Will the new European Medical Device Regulation help protect public health?

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

The MDR 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 MDR, 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.

First, notified bodies are commercial entities paid by manufacturers to undertake assessments. The MDR 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 (3) and the sector had total annual sales in Europe valued at €110 billion. (4)

While 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.

Second, unlike medicines regulation which requires clinical trials to establish safety and efficacy for the purposes of licensing, medical devices only require a "clinical investigation" to verify safety and performance, clinical benefit, and an acceptable benefit/risk ratio. The MDR's sole reference to efficacy relates to devices that incorporate medicinal products where the efficacy of the medicine (rather than the medical device) may be affected. As such, for medical devices that do not incorporate medicines, it is not necessary to demonstrate therapeutic benefit in ideal and controlled conditions (efficacy) before they are tested in real world settings (effectiveness).

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. (5) Clinical investigations are not required for high-risk devices if they are regarded as similar (substantially equivalent) to existing products or if they are custom-made. Vaginal meshes and metal-on-metal hips entered the market through the substantial equivalence route, which in both cases failed to protect patients from substantial harm. (6, 7)
Third is the issue of transparency and public access to information. 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. Under the MDR, Eudamed will be used to store and share information between Member States and the Commission, notified bodies and 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. Under the MDR, the public has more limited access to these data than regulatory authorities. These different levels of access allow the public to be just "adequately informed", while regulatory organisations are "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 of grave concern that the US is currently deregulating both medicines and devices, and although the UK Government has stated its intention to implement the MDR, the impact of Brexit is unknown.

The new rules require further tightening to protect public safety. At the very least, for all high risk devices: national authorities such as MHRA in the UK should take over conformity assessments to reduce commercial conflicts of interest; clinical studies of both efficacy and effectiveness should be a condition of pre-market approval (11-13); and all data including clinical studies and investigations should be available to everyone, ending differential rights of access for regulators and the public.


