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State of Play and Implementation of the EU Medical Device Regulation

Introduction

The new Medical Device Regulation (2017/745/EU) (the Regulation) represents the most radical shift in EU regulation of medical devices for decades.

Regulation 2017/745 was adopted by the EU in May 2017 and is to replace existing EU legislation dating back to the 1990s. These are the Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC).

The Regulation is designed to increase the health and safety protection of EU patients, add more control and oversight in the system, and adapt to new technologies and scientific progress in the medical device sector.

What Is to Change?

The new Regulation will impact many aspects of medical device regulation, from development and the need for clinical evaluation, registration and oversight of Notified Bodies, to greater controls over actors in the supply chain and vigilance and market surveillance arrangements.

Much effort has gone into plans for implementation of the Regulation, given the wide-ranging changes that will apply to manufacturers and Notified Bodies, and the need for development of new systems to carry out new processes.

Considerable concern has been raised about the timing of the implementation provisions and the ability of the industry and others to reach compliance by relevant deadlines.

When Does the Regulation Apply and Whom Does It Impact?

The Regulation entered into force on 26 May 2017 but has a transition period that will run, for some measures and in respect of some medical devices, for the next few years.

Important measures dealing with the application of the Regulation to existing medical devices and wider implementation rules are contained in Articles 120 and Article 122 of the Regulation.

There are some important dates to keep in mind following entry into force of the new Regulation.

New controls and designation of Notified Bodies began on 26 November 2017. There has been significant recent concern over the ability and capacity of the EU Notified Body system to deal with the new systems as they come into force. This concern has been amplified by the cessation of services from some Notified Bodies and the delay in accreditation of others.

EU MDR Crisis: Pressings Deadlines Demand Immediate Solutions

EUDAMED, the new system for registration of products, relevant actors and for dealing with market surveillance and information exchange, may go live as soon as 26 March 2020. However, the actual date for availability of new systems will likely be later than this, and manufacturers and others in the supply chain will need to monitor progress to establish when obligations are required to be fulfilled. Article 123 of the Regulation gives the EU considerable flexibility with respect to the implementation of the provisions on EUDAMED.

A significant date for manufacturers will be 26 May 2020. From this date, many provisions of the Regulation that relate to product requirements, assessment procedures and certifications will apply. There is, however, a further transition where existing certifications are valid for a maximum four-year period until 2024, as noted below.

The 26 May 2020 date is important because:

- Certain products (e.g. certain aesthetic devices) that were not previously covered by EU medical device controls will need to comply with the new medical device regulations on this date
- Actors in the supply chain have enhanced obligations and these will apply to different types of operators, e.g. to importers, authorised representatives and distributors

Additionally, under the Regulation, existing certificates that were issued under the previous medical device directive legislation will become void after 26 May 2024 – seven years after the Regulation comes into force, and taking account of the four-year maximum validity period noted above.

This note covers rules for general and active implantable medical devices. There is a separate new regulation that deals with the In Vitro Diagnostic Medical Device regime, which has separate requirements and provisions for implementation.

The Practical Impact

Given the complexity of the Regulation alongside the implementation rules, it is important that manufacturers and suppliers be aware of when new obligations will apply and carry out analysis of how they sit with current product portfolios and products that are being developed or coming to market soon.

Capacity issues in the system are also a concern, and planning around relevant support will be critical.

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