New Medical Devices Regulation (EU) 2017/745 coming into force: an insight to the most significant legislative changes

In light of the upcoming entry into force of Regulation (EU) 2017/745 on medical devices (the "MDR") on 26th May 2021 upon extension of the initial effective date due to the Covid-19 outbreak, the time has arrived for both economic operators and public authorities engaged throughout the entire medical device life cycle to confront all major changes in the European Union's regulatory framework which governs market access to the EU for medical devices.

The MDR brings EU legislation in line with technical advances, changes in medical science and progress in law making. The MDR aims to create a robust, transparent and sustainable regulatory framework, internationally recognised, which shall improve clinical safety and create fair market access for manufacturers. It should be noted that, in contrast to Directive 93/42/ EEC (the "**MDD**"), the MDR is directly applicable and does not need to be transposed into national law; therefore, MRD's provisions have, as of their entry into force, immediate effect in the Greek legal order.

Notwithstanding the foregoing, in order to avoid market disruption and to allow for a smooth transition from the MDD and the respective national provisions that have been enacted for the transposition of MDD's provision in each Member state, several grace periods have been put in place. More specifically, with regard to the timeline of the MDR, until May 2025, products certified under the Directive and products certified under the Regulation may coexist in parallel on the market. Both will be equally treated and no discrimination in public tenders may take place. In particular, a transition period has been provided as the MDR requires the designation of Notified Bodies ("**NBs**"). The process of designating Notified Bodies will take up a significant part of the transition period, meaning that there will be limited time for manufacturers to have all their products certified before the respective date of application (i.e. the 26th of May 2021, the "**DoA**"). This makes it unlikely that all devices available on the market will be certified under the MDR by the DoA, especially if the designation of Notified Bodies takes longer than originally foreseen. In addition, manufacturers need to meet more stringent criteria, particularly in terms of clinical and performance evaluation requirements. Therefore, in order to avoid unavailability of medical devices, manufacturers may, under certain conditions, continue to produce MDD compliant devices and place them on the market after the respective DoA; these may be placed on the market until 26 May 2024 and made available for sale to end customers until 26 May 2025.

Grosso modo, the MDR retains all requirements of the MDD, while adding certain new requirements of its own. Therefore, fundamental obligations such as to provide, upon request by the competent authority, all information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned or to give samples of the device free of charge or, where this is impracticable, to grant access to the device, remain intact. The MDR introduces, in general, a more stringent than

MDD legal framework, especially in terms of risk classes and the oversight provided by NBs. Compared to the current MDD, the MDR emphasises on a life-cycle approach to safety, backed up by clinical data and post-market monitoring ("vigilance" and "post-market surveillance").

The MDR intends to increase transparency, requiring the publication of information on devices and on clinical and performance studies related to their conformity. The new European Database for Medical Devices and In Vitro Diagnostic Medical Devices, the "**EUDAMED**", will play a key role in making data available and increasing both the quantity and quality of data (MDR Article 33). However, according to European Commission's Communication, EUDAMED will not be operational until 26 May 2022. Therefore, registration with the EOF Medical Device Registry of manufacturers (and their authorised representatives) having their registered seat in Greece, shall continue until 25 May 2022. Applicants shall submit an amending application for registration with EOF's electronic registry, where they shall post a Declaration of Conformity in accordance with Article 19 and Annex IV MDR. Lastly, the European Commission provides a range of guidance documents to assist stakeholders in implementing the MDR which may be useful and may be found in the following link.

Having said the above, in the following chapters, the key obligations of manufacturers, importers and distributors of medical devices shall be presented.

A. Obligations of Manufacturers

Under the MDR, manufacturers shall:

i. Establish, document, implement and maintain a system for risk management (as described in detail in Chapter 3 of Annex I of the MDR).

ii. Draw up a declaration that the device conforms to the MDR and add a CE-mark to the product. The declaration shall be kept up to date and available in the official language or languages required by the Member State(s) in which the product is made available. The information to be included in the declaration of conformity is detailed in Annex IV and the format of the CE mark is given in Annex V. Depending on the risk class of the device, conformity assessment may involve an appropriate NB. In particular, for medical devices falling under class III, IIa and IIb devices, the involvement of an NB is required for the conformity assessment; the same applies for respiratory patient ventilators, as well as for class I devices supplied in sterile condition or with measuring functions. On the other hand, the conformity assessment procedure for class I devices should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. Therefore, it becomes apparent that, while under the current regulatory regime manufacturers of medical devices take prime responsibility for getting their products CE-marked for the European market, now they need to manage the change to get their products CE-marked under the MDR.

iii. Plan, establish, document, implement, maintain and update a post-surveillance (**PMS**) system that is proportionate to the risk class and appropriate for the type of device; details of the PMS plan may be found in Annex III of the MDR. The PMS system is required to be an integral part of the manufacturer's quality management system (**QMS**). The PMS system shall actively and systematically gather, record, and analyse data on the quality, performance and safety of the device throughout its entire lifetime. Data gathered by the manufacturer's PMS shall be used, inter alia, to:

- update the benefit-risk determination and to improve the risk management;
- update the design and manufacturing information, the instructions for use and the labelling;
- update the clinical evaluation;
- identify the need for preventive, corrective or field safety correction action;

- identify options to improve the usability, performance and safety of the device;
- contribute to the PMS of other devices; and,
- detect and report trends.

iv. Post-market clinical follow-up (**PMCF**) is also required under the MDR, intended to update clinical evaluation in the context of the overall PMS plan. PMCF may include:

- gathering of clinical experience;
- collecting feedback from users;
- screening of scientific literature and of other sources of clinical data;
- evaluation of suitable registers;
- conducting PMCF studies.

