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A new dawn for regulation of medical technologies in the UK post-Brexit? From European directives to the proposed stand-alone regulatory regime for the future

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Last month the Medicines and Healthcare products Regulatory Agency (the "**MHRA**") launched a public consultation on the future of medical device regulation in the UK (the "**Consultation**"). This consultation comes approximately a month after the Report on Medical Devices (the "**Report**") of the UK's Regulatory Horizons Council (the "**Council**") recommended that "*Regulatory reform in medical devices is urgently needed*". As the Secretary of State for Health and Social Care ("**SoS**") has remarked, this consultation comes at a fitting moment a year following the Independent Medicines and Medical Devices Safety Review Report authored by Baroness Cumberlege, which emphasised that the "*MHRA needs substantial revision particularly in relation to […] medical device regulation*". The SoS has considered the need to enhance safety of medical devices used in the UK and that the UK's departure from the EU has provided the opportunity to reshape the regulatory framework tailored specifically to the Great Britain ("**GB**") industry, market and patients.

Those involved in research and development of medical technologies intended for international markets may be concerned with whether the outcome of this Consultation would lead to significant divergence of the UK domestic rules from the EU rules and international standards, and whether the proposed rules would affect the future of the UK-based industry in an increasingly competitive market.

As detailed below, the Consultation sets out an ambitious menu of fourteen principal themes with a view to developing a future regulatory regime for medical technologies that will achieve four key legislative objectives, namely:

- Improved patient and public safety;
- Greater transparency of regulatory decision-making and medical device information;
- Close alignment with international best practice; and
- More flexible, responsive and proportionate regulation of medical devices.

These overarching themes have also been addressed in the new EU regulatory framework for medical devices and in vitro diagnostic medical devices for the purpose of creating a robust, transparent and sustainable regulatory framework that improves safety of and fair market access to medical devices.

The overall effect of the proposals seeks to strike a balance between enhancing safety measures whilst incentivising innovation through earlier market access of an innovative medical device. The proposal is consistent with Government's policy to make the UK a more attractive market for international investment.

Background to the legislative framework

The proposed legislative changes would be based on the wide-ranging powers conferred by the primary legislation, the Medicines and Medical Devices Act (the "**Act**"), to make secondary legislation in relation to medical devices, medicinal products, clinical trials and veterinary medicines regarding such matters as their safety, availability and research and development.

The pre-existing UK regulatory framework is rooted in EU law, primarily Directive 93/42/EEC on medical devices (the "**MDD**"), Directive 90/385/EEC on active implantable medical devices (the "**AIMDD**") and Directive 98/79/EC on in vitro diagnostic medical devices (the "**IVDD**"). These Directives were transposed into domestic legislation in the UK by the Medical Devices Regulations 2002 (the "**UK MDR**"). Since these directives took effect, the pace of technological advancement and the intensity of innovation in the medical technology sector has been significant. Concern regarding the safety of some marketed medical devices has been raised in the context of high-profile cases such as the use of metal-on-metal hip replacements, PIP silicone breast implants, and pelvic mesh, indicative of the shortcomings in the regulatory framework. Indeed, the harm caused to patients by pelvic mesh failures was specifically considered as part of the Cumberlege review.

On 26 May 2021, Regulation (EU) 2017/745 on medical devices (the "**EU MDR**") took effect in the EU. The EU MDR introduced substantial changes to the regulatory framework in response to revolutionary technological development in digital health, artificial intelligence, including the anticipated arrival of adaptive algorithms, and machine-learning applications. The regulatory framework for in vitro medical devices ("**IVDs**") has also been overhauled, resulting in the adoption of Regulation (EU) 2017/746 on IVDs (the "**IVDR**"), which will begin to take effect throughout the EU on 26 May 2022.

The EU MDR and IVDR will not apply in GB because they were not part of the pre-existing EU-derived domestic legislation prior to the UK's departure from the EU. This means that since 31 January 2021, GB's existing regulatory framework based on the outdated MDD, AIMDD and IVDD continues to have effect in GB.

The Consultation

Similar to the EU MDR and IVDR, the proposals place greater emphasis on safety backed by clinical data and data generated from post-market surveillance. The MHRA has sought to take a balanced approach to simultaneously enhancing patient safety, attracting international investment, and supporting innovation in medical devices.

The key themes of particular relevance to manufacturers are set out below.

