LATHAM&WATKINS

Client Alert Commentary

Latham & Watkins Healthcare Regulatory Practice

30 June 2022 | Number 2974

UK's MHRA Publishes Response to Consultation on Future Medical Devices Regulation

The response includes a considered implementation plan to strengthen the regulation of medical devices and in vitro diagnostics, improve patient safety, and foster innovation post-Brexit.

On 26 June 2022, the UK Medicines and Healthcare products Regulatory Agency (MHRA) published its long-awaited response to its consultation on the UK's post-Brexit regulatory regime for medical devices and in vitro diagnostic (IVD) medical devices. The 10-week public consultation concluded in November 2021. The response factors in feedback and observations from almost 900 respondents, including views from industry, the wider healthcare sector, and patients. (For more on the consultation, see Latham's Client Alert UK's MHRA Seeks "Bold New Regulatory Regime" for Medical Devices and Diagnostics.)

Commenting on the MHRA's findings, the UK Secretary of State for Health and Social Care Sajid Javid stated, "Now we have left the EU, these new changes will allow innovation to thrive and ensure UK patients are among the first to benefit from technological breakthroughs". Separately, Secretary Javid said the UK will soon launch its inaugural MedTech strategy.

The package of reforms will apply to medical devices such as hearing aids, X-ray machines, and insulin pumps; new technologies such as smartphone apps and artificial intelligence (AI); and certain cosmetic products like dermal fillers. The MHRA has previously emphasised that it is keen to ensure the UK aligns with international best practice, and its response confirms that the new regulatory landscape will mirror many of the provisions of the EU regulatory regime, as contained within the new Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR). However, regulation in Great Britain is likely to deviate in certain areas. Please see Appendix that specifies which areas do and do not broadly align with MDR/IVDR, as well as areas that the MHRA has deferred its final opinion on.

This Client Alert summarises the key proposed changes, including the divergence with EU regulation, and outlines areas where the MHRA has enabled flexibility for future changes and guidance, such as pre-market approvals for higher-risk devices and the "airlock" classification rule for Software as a Medical Device (SaMD).

Key Proposed Changes

The new measures outlined in the MHRA's response include:

- **Improved patient safety.** The MHRA aims to safeguard public health by enabling access to a high-quality supply of safe and effective medical devices by providing more stringent regulatory oversight. The MHRA will therefore proceed with (i) preparing new regulations that reclassify products such as certain implantable devices, (ii) extending the scope of regulations to capture certain non-medical products with similar risk profiles to medical devices (e.g., dermal fillers), and (iii) strengthening and increasing post-market surveillance requirements to ensure better incident monitoring, reporting, and surveillance.

- **Transition to the new framework.** Whilst the government plans for new regulations to come into force in 2023, under transitional arrangements, products that already have conformity markings, either UKCA or CE, will be able to remain on the market after the regulations come into force. Medical devices with valid certification can continue to be placed on the market until the earlier of certificate expiry or for a period of three years (increasing to five years if certification is under the MDR) following publication of the new regulations. IVDs with valid certification can continue to be placed on the market until the earlier of certificate expiry or for a period of five years following publication of the new regulations. The transition period applicable to MDR and IVDR certified products may be subject to further review by the MHRA following the five-year extended period.

- **Support for innovation in medical devices.** This includes improving regulation of novel and growing areas such as SaMD and AI as a medical device (AIaMD) to offer alternative routes to market for rapidly evolving innovation. The MHRA received strong support to introduce routes to market that avoid duplication and minimise burden on industry and promote international collaboration with like-minded regulators whilst maintaining regulatory oversight. The MHRA also received support to introduce a pre-approval route for innovative devices and to broaden its role to host a conformity assessment function internally for specific scenarios and product groups. The MHRA aims to provide extended guidance in this regard.

- **Aligning with international best practice.** The proposed changes aim to ensure that the UK aligns with international best practice where standards are superior than current UK standards and introduce greater transparency of regulatory decision-making by updating the requirements that apply to Approved Bodies and increasing the consistency of conformity assessments. The government has indicated that it will introduce alternative routes to market, including domestic assurance to enhance the supply of devices.

