



Welcome to the EANM Policy Bulletin!

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

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

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

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## COOPERATION & COMMUNITY INVOLVEMENT

### **SIMPLERAD Project 'EU Legal Bases for Radiopharmaceuticals' Awarded and Launched**

The EANM is proud to announce to have won the SAMIRA study on the implementation of the Euratom and the EU legal bases with respect to the therapeutic uses of radiopharmaceuticals (SIMPLERAD) tender project by the European Commission, jointly with the European Institute for Biomedical Imaging Research (EIBIR) and the European Federation of Organisations for Medical Physics (EFOMP). The project officially started on May 1, 2022, whereas the kick-off meeting with the European Commission was held on May 23 with the Inception Report as the first milestone being approved. More information on Work Packages and EANM contributions is available [here](#).

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### **Radioligand Therapy (RLT) Academy Project Started**

Recently awarded to a pan-European consortium, including the EANM, the RLT Academy project aims at launching a multidisciplinary and transnational blended education programme for healthcare professionals on the use of radioligand therapies in cancer care. Within the Erasmus+ RLT project, the EANM takes the lead of Work Package 2, which consists of the development of training curricula and material on radioligand therapies. In parallel to survey development and based on Work Package 1 activities, Work Package 2 is currently working on the needs assessment for the curricula development. Stay tuned for more information on the online training platform!

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### **New SAMIRA Tender - Basic Safety Standards Provisions on Radiation Protection**

The European Commission has recently launched a [new call for tender](#) under the SAMIRA framework. The scope of this call for tenders is to review and assess the transposition and implementation of the requirements for Radiation Protection Experts (RPE), Radiation Protection Officers (RPO) and Medical Physics Experts (MPE) of the BSS Directive (Council Directive 2013/59) in the EU-27 Member States. The study shall have a particular focus on the practical implementation of the articles providing for the definition, roles and responsibilities, as well as education, training, and retraining of RPE, RPO and MPE as well as the detailed arrangements for their recognition. The total value is 250,000 EUR with a deadline on August 31, 2022.

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## New SAMIRA Tender - Reporting and Learning From Patient-related Incidents

The European Commission has recently launched a **new call for tender** under the SAMIRA framework. The scope of this call for tenders is to improve the reporting and learning from patient-related incidents and near misses in radiotherapy, interventional cardiology, Nuclear Medicine and interventional and diagnostic radiology. The study shall include the analysis of up-to-date information on the implementation of Council Directive 2013/59/Euratom requirements and develop best-practice guidance on the implementation of the above requirements. The total value is 250,000 EUR with a deadline on September 15, 2022.

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### PUBLICATIONS & POSITIONING

#### Nuclear Medicine. What it is. Where it goes. What it needs.

The EANM has recently published a **new overarching position paper**, providing basic information about Nuclear Medicine, its specificities and current most urgent policy needs. Focussing on the policy as of today, the statement highlights the need for high-quality and harmonised Nuclear Medicine training across Europe, the challenges of designing an optimal and efficient regulatory framework for equal access to Nuclear Medicine and the necessity to develop healthcare infrastructures that can accommodate Nuclear Medicine facilities. Building on the Europe's Beating Cancer Plan and the SAMIRA Action Plan, the statement aims at offering all stakeholders, at the European or national level, a better understanding of the specificities of the Nuclear Medicine sector.

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#### Enabling Guide on How to Set Up a Theranostics Centre

The EANM is proud to announce that the first '**Enabling Guide on How to set up a Theranostics Centre**' in collaboration with SNMMI and the IAEA has been published. The guide provides some elements of reply to the regulatory, financial and medical questions that may arise when developing a Theranostics Centre. Such guidance might be useful when developing the Comprehensive Care Centre Network to ensure all cancer patients across Europe can benefit from the theranostics procedures. The paper also raised the necessary financial support, both at the European and national level, to ensure that Theranostics Centres are accessible across Europe.

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#### Small Modular Reactors and Medical Applications of Nuclear Technologies

The European Commission has recently published a **report** from the Second High-level European Nuclear Roundtable to which the EANM contributed. The Roundtable explored opportunities and challenges in the areas of Small Modular Reactors and medical applications to identify possible Research & Innovation synergies between the Euratom Programme and other EU Programmes supporting EU policies relating to health and the energy transition.

