NUCLEAR MEDICINE EUROPE
the industry association

European Commission Biotech Act
Proposed Nuclear Medicine Europe amendments for radiopharmaceuticals

May 2026

Key Points

- **Radiopharmaceuticals are missing from the Biotech Act** : despite being a rapidly evolving treatment class, a key pillar of Europe's Beating Cancer Plan, and an EU strategic priority for innovation and isotope supply security.
- **Two regulatory barriers slow patient access:** Clinical trials require both clinical trial authorisation AND separate radiation protection approval (variable requirements/unharmonized timelines across Member States), while outdated radiation rules mandate individual patient dosing instead of evidence-based population dosing used for other medicines.
- **Proposed solution 1 - Align timelines:** Amendments to Regulation (EU) No536/2014 : to sync radiation protection approvals with clinical trial timelines (following Germany's "single gate" model already in place since July 2025).
- **Proposed solution 2 - Regulate as medicines:** Article 58(3) • Amend Directive 2013/59/EURATOM Article 56 to exempt therapeutic radiopharmaceuticals from individual dosing requirements, allowing population-based dosing like other medicines while maintaining radiation safety principles.
- **Technical update:** Align EU CTR Article 91 references with current Directive 2013/59/EURATOM (replacing outdated 1996-1997 Directives).

Why radiopharmaceuticals matter for patients, and why the Biotech Act must include them

The European Commission Biotech Act proposals[1] were published on the 16 December 2025 with the aim of positioning the EU as a leader in biotechnology

by advancing R&D, fostering an ecosystem where biotech innovation can thrive and boosting the growth potential of biotech companies in the EU.

The Biotech Act will achieve this with a combination of new provisions and amendments to key existing legislation, most notably, the EU Clinical Trial Regulation (CTR). Proposals to update the EU Medical Device and In Vitro diagnostic Device Regulations (MDR and IVDR) were published on the same day[2].

The need to future proof the EU landscape and regain global competitiveness was a key focus with the proposals referencing e.g. the Draghi report[3]. As a result, many of the proposals have been welcomed by industry with a raft of improvements to the EU CTR, MDR and IVDR as well as additional proposals such as 12-month Supplementary Protection Certificate extension for qualifying, innovative biotech medicines and ATMPs.

Radiopharmaceuticals are a rapidly evolving class of medicinal products with significant potential, challenged by an unclear EU legislative framework spanning across medicinal products and radiation protection requirements. Innovation is driven mainly by therapeutic radiopharmaceuticals, but also by diagnostic radiopharmaceuticals for theranostic approaches for therapeutic radiopharmaceuticals and beyond, for example in treatment for Alzheimer's disease.

Nuclear medicine, i.e., radiopharmaceuticals as specific class of medicinal products, are presently not included in the above provisions, despite their clear innovation potential and highly complex technology involved. Radiopharmaceuticals are also an EU strategic priority, as a key pillar of the Europe's Beating Cancer Plan, an area of EU leadership, with elements impacting strategic autonomy including radioisotope and raw material supply as part of the EU SAMIRA action plan including the European Radioisotope Valley Initiative. Not expressly including radiopharmaceuticals is a missed opportunity for a highly promising and evolving therapeutic modality, with some legislative challenges that is also an EU strategic priority.

Two regulatory barriers slowing patient access to radiopharmaceuticals

Firstly, to start a clinical trial with Radiopharmaceuticals in Europe, both a clinical trial authorisation and a separate radiation protection approval are needed. The latter varies by country and can cause delays due to unharmonized timelines.

Secondly, Directive 2013/59/EURATOM's requirement for individual dosing of therapeutic Radiopharmaceuticals has raised challenges and resulted in differing interpretations across Member States, increasing regulatory complexity.

The Biotech Act could help address legislative challenges in our sector in two ways:

1. Ensuring legislation in scope of the Biotech Act considers challenges impacting nuclear medicines/ radiopharmaceutical sector. See proposed amendment to EU CTR Article 4 below.

2. Expanding the scope of the Biotech Act to include Directive 2013/59/ EURATOM, allowing a rare opportunity for targeted change to this legislation, which was drafted with other therapeutic modalities utilizing ionizing radiation in mind. See Expansion of Biotech Act scope and amendment of Directive 2013/59/EURATOM section below.

