Announcement by the State Administration for Market Regulation on the Publication of the Compliance Guidelines for Pharmaceutical Companies to Prevent Commercial Bribery Risks. [1]

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Chapter I: General Provisions

Article 1

This guideline is formulated to prevent commercial bribery in the pharmaceutical industry, support and guide pharmaceutical companies to establish and improve compliance management systems. It aims to maintain fair competition order in the pharmaceutical market, safeguard the health rights and interests of the people, promote high-quality development of the medical and health industry and advance the construction of a healthy China. This guideline is formulated in accordance with laws and regulations such as the *Anti Unfair Competition Law of the People's Republic of China*, the *Drug Administration Law of the People's Republic of China* and combined with the actual situation of the pharmaceutical industry and anti-commercial bribery law enforcement practices.

Article 2

The development of the pharmaceutical industry should follow the fundamental principles of people and life, adhere to scientific research as the foundation and innovation as the guide, enhance the level of technological innovation, safeguard the bottom line of quality and safety, safeguard the interests of patients and continuously improve the level of medicine and medical care.

Pharmaceutical enterprises should adhere to the principles of fair competition, honesty and trustworthiness in their operations. Communication, exchange and cooperation with medical and health institutions should adhere to scientific rigor, openness and transparency; and should not interfere with the normal diagnosis and treatment behavior of medical and health institutions and personnel.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

Article 3

This guideline aims to provide reference for pharmaceutical enterprises and related third parties engaged in research and development, production and distribution of pharmaceutical products within the territory of the People's Republic of China. Encourage large and medium-sized pharmaceutical enterprises and related third parties to establish a comprehensive compliance management system for preventing commercial bribery risks in accordance with this guideline.

Small pharmaceutical enterprises can refer to this guideline to carry out commercial bribery risk compliance management work. The classification standards for large and medium-sized enterprises and small enterprises shall be implemented in accordance with relevant national regulations.

Article 4

The pharmaceutical products include drugs and medical devices. The pharmaceutical enterprises refer to legal person engaged in activities such as research and development, production and distribution of pharmaceutical products, including drug marketing authorization holders, medical device registrants, pharmaceutical enterprises in the field of manufacturing, pharmaceutical enterprises in the field of distribution, domestic enterprise legal person designated by overseas drug marketing authorization holders and domestic enterprise legal person designated by imported medical device registrants

The third party refers to individuals, legal people or non-legal organizations acting on behalf of pharmaceutical enterprises or providing goods or services to pharmaceutical enterprises. Legal people or non-legal organizations include pharmaceutical research institutions, pharmaceutical production organizations, pharmaceutical promotion service providers, relevant professional and industry associations, distributors, intermediaries, agents, etc.

Commercial bribery refers to the act of bribing the staff of the counterparty, the units or individuals entrusted by the counterparty to manage relevant affairs. Commercial bribery refers to individuals or entities that use their authority or influence, through money or other means, to gain business opportunities or competitive advantages in a transaction.

Article 5

Pharmaceutical enterprises are the primary entities responsible for preventing their own commercial bribery risks. They shall fulfill their principal responsibilities, strengthen internal controls and compliance management for preventing commercial bribery, and consciously resist any acts of commercial bribery.

Pharmaceutical enterprises and their staff shall strictly abide by laws, regulations, and relevant rules on integrity and professional conduct. Enterprises are encouraged to engage professional institutions to evaluate the establishment and implementation of their internal compliance management systems for preventing commercial bribery risks.

Industry associations and societies shall, under the guidance of government departments, strengthen industry self-discipline, establish and improve industry standards, promote the

development of compliance management systems for preventing commercial bribery risks within the industry, guide and supervise pharmaceutical enterprises in carrying out production and business activities in accordance with the law, and cooperate with and assist market regulation authorities in investigating and handling commercial bribery cases.

Pharmaceutical enterprises, related organizations, practitioners, and the general public are encouraged to monitor and report acts of commercial bribery in the pharmaceutical sector, promoting joint governance across society.

Medical and health institutions are encouraged to formulate supporting measures with reference to the provisions of these Guidelines, so as to jointly promote the orderly advancement of compliance management work for preventing commercial bribery risks among pharmaceutical enterprises.

Market regulation departments, in accordance with laws and regulations, are responsible for investigating and handling acts of commercial bribery by pharmaceutical enterprises within their jurisdiction, and for providing guidance on the establishment of compliance systems for preventing commercial bribery risks.

Chapter II : Construction of Compliance Management System for Pharmaceutical Enterprises to Prevent Commercial Bribery Risks

Article 6

The compliance awareness and support of the management team are important guarantees for the effective operation of the compliance management system to prevent commercial bribery risks in pharmaceutical enterprises. The management of pharmaceutical enterprises should set an example, actively promote the construction of the compliance management system for preventing commercial bribery risks and provide sufficient support in organizational structure and resource allocation.

