

## **Critical Medicines Act – Call for Evidence** **European Association of Nuclear Medicine feedback**

February 2025

The European Association of Nuclear Medicine welcomes the opportunity to provide feedback on the Critical Medicines Act. We believe that it has the potential to constitute a major step forward in ensuring access to medicines.

Nuclear medicine serves as an indispensable tool in diagnosing and treating a wide array of medical conditions, including cancer, heart disease, infectious diseases, and neurological disorders. Radiopharmaceuticals form the cornerstone of nuclear medicine practice, facilitating both diagnostic imaging and therapeutic interventions.

However, the intricate nature of radiopharmaceuticals, characterized by short half-lives and specialized production processes, renders them susceptible to supply chain disruptions.

The supply chain for radiopharmaceuticals is further complicated by the external dependency on raw materials, particularly those sourced from Russia, underscoring the importance of securing these critical inputs to maintain a resilient supply chain. A considerable number of radiopharmaceuticals administered to patients must be produced close to or prepared on-site in a hospital, highlighting the need for special considerations for radiopharmaceuticals.

In this respect, it is important that the Critical Medicines Act account for the specific challenges of supply security for radiopharmaceuticals, noting that more than 10 million patients in Europe benefit from the use of radiopharmaceuticals in nuclear medicine every year.

### **1. Considering critical radioisotopes for inclusion to the Union list of critical medicines**

The EANM calls for expanding the Union list of critical medicines to better account for emerging treatments like radioligand therapy (RLT), which is expected to play a crucial role in cancer care the coming years.

- Unfortunately, for diagnostic medical radionuclides, and for some of the already commercialised therapeutic radionuclides, the vulnerability of the supply chains has already been exposed, impacting hundreds of thousands of patients, and underscoring the fragility of the EU's supply of radioactive materials.
- In parallel the demand for radionuclides is expected to grow. The number of patients eligible for treatment is expected to grow exponentially in the coming years with new assets and line extensions for existing treatments. For example, a global growth of 15% is expected solely for Lutetium 177 PSMA for a future target population of prostate cancer patients larger than the population of cancer patients currently treated now with therapeutic radionuclides. These promising therapeutic radionuclides will face the same supply risk as the currently available radionuclides.

**To anticipate the growth of eligible patients and ensure timely access to therapies, it is crucial that the EU the EU establish a framework to meet the demand.**

**In that respect, the nuclear medicine community would welcome the integration of radionuclides into public health strategy, especially by updating the Critical Medicines List.** It should be updated regularly to account for new products.

We believe that the current approach to nuclear medicine products within the Union List of Critical Medicines does not mirror the actual clinical needs.

- Indeed, the two nuclear medicine products included are ALBUMIN (technetium, 99mTc) and ALBUMIN (iodine, 125I), two radiopharmaceuticals with generally limited use for cardiovascular diseases. While their supply may be at risk in the medium term, there is a broad consensus that other radiopharmaceuticals, vital for various diseases with limited alternatives, face more immediate supply challenges.
- In addition, as the availability of radiopharmaceuticals is highly dependent on the availability of radioisotopes, it would facilitate the development of appropriate mitigation measures if radioisotopes were included instead of radiopharmaceuticals.

**The nuclear medicine community very much welcomes that radiopharmaceuticals are considered for inclusion on the Union List of Critical Medicines. However, the main driver of accessibility of radiopharmaceuticals is the availability of radioisotopes, predominantly (but not exclusively) Tc-99m, F18, Ga-68 for diagnosis and I-131, Lu-177 and Y-90 for therapy. Therefore, we urge the European Medicines Agency to consider adapting the list to include radionuclides (rather than radiopharmaceuticals) as these are vital for diagnosing and treating a range of diseases.** In that respect, we look forward to engaging in discussion on how radioisotopes could be considered as critical medicines.

However, and mainly due to the regulatory hurdles impacting radiopharmaceuticals in Europe, only including radioisotopes or the finished products on a critical medicines list would not solve all the supply challenges.

