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EUROPE - Less Pharmaceutical Incentives On The Horizon

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Two significant revisions of current pharmaceutical legislation (“Revisions”) are ongoing in the European Union (“EU”) that will significantly impact U.S. and other pharmaceutical companies marketing medicinal products in the EU. The first Revision affects the fundamental pharmaceutical framework, *i.e.*, the cornerstones of the EU regulatory system and obligations for the approval and placing of medicinal products on the market. The second affects the Orphan Regulation and the Paediatric Regulation.

Together the two Revisions cover many topics, including the pharmaceutical incentives (or regulatory protections) that incentivize and support the development of medicinal products for the EU market, such as for rare and pediatric diseases. The initial impact assessments prepared by the European Commission indicate that innovative companies will be worse off unless they:

- launch their products in every national market of the EU within two years following approval; and
- for orphan products, in addition, address a “high unmet medical need.”

The requirement to launch on an EU-wide basis has not yet been elaborated. Depending on the definition, it could force companies to obtain pricing and reimbursement decisions and, possibly, to distribute the product in each Member State for a minimum period of time. Such requirements not only would be nearly impossible to meet for many companies but also would have an impact on prices in countries outside of the EU that use international reference pricing.

Specific legislative proposals and updated impact assessments are expected from the European Commission by June 2023. All companies should closely follow—and get involved in—the discussions and legislative processes because the Revisions will significantly impact



investments and the development and marketing of medicinal products in the European Union, and possibly countries around the world.

King & Spalding regulatory Life Sciences lawyers can help evaluate the potential changes and advocate important concepts in Europe.

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