Anti-Monopoly Guidelines for the Pharmaceutical Sector by the State Council Anti-Monopoly and Anti-Unfair Competition Commission[1]

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Chapter I: General Principles

Article 1: Purpose and Basis

In order to prevent and stop monopolistic behavior in the pharmaceutical sector, businesses are encouraged to strengthen anti-monopoly compliance, maintain fair competition in the pharmaceutical market, promote innovation, and protect the interests of consumers and the public. These guidelines are formulated based on the Anti-Monopoly Law of the People's Republic of China (hereinafter referred to as the 'Anti-Monopoly Law') and other relevant laws and regulations.

Article 2: Relevant Concepts

(1) Drugs refer to substances used to prevent, treat and diagnose human diseases that intentionally regulating human physiological functions. They are prescribed with indications or functional treatments, dosage and usage instructions. Drugs include traditional Chinese medicines, chemical drugs, biological products and other related substances. In this guideline, traditional Chinese medicine (TCM) refers to raw medicinal materials, decoction pieces, extracts, formula granules and prepared Chinese patent medicines. Chemical drugs include active pharmaceutical ingredients (APIs) and chemical preparations. Biological products include prophylactic (preventive) biologicals, therapeutic biologicals and diagnostic reagents managed as biological products.

(2) Chemical active pharmaceutical ingredients (hereinafter referred to as "APIs") refer to raw materials that comply with relevant laws and regulations on drug administration and are used to produce various types of chemical drug preparations. They are the active ingredients in chemical drug preparations.

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

(3) Chemical drug preparations refer to chemical drugs that comply with relevant laws and regulations on drug administration and are directly used for the prevention, treatment or diagnosis of human diseases.

(4) Pharmaceutical operators refer to natural persons, legal persons and unincorporated organizations engaged in pharmaceutical production and business, and approved by the relevant regulatory authorities. Domestic agents in China, designated by the overseas drug marketing authorization holder in accordance with the law, and pharmaceutical research institutions engaged in business activities, are also considered pharmaceutical operators.

Article 3: Basic Principles

Anti-monopoly enforcement agencies shall adhere to the following principles when carrying out anti-monopoly supervision and enforcement in the pharmaceutical field:

(1) Protecting fair market competition. Ensuring equal emphasis on regulatory norms and promoting development, treating all types of pharmaceutical operators equally, focusing on preventing and eliminating monopolistic behavior in the pharmaceutical sector and maintaining fair market competition order.

(2) Safeguard consumer interests. Vigorously crack down on all types of monopolistic behavior in the pharmaceutical sector, promote lawful and compliant business operations by pharmaceutical operators, ensure stable and effective drug supply, reduce the burden of medication costs for consumers, protect consumer interests and enhance public well-being.

(3) Stimulate the vitality of innovation and development. Support pharmaceutical operators in pursuing innovative development and exercising intellectual property rights in accordance with the law; effectively regulate the abuse of intellectual property rights used to exclude or restrict competition; encourage pharmaceutical research and development, technological improvement and quality enhancement.

(4) Adhere to high-efficiency scientific supervision and management. Deepen the understanding of the unique characteristics and market competition regulations of the pharmaceutical sector. Strengthen competition analysis and legal argumentation, enhance anti-monopoly efforts at every stage of supervision and management (preliminary, ongoing and post-supervision). Improve efficiency, scientific nature and specificity of law enforcement. Continue to elevate the overall level of supervision and management.

(5) Continue to strengthen legal deterrence. Intensify anti-monopoly enforcement in the pharmaceutical sector. In accordance with the law, impose stricter penalties for monopolistic behaviors that seriously undermine fair market competition, harm consumer or public interests or hinder innovation and development. Promote the standardized and healthy development of the pharmaceutical industry.

Article 4: General Regulations for Online Drug Sales

Operators engaged in online drug sales or providing online drug trading platform services shall comply with anti-monopoly regulations. They must not exploit data, algorithms, technological advantages, capital strength or platform rules to engage in a monopolistic behavior.

Article 5: Ant-monopoly compliance

Encourage and support pharmaceutical operators to strengthen anti-monopoly compliance, establish and improve an anti-monopoly compliance management system, effectively identify potential and actual anti-monopoly legal risks and take corresponding preventive and remedial measures. Industry associations in the pharmaceutical sector should strengthen industry self-discipline through competition advocacy, compliance guidelines and other methods.

Article 6: Definition of the Relevant Market

The definition of the relevant product and geographic markets in the pharmaceutical sector shall follow the basic criteria and general principles of relevant market definition. A substitutability analysis shall be conducted, considering the characteristics of the pharmaceutical sector, including technological factors and innovation-related aspects.

(1) Relevant Product Market

When defining the relevant product market in the pharmaceutical sector, a demand-side substitutability analysis may be conducted by comprehensively considering factors such as the intended use or therapeutic effect of the drug (indications or primary functions), price, treatment methods (e.g., administration route, treatment sequence), product characteristics, contraindications and adverse effects, preferences of physicians and patients, as well as regulatory and reimbursement policies. Where supply-side substitution imposes a similar competitive constraint as demand-side substitution, a supply-side substitutability analysis may also be conducted, taking into account factors such as market entry conditions, production capacity, adaptability of production facilities and technological barriers.

In cases where the relevant product market for traditional Chinese medicine (TCM) is defined, demand substitution analysis can also be conducted based on factors such as the source of medicinal materials, the quality of medicinal materials, brand recognition and usage habits. Supply substitution analysis can be conducted based on factors such as patent protection, protection of trade secrets, protection of TCM varieties and national medical culture.

