Appendix I

Compliance Guidelines for Healthcare Companies to Prevent Commercial Bribery Risks

(Draft for Public Comment)

State Administration for Market Regulation

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Chapter I. General Provisions

Article 1 In order to prevent and curb commercial bribery in the healthcare field, support and guide healthcare companies to establish a sound compliance management system, maintain the order of fair competition in the healthcare market, safeguard the health rights and interests of the people, promote the high-quality development of medical and healthcare undertakings, and push forward the construction of a healthy China, the Guidelines have been formulated in accordance with the provisions of the Anti-Unfair Competition Law of the People's Republic of China, the Drug Administration Law of the People's Republic of China, and other laws and regulations, combined with the actual situation of the healthcare industry and the practice of anti-commercial bribery law enforcement.

Article 2 The development of the healthcare industry should follow the fundamental principles of "people first and life first", adhere to the research-based and innovation-led approach, enhance the level of scientific and technological innovation, guard the bottom line of quality and safety, safeguard the interests of the majority of patients, and continuously improve the level of medicine and medical care.

Healthcare companies should adhere to the principles of fair competition, honesty and trustworthiness in their operations, and should adhere to scientific rigor, openness and transparency in their communications, exchanges and cooperation with healthcare institutions, and should not interfere with the normal diagnostic and therapeutic behaviors of healthcare institutions and healthcare practitioners.

Article 3 The purpose of the Guidelines is to provide reference for healthcare companies and relevant third parties engaged in the research and development, production and distribution of healthcare products in the People's Republic of China. Large and medium-sized healthcare companies and related third parties are encouraged to establish a complete compliance management system for preventing commercial bribery risks in accordance with the Guidelines, and small-sized healthcare companies may refer to the Guidelines to carry out compliance management of commercial bribery risks. Large and medium-sized companies and small companies are categorized in accordance with the relevant provisions of the national standards.

Article 4 Healthcare products under the Guidelines include drugs and medical devices.

Healthcare companies under the Guidelines refer to legal entities engaged in the research and development, production and distribution of healthcare products, including but not limited to the holders of the marketing authorization for healthcare products, the registrants (filers) of medical devices, the manufacturers of healthcare products, the commercial distributors of healthcare products, the domestic legal entities designated by the holders of the marketing authorization for overseas healthcare products, and the domestic legal entities designated by the registrants (filers) of the imported medical devices.

The third parties under the Guidelines refer to individuals, legal entities or other organizations acting on behalf of a healthcare company or providing goods or services to a healthcare company, including but not limited to research institutes, authorized manufacturers,

promotion service providers, relevant professional societies and industry associations, dealers, suppliers, distributors, intermediaries, agents and so on.

Commercial bribery under the Guidelines refers to the use of properties or other means to bribe the staff of the counterparty to the transaction, the entity or individual entrusted by the counterparty to handle the relevant affairs, and the entity or individual who can impact the transaction with their authority or influence, in order to seek opportunities for transaction or competitive advantage.

Article 5 Healthcare companies are the first ones responsible for preventing commercial bribery risks, they should bear the major responsibility, and should strengthen the prevention of commercial bribery risk through internal control and compliance management and consciously resist commercial bribery. Healthcare companies are advocated to introduce professional organizations to prevent commercial bribery risk of their own compliance management system construction, implementation and evaluation.

State-owned healthcare companies and their staff should strictly abide by laws and regulations and relevant provisions on integrity.

Industry associations and professional societies and other organizations should, under the guidance of government departments, strengthen industry self-discipline, establish and improve industry rules, promote the establishment of industry-wide compliance management system to prevent commercial bribery risks, guide and supervise the healthcare companies to carry out production and operation and other activities in accordance with the law, cooperate with and assist the Administration of Market Regulation to investigate and deal with commercial bribery.

Healthcare companies and other organizations, personnel and the public are encouraged to monitor and report on commercial bribery in the healthcare industry, and promote social governance.

Healthcare institutions are encouraged to develop supporting measures in line with the provisions of the Guidelines, and jointly promote the prevention of commercial bribery risk compliance management of healthcare companies in an orderly manner.

Market supervision departments are responsible for investigating and handling commercial bribery in healthcare companies within their authority in accordance with the provisions of laws and administrative regulations, providing pre-event guidance for healthcare companies to carry out commercial competition, and guiding and supervising the healthcare companies on the establishment and implementation of a compliance system for preventing commercial bribery risks.

