



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!

Interested in policy and regulatory topics? If you would like to help us in shaping the future of nuclear medicine, get in touch via our [contact form](#).

COOPERATION & COMMUNITY INVOLVEMENT

SIMPLERAD Project - New Steps Towards a Better Understanding of EU Legal Bases for Therapeutic Radiopharmaceuticals

The **SIMPLERAD** consortium, jointly consisting of EANM, EIBIR and EFOMP, held its first progress meeting with the European Commission (DG ENER) in November to discuss progress and next steps.

The final steps of Work Package 1 (*Analysis of the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/Euratom*) and Work Package 2 (*Survey and analysis of the implementation of relevant European legal requirements for therapeutic nuclear medicine*) were presented as successful milestones of the project. As part of these Work Packages, the conducted **literature review and survey helped identify the existing gaps and main barriers encountered in the development and use of therapeutic radiopharmaceuticals**. Work Package 3 (*Advancing coherent implementation of European legal requirements for therapeutic nuclear medicine*) has been kicked off and will now focus on developing **policy recommendations** based on evidence from Work Packages 1 and 2. Topics to be covered by these recommendations include the lack of European guidance for implementing BSSD and the lack of consideration in EMA guidance regarding marketing authorisations for items pertaining specifically to the safety of therapeutic radiopharmaceuticals.

First Steps of the Radioligand Therapy (RLT) Academy Project

As part of a pan-European consortium, including the EANM, the RLT Academy project aims to launch a **multidisciplinary and transnational blended education programme** for healthcare professionals on the use of radioligand therapies in cancer care. Within the Erasmus+ funded RLT project, the EANM takes the lead in Work Package 2, which consists of the development of training curricula and material on radioligand therapies. A **three-course training on radioligand therapy** has been rolled out, and a preliminary content programme has been developed. Topics will now be disseminated among the consortium, and a curriculum will be created in 2023 based on this evidence.

Upcoming Calls on the Medical Applications of Ionising Radiation

End of November, the European Commission adopted the **2023 annual work programme** of **EU4Health**, which is the **main EU financial support in the health area**.

The EU4Health work programme for 2023 consists of four overarching strands: Crisis preparedness; Health promotion & disease prevention; Health systems & healthcare workforce; Digital. Cancer is considered a fifth cross-cutting strand.

With a budget of € 735.8 million for 2023, special attention will be given to mental health, global health, the developments in digital health and medicinal products and the uptake of cancer screening.

As a heads-up to our community, the EANM would like to stress **two funding calls for 2023 that will support the implementation of the SAMIRA Action Plan**:

- Call for proposals – **organisation of clinical audit campaigns as a tool to improve the quality and safety of medical applications of ionising radiation**.
- Call for tenders – **study on the implementation of the EURATOM and the Union legal bases with respect to medical devices used in medical applications of ionising radiation**.

The EANM will carefully monitor the development and publication of these two calls and keep the nuclear medicine community informed.

PUBLICATIONS & POSITIONING

EANM-EAHP Joint Statement on the Availability of Radiopharmaceuticals in the Context of the Revision of the General Pharmaceutical Legislation

As part of a fruitful collaboration between the EANM and the European Association of Hospital Pharmacists (**EAHP**) on **hospital preparation and low-volume medical products**, a **new position paper** has recently been published on the availability of radiopharmaceuticals.

In the context of the revision of the general Pharmaceutical Legislation, this statement focuses on the **need for a flexible regulatory framework for low-volume products**. **Reducing the regulatory burden for small-scale preparations** should start with a **clear distinction between commercial and non-commercial preparations of medical products** in any regulatory framework. This paper explains how the revision of the Pharmaceutical Legislation could develop a specific approach to the regulation of small-scale preparation of radiopharmaceuticals, notably on marketing authorisation procedures. This paper also touches upon how the revised Pharmaceutical Legislation could support investment in education and the security of supply.

Read the full statement [here](#).

EANM Position on the European Radioisotopes Valley Initiative

As part of the SAMIRA Action Plan's pillar on the security of the supply of medical radioisotopes, the European Commission plans to establish a European Radioisotope Valley Initiative (**ERVI**), aiming at **maintaining Europe's global leadership role in the supply of medical radioisotopes**. To define further the objectives and scope of this initiative, the European Commission **launched a targeted** consultation in autumn to gather the positions of stakeholders on the ERVI objectives and the specific issues concerning the supply chain of medical radioisotopes.

The EANM provided feedback, highlighting the **crucial need for such an initiative**, given the recent large and unexpected outages ultimately impacting patients' procedures and considering that the demand for radionuclides will only increase in the future.

The EANM pointed out that, for such an initiative to be a success, a **holistic approach** should be taken:

- Considering the entire supply chain so that the produced **radioisotopes are easily available, at a fair price, anywhere in Europe**.
- Ensuring that the EU's strong tradition in Nuclear Medicine will

perpetuate in the next decades by **reducing the EU's reliance on foreign suppliers.**

- Focusing on the **development of new radioisotopes** and new production methods.

