



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

INTERACT-EUROPE Project - Launch of an Inter-speciality Cancer Training Programme for Europe

The EANM is pleased to announce its participation in the INTERACT-EUROPE project (Innovative collaboration for Inter-specialty cancer training across Europe). INTERACT-EUROPE is an 18-month project funded by the European Commission through the EU4Health programme. Coordinated by the European Cancer Organisation (ECO), the project started in July 2022. As a flagship initiative of the Europe's Beating Cancer Plan, INTERACT-EUROPE brings together 33 partners from 17 countries and aims at developing a European inter-speciality cancer training programme involving all main oncology disciplines and professions, cancer centres and patient groups, based on relevant needs assessment. As a beneficiary, the EANM is part of Work Package 2 the tasks of which relate to the training needs assessment and curricula development.

More updates and details on INTERACT-EUROPE can be accessed [here](#).

QuADRANT Project - Final Outcomes & Conclusions on the Integration of Clinical Audits

The EANM, jointly with its partners, the European Society of Radiology (ESR) and the European Society for Radiotherapy and Oncology (ESTRO), is proud to announce that the **QuADRANT project has been successfully concluded**, with the acceptance of the final project deliverable by the European Commission.

The project, which had started in January 2020, aimed at promoting the **constant improvement in the quality and safety of radiology, radiotherapy and nuclear medicine through clinical audits**. After identifying good practices across Europe, the consortium has developed guidance and recommendations on improving the integration of clinical audits into national healthcare systems and has ultimately identified the potential for further coordinated EU action on quality and safety of radiology, radiotherapy and nuclear medicine.

Stay tuned for the upcoming publication of the Recommendations & Guidance from QuADRANT in the European Commission's Radiation Protection Series later this year.

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

Jointly with its partners, the European Institute for Biomedical Imaging Research (**EIBIR**) and the European Federation of Organisations for Medical Physics (**EFOMP**), the EANM is pleased to inform you that the first actions and activities under the SAMIRA study on the implementation of *EURATOM and the EU legal bases with respect to the therapeutic uses of radiopharmaceuticals* ("SIMPLERAD") have been conducted over the summer.

A **literature review** on the analysis of the interrelations between EU pharmaceutical legislation and Council Directive 2013/59/EURATOM has been finalised. In addition, a **survey** on the implementation of relevant European legal requirements for therapeutic nuclear medicine is in preparation and will be shared with external stakeholders in the coming weeks.

More information on the work packages and the consortium is available [here](#).

PUBLICATIONS & POSITIONING

Artificial Intelligence in Nuclear Medicine

Recently, nuclear medicine has experienced a growing interest in artificial intelligence (AI)-based applications since significant improvements are expected from AI technology for both nuclear medicine purposes: diagnostics and therapy. In parallel, the **European AI Strategy**, devoting itself to making the EU a world-class hub for AI and ensuring AI is human-centric and trustworthy, offers new promises to healthcare professionals on the uptake of AI tools in clinical practice. Taking that into consideration, the **EANM Working Group on AI prepared a position paper**, providing the EANM's view on the introduction of AI in the clinical field of nuclear medicine and the preconditions for its implementation while giving some insights on the European Artificial Intelligence Regulation.

Read the position paper [here](#).

EANM Position on ICH Analytical Procedures Guidelines

In the context of the review of the International Commission for Harmonisation's (ICH) Guidelines on Analytical Procedures (*Analytical Procedures Development and Validation of Analytical Procedures*), which opened for public consultation in July 2022, the EANM provided feedback, highlighting the specificities of radiopharmaceuticals in any regulatory framework.

The EANM pointed out that, while such guidelines represent a general and commonly accepted basis for the development and validation of analytical methods for most drug substances and products, **these guidance documents do not fully address all the specific tests required for the analysis of radiopharmaceuticals and the latter should**

therefore be excluded of the scope of the ICH analytical procedures guidelines. In this respect, in the past years, the **EANM, in cooperation with EDQM, developed a guideline on the validation of analytical methods for radiopharmaceuticals.**

EANM - EAU Consensus Paper on the Importance of Theranostic Approach for Prostate Cancer

As part of a long-lasting and fruitful collaboration between the EANM and the European Association of Urology (**EAU**) on prostate cancer, a consensus paper has been published on the role of PSMA-based imaging and [177Lu]Lu-PSMA therapy, highlighting that PSMA PET/CT must be performed in every patient who is a candidate for [177Lu]Lu-PSMA therapy. This consensus is a crucial milestone for nuclear medicine, **emphasising the need for imaging before therapy.** The article calls for the adoption of clinical guidelines on PSMA PET/CT as an imaging tool to guide [177Lu]Lu-PSMA therapy.

Read the consensus paper [here](#).