Chapter II. Compliance Management Systems for Healthcare Companies to Prevent Commercial Bribery Risks

Article 6 The compliance awareness and support from the company management team is an important guarantee for the effective operation of the compliance management system for preventing commercial bribery risks in healthcare companies. It is advocated that

the top management of healthcare companies to set a good example by actively promoting the construction of compliance management systems for preventing commercial bribery risks and providing full support in terms of organization and resource allocation.

Article 7 Healthcare companies should establish a compliance management organization for preventing commercial bribery risks appropriate to their scale of operation and mode of operation, and deploy compliance management personnel. They should establish and improve a coordination system for compliance management with legal management, financial audit, internal control, risk management and other synergistic operation mechanism, strengthen cooperation and improve management effectiveness. The basic duties of the compliance management organization include, but are not limited to:

(a) Developing strategic planning and management plans for company compliance management.

(b) Identifying and assessing compliance risks;

(c) Developing and implementing internal company compliance management policies and processes;

(d) Conducting company compliance investigation and handling compliance reports;

(e) Monitoring the operation of company compliance management systems and carrying out evaluations, audits and optimizations.

(f) Handling compliance matters related to external regulators and partners;

(g) Carrying out company compliance counseling, compliance training, compliance assessment, compliance publicity and compliance culture building.

Article 8 Healthcare companies should promptly translate compliance requirements into rules and regulations or codes of conduct, and establish a compliance management system to prevent commercial bribery risks. The system should be revised and improved in a timely manner in accordance with changes in laws, regulations and regulatory policies, and the implementation of the system should be checked. Healthcare companies are encouraged to incorporate the anti-commercial bribery requirements into their employees' code of conduct to promote their understanding and implementation of the requirements.

Article 9 Healthcare companies should establish and improve the compliance operation mechanism based on the goal of preventing commercial bribery risk requirements, and effectively prevent and respond to commercial bribery risks through the systematic operation.

(a) Healthcare companies should establish a commercial bribery risk identification and assessment mechanism to reasonably determine the high-risk areas and positions according to the company's operating environment, business characteristics and types of partners, and comprehensively sort out the compliance risks in the operation and management activities, and form a list of commercial bribery risks; healthcare companies are encouraged to establish of a data analysis system, and empower the risk monitoring and analysis with data technology, and promote the effective identification of commercial bribery risks, and assess the risk level, scope of influence, degree of influence, etc.

(b) Healthcare companies should establish a compliance audit mechanism to prevent commercial bribery risks, focusing on the correct exercise of post authority and the legitimate income and expenditure of property. Healthcare companies are encouraged to embed compliance audits in the internal information management system, and effectively safeguard the independent exercise of the right to audit by the compliance management organization.

(c) Healthcare companies should establish a response mechanism to prevent commercial bribery risks, adopt timely response strategies, reasonably reduce compliance risks and effectively avoid adverse consequences. Healthcare companies are advocated to cooperate with market supervision departments to seek business guidance and policy support; healthcare companies are encouraged to take remedial measures take the initiative to report to the market supervision departments, and actively cooperate with the investigation and jointly manage commercial bribery when discovering misconduct potentially implicating commercial bribery.

(d) Healthcare companies are encouraged to establish internal reporting mechanisms to prevent commercial bribery risks, to open up reporting channels, and to eliminate whistleblowers' concerns about confidentiality of personal information and personal safety through technical settings and institutional arrangements, and to prevent retaliation against whistleblowers.

(e) Healthcare companies should establish a compliance training mechanism to prevent commercial bribery risks, regularly conduct compliance training for employees to prevent commercial bribery risks, and improve employees' awareness of compliance and their ability to deal with commercial bribery risks; healthcare companies are encouraged to organize differentiated training according to the different duties of the employees or their needs, and to improve the quality of the training; healthcare companies are encouraged to engage third parties to conduct compliance training for their employees.

(f) Healthcare companies should establish a monitoring mechanism for compliance management system for preventing commercial bribery risks. The effectiveness of the system should be evaluated on a regular basis, and problems and potential risks should be identified.

(g) Healthcare companies should take timely improvement measures based on the results of compliance monitoring, adjust management strategies and optimize process systems to ensure the adaptability and effectiveness of compliance management systems.

Article 10 Healthcare companies are advocated to create a law-abiding, honest, transparent and fair compliance culture, so that employees can deeply understand the importance of preventing commercial bribery risks, enhance the awareness of full compliance, consciously abide by the relevant laws and regulations, safeguard the reputation and image of the company, enhance the trust of partners in the company, improve the comprehensive competitiveness of the company, and promote the healthy and sustainable development of the company.

