

Anti-Monopoly Legal Compliance Risks in the Pharmaceutical Industry

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Abstract. Under globalization, cross-border pharmaceutical transactions are frequent, the raw material drug market has a high concentration, and covert monopolistic practices occur frequently. This article focuses on cross-border pharmaceutical transactions, outlining three core compliance risks: barriers to entry for active pharmaceutical ingredients (APIs), covert collusion, and regulatory transformation. The research results show that the registration and associated review system for APIs creates a natural market barrier, giving rise to the risk of passive collusion; The industry has seen the emergence of new types of cross-border cartels, such as "isolation cabin" architecture and encrypted paperless communication, rendering traditional cross-border auditing systems completely ineffective; country's anti-monopoly enforcement has shifted from single-point investigations to full-chain penetration supervision, establishing a model that prioritizes the accountability of organizers, with senior executives and actual controllers bearing independent legal responsibility. Based on this, this article proposes to establish three types of localized compliance mechanisms: dynamic price early warning, digital penetration internal audit, and full-cycle personnel risk control. This study clarifies new behavioral patterns of cross-border monopoly in the pharmaceutical industry, enriches the regulatory theory of the pharmaceutical industry under competition law, and provides practical guidance for multinational pharmaceutical companies to build an anti-monopoly compliance system adapted to Chinese regulations.

Keywords: Pharmaceuticals, anti-monopoly, pharmaceutical industry

1. Introduction

Against the backdrop of global economic integration, the problem of monopoly in the pharmaceutical industry is becoming increasingly prominent. Monopolistic practices not only weaken fair competition in the market, but also disrupt the drug supply system, drive up drug prices, and harm the public's vital interests. In response, China is continuously improving its anti-monopoly rules system. The revised Anti-Monopoly Law of the People's Republic of China in 2022 significantly increased the upper limit of fines for violations and strengthened the regular compliance obligations of operators; the Anti-Monopoly Guidelines in the Pharmaceutical Sector, implemented in 2025, established a systematic set of regulatory rules for the entire pharmaceutical business chain. In the field of antitrust, the pharmaceutical industry has become a key target of

regulation. However, when the pharmaceutical supply chain spans multiple countries, antitrust compliance risks exhibit complex transnational characteristics.

While there is a wealth of research on pharmaceutical anti-monopoly in academia and practice, there is still a lack of systematic research that specifically connects domestic and international compliance pathways and focuses on cross-border transactions. The United States and the European Union have established relatively mature anti-monopoly systems, which have certain reference value, but foreign rules cannot be directly adapted to China's legal system. Against this backdrop, it is necessary to face up to the cross-border compliance challenges faced by pharmaceutical companies and to take into account both domestic and international regulatory requirements.

This study focuses on risks in cross-border transaction scenarios and constructs a regulatory framework that "takes into account both domestic and cross-border aspects," providing precise strategies for enterprises' anti-monopoly behavior in the global market.

2. Literature review

In the current international pharmaceutical trade, the importance multinational companies attach to antitrust compliance directly determines the success or failure of the transaction. After the antitrust compliance models of Europe and the United States were introduced into China's pharmaceutical market, obvious adaptation problems emerged. The main challenges are as follows:

First, there is the supply chain monopoly that arises from the "raw material drug registration system".

According to recent literature, the concentration of China's active pharmaceutical ingredient market is extremely high, with nearly half (48.4%) of the products having fewer than three manufacturers, and even 24.7% of the products being produced by a single manufacturer [1]. This market structure is not entirely formed by free market competition; approval rules such as drug raw material registration and related review are important influencing factors. Due to the influence of special industry regulatory rules, overseas buyers find it difficult to screen for price monopoly risks through routine due diligence and are very likely to get involved in compliance disputes related to high-priced transactions.

Secondly, the "de-traceability" of monopolistic practices makes conventional auditing inadequate.

