EANM reply to the European Commission targeted evaluation on EU rules on medical devices and in vitro diagnostics.

More information here

The European Association of Nuclear Medicine (EANM) appreciates the opportunity to comment on the call for evidence for an evaluation of the EU rules on medical devices and in vitro diagnostics.

The EU Medical Device Regulation (MDR) has been crucial for healthcare professionals, 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 imaging (PET, SPECT), radiopharmaceutical handling (syringe shields, radionuclides calibrators), to do software-based analyses, predictions and diagnoses thereof, for radiopharmaceutical preparation (generators), and therapeutic radionuclide delivery (Yttrium-90 microspheres).

While the EANM strongly supports the need for reasonable regulation, we are concerned that the certification process for medical devices, particularly software, is overly complex, time-consuming and expensive, discouraging and hindering innovation.

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

The EANM, would like to comment on significant difficulties involving software as a medical device. The complex requirements discourage SMEs from developing or renewing innovative software for clinical use, as many lack the personnel and financial resources to achieve MDR compliance. Compliance often necessitates substantial investment in additional regulatory affairs staff, which is often not financially feasible for SMEs. In some cases, the consequence is this is that, even if software is developed, it is restricted to only research use because it fails to meet MDR standards or companies do not have the resources to go through the MDR approval process with, otherwise and substantially, very valid and useful software tools. The nuclear medicine community has observed that situation with dosimetry software developed by SMEs, that have in some cases been withdrawn from clinical use and restricted to research.
The requirement for detailed and clinical evidence poses a significant hurdle for small and medium-sized enterprises (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 the extensive clinical studies required before market approval, has already limited their ability to innovate. This limits the ability of HCPs to provide improved care and access advanced treatment options or leaves the clinical use to merely their full and only personal responsibility, respectively. One recent example is software to do pre-, intra- and post therapy dosimetric evaluations of radionuclide therapies. It is important to mention that MDR shall somehow leave the opportunity for healthcare professionals (HCPs) to inform procedures by the help of non-CE marked (formally non MDR compliant) tools and let the HCP take the full responsibility for any consequences of the use of such software if otherwise the validity is substantially proven, i.e. by scientific publications.
Such scenario shall be allowed in restricted conditions, including, but not limited to a strict versioning policy of the non MDR compliant tool by its manufacturer, the proof that the tool to be overtaken by the HPC

underwent risk mitigation and verification as well as the requirement towards the HCP that it guarantees to seal the given tool version, not allowing ad-hoc, uncontrolled updates or tweaks without the consent of the HPC by any third parties as well as the manufacturer.

Minor products updates in AI-based software as a medical device

Additionally, a second issue identified concerns AI-based software. Clarification on what constitutes a *minor product update* would be highly welcomed, as the nuclear medicine community has observed significant ambiguity in this definition. This lack of clarity has resulted in unnecessary recertification processes, creating additional burdens.
In this regard, we strongly encourage to consider following FDA's predetermined change control, which allows SMEs to pre-define, under which conditions such a minor product update is allowed without re-certifying the product. Since any medical software needs to undergo initial audits, the notified bodies – similarly to FDA – would have full control over what they allow to be defined as predetermined change control.
Finally, another issue identified is the classification of certain radiopharmaceutical products as medical devices. An example of this is the case of SIR-Spheres. Such situations would need further scrutiny, as the strategic use of regulations in this way could potentially compromise patient safety.

Delays and backlogs of Notified Bodies

In most Member States, Notified Bodies are low in number and often have limited capacities, which significantly undermines their ability to approve medical devices for healthcare professionals to use with patients in time. Delays in the certification process have become commonplace. This directly impacts the timely availability of new and innovative medical devices that healthcare professionals in the nuclear medicine community rely for patient treatment. This is because the introduction of the MDR has increased the demand for the Notified Bodies services, without an expansion on their number or operational capacity. The backlog created by these delays has already had negative effects in cancer treatments.

This is another reason that has led some SMEs to withdraw from the medical devices market altogether, citing long and unpredictable timelines for compliance.

Recommendations

- Making compliance processes simpler, particularly for low-risk and niche software applications as medical devices. Reducing clinical evidence requirements for low-risk software and providing practical, targeted guidance would enable healthcare professionals to access innovative tools, such as dosimetry software, more efficiently.
- The EANM would strongly recommend expanding the capacity and efficiency of Notified Bodies to address certification delays that limit healthcare professionals' access to critical medical devices. Increased resources for Notified Bodies are needed, particularly in lower-income Member States. Greater predictability and transparency in the certification process would reduce certification backlogs and thus support healthcare professionals in delivering high-quality care.
- The EANM would welcome clarification on the definition of *minor product updates* for AI-based software as a medical device to minimise unnecessary recertification (see above - preferencing FDA's

predetermined change control concept). Furthermore, the EANM would recommend a review of product classification criteria to address instances of misclassification.

- The EANM would welcome the creation of stakeholders' forums and participation of healthcare professional organisations them to monitor and provide advice on the implementation and evolution of the MDR. This would ensure that the perspectives and practical needs of healthcare professionals are adequately reflected in regulatory discussions.

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