Geographical Application

Under the terms of the Northern Ireland Protocol, Northern Ireland has implemented the MDR and IVDR. The MHRA's consultation response therefore only applies to Great Britain (England, Wales, and Scotland) unless there is a direction from the UK government to the contrary.

Next Steps

The UK Medicines and Medical Devices Act 2021 empowered Ministers to change medical device regulations via secondary legislation. Whilst the MHRA's consultation response is silent as to timeframes for next steps, the UK government will need to translate its proposals into legislation, via amendments to the UK Medical Devices Regulations (SI 2002 No 618, as amended).

As indicated in the response, the MHRA will also need to accompany legislative amendments with specific guidance documents to assist the devices industry with transitioning to the new regime. Unless there is a delay to the July 2023 deadline, this suite of guidance documents will likely need to be in place well in advance of July 2023 in order to allow manufacturers of new products to prepare for UKCA compliance and to ensure their products can gain lawful access to the UK market by this deadline.

Conclusion

The MHRA's consultation response provides the medical device and diagnostic sectors with welcome and timely clarity as to what the future UK regulatory regime will look like. Of particular relief will be the confirmation of transition periods that will apply to devices with existing and valid certifications, and which in many cases will avoid a compliance cliff edge on 1 July 2023. Notably, new devices, or devices that have undergone a "significant change" will be required to meet the new requirements by the original deadline in order to access the Great Britain market. Furthermore, post-market surveillance requirements set out within the new regulations will apply to all medical devices and IVDs from the original deadline, regardless of whether the transition periods have been applied to these products.

The MHRA has also suggested that certain areas of regulation may be revisited in the future, perhaps as part of further consultation processes. The government will also be producing a range of guidance documents to assist economic operators with implementing the legislative changes effectively. We further note, outside the scope of the consultation, the MHRA has also announced a work programme for the regulation (wider guidance, policy, and standards) of health-related software and AI that will deliver ambitious change, providing protection for patients and public and making the UK the home of responsible innovation in this sector.

Appendix

Table of key changes with indication of alignment[i] with MDR/IVDR

Change	Broadly aligns with the MDR/IVDR	Comments
Scope		
Expanded scope of UK medical devices regulations to include certain non-medical products such as dermal fillers and coloured contact lenses for aesthetic purposes within the definition of a medical device.	✓	Note that the proposals to include diagnostic tests for health and wellbeing, e.g., genomic testing for diet / nutrient optimisation and lactate testing for fitness training will not be taken forward at this point but may be considered in future.
Expanded definition of IVD to include software.	✓	
Classification		

Change	Broadly aligns with the MDR/IVDR	Comments
Reclassification of certain devices. In particular, surgical mesh, active implantable devices, certain medical devices incorporating nanomaterials (depending on potential internal exposure level), total/partial joint replacements (except ancillary components), and spinal disks will be in class III (highest risk class).	✓	
IVF/ART-related devices will be Class III if they are substance-based devices used *in vitro* in direct contact with human embryos before implantation or administration into the body.	✗	Note that the original proposal was to classify all IVF /ART devices as Class III.
Economic Operators		
Requirement that manufacturers must have sufficient financial coverage to be able to compensate any user/patients impacted by adverse incidents, e.g., by holding appropriate liability insurance.	✓	
UK Responsible Person (UKRP) will be legally liable for defective medical devices on the same basis as the manufacturer and must have a Qualified Person at their disposal.	✓	Equivalent role in the MDR/IVDR is fulfilled by the authorised representative.
UKRP must have an address in the UK where they are physically located and manufacturers will be obligated to draw up a changeover agreement when changing the UKRP.	✓	Equivalent role in the MDR/IVDR is fulfilled by the authorised representative.
New obligations applicable for importers and distributors to support improved traceability, including on document retention, QMS, and communicating with the manufacturer on complaints received.	✓	
Clarification that fulfilment service providers will fall within the “importer” or “distributor” definitions and will need to meet the relevant requirements.	✗	Note that MDCG guidance suggests that in certain cases third-party logistics companies could be an importer.

