## THE EANM POLICY BULLETIN

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.

If you have any questions, please contact us at euaffairs@eanm.org.

Enjoy the read!

The EANM EU Affairs Team

#### COOPERATION & COMMUNITY INVOLVEMENT

## Throwback to EANM'25

Thank you to everyone who joined our EU-focused activities at EANM'25! We were very happy to connect with so many of you. Here is a brief look back:

### **Policy Symposia**

Our two sessions attracted strong attendance and sparked insightful debate on major policy priorities:

#### 1. From Policy to Patients

Our first session focused on the regulatory recommendations from the <u>SIMPLERAD</u> study and examined how the <u>PRISMA</u> Joint Action can support their adoption across Member States and build capacity for the growing demand in RLT.

#### 1. The Growing Role of Health Technology Assessment (HTA)

Our second session was dedicated to the new <u>EU HTA Regulation</u> and its impact on national agencies, patient access, and the assessment of emerging technologies.

★ Missed them? Our Policy Symposia reports will be available soon. Stay tuned!

### **EU Projects Track**

Sessions in the EU Projects Track featured leading EU-funded collaborations, including <u>Accelerate.EU</u>, <u>CARE</u>, <u>CLAUD-IT</u>, <u>PRISMAP</u>, and <u>Thera4Care</u>. Each session

highlighted practical examples of how European partnerships are advancing research, clinical practice, and policy development in nuclear medicine.

## **Policy Workshop**

Our interactive Policy Workshop gave participants practical guidance on navigating the EU health-policy landscape and engaging effectively with decision-makers. Attendees exchanged concrete ideas on connecting scientific outcomes with policy priorities to improve patient care.



We already look forward to seeing you again at **EANM'26** in Vienna!

## "It Takes A Team" Campaign Launch

The <u>#ItTakesATeam campaign</u>, launched last week by the <u>European Medicines</u> <u>Agency</u> in partnership with healthcare and consumer organisations, highlights the human side of medicine shortages. Through stories, videos, and social media posts, the campaign shows how patients, clinicians and regulators work together to keep essential medicines available.

EANM proudly participated in this important initiative through a video featuring EANM President Paola Anna Erba, who highlights the need to prevent shortages of radiopharmaceuticals to ensure adequate patient care across Europe.

**WATCH NOW** 

Under the <u>2025 EU4Health Work Programme</u>, several new calls for proposals are now open, with a total indicative budget of over €56 million.

The calls cover a broad range of priorities, including:

- Pilot cancer screening programmes for gastric, lung, and prostate cancer
- Initiatives leveraging AI and health data for cardiovascular health
- · Lifelong prevention for a healthy life
- · Support for orphan medical devices
- Health data for biotech innovation within the European Health Data Space

Closing date: January 6, 2026

Interested organisations are strongly encouraged to explore these opportunities on EANM's dedicated webpage!

FIND OUT MORE

## Survey On Clinical Trials

EANM is inviting professionals with experience in clinical trials to contribute to the survey 'Barriers and Limitations in Clinical Trials in Nuclear Medicine in Europe'.

Deadline: December 31, 2025

We count on the participation of all stakeholders involved in clinical trials!

**PARTICIPATE NOW** 

## RHYTHM Project

Great news! Following EANM's involvement in the EU4Health <u>RHYTHM project</u> application (Radiation, Health, Safety and Quality for Youth: A Comprehensive Approach to Justification, Optimisation and Education), the project was awarded to our consortium by the European Commission! A kick-off meeting took place in Vienna on October 21-22, 2025.



Led by the <u>European Institute for Biomedical Imaging Research (EIBIR)</u>, RHYTHM aims to enhance radiation safety and the quality of CT imaging in children and young adults. The project brings together ESR, EANM, and around 15 centres across Europe.

EANM will contribute to the education, dissemination and communication efforts. The nuclear medicine perspective will be represented through the engagement of EANM senior experts and nuclear medicine departments ensuring scrutiny over the project development.

Make sure to follow the <u>RHYTHM LinkedIn page</u>, and find out more on the project's dedicated webpage!

**FIND OUT MORE** 

### PUBLICATIONS

## EANM's Reply to the EMA Consultation on the Union List of Critical Medicines

EANM submitted feedback to the European Medicines Agency (EMA) as part of the 2025 annual review of the <u>Union List of Critical Medicines</u>.

In its response, EANM underlined the essential role of radiopharmaceuticals in patient care and the importance of recognising their specific supply and production challenges within the EU framework.

**READ NOW** 

## EANM's Reply on the EU Cardiovascular Health Plan

EANM responded to the European Commission's <u>Call for Evidence on the EU Cardiovascular Health Plan</u>. Recognising that cardiovascular diseases (CVDs) continue to represent the leading cause of mortality in Europe, EANM strongly supports the Commission's efforts to establish a coordinated and forward-looking EU strategy.