When defining the relevant product market for chemical drug formulations in individual cases, the analysis can be based on factors such as usage or therapeutic effect. If multiple formulations have a close substitutive relationship, they may be considered as part of the same relevant product market. However, if a particular formulation is irreplaceable for a specific medical indication, it may be defined as a separate relevant market depending on the circumstances.

The pharmaceutical supply chain includes stages such as research and development, manufacturing and business operations. According to the specifics of the case, the relevant product market can also be defined based on the particular stage in the supply chain in which the business operator is involved.

In individual cases where the relevant product market for active pharmaceutical ingredients (APIs) is defined, due to the special role APIs play in the production of chemical drug formulations, a single API generally constitutes an independent product market, which may be further segmented depending on specific circumstances. If there is a close substitutive relationship among different types of APIs, it may be determined that multiple APIs form a single relevant product market.

(2) Relevant Geographic Market

When defining the relevant geographic market for pharmaceuticals, a demand-side or supply-side substitutability analysis may be conducted based on factors such as the qualifications required for pharmaceutical production and operation, regulatory standards, as well as the conditions of transportation and storage of the drugs.

The relevant qualifications and regulatory standards for drug production and operation vary between different countries or regions. In China, drug operators must comply with the relevant laws and regulations concerning market access, production quality and business management when producing and operating drugs. Imported drugs must be approved by the relevant supervisory and regulatory authorities in China. Therefore, the relevant geographical market for the production and operation of drugs is generally defined as the domestic market in China. Depending on the specific case, when pharmaceutical R&D and innovation activities are involved, the relevant geographic market may be defined as the global market. When pharmaceutical retail, distribution and related stages are involved, the relevant geographic market may be defined as a certain regional scope within China.

Chapter II: Monopoly Agreements

Article 7: Comprehensive Analytical Framework

The determination of monopoly agreements in the pharmaceutical sector shall be governed by Chapter II of the *Anti-Monopoly Law* and the *Provisions on the Prohibition of Monopoly Agreements*. In general, the first step is to determine whether the relevant behavior falls under the situations outlined in Article 17 and the first paragraph of Article 18 of the *Anti-Monopoly Law*. Then, an analysis is conducted to assess whether the business operator can prove that the behavior meets the conditions of non-prohibition or exemption as specified in the *Anti-Monopoly Law*.

Article 8: Fixing or Changing Drug Prices

If pharmaceutical operators with a competitive relationship reach the following agreements to fix or change drug prices, such conduct will generally constitute a monopolistic agreement prohibited under Article 17, Item 1 of the *Anti-Monopoly Law*:

(1) Fixing or altering the ex-factory price of drugs, the prices quoted to clients, other drug sale prices, purchase prices, price ranges, profit margins, discounts, service fees, or any other related charges;

(2) Agreeing to adopt standard formulas, algorithms, rules, etc., used to calculate drug prices;

(3) Pharmaceutical operators agree to limit each other's ability to set prices freely — they must set prices together or can't lower them individually.

(4) Pharmaceutical operators use meetings, platform or third parties to secretly coordinate or share info to align prices.

(5) Pharmaceutical operators fix or change prices in any other way, even if it's not explicitly mentioned above.

Article 9: Restricting the Quantity of Drug Production or Sales

Pharmaceutical operators who are in a competitive relationship and reach any of the following agreements to restrict the quantity of drug production or sales shall generally be deemed to have entered into a monopolistic agreement prohibited under Article 17, Paragraph 2 of the Anti-Monopoly Law:

(1) Restricting the quantity of drug production by jointly limiting output, fixing output, halting production, restricting the production quantity of specific varieties or specifications of drugs, or agreeing not to produce certain drugs or to limit their production quantity by compensating competing operators;

(2) Restricting the quantity of drug sales by limiting the amount released to the market, or limiting the sales quantity of specific varieties or specifications of drugs, or agreeing that competing operators will not sell to external parties or will limit their sales quantity;

(3) Restricting the quantity of drug production or sales by other means.

Article 10: Dividing the Sales Market or Raw Material Procurement Market

When pharmaceutical operators with a competitive relationship reach agreements to divide the sales market or raw material procurement market, such agreements generally constitute a monopoly agreement prohibited under Item 3 of Article 17 of the Anti-Monopoly Law.

(1) Dividing the pharmaceutical sales region, market share, sales targets, sales revenue, sales profit, types, quantities or timing of the pharmaceuticals sold;

(2) Dividing the procurement regions, types, quantities, timing or suppliers of raw materials such as pharmaceutical ingredients, excipients, packaging materials, containers, etc.;

(3) Dividing the pharmaceutical sales market or pharmaceutical raw material procurement market through other means.

Article 11: Restricting the Purchase of New Technologies, New Equipment and Restricting the Development of New Technologies or New Pharmaceuticals

When pharmaceutical operators with a competitive relationship reach agreements to restrict the purchase of new technologies, new equipment, or the development of new technologies or new drug formulations, such agreements generally constitute a monopoly agreement prohibited under Item 4 of Article 17 of the Anti-Monopoly Law.

(1) Restricting the purchase, lease, use of new technologies, new processes or new equipment for pharmaceutical production;

(2) Restricting investment or research in new drug varieties, formulations, uses, new technologies, processes or equipment for pharmaceutical production;

(3) Restricting the purchase of new technologies or equipment for pharmaceutical production, or otherwise hindering the development of new technologies or new drugs.

Article 12: Joint Boycott of Transactions

Drug operators with competitive relationships may reach the following agreement to jointly boycott transactions, which generally constitutes a monopoly agreement prohibited by Article 17, Item 5 of the Anti-Monopoly Law:

(1) By delaying, interrupting, or imposing restrictive conditions on transactions with specific operators, or by collectively refusing to supply or sell drugs to specific operators;

(2) Collectively refusing to purchase or sell drugs to specific operators.

