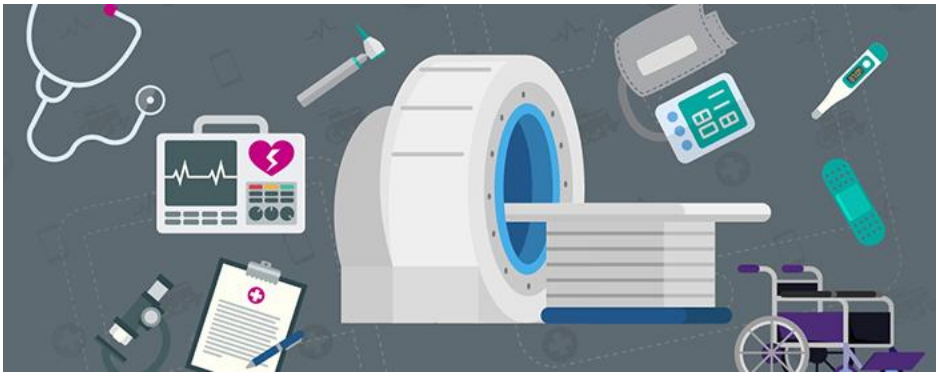
JULKAISTU NUMEROSSA 4/2021
TEEMAT

Medical device development is a challenge for regulation

Susanna Peltoniemi / Kirjoitettu 1.12.2021 / Julkaistu 16.12.2021



© Fimea

The legislation that applies to medical devices is undergoing a large and much anticipated renewal, which requires a lot of work from the authorities and operators.

Glasses, plasters and thermometers. Surgical masks, dental implants, walkers and at-home corona tests. All of these are CE marked medical devices. In addition to these devices that consumers are familiar with in their daily life, health care uses many more medical devices, ranging from stethoscopes and blood product bags to ventilators and X-ray machines.

One feature shared by these devices is the fact that their manufacturing, distribution and use are regulated by the EU's Medical Device (MD) regulation and the IVD regulation for in vitro diagnostic devices. The Finnish Medicines Agency Fimea is responsible for market surveillance in Finland.

The renewed regulation will take time and resources

> *The need to develop legislation related to medical devices became more acute around 10 years ago when investigating the breast implant scandal.*

The need to develop the legislation related to medical devices became more acute around 10 years ago when investigating the breast implant scandal. The new MD regulation finally took full effect in May of this year, and it includes a lot of new requirements. The aim is to improve patient safety.

The changes in legislation and the new MD regulation have a significant effect on the practical work of manufacturers, distributors and the competent authority. Adopting and applying the new requirements will take time and resources.

For example, the renewed regulation means that assessment by an external Notified Body will be required for more medical devices in the high risk class. This is a major change that manufacturers have to take into account in their own processes.

In addition to the legislative changes, the EU's joint European Database on Medical Devices (Eudamed) was taken in use in October 2021. The EU's joint open database is based on Eudamed and makes it possible for every patient, health care professional or distributor to check medical device information.

However, the database is not ready for use yet, because operators who are liable to file a notification have only just begun to register their devices in Eudamed. The deployment of Eudamed will take place in stages. With regard to Finland, registration of devices that comply with the MD regulation has already started, but the transition period is longer for other countries.

Marketing authorisation is not the basis for placing products on the market

Manufacturers often request marketing authorisation for a medical device from the supervisory authority, which is Fimea. At the same time, manufacturers would also like the authority to perform a final quality inspection and safety investigation on the device that could be utilised when selling the device.

Marketing authorisations are not part of the process of placing medical devices on the market in Europe.

However, marketing authorisations are not part of the process of placing a medical device on the market in Europe. The new regulation has not caused any changes in this area. This important difference in comparison to medicines can cause confusion in many cases, because the marketing authorisation process for medicines is a familiar and clear way to demonstrate conformity.

Even if it does not apply for and receive a marketing authorisation from the authority, every manufacturer is responsible for ensuring that a device is safe and meets the requirements outlined in the legislation. A CE mark must be added to devices to prove conformity. The devices must also be registered in the authority's databases. Furthermore, the manufacturer has to be able to provide a declaration of conformity, from which the device distributor or retailer can check the device information, such as risk class.

There are also essential differences regarding the distribution and use of medical devices in comparison to medicines. Off-label use of medicines is allowed in some situations at the discretion of a physician. Medical devices can only be used for the intended purpose specified by the manufacturer. The manufacturer has assessed the risks of this type of use to ensure that the device does not endanger the user or patient.

Regulation has to keep up with device development

There are approximately 500,000 CE marked medical devices in the European Union market. Technological development and innovations are moving the sector forward at a rapid pace. New devices, such as various applications, artificial intelligence software, implantable blood sugar sensors and implants that regulate the release of medicine, are placed on the market nearly every day.

The legislation in this rapidly developing sector has to keep up with product development in order to ensure that even the most advanced devices are safe for patients.

Despite the differences between medicines and medical devices, centralising their supervision with the same authority – Fimea – has provided synergy benefits.

In spite of the differences between medicines and medical devices, centralising their supervision with the same authority – Fimea – has provided synergy benefits. The supervision areas support each other regarding, for example, drug-device combinations. As devices and medicines develop, the interface between them can become blurred, and an increasing number of shared operating models to improve patient safety are being discovered.

The renewed legislation and better cooperation between device and medicine supervision mean that the safety of devices and medicinal products can be ensured even more effectively.

Legislation

Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, EUR-Lex website

Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices, EUR-Lex website

Medical Devices Act 719/2021 (Finlex.fi website)

Act on Certain Medical Devices Specified in EU Directives (629/2010) (Finlex.fi website, in Finnish)

Fimea Administrative Regulation 2/2021: Operator and device register notifications related to medical devices to the authorities (Finlex.fi website)

Susanna Peltoniemi

MSc (Technology)
Head of Unit, Fimea

LISÄÄ AIHEESTA