Change	Broadly aligns with the MDR/IVDR	Comments
Misleading claims regarding intended purpose, safety, or performance to be prohibited.	✓	
QMS to include requirements for management review and internal audit should be addressed.	✗	
Distributors and importers will be required to ensure that the end user does not receive a medical device past its expiry date and importers inform the manufacturer that they intend to import devices.	✗	Note that the MHRA will give further consideration to concerns raised regarding the ability of distributors and importers to ensure the end user does not receive an expired device.
Confirmation of proposals requiring economic operators to inform the MHRA if they become aware of any issues that will interrupt supply or cause a shortage of medical devices on the UK market.	✗	
Registration / Unique Device Identifiers		
Introduction of requirements for devices to have unique device identification (UDI) and to include a definition of UDI which is consistent with other jurisdictions such as the EU.	✓	
Extension of the data required as part of registration.	✓	Note that there are certain differences compared to the MDR/IVD, such as no requirement for data on which other countries the device is available and inclusion of an undertaking that manufacturers have measures in place for recompense for negative impacts of a medical device.
Approved Bodies		
Strengthened requirements applicable to Approved Bodies.	✓	The MDR/IVDR has strengthened obligations applicable to Notified Bodies, which are equivalent EU conformity assessment bodies.

Change	Broadly aligns with the MDR/IVDR	Comments
Option to allow Approved Bodies to conduct fully remote or hybrid audits in the event of disrupted circumstances.	✕	This is not included within the MDR/IVDR; however, recent EU guidance on audits in the context of the Covid-19 pandemic does allow for remote audits.
Conformity Assessment		
Amendment of the Essential Requirements to broadly reflect the General Safety and Performance Requirements of the MDR/IVDR.	✓	
Class IIb implantable devices (except for sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors) will be subject to complete review of their technical documentation by Approved Bodies, as opposed to a representative review.	✓	
Class III and Class IIb custom-made devices should be made to require a certified QMS.	✕	Under the MDR, the requirement for a certified QMS with respect to custom-made devices only applies to Class III implantables.
Removal of option to use batch verification (except for Class D IVDs) and type examination for all medical devices. For production quality assurance, this route will only be removed for class III, IIb devices and IVDs.	✕	
Clinical Investigation / Performance Studies		
Confirmation of more robust and specific requirements on clinical evaluations and performance evaluations, including a requirement to update clinical evidence throughout the lifecycle of the device.	✓	
Confirmation that non UK-based sponsors of clinical investigations and performance studies must appoint a UK-based legal representative.	✓	The EU has an equivalent rule requiring that non-EU based sponsors must appoint a legal representative who shall be based within the EU.

Change	Broadly aligns with the MDR/IVDR	Comments
Requirements will be added on clinical data equivalence to ensure that an equivalent device must be “entirely equivalent”, including on a physical, technical, and clinical basis.	✕	The response states that this is designed to prevent “product creep” where new devices on the market become very different from their “equivalent” devices. Equivalence would only be available where it is claimed for the whole device not just part of a device, which goes beyond the MDR equivalence requirements.
Exemptions from certain aspects of the clinical investigation and performance study requirements, for example where proof of concept or early feasibility studies are being conducted by academic institutes working together with health institutes.	✕	
Post-Market Surveillance and Vigilance		
Confirmation of strengthened and more detailed post-market surveillance requirements.	✓	
Post-market surveillance plan should include patient and public involvement.	✕	
IVDs		
Reclassification of IVDs, resulting in a significant increase in the number of IVDs which will need a review by an Approved Body, and introducing a specific rule for companion diagnostics and greater scrutiny on genetic tests classifying them as proportionate to their risk.	✓	
Intention to include a definition of “kit” in line with the IVDR.	✓	We note that the response suggests the definition of kit (as well as the definitions of “procedure pack” and “system”) will allow for external software to be considered as a component of the kit, procedure pack, or system, which is not aligned with the MDR/IVDR definitions.
Software as a Medical Device (SaMD)		

