



# 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. Read below about:

- **Cooperation & Community Involvement**
- **Publications & Positioning**
- **Policy Initiatives & Political Developments**
- **Events**
- **Statement**

Should you wish to bring any questions, feedback or inquiries forward, please contact the EANM via [e-mail](#).

Enjoy reading!

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## COOPERATION & COMMUNITY INVOLVEMENT

### Launch of the Erasmus+ Radioligand Therapy Academy's E-Learning Platform

The Erasmus+ Radioligand Therapy (RLT) Academy project, with a [consortium](#) led by KU Leuven and composed of 14 organisations from 9 European countries (including the EANM), was developed to enhance the wider adoption of RLTs.

This project was kindly supported by the European Commission (ERASMUS+) and is the first in Europe to offer specialised training and resources specifically designed for RLT healthcare providers and trainees across Europe and beyond.

Over the last two years, the consortium has worked on bridging the knowledge gap in RLTs and on facilitating their integration into standard cancer care protocols. The journey began with a comprehensive analysis of the [current training landscape on RLTs](#), pinpointing key educational deficiencies and evaluating the training needs of our target audience.

The e-learning platform was launched on April 4 during an event at the European Parliament in Brussels (if you missed it, you can watch the [event recording](#)). We are pleased to report that in just the first five days since the platform's launch, over 100 participants have already commenced the Basic course.

[ACCESS THE PLATFORM](#)



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## **SIMPLERAD – Seeking Consensus on the Project Recommendations**

Last December, the EANM, in collaboration with the European Institute for Biomedical Imaging Research (EIBIR) and the European Federation of Organizations for Medical Physics (EFOMP), organised a project workshop in Brussels.

Participants were able to discuss the consortium's efforts since the project launch in May 2022. Literature reviews, research, surveys, and expert interviews were conducted to delve into the legal requirements regarding the use of radiopharmaceuticals and the practice of therapeutic nuclear medicine across various EU and non-EU countries.

Key stakeholders, regulatory authorities, medical professionals, EU and international representatives, industry experts, and patient advocates participated in the workshop and shared their insights on the proposed recommendations.

The content presented at the workshop is now available on the [SIMPLERAD website](#). You can browse through all the different presentations and can access the [workshop proceedings](#).

Stay tuned for further updates on the publication of the final report!



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## Securing Funding for Nuclear Medicine

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

- **The 2024 EU4Health Work Programme** was launched with over €750 million available for EU4Health projects, supporting EU policies that seek to improve healthcare systems and patient outcomes. The 2024 work programme can be downloaded [here](#).
- Similarly, in March, the European Commission adopted the **second strategic plan for Horizon Europe: the [Horizon Europe strategic plan 2025-2027](#)**. The plan outlines the principal directions for the EU's research and innovation funding during the final phase of the programme, from 2025 to 2027. It aims to address pivotal challenges, like securing critical technologies and advancing brain health. These strategic directions will serve as a roadmap for Horizon Europe, shaping the annual work programmes. The EANM Office will keep the nuclear medicine community updated on any relevant funding opportunities.
- Two public consultations are open on the **Euratom research and training programmes**, which fund nuclear research and training activities. You can provide feedback to the European Commission (1) about the [evaluation of Euratom Research and Training Programme 2021-2025](#) and (2) to ensure [medical applications are a key priority for the next programme](#).

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## PUBLICATIONS

### **EANM Statement on the Union List of Critical Medicines**

Following the [publication of the Union List of Critical Medicines](#) by the European Medicines Agency (EMA), the EANM published a statement outlining the importance of including medical radioisotopes in this list to facilitate the mitigation of radioisotopes shortages across Europe.

The statement highlights the positive reaction of the nuclear medicine community to the inclusion of some radiopharmaceuticals on the Union List of Critical Medicines. However, it also states that the **main driver of accessibility of radiopharmaceuticals is the availability of radioisotopes**, predominantly (but not exclusively) Tc-99m, F18, Ga-68 for diagnosis, and I-131, Lu-177 and Y-90 for therapy. The position paper also urges the **EMA to consider adapting the list to include radionuclides** (rather than radiopharmaceuticals) as these are vital to diagnose and treat a wide range of diseases.

In that respect, and in cooperation with the Belgian presidency of the Council of the European Union, the EANM looks forward to participating in discussions on how radioisotopes could be considered as critical medicines. The EANM is also already engaged in an exchange with the EMA to review the mapping of active substance groups to be included in the Phase 2 of the Union Critical Medicines list. An updated Union List of Critical Medicines will be published in December 2024.