The latest practical research in 2026 shows that domestic monopolistic practices have evolved to be quite covert. Violators often use encrypted communication and a split operation model, commonly known in the industry as "isolation chambers," to sever information exchange between cooperating entities and deliberately create information barriers. In this model, the accounting records of all participating entities comply with formal regulations, and the actual transactions and collusion are only controlled by the behind-the-scenes mastermind. Traditional written contract audits and conventional risk control models used by multinational pharmaceutical companies are insufficient to identify such behavior, and their globally unified compliance systems have significant shortcomings in dealing with covert monopolistic practices.

Third, China's anti-monopoly enforcement approach has shifted, no longer merely imposing administrative fines on the companies involved, but relying on a penetrating regulatory mechanism to pursue the administrative and even criminal liability of the actual controllers and senior executives in accordance with the law.

What alarms cross-border transaction participants most is the restructuring of China's regulatory logic. Current anti-monopoly enforcement promotes full-chain penetration supervision, no longer simply punishing illegal companies, but legally piercing the corporate veil to hold behind-the-scenes executives, actual controllers and core organizers legally accountable. Changes in regulatory rules

and accountability logic require multinational pharmaceutical companies to abandon wishful thinking and build a localized risk prevention and control system that adapts to China's regulatory requirements.

3. Institutional risks in cross-border transactions: barriers to market access in China's API market

3.1. Current status and data analysis of the high concentration of the supply chain

In the international pharmaceutical supply chain, APIs are the core of drug formulations, and the stability of their supply directly determines the production continuity of multinational pharmaceutical companies. Based on China's anti-monopoly enforcement practices and industry empirical data, the Chinese API (Active Pharmaceutical Ingredient) market has long exhibited extreme structural exclusivity characteristics. The domestic API industry has a high concentration. Statistics show that 48.4% of API products have no more than 3 manufacturers, and 24.7% of products are produced by only a single company, which is very easy to generate anti-monopoly risks of abusing market dominance [2]. When there is such an extreme contraction in the upstream supply side and the downstream formulation side shows strong clinical rigidity in demand, the market will inevitably develop extremely strong entry barriers and extremely weak price elasticity [3]. For multinational pharmaceutical companies, this extreme concentration completely strips them of their bargaining power. If raw material manufacturers with market dominance engage in behaviors that abuse their market dominance, such as cutting off supplies or raising prices unreasonably, it will directly impact the production plans of multinational pharmaceutical companies and cause significant fluctuations in the supply chain [2, 3].

3.2. Legal impact of API registration system and related review and approval

China's unique administrative approval system is the underlying cause of its high degree of centralization. Unlike the independent review system in Europe and the United States, China's management of active pharmaceutical ingredients implements a "registration approval system" and a "linked review and approval system". Under the associated review model, APIs cannot enter the market independently; they must be closely linked with downstream formulation applicants and jointly apply for approval. This means that new entrants must persuade pharmaceutical companies to risk approval delays by submitting clinical and registration reviews that can take years. When complex administrative registration procedures are intertwined with the interests of exclusive incumbents, they form a natural institutional barrier, greatly lengthening the entry time for new suppliers and potential competitors [4]. This system, which is highly dependent on regulatory review, results in excessively high implicit compliance and time costs for changing suppliers in cross-border transactions [4, 5]. Due to the single supply problem caused by entry barriers, the bargaining power of overseas buyers is weakened, and they have long been passively accepting unreasonable transaction conditions, which poses a legal risk of being identified as a vertical monopoly agreement [5].

3.3. Local challenges faced by multinational pricing strategies

Pharmaceutical transactions in Europe and the United States are often based on highly free competition and flexible pricing models. However, when multinational pharmaceutical companies'

global pricing strategies encounter the policy-driven monopoly environment of China's raw material drug market, they are facing an unprecedented blow to localization. Because the price elasticity of raw pharmaceutical materials in China is extremely low, when upstream companies engage in malicious hoarding and speculation, prices often surge several times in a short period of time. The closed monopoly and vertical constraints of the upstream will directly lock up the pricing space of the downstream and quickly break through the global unified "cost-benefit" budget model of multinational corporations [6]. A deeper challenge lies in the fact that, under the anti-monopoly perspective, the national healthcare authorities and market regulators are conducting cross-departmental supervision through penetrating methods. Once multinational pharmaceutical companies are forced to accept high prices, this abnormal cost will be immediately captured in the terminal centralized procurement bidding process [7]. This has led to the accelerated fragmentation of the global unified price balance system that multinational pharmaceutical companies rely on for long-term stable input flows in the face of penetrating policy regulation [6, 7].

