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Health technology assessment in nuclear medicine: Challenges and opportunities in Europe

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ABSTRACT

Health Technology Assessment (HTA) is an essential multidisciplinary process for evidence-based decision-making in healthcare, influencing approval, pricing, and accessibility of medical technologies. The implementation of the European Union HTA Regulation (EU HTAR), in place since January 2025, marks a pivotal shift towards a more harmonized and collaborative approach to HTA across EU Members States at the European level. Nuclear medicine, particularly with the rapid evolution of targeted radionuclide therapy and theranostic approaches, must strategically position itself within this new framework. In this editorial we outline a strategic framework proposal for strengthening HTA integration in the field. By aligning healthcare innovation with regulatory standards for safety, efficacy, and reimbursement, the European Association of Nuclear Medicine (EANM) aims to support equitable patient access, inform national reimbursement decisions, and promote sustainable adoption of nuclear medicine technologies across Europe.

1. Introduction

Health Technology Assessment (HTA) provides evidence-based evaluations of the clinical effectiveness, safety, and economic value of health technologies. Amid rising costs, HTA is essential to sustaining publicly funded healthcare by guiding pricing and reimbursement decisions based on health outcomes (including impact on patients' quality of life and overall survival), cost-effectiveness, budget impact, and broader societal value. Heterogeneity in national HTA practices across Europe has led to unequal patient access, motivating EU-level action.

In 2017, the European Parliament urged the European Commission to harmonize HTA at the EU level to improve access to medicines and medical devices, ensure transparent HTA and reduce duplication. This culminated in Regulation (EU) 2021/2282 on HTA (EU HTAR), in place since January 2025 (Fig. 1) [1].

The HTAR covers medicinal products seeking centralized marketing authorisations and selected high-risk medical and in vitro diagnostic devices, with staggered implementation timelines. Since January 2025, the Regulation applies to cancer medicines and advanced therapy medicinal products (gene and cell therapies). From 2026, selected high-risk medical and in vitro diagnostic devices will undergo joint clinical assessment (JCA), with eligibility determined by the HTA coordination group (HTACG), unlike medicinal products assessed without prior selection. From January 2028, its scope will extend to orphan medicinal products, and from January 2030, it will cover all medicinal products.

Under the HTAR, a JCA report shall be published and is *"limited to a description of the scientific analysis: (a) of the relative effects of the health technology as assessed on the health outcomes against the chosen parameters which are based on the assessment scope […]; (b) of the degree of certainty of the relative effects, taking into account the strengths and limitations of the available evidence"* (art. 9 HTAR) [2]. In practice, the JCA, prepared by an assessor and co-assessor, is limited to evaluating the relative added value of the technology compared to existing alternatives and the associated uncertainty, without conclusions or recommendations, and is validated by all Member States. Ahead of JCAs, joint scientific consultations (JSCs) provide developers with early input on study design, endpoints, and relevant comparators to streamline evidence preparation and enhance quality.

While the HTAR aims at convergence of HTA methodologies, ultimate decision-making authority on pricing and reimbursement will remain with individual EU Member States. This preserves national healthcare priorities, cost-effectiveness considerations, budgetary constraints, and policy objectives. Accordingly, despite the growing role of joint EU-level assessments under the Regulation, national HTA bodies will retain their central role in healthcare access and adoption strategies.

2. Opportunities for nuclear medicine in europe

The timing is particularly pertinent for considering HTA in nuclear medicine (NM), a field currently undergoing profound transformation driven by the rapid expansion of targeted radionuclide therapy markets and evolving clinical applications. Under the EU HTAR framework, NM technologies evaluated may include radiopharmaceuticals (e.g., radiolabelled ligands of the prostate-specific membrane antigen, PSMA, to image and treat prostate cancer patients) and medical devices (e.g., artificial intelligence-based image analysis software).

