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Feedback from the German Social Insurance European Representation on the Extension of the transition period for medical devices

Feedback of the German Social Insurance dated January 17th 2023

The German Federal Pension Insurance (DRV Bund), the German Social Accident Insurance (DGUV), the National Association of Statutory Health Insurance Funds (GKV-Spitzenverband) and the national associations for statutory health and longterm care insurance and the Social Insurance for Agriculture, Forestry and Horticulture (SVLFG) have all joined forces to form the "German Social Insurance - European working group) in view of 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 participants in the context of current legislative proposals and initiatives.

As part of Germany's statutory insurance system, health and long-term care insurance, pension insurance and accident insurance provide effective protection against the consequences of major life risks.

I. Feedback

The European Commission presented a proposal to amend the Medical Device Regulation (MDR) on 6 January. The proposal extends the transition period for adapting to the new certification requirements under the MDR. This is the European Commission's response to the ongoing debate about impending shortages of urgently needed medical devices.

According to the German Social Insurance European Representation (DSV), the MDR is an important step towards improving patient safety and the quality of treatment with medical devices. This premise must absolutely remain in the proposed adaptation of the MDR. It is crucial that no safety and quality requirements of the MDR are weakened.

The temporary risk-based extension of transitional periods is reasonable in order to counteract bottlenecks in the supply of medical devices. However, to continue to ensure product safety, it is important that the strict conditions on the safety and quality of medical devices provided for in the Commission proposal are met. Manufacturers may only benefit

from time extensions if they can demonstrate, among other things, that an application for conformity assessment under the MDR was submitted before end of May 2024, that the medical device in question has not been substantially modified and that it does not pose unacceptable health risks under Directives 90/385/EEC and 93/42/EEC. The patient safety must be given the highest priority.

It is therefore necessary that companies fulfil their certification obligations despite the extension. In addition to further measures to improve the capacity of the Notified Bodies responsible for certification, it should also be clarified which measures companies can take to ensure that certificate applications are of the necessary quality to enable rapid processing by the Notified Bodies.

Transparency is key to the security of supply of medical devices. It is important to know which medical devices are at serious risk of market withdrawal, why exactly they are withdrawn from the market and whether individual member states have granted special authorizations. Therefore, the DSV calls on the European Commission to compile and publish this information.