4. Behavioral alienation in cross-border collaboration: covert collusion and the "isolation chamber" challenge

4.1. The intelligent and traceless characteristics of illegal methods

With the deepening of anti-monopoly enforcement, monopolistic practices in the domestic pharmaceutical sector have moved beyond the primitive stage of relying on written contracts to divide the market or fix prices. Illegal methods are undergoing a profound evolution towards greater intelligence, concealment, and "traceability." Some illegal operators circumvent written agreements by using WeChat and encrypted communication software to reach verbal agreements on pricing and market segmentation, making it difficult to secure evidence of illegal activities using traditional paper-based auditing methods. Paperless covert communication greatly increases the difficulty of obtaining evidence for anti-monopoly and challenges the traditional rules of presuming illegal facts based on paper certificates. Violators often disguise their monopolistic behavior under another legal guise [8]. In local law enforcement practice, the use of digital encryption tools has caused all the tacit signals of secret operations to drift outside the regular compliance network, resulting in the parent company in cross-border cooperation falling into a serious "audit failure" dilemma [9].

4.2. The "isolation chamber" mechanism and the risk of information disconnection

In the process of this illegal behavior becoming distorted, what alarms law enforcement most is the distortion of an organizational structure known as the "silo mechanism". Its core logic lies in "enterprises being unaware of each other, risk transfer, and a closed-loop profit system". In practice, the "isolation chamber" mechanism is implemented by designing a closed-loop system of "raw material control - organizer operation - formulation monetization", introducing third-party organizers or professional intermediaries affiliated with outside the supply chain as the core link for single-line contact. When faced with the opaque regional operations of overseas subsidiaries, severe geographical isolation and institutional barriers can lead to a "compliance blind spot" and a crisis of blind faith in the decision-making center of multinational parent companies [10]. Due to the physical isolation design of the "isolation cabin", all the collusion involved in violating the prohibition of anti-monopoly law is locked inside the specific "cabin". If the global compliance system of multinational groups is not adapted to domestic regulatory rules, the information gap between

domestic and foreign countries will make it difficult for the headquarters to grasp the real transaction behavior of subsidiaries, forming a blind spot in compliance control [9, 10].

4.3. Failure of the Axis protocol and cross-border firewalls

From the perspectives of competition law theory and antitrust practice, the "quarantine" mechanism and the "professional alliance" with multiple roles are a typical upgrade of the hub-and-spoke agreement in the pharmaceutical industry. In this type of organizational structure, third-party operators or local raw material pharmaceutical companies act as the "hub," while multinational pharmaceutical subsidiaries and formulation manufacturers distributed at different nodes of the supply chain act as the "spokes." The intermediary axis relies on vertical transaction relationships and profit sharing to encourage multiple pharmaceutical companies to reach a tacit agreement on horizontal unified pricing and market segmentation [11]. The most serious harm of the spokes protocol is that it can directly cause the traditional horizontal compliance firewall of multinational companies to become completely ineffective, because there is no horizontal contact between the spokes companies on the surface within the system [7]. Third-party operators often exploit vertical constraints to extract monopoly premiums from below the surface, perfectly circumventing the red line regulations set for horizontal cartels [12]. This new and complex organizational structure directly penetrates the compliance firewalls that multinational corporations maintain on paper [11, 12].

