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Opinion from German Social Insurance issued 23 October 2024

Adjustments to the European regulations for medical devices

I. Preliminary remark

The Medical Device Regulation (EU) 2017/745 (MDR) and the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) set out the fundamental requirements for the authorisation process for these products in the European Union (EU). The main objectives of the two regulations are to increase the safety of medical devices placed on the market, to tighten the requirements for the clinical evaluation of high-risk devices, to create transparency by introducing a central database (EUDAMED) and to harmonise the quality of the Notified Bodies throughout Europe.

The pan-European regulations for the approval of medical devices were tightened in 2017 in a targeted manner to increase patient safety. Around 20,000 instruments, devices and aids must therefore be (re-)certified. This was triggered by a breast and hip implants scandal, which uncovered numerous defects. The MDR came into force on 26 May 2020, followed by the IVDR on 26 May 2021. Long transition periods were granted for the adaptation to the new certification regulations, to allow the notified bodies responsible for certification and the manufacturing companies to prepare for the new rules. These were further extended in a fast-track procedure for medical devices on 15 March 2023 by Regulation (EU) 2023/607 and for in vitro diagnostics on 13 June 2024 by Regulation (EU) 2024/1860, staggered according to risk classes. In addition to the extension of the transition periods, the latter regulation also made two fundamental adjustments to the MDR. On the one hand, a reporting obligation for manufacturers of medical devices and in-vitro diagnostics in the event of an interruption or termination of the supply of medical devices and in-vitro diagnostics was introduced, and the introduction of EUDAMED was accelerated by provisions.

In light of the ongoing debate on ensuring the availability and supply of medical devices and in-vitro diagnostics, the upcoming fundamental evaluation of the regulatory scope of the MDR in 2025, and in view of the demands in the European Parliament resolution that early legislative changes or regulatory adjustments be made, particularly for orphan devices, DSV would like to use this paper to draw attention to the need for adjustments.

II. Opinion

The MDR is an important step towards improving patient safety and the quality of treatment with medical devices. This premise must remain in place during the planned evaluation and a possible adaptation of the MDR. From the DSV's point of

view, it is also not necessary to renegotiate the entire regulatory framework for medical devices and in vitro diagnostics. The current regulations already contain valuable safety and quality requirements. These must not be weakened in the course of an adaptation. To ensure the availability of medical devices that continue to meet the highest safety and quality standards set by the MDR, the following is crucial from the DSV's point of view:

1 _ Transparency

Transparency is key to ensuring the security of supply and the traceability of medical devices. It is essential to better inform policy development with clear evidence.

Ensuring high-quality and affordable medical device care and reliable availability through resilient production and supply chains is of central importance for the health and safety of patients in Europe. In order to improve the availability of medical devices through legislative and non-legislative adjustments, the DSV believes that a transparent factual basis is necessary as a first step.

_ Publication of a transparent and systematic report on market withdrawals and causes

The DSV criticises the fact that the European Commission has still not presented a systematic and transparent report on medical devices that have actually been withdrawn from the market due to the MDR or for which the manufacturer intends to withdraw from the market. In the DSV's view, more clarity and transparency are needed with regard to the types of products whose unavailability could seriously jeopardise patient care, as well as with regard to the exact reasons for withdrawals.

While the DSV welcomes the fact that, in addition to the adjustment of the transitional periods, an information requirement has also been introduced in the event of an interruption or termination of the supply of medical devices and in vitro diagnostics, the new Article 10a ‘Obligations in the event of an interruption in the supply of certain medical devices’ inserted into Regulation (EU) 2024/1860 contains useful provisions on the notification of expected interruptions or a cessation of supply of certain devices. However, what is missing from the DSV's point of view is the submission of a systematic and transparent report on the knowledge gained, in order to make appropriate legislative or non-legislative adjustments to the MDR based on this. This report must be the basis for this.

_ Ensure the functionality of EUDAMED

In addition, an essential transparency mechanism is the European Database for Medical Devices (EUDAMED), which is not yet fully functional. From the DSV's point of view, it is good that the European Commission has taken measures to accelerate the usability of EUDAMED in Regulation (EU) 2023/1860. Full functionality must be ensured as soon as possible.

