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Consequences of Brexit for the medical devices production industry

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BREXIT CALENDAR

- 23 June 2016

Referendum in the United Kingdom: 51.9% of votes in favour of "Brexit".

- 29 march 2017

Delivery of the Brexit notification letter

- 19 june 2017

Beginning of formal negotiations

- 8 december 2017

Preliminary agreement on divorce, start of the second phase of negotiations

- 25 november 2018

Validation of the agreement by EU leaders

- 15 january 2019

Rejection of the agreement by the House of Commons

- 12 march 2019

Second rejection of Theresa May's agreement

- 29 march 2019

Third rejection of the Theresa May agreement

- 11 april 2019

Brexit postponed to October 31

- 31 october 2019

Divorce between the United Kingdom and the EU

On the eve of the new European Commission taking office, the United Kingdom should stop being part of the European Union.

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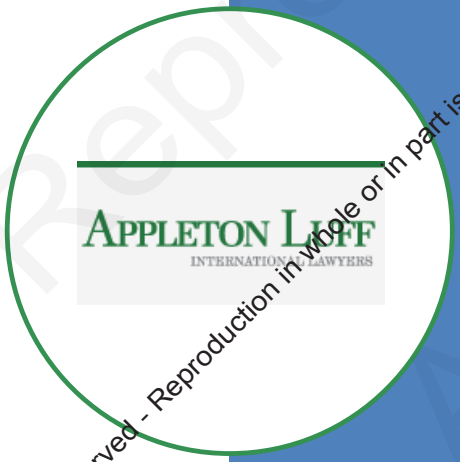
- The impact of Brexit is particularly far-reaching because of
  - the role of medical devices in life-saving and life-changing treatment,
  - the comprehensive regulatory framework,
  - cross-border supply chains, and
  - use of patient health data.

Ensuring the continued supply and safety of medical devices is paramount.



KEY TRADE RISKS

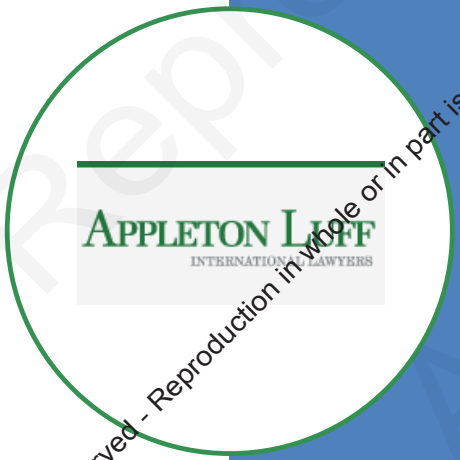
- Medical devices regularly cross borders during the supply chain.
- Components are sourced from different countries.
- Manufacturing stages are performed in different locations.
- Products may continue to be moved around once on the market for cleaning and maintenance.

Any increase in tariffs or non-tariff barriers such as increased processing times at customs resulting from Brexit signifcantly disrupt supply chains

RISK OF REGULATORY DIVERGENCE

- Much of the UK's current regulatory framework for medical devices stems from EU law.

- This framework has recently been overhauled with the introduction of two new regulations: the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR), which replace the three current EU medical device directives and apply from May 2020 and 2022 respectively.



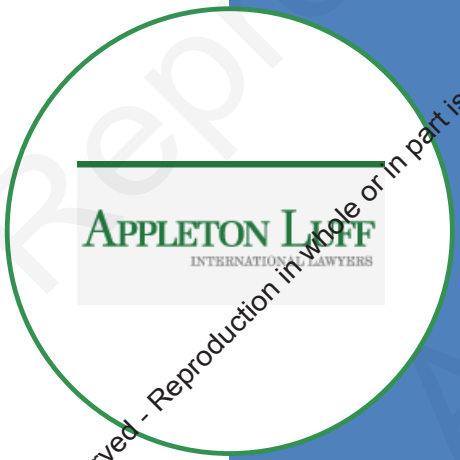
RISK OF REGULATORY DIVERGENCE

- The UK Government and industry are seeking close co-operation, regulatory alignment and minimal disruption for medical devices post-Brexit.

The UK has confirmed its intention to implement all key elements of the MDR and IVDR after exit.

RISK OF REGULATORY DIVERGENCE

- Unless the EU27 and UK agree otherwise, the UK regulator, the MHRA, will **not be able to participate in** the newly established **Medical Devices Coordination Group**, which is tasked with developing guidance and taking decisions on the interpretation and implementation of the new MDR and IVDR.
- The UK would also **no longer** have **access** to established EU structures such as the **European Databank on Medical Devices (EUDAMED).**



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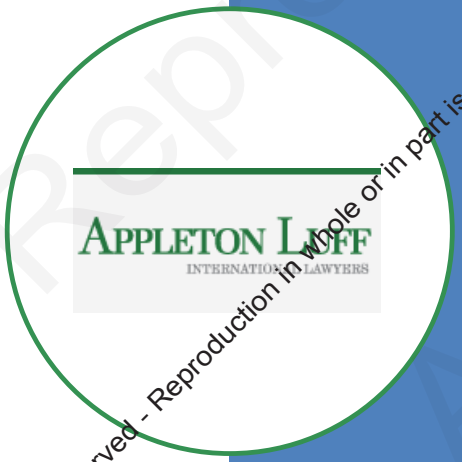
INNOVATION RISKS

- Brexit could impact on the **UK's participation in EU research funding and collaboration programs**, as well as **access to EU scientists**, researchers and other highly-skilled workers.