[READ THE EANM STATEMENT](#)

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## POLICY DEVELOPMENTS

### The European Health Data Space – Towards the Final Vote

The [European Health Data Space](#) (EHDS) is a proposed EU-wide framework designed to facilitate the use of health data for research, innovation, public health, policymaking, regulatory activities and personalised medicine.

After years of deliberations, negotiators from the [European Council](#) and the [European Parliament](#) reached a provisional agreement on the EHDS in March. While the text may still undergo some minor technical changes, it is expected to represent the definitive version of the legislative text. The preliminary agreement encompasses directives for the use and re-use of health data, provisions for opting out, clauses related to intellectual property and regulatory data protection, and the creation of a Stakeholders Forum.

The EHDS's journey to becoming official legislation involves endorsement and subsequent ratification by both the Council and the Parliament. The text is expected to pass during the plenary session scheduled for April 24. Following its formal adoption, the regulation will come into effect two years thereafter. **The infrastructure and administrative apparatus of the EHDS are projected to reach full operational status within a timeframe of three to five years.**

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## EVENTS

### PAST EVENTS

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#### The Belgian EU Presidency's Workshop on Radiopharmaceuticals

During its presidency of the Council of the European Union, Belgium is striving towards a brighter future for radiopharmaceuticals.



On February 28 in Brussels, the Directorate-General for Energy of the Federal Public Service Economy, SMEs, Self-Employed and Energy organised a workshop titled 'Belgian EU Presidency Workshop: Securing Access to Radiopharmaceuticals for all European Patients'.



The one-day workshop was divided into four sessions, each focusing on a specific topic:

1. Precision medicine in cancer therapy using radiopharmaceuticals.
2. The importance of doctor's knowledge to guarantee the patient's quality of life.
3. EU regulatory aspects.
4. Securing the radiopharmaceutical supply chain and fostering the EU's autonomy.

Each session included presentations from leading members of the radiopharmaceutical community. All presentations can be accessed [here](#).

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## Cancer Medicines Forum - A Way Forward for Treatment Optimisation

The EANM joined this event jointly organised by the European Medicines Agency (EMA) and the European Organisation for Research and Treatment of Cancer (EORTC).

The objective was to integrate the work of the academic sector into the regulatory decision-making process by acting as a unique channel between the regulator and academic clinical research.

The deliverables of the Cancer Medicines Forum are aimed at supporting policy decisions to facilitate treatment optimisation in Europe, with a focus on post-licensing questions based on clinically relevant endpoints for patients.

[READ MORE](#)

UPCOMING EVENTS

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## Critical Medicines Alliance – Inaugural Meeting of the Alliance’s Forum

The Critical Medicines Alliance is a consultative mechanism established by the European Commission. It brings together all relevant stakeholders, to identify priorities for action and to propose solutions to strengthen the supply of critical medicines in the EU, thus preventing and combatting their shortages.

The inaugural event will be the occasion to formally launch the Critical Medicines Alliance and exchange with all members on its objectives, challenges, and expected outcomes. As a member of the Critical Medicines Alliance, the EANM will join the event on April 25, 2024.

LEARN MORE

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## European Economic and Social Committee: Security of Medical Radioisotopes Supply

The Section for Transport, Energy, Infrastructure and the Information Society ([TEN](#)) within the Economic and Social Committee ([EESC](#)) is currently developing an own-initiative opinion titled *TEN/833 Europe’s Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply*.

For detailed information about the opinion's background, objectives, composition, and the expected timeline for its adoption, please visit [the dedicated webpage](#).

While formulating this opinion, the EESC has scheduled a hearing on April 17, 2024, to engage with a variety of stakeholders. This hearing is set to explore different facets of medical radioisotopes supply security and will inform the opinion's development. The EANM will participate in this hearing to share insights from the perspective of nuclear medicine healthcare professionals.

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### STATEMENT



"I am thrilled to witness the launch of the Radioligand Therapy Academy, a groundbreaking initiative aimed at advancing the adoption of RLTs across Europe. Over the past

two years, EANM has played a pivotal role within the consortium led by KU Leuven, shaping the educational platform of this exceptional project supported by the European Commission. Through meticulous analysis and collaboration, we have identified crucial gaps in RLT training and developed a comprehensive curriculum to address and overcome them. Today, as we unveil the RLT Academy, we mark a significant milestone in our mission to integrate RLTs into mainstream cancer care. This pioneering initiative will not only benefit healthcare professionals but will also pave the way for better patient outcomes."

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*Paola Anna Erba*  
*EANM President-Elect*



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**EU Transparency Register ID: 348978437245-85**

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