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Client Alert Commentary

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UK Issues New Guidance for Medical Device Regulation After Brexit

The MHRA offers new guidance on how medical devices will be regulated in the UK from 1 January 2021.

On 1 September 2020, the Medicines and Healthcare products Regulatory Agency (MHRA) published new guidance on how medical devices will be regulated in the UK from 1 January 2021, when the Brexit transition period is over.

Background

Medical devices in the UK are currently regulated by way of Directive 93/42/EEC on medical devices and its sister directives for active implantable medical devices and in vitro medical devices, as amended. These EU directives are given effect in UK law through the Medical Devices Regulations 2002 (SI 2002 No 618, as amended). These regulations (in the form in which they exist on 1 January 2021) will continue to have effect in the UK after 1 January 2021.

Changes to Medical Device Regulation in the EU

EU laws on medical devices will be significantly updated and harmonised when Regulation (EU) 2017/745 (EU MDR) becomes applicable. On 24 April 2020, the European Union postponed the date of application for the EU MDR by one year, in light of the COVID-19 crisis. The EU MDR will now become applicable in the EU on 26 May 2021, with the exception of certain provisions allowing for national derogations from the conformity assessment requirements, which became effective on 24 April 2020.

For more details, see Latham's *Client Alert* Time to Prepare for New EU Medical Device Regime and blog post New EU Medical Devices Regulation to Be Postponed Until 2021.

Changes to Medical Device Regulation in the UK

The UK government introduced The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 to mirror the EU MDR in UK legislation, with necessary amendments (UK MDR). Whether the UK MDR will be replaced or postponed in light of the postponement of the EU MDR remains to be seen. Currently, the UK MDR is set to become applicable on 31 December 2020.

In its current form, the UK MDR will:

- Broaden the regulatory regime to capture certain devices for aesthetic and other non-medical purposes for the first time
- Amend the classification of devices, resulting in "up classification" and stricter assessment procedures for devices in many cases
- Strengthen the rules around clinical evidence and data that are required to demonstrate conformity of devices
- Introduce a unique device identification system
- Introduce greater supply chain oversight, with new obligations for importers and distributors
- Strengthen the requirements relating to post-market surveillance of products

The UK government also introduced the Medicines and Medical Devices Bill (UK Bill), which completed a turbulent second reading before the House of Lords on 2 September 2020 and is awaiting Committee Stage review in the House of Lords. The UK Bill introduces extensive delegated powers in favour of the Secretary of State or an "appropriate authority" to amend or supplement regulations in the area of human medicines and medical devices, taking into account safety, the availability of human medicines and medical devices, and the "attractiveness" of the relevant part of the UK as a place in which to develop or supply human medicines and medical devices.

New MHRA Guidance

The proposals in the new MHRA guidance will take effect through legislative changes that will be introduced later in 2020 and are "still subject to parliamentary approval", according to the MHRA. Presumably, this means that the UK government will introduce the proposals via the delegated powers that it plans to introduce via the UK Bill, if and when approved.

Below are five key takeaways from the MHRA guidance for companies placing medical device products on the market in the UK:

1. UKCA marking required from 1 July 2023

The MHRA will continue to recognize EU CE marks until 30 June 2023, but from 1 July 2023, new devices placed on the Great Britain market will need to conform with the new UK Conformity Assessment (UKCA) marking requirements. Separate rules will apply to Northern Ireland (See Section 5 below).

The UKCA marking will be available for use from 1 January 2021, at which point UK conformity assessment bodies will be able to conduct assessments for this marking, in preparation for the 30 June 2023 deadline.

The UKCA marking was introduced by the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019/696. Although these regulations do not currently refer to medical devices, the UK government is likely to align these with the MHRA guidance with medical devices in due course.

2. UK Responsible Person required from 1 January 2021

From 1 January 2021, under the UK MDR and in line with the MHRA guidance, manufacturers based outside the UK will need to appoint a UK Responsible Person (which may be an individual or a corporate entity). Only a manufacturer established in the UK or a UK Responsible Person will be able to place a device on the UK market.

The responsibilities of the UK Responsible Person will largely align with those of the authorised representative under the EU MDR. The UK Responsible Person will act on behalf of a manufacturer established outside the UK to carry out specified tasks in relation to the manufacturer's obligations, which are similar to the responsibilities of the EU authorised representative under the EU MDR.

3. UK registration for all medical devices for the UK during 2021

From 1 January 2021, under the UK MDR and in line with the MHRA guidance, medical devices placed on the market in the UK must be registered with the MHRA, following a grace period ranging from four to 12 months for products not currently required to be registered with the MHRA, depending on the risk classification of the device:

- Deadline of 30 April 2021: Class III, Class IIb implantables, active implantable medical devices, and IVD List A
- Deadline of 31 August 2021: Other Class IIb and all Class IIa
- Deadline of 31 December 2021: Class I devices and general IVDs

The UK MDR requires all devices to be registered, whereas currently only limited classes of medical devices are required to register.

If a manufacturer does not have a registered place of business in the UK, the UK Responsible Person will be responsible for registering the device with the MHRA.

4. EEA notified body certificates valid in the UK until 30 June 2023

Certificates issues by EEA-based notified bodies will be valid in Great Britain until 30 June 2023.

5. Special rules for Northern Ireland

The regulatory position for medical device products to be placed on the market in Northern Ireland from 1 January 2021 is complicated, and may yet change in line with ongoing political debate regarding the Withdrawal Agreement and the Northern Ireland Protocol. Such products will need to comply with both the EU rules and the UK rules, but the devil is in the detail.

Conclusion

With less than three months to go until the end of the Brexit transition period, but with negotiations continuing between the UK and the EU in relation to their future relationship — and parliamentary debate continuing regarding the UK Bill — companies intending to place medical devices on the EU and UK markets following 1 January 2021 should familiarize themselves with the proposed new rules and monitor ongoing developments.

Latham & Watkins will continue to monitor and report on developments related to Brexit and the life sciences industry.

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