Regulatory Focus™
A RAPS Publication

Medical device regulation in the UK

Jacob EA Skinner, BSc Hons

Due to national and international influences, the regulatory framework of the UK in relation to medical and in vitro diagnostic devices has seen several major changes. Ongoing uncertainty about the applicable regulation and transition timelines, combined with the fast pace of change, has created significant challenges, such as increased compliance costs and business disruption for manufacturers. This article examines the cause and effect of recent changes to legislation and highlights the upcoming changes to the UK regulatory landscape.

Keywords – medical device, regulation, UK, UKCA, UKNI

Introduction

Regulation of medical devices in England, Scotland, Wales, and Northern Ireland, collectively known as the United Kingdom (UK), has undergone rapid and significant changes over the past six years. The fluidity of the regulatory landscape has been caused by several significant international and national influences, including introduction of the EU Medical Devices Regulation (MDR) 2017/745 and In Vitro Diagnostic Regulation (IVDR) 2017/746 in 2017, Brexit, and the COVID-19 pandemic.

For companies within the UK medical device industry, the situation has led to significant challenges relating to regulatory planning and increased costs associated with compliance activities. For manufacturers of medical devices based outside of the UK, it has created a unique opportunity to access the third-largest medical device market in Europe, where the publicly funded National Health Service's annual spending exceeded £6 billion on medical technology in 2019.[1] This article aims to explore the basis of UK medical device regulation and describe the UK regulatory requirements.

Background

The Medicines and Healthcare products Regulatory Agency (MHRA) is the competent authority for medical devices in the UK. Before January 2021, when

the UK formally left the EU, the MHRA was part of the EU system of regulatory approval.

As a member of the EU, the UK followed the EU regulatory system for medical devices, which consisted of compliance to three directives:

- Medical Device Directive (MDD) 93/42/EEC since 1993[2]
- In Vitro Diagnostic Medical Devices Directive (IVDD) 98/79/EC since 1998[3]
- Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC since 1990[4]

The exact requirements for compliance were heavily influenced by risk classification. The lowest-risk devices could be self-certified by the manufacturer through the issuance of a declaration of conformity claiming compliance to one of the directives above. Devices carrying a higher risk had to undergo conformity assessment by a notified body designated by the MHRA or another European competent authority. The process involved the notified body auditing the product's technical documentation to ensure compliance to the appropriate directive and harmonized standards, and in many cases, the notified body would also audit the manufacturer's quality management system. After successful conformity assessment, the notified body would issue the device an EC certificate, allowing the manufacturer to display the Conformité Européenne (CE) mark. Due to the UK's membership of the EU, products bearing the CE mark could be placed on the market anywhere within the EU without additional regulatory barriers.

Reasons for change

In 2017, the EU introduced the MDR to replace the MDD and AIMDD and the IVDR to replace the IVDD.[5] The EU MDR and IVDR aimed to address the shortcomings of the previous regulations, particularly in relation to technological advancements such as material science and the application of software in medical devices.[6] Changes include:

- Revised classification rules;[6]
- A focus on risk management, where manufacturers must consider the entire device lifecycle;[6]
- More rigor surrounding clinical evidence and postmarket surveillance, ensuring the safety and clinical performance of devices;[6] and
- Increased transparency and traceability of medical devices using unique device identification and the European Database on Medical Devices, often referred to as EUDAMED.[7]

Before the publication of the EU MDR, on 23 June 2016, the UK had narrowly voted in favor of leaving the EU.[8] This vote started a period of political turmoil and instability in the UK which, after several delays, led to a withdrawal agreement coming into force on 1 February 2020, confirming the UK's exit from the EU.[9] A transition period was then in place until 31 December 2020.

Due to the ongoing Brexit negotiations, the future direction of UK Medical Device Regulation was unclear. Pre-empting changes and with a lack of clear guidance, many manufacturers selling medical devices and in vitro diagnostic products in the UK began investing significant resources to bring their products into compliance with the EU MDR.

