Brexit snapshot:
Medical Devices

Do you hold a CE certificate of conformity issued by a UK notified body? Are your manufacturing activities, authorised representative, suppliers, customers or contracting parties located in the UK?

Brexit will affect you. What should you do now?
What is the latest on Brexit?

The UK is scheduled to leave the EU at 11pm on 29 March 2019. Currently, the UK is still part of the EU and EU law still applies in the UK. On leaving, the UK will become a “third country”.

EU law will be transposed into UK law.

The UK’s European Union (Withdrawal) Act will transpose all EU law directly into UK law. Assuming that happens on day one after Brexit, the law in the UK will still be the same as it is currently and the same as in the EU. Post-Brexit, the UK Government can then decide whether it wishes to make changes to that UK legislation.

But it’s not that simple in practice.

Transposing over 40 years of legislation is not straightforward. There are numerous references in EU law to a company or person being present within the EU, or the involvement of an EU institution or agency, or access to an EU system or database, which cannot simply be transposed. The UK cannot unilaterally legislate to continue participating in those EU bodies and systems. Depending on the outcome of negotiations with the EU, the UK may need to set up new bodies and systems to enable parts of UK legislation to operate post-Brexit.

The UK and EU have negotiated the withdrawal terms...

The EU27 and UK have negotiated draft terms on which the UK will leave the EU, known as the Withdrawal Agreement. This sets out what will happen to existing products and regulatory requirements in the UK and EU27 on withdrawal. It also provides for a “transition” period after the UK leaves to give businesses time before the new arrangements apply, which would run from 30 March 2019 to 31 December 2020.

...and an outline of the future trading relationship.

The EU operates as a single market with common regulatory standards and a customs union with no tariffs on imports between Member States and a common tariff for imports from “third countries”. The UK and EU have also negotiated a political declaration containing a high level outline of the future UK and EU relationship based on a free trade area with zero tariffs and quotas, a new customs arrangement and co-operation on goods. However, there is still much uncertainty as to the details of the future relationship at this stage.

The UK Parliament has rejected the withdrawal terms and outline.

While EU leaders have approved the terms of the Withdrawal Agreement and the political declaration on the future trading relationship, the UK Parliament has voted to reject them. Both the UK and the EU27 have been explicit that nothing is agreed until everything is agreed, which means that without approval of the Withdrawal Agreement and political declaration, the UK risks “crashing out” with no transition arrangements in place.

The likelihood of a “no deal” Brexit has increased

The default legal position is that the UK will leave the EU automatically at 11pm on 29 March 2019 with no “deal” in place, unless something else is agreed. The current political deadlock in the UK is unprecedented so it is difficult to predict what will happen next. The possibilities include trying to amend the existing draft Withdrawal Agreement, negotiating an alternative deal, “no deal”, a second referendum or a general election. Many of these options will take time and would likely require the date of Brexit to be delayed. Businesses need to prepare for the real possibility that the UK might leave the EU with no withdrawal terms in place.

To keep up to date with new developments, visit our Brexit hub and subscribe to our Brexit bulletin: hoganlovells.com/brexit
The impact of Brexit on medical devices

The key areas affected are regulation, trade, people and innovation

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

While some issues are common across industries, 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 means that the impact of Brexit is particularly far-reaching.

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, and 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 could significantly disrupt supply chains.

Key people and 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.

Brexit will also impact other relevant areas such as intellectual property.

There is a 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.

The MDR and IVDR will only partly be in force on the date of the UK's withdrawal from the EU, and therefore will not be automatically transposed into UK law under the European Union (Withdrawal) Act.

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.

However, 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).

Key regulatory risks

Depending on the final agreement reached between the EU and UK, the regulatory implications include:

Place of establishment: 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 an 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.

Notified Body assessment: Around 45% of all medical devices CE marked in the EU are reported to have been assessed by a UK Notified Body. Medical devices assessed by a UK Notified Body may need to be reassessed by a Notified Body in an EU27 state. The UK Government has confirmed that the UK will continue to recognise EU27 Notified Body assessments, at least in the near term. No equivalent undertaking has been given by the EU27.

Distributors: Distributors of medical devices in EU27 markets that have been manufactured in the UK may become 'importers' taking on additional responsibilities under the new MOR and IVOR.

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.

For a more detailed analysis of the regulatory issues impacting medical device companies, visit: hoganlovells.com/brexit
What should you do now to prepare?

For detailed advice on how to identify areas of legal and commercial business risk created by Brexit and contingency planning, visit our Brexit toolkit: hoganlovellsbrexit.com/brexit-toolkit

Much about Brexit remains unclear so deciding what changes to make and when is challenging. However what is clear is that you should make sure you have identified potential impacts and have a contingency plan in place so you are in a position to move quickly.

Specifically, medical device companies should be:

- Reviewing any regulatory arrangements and supply chain operations that involve the UK, including manufacturing activities, distribution and import sites, notified body assessments, and personal data processing.

- Conducting a gap analysis of any contracts involving the UK to identify any risk and opportunities created by Brexit and ensure they are aligned with any regulatory driven changes.

- Considering the wider business impact of any changes as a result of regulatory requirements. For example any tax or transfer pricing implications or significant IT systems and business process changes of relocating assets or activities to a company in the EU27.

- Monitoring Brexit developments and engaging with government and industry associations in the UK, Brussels and the EU27 to optimize the landscape for your business.

How can we help you?

We can:

- Carry out a gap analysis to identify and prioritise the steps that you should be taking to prepare for Brexit based on a tailored application of our Brexit toolkit.

- Advise you on which operations you might need to move and which EU27 countries you might consider moving them to.

- Implement changes to your business ranging from relocating entities, activities or people to IT and other operational changes.

- Analyse your contracts to identify and mitigate Brexit related risks in both existing contracts and template agreements.

- Develop an effective strategy to engage with policy makers to support your business priorities.

- Train your key stakeholders on the risks and opportunities of Brexit for your business.

Why work with us?

Expertise
Ranked Band 1 by Chambers for Life Sciences in Europe and by Legal 500 for our Brexit advisory work and commercial contracts.

Brexit focus
A dedicated taskforce analysing and alerting businesses to Brexit related issues. Our Brexit Hub covers latest developments and industry specific regulatory analysis.

Policy engagement
Our Chambers Band 1 ranked Public Law and Public Affairs practice is experienced in developing strategies to influence business-critical Brexit policy issues.

International integration
Our integrated cross-border team is experienced in developing practical solutions to pan-European issues.

Experience
We are advising a number of our life sciences clients on their preparations for Brexit.

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Where can you find out more? Visit hoganlovells.com/brexit