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ALERT
JULY 2020



Japan Tightens Foreign Direct Investment Regulations on Life Science Companies

Prior notification requirements under the Japanese regulations were expanded to cover investments in life science companies.

On June 15, 2020, the Japanese government implemented new regulations that designate the manufacture of pharmaceuticals for infectious diseases and the manufacture of highly-controlled medical devices (medical devices that are classified as Class III or Class IV in Japan, such as a heart-lung machines and ventilators) as both "Designated Businesses" and "Core Businesses" under the Foreign Exchange and Foreign Trade Act of Japan ("FEFTA"). The new regulations were adopted in light of the COVID-19 pandemic, with the Japanese government increasingly focused on maintaining domestic production capabilities in key life science industries to protect national security and the health and safety of its people.

Under FEFTA, a foreign investor in a Japanese company is generally required to submit a notification to the government with respect to the acquisition of (i) one percent or more of the shares in a listed Japanese company or (ii) any shares in an unlisted Japanese company. However, if the target Japanese company includes a Designated Business, then the foreign investor must submit a notification prior to the acquisition and the acquisition will be subject to a 30-day waiting period, during which the government may review and raise objections to the planned investment. Moreover, while several exemptions to this prior notification requirement are available for passive investments in Designated Businesses, if the Designated Business is also classified as a Core Business, like the life science businesses at issue here, most of those exemptions will not apply.

These new regulations will apply to foreign direct investments that are made on or after July 15, 2020. As a result of the new regulations, many foreign investments in Japanese life science companies, even including passive investments, may be newly subject to the prior notification and review requirement under FEFTA, and potential investors should consider this regulation carefully before moving forward with any proposed investments in the Japanese life sciences sector.



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