22 April 2026
EMA/92825/2026
Stakeholders and Communication Division

Highlights – European Medicine Agency (EMA) and European Association of Nuclear Medicine (EANM) bilateral meeting

20 April 2026, 16h00-17h30 CET

1. Introduction and tour de table

The Chief Medical Officer welcomed the EANM delegation to the bilateral meeting, emphasising the importance of maintaining a structured and continuous dialogue on regulatory science, clinical trials, scientific guidelines, and access to radiopharmaceuticals in Europe. Both organisations acknowledged the importance of recurring structured dialogues to address shared priorities and long-term scientific and public health objectives.

2. EANM overview and key activities relevant to EMA

EANM presented an overview of its mission as a non-profit scientific society dedicated to improving public health through education, research, and standardisation in nuclear medicine. The association has a multidisciplinary nature, involving physicians, pharmacists, physicists, chemists, technologists, and other healthcare professionals. Its strategic focus areas include oncology, neurology, and cardiology as the three principal pillars, with additional activity in inflammatory, infectious, and rare diseases.

EANM provided more detailed insights into the following areas of their work:

Education and training: delivery through the annual EANM Congress, the EANM School of Multimodality Imaging & Therapy (ESMIT), and dedicated training programmes (e.g. radioligand therapy, cardiac amyloidosis, Alzheimer's disease).

Guidelines and scientific output: development and dissemination of clinical, procedural, and technical guidelines, supported by new EANM journals focusing on innovation and best practice.

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Standardisation and accreditation: progress on scanner harmonisation, SUV standardisation, and the launch of theranostics centres of excellence, including plans for further levels incorporating dosimetry-related standardisation.

Workforce and future generation initiatives: activities targeting young professionals and early-stage students (e.g. the "Inspire" programme) to support sustainability of the nuclear medicine workforce.

Access and advocacy: engagement in initiatives to reduce inequalities in access to radioligand therapies across Europe and participation in multi-stakeholder platforms addressing personalised medicine.

3. Update on EMA guidelines

EMA provided updates on the status of key guidelines relevant to radiopharmaceuticals, acknowledging the complexity of balancing regulatory clarity with clinical feasibility, especially for short-lived radionuclides and small-scale or in-house preparations.

The draft **guideline on the quality of radiopharmaceuticals** was adopted for public consultation, with comments invited until the end of April 2026. Key changes include differentiation of requirements by radiopharmaceutical type, clarification of dossier expectations, and discussion of impurities and specifications.

The **guideline on radiopharmaceuticals based on monoclonal antibodies** is under revision, with a first draft planned for public consultation later in 2026.

EMA summarised progress on the drafting of a **guideline for clinical evaluation of therapeutic radiopharmaceuticals in oncology**, following extensive feedback on the earlier concept paper. Key challenges discussed included dosimetry approaches, feasibility in clinical trials, alignment with EU legislation (including Euratom requirements), and the need for appropriate flexibility across different disease settings. EMA confirmed the intention to publish a draft guideline for consultation by the end of 2026, followed by a dedicated workshop.

EANM expressed strong support for updated and dedicated EMA guidelines that recognise the specific characteristics of radiopharmaceuticals, emphasising the importance of generating proportionate dosimetry evidence, considering feasibility across diverse healthcare systems, and collecting real-world data to support long-term safety and effectiveness.

4. ACT EU and clinical trials in nuclear medicine

EANM presented its engagement with the ACT EU Multi-stakeholder Platform, focusing on barriers to academic and non-commercial clinical trials in nuclear medicine. Identified challenges included regulatory complexity, lack of harmonisation across Member States, limited funding opportunities, administrative burden, and infrastructure constraints. Their further contribution will focus on:

- Conduct of a Europe-wide survey to map barriers to nuclear medicine clinical trials.
- Participation in ACT EU focus groups on training and risk-based approaches.
- Development of guidance and educational activities tailored to nuclear medicine trials.

EMA welcomed EANM's contribution and invited further engagement, including presentation of survey results at an upcoming Multi-stakeholder Platform Advisory Group meeting. EMA highlighted

complementary initiatives under ACT EU and at European Commission level to support non-commercial sponsors, funding, infrastructure, and regulatory navigation.

5. Horizon scanning on radiopharmaceuticals

EMA presented a newly published horizon scanning report on radiopharmaceuticals, developed by EMA in collaboration with the EU Innovation Network. The report reviews current trends, regulatory status and initiatives, regulatory, scientific and manufacturing challenges, and opportunities in both diagnostic and therapeutic radiopharmaceuticals, and sets out recommendations primarily addressed to regulators.

EANM welcomed the report as a valuable initiative and encouraged closer involvement of professional societies and other stakeholders in future horizon scanning activities, including referencing existing scientific guidelines and position papers.

6. Areas for further collaboration

Both organisations agreed to maintain close contact through designated points of contact and to continue exchanges across expert groups, workshops, and multi-stakeholder platforms.

EANM invited EMA to contribute to future EANM scientific and regulatory sessions, while EMA encouraged EANM members to remain engaged in consultations and consider participation as experts where feasible.