GT GreenbergTraurig

China Newsletter | 2025 Q1/Issue No. 63

In This Issue:

Antitrust | Compliance | Corporate | Data Privacy & Cybersecurity | Foreign Investment | International Trade

---

This China Newsletter provides an overview of key Q1 2025 developments in the following areas:

Antitrust

China Releases Anti-Monopoly Guidelines for Pharmaceutical Sector

国务院反垄断反不正当竞争委员会正式发布《关于药品领域的反垄断指南》

China's State Council has introduced new Anti-Monopoly Guidelines for the pharmaceutical sector, effective Jan. 24, 2025. These Guidelines provide a detailed framework for the State Administration for Market Regulation (SAMR) to assess potential anticompetitive behaviors in the pharmaceutical industry, including some previously unaddressed conduct.

The pharmaceutical and life sciences sector is a key focus of SAMR's anti-monopoly enforcement. Since 2018, SAMR has penalized 28 cases of anticompetitive conduct and imposed remedies in three mergers within the industry. Additionally, Chinese courts have become significant arenas for patent litigation involving pharmaceutical companies, often involving anti-monopoly claims or defenses.

Highlights of the Guidelines include:

- Reverse Payment Agreements: For the first time, the Guidelines provide specific enforcement guidance on "reverse payment agreements," where brand-name pharmaceutical suppliers unjustifiably pay or provide benefits to generic drug manufacturers to delay market entry or avoid patent challenges. These agreements may be deemed anticompetitive, with outlined factors for assessing their potential effects.
- Resale Price Maintenance (RPM): RPM has long been a target for SAMR in the health care industry. The Guidelines clarify that financial incentives and penalties, as well as auditing sales records or monitoring resale prices through third parties or algorithms, may be considered indirect measures to implement RPM. Exceptions are made for certain common restrictions in the pharmaceutical sector, such as the "agency exception" and logistics-only distributors.
- Joint Research & Development and Innovation Exemptions: The Guidelines recognize the benefits of joint R&D and outline factors for granting exemptions, including the relationship between parties, market control, competition restrictions, and necessity for R&D completion. SAMR considers consumer benefits like drug effectiveness, safety, market entry time, cost reduction, and responses to public health crises.
- Unfairly High Prices: The Guidelines refine criteria for identifying excessive pricing, including practices like "layering up" prices through false transactions or markups. SAMR will compare prices with competitor drugs, regional prices, historical prices, and costs to determine if prices are unfairly high.

- Product Hopping: The Guidelines introduce "product hopping," where companies modify existing patented drugs to extend patent life. Although there are no enforcement cases in China yet, such practices could be deemed anticompetitive if the new product offers minimal improvement or hinders generic entry.
- Conspiracy to Monopolize the Market: Companies across different levels of the pharmaceutical supply chain could face scrutiny for collaborating to monopolize the market and share profits. The Guidelines allow SAMR to address complex anticompetitive practices involving multiple actors that do not fit neatly into traditional categories of abuse of dominance or direct collusion.
- Merger Review: The Guidelines clarify aspects of pharmaceutical merger reviews, indicating that intellectual property transactions may trigger reviews and proposing innovative behavioral remedies like licensing key IP, granting open access to R&D platforms, sharing R&D data, guaranteeing supply, or lowering prices.

The release of both the Anti-Corruption Guidelines for the Health Care Industry and the Anti-Monopoly Guidelines for the Pharmaceutical Sector in January 2025 indicates heightened scrutiny by Chinese regulators on these industries. Pharmaceutical and health care companies operating in China must comply with these Guidelines, or risk penalties. Companies considering mergers and acquisitions should also be aware of the broad range of remedies SAMR may employ during merger reviews.

