



## EDITORIALS

# Europe's new device regulations fail to protect the public

Commercial interests and lack of transparency remain key weaknesses

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The new EU Medical Devices Regulation ((EU) 2017/745) comes fully into force on 26 May 2020.<sup>1</sup> This “fundamental revision” of the existing regulatory framework is intended to “ensure a high level of safety and health whilst supporting innovation,”<sup>1</sup> to provide a better guarantee for the safety of medical devices, and to restore the loss of confidence<sup>2</sup> that followed high profile scandals around widely used hip, breast,<sup>2</sup> and vaginal mesh devices.<sup>3</sup>

The regulation is implemented through national competent authorities—such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK—and the notified bodies designated by them to assess devices’ conformity with regulatory standards. There are four notified bodies in the UK. Conformity assessments are based on the intended purpose and associated risk of a device: if a conformity assessment finds a device to be compliant with the European regulations, the manufacturer can brand their product with the CE (Conformité Européenne) mark and trade it within the EU internal market.

Despite its stated intention, the new regulation does not go far enough to ensure accountability, transparency, and the safety and efficacy of regulated medical devices.

Firstly, notified bodies are commercial entities paid by manufacturers to assess their products. The new regulation states that notified bodies should be independent and free from “all pressures and inducements, particularly financial.” But these commercial organisations compete against each other for business from manufacturers, raising serious questions about commercial influence and conflicts. A notified body that gets a reputation for turning down applications, for example, may lose business to other notified bodies with a reputation for lower thresholds of approval.

Conformity assessment is a growth industry: medical technology represented the largest number of European patent applications in 2017<sup>4</sup> and the sector had total annual sales in Europe valued at €110bn (£97bn; \$127bn).<sup>5</sup> Although the new regulation requires greater scrutiny of the designation, monitoring, and review of notified bodies, it does not do enough to ensure that public safety supersedes commercial concerns.

Secondly, unlike medicines regulation, which requires clinical trials to establish safety and efficacy before licensing, medical

devices only require a “clinical investigation” to verify safety, performance, and an acceptable benefit:risk ratio. Medical devices are classified into risk categories ranging from I for low risk, non-invasive devices such as spectacles to III for high risk, invasive long term devices such as pacemakers.<sup>6</sup> The only medical devices that are required to show therapeutic benefit in ideal and controlled conditions (efficacy) before use in the real world are those that incorporate medicinal products.

Under the new regulation even clinical investigations are not needed if a device is regarded as similar (substantially equivalent) to existing products or custom made. Vaginal meshes and metal-on-metal hips both entered the market through the substantial equivalence route, which failed to protect patients from substantial harm.<sup>3,7,8</sup>

Finally, transparency and public access to information remain a concern. In 1998, the European database on medical devices (Eudamed) was established to enable the exchange of legal information on devices between the EU and member states.<sup>9</sup> Under the new regulations, Eudamed will be used to store and share information between member states and the Commission, notified bodies, economic operators (manufacturers, authorised representatives, importers, and distributors), and the public. It will hold information on which notified bodies reviewed each device, summaries of clinical investigations, and post-market vigilance and surveillance, linked by unique device identifiers.

But the regulations give the public more limited access to these data than regulatory authorities. The public is required to be “adequately informed” whereas regulatory organisations should be “well informed.”

It took the international thalidomide tragedy to bring about radical changes in pre-market approvals for medicines in the UK and much of Europe. It is concerning that the US is currently deregulating both medicines and devices,<sup>10</sup> and although the UK government has stated its intention to implement the EU regulations,<sup>11</sup> the effect of Brexit is unknown.

The new rules require further tightening to protect public safety. At the very least, national authorities such as MHRA should take over conformity assessments for all high risk devices to reduce commercial conflicts of interest; clinical studies of both efficacy and effectiveness should be a condition of pre-market

approval<sup>12-14</sup>; and all data, including clinical studies and investigations, should be available to everyone, ending differential rights of access for regulators and the public.

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