

## China Legal Newsletter

October 2024

**This newsletter highlights key recent developments in China's laws and regulations. Specifically, it focuses on the laws and regulations related to foreign investment, market access, foreign debt administration, data economy, privacy and cybersecurity, labor and employment, life sciences and healthcare, as well as other topics.**

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## Foreign investment

### NDRC and MOFCOM releases the latest version of the negative list for foreign investment

On September 6, 2024, the National Development and Reform Commission (NDRC) and the Ministry of Commerce of China (MOFCOM) jointly issued the *Special Administrative Measures (Negative List) for Foreign Investment Access (2024 Edition)* (2024 Negative List), that will come into force on November 1, 2024. At the same time, the *Special Administrative Measures (Negative List) for Foreign Investment Access (2021 Edition)* (2021 Negative List) will be repealed.

Compared with the 2021 Negative List, the 2024 Negative List reduced the number of nationwide restrictive measures on foreign investment access from 31 to 29. Notably, all restrictive measures in the manufacturing sector have been completely abolished, including the following two measures: “for the printing of publications, the controlling stake must be held by the Chinese party” and “investment in the application of steaming, stir-frying, moxibustion, calcination and other processing techniques for Chinese herbal medicines, as well as the production of confidential prescription products of proprietary Chinese medicines shall be prohibited”. Hence, the manufacturing sector has been fully opened up to foreign investment.

## Market access

### New opinions released to improve the market access system

On August 1, 2024, the General Office of the CPC Central Committee and the General Office of the State Council issued the *Opinions on Improving the Market Access System*, which aim to improve the administration model of the *Negative List for Market Access*.

According to the opinions, the market access administrative measures set by laws, administrative regulations, decisions of the State Council and local regulations, as well as the temporary market access administrative measures set by the rules of governments of provinces, autonomous regions and municipalities directly under the Central Government in accordance with the law, should all be included in the national unified *Negative List for Market Access*. All types of national-level access lists and industrial policies, investment and environmental policies, territorial spatial planning and other items compiled as required by law and related to market access should all be included in the administration of the *Negative List for Market Access*. All types of business operators may enter fields outside this negative list on an equal basis in accordance with law. It is strictly forbidden to set up access permits outside this negative list, add access conditions, or set up access obstacles in the process of implementing franchising, designated operations, testing and certification, etc. in violation of regulations. The *Negative List for Market Access* will be dynamically adjusted.

The current *Negative List for Market Access (2022 Edition)* was issued by the National Development and Reform Commission and the Ministry of Commerce of China on March 12, 2022. The list is divided into two categories: prohibited businesses and licensed businesses. Market participants are not allowed to engage in prohibited businesses. For licensed businesses, including requirements and procedures for relevant qualifications, technical standards and licenses, etc., the market participants should submit an application for the administrative authority to decide on whether to grant access or not, or the market participants should enter the business in compliance with the access conditions and methods prescribed by the authority. The 2022 edition lists 6 items for which access is prohibited and 111 items that are subject to license requirements. All types of market participants may enter businesses that are not on the negative list on an equal basis in accordance with the law.

The *Negative List for Market Access* applies to both foreign and Chinese domestic investors. Meanwhile, foreign investors are also subject to the *Special Administrative Measures (Negative List) for Access of Foreign Investments*.

## Foreign debt administration

### NDRC releases measures to facilitate high-quality enterprises in borrowing foreign debt

On July 12, 2024, the National Development and Reform Commission of China (NDRC) issued the *Circular on Supporting High-Quality Enterprises in Borrowing Medium and Long-Term Foreign Debt and Promoting High-Quality Development of the Real Economy*, which has been implemented from July 29, 2024. In order to facilitate high-quality enterprises in obtaining cross-border financing, the circular provides simplified requirements for the approval and registration of medium and long-term foreign debt (which refers to debt instruments with a maturity of more than one year, denominated in domestic or foreign currency, borrowed from abroad by enterprises in the territory of China and their controlled overseas enterprises or branches, and the principal and interest of which are repaid as agreed) borrowed by such enterprises in China.