Compliance

China Finalizes Its First Anti-Corruption Guidelines for the Health Care and Life Sciences Industry

市场监管总局发布《医药企业防范商业贿赂风险合规指引》

On Jan. 10, 2025, China's State Administration for Market Regulation (SAMR) put into effect its Compliance Guidelines for Healthcare Companies to Prevent Commercial Bribery Risks (the Guidelines). The finalized version of the Guidelines is generally consistent with the draft version published by the SAMR Oct. 11, 2024, for public commentary (Draft Guidelines). Please see our November 2024 GT Advisory for analysis on the Draft Guidelines.

The Guidelines apply to pharmaceutical and medical device companies, as well as other third parties involved in the research, development, production, and distribution of medical products in China. They primarily address bribery risks in interactions with health care organizations (HCOs) and health care professionals (HCPs), regardless of whether they practice privately or publicly.

Key takeaways from the Guidelines include:

1. High expectations of compliance programs

   The Guidelines assign the primary responsibility for managing anti-corruption risks to businesses. Companies are expected to establish compliance programs that can detect, mitigate, and address such risks in accordance with international best practices. This initiative aims to bridge the gap between the stringent compliance requirements faced by multinational corporations (MNCs) operating in China and the potentially inadequate compliance infrastructure of domestic companies.

2. Nine Enforcement Focuses and Risk-based Approach

The Guidelines address nine business activities that companies in the health care and life science sector routinely engage in that have been identified as areas at risk for bribery, including (1) academic promotional activities, such as meetings with HCPs to provide academic information and technical consultations; (2) hospitality, e.g., meals and entertainment for HCPs during business interactions; (3) consulting service fees to HCPs; (4) outsourcing medical research, manufacturing, and other business activities to third parties; (5) financial incentives provided at the point of sale, e.g., discounts, rebates, and commissions; (6) donations, sponsorships, and grants; (7) free supply of medical devices to HCOs; (8) clinical research; and (9) sales through retail pharmacies.

The Guidelines further set out in each case the red flags and green flags for business practices:

- Green flags include mandatory or encouraged practices, and are classified into the following four levels:

Category	Examples
Mandatory (应当): Practices explicitly required by existing laws, regulations, and international or domestic industry standards.	*Hospitality-related expenses should be limited to reasonable and modest meals*. (Art. 15.)
Advisable (建议): Recommended compliance experience and typical practices to prevent bribery.	*It is recommended that health care manufacturers pay service fees to HCPs via bank transfer*. (Art. 18.)
Encouraged (倡导): Acts beneficial for establishing long-term mechanisms to combat bribery and fostering the high-quality development of the health care industry.	*Health care manufacturers are encouraged to obtain confirmation of the time and content of services from clinal trial organizations and researchers before paying service fees*. (Art. 39.)
Permissible (可以): Practices that are industry consensus but not legally mandatory.	*Health care manufacturers could assess the necessity and reasonableness of the donation based on the recipient's needs*. (Art. 27.)

- Red flags include prohibited or discouraged practices, which are further classified into three levels below:

Category	Examples
Prohibited (禁止): Acts explicitly prohibited by laws and regulations or identified in recent enforcement actions as constituting commercial bribery.	*Provision of activities such as entertainment, fitness, or tourism as hospitality is prohibited*. (Art. 16.)
To Be Avoided (避免) **or Restricted** (限制): Activities not clearly prohibited by law, but which	*Avoid paying service fees to HCPs in cash or cash-equivalent items*. (Art. 19.)

might, based on enforcement practices and industry consensus, be used to facilitate bribery.	
To Be Monitored (关注): Low-risk actions that do not align with general compliance principles and may lead to commercial bribery.	*Unreasonably frequent or excessive hospitality that goes beyond common business practices should be monitored*. (Art. 16.)

3. The finalized version of the Guidelines introduced a few changes from the draft version:

   - Article 13: In addition to prohibiting health care manufacturers from assigning sales targets to medical education personnel, the Guidelines now also forbid these employees from engaging in sales activities like collecting payments and handling purchase and sales invoices, further separating educational and sales functions.
   - Article 15: The Guidelines remove the prohibition on providing business hospitality to secure transaction opportunities or competitive advantages.
   - Article 24: The requirements for health care companies to establish clear rebate and discount policies have been expanded to include both providing and receiving rebates and discounts.

