

Exchange of views on 'Implant Files' in the European Parliament

MedTech Europe reaffirms its commitment to patient safety

On 27 February, MedTech Europe participated in an exchange of views before the Committee for Environment Public Health and Food Safety (ENVI) at the European Parliament (EP). Other participants included the International Consortium of Investigative Journalists (ICIJ) and the European Commission.

Serge Bernasconi, CEO of MedTech Europe, spoke and answered questions. He underlined the fundamental belief, shared by all at the meeting, that patient safety is the highest priority. The medical technology industry's role is to deliver products that are safe and perform. *'As an industry, we have a genuine responsibility to the patients we serve and we continuously work to uphold our commitment by providing safe medical devices that help save and improve people's lives,'* he said.

Mr Bernasconi set out MedTech Europe's longstanding support for the new Medical Device Regulation (MDR) as it provides the answers to the concerns that have been raised. However, significant challenges remain around the transition into the MDR by May 2020. Critical elements of the new system, such as Notified Bodies, will most likely not be in place early enough. The industry is ready to submit files for the needed re-certification of existing products but Mr. Bernasconi stressed, *'To get the tens of thousands of devices re-certified on time critical elements of the new system have to be in place well ahead of May 2020. This includes first and foremost having Notified Bodies designated and with sufficient capacity.'*

Finally, Mr Bernasconi flagged the risks of a "no-deal" Brexit. The UK's Notified Bodies have already certified many thousands of medical devices and diagnostic tests used throughout Europe. These devices will immediately become non-compliant in the EU27 at the moment of a "no-deal" Brexit and would have to be removed from the supply chains of European hospitals, healthcare professionals and patients. Alarming, the European Commission stated that it does not see the urgency of the matter nor the need for a contingency plan for Europe.

Mr Bernasconi reaffirmed that the medical technology industry remains committed to full compliance with the MDR's new requirements and will continue to fulfil its responsibility to provide products that work and that are safe for the benefit of all citizens.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.