



Mr. Michel BARNIER

EU Chief Negotiator
Task Force for the Preparation and
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the United Kingdom under Article 50 TEU
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Rt. Hon David DAVIS MP

Secretary of State
Department for Exiting the European Union
9 Downing Street
SW1A 2AG
London
United Kingdom

Brussels and London, 12 September 2017

Dear Mr. Barnier and Secretary of State,

As the trade associations representing the medical devices and *in vitro* diagnostics industry in Europe and the United Kingdom, MedTech Europe, the Association of British Healthcare Industries (ABHI) and the British In Vitro Diagnostics Association (BIVDA), we would like to highlight the importance of the medical technology industry for public health, and the need for sector specific measures during the ongoing “Brexit” negotiations between the European Union (EU) and the United Kingdom (UK). Such measures will not only ensure that patients continue to receive timely access to life saving technologies, but also ensure the future global competitiveness of an important sector for both the EU and UK economies.

In the UK, the medical technology industry employs around 90,000 people in 2,500 companies. The industry generates a turnover of £17 billion, and has seen an 11 per cent employment growth in recent years. Additionally, companies are supported by a service and supply sector of 1000 companies, employing 28,500 people with a turnover of nearly £5 billion.

In Europe, the sector employs more than 575,000 people in some 25,000 companies. As in the UK, 95 per cent of these companies are small and medium sized enterprises (SMEs). The industry files a patent every 50 minutes and has an annual turnover of €110 billion, with an average annual growth of 4 per cent over the past six years.

Like many sectors, the medical technology industry thrives due to the European Single Market, where both EU and UK citizens benefit from access to innovative medical technologies. A key element of this has been consistent, pan European regulatory arrangements.

EU wide Medical Devices and *In Vitro* Diagnostic Medical Devices legislations, which provide marketing approval via the CE marking process, have played a key role in delivering high quality care to patients for over 25 years, allowing them timely access to safe and effective medical technologies.

The current EU wide system is being updated in stages, and the new Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations will be applicable to EU members in full in May 2020 and May 2022, respectively. The UK is subject to these updates until it leaves the EU in March 2019. Unchecked, from that date, the UK's Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations will become increasingly divergent from the CE marking system. We believe that any such divergence would be unhelpful, and that, whatever other arrangements may be in place, a transitional period to implement secondary legislation for medical devices and *in vitro* diagnostic medical devices, and maintain parity of regulation with the EU, is needed. Ensuring the complete adoption of the Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations up until the end of May 2020 and May 2022 will protect the supply of medical technologies to patients throughout the EU and beyond.

Collaboration between organisations based in the UK and those in other Member States, has also played an important role in the development and administration of regulation throughout Europe. The UK's Competent Authority, the Medicines and Healthcare Products Regulatory Agency (MHRA) enjoys a preeminent position internationally, and with a trend towards global harmonisation, any weakening of existing EU wide networks would leave both parties poorer.

Similarly, the sharing of post market surveillance data does much to protect patients, and will be negatively impacted if current arrangements were to end.

Critical factors to ensure regulatory stability are:

1. The UK to remain an active part of the European regulatory framework (CE marking regime) for medical devices and *in vitro* diagnostic medical devices under a full implementation of the new Medical Devices and *In Vitro* Diagnostic Medical Devices Regulations;
2. The UK Notified Bodies (NBs) to remain European designated NBs;
3. Legal entities, such as Authorised Representatives or legal manufacturers located in the UK to be considered as "European-based" under the new regulations;
4. MHRA to participate formally in the European Commission's new Medical Devices Coordination Group (MDCG);
5. The UK to continue having full access to – and reliance on – the newly set European Database for Medical Devices (Eudamed): EU-wide pre and post-market data, registration of economic operators, details of clinical investigations, and so forth.

The points above should be included in a comprehensive agreement post-Brexit. Any regulatory divergence will increase both bureaucracy and cost. Creating two distinctive regulatory frameworks would disrupt innovation and growth in the industry, and hinder patient access to medical technologies.

To maintain and protect the health of both EU and UK citizens, it will also be important to ensure the movement of goods across borders remains as seamless as possible. Medical

technologies are often moved around different jurisdictions during their lifecycle. Components sourced from a number of different countries may be assembled in one, moved to another for packaging and sterilisation, and taken to a distribution hub in yet another, before being delivered to their end user. Similarly, finished products are also moved around for cleaning and maintenance. To protect the supply of medical technologies to patients, it will be critical to limit regulatory and administrative barriers for products being moved between the EU and the UK. Indeed, it is non-tariff barriers, such as those resulting from regulatory changes or extensive requirements at customs, that are likely to have a significantly higher impact on businesses and the markets they serve than macro-economic factors such as currency depreciation. For our sector, the consequences are disruption to the supply of devices and diagnostics critical to the delivery of modern healthcare, the maintenance of patient safety and the preservation of public health throughout Europe.

For the reasons outlined above we believe an appropriate transition period is essential for our sector to be able to implement the necessary measures to ensure the continuity of access to medical technologies in the UK and the EU post-March 2019.

We are keen to continue engaging with both the UK and EU authorities to ensure that the medical devices and *in vitro* diagnostics industry is well-represented and considered in ongoing negotiations. We hope to have the opportunity to meet with you in the near future to further discuss these issues in detail.

Yours sincerely,

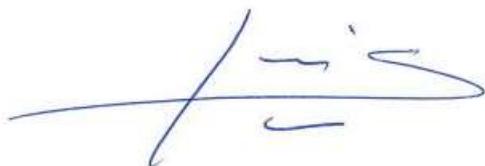
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c.c.: Lord James O'Shaughnessy, Secretary of State, Department of Health, England,
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