



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

SIMPLERAD - EU Legal Bases With Respect to the Therapeutic Uses of Radiopharmaceuticals

The SIMPLERAD project, jointly facilitated by EANM, the European Institute for Biomedical Imaging Research (EIBIR) and the European Federation of Organisations for Medical Physics (EFOMP), is currently in the process of developing **policy recommendations and guidance to advance the coherent implementation of European legal requirements for therapeutic nuclear medicine**. This work is based on the results from the survey performed over the autumn seeking to gather information on such topics as radiopharmacy, treatment optimisation and verification, dose constraints, patient release and waste management. Issues to be covered by these upcoming recommendations include the need for European guidance for implementing the Basic Safety Standards Directive and the lack of consideration in EMA guidance regarding marketing authorisations for items pertaining specifically to the safety of therapeutic radiopharmaceuticals.

INTERACT-EUROPE - A Cancer Training Programme for Europe

In the context of the EANM's involvement in the INTERACT project focusing on the **development of an inter-speciality cancer training programme across Europe**, the EANM participated in January in an INTERACT-Europe Healthcare professionals Workshop aiming at finalising the Training Needs Assessment and Curricula Development of the project. Indeed, based on a study conducted to assess training needs, the consortium, involving all main oncology disciplines and professions, is advancing the building blocks of such a curriculum. The EANM has shared specific input related to Nuclear Medicine training needs to ensure that Nuclear Medicine is well represented within the final curriculum.

SAMILERA Study - Incidents and Near Misses

New year, new project. The European Institute for Biomedical Imaging Research (EIBIR), together with the European Society Radiation Oncology (ESTRO) and the European Federation of Organisations for Medical Physics (EFOMP), has been granted the **SAMIRA Study on Reporting and Learning from Patient-related Incidents and Near Misses in Radiotherapy, Interventional Cardiology, Nuclear Medicine and Diagnostic Radiology**. The project officially started in February 2023 and will contribute to the overall SAMIRA objective of supporting the implementation of high standards for the quality and safety of medical

EURATOM Research & Training Programme - New Calls

Stay tuned for the publication of the EURATOM Work Programme 2023-2024 in the coming weeks! This programme complements Horizon Europe, using the same instruments and rules for participation, covering the area of nuclear research and training. It focuses on Fusion, nuclear safety, radiation protection and radioactive waste management and decommissioning. It is expected that the Work Programme 2023-2024 will have a **specific focus on medical applications**, with calls' deadline over the autumn.

PUBLICATIONS & POSITIONING

Supply of Medical Radioisotopes - Results of the Consultation on European Radioisotope Valley Initiative

The European Commission has started a process towards establishing a European Radioisotope Valley Initiative (ERVI) to **maintain Europe's global leadership in the supply of medical radioisotopes** and help accelerate the development and introduction of new radioisotopes and production methods. Between August and October 2022, the Commission carried out a **consultation to gather the positions of stakeholders**, including EANM, on the ERVI objectives and the specific issues concerning the supply chain of medical radioisotopes in order to **define a concrete roadmap for the ERVI initiative**, focusing on actions in which the EU can have decisive added value.

The results are presented in a **report** published in January 2023.

Over the next few years, the Commission will engage with stakeholders and launch feasibility studies before considering a legal framework for this initiative.

Reducing Bureaucracy in Clinical Trials

Together with partner organisations, including the European Hematology Association, the European Cancer Organisation, and the European Association of Urology, the EANM is part of this broad cross-disciplinary coalition of medical societies and patient advocates calling for **urgent action to make clinical trials less bureaucratic and more patient centred, efficient and cheaper**. At stake are the quality of clinical trials, access to innovative treatments and, crucially, patient safety. The coalition calls on regulators, policymakers, sponsors, and other stakeholders to collaborate to ensure that regulatory guidelines, safety reporting requirements and informed consent procedures do not harm what they are meant to protect: clinical trial quality and patient safety.

Read more about the coalition's activities and recommendations in **this article**.

EANM Comments on the European Medicines Agency's Good Manufacturing Practice Guide

The European Medicines Agency is updating **Annex 11 on Computerised Systems of the Good Manufacturing Practice (GMP) guide**. The current version issued in 2011 needs to give more guidance within several areas which are becoming increasingly important to GMP, such as **artificial intelligence and machine learning**. Therefore, the revision's objective is to embrace the application of new technologies which have gained momentum since the release of the existing version.

In the context of the revision, the EANM has highlighted that while protecting the integrity of GMP requirements, the review of Annex 11 should carefully ensure that it does not create an additional administrative burden for radiopharmacists.

ACT EU - Accelerating Clinical Trials in the EU

The ACT EU initiative aims to **develop the European Union further as a competitive centre for innovative clinical research**. Building on the **Clinical Trials Regulation** (CTR) launched on January 31, 2022, ACT EU seeks to gain back the EU's position among clinical research leaders worldwide.

