

To National Authorities

We are reaching out on behalf of the European Association of Nuclear Medicine (EANM) to discuss the critical stage of the EU Pharmaceutical Legislation revision, which is now under the Council's review. This legislative update presents a pivotal opportunity to address the rapidly evolving field of radiopharmaceuticals and to ensure that Europe remains at the forefront of medical innovation and patient care.

Unfortunately, the changes proposed by the European Commission and the European Parliament regarding radiopharmaceuticals failed to provide sufficient clarity, despite the significant advancements in this field since the last legislative update in 2004. It is with deep regret that we note the exclusion of the Nuclear Medicine community's recommendations from the European Parliament's final position. In this respect, **our concern is that the current regulatory framework will not adequately support the continued innovation and application of radiopharmaceuticals in Europe**, potentially hindering our continent from leading advancements in this crucial area of healthcare.

Nuclear Medicine has become integral to modern healthcare across Europe, with millions of patients benefiting from its diagnostic and therapeutic capabilities annually. From detecting and treating a wide range of diseases to advancing cancer care, Nuclear Medicine is a promising area of medical innovation. The European Union has already recognised its critical role, particularly in cancer care, through priority initiatives such as the SAMIRA Action Plan and Europe's Beating Cancer Plan. These initiatives have acknowledged Nuclear Medicine as an independent medical specialty and supported actions to enhance the supply of medical radioisotopes and improve the quality and safety of medical applications. **This recognition should go hand in hand with regulatory support to fully harness its potential for the health of European patients.**

The recent [Council Conclusions on Radioisotopes for medical use](#), as well as the European Economic and Social Committee opinion on [Europe's Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply](#) underscore the **current political commitment to facilitate the use of radioisotopes for medical diagnostics and therapy**. To ensure that the recommendations are put into action and that healthcare professionals have timely access to relevant medical radioisotopes to treat patients, we wish to share some key suggestions from the Nuclear Medicine community. These suggestions aim to **harmonise regulatory views and requirements in the preparation of radiopharmaceuticals and clarify legal requirements for producers**. Please find attached the EANM's detailed suggestions.

The revision of the EU Pharmaceutical Legislation represents a generational opportunity to secure patient access to radiopharmaceuticals. **We hope that, as the proposals are now under the Council's review, specific technical provisions concerning radiopharmaceuticals will be considered.**

We greatly appreciate your attention to this matter and are available for any questions you may have. We would welcome the opportunity to discuss this issue further in a meeting.

Thank you for your consideration.

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Head of EU Affairs

European Association of Nuclear Medicine (EANM)