EU POLICY & PROJECTS

Shaping the **future** of Nuclear Medicine in Europe **together**

INTEGRATING HEALTH TECHNOLOGY ASSESSMENT (HTA) INTO NUCLEAR MEDICINE: A NEW ERA OF EVIDENCE AND ACCESS

EU Policy Symposium 2 – Policy & Regulatory Affairs Council

EANM'25 Congress - Barcelona

Chairs:

Prof. Dr. Jolanta Kunikowska,

Prof. Nadia Withofs

ABOUT THIS REPORT

This report summarises the discussions and key insights of the **EU Policy Symposium 2** at **EANM'25**:

Integrating Health Technology Assessment (HTA) into Nuclear Medicine: a New Era of Evidence and Access

Organised by the **EANM Policy and Regulatory Affairs Council**, the symposium brought together policymakers, HTA experts, clinicians, and patient representatives to examine how the new EU HTA Regulation will shape the future of nuclear medicine research, evaluation, and patient access across Member States.

TABLE OF CONTENTS

About this Report 2

Executive Summary 4

Setting the Stage – the Future of HTA in Nuclear Medicine 5

The EU Regulation on Health Technology Assessment (HTAR) 7

The Impact of the EU HTAR on Research Protocols and National HTA 9

Patient-Centred Perspectives: Implications for Radioligand Therapy in Light of the New EU HTAR 11

Positioning Imaging in the HTA Process 13

Key Policy Recommendations 15

Imprint 16

EXECUTIVE SUMMARY

Health Technology Assessment (HTA) is a systematic process used to evaluate the clinical, economic, and societal value of new medical technologies. In the European Union, HTA ensures that healthcare innovations are safe, effective, and accessible, supporting evidence-based decisions by policymakers and healthcare providers.

With the implementation of the **EU HTA Regulation (HTAR, EU 2021/2282)** in January 2025, HTA is entering a coordinated phase. For the first time, Member States are harmonising assessments of health technologies, creating a framework that promotes **quality, transparency, and collaboration** while maintaining national authority over reimbursement and pricing decisions.

For nuclear medicine, which is advancing rapidly in radiopharmaceuticals, diagnostic imaging, and radioligand therapy, including novel alpha-emitting PSMA-targeted therapies, the HTA Regulation presents a unique opportunity to demonstrate the **clinical, economic, and patient-centred value** of these innovations, supporting timely patient access across Europe.

During the **EU Policy Symposium 2,** at **EANM'25,** experts from the European Commission, national HTA agencies, patient organisations, and professional societies examined the regulation's implications for research design, evidence generation, and patient access. Discussions highlighted:

- The need for **early dialogue** between innovators and assessors.
- The importance of **robust comparative evidence**, balancing randomised trials and real-world data.
- The **central role of patients** in defining relevant quality-of-life measures.
- The necessity of **integrating imaging** within HTA frameworks.
- The potential of the **European Health Data Space (EHDS)** for Artificial Intelligence (AI) validation.

The symposium concluded that **collaboration, transparency, and inclusivity** are critical to achieving the HTAR's objectives. By engaging early and collectively, the nuclear medicine community can ensure that innovation translates into **equitable and timely patient benefit,** thus strengthening healthcare decision-making across Europe.

