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China Newsletter | H2 2022/Issue No. 55

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This China Newsletter provides an overview of key developments during H2 2022 in the following areas:

Antitrust

- China's Supreme Court proposed revisions to civil litigation rules under the Anti-Monopoly Law, providing more comprehensive provisions over anti-monopoly civil litigation.

Civil Law

- Amendment to Law on the Protection of Rights and Interests of Women took effect, enhancing the protection of women's rights.
- China's Supreme Court proposed new judicial interpretations regarding the Contract Part of the PRC Civil Code, proposing several material changes to the regimes regarding the formation, validity, and termination of contracts.

Corporate

- China updated the draft amendment to the PRC Company Law, proposing new rules regarding liability for shareholder contributions, corporate governance, director liability, and mandatory cancellation.

Data, Privacy & Cybersecurity

- China initiated the mechanism for personal information protection certification, and updated the Guidelines for Certification of Personal Information Cross-Border Transfers.
- MIIT issued Measures for Data Security Management in Industrial and Information Technology, clarifying the scope and classification of data in the fields of industry and information technology, as well as the obligations of data processors.

Foreign Investment

- NDRC and MOFCOM jointly released the Catalogue of Industries for Encouraged Foreign Investment (2022 Version), further encouraging foreign investment in advanced manufacturing, modern service, and in the central, western, and northeastern regions.

Medical Treatment & Health

- The NMPA released newly revised Administration Measures for Drug Recalls, designating market authorization holders (MAHs) as the key responsible entity, and revising the regulatory framework.

Antitrust

China's Supreme Court Proposes Revisions to Civil Litigation Rules Under Anti-Monopoly Law

最高法计划修订反垄断民事诉讼司法解释

On Nov. 18, 2022, the Supreme People's Court (SPC) of China published an amended draft of the judicial interpretation (Draft Rules) of China's recently revised Anti-Monopoly Law (AML). The Draft Rules provide both procedural and substantive guidance for Chinese courts to hear and adjudicate litigation under AML, with a series of highlights as follows:

Exclusivity in jurisdiction of intellectual property (IP) and intermediary courts

The Draft Rules provide that all litigation brought under AML would be heard exclusively by the IP courts or the intermediary court appointed by SPC. A court of competent jurisdiction could hear and adjudicate any claim under AML, even when there was a valid arbitration clause between the parties.

Detailed rules on burden of proof

The Draft Rules propose detailed requirements surrounding allocation of burden of proof for different AML claims. For example, in civil litigation arising from illegal conduct as determined by the administrative body in an investigation, the plaintiff would not need to prove the existence of such illegal conduct, and the court could solicit opinions and explanations from the administrative body regarding the illegal conduct.

In addition, as a principle, the Draft Rules would require the plaintiff to prove the existence of a relevant market where the alleged illegal conduct occurred and provide supporting evidence. As an exception to the foregoing, plaintiffs alleging any horizontal monopolistic behavior as prescribed under sections (1) through (5) under Article 17 of AML (i.e., acts of cartel which are illegal per se under AML, like collusive price-fixing, reduction of supply, allocation of market, etc.) or any vertical monopolistic behavior as prescribed under sections (1) and (2) under Article 18 of AML (i.e., fixing resale price) would be exempt from the duty to prove the relevant market. The exception would lower costs for plaintiffs injured by prescribed illegal conduct.

Incorporation of the test formulated in the "pay-for-delay" case

The Draft Rules also incorporate rules SPC formulated in recent landmark AML cases. For example, in December 2021, SPC for the first time adjudicated the legality of a reverse payment agreement (i.e., a "pay for delay" deal), and formulated a two-step test to determine whether an agreement exists where a patent holder pays a non-patent drug maker for agreeing not to take actions including challenging the patent. The Draft Rules set forth a rule of general application that any agreement having the following two characteristics would be deemed illegal under AML:

- The patent holder grants or offers to grant the generic drug maker a substantial amount of money or compensation, and
- The generic drug maker promises not to challenge the patent at issue or delay the entry into market of its own drug product.

In setting forth the rule, the Draft Rules clarify that if the parties showed with evidence that such compensation was reasonable in amount to settle the patent-related dispute or has another justification, such an agreement would not be treated as violating AML.

