EANM reply to the European Commission EU life sciences strategy Call for Evidence
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The European Association of Nuclear Medicine (EANM) welcomes the opportunity to provide feedback on the Strategy for European life sciences. The EANM considers this Strategy as a timely and strategic initiative to reinforce the EU leadership in the healthcare sector and more specifically in nuclear medicine.

With the EU losing ground to its main global competitors, especially when it comes to innovative radiopharmaceuticals, the EANM would like to highlight the great potential of life sciences for increasing competitiveness, especially in the pharmaceutical sector. In this respect, the EANM strongly advocate for a sustained support to research and development (R&D) in nuclear medicine with both high society impact (such as non-communicable diseases) and high market potential.

Radioligand therapy (RLT) is one of the most promising medical advancements for treating non-communicable diseases. This innovative approach combines a radionuclide with a ligand that specifically targets cancer cells, delivering a high dose of radiation directly to the tumour lesions while minimizing damage to healthy tissues. When paired with appropriate diagnostic imaging for patient selection, this theranostic approach enables highly precise, personalized treatment, offering renewed hope to patients with metastatic disease and limited therapy options. Due to its proven efficacy and cost-effectiveness, RLT is expected to transition from a last-resort, compassionate-use therapy to an earlier line of treatment, expanding access to a greater number of patients. By 2035, it is projected that an additional 170,000 to 270,000 patients in the EU could become eligible for RLT. In addition, nuclear medicine imaging procedures remain pivotal for cardiovascular and neurological diseases in terms of disease staging and therapy response assessment. More specifically, nuclear medicine will be a key enabler of precision medicine in Alzheimer's care, ensuring that anti-amyloid therapies are given to the right patients and that their effects can be objectively evaluated.
However, it is important to recognize that the advancement and widespread clinical implementation of these imaging and therapeutic procedures across the EU still depend on a strong political commitment to integrating both diagnostic and therapeutic nuclear medicine procedures into standard patient care. This includes fostering public-private partnerships and ensuring sustained, long-term support for research and development.

The R&D requirements span the entire lifecycle of radiopharmaceutical development and clinical translation—from fundamental molecular research and clinical trials to health technology assessments (HTAs), the establishment of large-scale production infrastructure, and the expansion of therapy centres to guarantee patient access to RLT innovations.
With rapid advancements in radiopharmaceuticals fuelled by academic breakthroughs and major participation by key industry players, it is essential for the EU to seize this pivotal moment to position the EU as a global leader in RLT. The EANM therefore calls the European Commission to prioritise RLT and related technologies, which could be exemplified in the upcoming Strategy for European Life Sciences.
More specifically, the nuclear medicine community invites the European Commission to allocate resources to RLT R&D through the Strategy for European Life Sciences.

1. Strengthen the European supply chain for medical isotopes.

1.1. Invest in domestic production of stable isotopes.

Enrichment of stable isotopes is key for an efficient and reliable production of radionuclides. However, the EU is currently strongly depending on Russia with only one Russian industrial installation supplying the market for electromagnetic isotope separation and atomic vapour laser isotope separation.
Developing an EU enrichment capacity of stable isotopes is crucial to ensure the EU´s competitiveness and strategic autonomy.
The EANM would welcome that the European Commission takes the opportunity to support the development of domestic production capacities of stable isotopes to and in that respect, would act on the conclusions of the feasibility study by the European Radioisotopes Valley Initiative.

1.2. Invest in domestic production of metallic High-Assay Low-Enriched Uranium (HALEU).

Metallic HALEU fuels the EU research installations producing medical radionuclides and is a target material for the production of Molybdenum-99 (Mo-99). Mo-99 is a radionuclide that loaded into radiopharmaceutical generators to produce Technetium-99m (Tc-99m) which is critical for nuclear medicine practice as it is used in over 80% of all nuclear medicine procedures worldwide. Additionally, new advanced power reactors may also need HALEU in the future. However, , metallic HALEU currently comes from the U.S. and alternatively from Russia. If the EU wants to sustain the operation of its research reactors without depending exclusively upon imports, investing in a domestic HALEU metallic production capacity is necessary. In this respect, the EANM would invite the European Commission to financially and politically support the conclusions of the *„Preparatory phase for a European production capability to secure a supply of high-assay low-enriched uranium (HALEU) fuel* "study.