Scope

- The definition of 'medical device' has been expanded considerably. The definition includes products without an intended medical purpose but with similar functioning and risk profiles (e.g. non-corrective contact lenses, dermal fillers and liposuction equipment); products specifically intended for cleaning, disinfecting or sterilising devices; products which support conception; products for prediction or prognosis; products used for investigation, replacement or modification of a pathological process; and products which provide information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations. In contrast with the EU regime, the MHRA has also proposed the inclusion of "*Diagnostic tests for health and wellbeing e.g. genomic testing for diet/nutrient optimisation, genomic testing for skin care, lactate testing for fitness training*".

- The MHRA has proposed expanding the definition of *in vitro* diagnostic ("**IVD**") to include software; products providing information to predict treatment response or reaction (for example, companion diagnostics); products which provide information concerning a physical or mental impairment; and products which provide information concerning the predisposition to a medical condition or disease.

- Under the existing regime, the determination of whether a product qualifies as a medical device turns on whether the device has an 'intended medical purpose'. The medical purpose can be inferred from the claims made by the manufacturer, having regard to the labelling, the instructions for use and/or the promotional materials. The proposal clarifies what is meant by 'intended purpose'. The MHRA considers that the term should be construed

objectively and is not a question of what the subjective intention of the manufacturer might be. Such an assessment may take account of the manufacturer's technical documentation, including the results of clinical evaluations. The approach would align the definition used in the UK MDR with that used in other key jurisdictions, such as the US.

Device classification

- In light of significant technological progress, the proposal considers that the existing classification rules are, in some respects, out of step with best international practice—particularly for implantable medical devices such as surgical mesh and software as a medical device. The MHRA considers the need to amend the classification rules to reflect changes in technology, taking account of the mode of use including the level of invasiveness and potential toxicity of certain devices.

- The updated classification rules seek to better align with best international practice and to ensure that the scrutiny a medical device receives is commensurate with the level of risk that the device presents. For example, the MHRA has suggested that surgical meshes could be classified as class III, and active medical devices which have an integrated or incorporated diagnostic function (e.g., closed loop systems) could be classified as class III. The MHRA's proposed classification rules set out in the Consultation document reflect those recently published by the EU's Medical Device Coordination Group.

Economic operators

- Consistent with the Cumberlege review, the MHRA considers that those adversely impacted by an experience with medical devices are adequately compensated where appropriate. Accordingly, the MHRA has proposed the need for device manufacturers to cover any legal liability arising from adverse incidents with medical devices that are being placed on or supplied to the UK market such as the holding of liability insurance proportionate to the risk class, type of device and the size of the company.

- Currently, the UK MDR does not impose any additional requirements on entities who sell medical devices at a distance. By distance sales, the MHRA contemplates medical devices that are sold at a distance via electronic means such as websites and app stores. The MHRA has proposed introducing new requirements around such sales, for example, making it the responsibility of the seller to ensure that the devices it sells comply with the UK MDR.

- In this context, it should be noted that when the UK left the EU, manufacturers based outside the UK were required to appoint a UK responsible person ("**UKRP**") to act on their behalf (which is analogous to the role of EU Authorised Representative). UKRPs are required to carry out tasks which would ordinarily be performed by the manufacturer such as the registration of the manufacturer's devices with the MHRA prior to their placement on the UK market. The UK medical devices regulations currently provide that a UK RP may be proceeded against a person supplying or placing a device on the UK market. The Regulations could be amended to provide that the UKRP is legally liable (responsible or answerable in law) for defective medical devices on the same basis as the manufacturer. The MHRA considers that the proposal would enhance public and patient safety by ensuring that there is a UK point of contact with liability for defective medical devices in cases where the manufacturer is based outside the UK.

- The MHRA has proposed that all manufacturers should appoint a Qualified Person ("**QP**") who would assist RPs to assist them in fulfilling their obligations. QPs would be required to have a minimum level of relevant qualifications or experience. This could include, for example, a formal qualification in law, medicine, pharmacy,

engineering or another relevant scientific discipline, or sufficient professional experience in regulatory affairs or in QMSs relating to medical devices.

Registration and UDI

- The MHRA has proposed enhancing device traceability by establishing a unique device identifier ("**UDI**") system, analogous to the one described in the EU MDR and in keeping with the International Medical Device Forum guidance. This will require amendment to be made to the UKMDR to require that economic operators share more information with the MHRA about the supply of medical devices, and accordingly, economic operators are required to ensure that appropriate traceability of medical devices.

- The objective of the proposal would be to improve the traceability of medical devices being sold or in the supply chain in the event of need for such regulatory measures as field corrective actions. In order to enhance transparency and to ensure effective market surveillance activities, the MHRA has proposed bringing together all device-specific data into a single database. This database would include registration data, vigilance, post-market surveillance and market surveillance.

