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 euaffairs@eanm.org.

Enjoy the read!

The EANM EU Affairs Team

COOPERATION & COMMUNITY INVOLVEMENT

CARE Project I Kick-Off Meeting

Following a successful application in the summer of 2024, the CARE project has been awarded funding. This two-year initiative, launched in November 2024, brings together EIBIR, ESR, EFOMP, and EANM to advance radiological safety and quality across Europe.

On January 13, 2025, the CARE project held its kick-off meeting, bringing together EANM experts Michel Koole (EANM Scientific Liaison Officer), Laetitia Imbert, and Johannes Tran-Gia, alongside representatives from the European Commission and the Article 31 Working Party on Medical Exposures.

Over the next 24 months, the project will focus on updating the criteria for the acceptability of medical radiological equipment, addressing technological and regulatory advancements in diagnostic radiology, nuclear medicine, and radiotherapy since the publication of Radiation Protection Series No. 162 in 2012.

FIND OUT MORE

SIMPLERAD I Final Report

Over the past 24 months, the SIMPLERAD (*SAMIRA Study on the Implementation of the Euratom and EU Legal Bases with Respect to the Therapeutic Uses of Radiopharmaceuticals*), funded by the European Union, was carried out as a collaborative effort between EANM, EFOMP, and EIBIR.

The project focused on improving the understanding of the links and interdependencies between European pharmaceutical legislation and Euratom

radiation protection requirements, while identifying potential barriers to the coherent implementation of radiopharmaceutical therapies in clinical practice.

With the conclusion of this project, EANM extends its sincere gratitude to all experts who contributed to the success of SIMPLERAD!

The final report provides practical guidance and recommendations to support a harmonised and effective implementation of these regulations, ensuring a streamlined approach to the therapeutic use of radiopharmaceuticals.

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PUBLICATIONS

EANM'24 EU Policy Reports

At the EANM'24 congress in Hamburg, our two EU Policy Symposia gathered key experts to discuss the future of nuclear medicine in Europe and the EANM's involvement in EU projects and tenders.

The first focused on EU Pharma Legislation, while the second addressed the future of the nuclear medicine workforce. If you missed these insightful events, our reports are now available!

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EANM's Response to EMA's Concept Paper

In November, the **European Medicines Agency (EMA)** invited public feedback on its concept paper focused on the clinical evaluation of therapeutic radiopharmaceuticals in oncology. Once finalised, the draft guideline will undergo a three-month public consultation period to gather further feedback.

The guideline aims to provide clear guidance on how key principles from pharmaceutical legislation (2001/83/EC) and radiation protection legislation (Directive 2013/59/Euratom) should be applied to the clinical development of therapeutic radiopharmaceuticals for marketing authorisation applications.

EANM submitted a response to the public consultation. Key points from the EANM's response included:

- **Individual dosimetry**: EANM stressed the need for robust clinical evidence to demonstrate the benefits of personalised dosimetry compared to simplified or fixed-activity approaches.
- **Access and feasibility concerns**: Stakeholders expressed concerns about the potential impact of dosimetric mandates on patient access to therapies and industry investment in the EU.
- **Collaborative solutions**: EANM proposed initiatives such as establishing a unified database for dosimetric data across Europe to enhance evidence

generation and accessibility.

- **Prevention of monopolies**: EANM underscored the importance of enhancing competitiveness and preventing monopolistic practices in the radiopharmaceutical market.

- **Facilitating clinical practice**: EANM stressed that the guideline should ensure clinically manageable and cost-effective study designs. Given workforce shortages, an increase in mandatory dosimetry procedures could exacerbate disparities across Europe unless implemented in a cost-effective and resource-efficient manner.

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POLICY DEVELOPMENTS

European Shortages Monitoring Platform (ESMP)

The **European Shortages Monitoring Platform (ESMP)** was officially launched in December 2024 with a core set of functionalities, enabling efficient information exchange between regulators and pharmaceutical companies.

This digital tool, as a part of EMA's extended mandate, marks a significant step forward in addressing and informing healthcare professionals about ongoing medicine shortages—thus ensuring patients have timely access to the treatments they need.

ACCESS NOW

HTA Regulation for the Evaluation of Oncology Products

We would like to highlight the new EU Health Technology Assessment (HTA) Regulation (EU) 2021/2282, which took effect on January 12, 2025, and now applies to all oncology products. With this new regulation, new cancer treatments seeking EU market authorisation must undergo a coordinated evaluation across Member States.