Article 7

Pharmaceutical enterprises shall establish a compliance management organization suitable for their business scale and operational model to prevent commercial bribery risks and allocate compliance management personnel. A sound collaborative operation mechanism between compliance management and legal management, financial audit, internal control and risk management should be established to strengthen overall coordination and improve management efficiency. The basic responsibilities of the compliance management organization include:

a. Formulating corporate compliance management strategic planning and management plans;

b. Identifying and evaluating compliance risks;

c. Developing and implementing internal corporate compliance management systems and processes;

d. Conducting corporate compliance investigations and handling compliance reports;

e. Monitoring the operation of the corporate compliance management system and carrying out evaluation, auditing and optimization;

f. Handling compliance matters related to external regulatory authorities and partners;

g. Conducting corporate compliance consulting, compliance training, compliance assessment, compliance publicity and compliance culture development.

Article 8

Pharmaceutical enterprises shall promptly transform compliance requirements into regulations or codes of conduct. Pharmaceutical enterprises shall establish a compliance management system to prevent commercial bribery risks. The system should be revised and improved in a timely manner according to changes in laws, regulations and regulatory policies. Moreover, its implementation should be inspected. Pharmaceutical enterprises are encouraged to integrate anti-commercial bribery requirements into employee codes of conduct to promote understanding and adherence to the rules.

Article 9

Pharmaceutical enterprises shall establish and improve a compliance operation mechanism based on the goal of preventing commercial bribery risks. Through systematic operation, they should effectively prevent and respond to commercial bribery risks.

a. Pharmaceutical enterprises shall establish a commercial bribery risk identification and assessment mechanism. They should reasonably determine high-risk areas and positions for commercial bribery based on the business environment, business characteristics and types of partners. A comprehensive review of compliance risks in business management activities should be conducted to form a commercial bribery risk list. Enterprises are encouraged to establish data analysis systems to empower risk monitoring and analysis with data technology, promoting effective identification of commercial bribery risks and evaluating risk levels, impact scope and severity.

b. Pharmaceutical enterprises shall establish a compliance review mechanism for preventing commercial bribery risks, focusing on the proper exercise of job authority and the legal receipt and expenditure of funds. Embedding compliance review processes into internal information management systems may be an efficient method to effectively ensure the independent exercise of review rights by compliance management organizations.

c. Pharmaceutical enterprises shall establish mechanisms for responding to commercial bribery risk, take timely countermeasures, reasonably reduce compliance risks, and effectively avoid adverse consequences.

Pharmaceutical enterprises are encouraged to take prompt action when suspected commercial bribery is discovered, to report such matters proactively to market regulation authorities, and to actively cooperate with investigations, in order to jointly combat and prevent commercial bribery.

d. Pharmaceutical enterprises are encouraged to establish an internal reporting mechanism for preventing commercial bribery risks, ensuring smooth reporting channels. Moreover, Pharmaceutical enterprises shall eliminate concerns about confidentiality of personal information and personal safety through technical settings and institutional arrangements. Retaliation against whistleblowers should be prevented.

e. Pharmaceutical enterprises shall establish a compliance training mechanism to prevent commercial bribery risks and provide regular compliance training to employees in order to enhance their compliance awareness and ability so as to handle commercial bribery risks. Differentiated training should be organized based on employees' different responsibilities or needs to improve training quality. Enterprises are encouraged to support third-party compliance training for their employees.

f. Pharmaceutical enterprises shall establish a compliance management system monitoring mechanism to prevent commercial bribery risks, in order to conduct regular evaluations of system effectiveness to identify existing issues and potential risks.

g. Pharmaceutical enterprises shall take timely improvement measures based on compliance monitoring results, adjust management strategies and optimize process systems to ensure the adaptability and effectiveness of the compliance management system.

Article 10

Pharmaceutical enterprises foster a culture of compliance characterized by legality, integrity, transparency and fairness. Employees should deeply understand the importance of preventing commercial bribery risks. They shall enhance their compliance awareness and consciously abide by relevant laws and regulations. Employees’ tasks include safeguarding the company's reputation and image, strengthen partners' trust in the enterprise, improve the company's overall competitiveness and promote its healthy and sustainable development.

Chapter III: Identification and Prevention of Commercial Bribery Risks in Pharmaceutical Enterprises

Section 1- Commercial Bribery Risks in Academic Visits and Exchanges

Article 11

The academic visits and exchanges mentioned in this guideline refer to academic promotion activities conducted by pharmaceutical representatives and medical device promotion personnel for healthcare professionals regarding pharmaceutical products. Pharmaceutical enterprises shall arrange for their pharmaceutical representatives and medical device promotion personnel to engage in academic visits and exchanges, while sales personnel and other individuals shall not participate in such activities. The definition of "pharmaceutical representative" in this guideline follows the Regulations on the Administration of Pharmaceutical Representatives.

