■ EDITORIAL

The impact of the European Union's Medical Device Regulation on orthopaedic implants, technology, and future innovation

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The European medical device industry is worth over €10 billion and accounts for approximately 675,000 jobs.[1] In 2017, this industry underwent its most extensive reform to date with regulation 2017/745 of the European Parliament and of the Council 5 April 2017, also known as the European Union's Medical Device Regulation (EUMDR).[2] This replaced the Active Implantable Medical Devices Directive (AIMDD) from 1990 (90/385/EEC) and the original Medical Device Directive (MDD) from 1993 (93/42/EEC).[3,4] The main impetus for this new regulation was the apparent deficiency in safety and transparency associated with various medical devices that had gained entry to the European market within the existing regulatory framework. In 2012, a group of journalists mounted an undercover exercise to demonstrate the lack of diligence by the certifying body of one member state, which granted approval to a fake application of a device aleady withdrawn by its manufacturer following adverse outcomes. The investigation revealed weaknesses in the system.[5]

Moreover, adverse events had been reported with medical devices across several specialties, including pelvic floor mesh repair in gynaecology, prosthetic implants in breast surgery, and metal-on-metal hip components in orthopaedics.[6-12] After a transition period of four years, including a one-year postponement due to the COVID-19 pandemic, the EUMDR became fully binding and applicable in May 2021. This article discusses the pertinent points of the EUMDR in relation to orthopaedic medical devices, and explores how this new regulation affects patient safety, technological advances, and future innovation capacity in orthopaedics.

The EUMDR represents an important step with regard to its legislative power and its enforcement. While EU directives must be incorporated into the national law to become applicable, EU regulations override the national law of member states and come into force within 20 days of being published in the official EU journal.[13] It is therefore mandatory for all orthopaedic implants and devices to be fully compliant with the policies of the new regulation. To ensure smooth transition from the old to the new regulation, it is obligatory for information relating to the safety and performance of medical devices to be stored on the European database on medical devices (Eudamed).[2] This will come into effect 18 months after the date of application of the EUMDR. Previous certificates for orthopaedic implants issued under the AIMDD and MDD will become void by May 2024 and cannot be put into service or made available on the market after May 2025. As the EUMDR applies to all orthopaedic implants, manufacturers will need to ensure that all elective and trauma implants including joint arthroplasties, intramedullary nails, screws, plates, and cables are all certified using the new regulations. The European Commission will assess how the EUMDR has been applied in May 2027, with special attention to the traceability of these medical devices.

The EUMDR states that in order for a new device to be available for clinical use, manufacturers must conduct a clinical evaluation of the available clinical evidence by: critically evaluating relevant scientific literature; critically evaluating the results of all available clinical investigations; and considering currently available alternative treatments.[2] If this is not possible, then similar to the MDD, the manufacturer may conduct a clinical evaluation by demonstrating the equivalence of the clinical, biological, and technical characteristics of a device to those of a predicative one (i.e. a product that has already been available). Importantly, a critical review of the existing literature is sufficient for placing most devices on the market. The key components of the post-market surveillance include mechanisms to ensure the identifiability and traceability of medical devices implanted. Manufacturers must also create post-market surveillance plans to inform appropriate authorities and notify bodies about any serious incidents, side-effects, and complaints about the medical device.

Implementation of the EUMDR has evoked mixed reactions from the various stakeholders, as the new regulations will affect both new and existing orthopaedic implants. Newly introduced implants will have undergone extensive preregulatory review and receive stringent post-marketing surveillance of their performance and

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suvivorship.[14,15] Some scholars have reported that this will improve patient safety and ensure that new medical devices are only implanted after their risk profiles have been fully established.[10] However, some companies fear that the more stringent safety and performance requirements will lead to fewer orthopaedic implants being introduced, as additional costs related to administration, legal representation, and research trials to ensure full compliance with these guidelines will eventually lead to higher implant costs.[16-18] For existing implants, the EUMDR requires manufacturers to provide a clinical evaluation report to prove their safety and performance. This has created some apprehension among clinicians and academics as these data are not routinely collected and/or available for analysis, and may limit the portfolio of implants provided by some large global manufacturers.[15] This may lead to a significant negative effect for devices that are used less frequently. Low-volume implants, such as those used in orthopaedic oncology, might be less accessible, which could hinder patient treatment and compromise the outcome when it is dependent on the timing of surgery. The administrative and legal delays could also lead to some small- and medium-sized enterprises closing as they become unprofitable.[19,20]