In March 2020, the world was thrown into greater uncertainty by the COVID-19 pandemic. This eventually led to the European Commission extending the date of application of the EU MDR until 26 May 2021.[10] In the context of UK regulation, this was particularly important, as the revised date of application for the EU MDR now fell after the end of the Brexit transition period.[9]

At the end of the transition period on 31 December 2020, the UK was no longer bound by EU law, including the MDD. The UK amended its medical device regulation to create a standalone regulatory framework, which came into effect on 1 January 2021 and is known as the Medical Devices Regulations 2002 (as amended).[11-13]

UK Medical Devices Regulations 2002 (as amended)

The UK Medical Devices Regulations 2002 (as amended), or UK MDR 2002, essentially adopted the EU's three directives (MDD, IVDD, and AIMDD) into UK law with several changes.[11-13] Most notably:

- The introduction of UK-approved bodies to perform conformity assessment (replacing EU notified bodies);[14]
- A new conformity assessment mark, known as the UK Conformity Assessed (UKCA) mark, to demonstrate conformity to the regulations;[14]
- A requirement to register all medical devices and economic operators with the MHRA;[15]
- Introduction of the role of the UK responsible person to represent manufacturers based outside of the UK;[15]
- Transitional arrangements for the placing of CE-marked devices on the UK market;[15] and
- Special provisions for Northern Ireland, including the continued use of CE marking and introduction of the UKNI mark.[15,16]

The last three changes have been the most challenging and are discussed below in more detail.

Special provisions for Northern Ireland

The country of Northern Ireland has a complex political and social history within the UK and EU. Post-Brexit, the geopolitics of Northern Ireland became particularly important, as it shares a land border with the Republic of Ireland, which remains a full EU member state. Because this border is not enforced and Northern Ireland remains part of the EU single market, free movement of people and goods can occur between the two countries.

For the EU, as part of the UK exit arrangements, medical devices placed on the market in Northern Ireland must continue to meet the same standards as those placed on the EU market. On the contrary, for the UK government, it was imperative to ensure unfettered access to the Northern Ireland market for UK businesses operating in Northern Ireland. Therefore, CE-marked products complying to EU regulations can continue to be placed on the Northern Ireland market, even after the end of the UK transition period.[16]

UKCA marking is not accepted in Northern Ireland. However, the UKNI mark was developed for situations where a UK-based manufacturer wishes to place devices on the market in Northern Ireland, using a UK-approved body for the conformity assessment against the EU MDR. The UKNI mark is sometimes called the CE UKNI marking, as it can only be displayed alongside the CE mark. The UKNI mark is only accepted in Northern Ireland and cannot be used to place devices on the market in Great Britain (England, Scotland, and Wales) or the EU.

In practice to date, there are currently no UK-approved bodies designated for conformity assessment against the EU MDR or EU IVDR, and therefore the UKNI marking cannot currently be used by UK manufacturers.[15]

UK responsible person

The role of the UK responsible person was introduced post-Brexit to ensure that manufacturers based outside the UK appointed a UK-based representative to carry out specific requirements relating to product registration and vigilance.[14,15] Each manufacturer based outside of the UK must appoint a single UK responsible person to take responsibility for all their medical devices.

The role of the UK responsible person is to act on behalf of a non-UK device manufacturer to carry out the manufacturer's obligations for device registration, postmarket surveillance, and vigilance. They must review the device's technical documentation and declaration of conformity, checking that the correct conformity assessment procedure has been followed. The UK responsible person must keep a copy of the technical documentation, declaration of conformity, and any CE certificate issued by an EU notified body.[14]

Once the UK responsible person is satisfied that the product complies with UK regulation, and before the device is placed on the market, the UK responsible

person must act to register the manufacturer and each device with the MHRA, via the MHRA Device Online Registration System.[15]

The UK responsible person should be kept up to date with any changes or amendments to the device and must make this documentation available to the MHRA upon request.[14]

In addition, the UK responsible person must maintain a line of communication between the MHRA and the device manufacturer, including cooperation with the MHRA on any preventative or corrective action to eliminate or mitigate risks relating to the device. At all times, the UK responsible person must immediately communicate all complaints or reports of incidents and/or adverse events to the manufacturer of the device.[14]

The UK responsible person must ensure the device manufacturer acts within its obligations under the UK MDR 2002. Where the manufacturer acts contrary to these obligations, the UK responsible person must terminate their relationship with the manufacturer and inform the MHRA of this termination.[14]

The UK responsible person must be either an individual British citizen resident in Great Britain, or a UK registered company.[14] Given the above requirements of the UK responsible person, it is advisable that the UK responsible person has relevant experience in regulatory affairs, including a sound understanding of the provisions set out in the UK MDR 2002 and additional MHRA guidance relevant to the nature and classification of the device(s).

