THE EANM POLICY BULLETIN

SHAPING THE FUTURE OF NUCLEAR MEDICINE IN EUROPE TOGETHER

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 office@eanm.org.

Enjoy reading!

The EANM EU Affairs Team

COOPERATION & COMMUNITY INVOLVEMENT

Throwback to the EANM'24 Congress

With an incredible **turnout of over 8,680 participants**, our EANM'24 congress marked our largest congress to date! Beyond the impressive numbers, we were delighted by the enthusiastic engagement with our EU initiatives, which showcased the EANM's EU strategy and projects. These included:

- **Two EU Symposia** (read more below)
- **A key talk by Wim Oyen**—Chair of the EANM Policy & Regulatory Affairs Council—who presented the EANM's advocacy strategy for shaping the future of nuclear medicine in Europe. His presentation focused on reforming the EU Pharmaceutical Legislation to better support nuclear medicine, securing a stable supply of radioisotopes, and strengthening the EU's autonomy in radiopharmaceutical production.
- **Our EU Policy Affairs Booth,** which provided congress attendees with the opportunity to explore our ongoing EU projects.

Thank you to everyone who showed such strong interest in our events and initiatives throughout the congress!

Want to get involved? Contact us at euaffairs@eanm.org—we look forward to hearing from you!

CLAUD-IT Project

Since September 1, 2024, the EANM has been collaborating with the **European Institute for Biomedical Imaging Research (EIBIR)** and 11 clinical partners across Europe on the new EU4Health CLAUD-IT initiative.

Background: The project launch took place on September 12 and 13, 2024, at the Universitat de Barcelona, Spain. Representing the Nuclear Medicine community, **Laura Evangelista**, acting as the CLAUD-IT Scientific Coordinator for Nuclear Medicine, and **Pedro Fragoso-Costa**, as Co-Lead, were present onsite. In addition, the CLAUD-IT Nuclear Medicine subgroup convened during the EANM'24 congress to further develop the new clinical audit guidelines for Nuclear Medicine.

Objectives: This project focuses on implementing clinical audits across Europe, taking a hands-on, multidisciplinary approach to elevate healthcare quality and safety. Over the next 36 months, the team will support EU Member States in meeting the requirements of the Basic Safety Standards Directive. The consortium seeks to develop clear and evidence-based materials to guide clinical audits. Pilot clinical audits will be launched in 9 Member States.

Learn more about CLAUD-IT through the project's dedicated **LinkedIn page** and **website**.

Thera4Care Project

Since October 1, 2024, the EANM has been working alongside 25 partners—including universities, research organisations, public institutions, non-profits, and industries across Europe—on the new Innovative Health Initiative (IHI) project, Thera4Care. The EANM proudly participated in the project's kick-off meeting at the Università Cattolica del Sacro Cuore (UCSC) in Rome, Italy.

What is Thera4Care? This project aims to establish an integrated, collaborative European ecosystem for theranostics that brings together leading academic centres, healthcare providers, SMEs and industry stakeholders to support healthcare system readiness for theranostics.

The project aims to:

- Strengthen the manufacturing and supply chain of radiotheranostics.
- Develop cancer models for testing and studying theranostics in laboratory settings.
- Deliver a comprehensive framework for phase 1 clinical trials of radiopharmaceuticals.
- Optimise the clinical use of radiotheranostics through artificial intelligence-based advancements in imaging.

Find out more about Thera4Care through the project's dedicated **LinkedIn page** and **website**.

Heads-Up!—New Funding Opportunities

We would like to draw your attention to the following funding opportunities:

- IHI Call 9: **Boosting Innovation for a competitive European health ecosystem**
  Official call launch: Early 2025

- EU4Health**: Call for Proposals on radiation safety and quality of computed tomography imaging of children and young adults**
  Application deadline: January 22, 2025

- EU4Health: **Call for proposals to support the establishment of new networks of expertise on cancer and cancer conditions**
  Application deadline: January 22, 2025

For more information, please contact us at **euaffairs@eanm.org.**

PUBLICATIONS

EANM Roadmap 2024-2029

The EANM just published its new manifesto titled ‘Roadmap 2024-2029: Nuclear Medicine Looking Towards 2029—Achieving Better Patient Care With Nuclear Medicine’.

With the publication of this roadmap—marking the start of a new legislative term—the EANM aims to collaborate with newly elected members of the European Parliament and incoming European Commission officials to address key health priorities.

Considering the 2024 European elections and significant leadership changes, this document seeks to raise awareness about the Nuclear Medicine sector and communicate the community’s expectations to decision-makers as we work together to shape future health policies.

Driven by a strong commitment to ensuring equal and timely access to high-quality Nuclear Medicine services for all patients in Europe, the EANM looks forward to engaging with stakeholders to build a more sustainable and equitable health system.

Read the EANM 2024-2029 roadmap **here**.

EANM's Reply to the EMA Consultation on Handling Competing Interests

In November, the European Medicines Agency (EMA) sought public feedback on its **revised conflict-of-interest rules** following a **court ruling** that identified gaps in managing expert conflicts. The review revealed that 11% of its 4,122 experts had **direct industry ties**, while 8% had indirect conflicts.

The EANM responded to the public consultation, emphasising that the EMA's approach to managing competing interests should balance its legal obligations. This includes ensuring that committee members and experts remain impartial, free from conflicts of interest with pharmaceutical companies, while also securing access to top scientific expertise.