Must Read from the EU Health Arena

This autumn has been particularly valuable in terms of publications, notably with the publication of a new study by the Lancet Oncology Commission: **European Groundshot-addressing Europe's cancer research challenges.** Recognising the pivotal importance of research to build better European cancer services and systems for patients tomorrow, the Lancet Oncology European Groundshot Commission brought together a wide range of experts, together with detailed new data on cancer research activity across Europe during the past 12 years and ultimately identified 12 key recommendations within a call to action to reimagine cancer research and its implementation in Europe.

In addition, we invite our French-speaking readers to screen the former **French Presidency report on Nuclear Skills in Europe.** As a conclusion to France's six-month presidency of the Council of the European Union, this report highlights how the EU can contribute to the maintenance of skills and knowledge in the nuclear field, with a specific focus on medical applications.

POLICY INITIATIVES & POLITICAL DEVELOPMENTS

EANM Involvement in the European Radioisotopes Valley Initiative

In the context of the **European Radioisotopes Valley Initiative (ERVI)**, the EANM is very pleased to have been invited by the European Commission to join the **ERVI Stakeholders' Group.** The first meeting in November, with a wide range of stakeholders involved in the supply chain of medical radioisotopes, was a valuable opportunity to discuss the ERVI consultation outcomes but also tentative upcoming feasibility studies and positions of several organisations.

In addition, the EANM is also very honoured to be part of the **ERVI Steering Group,** along with **PRISMAP** and **Nuclear Medicine Europe (NMEU),** to support the European Commission in developing the ERVI roadmap and first implementation building blocks in the coming two years. The EANM is looking forward to bringing expertise from the clinician's perspective and engaging further in this initiative.

Stay tuned for further information in 2023 on ERVI scenarios development and implementation roadmap!

Inequality in Cancer Care & Treatment - the European Cancer Inequalities Registry

The European Cancer Inequalities Registry is a **flagship initiative of Europe's Beating Cancer Plan.** It aims at providing **sound and reliable data on cancer** prevention and cares to identify trends, disparities and inequalities between Member States and regions. Data mainly come from national and European official sources, such as Eurostat.

With the newly launched **Inequalities Registry data tool online,** developed by the European Commission Joint Research Center, you can easily explore inequalities across Europe with six different inequality dimensions and already 27 data variables (on cancer burden, prevention, early detection, diagnosis and treatment). Check out PET and CT scanner data across Europe.

Should you have any feedback on the data provided or if you are aware of any potentially useful data sets for this project, please share your insights with euaffairs@eanm.org.

As a valuable complement to the European Cancer Inequalities Registry, check out the **European Cancer Organisation Cancer Pulse,** a data visualisation tool allowing you to discover cancer care disparities in 34 countries quickly.

35th Annual Congress of the European Association of Nuclear Medicine

At the **EANM annual scientific Congress** in Barcelona, two sessions discussed radiopharmaceuticals' preparation and related regulatory issues in daily clinical practice and basic and clinical research: **'Radiopharmaceuticals Regulations: Quo Vadis?' & 'Getting to the top QuADRANT. A European initiative to improve quality for patients'**. These were two very insightful sessions with views from the European Commission's DG ENER, the Agencia Española de Medicamentos y Productos Sanitarios and the Swiss Federal Office of Public Health (FOPH) on the need for potential adaptations in current EU legislation for radiopharmaceuticals.

European Cancer Summit

This year's **European Cancer Summit** on November 16–17 focused on the **implementation of Europe's Beating Cancer Plan and the EU Cancer Mission's recommendations**, bringing together leading oncology experts, experienced patient advocates, key opinion leaders, policymakers and politicians to discuss key issues in reducing the burden of cancer, saving, and improving the lives of patients and the public. The Summit Report is available [here](#), including insights from all sessions.

UPCOMING EVENTS

European Commission - 3rd High Level Nuclear Round Table

On February 13, the European Commission is organising the 3rd High-Level Nuclear Roundtable (by invitation only), specifically focusing on **nuclear competencies and research and development infrastructures**. The EANM is delighted to have been invited again and will join the discussion, presenting the **clinical perspective on the competencies needed to enable the safety and quality of radionuclides technologies**. Stay tuned for the following publication.

STATEMENT



'Looking back at the past year, 2022 has been a valuable year for nuclear medicine in Europe. Not only have we witnessed the first steps of the implementation of the SAMIRA Action Plan by the European Commission, but the EANM also had the opportunity to have a critical role in these discussions. Internally, the Policy & Regulatory Affairs Committee has been very active in its first year of existence, engaging in in-depth discussions on radiopharmaceuticals' regulations and supply and providing advice to the Board on the EANM's involvement in projects and tenders. 2023 will be crucial to ensure that nuclear technologies continue to benefit the health of EU citizens and contribute to the fight against cancer and other diseases.'

Jolanta Kunikowska,
EANM President

