European Medical Device Regulation (MDR)

Waiting is not an option

The Medical Device Regulation was on the agenda at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) in mid-June, where the health ministers of the European member states discussed implementation problems. However, the EU Commission will probably not present any solutions until the end of 2022. "It is a good thing that the EU Commission and the member states are taking the concerns of clinics, doctors and med-tech companies seriously and striving for pragmatic solutions. But: Waiting is not an option! We need concrete solutions and measures now and cannot wait until the EU Commission's next status report in December 2022", said Dr Marc-Pierre Möll, Managing Director and board member of the powerful German Medical Technology Association (Verband Medizintechnologie, BV-Med), commenting on the outcome of the meeting.

Only 1,000 MDR certificates issued so far

BV-Med welcomes the fact that EU Commissioner Stella Kyriakides has recognized and identified the problems at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) and that a full 18 member states have spoken out in favour of pragmatic solutions. Only 1,000 MDR certificates have been issued so far, said the Commissioner. By the end of the transition period in May 2024, however, some 24,000 certificates will expire. She said that action must be taken quickly and decisively, that manufacturers must submit applications, while the Commission must also ensure that sufficient capacity is available on the part of the Notified Bodies. Kyriakides referred to solutions already discussed: relieving the burden on Notified Bodies; focusing on MDR certifications; easing the transition for manufacturers; working with hybrid audits. The Commission is monitoring

MDR-related developments and will provide an update at the next meeting, to be held at the end of the year. "However, what is needed now is not announcements, but harmonized and pragmatic solutions across Europe involving the medical device industry, as suggested by Austria", Möll said. "This is where the Commission has a responsibility – now and not in December 2022."

BV-Med supports the statements by the Irish representative and by Dr Thomas Steffen, German secretary of state, that the EU Commission must coordinate Europe-wide solutions and ensure simpler solutions and the cutting of red tape. "But we need these measures now. We need action, not announcements", Möll insisted.

BV-Med proposes "conditional certificates"

BV-Med had already presented three potential solutions the week before the meeting to address the problems in implementing the MDR:

- Increased capacity: increasing resources at Notified Bodies; expediting notification of additional Notified Bodies
- Expedient deployment of existing capacities: pragmatic grandfathering-in transfer of "legacy devices" (existing products under the old MDD guidelines) by issuing conditional certificates; exemptions for niche products; sufficient resources for innovations
- More time: postponing the deadlines if the measures cited are not sufficient

According to BV-Med, capacity bottlenecks at the Notified Bodies are the main problem. Increasingly, applications by manufacturers are rejected for lack of capacity, or existing long-term contracts are being terminated. The average duration of the certification process is about 18 months. Given a transition period until May 2024, this would mean that business decisions – such as on what medical devices should be withdrawn from the market – would have to be made by the third quarter of 2022 at the latest. "If we don't take political action, healthcare will be jeopardized, and we may completely lose an estimated 10 per cent of manufacturers in Germany and Europe – especially small and medium-sized ones who account for 30 per cent of the overall product inventory and for much of the power of innovation. That's why we need solutions now!"

At the EPSCO meeting, the Medical Device Regulation was also on the agenda. The problems with the implementation of the EU MDR were discussed extensively. However, concrete solutions and measures on the part of the EU Commission are not expected to be presented until the end of 2022.

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BDIZ EDI's point of view

It was even before the Corona pandemic when BDIZ EDI demanded a delay of two to three years to ensure the MDR's viability. Unfortunately, the MDR has been in force since 26 May 2021. All predicted implementation problems came true. BDIZ EDI welcomes the fact that the EU Commission is moving. However, time was too short to guarantee the functionality of the MDR. Among other things, there is still a lack of Notified Bodies and a non-functional central EUDAMED database. None of the objectives of the MDR can be achieved, even though EUDAMED was postponed. Market observers and especially the entire dental sector see the MDR as a roadblock to innovation – with serious repercussions for the practice of medicine and dentistry and ultimately for patients as the steam of new and innovative products dries up. Our fear still is that especially small and medium-sized manufacturers of medical devices will be at risk.