The report includes contributions from the EANM President, Professor Jolanta Kunikowska and Dr Margarita Kirienko (National Cancer Institute Milan). In her chapter, Jolanta Kunikowska highlights the promises and needs of Nuclear Medicine, which touch on, among other things, equipment, personalised medicine and radioisotope shortages. Most importantly, the EANM President makes recommendations on how to achieve equal access to high-quality Nuclear Medicine services. In her chapter, Margarita Kirienko stresses how Artificial Intelligence enabled technologies are driving innovation in Nuclear Medicine.

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### POLICY INITIATIVES & POLITICAL DEVELOPMENTS

#### The EU Non-communicable Diseases (NCDs)

## Initiative

The European Commission has recently published a new initiative on NCDs, '**Healthier Together**', with the aim of supporting European countries in reducing the burden of NCDs. The initiative focuses on five main areas, including: cardiovascular diseases; diabetes; chronic respiratory diseases; mental health and neurological disorders; and health determinants. The initiative will provide support for EU countries all along the care pathway, by developing guidelines, rolling out innovative approaches, transferring best practices and using EU funding instruments.

The EANM has been involved in the consultation process for the neurological and cardiovascular strands. Main elements of our reply included: elaborating a European system for data generation and collection on NCDs; harmonisation of cardiovascular and neurological data for PET/CT scans; harmonisation of proof-of-concept studies for Radiopharmaceuticals.

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## The European Health Data Space (EHDS)

On May 3, the European Commission published its eagerly awaited **legal proposal on the creation of a EHDS**. The EHDS aims at promoting better exchange and access to different types of health data (e.g. electronic health records, genomics data, data from patient registries) to support both health care delivery (primary use of data) and health research and health policy-making and regulatory purposes (secondary use of data).

The EHDS aims at empowering individuals through better digital access to their personal health data; supporting the free movement by ensuring that health data follow people and unleashing the data economy by fostering a genuine single market for digital health services and products.

The European Commission's proposal will now undergo the legislative procedure during which the Council and Parliament will amend and decide on the proposal. The EANM, alongside other organisations, will engage with the scrutiny of the proposal and its potential enhancement via Parliamentary procedure in autumn.

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## EVENTS

### PAST EVENTS

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#### European Radioecology Alliance Webinar on the Impact of Production, Use and Disposal of Radiopharmaceuticals

The **webinar**, 'assessing the impact of production, use and disposal of radiopharmaceuticals on members of public and the environment', aimed at gathering information including insight experiences from regulators, producers of radiopharmaceuticals and experts in the field of Nuclear Medicine on the regulatory framework and national perspectives on the use of medical radionuclides in Europe. Interesting approaches to exposure assessments and environmental assessments were discussed.

### UPCOMING EVENTS

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#### 18th Plenary of the EU Observatory for the Supply of Medical Radioisotopes

On June 29, the EU Observatory for the Supply of Medical Radioisotopes will hold its 18th Plenary session. Aiming at bringing together all relevant information to the decision makers in the EU institutions and national governments in order to assist them in defining strategies and policies, all relevant stakeholders in the supply of radiopharmaceuticals have been invited to share their views on the current status of radiopharmaceuticals' supply chains.

The EANM President, Jolanta Kunikowska, will attend the event and provide an EANM update.

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#### European Cancer Summit - Call for Abstracts

Ahead of the European Cancer Summit 'Delivering Effective & Equitable Care Together' (November 16-17), the European Cancer Organisation has opened a call for abstracts. The organisation welcomes research abstracts

which fit the priority areas within Europe's Beating Cancer Plan and the EU Cancer Mission recommendations. Junior clinical and academic faculty are particularly encouraged for submissions as the presentations will form part of a special session of the Summit with young cancer professionals and leaders. More information on the submission deadline and requirements is [here](#).

## STATEMENT



'The EANM is very pleased to be working on the SIMPLERAD project with its partner and the European Commission to ensure a better understanding and increased awareness of the European legal basis for the use of radiopharmaceuticals in radionuclide therapies. We hope that this will lead to an advancement of the coherent implementation of the European legal requirements with respect to therapeutic Nuclear Medicine.'

Professor Michael Lassmann,  
Ex-Officio member of the EANM Policy  
and Regulatory Affairs Committee



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