CHINA REGULATORY UPDATES



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FOREIGN INVESTMENT / 外商投资

China Continuously Shortened Its Negative List for Foreign Investments 2024年版外商投资准入负面清单正式发布

2024年9月8日,国家发改委、商务部发布了《外商投资准入特别管理措施(负面清单)(2024年版)》,自2024年11月1日起施行。2024年版负面清单将外资准入的限制措施由31条压减至29条,取消了制造业领域仅剩的2条限制措施,即:"出版物印刷须由中方控股"以及"禁止投资中药饮片的蒸、炒、炙、煅等炮制技术的应用及中成药保密处方产品的生产"。

On September 8, 2024, the National Development and Reform Commission and the Ministry of Commerce or the "MOFCOM" jointly issued the *Special Administrative Measures on Access by Foreign Investments (Negative List) (2024 Edition)* (the "2024 National Negative List"), which will come into effect on November 1, 2024. The 2024 National Negative List reduced the total number of restrictions from 31 to 29, thereby completely removing foreign investment access restrictions in the manufacturing sector. Specifically, the following two restrictions in the manufacturing sector have been abolished: (i) the requirement for the Chinese Party to hold a controlling stake in the printing of publications; and (ii) the prohibition on foreign investment in the application of steaming, stir-frying, moxibustion, calcination and other processing techniques for Chinese herbal medicines, as well as the production of proprietary Chinese medicines with confidential prescriptions.

China Expanded Pilot Program for Foreign Investment in Healthcare Sector 中国进一步开展医疗领域的外资准入试点

2024年9月7日,商务部、国家卫生健康委、国家药监局发布《关于在医疗领域开展扩大开放试点工作的通知》("《试点通知》"),拟在生物技术和独资医院领域进一步开展外资准入试点,主要内容包括:

- 1. 允许外商投资企业在中国(北京)自由贸易试验 区、中国(上海)自由贸易试验区、中国(广 东)自由贸易试验区和海南自由贸易港从事人体 干细胞、基因诊断与治疗技术开发和技术应用, 以用于产品注册上市和生产。
- 2. 允许在北京、天津、上海、南京、苏州、福州、 广州、深圳和海南全岛设立外商独资医院(中医 类除外,不含并购公立医院)。

总体来看,《试点通知》为医疗领域的外资准入开放 提供了原则性的政策支持,但其中也明确要求拟进行 试点的外商投资企业应遵守人类遗传资源管理、药品 临床试验等规定要求,且需符合后续出台的外商独资 医院设立的具体条件、要求和程序等。我们将密切关 注后续具体配套措施的出台和实践进展。 On September 7, 2024, the MOFCOM, the National Health Commission and the National Medical Products Administration have jointly issued a *Notice on Expanding Pilot Programs to Open up the Healthcare Sector to Foreign Investment* (the "Notice"), moderately relaxing restrictions on foreign investment in biotechnology and wholly foreign-owned hospitals. Specifically, the Notice allows:

- foreign-invested enterprises to engage in the development and application of human stem cells, gene diagnostics and therapy technologies in designated free-trade zones, including Beijing, Shanghai, Guangdong and Hainan, for the purposes of product registration, listing and production; and
- The establishment of wholly foreign-owned hospitals (excluding traditional Chinese medicine hospitals and the acquisition of public hospitals) in Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou, Shenzhen, and Hainan.

Overall, the Notice provides policy support in principle for foreign investment in the medical sector. However, it also explicitly states that foreign-invested enterprises in pilot programs shall, as applicable, comply with regulations on human genetic resources, drug clinical trials, the specific conditions, requirements and procedures for establishing wholly foreign-owned hospitals (expected to be released later) and among others. We will continue to monitor regulatory developments in this area.

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