Radiotheranostics in NM presents unique HTA challenges distinct from those encountered with conventional pharmaceuticals, including the complexity of diverse imaging modalities, variable production, logistical and operational costs, and the intricate interplay between

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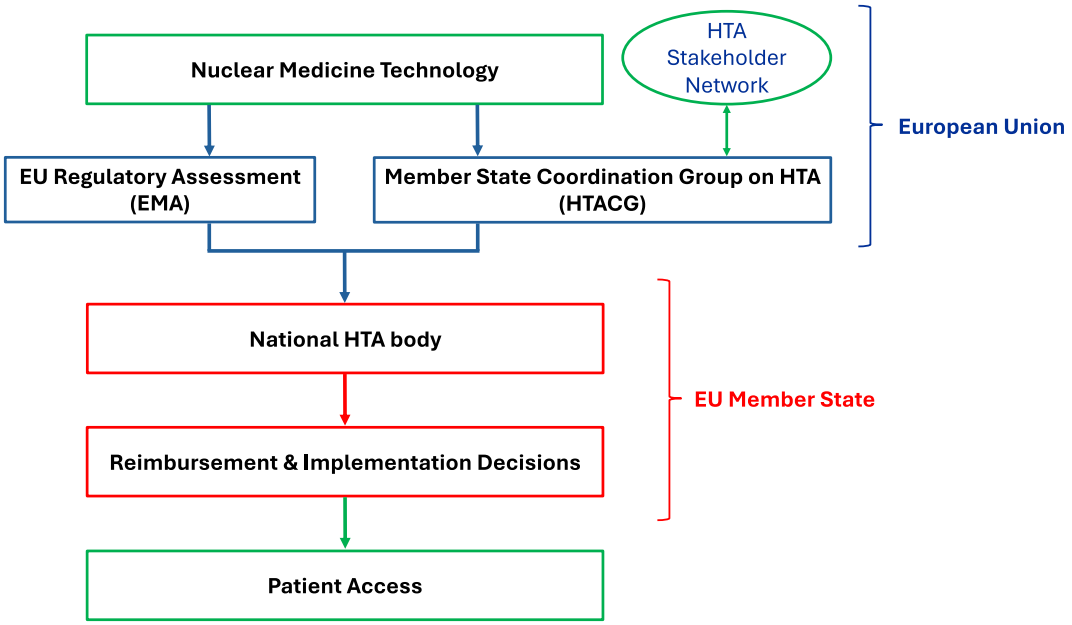

Fig. 1. Overview of the HTA process under the EU HTAR. Following submission of a new health technology (e.g., a therapeutic radiopharmaceutical), regulatory evaluation of safety, quality, and efficacy is performed at the European level by the European Medicines Agency (EMA), while a Joint Clinical Assessment (JCA) of relative clinical effectiveness is conducted by the Member State Coordination Group on HTA (HTACG). Economic evaluation, including assessment of cost-effectiveness and budget impact in the national context, is performed at the EU Member State level by national HTA bodies. These national HTA assessments inform pricing, reimbursement, and implementation decisions, ultimately determining patient access in clinical practice. HTA thus serves as a bridge between clinical evidence generation and patient access to innovative NM technologies, supporting informed reimbursement and implementation decisions.

diagnostic accuracy and subsequent therapeutic decisions. Theranostics, using the same molecular targets for imaging and therapy, not only poses challenges, but at the same time offers HTA opportunities, enabling upfront evaluation of biodistribution and tumour targeting to improve patient selection and cost-effectiveness. The HTA approach for the imaging component of theranostics may be aligned with, but remains distinct from, assessment of the therapy component. Imaging may be justified as a screening test to determine eligibility for treatment with a radiopharmaceutical (i.e. an imaging biomarker for the upfront selection of patients for a specific treatment), or it may be approved on the basis of diagnostic accuracy and impact on clinical management (e.g., PSMA imaging as a diagnostic procedure to determine the broader patient management). These two indications are fundamentally different and therefore require a nuanced approach to HTA submission and review. Novel positron emission tomography (PET) and single photon emission computed tomography (SPECT) imaging agents represent an area of increasing academic and industry-based clinical trials, yet HTA mechanisms and timelines remain unclear, with approval pathways continuing to vary across EU countries.