POLICY INITIATIVES & POLITICAL DEVELOPMENTS

SAMIRA Action Plan - Recent Activities

Published in February 2021 as a follow-up to the **Europe's Beating Cancer Plan**, and aspiring to ensure 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, especially for the first **pillar on the security of supply of medical radioisotopes.**

- Preparatory work towards the establishment of a **European Radioisotopes Valley Initiative** is in progress, including the upcoming establishment of an **ERVI Stakeholders Group.**
- In parallel, several **EU-funded projects** have started, such as **TOURR, PRISMAP** or **LEU-FOREver** with the aim of supporting the long-term sustainability of radioisotope production.
- In addition, a study on Safe and Sustainable Operation of Research Reactors in the EU, led by ENCONET Consulting, started in January 2022, with the goal of assessing **safety requirements for research reactors** in EU Member States.
- The **European Nuclear Safety Regulators Group** is currently reviewing approaches in the **regulation and management of radioactive waste** arising from non-energy uses of nuclear and radiation technologies, focusing on the management of radioactive waste coming from medical applications. A preliminary analysis should be available by the end of 2022.

Stay tuned for further updates on the SAMIRA Action Plan!

The European Radioisotopes Valley Initiative - Public Consultation Open

As part of the SAMIRA Action Plan's pillar on security of 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** and help accelerate the development and introduction of new radioisotopes and production methods.

To define further the objectives and scope of this initiative, the European Commission, with the support of NucAdvisor, has recently **launched a targeted consultation** to gather the positions of stakeholders on the ERVI objectives and the specific issues concerning the supply chain of medical radioisotopes.

The consultation is open until October 14, 2022. We invite all interested stakeholders to reply to the consultation [here](#). Upon request, the EANM will share further information and key elements of its own reply. Contact us at euaffairs@eanm.org to learn more.

The Review of the General Pharmaceutical Legislation - Update & Next Steps

The **EU's general pharmaceutical legislation** is currently being subject to a review by EU policymakers, with the **aim of ensuring a future-proof and crisis-resistant medicines regulatory system**. It is expected that the review will consider potential reform in a wide range of areas, including improving access to and affordability of medicines; ensuring security of supply of medicines; adapting the regulatory approach to account for 'novel products'. The anticipated proposals and amendments might have important impacts on radiopharmaceuticals' definition, sourcing, authorisations and procedures. The publication of the updated legislative proposal, which should follow a thorough impact assessment, was expected for December 2022. However, considering that the **European Commission Regulatory Scrutiny Board recently issued a negative opinion on the impact assessment, the publication of the legislation proposal might be delayed**.

The EANM Policy & Regulatory Affairs Committee is closely following the development of this initiative.

EVENTS

PAST EVENTS

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

On June 29, the EU Observatory for the Supply of Medical Radioisotopes held its 18th Plenary session. Striving to bring 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 were invited to share their views on the current status of radiopharmaceuticals' supply chains**.

Nuclear Medicine Europe (NMEU), the International Atomic Energy Agency (IAEA) as well as the Working Group on European Production of LEU gave updates on their recent activities and publications. In addition, the EANM has been pleased to see the commitment of MEP Bartosz Arlukowicz to ensure that Nuclear Medicine is available to all European citizens.

The EANM President, Jolanta Kunikowska, attended the event and provided an update on the EANM's activities and priorities.

UPCOMING EVENTS

35th Annual Congress of the European Association of Nuclear Medicine

Every year at its **annual scientific Congress**, the EANM features plenary lectures, free paper sessions, symposia and debates on the most relevant advances in nuclear medicine, attracting approx. 7000 delegates from all over the world. This year, the EANM would like to leverage the momentum of the SAMIRA Action Plan implementation to discuss radiopharmaceuticals' preparation as well as related regulatory issues in daily clinical practice and in basic and clinical research. **You might want to join us for two EU-related sessions: 'Radiopharmaceuticals Regulations: Quo Vadis?' & 'Getting to the top QuADRANT. A European initiative to improve quality for patients'**.

European Cancer Summit

Every year, at the **European Cancer Summit**, the European Cancer Organisation (E.C.O.) brings together leading oncology experts, experienced patient advocates, key opinion leaders, policy makers and politicians to discuss key issues in reducing the burden of cancer, saving, and improving the lives of patients and the public.

This year's **European Cancer Summit on November 16-17 will focus on the implementation of Europe's Beating Cancer Plan and the EU Cancer Mission's recommendations**.

Representatives from the EANM Board will join live in Brussels. Interested participants can still register [here](#) - virtual participation is possible.

STATEMENT



'There are high expectations towards the European Radioisotopes Valley Initiative: the current European research reactors fleet is not sufficient to meet the future increasing demand for radiopharmaceuticals, and full dependence on external partners could become critical in the future.

If implemented successfully, and provided that all relevant partners are involved, ERVI might have the potential to create new synergies towards a common objective: securing the supply of radioisotopes and making radiopharmaceuticals accessible & affordable for all patients across Europe'.

Professor Wim Oyen,
Chair of the
EANM Policy & Regulatory Affairs
Committee



European Association of Nuclear Medicine | Schmalzhofgasse 26 | 1060 Vienna | AUSTRIA

Phone: +43 1 890 44 27 | Fax: +43 1 890 44 27-9 | M: office@eanm.org

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