UK transitional arrangements

Originally, the UK MDR 2002 provided provision for acceptance of CE-marked medical devices on the Great Britain (GB) market until 30 June 2023.[12,13]

On 27 April 2023, the UK government announced its intention to modify the transitional arrangements set out in the UK MDR 2002. The new provisions intend to support the ongoing supply of safe and regulated medical devices and in vitro diagnostics to Great Britain, while affording manufacturers sufficient time to transition to the future regulation.[17]

The UK government formally introduced this legislative change on 9 June 2023 with the Medical Devices (Amendment) (Great Britain) Regulations 2023 (SI 2023 No. 627).[18] Under the amendment, the following transitional provisions entered into force on 1 July 2023.[18]

Medical devices[17-19]

- All medical devices with a valid EU MDR certificate or declaration of conformity may remain on the GB market until 30 June 2030.

- Class III and IIb implantable legacy devices with a valid EU MDD/AIMDD certificate from an EU notified body may remain on the GB market until 31 December 2027. For legacy devices, the provisions set out in Extension Regulation (EU) 2023/607 for extension of CE certificate validity will be recognized as valid for placing CE-marked devices on the GB market.[13]

- Class Iib (nonimplantable) and Class Iia legacy devices with a valid EU MDD certificate from an EU notified body may remain on the GB market until 30 June 2028.

- Class I sterile devices or those with a measuring function, which required notified body involvement under the EU MDD, that have a valid certificate may remain on the GB market until 30 June 2028.

- Class I devices that did not require notified body conformity assessment under the EU MDD but have been reclassified by the EU MDR to a higher-risk classification and may remain on the GB market until 30 June 2028, providing a declaration of conformity with the EU MDD was drawn up prior to 26 May 2021.

- Class I devices that do not require notified body involvement cannot be placed on the GB market under an EU MDD certificate and must self-issue a declaration of conformity with the EU MDR or UK MDR 2002.

***In vitro diagnostic devices*[17-19]**

- All devices with a valid IVDR CE certificate may be placed on the GB market until 30 June 2030.

- List A, List B, or self-test devices with a valid IVDD CE certificate may be placed on the GB market until 26 May 2025.

- General IVDs with an IVDD self-declaration made before 26 May 2022 may be placed on GB the market until 30 June 2030.

Outlook for UK regulation

Between September and November 2021, the MHRA consulted on proposed changes to UK medical device regulation.[20] This consultation sought the views of patients, research groups, manufacturers, suppliers, clinicians, other healthcare professionals, and the public with the hope of developing the future legislation.

The new regulations are expected to be published in full in December 2023/January 2024 with a proposed date of application of July 2025. Both the

aforementioned changes and short timelines for application show that it is important for manufacturers to be proactive in considering the revised regulations as early as possible. However, the extension of acceptance of CE marking in Great Britain until 2030 means that careful consideration should be made to regulatory strategic planning, with the pros and cons of each approach carefully considered.[17-19]

On 26 July 2023, the MHRA notified the World Trade Organization (WTO) of its intention to further amend the UK MDR 2002 with respect to more stringent postmarket surveillance requirements.[21] The intention of these changes is to create a framework for clear and proportionate postmarket surveillance requirements to better safeguard public health.

Greater alignment with the EU MDR

One of the key aims of the consultations was to develop future legislation that delivers closer alignment with international best practice. Considering this, the proposals describe greater alignment with the EU MDR regulation.

It is expected that the UK will adopt the EU MDR Annex I General Safety and Performance Requirements within a UK context, with additional requirements to list allergenic or sensitizing components.[20] Furthermore, classification rules are likely to be updated to align with the EU MDR and include special considerations for aesthetic devices and those without an intended medical purpose. As within the EU regulations, conformity assessment routes will be risk-based with increased scrutiny of high-risk devices.