Manufacturers of Class I products are required to prepare a PMS report which shall be updated and made available to the competent authority upon request.

v. Report serious incidents and field safety corrective actions. A serious incident may be associated, among others, with the temporary or permanent serious deterioration of a user's state of health.

vi. Comply with the obligations relating to the Unique Device Identification system (the "**UDI system**"), which shall allow for the identification and traceability of devices, along with the pertinent registration obligations with the UDI database. The UDI system shall consist of: (i) the production of a UDI that comprises a UDI device identifier ("**UDI-DI**") specific to a manufacturer and a device, providing access to the information, and a UDI production identifier ("**UDI-PI"**) that identifies the unit of device production and if applicable the packaged devices, (ii) the placing of the UDI carrier on the label of the device or on its packaging or in case of reusable devices on the device itself (direct marking), (iii) the storage of the UDI, (iv) the establishment of an electronic database for Unique Device Identification (the "**UDI database"**), which is part of EUDAMED, in accordance with Article 28 of MDR.

B. Obligations of Importers

With regard to importers' obligations, the following are to be noted. In particular, importers shall:

i. make sure that the devices they place on the market bear the CE marking, are accompanied by the required information and labelled in accordance with the MDR, and have been assigned a UDI, where applicable;

ii. verify that devices are registered in EUDAMED and register the facility as "Importer" in EUDAMED;

iii. notify the manufacturer, the authorised representative, and, if necessary, the competent authorities in case of real or potential problems about the device;

iv. indicate on the device or on its packaging or in a document accompanying the device their corporate name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be detected. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer;

v. keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements for a period of at least ten (10) years after the last device covered by the EU declaration of conformity has been placed on the market;

vi. all other existing obligations and more specifically materiovigilance and maintenance of a register of complaints, of non-conforming devices and of recalls and withdrawals, obligation to report suspected incidents related to a device, to inform the manufacturer or its authorised representative in case a device is not in conformity with the requirements of the MDR, to withdraw or

recall a product found to lack conformity with the requirements of the MDR and to immediately inform the manufacturer or its authorised representative as well as to ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements and comply with the conditions set by the manufacturer have remained in place.

C. Obligations of Distributors

Before making a device available on the market, distributors shall verify that all of the following requirements are met:

i. the device has been CE-marked and the EU declaration of conformity of the device has been drawn up;

ii. the device is accompanied by the information to be supplied by the manufacturer, and in particular labels and instructions for use are provided in the official languages of the Member States in which the device is made available (or in languages accepted by those Member States);

iii. for imported devices, the importer has complied with the requirements set out in point (iv) hereinabove;

iv. a UDI has been assigned by the manufacturer, where applicable;

v. In order to meet the requirements referred to in points (i), (ii) and (iii), distributors may apply a sampling method that is representative of the devices supplied by that distributor.

vi. As to the rest of the obligations applicable to distributors and, in particular, their obligations not to place on the market devices that are not in conformity with the MDR and to abstain from such placement until the device has been brought into conformity, as well as to inform the manufacturer and, where applicable, the manufacturer's authorised representative, the importer and the competent authority (if the device entails a serious risk or is a falsified device) about the lack of conformity, to ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer, to withdraw or recall a product lacking conformity with the requirements of the MDR and to immediately inform the manufacturer or its authorised representative, to fulfill their materiovigilance requirements and to maintain a register of complaints, non-conforming devices and recalls and withdrawals and to report suspected incidents related to a device, these have been also included in the MDR.

D. The upgraded "roles" of all Economic Operators

In light of the above, it becomes apparent that, under the MDR, roles of key economic operators engaged in the manufacturing, distribution and marketing of medical devices have been narrowly defined. Each economic operator must ensure that its corresponding role is fully understood and taken adequately into account and in this regard, any agreements concluded shall be drafted accordingly. In particular, with regard to distributors and importers, both are required to cooperate with manufacturers or authorised representatives in order to achieve an appropriate level of traceability of devices, as well as to implement and keep up-to-dated a Quality Management System to fulfill their obligations, as described hereinabove.

The MDR will likely have a significant impact on all medical device developers in one way or another; it remains to be seen if that impact may positively contribute to achieving the fundamental objectives of the MDR or whether the new rules set up by the Regulation may result in a more complicated regulatory framework.

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