Introduction of the "single economic entity" theory into determination of "horizontal monopoly"

The Draft Rules introduce the concept of a "single economic entity" (SEE) when clarifying that if two business undertakings constitute a SEE, they would not be treated as competitors; thus, any horizontal agreement between such constituent entities of a SEE would be exempt from the prohibition against horizontal monopoly under AML. Without defining a SEE, the Draft Rules ask the court to look into whether a particular entity has control or the ability to impose decisive influence over the other entity, or if both entities are controlled by or being decisively influenced by a third party when deciding whether they belong to a SEE.

Reasonable test to evaluate vertical restraints

The Draft Rules clarify that, in civil claims, the prohibition against vertical restraints would be subject to a reasonable test, i.e., the court would find an alleged vertical restraint illegal when (a) the evidence showing the restrictive effect on competition outweighed the evidence of pro-competitive effect, and (b) the defendant had significant market power in the relevant market. Such potential restrictive effect on competition would include increasing the barriers to market entrants, impeding improved efficiency in distribution, and restricting inter-brand competition; potential pro-competition effects would include preventing free-riding, increasing intra-brand or inter-brand competition, protecting a brand, improving pre-sale or post-sale services, and improving incentivizing innovation.

Importantly, the Draft Rules would provide for three exemptions to the vertical restraint prohibition in civil claims if the defendant could prove that: (a) the counterparty is a mere agent of the defendant without bearing any substantive commercial or operational risk, or (b) the defendant's market share is lower than a threshold % as published by the State Administration for Market Regulation (SAMR) under the "safe harbor rule," or (c) the restraint is to incentivize the counterparty to market new products and is implemented within a reasonable time period. As background, in a draft "safe harbor rule" SAMR published in June 2022 (not in effect yet), unless there is countervailing evidence that the anti-competition effect exists, the vertical restraint between two business undertakings would not be prohibited if the market share of each undertaking in the relevant market was below 15%.

Clarifying rules to determine dominant market power and abusive practices

The Draft Rules would allow the court to presume that dominance existed in a relevant market if there was evidence to support that (a) the business undertaking was able to, in a comparatively long period of time, maintain the price obviously higher than the market level and there was an obvious shortage of competition, innovation, and new entrants in the relevant market, or (b) the undertaking was able to in a comparatively long period of time maintain the market share obviously higher than the other competitors, and there was obvious shortage of competition, innovation, and new entrants in the relevant market. The Draft Rules request that courts consider the actual market and competition structure and apply common sense and economic theory when determining whether the dominance exists.

The Draft Rules would further clarify the "rule of thumb" to determine the existence of typical abusive practices by an undertaking holding dominant market power.

For example, for unfair pricing (i.e., excessively high or low sales/purchase price), the Draft Rules would allow a court to find a market-dominant undertaking's practice abusive if both of the following conditions were satisfied: (1) the sales/purchase price effective between undertaking and its customer/supplier was higher/lower than the price the same undertaking was selling/purchasing the same or comparable commodity in the upstream/downstream markets, and (2) the difference between the prices mentioned above was squeezing the margin of the counterparty and preventing the counterparty from being competitive in the relevant market. Except for the price in the upstream/downstream markets as referenced in the first part of the test, the Draft Rules would also ask the court to look into whether the alleged price was "appreciably" higher/lower than the comparable price by other competitors or in other geographic markets.

As another example, the Draft Rules would provide for a three-part test for a court to determine the existence of illegal "refusal to deal" by an undertaking with dominance in the relevant market: (1) the undertaking has either refused to enter into the transaction with the counterparty or insisted on unacceptable conditions resulting in the failure of the transaction, (2) the transaction is feasible from commercial, technical, and legal perspectives, and (3) the "refusal" has an appreciable effect on restricting competition in upstream or downstream markets. The Draft Rules would provide for examples of "justifiable causes" as exemptions to the abusive act satisfying the above three-part test, including change of circumstances or force majeure preventing the conclusion of the transaction, acts of bad faith, or other events on the part of the counterparty resulting in the reduced capability to conclude the transaction, etc.

For predatory pricing (i.e., selling at price below cost), the Draft Rules would allow a court to find such act by a business with market dominance abusive in either of the following circumstances: (a) the business undertaking is selling the commodity consistently below the average variable cost (AVC) or the average avoidable cost (AAC) during a comparatively long period of time, or (b) despite a price above AVC or AAC,

the undertaking is selling the commodity below the average total cost at a comparatively long period of time, in addition to evidence of the intent to prevent competition in the relevant market.

