Clin Orthop Relat Res (2020) 478:928-930
DOI 10.1097/CORR.0000000000001154

Clinical Orthopaedics and Related Research®
A Publication of The Association of Bone and Joint Surgeons®

Editorial

Published online: 29 January 2020

Guest Editorial: New Medical Device Regulation in Europe: A Collaborative Effort of Stakeholders to Improve Patient Safety

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A Collaborative Effort for Quality

In response to recent reports in the lay media and scientific journals about complications associated with joint arthroplasties and other medical devices [3, 12, 13], the Presidents of the European Knee Society (EKS) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT) met with stakeholders in Brussels, Belgium in April 2019 [7] to discuss the European Union's (EU) new Medical Device Regulation (Regulation 2017/745 of the European Parliament and of the Council 2017/745 of 5 April 2017 [9] concerning medical devices, OJ No L 117/1 of 2017-05-05). This regulation overhauls the current medical device safety regulations in the EU and is scheduled for implementation in May 2020.

*A note from the Editor in Chief: In April of 2019, the European Parliament's Science and Technology Options Assessment Panel met with leaders from the European Knee Society and the European Federation of National Associations of Orthopaedics and Traumatology in Brussels, Belgium. There, they discussed the European Union's new Medical Device Regulation (Regulation 2017/745 of the European Parliament and of the Council 2017/745 of 5 April 2017[1] concerning medical devices, OJ No L 117/1 of 2017-05-05), which overhauls the current medical device safety regulations in the European Union and is scheduled for implementation in May 2020. In this month's guest editorial, Emmanuel Thienpont MD, MBA, PhD—*CORR*'s liaison to the European Knee Society—and his group detail why these new regulations are necessary, and some of the concerns among stakeholders and healthcare professionals that still remain.*

One author (ET) reports personal fees from Lima (Udine, Italy) in the amount of USD 10,000-USD 100,000; Medacta (Castel San Pietro Switzerland) in the amount of USD 10,000-USD 100,000; Zimmer Biomet (Warsaw, IN, USA) in the amount of USD 10,000-USD 100,000; Convatec (Oklahoma City, OK, USA) in the amount of less than USD 10,000; KCI 3M (Maplewood, MN USA) in the amount of less than USD 10,000; and OrthoSensor (Dania Beach, FL, USA) in the amount of less than USD 10,000.

One author (ET) has received royalties for a patent from Zimmer Biomet (Warsaw, IN, USA) in the amount of USD 10,000-100,000.

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Wolters Kluwer

Editorial

EU Medical Device Regulation 2017/745

The new EU Medical Devices Regulation (EU 2017/745) goes into effect on May 26, 2020 and governs all aspects of a medical device's lifecycle [9]. The new regulation seeks to restore confidence in the safety of medical devices among EU patients, consumers, and healthcare professionals following several high-profile device recalls, and instances where medical devices did not perform as expected [3, 12, 13]. Because of these performance issues, the European Parliament called on the European Commission to renew efforts to overhaul safety regulations [6], and at the recent meeting in Brussels, researchers and decision-makers debated the merits of Medical Device Regulation 2017/745 [7]. The revision of the legislation is not only meant to ensure a consistently high level of health and safety protection for orthopaedic patients in the EU, but it also considers the technological and scientific advances that have occurred in this sector in the last 20 years. The European Commission proposed the new regulation on medical devices in 2012, which was adopted by the European Parliament and the European Council in 2017.

Advantages of the New Regulation

The new regulation will implement stronger patient safety requirements, including a mandatory clinical investigation where a device is evaluated in patients, a conformity assessment where the safety and performance of the device is verified by a notified body, and the constant monitoring of incidents once the device is on the market. The notified bodies are independent entities that have been designated by their national authorities to ascertain whether products meet EU legal requirements [4, 5].

The new regulation should also increase engagement between manufacturers and experts. Expert panels (coordinated by the European Commission) will provide scientific, technical, and clinical advice. Manufacturers will be invited to consult expert panels on their proposals for clinical investigations and notified bodies must request expert scrutiny of their clinical evaluation assessment reports concerning high-risk (Class III) implantable devices. The members of expert panels should work with impartiality and objectivity, and they are required to declare and make public all relevant financial conflicts of interest [10].

The new rules also will strengthen post-market surveillance systems, requiring manufacturers to collect data performance on their products once devices are on the market; in parallel, EU Member States will be required to improve coordination mechanisms on vigilance and market surveillance [4, 5]. Under the new law, patients will receive a card containing information about any devices implanted in their body, and a mandatory device-traceability system, which will be based on a unique device identifier created for every implant and that will be recognized in the EU database of medical devices, called Eudamed [4, 5].

Criticisms and Concerns

Despite these changes, the new regulation has been criticized mainly on (1) the need for still-more transparency and public access to information, and (2) the independence of notified bodies [1, 2, 8, 11, 14].

Transparency and public access to information remains a concern. Under the new rules, Eudamed will be used to store and exchange information among EU Member States, the European Commission, notified bodies, manufacturers, and the public. However, the new rules give the public less access to these data compared to regulatory authorities [1, 8, 11]. Some of this information is restricted for legal reasons or because the data are covered by confidentiality rules, intellectual or commercial property laws, or statutory restrictions on exchange of information between competent authorities. And while summaries of each manufacturer's safety and clinical performance reports will be publicly available, the clinical evaluation reports (submitted by the manufacturer of a medical device to a notified body) and the clinical evaluation assessment reports (produced by the notified bodies) will not be open to the public. Currently, the European Commission and the responsible national authorities are in early discussions regarding public access to other vigilance studies and market surveillance information, which will be registered in Eudamed.

We have also seen criticisms pertaining to the independence of the notified bodies. Although their activities are regulated by the EU, the notified bodies are funded by manufacturers to assess their products [1, 11]. We note that the legislation has several mechanisms in place to ensure impartiality and independence of the notified bodies: (1) Oversight and inspections of their activity, (2) joint assessment by the European Commission and national competent authority experts from countries other than the one that designated the notified body; (3) scrutiny of every designation by the Medical Device Coordination Group (the governance body of the EU system on medical devices consisting of all EU Member States); and (4) a designation over a limited time with re-assessment.

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Conclusions

Any new regulations on medical discoveries and interventions inevitably raise concerns about whether they might stifle innovation. Despite this possibility, and despite the concerns outlined above, we concur with the new EU medical device regulations. We do not believe that the burdens imposed by the new law will substantially interfere with innovation that can come from high-quality research and development projects that have advanced patient care in the last decade, and which will be equally important going forward.

Acknowledgment We are grateful to Professor Alan G. Fraser, Emeritus Professor of Cardiology for the School of Medicine at Cardiff University, who provided many thoughtful suggestions that improved this essay. Likewise, we appreciate the insightful feedback and perspective from Jelena Malinina from the European consumer organisation and from Katie Gallagher, from the European Patients' Forum. Finally, we want to thank Professor Marcel Van de Voorde from the Max Planck Institute in Germany for his continuing commitment to this problem.

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