

Position Paper on the Revision of the EU Regulations for Medical Devices and in vitro diagnostic Medical Devices

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The Austrian Social Insurance considers the targeted revision of EU rules on medical devices (MDR) and in vitro diagnostics (IVDR) an important step towards ensuring a high level of protection of patient health and safety while supporting the internal market as stated in the first two recitals of Regulation 745/2017. We also fully support the goal of the revision, namely, to simplify EU rules in this respect, especially to support a facilitated market access for SMEs as well as non-legislative solutions to strengthen the capacity of Notified Bodies. However, we would emphasise the overall need for further clarifications of partly newly introduced terms and definitions.

Reducing administrative burden, simplify rules and streamline procedures as well as reporting obligations

We generally acknowledge the importance of reducing redundant documentation requirements and moving towards fully digitalised processes, wherever feasible, to reduce workload for both manufacturers and Notified Bodies without compromising safety and quality as initial goals of the two Regulations. All digitalisation efforts foreseen in the proposed text, i.e. the digitalisation of the technical documentation, the conformity assessments and reports (**Article 52b**), to simplify, streamline and adapt it to the state of the art of the 21st century, are therefore to be welcomed. The same applies to the possibility for manufacturers of class IIb and class III devices to consult an expert panel at an earlier stage for an evaluation of their clinical development strategy and planned clinical investigations (**Article 61(2)**). An early involvement of such an independent panel can in our view provide for significant added value to manufacturers, especially SMEs, as to an increased predictability and streamlining of marketing processes.

However, the notion is on reducing redundant documentation and streamline reporting obligations for manufacturers with the aim of avoiding duplication. The proposals are however much more detailed, far-reaching as initially foreseen and go far beyond solely reducing documentation requirements etc.

First and foremost, the suggested deletions, namely in **Article 10** etc., are seen with great concern and should only be done giving due consideration to measures on how to safeguard adequate patient safety and transparency. In this context, the Austrian Social Insurance rejects the proposed deletion of obligatory patient information as well as compensation claims and legal liability of the authorised representative (**Article 11**) in cases of defective devices or damages, namely:

- the deletion of the provision requiring authorities to inform patients, insurers, or other third parties affected by harm caused by a medical device; the deletion of compensation rules for injured natural or legal persons as well as the requirement for manufacturers to maintain adequate financial coverage.

We generally also welcome the introduction of a new category of so-called well-established medical devices (**2(72), 3(1), 3(2)**), i.e. a well-established technology (WET), instead of a fixed list as in the current text, to be amended through delegated acts by the European Commission. This provides for more flexibility in the text as to the specific medical devices and enables changes as well as extensions when needed. However, this entails in our view a certain risk of loosening measures to ensure safety and quality for a broad list of products we do not yet know. Hence, establishing this list should be done with great caution, closely aligned with the respective criteria of well-established medicinal products as laid down in the revised Directive 2001/83/EU.

In this context, we would like also to highlight the possible classification and hence marketing of certain class III products as non-implantable class IIb devices based on the technical documentation of one representative device per generic group (**Article 52(3)**). However, it is in our view unclear whether any class III product will eventually qualify as WET, and if none do, this paragraph may be not necessary or needs further clarification. And last but not least, we strongly agree with the suggested amendments to **Article 17**, especially when it comes to the requirement for manufacturers to justify why their product is intended for single-use only. This is not only a valuable point from an ecological as well as economic perspective but is also a way of clarifying and strengthening the possibilities to re-use certain kind of medical devices. However, we urge the co-legislators for further clarification of the authorities involved in assessing the justification for single-use and of possible respective steps in case of conflicting positions. In cases of reprocessing of medical devices not intended for single use, we also do support the requirement of adding information on an appropriate reprocessing/refurbishing procedure in the instructions for use by the manufacturer. When it comes to refurbishing single-use devices, we welcome this as a positive and logical expansion of the overall legal framework.

Evidence generation and provisions to ensure patient safety

To ensure the availability of medical devices and IVDs that meet the highest safety and quality standards and remain fully aligned with the objectives of the Regulations, it is essential that evidence requirements focus on safeguarding patient safety while demonstrating (added) clinical benefit. In our view, it is not sufficient to refer solely to an “expected clinical benefit” when certifying a product but rather include long-term clinical evidence as proof of a clinical benefit. In cases where it is not possible for a manufacturer to submit such evidence prior to CE certification/conformity certification, strict requirements for the post-marketing phase must be introduced to ensure safety and efficacy.

