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The effect of Brexit on, and changes in, the European Union medical device regulations

With the exit of the UK from the European Union and the European Union Regulation 201/745 coming into effect on 26 May 2021, the regulatory landscape for medical devices is undergoing a substantial change, the implications of which will be felt by those procuring and using medical devices in clinical settings. This article outlines the changes that clinicians, as users of medical devices, should be aware of in the immediate future.

Mike Pogose[1]

Karandeep Badwal[1]

Xiao Liu[1,2]

Hugh Harvey[1,3]

Author details can be found at the end of this article

Correspondence to:
Mike Pogose; mike@hardianhealth.com)

Introduction

The European Union's Medical Device Regulations 2017/745 (European Parliament and Council of the European Union, 2017a), which replaces the Medical Devices Directive and Active Implantable Medical Devices Directive, will come into effect on 26 May 2021. Originally anticipated on 26 May 2020, the implementation of the new regulations was delayed by 1 year as a result of the COVID-19 pandemic. This, in combination with the new UK regulatory landscape in light of the UK's exit from the European Union, gives rise to a complex and uncertain immediate future for procurers and manufacturers of medical devices operating within and outside of the UK. One key question is what the impact will be on frontline clinical practitioners, as users of medical devices.

This article discusses the impact of the UK's exit from the European Union on the Medical Device Regulations and its implications for healthcare professionals as users of medical devices and in-vitro diagnostic devices. It will discuss the effects of Brexit on clinicians working within and outside of the EU and the new EU device regulations.

The Brexit effect

For ease of explanation, the implications of Brexit have been separated into four groups, depending on where the clinician is practising (ie where the medical device or in-vitro diagnostic device is being used):

1. Those practising in Great Britain (England, Scotland, Wales)
2. Those practising in Northern Ireland
3. Those practising in any of the remaining 27 member states of the EU
4. Those practising outside of the UK or the EU.

For each group, this section outlines the regulation which medical devices and in-vitro diagnostic devices will be required to conform to and upcoming dates for key changes. Specifically, clinicians and other medical professionals should be aware of the changes in point-of-contact for devices, depending on the location of the manufacturer. This is relevant for clinicians for the purposes of reporting adverse events.

For those practising in Great Britain

In the immediate future, the effects of Brexit from the viewpoint of practising clinicians using medical devices and in-vitro diagnostic devices in Great Britain will be minimal. The UK government has proposed a timeline (Medicines and Healthcare Product Regulatory Agency, 2020) that allows for the existing CE mark certification to continue to be recognised until mid-2023. If a product has received or will receive its certification before 26 May 2021, when the Medical Device Regulations comes into effect, then that certification will continue to be recognised until 30 June 2023.

Clinicians should work with their local hospital procurement teams, who will be experienced in running due diligence checks as part of regular procurement exercises. There may be a perceived risk around use of CE marked products, in terms of future-proofing the continued use of such products. In such cases, a series of enquiries regarding

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Table 1. Product label indicating the manufacturer's address and information on the UK Responsible Person for device manufacturers outside the UK

	The name and address of the manufacturer including country
	If the manufacturer is from outside the EU, the current company for dealing with complaints and other feedback will be shown here. In due course this will be replaced by the UK Responsible Person. If the manufacturer is UK-based then you would not see this symbol and the contact will not change

the company's track record at maintaining its regulatory responsibilities and whether a clear plan for transition to the UK Conformity Assessment is in place can be informative and provide peace of mind.

One specific change will be the point-of-contact for the device manufacturer, where the device comes from a company that is not UK-based. As of 1 January 2021, manufacturers based in the EU or anywhere outside of the UK must appoint a UK Responsible Person (Table 1). The UK Responsible Person is an appointed representative of the company within the UK, who acts on behalf of the device manufacturer to carry out specific tasks, including registration of the device, ensuring conformity and technical documentation is in place, and responding to requirements from the Medicines and Healthcare products Regulatory Agency.

For clinicians working in the field of experimental or custom devices, new rules apply regarding registration with the Medicines and Healthcare products Regulatory Agency, but otherwise the regulatory framework remains the same as pre-Brexit.

It should be noted that the point at which the above points were made during writing (mid-December 2020), the relevant UK legislation (The Medical Devices (Amendment etc.) (EU Exit) Regulations, 2020) had not yet been enacted. The Medicines and Healthcare products Regulatory Agency (2020) website at the time stated: 'The proposals outlined in this guidance notice will take effect through legislative changes and are still subject to parliamentary approval'.

For those practising in Northern Ireland

At the time of writing, the regulatory framework of the EU will continue to be followed in Northern Ireland, as a consequence of the Northern Ireland Protocol (2020). This means medical devices may only be placed on the market, and used, if certified under the Medical Device Directive (The Council of the European Communities, 1993) or the Active Implantable Medical Device Directive (Council of the European Union, 1990) until 25 May 2021, after which they must be certified under the Medical Device Regulation (European Parliament and Council of the European Union, 2017a). Similarly, in-vitro diagnostic devices may only be placed on the market, and used, if certified under the In-vitro Diagnostic Medical Devices Directive (European Parliament and Council of the European Union, 1998) up until 25 May 2022, after which certification is required under the in-vitro diagnostic device Regulation (European Parliament and Council of the European Union, 2017b). These changes will be felt mostly by the manufacturers, rather than users such as clinicians.

