BREXIT

From a medtech perspective

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INTRODUCTION

On February 1, 2020 the United Kingdom ("**UK**") left the European Union ("**EU**"), a.k.a. "Brexit". This was followed by an 11-month transition period which ended on December 31, 2020. The consequences of Brexit impact countless areas of the UK economy as well as other economies. The ideas behind the creation of the EU - and the laws and regulations applied within it - were to create transparency and enhanced conditions for trade and free movement of goods, persons, services and capital within EU's internal market. With the UK having decided to leave the internal market, it is now legally seen as a "third country", which has considerable legal effects on many EU-based legislations. Whilst the UK has left the EU, Northern Ireland continues to follow many of the EU's rules, and there is a new "regulatory" border between Northern Ireland and Great Britain (England, Scotland and Wales). As is the case for many sectors, Brexit impacts the medical device[1] industry and this white paper aims to explore implications for those involved in the development, manufacturing, and marketing of medical devices.

Disclaimer

The information provided in this white paper is the authors' interpretation of the impact of Brexit and shall not constitute legal advice. An individual interpretation must be made in each specific case. Hence, readers are responsible for their interpretation and should assess and interpret the impact on their specific medical device(s) and operations.

[1] Including *in vitro* diagnostic and active implantable medical devices

EXECUTIVE SUMMARY

The medical device industry is significantly impacted by Brexit, primarily due to the change in the legal landscape. Notably, the departure by Great Britain from the EU medical device regulatory framework leads to the following:

- Product registration with the UK regulator, the Medicines and Healthcare products Regulatory Agency ("**MHRA**"), is required for all device classes and is implemented based on device classification.

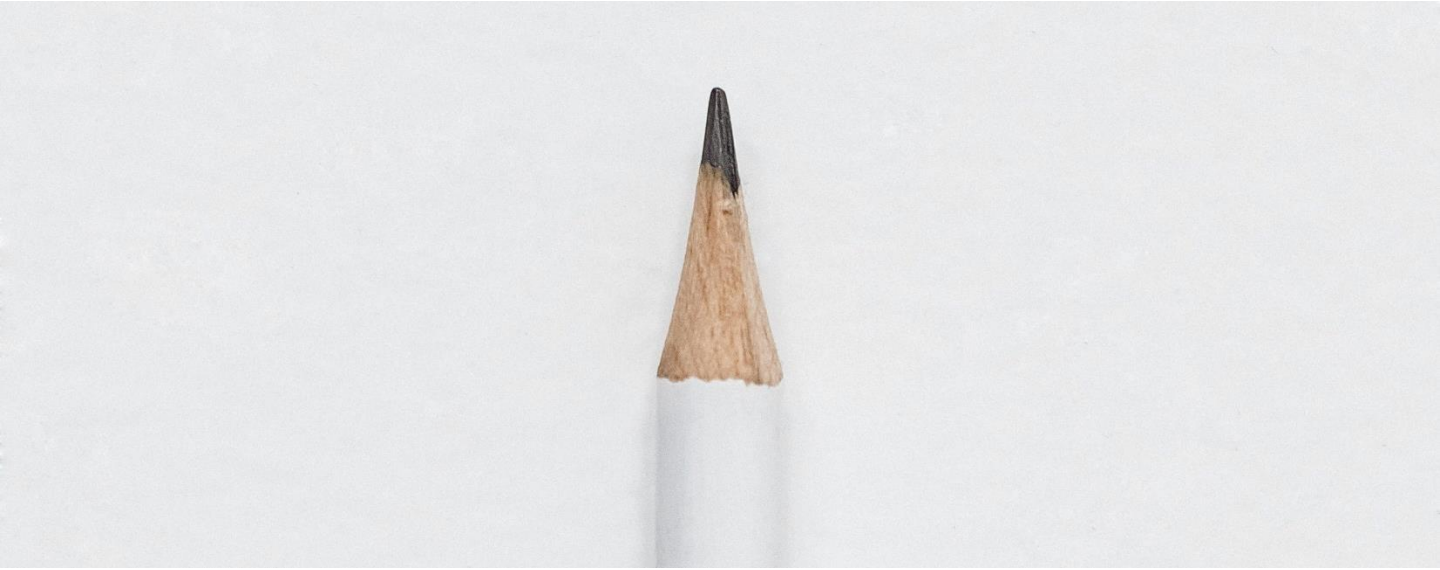
- A UK Responsible Person will be required for manufacturers based outside the UK.

- The CE mark will be recognized in Great Britain until June 30, 2023 and thereafter a UKCA mark will be required.

