**UK minister says EU med device rules will apply after Brexit**

-- By Helen Collis
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LONDON — The U.K.’s medical devices sector will continue to follow EU regulations after Brexit even if the country crashes out of the EU under the “no deal” scenario, junior health minister James O’Shaughnessy said today.

This includes the new medical devices regulations that came into force in May, he told delegates at the Association of British Healthcare Industries conference in London. The new rules [tighten quality and safety standards](http://politico.us8.list-manage.com/track/click?u=e26c1a1c392386a968d02fdbc&id=3a35ae219c&e=9a5b501a6c) across EU medical devices, prompted by leaky breast implants and shoddy metal hips.

Noting the latest rules will be transposed into U.K. law through the EU Withdrawal Bill, he said: “The U.K. has already welcomed these new regulations.”

“It’s important to provide some certainty to the sector,” he said.

O’Shaughnessy said he is confident the U.K.’s strength in assessing medical devices — similar to its major role in assessing new medicines — would be a positive lever in concluding a firm agreement with the EU on regulatory alignment.

He said the U.K.’s five notified bodies for approving new medical devices regulate a “disproportionately” high number of products for the EU market. The U.K. oversees between 50 and 60 percent of the highest-risk products, he said.

“That’s why we believe the EU should respond positively to our recent [position papers”](http://politico.us8.list-manage.com/track/click?u=e26c1a1c392386a968d02fdbc&id=3bd41c4c19&e=9a5b501a6c) on regulatory alignment, he said, “to prevent the risk of disruption that could affect patients in the U.K. and Europe.”

Echoing a [call made in July](http://politico.us8.list-manage.com/track/click?u=e26c1a1c392386a968d02fdbc&id=dfa9c96506&e=9a5b501a6c), O’Shaughnessy asked the medtech sector to “lobby hard” for a mutually beneficial arrangement. “Paint a positive picture of what can be achieved through these negotiations,” he said.

# Keep Regulatory Status Quo Post-Brexit, Industry Tells Negotiators

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#### Executive Summary

The future regulatory outlook for the UK after the country leaves the EU has not been clear during discussions to date. Now medtech industry associations have spoken out. They warn divergence will hit patient safety and must be avoided.



The European institutions and the UK government may be at loggerheads over Brexit negotiations, but there is unity in the medtech sector over concerns that industry could be heading for disaster unless sector-specific measures are agreed to.

The European level and UK medical device and IVD industry associations have sent a strongly-worded joint [letter](http://www.medtecheurope.org/sites/default/files/resource_items/files/Joint%20Medical%20Technology%20Associations%20Brexit%20Letter.pdf) spelling out their concerns surrounding Brexit to relevant negotiators in Brussels and the UK.

The groups are calling for the UK to remain very much part of the EU regulatory scene, arguing that the consequences of new regulatory and/or trade barriers would be "disruption to the supply of devices and diagnostics critical to the delivery of modern health care, the maintenance of patient safety and the preservation of health throughout Europe".

The letter from MedTech Europe, the Association of British Healthcare Industries (ABHI) and the British In Vitro Diagnostics Association (BIVDA) argues for several critical factors to be considered to guarantee regulatory stability, patient access, and innovation.

The industry recommendations would effectively maintain the UK in its current path, moving towards the same regulatory future under the Medical Device Regulations as the rest of the EU.

The letter asks for additional time after Brexit takes effect in March 2019 for the UK and EU industries to work together towards joint implementation and alignment under the regulations before the new Medical Device Regulation becomes mandatory in May 2020 and IVD Regulation does so in May 2022. After those dates, the regulations should apply in the UK just as in the EU, the associations argue. This, they say, should ensure the continuity of access to medical technologies in the UK and the EU post-Brexit.

The letter also calls for:

* The UK to remain an active part of the European regulatory framework, with full implementation of the new Medical Device and IVD Regulations;
* UK notified bodies to remain European designated bodies, and other legal entities – such as authorized representatives or legal manufacturers based in the UK – to be considered as European-based;
* The UK authority, the MHRA, to participate in the Commission's new Medical Devices Coordination Group (MDCG); and
* The UK to have full access to – and reliance on – the new European medical device database (Eudamed), which will include pre- and post-market data, registration details on economic operators, details of clinical investigations and more.

The document, signed by Peter Ellingworth, chief executive of ABHI, Doris-Ann Williams MBE, chief executive of BIVDA, and Serge Bernasconi, chief executive officer of the EU trade association, MedTech Europe, notes that consistent, pan-European regulatory arrangements have been a key element to the medtech industry thriving.

Any regulatory divergence, it warns, will increase bureaucracy and cost. And creating two distinctive regulatory frameworks would disrupt trade, innovation and growth in the industry and hinder patient access to medical technologies.

Medical technologies, they point out, often move through different jurisdictions during their lifecycle, with components sourced from, and assembled and packaged in, several different countries and moved around for cleaning and maintenance. To guarantee ongoing supply, it is essential to limit regulatory and administrative barriers.

The trade associations have asked for an opportunity to meet with the two negotiators to whom the document is addressed, – Michael Barnier, EU chief negotiator at the Commission negotiations task force, and Rt Hon David Davis MP, secretary of state at the UK Department for Exiting the EU, to further discuss the issues in detail.

They are also intending to issue a technical position paper on the topic shortly.

Whether the patient safety argument will convince negotiators to be particularly mindful of its approach in this, and potentially other health sectors, remains to be seen. The arguments are strong in the context of responsibilities to citizens in the UK and the EU, but whether they can prevail politically is another matter.

**Facts And Figures**

THE LETTER TO NEGOTIATORS REPORTS THESE FIGURES RELATED TO THE MEDTECH INDUSTRY

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|  | UK | Europe |
| No**.** employed in the industry | 90,000 | 575,000 |
| No**.** of companies | 2,500 | 25,000 |
| Annual turnover | £17bn | E110bn |
| % of companies that are SMEs | 95% | 95% |