



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!

COOPERATION & COMMUNITY INVOLVEMENT

EANM New Policy & Regulatory Affairs Committee

The EANM is proud to announce the foundation of a **new Committee** that facilitates the coordination and implementation of the EANM's policy activities following its key strategic objectives. The Committee advises and supports the EANM Board by engaging in a **permanent dialogue with EU policymakers** in pursuit of the overall EANM mission. Chaired by Wim Oyen, the multidisciplinary Committee is now off to a good start following its constitution meeting last month.

European Medicines Agency Engagement

The EANM is delighted that it was accepted as an **eligible healthcare organisation** by the EMA earlier this year. This makes the EANM part of a group of 39 organisations ensuring that the needs and concerns of healthcare professionals are represented via direct contact with the EMA.

Tender Submission on EU Legal Bases for Radiopharmaceuticals

In cooperation with EARL, EFOMP and EIBIR, the EANM has submitted an application in January 2022 to a DG ENER call for tender for a **study on the "Implementation of the Euratom and the EU Legal Bases with Respect to the Therapeutic Uses of Radiopharmaceuticals"**. The objective is to improve the understanding of the links and the inter-dependencies between the European pharmaceutical legislation and the Euratom radiation protection requirements. The assessment result will be published in the coming months.

Radioligand Therapy Academy Receives Erasmus+ Grant

As part of a pan-European consortium, the EANM and its partners recently were awarded an Erasmus+ grant to build a Radioligand Therapy (RLT) Academy. This initiative is a **first-of-its-kind European-level training opportunity**. Over 30 months, the EANM will co-shape the academy with its consortium partners. These partners include leading institutions in the field and the EAU as a clinical partner. Furthermore, the academy is supported by the European Oncology Nursing Society (EONS), Advanced Accelerator Applications (AAA) and the International Atomic Energy Agency (IAEA), which act as associate partners.

New EU4Health Call - Workforce Availability, Education and Training for Medical Applications of Ionising Radiation

The European Commission has recently launched a new [call](#) under the EU4Health programme. The scope of this call for tenders is to provide an analysis on workforce availability, education and training in quality and safety aspects of medical applications of ionising radiation in the EU. The service contract also foresees the development of staffing and education/training guidelines for key professional groups involved in ensuring radiation safety and quality of medical radiation applications in the EU Member States. The total value is 500,000 EUR with a deadline on April 08, 2022.

PUBLICATIONS & POSITIONING

[EANM position on the in-house preparation of radiopharmaceuticals](#)
Eur J Nucl Med Mol Imaging (January 2022). This paper expresses EANM commitment and support to the non-commercial in-house preparation of Radiopharmaceuticals for direct use in accordance with European and national regulations.

[EANM Statement for a better inclusion of the particularities of Radiopharmaceuticals within the Review of Directive 2001/83EC on Pharmaceutical Legislation](#) (December 2021). In the context of the upcoming review of the European Pharmaceutical Legislation, this statement, addressing current regulatory challenges, is intended to provide input for the consideration of specificities of Radiopharmaceuticals within this review.

[EANM statement on posology for Radiopharmaceuticals: contradictory legal requirements between BSS Directive 2013/59/Euratom and EMA marketing authorisations schemes](#) (December 2021). This paper, providing an overview of EU requirements for the use of radiopharmaceuticals in patients and for posology, puts forward suggestions to facilitate coordination between the different legal basis and ensure that are fitting the needs of patients.

POLICY INITIATIVES & POLITICAL DEVELOPMENTS

BECA Report Adopted

The final [report](#) of the Special Committee on Beating Cancer (BECA) was put to a vote by the European Parliament Plenary on February 16, 2022. The results were clearly in favour of Europe's Beating Cancer Plan being adopted. The proposals and measures are calling for the **affirmation of nuclear medicine as a fully independent medical speciality**, the promotion of **training standards**, the **investment** in nuclear medicine research and supply chain as well as the **harmonisation** of market access and HTA for radiopharmaceuticals. The report's adoption is warmly welcomed by the EANM as **nuclear medicine receives its deserved recognition** in the joint fight against cancer.

