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Deutsche Sozialversicherung
Europavertretung | DSV

Opinion from the German Social Insurance dated 14th February 2024

Proposal for a Regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain in vitro diagnostic medical device

I. Preliminary remark

On 23 January, the European Commission published a proposal for a regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 with regard to the gradual introduction of EUDAMED, the obligation to provide information in the event of supply disruptions and the adaptation of the transitional provisions for certain in vitro diagnostic medical devices (IVDs). IVDs are tests that use biological samples to determine a person's state of health, e.g. HIV tests, pregnancy tests or blood glucose meters. Similar to the Medical Device Regulation (MDR), which was amended last year, the Commission proposal provides for an amendment to the In Vitro Diagnostic Medical Devices Regulation (IVDR) in order to give manufacturers more time to certify IVDs. In addition to extending the transitional periods, the European Commission is also proposing two fundamental changes that also affect the MDR. Firstly, an obligation for manufacturers of medical devices and IVDs to provide information in the event of supply interruptions and, secondly, an accelerated introduction of the European Database on Medical Devices (Eudamed).

II. Opinion

The DSV expressly welcomes the European Commission's proposals.

Extension of transition periods for IVD

The temporary risk-based extension of the transitional periods for IVDs makes sense in order to counteract supply bottlenecks for these products. In view of the low number of certifications and notified bodies so far, this is understandable. However, in order to continue to guarantee product safety, it is important that the strict requirements for the safety and quality of medical devices set out in the Commission proposal are met.

Accelerated roll-out of Eudamed

The accelerated roll-out and mandatory use of already functioning Eudamed modules is very welcome from the DSV's point of view. The previous obligation to use the database only once all modules are functional has proven to be restrictive.

Information obligation in case of interruption of supply

With the draft regulation, Article 10a of Directive (EU) 2017/745 and Directive (EU) 2017/246 is intended to stipulate that manufacturers must in future inform the competent authority of the Member State in which they are based in the event of interruptions to the supply of their products. Notification is mandatory if the interruption has or may have a serious impact on the health of patients or public health. The notification should be made six months before the start of the anticipated supply interruption.

The provisions envisaged by the European Commission on the obligation for manufacturers to report when "critical" products are withdrawn from the market are very much welcomed by the DSV. Transparency is the key to securing the supply of medical devices and IVDs. The planned regulation is intended to ensure that the competent authorities are informed of supply bottlenecks for medical devices and IVDs at an early stage. In addition, these mandatory notifications will enable the authorities to inform the treating institutions, patients and social insurance organisations of expected supply bottlenecks at an early stage and, if necessary, to take measures to avert any resulting risks.

However, the proposed provision is still too unspecific, which is why the DSV proposes the following adjustments:

1. supply shortages of medical devices and IVD arise not only from market withdrawals by manufacturers, but also from the cessation of marketing. This should be supplemented in order to create clarity here.

2. in order to be able to systematically understand the reasons for the occurrence of bottlenecks and, if necessary, to make targeted adjustments to the MDR, provision should be made for the Commission to regularly publish an evaluation of the bottleneck reports received from the national authorities.

3. it is unclear under which conditions "serious harm or risk of serious harm to patients or public health in one or more Member States" is to be assumed. The DSV proposes that the expert groups of the EU Commission should be instructed in accordance with Article 106 of Regulation (EU) 2017/745 to name specific areas of treatment (e.g. paediatric cardiology, paediatric oncology) in which there is always a risk of serious consequences for patients due to a shortage of supply or even a withdrawal of medical devices from the market and in which a notification must always be made.

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 74 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.