The EUMDR will have a major influence on the development and implementation of technological innovations in orthopaedics.[18] Recent advances in artificial intelligence-based algorithms, predictive analytics, virtual reality, smart devices, and robotic arm-assisted surgery are proving to be invaluable adjuncts across various orthopaedic subspecialties.[21-38] Previously, the MDD could give fast-track approvals for these "Software as Medical Device" (SaMD) applications using substantial equivalence to existing products. However, it has been suggested that this fast-track application system created a loophole in the certification process for some technological innovations, with premature implementation of SaMD applications that compromised patient safety.[39-42] In the EUMDR, there is no specific guidance on SaMD applications in relation to the required level of clinical evidence or suggested frameworks for assessing their clinical safety.[43,44] Furthermore, there is growing belief that the risk categorization for most SaMDs will change from Class I (low risk) to Class IIa/IIb (medium risk) or even Class III (high risk).[45] Consequently, these SaMDs will need to be designed, tested, and re-evaluated with significantly more rigour than previously under the MDD. A potential drawback of this is that manufacturers will be more reluctant to endorse and invest in early-stage SaMD applications, which may further limit the development of new technology in orthopaedics.

It is important to consider that despite the aforementioned concerns, the EUMDR may provide opportunity for improving administrative standardization, increasing legal certainty, and maintaining surgical innovation, while reducing medical device-related complications.[18] Under the previous regulations of the MDD, clinician input was rarely needed during the implant approval process. The new EUMDR requires continuous clinical validation, and clinicians to be more involved in the conceptualization, development, and post-market surveillance of medical devices. The challenges of fulfilling the various criteria from the EUMDR bring together an opportunity for greater collaborative studies between healthcare institutions, academic centres, and implant manufacturers. For example, the Coordinating Research and Evidence for Medical Devices (CORE–MD) project includes several medical associations, academic institutions, national health organizations, and national regulatory authorities working collaboratively to identify and investigate high-risk medical devices.[44] In May 2023, the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) published their first consensus paper on the medical and research requirements for the introduction of joint arthroplasty devices.[46]

Since the withdrawal of the UK from the EU on 31 January 2020, new regulations have been developed to ensure that safe and effective medical devices are released for patients in the UK. Previously, medical devices in the UK required conformity assessment, resulting in the Conformité Européenne (CE) mark. To achieve this mark, a notified body designated by one of the EU member states would assess the medical device to ensure it was compliant with the essential technical requirements published in the EU directives or regulations. On 1 January 2023, the UK conformity assessment (UKCA) mark came into force, covering most medical devices that were previously covered under directives and regulations for CE marking. The initial plan was to discontinue using the CE marking and instead start using the UKCA mark on most new medical products in the UK from 1 July 2023. This deadline has now been revised to either 31 December 2027 or 30 June 2028, depending on the risk classification of the medical device, in order to provide manufacturers and business more time to adjust to the new regulatory requirements. As it currently stands, if a manufacturer wants to sell a product in the EU and UK, they will need both the EC and UKCA markings. Importantly, the UKCA mark is not currently recognized in the EU market, and these products will still require a CE mark to be marketed in the EU.

In terms of traceability and post-market surveillance, the UKMDR and EUMDR both have a low threshold for reporting adverse events and stipulate the use of a unique device identification number (UDI). Over the last few years, several reports have been published in relation to the traceability of implantable devices in the UK. Baroness Cumberlege mentioned in her "First Do No Harm – The Independent Medicines and Medical Devices Safety Review" that all implantable devices, and their respective patient-reported outcome measures, should be monitored in registries.[47] This would have a substantial impact on the orthopaedic community as routine implants, such as anchors or screws, would have to be recorded in their own registries. Additionally, patterns or trends in adverse events or complications might not be as clearly recognizable as with joint arthroplasties, especially if the evaluation and interpretation of the acquired data is performed by non-experts within the field. Therefore, governments and policy-makers should work closely with organizations like "Beyond Compliance" or the Orthopaedic Data Evaluation Panel (ODEP) devoting their work to implant risk assessment and providing data on the performance of orthopaedic implants.

Overall, the EUMDR presents great opportunities for improving patient safety, reducing the risk of adverse events, improving implant traceability, and promoting collaborative research in medical devices. However, the EUMDR is

associated with contemporary, logistical issues in relation to the expiry of existing MDD certification, additional requirements for clinical evidence, and spiralling costs for the recertification of existing and new implants. As manufacturers and companies work to comply with these stringent new safety and performance requirements, this may lead to a reduced choice of implants available to clinicians, and significant delays in technological innovation. There is concern that these new regulations may have negative consequences in the treatment of patients. In particular, this might be the case for implants from smaller companies or in the field of low-volume devices like orthopaedic oncology. Clinicians, academics, healthcare policy-makers, managers, and industry partners will need to work in close collaboration and use the EUMDR to maintain high standards of quality and safety for orthopaedic devices, but also ensure the administrative and research bottlenecks do not delay the delivery of novel and innovative technology to patients.

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