SETTING THE STAGE – THE FUTURE OF HTA IN NUCLEAR MEDICINE

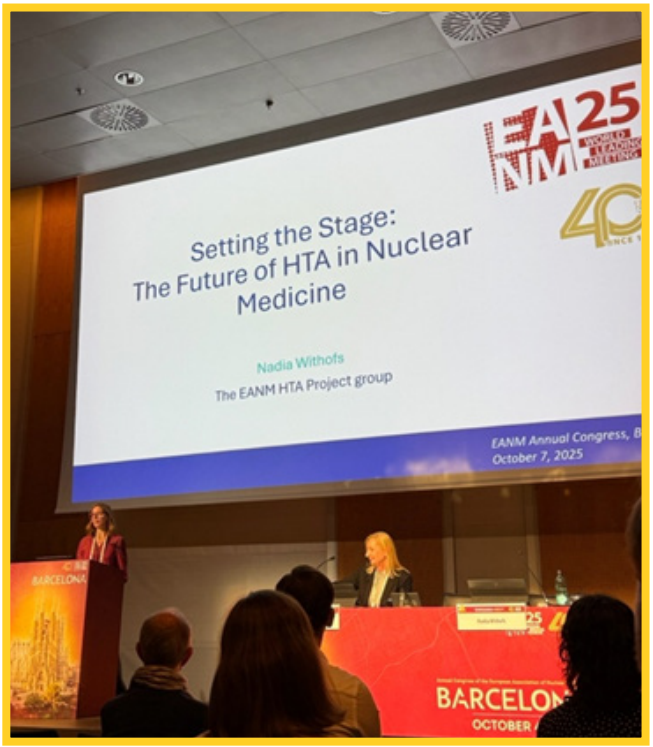
Prof. Nadia Withofs, Liège University Hospital

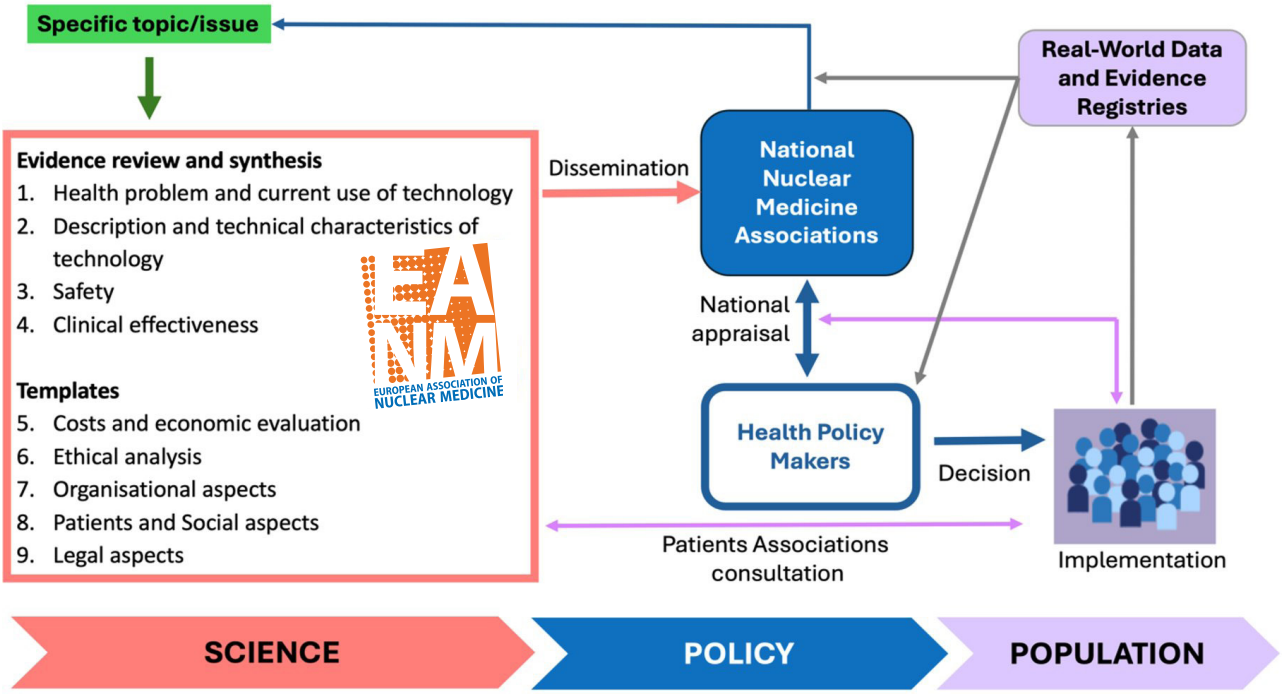
The European Health Technology Assessment Regulation, entering into application in **January 2025**, represents a major milestone in the EU's health policy framework. It aims to establish a coordinated approach for assessing new medical technologies across all Member States. The new regulation will have a direct impact on **radiopharmaceuticals, diagnostics, and therapeutic innovations** in nuclear medicine.