While the Guidelines are not legally binding in China, they closely align with established Chinese anti-bribery laws. By providing detailed examples and frameworks that clarify existing provisions, the Guidelines are expected to serve as key reference points for enforcement agencies and may influence enforcement practices. Multinational corporations (MNCs) should carefully review and the Guidelines.

Corporate

China Streamlines Company Registration: Key Changes Effective February 2025

《公司登记管理实施办法》自 2025 年 2 月 10 日起实施

China's SAMR has implemented the *Implementation Measures for the Administration of Company Registration* (the Measures) to enforce the new Company Law, aiming for greater transparency and efficiency in business registration. Here's what companies need to know:

- Strict Capital Contribution Deadlines:

  New companies must pay subscribed capital in full within five years of establishment or capital increase. Existing companies (incorporated before July 1, 2024) must adjust capital schedules if remaining payment periods exceed five years from July 1, 2027. Full payment is due by June 30, 2032.

- Expanded Capital Contribution Forms:

  Following the rules of the new PRC Company Law, the Measures confirm the capital contributions via cash, in-kind assets, IP, land use rights, equity, or creditor's rights. In addition, the Measures explicitly allow contributions using data and network virtual property (subject to legal exclusions). All non-monetary contributions require proper valuation.

- Supervision by Company Registration Authority

  Pursuant to the new PRC Company Law, the company registration authority may require the company to make timely adjustments according to the law when the capital contribution period and amount are found obviously abnormal. The Measures further specify the standard of what is considered "obviously abnormal" for companies registered before June 30, 2024:

  - The period for subscribed capital contribution exceeds 30 years;
  - The registered capital exceeds RMB 1 billion;
  - Other circumstances that obviously fail to conform to objective common sense.

  Under these circumstances, the company registration authority must conduct comprehensive research and judgment on the authenticity and rationality of the registered capital.

- Enhancing the Company Liaison Officer System

  The Measures also refine the system for company liaison officers to ensure effective communication between companies and registration authorities:

  - Clarified scope of appointment: A company liaison officer can be appointed from a range of personnel, including the legal representative, directors, supervisors, senior management, shareholders, or employees of the company.
  - Registration and responsibilities: During company establishment, the liaison officer must be registered with the authorities and provide commonly used contact information such as a phone number and email address. The liaison officer is entrusted with handling communication between the company and the registration authority to ensure smooth interactions.
  - Change notification requirement: If the liaison officer changes, the company must update the registration with the authorities within 30 days of the change, ensuring continued accountability and communication.

- Removal of Director, Supervisor, and Senior Executive

  Article 178 of the new PRC Company Law stipulates the circumstances in which a person cannot serve as a director, supervisor, or senior manager of a company, including but not limited to such person being sentenced to a criminal penalty, being listed as a dishonest person by the PRC court, and others.

  The Measures further clarify that in any of the above circumstances, the company should remove the person from the position within 30 days from the date the company became aware or should have become aware of the situation.

To effectively navigate the updated regulatory landscape, businesses should prioritize compliance and governance by aligning internal processes with new requirements, particularly in shareholder capital contributions, recordkeeping, and public disclosures. Strengthening governance structures and ensuring operational integrity through stringent checks may prevent penalties. Maintaining robust communication with regulatory authorities and seeking professional support for complex filings, while choosing reliable service providers, is also important.

Data Privacy & Cybersecurity

China Issues Personal Information Compliance Audit Rules

国家网信办公布《个人信息保护合规审计管理办法》

Effective May 1, 2025, the Cyberspace Administration of China formally enacted the Measures for Compliance Audits of Personal Information Processing (the Compliance Audit Measures), that extend and clarify obligations under the Personal Information Protection Law and the Data Security Law.