There is also suggestion that the UK will amend the requirements for the UK responsible person to more closely reflect the requirements for the EU authorized representative as set out in Chapter 11 of the EU MDR.[20] Expected changes include mandating the UK responsible person for joint liability for defective devices and specific requirements for retention and availability of technical documentation.

The role of qualified person may also be introduced for all manufacturers selling into the UK and for UK responsible person organizations. The role of the qualified person looks to be an adoption of Chapter 15 of the EU MDR relating to the person responsible for regulatory requirements, and the requirements are likely to be similar in nature and scope.[20]

Postmarket surveillance

Chapter 8 of the consultation[22] proposes changes aimed at strengthening postmarket surveillance activities for all manufacturers placing devices on the UK market. As a result, the UK government plans to proceed with plans to amend the UK MDR 2002 to clarify and strengthen requirements for implementation of postmarket surveillance systems.

The draft statutory instrument notified to the WTO on 26 July 2023 outlines this new postmarket system.[21] The key changes outlined are:

- Increased scope, to include CE-marked devices placed on the UK market;
- Minimum requirements for postmarket surveillance systems within medical device manufacturers;
- New requirements for the reporting and investigation of serious incidents;
- Mandatory requirement to submit field safety notices for all field safety corrective actions, with minimum defined contents;
- New requirements for periodic safety update reporting for devices above Class IIa; and
- Requirements for trend reporting of device-related incidents.

Conclusion

The convoluted history and confusion surrounding the UK regulations created due to EU MDR transition, Brexit, and COVID-19 seems to be calming. The UK government and regulators have begun to publish clear guidance on the future direction and the effects on legacy devices and those CE marked under the EU MDR or IVDR.

The regulatory framework continues to evolve at a rapid pace as the UK government and MHRA attempt to forge an internationally respected system that promotes innovation in healthcare while ensuring the highest standard of care and safety of patients.

Currently, manufacturers based outside of the UK can benefit from extended timelines allowing CE-marked devices to be placed on the UK market. However, they should be aware of upcoming changes to postmarket requirements from mid-2024 and focus their attention on the upcoming release and application of the future regulations. Importantly, manufacturers should plan their regulatory strategy accordingly to ensure that their devices can remain on the market after UKCA transition.

Abbreviations

AIMDD, Active Implantable Medical Devices Directive; **CE,** Conformité Européenne; **EUDAMED,** European Database on Medical Devices; **EU MDR,** EU Medical Devices Regulation; **GB,** Great Britain; **IVDD,** In Vitro Diagnostic Medical Devices Directive; **IVDR,** In Vitro Diagnostic Regulation; **MDD,** Medical Device Directive; **MHRA,** Medicines and Healthcare products Regulatory Agency [UK]; **UK MDR,** UK Medical Devices Regulations 2002 (as amended); **UKCA,** UK Conformity Assessed [mark]; **UKNI,** UK Northern Ireland [mark]; **WTO,** World Trade Organization

About the author

Jacob Skinner, BSc Hons, is a medical device RA/QA Consultant at Med-Di-Dia, with five years of experience in UK and European regulatory affairs. He specializes in providing comprehensive regulatory support to medtech companies and medical device manufacturers, including regulatory

strategy and planning, ISO 13485:2016 quality management system integration, and medical device classification services. Skinner has a bachelor of science honors degree in human biology from Sheffield Hallam University in the United Kingdom. He can be reached at Jacob@mddltd.com

Citation Skinner JEA. Medical device regulation in the UK. Regulatory Focus. Published online 31 August 2023. https://www.raps.org/News-and-Articles/News-Articles/2023/8/Medical-device-regulation-in-the-UK

References

All references accessed and/or verified on 31 August 2023.

