

February 2024

# The European Association of Nuclear Medicine's Statement on the Union List of Critical Medicines

## Rationale for inclusion of radioisotopes

The European Association of Nuclear Medicine (EANM) acknowledges the importance and potential efficacy of the [Union list of critical medicines](#) in addressing medicine shortages and ensuring the continuity of patient care across Europe. We commend the collaborative efforts of the European Medicines Agency (EMA), the European Commission, and the Heads of Medicines Agencies in developing and implementing proactive measures to safeguard the supply of critical medicines.

### Radiopharmaceuticals – Critical & Unique

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.**

### Considering critical radioisotopes for inclusion to the Union List

The EANM welcomes that radiopharmaceuticals fall within the scope of the list, and that some would be included should they meet the criteria for inclusion. The inclusion of radiopharmaceuticals on the Union List of Critical Medicines is a significant step towards ensuring the availability and accessibility of these essential medical products.

Already, the inclusion of two radiopharmaceuticals in the first version of the list, since December 2023, paves the way for a more comprehensive and holistic approach to the supply of medical radioisotopes across the EU.

However, 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,  $^{99m}\text{Tc}$ ) and ALBUMIN (iodine,  $^{125}\text{I}$ ), 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, F-18, 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, and in cooperation with the Belgian presidency of the Council of the European Union, we look forward to engaging in discussion on how radioisotopes could be considered as critical medicines.

## Mitigation measures to ensure supply of medical radioisotopes

The nuclear medicine has been facing numerous shortages of medical radioisotopes in the past years, causing major delays in diagnosis and treatment for patients across Europe. In light of the upcoming revisions of the Union List of Critical Medicines, and considering that products on this list will be prioritised for EU-wide actions to strengthen their supply chains and minimise the risk of supply disruptions by the [Critical Medicine Alliance](#), the EANM proposes several measures to mitigate shortages and enhance 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.

The EANM reaffirms its commitment to ensuring the availability and accessibility of radiopharmaceuticals for patients across Europe. We believe that the Union List of Critical Medicines, coupled with targeted measures to address supply chain challenges, will play a pivotal role in safeguarding the continuity of nuclear medicine services and advancing patient care.