Chapter III. Identification and Prevention of Commercial Bribery Risks in Healthcare Companies

Section 1: Commercial Bribery Risks in Academic Visits and Communications

Article 11 Academic visits and communications under the Guidelines refers to the academic promotion activities of medical representatives and medical device promoters to medical and healthcare practitioners regarding healthcare products. Healthcare companies should arrange the company's medical representatives and medical device promoters to engage in academic visits and communications, sales personnel and other personnel should not participate in academic visits and communications.

The Measures for the Administration of Healthcare Representatives should be referred to for the definition of "healthcare representative" in the Guidelines to t

Article 12 Healthcare companies should pay attention to the following matters when carrying out academic visits and communications:

(a) Healthcare companies are required to comply with laws, regulations, government guidelines, and management regulations of healthcare departments and institutions regarding the reception of healthcare representatives and medical device promoters, and standardize the duties and behaviors of healthcare representatives and medical device promoters of the companies.

(b) Healthcare companies are required to file and publicize information for healthcare representatives in accordance with relevant regulations; where medical and health institutions and their competent authorities have other regulations for visiting personnel, such regulations should apply.

(c) Healthcare companies are required to urge healthcare representatives and medical device promoters to strictly abide by the provisions of the healthcare institutions to carry out academic visits and communications in the allowed time frames and locations.

(d) Healthcare representatives and medical device promoters are permitted to communicate with healthcare practitioners, provide academic information and technical advice, and carry out academic promotion.

Article 13 Healthcare companies should pay attention to identify and prevent the following behavioral risks when carrying out academic visits and communications:

(a) Healthcare companies are prohibited from assigning sales targets to medical representatives and medical device promoters.

(b) Medical representatives and medical device promoters are prohibited from interfering with or influencing the rational use of medicinal products by healthcare practitioners.

(c) Medical representatives and medical device promoters are prohibited from requesting or collecting usage information of various healthcare products prescribed or used by healthcare institutions, departments within healthcare institutions, or healthcare practitioners under the pretext of academic visits.

(d) Healthcare representatives and medical device promoters are prohibited from directly or indirectly giving properties or other improper benefits to healthcare practitioners to induce them to prescribe or recommend, use or purchase healthcare products.

Section 2: Commercial Bribery Risks in Hospitality

Article 14 Hospitality under the Guidelines refers to arrangements such as meals provided by healthcare companies to external stakeholders during business activities.

Article 15 Healthcare companies should pay attention to the following matters when providing hospitality in their business activities:

(a) Healthcare companies are required to formulate a system to clarify the scope and standards of hospitality, etc., and the standards of hospitality should be in line with the various types of management regulations applicable to the persons who will receive the hospitality.

(b) The types of expenses that can be incurred in business hospitality are required to be limited to reasonable and modest meals.

(c) Healthcare companies are suggested to keep records of business receptions.

Article 16 Healthcare companies should pay attention to identify and prevent the following behavioral risks when providing hospitality in their business activities:

(a) Noting the business receptions that are unreasonably frequent or that exceed business practices.

(b) Avoiding arranging business receptions at scenic spots or high-class luxury locations, or choosing venues associated with entertainment activities.

(c) Prohibiting providing business hospitality and gifts to unrelated persons, such as close relatives of the person who will receive the hospitality, or to transfer benefits or make payments to such unrelated persons in the name of hospitality.

(d) Prohibiting arrangements for travel, fitness, entertainment and other activities during hospitality.

(e) Prohibiting misrepresenting or concealing the cost of hospitality in the name of meetings, training, research or any other items.

(f) Prohibiting seeking transaction opportunities or competitive advantages through the provision of hospitality.

Section 3: Commercial Bribery Risks in Consulting Services

Article 17 The consulting service under the Guidelines refers to the engagement with healthcare practitioners by healthcare companies for professional services with their

professional knowledge, experience and methodology, and the payment of reasonable remuneration.

Article 18 When engaging healthcare practitioners to provide consulting services, healthcare companies should pay attention to the following matters:

(a) Healthcare companies' engagements of healthcare practitioners for lectures, research and other consulting services are required to be based on real, reasonable and legitimate business needs.

(b) Healthcare companies are required to base their selection of healthcare practitioners who meet their business needs to provide consulting services using objective criteria such as specialized knowledge, professional skills and work experience.

(c) When engaging healthcare practitioners to provide consulting services, healthcare companies are required to comply with the relevant regulations of the healthcare institutions in which they practice.

