

Postmarket Compliance and Enforcement Actions

It's a reality that medical devices intended to help patients can sometimes cause harm or malfunction. When that happens, how is your company prepared to deal with applicable regulatory requirements?

Hogan Lovells helps companies navigate the complex framework of reporting adverse events to regulatory bodies and governmental agencies related to the use of their devices. Our wealth of experience in this nuanced area allows us to help determine whether an event is reportable and to develop strategies that ensure adverse events are handled effectively, consistently, and in compliance with the law, while in certain instances seeking to develop alternative reporting approaches to streamline regulatory requirements.

We are also able to assist companies in developing remediation strategies and improvement plans where warranted.

Representative experience

We establish regulatory training programs to educate internal units of major medical device and combination product companies about adverse event reporting requirements and procedures.

We have assisted clients in responding to enforcement actions related to inadequate adverse event reporting and helped develop procedures to protect against future enforcement.

Contacts

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Practices

Medical Device and
Technology Regulatory

Helped clients conduct retrospective reviews of their files to assess their obligations in submitting Medical Device Reports to the FDA and bring their reporting up to date.

Latest thinking and events

News

Payback and Health Technology Assessment in Italy: a new governance for medical devices?

Insights and Analysis

Life Science Law Update – Key developments for pharma and device companies in EU and EU Big Five

News

FDA expands inspection obstruction guidance to apply to device facilities

News

Modernization of U.S. cosmetics regulation will be phased in over time

News

UK MHRA delays new medical devices legislation until July 2024

News

FDA delays UDI database enforcement for low-risk devices