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Client Alert Commentary

Latham & Watkins Healthcare & Life Sciences Practice

24 May 2019 | Number 2503

Time to Prepare for New EU Medical Device Regime

Companies should act now to prepare for the full implementation of the MDR and IVDR.

On 26 May 2020, Regulation (EU) 2017/745 on medical devices (MDR) will become fully active, reflecting an overhaul of the current regulatory framework for medical devices in the EU. This change will be followed on 26 May 2022 by Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR). Together, the new regulations aim to increase harmonisation across the EU with respect to medical devices and in vitro diagnostic devices and to address weaknesses in the current regimes, with the goal of increasing protection for consumers. While the MDR and IVDR will not be fully active for another 12 to 36 months, respectively, companies should act now to ensure that they have appropriate systems in place to comply.

Timelines

The MDR and IVDR entered into transitional periods on 25 May 2017 following lengthy negotiations. During these transitional periods, certificates of conformity issued under the current directives governing medical devices and in vitro diagnostic devices will continue to be valid, and devices may continue to be placed on the market under such certificates. Certificates of conformity — which are required in order to place devices on the market — may also be issued under the new regime during the transitional periods, if the device fully complies with the MDR or IVDR. However, beginning in May 2020 and May 2022, certificates of conformity must be issued under the new regime.

The legislation permits a grandfathering period following implementation of the MDR and IVDR, during which certificates issued under the old directives (Directive 94/42/EC and Directive 98/79/EC) before May 2020 or May 2022, respectively, will continue to be valid until the end of the period indicated on the certificate. From 27 May 2024, however, all certificates issued under the old directives will become void. Devices already lawfully placed on the market and covered by those certificates may continue to be made available or put into service until 27 May 2025. New requirements in relation to post-market surveillance, market surveillance, vigilance, and registration will, however, apply to these devices.

Key Changes

The MDR and IVDR will introduce wide-ranging changes that will affect all aspects of the supply chain and life cycle for medical devices and in vitro diagnostic devices. The authors of this *Client Alert* have set out some of the key changes below.

Definitions and scope

The MDR has amended the definition of a medical device to specifically include implants and reagents. In addition, the MDR clarifies that software qualifies as a medical device when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the MDR.

The scope of the MDR also broadens the existing regime to include devices for aesthetic and other non-medical purposes that are similar to medical devices in terms of functioning and risk profile, including:

- Contact lenses
- Products intended to be totally or partially introduced into the body for the purpose of modifying the anatomy or fixation of body parts, except for piercings and tattooing products
- Substances intended to be used for facial or other dermal or mucous membrane filling, with the exception of tattooing
- Equipment for liposuction, lipolysis, or lipoplasty
- High-intensity electromagnetic radiation emitting equipment, such as lasers for skin resurfacing or tattoo or hair removal
- Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields

In addition, the IVDR has amended the definition of an in vitro medical device to specifically include tests that provide information on the predisposition to a medical condition or disease, such as genetic tests, and tests that provide information to predict treatment response or reactions, such as companion diagnostics. The IVDR further clarifies that software qualifies as an in vitro diagnostic device when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the IVDR.

Classification

The current rules on classification of devices will also change, requiring stricter assessment procedures in many cases. In particular:

- New classification rules will be introduced with respect to software.
- Many active implantable devices that have come under regulatory scrutiny in recent years, such as breast implants, surgical meshes, and joint replacements, will be considered Class III (the highest category).
- Under the IVDR, approximately 80% of in vitro diagnostic devices will require a conformity assessment by a notified body (currently, the majority of devices are subject to a self-certification system).

Clinical evidence

Under the MDR and IVDR, conformity assessments will require clinical evidence and data to demonstrate the performance and safety of a device, the evaluation of undesirable side effects, and the acceptability of the benefit-risk ratio.

Under the MDR, as a general rule, clinical data for implantable devices and Class III devices should be sourced from clinical investigations that have been carried out under the responsibility of a sponsor. Under the IVDR, as a general rule, clinical evidence should be sourced from performance studies that have been carried out under the responsibility of a sponsor. Thus, reliance on data on file based on claimed equivalence with other medical devices will be limited. Devices that were previously placed on the market with minimal clinical evidence may have difficulty satisfying this new requirement.

Unique Device Identifiers

The MDR and IVDR will introduce a unique device identification system to allow for the identification and traceability of medical devices, which is intended to enhance the effectiveness of post-market safety-related activities. Before placing a device on the market, a manufacturer will be required to assign a unique device identifier (UDI), created in accordance with the rules of an issuing entity. The European Commission has yet to designate these entities by means of implementing acts.

Eudamed

To further increase transparency and adequate access to information; avoid multiple reporting requirements; and facilitate the exchange of information among Member States, economic operators, notified bodies, and sponsors, the EU database on medical devices (Eudamed) will be required to collate and process information regarding devices placed on the market as well as the economic operators, certain aspects of the conformity assessment, notified bodies, clinical investigations, vigilance, and market surveillance.

Supply chain oversight

The MDR and IVDR will regulate the entire supply chain for medical devices and in vitro diagnostic devices, with new requirements for economic operators, including the manufacturer as well as importers, distributors, and authorised representatives.

