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Client Alert Commentary

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UK's MHRA Seeks "Bold New Regulatory Regime" for Medical Devices and Diagnostics

The agency's consultation on the post-Brexit regulatory framework for medical devices and diagnostics aims to support innovation and sustainability, among other goals.

A 10-week consultation launched by the UK's Medicines and Healthcare products Regulatory Agency (MHRA) on the future regulation of medical devices, including in vitro diagnostics (IVD), will close on 25 November 2021 at 11:45 p.m. GMT.

The backdrop for the consultation is the UK Medicines and Medical Devices Act 2021 (the Act), which came into force on 11 February 2021 and paved the way for new regulations to shape the post-Brexit landscape for medicines and medical devices in the UK. The Act introduced 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.

As the Secretary of State for Health and Social Care noted in opening the consultation, "[the UK's] departure from the European Union has provided us with a newfound regulatory freedom and a unique chance to reshape our rules."

This *Client Alert* analyses the most substantive proposed changes and includes an Appendix that provides a detailed summary, as well as commentary on whether the proposal aligns with or diverges from the EU regulatory framework. As described below, the proposals are generally aligned with the EU regimes, but in some cases are more flexible and in some cases more stringent.

Background

The consultation aims to amend the UK Medical Devices Regulations 2002 (which are based on EU law, primarily Directive 93/42/EEC on medical devices, Directive 90/385/EEC on active implantable medical devices, and Directive 98/79/EC on in vitro diagnostic medical devices) with a view to the UK.

In particular, the consultation aims to:

- Create new access pathways to support innovation
- Create an innovative framework for regulating software and artificial intelligence (AI) as medical devices

- Reform IVD regulation
- Foster sustainability through the reuse and remanufacture of medical devices

The consultation is the first step in creating a "bold new regulatory regime" for medical devices in the UK. The regime is scheduled to come into force in July 2023, coinciding with the end of the acceptance period for EU CE marks in Great Britain, subject to appropriate transitional arrangements. The consultation indicates that the MHRA will publish guidance in relation to the changes to the regulatory framework and may rely more heavily on guidance to add flexibility to the regime.

The Proposed Changes

The consultation covers 15 key areas, including the scope of the regulations, classification of medical devices, economic operators, registration, and unique device identifiers, conformity assessment, clinical studies, IVDs, software, and routes to market.

As required under the Act, the objective of the consultation is to seek feedback on how the proposed changes might affect:

- The safety and effectiveness of medical devices and IVDs
- The availability of medical devices and IVDs
- The likelihood of the UK being seen as a favourable place in which to carry out research, development, manufacture, or supply of medical devices and IVDs

For the most part, the proposed changes in many of these areas align with the new EU regime under Regulation (EU) 2017/745 (EU MDR) and Regulation (EU) 2017/746 (EU IVDR), which is not surprising given the UK was a key player in the development of the EU MDR and IVDR. However, there are some notable divergences. In particular, the consultation suggests the following departures from the EU regime:

- New rules around software medical devices, including a definition of "placing on the market", a provision for temporary classification, and additional "essential requirements" for software medical devices
- New requirements for the environmental and public health impact of medical devices, including impact assessments and supply chain waste management responsibilities
- New routes to market, including a single regulatory audit of quality management systems to meet requirements of multiple jurisdictions; acceptance of approvals from other non-UK medical device regulators; and an alternative pathway for "innovative MedTech", such as innovative devices, devices used to treat rare conditions, or devices manufactured by small- and medium-sized enterprises
- More stringent requirements for the remanufacture of devices and for assemblers of systems, procedure packs, and kits, and manufacturers of custom-made devices
- Regulation of fulfilment service providers and new requirements for economic operators to inform the MHRA if they are aware of any issues that will interrupt supply or cause a shortage on the UK market

- Additional requirements for in-house manufacture, including requirement for health institutions to register medical devices manufactured or modified in-house

Software and AI

In parallel with the consultation, the MHRA published a set of 11 work packages detailing the UK's proposals to develop a regulatory framework for software and AI medical devices that provides a high degree of protection for patients and the public and also ensures that the UK is the home of responsible innovation for medical device software. These work packages cover the following areas:

- Qualification
- Classification
- Pre-market
- Post-market
- Cyber-secure medical devices
- Innovative access
- Software as a medical device "airlock classification rule"
- Mobile health and apps

The remaining three work packages consist of projects designed to develop frameworks for AI as a medical device, interoperability, and adaptivity of AI medical devices.

The MHRA plans to deliver key elements of each work package from Autumn 2021 until Summer 2023.

The EU Position

EU laws on medical devices were significantly updated and harmonised when the EU MDR became applicable in the EU on 26 May 2021. However, the EU MDR does not apply in Great Britain and has not been implemented into UK law. The EU MDR will apply in Northern Ireland under the terms of the Northern Ireland Protocol.

Similarly, the EU IVDR, which overhauls the existing EU regime on IVDs and is due to apply in the EU from 26 May 2022 (with specific transitional periods depending on the type of IVD), will not apply in Great Britain, but will apply in Northern Ireland. Consequently, since 31 January 2021, Great Britain's existing regulatory framework, which is based on the outdated EU regime, continues to apply.