ACCESS TO THE EU

AUTHORISED REPRESENTATIVES (AR)

- A manufacturer supplying devices to the European market can only do so if the company is based in the EU or by using an authorised representative (AR).
- The Commission has clarified that following a no-deal Brexit, **the EU will not recognise UK-based Authorised Representatives**.

ACCESS TO THE EU

AUTHORIZED REPRESENTATIVES (AR)

- UK manufacturers may need to set up an establishment or appoint a third party authorised representative (AR) in a remaining EU27 state.
- Similarly, manufacturers based outside the EU that currently have a UK AR may need to appoint a new AR located in a EU27 state.
- Changes may also need to be made to product labels and instructions for use (IFUs) to include the details of new establishments or ARs

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ACCESS TO THE EU

NOTIFIED BODIES

- CE certificates for EU regulations can only be issued by notified bodies based in the EU.
- This means that all certificates issued by notified bodies based in the United Kingdom will become void after the withdrawal from the United Kingdom
- In other words, a manufacturer will no longer be able to place devices on the European market that require a valid CE certificate using a British notified body

ACCESS TO THE EU

NOTIFIED BODIES

- **Medical devices assesssed by a UK Notified Body may need to be reassessed by a Notified Body in an EU27 state**.
- UK notified bodies cover between 30 and 40% of medical devices used in the EU.
- In key areas such as emergency and routine care, the role of UK notified bodies covers more than two thirds of all devices used in the EU, for example by:
  - Tests to ensure the safety of the blood supply (IVD)
  - Orthopaedic implants (knee and hip prostheses in particular)
  - Surgical sutures
  - Ophthalmology

ACCESS TO THE EU

EU DISTRIBUTORS BECOME IMPORTERS

- Distributors of medical devices in EU 27 markets that have been manufactured in the UK may become ‘importers’ taking on additional responsibilities under the new MOR and IVOR.
- Companies established in the United Kingdom can no longer be used by other third countries as importers for the EU.

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ACCESS TO THE UK

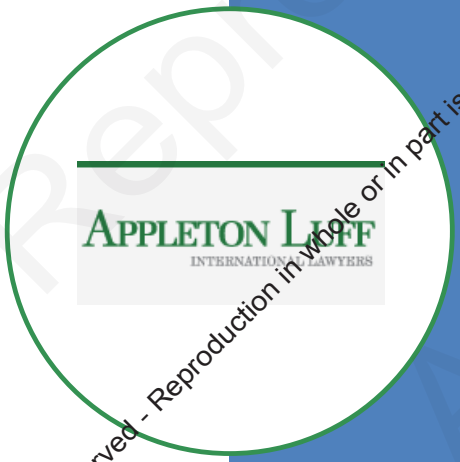
UK RESPONSIBLE PERSON

- The Exit Regulations provide that any manufacturer not based in the UK (including those in the EU) must appoint a UK Responsible Person if they have devices on the UK market.
- This Person must be physically located in the UK and capable of being contacted at any given time by the MHRA

ACCESS TO THE UK

NOTIFIED BODIES AND CONFORMITY ASSESSMENTS

- The UK Government has confirmed that the **UK will continue to recognise EU27 Notified Body assessments**, at least in the short term (including against the Medical Devices Directive 93/42/EEC and the EU MDR, once in effect).
- The Exit Regulations provide for CE-marked products to continue to be placed on the market in the UK for a limited period of time.



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ACCESS TO THE UK

REGISTRATION

- Whereas previously only a narrow class of devices needed to be registered with the MHRA, following a no-deal Brexit, the Exit Regulations require all devices and IVDs being placed on the UK market to be registered, regardless of whether they have also been registered in an EU-27 country

ACCESS TO THE UK

REGISTRATION

- The Exit Regulations provide for a transition period to enable manufacturers to come into compliance with the new registration requirements
  - 4 months for higher risk devices
  - 8 months for medium risk devices
  - 12 months for lower risk devices

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PERSONAL DATA TRANSFERS

- Many medical devices generate and transfer patient health data to support patient care.
- Additional safeguards may need to be put in place for transfers of patient data between the UK and EU27.

WHAT'S NEXT?

No Brexit deal: hard Brexit.

Deal is signed: transition period

- Option 1 : Single Market
- Option 2 : Customs Union
- Option 3 : Free Trade Area
- Option 4 : Mutual Recognition Agreement (MRA)

MRAS already exist with **Australia, Canada, Japan, New Zealand, the USA, Israel and Switzerland**

Thank you for your attention !

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