Two Audit Types: Self-Audit & Mandated Audit

At their core, the Compliance Audit Measures introduce a dual-path audit system that balances proactive internal review with mandatory external audit, to ensure data handlers operating within mainland China adhere to relevant legal mandates in their processing of personal data. On the proactive side, all data handlers must conduct regular "self-audits," among which data handlers processing personal data of more than 10 million individuals are legally required to undergo audits at least once every two years. While smaller data handlers are not bound by minimum frequency, they are expected to set up rational audit cycles based on their processing volume, risk levels, and business context. Furthermore, those handling personal data of more than one million individuals are required to appoint a data protection officer and establish an independent oversight body led by external experts when conducting the compliance audit. In contrast, "mandated audits" are triggered by regulatory authorities, especially in cases when severe risks arise, when there is evidence of harm to a broad group of individuals, or large-scale data breaches—such as leaks of over 1 million general records or 100,000 sensitive records—or potential mass rights violations. In such cases, regulators may compel organizations to engage an accredited third-party audit firm.

Professional Audit Agencies

The Compliance Audit Measures also provide rigorous requirements for third-party audit agencies. To facilitate implementation, data handlers may choose to conduct audits internally or commission accredited agencies at their own expense, ensuring proper rectification where needed. Professional audit agencies must demonstrate adequate professional capacity—including competent staff, secure facilities, and financial resources—to conduct these audits. They are expected to uphold independence, and to prevent conflicts of interest, the same entity cannot audit a single client for more than three consecutive audits.

Audit Standards

Both self-initiated and mandated audits must follow the "Personal Information Protection Compliance Audit Guidelines" annexed to the Compliance Audit Measures, as well as the TC 260-Practice Guidelines issued by the National Technical Committee for Cybersecurity Standardization. These documents establish the audit framework and key assessment areas, including the lawfulness basis, where consent mechanisms and legal exceptions are reviewed; transparency, which ensures clear user disclosures and timely notification of policy updates; liability allocation, assessing contractual terms in entrusted processing and rights protections in joint processing; and internal governance, verifying data classification systems, incident response protocols, and the accountability of the data protection officer.

Enforcement and Oversight

Supervision and enforcement mechanisms underpin the Compliance Audit Measures' effectiveness. Regulatory authorities will conduct random inspections, accept public reports, and take legal action against violations. Additionally, the Compliance Audit Measures reinforce a participatory oversight model where any individual or entity may report non-compliance observed during an audit to regulators, who are obligated to review and respond to such complaints. Noncompliant data handlers may face penalties under the Personal Information Protection Law, with criminal liability imposed for serious infractions.

China Issues Regulation for Facial Recognition Technology Applications

国家互联网信息办公室、公安部联合公布《人脸识别技术应用安全管理办法》

Effective June 1, 2025, the Cyberspace Administration of China and the Ministry of Public Security jointly released the Measures for the Security Management of Facial Recognition Technology Applications (the FRT Measures). The FRT Measures establish a comprehensive governance framework for the use of any facial recognition technology (FRT) within mainland China, aiming to strike a clear balance between innovation and individual privacy rights. The FRT Measures apply to all FRT applications that process facial recognition data in *operational* settings—such as identity checks or public surveillance—but explicitly exclude activities solely related to research and algorithm training that do not involve live deployment.

At the heart of the FRT Measures lies a firm commitment to the principles of purpose specificity and data minimization. Data handlers leveraging FRT must clearly define each use case and demonstrate that no less intrusive methods are adequate. If another non-biometric method (e.g., QR codes, passwords) can serve the same need, FRT cannot be the sole verification method—alternative options must also be available.