Article 12

When conducting academic visits and exchange activities, pharmaceutical enterprises shall pay attention to the following matters:

a. Pharmaceutical enterprises shall comply with laws, regulations, government guidelines, management regulations of health authorities and medical institutions regarding the reception of pharmaceutical representatives and medical device promotion personnel.

b. Pharmaceutical enterprises shall register pharmaceutical representatives in accordance with relevant regulations and publicly disclose relevant information. If medical institutions and their governing authorities have additional requirements for visiting personnel, those requirements shall prevail.

c. Pharmaceutical enterprises shall ensure that pharmaceutical representatives and medical device promotion personnel strictly adhere to the regulations of medical institutions and conduct academic visits or exchange activities only at permitted times and locations.

d. Pharmaceutical representatives and medical device promotion personnel may communicate with healthcare professionals, provide academic materials, offer technical consultations and conduct academic promotions.

Article 13

Pharmaceutical enterprises that conduct academic visits and exchanges shall identify and prevent the following behavioral risks:

a. Pharmaceutical enterprises are prohibited from assigning sales tasks to pharmaceutical representatives and medical device promotion personnel.

b. Pharmaceutical representatives and medical device promotional personnel are prohibited from interfering with or influencing healthcare professionals' rational use of pharmaceutical products.

c. Pharmaceutical representatives and medical device promotion personnel are prohibited from using visits as a pretext to obtain or collect information on the usage volume of various pharmaceutical products prescribed by healthcare institutions, their departments, or their personnel.

d. Pharmaceutical representatives and medical device promotion personnel are prohibited from directly or indirectly offering financial or other improper benefits to healthcare professionals to induce them to prescribe, recommend, use or procure pharmaceutical products.

Section 2- Risks of Commercial Bribery in Hospitality

Article 14

The term "hospitality" referred to in these guidelines refers to the provision of meals and other arrangements by pharmaceutical companies to external stakeholders during business activities.

Article 15

Pharmaceutical companies should pay attention to the following points when conducting business hospitality:

a. Establishing a Hospitality System: Pharmaceutical companies should establish a system that clearly defines the scope and standards of hospitality. The hospitality standards should comply with the applicable management regulations for the hosted individuals.

b. Limitation of Hospitality Expenses: The types of expenses that may occur during business hospitality should be limited to reasonable and moderate meals only.

c. Retention of Hospitality Records: It is recommended that pharmaceutical companies retain records of business hospitality activities.

Article 16

When conducting business receptions during commercial activities, pharmaceutical enterprises shall identify and prevent the following behavioral risks:

a.Pharmaceutical enterprises shall pay attention to business receptions that occur with unreasonable frequency or exceed normal commercial practice.

b.Pharmaceutical enterprises shall avoid arranging business receptions at famous tourist attractions, luxury venues, or locations associated with entertainment activities.

c.Pharmaceutical enterprises are prohibited from providing business receptions to close relatives or other unrelated persons of the guests, or from transferring benefits or making payments to such unrelated persons under the pretext of business receptions.

d.Pharmaceutical enterprises are prohibited from including tourism, entertainment, or similar activities as part of business receptions.

e.Pharmaceutical enterprises are prohibited from falsely listing or concealing business reception expenses under other names such as meetings, trainings, or research activities.

Section 3- Risks of Commercial Bribery in Consulting Services

Article 17

The consultation services referred to in these guidelines are those in which pharmaceutical companies engage and pay healthcare professionals to provide professional services based on their knowledge, experience and methods.

Article 18

When engaging healthcare professionals to provide consultation services, pharmaceutical companies should pay attention to the following matters:

a. Pharmaceutical companies should base the engagement of healthcare professionals for activities such as lectures and research on real, reasonable and legitimate business needs.

b. Pharmaceutical companies should select healthcare professionals based on objective criteria, such as professional knowledge, skills and work experience, so as to meet the business needs.

c. Pharmaceutical companies should comply with the relevant regulations of the healthcare institutions where the professionals are employed.

d. Pharmaceutical companies should reasonably establish a standard fee for the consultation services provided by healthcare professionals. It is recommended that the standard be based on objective conditions such as project scale, service duration, professional level and refer to applicable regulations or market fair prices.

e. It is recommended that pharmaceutical companies limit the number of times for a single healthcare professional engaged within a certain period. Pharmaceutical enterprises should limit the total amount of consultation fees paid to them.

d. Pharmaceutical companies should truthfully record and properly retain service records, service outcomes and detailed content of services provided by healthcare professionals in order to prove the authenticity, reasonableness and equivalence of the services.

e. It is recommended that pharmaceutical companies pay the service fees to healthcare professionals through bank transfer.