The EANM's response included specific recommendations, particularly regarding:

- Clarifying the involvement of experts in research organisations, distinguishing between manufacturing for institutional use and market purposes.
- Differentiating fundamental research funded by grants from direct company affiliations.

Read the EANM's full reply **here**.

POLICY DEVELOPMENTS

European Health Data Space Set to Launch by 2025

The **European Health Data Space (EHDS)** is an EU regulation aimed at **enabling secure, cross-border access and reuse of health data to support healthcare delivery, research, innovation, and policymaking.** On April 24, 2024, the European Parliament voted in favour of and approved the creation of the EHDS.

The regulation is **expected to come into force by early 2025.** Following its publication, the European Commission will need to establish detailed rules for implementation through implementing and delegated acts, which are anticipated to be finalised by late 2026 or early 2027.

The EANM will closely monitor the development of these implementing acts and, where possible, contribute to public consultations. Input from the Nuclear Medicine community, along with collaboration with other medical societies and civil society organisations, will play a key role in shaping EANM's responses.

Stay tuned for more updates!

EU HTA Implementation for Oncology and Advanced Therapies

The **EU Health Technology Assessment (HTA) Regulation** is a new regulation that aims to establish a standardised process for evaluating the value and effectiveness of new medical products, such as medicines and medical devices. Its goal is to ensure these products are safe, effective, and provide tangible benefits to patients and healthcare systems.

A key feature of the regulation is the **creation of a uniform assessment process at the EU level.** Implementation will be phased, beginning with joint clinical assessments for oncology medicines and advanced therapy medicinal products starting on **January 12, 2025**. From this date, new cancer treatments seeking EU market authorisation will undergo a coordinated evaluation process across Member States.

The EANM will closely monitor developments related to the joint clinical assessments of radiopharmaceuticals and share relevant updates with the Nuclear Medicine community. Additionally, since November 2024, **the EANM has been a proud member of the European Commission's Health Technology Assessment Stakeholder Network** and looks forward to actively contributing to future discussions.

European Parliament's Calling for Major Revisions to the EU Medical Device Regulation

The **Medical Device Regulation (MDR)**, first implemented in 2017 to enhance the safety and efficacy of medical devices across the EU, has faced significant challenges. In response, the European Parliament passed a resolution on October 21, 2024, calling for a **comprehensive revision of the MDR by early 2025.**

Key concerns include the need for streamlined regulatory processes for SMEs, fast-track pathways for emerging technologies, improved support for orphan devices, and the establishment of clear certification timelines, among other issues.

The **EANM Policy & Regulatory Affairs Council (PRAC)** will closely monitor these developments to ensure the views and priorities of the Nuclear Medicine community are well represented in ongoing discussions.

We will make sure to provide you with more updates in due course!

THROWBACKS

Two EU Policy Symposia at the EANM'24 Congress

Once again this year, two EU policy symposia were held during our congress, attracting high attendance:

- **Bridging the Basic Safety Standards—Navigating Legal Complexity in Member States**
  This session delved into the intersections between the EU Pharmaceutical Legislation and the complexities of the Basic Safety Standards Directive. It featured recommendations from the SIMPLERAD project as well as case studies from the Netherlands and Switzerland.

- **Empowering Tomorrow—the Nuclear Medicine Community's Strategic Role within EU Projects & Tenders on Workforce**

This symposium explored the importance of EU projects and tenders for professional societies. It included presentations on initiatives like the RLT Academy, EUREST, and INTERACT-EUROPE. Afterwards, a panel discussion examined future EU funding opportunities, strategies for successful project proposals, and eventually emphasised long-term goals such as addressing the growing demand for qualified nuclear medicine professionals.

Our report will be released soon—stay tuned!

Workshop on Basic Safety Standards Provisions

On October 3-4, 2024, the EANM joined over 100 experts at a European Commission workshop in Luxembourg to discuss key roles in radiation protection, focusing on Radiation Protection Experts, Radiation Protection Officers, and Medical Physics Experts. The workshop featured initial findings and recommendations, prompting valuable discussions on member experiences and future steps.

European Observatory Meeting on the Supply of Medical Radioisotopes

The EANM was proudly represented by its President Elect, **Paola Anna Erba**, at the **21st Plenary Meeting of the European Observatory on the Supply of Medical Radioisotopes**.

Hosted by the European Organization for Nuclear Research (CERN) in Geneva, Switzerland, the event brought together key stakeholders to address critical challenges related to the security and supply of medical radioisotopes. Discussions focused on securing supply chains, preventing shortages, and ensuring patients' access to radiopharmaceuticals.

With strong political support, attendees also had the opportunity to tour the **ISOLDE and MEDICIS facilities.**

OECD NEA's Second International Workshop

Represented once again by our President Elect **Paola Anna Erba**, the EANM participated in the **2nd International Workshop on Medical Radioisotope Supply**, hosted by the **OECD Nuclear Energy Agency** in Paris, France.

Co-organised by the U.S. Department of Energy (DOE) and the European Commission's Joint Research Centre, this year's workshop focused on the market potential of innovative medical radioisotopes such as **Lutetium-177 (Lu-177)** and **Actinium-225 (Ac-225)**. Discussions centred on strengthening the resilience of the medical radioisotope supply chain, monitoring supply and demand, and addressing critical infrastructure needs across healthcare systems.

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