Approved bodies

- In the EU, the involvement of a Notified Body, an independent entity designated by the competent authority of a EU Member State, is needed for all devices above Class IIa, as well as some specific Class I devices in the conformity assessment. The purpose of the conformity assessment is to ensure that the design and performance characteristics of the medical device comply with the requirements commensurate with risk classification of the device. The UK rules now require conformity assessments to be performed by Approved Bodies ("**AB**"), before affixing a mark denoting UK Conformity Assessed ("**UKCA**") for a medical device to be placed on the market. However, in order to ease the industry's transition to the domestic regime, the MHRA has provided a grace period during which medical devices which have been assessed to be in conformity with the EU rules by Notified Bodies can still be placed on the UK market. This grace period will expire on 1 July 2023 at which point UKCA marks will become mandatory for all medical devices placed on the UK market. There has been a noticeable reduction in the number of entities which are able to perform third-party conformity assessments for the UK market. The existing Notified Bodies seemingly have shown little interest in seeking AB designations from the MHRA, potentially due to their increased workload caused by the EU's transition to the EU MDR. The "*drastic reduction in capacity*" was specifically flagged by the Council in its Report as a significant emerging issue which could hinder the success of any reform and make the UK a less attractive place for international investment. In the Consultation, the MHRA proposed setting out the high-level criteria that ABs must meet for them to be designated by the MHRA, including such considerations as the necessary competence, experience and facilities to perform the conformity assessment.

- The MHRA has also proposed that the UK MDR could set out more detailed requirements for ABs to improve patient safety by improving the standards across all ABs. The new requirements could cover organisational structure, independence and impartiality, liability, quality management, personnel qualifications, and adequate procedures to conduct conformity assessment.

Conformity assessments

- In order to improve transparency and consistency in conformity assessments, the MHRA has proposed clarifying and strengthening conformity assessment procedures. The MHRA envisages revisions to the AB conformity assessment procedures and requirements by, for example, (a) removing the option for manufacturers of Class IIa, IIb and III medical devices to use production quality assurance alone for satisfying the conformity assessment;

(b) requiring implantable Class IIb device technical documentation to be reviewed on a 100% basis rather than on a representative basis; (c) requiring that reusable surgical instruments undergo conformity assessment for aspects relating to the reuse of the device.

Clinical investigations

- Consistent with EU MDR, greater emphasis is placed on adequate clinical evaluation of medical devices. As part of the conformity assessment procedure, and prior to affixing a UKCA mark, manufacturers must ensure that the design and manufacture of their devices do not compromise the clinical condition of patients and device users. In addition to relying on pre-existing data, manufacturers may carry out a clinical investigation to verify that under normal conditions of use the performance characteristics of the device are those intended by the manufacturer and the benefit/risk balance is favourable.

- It is established practice that clinical investigation may be based on a variety of data sources. This may be based on data extrapolated from clinical investigation of an equivalent device. The MHRA has proposed tightening the requirements for claiming equivalence, including that a medical device must be "*entirely equivalent*" to the manufacturer's device in respect of biological, physical and clinical characteristics rather than equivalent to merely a part of an existing device, as is currently the case. The latter can result in 'product creep' where new devices on the market in practice become very different from their equivalent devices.

- In view of the proposed change to the definition for a medical device, the MHRA has proposed requiring clinical investigations to be conducted on products which do not have an intended medical purpose, for example, coloured contact lenses or dermal fillers.

- Currently, the UK MDR does not include any specific requirements for obtaining informed consent from individuals participating in clinical investigations of performance studies. The MHRA has proposed ensuring that those conducting clinical investigations or performance studies effectively obtain informed consent from study participants.

Post-market surveillance

- Currently, manufacturers are required to monitor the performance of their medical devices continually. Such requirements are set out in the applicable UK and EU guidance. The MHRA has proposed strengthening the post-market surveillance requirements by, for example, specifically setting out in the UK MDR exactly what the post-market surveillance plan should address and what should be included, and setting out clear requirements for reporting serious incidents and field safety corrective actions.

IVDs

- The UK MDR does not currently include specific requirements relating to genetic testing, but in recent years there has been a marked increase in the availability of genetic home-tests which can provide information on a person's predisposition to developing a medical condition or disease. The MHRA has proposed that the UK MDR could be updated to ensure that users of such tests are provided with the appropriate information on the nature, significance and implications of their test.