#### 1. Eligibility criteria for high-quality enterprises:

According to the circular, the NDRC will focus on supporting high-quality enterprises that meet all of the following conditions at this stage:

- (a) In compliance with the requirements of the *Administrative Measures for Review and Registration of Medium and Long-term Foreign Debts of Enterprises* (NDRC Order 2023 No. 56) and other related regulations;
- (b) Production and operation are in compliance with national macroeconomic control and industrial policies;
- (c) The operating income scale has ranked among the top five in the industry in the past year, with indicators such as the asset-liability ratio better than the industry average;
- (d) Have an international credit rating of investment grade (BBB- or above) or a domestic credit rating of AAA; and
- (e) In the past three years, (1) there has been no default on domestic or foreign debt and there is no continuous delay in the payment of principal and interest; (2) there has been no major violations of any law or regulation, and the enterprise has not been included in the list of seriously untrustworthy entities; (3) the financial statements have not been issued by a certified public accountant with a negative opinion or being unable to express an opinion, and if the certified public accountant has issued a qualified opinion, the material impact of the matters covered by the qualified opinion has already been eliminated.

Enterprises seeking to apply the simplified requirements need to provide supporting documents to the NDRC to prove its eligibility.

#### 2. Simplified requirements on the approval and registration of foreign debt:

For eligible enterprises, the NDRC will offer special review with simplified requirements to expedite the approval and registration of foreign debt. The simplified requirements include:

- (a) The enterprise is allowed to submit an application for an annual planned consolidated foreign debt quota which also covers its subsidiaries, which is expected to provide flexibility for group companies in allocating the foreign debt quota among different entities;
- (b) For an international commercial loan, if the enterprise is unable to provide the signed loan agreement but can provide the intention document of the lending institution, it can obtain the registration without the loan agreement, which should be supplemented afterwards when submitting information to the NDRC after the first drawdown of the loan;
- (c) For the issuance of overseas bonds, if the lead underwriter has not yet been determined, the enterprise can still obtain the registration. When the enterprise submits information to the NDRC after the issuance of each overseas bond, it should supplement the due diligence report and the letter of commitment to authenticity of the lead underwriter;
- (d) For the enterprise with domestic credit rating of AAA and international credit rating of A- or above, the legal opinions of a professional institution in the application documents could be issued by the internal legal or compliance department of the enterprise (while the standard requirement for general enterprises is that the legal opinion should be issued by a professional institution).

## Data economy, privacy and cybersecurity

### TC260 releases the practical guide for identifying sensitive personal information

On September 14, 2024, the National Technical Committee 260 on Cybersecurity of Standardization Administration of China (TC260) released the *Circular on the Practical Guide to Cybersecurity Standard - Guide for Identifying Sensitive Personal Information*. This guide aims to guide personal information processors in identifying sensitive personal information (SPI) and provide a reference for the processing and protection of such information.

Under the *Personal Information Protection Law of China*, SPI is defined as personal information that, once leaked or illegally used, can easily lead to infringement of human dignity or harm to the personal or property safety of a natural person. The guide further elaborates on the rules for identifying SPI and provides common categories and examples.

According to the guide, personal information processors shall identify SPI based on the following rules:

1. Personal information that meets any of the following conditions shall be identified as SPI: (a) once leaked or illegally used, it can easily lead to the infringement of human dignity; (b) once leaked or illegally used, it can easily lead to harm to personal safety; (c) once leaked or illegally used, it can easily lead to harm to property safety.
2. Personal information belonging to common categories of SPI shall also be identified as SPI, including information related to biometric recognition, religious beliefs, specific identity, medical and health data, financial accounts, personal location tracking, minors under the age of 14, and other common SPI. The guide also provides a definition and a list of examples for each common category.
3. For multiple pieces of general personal information (non-SPI), it is necessary to consider their overall attributes once aggregated or integrated, as well as the potential impact, if leaked or illegally used. If any of the conditions described in point 1 above is met, the aggregated or

fused personal information as a whole should be identified and protected with reference to SPI.

4. Personal information prescribed as SPI by specific laws and regulations shall also be identified as such.

Business operators are suggested to review whether their practices regarding SPI identification and personal information processing comply with the guide.

## Labor and employment

### Standing Committee of the NPC issues policy on extending retirement age

After years of discussion, on September 13, 2024, the Standing Committee of the National People's Congress (NPC) finally issued the *Decision on Implementing the Gradual Extension of the Statutory Retirement Age*, which will take effect on January 1, 2025. The decision also approves the *Measures of the State Council on the Gradual Extension of the Statutory Retirement Age*, which provide practical rules for implementing the decision.

