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MAJOR PHARMA MANUFACTURER SELECTS NAVIGANT TO ASSIST WITH DRUG-DEVICE SAFETY REPORTING REQUIREMENTS

CHALLENGE

In 2016, the Food and Drug Administration (FDA) released its final rule for postmarketing safety reporting requirements for combination treatments that involve a drug, device, and/or biological product. Pharmaceutical and medical device manufacturers nationwide are required to comply with the new regulations by July 31, 2019, or face potential penalties.

SOLUTION

Building off a longstanding relationship, a major pharmaceutical manufacturer partnered with Navigant to guide them in their preparation for the new legislation. The company is leveraging Navigant's experience advising medtech and pharmaceutical companies with combination products to better understand and implement industry best practices.

Navigant has helped the pharmaceutical manufacturer map its existing adverse event reporting processes and identify gaps that arise due to the new reporting requirements. In addition, the organizations are working to amend existing processes to ensure that the combination product reporting requirements are fully met. This includes training staff on the new processes and creating scenarios to pilot through the processes to ensure adequate performance.

Navigant has also advised the client on topics associated with the new reporting requirements, including how to:

- Identify a combination product when its marketing application does not characterize it as a combination product, or when the drug and delivery device is packaged and distributed separately.
- Distinguish between a device malfunction, use error, or design flaw.
- Incorporate clinical expertise in deciding whether a device malfunction could cause or contribute to death or serious injury if the malfunction were to recur. This helps ensure reporting when appropriate, and consistency within reports of a single product and across product lines.
- Conduct an appropriate investigation of potential device malfunctions.
- Consider device events when determining the need for a drug field alert report.
- Determine appropriate language in reports of device events, and how to submit combination product reports electronically.
- Determine the need for a Section 806 report due to a device correction or removal.

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About Navigant

Navigant Consulting, Inc. (NYSE: NCI) is a specialized, global professional services firm that helps clients take control of their future. Navigant's professionals apply deep industry knowledge, substantive technical expertise, and an enterprising approach to help clients build, manage, and/or protect their business interests. With a focus on markets and clients facing transformational change and significant regulatory or legal pressures, the firm primarily serves clients in the healthcare, energy, and financial services industries. Across a range of advisory, consulting, outsourcing, and technology/analytics services, Navigant's practitioners bring sharp insight that pinpoints opportunities and delivers powerful results. More information about Navigant can be found at navigant.com.

IMPACT

Although an adequate adverse event reporting system requires constant oversight and refinement, it is anticipated that the pharmaceutical manufacturer will be ready to comply with the FDA's new adverse event reporting requirements by the effective date.

As the FDA's reporting requirements are just one piece of a global puzzle, the pharmaceutical manufacturer is also expected to take advantage of Navigant's European regulatory presence to meet new European Union Medical Device Regulation requirements.

 healthcare@navigant.com

 linkedin.com/company/navigant-healthcare

 twitter.com/naviganthealth