In addition to abusive conduct in offline markets, the Draft Rules would also provide for special considerations that the court should take into account when determining the existence of "dominance" or typical abusive practice for internet platform businesses.

Civil Law

Amendment to Law on the Protection of Rights and Interests of Women, in Effect as of Jan. 1, 2023

新修订的《妇女权益保护法》于2023年1月1日生效

On Oct. 31, 2022, the amendment to the Law on the Protection of Rights and Interests of Women (Amendment) was approved and passed by the NPC Standing Committee, to take effect Jan. 1, 2023.

The Amendment aims to strengthen the protection of the rights and interests of women and has added new articles to enhance women's protection in areas ranging from: (a) enjoyment of health, including but not limited to access to health care services, equality in reproductive health, etc.; (b) enhancing schools and employers' obligations in sexual harassment prevention; (c) equality in recruitment and employment; (d) property rights in rural collective economic organizations; and (e) related relief measures.

Key takeaways for employers:

- Develop and endorse a workplace harassment policy, which means employers should actively implement preventative measures to minimize harassment and to respond appropriately when harassment occurs;
- Realize equal employment opportunity for women. The employer should ensure there is no direct or indirect discrimination relating to gender, marriage, pregnancy, and maternity, and should oppose and avoid all forms of unlawful discrimination. This may include in (a) pay and benefits; (b) terms and conditions of employment; (c) dismissal; (d) selection for employment, promotion, training, or other development opportunities;
- Revise employment contracts to include "special protection clauses" for women employees. The specifics of such clauses remain unclear at the moment; based on current laws and regulations, "special protection clauses" may contain special labor protection during female employees' menstrual, pregnancy, maternity and lactation periods;
- Arrange women's health examinations annually. Achieve workplace safety for female employees by taking labor protection measures.

SPC solicits comments on Draft Interpretations on Book III of PRC Civil Code

最高法就民法典合同编通则解释征求意见

On Nov. 4, 2022, the Supreme People's Court (SPC) promogulated the Interpretations on the *Application of the General Provisions of Contracts of the Civil Code (Draft for Comment)* (《关于适用〈中华人民共和国民法典〉合同编通则部分的解释（征求意见稿）》) (the "Draft Interpretations"), seeking public comment.

The Draft Interpretations integrate and supplement the existing judicial interpretations on contract law, propose some material changes to the old regimes, and introduce new provisions as follows:

- Third-party liability for *culpa in contrahendo* (fault in conclusion of a contract): Article 6 of the Draft Interpretations provides that if a contracting party concludes a contract against its true intention due to third party's fraud or coercion and has suffered losses therefrom, the contracting party can hold such third party liable. Furthermore, if formation of a contract is based on a contracting party's special reliance on the third party, or the knowledge, experience, or information the third party provides, such third party may also be held liable for the contracting party's losses if it acts in bad faith or is at fault. This new provision would provide contracting parties a new approach to claim for the liabilities of the third party other than breach of contract or tort, and might substantially expand the liabilities of the third-party agents such as commercial banks, securities firms, accounting firms, appraisal firms and law firms, etc.
- The standard for formation of preliminary agreement and liability for breach: Article 7 of the Draft Interpretations proposes a three-step test for determining whether a preliminary agreement is formed: (i) the contracting parties agree to conclude a contract within a certain period either in the form of subscription letter, order letter, reservation letter, letter of intent, memorandum etc., or by paying a deposit, (ii) the parties and subject matter of such contract is definite, and (iii) the subscription letter, letter of intent, etc. is agreed to be "legally binding" between the parties.
- After execution of the preliminary contract, if one party refuses or fails to conclude the contract without justification or in bad faith, the other party may claim the losses suffered therefrom. If the preliminary agreement covers most of the contract terms to be concluded in the final agreement, the non-breaching party of the preliminary agreement may have a claim for expectation damages under the contract.
- Validity of a contract executed beyond authority: If an employee enters into a contract on behalf of his or her company on a matter beyond the scope of his or her authority or power, such contract should be void unless it constitutes an apparent agency. If a bona fide party to the contract make claims against such company, the company should assume the liability first and then may seek indemnification from such employee.
- Limitation to the termination of contract due to breach: Generally, the non-breaching party can elect to terminate the contract if the other party commits a breach; this falls into the scope of termination events. However, Article 55 of the Draft Interpretations proposes a restriction to such termination right, i.e., in the event the breaching party's breach is "significantly slight," this will not affect the non-breaching party's right to achieve the purpose of the contract; the non-breaching party can only choose to ask the breaching party to assume the corresponding liability for breach of contract or take other remedial measures, instead of terminating the contract. However, this proposed new rule is under debate.