Key highlights of the decision and the measures include:

1. Gradual extension of statutory retirement age: the decision aims to extend the statutory retirement age for male employees from the current 60 years to 63 years. For female employees, the statutory retirement age will increase from the current 50 years (applicable to non-management and non-technical positions) and 55 years (applicable to management and technical positions) to 55 years and 58 years, respectively. The extension will be implemented gradually over 15 years, starting from January 1, 2025. As further specified in the measures, the new statutory retirement age will be connected with the date of birth, meaning that the later a person is born, the later his/her retirement age will be. The measures also provide detailed tables of statutory retirement age corresponding to the date of birth.
2. Gradual increase in minimum social security payment years: employees who reach the statutory retirement age must also meet the minimum social security payment years requirement to receive their pension. The measures will increase such requirement from the current 15 years to 20 years. The increase will be achieved gradually from January 1, 2030, by adding 6 months' social security payment requirement each year.
3. Flexible retirement options: according to the measures, employees who meet the minimum social security payment years may voluntarily opt for early retirement (before the statutory retirement age), provided that the early retirement period does not exceed 3 years, and that the early retirement age is not lower than the current statutory retirement age (50 or 55 years for female employees and 60 years for male employees). Meanwhile, for employees who reach the statutory retirement age, their retirement may be delayed based on mutual agreement between employers and employees, with the delayed period not exceeding 3 years unless otherwise specified by law.

## Life sciences and healthcare

### Further pilot opening up to foreign investment in medical sector

According to the *Special Administrative Measures (Negative List) for Foreign Investment Access (2024 Edition)* (2024 Negative List) issued by the National Development and Reform Commission

and the Ministry of Commerce on September 6, 2024, "the development and application of technologies of human stem cells and gene diagnosis and therapy" is still prohibited from foreign investment. Additionally, foreign investment in medical institutions is still limited to the form of equity joint ventures with Chinese partners. However, almost simultaneously with the release of the 2024 Negative List, the Ministry of Commerce, the National Health Commission and the National Medical Products Administration issued the *Notice on Carrying out Pilot Work on Expanding Opening-up in the Medical Sector* on September 7, 2024, which sets the tone for pilot opening up to foreign investment in the afore-mentioned fields.

According to the notice, starting from September 7, 2024, foreign-invested enterprises are allowed to engage in the development and application of technologies related to human stem cells as well as gene diagnosis and treatment in the Pilot Free Trade Zones of Beijing, Shanghai, Guangdong and the Hainan Free Trade Port. This includes the registration and production of relevant products. All products that are duly registered and approved for production may be used nationwide. In addition, the notice explicitly proposes to allow the establishment of wholly foreign-owned hospitals in Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou, Shenzhen, and the entire Hainan Island (excluding hospitals practicing traditional Chinese medicine and M&A of public hospitals). The relevant specific conditions, requirements and procedures will be announced separately. Previously, relevant laws and regulations only allowed Hong Kong, Macao and Taiwan service providers to set up wholly owned hospitals in mainland China. The notice aligns with China's policy direction of relaxing market access in the medical sector and is expected to further promote its opening.

### **NMPA publicizes Medical Device Administration Law (Draft for Comment)**

On 28 August 2024, the National Medical Products Administration (NMPA) issued the *Medical Device Administration Law (Draft for Comments)* and solicited public opinions. The draft is supposed to be the first statute to regulate medical device in China. At present, the highest-level regulation in this field is the *Medical Device Supervision and Administration Regulations*, which is an administrative regulation promulgated by the State Council, with its hierarchy lower than the statute.

The draft has 11 chapters and 190 articles in total, including chapters of general provisions, standards and classifications of medical devices, research and development, production, sale, import and export, use, warning and recall of medical devices, supervision and administration, legal responsibilities and miscellaneous provisions. The draft covers the supervision and administration of all aspects throughout the lifecycle of medical devices.

Highlights of the draft include:

