



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

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

On May 15, the consortium members of the SIMPLERAD project – the EANM, the European Institute for Biomedical Imaging Research (EIBIR) and the European Federation of Organisations for Medical Physics (EFOMP) – met with the European Commission for a 2nd progress meeting.

The European Commission expressed its satisfaction with the overall progress and achievements within the individual work packages. Based on the feedback we received, several topics will be included in the final deliverables, including the **need for European guidance for implementing the Basic Safety Standards Directive** and the lack of consideration in the European Medicines Agency's guidance regarding marketing authorisations for items pertaining specifically to the safety of therapeutic radiopharmaceuticals.

The SIMPLERAD consortium will finalise the deliverables and is looking forward to proceeding with the implementation of the EU legal requirements for therapeutic nuclear medicine. A follow-up workshop will also be organised in Brussels later this year.

Find more information about the SIMPLERAD project [here](#).

Stay tuned for Upcoming Calls & Projects

We invite the European nuclear medicine community to stay tuned regarding the upcoming **new Open Calls and Tenders related to medical applications of ionising radiation**.

More specifically, two calls for proposals and tenders of potential interest for the nuclear medicine community are expected to be launched before the summer:

1. The first project will be related to the organisation of **clinical audit campaigns** as a tool to improve the quality and safety of medical applications of ionising radiation (more information [here](#))
2. The second project should touch on the implementation of **the EURATOM and the Union legal bases** with respect to medical devices used in medical applications of ionising radiation

Should you have any questions or interest in these projects, do not hesitate to contact us [here](#).

Supply of Medical Radioisotopes - Extended Analysis of the Consultation on the European Radioisotope Valley Initiative (ERVI)

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 to 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 the EANM, on the ERVI objectives and on the specific issues concerning the supply chain of medical radioisotopes. The main objective was to **define a concrete roadmap for the ERVI initiative**, focusing on actions in which the EU can have decisive added value.

The ERVI consultation gathered the positions of several stakeholders on the ERVI objectives and the specific issues concerning the supply chain of medical radioisotopes. A total of 37 issues were identified, covering both the intrinsic challenges faced at the different steps of the radioisotopes supply chains (**supply of source material, enrichment, irradiation, processing, logistics**) and the transversal ones faced by the stakeholders (e.g., **need for better collaboration at the national and European levels, regulatory issues, support to the research and workforce considerations**).

The results are presented in an extended analysis **report** published in April 2023.

3rd EU High-Level Nuclear Roundtable on Medical Applications

On February 13, the European Commission held a **3rd EU High-Level Nuclear Roundtable** and brought together stakeholders from EU Member States, the industry, the research community, and European organisations involved in medical applications of nuclear science.

The primary goal of the Roundtable was to delve into the main **challenges faced by medical applications of nuclear technology**, with a special focus on **research infrastructures and nuclear competencies**. The proceedings highlight the obstacles that hinder technological advancements in radionuclide procedures from reaching EU patients in need.

The report includes contribution from the EANM President-Elect, Professor Paola Anna Erba, on nuclear medicine competencies, in which she highlights **the current shortage of qualified nuclear medicine professionals** in certain regions of Europe. In this piece, she also stresses the need to support innovation and develop **standardised curricula and training programs** for nuclear medicine professionals across the EU.

Check out the full report [here](#).

POLICY INITIATIVES & POLITICAL DEVELOPMENTS

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

In April, the European Commission published the long-awaited revision of the European Pharmaceutical Legislation, which was 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. The EANM will continue advocating for a **supportive regulatory environment for nuclear medicine that recognises the sector's specificities**. The EANM will also attempt to further elaborate on specific provisions for radiopharmaceuticals, including the importance of in-house preparation.

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.

Until then, we encourage you to read the EANM previous **policy statement** on the revision of the European Pharmaceutical Legislation.

ACT EU - An Opportunity to Facilitate Clinical Trials within 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) and Clinical Trials Information Systems (CTIS) 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 the academia
- Modernising **good clinical practices** by supporting the adoption and implementation of revised EU guidelines in clinical trial design

On June 23 and 24, the EANM will join the first meeting of the ACT EU multi-stakeholder platform (more information and live broadcast [here](#)). This meeting will be pivotal for ACT EU. It will in fact pave the way for the creation of a unifying platform involving all stakeholders to support a more holistic discussion across the clinical research landscape.

EVENTS

UPCOMING EVENTS

36th Annual Congress of the European Association of Nuclear Medicine

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

Join us on September 12 for two EU-related sessions titled 'EU Policy Symposium on Supply & Shortages of Radiopharmaceuticals' and 'EU Policy Symposium on Radiopharmaceuticals' Regulatory Challenges in Europe'. Check out the EANM'23 Congress' full programme [here](#).

World Cancer Series - The Economist

The Economist's 9th Annual World Cancer Series: Europe will take place in **Brussels on September 20-21**. The two-day summit will feature

over 90 speakers, and will welcome an audience representing policymakers, healthcare providers, industry leaders, academics, patient groups and investors.

The 2023 agenda will build on last year's themes of innovation – equity and excellence – which lie at the heart of the European Beating Cancer Plan. Now that we are more than two years into the implementation roadmap for the plan, the summit will discuss what is working and what isn't.

Find out more about the event [here](#).

PAST EVENTS

Beating Cancer – Turning the Tide with Medical Isotopes

On April 17, the EANM was represented at the 'Beating Cancer – Turning the Tide with Medical Radioisotopes' organised by the European Nuclear Society. This event was an opportunity to discuss both future clinical developments and the challenges ahead.

The EANM highlighted that the number of patients who will benefit from diagnosis and treatment of cancer through medical isotopes is expected to rise exponentially in the next decades, and that disruptions in the supply chain of medical isotopes can impact patients' timely access to the right procedure.

Check out the event's recording and the speakers' presentations [here](#).

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

On April 27, the EANM was represented at the **High-Level Workshop on Security of Supply of Medical Radioisotopes**, organised by the European Commission's Directorate-General for Energy, alongside all actors of the supply chain. The EU Commissioner for Energy, Kadri Simson, the Swedish Minister for Health Care, Acko Ankarberg Johansson, and the Dutch Minister of Health, Welfare and Sport, Ernst Kuipers, were also present.

During the workshop, participants assessed the current supply of radionuclides, the EU dependency on foreign suppliers, the EU industrial readiness, identified supply chain vulnerabilities, and explored collaboration with key global partners.

STATEMENT



"The European nuclear medicine community is eagerly awaiting the revision of the European Pharmaceutical Legislation.

To ensure that all patients in Europe have equal and timely access to high quality nuclear medicine services, a legislative proposal is needed that provides a supportive regulatory framework and acknowledges the specific characteristics of the nuclear medicine sector. To achieve better access of patients to crucial nuclear medicine procedures, it is of the utmost importance that small-scale in-house preparation of radiopharmaceuticals is supported and facilitated across Europe. EANM calls for reduction of the regulatory burden for small-scale production, improved security of the supply of radionuclides and radiopharmaceuticals and a concerted action to support and train healthcare professionals across Europe."

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

Meet the Expert Webinar

How to diagnose angina without obstructive CAD using noninvasive imaging

Thursday, 06 July, 2023
18:00-19:00 CEST

[CLICK HERE TO REGISTER FOR THE WEBINAR](#)

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