Article 19

Pharmaceutical companies engaging healthcare professionals to provide consultation services should pay attention to the identification and prevention of the following behavioral risks:

a. Avoid paying service fees to healthcare professionals in cash.

b. Prohibit pharmaceutical companies from using the employment of healthcare professionals to provide related consultation services as a means of rewarding or inducing them to issue prescriptions for pharmaceutical products; or to recommend, promote, procure or use the company's pharmaceutical products.

c. Prohibit delivering improper benefits to healthcare professionals under the guise of consultation services.

Section 4: Commercial Bribery Risks in Outsourcing Services

Article 20

The outsourcing services referred to in these guidelines refer to various services provided by third parties to pharmaceutical enterprises, including research and development, production and distribution of pharmaceutical products.

Article 21

When pharmaceutical enterprises engage third parties to provide relevant services, they shall pay attention to the following matters

1.Pharmaceutical enterprises shall establish mechanisms for the selection and engagement of outsourced service providers, and are encouraged to adopt competitive methods in choosing partners. The selection process shall follow the principles of openness and transparency, with complete records retained. Pharmaceutical enterprises shall require outsourced service providers to submit necessary supporting documents, including but not limited to registration certificates, qualifications, financial and tax information, premises, personnel, business capabilities, records of violations, and social credit records. Enterprises are encouraged to conduct due diligence on outsourced service providers.

2.Pharmaceutical enterprises shall enter into service contracts with outsourced service providers, specifying in full the scope of services, deliverables, fee standards, service duration, and anti-commercial bribery clauses. It is recommended that contracts explicitly stipulate that the pharmaceutical enterprise has the right to carry out necessary supervision or compliance audits regarding the performance of outsourced matters.

3.Pharmaceutical enterprises are advised to develop a “negative list” and, through contracts or letters of commitment signed with outsourced service providers, clearly define prohibited behaviors during the service process.

4.Pharmaceutical enterprises are advised to conduct regular supervision or compliance audits of the performance of outsourced service providers in accordance with the agreed contractual

terms, with particular attention to changes in key risk factors such as personnel, funds, and premises.

5.If an outsourced service provider engages in commercial bribery, the pharmaceutical enterprise shall take timely measures in accordance with relevant compliance management requirements.

6.Pharmaceutical enterprises shall evaluate the performance of outsourced service providers in accordance with contractual provisions, and such evaluations shall serve as the basis for settlement of service fees.

Article 22

Selecting third parties shall identify and prevent the following behavioral risks:

a. Monitoring Fair Pricing: Pharmaceutical enterprises shall assess whether the outsourced service fees stipulated in the contract, or the actual payments significantly deviate from fair market prices.

b. Proper Access Procedures: Pharmaceutical enterprises shall avoid directly signing agreements and conducting business with outsourced service providers without following appropriate access procedures.

c. Prohibition of Control Over Third Parties: Pharmaceutical enterprises are prohibited from controlling third parties or their funds by arranging for employees to establish companies or other similar methods.

d. Prohibition of Fraudulent Transactions: Pharmaceutical enterprises are prohibited from using outsourced service providers to misappropriate funds through false or non-existent services.

e. Prohibition of Bribery Through Outsourcing: Pharmaceutical enterprises shall not explicitly or implicitly instruct, permit, or acquiesce to outsourced service providers using outsourcing fees or other funds to bribe others in exchange for prescriptions, recommendations, promotions or procurement. Pharmaceutical enterprises shall not use the company's pharmaceutical products to gain competitive advantage or business opportunities.

Section 5- Risks of Commercial Bribery in Discounts, Rebates, and Commissions

Article 23

The terms "discounts" and "rebates" in this guideline refer to price concessions granted by pharmaceutical enterprises when selling pharmaceutical products, which are explicitly stated and accurately recorded in financial accounts. These include both immediate deductions from the total transaction amount at the time of payment and refunds of a certain percentage after

full payment has been made. The term “commission” in this guideline refers to remuneration paid to legally qualified intermediaries for services provided in a transaction.

Article 24

Medical and pharmaceutical enterprises shall observe the following provisions when paying discounts, rebates and commissions:

a. Pharmaceutical enterprises shall establish policies and standards for discounts, allowances, and commissions, clearly specifying the applicable scope, target recipients, and detailed operational procedures.

b. Approval System: Medical and pharmaceutical enterprises shall establish an approval system for discounts, rebates and commissions. Moreover, pharmaceutical enterprises shall specify approval authority, procedures and the required supporting documents and evidence.

c. Contractual Requirements: Medical and pharmaceutical enterprises shall sign contracts with transaction counterparties, specifying the discount rate and payment methods. Similarly, contracts with intermediaries shall specify the commission rate and payment methods.

d. Compliance Review: Recipients of discounts, rebates or commissions shall maintain ledgers and conduct compliance reviews to prevent such funds from being used for illegal purposes, such as commercial bribery.

e. Financial Records: Payments and receipts of discounts, rebates and commissions shall be accurately, timely and completely recorded in financial books in accordance with financial and accounting regulations.