(d) Healthcare companies are required to set reasonable payment standards for consulting services provided by healthcare practitioners, they are suggested to set the payment standards based on objective conditions such as the scale of the project, the length of the service and the degree of specialization, and refer to the standards set by the relevant regulations or to fair market values.

(e) Healthcare companies are suggested to set reasonable limits on the number of times a single healthcare practitioner may be engaged in a given cycle, and on the total amount of service fees to be paid.

(f) Healthcare companies are required to truthfully record and properly retain the service records, service results and service details of healthcare practitioners to prove the authenticity, reasonableness and values of the service.

(g) Healthcare companies are suggested to pay healthcare practitioners for their services through bank transfer.

Article 19 Healthcare companies should pay attention to identify and prevent the following behavioral risks when engaging healthcare practitioners to provide consulting services:

(a) Avoiding paying healthcare practitioners for services in cash or cash equivalents.

(b) Prohibiting using service engagements with healthcare practitioners to reward or induce them to prescribe healthcare products, or to recommend, publicize, procure or use the healthcare products.

(c) Prohibiting the transfer of improper benefits to healthcare practitioners under the cover of consulting services.

Section 4: Commercial Bribery Risks in Outsourced Services

Article 20 Outsourcing services under the Guidelines refer to all kinds of services

provided by third parties to healthcare companies in relation to the research and development, production and distribution of healthcare products.

Article 21 Healthcare companies should pay attention to the following matters when selecting and hiring a third party to provide relevant services:

(a) Healthcare companies are required to establish a mechanism for outsourcing service provider selection and recruitment and are encouraged to use the competition mechanism when selecting partners; selection and recruitment should follow the principle of openness and transparency, and a complete record of selection and recruitment should be retained; healthcare companies are required to require outsourcing service providers to provide the necessary supporting information, including but not limited to proof of registration, qualifications, financial, tax, site, personnel, business capacity, illegal records, social credit records; healthcare companies are required to implement due diligence on outsourcing service providers.

(b) Healthcare companies are required to sign service contracts with outsourcing service providers that fully set out the content of the services, the results of the services, the payment standards, the duration of the services and the anti-commercial bribery clauses; they are suggested to explicitly provide in the contracts that healthcare companies have the right to carry out the necessary supervision or compliance audits of the performance of the outsourced matters.

(c) Healthcare companies are suggested to establish negative lists to specify prohibited behaviors in the course of their services through, for example, contracts or letters of commitment with outsourcing service providers.

(d) Healthcare companies are suggested to regularly monitor or conduct compliance audits of the contractual performance of outsourced service providers in accordance with the contractual terms agreed upon by both parties, focusing on changes in key risk factors such as personnel, capital and premises.

(e) When outsourcing service providers commit commercial bribery, healthcare companies are required to timely and relevant handle the issue in accordance with the contract and the commitment letter.

(f) Healthcare companies are required to, in accordance with the contract, evaluate the performance of outsourcing service providers, and settle the payments for services based on the evaluation.

Article 22 Healthcare companies should pay attention to identify and prevent the following behavioral risks when selecting and recruiting a third party to provide relevant services:

(a) Noting whether the fee rates for outsourcing services provided in the agreements or the actual price paid significantly deviate from the fair market values.

(b) Avoiding directly entering into agreements and doing business with outsourced service providers without proper entry procedures.

(c) Prohibiting exercising de facto control over third parties and their funds, for example by arranging for healthcare company employees to set up companies.

(d) Prohibiting obtaining funds through outsourced service providers by falsified or untruthful services.

(e) Prohibiting instructing or allowing, either explicitly or implicitly, outsourcing service providers to use outsourcing service fees and other funds to offer bribes to others in exchange for actual or promised prescription, recommendation, publicity, purchases, or use the company's healthcare products, in order to seek competitive advantages or transaction opportunities.

Section 5: Commercial Bribery Risks in Discounts, Rebates and Commissions

Article 23 Discounts and rebates under the Guidelines refer to price concessions provided by healthcare companies to a counterparty when selling healthcare products in a manner that is clearly stated and truthfully recorded, including immediate deduction of a certain percentage from the total price when the price is paid and refund of a certain percentage after the total price is paid.

Commissions under the Guidelines refers to the remuneration for services given to an intermediary with legal business qualifications who provides services in the transaction.

