



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](#).

Enjoy reading!

COOPERATION & COMMUNITY INVOLVEMENT

INTERACT: Learnings and Recommendations on Pioneering Inter-Specialty Cancer Training in Europe

In the context of the EANM's involvement in the INTERACT project focusing on **the development of an 'European Inter-Specialty Cancer Training Programme Curriculum'**, the final curriculum was recently published and can be accessed [here](#).

The curriculum, developed collaboratively with key oncology disciplines, cancer centres, and patient groups, aims to promote patient-centred, quality cancer care through interdisciplinary teamwork.

Following the completion of INTERACT 1, EANM will engage in **INTERACT 2**, a project supporting the second phase of this inter-specialty cancer training program led by the European Cancer Organisation. Starting in December 2023, this project seeks to position Europe as a global leader in multidisciplinary cancer care through the implementation of a technology-enabled training program. EANM will collaborate with 38 organizations across 16 countries to support various aspects of the project.

Furthermore, a **one-day INTERACT Showcase event** will be held **on November 17 at the Radisson Collection Hotel Brussels** as part of the European Cancer Summit. **Online participation** is also possible. Register [here](#).

ERASMUS+: Building a Radioligand Therapy Academy

As part of a pan-European consortium managed by the RPP Agency, the EANM is joining forces in the Erasmus+ grant to **build a Radioligand Therapy (RLT) Academy**. This initiative is a **first-of-its-kind European-level training opportunity**. In the past months, the EANM has co-shaped the academy with its consortium partners, mainly focusing on developing training curricula and material on radioligand therapies.

It is expected that the training material will respect the differences between the various target groups in such a way that the different levels of training (medical doctors, nurses and technicians, medical physicists), clinical experience (board certified attendings, residents, medical students), and previous exposure to nuclear medicine and RLT (minimal vs. high-level

knowledge on RLT) are taken into consideration.

While the curriculum is currently being formed, we invite you to learn more about the Radioligand Therapy Academy thanks to [this overview](#).

Take Advantage of New Funding Opportunities!

The **Innovative Health Initiative** (IHI) has recently launched new calls for proposals. IHI is a partnership between the EU and Europe's health industries, with funding standing at nearly EUR 200 million, coming from **Horizon Europe**, the EU's research and innovation programme.

The EANM wants to draw the nuclear medicine community's attention to the following call: **'Development and proof of principle of new clinical applications of theranostics solutions'**.

The project(s) funded under this topic are expected to cover all the following objectives:

- Developing innovative theranostic solutions and considering conducting early phase clinical trial(s) as proof of concept(s) to demonstrate the added value of the proposed theranostic solutions for patients.
- Facilitating the development of tools to increase European theranostic manufacturing capabilities and treatment capacities, including guidance on quality assurance and improving logistics of supply at the EU level.
- Producing education and training materials on the deployment of multi-modal theranostic solutions and their integration in clinical settings, including recommendations for the organisation and composition of disease-specific medical expert boards.

Find out more [here](#).

Should your organisation be interested in this project, please do not hesitate to reach out to us via euaffairs@eanm.org. We would be very happy to connect you with other potential partners.

PUBLICATIONS & POSITIONING

The European Association of Nuclear Medicine's Statement on Animal Testing in the EU – The Potential Adverse Effect of a Ban on Biomedical Research

Over the summer, the EANM reacted to a recent European Citizens' Initiative aiming at banning animal testing in the EU. Our experts looked at the adverse effects this would have on biomedical research and the availability of radiopharmaceuticals.

Main take-aways include:

- A ban on animal testing would not only threaten the European Union's leading role in the development of medical diagnostics and treatments opportunities, but it would also have a significant impact on future diagnostic and therapeutic options for EU patients.
- Despite the progressive development of alternative methods, the current state of the art of non-animal models does not yet provide the same level of insights as animal studies. Animal experiments for biological and medical research will remain necessary in the foreseeable future.
- The nuclear medicine community therefore urges EU policymakers not to support a full and immediate ban on Animal Testing. Instead, **the EANM advocates for a more gradual approach towards reducing animal experiments when scientifically viable.**

Read the EANM position statement [here](#).

The QuADRANT Study: Current Status and Recommendations for Improving Uptake and

Implementation of Clinical Audit of Medical Radiological Procedures in Europe - The Nuclear Medicine Perspective

Check out the article about the QuADRANT Study that was recently published!