## 2. Considering the specificities of radiopharmaceuticals.

It is of the utmost importance that the Critical Medicines Act consider the specificities of certain products, including radiopharmaceuticals.

- For example, while it is commendable to establish an obligation to stock unfinished medicinal product for all marketing authorisation holders as proposed by the Critical Medicines Alliance, it is important that certain products are excluded. In that specific case, radiopharmaceuticals cannot be stockpiled due to their decay period.
- Similarly, we call for the Critical Medicines Act to evaluate relevant data connected to manufacturing and storage capacities. Based on such evaluation, it might also be needed to approach some categories of medicinal products differently than others. It might be the case for seasonal medicinal products, hospital pharmacies and radio pharmacies.

The EANM welcomes that the initiative will cover critical medicines. In that respect, **this should apply to all critical medicines, and not only those indented for commercial purposes.** In-house preparations, usually prepared for non-commercial purposes and made to meet specific clinical needs, also suffer from shortages. In the case of radiopharmaceuticals, the availability of radioisotopes would be the issue.

As explained above, the nuclear medicine community has faced numerous shortages of medical radioisotopes in recent years, resulting in significant delays in diagnosis and treatment for patients across Europe. In the light of the forthcoming publication of the Critical Medicines Act, and in view of future proposals for EU-wide measures to strengthen supply chains and minimise the risk of supply disruptions for critical medicines, the EANM proposes several measures to mitigate shortages and improve the availability of radioisotopes:

- **Risk Assessment and Monitoring:** Conducting comprehensive risk assessments of the radiopharmaceutical supply chain to identify vulnerabilities and establish monitoring mechanisms. This could be done in collaboration with initiatives such as the European Radioisotopes Valley Initiative and could facilitate the development of databases for needs assessment and database of manufacturing capabilities, in collaboration with national authorities, healthcare professionals and industry.
- **Enhanced Collaboration:** Leveraging existing platforms such as the EU Observatory on the Supply of Medical Radioisotopes to foster collaboration and coordination efforts among stakeholders in the nuclear medicine community. To minimise patient impact, all supply chain actors, including healthcare professionals, wholesalers, manufacturers, and national competent authorities, should have the obligation and responsibility to collaborate more closely in terms of not only monitoring but addressing the shortage problem. Such communication should be carried out in a timely manner and contain insights on how imminent the issue is, the expected duration of the shortage and whether alternatives are available.
- **Investment in Infrastructure:** Supporting investments in infrastructure and technology to enhance production, storage, and transportation capabilities for radiopharmaceuticals, thereby improving supply chain resilience.

### 3. Allocating a budget to the European Radioisotopes Valley Initiative that aligns with the objectives of the SAMIRA action plan.

The SAMIRA action plan, designed to strengthen the EU's resilience in the supply of medical radioisotopes, aims to establish a European Radioisotope Valley Initiative (ERVI).

ERVI aims to ensure a reliable supply of medical radioisotopes in Europe by coordinating supply chains, supporting research and innovation, and enhancing collaboration among industry stakeholders, institutions, and national authorities. It also focuses on maintaining high-quality evidence, monitoring demand and supply, and addressing workforce availability, education, and training needs.

ERVI is currently developing scenarios and feasibility studies on several projects of European interest in the sector. **This should go hand in hand with a political will and commitment to provide an appropriate framework and dedicated budget to implement the recommendations from ERVI preparatory phase.**

The EANM supports ERVI and believes that ERVI holistic & multidisciplinary approach is the right one to provide timely access to radiopharmaceuticals for all patients across Europe.

Especially, in the context of the Critical Medicines Act, the EANM would welcome a focus on the following elements:

- Optimising a network of production installations to ensure flexible, resilient, sustainable, safe, equal and affordable access of EU citizens to routinely used medical isotopes.
- Federating a European network of installations to secure evolving, resilient and sustainable access to not readily available isotopes to develop innovative cancer treatments.
- Building a European mechanism for monitoring and forecasting the demand and supply of medical radioisotopes.

The EANM remains open to further engagement with the European Commission to discuss radiopharmaceuticals as critical medicines and appropriate mitigation strategies.