Among the flagship initiatives of ACT EU, EANM is looking forward to contributing to the following:

- Establishing a process to **support academic sponsors** in enabling large multinational clinical trials.
- Setting up a multi-stakeholder platform to **facilitate dialogue** between clinical stakeholders, including patients, healthcare professionals and academia.
- Modernising **good clinical practices** by supporting the adoption and implementation of revised EU guidelines in clinical trial design.

European Health Data Space - A New Framework for Health Data Sharing in Europe

The **European Health Data Space** (EHDS), presented by the European Commission in May 2022, aims to **regulate the transmission and sharing of health data** across the EU for private individuals, researchers, and policymakers. The EHDS has the potential to create harmonisation by establishing well-governed access to health data for the delivery of healthcare services and by regulating a wide range of secondary use purposes to support better health outcomes.

The EU lawmakers – the European Parliament and the Council of ministers – are preparing their amendments to the Commission's proposal before entering into interinstitutional talks to approve the new rules. However, important elements remain to be agreed on, such as consent models for the secondary use of data and alignment with all relevant horizontal and sectoral European legislation, including the General Data Protection Regulation, the Medical Devices Regulation and the AI Act.

European Cancer Imaging Initiative - A European Common Oncology Imaging Database

The European Commission has recently launched the **European Cancer Imaging Initiative** to support healthcare providers, research institutes and innovators in making the best use of innovative data-driven solutions for cancer treatment and care. The European Cancer Imaging Initiative aims to **foster innovation and deployment of digital technologies in cancer treatment and care**, to achieve more precise and faster clinical decision-making, diagnostics, treatments and predictive medicine for cancer patients. Specifically, the initiative, a flagship action under **Europe's Beating Cancer Plan**, will work towards creating a **digital infrastructure linking up resources and databases of cancer imaging data across the EU** while ensuring adherence to high ethical standards, trust, security and protection of personal data.

EVENTS

PAST EVENTS

IAEA Technical Meeting on Health and Pharmaceutical Regulations for Radiopharmaceuticals

On March 6-10, the International Atomic Energy Agency organised a technical meeting to discuss and review the **updates related to health regulatory practices for radiopharmaceuticals** in different Member States and discuss ways to improve the adaptation of appropriate regulatory practices wherever required.

Bringing together representatives from radiopharmaceutical producers, health regulatory agencies, and international and regional professional organisations of radiopharmaceuticals, such as the EANM and SNMMI, a publication will follow the meeting.

European High-level Nuclear Roundtable on Medical Applications and Research Infrastructures

On February 13, the EANM was invited by the European Commission to join the discussion, with the participation of Mariya Gabriel, European Commissioner for Innovation, Research, Culture, Education and Youth, and representatives from Member States, Euratom Supply Agency and other organisations. Focusing on **R&D infrastructures and competencies**, all stakeholders shared a **joint commitment to ease the vital role of nuclear technologies for medical applications benefiting all patients across Europe**. The EANM highlighted the importance of solving the current shortage of qualified nuclear medicine professionals and developing and implementing standardised curricula & training programmes across Europe.

Stay tuned for the publication of the outcomes of the Roundtable!

UPCOMING EVENTS

Beating Cancer - Turning the Tide With Medical Isotopes

The Euratom Supply Agency (ESA) and the European Nuclear Society (ENS) are organising a special session on medical radioisotopes, **sharing insights on recent developments in nuclear medicine** and their contribution to **personalised medicine**. Looking at the different **production methods** of radioisotopes, speakers will discuss what is needed to benefit from the advances in nuclear medicine fully and to make sure that all patients receive adequate and timely procedures.

Join ESA, ENS and EANM on **Monday, April 17**, by registering [here](#).

European Commission - High Level Workshop on Security of Supply of Medical Radioisotopes

In the context of the **European Radioisotopes Valley Initiative**, the European Commission will organise a High-Level workshop with institutional, industrial and research stakeholders, aiming to raise awareness of the challenges and the most recent developments in the **supply of medical radioisotopes** and reflect on **how to secure the supply of the most vulnerable isotopes, through EU-level action and better cooperation with key global partners**.

Mark your calendar for **Thursday, April 27!**

STATEMENT



'Providing high-quality care to patients no matter where they live is what matters the most to Nuclear Medicine professionals. To keep up with the innovation pace, education and training are of the utmost importance. Together with the EANM's own initiatives, we are pleased to see the European Commission's commitment to improving both workforce availability and education & training, aiming to mitigate the gaps between workforce supply and demand and ensure that all categories of staff involved in nuclear medicine receive adequate education, training and continuous professional development in quality and safety issues.'

Paola A. Erba,
EANM President-Elect