Article 24 Healthcare companies should pay attention to the following matters when paying discounts, rebates and commissions:

(a) Healthcare companies are required to formulate policy standards for discounts, rebates and commissions, and clearly specify the scope of application of discounts, rebates and commissions, as well as their targets and specific operation rules; the subjects for payment of discounts and rebates by healthcare companies should be limited to the counterparties to the transaction.

(b) Healthcare companies are required to establish an approval system for discounts, rebates and commissions, specify the approval authority and approval process, and stipulate the materials and supporting documents to be submitted for approval.

(c) Healthcare companies are required to sign contracts with counterparties setting out the extent of discounts to be granted, the method of payment, etc.; healthcare companies are required to sign contracts with intermediaries setting out the percentage of commission to be granted, the method of payment, etc.

(d) Where discounts, rebates or commissions are accepted, accounts are required to be established and compliance reviews are required to be implemented to prevent the relevant funds from being used for illegal purposes such as commercial bribery.

(e) Payment and acceptance of discounts, rebates or commissions are required to be accurately, timely, and completely recorded in books in accordance with finance and accounting requirements.

Article 25 Healthcare companies should pay attention to identify and prevent the following behavioral risks when paying discounts, rebates and commissions:

(a) Noting payments of discounts, rebates or commissions without executing a contract or

not in accordance with an executed contract.

(b) Avoiding inadequate separation of duties between the department or personnel within healthcare companies which formulate discount and rebate policies and approve policies, and the department or personnel who implement these policies.

(c) Prohibiting failure to truthfully record the payment or acceptance of discounts, rebates or commissions in financial books, including gifts in cash, goods and other benefits.

(d) Prohibiting instructing or allowing, either explicitly or implicitly, to use discounts, rebates or commissions as bribes to other persons in exchange for actual or promised prescription, recommendation, publicity, purchases, or use the company's healthcare products, in order to seek competitive advantages or transaction opportunities.

Section 6: Commercial Bribery Risks in Donations, Sponsorships and Grants

Article 26 Donations under the Guidelines refer to voluntary and gratuitous provision of funding, healthcare products or other property to the recipient by healthcare companies in accordance with laws and regulations.

Article 27 Healthcare companies should pay attention to the following matters when providing donations:

(a) Healthcare companies providing donations are required to do so based on legitimate and public welfare purposes, maintain voluntary and gratuitous nature, and clearly state and truthfully record the donations; healthcare companies can assess the necessity and reasonableness of the donation based on the needs of the recipient.

(b) Healthcare companies are permitted to donate through charitable organizations or directly to the recipients; the background and capacity of charitable organizations, the selection of recipients, and the reasonableness of donated products should be assessed.

(c) Donations provided by healthcare companies are required to comply with relevant legal provisions. Healthcare companies are suggested to ensure that donations are authentic and for public welfare through due diligence and other means, and set up and fulfill internal donation approval systems and processes.

(d) Any donation agreements between healthcare companies and the recipients of donations are required to be entered into voluntarily, and healthcare companies are required to properly maintain information relating to the approval, execution and performance of the donation agreement, including but not limited to internal reviews and approvals, and proof of actual performance.

(e) If the donated property is non-monetary goods, the quality and qualification is required to be in line with the national standards and requirements; the recipient is suggested to engage a third-party organization to evaluate, confirm or notarize the value of the non-monetary donated property; the donated property is suggested to be delivered directly to the responsible department of the recipient or to the official premises of the recipient. If the donated property is monetary, healthcare companies are required to provide it to

the recipient's account through bank transfer.

(f) Healthcare companies are required to obtain a charity donation receipt which is printed uniformly by Administration of Finance and stamped with the official seal of the recipient legal entity, and is in line with the value of the donated property that is actually received.

(g) If healthcare companies provide donations to entities associated with or other organizations supervised by various levels of government agencies in charge of healthcare, traditional Chinese medicine, disease control, the rules and requirements of the above mentioned government agencies as well as the government agencies of social work and civil affairs are required to be complied with.

Article 28 Healthcare companies should pay attention to identify and prevent the following behavioral risks when providing donations:

(a) Prohibiting designating specific beneficiaries for donations used for the training and development of healthcare practitioners, academic activities in healthcare area and scientific researches.

(b) Donations to the healthcare department must be uniformly accepted by a healthcare institution recipient. The recipient must not be any department, or other internal functional unit, individual, or other unit designated by the healthcare institution.

(c) Prohibiting using donations as a cover to obtain transaction or service opportunities, prescriptions or use of their healthcare products, favorable treatment, or attaching requests or claims on economic benefits, intellectual property rights, scientific research results, industry data and information, and other benefits related to the donations.

