Legal Commentary

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China Pilots Lifting Restrictions on Foreign Investment in Stem Cell, Gene Therapy, and Genetic Diagnosis Sectors in Four Free Trade Zones

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On September 8, 2024, the Ministry of Commerce, together with the National Health Commission and the National Medical Products Administration (hereinafter referred to as the "**Three Departments**"), publicly issued the *Notice on Carrying Out Pilot Programs to Expand Opening-Up in the Healthcare Sector* (hereinafter referred to as the "**Notice**"), announcing that, **effective immediately, foreign-invested enterprises are permitted to engage in the development and application of human stem cells, gene diagnostic and therapy technologies for product registration and manufacturing in the China (Beijing) Pilot Free Trade Zone, China (Shanghai) Pilot Free Trade Zone, China (Guangdong) Pilot Free Trade Zone, and Hainan Free Trade Port**.

This exciting news is very encouraging, marking another significant step forward for China's biopharmaceutical industry on the path of open development. Drawing on our previous participation in legislative consultation work, we will share our insights on this new policy and provide a reference for the industry.

Review of policy developments

The *Catalogue of Industries Encouraging Foreign Investment* and the *Special Administrative Measures for the Market Entry of Foreign Investment (Negative List)* of China have provided key guidance and regulation for foreign investment. The restriction regarding foreign investment in "development and application of human stem cells, gene diagnostic and therapy technologies" has remained in place since the *Catalogue for the Guidance of Foreign Investment Industries (Revised in 2007)* was promulgated in 2007, where it was first listed as prohibited.

While ensuring the biosecurity of China, moderately relaxing the existing policy restrictions on foreign investment in development and application of human stem cells, gene diagnostic and therapy technologies has been a shared and long-awaited direction of the industry and regulatory authorities. Since 2019, regulatory authorities in Shanghai, Beijing, Shenzhen, Tianjin, and other cities have issued following documents proposing the exploration of pilot policies.

- **Shanghai**: In Shanghai's *Measures for Further Opening-Up of the Service Industry* issued on August 13, 2019, it was explicitly stated "to promote collaboration in projects in the field of medical technology and **remove restrictions on market entry of foreign investment, and to strive for allowing foreign investment in development and application of human stem cells, gene diagnostic and therapy technologies**". The *Regulations on Promoting the Development of Zhangjiang Biopharmaceutical Industry Innovation Hub in Pudong New Area, Shanghai*, which came into effect on January 1, 2022, also proposed "to support qualified and diversified investors in conducting development and research on human cell and gene technology and promoting industrialization under the premise of controllable risks".

- **Beijing**: The *Work Plan for Supporting Beijing in Deepening the National Comprehensive Demonstration Zone for Expanding the Opening-Up of the Service Industry* issued on November 18, 2023, and the *Implementation Plan for Promoting the Expansion of Opening-Up in the Service Industry and Foreign Investment in Beijing* issued on July 3, 2024, proposed to promote the opening development in the healthcare sector, support international cooperation in stem cell and gene research, and, in accordance with relevant national guidelines, **to select several eligible foreign-invested enterprises in free trade zones to conduct pilot explorations of expanded openness in fields such as the development and application of gene diagnostic and therapy technologies**.

- **Shenzhen**: The *Notice of the Shenzhen Government on Issuing Measures to Further Enhance the Attraction and Utilization of Foreign Investment*, issued on May 18, 2024, encourages foreign-invested enterprises to conduct clinical trials in Shenzhen for cell and gene therapy drugs that have already been approved overseas, and **to allow qualified foreign-invested enterprises to participate in pilot programs for expanding openness in the development and application of gene diagnostic and therapy technologies**.

- **Tianjin**: The *Work List for the Implementation of Actions to Promote High-Level Opening-Up and to Further Attract and Utilize Foreign Investment*, issued on August 5, 2024, proposes actively seeking to relax the restrictions on market entry of foreign investment in the field of technological innovation through pilot programs. It encourages foreign-invested enterprises to conduct clinical trials in Tianjin for cell and gene therapy drugs that have already been approved overseas and **to allow qualified foreign-invested enterprises in the Tianjin Free Trade Zone to engage in the development and application of gene diagnostic and therapy technology**.

Significantly, the General Office of the State Council issued the *Action Plan for Promoting High-Level Opening-Up and Further Attracting and Utilizing Foreign Investment* on March 19, 2024, announcing the relaxation of market entry of foreign investment in the field of technology innovation. **It will allow free trade zones in Beijing, Shanghai, Guangdong, and others to select qualified foreign-invested enterprises to engage in pilot programs for development and application of gene diagnostic and therapy technology.** The industry has been eagerly anticipating this progress.

