Welcome to the EANM Policy Bulletin!

This newsletter provides you with an overview of policy updates related to nuclear medicine, hand-picked by the EANM just for you. Read below about:

- Cooperation & Community Involvement
- Publications & Positioning
- Policy Initiatives & Political Developments
- Events
- Statement

Should you wish to bring any questions, feedback or inquiries forward, please contact the EANM via <u>e-mail</u>.

Enjoy reading!

COOPERATION & COMMUNITY INVOLVEMENT

Take Advantage of New Funding Opportunities

We would like to draw your attention to the following opportunities:

- The European Commission Directorate for Energy recently announced a new call for tenders under the SAMIRA Action Plan. The SAMIRA study on Criteria for Acceptability of Medical Radiological Equipment will review and revise the publication titled Radiation Protection 162 (RP 162), which was published in 2012. The revised guidance will define essential parameters that will be used to assess the performance of radiological medical equipment. It will also set up updated criteria to determine the acceptability of this equipment, taking into consideration the most recent technological developments and the new standards and requirements that have been set since the publication of RP 162. Find out more here.
- An EU4Health call on radiation safety and quality of computed tomography imaging of children, adolescents and young adults will be launched in the fall. The aim of the call is to enhance the quality and radiation safety of medical applications of ionising radiation in children, adolescents and young adults. The follow-up actions that will be implemented will focus on computed tomography procedures in children and young adults and will aim to reduce the associated risk of adverse secondary effects (i.e., brain and other types of cancer).

For more information, please contact us at euaffairs@eanm.org.

In February 2022, the EU-funded <u>MEDIRAD</u> project was finalised. Its overall aim was to enhance the scientific basis and clinical practice of radiation protection in medicine, by further understanding and evaluating the health effects of exposure to low-dose ionising radiation resulting from diagnostic and therapeutic procedures.

As part of MEDIRAD, a first large-scale survey was conducted in 2019 to gather information on the status and current use of multimodality imaging in nuclear medicine. As part of a follow-up study, a new survey has recently been developed. The most relevant questions included in the original survey have been reused to detect potential evolutions in the use of CT in nuclear medicine between 2019 and 2024.

Please participate in <u>the new survey</u>, which should take only 5 to 10 minutes! At the end of the survey, you will be able to download the results of the original survey.

READ MORE

PUBLICATIONS

EANM-NMEU Joint Communication on the Revision of the European Pharmaceutical Legislation

In a new policy statement released in April, the EANM and Nuclear Medicine Europe (NMEU) expressed their disappointment over the European Parliament's recent vote on the Pharmaceutical Regulation and Directive. The vote overlooked the proposed amendments covering radiopharmaceuticals, which would have engendered significant advancements since the last update of the Pharmaceutical Legislation back in 2004.

The EANM and NMEU, representing both clinical/academic and industry interests, fear that the current regulatory framework will hinder the EU's progress in radiopharmaceuticals. Despite the EU's recognition of nuclear medicine's pivotal role, especially in cancer care, the regulatory acknowledgment is still lacking. The revision of the European Pharmaceutical Legislation represents a generational opportunity to establish a regulatory framework that fosters the integration of nuclear medicine into mainstream healthcare. However, the great technological advancements in radiopharmaceuticals have not yet been acknowledged.

In this respect, the EANM and NMEU urge policymakers to reconsider radiopharmaceutical developments and ensure that the updated regulatory framework will unlock the promises of nuclear medicine, improving patient care for EU patients. Now that the dossier is shifting to the Council of the EU, the EANM remains firmly committed to maintaining dialogue.

EANM-NMEU POSITION PAPER

Must Reads from the EU Health Arena

This spring has been particularly valuable for publications from EU institutions, putting nuclear medicine at the forefront. Here are some key highlights:

Newly adopted opinion on Europe's Beating Cancer Plan

This comprehensive opinion from the European Economic and Social Committee (EESC) recognises the importance of nuclear medicine in the fight against cancer. It also showcases the EU's strong political commitment to ensuring access to crucial medical radioisotopes for all patients. It calls for prioritising funding for medical radiological and nuclear technologies, encouraging production incentives for better strategic autonomy in radioisotope supply, monitoring supply closely, and supporting industrial competitiveness.

LEARN MORE

EU Commission Recommendation on clinical audits of medical radiological practices

This recommendation outlines specific measures and best practices for establishing and maintaining national audit systems in radiology, radiotherapy, and nuclear medicine, aiming at helping EU countries comply with the EU Basic Safety Standards Directive on radiation protection.