Corporate

China Updates Amendment to Company Law

公司法修订草案二审稿公开征求意见

On Dec. 31, 2022, the National People's Congress released the *Second Deliberation Draft of the Amendment Bill to the PRC Company Law* (《中华人民共和国公司法(修订草案二次审议稿)》, the "Second Deliberation Draft"), seeking public comment (period now closed). Compared with the current Company Law and the *First Deliberation Draft of the Amendment Bill to the PRC Company Law* (the "First Deliberation Draft") released in December 2021, the Second Deliberation Draft proposes some significant changes as follows:

1. Reforms Related to Company Capital:

   - Authorized Capital: The First Deliberation Draft introduced an authorized capital mechanism, i.e., for the companies established as a Company Limited by Shares, through which the bylaws or company shareholder meeting can authorize the board of directors to issue new shares after establishment. The issuance of the new shares shall be approved by a two-thirds majority of the board. The Second Deliberation Draft further provides that the bylaws or the shareholder meeting can authorize the board to issue shares not exceeding 50% of the issued shares for consideration of cash only within three years.
   - Different Classes of Shares: Under the First Deliberation Draft, companies in the form of Company Limited by Shares may issue other classes or series of shares besides ordinary shares. Article 145 of the Second Deliberation Draft further provides that the bylaws shall specify priority of dividends, voting rights, transfer restrictions of other classes of shares, and measures to be taken to protect the rights and interests of minority shareholders. Furthermore, each share of other classes shall have the same number of votes as each share of ordinary shares for the election of supervisors or audit committee members.
   - Loss of equity ownership due to failure in capital contribution: The First Deliberation Draft introduced the so-called "loss of power" mechanism. If the company finds that any of its shareholders fail to make the full capital contribution within a certain period as ascribed in the bylaws, the board of directors shall send a written notice to such shareholder calling for the capital contribution and may grant a grace period of at least 60 days upon such notice. If such shareholder continues to fail to make the full contribution within such grace period, the company can send a notice of loss of power, and the shareholder will lose its ownership in equity that is not fully contributed upon the notice. In this case, such equity without an owner shall be transferred or deregistered (with reduction of capital). Based on the "loss of power" mechanism in the First Deliberation Draft, the Second Deliberation Draft further provides that (i) if such equity without an owner cannot be transferred or deregistered within six months, the other company shareholders shall make up for the uncontributed parts in proportion, and (ii) the shareholder that fails to fully contribute on time must compensate the losses suffered by the company.
   - Acceleration for capital contribution: The shareholder may need to make the capital contribution in advance. According to Article 53 of the Second Deliberation Draft, where a limited liability company is unable to pay off its overdue debts, the company or its creditors can require shareholders who have subscribed for equity but not made their capital contributions to accelerate their capital payments.

2. Strengthening director, supervisor and senior management liabilities:

   – Article 190 of the Second Deliberation Draft provides that, if a third party suffers from losses or damages due to director or senior management staff performance of their duty, the company shall be liable for such losses or damages; if such director or senior management staff is at fault or responsible for serious negligence, they too shall also be liable for losses or damages.
   – The company can also purchase D&O insurances for its directors, as newly provided by Article 192 of Second Deliberation Draft, and the board of directors shall notify the shareholder meeting with the insurance amount, coverage and premium rates, etc.

3. Changes to Corporate Governance:

   – The shareholder meeting may authorize the board of directors to make resolutions on the issuance of corporate bonds. Article 59 of the Second Deliberation Draft removes from the following shareholder meeting duties: (i) deciding on the company's business policy and investment plan, and (ii) approving the company's annual financial budget and final account plans.
   – Pursuant to the Second Deliberation Draft, a limited liability company may not need to set up a board of supervisors or supervisor(s) if the company has set up an audit committee within the board of directors according to its bylaws. Furthermore, upon the unanimous consent of all shareholders, a small-scale limited liability company may even have no supervisor.