The evolving EU regulatory framework offers an unprecedented opportunity to integrate NM more centrally into evidence-based healthcare systems. In particular, the significant growth of targeted radionuclide therapy and theranostics amplifies the necessity for a harmonized HTA approach to ensure equitable and sustainable access to these innovative diagnostics and treatments, in line with the EU HTAR.

Several countries, including the UK, Australia, and Canada, have conducted numerous HTAs on NM technologies, generating evidence on clinical efficacy and cost-effectiveness. UK reports under the National Institute for Health and Care Research (NIHR) HTA program contributed to the adoption of NM imaging in routine practice, with a subset recently highlighted in an editorial [3]. The Australian PET Data Collection program, which ran from 2001 for over 10 years, resulted in multi-center trials for evidence on the clinical utility and management impact of 2-deoxy-2-[^{18}F]fluoro-D-glucose ([^{18}F]FDG) PET in cancer that informed Medical Services Advisory Committee (MSAC) HTA reviews and ultimately led to regulatory recognition and Medicare reimbursement [4–6]. However, despite national advances, Europe lacks a centralized coordination platform for NM HTA, and data sharing across EU Member States remains limited. This fragmentation impedes harmonization, reduces accessibility and practical use of HTA evidence, and contributes to duplicated assessments and disparities in patient access to innovation.

Harmonization between imaging and clinical guidelines represents an additional opportunity for NM in Europe, as EANM recommendations are not always incorporated into multidisciplinary clinical guidelines. HTA could help bridge this gap by aligning imaging-specific evidence with broader clinical decision pathways.

In the absence of industry-supported trials in diagnostic NM, strengthening European collaboration through coordinated multicenter clinical studies represents an opportunity to generate robust data for HTA. The creation of a centralized European NM data platform could further strengthen the evidence base and support consistent adoption of innovative imaging technologies.

To address this gap, the European Association of Nuclear Medicine (EANM) established a Piloting Group on HTA in January 2024, which has since evolved into a Project Group focused on exploring effective implementation strategies for HTA within the EANM framework. This group is engaged in identifying relevant data sources, developing appropriate methodologies, deploying strategic tools, and fostering collaborative partnerships. Enhancing the accessibility and applicability of HTA findings in NM, particularly through EANM-led initiatives, holds significant potential to support evidence-based decision-making and reimbursement processes within European healthcare systems. However, the effective implementation of HTA for NM under the EU HTAR fundamentally depends on building strong collaborations with key stakeholders, thereby highlighting the need for a clear and coordinated strategic framework to support HTA integration.

3. Proposed EANM strategic framework for HTA integration in NM

With the European Commission actively inviting collaboration from

medical societies, the EANM is leveraging this momentum through its dedicated HTA Project Group. Professional societies and patient organisations can contribute directly to HTA processes via the Commission's HTA Stakeholder Network (HTA SN), established under Regulation (EU) 2021/2282 [1]. The HTA SN is a structured advisory and consultative platform that fosters dialogue with the HTACG, integrates the perspectives of patients and professionals, and contributes to transparency in HTA processes. Through this platform, stakeholders can provide input on work programme priorities and emerging technologies and participate in JCAs and JSCs as clinical experts. Professional societies can not only propose clinical experts to participate in JCAs and JSCs, but, as organisations, they can also be consulted. The EANM has been an active member of the HTA SN since 2024, contributing its expertise and representing the NM community in these processes.

3.1. Partnerships with HTA stakeholders

Engagement continues with patient organisations, such as the European Prostate Cancer Coalition (Europa Uomo), and clinical societies, including the European Association of Urology (EAU). These relationships strengthen scientific consensus, support the integration of NM into clinical pathways, and enable coordinated contributions to EU-level HTA processes through the EU HTA SN, including participation in JCAs and JSCs led by the HTACG [7].

This framework focuses on three key partnership areas.

3.1.1. Placing patients in the core of HTA

Integration of patient organisations into EANM activities ensures that HTA-related initiatives reflect patient priorities and support transparency, legitimacy, and effectiveness.

