Relaxation of Long-Standing Restrictions on Foreign Investment in the Healthcare Sector in China

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OVERVIEW

The demand for medical services in China is growing, with the country's ageing population set against its potential for economic development. A joint circular released by China's Ministry of Commerce, National Health Commission and the National Medical Products Administration in September signals a relaxation of China's long-standing restrictions on foreign investment in the healthcare sector. Given a decline in foreign direct investment (FDI) in China generally, the announcement has garnered significant global attention.

IN DEPTH

What's New

The joint circular is a significant relaxation of China's restrictive policies on foreign investment in the healthcare sector and is aimed at facilitating the registration, launching, and production of related products, which, once registered and approved, can be used nationwide.

The key components of the joint circular were twofold, announcing that China will allow:

1. Wholly foreign-owned hospitals to be set up in several major cities, including Beijing and Shanghai; and

2. Foreign invested enterprises to engage in biotechnology, in particular, to offer human stem cell and gene therapy services in pilot free-trade zones. These pilot programs are a clear signal of the region's intention to bring back foreign investment and stabilise growth.

The move from Beijing comes less than two months after the country's leadership pledged to further open up the market at their key policymaking third plenum, and after Vice-Premier He Lifeng vowed to expand international cooperation and build a new open high-level economic system at the China International Fair for Investment and Trade in the southeastern city of Xiamen, announcing that foreign investment is "an important part of China's economy and an important force in China's modernisation drive".

1) Significance for the establishment of wholly foreign-owned hospitals

Despite China's 2014 pilots for wholly foreign-owned hospitals, foreign investment has historically been limited to joint ventures regarding established hospitals rather than sole ownership.

As a result of the joint circular, the restriction that foreign investors can only operate medical institutions in joint ventures has been relaxed, and wholly foreign-owned hospitals can now be opened in the cities of Beijing, Tianjin, Shanghai, Nanjing, Suzhou, Fuzhou, Guangzhou and Shenzhen, as well as in the southern island province, Hainan.

- Commentators have noted that the joint document issued by the three departments has a wider scope of opening up than in the past, with the term "wholly foreign-owned" regarded as a breakthrough change which can allow more places to benefit from foreign-funded medical resources.
- Wholly foreign-owned hospitals are now poised to introduce international medical technologies, talent, nursing models, service concepts, and management practices and are an area of interest for foreign investors across the globe.

The joint circular not only assists opening China further for foreign investment, but promotes the in-depth implementation of the Health China strategy. The joint circular presents the opportunity for China to:

- Build a more flexible, incisive and efficient medial service system, with the demand for medical services within China potentially resulting in further prohibitions being lifted beyond the pilot regions in future; and
- Improve the overall medical level, improve the medical environment, and also provide convenience for foreigners seeking medical treatment in China.

The detailed requirements and procedures for wholly foreign-owned hospitals and the foreign investment itself are yet to be released; however, it is already known that foreign investors will not be allowed to acquire public hospitals or run businesses relating to Chinese medicine.

While the joint circular did not provide any information on what the regulations may contain, previous regulations regarding the Shanghai free trade zone pilot indicate that future guidelines may include stipulations on total investment and the level of medical technology required.

Further, due to the involvement of health data and other national information, wholly foreign-owned hospitals may face different regulations in areas such as pre-approval and medical care services. Investors will need to closely monitor the development and implementation of regulations for wholly foreign-owned hospitals, particularly issues related to national treatment, regulatory models, and the free flow of foreign capital.

2) Significance for Biotechnology Development and Application

China’s Negative List has explicitly prohibited “foreign investment in the development and application of human stem cells, gene diagnosis, and treatment technologies” since 2007. With the issuance of the joint circular, foreign investment entities can now engage in these activities within the free trade zones of Beijing, Shanghai, Guangdong, and the Hainan Free Trade Port for the purposes of registration, market authorisation and manufacturing. Once approved, these products may be used nationwide.

The relaxation of restrictions on foreign investment in the development and application of stem cell and gene diagnosis and treatment technologies, must be balanced against ensuring China’s biosecurity, and this has been a long-standing call and effort within the industry. Accordingly, foreign investment entities participating in the pilot program will need to ensure they are aware of and adhere to the relevant Chinese laws and regulations. This includes regulations relating to human genetic resource management, drug clinical trials, drug registration and listing, drug production, and ethical review. Foreign investment entities must also ensure they follow the necessary management procedures.

In addition, foreign investors must be cognisant of the fact that while China’s healthcare market is continuously growing and dynamic, making it one of the most attractive in the world, it is heavily regulated, with high compliance requirements and strong competition. For foreign investors to benefit from the opportunity provided by the joint circular and successfully enter the market, it is crucial they understand and stay abreast of changes in the relevant industry policies and compliance requirements and develop a well-tailored strat

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