HTA is a structured process that evaluates new medical technologies based on **clinical safety, effectiveness, and cost considerations**, providing a bridge between scientific research, regulatory approval, and patient access. At the European level, the **EU HTAR** introduces joint assessments that bring consistency and transparency to the evaluation process.

In anticipation of these developments, the **European Association of Nuclear Medicine (EANM)** has established a **multi-disciplinary HTA project group** composed of nuclear medicine physicians, HTA experts, a patient representative, and two liaison members connecting with the EANM Policy & Regulatory Affairs Council and relevant EANM committees. This initiative positions EANM as an active contributor to HTA, reinforcing its role as both a **scientific and policy actor**.

Prof. Withofs highlighted that EANM is strengthening its partnerships with other European scientific societies, such as the **European Society of Radiology (ESR)**, to ensure nuclear medicine is represented both **scientifically and politically**. Through this collaboration, EANM aims to advocate for **timely and equitable patient access** to innovations in nuclear medicine, aligning research outcomes with societal and policy needs.




Specific topic/issue
Evidence review and synthesis
1. Health problem and current use of technology
2. Description and technical characteristics of technology
3. Safety
4. Clinical effectiveness
Templates
5. Costs and economic evaluation
6. Ethical analysis
7. Organisational aspects
8. Patients and Social aspects
9. Legal aspects
EUROPEAN ASSOCIATION OF NUCLEAR MEDICINE
Dissemination
National Nuclear Medicine Associations
Real-World Data and Evidence Registries
National appraisal
Health Policy Makers
Decision
Implementation
Patients Associations consultation
SCIENCE
POLICY
POPULATION

THE EU REGULATION ON HEALTH TECHNOLOGY ASSESSMENT (HTAR)

Julie Spony, European Commission, DG SANTE (Unit C2 – HTA)

The **HTA Regulation (EU 2021/2282),** which came into application in **January 2025**, establishes a **permanent and structured collaboration** between EU Member States for assessing health technologies. It sets out common procedures for evaluating clinical aspects of medicines and selected medical devices, while preserving Member States' authority over national pricing, reimbursement, and broader health system decisions.

The HTA Regulation aims to ensure that assessments are **high-quality, transparent, inclusive, and efficient.** It introduces several new collaborative mechanisms:

