EANM EU POLICY & PROJECTS
Shaping the future of Nuclear Medicine in Europe together

THE EANM POLICY BULLETIN

Welcome to the EANM Policy Bulletin!

This newsletter provides you with an overview of policy updates related to nuclear medicine, hand-picked by the EANM just for you.

If you have any questions, please contact us at euaffairs@eanm.org.

Enjoy the read!

The EANM EU Affairs Team

COOPERATION & COMMUNITY INVOLVEMENT

SIMPLERAD Final Report

The final report of the SIMPLERAD project was released on April 16, concluding more than two years of research into **the intersection of European legislation on pharmaceuticals and radiation protection**.

Undertaken at the request of the European Commission (Contract Number ENER/2022/NUCL/SI2.869532), the study was carried out in partnership with the European Institute for Biomedical Imaging Research (EIBIR), the European Federation of Organisations for Medical Physics (EFOMP), and EANM. It provides a comprehensive legal analysis, presents findings from a pan-European survey, and offers recommendations to improve consistency in the regulation of therapeutic radiopharmaceuticals within the frameworks established by Euratom and the European Union.

Following the report's publication, EANM has initiated internal discussions on how best to implement and sustain its recommendations. An in-person meeting in Vienna on April 23 provided a platform for EANM members to explore practical next steps for translating the findings into long-term strategies. These efforts reflect a strong commitment to ensuring that the SIMPLERAD project's outcomes lead to tangible improvements in the regulation and application of therapeutic radiopharmaceuticals across Europe.

Read the report to find out more!

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CLAUD-IT NuCline Guide

The CLAUD-IT Nuclear Medicine Experts Group is pleased to announce the successful delivery of a major milestone within the CLAUD-IT project: the publication of the **'NuCline' guide**!

NuCline is a **comprehensive guide to clinical audits in nuclear medicine, designed to support best practices, ensure regulatory compliance, and drive quality improvement.** It aligns with European frameworks such as the Commission Recommendation (EU) 2024/1112 on clinical audits of medical radiological practices.

The European legal framework for clinical audits in nuclear medicine is governed by the Basic Safety Standards Directive, which ensures high standards of radiation protection and patient safety. EANM plays a key role in this context, by promoting audits as a tool for continuous quality improvement and regulatory compliance across Europe.

NuCline outlines EANM's approach and ongoing efforts to support clinical audits in nuclear medicine, emphasising their importance for quality and compliance. It also serves as a **guideline to conduct clinical audits**, featuring multiple audit templates developed by experts from the CLAUD-IT consortium. It addresses key topics such as clinical practices, quality control of nuclear medicine equipment, radiopharmacy and regulatory audits.

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PUBLICATIONS

EANM's Response to the Revision of the Medical Devices Regulation (MDR)

EANM has contributed to the European Commission's targeted evaluation of EU rules on medical devices and in vitro diagnostics. While recognising the importance of the Medical Device Regulation (MDR) in ensuring safety and reliability, EANM highlights unintended barriers created by the current regulatory landscape—particularly for software-based medical tools and SMEs.

In nuclear medicine, such software is often essential for dosimetry and therapy planning. However, the complexity and cost of compliance under the MDR have led to the withdrawal of several promising innovations or their restriction to research-only use.

EANM calls on the European Commission to:

- Streamline certification processes for low-risk, niche technologies
- Strengthen the capacity of Notified Bodies, whose current delays limit patient access to vital medical tools
- Establish clearer guidance on AI-related software updates
- Adopt more adaptive regulatory practices
- Involve healthcare professionals more closely in regulatory development, to ensure that future frameworks remain aligned with clinical needs

Check out the full statement to explore our recommendations for a more innovation-friendly regulatory future!

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EANM's Reply to the Call for Evidence Towards a Strategy for European Life Sciences

The European Commission is preparing a new strategy for European Life Sciences. This strategy will address different sectors, aiming to strengthen life sciences research and innovation in Europe. In this context, EANM has replied to the European Commission call for evidence, providing input on securing Europe's leadership in healthcare.

Emphasising the urgent need to reassert EU leadership in healthcare innovation, **EANM highlights that nuclear medicine is a critical driver of competitiveness, particularly through the advancement of radioligand therapy (RLT)**. This groundbreaking approach, which delivers targeted radiation to tumours while sparing healthy tissues, represents a promising shift in the treatment of non-communicable diseases, with the potential to benefit hundreds of thousands more patients by 2035.

