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EUROLAB Special Briefing

Press Research - Implant Medical Devices

On Monday 26 November a number of articles on defective or otherwise non-compliant implant medical devices were published. These articles derive from the research of the international consortium of investigative journalist (ICIJ), which published a series of articles on the same day.

The research concludes that in some cases products that were found to be unsafe remained in the market. Moreover, it criticises the differences among jurisdictions that allow products considered unsafe in one world region to be circulated in another. It also criticises in principle the fact that devices may not be tested to humans before entering the market.

ICIJ developed also a database to allow patients to explore recalls and safety alerts.

As you know, in the EU medical devices are regulated by two Regulations that apply since 2017. The conformity assessment of medical devices largely involves third-party certification in the EU. According to Bloomberg, the European Commission called on Member States to fully apply the rules as a follow-up to the ICIJ's research.

It is also worth noting, that the EU faced over the past years large problems with standards concerning medical devices, being published in the Official Journal of the EU (and becoming harmonised).

In the US, the main authority is the Food and Drug Administration (FDA). In April of this year, FDA released its Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health, aiming to improve the safety of medical devices. Last week, FDA published a review of the steps taken according to this action plan, including research on certain implants.

Following the end of a public consultation, FDA Commissioner Scott Gottlieb, M.D. and Jeff Shuren, M.D., Director of the Center for Devices and Radiological Health, announced today that they will go forwards with the review of FDA's 510(k) program, as this is the most commonly used device premarket review pathway in the US.

According to the statement, the review will aim at changing the rules for comparative testing to ensure that newer devices are compared to the benefits and risks of more modern technology. It might also lead to proposals to sunset certain older predicates and promote the use of more modern predicates.

Moreover, FDA published a performance report of the existing system. Furthermore, please note that in the latest EU-US regulatory talks, medical devices emerged as a potential area where regulatory cooperation & coordination might be easier than other sectors. Therefore, it could be used as a "pilot".

Finally, the trade associations of medical devices reacted. the EU association of medical devices, MedTech Europe, published a press release on ICIJ's research, while AdvaMed published a statement on the 510(k) upcoming changes and on ICIJ's research.