For those practising in the EU

As the UK is no longer a member of the EU, UK products will be treated as if they come from any non-EU member state. For device manufacturers, this means an EU contact is required of UK manufacturers with products in the EU market, as would be usually expected of any non-EU member state. Once again, the product label will state the name and address of the manufacturer, as well as the contact for the device, within the EU (Table 2).

For those practising outside the UK or the EU

For products already carrying the CE mark, there will be existing arrangements which permit its use locally. This exact nature of the arrangement depends on the local jurisdiction. For

Table 2. Product label indicating the manufacturer's address and information on the UK Responsible Person for device manufacturers outside the UK

	The name and address of the manufacturer including country
	If the manufacturer is from outside the EU, including from the UK, this symbol will be present to denote your contact within the EU

Figure 1. Official notation for the CE mark, the UK Conformity Assessment mark and the UKNI mark.

example, there may be a completely separate regulatory regime requiring its own certification or market clearance, as found in the USA. Alternatively, there may be an existing agreement that CE marked products can be cleared under its existing certification, such as is the case in Australia, or countries enrolled in the Medical Devices Single Audit Programme. UK manufacturers have the option of applying the UK Conformity Assessment mark instead of a CE mark as of 1 January 2021, for the GB market (and the UKNI mark for the Northern Ireland market) (Figure 1); as of 1 July 2024 the UK Conformity Assessment mark will be compulsory. Exactly how this will relate to regulatory requirements in jurisdictions outside the EU is yet to be determined.

The new EU medical device regulations

The new EU Medical Device Regulation and in-vitro diagnostic device Regulation requirements are significantly more comprehensive in regard to data transparency, post-market surveillance and implant information availability. Not only is the Medical Device Regulation four times longer than the Medical Device Directive, the word 'safety' appears 290 times in the Medical Device Regulation, compared to 40 in the Medical Device Directive.

The scope of inclusions now extends to include Active Implantable Medical Devices, devices incorporating ancillary medicinal products (including those derived from human blood and plasma) and devices incorporating non-viable human tissues and cells. Aesthetic products (like coloured contact lenses) and cleaning or sterilisation products (previously considered accessories to medical devices) have also been included in the Medical Device Regulation. Additional requirements have been added to the declaration of conformity and CE marking for the manufacturer to keep updated and available in languages of all the member states where the device is supplied. The requirements for reporting of serious incidents has become more heavily incorporated into the legal text, with the scope for reporting increased (for example, the timeline for reporting is decreased from 30 to 15 days and with temporary serious deterioration in health added as explicitly reportable) (European Parliament, Council of the European Union, 2017a).

A major change in the Medical Device Regulation are the more stringent requirements for post-market surveillance and post market clinical follow up, which is included in the Medical Device Directive as a requirement for the manufacturer to institute a post-market review procedure and instigate necessary corrective action, but without granularity of how this should be done. Conversely, the new Medical Device Regulation requires manufacturers to specify a detailed post-market surveillance plan, which actively and systematically gathers and analyses the performance and safety of the medical device. These data are

Key points

- Post-Brexit, the UK is moving away from the EU CE marking process for medical devices to its own UK Conformity Assessment system (largely based on the Medical Devices Directive).
- The CE mark will only be accepted in the UK until June 2023, after which all devices on the GB market must undergo a UK Conformity Assessment audit.
- The content of the new UK Conformity Assessment procedure, applicable to the GB market as of June 2023, remains undecided at the time of writing.
- The EU is transposing to the new Medical Devices Regulation from May 2021, with increased scrutiny of safety and efficiency compared to the Medical Devices Directive, and upclassing of many software-based medical devices.

used to periodically inform updating of the device risk management, instructions for use and labelling, the summary of safety and clinical performance, planning for preventative and corrective action (including options for improving the usability and performance of the device) and to contribute to post-market surveillance of other devices (European Parliament, Council of the European Union, 2017a).

The effects of the upgrade in regulation should lead to greater patient safety and, in the case of devices with an information technology element, greater security of patient information.

Software as medical device

An area of development in recent years is the rapid increase in software as a medical device: including computer-aided detection and computer-aided diagnostic systems, as well as apps used to facilitate treatment for various conditions. The Medical Device Directive was introduced in 1993, nearing 30 years ago, when such software did not exist beyond the experimental world; indeed, software as a medical device did not receive full regulatory attention in Europe until the September 2007 revision of the Medical Device Directive, which:

- Stated that 'It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device'
- Recognised that '… the growing importance of software in the field of medical devices, be it as stand alone or as software incorporated in a device, validation of software in accordance with the state of the art should be an essential requirement'
- Stipulated that 'stand alone software is considered to be an active medical device' (European Parliament, Council of the European Union, 2007).

A consequence of the Medical Device Regulation is that the rules governing classification of devices, including software, have been modified to increase the rigour by which these devices, and the companies manufacturing them, are scrutinised before the devices may be placed on the market. This applies to both the companies' approach to quality management, as well as the resulting fitness for intended use of their products.

Conclusions

While the implications of Brexit will be felt mainly by device manufacturers, practising clinicians and their local procurement teams may be understandably anxious about device procurement and continued secure supply of essential medical devices. This article outlines several changes that frontline clinicians, as users of medical devices, should be aware of in regard to key dates for regulatory changes and points of contact for device manufacturers. Key changes included in the new Medical Device Regulation are also summarised, which should provide reassurance to clinicians of the increased scrutiny to safety and efficacy of medical devices.

Author details

[1]Hardian Health, Haywards Heath, UK

[2]Department of Ophthalmology, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

[3]Institute of Cognitive Neuroscience, University College London, London, UK

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