Aligning radiation protection approvals with clinical trial timelines

The Biotech Act recognises that fragmentation and complexity of the EU regulatory framework are factors that make the EU less attractive for translating cutting-edge research and innovation into marketable products. Amending Article 58(3) - Amendments to Regulation (EU) No 536/2014 : Amending CTR Article 4 of the proposed EU Biotech Act seeks to increase the efficiency of clinical trials involving radiopharmaceuticals by aligning radioprotection agency approvals with those under the CTR. As a notable example, Germany has already taken steps to address this fragmentation at national level. Germany has redesigned its radiation-protection approval system so that, as of 1 July 2025, applications or notifications under radiation-protection law are submitted together with the clinical trial application via CTIS. This “single gate” submission approach enables coordinated and partly parallel review by the Federal Office for Radiation Protection (BfS), ethics committees, and the competent medicinal product authorities. While radiation protection and clinical trial authorisations remain legally separate procedures, the reform harmonises timelines and documentation requirements, reduces duplicative assessments, and improves procedural efficiency.5 Similarly, any other local protocol review and approval requirements by local radioprotection agencies or similar official bodies must not lead to prolonged approval timelines and undue procedural complexity that could be prohibitive to conducting clinical trials with radiopharmaceuticals.

Article 4 Article 58(3) • Amendments to Regulation (EU) No 536/2014 : Amending CTR) states:

> *“Each Member State shall ensure that the organisation, timelines and procedures for the review by an ethics committee are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a clinical trial and substantial modifications thereof.”*

As Article 4 is not specific to ethics committees, similar text for RPA could be included to ensure aligned timelines in the EU Member States where these approvals are required. Biotech Act Article 4 replacement in box with proposed amendment.

Proposed amendment to Directive 2013/59/EURATOM for therapeutic radiopharmaceuticals

Therapeutic radiopharmaceuticals (tRPs) including theranostics are fast evolving class of medicinal products with great potential for patients, challenged by an unclear EU legislative framework that spans across medicinal products and radiation protection requirements.

As tRPs are medicinal products, it is important that the EU legislative framework clearly states they are regulated as medicinal products, appropriately considering the requirements for radiation protection. This would reflect the pharmacological and pharmacokinetic properties of (systemic) administered tRPs which allow for population-based, standardized dosing with the same considerations as for non-radioactive drugs. This also allows the development of a clear framework, unlocking the potential of this treatment class for the benefit of patients.

Euratom Directive Art 56 should therefore be amended via the Biotech Act to ensure the EU legislative framework is clear and future proof, allowing the full potential of both academic research and medicinal product evidence generation to be applied to tRP.

Article 56(1) amendment: enabling standard dosing for radiopharmaceutical medicines

The current Directive is based on knowledge obtained with External Beam Radiotherapy (EBRT), externally applied local radiation therapy through radiation emitting equipment or devices. However, systemic tRP medicinal products behave differently from radiation delivered by an external device (EBRT) due to their pharmacological and pharmacokinetic properties contributing to their safety and efficacy.

The approach described in Article 56.1 only speaks to the physical effect of ionising radiation but does not take into account the different behaviours of systemic tRPs compared to radiation therapy applied externally and locally though radiation emitting equipment or devices.

Under the current medicines legislation (Directive 2001/83/EC), the choice of dosage is based on the results of clinical trial(s) where the effect of different dosages of a medicine is compared in defined patient populations with a given condition. Based on clinical data, dosing recommendations are developed specific to patient populations.

Per Article 56 of the EURATOM Directive, tRP absorbed dose would by default guide individualised treatment for each patient based on procedures that estimate how much radiation a given patient is actually absorbing, irrespective of patient population assessments backed up by robust clinical data. This approach would result in significant burden (logistics, health care systems, and research), without adding value if dosing can appropriately be addressed by specific population-based approaches as done for medicinal products under the medicines legislation.

Based on the above rationale, the proposed amendments to the Euratom Directive below, would exempt tRPs from those elements of Article 56 that mandate customised dosing per patient, whilst ensuring the principles in the Euratom Directive are considered in tRP development.

The statement that tRPs are regulated as medicinal products would also allow the European Medicines Agency (EMA) to take the lead in framework development, appropriately considering radiation protection, removing current ambiguities and reducing the risk of divergent or overly prescriptive interpretations across Member States. Future requirements for tRPs could for example, be captured in Annex 1 of the medicinal products Directive 2001/83/EC.

The amendment would also facilitate a clearer role and improved oversight of tRP medicinal products by the EMA, consistent with a similar direction of travel for the Agency regarding drug-device/ IVD combinations for example.

Updating EU CTR Article 91 to reflect current Euratom Directive

The references to radioprotection legislation included in EU CTR Article 91 do not reflect the entry into force of Directive 2013/59/EURATOM.

This is not a major amendment but the references to Council Directives 97/43/ Euratom and 96/29/Euratom in EU CTR Article 91 need to be replaced by Council Directive 2013/59/EURATOM through the Biotech Act.

(1) Council Directive 97/43/Euratom of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/Euratom (OJ L 180, 9.7.1997, p. 22).

(2) Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation (OJ L 159, 29.6.1996, p. 1).

(3) Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106, 17.4.2001, p. 1).

(4) Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).

(5) Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC - (OJ L 33, 8.2.2003, p. 30).

(6) Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).

(7) Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro organisms