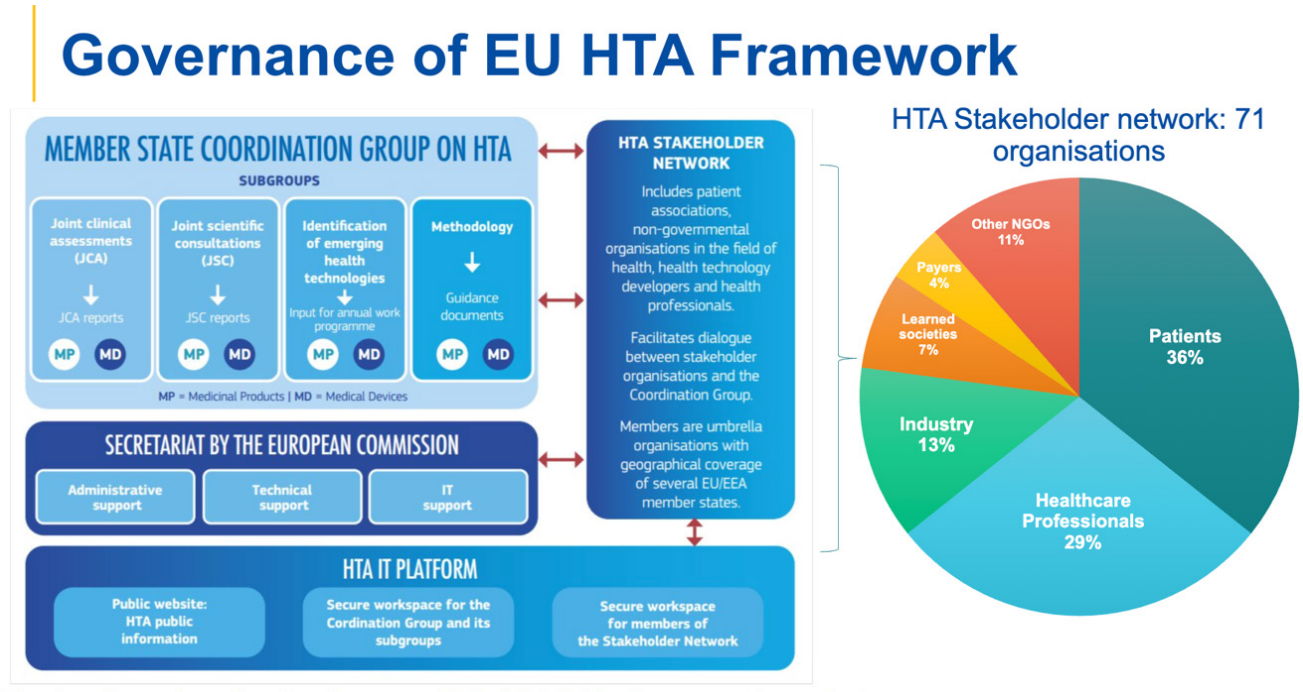
- **Joint Clinical Assessments (JCA):** JCAs assess the relative **clinical effectiveness and safety** of new medicines and certain high-risk medical devices. They are conducted in parallel with the European Medicines Agency's centralised regulatory procedures and will be **publicly available**. JCAs incorporate stakeholder input from **clinicians and patients**. The process begins with a **scoping phase** (defining the PICO question: Population, Intervention, Comparator, Outcomes), followed by submission of the dossier by the industry, and the evaluation by the assessor and co-assessor. By October 2025, **nine JCAs** had already been initiated. The EU-level JCA focuses on clinical aspects, while national HTA bodies may include **additional dimensions** such as ethical, economic, or social considerations.
- **Joint Scientific Consultations (JSC):** JSCs provide early, coordinated advice to developers on **clinical trial design and evidence-generation plans**. These consultations may be in parallel with EMA scientific advice to ensure consistency between regulatory and HTA requirements. The process involves a **briefing package**, identification of key issues, structured meetings, and a final outcome document offering guidance for developers. During 2025, two **request periods** were completed, with **initial assessment packages** selected for the period **October–December 2025**.

» **Emerging Health Technology (Horizon Scanning):** This mechanism identifies **promising technologies at an early stage**, allowing healthcare systems and HTA bodies to prepare for future assessments and adoption.

The HTA framework is overseen by a **Member State Coordination Group**, supported by technical subgroups. **Stakeholder organisations**, including EANM, provide input and technical support to Member States. The HTA Regulation is the **first EU legal framework** to systematically involve **patients and clinicians** in the joint assessment process.

Implementation is progressing in phases.

The JCA implementation for medicinal products follows a staged approach, with all centrally authorised medicines coming under its scope by 2030. For medical devices and in vitro diagnostic medical devices, the process will begin in 2026.