Overall, the Austrian Social Insurance stresses its concerns regarding the concept of faster, simplified and more streamlined certification processes based on immature and insufficient evidence. This would entail increased risk shifting from the pre- to the post-marketing phase to the detriment of patients and device users.

Especially problematic in our view when it comes to ensuring patient safety is the suggested inclusion of the possibility to demonstrate conformity based solely on non-clinical data (**Articles 61(1) and (5)**). A clinical evaluation based exclusively on non-clinical data is considered conceptually contradictory and should remain a strict exception, limited at most to low-risk Well-Established Technologies (WET) and only in duly justified cases.

We also strongly oppose the suggested changes to **Article 62** together with the deletion of **Article 82** restricting clinical investigations to studies of devices not yet placed on the market or put into service. This may exclude studies involving marketed devices – including investigator-initiated trials (IITs) – from the scope of the regulation. This is particularly concerning where manufacturers indirectly support such studies or where devices are used outside their intended purpose. From an ethical perspective, it is therefore argued that studies conducted beyond the declared intended purpose should also fall under this Regulation. Moreover, Post-Market Clinical Follow-up (PMCF) studies are no longer considered clinical investigations according to the amended provisions, unlike Phase IV trials in the pharmaceutical sector, which remain regulated and require approval. This would in our view jeopardise once again the high safety and quality well as ethical standards for clinical trials, watering down the initial goal of the Medical Devices Regulation.

We are equally concerned about the proposed provisions narrowing the scope of requirements even further, i.e. the replacement of all implantables by class IIb implantables in the current text. This affects, amongst others, the obligation to draw up a patient-understandable summary of safety and clinical performance in **Article 32** as well as the obligation for a clinical evaluation in **Article 61** and jeopardises therefore once more the initial goal of the Regulations of strengthening safety, quality and transparency of the medical devices. Overall, we welcome the intent of reducing obligations for manufacturers, but exemptions should solely apply to implantables remaining permanently in the human body. Therefore, we suggest a distinction between permanent and temporary implantables.

The same goes for amendments to **Article 54** further limiting the clinical evaluation consultation procedure, the so-called “scrutiny procedure” to only class III implantable devices, hence exempting once again class IIb devices. In our view, both risk classes should be maintained in the scope of this article undergoing an EU-level HTA process which represents another guarantee for highest quality standards and efficacy of marketed devices.

Furthermore, the Austrian Social Insurance acknowledges the objective of the proposed **Article 5** to provide healthcare institutions with sufficient time to transition from in-house manufactured devices to CE-certified alternatives once such alternatives become available. However, we consider a continued use period of up to ten years after the healthcare institution becomes aware of an available CE-certified product to be disproportionate. In the interest of patient safety and evidence-based care, we therefore support a shorter maximum continued use period of five years. Such a limitation would provide healthcare institutions with a realistic transition window while ensuring that CE-certified products remain the regulatory standard where they are available and appropriate.

We further call for further clarifications in **Article 61(5)** when it comes to the equivalence of medical devices and the proposed exemption from the obligation of clinical investigations. Taking into account an average innovation cycle, especially changes to material and design, of roughly six years, we strongly advocate for introducing a fixed timeline on how long a reference to an already marketed device is possible.

Eventually, the introduction of so-called regulatory sandboxes (**Articles 59b and 59c**), intended to establish a structured framework for testing innovative technologies and processes in a real-world setting, must be treated in our view with caution due to their potential impact on

the soundness of regulatory processes in the future. We generally acknowledge the need for such a regulatory alternative pathway for certain kind of products. However, we would like to stress that these sandboxes have never been tested before in the context of healthcare provision and treatment, meaning that their consequences cannot yet be foreseen. And even in areas where such sandboxes have already been used since several years, e.g. Fintech, “there is no consensus in the literature over the ultimate benefit of establishing a regulatory sandbox”¹. Furthermore, Guio Español/Koenig argue that regulatory sandboxes should primarily serve as a possibility to increase policymakers’ understanding of respective technologies developed and tested within a sandbox, rather than solely a protected environment to support research and development as well as an alternative authorisation pathway.²

Ensure security of supply and improved management of shortages

Furthermore, in light of the rapidly increasing incidence of medicinal product shortages and their detrimental effects on the provision of healthcare, the Austrian Social Insurance supports all measures aimed at strengthening the monitoring and surveillance of supply shortages, as well as enhanced notification and reporting obligations for manufacturers (**Article 10a**). In order to further improve the effectiveness of shortage monitoring and reporting mechanisms, consideration should also be given to the introduction of proportionate sanctions in cases of non-compliance with these obligations or breaches of the relevant provisions, as well as to the mandatory public disclosure of related information.

