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European Association of Nuclear Medicine and Nuclear Medicine Europe joint statement on the revision of the European Pharmaceutical Legislation *Time to Act for Nuclear Medicine*

The New EU Pharmaceuticals Law is a very important legislation for the future of healthcare in the European Union and we, **European Association of Nuclear Medicine (EANM)** and **Nuclear Medicine Europe (NMEU)** would like to draw attention to some specific aspects that touch on the field of Nuclear Medicine.

The **EANM**, as the largest organisation dedicated to Nuclear Medicine in Europe and representing **Nuclear Medicine healthcare professionals**, jointly with **NMEU** representing the majority of the **pharmaceutical & imaging equipment companies** in the field of Nuclear Medicine, have been following closely the **Revision of the EU general pharmaceuticals legislation**, as well as all connected European initiatives pertaining to medical applications of ionising radiation.

As umbrella organisations, **together, the EANM and NMEU represent the whole Nuclear Medicine sector**, from irradiation of starting materials to delivery of finished products to patients, from academic research to developing and registering new imaging agents and treatments. Together, we aim at **advancing science and education in Nuclear Medicine for the benefit of public health**, and therefore welcomed the attention that Nuclear Medicine has been receiving in the recent years as an effective way to manage many diseases.

As a medical application of nuclear technology, Nuclear Medicine uses radioactive drugs (radiopharmaceuticals), which are employed to diagnose patients through imaging or to treat patients (with a specific focus on cancer - more than 80% of all nuclear-medicine therapies are related to cancer treatment). **Every year, more than 9 million patients in Europe benefit from the use of radiopharmaceuticals** in nuclear medicine for unique diagnostic procedures and specific treatment target options, with a large number of different radiopharmaceuticals in clinical use in Europe, but only **very few centrally approved** by the European Commission under the existing EU legislation¹. This underlines the current importance of **national** registration procedures and other national routes of patient access, especially for diagnostic radiopharmaceuticals.

¹ 4 therapeutic radiopharmaceuticals and 12 diagnostic radiopharmaceuticals (europa.eu; accessed 19 Sept 2023)

Radiopharmaceuticals are a very diverse class of medicinal products with radioactivity as the common denominator. The **radioactive decay** is responsible for **unique logistical challenges** for radiopharmaceuticals due to short (days) to very short (minutes) half-lives of the radionuclides, therefore keeping ready-available stocks impossible. Therefore, **a considerable fraction of all radiopharmaceuticals that are applied to patients must be produced close to or prepared on-site in the hospital, justifying the need for special consideration for radiopharmaceuticals.**

Continuing to meet the needs of patients across Europe, while fostering innovation, should, in the opinion of the EANM and NMEU, be one of the guiding principles for the revision of the general pharmaceutical legislation.

The radiopharmaceutical landscape has dramatically advanced in the last 20 years with a much greater focus on therapeutic radiopharmaceuticals and a wave of new therapeutic and diagnostic radiopharmaceuticals are coming to the market in Europe, holding the promise to represent **a new pillar of cancer care**² and offering new opportunities in terms of **personalised medicine**. These advances now need to be adequately supported by a **tailored regulatory framework** in order to maintain Europe's leadership position in this field. Furthermore, the two main stakeholders would like to draw the attention of the Commission and the European Parliament to the fact that radiopharmaceuticals are governed **by DG SANTE and DG ENER** (regarding radiation safety) and have to adhere to both sets of legislative requirements ("dual governance").

Given the recent innovation in Nuclear Medicine, it is reasonable that the requirements laid out in the Directive 2001/83 EC are not adequate anymore. The challenges posed by the implementation of this outdated regulatory framework manifest in different ways:

- Uncertainties among Member States' authorities as well as producers and users in how to interpret the Directive;
- Resulting in an increased level of heterogeneity in the interpretation of the Directive among Member States;
- Ultimately impacting on the availability of radiopharmaceuticals for patients.

The EANM and NMEU therefore welcome the European Commission's proposal for a revision, as well the efforts and commitment of the European Parliament to ensure that the regulatory framework for medicinal products, including radiopharmaceuticals, is not only adapted to support the current practice, but also to foster innovation and secure patient access in the future.

² European Commission (2021). Europe's Beating Cancer Plan, COM (2021/44), p. 19.

To support this aim, the EANM and NMEU urge the legislators to **adapt the Directive 2023/0132 (COD) and** to ameliorate the proposal in the following aspects:

- 1. Definitions (article 4) should reflect today's nuclear medicine and radiopharmacy practices. Updated definitions** (substance, radiopharmaceuticals, kit, generator...) will lay the **foundation** of an **updated regulatory framework** with adjustments for **unique aspects of radiopharmaceuticals and radiopharmacy practices.** (*for details see Technical Amendment*)
- 2. Specific considerations for industrial and in-house production** of radiopharmaceuticals required for the **innovations** of the field aiming towards **harmonization, strengthening access and alignment** with existing regulations³.
- 3. Specific considerations for radiopharmaceuticals in relation to new proposed items** (such as broadened mandate for **centralized procedure** which now also applies to diagnostic radiopharmaceuticals, **market exclusivity** depending on bringing the product on the market in all European countries within a specific timeframe, **stock piling** for drug shortage mitigation) due to **intrinsic characteristics** of and thereby limitations for radioactive drugs.
- 4. Clarification of the relation of BSSD and Pharma Directive**⁴.

As a recognised multidisciplinary medical specialty, nuclear medicine differentiates itself from radiotherapy and radiology. In this respect, **nuclear medicine requires dedicated EU policy attention.** We recommend the establishment of dedicated legislative acts such as directive or regulation which acknowledge radiopharmaceuticals as a **separate class of medicinal products** with its own regulatory framework integrating/coordinating the “dual governance” (pharmaceutical and radiation safety).

The EANM and NMEU strongly believe that the above points will not only help to increase the level of compliance among Member States but will also **support harmonisation across Europe** while ensuring patient safety and patient access, supporting robust supply chains as well as ample research opportunities.

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³ Regulation 536/2014

⁴ It is acknowledged that in Recital 19 of the proposed legislation reference is made to the **Basic Safety Standards Directive (Council Directive 2013/59/Euratom)** which needs to be taken into consideration for Radiopharmaceuticals. However, neither the positioning (as a Recital) nor the *verbatim* quote of the Euratom Directive (which in the spirit of the European Commission's own pledge for regulatory harmonisation through SAMIRA Action Plan should be avoided) are expected to help in establishing a clear and feasible approach for radiopharmaceuticals which takes into account the major innovations in the field and aligns the regulatory provisions of BSSD and pharma legislation.