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Medical devices: reformulation of the statutory framework

In the autumn of 2012, the European Commission launched the revision of the European legislative framework for medical and in-vitro diagnostic medical devices. The main objective of the two draft regulations is to ensure that medical devices are safe. The Poly Implant Prothèse (PIP) scandal made it clear that immediate improvements in the oversight of medical devices were needed. This is why the European Commission and Member States agreed on an Action Plan aiming at improving the control on the basis of existing legislation. In the spring of 2017, two new regulations in this area came into force that have resulted in certain changes and also necessitate amendments to national legislation. A focus was put on four key areas: the functioning of notified bodies; market surveillance; coordination in the fields of vigilance; communication and transparency.

The Commission for Occupational Health and Safety and Standardization (KAN) has published a detailed article on *Medical devices: reformulation of the statutory framework*. Please find below relevant information taken from this article touching upon several aspects regading the **new European statutory framework for medical devices and in vitro diagnostic devices.**

Definition of Medical Devices

Medical devices are instruments, apparatus, appliances, materials and preparations intended for use for medical purposes such as for the diagnosis, prevention, monitoring, treatment or alleviation of disease. In contrast to pharmaceuticals, their primary effect in or upon the human body is attained not by pharmacological, immunological or metabolic means, but primarily by physical means. Active medical devices employ a source of energy such as electric power or compressed air. Examples of medical devices are technical medical equipment (including the requisite software) such as x-ray machines, catheters, cardiac pacemakers, and also implants, medical instruments, products for injection, infusion, transfusion and dialysis, dental products, dressings, optical aids, contraceptive products, and in-vitro diagnostic products.

Requirements for market access

In order for medical devices to be placed on the Single Market and operated within it, they must bear a CE mark. The CE mark may be applied only if the product satisfies the essential safety and performance requirements set out in the relevant EU directives, the purpose of which is to protect patients and users alike during use of the products. The medical device must first undergo a procedure for minimization of risks, a clinical assessment, and a risk-benefit analysis. The specific requirements concerning the manufacture, performance and safe design of the medical devices are set out in the corresponding harmonized European standards. The European Medical Devices Directive contains rules by which the products are assigned to three risk classes. Depending upon the risk class of the product, performance of the conformity assessment procedure may require the involvement of an independent test and certification body (notified body) that is subject to a state notification process and is monitored by the responsible authority. Only in the lowest risk class (I) may the manufacturer perform the procedure on his own account.

Medical devices bearing the CE mark may be placed on the market throughout the European Economic Area. However, they are subject to surveillance by the authorities of the Member States and to an observation and

reporting system for the detection and avoidance of risks that become apparent retrospectively (vigilance system). Manufacturers must also be able to demonstrate, with reference to clinical data, the performance and the acceptability of the risk-benefit ratio of their products, as well as their technical safety.

New European statutory framework for medical devices and in vitro diagnostic devices

The new Medical Devices Regulation (EU) 2017/745 and Regulation (EU) 2017/746 on In Vitro Diagnostic Devices (IVDR) entered into force on 25 May 2017.

Areas for which the Medical Devices Regulation contains new requirements include the following:

- Medical devices are now subject to stricter requirements concerning clinical testing and evaluation.
- The conformity assessment bodies must be renotified. They are listed as before in the European NANDO database with indication of the scope of their notification.
- Certain high-risk products must undergo an additional test procedure performed by expert bodies ("scrutiny procedure").
- The EUDAMED European Database for Medical Devices is to be extended, and in future will include a unique device identifier (UDI); parts of the database will be made accessible to further groups such as manufacturers, notified bodies and the general public.
- The rules for the risk classes have been reformulated, particularly for software, nanoproducts, medical devices composed of substances and reusable surgical instruments, which now fall within a higher risk class.
- Several new reports are required, for example in the sphere of post-market (clinical) follow-up and the reporting of serious incidents and field safety corrective actions (vigilance).
- The technical documentation must satisfy more detailed requirements and be updated continually.
- Should harmonized standards be inadequate or not exist, the European Commission will set out substitutes in the form of "common specifications"; one function of these is to support the essential performance and safety requirements of the regulation, and they give rise to the presumption of conformity.
- Manufacturers must appoint a qualified person who possesses the required specialist knowledge of medical devices and the legislation.
- Manufacturers are obliged to provide sufficient financial coverage in respect of their potential liability.

Extensive action is now required at national level: contradictions and national legislation identical to the EU regulations must be eliminated, and considerable amendments must be made to the MPG for this purpose. The regulation also contains numerous requirements for the Member States to enact new legislation, for example concerning the involvement of ethics commissions in the authorization procedures for clinical tests. Problems relating to application of the Medical Devices Regulation and IVDR are currently being identified in the national working group for implementation of the Medical Devices Directive/IVDR, where they are to be resolved if at all possible.

Transitional periods

The EU regulation officially came into force on 25 May 2017. Application of the Medical Devices Regulation becomes mandatory on 26 May 2020 (at the end of a three-year transition period) and of the IVDR on 26 May 2022 (at the end of a five-year transition period). EU regulations always apply directly and take priority over other legislation; they do not therefore need to be transposed into national law. Within the transition period, manufacturers may choose to be certified either under the existing legislation or, subject to certain conditions, under the new legislation.

Sources:

- KAN article: Medical devices: reformulation of the statutory framework https://www.kan.de/en/publications/kanbrief/standardization-in-healthcare/medical-devices-reformulation-of-the-statutory-framework/

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