(3) Jointly restricting specific operators from conducting transactions with pharmaceutical operators that are in competition with them.

(4) Through other means of joint resistance to transactions.

Article 13: Reverse Payment Agreements

There is an actual or potential competitive relationship between the patent holder of the original drug and the applicant for the generic drug. If the patent holder of the original drug provides or promises to provide direct or indirect financial compensation to the generic drug applicant without justifiable reasons, and the generic drug applicant makes commitments not to challenge the validity of the patent, delay entry into the related market, or not sell the generic drug in specific regions (such as non-compete commitments), this reverse payment agreement may constitute a monopoly agreement prohibited under Article 17 of the Anti-Monopoly Law. To assess whether a reverse payment agreement constitutes a monopoly agreement, the following factors can be considered:

(1) Whether the financial compensation provided by the patent holder to the generic drug applicant is significantly above the dispute resolution costs of the related patent and cannot be reasonably explained.

(2) Whether the agreement effectively extends the patent holder's market exclusivity or obstructs or affects the entry of the generic drug into the relevant market.

(3) Other factors that exclude or restrict competition in the relevant market.

Article 14: Fixed Resale Prices and Restricted Minimum Resale Prices

Agreements between pharmaceutical operators and their commercial counterparts to fix the resale price of drugs or establish a minimum resale price for drugs generally constitute a monopoly agreement prohibited under Article 18, Section 1, Items 1 and 2 of the Anti-Monopoly Law.

(1) Through written agreements, verbal agreements, price adjustment notices, price maintenance notices and other forms, fixing the resale price level, price fluctuation range, or setting a minimum price level, price fluctuation range, etc., for the counterpart to resell drugs to a third party.

(2) Fixing or restricting the profit level, discounts, rebates, handling fees, or other costs of the counterpart in a way that indirectly fixes the resale price of drugs or sets a minimum resale price for the drugs.

(3) Fixing the resale price of drugs or setting a minimum resale price for the drugs through other means.

Pharmaceutical operators implementing fixed resale prices or setting minimum resale prices may use penalty measures such as reducing rebates or discounts, charging penalties or deposits, refusing to supply goods or terminating agreements. Alternatively, they may offer reward measures like providing rebates or discounts, prioritizing supply, or offering support to force or indirectly force trading counterparts to adhere to resale price limits. Additionally, they may monitor and supervise resale prices through checking sales records and invoices of trading counterparts, hiring third parties or using data and algorithms.

If pharmaceutical operators and their trading counterparts reach an agreement as described above, anti-monopoly enforcement agencies presume that the agreement has the effect of excluding or restricting competition, thus constituting a monopoly agreement. If the pharmaceutical operator can prove that the agreement does not have such anti-competitive effects, it will not be prohibited. To prove that the agreement does not exclude or restrict competition, the pharmaceutical operator must provide evidence showing that the agreement will not eliminate or restrict competition between brands and will not result in cumulative anti-competitive effects. Additionally, the operator must prove that the agreement will not lead to higher drug prices, reduced drug supply, increased difficulty in entering the drug market or other adverse competitive consequences.

Article 15: Situations Not Constituting Monopoly Agreements

Pharmaceutical operators engaging in the following activities generally do not constitute monopoly agreements as defined in Article 18 of the Anti-Monopoly Law:

(1) Entrusting others to act as agents for the sale of pharmaceuticals, while setting the sales price or other transaction conditions related to the agency business;

(2) In drug procurement carried out in accordance with centralized drug procurement rules, where the pharmaceutical operator bids or negotiates and the counterpart sells the drugs to terminal medical institutions within the centralized procurement scope based on that price;

(3) Where the pharmaceutical operator is responsible for drug sales, promotion, etc., and sets the sales price, while the counterpart only provides auxiliary services such as importation, distribution, payment collection, invoicing and technical support.

Article 16: Organizational and Substantial Assistance Acts by Operators

The following acts by operators may constitute organizational or substantial assistance acts prohibited by Article 19 of the Anti-Monopoly Law:

(1) Operators providing pharmaceutical e-commerce platform services, or other third-party operators, playing a decisive or leading role in determining the scope of parties, key content, execution conditions of a monopoly agreement during its formation or implementation;

(2) Organizing, coordinating or facilitating competing pharmaceutical operators to obtain or exchange competitively sensitive information, communicate intentions and reach or implement a monopoly agreement;

(3) Providing price monitoring services, using platform rules, data, algorithms, etc., to support or facilitate the formation or implementation of monopoly agreements by offering necessary support, critical favorable conditions, or other significant assistance.

(4) Organizing or substantially assisting the formation of monopoly agreements through other means.

Article 17: Organizational Actions by Industry Associations

Industry associations in the pharmaceutical sector shall not organize pharmaceutical operators to reach or implement monopoly agreements, nor shall they provide facilitating conditions for the formation or implementation of monopoly agreements by pharmaceutical operators.

Article 18: Exemption System

Pharmaceutical operators who claim that an agreement is applicable under Article 20 of the Anti-Monopoly Law must provide evidence proving that the agreement meets the conditions outlined in Article 20 of the Anti-Monopoly Law and the provisions of Article 20 on the prohibition of monopoly agreements. The anti-monopoly enforcement agency will make a determination based on the specific circumstances of each case according to the law.

Pharmaceutical operators who enter into joint research and development agreements or agreements where they pay others for research and development, in order to study and develop new drug varieties, dosage forms, uses, new technologies, processes and equipment for drug production, may be suspected of constituting monopoly agreements. In such cases, they can claim an exemption under Article 20, Paragraph 1, Item 1 of the Anti-Monopoly Law.