This regulation aims to accelerate access to innovative health technologies by enhancing collaboration between the EMA, HTA bodies, and Member States. It introduces joint clinical assessments and scientific consultations to ensure efficient and consistent evaluations across the EU.

As a member of the European Commission's HTA Stakeholder Network, EANM is closely monitoring developments related to radiopharmaceutical assessments.

ACT EU

As part of the Accelerating Clinical Trials in the European Union (ACT EU) initiative, EMA and the European Commission aim to support smarter clinical trials through regulatory, technological, and process innovation.

This initiative seeks to transform how clinical trials are initiated and designed, supporting academic sponsors, modernising good clinical practice, and enhancing clinical trial innovation.

As a member of the ACT EU Multistakeholder Platform, EANM is closely monitoring the 2025-2026 workplan, which focuses on improving clinical trial efficiency and impact across Europe. Key priorities include optimising trial operations, addressing public health emergencies, and leveraging trial analytics for better training and communication.

To ensure EANM's meaningful contribution, a dedicated ACT EU project group will be established. The first action will focus on assessing clinical trial training needs for academia and SMEs. Stay tuned!

EVENTS

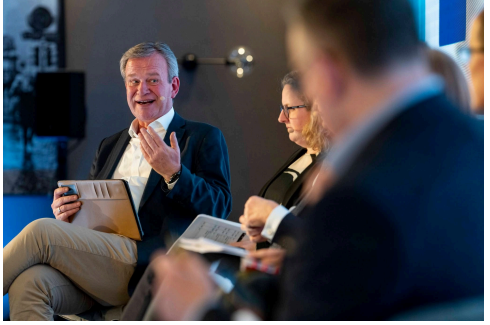
THROWBACKS

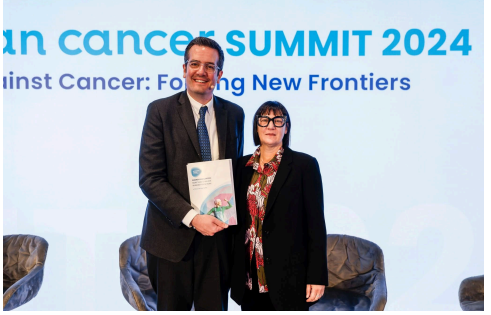
2024 European Cancer Organisation Summit

The European Cancer Organisation (ECO) Summit, '*United Against Cancer: Forging New Frontiers',* took place in November 2024.

Paola Anna Erba, EANM President, participated in a panel discussion to present the findings of the Women and Cancer report. This report underscores the urgent need to address gender disparities in cancer care across Europe, offering 16 key recommendations to tackle inequities in prevention, treatment, caregiving, and the economic impact on women affected by cancer.

Wim Oyen, Chair of the EANM Policy & Regulatory Affairs Council (PRAC), co-chaired the session '*Building the Digital Future: From Legislation to Implementation'.* This session focused on advancing digital health through legislative frameworks, coordinated care, data integration, and patient-centric innovations in oncology. The session also featured MEP Tomislav Sokol, who led the work on the European Health Data Space.





European Parliament Event on the Outpatient Model in Nuclear Medicine

EANM President Paola Anna Erba recently participated in the event '*Nuclear Medicine: Is the Outpatient Model a Solution for Ensuring Equitable Access to Targeted Internal Radiotherapy in Europe?',* which was hosted by MEPs Vlad Voiculescu and Laurent Castillo.

Discussions focused on insights from France, particularly the benefits of the outpatient model. Panellists then explored various organisational models for nuclear medicine centres and the EU policy measures needed to improve access.