The article showcases the QuADRANT project, an extensive study aimed at enhancing clinical audits in nuclear medicine. The project aimed to assess the current state of clinical audit implementation in the EU27+4, identifying best practices and available resources. The project also sought to guide the improvement and integration of clinical audits into national healthcare systems.

The article underscores the potential for increased coordinated EU action to enhance the quality and safety of radiology, radiotherapy, and nuclear medicine. Key points highlighted include:

- The necessity for increased dedication to regulatory inspections that encompass clinical audits, affecting all clinical fields and specialties associated with patient exposure to ionising radiation.
- Another significant aspect is the integration of clinical audit processes, as outlined in the BSSD, within the broader framework of clinical audits, considering governance structures and resource allocation.

Read the article [here](#).

POLICY INITIATIVES & POLITICAL DEVELOPMENTS

Revision of the European Pharmaceutical Legislation - A Milestone for the Pharmaceutical Sector

Earlier this year, the European Commission published the long-awaited revision of the European Pharmaceutical Legislation, which is in the process of being revised for the first time in twenty years.

This proposal has the potential to significantly impact medical products regulations in the EU. It aims to ensure timely access to safe medicines for all EU patients and to enhance the attractiveness of the EU pharmaceutical industry. It also introduces provisions on **regulatory protection, pharmacy and hospital exemptions, environmental risk assessments and regulatory sandboxes**.

The EANM welcomes this revision, which is more adapted to the evolving field of nuclear medicine. Over the summer, the EANM Policy & Regulatory Affairs Committee (PRAC) further analysed the European Commission's proposal and identified the needed provisions to advocate for **a supportive regulatory environment for nuclear medicine**.

The EANM has identified 8 priorities to ensure that the needs of the nuclear medicine community are well considered within the revised Directive.

1. A supportive regulatory framework is crucial for the field of nuclear medicine. The EANM calls for a **reduction in regulatory burden for small-scale production, improved security of supply for radiopharmaceuticals**, and concerted action to support and train healthcare professionals.
2. The EANM encourages health authorities to **invest in in-house production services**, including compounding services and the preparation of radiopharmaceuticals.
3. Small-scale in-house preparation of radiopharmaceuticals deserves strong support across the EU. The EANM advocates for a **specific regulatory approach to address the differences between commercial and non-commercial production**, ensuring safe and effective practices.
4. **To combat radionuclide shortages**, the EANM emphasises the need for improved information exchange between authorities and supply chain actors.
5. The discrepancy between the EU Pharmaceutical Legislation and

Euratom radiation protection rules is causing uncertainties and liability issues. The EANM calls for the reconciliation of medicinal products and radioprotection regulations to facilitate the market access of radiopharmaceuticals.

6. With significant advancements in the field of nuclear medicine since 2000, it is necessary to **update definitions of radiopharmaceuticals, kits, and generators**. Keeping these definitions aligned with current practices will ensure the availability of novel radiopharmaceuticals.
7. The EANM highlights the **need for a limited demand for marketing authorisations within radiopharmacies**. Strict limitations should apply to starting materials and radionuclide precursors used in kit procedures, rather than complex radiopharmaceutical preparations.
8. The current Good Manufacturing Practice (GMP) rules present challenges for compliance and hinder innovation in clinical settings. The EANM advocates for a **relaxation of GMP requirements for investigational medicinal products, including in-house diagnostic radiopharmaceuticals**.

This publication initiates a new stage of debates, meaning that the European Parliament can now make substantial amendments to the European Commission's proposal. Furthermore, this is an opportunity for all stakeholders, including the EANM, to influence the proposal ahead of the final vote. In the coming weeks, the EANM will continue its advocacy efforts together with partners to ensure that the voice of the nuclear medicine community is well represented within the discussions on the Reform of the EU Pharmaceutical Legislation.

While the EANM is currently finalising its positioning, we encourage you to read the EANM previous **policy statement** on the revision of the European Pharmaceutical Legislation.

EVENTS

UPCOMING EVENTS

9th Annual World Cancer Series Europe

'The Economist Impact's 9th Annual World Cancer Series: Europe' will be taking place in Brussels on September 20-21.

The two-day summit will feature over 90 speakers and welcome an audience representing policymakers, healthcare providers, industry leaders, academics, patient groups and investors.

The 2023 agenda builds on last year's themes of innovation – equity and excellence – which lie at the heart of **Europe's Beating Cancer Plan**.