_ Avoiding non-transparent national special Exemptions

The MDR contains provisions in Article 59 allowing Member States, in cases of emergency or exceptional circumstances—in the interest of public health or patient safety or health—to place medical devices on the market without a complete or successful conformity assessment procedure. Currently, these exemptions are being used for certain products. From the DSV's perspective, market fragmentation through national exemptions contradicts the European principle and is not in line with the MDR's intent. Therefore, the European Commission should publish the information it receives about national approvals, as this information also includes data on the safety, clinical performance, and validity period of the approvals for the respective products. Additionally, manufacturing companies should be required to state the reasons why a conformity assessment at the European level could not be conducted. At the same time, appropriate safeguards must be put in place to ensure that the use of these products is restricted to patients who genuinely need them.

2 _ Orphan devices

The adoption of transparent and harmonised measures at the European level is important to regulate the market access of supply-relevant medical devices, in particular orphan devices, in a legally secure manner, while ensuring a high level of safety, quality and transparency.

‘Orphan devices’ are medical devices intended for the treatment, diagnosis or prevention of diseases or conditions that affect only a small number of people - no more than 12,000 per year in the EU. In June 2024, the Medical Device Coordination Group (MDCG) published guidance on the handling of orphan devices (MDCG 2024-10). Many of the recommendations are reasonable and welcome. The DSV recommends that the following aspects be regulated by law:

_ Integrate unambiguous definitions into the MDR

From the DSV's point of view, the processes for recognising medical devices as ‘orphan devices’ and placing them on the market must be bindingly integrated into the MDR. A regulation based on recommendations creates ambiguity and legal uncertainty. The definitions of ‘orphan device’, ‘orphan population’ and ‘orphan subpopulation’ set out in the MDCG must be integrated into the definitions in Article 2 of the MDR to create legal clarity.

_ Implement a structural division of the conformity assessment for orphan devices between the notified body and a central review authority on European level

The DSV proposes that special conformity assessment procedures be established for products with orphan device status. The assessment of the technical documentation should be carried out by the responsible notified bodies, as they have the necessary expertise for this task. However, the clinical evaluation and the intended purpose should be reviewed by a central review body at the European level, involving the expert panels of the European Medicines Agency (EMA). The central review body should also decide which products are granted orphan device status. The notified bodies should remain the first point of contact for manufacturers. Centralizing the medical expertise, as well as the related assessment and decision-making authority, ensures that the affected medical devices are evaluated uniformly and with minimal effort. The notified bodies will be relieved, as they will no longer need to maintain expert personnel for the highly specialized and relatively rare clinical evaluation of orphan devices.

_ Requirements for clinical evaluation and market surveillance should be regulated

The DSV demands that the MDCG recommendations for the clinical evaluation of orphan devices and for their post-market surveillance should become an integral part of the MDR. Due to the limited clinical data available for these products, it should be ensured that clear quality requirements are specified for users and institutions (hospitals, medical practices, etc.) as part of the approval process, and that binding requirements are set for the collection of missing clinical data. The manufacturer can make suggestions; however, the central review body at the European level should decide on the corresponding requirements.

_ Pan-European collection and central bundling of clinical data with orphan devices is necessary

Orphan devices are used only in small patient groups. Therefore, obtaining meaningful clinical data is a major challenge. In order to obtain an overview of the quality of care in the affected indications and at the same time to give manufacturers the opportunity to collect necessary clinical data, the DSV calls for the establishment of Europe-wide clinical registries or the pooling of data from existing national registries. Ideally, data on all affected patients should be recorded in these registers throughout the EU. If several orphan devices are available on the market for the indication in question, the associated treatment data should be collated in a single register, analysed and published at regular intervals.

About us

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband), the national associations for statutory health and long-term care insurance funds at the federal level and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have joined forces to form the "German Social Insurance - Working Group Europe" (Deutsche Sozialversicherung Arbeitsgemeinschaft Europa e. V.) with a view to their common European policy interests. The association represents the interests of its members vis-à-vis the bodies of the European Union (EU) as well as other European institutions and advises the relevant stakeholders in the context of current legislative projects and initiatives. As part of the statutory insurance system in Germany, health and long-term care insurance with 75 million insured persons, pension insurance with 57 million insured persons and accident insurance with more than 70 million insured persons in 5.2 million member companies offer effective protection against the consequences of major risks of life.