Under the MDR and IVDR, the manufacturer — *i.e.*, the party that manufactures or fully refurbishes a device or has a device designed, manufactured, or fully refurbished, and markets that device under its name or trademark — will have additional obligations. In particular, the manufacturer must:

- Have available at their organisation at least one person who possesses a demonstrable expertise in the field of medical devices to be responsible for regulatory compliance
- Put measures in place to provide sufficient financial coverage in respect of liability for defective devices

An importer, *i.e.*, a party established in the EU that places a device from a third country on the market, will have to:

- Verify that the device has been CE marked
- Verify that a UDI has been assigned to the device, if applicable
- Verify that the manufacturer has been identified, and an authorised representative has been designated, if applicable
- Verify that the device is labelled in accordance with the requirements of the MDR and IVDR, that it is accompanied by required instructions for use, and that the device is registered in Eudamed

- Comply with the manufacturer's conditions regarding storage and transport
- Keep a register of complaints, non-conformities, recalls, and withdrawals
- Report complaints or suspected non-conformity to the manufacturer

A distributor, *i.e.*, the party in the supply chain, other than the manufacturer or importer, that makes the device available on the market up until the point of putting it into service, will have to:

- Verify that the device has been CE marked
- Verify that a UDI has been assigned to the device, if applicable
- Verify that the device is accompanied by the relevant information to be supplied by the manufacturer
- Verify, where applicable, that the importer has complied with its obligations regarding labelling and packaging
- Comply with the manufacturer's conditions regarding storage and transport
- Report complaints or suspected non-conformity to the manufacturer

An authorised representative, *i.e.*, a party that acts on the manufacturer's behalf in relation to specified tasks in case the manufacturer is not established in the EU, will have to perform the tasks specified in the mandate agreed between it and the manufacturer, the requirements of which are set out in the MDR and IVDR.

Notified bodies

The MDR and IVDR will enhance the designation and monitoring of notified bodies. In particular, competent authorities will critically evaluate notified bodies' assessment of a manufacturer's technical documentation. In addition, notified bodies will be obliged to subject to the scrutiny of expert panels their clinical evaluation assessment reports for (i) Class III implantable devices and Class IIb active devices intended to administer and/or remove a medicinal product (MDR), and (ii) innovative Class D devices for which no common specifications exist (IVDR).

Existing notified bodies must obtain designation as a notified body for the purpose of each of the new regulations. To date, only one UK notified body has been designated under the MDR, and no notified body has been designated under the IVDR. Due to the increased workload of notified bodies following the reclassification of in vitro devices and the potential loss of UK-based notified bodies following Brexit, companies may see a substantial backlog for certification.

The position of notified bodies vis-à-vis manufacturers will be strengthened. In particular, notified bodies will carry out unannounced on-site audits and conduct physical or laboratory tests on devices to ensure continuous compliance by manufacturers after receipt of the original certification.

Post-market surveillance

The MDR and IVDR will strengthen the requirements relating to post-market surveillance of products. Under the new regimes, manufacturers, in cooperation with other economic operators, will be obligated to implement a post-market surveillance system proportionate to the risk class of the device to ensure

ongoing safety for the lifetime of the device. Manufacturers must prepare a post-market surveillance report and periodic safety update reports (PSURs) that summarise the results and conclusions of the analyses of the post-market surveillance data gathered, including the main findings of post-market clinical follow-ups. Additionally, the new regimes will impose extended vigilance and market surveillance requirements, including mandatory reporting of serious incidents and field safety corrective actions and trend reporting of non-serious and expected undesirable side effects.

Brexit

As with other regulated industries, the UK's exit from the EU will have a major impact on the medical technology sector. The UK's five notified bodies for medical devices have overseen the majority of devices placed on the market in the EU,[1] and an estimated 50% of authorised representatives in the EU for non-EU medical device manufacturers are based in the UK.

However, apart from measures to be taken immediately due to the fact that there is currently no deal between the UK and the remaining Member States, economic operators in the UK must prepare for the MDR and IVDR, as the UK government has stated that it will comply with all key elements of those regimes and will put in place a mirroring regulatory system that will follow those regimes' timetable for implementation.

The UK government has declared that, for a time-limited period, the UK will recognise medical devices approved and CE-marked for the EU market. The Medicines and Healthcare products Regulatory Agency (MHRA) has stated that UK law will not require any changes to product labelling and will continue to accept labelling in English that includes information from other jurisdictions, such as Ireland. The UK will also continue to recognise existing clinical investigations approvals. The MHRA will give UK-based notified bodies ongoing legal status and continue to recognise certificates issued by them for the UK market.

This approach will not, however, be reciprocal, and manufacturers whose devices are currently certified by a UK-notified body must have the device re-certified by a notified body based in the EU-27 in order for the device to be eligible for the EU market. Additionally, UK-based authorised representatives will no longer be recognised under EU law.

Notably, the UK is not likely to have access to the Eudamed platform for sharing information with other European regulators.

The MHRA has stated that it intends to introduce a new requirement to register all medical devices, active implantable medical devices, in vitro diagnostic devices, and custom-made devices prior to their introduction to the UK market. Along with this change, the MHRA aims to introduce grace periods for registration depending on the classification of the device.

Practical Steps for Companies to Take Now

Companies should engage in preparations for the implementation of the MDR and IVDR as soon as possible due to the sheer scope of the review and work involved. Early preparation may give companies a competitive advantage and reduce headaches in the run-up to May 2020 and 2022. The authors of this *Client Alert* recommend that companies:

- Engage with key stakeholders as soon as possible, and get senior management on board with preparing for the MDR and IVDR.

- Conduct portfolio reviews and determine what assessments and clinical evidence will be required to keep existing products on the market.
- Engage with an EU-27-based notified body as early as possible, and determine what certifications and re-certifications are required.
- Review the entire supply chain, including arrangements with importers, distributors, and authorized representatives, to determine if any revisions are needed or agreements need to be renegotiated.
- Ensure the required personnel are in place, including a person responsible for regulatory compliance.

Latham & Watkins will continue to monitor and report on developments related to the MDR and IVDR.

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Endnotes

[1] https://www.gov.uk/government/news/medicines-and-healthcare-products-regulatory-agency-statement-on-the-outcome-of-the-eu-referendum.