When determining whether the above-mentioned research and development agreements meet the exemption conditions, the anti-monopoly enforcement agency will comprehensively consider the economic and social benefits of the research and development results, the relationship between the parties to the agreement and their control over the relevant market, the content, method, degree of competition restriction in the agreement, the necessity of the agreement for completing the research and development.

The anti-monopoly enforcement agency will consider the following factors when determining whether the agreement investigated allows consumers to share the benefits arising from it:

(1) Increase in drug varieties;

(2) Improvement in drug safety, efficacy and accessibility;

(3) Shortening of drug market approval cycles;

(4) Reduction in consumers' medication burden;

(5) Ensuring the effective supply of drugs needed during public health emergencies or for national drug reserves.

Chapter III: Abuse of dominant market position

Article 19: Comprehensive Analytical Framework

To determine behavior of abuse of a dominant market position in the pharmaceutical sector, in accordance with chapter 3 of Anti-monopoly Law and Provisions on Prohibition of Abuse of Market Dominance. Generally, first it's necessary to define the relevant market, to determine whether the drug operator has a dominant position in the relevant market. Additionally, consider the legitimate reasons presented by the pharmaceutical operator and whether the related actions exclude or restrict competition, A concrete analysis of whether it constitutes an abuse of market dominance.

Article 20: Determination of Market Dominance

Anti-monopoly enforcement agencies shall determine or presume that a pharmaceutical operator has market dominance in accordance with the provisions of Articles 23 and 24 of the Anti-Monopoly Law. Anti-monopoly enforcement agencies may, considering the characteristics of the pharmaceutical field, consider factors such as the pharmaceutical operator's ownership of patents and other intellectual property rights, control over the pharmaceutical supply chain, the impact of regulatory laws, regulations and policies, and the countervailing power of trading counterparties.

In determining that two or more pharmaceutical operators have market dominance, factors such as the consistency of the operators' behavior, market structure, market transparency and the degree of homogeneity of the relevant pharmaceutical products should also be considered.

Article 21: Unfair High Price

A pharmaceutical operator holding a dominant market position could abuse it by imposing unfairly high prices for drugs. To assess whether the conduct constitutes the unfair high pricing prohibited under Article 22, Paragraph 1, Item 1 of the Anti-Monopoly Law, the following factors may be considered:

(1) The sales price of the drug is significantly higher than the price at which other operators sell the same or comparable drugs under identical or similar market conditions.

(2) The sales price of the drug is significantly higher than the price at which the same operator sells the same or comparable drugs in different regions under identical or similar market conditions.

(3) The sales price of the drug is significantly higher than the price at which the same operator sold the same or comparable drugs during different periods under identical or similar market conditions.

(4) Raising the sales price of the drug beyond a normal range despite the cost remaining generally stable.

(5) Where there is an increase in cost, the extent of the drug price increase is significantly higher than the extent of the cost increase.

(6) Improperly raising the drug sales price through fraudulent transactions, layered price increases and other similar methods.

Article 22: Refusal to Trade

A drug operator with a dominant market position may abuse its dominance by refusing to engage in trade with a counterparty without justifiable reasons. To assess whether such behavior constitutes a prohibited refusal to trade under Article 22, Paragraph 1, Item 3 of the Anti-Monopoly Law, the following factors should be considered:

(1) Substantially reducing the existing transaction volume with the counterparty by reducing the scale of drug production or the quantity of drug supply;

(2) Delaying or interrupting the existing transaction with the counterparty by delaying drug supply or halting drug production;

(3) Refusing to engage in new transactions with the counterparty;

(4) Refusing to engage in trade with the counterparty by means such as false self-use claims;

(5) Refusing to engage in trade with the counterparty by imposing high deposits or other restrictive conditions that seriously harm the counterparty's interests.

A drug operator with market dominance overactive pharmaceutical ingredients, without justifiable reasons, may reduce the market supply of active pharmaceutical ingredients, raise their sales prices, eliminate or restrict downstream market competition by refusing to trade. If such actions result in unfair competitive advantages for themselves or certain operators, the anti-monopoly enforcement authorities may determine that this constitutes an abuse of market dominance, prohibited under Article 22, Paragraph 1, Item 3 of the Anti-Monopoly Law.

Article 23: Exclusive Dealing

A pharmaceutical operator with a dominant market position may abuse that position by engaging in exclusive dealing practices without legitimate reasons. To assess whether the conduct falls under the exclusive dealing practices prohibited by Article 22, Paragraph 1, Item 4 of the Anti-Monopoly Law, the following factors can be considered:

(1) Restricting the trading counterparty to purchase or sell pharmaceutical products only from/to the dominant operator and prohibiting transactions with other business operators.

(2) Requiring the counterparty to buy or sell medicines only through sellers or buyers chosen by the dominant company.

(3) The trading counterparty is prohibited from engaging in transactions with specific operators.
Engaging in the above-mentioned restrictive trade practices can be done through direct restrictions, or by using punitive or incentive measures to indirectly impose the restriction.

Article 24: Bundling

Pharmaceutical companies with a dominant market position may abuse their dominance by departing from standard trade practices without a valid reason. This can include using tied or bundled sales strategies that limit the ability of customers — such as hospitals, pharmacies, or distributors — to freely choose, modify, or decline products. To determine whether such behavior constitutes illegal bundling under Article 22, Paragraph 1, Item 5 of the Anti-Monopoly Law, the following factors should be considered:

(1) Bundling other pharmaceuticals;

(2) Bundling pharmaceutical excipients, packaging materials, medical devices, etc.;

(3) Bundling other goods.

