POSITION PAPER

Position Paper

of the German Insurance Association (GDV)
ID-number 6437280268-55

on the Proposal of the European Commission (2025)1023 on the amendment of the Medical Device Regulation (EU) 2017/745 and the In Vitro Diagnostics Regulation (EU) 2017/746

1. Introduction

The proposal aims to improve the functioning of the current regulatory framework, in particular as regards the smooth functioning of the single market, while ensuring a high level of health protection for patients. GDV welcomes this goal and the proposed deletion of Article 10 (16) of the Medical Device Regulation (EU) 2017/745 (MDR) and of Article 10 (15) of the In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR). Insurers, however, warn against the introduction of mandatory European liability insurance for manufacturers of medical devices and in vitro diagnostics. Such mandatory insurance would place an additional burden on European manufacturers of medical devices and in vitro diagnostics.

2. Background

Under Article 10 (16) of the MDR and Article 10 (15) of the IVDR, manufacturers are obliged to have in place measures providing sufficient financial coverage to cover potential liability claims. The aim of the proposal (2025)1023 is to establish

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a **leaner and more cost-effective regulatory framework** and to promote further harmonisation, creating a more competitive and innovative EU market. Accordingly, the above obligation to provide coverage is deleted under Article 1 para (9) (h) and Article 2 1 para (9) (h) of the proposal both in the MDR and in the IVDR.

3. GDV Position in detail

a) GDV welcomes the proposed deletion of the obligation to provide coverage.

The deletion takes into account that it is in the manufacturers' **own interest to take-out third-party liability insurance** in order to protect themselves against possible claims of third parties. GDV assumes that companies which can be held liable for damages arising from the manufacture of medical devices will take out sufficient insurance coverage in their own interest and independently of the statutory obligation to provide coverage. This is particularly relevant given that manufacturers, following the revision of the Product Liability Directive, are likely acutely aware of their heightened liability for damages caused by medical devices.

b) Considering the discussions regarding compulsory insurance for medical devices, we would like to point out that we view the potential introduction of mandatory insurance very critically.

The following aspects argue against mandatory insurance:

- In general, mandatory insurance is not necessary if manufacturers obtain adequate insurance coverage on a voluntary basis. An uninsured liability claim can mean immediate business closure, especially for a small- or medium-sized company and can also lead to personal liability for the owners. Accordingly, it is in the manufacturers' own interest to protect themselves against their own liability risks. **For this reason, the level of insurance coverage on a voluntary basis is and has already been high**; also before MDR and IVDR were implemented.
- The risk associated with medical devices is very **heterogeneous**. It depends on many factors, as for example the kind of the medical device (e.g. patch or pacemaker), the production process, the batch size and the recipient (e.g. ill or healthy, old or young). **Voluntary insurance enables "tailor-made" insurance coverage** for each and every individual risk.
- On the other hand, the scope and design of mandatory insurance cover require further concrete definition. The design is typically based on the greatest possible risk, making tailor-made solutions unviable. As a consequence, for companies and products with low risks the insurance cover on mandatory basis might **become unnecessarily – and in some cases significantly – more expensive.**

- As a result, mandatory insurance could cause a **significant financial burden for small and mid-sized companies**. This can lead to severe consequences including: a reduction in manufacturers' ability to invest in active risk management; an increase in consumer prices with no increase in product quality; and for the many small and mid-sized companies which characterise the European market, the future economic viability of producing such devices may even be put into question.
- Furthermore, it must be stated that even liability insurance cannot cover every type of damage. In general Insurers do not issue compensation for intentional damages, as this would be contrary to the fundamental concept of insurance and to the interest to those policyholders who act fairly. If Insurers were required to compensate for criminal actions, any incentive to adequately manage risks would be undermined. **Improved market surveillance, rather than mandatory liability insurance for manufacturers, is crucial to prevent damages caused by criminal activities.**
- To fulfil its purpose mandatory insurance would require **permanent governmental supervision**. Authorities would have to monitor whether legal requirements are met. Governmental supervision would however further **increase the administrative efforts for the manufacturer,** the insurer and for supervisory authorities in every member state. The question also arises whether the supervision should be established on a European basis rather than in the member states. In both cases – national and European supervision – mandatory insurance would lead to higher costs for the manufacturer, which would ultimately have to be borne by the consumer. **As a result, the proposal's goal of reducing administrative burdens for manufacturers would be undermined by the introduction of mandatory insurance.**

Fallback: We maintain our position that the obligation to provide coverage is not necessary and that Article 10 (16) of the MDR and Article 10 (15) of the IVDR should be deleted as proposed. However, if a provision for financial security is deemed necessary, we recommend maintaining the current obligation to provide coverage rather than introducing compulsory insurance.

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