- Currently, the UK MDR does not include specific regulatory requirements around IVD products placed on the market through distance sales. The MHRA has proposed that distance-selling of IVDs should be required to comply with the UK MDR in order to be placed on the UK market. This requirement is reflective of the EU IVDR.

Software as a medical device

- The MHRA has proposed adding a new definition of "*software*" to the UK MDR; such definition would reflect the definition set out in MEDDEV 2.1/6.

- Software as a medical device ("**SaMD**") is routinely deployed to UK websites and app stores, for example, via Google Play and the Apple Store. The MHRA has proposed modifying the definition of "*placing on the market*" to include situations where SaMD is offered in this way.

- The MHRA has proposed changing the classification of SaMD to align with that used by the International Medical Device Regulators Forum's SaMD: Possible Framework for Risk Categorisation and Corresponding Considerations. The MHRA hopes that by doing so, the scrutiny applied to these medical devices will be more commensurate with their level of risk.

Implantable devices

- The MHRA has proposed up-classifying certain implantable devices and introducing enhanced pre- and post-market requirements. The MHRA also considers the need to reduce the reliance on equivalence in the assessment of implantable medical devices.

- Moreover, the proposal contemplates more controlled access to implantable medical devices and stricter post-market requirements to monitor the safety of patients who have received an implant and to provide relevant information to patients and healthcare professionals. For example, patients will be provided with patient implant information in both digital and physical card or leaflet format containing such particulars as UDI, medical device model, warnings, precautions, etc. The proposed changes reflect the position of the recently conducted safety reviews for certain implantable medical devices.

Other product-specific changes

- Currently, the UK MDR does not contain specific requirements for parts and components of a medical device. The MHRA has proposed requiring that any individual who places on the market, or puts into service, a part or component which is intended to replace an identical or similar part or component of a medical device, must ensure that the item does not negatively affect the safety and performance of the medical device.

Environmental sustainability and public health impacts

- The UK Government has declared its ambition for plans for a green industrial revolution. The National Health Service has also embraced the policy in the procurement and supply chain processes by becoming the world's first net zero health service provider.

- Consistent with this environmental policy, the MHRA has proposed a number of amendments to the UK MDR, which could help promote more environmentally sustainable manufacture, use and disposal to ultimately improve and safeguard public health. This will include introducing to the conformity assessment procedure an assessment of the device's impact on both the environment and public health and broadening the circumstances in which electronic (rather than paper) labels and instructions can be used for medical devices.

Routes to market

- The MHRA has proposed considering introducing routes to the UK market which can be utilised by manufacturers with a Medical Device Single Audit Programme ("**MDSAP**") certificate, or with an approval from certain other international regulators. The MDSAP allows a single audit of a medical device's QMS, which would meet the requirements of multiple jurisdictions. Countries involved in MDSAP include Australia, Brazil, Canada, Japan and the United States. The EU, Argentina, South Korea and Singapore are affiliate members and the UK currently has observer status. The UK is an Auditing Organisation under MDSAP. The new regulatory system for the UK could make provision to take MDSAP assessments carried out by Auditing Organisations into account. The MHRA could accept approvals from other international medical devices regulators. Devices with approvals accepted by the MHRA could be subject to a domestic assurance process in which ABs could perform an abridged assessment of the device with appropriate levels of scrutiny to ensure that it meets the UK requirements.

- The MHRA has indicated that it embraces a move towards a global technical document review process in which the Agency will be fully involved in its development. Once this initiative is implemented, it can be incorporated into the UK MDR.

- The MHRA is also considering introducing an alternative structured pathway for innovative devices that meet certain criteria. These criteria are likely to include the size of the patient population (e.g. rare conditions); the scale of innovation (e.g. devices which would be considered "*game changers*" for end users); and the size of the manufacturer, targeting small and medium-sized enterprises. Under the proposed pathway, the MHRA would grant approval for the manufacturer to make the device available on the market prior to obtaining a UKCA mark for the device to be used in specific limited circumstances. The MHRA would partner with the UK's health technology assessment body, the National Institute for Health and Care Excellence and other key healthcare partners. A similar scheme is currently being run for medicinal products in the UK for timely access to innovative medicines.

What happens next?

The Consultation was launched on 16 September 2021 and will close on 25 November 2021.

The new regime will be developed by virtue of the powers of the Act. In view of the Brexit grace periods, amendments to create the new regime must be in force on 1 July 2023 to reflect the date from which the UK is due to stop accepting CE-marked medical devices in GB, and from when the UKCA mark will be mandatory. The MHRA has proposed that any new requirements could be phased in at different times depending on, for example, device type or the level of risk it presents.