07 December 2018

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

**European regulatory changes elevate life sciences market uncertainty**

In the European Union, the pharmaceutical, biotechnology, and medical device industries are required to constantly adapt to new regulatory developments. Since April 2017, the adoption of medical devices regulations and the EU General Data Protection Regulation (GDPR), the aftermath of Britain’s vote to exit the EU, and the debate over drug pricing have caused challenges for life sciences companies in the EU as they attempt to identify and comply with applicable laws.

**Medical devices regulations to establish uniform EU framework**

In April 2017, the EU Medical Devices Regulations (MDR) and the In Vitro diagnostic medical Devices Regulation (IVDR) were adopted, which will repeal and replace the EU Medical Devices
Directives. Unlike directives, which must be implemented into the national laws of the EU member states, the MDR and IVDR will be directly applicable in the EU member states. The MDR and IVDR are, among other things, intended to establish a uniform, transparent, predictable, and sustainable regulatory framework across the EU for medical devices and ensure a high level of safety and health while supporting innovation. They will have significant implications on the way medical devices are currently regulated in the EU. The MDR will be applicable as of May 26, 2020, and the IVDR as of May 26, 2022.

**Brexit prompts industry restructuring**

With the advent of Brexit, the United Kingdom is set to leave the EU on March 29, 2019, and the European Medicines Agency (EMA) headquarters is moving from London to Amsterdam. For pharmaceutical and biotechnology companies, Brexit has prompted the transfer of several regulatory activities from the UK to other EU member states, including marketing authorizations, batch release, and the Qualified Person for Pharmacovigilance. In addition, many life sciences companies are restructuring their European distribution models; in particular, the Netherlands and Ireland appear to have attracted interest from life sciences companies. While the Brexit vote raised several questions that remain unanswered, EU authorities have recommended that the life sciences industry prepare for a no-deal Brexit.

**EU reacts to claims of excessive drug prices**

The industry is also faced with the increasing complexities and challenges related to pricing and reimbursement mechanisms, including the increasing use of health technology assessments by the pricing and reimbursement authorities. Although pricing and reimbursement are dealt with at a national EU member state level, there is increased collaboration between the member states. For example, in the "BeNeLuxA" initiative, Belgium, the Netherlands, Luxembourg, Austria, and Ireland have joined forces to exchange information and conduct joint price negotiations for expensive medicines. In 2018, the European Commission issued a much-debated legislative proposal for joint health technology assessment (HTA) among the EU member states.

The debate about drug pricing and perceived excessive pricing has prompted political debate in some EU member states about possibilities to apply cheaper alternatives such as off-label use, pharmacy compounding, personal import from outside the EU, or even compulsory patent licenses. However, some of these suggestions may be questionable from an EU pharmaceutical regulatory law perspective, which requires a marketing authorization based on an appropriate data package in order to place a medicinal product on the market. The antitrust and competition authorities are also investigating potential cases of excessive drug pricing.

**Exclusivity rights: court rulings and European Commission assessment**

In the area of regulatory data exclusivity and orphan exclusivity in the EU, several court decisions in 2018 – both by the Court of Justice of the European Union and by national courts in the UK
and the Netherlands – confirmed the exclusivity rights for innovator pharmaceutical and biotech companies. In 2018-2019, the European Commission is conducting an assessment of the EU regulatory regimes for orphan medicinal products and for pediatric medicinal products. In May 2018, two extensive study reports were published on the economic and legal implications of supplementary protection certificates (SPCs – which extend a patent) and of pharmaceutical incentives such as regulatory data exclusivity and orphan exclusivity. Also in May 2018, the European Commission published a legislative proposal to introduce an SPC manufacturing waiver. The waiver would allow generics and biosimilars manufacturers to manufacture generics/biosimilars in the EU intended for export to outside the EU while an SPC is still in force.

Recent regulatory approvals of medicinal products in the areas of immuno-oncology and gene therapy have attracted attention not only medically and commercially but also contribute to development of regulatory guidance in these areas.

**Data privacy affected by GDPR**

In May 2018, the GDPR created new challenges for pharmaceutical and biotechnology companies. As a consequence of the GDPR, companies must completely re-assess the way they collect, process, and transfer personal data as part of their activities. As an illustration, the GDPR requires a number of changes to the informed consent forms used by companies to collect the consent of patients for participating to clinical studies.

**Increased focus on Sunshine rules and other compliance topics**

Last, health care compliance continues to be an important area of focus in the EU. Increasingly, EU member states implement transparency requirements, or so-called “Sunshine rules,” on disclosing transfers of value made to health care professionals, institutions, and patients organizations. The competent authorities appear to take a relatively active approach in investigations and enforcement. Investigations have focused on excessive payments to health care professionals, pre-approval promotion, and direct-to-consumer promotion of prescription-only medicines.

**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.

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