

## MedTech Europe: Brexit deal must ensure continued access to needed medtech

09 November 2017 - MedTech Europe, the trade association representing the medical technology industry, wants negotiators to be highly sensitive to the impact of Brexit to patients and the SME-based medical technology industry. The association calls for effective arrangements that will mitigate potential risks to patients' access or to the competitiveness of the sector on both sides of the channel.

*"Medical technologies help save and transform people's lives across the whole continuum of care. The ongoing Brexit negotiations should seek to avoid any risks to patients and their continued access to needed diagnostics and medical devices caused by the disruption of the supply chain or the region's regulatory convergence,"* said Serge Bernasconi, CEO of MedTech Europe.

### Access to needed medical technologies must be ensured

MedTech Europe, in a new position paper, emphasizes that it is critical for the negotiators to ensure continuous access to needed and innovative medical technologies for patients and healthcare providers across Europe. Any disruption in the supply of medical technologies could impact the delivery of healthcare both in the EU and the UK.

In particular, the association pinpoints several specific challenges that could impact industry's capacity to supply medical technologies to both markets. These include:

- Just-in-case distribution: "Just-in-time" delivery of parts or finished products risks to be hampered by new customs regime
- Refurbishment: Refurbishment and repair services of medical technology products that imply crossing the new border risk to face significant hurdles, due to cost and time levied by a new customs regime
- Tariffs: Medical devices and *in vitro* diagnostics might be subject to tariffs therefore increasing the manufacturing costs

### Divergence in regulatory systems impacts sector competitiveness

With the medical technology industry also at the forefront of implementing the new *in vitro* diagnostics regulation and medical device regulation, the trade association also calls for ensuring that the UK remains in alignment with the EU27 regulatory system. Any divergence of the regulatory systems, also in secondary legislation, will impact manufacturers and suppliers on both sides by adding costs and complexity in bringing needed solutions to the market.

*"An area of concern, for example, will be on notified bodies where the industry is concerned if there will be sufficient capacity available at notified bodies at early stage to manage the workload under the current and*

*future regulatory framework. UK notified bodies are used for large amounts of CE marking activity and the risk to lose this capacity due to Brexit needs to be mitigated”, Serge Bernasconi adds.*

The association calls for measures that will ensure the full availability of medical technologies for patients once the Brexit negotiations have come to an end.

*“We want to make negotiators aware of the tangibly sensitive areas that are important for the medical technology sector to deliver healthcare solutions seamlessly. For each point, we propose solutions to minimise the impact to patients and SMEs and we encourage negotiators to incorporate these concerns into future arrangements,” he adds.*

MedTech Europe and its members will continue to engage with relevant stakeholders to ensure that solutions are considered by Brexit negotiators on both sides of the table.

### **About MedTech Europe**

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are multinational companies and national medical technology associations operating in Europe and worldwide.

There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors.

Our sector employs more than 650,000 people. There are more than 26,000 medical technology companies in Europe, of which 95% are SMEs.

### **Press Contact**

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