Article 25

When pharmaceutical enterprises pay or receive discounts, allowances, or commissions, they shall identify and prevent the following behavioral risks:

a.Pharmaceutical enterprises shall pay attention to situations in which discounts, allowances, or commissions are paid or received without being stipulated in a contract or not in accordance with contractual terms.

b.Pharmaceutical enterprises shall avoid circumstances where there is insufficient segregation of duties between departments or personnel responsible for establishing discount and allowance standards and approval procedures, and those responsible for their actual implementation.

c.Pharmaceutical enterprises are prohibited from failing to record truthfully in financial accounts the payment or receipt of discounts, allowances, or commissions, including any cash, in-kind gifts, or other benefits.

d.Pharmaceutical enterprises are prohibited, whether explicitly or implicitly, from directing third parties to use discounts, allowances, or commissions to bribe others in order to obtain prescriptions, recommendations, promotion, procurement, or use of their pharmaceutical products, or any promises thereof, for the purpose of gaining competitive advantage or business opportunities.

Section 6- Risks of Commercial Bribery in Donations, Sponsorships and Financial Support

Article 26

The term "donation" in this guideline refers to the voluntary and gratuitous transfer of funds, medical products or other assets by a pharmaceutical enterprise to a recipient in accordance with laws and regulations.

Article 27- In case of conducting donation activities, pharmaceutical enterprises shall pay attention to the following matters:

a. Legality and Public Interest: donations must be made for legitimate and charitable purposes, adhering to the principles of voluntariness and gratuity. Donations must be explicitly disclosed and accurately recorded in financial accounts. Enterprises may evaluate the necessity and reasonableness of the donation plan based on the recipient's needs.

b. Donation Methods and Evaluation: donations may be made directly to recipients or through charitable organizations. Enterprises should evaluate the background and capability of charitable organizations, the selection of recipients and the appropriateness of the donated products.

c. Compliance and Due Diligence: donations must comply with relevant legal provisions. Enterprises are encouraged to conduct due diligence to ensure the authenticity and public benefit of donation projects and establish an internal approval system for donations.

d. Donation Agreements and Documentation: enterprises should voluntarily sign a donation agreement with the recipient and properly retain relevant documentation, including but not limited to internal approvals, signed agreements and proof of execution.

e. Donation Asset Standards and Delivery:

- Non-Monetary Donations: Donated goods must meet national quality and qualification standards. Recipients are encouraged to engage third-party evaluation agencies for assessment, verification or notarization of donated assets. Direct delivery to the recipient's department responsible or official premises is recommended.

- Monetary Donations: Donations should be transferred via bank transactions into the official bank account of the recipient organization.

f. Donation Receipts and Financial Records: enterprises must obtain a donation receipt issued by the financial authority, stamped with the official seal of the recipient organization and reflect the actual value of the received donation.

g. Donations to Government-Related Institutions: donations to public institutions and social organizations under the jurisdiction of health, traditional Chinese medicine and disease control authorities must comply with the relevant regulations of these departments, as well as the social affairs and civil affairs authorities.

Article 28

Pharmaceutical enterprises must identify and prevent the following behavioral risks when conducting donation activities:

a. Prohibition on Designating Beneficiaries: for donations related to medical personnel training, academic activities and scientific research in the healthcare sector, pharmaceutical enterprises are prohibited from designating specific beneficiaries.

b. Centralized Acceptance of Donations by Health Institutions: donations to recipient entities within the healthcare system must be uniformly accepted by the designated healthcare institution. The donation recipient cannot be a specific department, internal functional unit, individual or another entity designated by the healthcare institution.

c. Prohibition on Using Donations for Improper Business Gains: pharmaceutical enterprises are prohibited from using donations to secure business transactions, service opportunities, preferential treatment, prescription or usage of their medical products or any other economic benefits related to the donation. Donations must not be used as leverage to obtain intellectual property, research results, industry data or other rights and claims.

d. Avoidance of Bypassing Procurement Regulations: enterprises must not use donations to circumvent bidding processes or government procurement regulations.

e. Donations must not serve as a disguised method to introduce specific medical equipment into hospitals to facilitate the sale of related products.

Article 29

The term “sponsorship” in this guideline refers to the support provided by pharmaceutical enterprises to a sponsored party in the form of financial or material resources or services in exchange for opportunities to promote the company’s image, brand or products.

Article 30

When providing sponsorship, pharmaceutical enterprises shall adhere to the following principles:

a. Legality, Transparency and Public Disclosure: sponsorship must be conducted in accordance with the law, in an open and transparent manner. Sponsorship arrangements can be based on publicly issued commercial invitations or sponsorship solicitations.

b. Formal Agreements for Sponsorship of Commercial Events: when sponsoring third-party commercial events, pharmaceutical enterprises must sign a commercial sponsorship agreement. The agreement should explicitly define the benefits the enterprise will receive, such as naming rights, advertising space or other promotional opportunities.