The European Commission has also published a proposed regulation for AI.

Appendix

Proposed Change	Aligns With EU MDR/ IVDR	Comments
Scope		
Expanded scope to include certain non-medical products; products for cleaning, disinfection, or sterilisation of devices; products that support conception; products for prediction of or prognosis of disease; products used for investigation, replacement, or modification of a pathological process; and products that provide information by means of in vitro examination of specimens	✓	The consultation suggests adding diagnostic tests for health and well-being, e.g., genomic testing for diet, skin care, etc., which are not addressed in the EU MDR.
Expanded definition of IVD to include software	✓	
Classification		
Higher classification for many devices, including active implantable devices, surgical meshes, total or partial joint replacements, medical devices incorporating nanomaterial and invasive medical devices	✓	The consultation proposes a new rule classifying IVF and assisted reproduction technologies as Class III, which is not addressed in the EU MDR or EU IVDR. The classification of non-invasive medical devices that come into contact with the mucous membrane is proposed as Class I-IIa depending on intended use, whereas under the EU MDR these are Class I-IIb.
Economic Operators		
Further detail on the essential requirements for medical devices	✓	The consultation suggests a requirement that information provided with a device should reflect what is known about the medical device, including uncertainties about long-term impacts of use. This is not addressed in the EU MDR.
Manufacturers required to have measures in place to cover any legal liability arising from adverse incidents	✓	
Medical devices manufactured “in-house” must meet essential requirements but need not be UKCA marked	✓	

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Health institutions to be required to register medical devices manufactured or modified in-house	X	
MHRA to restrict the use of "in-house" devices and inspect activities of health institutions	X	
UK medical devices regulations, including the requirement to provide a copy of the Declaration of Conformity, to apply to any person selling or offering medical devices through distance sales by electronic means	✓	
Misleading claims regarding intended purpose, safety, or performance to be prohibited	✓	
Requirements for manufacturer's quality management system to be clarified	✓	The consultation proposes that requirements for management review and internal audit should be addressed. These are not in the EU MDR.
Manufacturers (excluding SMEs) or UK Responsible Person to keep permanently at its disposal at least one Qualified Person	✓	
New obligations for distributors and importers of medical devices, including record keeping, inspection of labelling, notification, and cooperation requirements	✓	The consultation proposes that distributors and importers ensure that the end user does not receive a medical device past its expiry date and that importers inform the manufacturer that they intend to import devices. These obligations are not addressed in the EU MDR.
Fulfilment service providers (i.e., companies carrying out warehousing, packaging, addressing, and dispatching) could be regarded as importers	X	
Economic operators to inform the MHRA if they are aware of any issues that will interrupt supply or cause a shortage on the UK market	X	
Registration / Unique Device Identifiers		
Economic operators to achieve an appropriate level of traceability to identify and record supplies of devices	✓	The consultation proposes that economic operators be required to identify and record any lay person /

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		user directly supplied with devices. This is not addressed in the EU MDR.
Devices (other than custom-made devices or investigational devices) to be assigned a Unique Device Identifier (UDI) before being applying for conformity assessment and being placed on the market	✓	The MHRA will designate one or more issuing entity for UDIs.
Manufacturers, economic operations, and healthcare professionals/healthcare institutions to store UDIs of supplied devices	✓	
UK database of medical device information (including registration, vigilance, and market surveillance) to be established	✓	This mirrors the EUDAMED database under the EU MDR.
Approved Bodies		
Increased standards for Approved Bodies, including in relation to organisational structure, independence and impartiality, liability, and quality management	✓	The consultation proposes a specific provision for remote audits by Approved Bodies. This is not addressed in the EU MDR, but is a consequence of the COVID-19 pandemic and has also been proposed by the Medical Device Coordination Group for the EU.
Approved Bodies must have a meaningful presence in the UK, with key roles physically based in the UK	✓	The EU MDR requires Notified Bodies to be established under the national law of a Member State or third country which the EU has an agreement with.
Approved Bodies to be re-assessed within five years after designation where there is sufficient designation	X	The EU MDR requires annual re-assessment.
New measures governing suspension, withdrawal, or continuation of certificates if an Approved Body's designation is withdrawn	✓	

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Conformity Assessment		
Strengthened conformity assessment procedures, including in relation to review of documentation, timelines, and notification of withdrawn applications	✓	
Removal of batch verification, product quality assurance, and type examinations as conformity assessment routes	X	
Increased scrutiny for various types of devices, including implantable devices, highest-risk IVDs, and AI/machine learning-based devices	✓	The EU MDR does not reference AI/machine learning-based devices as devices requiring additional expert panel scrutiny.
Approved Bodies can restrict use of devices to certain groups of patients or require manufacturers to undertake specific post-market clinical follow-up	✓	
Information on certificates issued by Approved Bodies to be included in MHRA register	✓	
Clinical Investigation / Performance Studies		
Stricter requirements for claiming equivalence to studies of similar devices	✓	
Increased clinical evidence requirements, including a requirement to update the clinical evidence through the lifecycle of the device	✓	
Non-UK sponsors of clinical investigations must appoint a UK-based representative	✓	
Increased requirements for sponsors of clinical investigations, including publication of summaries, keeping technical documentation, reporting of adverse events, and preparation and publication of clinical investigation reports	✓	
Increased requirements for design and conduct of clinical investigations, including a clinical investigation plan, personnel requirements, and the right of participants to withdraw	✓	
New requirements for conduct of performance studies for IVDs, including the conditions of use of the IVD, obligations of sponsors, implementation of a clinical performance study	✓	

