NUCLEAR MEDICINE EUROPE
the industry association

# What is nuclear medicine, & how can it help Europe beat cancer?

**Nuclear Medicine Europe (NMEU) represents the major players in the nuclear medicine sector. It informs public authorities about the challenges the industry is facing and proposes ways to address them.**

## Nuclear medicine: a vital technology

What is nuclear medicine? It may sound like a recent technology, but the science is far from new. It has been a vital imaging and therapeutic technique for almost a century. Today, it is more precise and sophisticated than ever thanks to a range of modern technologies from fields such as medical physics, radiochemistry and informatics.

How does it work? Nuclear medicine uses radiopharmaceuticals to capture physiological or pathological processes. A radiopharmaceutical is a molecule that takes usually part in a physiological process (e.g. metabolism) or attracted specifically by cellular or other targets (e.g. oestrogen receptor-positive breast cancer lesions). On this molecule a short-lived radioactive element is chemically attached. In this way the radiopharmaceutical targets accurately physio/pathological processes and registers their position by the emitting radiation. These radioactive elements have a relatively short half-life that emits a photon or a positron. Sophisticated medical devices, called PET and SPECT, detect these particles to create functional images of internal processes. They can capture physiological or pathological pathways directly related with the disease status of the patient. Coupled with anatomic imaging systems like CT or MRI, nuclear medicine gives doctors precision tools to diagnose and treat cases in cardiology, oncology, neurology and other medical areas.

Nuclear medicine has treated thyroid cancer since 1941, with excellent results. In the past decade, research has moved fast: clinical trials and product development have accelerated in other types of cancers, including neuroendocrine and prostate cancer, creating new ways to treat tumours with radiation through targeted radioligand therapy (TRT).

The combined use of the same drug for both diagnosis and therapy has developed swiftly under the name theranostics, which is expected to become a vital tool in the treatment of many types of cancers in the near future.

Nuclear medicine has a huge potential to diagnose and treat patients. However, many issues must be addressed if it is to fulfil its promise in Europe and elsewhere. This paper lists the major obstacles for the nuclear medicine industry and offers a framework for action that the Nuclear Medicine Europe (NMEU) trade association sees as essential to keep building the sector.

## What are the four main challenges facing Europe's nuclear medicine sector?

- **Secure and reliable supply** for current and future radioisotopes for both therapy and diagnosis, grounded in resilient European infrastructures.
- **Regulation that adapts to the specificities of radiopharmaceuticals** for marketing authorisations, product registration, preparation, transport/delivery and radioprotection.
- **Support for innovation and technical development** across the EU, through training and certification of healthcare professionals and equipment so all EU citizens can access the full benefits of nuclear medicine with equal opportunity.
- **Raising awareness** and understanding of nuclear medicine's benefits with healthcare professionals, patients and the general public.

# Secure and reliable supplies

## Context

Europe produces more than half of the world's medical radioisotopes. It uses bulk High Assay Low Enriched Uranium (HALEU; <19.9% 235U), imported from the United States that is turned into research reactor fuel and medical isotope production targets at a few research nuclear reactor facilities. If Europe's ageing research reactors are not replaced soon, by new research reactors and/or other innovations, it could aggravate our reliance on external supplies. Europe must address this issue for both current medical isotopes at risk (e.g. 99Mo, 131I), 177Lu that is expected to form the bulk of the next wave of therapeutic applications and for new ones that are expected to develop for therapy in the coming years (e.g. 225Ac).

## NMEU position

NMEU backs measures that secure Europe's supply. We want to maintain European leadership in the production and supply of medical radioisotopes throughout the production chain. However, new technologies and innovations will require public support to ensure the long-term sustainability of the entire supply chain.

## NMEU proposed actions

• We need to move forward with contingency plans. Significant work has already been done to understand the current situation, notably the European Commission-funded studies on Sustainable and Resilient Supply of Medical Radioisotopes in the EU (SMER); the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA); and the Commission report,
'Coordinated approach to the development and supply of radioisotopes in the EU'.
The recommendations from these reports should be followed up as soon as possible.

• NMEU's resources and expertise are available to support the implementation of the new SAMIRA Action Plan, in particular, the European Radioisotope Valley Initiative (ERVI).

• Implement the advice from the OECD as put forward in their report on "The supply of medical radioisotopes the path to reliability 2011" * (with minor edit) notably:

### Governments should:

• In cooperation with healthcare providers and private health insurance companies, monitor radiopharmaceutical price changes in order to support the transparency of costs.

• Periodically review payment rates and payment policies with the objective of determining if they are sufficient to ensure an adequate supply of Radiopharmaceuticals to the medical community.

• Consider moving towards separating reimbursement for isotopes from the radiopharmaceutical products as well as from the diagnostic imaging procedures.

# Regulation that recognises radiopharmaceutical needs

## Context 1: Radiopharmaceutical regulation

Current regulatory guidelines do not take account of the particular needs of radiopharmaceuticals (microdoses, half-lives, production specificities) when it comes to developing new products. These regulatory obstacles delay Europe's market access to radiopharmaceuticals (compared to the US), and result in a) fewer new product approvals in recent years, and b) many EU patients lacking access to new diagnoses, therapies and treatments for unmet medical needs.

## NMEU Position

Radiopharmaceuticals need safety guidelines. However, the regulatory guidance and policies also need to recognise the unique properties of radiopharmaceuticals for diagnostic and therapeutic purposes. They also need to support the development of novel radiopharmaceuticals for diagnosis and targeted treatments.