2. Facilitate EU-wide R&D collaboration.

2.1. Develop a comprehensive EU R&D program on radiopharmaceuticals.

The EANM appreciates the current HORIZON (PRISMAP and SECURE), EURATOM (TOURR) and IHI (Thera4Care, ILLUMINATE and ACCELERATE.EU) projects aiming at further innovating in radiopharmaceuticals and securing the supply of radionuclides for medical applications. Those EU funded projects clearly show the European Commission´ willingness to further support medical radionuclide developments. The EANM would welcome that the European Commission continues dedicating funding for medical applications of ionising radiation.

To ensure coordination with existing efforts and to sustain future needs, the EANM calls for a strategic roadmap to optimise a coherent European supply of medical radioisotopes. Such a roadmap could pave the way for a more ambitious R&D programme on medical isotopes in synergies with existing funding schemes (IHI, EU4Health, EURATOM…). The development of the roadmap could be entrusted to the European Observatory on the Supply of Medical Isotopes.

2.2. Establish a dedicated EU RLT Research Programme.

Collaborative research often struggles with mismatched or limited funding from each partner's side. The EANM would welcome joint funding programmes that pool resources from multiple Member States and support cross-border R&D. Such Horizon Europe mission or public-private partnership (PPP) focused specifically on RLT would focus on accelerating innovation, strengthening Europe´s strategic autonomy and fostering cross-border collaboration. Topics for the first open calls could include innovative isotope production techniques, next generation radioligand development and multinational clinical trials. Ultimately, this Horizon Europe mission or public-private partnership (PPP) would result into international innovation hubs or virtual R&D networks.

Multidisciplinary translational research, which is essential to bridge academic research with clinical applications, should be further encouraged. Investment in dedicated nuclear medicine and radiopharmaceutical hubs can provide shared facilities and know-how to support early clinical development. These public-private partnerships could be supported by the European *Innovative Health Initiative (IHI)* bringing pharma, MedTech, and academic sectors together to co-develop and co-finance RLT innovations.

3. Support clinical translation and market access of advanced nuclear therapies.

3.1. Harmonize regulatory pathways.

The existing regulatory framework governing the development and use of radiopharmaceuticals is complex and depends on multiple pieces of EU and national legislations. When it comes to radiopharmaceuticals, EU radiation protection regulations and Pharma legislation often overlap, sometimes conflict, and can be challenging to align in a cost-effective way. Striking the right balance between facilitating patient access to innovative (RLT) while ensuring the safety of patients and healthcare professionals remains complex within the current regulatory framework. This regulatory landscape poses a significant barrier to the clinical translation of new radiopharmaceuticals, making it difficult for treating physicians to offer these new therapies to their patients and for patients to access them. This should be considered in the Strategy for European life sciences in view of strengthening the EU's competitiveness and leadership, especially in high-value-added and critical domain of radiopharmaceuticals and RLT. Streamlined and adaptive approval routes for RLT innovations is crucial for the EU to remain a global leader in the RLT ecosystem, and the EANM would welcome an alignment between the EU Pharma Law, Basic Safety Standard Directive and the Strategy for European life sciences on that matter.

3.2. Invest in Workforce

Healthcare professionals and researchers are the backbone of our healthcare systems and our research efforts. Yet we face significant shortages that threaten both patient care and innovation. Addressing these workforce shortages requires proactive strategies to attract and retain talent in the EU. We need policies that build a resilient workforce prepared to tackle the healthcare challenges of tomorrow and drive innovations. The EU cannot boost its competitiveness without the appropriate incentives for healthcare professionals and researchers.

Such investments will not only accelerate medical innovation but also reinforce Europe's resilience and leadership in critical health technologies.

The EANM calls for the Strategy for European life sciences to:

- **Recognise medical radioisotopes and radiopharmaceuticals as a critical part of a highly efficient healthcare system.**
- **Commit to ensure patient access to new RLT procedures across the EU, providing our cancer patients with the best possible care and the highest chance of survival.**
- **Commit to maintain and secure Europe´s autonomy on the supply of medical radioisotopes and reduce foreign dependencies for source materials.**