Hogan Lovells

Regulatory Insights for Life Sciences and Health Care Investments: CFIUS reporting obligations

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Investing in the life sciences industry without an understanding of the key regulatory factors that could determine a product's success or failure could cost you millions of dollars.

As the industry readies itself for the 2019 edition of the annual pilgrimage to the J.P. Morgan Healthcare Conference in San Francisco, our market-leading Global Regulatory Team has prepared a series of updates covering the following topic areas that we hope will help guide your 2019 investment decisions.

- Drug pricing and reimbursement
- Regulatory changes in Europe
- Medical device and technology
- Digital health
- Data privacy and cybersecurity
- Value-based purchasing
- Cell and gene therapies
- CFIUS reporting obligations

Cutting-edge life sciences companies have new reporting obligations under CFIUS

On November 10, 2018, the U.S. Treasury Department's Committee on Foreign Investment in the United States (CFIUS) initiated a new pilot program as part of a major expansion of CFIUS's jurisdiction. Significantly, the pilot program – for the first time – makes CFIUS filings mandatory for the transactions covered by the pilot. There are substantial fines for companies that fail to make the mandatory filing, so understanding the new rules is critical.

The pilot program covers transactions in a wide variety of cutting-edge industries,

such as biotechnology, nanotechnology, optical instrument and lens manufacturing, wireless communications, petrochemical manufacturing, and telephone apparatus manufacturing. The pilot covers any U.S. business that produces designs, tests, manufactures, fabricates, or develops critical technology that is:

- utilized in connection with the U.S. business's activity in one of these identified industries; or
- designed by the U.S. business for use in one of these industries.

The term "critical technologies" is fairly precisely defined in the CFIUS regulations, but a determination of whether technology is a critical technology turns in part on the technology's export classification. Unlike in the past, under the pilot program, a foreign entity does not need to assume "control" of the U.S. business to trigger CFIUS's jurisdiction. Instead, an investment, in addition to meeting the critical technology and industry criteria above, would only need to give the foreign investor:

- access to any material nonpublic technical information in the possession of the U.S. business;
- certain rights, such as membership or observer rights on the board of directors or the right to nominate a person to the board of directors; or
- any involvement, other than through voting shares, in substantive decision-making of the U.S. business, regarding the use, development, acquisition or release of critical technology.

This pilot program expands the reach of CFIUS beyond the traditional CFIUS scope to which companies are accustomed. This expansion was directed by the Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA), passed by the U.S. Congress this summer. Companies need to familiarize themselves with the new mandates in the legislation to ensure they do not run afoul of the new law.

Does your transaction fall under the new pilot program, which imposes mandatory filing requirements? Does your transaction touch one of the specified industries covered by this new program, such as biotechnology? Does your transaction involve a technology that makes it subject to the CFIUS pilot program? Certainty over the answers to these questions is critical to avoid substantial penalties.

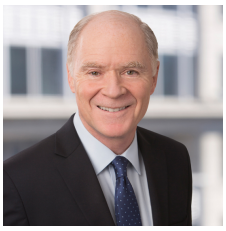
Our Global Regulatory Team

We help organizations navigate the world's multiplying regulatory regimes as they cross industries and borders alike. At Hogan Lovells, we believe that regulation is neither a force to be feared nor an obstacle to be overcome. Regulation is simply a reality of doing business today, and the organizations that understand it holistically and navigate it well are the ones that will succeed. Our team helps industry understand, anticipate, and influence the shifting – and often volatile – regulatory landscape. We partner with your business to create smart, operational solutions that mitigate risk, create new opportunities, and power your enterprise to advance.

Our Global Life Sciences and Health Care Team

Navigating complexities in the life sciences and health care industries is no easy task. Successfully competing in the space requires a partner with a holistic, collaborative approach and a global perspective. For life sciences innovators of all sizes, anywhere in the world, Hogan Lovells is that partner – from cutting-edge start-ups and boutique venture funds to world-renowned research institutions and health systems to global biopharmaceutical conglomerates. With more than 500 life sciences and health care lawyers around the world, we provide a seamless experience everywhere you do business. And no matter the challenge – from creation to commercialization of a life-saving therapy, regulatory compliance to an international patent dispute, the formation of a strategic alliance to a complex, global merger – we've been there before and we understand how to prepare you for what happens next, helping you to anticipate risks and address future issues before they arise.

Contacts



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