BVMed Bundesverband Medizintechnologie e.V.

Position

Product legislation – ensuring futureproof rules (revision of the New Legislative Framework - NLF)

15th August 2025

Introduction

BVMed is the largest German MedTech Association and represents more than 300 manufacturers, suppliers, and distributors in the MedTech industry, as well as providers of medical aids and homecare services.

With its technologies, products, and processes, the MedTech industry contributes to better patient care, more efficient processes and reduced workload for medical staff. MedTech is indispensable for our healthcare system and part of the solution to the challenges of the future.

We fully welcome the European Commission's goal and timely efforts to improve the consistency in EU product legislation under the New Legislative Framework (NLF) to increase the competitiveness within Europe.
As mentioned in the call of evidence we fully support simplification as the most salient goal and objective.

Competitiveness in Europe must be promoted through uniform definitions within sectoral and horizontal legislation and through predictable, clear and efficient conformity assessment procedures. Specific attention must be paid to SME-intensive sectors.

In general, any changes within the NLF framework that increase competitiveness and add simplification for economic operators, should be applied to existing product regulations by revising them in a timely manner.

This also means to reduce potential cases of different interpretations of law by different Notified Bodies, which leads to massive administrative and technical burden to economic operators and especially affect SMEs.

We would also like to point out that the planned changes and initiatives within the framework of the NLF revision must be in line with the MDR revision (targeted evaluation) announced for 2025.

1.
Medical Device Regulation

We welcome the inclusion of digital and circularity elements into the legislative framework and want to emphasise that coherence and consistency with the sector specific framework for medical devices and its upcoming reform must be absolutely guaranteed.

The Regulation (EU) 2017/745 (“MDR”) represents a sector specific product regulation and, therefore, the rules applicable to medical devices should be aligned, where appropriate, with the NLF (cf. Recital (25) MDR).
BVMed supports the NLF approach for medical devices as because different mechanisms of action (physical) require different tests for safety and efficacy for medical devices and medicinal products even if there are similarities to medicinal products due to their use in healthcare.
However, it has to be recognised that the MDR differs significantly from other product regulations and must not be considered and treated in the same way. Medical devices are heavily regulated and subject to very extensive conformity assessment procedures.
The high level of complexity of the regulation can be seen by the total number of 323 pages legal text, supplemented by 18 implementing acts and 3 delegated acts, as well as 126 guidance documents on the interpretation of the law.
For this reason, we are fundamentally skeptical about option 2 as described in the call for evidence. The sector does not need any more non-binding guidance documents which increase the complexity of the whole legal and regulatory system. The effort required to read and implement further guidance is unreasonable, especially for SMEs.

The primary objective and aim must be to harmonise sectoral legal areas within themselves and with horizontal areas in line with the principles of better regulation. Legal texts must be simple, consistent in themself and easy to implement without much room for interpretation.

This also includes the correct translation of definitions and interpretations in the legal texts, but also other already existing documents like for example the “Blue Guide 2022”.

2.
Consideration of SME interests

Strengthening of micro, small and medium-sized enterprises ("SMEs") in Europe is essential for the competitiveness of the EU. The medical technology sector clearly reflects this need: The backbone of the medical technology industry in Germany and Europe are SMEs, which are often not well known to the general public but are regularly world market leaders and drivers of innovation in their business area. Therefore, it is essential to consider the interests of SME within legislative procedures to ensure the high innovative strength in the future.

In the past years the number of product regulations increased significantly. Especially SME struggle with different and noncoherent requirements of horizontal and sectoral legislations. We therefore call for increased sectoral coordination within the legislative institutions and structured stakeholder dialogues.

3.
Digitalisation and Sustainability

The revision of the NLF framework is expected to form the basis for product regulations for the next 20 years.

The principle underlying product regulations is safety and performance. Integrating digitalisation and sustainability into the framework is reasonable and necessary; however, it is essential to ensure that this does not cause implementation problems, especially when multiple product regulations must be complied with.

It is therefore extremely important to define the scope of application of any horizontal legislation at an early stage and to take the aspects of sectoral medical device law into account accordingly. It must be ensured that both horizontal and sectoral legislation is taken into account and that any additional horizontal requirements are consistent and clear in relation to sectoral requirements under the MDR. In case of doubt, medical device law must always take precedence.

One example is the Ecodesign for Sustainable Products Regulation (EU) 2024/1781 (ESPR). The MedTech sector is within the scope of the ESPR, therefore the provision of a Digital Product Passport (DPP) for medical devices is sooner or later most likely, depending on the implementing acts.

To ensure realistic results and proportionate requirements aligned with existing requirements under the MDR (for example EUDAMED) industry must be involved at an early stage of discussion and drafting the implementing acts as regards the scope of information accessible in the DPP but also, in general, in relation to digitalisation and sustainability topics.

Taking into account the development of digitalisation the concept of digital labelling should also be included in the NLF. Union harmonization should allow that information to be supplied by the manufacturer may, on a voluntary basis, be supplied by digital means instead of on the device, its packaging or accompanying documents. Placing information on the product/packaging should only be mandatory if it is required to avoid a serious risk.

4.
Centralisation of responsibilities regarding Notified Bodies

Additionally to the harmonisation in between different product legislation we want to point out a call for harmonisation within the Union as well.
As pointed out in the “BVMed/VDGH-Whitepaper | Future Development of the MDR and IVDR”[1] and in the MedTech Europe “Joint discussion paper on the future governance of medical technologies in Europe”[2] we see huge potential and advantages in an unionwide designation and notification and also oversight of Notified Bodies to ensure harmonisation.

Experience with the MDR and IVDR since they entered into force in 2017 has shown that the designation of Notified Bodies has been far too slow. Exactly the same problem is now recurring with the AI Act.

An unionwide designation and oversight could help to speed up the processes and ensure harmonisation.

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[1] https://www.bvmed.de/whitepaper (see page 52)
[2] https://www.medtecheurope.org/resource-library/joint-position-paper-on-the-future-governance-of-medical-technologies-in-europe/