EANM Position: Proposal for a Revision of the Medical Device Regulation

The European Association for Nuclear Medicine (EANM) welcomes the European Commission's proposal for a revision of the Medical Device Regulation (MDR). The MDR has been crucial for healthcare professionals (HCPs), including for the nuclear medicine community, as it establishes a robust framework to ensure the safety, quality, and performance of medical devices used in diagnostics and therapy. By strengthening clinical evaluation and post-market surveillance, the MDR enhances patient safety and trust.

In nuclear medicine, medical devices play an essential role in diagnosis and treatment, increasing the effectiveness of therapies and significantly improving survival rates. Medical devices in nuclear medicine are mainly used for molecular imaging (PET, SPECT[1]), handling of radioactive materials and pharmaceuticals, to do patient specific quantitative measurements, analyses and (dose-) prediction (software), as well as for radiopharmaceutical preparation (generators). A supportive regulatory framework is pivotal in ensuring that innovative nuclear medicine devices can be developed and reach patients.

While the EANM strongly supports the need for a robust and reliable regulatory framework, there are concerns that the certification process for medical devices, particularly software and in-house devices, is overly complex, time-consuming and expensive, discouraging and hindering innovation. This creates barriers to innovation and may limit timely patient access to novel solutions. These challenges should also be considered in the context of increasing global competition in medical device innovation, where an unattractive regulatory environment risks slowing innovation in the EU.

Main recommendations

To ensure that the Medical Device Regulation reaches its full potential and delivers on equitable access to innovative devices for patients, the EANM respectfully urges the co-legislators to include the following points during the legislative process:

- Reduce disproportionate burden on SMEs and in-house development
- Remove barriers to software innovation and clinical use
- Improve the capacity of Notified Bodies to reduce delays
- Provide clear guidance to facilitate harmonized interpretation and application of the legislation

[1] Positron emission tomography (PET) and Single photon emission computed tomography (SPECT) are Nuclear Medicine imaging procedures. PET uses positrons and SPECT single photons to depict body-internal biological processes. The use of PET and SPECT depends on the kind of particle/radiation emitted by the radioisotope.

1. Requirements for compliance and certification

a. Clarify rules for edge cases

Some products may fall at the interface between the definition of medical devices and medicinal products, raising questions regarding the most appropriate regulatory framework. This is particularly relevant for products that exert a direct therapeutic effect and may share characteristics of both categories.

Microspheres, which are implantable radioactive devices, including Yttrium-90-labeled microspheres and resins, intended to deliver localised therapeutic radiation doses to target lesions, are an illustrative example. These products are currently categorised as medical devices, which can be appropriate. However, this classification means that certain pharmacovigilance mechanisms applicable to medicinal products do not apply to them. Such situations need further scrutiny to ensure that the right balance is struck between patient safety and avoiding unnecessary regulatory complexity.

b. In-house development and development by small enterprises

The EANM would like to highlight the significant challenges faced by small and medium-sized enterprises (SMEs) and clinical institutions in developing medical devices. Compliance with the MDR often requires substantial investment in dedicated regulatory expertise, which is often not financially viable for SMEs or clinical institutions. As a result, even where promising devices are successfully developed, they are restricted to research use due to an inability to meet formal MDR standards or to sustain the resource-intensive MDR approval process, despite their clear clinical value.

The exemption for in-house devices is therefore essential. However, the associated obligations continue to impose considerable burdens. In particular, the requirement to establish and maintain quality management (QMS) and post-market surveillance systems (PMS) constitute a disproportionate burden for researchers, developers and clinicians that is often not feasible to carry. At the same time, the proposed provision allowing the transfer of such devices between institutions on a non-commercial basis is strongly welcomed, as it can significantly improve the use of common devices and enhance collaboration within EU projects and facilitate broader access to innovative solutions in patient care.

Recommendations:

- SMEs and clinical institutions should not be subject to the same regulatory burden as large scale commercial manufacturers. Requirements related to documentation, QMS, and PMS obligations should be risk-based, proportionate and adapted to the scale and nature of activities, to avoid disincentivising in-house development.
- Further practical guidance is needed on how to interpret and implement MDR requirements both for manufacturers and for Notified Bodies.

c. Complexity of regulation and clinical data requirements on software as a medical device

Software is a type of device for which compliance is particularly difficult to demonstrate. The requirement for detailed and clinical evidence poses a significant hurdle for SMEs working with software as a medical device to enter and stay in the market. These businesses often lack the necessary financial and technical resources to undertake and sponsor extensive clinical trials required before market authorisation, already limiting their ability to innovate. This impacts the ability

of HCPs to provide high quality care and advanced treatment options or leaves the clinical use to their full personal responsibility. One particular example is software for pre-, intra- and post therapy dosimetric evaluations of radionuclide therapies.[2] Since medical software is a quickly developing sector, regulation must be sufficiently flexible to allow Europe to stay competitive.

Recommendations:

- HCPs should be allowed to use well-validated, safe software under clear, controlled pathways in their clinical work, while being responsible for any consequences of using such software. The conditions would need to include proof that the tool to be overtaken by the HPC underwent risk mitigation and verification, as well as restricting uncontrolled updates or tweaks.
- In addition, adapting clinical evidence requirements for low-risk software and providing practical, targeted guidance would enable HCPs to access innovative tools, such as software for radionuclide internal dosimetry, more efficiently.

d. Quantify the criteria for well-established technology devices

The introduction of the 'well-established technology device' category, allowing for a more risk-based approach, is a positive development. Simplifying the Quality Management System and clinical data required in a proportionate manner can relieve the manufacturers of such products of unnecessary burdens. However, the definition remains unclear, relying on vague and open to interpretation notions such as 'long history' or 'little evolution', which should be better specified.