3.1.2. Strengthening collaboration with clinical associations and umbrella organisations

Partnerships with multidisciplinary clinical societies, such as the European Hematology Association (EHA), the EAU and the European Society of Radiology (ESR), optimize scientific input into the HTA process and strengthen NM's integration into care pathways. The same applies to collaborations with the European Society of Cardiology (ESC) on the EU Cardiovascular Health Plan and with the Brain Health Mission of the European Academy of Neurology (EAN). Furthermore, EANM is actively working with the European Cancer Organisation (ECO), the European Organisation for Research and Treatment of Cancer (EORTC) and the Biomedical Alliance in Europe (BioMed Alliance).

3.1.3. Involving EANM Member Societies

The EANM Delegates' Assembly, serving as the primary forum for EANM Member Societies, can highlight national needs and coordinate strategies to ensure effective implementation of EANM HTA positions within country-specific frameworks. A recently formed EANM Member Societies Council will further support communication, collaboration, and the reimbursement of NM innovations across EU countries.

3.2. Evidence generation

Through its HTA-related activities, the EANM will ensure that evidence is made available for the HTA processes both at the EU level under HTAR and for EU Member States to support reimbursement decisions. Although HTAs conducted in non-EU countries (e.g., Australia [8–10]) offer valuable insights for the EANM, dossiers prepared for EU-directed HTAs must remain comprehensive, incorporating all available primary studies and relevant data to inform the assessment.

A deep understanding of the similarities and the differences between the European Medicines Agency (EMA) and HTA requirements is crucial. The EU supports this understanding by providing guidance documents on topics such as outcomes for JCAs, direct and indirect comparisons, the validity of clinical studies for JCAs, and the scoping process [11]. It is important to note that assessment methodology itself cannot be tailored, but the appraisal of the evidence can. Therefore, requests for tailored methodologies should be avoided. Strengthening knowledge at the European level, supported by professional societies such as the EANM, can further inform EMA and HTA procedures as well as national reimbursement decisions.

As reimbursement remains a national prerogative, the active and direct involvement of EANM Member Societies is crucial. The EANM HTA Project Group will provide resources and guidance, ensuring HTA evidence is embedded in EANM guidelines, and accessible to EANM Member Societies and the broader international community. A centralized repository consolidating HTA studies from international sources, the International HTA Database (https://database.inahta.org), is already available.

Collaborative guideline development will be strengthened through partnerships with other clinical societies and patient representatives, ensuring comprehensive and harmonized evidence generation.

3.3. Internal capacity building: HTA education and training programs

To enhance understanding of HTA and enable participation in European-level assessments under the EU HTAR, the EANM will develop dedicated HTA education within its ESMIT platform (European School of Multimodality Imaging & Therapy). In parallel, clinical experts in NM are being identified for JSCs and JCAs, carefully avoiding potential conflicts of interest. Mechanisms will also be established to ensure timely identification of emerging NM health technologies and to raise awareness within the NM community of the importance of integrating HTA considerations early in the innovation process.

3.4. Communication & advocacy

The success of this HTA framework depends on effective communication, advocacy, and support for implementation. Through its HTA Project Group, Policy & Regulatory Affairs Council (PRAC), and EANM Member Societies Council, the EANM ensures that HTA findings in NM are disseminated, understood, and useable across Europe.

Advocacy priorities include integrating NM into EU HTA processes, promoting the inclusion of imaging in JCAs, and engaging early in rule-setting under the EU HTAR. The EANM also works with EU institutions to guarantee expert participation in JCAs and JSCs and contributes to the EU HTA SN, formal channel for professional societies and patient organisations input (Fig. 2).

4. Expected benefits and conclusion

The EANM strategic HTA framework aims to support a more harmonized and efficient approach to HTA across Europe, reducing duplication while promoting consistent assessment approaches to inform national decision-making.