**READ NOW** 

# Recommendations by the Coalition for Reducing Bureaucracy in Clinical Trials

Investigators conducting clinical trials are increasingly overwhelmed by legal, regulatory and sponsors' requirements, taking valuable time away from patients. To address these challenges, EANM joined the <u>Coalition for Reducing Bureaucracy in Clinical Trials</u>, launched in 2020 by the European Hematology Association (<u>EHA</u>) in collaboration with the <u>Biomed Alliance</u>.

This cross-disciplinary initiative brings together medical societies and patient advocates who first delivered a joint statement, followed by an initial set

of <u>recommendations in 2021</u>. The Coalition has since released its updated 2025 Coalition Recommendations, outlining key actions to make clinical research in Europe more efficient and less administratively burdensome.

EANM aligns closely with these goals and supports the Coalition's call for practical reforms to improve trial design, operations and regulatory processes.

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### POLICY DEVELOPMENTS

## HTA Sixth Implementing Regulation into Force Since November 9

The European Commission adopted the Commission Implementing Regulation (EU) 2025/2086, establishing detailed procedural rules for the preparation and update of joint clinical assessments (JCAs) of medical devices and in vitro diagnostic medical devices under the Health Technology Assessment (HTA) Regulation.

The act defines how Member States, the European Commission, notified bodies and expert panels will cooperate throughout the JCA process. It also sets out rules for stakeholder engagement — including health technology developers, patients and clinical experts — and provides standardised templates for dossiers and assessment reports. This is the sixth implementing act adopted under the HTA Regulation, marking another step towards a harmonised EU approach to assessing medical technologies.

**FIND OUT MORE** 

## CTIS Map Now Available in All EU Languages

The Accelerating Clinical Trials in the EU (ACT EU) initiative made its interactive map of clinical trials across the EU, Norway, and Iceland available in all EU languages!

Launched in March 2025, the map provides patients, healthcare professionals, and the wider public with easy access to up-to-date information from the Clinical Trials Information System (CTIS), where all EU clinical trials must be registered.

**ACCESS NOW** 

## **EU Commission Splits the BioTech Act into Two Parts**

The European Commission is introducing the EU Biotech Act in two stages:

1. The first part, concentrating on health-related biotechnology, is expected before the end of 2025 and will include simplification measures for clinical trials and certain aspects of the food and feed industry. The Commission has confirmed that this initial part will not include a dedicated impact assessment, instead drawing on existing evidence and stakeholder

consultations.

1. The second part, covering the wider biotech ecosystem, is now expected in the third quarter of 2026.

EANM, together with other stakeholders, will continue to push for a framework that supports innovation, ensures responsible use of health data under the EHDS, and strengthens Europe's position as a global leader in biotechnology.

FIND OUT MORE

#### UPCOMING EVENTS

## European Foresight Workshop on Nuclear Workforce & Skills

The <u>European Commission's Joint Research Centre (JRC)</u> will host the European Foresight Workshop on Nuclear Workforce and Skills on November 12-13, 2025, in Brussels.

The two-day event will gather experts from across Europe to discuss long-term strategies for building and maintaining nuclear competences. EANM will be represented by Oliver Kiß, member of the <u>EANM Policy and Regulatory Affairs Council (PRAC)</u>.

**FIND OUT MORE** 

## **European Cancer Summit 2025**

The European Cancer Summit will take place on November 19-20 in Brussels and online. EANM will be onsite to represent the nuclear medicine community.

The event brings together the entire cancer community to tackle the challenges of a changing global landscape, from political uncertainty and budget pressures to the need for innovation in patient care.

**FIND OUT MORE** 

## **EMA PCWP/HCPWP Meeting**

On November 18-19, EANM will be represented at the two-day meeting of the European Medicines Agency's Patients' and Consumers' Working Party (<u>PCWP</u>) and Healthcare Professionals' Working Party (<u>HCPWP</u>).

The meeting will bring together eligible patient, consumer, and healthcare professional organisations to discuss key topics including updates on the pharmaceutical legislation, clinical trials, real-world evidence, medicine availability

and supply, gender equality and women's health, product information, and outreach activities.

#### **FIND OUT MORE**

## STATEMENT



"We are truly encouraged by the high turnout and strong engagement in this year's EU affairs activities at the EANM Annual Congress in Barcelona. It is clear that our community recognises the importance of a coherent and forward-looking policy environment for nuclear medicine in all its multidisciplinary dimensions. We highly value the expertise and commitment you brought to each session. Your participation is

essential for EANM to continue representing nuclear medicine at the European level, advocating for practical, evidence-based policy solutions, and supporting harmonised progress across Member States. We look forward to building on this momentum together!"

Wim Oyen, PRAC Chair

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