Compliance & Risks

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In Practice Series

The Future Medical Device Regulations Within The UK

8 Step Checklist to Avoid Legal Risks

On 26 June 2022, the UK's medical device regulator, the Medicines and Healthcare products Regulatory Agency (MHRA) published their response to the consultation on the "future regulation of medical devices in the UK", which indicates a future wide-reaching change for the UK medical devices regulatory regime going forward.

Following the UK's exit from the EU and the sweeping reform of the medical device regime currently being undertaken at an EU level, the MHRA has noted that there is now a unique opportunity for the UK to review the MDR 2002 (which is based on EU retained law) and improve how medical devices and IVD medical devices are regulated in the UK post-Brexit.

As part of this, the Medicines and Medical Devices Act 2021, which came into force on 11 April 2021, vests power in the MHRA to allow them to make amendments to the existing regime in the UK, the MDR 2002.

The MHRA's response to the consultation sets out the current intention for the UK's future Medical Device Regulations, which includes the following changes:

- [ ] Manufacturers should undertake a "readiness" review of their product portfolio to include an analysis of the implications of the UK's future Medical Device Regulations on device classification and ensure that their medical device conforms with the device's classification assessment. Manufacturers should use the response document to the consultation as a guide for the changes that will be implemented in the UK.

- [ ] Manufacturers whose products are not currently in the scope of the MDR 2002 or who are at risk of a change in classification, should consider whether they may now be brought into the scope and, whether their product meets the more stringent requirements. This is particularly the case for borderline products and aesthetic products claiming no medical purpose. The latter would include dermal fillers, which will now be classified as a medical device.

- [ ] There remains a relatively small number of UK-approved bodies for carrying out conformity assessments and it is understood that current lead times are long. Therefore, steps should be taken now to put in place assessments where required.

- [ ] Manufacturers must have in place an appropriate QMS. Although the MHRA have expressed that they will be providing further guidance on specific requirements, stakeholder responses to the consultation have confirmed that the requirements should align with the EU MDR, EU IVD Regulation, and ISO 13485.

- [ ] Manufacturers should take steps to ensure that they have, within their organization, at least one qualified person with qualifications or regulatory experience that exceeds the minimum standards that would be set out in the UK's future Medical Device Regulations. It is the MHRA's intention to require that SMEs have a qualified person permanently and at their continual disposal to ensure that appropriate regulatory support will be available to them.

- [ ] Manufacturers should ensure that their post-market surveillance meets the strengthened requirements which will be outlined in the UK's future Medical Device Regulations.

- [ ] Developing and maintaining good ongoing relationships with the MHRA and conformity assessment bodies will ensure manufacturers are better placed to respond to future regulatory changes.

- [ ] Consider and create unity between any newly implemented EU requirement, where possible, to limit differing risk profiles across the regions.

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In a world full of regulatory change, practical advice is required to better manage product compliance.

Compliance and Risks and Kennedys Law LLP have created the 'In Practice Series' to ensure you have access to practical insights backed by comprehensive, in-depth regulatory expertise.

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Providing you and your team with the practical insights and actionable takeaways to ensure you have the tools to build consumers safe, sustainable products in a world full of change.

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Our clients are manufacturers, leading distributors and retailers, as well as their insurers and reinsurers.

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