THE EANM POLICY BULLETIN

SHAPING THE FUTURE OF NUCLEAR MEDICINE IN EUROPE TOGETHER

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**
- **Policy 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

SIMPLERAD – Seeking Consensus on the Project Recommendations

Last December, the **EANM**, in collaboration with the **European Institute for Biomedical Imaging Research (EIBIR)** and the **European Federation Of Organizations For Medical Physics (EFOMP)**, organised a project workshop in Brussels, Belgium.

The event marked the **highlights of the consortium's efforts** since the project was launched back in May 2022. **Literature reviews, research, surveys, and expert interviews** were conducted to delve into the legal requirements regarding the use of radiopharmaceuticals and the practice of therapeutic nuclear medicine across various EU and non-EU countries. The overarching aim was to use this data to **provide clear recommendations concerning therapeutic radiopharmaceuticals** within the European Union.

Key stakeholders, regulatory authorities, medical professionals, EU and international representatives, industry experts, and patient advocates participated in the workshop and **shared their insights** on the proposed recommendations. Their feedback will play a pivotal role in refining the consortium's guidance.

In the upcoming weeks, the content presented at the workshop will be made available on the **SIMPLERAD** website. **Stay tuned for further updates!**

New Project — SAMIRA Study on the Definition of Key Performance Indicators on Quality and Safety of Medical Applications of Ionising Radiation

Over the coming years, and jointly with Technopolis, the European Society of Radiology (ESR) and the European Society for Radiotherapy and Oncology (ESTRO), the EANM will be working on a new tender study.

This **tender intends to support** the European SAMIRA actions in the area of **quality and safety** of medical applications of **ionising radiation**. Ultimately, this project aims at supporting the implementation of high standards regarding the quality and safety of medical radiation applications into the EU Member States' health systems.

Experts will focus on developing a common set of indicators that provide a quantitative and/or qualitative indication of the effects and the practical aspects of implementation of the relevant Basic Safety Standards Directive (BSSD; Council Directive 2013/59/Euratom) requirements in the Member States. They should further enable monitoring the evolution over time in the respective areas of the Directive, identifying gaps and areas of improvement where additional implementation support might be needed at the national level and/or the EU-level.

You can expect to receive further information on any relevant developments via this newsletter!

EU4Health & EURATOM — Take Advantage of New Funding Opportunities!

Last December, the European Commission adopted the **2024 annual work programme** of **EU4Health**, which is the main EU financial support in the health sector. This followed the publication of the **Euratom Work Programme 2023-2025** last October. These two funding programmes represent **important funding streams** for **medical applications of ionising radiation**.

The EANM encourages its community to monitor the **two following funding calls** for 2024, which will support the implementation of the SAMIRA Action Plan:

1. Call for proposals on radiation safety and quality of computed tomography imaging of children, adolescents and young adults.
2. Call for proposals on safety of low enriched fuel for research reactors - securing the supply of medical radioisotopes.

No information about these two calls have been shared yet. The EANM will make sure to keep its community informed once more instructions are received.
Stay tuned!

PUBLICATIONS

The Revision of the Pharmaceutical Legislation — It Is Time to Act for Nuclear Medicine in Europe

The revision of the EU Pharmaceutical Legislation has the potential to substantially modify the way radiopharmaceuticals are prepared and delivered in the decades to come. As a result, the EANM underwent significant advocacy efforts to **bring nuclear medicine to the attention of EU decision-makers**.

The EANM Policy & Regulatory Affairs Committee (PRAC) summarised these efforts and the EANM's viewpoint in an editorial.

Read Now

The EANM & NMEU Join Forces on the Revision of the EU Pharmaceutical Legislation

Throughout the past months, the EANM and Nuclear Medicine Europe (NMEU) joined **forces to identify** the specific aspects of the revised EU Pharmaceutical Legislation that might affect the nuclear medicine community.

The **EANM and NMEU** applaud the proposed revision. Specifically, they praise it for crafting a regulatory framework that does not only support current practices but also fosters innovation. To support harmonisation across the EU, both organisations highlighted the need to:

- **Adapt definitions** so that they reflect today's nuclear medicine and radiopharmacy practices.
- **Develop** specific considerations for **industrial and in-house production of radiopharmaceuticals** required for the innovations of the field aiming towards harmonisation, strengthening access and alignment with existing regulations.
- **Clarify** the relation of the **Basic Safety Standards Directive** and the **EU Pharmaceutical Legislation**.

For more insights, please **read the full EANM/NMEU statement here**.

The Revision of the European Medicines Agency's Guidelines Related to Radiopharmaceuticals

The **European Medicines Agency (EMA)** is in the process of revising its **Guidelines on Radiopharmaceuticals**, which were last updated in 2008. With significant advancements and innovations in Radiopharmaceuticals over the past 16 years, an update has been much needed.

This revision aims to:

- **Provide** further **clarity** on issues that have led to non-harmonised interpretations.
- **Address topics** that were inadequately covered or detailed in the current guidelines.
- **Offer guidance** on emerging issues resulting from recent developments and evolving practices.

A consultation process took place, open to all the stakeholders who wished to share their **input and feedback with the EMA**. The EANM replied to the consultation on the Concept Paper on the revision on the Guideline on Radiopharmaceuticals (**the EANM's reply is available here**) and on the Concept Paper on the revision of the Guideline on Radiopharmaceuticals based on Monoclonal antibodies (**consult the EANM's reply here**).

More detailed consultations on the revision will take place in 2024, once the first drafts of the new guidelines will be made available.

POLICY DEVELOPMENTS

An EU Health Data Space to Boost Access to Data and Research

Last December, the European Parliament shared its position on creating a **European Health Data Space** to ease access to personal health data and boost secure sharing.