## NMEU proposed actions

The European Medicines Agency (EMA) and EU Member State health regulatory authorities should strengthen links with the nuclear medicine community, such as the medical professional societies (EANM), and the radiopharmaceutical industry to develop a better understanding of the difficulties and peculiarities of the sector. We notably recommend the following:

- EMA should have an in-house nuclear medicine expert to liaise more efficiently with the nuclear medicine community.
- Specific radiopharmaceutical guidelines should be developed to address a) challenges implementing comparative studies with PET products and b) co-development of diagnostic and therapeutic variants of the same radiopharmaceutical as theranostics.
- A review of labelling guidelines should simplify local language requirements.
- A review of the definitions is needed in the directive 2001/83/EC for radioisotopes as starting material.

## Context 2: Radioprotection coordination

Medicinal product regulation and radioprotection regulations in Europe are not aligned. The two competing authorities within the EU and at national level do not have formal communication channels on the assessment and market authorisation of radiopharmaceutical entities. This results in an unclear development process for radiopharmaceutical manufacturers developing and marketing novel radiopharmaceuticals in Europe.

## NMEU Position and proposed actions

Medicinal product regulations and radioprotection regulations have to be aligned at European and national levels.

# Support innovation and technical development

## Context 1: The organisation of healthcare systems

Current healthcare systems cannot ensure the rollout of radioligand therapy (RLT) as there are not enough centres and trained professionals in most European countries.

## NMEU position and proposed actions

A re-evaluation of the organisation of the healthcare system is needed to address the complex mix of competencies and technicalities required for modern nuclear medicine, especially for the development of RLT (oncologist, radiotherapist, nuclear medicine physician, radiologist, radiopharmacist).

## Context 2: Equipment quality across EU countries

If patients are to have equal access to nuclear medicine across the EU, then all Member States need equal access to modern equipment and procedures. There are currently significant disparities between EU countries concerning the age and configuration of nuclear medicine equipment. These differences may impact the diagnostic accuracy and availability for procedures – and even the ability to manage patient throughput at a pace needed to manage diseases in a timely fashion.

## NMEU Position

NMEU supports the SAMIRA initiatives on the implementation of the Basic Safety Standards Directive requirement and the inclusion of key ionising radiation technologies in national cancer plans, and the replacement of equipment.

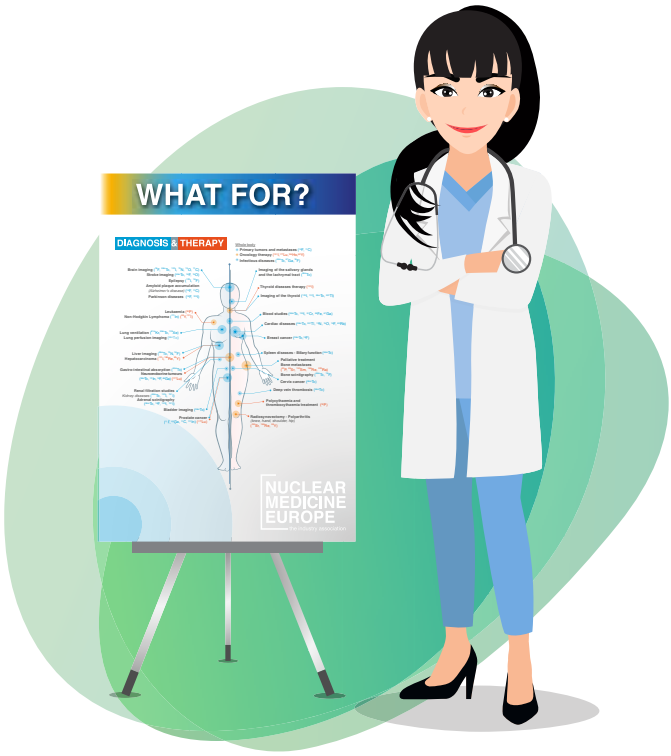
## NMEU proposed action

- Provide opportunities for national stakeholders to align their regional or national cancer plans with the EU's Beating Cancer Plan and SAMIRA, including RLT as a new pillar of cancer care.
- Create national comprehensive cancer care (NCCCs) centres.
- Promote a European training curriculum for nuclear medicine through cooperation between public and private stakeholders, so EU Member States can develop specific capacities for the use of radiopharmaceuticals.

# Raise awareness about nuclear medicine

## Context

Nuclear medicine is often ignored in EU health policies because of its low visibility compared with other medical disciplines.




## NMEU position and proposed actions

We need to raise awareness of nuclear medicine among EU and Member States policy decision-makers. EU institutions should consider:

- Public-private partnership education projects, using some of the funding in the Beating Cancer Plan and the SAMIRA Action Plan.
- International and cross-sectoral education in nuclear medicine to address the knowledge gap around diagnostic and therapeutic applications among healthcare professionals and to facilitate patient access to radiopharmaceuticals.
- Educational projects such as Erasmus+ and financing of key research projects for radiopharmaceuticals and technological developments.
- Involving the OECD Cancer inequalities Register, as suggested in the EU4Health Work Programme 2021.
- Strengthening engagement with the European Parliament, which already led to three vital amendments to a February 2022 Resolution related to the supply of radioisotopes in Europe.

**NMEU's primary goal is to bring together experts to produce informed advice about how nuclear medicine can improve patient care within Europe.** NMEU offers this expertise to all stakeholders.

# NUCLEAR MEDICINE EUROPE

the industry association

nmeu.org