THE IMPACT OF THE EU HTAR ON RESEARCH PROTOCOLS AND NATIONAL HTA

Dr. Mattias Neyt, Belgian Health Care Knowledge Centre (KCE)

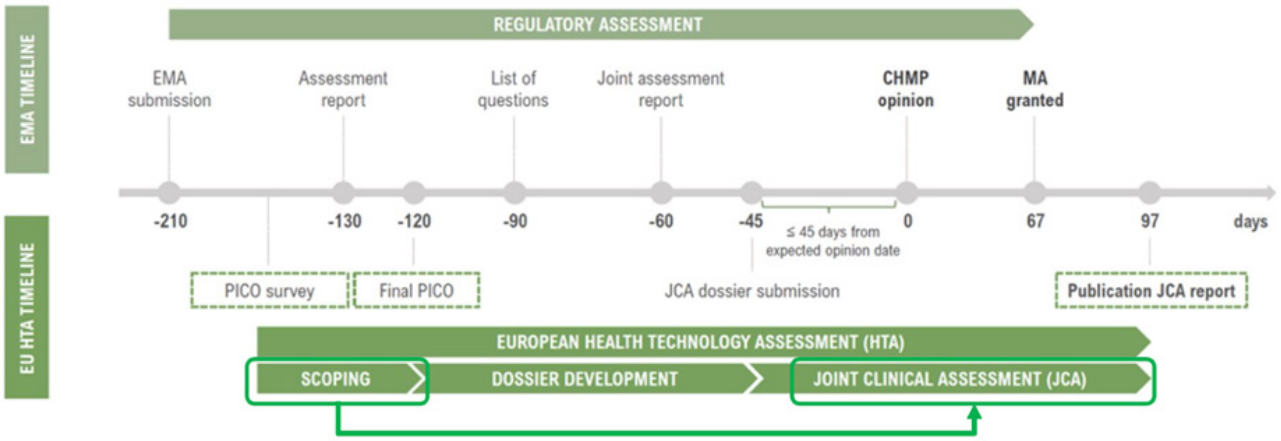
Dr. Neyt emphasised that HTA is by nature **multidisciplinary,** combining **clinical, economic, ethical, and organisational perspectives**. The clinical dimension, however, remains the foundation upon which all others are built. Several **challenges** currently limit the robustness and comparability of HTA outcomes:

- **Evidence gaps** exist between **EMA regulatory requirements** and **HTA expectations**, particularly concerning **comparative effectiveness** and **real-world relevance**.
- Many clinical trials rely on **surrogate endpoints** (such as PFS) that are not always validated as proxies for OS or quality of life.
- **Head-to-head comparisons** between therapies are often lacking.
- **Control group selection** remains difficult, especially when data must be extracted retrospectively.
- **Quality of life** data are frequently not gathered, while being a very important patient-relevant outcome.

The new HTA Regulation introduces several innovations:

- A **structured scoping phase** (PICO) that allows Member States to align priorities and ensure assessments address relevant policy questions.
- **Joint Scientific Consultations (JSCs)** offer developers the chance to seek early feedback from HTA bodies and regulators on what evidence is needed. These consultations are advisory and confidential, helping researchers design studies that will later satisfy both regulatory and HTA expectations. If developers later deviate from this advice, **clear justification** will be required.
- The European Commission continues to update **HTA guidance documents**, which now provide improved recommendations on:
  - **Direct and indirect comparisons**, emphasising randomised clinical trials as the preferred standard.
  - Preference for **final patient-centred outcomes** and requiring evidence for the **validity of surrogate endpoints.**
  - **Comprehensive reporting requirements** for Joint Clinical Assessments.

Dr. Neyt concluded that as new radiopharmaceuticals enter the market, their **evaluation and adoption** will increasingly depend on **early scientific alignment** and **transparent evidence generation**. HTA will play a crucial role in ensuring innovations are both **clinically effective** and **accessible to patients** across Europe.