Article 25: Imposing Other Unreasonable Trading Conditions

Pharmaceutical companies with a dominant market position may abuse that dominance by, without valid justification, imposing unreasonable trading conditions in pharmaceutical transactions. To determine whether this behavior violates Article 22, Paragraph 1, Item 5 of the Anti-Monopoly Law, the following factors may be considered:

(1) Imposing unreasonable restrictions on the quantity of pharmaceutical purchases;

(2) Imposing unreasonable restrictions on the sales target, region, price or quantity of the pharmaceuticals;

(3) Requiring the trading counterpart to pay unreasonable security deposits or attaching other unreasonable fees beyond the price of the drugs;

(4) Imposing unreasonable restrictions on the contract term, payment method, delivery or transportation terms of the pharmaceutical sales;

(5) For operators supplying active pharmaceutical ingredients (APIs), requiring exclusive or partial sales rights to the drugs produced by the counterpart or demanding sales rebates from them;

(6) Imposing other unreasonable trading conditions that are unrelated to the subject matter of the transaction.

Article 26: Discriminatory Treatment

Pharmaceutical operators with a dominant market position may abuse that position by, without justifiable reasons, applying discriminatory treatment in trading conditions toward trading counterparts under the same conditions. To assess whether conduct constitutes a violation of Article 22, Paragraph 1, Item 6 of the Anti-Monopoly Law, the following factors may be considered:

(1) There is a significant difference in the transaction price of the pharmaceuticals or in the discounts offered;

(2) The quantity, variety, or grade of the pharmaceuticals is significantly different;

(3) The payment method, delivery method and other conditions related to the pharmaceutical transaction that significantly affect the trading counterpart's ability to compete in the market are noticeably different;

(4) The same conditions refer to the pharmaceutical transactions between counterparts in terms of transaction security, transaction costs, scale and capability, credit status, position in the transaction process, transaction duration and other aspects, where there are no substantial differences that affect the transaction.

Article 27: Other Abuses of Market Dominance

When pharmaceutical operators engage in unfair low-priced purchasing, selling goods below cost or other abuses of market dominance as determined by the anti-monopoly enforcement authority under the State Council, such conduct shall be evaluated in accordance with Chapter III of the Anti-Monopoly Law and the Provisions on the Prohibition of Abuse of Market Dominance.

Where a pharmaceutical patent holder with a dominant market position obtains new pharmaceutical patents by redesigning existing patented technical solutions and then takes actions such as halting sales or repurchasing products to switch from the original patented drug to a new patented drug — thereby engaging in product hopping that impedes generic drug manufacturers from effectively competing — such conduct may constitute an abuse of market dominance prohibited under Article 22, Paragraph 1, Item 7 of the Anti-Monopoly Law. To assess whether product hopping behavior constitutes an abuse of market dominance, the following factors may be considered:

(1) Whether the new patented drug fails to significantly improve the drug's intended use or efficacy or to significantly enhance its safety;

(2) When implementing the conversion from the original patented drug to the new patented drug, the relevant operators may have already planned to launch generic drugs;

(3) Whether the conversion from the original patented drug to the new patented drug obstructs or affects the entry of generic drugs into the relevant market or the ability to engage in effective competition;

(4) Whether the range of choices for patients and physicians is subject to substantial restrictions;

(5) Whether there is a legitimate reason.

Article 28: Abuse of Market Dominance through Division of Labor and Cooperation

If two or more pharmaceutical operators engage in the production and business activities of drugs through division of labor and cooperation and abuse their dominant market positions in a coordinated manner, the anti-monopoly enforcement authorities may, based on the specific case, determine that these operators are joint subjects of the abuse of market dominance. To assess whether two or more pharmaceutical operators are joint subjects of the abuse of market dominance, the following factors may be considered:

(1) Participation or control of the same or different stages of the pharmaceutical supply chain;

(2) Division of labor in participating in activities such as drug procurement, production or sales;

(3) The actions of different pharmaceutical operators are indispensable for the implementation of the monopolistic behavior;

(4) Jointly obtaining and distributing monopolistic profits.

Chapter IV: Concentration of operators

Article 29: Comprehensive Analytical Framework

The Anti-Monopoly Law prohibits undertakings from engaging in concentrations that have or may have the effect of excluding or restricting competition. If the concentration of operators in the pharmaceutical sector meets the filing threshold specified in the State Council's Provisions on the Filing Standards for Concentrations of Undertakings, it must be filed in advance with the State Council's Anti-Monopoly Enforcement Agency. Concentrations that are not filed or have not been approved after filing cannot be implemented. The State Council's Anti-Monopoly

Enforcement Agency shall review concentrations in the pharmaceutical sector in accordance with the Anti-Monopoly Law and the Regulations on the Review of Concentrations of operators and investigate concentrations that are implemented in violation of the law.

Article 30: Mergers and Acquisitions Below the Reporting Threshold

Due to the relatively small market size of certain drug varieties or the fact that pharmaceutical operators are in the early stages of development, the annual revenue of these operators may not meet the reporting threshold set by the State Council. If a concentration of pharmaceutical operators does not meet the reporting threshold but there is evidence to prove that the concentration has or may have an effect of eliminating or restricting competition, the State Council's anti-monopoly enforcement agency may require the operators to submit a report and notify them in writing.

Any unit or individual who discovers a concentration of operators below the reporting threshold but with the potential to eliminate or restrict competition may submit a written report to the State Council's anti-monopoly enforcement agency, providing relevant facts and evidence. After investigation, if the anti-monopoly enforcement agency finds evidence proving that the concentration, although below the reporting threshold, has or may have an effect of eliminating or restricting competition, it will handle the case in accordance with Article 8 of the "Regulations on the Review of Concentrations of Operators."

