Case study finds regulatory challenges are affecting MedTech innovation in the UK

October 31 2023

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General trends in the United Kingdom and European Union suggest that

regulations on new medical devices are becoming more stringent. Consequently, EU Notified Bodies and UK Approved Bodies, which audit manufacturers against regulations, are experiencing an increased burden imposed by these changes; the total number of these bodies has also decreased.

To highlight the impact on medical technology-based innovation in the UK, the group illustrated a case study on a virtual reality surgical planning tool which is currently under development at King's. The work has been published in *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine*.

To use the device prospectively and meet their timeframes, the researchers originally removed some functionality from their device to be able to self-certify without UK Approved Body involvement. However, this caused a reduction of the potential benefits to UK clinicians and patients.

The authors noted that for such reasons, the development team at King's, as well as other MedTech innovators across the UK tend to look toward the United States to obtain FDA approval and subsequent market access. They synthesize that this trend serves as a detriment to clinicians in the UK, who are already noticing a reduction in medical devices available for clinical use in the country.

At the School of Biomedical Engineering & Imaging Sciences, infrastructure has been steadily put in place to support medical device development projects through a dedicated Quality and Regulatory team, led by Dr. Heaysman. They offer a Quality Management System (QMS) and bespoke regulatory support for medical device development and are available to help all research projects with Quality Management and Documentation.

This work ties in directly with our vision for a MedTech Hub which aims to translate research rapidly into new products and technologies that will benefit patients, says Dr. Anne Vanhoestenberghe, professor of active implantable medical devices (AIMD) and Director of the MAISI Facility.

Assessing the response from UK and EU regulators on the issue, researchers suggested that while bodies such as the UK's Medicines and Healthcare Products Regulatory Agency (MHRA) and the EU's Medical Device Coordination Group (MDCG) do recognize the limitations of approval procedures at present, they must also take steps to maintain and improve the viability of the market by introducing shorter timelines for designation, creating a stable regulatory environment, accepting approvals from other countries, or granting initial market approval for innovative medical devices.

The study concluded that to position the UK as an attractive place to launch transformative medical devices, the MHRA must implement feedback taken from consultations, work with industry and Approved Bodies, and assess their regulations' impact on timeframes and support available for those who wish to enter the UK market.

More information: Jacqueline Beddoe-Rosendo et al, Medical device regulatory challenges in the UK are affecting innovation and its potential benefits, *Proceedings of the Institution of Mechanical Engineers, Part H: Journal of Engineering in Medicine* (2023). DOI: 10.1177/09544119231203776

Provided by King's College London