Equally to be welcomed is the amendment to **Article 59** regarding derogations from conformity assessments, i.e. the possibility for Member States to authorise medical devices in certain justified cases. As also advocated for on several occasions by social security institutions and other relevant stakeholders, the proposal would now foresee a time limit for these national authorisations. This is especially important in order to maintain an equal, harmonised as well as legally strong system and internal market for medical devices. The overarching goal must always be the authorisation through a conformity assessment as provided for in this Regulation, exemptions should only be made on duly justified grounds and limited in time.

However, a clear and transparent report on the medical devices at risk of withdrawal from the EU market due to the revised Regulations has not yet been produced as called for by payers and civil society on multiple occasions. The Austrian Social Insurance strongly recommends elaborating on possible reasons for withdrawals, combined with clear data regarding the types of devices at risk. Furthermore, we call for a thorough analysis of the root causes leading to supply disruptions by the European Commission and in close cooperation with the Notified Bodies, manufacturers and national authorities (such as AGES in Austria). Transparency is key for ensuring safety and traceability of medical devices and IVDs. This is crucial to better target the necessary policy measures based on strong evidence.

¹ Gumbo et al, Regulatory sandbox as a frontier for innovation and sustainability: a systematic review, 29.05.2025, <https://www.tandfonline.com/doi/full/10.1080/23311975.2025.2510555>.

² See Guio Español and Koenig, Regulatory sandboxes for AI in the majority world: A learning-centric approach to legal adaptation, 10.12.2025, <https://www.cambridge.org/core/journals/cambridge-forum-on-ai-law-and-governance/article/regulatory-sandboxes-for-ai-in-the-majority-world-a-learningcentric-approach-to-legal-adaptation/2352427E99FCEA2B34F4B8DB1DC18095>.

Support for innovation and the development of breakthrough technologies and orphan devices

As to so-called breakthrough devices or devices for small patient populations (namely orphan devices, **Article 52a**), especially children, we do support the introduction of a definition of such specific devices taking into account the recommendations by the MDCG. We of course support the development of specific provisions for such products, ensuring early but controlled patient access, i.e. priority assessment and rolling reviews, while safeguarding evidence generation during early post-market clinical follow-up. However, the definition of and the criteria for breakthrough and/or orphan devices could be further clarified and should be closely aligned with respective definitions in the pharmaceutical framework currently under revision.

Furthermore, accelerated access, as stated in **Article 52**, must not come at the expense of robust clinical evidence. In particular, the Austrian Social Insurance considers the wording of **Article 52a(7)** insufficiently clear where certificates may be granted on the basis of limited clinical data if “the benefit of immediate availability on the market outweighs the risk”. Any such flexibility should remain strictly conditional on a favourable product-specific, patient-centred benefit-risk profile. Limited pre-market evidence must be accompanied by binding and enforceable obligations for post-market clinical follow-up, including clear evidence-generation targets, timelines and consequences in case of non-compliance. Where substantial clinical data are still missing at the time of market access, manufacturers should be required to conduct structured market-entry clinical studies to generate the missing evidence as early as possible. Breakthrough and orphan devices should also be linked to EU and national HTA processes to ensure that regulatory flexibility is aligned with evidence-based reimbursement and responsible use of healthcare resources.

We also advocate for setting up a central authority responsible for such devices in charge of granting and where necessary revoking breakthrough/orphan status, greenlighting clinical evaluation and coordinating the expert panel mentioned in **Article 106**. In line with orphan medicinal products (OMP), a disease-specific central registry should be established within the mentioned central authority to strengthen transparency throughout the system, including the designated as well as authorised, marketed devices. Ultimately, we strongly recommend including those devices due to their specific characteristics into the Joint Clinical Assessments in the context of the HTA Regulation by adding them to the scope of **Article 54** of the proposed text.