- UK-based Notified Bodies are now known as Approved Bodies and will be needed to obtain a UKCA mark for products subject to third party conformity assessment.

- Clinical evidence requirements will differ in Great Britain compared to EU and Northern Ireland for some time once the new EU regulations fully apply. Clinical investigations are affected by the UK's status as a third country; in particular via the effect on Authorised Representatives.

Economic operators and sponsors are advised to be aware of the different requirements for Northern Ireland. Impact is not limited to device-specific regulation, and in relation to data transfers, the UK is now a third country under GDPR. However, until June 30, 2021, data can be freely transferred between EU Member States and the UK. After this date, the provisions of GDPR Chapter V have to be met for such transfers. Other affected areas of importance include intellectual property rights and taxes.



LEGAL BACKGROUND

All EU Member States have adapted most of their legislation to EU and undertaken obligations not to have laws that are contrary to the EU legislation. However, sometimes an EU Member State law and an EU law oppose each other. In most such situations it is the EU law that applies, known as EU law taking precedence. Many of the laws that the EU institutions (the European Parliament and the Council) decide to adopt are directly applicable and apply in all Member States without being incorporated or transformed into national law, i.e., such laws become part of national law with its entry into force and is known as a regulation. The data protection regulation ("**GDPR**") is one example of such regulation that entered into force, in the exact same wording, in all Member States in 2018. Directives, another type of EU law, such as the medical device directive which will soon be replaced by the medical device regulation, on the other hand aim to harmonize Member States' national legislation in different areas. A directive prescribes the results to be achieved by the Member States but leaves it to them to determine the form and procedure for implementation merely stating when it must be implemented in the Member States at the latest.

As can be noted from the foregoing, EU laws affect all EU Member States even though it is not always clear to the citizens. However, with regard to the UK, its companies and citizens, they can no longer rely on the EU legislation. Against this background, it is important to be aware of the need to comply with a whole new set of rules as of now. No matter if an actor is based within the UK, using suppliers in the UK or if the actor is targeting customers in the UK.

The EU and the UK managed to reach an exit agreement in December 2020. The agreement, which sets out the rules for economic relations between the EU and the UK, ensures, among other things, continued duty-free trade in goods. In relation to privacy, the EU and the UK entered into a temporary agreement for the transfer of personal data between the EU and the UK.

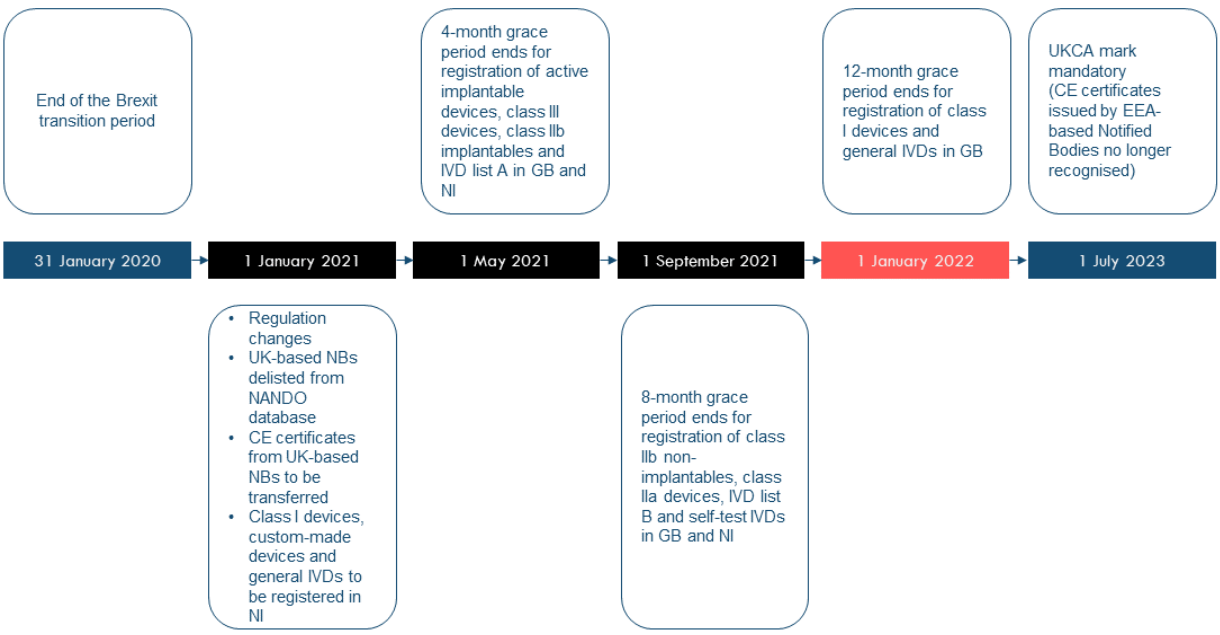
This white paper focuses on implications of Brexit in relation to medical devices. Other impacted areas that are key to medical devices and the broader field of life sciences are, for instance, the three intellectual property systems: the EU trademark system, the EU design registration system, and also the forthcoming Unitary Patent System. As an example, after December 31, 2020, an applicant for an EU trademark will no longer receive protection for this trademark in the UK. Already registered EU trademarks (registered before December 31, 2020) will, however, be automatically converted into two trademark registrations, one for the EU and one for the UK. Other areas that are very much affected are tax, customs and privacy regulations.