1. Med-Tech Innovation News. GTMA and the UK medical manufacturing supply chain. Published 7 October 2020. Accessed 17 July 2023. https://www.med-technews.com/news/gtma-and-the-uk-medical-manufacturing-supply-chain/#:~:text=The%20UK%20is%20the%20third%20largest%20medical%20device,2019%20by%20the%20Academic%20Health%20Science%20Network%20%28AHSN%29
2. Council of the European Communities. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Accessed 31 August 2023. https://www.legislation.gov.uk/eudr/1993/42/adopted
3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic devices. Accessed 31 August 2023. https://www.legislation.gov.uk/eudr/1998/79/adopted
4. Council of the European Communities. Council Directive 90/385/EEC of 20 June 1990 concerning active implantable medical devices. Accessed 31 August 2023. https://www.legislation.gov.uk/eudr/1990/385/adopted
5. European Commission. Getting ready for the new regulations. Last updated 31 August 2023. Accessed 31 August 2023. https://health.ec.europa.eu/medical-devices-new-regulations/getting-ready-new-regulations_en
6. BSI. Comparison of the articles of the European MDD and the MDR. Not dated. Accessed 31 August 2023. https://www.bsigroup.com/en-US/medical-devices/resources/Whitepapers-and-articles/comparison-eu-mdd-mdr/
7. European Commission. EUDAMED database. Not dated. Accessed 31 August 2023. https://ec.europa.eu/tools/eudamed
8. BBC News. UK EU referendum results. Last updated 28 July 2016. Accessed 31 July 2023. https://www.bbc.com/news/politics/eu_referendum/results
9. European Commission. The EU-UK withdrawal agreement. Current as of 6 July 2020. Accessed 31 July 2023. https://commission.europa.eu/strategy-and-policy/relations-non-eu-countries/relations-united-kingdom/eu-uk-withdrawal-agreement_en
10. Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions. Accessed 17 July 2023. https://eur-lex.europa.eu/eli/reg/2020/561/oj
11. The Medical Devices Regulations 2002. Legislation.gov.uk website. Current as of 30 August 2023. Accessed 17 July 2023. Published 20 May 2002. https://www.legislation.gov.uk/uksi/2002/618/contents/made
12. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019. Legislation.gov.uk website. Accessed 17 July 2023. Published 1 April 2019. https://www.legislation.gov.uk/uksi/2019/791/introduction/made
13. The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020. Accessed 17 July 2023. https://www.legislation.gov.uk/uksi/2020/1478/contents/made
14. Medicines and Healthcare products Regulatory Agency [UK]. Regulating medical devices in the UK [guidance]. Last updated 20 July 2023. Accessed 31 July 2023. https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk

15. Medicines and Healthcare products Regulatory Agency [UK]. Register medical devices to place on the market [guidance]. Updated 3 August 2023. Accessed 31 August 2023. https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market
16. The Medical Devices (Northern Ireland Protocol) Regulations 2021. Legislation.gov.uk website. Published 26 July 2021. Accessed 17 July 2023. https://www.legislation.gov.uk/uksi/2021/905/contents/made
17. Medicines and Healthcare products Regulatory Agency [UK]. Implementation of the future regulations. Updated 27 July 2023. Accessed 31 July 2023. https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period/implementation-of-the-future-regulations
18. The Medical Devices (Amendment) (Great Britain) Regulations 2023. Legislation.gov.uk website. Accessed 31 July 2023. https://www.legislation.gov.uk/uksi/2023/627/contents/made
19. Medicines and Healthcare products Regulatory Agency [UK]. Extension of CE certificates. Published 28 March 2023. Accessed 31 July 2023. https://www.gov.uk/government/news/extension-of-ce-certificates
20. Medicines and Healthcare products Regulatory Agency [UK]. Consultation on the future regulation of medical devices in the United Kingdom. Last updated 26 June 2022. Accessed 17 July 2023. https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom
21. World Trade Organization. The Medical Devices (post-market surveillance requirements) (Amendment) (Great Britain) Regulations 2023 [notification]. Published 26 July 2023. Accessed 31 July 2023. https://epingalert.org/en/Search?domainIds=1&countryIds=C826&viewData=G%2FTBT%2FN%2FGBR%2F64
22. Medicines and Healthcare products Regulatory Agency [UK]. Chapter 8 – Post-market surveillance, vigilance, market surveillance. Updated 26 June 2022. Accessed 17 July 2023. https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom/outcome/chapter-8-post-market-surveillance-vigilance-market-surveillance