Data, Privacy & Cybersecurity

China Initiates PIP Certification, Updates Guidelines for Certification of PI Cross-Border Transfers

中国启动实施个人信息保护认证并修订个人信息跨境处理活动安全认证规范

On Nov. 18, 2022, the State Administration for Market Regulation (SAMR) and the Cyberspace Administration of China (CAC) jointly released the *Rules on Implementation of Personal Information Protection Certification* (《个人信息保护认证实施规则》) (the Rules). To maintain compliance with the Rules, the National Information Security Standardization Technical Committee of China (TC260), an organization affiliated with the Standardization Administration of China and governed by CAC, issued the revised *Security Certification Specification for Cross-border Processing of Personal Information* (TC260-PG-20222A) (Cross-border Certification Guidelines V2.0) on Nov. 8, 2022 , replacing Version 1.0 of the Cross-border Certification Guidelines issued on June 24, 2022. The promulgation of the Rules and the Cross-border Certification Guidelines V2.0 marks the initiation of the Personal Information Protection Certification (PIP Certification) mechanism in China.

1. Who may rely on PIP Certification for cross-border data transfer?

According to the description and Article 1 of the Rules, personal information handlers ("个人信息处理者") conducting personal information (PI) processing activities, which include collection, storage, use, handling, transmission, provision, disclosure, deletion and cross-border processing, are "encouraged" to obtain the PIP Certification. The same goals are also reflected in the Cross-border Certification Guidelines V2.0, although the Guidelines 2.0 note that PIP Certification should be a "voluntary" certification.

Notably, the Cross-border Certification Guidelines V2.0 define "PI handlers" as the "organization or individual who determines the purposes and means of the processing," which is more similar to the concept of data controller under Europe's General Data Protection Regulation (GDPR).

Under Article 38 of the *Personal Information Protection Law* (PIPL), PIP Certification is recognized as one of the legal bases to transfer PI outbound, along with the national security assessment and the standard contracts. For multinational companies with multiple offices both in and out of China, if they do not meet the thresholds for declaring a national security assessment (mainly including (i) transferring critical data outbound, (ii) having a procession of China-based PI of more than one million individuals, or (iii) having transferred personal information of 100,000 individuals or sensitive personal information of 10,000 individuals in total outbound since Jan. 1 of last year), the PIP Certification would be a better choice to keep in compliance. According to Section 2 of the Cross-border Certification Guidelines V2.0, multinational enterprises or foreign PI handlers who operate China businesses may designate their Chinese subsidiaries, affiliates or third-party agencies to apply for PIP Certification. However, Guidelines V2.0 also require PI handlers which apply for the PIP Certification to be legal persons (i.e., excluding individuals, partnerships, branches, representative offices, etc.) in good standing with good reputation and credit.

2. The Certification Body:

Currently, the only certification body for PIP Certification is the China Cybersecurity Review Technology and Certification Center (CCRC), an organization affiliated to SAMR carrying out various cybersecurity certifications, such as APP Security Certification and Data Security Management Certification, etc. Notably, at the end of January 2023, CCRC released the webpage for the PIP Certification, along with the online application portal and the application form, indicating that CCRC has officially started accepting applications for PIP Certification. Currently, the application should be submitted in Chinese and an applicant should provide the following information in the application form:

- The basic information about the applicant, including applicant's full name, address, legal representative, data protection officer, etc.;
- The scope of the PI processing activities and the volume of the PI to be processed. In case of cross-border transfer, the applicant should also provide certain information about the overseas PI receiver(s) (including its name, address, contactor; the volume of the data; the purpose of the transfer; the scope, type, sensitivity, transfer method, storage period and storage place of the PI to be transferred); and
- Materials or documents such as (i) applicant's certificate of good standing, (ii) the privacy impact assessment report and relevant materials, (ii) business processes and descriptions, (iv) organization chart and function description, (v) the data catalogue.