(d) Prohibiting using the cover of donations to bypass the bidding process and the government procurement system to fulfill hospital listing of the relevant equipment and sales of the relevant products.

Article 29 Sponsorships under the Guidelines are the provision of support in the form of property or services by a healthcare company to a sponsored party in order to obtain the opportunity to promote the company's image, brand or products.

Article 30 Healthcare companies should pay attention to the following when offering sponsorships:

(a) Sponsorships provided by healthcare companies are required to be law-abiding, open, and transparent, and are permitted to be based on an open business invitation or solicitation letter.

(b) When a healthcare company provides a sponsorship to a third party for commercial activities, it is required to sign a commercial sponsorship agreement, specifying that the company can obtain naming rights, advertising booths and other benefits.

Article 31 Healthcare companies should pay attention to identify and prevent the following behavioral risks when providing sponsorships:

(a) Avoiding providing sponsorship directly to healthcare institutions or departments within healthcare institutions , or to individual healthcare practitioners, or designating

the sponsored party through a third party.

(b) Prohibiting using the cover of sponsorships to influence healthcare practitioners to prescribe healthcare products or facilitate the recommendation, publicity, procurement and use of their healthcare products, in order to seek competitive advantages or transaction opportunities.

Article 32 Grants under the Guidelines refer to the gratuitous financial support provided by healthcare companies to healthcare institutions to help them upgrade their healthcare services, including medical or scientific research and improvement of healthcare facilities.

Article 33 Healthcare companies should pay attention to the following matters when providing grants:

(a) Before providing grants, healthcare companies are suggested to conduct appropriate due diligence on the recipient to understand the funded projects and their management practices, and to keep relevant records.

(b) Healthcare companies are required to comply with relevant laws and regulations and adopt the necessary and appropriate approval procedures to ensure that the grants will not be used for the purpose of illegal inducement when providing grants.

(c) Healthcare companies are required to sign a contract with the recipient to specify the purpose of the grants.

Article 34 Healthcare companies should pay attention to identify and prevent the following behavioral risks when providing grants:

(a) Prohibiting providing grants directly to any department or individual within the recipient.

(b) Prohibiting providing grants to specific healthcare practitioners.

(c) Prohibiting using grants in exchange for the recipients' actual or promised prescription, recommendation, publicity, purchases, or use the company's healthcare products, in order to seek competitive advantages or transaction opportunities.

Section 7: Commercial Bribery Risks in Free Placement of Medical Devices

Article 35 The free placement of medical devices under the Guidelines refers to the provision of medical devices (including related consumables, accessories, etc.) without compensation by healthcare companies to healthcare institutions under the premise of fair competition and on the basis of justifiable reasons to help promote the correct, safe and effective use of the products and pre-market clinical trials.

Article 36 Healthcare companies should pay attention to the following matters when engaging in free placement medical devices:

(a) The free placement of medical devices by healthcare companies in healthcare institutions are required to be based on reasonable use, including collecting feedback for research and development and improvement of products, facilitating healthcare

institutions to carry out product performance evaluation, helping healthcare practitioners to improve the efficiency of product use and carrying out patient education.

(b) Healthcare companies are permitted to place free medical devices to healthcare institutions without transferring ownership, but the ownership rights should be clearly stated in the contract.

(c) Healthcare companies are required to conduct prudent review of projects for the free placement of medical devices, formulate and effectively implement relevant tracking procedures and requirements, and retain relevant supporting documents for inspection, so as to ensure the legitimacy of the use of the products being placed.

(d) When the free placement of medical devices is aimed to help healthcare institutions to carry out performance evaluation of their products, healthcare companies are required to reasonably determine the time period and number of products for placement following the principle of necessity and combined with the characteristics of the product and the needs of the evaluation.

(e) Healthcare companies are required to truthfully collect and record the use of and feedback on relevant devices placed in healthcare institutions, and properly handle the post-placement matters.

Article 37 Healthcare companies should pay attention to identify and prevent the following behavioral risks when engaging in free placement medical devices:

(a) Prohibiting using free placement of medical devices to improperly obtain transaction opportunities and competitive advantages by placing, or to agree with healthcare institutions on minimum quantities or amounts of the consumables, relevant accessories, medicines and services to be procured, or to agree on procurement prices that are significantly higher than market prices.

(b) Prohibiting using the guise of free placement medical devices to bypass or interfere with the public bidding and procurement procedures carried out by healthcare institutions for medical devices under applicable laws or regulations, and influence the results of the public bidding and procurement.