Article 31

Pharmaceutical enterprises must identify and prevent the following behavioral risks when providing sponsorship:

a. Avoiding Direct Sponsorship to Healthcare Institutions or Individuals: pharmaceutical enterprises should avoid providing sponsorship directly to healthcare institutions, internal departments of healthcare institutions or individual healthcare personnel. Sponsorship should not be channeled through third parties to designate specific recipients.

b. Prohibition on Using Sponsorship for Improper Influence: pharmaceutical enterprises are prohibited from using sponsorship to influence healthcare personnel in prescribing medical products or providing facilitation for recommending, promoting, purchasing or using the company's medical products. Sponsorship must not be used to gain competitive advantage or business opportunities through improper influence over healthcare professionals.

Article 32

The term “funding” in this guideline refers to financial support provided by pharmaceutical enterprises for healthcare institutions to assist in improving healthcare services, including support for medical or scientific research and improvements in medical facilities.

Article 33

When providing funding, pharmaceutical enterprises should pay attention to the following matters:

a. Due Diligence: before providing funding, it is recommended that pharmaceutical enterprises conduct appropriate due diligence on the recipient to understand the funded project and its

management measures. Relevant records should be kept ensuring transparency and accountability.

b. Compliance with Laws and Regulations: pharmaceutical enterprises must comply with relevant laws and regulations when providing funding. Pharmaceutical enterprises should follow necessary and appropriate approval procedures to ensure that the funding is not misused for illegal inducement or bribery purposes.

c. Funding Agreements: pharmaceutical enterprises should enter a contract with the recipient and clearly specify the purpose of the funding.

Article 34

When providing funding, pharmaceutical companies must be aware of the following behavioral risks and take necessary preventive measures:

a. Prohibition of Direct Funding to Internal Departments or Individuals: Pharmaceutical companies are prohibited from directly providing funding to internal departments or individuals within the recipient organization.

b. Prohibition of Funding to Specific Healthcare Professionals: Pharmaceutical companies are prohibited from providing funding to specific healthcare professionals.

c. Prohibition of Using Funding as a Bargaining Tool: Pharmaceutical companies are prohibited from using funding as a way to obtain promises or results from the recipient in the form of issuing prescriptions, recommending, promoting, purchasing; or using the company's pharmaceutical products with the aim of gaining a competitive advantage or securing business opportunities.

Section 7- Risks of Commercial Bribery in the Free Provision of Medical Devices

Article 35

The free provision of medical devices, as referred to in these guidelines, refers to the act of a pharmaceutical company providing medical devices (including related consumables, accessories, etc.) to healthcare institutions free of charge, based on reasonable justifications for promoting the correct, safe and effective use of the products and facilitating pre-market clinical trials, all under the premise of fair competition.

Article 36

Pharmaceutical companies providing free medical devices should pay attention to the following matters:

a. When pharmaceutical enterprises provide medical equipment to healthcare institutions free of charge, it shall be based on legitimate purposes, including collecting feedback for research and product improvement, or facilitating healthcare institutions in conducting product performance evaluations.

b. Non-Transfer of Ownership: Pharmaceutical companies can provide medical devices to healthcare institutions free of charge without transferring ownership but should clearly specify the ownership of the devices provided in a contract.

c. Careful Review and Tracking Procedures: Pharmaceutical companies should conduct careful reviews of the free provision projects for medical devices, establish and effectively implement relevant tracking procedures and requirements. Pharmaceutical enterprises should retain relevant supporting documents for verification, ensuring that the purpose of the provided products is legitimate.

d. Adherence to the Necessity Principle in Evaluations: When assisting healthcare institutions in evaluating the performance of their products via free provision of medical devices, pharmaceutical companies should follow the principle of necessity, setting reasonable timeframes and quantities based on the characteristics of the products and the needs of the evaluation.

e. Proper Collection and Disposal of Feedback and Usage Data: Pharmaceutical companies should truthfully collect and record relevant usage information and feedback from healthcare institutions regarding the provided devices and ensure proper handling of the devices after use.

Article 37

When providing free medical devices, pharmaceutical companies should be aware of and take measures to prevent the following behavioral risks:

a. Prohibition of Unlawful Agreements on Purchases: Pharmaceutical companies are prohibited from using the free provision of medical devices to agree with healthcare institutions on minimum quantities or amounts of consumables, supporting equipment, medicines or services to be purchased. Furthermore, Pharmaceutical enterprises are prohibited from using agreements on purchase prices that are significantly higher than market prices. Such actions would lead to the improper acquisition of business opportunities and competitive advantages.

b. Prohibition of Avoiding Legal Tendering Processes: Pharmaceutical enterprises are prohibited from using the free provision of medical devices to circumvent or interfere with the public tendering and procurement processes for medical devices that healthcare institutions must follow in accordance with the law and regulations.

c. Prohibition of Illegal Profit Transfer: Pharmaceutical companies are prohibited from using the free provision of medical devices as a pretext to offer illegal benefits to healthcare institutions or medical professionals. They must not create conditions that facilitate the illegal profit-making of healthcare institutions or healthcare personnel through the free provision of devices.

