that apply to government officials versus HCPs.[9] A company should carefully consider how to define government officials and HCPs in its policies in light of its business operations and compliance priorities, such as the desire to have consistent definitions across different geographic areas where the company operates.

(2) Gifts and Meals

The Compliance Standards prohibit personal gifts and services to HCPs, but allow "cultural gifts" (风俗礼品) and souvenirs of "appropriate value" (金额适当) to HCPs.[10] The Compliance Standards instruct that each company should determine what it considers "appropriate" but suggest that gifts not exceeding RMB 300 per item could be allowed.[11] In our experience, a large majority of multinational life sciences companies in China prohibit all personal gifts and services and do not have exceptions for cultural gifts and souvenirs of any value. In addition, the RDPAC Code of Practice specifically prohibits giving "cultural gifts" (风俗礼品) to HCPs, and does not have an exception for souvenirs. The AdvaMed China Code does not mention cultural gifts or souvenirs but allows branded promotional items of minimal value (defined as RMB 200 or less) to HCPs. The IFPMA Code of Practice prohibits all personal gifts, including "social courtesy gifts" to HCPs.[12]

Similar to the RDPAC Code of Practice, the Compliance Standards allow giving promotional aids of "minimal value" (最小价值) only in the context of promoting over-the-counter medical products, and cap the value of promotional aids at RMB 100 per item.

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[8] Annex A, Section A.3.17.
[9] For example, physicians in China are subject to laws such as the Law of the People's Republic of China on Medical Practitioners (中华人民共和国执业医师法), and government officials in China are subject to regulations such as the Administrative Branch Civil Servant Disciplinary Action Regulations (行政机关公务员处分条例). In many cases, prescribing HCPs who take bribes are punished under commercial bribery laws applicable to "non-state functionaries," whereas hospital administrators and traditional government officials are punished under more stringent laws applicable to "state functionaries."
[10] Annex A, Section A.4.6.2.2.
[11] *Id.*
[12] International Federation of Pharmaceutical Manufacturers and Associations, Code of Practice (2019), section 7.5.1.

Lastly, the Compliance Standards allow "appropriate meals" (适当餐饮) with HCPs, but, unlike the RDPAC Code of Practice, do not provide a specific monetary standard for HCP meals.[13]

(3) Prohibitions on Sponsorships, Grants, and Donations to Individual HCPs

Section 4.5.1 of Annex A of the Compliance Standards prohibits providing sponsorships, grants, and donations directly to individual HCPs. This requirement reflects the broader trend of multinational pharmaceutical companies in China gradually phasing out grants to individual HCPs[14] to avoid an appearance of a quid pro quo. Companies that wish to continue to fund HCP educational activities and other permissible HCP activities have been transitioning funding to reputable Chinese medical associations with sole discretion to determine which HCPs will benefit from the funding.

The RDPAC Code of Practice and the IFPMA Code of Practice do not prohibit companies from retaining influence in selecting which HCPs will benefit from grants made to healthcare organizations. In contrast, the AdvaMed China Code and the AdvaMed Code of Ethics on Interactions with US Healthcare Professionals prohibit companies from selecting or influencing the selection of HCPs who will benefit from such funding.[15]

The Compliance Standards, the RDPAC Code of Practice, and the AdvaMed China Code all prohibit transferring any sponsorship funds to HCPs or hospital departments.

(4) Guidelines on Donations and Patient Assistance Programs

Consistent with the practice of most multinational life sciences companies, the Compliance Standards state that companies should not derive commercial benefits from donations. Notably, the Compliance Standards appear to use the term "donation" (捐赠) to refer to funding medical education and scientific research that contribute to HCP education, patient welfare, and public health,[16] while most multinational life sciences companies limit the definition of donations to purely charitable purposes, such as disaster relief or responding to a public health crisis.[17]

The Compliance Standards state that patient assistance programs should be limited to the provision of free products to indigent patients through charitable organizations. Companies are also prohibited from collecting patient personal information or conducting promotional activities through patient assistance programs.

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[13] The RDPAC Code of Practice caps most meals with HCPs at RMB 300 per person per meal. Neither the AdvaMed China Code nor the AdvaMed Code of Ethics on Interactions with US Healthcare Professionals provides a cap on the value for a meal provided to an HCP.
[14] Companies typically pay these grants to healthcare organizations or to medical associations, and companies determine which HCPs will benefit from the funding.
[15] AdvaMed China Code, Article IV, Section 2B. The AdvaMed China Code allows providing support directly to HCPs to attend procedure trainings organized by third parties.
[16] The RDPAC Code of Practice categorizes such funding as "grants" (资助).
[17] The RDPAC Code of Practice does not provide detailed guidelines on donations while AdvaMed China Code allows the use of charitable donations to support indigent care, as well as patient and public education.

With the proliferation of patient assistance programs in China in recent years, additional compliance guidance on this topic would have been particularly helpful to life sciences companies seeking to develop compliance controls tailored for risks in this area.[18]

Observations and Recommendations

- Because the anti-bribery/anti-corruption guidance in the Compliance Standards is generally in line with existing industry guidelines (such as the RDPAC Code of Practice), multinational life sciences companies that have developed and refined compliance programs are unlikely to need to make major changes in response to the Compliance Standards. In a few places where the Compliance Standards differ from companies' existing compliance policies, we anticipate that companies will follow the more stringent requirements to avoid regulatory scrutiny by Chinese enforcement authorities as well as adverse perceptions.

- The Compliance Standards stress the importance of periodic risk assessments and evaluations as part of an effective compliance program. Several documents issued by U.S. regulators — including the FCPA Resource Guide (updated July 2020) and the Evaluation of Corporate Compliance Programs (updated June 2020) — emphasize that risk assessments are a vital part of any robust compliance program and can help evaluate whether the compliance program is well-designed and tailored to the company's risk profile, whether the compliance program is periodically tested and updated, and whether the compliance program works in practice.

- The broad scope of the Compliance Standards underscores the need to avoid "compliance silos" where a company's compliance programs for different risk areas (such as anti-bribery/anti-corruption, anti-monopoly, anti-money laundering, trade controls, and cyber security) operate in isolation without communication with each other. The same compliance tools for risk assessment and reporting can be leveraged in multiple areas, and a company's compliance program would be more effective if it aligned incentives across enforcement areas.

- Unlike the RDPAC Code of Practice and the IFPMA Code of Practice, the Compliance Standards do not include an enforcement mechanism for reporting and adjudicating violations of its guidelines. It remains to be seen what impact the Compliance Standards will have on the compliance programs in the life sciences industry, particularly ones in the early stages of development.

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[18] The RDPAC Code of Practice does not address patient assistance programs.

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