(c) Prohibiting providing illegal benefits to healthcare institutions under the guise of free placement of medical devices. Prohibiting facilitating healthcare institutions or healthcare practitioners to illegally profit from the free medical devices placed.

Section 8: Commercial Bribery Risks in Clinical Research

Article 38 Clinical research under the Guidelines refers to research activities such as clinical trials, post-marketing studies, adverse event monitoring and other research activities related to health products that are initiated, participated in or commissioned to third parties by healthcare companies, as well as clinical research initiated by researchers in healthcare institutions and funded directly by healthcare companies or by third parties on their behalf (for

relevant definitions, please refer to the "Administrative Measures for Clinical Research Initiated by Medical and Health Institutions").

Article 39 Healthcare companies should pay attention to the following matters when carrying out clinical research:

(a) Healthcare companies are required to sign contracts with researchers, clinical trial (clinical research) institutions and other participants on the performance of clinical research projects, specifying the responsibilities of each party, including payment details, payment milestones and technical requirements; clinical trials are required to comply with the quality management standards of the healthcare regulatory authorities for clinical trials, and clinical research is required to comply with the management requirements of the health authorities for clinical research.

(b) Healthcare companies are required to verify the registration (filing) of clinical research projects to ensure authenticity.

(c) Where a healthcare company fully or partially commissions a third party to carry out clinical research, it is required to set out in the contract the content of the services, the results of the services, the payment rates, the duration of the services as well as the anti-commercial bribery clauses; in case there are any expenses that need to be reimbursed by the healthcare company, it is required to prudently review the authenticity and reasonableness of the expenses incurred prior to making the payment; before paying fees for a third party's services, healthcare companies are encouraged to obtain the clinical trial organization and the researchers' confirmation of the service time and service content; for the third-party management, relevant provisions on outsourcing services in Section IV of this Chapter can be referred to.

(d) Healthcare companies are required to properly retain research data and results in accordance with the contracts and the scope and extent of their participation in clinical research.

Article 40 Healthcare companies should pay attention to identify and prevent the following behavioral risks when carrying out clinical research:

(a) Prohibiting transferring improper benefits to clinical trial organizations and researchers through the establishment of false projects or under the guise of clinical research in exchange for competitive advantages or transaction opportunities in the hospital listing, promotion or sales of healthcare products.

(b) Prohibiting transferring improper benefits to a clinical trial organization or an individual researcher, either directly or through a third-party service provider, in exchange for accelerating or advancing a clinical research or manipulating clinical research data to make the results of a clinical research favorable to the healthcare company's products.

Section 9: Commercial Bribery Risks in Retail Sales

Article 41 Retail sales under the Guidelines refers to the sales and promotion and publicity activities carried out by healthcare companies relying on retail pharmacies (including online sales companies) of the healthcare products.

Article 42 Healthcare companies should pay attention to the following matters when conducting retail sales:

(a) Healthcare companies are permitted to visit retail channels to convey information on reasonable drug use, innovative research results and expanded therapeutic areas, and collect information on seasonal drug demand and adverse events.

(b) Healthcare companies are required to sign promotional agreements with retail channels and ensure that such activities are in compliance with laws, regulations and regulatory rules, and both parties must keep accurate and clear records of their respective accounts.

(c) Healthcare companies are suggested to sign integrity and compliance agreements with retail channels to clarify the requirements related to law-abiding operation and to promote the lawful operation of retail channels.

(d) If healthcare companies engage retail channel employees to provide services in the form of speeches, research and consultation, the relevant provisions of Section III of this Chapter on consulting services should be referred to.

(e) If healthcare companies are required to pay discounts to retailers in accordance with the agreement, further requirements can refer to the provisions of Section V on discounts, rebates and commissions.

Article 43 Healthcare companies should pay attention to identify and prevent the following behavioral risks when conducting sales through retail channels:

(a) Prohibiting inducing retail channels to facilitate or obtain unfair transaction opportunities in the procurement of healthcare products, in-field display and promotion of products through giving cash rebates or other benefits.

(b) Prohibiting colluding with retail channels to obtain prescription information by transferring benefits to healthcare practitioners; prohibiting calculating the volume of prescriptions through retail channels and transferring benefits to healthcare institutions or healthcare practitioners.

(c) Prohibiting using improper benefits to influence the employees of online retail companies to distribute and sell the healthcare products, fail to strictly review the prescriptions, or reusing prescriptions.