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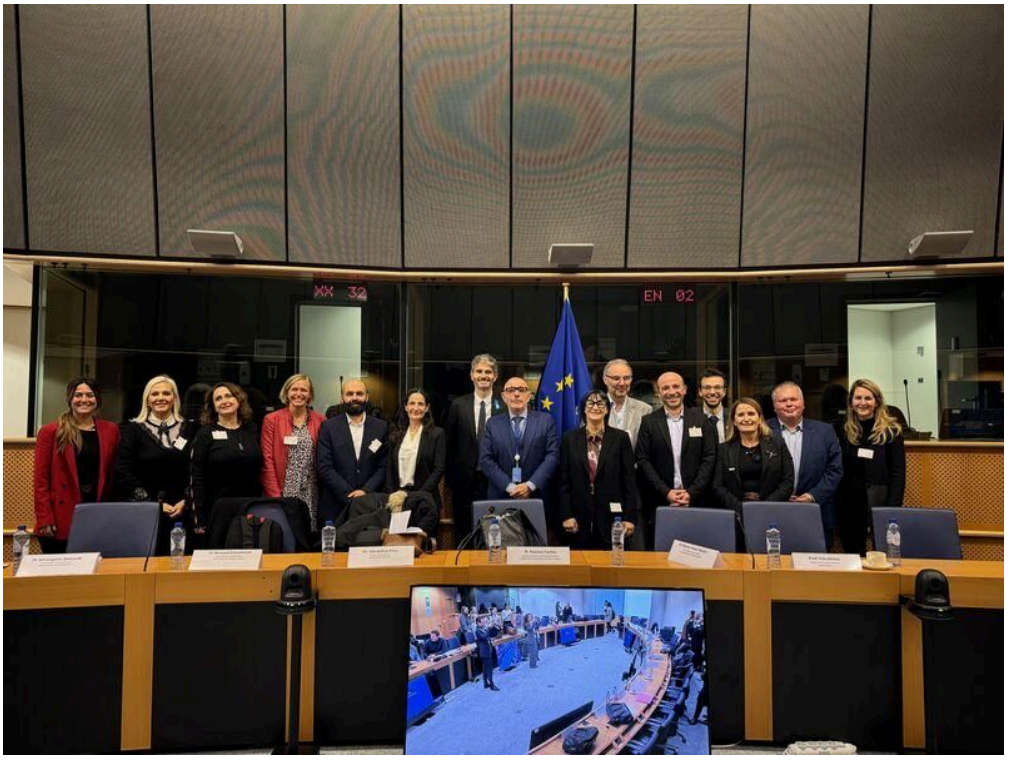

EMA Meets Healthcare Professionals Organisations

EANM participated in the joint meeting of the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP), organised by EMA in November.

This event brought together representatives from patient, consumer, and healthcare professional organisations to discuss regulatory science and innovation, with a

particular focus on clinical trials and the implementation of the EU Clinical Trials Regulation.

Attendees also explored EMA's ongoing work in medical devices and strategies to address medicine shortages. EMA reaffirmed its commitment to continued collaboration with stakeholders to ensure alignment on shared priorities.

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COMING UP

European Association of Hospital Pharmacists Congress

EANM will be represented at the 29th EAHP Congress, which will take place in Copenhagen on March 12-14, 2025. Hospital pharmacists around Europe will again have the opportunity to share their expertise and discuss the latest developments in the field to advance patient outcomes. At a time when the hospital pharmacy policy and legislation landscape is evolving, it is key for EANM and EAHP to strengthen their cooperation.

European Congress of Radiology

The European Institute for Biomedical Imaging Research (EIBIR), together with the EuroSafe Initiative, is organising free sessions at the European Congress of Radiology (ECR) to present current EU projects and tenders.

Do not miss the session 'Working in partnership towards highest quality and safety in imaging: implementing the SAMIRA Action Plan of the European Commission' and get to know more about the MARLIN and CLAUD-IT projects.

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Thera4Care Annual Meeting

Since October 2024, EANM has been working with 25 partners on Thera4Care, an Innovative Health Initiative (IHI) project. The project aims to create a collaborative European ecosystem for theranostics. By bringing together academic centres, healthcare providers, SMEs, and the industry, Thera4Care seeks to enhance healthcare system readiness for theranostics.

As a consortium member, EANM is primarily involved in Work Package 9, focusing on disseminating project outcomes across Europe through strategic communication, stakeholder engagement, and an educational platform for healthcare professionals.

On May 12-13, 2025, the annual consortium meeting will take place in Budapest, hosted by GE Healthcare. The meeting will review progress since October 2024 and define the next steps for moving forward. Stay tuned for further updates!

STATEMENT

'The SIMPLERAD report and the EMA concept paper on the clinical evaluation of therapeutic radiopharmaceuticals in oncology highlight nuclear medicine's growing prominence on the policy agenda. EANM welcomes regulators' efforts to strengthen and harmonise the legal framework. In this context, EANM advocates for prioritising stakeholder engagement before issuing formal guidance. A balanced approach will be essential to achieving consensus and ensuring that proposed measures both support patient care and advance nuclear medicine therapies'.

Paola Anna Erba I EANM President

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