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MEDICAL DEVICES AND THE EVOLVING RISK LANDSCAPE

The medical device industry has faced several significant product safety challenges already in 2021 – from a high number of safety issues with cardiology devices to sterilisation issues across a broad spectrum of devices. But the risks don't stop there. As new devices are introduced, the regulatory environment evolves, and patients and healthcare professionals embrace telehealth services, companies should consider how to mitigate current and new safety risks in a way that protects the company's operations and reputation.

Cardiology devices in the spotlight

Cardiology devices have been the subject of more field safety notices (FSNs) than any other type of medical device in the UK so far this year. Those affected have included ventilators, vascular access devices and infusion devices. Identified safety concerns have covered issues such as degradation of materials, leakages from devices and sterilisation issues.

The high number of safety issues with cardiology devices in the UK may be a sign of increased demand for them from National Health Service (NHS) trusts potentially because of greater numbers of patients being diagnosed with cardiology issues. At the same time, there remain enduring challenges associated with commercialising high-tech innovative devices that generate regulatory concerns.

Sterilisation shortcomings

Shortcomings in sterilisation equipment has been an issue for several device manufacturers this year. Following reports of non-compliance by an Italian sterilisation plant, 28 manufacturers informed the Medicines and Healthcare products Regulatory Agency (MHRA) of field safety corrective actions (FSCAs) relating to this sterilisation issue. The large-scale impact of this incident provides a timely reminder for device manufacturers of the importance of rigorously vetting proposed third parties within the supply chain before contracting.

This incident also provides insight into how some regulators are taking an increasingly proactive approach in response to large-scale, cross-border safety incidents. In this case, the MHRA identified affected manufacturers known to have significant supply into the UK and proactively contacted them to request that they undertake a risk assessment. The agency also shared risk assessments to inform clinical decision-making, negotiated with manufacturers to ensure the feasibility of actions in FSNs, developed supporting guidance for healthcare professionals and patients, and shared resulting best practice on recalls with international medical device regulators. The high level of engagement shown by the MHRA in this case may well be something that we will see more of in the future.

Development of diagnostic devices for detection of SARS-COV-2

Devices designed to detect markers of SARS-COV-2 (i.e., the virus that causes COVID-19) seem likely to continue generating significant interest. As a new ecosystem of diagnostic products emerges, it seems likely that such products will increasingly capture the attention of regulators, legislators and other stakeholders responsible for oversight of such products. Indeed, regulators are already sitting up and paying attention: in May 2021, the EU's Medical Device Coordination Group issued guidance to manufacturers of such devices that underlined their responsibilities to continually assess the impact of newly identified genetic variants of SARS-COV-2 on the ability of those devices to meet their safety claims.

In vitro diagnostic medical devices (IVDs) concerns

The implementation date for the InVitro Diagnostic Medical Device Regulation (IVDR) in Member States is 26 May 2022. One concern the EC has flagged recently is the potential future risk of shortages in the supply of IVDs in Europe due to lack of certification capacity. It seems likely that there will be greater demand for the services of notified bodies under the IVDR: it has been estimated that, under the current regime, around 10% of all IVDs placed on the market need notified body involvement, whereas under the IVDR this will rise to 80-90%. Manufacturers will therefore need to think carefully about developing a contingency plan to ensure they can bring their IVD products to market in a timely way, taking into account the possibility of delay and/or disruption at the certification stage.

Wider adoption of telehealth

While early adopters of telehealth have typically been patients in remote communities with inadequate access to traditional health services, adoption rates increased steadily during the COVID-19 pandemic because of a broader need to treat patients remotely, when possible, to adhere to social distancing requirements. Continued attention on this topic is likely to have implications across a range of issues, such as the consideration of the types of patient inquiries suitable for telehealth services, data security issues and confidentiality concerns related to video or audio recording of services.

Just as data and privacy risks know no borders, there is a growing prevalence of safety incidents that involve a cross-border element. Combined with the long-term trend towards globalisation of supply chains for medical devices, companies should expect safety regulators to collaborate when responding to potential safety incidents. The UK's MHRA has already shown a willingness to coordinate a global response. There will be plenty more opportunities in the future for regulators of medical devices to work together, and companies should prepare accordingly.