



**EANM-NMEU joint communication on the European Pharmaceutical Legislation revision**  
**Turning the tide – A Critical Call for Unlocking Nuclear Medicine Potential in Europe**  
*April 2024*

The **European Association of Nuclear Medicine (EANM)** and **Nuclear Medicine Europe (NMEU)** take note of the recent vote in the European Parliament Plenary session on the Pharmaceutical Regulation and Directive earlier this month.

The original European Commission proposal for a Directive on Medicinal products for human use (2023/0132) and the original European Commission proposal for Regulation laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency (COM/2023/193) had only included minor change regarding radiopharmaceuticals. Whilst these proposed changes were appreciated, they did not provide sufficient clarity to account for the major developments in the field of radiopharmaceuticals since the last update of the Pharmaceutical Legislation in 2004. During the deliberations in the European Parliament, our two organisations issued joint communications outlining simple amendments pertinent only to radiopharmaceuticals that could ensure that this generational opportunity to update pharmaceutical policy would also ensure to build a sound framework for the growth of radiopharmaceuticals to support European patients.

It is therefore with **great regret that we see that the recommendations of our joint proposals were not included in the final position of the European Parliament.** EANM and NMEU are the two leading organisations for radiopharmaceuticals in the EU, representing clinical/academic interests (EANM) and Industry interests (NMEU) and together we develop and deliver radiopharmaceuticals to patients in Europe. Our concern is that the **regulatory framework for radiopharmaceuticals is not well served by the final position**, which means that **Europe is unlikely to be at the forefront of advances in radiopharmaceuticals in the future** and modern radiopharmaceuticals will continue to struggle with the existing regulatory framework.

## Unlocking Hope: Nuclear Medicine's Vital Role in Diagnosis and Therapy for Countless Patients

In Europe, Nuclear Medicine has become a cornerstone of modern healthcare, with millions of patients benefiting from it through diagnostic and therapeutic procedures every year. From detecting and treating various diseases to advancing cancer care, Nuclear Medicine stands at the forefront of medical innovation. In fact, its impact extends beyond cancer, encompassing a spectrum of major diseases.

The European Union has already acknowledged the pivotal role of Nuclear Medicine, especially in cancer care, evident through priority initiatives like the SAMIRA Action Plan as first action in Europe's Beating Cancer Plan. These major European initiatives well recognised Nuclear Medicine as an independent medical specialty, and supported actions strengthening supply of medical radioisotopes and fostering quality & safety of medical applications. This recognition **must now be complemented by a regulatory acknowledgment** to fully realise its potential for the health of European population.

### It's Time for Nuclear Medicine to speak up

With the revision of the European Pharmaceutical Legislation, there is a **generational opportunity** to establish a regulatory framework that fosters the **integration of Nuclear Medicine into mainstream healthcare**. While the research, medical and industry sectors are transitioning from a *niche* field to an indispensable component of medical practice, it is time for this transition to operate also at the regulatory level. An adapted regulatory environment is now needed to support Nuclear Medicine radiopharmaceuticals growth and full accessibility to European Citizens.

The European Pharmaceutical Legislation aimed at addressing the regulatory gaps triggered by scientific and technological developments since its entry into force, unfortunately the great technological advancements in the field of radiopharmaceuticals **have not been acknowledged**.

The EANM and NMEU are proud of the outstanding innovations in the field of Nuclear Medicine and in the advancement of radiopharmaceuticals with growing numbers of industry-led clinical trials to accelerate the development of novel radiopharmaceuticals, using a unique combination of a targeting ligand and a radionuclide to deliver targeted radiation to selected locations in the body. These developments have their roots in Europe and they have substantially improved patient care, especially in oncology. The evolution of new radiopharmaceuticals, including targeted radiotherapeutics, have paved the way for a new paradigm in patient care. As such, the requirements laid out in the Directive 2001/83 EC and Regulation 726/2004/EC, which are also applicable for radiopharmaceuticals, **are no longer adequate**. A significant example is the definitions related to Nuclear Medicine in Article 1 of Directive 2001/83 EC or Article 4 of the proposed revised Directive, for which no updates were voted by the European Parliament. **Updated definitions** pertaining to radiopharmaceuticals are key in ensuring a regulatory framework that is fit for the upcoming generations of radiopharmaceuticals, recognising the unique aspects of these drugs.

## **A missed opportunity? Reimagining Nuclear Medicine's Role in the European Pharmaceutical Legislation Revision**

Following the European Parliament's vote on April 10<sup>th</sup>, which failed to consolidate any changes for radiopharmaceuticals, the persistence of this outdated regulatory framework will perpetuate, leading to significant challenges for the European Nuclear medicine Industry and clinical sectors. This ongoing situation is breeding uncertainties among Member State authorities, producers, and users regarding the Directive's interpretation, consequently amplifying the divergence in interpretations among Member States. This ultimately will **reduce the availability of radiopharmaceuticals** for patients across Europe.

The European Parliament has recognised the technological developments in so many areas within the revision of the European Pharmaceutical Legislation and in this regard, EANM and NMEU would respectfully request that such an update also be made for radiopharmaceuticals to reflect the many innovations in nuclear medicine over the past two decades.

**We understand that proposals to update regulatory frameworks require deliberation and close consideration, and we remain committed to dialogue with experts from European agencies, to evidence the practicality of our proposals, and with Members of the European Parliament, officials from the European Commission and experts of the Council of the European Union to highlight the importance of considering the specificities of radiopharmaceuticals in the final text to be voted in plenary.**

**Now that the focus shifts to the Council of the EU, we urge policymakers to reconsider radiopharmaceuticals developments, and ensure that the updated regulatory framework unlocks the promises of Nuclear Medicine, granting patients in the EU maximal benefit of the major achievements in our field.**

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