King & Spalding

Client Alert

FDA and Life Sciences

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Europe – New Regulation on Blood, Tissues, Cells, and Other Human-Derived Substances and Related Activities – Impacts on Pharmaceutical and Medical Devices Manufacturers

On July 17, the European Union adopted a regulation on standards of quality and safety for substances of human origin ("SoHOs") intended for human application ("SoHO Regulation"). The SoHO Regulation, which updates and replaces the EU Blood Directive and the EU Tissue and Cells Directive, will become applicable by mid-2027.

Geneviève Michaux and Georgios Symeonidis published an article on the SoHO Regulation in *Law360*.

The article focuses on the implications for companies involved in the development and manufacture of medicinal products and medical devices using human-derived substances (blood, tissues, cells, bone marrow, etc.) as the SoHO Regulation strengthens the safety and quality standards applicable to the starting and raw materials used for those products, imposes more obligations on entities active in the SoHO sector, and expressly addresses borderline products. Moreover, the SoHO Regulation regulates the export and import of SoHO, which is especially relevant for U.S. companies active on the EU market.

Read the full Law360 article.

The SoHO Regulation is a complex legislation that regulates products, activities, and entities. Our life science lawyers can help you understand its interplay with the EU pharmaceutical and medical devices regulatory regimes, its ties to the current U.S. rules on blood, tissues, and cells, and, more generally, its impacts on your products and supply chain.

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