Change	Broadly aligns with the MDR/IVDR	Comments
Introduction of a definition for software ("*A set of instructions that processes input data and creates output data*").	✓	This is aligned with the definition contained within EU guidance.
Introduction of a risk-based classification rule for SaMD which is based on the IMDRF classification rule.	✓	Whilst the MDR rules do not completely align with the IMDRF guidelines the approach is based on the same principles and the IMDRF guidelines are extensively referred to within EU guidance.
Essential Requirements for SaMD will generally mirror the MDR's General Safety and Performance Requirements 17, including with respect to cybersecurity provisions. The response stated that there is a strong argument to retain alignment with the EU unless divergence is necessary for the protection of UK patients.	✓	
Confirmation that no specific Artificial Intelligence as a Medical Device requirements to be set in legislation. The government does not propose to define AIaMD or set specific legal requirements beyond those being considered for SaMD.	✓	Note that separate horizontal legislation is proposed on artificial intelligence at EU level.
Implantable Devices		
Requirement for implant cards to be provided with implantable devices.	✓	Note that certain mandatory information will need 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		
Medical devices manufactured "in-house" by health institutions will have to comply with the Essential Requirements and have a Quality Management System (QMS) but will remain exempt from full UKCA marking requirements.	✓	

Change	Broadly aligns with the MDR/IVDR	Comments
Health institutions will be required to register medical devices manufactured or modified “in-house” and will be subject to inspection by MHRA.	✕	
Allowing for alternative routes to market involving the recognition of MDSAP (single audit program involving the US, Japan, Canada, Brazil, and Australia) certifications and domestic assurance mechanisms which recognises approvals granted by certain other countries/regulators.	✕	

Areas which the MHRA has deferred its final opinion on
MHRA intends to apply additional scrutiny mechanisms to higher risk devices but it has not been decided whether this will be set out in the revised regulations as part of the current exercise or if it will instead be subject to a future regulatory update. Expert panels perform this role within the EU.
MHRA may revisit in future the original proposals to include diagnostic tests for health and wellbeing, e.g., genomic testing for diet/nutrient optimization and lactate testing for fitness training.
MHRA will have further cross government discussions on the merits of introducing specific provisions relating to the placing on the market of software in order to remain aligned to other product sectors. There are no such provisions within the MDR.
MHRA will further consider whether clarifications and strengthening of the requirements for software sold via distance sales is necessary. There are no such provisions within the MDR.
MHRA remains interested in the original proposal to include an “airlock” classification rule for software as a medical device, which would allow for a temporary classification for software to facilitate early market entry. However the MHRA plans to scope further detail about this change and possibly include it in a future public consultation to obtain further feedback before potentially adding it to the UK regulations. There is no such mechanism within the MDR/IVDR.
MHRA remains focused on exploring whether and how best its registrations database can operate as part of a series of integrated databases for capturing and processing information submitted to the MHRA about medical devices (such as data on registration, requirements for Approved Bodies to enter information about conformity certificates, vigilance, post-market surveillance, and market surveillance regarding medical devices).
MHRA intends to consider further whether to introduce a requirement for manufacturers to register with the MHRA before applying to an Approved Body for conformity assessment and for the Approved Body to verify this registration.
Original proposals to require environmental impact assessments and to introduce waste management responsibilities into the supply chain will not be included as part of this this exercise, but may be subject to further consultation.

If you have questions about this Client Alert, please contact one of the authors listed below or the Latham lawyer with whom you normally consult:

Eveline Van Keymeulen
eveline.vankeymeulen@lw.com
+33.1.40.62.20.60
Paris

Sara Patel
sara.patel@lw.com
+44.20.7710.1161
London

Oliver Mobasser
oliver.mobasser@lw.com
+44.20.7710.1000
London

Ranulf Barman
ranulf.barman@lw.com
+44.20.7866.2651
London

You Might Also Be Interested In

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

Life Sciences Law Review — 10th Edition, France Chapter

European Healthcare & Life Sciences Market Update H1 2022

Time to Prepare for New EU Medical Device Regime

MHRA Releases No-Deal Brexit Guidance for Life Sciences Companies

Endnote

[i] Please note that this assessment is not definitive and does not include every change included in the response.