MedTech Europe
from diagnosis to cure

Vitenis Andriukaitis
Commissioner
Directorate-General for Health and Food Safety
European Commission
Rue de la Loi 200
B- 1049 Brussels

Brussels, 07 March 2019

Prior via email

Re.: Open letter on the Impact of the Withdrawal of the UK from the EU on Healthcare delivery in the European Union

Dear Commissioner Andriukaitis,

I am writing to draw your attention to the impact that the withdrawal of the United Kingdom from the European Union will have on the medical technology sector. The supply of critical medical technologies could be compromised leading to disruptions within the EU-27 due to shortages in the supply of blood and blood products (shortage of tests to ensure the safety of the blood supply), emergency surgery and care (shortage of sutures, reconstructive orthopaedic devices, emergency interventions in ophthalmology) and other healthcare interventions.

For the benefit of patients, I urge the Commission to intervene and ensure the continued supply of medical devices to the EU-27. It is of extreme concern that no contingency measures are even being considered to allow patients in the EU continued access to devices required for essential therapies. Such measures would only be required for a limited time. Given the impact that the withdrawal of the United Kingdom from the European Union will have on the ability of healthcare systems to ensure patient care, we urge that you consider this as a priority.

Under existing EU legislation, medical devices need to be certified by a notified body. UK notified bodies play a central role in this certification, covering between 30-40% of medical devices used in the EU. However, in key fields such as emergency and routine care, the role of UK notified bodies is even more important as they cover over two thirds of all devices used in the EU, for instance in:

- Tests to ensure the safety of the blood supply (IVDs)
- Orthopaedic implants (knee and hip replacements in particular)
- Surgical sutures
- Ophthalmology

Without a valid certification it would no longer be legal to place these products on the EU market, potentially leading to shortages and disruptions for healthcare delivery and more specifically, blood supply.

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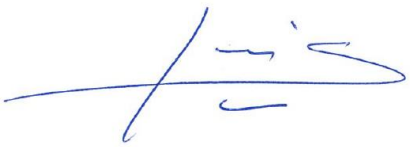
In the absence of a European approach, national authorities across the European Union are taking measures to address the situation and safeguard national healthcare systems. However, these measures are not consistent.

Some Member States consider that only specific derogations will be granted and even then, in only in very narrow cases. Other member states seek to implement a systemic approach to mitigate the impact. Such a disjointed approach will inevitably create disparities in patient care across the EU and cause significant disruption of the internal market.

I remain at your disposal to help ensure a rapid resolution to this pressing problem.

Yours sincerely,



Serge Bernasconi
Chief Executive, MedTech Europe

Cc: Jyrki Katainen – Vice President – Jobs, Growth, Investment and Competitiveness
Cc: Michel Barnier – Chief Negotiator – Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU
Cc: Andrzej Rys – Director – Health Systems, Medical Products and Innovation