5. Restructuring Chinese-style regulation and responsibility responses of transnational entities

5.1. Failure of the Axis protocol and cross-border firewalls

Faced with monopolistic practices in the pharmaceutical field that have been repeatedly prohibited but not stopped, and whose methods are characterized by their covert nature, China's anti-monopoly enforcement is undergoing a disruptive upgrade. China's anti-monopoly enforcement is no longer limited to punishing a single violating company, but has transformed into a comprehensive, penetrating regulatory model that "strikes early and targets small-scale violations, and conducts simultaneous investigations across the entire upstream and downstream supply chain." Penetrating supervision fundamentally breaks the previous isolated situation of "treating the symptoms but not the root cause" and examines raw material drug companies, distributors and intermediate distributors as an organic whole [11]. Modern competition law utilizes cross-data to conduct penetrating investigations, which can completely break down the compliance disguises created by enterprises using false contracts [13]. Regulatory authorities rely on funds and transaction data to conduct full-chain traceability investigations, which are not limited by a single independent legal entity, and simultaneously verify the illegal and related behaviors of all related companies within the group [14].

5.2. "Organizer annihilation" and individual risk under responsibility restructuring

With the implementation of the penetrating regulatory paradigm, the country has also ushered in a milestone restructuring of the mechanism for allocating anti-monopoly legal responsibilities. Simply imposing fines on companies has significant limitations when dealing with highly profitable pharmaceutical monopoly alliances. Therefore, current legislative and enforcement trends are firmly implementing a deterrent strategy that prioritizes "eliminating organizers" over "punishing

participants." The focus of law enforcement has shifted entirely to the in-depth investigation of the personal responsibilities of the actual manipulators and professional organizers behind the scenes. In Europe and the United States, as well as in China, anti-monopoly enforcement has gradually strengthened the legal responsibility of natural persons. However, in other countries, administrative fines for enterprises are still the main means of punishment. China has a stronger accountability for organizers, which has significantly enhanced the deterrent effect of law enforcement on natural persons [15]. For local executives and procurement decision-makers of multinational pharmaceutical companies, this means that executives can no longer hide behind the corporate shell. Once they are found to have engaged in "organizing, instigating or condoning" such behavior, they will face huge personal administrative fines and even the risk of criminal cross-accountability [11, 15].

5.3. Recommendations for localization and compliance in cross-border transactions

Faced with the structural monopoly minefield in China's API market, the penetrating challenges of intelligent "isolation chambers," and the new situation of iron-fisted regulation that "penetrates the entire chain and eliminates organizers," multinational pharmaceutical companies cannot adapt to the domestic penetrating regulation and the special industry rules of APIs by directly applying overseas general anti-monopoly compliance templates. This results in significant loopholes in compliance control. Multinational pharmaceutical companies must build a localized, penetrating compliance system that is truly grounded in the Chinese context and possesses technological offensive and defensive capabilities [7].

Specifically, multinational corporations should implement the following three core strategies in their cross-border transaction and compliance management programs:

First, establish an early warning mechanism based on a "dynamic fair price benchmark" in the Chinese market. Multinational pharmaceutical companies should implement dynamic monitoring of the approval status and market invoicing price of target products in the domestic API registration platform. Once it is discovered that the purchase price deviates from the normal cost and reasonable profit range, the compliance circuit breaker mechanism must be triggered immediately [7, 11].

Second, implement "penetrating anti-money laundering and anti-monopoly dual internal audits" across the entire supply chain. In response to the challenges of intelligent trace removal and "isolation chambers", internal audit teams must upgrade their toolbox and introduce electronic data recovery and big data collaborative investigation methods [13] to strictly investigate whether there are any secret behaviors that use third-party "consulting fees" and "market expansion fees" as a cover to build "isolation chamber" firewalls [9].

Third, reconstruct a full-life cycle personnel risk control model that shifts from "corporate liability to natural person liability". In response to the latest trend of individual accountability in China and global deterrence regulations, multinational corporations should clearly link anti-monopoly compliance performance with the legal responsibilities of local senior managers and core procurement personnel [15]. Third, by conducting regular "Dawn Raid Simulations", people can ensure that frontline personnel can cooperate in accordance with the law and not destroy evidence when faced with surprise inspections, thereby completely offsetting the institutional and non-compliance risks in cross-border transactions [14].

