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New EU Regulation on Medical Devices Aims at Enhanced Product Safety and Further Harmonization

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On May 5, 2017, the new Regulation on Medical Devices (MDR) and the new Regulation on In Vitro Diagnostics (IVDR) were published in the *European Official Journal*. The Regulations will become effective 20 days after publication (*i.e.*, on May 26, 2017) and will be fully applicable after a transition period of three years for the MDR regulation and five years for the IVDR regulation, respectively.

Background

The European market for medical devices is large and diverse–including products as different as contact lenses, pacemakers, breast implants and ultrasound machines, plus in vitro diagnostics such as HIV tests, pregnancy tests and blood sugar monitoring systems. In total, there are over 500,000 different types of medical devices on the European Union (EU) market. Under the current framework, medical devices are classified into the following classifications based on risk: (1) class 1 (low risk); (2) class IIa and IIb (moderate risk); (3) class III (high risk). This regime is similar to the US Food and Drug Administration's (FDA) device classification regulations, with some distinctions in the types and categories of device that belong to each class.

The existing EU regulatory framework for medical devices consists of three directives that were issued in the 1990s: (1) the Directive on Medical Devices (Dir. 93/42/EC), (2) the Directive on Active Implantable Medical Devices (Dir. 90/385/EEC), and (3) the Directive on In Vitro Diagnostic Medical Devices (Dir. 98/79/EC). These three directives will now be replaced by only two regulations, as active implantable medical devices will be covered by the MDR. The primary objectives of the new law are to improve quality, safety and reliability of medical devices. Reform efforts were triggered by the Poly Implant Prothèse (PIP) breast implant scandal, where breast implants made of industrial silicone were marketed as medical devices and received a European Conformity (CE) certificate from a renowned notified body. The new Regulations impose additional requirements on notified bodies and set higher standards for clinical evaluation of medical devices. However, the general processes for obtaining market authorizations have remained largely unaffected.

Significant Changes

Clinical Evaluation and Post-Marketing Surveillance: The new Regulations place greater emphasis on clinical data to support medical device registration and post-market safety. Under the MDR, manufacturers have to create a clinical development plan that includes a plan for post-marketing surveillance. As part of the technical documentation, manufacturers have to provide a report on the clinical evaluation. Once devices are available for use on the market, manufacturers will be required to collect data about their performance and EU countries will coordinate more closely in the field of market surveillance. Documentation will be required on a regular basis, *i.e.*, under certain conditions, manufacturers will have to provide a Post Market Surveillance Plan/Report (PMS), a Post Market Clinical Follow-up Report (PMCF), Periodic Safety Update Report (PSUR) and/or a Summary of Safety and Clinical Performance (SSCP). Furthermore, for more medical devices and in vitro diagnostics, clinical trials will have to be performed–and regulatory requirements for such clinical trials will be stricter, including but not limited to the new obligation of the sponsor to provide damage compensation insurance for participants (Article 69 MDR / Article 65 IVDR).

Supervision and Advisory of Notified Bodies: The MDR rules will impose stricter controls on high-risk devices. Similar to the FDA Advisory Committees that provide recommendations to the FDA regarding the approval of certain devices for the US Market, the MDR provides that a pool of experts at the EU level will have to be consulted before placing certain devices on the market. This requirement applies to class III implants and class IIb products that deliver a medicinal product (*e.g.*, certain drug delivery devices or combination products). Furthermore, according to Article 35 of the MDR / Article 31 IVDR, each Member State has to appoint an authority that will be responsible for the oversight and review of notified bodies. This authority is entitled to review whether notified bodies comply with the requirements for notified bodies listed in Annex VII MDR. Under the new Regulations, notified bodies can start to be re-certified six months after the date they become applicable–*i.e.*, from end-November 2017. Three years after first notification, and again every four years thereafter, a re-assessment will take place. Furthermore, the competent authority is entitled to review an appropriate number of notified body assessments of manufacturers' technical documentation.

The Unique Device Identifier (UDI): The UDI requirement introduces greater parity between the FDA and EU requirements. Like the recently implemented FDA requirements, the MDR and the IVDR require a unique product number to be assigned once for each medical device. The UDI consists of UDI device identifier (UDI-DI) specific to a manufacturer and a device, providing access to the information described in Part B of Annex VI and UDI production identifier (UDI-PI) that identifies the unit of device production and, if applicable, the packaged devices, as specified in Part C of Annex VI. This information must be stored in an electronic system for Unique Device Identification (UDI database) in accordance with Article 28 MDR / Article 25 IVDR.

Furthermore, it is noteworthy that the MDR extends the applicability of the medical devices regime to certain products that do not have a medical purpose but are considered equivalent in terms of risk. These products are listed in Annex XVI of the MDR and include, among other things, cosmetic contact lenses and skin fillers. Some of the classification rules in Annex VIIIthe Annex providing the rules for risk classification—have changed. As a result, several medical devices have been reclassified into a higher risk class. One example of this reclassification is mobile medical apps for smartphones and other mobile devices. According to Rule 11 in Annex VIII MDR, software for diagnostic or therapeutic purposes is generally risk class IIa, but under certain conditions can be risk class IIb or III. While under the old regime, medical apps were mostly in class I, hence manufacturers could self-certify without the involvement of a notified body, keeping the procedure simple and costs low; it is likely that in the future, a notified body will often be required for registration of a medical app.

Next Steps

Because the new legal framework was issued as regulations, the individual EU Member States are not required to issue their own implementing laws to codify the MDR and IVDR. Instead, both regulations will be directly applicable in the 28 Member States of the EU. Furthermore, the Member States will have less discretion to interpret their national laws to impose different or new requirements because these Regulations are more detailed and proscriptive than the current medical device regime based on the Directives.

Upon expiry of the transition periods in 2020 (MDR) and 2022 (IVDR), the new Regulations will become fully applicable. During the transition periods, manufacturers may choose whether they want a medical device to be certified under the old or the new regime. However, four years after the effective date of the MDR, *i.e.*, in 2024, all CE-certificates issued under the old rules of the MDR will expire. By then at the latest, all medical devices marketed in the EU will have to comply with the new regime. The transition periods are not as long as some would have hoped, given the significance of the changes. These changes will require medical device manufacturers to review and evaluate current operations and systems to ensure compliance with new and enhanced requirements. While the new Regulations reflect a trend toward greater harmonization of EU and US requirements, companies with global operations, distributions and products should take a holistic approach to compliance and implement regulatory and compliance processes that are appropriate, adaptable and scalable for a global marketplace.

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