SAMIRA Action Plan Updates

Published in February 2021, as a follow-up to Europe's Beating Cancer Plan and aiming at ensuring EU coordination in the contribution of radiological and nuclear technologies to the fight against cancer and other diseases, the SAMIRA Action Plan has moved to the [implementation phase](#) in the past months.

- Several studies have been launched on the **Quality and Safety of Medical Applications** (legal basis, BSS Directive and workforce) and a new Steering Group on Quality and Safety has been established.
- The EANM is involved in several EU projects related to the **Innovation and Technological Development** pillar of SAMIRA.
- The EANM is looking forward to the development of, and its potential involvement in, the European Radioisotope Valley Initiative to

Review of the European Pharmaceutical Legislation

The European Commission plans to evaluate and revise the EU's general legislation on medicines for human use. Legal proposals to review Directive 2001/83/EC and Regulation EC/726/2004 are to be expected for the end of 2022 and all stakeholders were invited to share their views. The EANM's main points of [reply](#) included: definition of terms to reflect today's nuclear medicine and radiopharmacy practices; differentiation in regulations between kit-based RP preparation and complex RP preparation; differentiation in regulations considering production settings. The Nuclear Medicine community is very pleased that nuclear medicine practitioners have been identified as the first campaigners in the consultation process, calling for the adaptation of the legislation to facilitate the production and marketing authorisation of radiopharmaceuticals and to simplify regulations for dispensing radioactive medicinal products.

EVENTS

PAST EVENTS

Improving European policies to unlock radioligand therapies' potential: what is the state of play?

Stakeholder Political Alliance for Radioligand Cancer Therapies (SPARC-Europe) organised this event in February to take stock of progress made thus far in the field of cancer care at the EU level, highlighting that the implementation of Europe's Beating Cancer Plan in synergy with the SAMIRA Action Plan and EU4Health programme, prove to have tremendous potential in addressing Europe-wide inequalities in terms of access to radioligand cancer therapies. An investment Pathway guide was launched at the event, laying down the needs for adequate delivery of radioligand cancer therapies and matching those needs with available funding mechanisms at the EU level. More information [here](#).

Radioisotopes for Life/Ensuring European Supply - Stakeholders and Opportunities

The European Nuclear Society organised this webinar in February in collaboration with Euratom Supply Agency, SCK CEN, PALLAS and the EU Commission DG ENER. Points related to the production and supply of radioisotopes in Europe were discussed, stressing the crucial role medical radioisotopes play in beating cancer and the necessity to secure reliable, stable production and supply chain for the future. The webinar concludes that common efforts should converge towards strong cooperation and a long-term Action plan at the European level. The recording is available [here](#).

UPCOMING EVENTS

10th Euratom Conference on Reactor Safety & 10th Euratom Conference Radioactive Waste Management

The Euratom Conferences FISA 2022 - EURADWASTE '22 organised by the French Presidency of the Council of the EU and the European Commission will take place from May 30, 2022, to June 3, 2022, in Lyon, France. The main objective of these high-level policy conferences is to present progress and key achievements of the Euratom research and training projects carried out since 2019 and to stimulate discussions on the state of play of Research and Innovations, key national, European and international challenges and opportunities, as well as exploring future perspectives. More information [here](#).

SAMIRA Conference

The European Commission is planning to organise a SAMIRA Conference in

June, taking stock of progress since the publication of the SAMIRA Action Plan and discussing future directions. All relevant stakeholders will be invited, and the event should cover the three pillars of the SAMIRA Action Plan: security of supply of medical radioisotopes, quality and safety of medical applications of ionising radiation, innovation and technological developments.

STATEMENT



"The EANM welcomes the European Parliament's vote recognising Nuclear Medicine as a fully independent medical speciality and recognising the significant contribution of Nuclear Medicine to the fight against cancer in Europe. We hope this will act as a significant boost to make Nuclear Medicine more accessible to all European patients".

Jolanta Kunikowska
EANM President 2021-2022



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