(source: Pharma.be presentation)

PATIENT-CENTRED PERSPECTIVES: IMPLICATIONS FOR RADIOLIGAND THERAPY IN LIGHT OF THE NEW EU HTAR

Dr. Erik Briers, Europa Uomo

Dr. Erik Briers provided the **patient' perspective**, emphasising that patients primarily want **a cure**, and when that is not possible, they seek **effective disease control** that maximises survival and **quality of life (QoL)** while minimising side effects. Key priorities were identified:

» **Access and Awareness**.
If a patient is eligible for a given treatment, such as **radioligand therapy (RLT)** for prostate cancer, they should be able to **access it quickly and equitably**. Access depends not only on regulatory approval but also on **reimbursement systems, treatment availability**, and **infrastructure readiness**. Ensuring **awareness among both patients and clinicians** about new therapies and their availability is essential to reduce disparities.

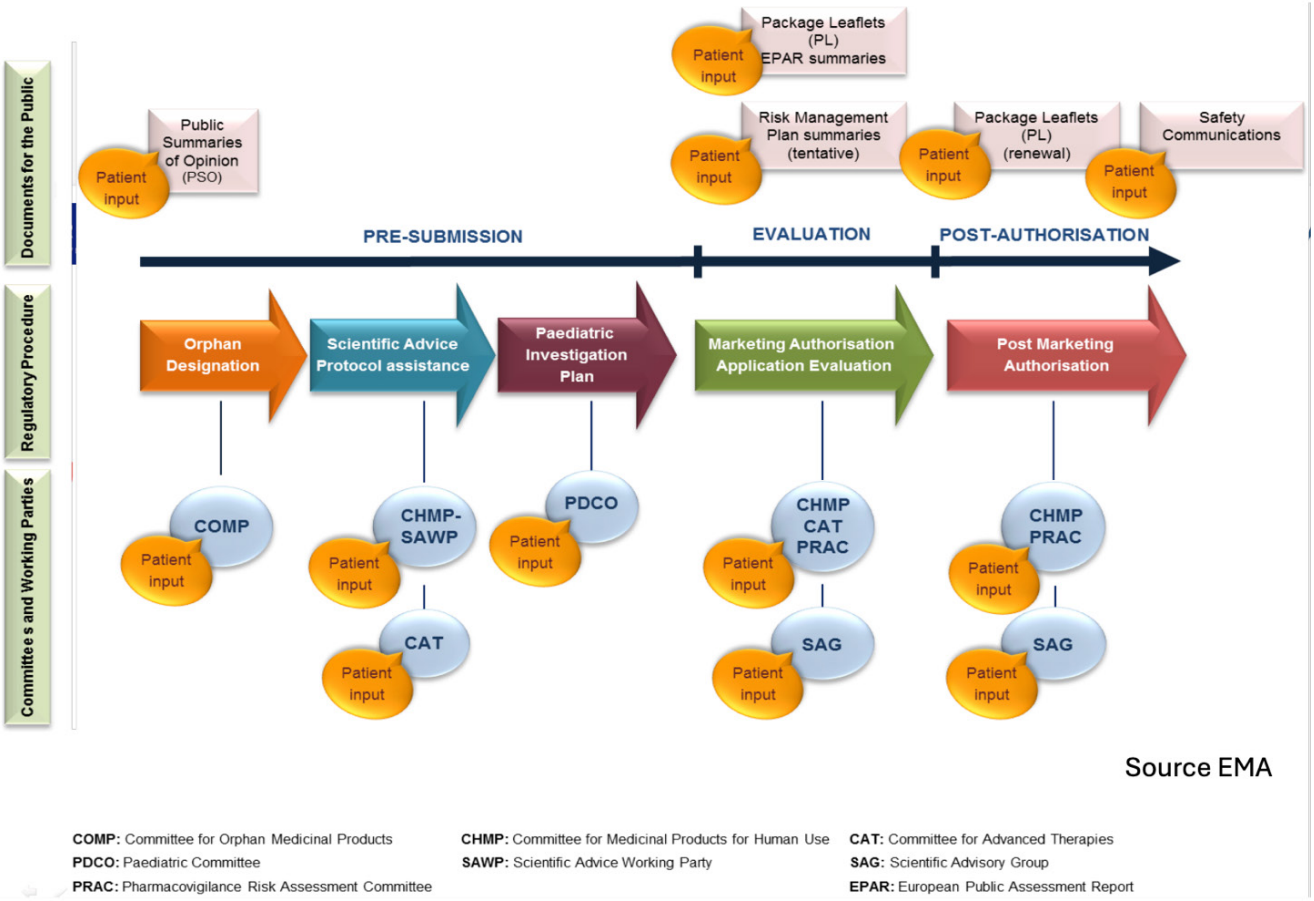
» **Patients Involvement**.
Patients should be engaged from the **earliest stages of therapy development,** ensuring their needs and experiences inform research and policy. While the EMA already involves patients in many processes, the **EU HTA Regulation** extends this engagement across the full technology assessment pathway. However, patient participation varies widely across EU Member States. Among current HTA stakeholders, **36%** are patient organisations, but **training and representativeness** remain inconsistent. To act as **expert advocacy patients**, individuals need training in disease knowledge, EU health policy, and HTA processes.