Key requirements in the FRT Measures include:

- **Notice and Explicit Separate Consent.** Data handlers must provide clear information on the purpose, storage duration, and other relevant details before collecting personal data. Separate consent must be obtained, and guardian approval is required for processing minors' information.
- **Device-level Data Localization and Time-Limited Storage.** Facial recognition data should be stored locally on facial recognition devices themselves and must not be transmitted over the internet unless legally required or with the individual's explicit separate consent. Any facial recognition data that must be retained should only be stored for the minimal time necessary.
- **Non-Sole Verification Method.** Facial recognition should not be the sole verification method when other alternatives exist. Individuals must be given the option to use alternative verification methods such as passwords or swipe cards if they decline facial recognition.
- **Use Limitation in Public Spaces.** Facial recognition devices may only be installed for public safety purposes and must be provided with clear signage. Collection areas must be legally designated to prevent excessive data collection.
- **Formal Registration for Large Scale Processing.** Once facial data storage exceeds 100,000 unique faces, data handlers must register with provincial-level cyberspace authorities within 30 working days. The filing document must include organizational background, the purpose and scope of facial data use, storage volume, security protocols, handling rules, operational procedures, and the

personal information protection impact assessment report. Any substantive operational change or cessation of FRT must also be reported within 30 days.

- **Collaborative Supervision and Public Participation**. Cyberspace and public security authorities have established information-sharing mechanisms to enhance inspections and enforcement. The public may file complaints to safeguard their rights, and violations will result in legal accountability.

China Issues Measures for Labeling AI-Generated and Synthetic Content

四部门联合发布《人工智能生成合成内容标识办法》

On March 14, 2025, the Cyberspace Administration of China, along with three other ministries, issued the Measures for Labeling AI-Generated and Synthetic Content (the Measures). The Measures, set to take effect Sept. 1, 2025, aim to standardize the labeling of AI-generated content to enhance information security and safeguard public interests.

The Measures introduce a dual-labeling system to ensure transparency:

- **Explicit Labels** – AI-generated content must be visibly marked with text, graphics, or other identifiers (e.g., watermarks stating "AI-generated").
- **Implicit Labels** – Metadata, digital watermarks, or other technical markers must be embedded within file data to enable traceability.

And different stakeholders must comply with the labeling requirements:

- **Content Generators** – Must apply both explicit and implicit labels to AI-generated content as specified.
- **Platforms & Distributors** – Required to implement technical measures to regulate dissemination and verify compliance.
- **Public Conduct** – Tampering, deletion, or forgery of labels is strictly prohibited, including the provision of tools enabling such actions.

By enforcing a dual-labeling approach and an end-to-end accountability system, the Measures provide a structured regulatory framework for AI-generated content. These rules aim to strike a balance between technological advancements and the need for robust information security.

Foreign Investment

China publishes 2025 Action Plan for Stabilizing Foreign Investment

《2025 年稳外资行动方案》发布

The 2025 Action Plan for Stabilizing Foreign Investment (the Plan) was released Feb. 19, 2025. Key points of the Plan include:

Expanding Opening-Up Sectors

To further open key industries, the Plan promotes pilot programs in telecom, health care, and education, supporting value-added telecom services, biotechnology advancements, and wholly foreign-owned hospitals. Additionally, authorities will explore new opening-up policies for the education and culture sectors to create a more globally integrated environment.

In manufacturing, all foreign investment restrictions will be abolished, ensuring equal treatment of domestic and foreign capital. Market access negative lists will be revised to promote consistency in regulations. Meanwhile, efforts to deepen service sector liberalization will focus on optimizing comprehensive pilot zones, broadening their scope, and prioritizing policy trials. The Plan also aims to advance biomedical innovation, allowing foreign investment in segmented biopharmaceutical production, facilitating innovative drug approvals, and streamlining medical device procurement to enhance access to cutting-edge health care technologies.

Enhancing Investment Facilitation

The Plan eases equity investment rules by lifting restrictions on domestic loans for foreign-invested companies, enabling cross-border share swaps through revised merger and acquisition regulations. To guide investment into high-quality manufacturing and modern services, the Catalogue of Industries Encouraging Foreign Investment will be updated, with a particular focus on developing central and western regions.

Additionally, policies will be explored to encourage foreign firms to reinvest their profits domestically, with pilot programs for investment reporting to improve transparency and track reinvestment trends.