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plan, publication of a clinical performance study report, ethical review, personnel requirements, insurance, and the right of participants to withdraw		
Performance studies of companion diagnostics to be subject to same requirements as other performance studies	✓	
More detailed requirements for obtaining informed consent from study participants and for studies on minors and breastfeeding people	✓	
Detailed requirements for clinical investigation and performance study applications and timelines	✓	The consultation proposes slightly different timelines for MHRA evaluation of applications (60 days for assessment and 10 for validation, versus 45 days from validation under the EU MDR).
Additional requirements regarding deviations from clinical investigation plans, recalls, and inspection of sites by the MHRA.	✓	
New procedures for modification of clinical investigation or performance study, early termination, and corrective measures by the MHRA.	✓	
Certain exemptions for clinical investigations and performance studies conducted by academic institutes or health institutions	X	
New requirements for publication of a "summary of safety and clinical performance" (SSCP) and validation by the Approved Body	✓	The consultation proposes inclusion of metrological traceability of assigned values and a summary of the Approved Body conformity assessment, which are not addressed in the EU MDR.
Post-Market Surveillance and Vigilance		
Increased post-market surveillance requirements, including the manufacturer's post-market surveillance plan, post-market performance follow-up for IVDs, and preparation and publication of post-market surveillance reports	✓	

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including a periodic safety update report for higher-risk devices.		
New reporting criteria, procedures, and timescales for serious incidents and field safety corrective actions	✓	
New trend reporting and field safety notice requirements	✓	The consultation considers mandatory patient and public involvement as part of manufacturers' vigilance obligations, which is not addressed in the EU MDR or IVDR.
IVDs		
Changes to classification rules to increase level of scrutiny based on intended purpose	✓	
Specified requirements for genetic tests, including information provided to individuals on the nature, significance, and implications of the tests	✓	
New classification rules and clinical evidence requirements for companion diagnostics	✓	
Software as a Medical Device		
New definition of "placing on the market" for software medical devices to clarify when deployment websites, app stores and other electronic means amounts to placing on the market	X	
New classification rules for software medical devices	✓	
New "airlock rule" allowing temporary classification, early access to market, and ongoing monitoring where risk profile is unclear	X	
Additional "essential requirements" for software medical devices to ensure adequate pre-market scrutiny	X	
Minimum requirements in relation to cybersecurity and information security	✓	

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New performance evaluation requirements for medical devices incorporating AI software	X	
Implantable Devices		
Expanded scope of implantable devices to include temporarily implanted devices	X	
Limited access to high-risk implantable devices, such as supply only from specialised centres or by specialist practitioners	X	
New requirements for implant information to be provided to patients, e.g., implant cards	✓	The consultation proposes mandatory information to be provided to clinicians and patients about the requirements around management and ongoing use of obsolete models. This is not addressed in the EU MDR.
Other Changes		
New requirements for re-manufacture of single-use devices, including conformity assessment and quality management systems of re-manufacturers, labelling, liability, and post-market surveillance	X	
Assemblers of systems, procedure packs, and kits to be responsible for selection and control of suppliers, risk management, handling of complaints, and management of corrective and preventive actions	X	
New requirements for parts and components of medical devices, particularly items intended to replace a part component or function of a medical device	✓	
More detailed information and surveillance requirements for manufacturers of custom-made devices	✓	
Manufacturers of certain custom-made devices to implement a quality management system certified by an Approved Body	X	

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Environmental Sustainability and Public Health Impacts		
New requirements for environmental and public health impact assessments as part of conformity assessment of medical devices	X	
New supply chain waste management responsibilities	X	
New requirement that devices be designed and manufactured in a way that reduces risks to public health	X	
Broader use of electronic labels and instructions for use	X	
Routes to Market		
New Medical Device Single Audit Programme to allow single regulatory audit of quality management system to meet requirements of multiple jurisdictions, including the US, Canada, Brazil, Japan, Australia, the EU, Argentina, South Korea, and Singapore	X	
Acceptance of approvals from other non-UK medical device regulators, with domestic assurance process whereby UK Approved Bodies perform an abridged assessment	X	
EU Notified Bodies that also have designation of UK Approved Body could grant “CE plus UKCA” certification route for both EU and UK markets	X	
Alternative pathway for “innovative MedTech”, involving MHRA support of manufacturers’ research and data-gathering activities and approval from the MHRA to place certain devices on the market prior to UKCA marking in specific circumstances	X	

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