Section 8- Risks of Commercial Bribery in Clinical Research

Article 38

The "clinical research" referred to in these guidelines refers to clinical trials, post-marketing research, adverse reaction monitoring and other research activities related to pharmaceutical products, initiated or participated by pharmaceutical enterprises or commissioned to third parties. It also includes clinical research funded directly by pharmaceutical companies or by a third party on behalf of the pharmaceutical company, initiated by researchers from healthcare institutions.

Article 39

Pharmaceutical enterprises that conduct clinical research should pay attention to the following matters:

a. Pharmaceutical enterprises should sign contracts with researchers, clinical trial institutions and other participants involved in the clinical research project, clearly defining each party's responsibilities, including cost details, payment traceability and technical requirements. Clinical trials must comply with the quality management standards set by pharmaceutical regulatory authorities. Clinical research must comply with the management requirements set by health authorities.

b. Pharmaceutical companies should verify the registration status of clinical research projects to ensure authenticity.

c. If the pharmaceutical enterprise fully or partially commissions a third party to conduct clinical research, the contract should specify the scope of services, deliverables, fee standards, service duration, and anti-commercial bribery clauses. If there are costs that need to be reimbursed by the pharmaceutical company, the authenticity and reasonableness of these expenses should be carefully verified before payment. It is recommended that pharmaceutical enterprises obtain confirmation from the clinical trial institution and researchers regarding the service time and content before paying third-party service fees. Third-party management may refer to the relevant provisions on outsourcing services in Section 4 of this chapter.

d. Pharmaceutical enterprises should properly retain research data and results based on the contractual agreement and the scope.

Article 40

Pharmaceutical enterprises conducting clinical research must be vigilant in identifying and mitigating the following behavioral risks:

a. Prohibition of Fabricating Projects or Exploiting Clinical Research as a Pretext: Pharmaceutical enterprises are expressly prohibited from fabricating projects or using clinical research as a pretext for offering improper benefits to clinical trial institutions and researchers. This includes providing such benefits in exchange for gaining a competitive advantage or securing opportunities related to the approval, promotion, or sale of pharmaceutical products.

b. Prohibition of Offering Improper Benefits: Pharmaceutical enterprises must refrain from directly or indirectly offering improper benefits, including through third-party service organizations, to clinical trial institutions or individual researchers, in exchange for accelerating or expediting the progress of clinical research. Furthermore, pharmaceutical enterprises are prohibited from manipulating clinical research data in order to produce results that are favorable to the company's products.

Section 9- Risks of Commercial Bribery in Retail Terminal Sales

Article 41

The "retail terminal sales" referred to in this guideline refers to the sales and promotional activities of pharmaceutical products conducted by pharmaceutical enterprises through retail pharmacies (including online pharmaceutical sales enterprises).

Article 42

Pharmaceutical companies engaged in retail terminal sales should pay attention to the following matters:

a. Pharmaceutical enterprises' visits to retail terminals shall be based on legitimate and reasonable purposes, such as conveying information on proper medication use, sharing innovative research results, expanding treatment areas, collecting seasonal drug demand, obtaining patient feedback on medication, and monitoring adverse drug reactions.

b. If pharmaceutical enterprises entrust retail terminals to carry out pharmaceutical product promotion activities, they shall sign a promotion agreement with the retail terminal and ensure that such activities comply with laws, regulations, and regulatory rules. Both parties must accurately record their respective accounts in an explicit manner.

c. Signing Clean and Compliant Agreements: it is recommended that pharmaceutical enterprises sign integrity and compliance agreements with retail terminal sales, specifying the legal operational requirements to promote the lawful operation of the retail terminal.

d. Hiring Retail Staff for Services: when pharmaceutical enterprises hire retail staff for services such as speeches, surveys or consultations; they should refer to the relevant regulations for consultation services as outlined in Section 3 of this chapter.

e. Paying Discounts on Retail Terminals: pharmaceutical enterprises should pay discounts to retail terminals according to the terms specified in the agreement. The specifics can be referred to the relevant regulations in Section 5 regarding discounts, allowances and commissions.

