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European Medicines Agency

Highlights- 5th EMA-Nuclear Medicine Europe (NMEU) bilateral meeting

Chair: Juan Garcia Burgos, Head of Public and Stakeholder Engagement Department

1. Welcome and introductions

The Chair welcomed the delegation from Nuclear Medicine Europe (NMEU), highlighting the strategic importance of therapeutic radiopharmaceuticals and theranostics for Europe's healthcare system. Continued dialogue was encouraged to deepen mutual understanding of the sector-specific challenges and constraints faced by the nuclear medicines community.

NMEU welcomed the opportunity to hold this bilateral meeting at a pivotal time, marked by the upcoming Biotechnology Act proposal and the forthcoming implementation of the revised EU pharmaceutical legislation.

2. Nuclear Medicine Europe priorities and developments in the field since 2024

NMEU presented the perspective of its members, representing the entire nuclear medicines value chain, and highlighted key priorities and challenges affecting the sector.

Participants acknowledged the need to strengthen Europe’s competitiveness in the clinical trial landscape to support the development of innovative therapies and improve timely patient access to them.

EMA highlighted the ongoing discussions on barriers to clinical trials for nuclear medicines within the

ACT EU multi-stakeholder platform Advisory Group (MSP AG). As the composition of the MSP AG is expected to be renewed in Q4 2026, NMEU was encouraged to apply when the forthcoming call for expressions of interest is launched. EMA also welcomed further insights from NMEU on the root causes of the clinical trial barriers affecting the nuclear medicines sector.

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NMEU's active contribution to consultations on sector-specific guidance and the Biotech Act, as well as its participation in the Industry Stading Group, was acknowledged.

EMA provided an update on several ongoing guideline developments relevant to the nuclear medicines sector, including:

- Guideline on the quality of radiopharmaceuticals, for which the public consultation closed on 30 April 2026, and publication of the final guideline is expected in 2027.
- Concept paper on the revision of the Guideline on radiopharmaceuticals based on monoclonal antibodies, for which the public consultation closed on 31 October 2023, and publication of the draft guideline for public consultation is anticipated by end of 2026.
- Concept paper on clinical evaluation of therapeutic radiopharmaceuticals in oncology, for which the public consultation closed on 31 January 2025, and publication of the draft guideline for public consultation is anticipated by end of 2026.
- Guideline on the non-clinical requirements for radiopharmaceuticals, for which the public consultation closed on 30 June 2019 and whose finalisation is currently reflected in Work plan non-clinical domain 2026-2028).
- Concept paper on the revision of the Guideline on Clinical Evaluation of Diagnostic agents and its appendix 1 on imaging agents, for which the public consultation concluded on 30 April 2026, and the publication of the draft guidelines for public consultation is anticipated by 2027.

It was highlighted that the consultations on the above guidelines might be complemented by multi-stakeholder workshops, if needed.

EMA also highlighted its ongoing engagement with international regulatory partners to promote alignment where feasible, while noting the need to ensure compliance with the specific requirements of the EU legislative framework. Clarifications were provided on the process for nominating relevant European Experts to guideline development groups.

NMEU's interest in the Horizon Scanning Report on Radiopharmaceuticals prepared by the EU Innovation Network (EU-IN) was welcomed. Clarifications were provided regarding the recommendations set out in the report, whose primary relevance is for national competent authorities. Nevertheless, in addition to continuing its active participation in future public consultations and stakeholder engagement activities, NMEU was encouraged to raise sector-specific concerns through the EU-IN to further support regulatory preparedness and innovation in the field. In addition to keep contributing to future public consultation and activities, NMEU was invited to flag sector specific challenges, opportunities and novel developments via the EMA Innovation Task Force.

3. Nuclear Medicine Europe views on regulatory and policy framework developments relevant to radiopharmaceuticals

NMEU outlined its position on the opportunities represented by the Biotech Act and the revised pharmaceutical legislation for innovative radiopharmaceutical products and to address fragmentations across Europe. In the context of the Biotech Act, EMA highlighted the importance of collaboration with other stakeholders to strengthen the collective voice of the nuclear medicine community in discussions on a supportive regulatory framework.

Concerns were also raised on the interaction between radioprotection legislation and evidence-based drug development, particularly around dosimetry requirements and implementation of Euratom provisions.

EMA acknowledged the challenge compliance with the BSSD (Euratom Directive 2013/59/Euratom) is expected in medicinal product development and confirmed the intention to provide more guidance to ensure harmonisation of approaches across member states.

NMEU's challenges and experience in relation to theranostic agents were discussed and noted. NMEU was encouraged to continue raising these important issues with the European Commission, alongside other relevant stakeholder groups, to support ongoing policy and legislative discussions. The association was also invited to keep the Agency informed of developments in the sector, including through the sharing of relevant updates, evidence, and case studies that could further enhance regulatory understanding of the challenges and opportunities associated with theranostics.

NMEU points on the need for more clarity and predictability around quality documentation expectations for radiopharmaceutical clinical trials were acknowledged and further guidance will be considered.

Also in relation to quality documentation, EMA confirmed agreement with Co-ordination group for Mutual recognition and Decentralised procedures – human (CMDh) AND Quality Working Party (QWP) on the use of Active Substance Master File to provide information on radionuclides and confirmed the expectation to formalise this practice during the implementation of the revised pharmaceutical legislation.

4. Radioisotopes security of supply

The longstanding collaborative mechanisms used across Europe to manage radioisotope supply risks, including cross-industry support arrangements and coordination through the European Observatory was outlined.

EMA confirmed following closely this topic and provided details on the Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to address vulnerabilities in the supply chain of radiopharmaceuticals and on the templates and guidance for shortage prevention plans for prescription medicines, following stakeholders consultation.

5. Conclusions and next steps

Both parties acknowledged the importance of maintaining an ongoing dialogue in the light of evolving legislative, scientific and regulatory developments. Further collaboration was encouraged through the Industry Standing group, ACT EU initiatives, guideline consultations and supply chain activities to support innovation, patient access and security of supply.