Recommendation: Refine the definition of 'well-established technology device' by including clear, measurable and quantifiable criteria.

e. Need for clarity on necessary independent data to show safety

The EANM would like to note that the type, amount and level of independence of data necessary to show that a product is safe can vary significantly. These requirements depend not only on the type of device, its intended use, and the availability of existing clinical evidence, but also on the applicable regulatory context, including the interpretation of requirements by different Notified Bodies and the specific clinical circumstances in which the device is evaluated. In addition, the clinical data used are often not publicly accessible, meaning that professionals using the device or other interested parties cannot independently verify its safety profile.

Recommendations:

- Guidance is required to explain what type and level of evidence are considered sufficient under specific circumstances to ensure a harmonised application of the regulation across Member States and Notified Bodies.
- Clinical evidence submitted as part of an applications should, where appropriate, be made publicly available to allow users of the device to better assess and understand its safety profile.

2. AI Act

The proposed change under which AI-enabled medical devices no longer have to comply with the substantive provisions of the AI Act raises potential concerns. On one hand, it is positive to reduce regulatory burdens for lower-risk AI that is deterministic and therefore more predictable. However,

[2] Radionuclide therapy is a systemic and targeted therapy which uses unsealed radioactive sources.

generative AI require a more comprehensive assessment than is currently foreseen under the MDR, as inadequate assessments could impact patient, occupational, and public safety. Fully exempting such products from compliance with the substantive provisions of the AI Act could lead to situations where the behaviour and evolution of AI systems placed on the market remain insufficiently understood or controlled.

Recommendation: The substantive provisions of the AI Act should continue to apply to more complex, particularly generative, AI-enabled medical devices, while simpler, deterministic AI systems should be exempted as proposed, on the basis that the assessment under the MDR is sufficient.

3. Post authorisation

a. Specify provisions on the predetermined change control

Another issue concerns product updates, particularly for software involving AI-based methodology. The EANM welcomes the fact that the Commission foresees an adjustment to the Annexes, stating that the Notified Body should clearly specify which types of updates do not need to be notified, which do need to be notified but do not require approval, and which require explicit approval. It is particularly positive that the inclusion of a predetermined change control plan is encouraged.

However, the text does not clarify which types of changes should be classified under each category, potentially leading to fragmentation and unpredictability for manufacturers. This is especially relevant for AI-based software, which inherently evolves through new input and – in some cases – continuously learns from user interactions and generated outputs.

Recommendation: The EANM would welcome further clarification as to which changes would not need to be notified, which would need to be notified but not approved, and which would need approval, especially regarding AI-based software.

b. Periodic review must ensure patient safety

Moving from mandatory recertification every five years to relying on periodic safety update reports, depending on the device category, is a constructive step towards reducing the burden on manufacturers as well as Notified Bodies. This approach is appropriate, provided that the assessment of such reports is sufficiently robust, comprehensive and informed to ensure that no safety risks arise from devices remaining on the market. However, for implantable class IIb and all class III devices, recertification every five years should continue to apply to ensure that they remain safe and that all changes to the device as well as changes in scientific understanding are taken into account.

4. Improving the capacity and efficiency of Notified Bodies

Structural challenges related to Notified Bodies' capacity remain a significant concern. In many Member States, the number of Notified Bodies is limited, while their scope of responsibilities is broad and resource intensive.

This imbalance significantly undermines their ability to assess and certify medical devices in time for HCPs to use. As a result, delays in the certification process have become commonplace, which directly impacts the timely availability of new and innovative medical devices that HCPs in the nuclear medicine community, and beyond, rely on for patient treatment. These delays also have broader market consequences. In particular, SMEs are disproportionally affected, with some withdrawing

from the market altogether, citing long and unpredictable cost, resource demand and unpredictability associated with achieving and maintaining MDR compliance.

While the removal of the mandatory five-year recertification for most devices, among other simplifications, may help alleviate part of the workload faced by Notified Bodies, such measures alone are unlikely to sufficiently address existing bottlenecks. Without a parallel increase in capacity and resources, certification delays are likely to persist.

Recommendations:

- Expanding the capacity and operational efficiency of Notified Bodies to address certification delays that limit HCPs' access to medical devices, as their timely availability for clinical routine use is crucial.
- Increasing financial and human resources for Notified Bodies, particularly in lower-income Member States.
- Ensuring greater predictability and transparency in the certification process, thereby reducing certification backlogs and enabling HCPs to deliver high-quality care without disruption.

5. Stakeholder Forum

Considering the above, the increased involvement of expert panels to advise Notified Bodies and manufacturers is a positive development, contributing to more consistent, high-quality and harmonised decision-making. However, HCPs should also be able to provide their advice in a structured format on the broad implementation and evolution of the MDR framework.

Recommendation: The EANM would welcome the creation of stakeholder forums and participation of HCP organisations to monitor and provide advice on the implementation and evolution of the MDR, for example as a consultative body to the Medical Device Coordination Group. Such forums would provide a platform to monitor implementation, share practical experience, and offer expert input on the ongoing evolution of the MDR framework, ensuring that regulatory developments remain aligned with clinical realities and patient needs.

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