Chapter IV. Handling of Commercial Bribery Risks in Healthcare Companies

Section 1. Internal mitigation of risks

Article 44 Healthcare companies that identify commercial bribery risks in their business practices should immediately stop the risky behavior and take the following measures:

(a) Healthcare companies may carry out investigations on their own or by hiring third-party professional organizations in accordance with the law, and the contents of the investigations should be as truthful and objective as possible.

Investigation methods include but are not limited to verification of risk matters, interviews with those involved and those with knowledge of the matter, review of information on the matter, and proper retention of evidential materials to prevent loss or malicious alteration or deletion.

(b) Healthcare companies can assess the risk level, scope of influence and degree of impact of the behavior involved based on the results of internal investigations, and conclude an assessment result.

Article 45 Healthcare companies should, based on the results of the risk assessment, take timely and effective measures, including but not limited to holding implicated personnel and third parties liable, eliminating negative impacts, revising rules and policies, improving management processes, strengthening compliance training, and improving compliance management system for preventing commercial bribery risks.

Healthcare companies are advocated to improve the long-term mechanism through continuous improvement, monitoring, assessment and review in conjunction with the results of the mitigation, so as to avoid the recurrence of similar risks.

Section 2: Cooperation with regulatory enforcement

Article 46 Healthcare companies are encouraged to take the initiative to report to the administration of market regulation with relevant supporting materials when they identify that commercial bribery is implicated in their business activities. Proactive reporting should include the following:

(a) The source of the matter, the investigation process and other circumstances;

(b) The situation of the subjects involved;

(c) Facts currently verified;

(d) Remediations taken;

(e) The establishment and implementation of a compliance management system to prevent commercial bribery risks;

(f) Other matters to be reported.

Article 47 Healthcare companies subject to government investigation by the administration of market regulation should cooperate with the investigation work and truthfully provide relevant information and the actual situation in accordance with the requirements of the administration of market regulation. Healthcare companies should not engage in the following conduct:

(a) Refusing or obstructing law enforcement officers from entering the premises for inspection;

(b) Refusing to be questioned or to provide information relating to the conduct of the investigation;

(c) Obstructing investigations using the excuses of business secrets, the absence of the person in charge or relevant personnel, the lack of authorization, or the failure to comply with internal approval procedures;

(d) Concealing, destroying or transferring evidence, or instructing or helping the relevant parties to engage in the above acts;

(e) Providing falsified materials and information;

(f) Retaliation against persons or relevant parties who cooperate with investigations and provide evidence and information on their own initiative;

(g) Other misconduct of refusal or obstruction of investigation.

Article 48 When healthcare companies cooperate with the administration of market regulation in the process of investigation, the administration of market regulation may consider reducing the administrative penalties or imposing lower administrative penalties from a statutory range if one of the following conditions is met:

(a) Proactively reporting illegal conduct before the administration of market regulation initiates the investigation.

(b) Proactively reporting illegal conduct and mitigate the harm caused through effective measures after the administration of market regulation initiates the investigation and before it knows about the illegal conduct.

(c) Proactively confessing the illegal conduct that the administration of market regulation has not known about after the administration of market regulation initiates the investigation, the confession may include other illegal conduct of the companies themselves and others' illegal conduct that has been verified.

(d) Actively cooperating with the inspection by the administration of market regulation, and within the required time frame, accepting inquiries, truthfully answering questions, and actively providing evidence and materials related to accounting books, expense approvals, flow of funds, and business agreements.

(e) Having meritorious performance when cooperating with the administration of market regulation to investigate and handle illegal conduct; including but not limited to uncovering key leads or evidence of major commercial bribery or other major violations of the law in healthcare industry which are verified.

(f) Engaging in minor illegal conduct and causes little harm to the society.

(g) Being directly involved in the implementation of commercial bribery, but playing a minor role in the entire illegal conduct; healthcare companies may provide explanations based on its role in a joint action, the actual degree of participation (the number of bribes, the amount of bribes, etc.), the role in causing harm.

(h) Other conditions where administrative penalties should or can be imposed from a lower end of a statutory range or reduced in accordance with the law.

Article 49 When healthcare companies to cooperate with the administration of market regulation to investigate, the administration of market regulation may decide to not impose administrative penalties if one of the following conditions is met.

(a) If the misconduct is minor and rectified in time, without causing harmful consequences;

(b) If the company violates the law for the first time and the consequences of the harm are minor and are rectified in a timely manner;

(c) Others conditions where administrative penalties should or can be exempted in accordance with the law.