Article 31: Pharmaceutical operators shall implement the provisions on concentration of business operators in accordance with the law

Pharmaceutical operators can expand their business scale and improve market competitiveness, particularly in drug research and development innovation, through fair competition, voluntary associations and legal implementation of concentration.

Article 32: Common Types of Concentration of Operators in the Pharmaceutical Sector

Concentration of operators in the pharmaceutical sector includes horizontal, vertical, and mixed concentrations. Horizontal concentration refers to a merger involving participants who are actual or potential competitors within the same relevant market. In the pharmaceutical sector, assessing whether a merger involves potential competitors may require examining the status of unlisted drugs, including those still in development.

Vertical concentration refers to mergers between operators with upstream and downstream relationships. In the pharmaceutical sector, vertical concentration includes—but is not limited to—mergers between upstream raw material pharmaceutical manufacturers and downstream drug production companies, between upstream drug research and development service

providers and downstream drug manufacturers and between upstream drug manufacturers and downstream drug distributors.

Mixed concentration generally refers to mergers between operators that do not share either a horizontal competitive relationship or a vertical supply chain relationship. In the pharmaceutical sector, anti-monopoly enforcement agencies primarily focus on mergers between operators that have adjacent or complementary business relationships.

Article 33: Situations Where Transactions Involving Intellectual Property May Constitute Operator Concentration

The pharmaceutical industry is highly intensive in intellectual property. An operator, through a transaction involving pharmaceutical intellectual property, may acquire control over or be able to exert decisive influence on another operator, which may constitute a concentration of undertakings.

Article 34: Discussions Between Operators and Enforcement Agencies

Operators in the pharmaceutical sector are encouraged to engage in early discussions with anti-monopoly enforcement agencies regarding relevant issues before implementing concentration of undertakings.

Article 35: Considerations in the Review of Concentration of Operators in the Pharmaceutical Sector

When reviewing concentrations of operators in the pharmaceutical sector, the anti-monopoly enforcement agency of the State Council, in accordance with Article 33 of the Anti-Monopoly Law and Chapter III of the Provisions on the Review of Concentrations of Undertakings, may consider the following factors:

(1) To assess the competitive impact of concentration involving pharmaceutical operators, several key factors may be considered. These include the market share of the operators involved and the extent of their control over the relevant market, as well as the degree of substitutability of the drugs they offer. Evaluators may examine the operators' ability to influence the pharmaceutical sales market or the procurement of pharmaceutical raw materials, alongside their financial strength and capacity for research and innovation. Consideration is also given to whether the operators possess marketing authorization qualifications, patents, proprietary technologies, pharmaceutical data or other valuable assets. Their involvement in, or control over, various segments of the pharmaceutical industry chain may also be relevant. The structure of the relevant market, the research, development, and production capabilities of other market participants and the purchasing power of downstream customers—especially their ability to

switch suppliers, are important factors as well. Additionally, the likelihood of new competitors entering the market and mitigating any potential anti-competitive effects may be considered.

(2) The market concentration in the relevant market, including factors such as the number of operators in the relevant market and their market share.

(3) When evaluating the impact of operator concentration on market entry, consideration may be given to how pharmaceutical companies influence access to the market by controlling key production factors—such as raw materials, sales and procurement channels, critical technologies, essential facilities, marketing authorization qualifications and pharmaceutical data. Additionally, the likelihood, timeliness and adequacy of market entry should be carefully assessed. When assessing the impact on technological progress, it is important to consider how concentration may affect the motivation and capacity for innovation in pharmaceutical research and development. This includes the level of investment in R&D, the application of pharmaceutical manufacturing technologies, and the ability to integrate and coordinate technological resources.

(4) Impact of concentration on consumers and other relevant market participants. When assessing the impact of concentration in the pharmaceutical sector on consumers, it is important to consider how it may influence the range of available medicines, their safety, effectiveness, quality control, accessibility and the stability of their supply. Additionally, attention should be given to whether the concentration shortens the time needed to bring new drugs to market or reduces the financial burden of medications on consumers. These factors directly affect consumers' access to healthcare and their overall rights and interests. For other market participants, the assessment should examine how the concentration might impact their ability to enter or compete in the market, their access to trading opportunities, and the overall competitive conditions. This includes businesses operating not only in the same market but also upstream, downstream or related markets.

(5) When assessing the competitive impact of concentration in the pharmaceutical sector, additional factors may also be considered. These include the impact of concentration on national economic development, public interest and whether any of the operators involved in concentration are companies on the verge of bankruptcy.

Article 36: Additional Restrictive Conditions

For mergers that have or may have the effect of excluding or restricting competition, the State Council's anti-monopoly enforcement agencies shall make a decision in accordance with Article 34 of the Anti-Monopoly Law. For concentrations that are not prohibited, the anti-monopoly enforcement agencies may impose additional restrictive conditions to mitigate the adverse impact of concentration on competition. Depending on the specific circumstances of the concentration transaction, the restrictive conditions may include the following types:

(1) Divestiture of tangible assets, intellectual property, data and other intangible assets or related rights (such as specific pharmaceutical businesses, in-development pharmaceutical projects, pharmaceutical R&D platforms, pharmaceutical R&D data, core pharmaceutical R&D

teams, pharmaceutical production and marketing authorizations), among other structural conditions.

(2) Commitments to continue research and development projects without termination, maintain R&D investment, license key technologies (including patents, proprietary technologies, or other intellectual property), terminate exclusive or monopolistic agreements, maintain independent operations, open pharmaceutical R&D platforms, share pharmaceutical R&D data, ensure supply, reduce prices and other behavioral conditions.

