Mr. Michel BARNIER
Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU
European Commission
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0149 Brussels
Belgium

Rt Hon David DAVIES MP
Secretary of State
Department for Exiting the European Union
9 Downing Street
SW1A 2AG
London
United Kingdom

26 October 2017

Dear Mr Barnier and Secretary of State,

As the trade associations representing the dental industry in Europe and the United Kingdom, the Federation of the European Dental Industry (FIDE) and the British Dental Industry Association (BDIA), we would like to highlight the important role that dental technology and the dental devices sector plays in public health, and the measures that can be taken to safeguard the sector during the ongoing “Brexit” negotiations.

In the UK, the dental industry employs around 8,000 people in over 300 companies. The industry generates a turnover of €490 million annually and supports the treatment of over 15 million UK patients every year. This represents one of the leading markets in Europe, where the industry has a total annual turnover of around €6.7 billion, average annual growth of 2.7% for the past five years and employs about 45,000 people in 550 companies.

The dental industry and the EU and UK citizens it serves have benefitted greatly from the European Single Market and a consistent, shared regulatory environment. EU-wide medical device legislation, which provides market authorisation via CE marking, has facilitated delivery of high quality care to patients for over 25 years, enabling timely access to safe, effective and innovative dental technologies.

Recently published EU legislation, the Medical Device Regulation (2017/475), will be applicable in the UK until it leaves the EU in March 2019. Thereafter, there is a risk that UK and EU legislation may diverge, to the detriment of patients and businesses across Europe. We believe that there should be a commitment to parity of UK and EU legislation, and that a transition period may be necessary to achieve this.

The UK has played a major role in the development of dental and medical device regulation in Europe for many years. The UK’s Competent Authority, the Medicines and Healthcare Products Regulatory Agency (MHRA), enjoys a preeminent position internationally and it would benefit all parties concerned for this to continue, especially in the context of a trend towards global harmonisation.
The production and supply of dental devices often involves a complex cross-border network across Member States. In other international markets it is non-tariff barriers, often arising from conflicting regulatory regimes, that most seriously limit trade. Ensuring that such barriers do not emerge between the EU and UK will be crucial in protecting the future oral health of EU and UK's citizens, and the global competitiveness of European dental businesses.

A comprehensive agreement including the following points would avoid disruption to innovation and growth, increases in bureaucracy and cost, or limiting patient access to treatment:

1. EU Medical Device Regulations to be adopted in the UK;

2. The UK is able to remain an active participant alongside Member States in the European regulatory framework (CE marking regime) for medical devices;

3. UK Notified Bodies (NBs) would remain European designated NBs

4. Legal entities located in the UK, such as Authorised Representatives or legal manufacturers, would be considered as "European-based" under the MDR;

5. The MHRA has the opportunity to participate formally in the European Commission's new Medical Devices Coordination Group (MDCG);

6. The UK maintains full involvement and participation in the European Database for Medical Devices (Eudamed)

For these reasons we believe an appropriate transition period may be necessary to allow our sector to allow implementation of the necessary measures to ensure the continuity of access to dental technologies in the UK and the EU post-March 2019, while providing much needed certainty and stability for business.

We are keen to continue engaging with both the UK and EU authorities during the ongoing negotiations, and would welcome the opportunity to discuss these issues with you in greater detail.

Yours sincerely,

Dr. Alessandro Gamberini
President
FIDE

Sonia Tracey
President
BDIA