

Medical device regulation in the EU and US needs urgent reform, say experts

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Medical devices approved first in the European Union (EU) are associated with a greater rate of safety issues, finds a study published by *The BMJ* today.

Clinical trial results for many new medical devices that could guide [treatment decisions](#) also remain unpublished or unavailable up to five years after approval, the findings show.

As such, the researchers call for greater regulatory transparency to enable patients and clinicians to make informed decisions about treatment.

Medical devices play an important role in [patient care](#), but their approval and regulation are handled differently in the EU and US.

In the EU, devices can be marketed if they perform "as intended" and are likely to be safe, but clinical testing may only be required for some high-risk devices. In the US, however, high-risk devices must demonstrate reasonable safety and effectiveness in clinical trials before they can be used by patients.

As a result, many high-risk devices are approved faster in the EU than in the US. This has led to controversy over their safety and calls for regulatory reforms in both the EU and US.

So a team of UK and US researchers decided to evaluate safety issues

related to high-profile medical devices introduced in the EU and subsequent approvals in the US.

They searched public and commercial databases for announcements about new medical devices approved in the EU between 2005 and 2010.

They identified a total of 309 devices (245 cardiovascular, 36 orthopedic, and 28 neurologic devices). Nearly a quarter (75 of 309, 24%) were classified as major interventions.

The majority (206 of 309) of devices identified were approved in both the US and EU, of which 63% (129 of 206) were approved first in the EU.

Overall, roughly a quarter (24%) of the devices were associated with safety issues after they reached the market. Devices approved first in the EU were also associated with a nearly three-fold greater rate of safety alerts and recalls.

Among the 75 devices classified as major interventions, pivotal trial results were published for 37 (49%), with an overall publication rate of 37% five years after approval.

The authors point to some study limitations, but say this study "provides an important empirical measure of the trade-offs associated with the US and EU frameworks for regulating [medical devices](#)."

"Patients and clinicians need access to, and balanced presentation of, the available evidence of the safety and effectiveness of novel devices, as well as clear communication about the evidentiary gaps," they write.

"Our findings suggest that products introduced earlier in their development cycle are also more likely to increase the risk of harms,

underscoring the urgent need for transparency to make truly informed decisions," they conclude.

More information: Comparison of rates of safety issues and reporting of trial outcomes for medical devices approved in the European Union and United States: cohort study, *The BMJ*, www.bmj.com/content/353/bmj.i3323

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