3. Certification Marks and Technical Standards:

Depending on whether the processing activities involve cross-border transfer, PI handlers must comply with different technical standards, and the PIP Certification marks granted to the PI handlers will be different, as shown in the following table. Strictly speaking, the Cross-border Certification Guidelines themselves are not "technical standards" but "practical guidance." Therefore, China now is drafting another National Standard called the *Information Security Technology — Certification Specification for Cross-border Transfer of Personal Information* (《信息安全技术 个人信息跨境传输认证要求》), to replace the Guidelines in the future.

Certification Type:	**PIP**	**PIPCB**
Applicable Scenarios:	PI processing without cross-border transfer	PI processing involving cross-border transfer
Technical Standards:	*Information Security Technology — Personal Information Security Specification* (GB/T 35273).	GB/T 35273; and
Certification Marks:		
	* "A B C D" stands for the code of the certification body.	

4. Certification Procedure:

Currently, the applicant has to submit its application for PIP Certification via CCRC's online portal as mentioned above, where the applicant should register an account and file some basic information such as the name, address, and person in charge of the company first. The CCRC staff would briefly review the information provided and decide whether the account could be created. Upon account creation, the applicant can procced with the application and file the application form online.

Once the applicant has submitted the application materials, CCRC will conduct the review as follows: (i) review the submitted materials and ask for supplemental information (if any), (ii) designate a technical verification agency to conduct the technical verification, and (iii) conduct an on-site examination. The applicant would be given a chance to rectify any errors if it fails to pass the technical verification or the on-site examination the first time. However, if the rectification by the applicant still fails to meet certification requirements, CCRC will terminate the certification procedure by written notice. However, if the applicant passes all the above steps or the rectification (if any) is acceptable, CCRC will issue the PIP Certification. After obtaining the certificate, the applicant remains subject to CCRC supervision.

5. Validity of the Certification:

Once granted, a PIP Certification will be valid for three years, provided the PI handlers continuously meet the requirements during the post-certification CCRC supervision. If the PI handlers fail to meet the requirements, the certificate granted to the PI handlers would be suspended or even revoked. If the PI handlers need to renew the PIP Certification certificate upon its expiration, the PI handlers should submit a renewal application to the certification body within six months before the expiration date.

6. Updates to Cross-border Certification Guidelines V2.0:

In Version 1.0 of Cross-border Certification Guidelines, the applicability of the PIP Certification is only limited to two scenarios: (i) the intracompany transfer within the multinational companies and (ii) processing activities over China-based PI by oversea PI handlers. However, Version 2.0 breaks this limitation, indicating that the PIP Certification could apply to all cross-border scenarios. The Cross-border Certification Guidelines V2.0 also supplement and detail the basic requirements for the data transfer agreement, data protection department, Privacy Impact Assessment, protection to PI, and the

obligations of the PI handlers and overseas PI importers, in order to remain compliant with the Rules, other regulations, and the draft Standard Contractual Clauses for cross-border transfer of PI of China. Notably, the Cross-border Certification Guidelines V2.0 require that:

- The PI handler who applies for the PIP Certification should be a lawful legal person (i.e., excluding individuals, partnerships, branches, representative offices etc.) in good standing with good reputation and credit.
- the PI handler and overseas PI importer must specify the allocation of liabilities arising from the violation of data subjects' rights in their data transfer agreement;
- the data protection department established by the PI handler and overseas PI importer must conduct regular audits on the compliance with China's data and cybersecurity laws, maintain a record of cross-border data transfer for at least three years and present it to the Chinese regulators as needed, and accept the supervision of the certification body over the PI processing activities;
- the PI handler and overseas PI importer must acknowledge and facilitate specific data subject rights, including that the data subjects may make claims against either the PI handler or the overseas PI importer for compensation in case of any infringement of their rights;
- the PI importer must monitor the data protection laws in its jurisdictions. If the legal landscape in its jurisdiction changes and makes it impossible to satisfy the PIP Certification requirements, the PI importer must inform the PI handler and the certification body immediately;
- the PI importer shall agree that any dispute over the cross-border data transfer will be governed by Chinese law.

MIIT Issues Measures for Data Security Management in Industrial and Information Technology

工信部出台《工业和信息化领域数据安全管理办法》

On Dec. 13, 2022, the Ministry of Industry and Information Technology (MIIT) issued the *Measures for Data Security Management in the Field of Industrial and Information Technology (for Trial Implementation)* (hereinafter referred to as "Measures"), effective Jan. 1, 2023. As the supervisor of the data in the field of industry and information technology, the MIIT brought the Measures to the land aiming to launch the mechanism of data classification and grading as specified in the Data Security Law, and to enhance data processors' obligation for data security management.