As the plan is put into action, it is essential to assess how the state of cancer care in the region corresponds to the initial objectives. During the summit, participants will highlight what has been achieved and will pinpoint areas that require further focus and improvement.

More information on the event and the registration process can be found [here](#).

European Commission Workshop - Competences for Medical Applications of Nuclear Science

The 2nd Stakeholders' Consultation Workshop, titled 'Competences for Medical Applications of Nuclear Science', jointly organised by the Joint Research Centre (JRC) and the European Nuclear Education Network (ENEN), will take place **on October 24 at the European Commission's JRC site in Petten, The Netherlands**. This workshop will be conducted as a hybrid event, **enabling both in-person and online participation**.

The primary focus of this workshop lies in **defining the crucial nuclear competences and skills required to ensure the long-term sustainability of medical applications involving nuclear science**. These specific competences and a skilled workforce are essential in guaranteeing the continuous availability of medical radionuclides across

their entire lifecycle, spanning research, production, and clinical utilisation.

Read more about the event and the registration process [here](#).

European Commission Workshop - Research and Innovation for Sustainable Medical Radionuclide Supply in the EU

The third stakeholder consultation workshop on '**Research and Innovation for Sustainable Medical Radionuclide Supply in the EU**', organised by the Joint Research Centre (JRC) together with the Euratom Supply Agency (ESA), will take place at the European Commission's JRC site **in Karlsruhe, Germany, on November 22, 2023**. The workshop will be held as a hybrid event (both onsite and online participation are possible).

The workshop will focus on research and innovation and their importance in medical radionuclide applications, crucial for the sustainability of supply, equal access and quality/safety in the use of radiopharmaceuticals in the EU. It will highlight the role of infrastructures and innovation in enabling breakthroughs in nuclear science for health applications.

European Cancer Summit

Every year, at the **European Cancer Summit**, the **European Cancer Organisation** brings together leading oncology experts, experienced patient advocates, key opinion leaders, policymakers and politicians to engage in vital discussions on mitigating the cancer burden and enhancing the well-being of patients and the broader community.

This year, the European Cancer Summit will focus on the implementation of **Europe's Beating Cancer Plan** and is titled '**Accelerating Momentum: A manifesto to 2030**'. The event will take place **on November 15-16**.

Representatives from the EANM Board will be joining in Brussels. Interested participants can still register [here](#) (online participation is possible).

SIMPLERAD Workshop

On December 11-12, the SIMPLERAD tender project, jointly facilitated by the EANM, EIBIR and EFOMP, will hold a **workshop in Brussels, Belgium**.

The event will focus on presenting the SIMPLERAD project and its results. The workshop comes near the conclusion of the SIMPLERAD project, providing an opportunity to present the consortium's achievements since its launch in May 2022. Since then, the SIMPLERAD team has gathered insightful information and data on the regulatory frameworks in several EU and non-member countries to understand and compare the legal requirements for authorisation of radiopharmaceuticals and practice of therapeutic nuclear medicine.

The workshop will bring together essential stakeholders of the consortium, including its Advisory Board, the Article 31 Working Party on Medical Exposures (WP MED), the SAMIRA Steering Group on Quality and Safety (SGQS), along with regulatory authorities, medical professionals, and patient advocacy groups.

Check out [the programme](#) and [the SIMPLERAD website](#) to get more information about the event.

PAST EVENTS

EANM'23 - 36th Annual Congress of the EANM



Thank you to all the participants who joined the two EU-related policy sessions at the EANM'23, which were titled **'EU Policy Symposium on Supply & Shortages of Radiopharmaceuticals'** and **'EU Policy Symposium on Regulatory Challenges of Radiopharmaceuticals'**. Their valuable insights on harnessing the SAMIRA Action Plan's momentum for discussions on radiopharmaceuticals' production and associated regulatory matters in both clinical practice and research were truly enlightening.

Stay tuned for the publication of the Action Report from both sessions.

STATEMENT



"The EANM Board and the EANM Policy & Regulatory Affairs Committee are extremely pleased to witness the attention that Nuclear Medicine is getting at the EU level. 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. We are very much looking forward to all the events taking place this fall to discuss with partners how to ensure that nuclear technologies continue to benefit the health of EU citizens and contribute to the fight against cancer and other diseases."

Michel Koole,
EANM Scientific Liaison Officer 2023-
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