Strengthening Platform Efficiency

National economic development zones will undergo reforms to delegate authorities and enhance infrastructure support, strengthening their appeal to foreign investors. Meanwhile, pilot free trade zones, including Hainan Free Trade Port, will see accelerated policy implementation to promote institutional opening-up and further integrate foreign investment into China's economy.

Improving Service Support

The Plan prioritizes key foreign investment projects, integrating them into national priority lists with streamlined policy and service guarantees. Financial institutions will be encouraged to offer funding support, while trade facilitation measures will optimize equipment inspections and combat intellectual property infringement.

To improve personnel mobility, negotiations for visa waivers will be accelerated, alongside optimizations in port visa policies for foreign business professionals.

International Trade

China promulgates Regulations for Implementing Anti-Foreign Sanctions Law

李强签署国务院令公布《实施〈中华人民共和国反外国制裁法〉的规定》

Premier Li Qiang has issued a State Council decree promulgating the Regulations for Implementing Anti-Foreign Sanctions Law of the People's Republic of China (the Regulations). The Regulations, which took effect immediately upon issuance, provide a comprehensive legal framework for enforcing countermeasures against foreign sanctions. Key points of the Regulations are:

- **Clarification of Property-Related Countermeasures**

  Article 7 defines the scope of "other types of property" referenced in Article 6, Item 2 of the Anti-Foreign Sanctions Law. These assets include cash, negotiable instruments, bank deposits, securities, fund shares, equities, intellectual property rights, accounts receivable, and other forms of property. To enforce countermeasures, departments such as the Ministry of Public Security, the Ministry of Finance, and the Ministry of Natural Resources are authorized to seize, detain, and freeze relevant assets.

- **Definition of Restricted Activities**

  According to Article 8, restrictions on transactions, cooperation, and engagements between Chinese entities and sanctioned parties extend across multiple sectors. These include, but are not limited to, education, science and technology, legal services, environmental protection, trade, culture, tourism, health care, and sports. The Ministry of Education, the Ministry of Science and Technology, and the Ministry of Justice will oversee enforcement within their respective domains.

- **Supplementation of Other Necessary Measures**

  Article 9 further outlines "other necessary measures" referenced in Article 6, Item 4 of the Anti-Foreign Sanctions Law. These may involve prohibitions on imports, exports, and investments within China, as well as restrictions on data and personal information transfers. Additionally, measures such as revocation or limitation of work permits, residency rights, and financial penalties may be enforced as required.

- **Authorization of Investigation and Consultation Powers**

  Under Article 4, relevant State Council departments are granted authority to conduct investigations and engage in foreign consultations to support the implementation of countermeasures.

- **Unified Standards for Decision Announcements**

  Article 5 mandates that countermeasure decisions specify key details, including targeted entities, measures to be applied, and their effective date. Furthermore, Article 11 requires official government websites to publish and promptly update announcements on the implementation, suspension, modification, or revocation of countermeasures.

- **Punishment Mechanism for Non-Compliance**

  Article 13 empowers authorities to impose corrective measures on entities that fail to comply with countermeasures. Sanctions may include exclusion from government procurement, tendering processes, international trade, and import/export activities. Restrictions may also be applied to data transfers, residency rights, and travel outside China.

- **Application Process for Adjustments**

  Under Article 14, affected organizations or individuals may submit applications to modify, suspend, or revoke countermeasures imposed on them. Applicants must provide evidence of corrective actions taken and demonstrate efforts to eliminate any consequences resulting from prior conduct.

** This GT Newsletter is limited to non-U.S. matters and law.*

Read previous issues of GT's China Newsletter.

Authors

This GT Newsletter was prepared by:

- George Qi | +86 (0) 21.6391.6633 | qig@gtlaw.com
- Dawn Zhang | +86 (0) 21.6391.6633 | zhangd@gtlaw.com
- Philip Ruan | +86 (0) 21.6391.6633 | ruanp@gtlaw.com