Guidelines for pharmaceutical companies to prevent Commercial Bribery risks

China – State Administration for Market Regulation

Main information

Scope of Application:

Pharmaceutical and Medical Devices large and medium-size Enterprises, included foreign-invested and foreign established, insofar they somehow operate in China

Effective Date:

January 10th, 2025

Related Provisions:

- Ministry of Health, Notice no. 25/2023 Key points to implement for correction of malpractices in medical procurement
- Anti unfair Competition Law
- Criminal Law, art. 390 – Punishment for the Crime of Bribery – XII amendment
- Criminal Law, art. 165 et al – Offense against Companies – XII amendment

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Key Topics

Framework

- **Pharmaceutical Companies are "the first responsible parties for preventing their own commercial bribery risks" (art. 5).**
- **Expressly applicable to all MAHs, and to Domestic Responsible Person designated by overseas MAH (art. 4).**
- **Prevalence over Confidentiality:** "Companies shall eliminate the concerns of informants on keeping personal information confidential, personal safety, and other aspects through technical settings and institutional arrangements, and prevent retaliation against informants" (art. 9 no. 4).

What's new

- Nine typical "Risks of Bribery" areas: Academic Visits and Exchanges; Hospitality; Consulting Services; Outsourcing Services; Discounts, Rebates and Commissions; Donations, Sponsorships and Funding; Free Provision of MD; Clinical Research; Retail Terminal Sales.
- Companies **must have Preventive Measures** for each typical "Risk of commercial Bribery" set forth in the Guidelines: Guidelines outline specific "relevant matters" and "behavioral risks" to pay attention to.
- **Mandatory integrative contractual provisions in Service Contracts with Providers such as R&D, Manufacturing, Distribution.** MAH must include the antibribery clauses in the relevant agreements with CRO and other providers (art. 21 no. 2).
- In Clinical Research, the leading role of CRO does not imply the lack of liability of the MAH for the misbehavior committed by other entities involved in the Clinical Trial. The Sponsor is encouraged to supervise the transparency by "obtaining the confirmation of service time and service content by clinical trial institutions and researchers before the payment of service fees to a third party" (art. 39 no. 3)

Sensitive Factors

- **Interaction with Anti unfair competition provisions**
- **Interaction with Crimes committed by bribery or by Offense Against Company (even without bribery)**

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Drivers

- **Transparency:** expenses, financial commitments and remittances must be consistent with related agreements and fully traceable
- **Mandatory integrative provisions in contracts:** where negotiating agreements with third parties (entrusted producers, distributors, CRO, suppliers, etc) the company must include specific provisions on antibribery preventive measures according to the Guidelines
- **Internal Policies:** Companies must provide themselves with several Poliices to put in practice the Guidelines in the different "Risk of Bribery" areas
- **Criminal prevention:** according to XII amendment of Criminal Law, Bribery in pharmaceutical sector is deemed as particularly heavy, with punishments harsher than other sectors (art. 390 no. 2). Furthermore, special provisions on Crimes against Companies shall be considered. Even though this does not constitute Bribery,
  - **Illegally operating similar business (art. 165)**
  - **Illegally making profits for relatives and friends (art. 166)**
  - **Illegally converting shares at low price for favoritism (art. 169)**

  Integrates Crimes with punishments similar to Bribery, regardless of acts of Bribery have been committed by the Company managers or staff.

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