READ MORE

Report by the Joint Research Centre (JRC)

The JRC released a report following the October 2023 workshop on competencies for medical applications of nuclear science. The report highlights the need for coordinated EU-level efforts in nuclear education and training for health professionals. It recommends creating an EU network of training institutions and encourages collaboration among education providers.

Additionally, the report calls for regulators in pharmaceutical and nuclear fields to discuss their overlapping mandates and endorses an EU-level accreditation model for radiation protection education and training.

CHECK THE REPORT

Publication on Medical Applications of Ionising Radiation

As a major outcome of the EURAMED Roc'N'Roll Project, the European Commission released a publication titled 'Medical Applications of Ionising Radiation for Better Patients' Lives: A European Research Roadmap'.

Based on a patient-centric approach, this roadmap presents 8 potential breakthroughs that may significantly impact medical applications of ionising radiation. The aim of this roadmap is to provide guidance to EU policymakers, funders, and the scientific and clinical communities regarding priority research, infrastructure development, and education and training actions.

ACCESS IT NOW

Ensuring a Flexible Framework for Radiopharmaceuticals

The EANM recently had the honour of visiting the European Commission and engaging with the cabinet of Stella Kyriakides - the current European Commissioner for Health and Food Safety.

The discussion focused on enhancing patients' access to nuclear medicine services across the EU, including ensuring a flexible regulatory framework for radiopharmaceuticals and securing a stable supply of radiopharmaceuticals.

We also delved into Europe's Beating Cancer Plan, the revision of the EU Pharmaceutical Legislation and the <u>SAMIRA Action Plan</u>, emphasising the transformative potential of nuclear medicine in treating cancer and other diseases.

We hope that this pivotal meeting will contribute to bringing the point of view of the nuclear medicine community into high-level policy discussions on the EU Pharmaceutical Legislation.



Council Conclusions on Radioisotopes for Medical Use

The new EU Council Conclusions on medical radioisotopes highlight the need for a reliable supply and European autonomy, marking a significant step forward regarding the EU's political commitment to nuclear medicine!

This important commitment from the Council of the EU is the result of Belgium prioritising the security of the EU's medical radioisotopes supply during its Council presidency.

The Council Conclusions urge the Commission to:

• Maintain Europe's leadership in the supply of medical radioisotopes.

- Develop mechanisms to monitor and forecast demand and supply.
- Support research and innovation.
- · Assess the transportation of medical radioisotopes.

Additionally, it calls on the European Medicines Regulatory Network 'to assess, according to existing methodology, the criticality of the radiopharmaceuticals authorised in Europe'.

Furthermore, the Conclusions stress the need for a better interaction between the EU's legal frameworks, particularly those concerning pharmaceuticals and radiation protection.

COUNCIL CONCLUSIONS

EVENTS

PAST EVENTS

Inaugural Meeting of the Critical Medicines Alliance

The Critical Medicines Alliance is a consultative mechanism established by the European Commission. It brings together all relevant stakeholders, to identify priorities for action and to propose solutions to strengthen the supply of critical medicines in the EU, thus preventing and combatting their shortages.

The inaugural event was the perfect opportunity to formally launch the Critical Medicines Alliance and exchanged with all members on its objectives, challenges, and expected outcomes. As a member of the Critical Medicines Alliance, the EANM proudly joined the event on April 25, 2024.

READ MORE

UPCOMING EVENTS

EANM'24 – 37th edition of the EANM Annual Congress

Every year, the EANM Annual Congress features plenary lectures, free paper sessions, symposia and debates on the most relevant advances in nuclear medicine, attracting about 7,000 participants 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.

SAVE THE DATE! Join us in Hamburg on October 22, 2024, for our two EU Policy Symposia titled:

- 'Bridging the Basic Safety Standards Navigating Legal Complexity in Member States'
- 2. Empowering Tomorrow the Nuclear Medicine Community Strategic Role within EU Projects & Tenders on Workforce'.



"Over the past months, the EANM has been delighted to notice increased attention from European policymakers towards the nuclear medicine specialty, particularly their strong political commitment to securing the supply of medical radioisotopes. This commitment is evident in the Union List of Critical Medicines, the Council Conclusions on Radioisotopes for Medical Use, and the European Economic & Social Committee's opinion on the security of medical radioisotope supply. We have seen a collective willingness to identify innovative actions that support access to crucial nuclear medicine services for patients across Europe. Now, it is time to implement these initiatives. As always, the EANM remains dedicated and eager to cooperate."

Michel Koole
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