TRANSITION TIMELINE AND REGULATION CHANGES

On December 31, 2020, the transition period ended meaning that as of January 1, 2021, several changes for manufacturers placing medical devices on the market in Great Britain were introduced. The UK Competent Authority, the MHRA, now has an even more prominent role in regulating the UK medical devices market, as it has taken on responsibilities previously with the EU.

In Great Britain, devices are currently regulated under the three directives, EU AIMDD (90/385/EEC), EU MDD (93/42/EEC) and EU IVDD (98/79/EC), implemented in UK law through UK Medical Devices Regulations 2002 (UK MDR 2002). Great Britain continues to operate under these directives until the new UK regulatory framework is introduced via the Medicines and Medical Devices ("**MMD**") bill 2019-21.

Since the transition period ended before the EU Medical Devices Regulation 2017/745 ("**EU MDR**") and the EU In Vitro Diagnostic Medical Devices Regulation 2017/746 ("**EU IVDR**") came into effect, these were not automatically retained by the EU Withdrawal agreement, hence will not be implemented in Great Britain. Due to the Northern Ireland Protocol, the EU MDR and EU IVDR will apply in Northern Ireland with the same timelines as for the EU implementation.



IMPACT ON MEDICAL DEVICE MANUFACTURERS ESTABLISHED OUTSIDE THE UK

CE mark, UKCA mark and UK Approved Bodies

CE marked medical devices and *in vitro* diagnostic medical devices ("**IVDs**") that conform fully to any of the following EU legislations; EU AIMDD, EU MDD, EU IVDD, EU MDR or EU IVDR, will continue to be accepted in Great Britain until June 30, 2023. This includes devices that are subject to self-certification. Certificates issued by EU Notified Bodies will also continue to be valid until this date.

As of July 1, 2023, the UKCA mark will be required in order to place a medical device on the market in Great Britain. For device classifications where a third-party conformity assessment is required, a UK Approved Body must be consulted. CE marking is still required in Northern Ireland, which means EU rules shall be met.

All Notified Bodies located in the UK were removed from the NANDO database when the transition period ended on December 31, 2020, and have now been re-designated as UK Approved Bodies[2]. CE certificates issued by a UK Notified Body are no longer valid in the EU and economic operators wishing to retain a CE certificate should have either applied for a new certificate issued by an EU Notified Body, or organised a transfer of the file and certificate from the UK-based Notified Body to an EU Notified Body.

UK CA

The UKCA mark

Registration and UK Responsible Person

As of January 1, 2021, medical devices and IVDs placed on the market in Great Britain must be registered with the MHRA, with grace periods for when registration shall be completed depending on the classification of the device (please see timeline schematic). Manufacturers not established within the UK must appoint a UK Responsible Person to register and act on their behalf. It is possible for a single entity to act as both an Authorised Representative based in Northern Ireland and a UK Responsible Person. Manufacturers are encouraged to appoint a UK Responsible Person as soon as possible in order to complete the registration in time. All responsibilities of the UK Responsible Person are expressed in detail in the UK MDR 2002.

Manufacturers based in the EU or the EEA must appoint a UK Responsible Person if they intend to place devices on the Northern Ireland market. This is with the exceptions of manufacturers of class I medical devices, general IVDs and custom-made devices, already registered with a competent authority within the EU, who do not need to appoint a UK Responsible Person for placing a product on the Northern Ireland market.