To reach this goal, EANM urges the Commission to:

- Prioritise sustained research and development in nuclear medicine
- Reinforce Europe's autonomy in isotope production
- Streamline regulatory pathways to enable broader clinical adoption
- Enhance support for RLT-focused public-private partnerships, pan-European research programmes, and strategic investments in workforce development—which are essential pillars for success

Check out the full statement to see how the EANM proposes to secure Europe's leadership in life sciences and patient-centred innovation!

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EANM's Response on the Critical Medicines Act

In March 2025, the European Commission introduced the Critical Medicines Act (CMA) to improve the availability, supply and production of critical medicines within the EU. The CMA also aims to increase access to other medicines of common interest, such as those for rare diseases, and to address the fact that some medicines are not available on certain markets. As the supply of critical medicines is one of EANM's key priorities, we have replied to the European Commission's call for evidence.

With over 10 million European patients benefiting annually from nuclear medicine procedures, EANM emphasises the urgent need to secure access to the radioisotopes that underpin both diagnostics and therapy. Given the complexity and volatility of the radiopharmaceutical supply chain—including short half-lives, site-specific

preparation, and reliance on vulnerable external sources—EANM urges the Commission to tailor its approach accordingly.

The EANM also recommends the inclusion of key radioisotopes—such as Tc-99m, F-18, Lu-177, and Y-90—on the Union list of critical medicines, rather than finished radiopharmaceuticals, to better reflect real clinical needs. It also calls for tailored regulatory approaches that account for the impossibility of stockpiling and supports investment in infrastructure and coordination through the European Radioisotopes Valley Initiative (ERVI).

Check out the full response to read our detailed recommendations on securing Europe's radiopharmaceutical future!

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POLICY DEVELOPMENTS

PRISMA Pre-Joint Action

The SAMIRA Joint Action aimed at optimising radiation safety and quality in medical applications of ionising radiation)-is progressing toward a full launch in early 2026. Areas of focus include radionuclide therapy, CT procedures, interventional radiology, and paediatric imaging, with the overarching goal of strengthening radiation protection and establishing diagnostic reference levels across Europe.

As part of the preparatory phase, a two-day meeting in Zagreb (Croatia) brought together over 150 participants from 24 countries, including EANM Scientific Liaison Officer Michel Koole. For EANM, key outcomes include ensuring its expertise informs the definition of project topics and deliverables.

The preparatory Joint Action will transition into a fully-fledged Joint Action in 2026, comprising multiple sub-projects. EANM intends to engage actively across several of these initiatives, helping to shape practical outcomes relevant to nuclear medicine. A list of the current draft project proposals is available here, offering insight into the areas where EANM expertise may be most impactful.

EMA's New Conflict of Interest Policy

The European Medicines Agency (EMA) has published revised rules for handling competing interests, aiming to **enhance transparency and protect the independence of its scientific work**. Effective from June 1, 2025, the updated policy introduces **clearer criteria for evaluating potential conflicts of interest,** particularly concerning financial and professional links.

In practice, this means the following:

- Increased and aligned restrictions across roles and groups for experts with a **current interest** in a product: in such cases, experts will continue to be excluded from procedures related to the product concerned but now also for products in the same declared condition. Experts with an interest as **principal investigator** and **investigator** will now be subject to the same restrictions.
- Aligned restrictions across roles and groups, in case of **past employment** in a pharmaceutical company, of a past consultancy or strategic advisory role and of past activity as (principal) investigator, with a unified three-year cooling-

off period. Consequently, the same rules that already applied to committee members will now also apply to experts who may be brought into the assessment process on an ad-hoc, consultative basis to provide their input on specific points.

Our members involved in EMA activities, or those invited as external experts, are encouraged to familiarise themselves with the new rules and updated declaration forms. EANM is also planning to prepare a detailed description of the new rules for the community to ensure a smooth and effective selection of experts in the future.

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Updates on the European Radioisotopes Valley Initiative

As a flagship initiative of the SAMIRA Action Plan, the European Radioisotope Valley Initiative (ERVI) aims at maintaining Europe's global leadership in the supply of medical radioisotopes and helping accelerate the development of new radioisotopes and production methods. The EU Commission has engaged with stakeholders and develop feasibility studies before considering a legal framework for this initiative.

Throughout two years of intensive work with the ERVI Steering Group on the ERVI Basic Design, the EU Commission has engaged with stakeholders to develop feasibility studies along the following pillars: Investments, Research & Development, and Monitoring & Forecasting. Now is finally time for the group to move to the implementation, to consider a legal framework for this initiative, and to prioritise projects.

