Clearing legal hurdles with confidence

The 4th amendment of the Medical Devices Directive (MDD), effective as of 21.03.2010, will have a considerable impact: in future, for example, dedicated software which performs defined relevant medical functions will in future be counted as an active medical device. And operators will be subject to more stringent regulations with regard to in-house products: wherever networked medical systems are created, these can be defined as medical devices according to the 4th MDD amendment.

March 21st 2010, an important date: it is the day on which the 4th amendment of the Medical Devices Directive comes into force. Manufacturers of medical devices must have implemented the new regulations by this date. Otherwise, products may not be put into circulation that do not comply with this legislation.

The European Medical Device Directive 2007/47/EEC alters the existing guidelines 90/385/EEC (relating to active implantable medical devices) and 93/42/EEC (relating to medical devices). With its implementation in national legislation, the 4th amendment of the Medical Devices Directive (MDD) has now been brought into line with pharmaceutical law in certain key points. Manufacturers' obligations have been extended. In particular, there are tougher requirements with regard to compliance assessment, technical documentation, clinical testing and evaluation and follow-up market monitoring. What is more, the group of companies affected has been expanded to include manufacturers of medical software.

As a result, a whole new situation will apply to most software manufacturers operating in the medical field: dedicated software which performs relevant medical functions will in future be counted as an active medical device – which is one of the main changes. While previously there were no legal provisions relating to product safety, manufacturers will now have to address the complex requirements of the MDD. The essential point will be whether or not the software serves the purpose of a medical device. This is difficult to judge

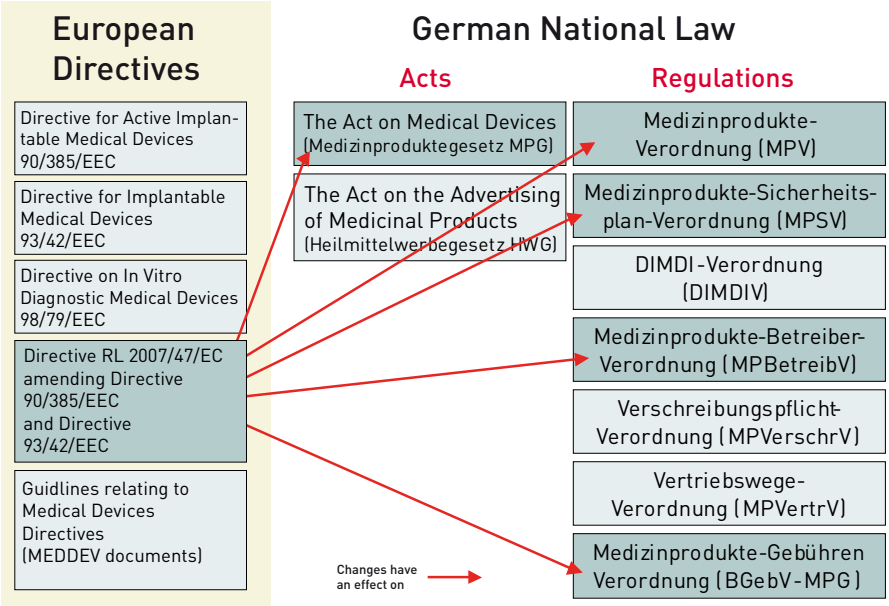
and is causing considerable uncertainty within the sector: for example, in which areas does a Clinical Information System (CIS) serve or not serve the purpose of medical device? "As we see it, the entire CIS can in no way be defined as a medical device – software designed for documentation or supporting the decision-making process has nothing in common with medical devices," states Peter Wegmann, Head of Product Management with systema Deutschland GmbH, a full-range e-health provider. "On the other hand, therapy planning programs do perform the function of a medical product. But exactly where this distinction is drawn in detail cannot be clearly deduced from the regulations." It remains to be seen where the distinction will be made in practice during the weeks and months after the directive comes into effect.

Users and operators of software which is defined as a medical device will also be subject to new requirements: they will have to adhere to the Medical Devices Operator Ordinance (MPBetreibV), which requires extensive testing after updates, among other aspects.

Operators will also be subject to more stringent regulations in terms of in-house products: wherever networked medical systems are created, these can be defined as medical devices according to the 4th MDD amendment. Johannes Dehm, Managing Director of the VDE Initiative MikroMedizin, provides an example to illustrate the kind of practical consequences involved for operators

A range of medical devices will be classified in a higher risk group as of March 21st 2010

in view of these blurred MDD distinctions between a medical device and an IT network: "In telemedicine the safety-critical functions of medical devices are increasingly being transferred to IT networks, such as medical device alarms passed on from intensive care units. Under no circumstances may a conflict occur in the network when an alarm signal is relayed. As the operator, the hospital is required to adhere to the MDD and its regulations for the entire system." Classification rules are also affected by the amendment and have become more stringent. As a result, a range of medical devices will be classified in a higher risk group as of March 21st 2010 and will therefore be required to undergo more extensive compliance procedures.



Changes to the European directive and their effects on national legislation.

In future, clinical evaluation will be required for all active implants and medical devices. Only under certain circumstances and where sufficient clinical data is available (e.g. in relation to a similar medical device) can this evaluation be carried out based on a review of the scientific literature.

In terms of clinical testing there will be a requirement to obtain authorisation rather than a disclosure obligation – as is the case with pharmaceutical products. This means that clinical testing cannot be started until the scientific and technical approval of the Federal Institute for Drugs and Medical Devices (BfArM) has been obtained, along with the supporting ethic and legal evaluation of the ethics commission. This compulsory authorisation will be waived for medical devices with a low safety risk. Details are to be set out in a statutory ordinance which was not available at the time of going to press.

Marketed products will also be subject to clinical monitoring in future (Postmarket Clinical Follow-Up, PMCF). Once again, considerable additional expenditure can be expected here since manufacturers will have to carry out repeat evaluations of clinical tests and keep devices up-to-date according to a test schedule.Medical devices which are also machines as defined by the machinery directive (2006/42/EEC) will have to meet the requirements of both directives. However, this will only apply where the requirements of this directive are more specific and the relevant risk actually applies.

A similar ruling will apply to personal protective equipment (PPE): if medical devices are defined as PPE according to 89/696/EEC, they will be required to comply with both directives.
With all these new developments it remains to be seen just what difficulties will arise in practice. We will be observing and analysing developments in subsequent issues.

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1) Johannes Dehm, VDE Initiative MikroMedizin: "In telemedicine the safety-critical functions of medical devices are increasingly being transferred to IT networks."
2) Peter Wegmann, systema Germany: "As we see it, the entire CIS can in no way be defined as a medical device."