(3) A combination of structural and behavioral conditions as comprehensive conditions.

The divestiture of a business should generally include all the elements necessary for effective competition in the relevant market, including tangible assets, intangible assets, equity, key personnel, as well as customer agreements or supply agreements and other related rights. The divestiture target may be a subsidiary, branch or business department of the participating operator.

Under normal circumstances, the aforementioned remedies are first proposed as commitments by the operators participating in the concentration. After evaluating the effectiveness, feasibility and timeliness of the proposed commitments, the State Council's anti-monopoly enforcement agency may approve the concentration with additional restrictive conditions based on the commitments, if it determines that they can effectively reduce the adverse impact on competition.

Chapter V: Fair Competition Review and the Abuse of Administrative Power to Eliminate or Restrict Competition

Article 37: Fair competition review

Administrative authorities and laws, organizations authorized by law and entrusted with the function of managing public affairs draft laws concerning the economic activities of pharmaceutical sector operators, administrative regulations, local regulations, statutes, regulatory documents and concrete political measures, fair competition reviews should be conducted in accordance with relevant regulations.

Article 38: Restriction of Transactions

Administrative authorities and organizations authorized by law or regulation to manage public affairs must not abuse their powers. They are prohibited from explicitly or implicitly requiring, suggesting, refusing, delaying administrative approvals, registrations and inspections, or denying access to platforms or networks. Furthermore, they must not impose restrictions based on the location, ownership structure or organizational form of bidders. The creation of project databases, directories, alternative lists or qualification databases must not be used in an

unreasonable manner to unfairly restrict or indirectly limit the operation, procurement, or use of drugs supplied by specific operators.

Article 39: Hinder drug operators from entering relevant markets through methods such as signing cooperation agreements or memoranda of understanding

Administrative authorities and organizations authorized by laws and regulations to manage public affairs must not abuse their administrative power. By signing cooperation agreements, memoranda and other methods with operators, hinder other drug operators from entering the relevant market or subject other drug operators to unequal treatment, thus excluding or restricting competition.

Article 40: Obstruction of Free Circulation of Pharmaceuticals Between Regions

Administrative authorities and organizations authorized by laws and regulations to manage public affairs must not abuse their administrative power to hinder the free circulation of pharmaceuticals between regions. They are prohibited from setting discriminatory charges, fee standards or prices for pharmaceuticals from other regions; adopting discriminatory technical measures; using administrative licensing specifically targeting out-of-region drugs to block their entry into the local market. Additionally, they must not establish checkpoints or implement internet blocks and take any other actions that obstruct the entry of pharmaceuticals from other regions or the export of local pharmaceuticals.

Article 41: Exclusion or restriction of drug operators from participating in bidding and other business activities

Administrative authorities and organizations authorized by laws and regulations with the function of managing public affairs must not abuse administrative power by releasing information unlawfully, setting discriminatory qualification requirements, evaluation criteria, establishing qualification, technical and business conditions that are incompatible with actual needs or unrelated to the fulfillment of the contract, thereby excluding or restricting drug operators from participating in bidding and other business activities.

Article 42: Excluding, restricting, coercing or indirectly coercing external drug operators from investing or establishing branch offices locally

Administrative authorities and organizations authorized by laws and regulations with the function of managing public affairs must not abuse administrative power by treating local drug operators unfairly or by adopting methods that exclude, restrict, or indirectly coerce external drug operators from investing or establishing branch offices locally.

Article 43: Coercing or indirectly coercing drug operators to engage in monopolistic behaviors as defined by the Anti-Monopoly Law

Administrative authorities and organizations authorized by laws and regulations with the function of managing public affairs must not abuse administrative power to coerce or indirectly coerce drug operators into engaging in monopolistic behavior as defined by the Anti-Monopoly Law.

Article 44: Formulating Regulations Containing Provisions that Exclude or Restrict Competition

Administrative authorities and organizations authorized by laws and regulations with the function of managing public affairs must not abuse administrative power to formulate or issue regulations that contain provisions for excluding or restricting competition in the pharmaceutical market, in the form of measures, decisions, announcements, opinions, meeting minutes, letters or other similar documents.

Chapter VI: Application of Legal Responsibility

Article 45: Basis for the Application of Legal Responsibility

If operators and relevant individuals in the pharmaceutical field violate the Anti-Monopoly Law, the anti-monopoly enforcement authorities shall impose penalties in accordance with Chapter 7 of the Anti-Monopoly Law. If the violation constitutes a criminal offense, criminal responsibility shall be pursued according to the law.

If the monopolistic behavior investigated by the anti-monopoly enforcement authorities involves centralized procurement of pharmaceuticals, the enforcement authorities shall report the outcome of the investigation to the pharmaceutical pricing management department and encourage the operators to make corrections in accordance with the law. When anti-monopoly enforcement agencies investigate and handle violations of the Anti-Monopoly Law in the pharmaceutical sector, they may, at their discretion, consider the construction and implementation of the business operators' anti-monopoly compliance management system.

Article 46: Handling of Non-fulfillment of the Obligation to Cooperate with Investigations

The investigated pharmaceutical operators interested parties or other relevant units or individuals shall cooperate with the anti-monopoly enforcement agencies in performing their duties according to the law and shall not refuse or obstruct the investigation by the anti-monopoly enforcement agencies. For those who actively cooperate with the investigation and voluntarily provide evidence and materials, the anti-monopoly enforcement agency may, in

accordance with the law, impose a lighter or mitigated punishment. Those who refuse to provide relevant materials or information, provide false materials or information, conceal, destroy, transfer evidence, refuse or obstruct the investigation, may be subject to a heavier punishment by the anti-monopoly enforcement agency when determining the legal liability of the business operator for engaging in monopolistic conduct.