» **Contribution to Research and HTA**.
Patients contribute essential insights in clinical trial design, endpoint selection, and **quality-of-life assessment.** HTA should focus on **data that are critical for decision-making,** rather than "nice-to-know" information, to respect patient time and ensure relevance.

» **Radioligand Therapy.**
RLT offers significant benefits and can be applied at **different disease stages**. While overall survival (OS) remains a key endpoint, **progression-free survival (PFS), side effects**, and **treatment costs** are also critical. Some topics, such as **infertility** in late-stage prostate cancer, may hold low importance relative to immediate survival and QoL outcomes.

» **Real-World Data and Diversity.**
Briers emphasised the importance of **real-world data (RWD)** and **diversity in patient representation**. HTA should integrate lived experiences from a broad patient population, capturing variation in response and side-effect profiles. Such diversity ensures more equitable and meaningful evidence generation.

Overview of patient involvement along the medicines lifecycle at EMA



Source EMA

COMP: Committee for Orphan Medicinal Products
PDCO: Paediatric Committee
PRAC: Pharmacovigilance Risk Assessment Committee
CHMP: Committee for Medicinal Products for Human Use
SAWP: Scientific Advice Working Party
CAT: Committee for Advanced Therapies
SAG: Scientific Advisory Group
EPAR: European Public Assessment Report

POSITIONING IMAGING IN THE HTA PROCESS

Prof. Minerva Becker, European Society of Radiology (ESR)

Prof. Becker underlined that HTA has traditionally focused on **pharmaceuticals**, while **imaging technologies**, integral to both diagnosis and therapy, have been evaluated only indirectly. To ensure proper recognition of imaging's value, radiology must be considered both as a **diagnostic tool** and as a **technology-driven speciality**.

Assessing imaging's contribution to clinical outcomes requires **distinct methodological standards**. Prof. Becker called for the development of **radiology-specific endpoints**, including diagnostic accuracy, impact on clinical decision-making, and real-world utility. The use of **comparative studies** and **real-world data** is essential, particularly in contexts where randomised controlled trials (RCTs) are not feasible.

She stressed the need for:

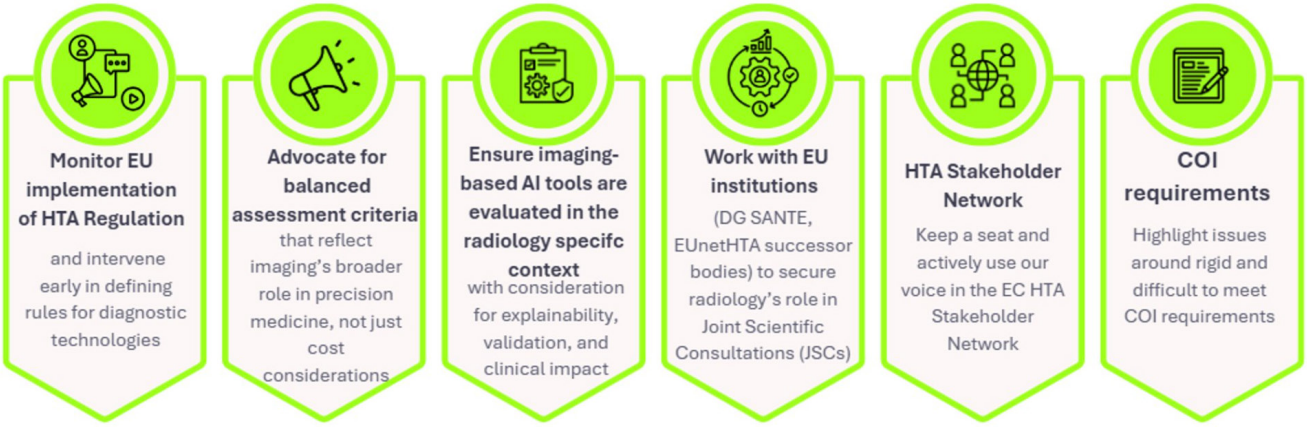
- **FAIR data principles** (Findable, Accessible, Interoperable, Reusable) in imaging data sharing.
- **Harmonised standards** for AI validation and clinical use.
- **Leveraging the European Health Data Space (EHDS)** to promote interoperability and facilitate secondary use of imaging data.

To secure radiology's place in HTA, the ESR is developing **alliances with European societies, patient groups, and industry**. Building HTA expertise among radiologists through **training and expert networks** is a key component of ESR's strategic vision.

Radiology's inclusion in HTA requires continued **policy advocacy**, addressing not only cost-effectiveness but also **AI explainability, conflict of interest**, and **transparency**. The ESR's **Strategic Plan to 2030** aims to establish ESR as the **reference body for imaging in HTA** across Europe.

Policy advocacy and lobbying

acy and ..., Slide 18 of 23



ESR EUROPEAN SOCIETY OF RADIOLOGY

KEY POLICY RECOMMENDATIONS

The symposium concluded that the **EU HTA Regulation** ushers in a new era of **evidence generation and collaboration** for nuclear medicine. It presents challenges, especially regarding data requirements and alignment across jurisdictions, but also significant opportunities to strengthen the position of nuclear medicine and radiology in European healthcare decision-making.

Key directions identified include:

Early and structured engagement: Nuclear medicine professionals, HTA experts, and regulators must collaborate from the earliest stages of technology development.

Integration of Joint Scientific Consultations (JSCs): Researchers should use JSCs to ensure study designs address both regulatory and HTA evidence needs.

Stronger data alignment: Combine **randomised clinical trials (RCTs)** with **real-world data (RWD)** to build comprehensive evidence bases that reflect clinical realities.

Patient engagement: Invest in patient education and capacity-building to ensure their voices are meaningfully integrated in assessments.

Imaging inclusion: Ensure that imaging is fully integrated within **Joint Clinical Assessments (JCAs)**.

Collaboration across sectors: Foster cooperation between professional societies, HTA agencies, patient groups, and EU institutions.

Use of digital infrastructure: Leverage the **European Health Data Space (EHDS)** to enhance data interoperability, FAIR data use, and AI validation.

The discussions at the symposium underscored that this collaborative, evidence-driven approach will be vital to ensuring **equitable, timely, and patient-centred access** to nuclear medicine innovations across Europe.

IMPRINT

PUBLISHER

European Association of Nuclear Medicine

Schmalzhofgasse 26,
1060 Vienna, Austria

+43 1 890 44 27

office@eanm.org

www.eanm.org

EDITORS

EANM Executive Office

Amélie de Martini,

Daria Ferrara,

Mirka Kurčíková,

Moritz Zieglmeier

LAYOUT & DESIGN

EANM Executive Office

Olga Dogadina

CONTENT

While every effort has been made to ensure accuracy, the EANM Executive Office cannot assume responsibility for any inadvertent errors or omissions.

CONTACT

EUaffairs@eanm.org