A ERVI Stakeholder Forum will take place in September and will mark the official launch of ERVI. Stay tuned!

EANM Policy & Regulatory Affairs Council's Strategy Meeting

On March 7, the EANM Policy & Regulatory Affairs Council (PRAC) met in person at the EANM headquarters in Vienna. The meeting brought together experts to discuss the full range of EANM's activities, with particular focus on PRAC's future direction and development. Our PRAC members look forward to putting these strategies into action to benefit the nuclear medicine community!

EVENTS

THROWBACKS

European Association of Hospital Pharmacists Congress

At this year's EAHP Congress in Copenhagen (Denmark), EANM was represented by Oliver Kiß from the EANM Policy & Regulatory Affairs Council (PRAC). The event provided a **valuable platform to exchange ideas on shared goals, particularly in areas like pharmaceutical policy, medicine availability, and strategies to address supply shortages.**

Engaging with peers on these pressing issues highlights the importance of collaboration across sectors. We're grateful to be part of these forward-looking discussions and are eager to see them inspire meaningful progress in the months ahead!

Launch of the MEP Cardiovascular Health Group in the European Parliament

Key stakeholders gathered on April 23 in Brussels for the official launch of the MEP Cardiovascular Health Group. This cross-party initiative brings renewed focus to the prevention and treatment of cardiovascular disease (CVD)–Europe's leading cause of death–and aims to place it firmly on the EU's health agenda.

The Group, coordinated by the European Alliance for Cardiovascular Health (EACH), will act as a collaborative forum for MEPs to promote EU-wide action on CVD through policy, innovation, and equitable access to care. During the inaugural session, MEPs and partners discussed their shared vision and the urgent need for coordinated efforts. They also unveiled a strategic publication outlining priorities to

improve cardiovascular outcomes across the EU, called 'A European Cardiovascular Health Plan: The Roadmap'.

FIND OUT MORE

Thera4Care

Since October 2024, EANM has been collaborating with 25 partners on Thera4Care, an Innovative Health Initiative (IHI) project aimed at building a European theranostics ecosystem.

EANM was pleased to take part in the **Thera4Care annual meeting** in Budapest on May 12-13! It was a valuable opportunity to connect with consortium partners, share progress, and align on next steps towards advancing innovation in theranostics.

In line with the project's growing governance structure, we are happy to share that EANM now has a seat on the newly formed Ethics Advisory Board, represented by Michel Koole, our Scientific Liaison Officer.

Further, Thera4Care has launched its **first public survey**—a key step in assessing the current landscape of theranostic radiopharmaceuticals in Europe. Your input matters —please share it with us by June 30, 2025!

PARTICIPATE NOW

UPCOMING EVENTS

SECURE Special Event

The Strengthening the European Chain of sUpply for next generation medical RadionuclidEs (SECURE) project focuses on the **sustainability and safe application of medical isotope production across Europe**. By advancing the design of irradiation targets and exploring new production routes for isotopes critical to nuclear therapy and diagnostics, SECURE addresses key challenges in ensuring their future availability.

The project will gather on May 28, 2025, in Brussels for a SECURE special event on 'Next-generation Medical Isotopes: The Innovation Path to Safety and Sustainability'. Paola Anna Erba, EANM President, will be participating in the event.

FIND OUT MORE

Event at the Permanent Representation of Germany to the EU

The European Partnership for Radiation Protection Research (PIANOFORTE partnership), launched in 2022 with 58 partners and coordinated by ASNR, will host the event 'From Nuclear Risks to the Fight against Cancer–The Key Role of Radiation

Protection for a Secure and Healthy Europe' on June 3, 2025, at the Permanent Representation of Germany to the European Union in Brussels.

This event will focus on nuclear risk preparedness and the vital role of radiation protection in the health sector, particularly in the fight against cancer. EANM will be participating in the event, reinforcing its commitment to the safe and effective application of radiation in medicine.

FIND OUT MORE

STATEMENT

"The preparatory phase of the PRISMA Joint Action presents a crucial opportunity to integrate nuclear medicine expertise into Europe's efforts to enhance radiation safety and quality. EANM views this as a key moment to help shape projects that are grounded in clinical reality and scientific rigor. For successful implementation, these efforts must reflect both technical insight and national contexts. EANM is committed to engaging proactively to ensure that the unique contributions of nuclear medicine are recognised and that evolving safety standards continue to support both patient care and continued innovation."

Michel Koole I EANM Scientific Liaison Officer

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