Article 47 Legal Liability for Organizing and Substantive Assistance in Monopolistic Conduct

Where an operator organizes pharmaceutical operators to reach a monopolistic agreement or provides substantive assistance to pharmaceutical operators in reaching such an agreement, the operator shall bear corresponding legal liability in accordance with Article 56, Paragraph 2 and Article 59 of the Anti-Monopoly Law.

When determining the legal liability of a business operator for organizing or providing substantial assistance in reaching a monopoly agreement, the anti-monopoly enforcement agency may take into consideration factors such as the nature and harmful consequences of the monopoly agreement, the operator's role in the formation and implementation of the agreement, the duration of participation, the degree of harm, the level of intent or fault and the social impact.

If a business operator provides substantial assistance to a pharmaceutical business operator in reaching a monopoly agreement, and the circumstances are minor, with timely actions taken to eliminate or reduce the harmful consequences of the conduct, the anti-monopoly enforcement agency may, at its discretion, impose a lighter or reduced penalty on the operator.

Article 48: Leniency System

Pharmaceutical operators who encourage the formation of monopoly agreements are encouraged to voluntarily report the relevant circumstances of the monopoly agreement and provide important evidence to the anti-monopoly enforcement agency, promptly cease the implementation of the monopoly agreement and cooperate with the investigation. For pharmaceutical operators who meet the conditions for leniency, the anti-monopoly enforcement agency may, at its discretion, reduce or exempt penalties. Business operators who organize the formation of monopoly agreements or provide substantial assistance, as well as the legal representatives, key responsible persons and directly responsible personnel of pharmaceutical operators who bear personal responsibility for the formation of monopoly agreements, may also be eligible for the leniency system.

Article 49: Legal Liability for the Abuse of Market Dominance through Division of Labor and Cooperation

If two or more pharmaceutical operators divide labor and cooperate in the production and business activities of pharmaceuticals and abuse their market dominance through mutual coordination, they shall bear corresponding legal responsibility in accordance with Articles 57 and 59 of the Anti-Monopoly Law. The anti-monopoly enforcement agency, when determining the specific fine for the above operators, may consider the following factors, based on the individual case:

(1) The situation of their involvement in decision-making;

(2) The circumstances of their mutual coordination in carrying out the illegal conduct;

(3) The different roles played in the illegal conduct;

(4) The distribution of monopoly profits.

Article 50: Legal Liability for Operators with a Control Relationship Abusing Market Dominance

When two or more pharmaceutical operators are involved in the abuse of market dominance, and one operator controls or exercises decisive influence over the others—or all are controlled by, or subject to the decisive influence of, the same third party—the anti-monopoly enforcement agency may treat them as a single entity. Based on the specific circumstances of the case, appropriate penalties may be imposed for monopolistic conduct.

In determining whether the circumstances prescribed in the preceding paragraph—namely, having control or being able to exert decisive influence—exist, the anti-monopoly enforcement agency may consider factors such as the equity structure, personnel arrangements, business decision-making, and financial relationships of the pharmaceutical operators.

Article 51: Harsher Penalties

Where a pharmaceutical operator violates the *Anti-Monopoly Law* and is found to have engaged in monopolistic conduct multiple times, deliberately caused shortages in the supply of pharmaceuticals, resulted in significant losses to medical insurance funds, or endangered public health, the anti-monopoly enforcement agency may impose harsher penalties in accordance with the law.

Where pharmaceutical operators and other relevant entities or individuals violate the Anti-Monopoly Law under particularly serious circumstances, with especially egregious impact and extremely severe consequences, the anti-monopoly enforcement agency under the State Council may, in accordance with Article 63 of the Anti-Monopoly Law, determine the specific amount of the fine to be between two and five times the amount specified in Articles 56, 57, 58, and 62.

Article 52: Credit Penalty

If a pharmaceutical operator is administratively penalized for violating the provisions of the Anti-Monopoly Law, the penalty will be recorded in the credit record in accordance with relevant national regulations and publicly disclosed to society through the National Enterprise Credit Information Disclosure System.

Article 53: Coordination between Anti-Monopoly Enforcement Agencies and Other Departments

During investigations of monopolistic behavior in the pharmaceutical sector, if the anti-monopoly enforcement agency discovers the following situations, it shall promptly take action in accordance with the law:

(1) If a pharmaceutical operator is suspected of violating industry regulations such as pharmaceutical laws and regulations, the agency shall transfer the issue clues to the relevant industry supervision and management department.

(2) If relevant units or individuals are suspected of committing a crime, the issue clues shall be transferred to the public security authorities.

(3) If public officials are suspected of violating their duties or committing official crimes, the issue clues shall be transferred to the disciplinary inspection and supervision authorities.

Relevant departments discovering suspected monopolistic behavior in the pharmaceutical sector should promptly transfer the issue clues to the anti-monopoly enforcement agency.

Chapter VII: Supplementary Provisions

Article 54: Scope of Application

This guideline applies to all operators in the pharmaceutical field and their production and business activities; it also applies to pharmaceutical excipients, pharmaceutical packaging materials, pharmaceutical intermediates and relevant services in the pharmaceutical field.

Article 55: Implementation of the Guidelines

These Guidelines shall be interpreted by the Office of the Anti-Monopoly and Anti-Unfair Competition Commission of the State Council and shall come into force as of the date of their promulgation. The *Anti-Monopoly Guidelines on the Active Pharmaceutical Ingredient (API)*

Sector issued by the Anti-Monopoly Commission of the State Council shall be repealed simultaneously.