Article 43

Pharmaceutical enterprises engaged in retail terminal sales should pay attention to the following behavioral risks and take measures for identification and prevention:

a. Prohibition of Cash Kickbacks and Unfair Trade Practices: pharmaceutical enterprises are prohibited from offering cash kickbacks or other benefits to induce retail terminals to provide conveniences or gain unfair trading opportunities in aspects such as the procurement, display or promotion of pharmaceutical products.

b. Prohibition of Collusion with Retail Terminals for Prescription Information: pharmaceutical enterprises are prohibited from colluding with retail terminals to deliver benefits to healthcare personnel in exchange for prescription information. Additionally, pharmaceutical enterprises are prohibited from using retail terminals to collect prescription data and provide benefits to healthcare institutions or healthcare personnel.

c. Prohibition of Improper Influence on Online Retail Employees: pharmaceutical enterprises are prohibited from influencing online retail employees to allocate their products improperly, failing to strictly review prescriptions or reusing prescriptions inappropriately through the provision of improper benefits.

Chapter IV: Managing the Risks of Commercial Bribery in Pharmaceutical Enterprises

Section 1 - Internal Risk Management and Disposal

Article 44

When a pharmaceutical enterprise discovers that its business activities involve risks of commercial bribery, it shall immediately cease the risky behavior and take the following measures:

a. The pharmaceutical enterprise may investigate independently or engage a third-party professional institution to carry out the investigation in accordance with the law. The investigation should strive to be truthful and objective. Investigation methods may include verifying risk-related matters, interviewing involved and knowledgeable personnel and

reviewing relevant documents. Evidence should be properly preserved to prevent loss, malicious tampering or deletion.

b. Based on the internal investigation results, the pharmaceutical enterprise shall evaluate the risk level, scope of impact and severity of the incident so as to form an evaluation report.

Article 45

Pharmaceutical enterprises shall, based on the results of risk assessments, promptly take effective measures, including but not limited to holding responsible parties and third parties accountable, eliminating negative impacts, improving management processes, revising rules and regulations, and strengthening compliance training.

Pharmaceutical enterprises are encouraged to, in combination with the outcomes of such measures, continuously improve and refine long-term mechanisms through ongoing monitoring, evaluation, and review, in order to establish a robust compliance management system for preventing commercial bribery risks and to prevent the recurrence of similar risk behaviors.

Section 2- Cooperation with Regulatory Enforcement

Article 46

Pharmaceutical enterprises are encouraged to proactively report to market regulatory authorities when they discover that their business activities are suspected of involving commercial bribery, along with relevant supporting materials. The voluntary report should include the following information:

a. Source of the issue and details of the investigation process;

b. Information on the parties involved;

c. Facts currently known;

d. Measures already taken;

e. Establishment and implementation of the compliance management system for preventing commercial bribery risks;

f. Other matters that need to be reported.

Article 47

When a pharmaceutical enterprise is subject to an investigation by market regulatory authorities, it shall cooperate as required, truthfully provide relevant materials and disclose accurate information. The following actions are prohibited:

a. Refusing or obstructing law enforcement officers from inspecting business premises;

b. Refusing to be questioned or to provide materials related to the investigation;

c. Hindering the investigation under the pretense of trade secrets, the absence of responsible personnel, lack of authorization or failure to complete internal approval procedures;

d. Concealing, destroying, transferring evidence, instructing or assisting others in doing so;

e. Providing false materials or information;

f. Retaliating against individuals or entities that cooperate with the investigation or voluntarily provide evidence;

g. Any other actions that refuse or obstruct the investigation.

Article 48

During the investigation by market regulatory authorities, if a pharmaceutical enterprise meets any of the following conditions, it may be considered for a reduced or mitigated administrative penalty:

a. Voluntarily reporting illegal conduct before the market regulatory authorities initiate an investigation.

b. Voluntarily reporting illegal conduct after the authorities have begun their investigation but before they uncover the violation and take effective measures to mitigate the consequences.

c. Confessing to previously undiscovered violations after the investigation has started, including both the enterprise's own violations and those of others, with the confession being verified as true.

d. Actively cooperating with the investigation by responding to inquiries within the required timeframe, truthfully answering questions and voluntarily providing relevant evidence, such as financial records, expense approvals, fund flows and business agreements.

e. Making meritorious contributions to the investigation, such as exposing major commercial bribery or other significant illegal activities in the pharmaceutical sector, with key leads or evidence verified as accurate.

f. Committing a minor violation with minimal social harm.

g. Playing only a minor role in bribery activities despite direct involvement, with explanations provided regarding the enterprise's position, level of participation (e.g., number of bribery instances, amounts involved) and contribution to the harmful outcome.

h. Any other circumstances under which a lighter or reduced administrative penalty is legally warranted.

Article 49

If a pharmaceutical enterprise cooperates with the investigation by market regulatory authorities and meets any of the following conditions, it may be considered for exemption from administrative penalties:

a. The violation is minor, promptly corrected, and has not caused any harmful consequences.

b. It is a first-time offense, the consequences are minimal, and the violation is promptly corrected.

c. Other circumstances where exemption from administrative penalties is legally warranted.