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Feedback from German Social Insurance issued 2 October 2025

European Commissions Call for Evidence on Medical devices and in vitro diagnostics – targeted revision of EU rules

I. Preliminary remark

The Regulation (EU) 2017/745 on medical devices (MDR) and the Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR) set out the fundamental requirements for the authorisation process for these products in the European Union (EU).

Against the background of the ongoing debate on ensuring the availability and supply of medical devices and in vitro diagnostics, the evaluation of the regulatory framework scheduled for 2025/2026, and criticism of its practical implementation, the European Commission sees a need for action. The European Commission is therefore planning a targeted revision of the MDR and IVDR. The aim is to streamline the regulatory framework by reducing administrative burdens, increasing predictability for manufacturers, notified bodies and national authorities, and achieving greater cost-efficiency, while ensuring a high level of patient safety and health protection.

Targeted legislative adjustments can therefore be useful in achieving the objectives of the MDR and IVDR, also in view of the considerable difficulties manufacturers and notified bodies faced during the transition from the previous legal framework. From the DSV's perspective, a targeted revision of the MDR and IVDR is only justified if it reduces unnecessary administrative burdens and facilitates access to medical devices and in vitro diagnostics – provided that patient safety and the quality of clinical data remain fully guaranteed. At the same time, the DSV emphasises that any reform will only be sustainable if it remains balanced, based on sound evidence, and continues to secure and improve the care of patients in the long term. For this reason, an impact assessment according to the standards of the EU's "Better Regulation" principle is indispensable.

In principle, however, the DSV welcomes measures that accelerate certification processes for medical devices and in vitro diagnostics and create incentives for manufacturers to remain present on the European market. Such measures, however, must be addressed in separate legislation and must not be conflated with the currently planned targeted adjustments. Any more extensive legislative changes to the MDR and IVDR should only be based on reliable evidence from the ongoing evaluation.

II. Opinion

1 _ Reducing bureaucracy while safeguarding the objectives of the MDR and IVDR

From the DSV's perspective, adjustments to the EU regulations for medical devices and in vitro diagnostics must not come at the expense of patient safety. Any amendment must ensure that the core objectives of the MDR and IVDR are maintained: improving the quality of clinical data, increasing transparency through consistent use of EUDAMED, and harmonising the work of notified bodies across Europe. The focus of a revision should therefore be on relieving manufacturers and notified bodies from unnecessary documentation requirements. Wherever possible, the required documentation and reporting procedures should be digitalised.

2 _ Orphan devices: facilitate access, safeguard safety

Both manufacturers and healthcare providers emphasise the urgent need to facilitate market access for orphan medical devices intended for the treatment of rare diseases or conditions. Without adjustments, there is a risk that especially small and medium-sized enterprises, as drivers of innovation, will be discouraged from launching products in Europe due to the requirements of the MDR and IVDR.

Integrate unambiguous definitions into the MDR

'Orphan devices' are medical devices intended for the diagnosis, treatment or prevention of diseases that affect no more than 12,000 patients per year in the EU. The Medical Device Coordination Group (MDCG) has published guidance on this (e.g. MDCG 2024-10). Many of the recommendations are reasonable and welcomed by the DSV, and their content should therefore be incorporated into the legal basis of the MDR and IVDR.

To reduce the administrative burden on manufacturers and notified bodies, clear definitions and unambiguous terminology are required. From the DSV's perspective, the procedures for the recognition of orphan devices and their placing on the market must be bindingly, centrally, uniformly and transparently integrated into the MDR. The definitions proposed by the MDCG – 'orphan device', 'orphan population' and 'orphan subpopulation' – should be incorporated into the MDR to create legal clarity.

Requirements for clinical evaluation and post-market surveillance

It is crucial that patient access to orphan devices – when insufficient clinical data on safety and efficacy are available at the time of CE certification – takes place only under clinically controlled conditions. Given the limited data available, it must be ensured during approval that clear quality requirements apply to users and institutions (e.g. hospitals, medical practices) and that binding provisions exist for the collection of the missing data. These data must be collected in the early phase of the Post-Market Clinical Follow-up (PMCF) period. The requirements for evidence of clinical performance must remain as strict as for other high-risk products.

Pan-European collection and central pooling of clinical data on orphan devices

Orphan devices are only used in small patient groups. Obtaining meaningful clinical data therefore poses a particular challenge. In order to systematically record the quality of care in the relevant indications and at the same time give manufacturers the opportunity to generate the necessary evidence, the DSV calls for the establishment of Europe-wide registries or the pooling of existing national registries. Ideally, all affected patients should be recorded in these registries throughout the EU. If several orphan devices are available for an indication, the associated treatment data must be jointly documented, analysed, and published at regular intervals.

In this context, the DSV has already presented recommendations on certification and approval procedures for orphan devices in a previous statement.

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.