It will reinforce collaborative networks among regulators, clinicians, patients, payers, and industry, while building sustainable capacity within the NM community. Moreover, by providing high-quality data platforms, the framework will facilitate evidence-based regulatory and reimbursement decisions across EU Member States. With the ultimate aim of enhancing patient access to innovative NM technologies and equity, this framework pivots towards patient-centred care.

CRediT authorship contribution statement

Nadia Withofs: Conceptualization, Writing – original draft, Writing – review & editing. **Sietse van Mossel:** Conceptualization, Validation, Writing – review & editing. **Mathieu Gauthé:** Conceptualization, Validation, Writing – review & editing. **Kristoff Muylle:** Conceptualization, Validation, Writing – review & editing. **Jolanta Kunikowska:** Conceptualization, Validation, Writing – review & editing. **Erik Briers:**

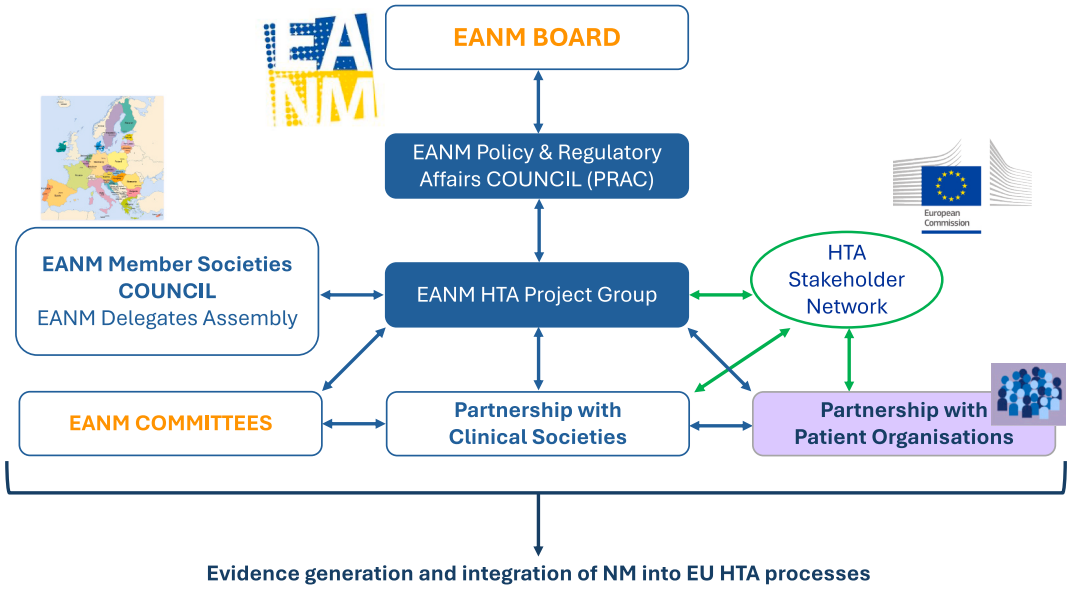

Fig. 2. Organisational structure and communication pathways supporting HTA communication and advocacy within the EANM. The EANM HTA Project Group operates under EANM governance (EANM Board), and in close interaction with the Policy & Regulatory Affairs Council (PRAC). It interacts with the EANM Committees and the EANM Member Societies council, to support coordination and dissemination of HTA-related knowledge in NM. Through its participation in the EU HTA Stakeholder Network, and in collaboration with external stakeholders including clinical societies and patient organisations, the EANM contributes expert input to EU-level HTA processes.

Conceptualization, Validation, Writing – review & editing. **Mattias Neyt:** Conceptualization, Validation, Writing – review & editing. **Amelie De Martini:** Conceptualization, Validation, Writing – review & editing. **Tessa Buckle:** Conceptualization, Validation, Writing – review & editing. **Wim J.G. Oyen:** Conceptualization, Validation, Writing – review & editing. **Andrew M. Scott:** Conceptualization, Validation, Writing – review & editing. **Giorgio Treglia:** Conceptualization, Validation, Writing – review & editing.