On September 8, 2024, the National Development and Reform Commission and the Ministry of Commerce publicly released the 2024 Edition of the Negative List (hereinafter referred to as the "**2024 Negative List**"), which will come into effect on November 1, 2024. Although the 2024 Negative List retains the restriction

on foreign investment in the development and application of human stem cells, gene diagnostic and therapy technology, the Three Departments has meanwhile jointly issued the *Notice*, announcing the opening-up of pilot policies. This marks a historic policy breakthrough in foreign investment in the development and application of human stem cells and gene diagnostic and therapy technology in China.

Policy interpretation

Although the 2024 Negative List have not yet lifted restrictions nationwide, the issuance of the *Notice* establishes a policy framework for pilot programs in four regions: China (Beijing) Pilot Free Trade Zone, China (Shanghai) Pilot Free Trade Zone, China (Guangdong) Pilot Free Trade Zone, and Hainan Free Trade Port. **Qualified foreign-invested enterprises in these regions may be allowed to engage in the development and application of stem cell and gene diagnostics and therapy technologies.**

It is worth noting that the *Notice* specifically mentions that foreign-invested enterprises participating in the pilot programs must comply with China's **regulations on human genetic resources**. As foreign investment regulations are relaxed, the human genetic resource regulations in ensuring national biosecurity will gain more importance. With regard to the latest regulatory developments and requirements on human genetic resources, please refer to our articles: *Highlights on HGR Regulation Implementation Rules*, and *Key Takeaways of the New HGR Guidelines*.

Notably, in our previous participation in legislative consultations regarding the Negative List, we discussed the effective regulatory framework in China for human genetic resources, which serves as the regulatory foundation for opening foreign investment in gene diagnostics and therapy. We also proposed piloting such reforms in certain free trade zones, with a gradual nationwide rollout to follow. **We are pleased to see that the exploratory approach in the *Notice* coincide with our previous suggestions.**

We anticipate that the new policy will have a profound impact on the stem cell and gene diagnostics and therapy industry in China, including but not limited to in the following aspects:

- Foreign investment access and industry development: Encouraged by this landmark new policy, foreign-invested enterprises can seize the significant opportunities for industrial development in the four free trade zones (ports) by **investing, establishing new entities, engaging in mergers and acquisitions, relocating businesses, or expanding business scopes, thus promoting industrial clustering and innovation**.

  This policy will provide foreign companies and investors with access to China's stem cell and gene diagnostics and therapy industry, while domestic biopharmaceutical companies (e.g., Biotech) will be able to take foreign investment and enhance international cooperation without adopting the VIE structure. This will benefit the development of numerous industries, including **iPSCs (induced pluripotent stem cells), CAR-T, TCR-T, CAR-NK, TILs, mRNA, gene sequencing, in vitro diagnostics (IVD/LDT), among others**. With regard to the latest regulatory developments in the field of cell and gene therapy (CGT), please refer to our article in Chinese: *汉坤 • 观点 | CAR-T/NK 监管靴子落地 — 解读《体细胞临床研究工作指引要点（试行）》*).

- Corporate/group restructuring: Previously, to circumvent restrictions in the Negative List, many

companies/groups adopted the VIE structure to engage in the development and application of human stem cells and gene diagnostics and therapy technologies. With the removal of foreign investment restrictions, companies **may consider reorganizing into wholly foreign-owned enterprises (WFOEs) or joint ventures, depending on their specific needs**, thereby avoiding the instability associated with the VIE structure. We anticipate that, following the release of the new policy, there may be a wave of VIE structure dismantling across the industry. We will closely monitor this trend and actively provide corresponding assistance.

- Enhanced regulation of human genetic resources: As the *Notice* explicitly states that pilot enterprises must comply with regulations on human genetic resources, we expect that the National Health Commission will adopt a more cautious approach to the regulation of human genetic resources in the future. **While companies embrace the favorable policies, they may also face stricter regulatory pressure. Companies need to carefully establish compliance standard operating systems (SOPs)** and actively fulfill applicable administrative approval, filing, and prior reporting requirements for international collaborative scientific research.

Conclusion

We understand that after the issuance of the *Notice*, supplementary and specific measures in the pilot free trade zones (ports) are yet to be introduced, such as **the qualifications and application procedures for pilot enterprises**. We will continue to monitor these developments. It remains to be seen whether more pilot regions will open up in the future to promote the robust development of the stem cell and gene diagnostics industry nationwide.

As China's healthcare industry undergoes deeper reform and opening-up and the pace of internationalization of innovative drug development accelerates, we have witnessed the joint efforts of national regulatory authorities and domestic innovative pharmaceutical companies. We look forward with great anticipation to the new development opportunities that await China's stem cell and gene diagnostics and therapy industry. Together, we hope China's biopharmaceutical industry could enhance the international competitiveness, and China could advance into an innovative drug powerhouses, allowing innovative drugs and therapies to benefit patients worldwide and contribute to global health.

Important Announcement

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