Scope and Subjects:

The Measures regulate all data processors in industrial and information technology. To give clarity on the Measures' scope of subjects and target activities, the Measures define that "the data in the field of industrial and information technology" covers three categories of data: industrial data, telecommunications data, and radio data:

Categories of Data	Definitions	Remarks
Industrial Data	data generated and collected in the course of research and development, design, production, administration, maintenance, platform	Such data might also include the personal data generated and collected therefrom (e.g., human faces image collected by autonomous vehicles); In such

Categories of Data	Definitions	Remarks
	operation, etc. in various industrial sectors.	scenarios, the data processors should also comply with Personal Information Protection Law ("PIPL"), as well as the Measures.
Telecommunications Data	data generated and collected in the course of telecommunications operations	
Radio Data	radio frequencies, transmitters (stations), and other radio wave parameters generated and collected in the course of conducting radio business	

Accordingly, the Measures further define that "data processor in the field of industrial and information technology" refers to industrial enterprises, software and IT service enterprises, telecom operators and radio data operating entities that conduct data processing activities including, without limitation, collecting, storing, using, processing, transmitting, providing or publicizing data.

Data Classification:

According to the degree of potential damage in the event of data being tampered, destroyed, disclosed, illegally obtained or used, the Measures divide data into three classes, i.e., general data, important data, and core data, and implement a differentiated regulatory requirement based on the classification of the data. The Measures further provide that MIIT will develop an industry-specific catalog for important data and core data and publish specifications and standards to guide data processors to conduct data classification and prepare its own data catalog.

The details of the data classification and regulatory requirements are set forth below:

Data Classification	Scope	Regulatory Requirement
General Data	1. Data that has little negative impact on the public interest or legitimate interests of individuals and organizations; 2. Data with few affected customers or enterprises, small scope of production and living areas, short duration, small impact on business operations, industry development, technological progress, and industrial ecology.	N/A
Important Data	1. Data that threatens the following areas: political, territorial, military, economic, cultural, social, scientific and technological, electromagnetic, network, ecological, resource, nuclear security, etc., affecting overseas interests, biological, space, polar, deep sea, artificial intelligence or other key areas related to national security;	The data catalog for important data and core data prepared by data processors must be filed with the local competent authorities. The filing must cover information including the data sources, classification, levels, sizes, carriers, processing purposes and methods, scope of

Data Classification	Scope	Regulatory Requirement
	2. Data that seriously impacts the development, manufacture, operation, or economic interests of the industry and information technology sector; 3. Data that causes a major security incident or production incident, with serious impact on public interests or the legitimate rights and interests of individuals and organizations, as well as a large negative social impact; 4. Data that has cascade effects, with the scope of impact involving multiple industries, regions, or multiple enterprises in the industry, or with a long duration of consequences causing serious impact on industry development, technological progress, or industrial ecology.	use, responsible units, external sharing, cross-border transmission, security protection measures, etc., excluding the data content itself. In the event of material change to the content of the filing, data processors must alter the filing within 3 months. "Material change" refers to a certain type of important data and the size of the core data (the number of data entries or the total amount of storage, etc.) changes of more than 30%, or other changes in the content of the filing record.
Core Data	1. Data that threatens the following areas: political, territorial, military, economic, cultural, social, scientific and technological, electromagnetic, network, ecological, resource, nuclear security, etc., overseas interests, biological, space, polar, deep sea, artificial intelligence, or other key areas related to national security; 2. Data that causes significant impact on the field of industry and information technology and its important backbone enterprises, key information infrastructure, important resources, etc.; 3. Data that causes significant damage to industrial production operations, telecommunications networks or internet operation services, radio business development, etc., resulting in widespread shutdowns and production stoppages, large-scale radio service interruptions, large-scale network and service paralysis, or loss of a large number of business processing capabilities.	

Data Security Management Obligations of Data Processors:

The Measures also require data processors to implement a data security management system that covers the entire lifecycle including collection, storage, processing, transmission, provision, publication, destruction, cross-border transmission, transfer, and delegated processing of the data concerned.

