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Press Release

Forum MedTech Pharma e.V.

For additional information on this subject, see:
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Forum MedTech Pharma publishes position paper and recommendations on Medical Device Regulation (MDR)

Nuremberg – Regulation (EU) 2017/745 on medical devices (Medical Device Regulation, MDR) came into force on 25 May 2017. It will become mandatory in May 2020, at the end of a three-year transitional period.
Given its extensive membership structure, Germany's largest network in the medical technology sector – Forum MedTech Pharma e.V. – has assessed the new regulation from a collective viewpoint and issued recommendations.

In their statement, the network, which represents many different fields within the healthcare industry, expressly speaks in favour of ensuring the best possible healthcare for the benefit of the patients. There can be no question that there is merit in constantly adapting regulations in accordance with changes in the industry. But the authors note that safety and quality must take priority over speed. CEO Dr Matthias Schier considers, however, that implementing changes in the form of the new MDR and IVDR poses challenges for the industry that could significantly impact on the dynamics of innovation, product range and future viability: "In some cases, there is no discernible positive influence on patient safety, for example with regard to the re-certification of proven, existing products. In this context, if established or innovative medical products cannot overcome regulatory hurdles because of limited resources or requirements that are difficult to fulfil, and as a result are not available to provide optimum patient care, this does not tally with the collective goal of ensuring the best possible healthcare."
The position paper identifies extremely short transitional periods as examples of particularly difficult challenges. The increase in the scope of requirements for clinical assessment, technical documentation and market observation means that bottlenecks can be expected in terms of finance, time and human resources. These would represent a major burden for small and medium-sized enterprises (SMEs) in particular, since these do not have enough financial and HR flexibility to make major advance outlays at short notice.

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The experts also criticise the fact that the cost of re-certification for existing products will be so high in some cases, based on the requirements of the MDR, that distributors will find themselves constrained to remove established products with an important role to play in healthcare from the market altogether.
Continued availability for use with patients would be questionable in such circumstances.
The far-reaching changes in requirements for clinical assessment constitute a particular challenge for the industry. The much larger number of products requiring clinical studies will lead to bottlenecks in the very hospitals that lack the necessary infrastructure for medical technology studies. The position paper also notes that the number of patients with the suitable inclusion criteria is also limited.
The great majority of players in Forum MedTech Pharma e.V. are in favour of modifying the MDR and its conditions of implementation to make it a more innovation-friendly and practicable regulation that truly encourages the best possible healthcare for the benefit of the patients.
They also call for the National Working Group for Implementing the MDR/IVDR (Nationaler Arbeitskreis zur Implementierung der MDR/IVDR, NAKI) to ensure that the implementation or creation of legislative acts for implementation does not cause the rules to be tightened further, but that efforts will be made instead to relax requirements in terms of transitional periods, for example, within the available room to manoeuvre.
Attention must focus on the situation facing the entities mentioned – resource bottlenecks and the need for a uniform approach – to prevent serious impediments to innovation from arising. The medical technology sector needs to be able to plan reliably.
The network is in favour of comprehensive accompanying measures to support the industry in the face of the serious challenges the new Regulation will create. Specific options could include neutral public advisory offices and centres of competence; digital platforms to gather and analyse data (e.g. mandatory registers); expanded material on Regulatory Affairs in training and professional development courses or in targeted courses of study; expanding the infrastructure in the area of clinical studies; and incentives for hospitals, patients and doctors to take part in clinical studies.

For the full position paper, see: www.medtech-pharma.de