The new European Health Data Space (EHDS) would **empower citizens to control their personal healthcare data** and facilitate **secure sharing for research** and altruistic (i.e. not-for-profit) purposes.

- **Better healthcare with portability rights**:
  The law would give patients the right to access their personal health data across the EU's different healthcare systems (so-called 'primary use'). It would also allow health professionals to access their patients' data, strictly based on what is necessary for a given treatment. Summaries, electronic prescriptions, medical imagery and laboratory results would be accessible. Each country would establish national health data access services. The law would also set out rules on the quality and security of data for providers of Electronic Health Records (EHR) systems in the EU, to be monitored by national market surveillance authorities.
- **Data-sharing for the common good with safeguards:**
  The EHDS would allow aggregated health data, including on pathogens, health claims and reimbursements, genetic data and public health registry information, to be shared for public interest reasons, including research, innovation, policymaking, education and patient safety purposes (so-called 'secondary use'). Sharing data for advertising or for assessing insurance requests would be banned.
- **Stronger safeguards for sensitive data:**
  The European Parliament wants EU patients to have more say in how healthcare providers use their data. They propose an opt-out system for the secondary use of most health data, and demand that it be mandatory to have a patient's explicit consent for the secondary use of certain sensitive data (e.g.,

genetic and genomic information). The EP also aims to expand the secondary uses to be banned, for example in the labour market or for financial services.

Explore More

EVENTS

UPCOMING EVENTS

Participate in ‘Europe’s Beating Cancer Plan: Joining Forces’!

Turning the tide on cancer is one of the main priorities of the European Commission in the health domain. Three years after the publication of **Europe’s Beating Cancer Plan**, **Stella Kyriakides**, European Commissioner for Health and Food Safety, will **host a high-level event on Wednesday 31 January 2024** to take stock of the EU’s efforts to improve the lives of everyone affected by cancer and to take the lead in the fight against this disease.

Register for the event **here**.

PAST EVENTS

European Commission’s Workshop on Competences for Medical Applications of Nuclear Science

The second 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)**, took place on October 24 at the European Commission's JRC site in Petten, The Netherlands.

The primary focus of this workshop was to **define the crucial nuclear competences and skills** required to ensure the **long-term sustainability of medical applications** involving nuclear science. Panellists agreed that 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.

A detailed publication will be disseminated in due time. We will make sure to share it with you in our future editions of the EANM Policy Bulletin.

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)**, took place at the European Commission's JRC site in Karlsruhe, Germany, on November 22, 2023.

The **workshop focused 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**. Panellists highlighted the role of infrastructures and innovation in enabling breakthroughs in nuclear science for health applications.

Once finalised, we will share the workshop's publication with you.

A Busy Fall Full of Policy Events

Last fall, the EANM carved a significant presence in high-stakes policy events across the EU, engaging in discussions on nuclear proficiencies, the radioisotope supply chain, and the integral role of nuclear medicine in the fight against cancer.

- Our busy fall started in Brussels with **Nuclear Medicine Europe (NMEU)'s Symposium**, which took place in the European Parliament. The NMEU Symposium focused on the strengths that **nuclear medicine adds to the Europe's Beating Cancer Plan.** Featuring special guests such as members of the European Parliament and officials from the European Commission, a diverse panel of high-level experts underscored the importance of nuclear medicine for cancer care, highlighted the various challenges the nuclear medicine community meets, and discussed how harmonising legislation at the European level could significantly improve patient care.

- In Amsterdam, the EANM engaged in the **European Medicines Agency (EMA)'s Patients, Consumers, and Healthcare Professionals meeting**. This event provided an invaluable opportunity to delve into the EMA's activities focusing on regulatory science and innovation. Additionally, it allowed the EANM to gain insights into the endeavours of other professional societies across Europe. Many topics relevant to nuclear medicine were on the agenda, including availability of medicines, HTA, shortages, and digitalisation.

- In Luxembourg City, the EANM was invited by the **European Commission** and **NucAdvisor** to a workshop, to discuss the outcomes of the tender study on the **Implementation of Council Directive 2013/59/Euratom Supply Agency**

Requirements (BSSD) for Medical Equipment for Monitoring Patient's Radiation Exposures. This was a very engaging session, that fostered discussions on radiation dose monitoring in nuclear medicine.

- Lastly, in Brussels again, the EANM participated in the **European Cancer Organisation (ECO)'s Summit**. This forum united academia, patients, healthcare professionals, policymakers, and industry leaders to address pressing onco-policy issues such as workforce shortages, digital health, and survivorship. The summit also introduced the recently published the European Cancer Manifesto for 2024, titled **'Time to Accelerate: Together Against Cancer'.**

STATEMENT

"2023 was a landmark for the EANM in amplifying its EU advocacy efforts. The Board would like to use this year's last edition of the EANM Policy Bulletin to provide a snapshot of our milestones.

While we have carved a significant presence in high-stakes policy events across the EU, engaging in discussions on nuclear proficiencies, the radioisotope supply chain, and the integral role of nuclear medicine in the fight against cancer with relevant partners, we also actively shaped the revision of the EU Pharma Legislation, ensuring that the newly developed framework considers the specificities of radiopharmaceuticals and ensures that all patients across the EU have access to nuclear medicine procedures. The EANM also bolstered its participation in EU projects and tenders, joining forces with partners to drive advancements in the cancer workforce, education, and regulatory guidelines.

We look forward to continuing strengthening the EANM's policy and regulatory activities in 2024!"

Michel Koole,
EANM Scientific Liaison Officer 2023–2024

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