1. **Allowing transfer of registration certificates:** the draft stipulates that, with the approval of the drug supervision and administration departments, the registrant of medical device can transfer the medical device registration certificates. As there is no clear path for the transfer of medical device registration certificates under the current regulatory regime, the draft intends to make breakthrough in this regard in order to meet the practical needs of the market.
2. **Strengthening responsibilities of domestic agents in China:** the draft defines domestic agents of imported medical devices as "Domestic Responsible Persons" and stipulates that (a) the Domestic Responsible Person shall be a corporate legal person that has obtained a medical device production or operation license in China; and (b) the Domestic Responsible Person shall bear joint and several liability with the registrant or recorder of the imported medical device.
3. **Cancelling the mandatory industry standard requirements:** the current regulatory regime requires that the medical device products shall comply with corresponding mandatory national



standards; if there is no mandatory national standard, the products must comply with corresponding mandatory industrial standards. This requirement contradicts what is established in the *Standardization Law*, which stipulates that the industrial standards are only recommended rather than mandatory. And inconsistency has therefore been caused in practice when the regulatory authorities of different levels and different places review the medical device registration applications. To cope with this dilemma, the draft deletes the requirement of compliance with mandatory industrial standards and indicated that, in case there is no mandatory national standard, it is encouraged to adopt recommended national standards.

4. Establishing the medical device warning system: China has established the medical device adverse event monitoring system. However, to cover the quality and safety of medical devices throughout their lifecycle, a more comprehensive warning system would be required. The draft proposes the establishment of a medical device warning system to monitor, identify, evaluate and control adverse events of medical devices and other harmful events related to the use of medical devices that cause or may lead to human injuries. The draft also proposes supporting measures and requirements related to the warning system.
5. Emphasizing innovations and encouraging cross-disciplinary research: the draft requires the strengthening of originality, leading science and technology, and core technology research. In addition, the Draft explicitly encourages the cross-disciplinary research in scientific fields such as life science, materials science, applied science, etc. It is expected that local governments may provide more favorable policies accordingly in the future.

## Other topics

### **Supreme People's Court clarifies the validity of "pay-if-paid" clause between large enterprises and small/medium-sized enterprises**

On August 27, 2024, the Supreme People's Court issued the *Reply Regarding the Validity of Clauses Between Large Enterprises and Small/Medium-sized Enterprises Stipulating Payments Contingent on Third-Party Payments* to further clarify the validity of "pay-if-paid" clause in contracts between large enterprises and small/medium-sized enterprises.

According to the reply, if a large enterprise agreed with a small or medium-sized enterprise in a contract for construction or procurement of goods or services that payment by the large enterprise shall be subject to its receipt of payment from a third party, such clause shall be deemed invalid as it violates the *Regulations on Guaranteeing Payment of Funds to Small and Medium-sized Enterprises*.

The reply further specifies that, after determining that the clause is invalid, the people's court shall reasonably determine the payment term of the large enterprise and corresponding liability for breach of contract liability in accordance with the specific circumstances of the case, taking into account the industry norms and trading habits of the parties. If the parties have agreed on the standard for calculating and paying interest on the arrears, it shall be decided in accordance with the agreement; if the agreement is illegal or there is no agreement, the interest shall be calculated according to the one-year loan market prime interest rate announced by the China Foreign Exchange Trade System. Where a large enterprise requests a reduction of liability for breach of contract on the ground that the contract price already includes compensation for late payment, the people's court may support it if such defense is sustained upon review by the court.

Under the Chinese law, small/medium-sized enterprises shall be determined according to relevant classification criteria approved by the State Council. The criteria are based on the number of

employees, business income, total assets and other indicators and are in light of the characteristics of the relevant industries. Large enterprises are those other than the small/medium-sized enterprises.

### **GAC optimizes the record-filing process for importers and exporters of imported foods**

On August 13, 2023, the General Administration of Customs (GAC) issued the *Announcement on Matters Concerning the Launch of Filing Functions for Importers and Exporters of Imported Foods in the Unified Management Subsystem for Parties subject to Customs Administration (3.0 Version)*, which became effective since September 5, 2024.

According to the announcement, the GAC has launched the record-filing management function for importers and exporters of imported foods in the Unified Management Subsystem for Parties subject to Customs Administration (Version 3.0). Overseas exporters or agents as well as food importers in China may submit record-filing applications to customs through the China International Trade "Single Window" or "Internet + Customs" platform online. Alternatively, food importers may submit the paper Record-Filing Application Form for Consignees and relevant materials to the customs office in their place of domicile to apply for the record-filing.

Upon completion of the record-filing, customs will issue an 18-digit unified code to overseas exporters or agents for customs clearance purpose. Food importers should use their Unified Social Credit Code for customs clearance after record-filing. For overseas exporters/agents and food importers that have already completed the record-filing before the effective date of the announcement, their original Enterprise Filing Number will be discontinued. The customs will automatically issue the 18-digit Unified Code to said overseas exporters/agents, while said food importers should use their Unified Social Credit Code afterwards.



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