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JK reports participation on a Data Safety Monitoring Board and Advisory Board from Novartis (personal fees); Consultant for Curie Science Center; lecture honoraria from Monrol and Novartis.

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SvM none.

NW is a member of the Scientific Advisory Board of SCK CEN, a member of the Board of Elysia-Raytest, and receives honoraria or consultation fees from Novartis, Johnson & Johnson and Ipsen.

WJGO, JK, and GT are Editorial Board Members, and AMS is Associate Editor of The EANM Journal, but they were not involved in any way in the evaluation, revision, or decision process of this article.

Declaration of generative AI and AI-assisted technologies in the manuscript preparation process

During the preparation of this work the author(s) used ChatGPT/OpenAI in order to assist with editing the text and Google Search Generative Experience to support literature searches. After using this tool/service, the author(s) reviewed and edited the content as needed and take(s) full responsibility for the content of the published article.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Nadia Withofs reports a relationship with Elysia-Raytest, SCK CEN, Novartis, Johnson & Johnson and Ipsen that includes: board membership, consulting or advisory, and speaking and lecture fees. WJGO, JK, and GT are Editorial Board Members, and AMS is Associate Editor of The EANM Journal, but they were not involved in any way in the evaluation, revision, or decision process of this article. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Data availability

No data was used for the research described in the article.

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Nadia Withofs[a,b,*], Sietse van Mossel[c,d], Mathieu Gauthé[e], Kristoff Muylle[f], Jolanta Kunikowska[g], Erik Briers[h], Mattias Neyt[i], Amelie De Martini[j], Tessa Buckle[k], Wim J.G. Oyen[l,m,n], Andrew M. Scott[o,p], Giorgio Treglia[q,r]

[a] *Division of Nuclear Medicine and Oncological Imaging, Department of Medical Physics, ICAB Route 610, CHU of Liege, Liege, Belgium*
[b] *GIGA-Laboratory of Experimental Nuclear Medicine, University of Liege, Liege, Belgium*
[c] *Department of Radiology, Leiden University Medical Center, Leiden, the Netherlands*
[d] *Health Technology and Services Research, University of Twente, Enschede, the Netherlands*
[e] *Saint-Mandé, France*
[f] *Department of Nuclear Medicine, AZ Delta, Roeselare, Belgium Department of Nuclear Medicine, University Hospital Brussels (UZ Brussel), Brussels, Belgium*
[g] *Nuclear Medicine Department, Medical University of Warsaw, Warsaw, Poland*
[h] *European Prostate Cancer Coalition (Europa Uomo), Antwerp, Belgium*
[i] *Belgian Health Care Knowledge Centre (KCE), Belgium*
[j] *Head of EU Affairs at the European Association of Nuclear Medicine, Vienna, Austria*
[k] *Interventional Molecular Imaging Laboratory, Leiden University Medical Center, Leiden, 2333 ZA, the Netherlands*
[l] *Humanitas University, Department of Biomedical Sciences Ad Humanitas Clinical and Research Center, Department of Nuclear Medicine, Milan, Italy*
[m] *Rijnstate Hospital, Department of Radiology and Nuclear Medicine, Arnhem, the Netherlands*
[n] *Radboud University Medical Center, Department of Medical Imaging, Nijmegen, the Netherlands*
[o] *Department of Molecular Imaging and Therapy, Austin Health, and Faculty of Medicine, University of Melbourne, Melbourne, Australia*
[p] *Olivia Newton-John Cancer Research Institute, and School of Cancer Medicine, La Trobe University, Melbourne, Australia*
[q] *Division of Nuclear Medicine, Imaging Institute of Southern Switzerland, Ente Ospedaliero Cantonale, Bellinzona, Switzerland*
[r] *Faculty of Biomedical Sciences, Università Della Svizzera Italiana, Lugano, Switzerland*

[*] Corresponding author. Division of Nuclear Medicine and Oncological Imaging, Department of Medical Physics, ICAB Route 610, CHU of Liege, Liege, Belgium.
E-mail address: nwithofs@chuliege.be (N. Withofs).