6. Conclusion

This study focuses on antitrust compliance risks in international pharmaceutical cross-border transactions. First, due to the unique registration and approval system for APIs and related reviews

in China, the market supply of certain drug raw materials is easily monopolized by a very small number of domestic companies. When procuring raw materials needed for essential clinical formulations, multinational pharmaceutical companies often find it difficult to avoid malicious hoarding and unfairly high prices, thus facing the risk of being passively drawn into the compliance red line of price monopoly. Secondly, some local professional operators tend to use the "isolation chamber" mechanism to build a closed chain of interests, and isolate risks through vertical constraints, resulting in serious information gaps and compliance blind spots in the traditional internal audit system of multinational parent companies. Furthermore, China's anti-monopoly regulatory paradigm is undergoing a profound restructuring, with law enforcement agencies shifting to "full-chain penetration" supervision supported by big data. This not only severely punishes the legal entities involved but also firmly implements the iron-fisted trend of "annihilating the organizers," making local executives face significant administrative and criminal legal risks. In conclusion, this study argues that cross-border pharmaceutical transaction entities must completely abandon the arrogance and blind faith in a "globally uniform template" and urgently need to build a localized compliance early warning and penetrating audit system that is adapted to China's penetrating supervision and has technical attack and defense capabilities, so as to hedge against institutional and compliance risks in cross-border transactions throughout the entire life cycle.

References

- [1] Hua, Y. Z., Xie, J. P., & Shao, R. (2025). A brief analysis of the current status of API registration and management system challenges in China—from the perspective of anti-monopoly. Nanjing: Institute of Drug Regulatory Science, China Pharmaceutical University.
- [2] Ding, J. X. (2022). Research on the causes, characteristics and anti-monopoly regulation path of raw material drug monopoly in China. *Chinese Pharmaceutical Journal*, 57(14), 1211–1218.
- [3] Blair, R. D., & Sokol, D. D. (2021). Antitrust focus on the pharmaceutical industry: Market power, pricing, and international supply chains. *Journal of Antitrust Enforcement*, 9(2), 211–230.
- [4] Carrier, M. A. (2018). Antitrust, market exclusivity, and transparency in the pharmaceutical industry. *JAMA*, 319(22), 2271–2272.
- [5] Hovenkamp, H. (2020). *Federal antitrust policy: The law of competition and its practice*. West Academic Publishing.
- [6] Elhauge, E. (2022). Horizontal shareholding and pharmaceutical cartels: The limits of traditional corporate compliance. *Harvard Law Review*, 135(6), 1612–1655.
- [7] Sokol, D. D. (2022). Cartels, hub-and-spoke configurations, and the breakdown of transnational corporate compliance. *Southern California Law Review*, 95(5), 1123–1168.
- [8] Ezrachi, A., & Stucke, M. E. (2016). *Virtual competition: The promise and perils of the algorithm-driven economy and sophisticated cartels*. Harvard University Press.
- [9] Liu, J. (2023). The evolution trend of covert collusion in pharmaceutical cartels and China's anti-monopoly response mechanism. *Anti-Monopoly Law Review*, 12(1), 85–99.
- [10] Kovacic, W. E. (2020). Transnational corporate structures and procedural fairness in global antitrust enforcement. *Antitrust Law Journal*, 83(2), 355–388.
- [11] Lin, P. (2023). Definition and full-chain regulatory penetration of axis-width agreements in China's pharmaceutical anti-monopoly cases. *Anti-Monopoly Law Review*, 12(2), 44–59.
- [12] Hovenkamp, H. (2024). Hub-and-spoke conspiracies and vertical restraints in globalized pharmaceutical markets. *Antitrust Law Journal*, 86(1), 101–145.
- [13] Podszun, R., & Bongartz, S. (2021). Surveillance and digital compliance in competition law: Redefining antitrust investigations. *World Competition*, 44(2), 165–188.
- [14] Whish, R., & Bailey, D. (2021). *Competition law*. Oxford University Press.
- [15] Jenny, F. (2020). Changing patterns of antitrust enforcement in the healthcare sector: Corporate liability and individual accountability. *European Competition Law Review*, 41(8), 385–399.