Foreign Investment

NDRC and MOFCOM jointly released the Catalogue of Industries for Encouraged Foreign Investment (2022 Version)

国家发展和改革委员会、商务部发布《鼓励外商投资产业目录（2022年版）》

On Oct. 26, 2022, the National Development and Reform Commission (NDRC) and the Ministry of Commerce (MOFCOM) jointly released the updated *Catalogue of Industries for Encouraged Foreign Investment* (2022 Catalogue), which supersedes the 2020 version and took effect Jan. 2, 2023.

Similar to the previous version, the 2022 Catalogue consists of two sub-catalogues, a national catalogue that covers the entire country and a central and western catalogue that covers central, western, and northeastern regions and the Hainan province. The 2022 Catalogue contains 1474 items, 239 additional and 167 revised items, and further expands the scope of encouraged foreign investment.

Key changes in the 2022 Catalogue:

- Further encourage foreign investments in the advanced manufacturing and modern service sectors;

  New added or revised items (for instance and without limitation):

  - *Health care*: R&D and production of drugs for rare diseases and special drugs for children; R&D and production of consumables related to the pharmaceutical manufacturing industry; separation and purification media, solid phase synthesis media, chiral resolution media, consumables for drug impurities control and detection, etc.
  - *Advanced Material*: Manufacture of organic polymers, manufacture of high-tech non-ferrous metal materials and relevant products, etc.
  - *Artificial Intelligence*: R&D and manufacture of smart healthcare products for the elderly.
  - *Energy Efficiency*: advanced system integration technology and service of low carbon, environmental protection, green energy saving and water saving, cleaning of traditional energy, engineering construction and technical service, clean production evaluation, certification, audit, etc.
  - *Vocational Education*: human resources services; non-academic training institutions, etc.

- Further encourage foreign investments in central, western, and northeastern regions. The 2022 Catalogue adds multiple new items catering to the specific advantages (e.g., advantages of labor force, resources, and location) of central, western, and northeastern regions.

  New added or revised items (for instance and without limitation):

  - *Hainan province*: Manufacture and process new types of medical devices, equipment, and medical materials, especially from entities that own their intellectual property.
  - *Shanxi province, Hunan province, and Anhui province*: Development and manufacture of intelligent terminal products like smart phones, tablet PCs, and related key components.
  - *Heilongjiang province*: R&D and innovation of black soil conservation and utilization technology.
- Consequently, favorable policies will be available to qualified foreign investments as follows:
  - Any equipment/tools imported for self-use with a value less than the total investment can be imported duty free;
  - Industrial land would be preferentially supplied with intensive land use and the land transfer floor price would be equal to 70% of the national minimum price of industrial land;
  - The rate of corporate income tax would be reduced to 15% for qualified enterprises which are engaged in encouraged industries in the western region and Hainan province.

Medical Treatment & Health

The NMPA released the newly revised Administration Measures for Drug Recalls

国家药监局发布《药品召回管理办法》

Following the revision of the PRC Drug Administration Law and the PRC Vaccine Administration Law, on Oct. 24, 2022, the National Medical Products Administration (NMPA) issued the newly revised Administration Measures for Drug Recalls (Measures), which took effect Nov. 1, 2022.

Key changes of the revised Measures:

- *Change of responsible entity*: Market authorization holders (MAH), instead of manufacturers, are the key responsible entity of drug recalls;
- *Further clarification of the scope of drug recalls*: Any drugs with quality or safety issues, i.e. in violation of laws and regulations administered by the NMPA during research, manufacture, storage, labeling, etc., should be recalled following procedures prescribed in the Measures. Any drug that has already been seized or impounded by the drug supervision and management authorities does not fall within the scope of drug recalls;
- *Overseas drug recalls*: For drugs manufactured overseas and involved with recalls in China, the domestic authorized agent designated by the overseas MAH should fulfill the required recall obligations;
- *Public notification*: The MAH should publish the drug recall announcement on their official website or via news media (which focuses on medical and health news). Any class I or class II drug recalls need to be announced on the provincial drug administration department's website.

In addition to the above key changes, the Measures also clarify the procedures of drug recalls, methods of dealing with recalled drugs, etc. Any violations of the Measures will be punished according to the Article 135 of the Drug Administration Law of the PRC, which includes a fine of not less than five times but not more than ten times the value of the recalled drug.

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

Read previous issues of GT's China Newsletter.

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