[2] https://www.gov.uk/government/publications/medical-devices-uk-approved-bodies

CLINICAL DATA

Clinical evidence continues to be of importance to demonstrate safety and performance of medical devices and IVDs as it is a requirement for market access. There will be a period where the requirements for clinical evaluation (devices)/performance evaluation (IVDs) and clinical investigations (devices)/clinical performance studies (IVDs) will differ between EU and Great Britain. Clinical/performance evaluations, and the clinical studies supporting them, performed for products to be marketed in Great Britain will need to be completed in accordance with the MDD, AIMDD and IVDD as incorporated into UK law, as Great Britain continues to operate under these directives until the new UK regulatory framework is introduced via the MMD bill 2019-21; whereas for the EU and Northern Ireland, the EU MDR and EU IVDR will fully apply from May 2021 and May 2022, respectively.

Clinical investigations and clinical performance studies may be impacted by Brexit when the sponsor, or Authorised Representative[3] of a non-EU sponsor, is based in the UK and/or when there are UK investigation sites. There are no immediate changes to safety reporting, i.e., all serious adverse events must still be reported to the Competent Authority in every country where a clinical investigation is taking place; however, once the new EU regulations fully apply, safety reporting in the EU and Northern Ireland shall be performed in line with the new regulations, as described in MDCG 2020-10/1. Manufacturers/sponsors with ongoing investigations are advised to communicate with the relevant Competent Authority(ies) to mitigate the risk of investigation suspension or termination.

Clinical studies in the EU with UK-based sponsors

UK-based sponsors wishing to carry out a clinical study including sites located within the EU will need to appoint an EU-based Authorised Representative to comply with EU law. Similarly, sponsors with a UK-based Authorised Representative will need to transfer to an EU/EEA-based Authorised Representative if the investigation includes EU/EEA investigation sites.

Clinical studies in the UK with EU-based sponsors

The MHRA has not updated its guidance for device investigations in the aftermath of Brexit.[4] There is, however, new guidance for clinical trials of medicinal products stating the MHRA will accept sponsors based in the UK or sponsors/Authorised Representatives in a country on the approved list of EU/EEA countries for trials with only UK sites.[5] There are no obvious reasons why a stricter approach – such as a requirement for a UK Responsible Person – would be applied to medical devices.

[3] Authorised representative is used for studies carried out under the MDD, AIMDD, and IVDD whereas legal representative is used for studies carried out under the MDR/IVDR.
[4] https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-medical-device
[5] https://www.gov.uk/guidance/clinical-trials-for-medicines-apply-for-authorisation-in-the-uk#trial-sponsor-and-legal-representative

GDPR AND BREXIT DATA TRANSFERS

General about data transfers outside of EU/EEA

The GDPR gives individuals in all EU Member States equal protection of personal data and privacy. This also applies to the EEA countries. Therefore, personal data can be transferred freely within this area without restrictions.

Outside the EU/EEA, on the other hand, there are no general rules that provide corresponding guarantees. The GDPR therefore contains specific provisions in Chapter V (Articles 44 to 50) on the conditions under which it is permitted to transfer personal data to countries outside the EU/EEA area. A transfer of personal data outside the EU/EEA is only allowed under the following conditions:

a) there is a decision from the European Commission that, for example, a certain country outside the EU/EEA ensures a so-called adequate level of protection;

b) the exporter of personal data have taken appropriate protective measures, such as Binding Corporate Rules (BCR) or Standard Contractual Clauses (SCCs); and

c) in other special situations and individual cases as described in Chapter V.

Brexit data transfers

With the UK's withdrawal from the EU, the UK is, from January 1, 2021, to be considered as a third country under GDPR. The transfer of personal data to third countries may only take place if it complies with the provisions of Chapter V of the GDPR. However, on December 24, 2020, the European Commission and the UK agreed on an agreement to regulate the relationship between them regarding transfer of personal data from January 1, 2021. The concluded agreement currently means that personal data can still be freely transferred from EU Member States to the UK for a limited period, until June 30, 2021, without the requirements of Chapter V having to be met. The agreement does not constitute an adequacy decision as referred to in Article 45 of the GDPR. It is instead a temporary solution pending, hopefully, a possible decision on an adequate level of protection in the UK.

CONCLUSION

Brexit impacts the medical device industry primarily due to the change in the legal landscape. In Great Britain, devices are currently regulated under the three EU medical device directives and Great Britain continues to operate under these directives until the new UK regulatory framework is introduced. Northern Ireland has a unique status and economic operators with activities there should be mindful of the implications. A number of changes for those involved in the development, manufacturing and marketing of medical devices have been introduced with further changes introduced gradually. Changes are not limited to device-specific regulation and economic operators working with devices should be aware of the impact on, for example, data transfers, intellectual property, and taxes.

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