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by the European Association of Nuclear Medicine

POLICY BRIEF

The Biotech Act: Main Considerations for Nuclear Medicine

Key message: Targeted adjustments are needed to ensure that the Biotech Act improves European competitiveness while supporting radiopharmaceutical innovation, enabling proportionate and efficient clinical trials, and improving patient access.

BACKGROUND

The Biotech Act is a proposed EU policy framework intended to accelerate the translation of biotechnology research into application across Europe. The European Association of Nuclear Medicine (EANM) **strongly supports the objectives of the Act** and welcomes the European Commission's aims to strengthen Europe's biotechnology ecosystem, improve competitiveness and advance innovation.

Nuclear medicine represents a rapidly evolving and growing area of health biotechnology, providing substantial potential to advance precision medicine, enhance European innovation capacity and improve patient outcomes. Approximately **10 million nuclear medicine procedures are performed annually** across Europe, while demand for radioligand therapies and theranostic approaches is expected to increase substantially in the coming years. Nuclear medicine thus presents **a strategic and competitive opportunity for Europe's biotech sector.**

Given its **unique contribution to precision diagnostics**, **molecular imaging, and targeted radionuclide therapies**, nuclear medicine should be explicitly recognized within this framework. Continued support for innovation in nuclear medicine will be critical to strengthening the European health biotechnology ecosystem, accelerating the **translation of scientific discoveries into patient benefit**, and ensuring that Europe remains a global leader in medical innovation.

CHALLENGE

The Act presents a step in the right direction as it is a **landmark legislative package** redefying the **biotechnology regulation** to become **more coherent**. However, several provisions of the proposed Act do **not fully reflect the specific characteristics** of radiopharmaceuticals and nuclear medicine. Unlike conventional medicinal products, radiopharmaceuticals rely on **decentralised production, short-lived isotopes, specialised infrastructure** and close interaction with **radiation protection** frameworks.

*Read more on Nuclear Medicine in our paper **Nuclear Medicine: What it is. Where it goes. What it needs.***

Without targeted adjustments, the legislation risks creating uncertainty, limiting innovation and **reducing Europe's attractiveness for radiopharmaceutical research and development.**

EANM has therefore developed a **comprehensive set of amendment proposals** covering the Act's provisions on health biotechnology definitions, strategic projects, industrial capacity, artificial intelligence, data infrastructure, regulatory support mechanisms and clinical trials. **Increasing international competition** for biotechnology investment and clinical research means that Europe must **ensure** its **regulatory framework remains innovation-friendly** while maintaining **high standards of safety and patient protection**.

POLICY RECOMMENDATIONS

1	**Provide Legal Clarity for Radiopharmaceutical Innovation:** Radiopharmaceuticals should be explicitly recognised within the scope of health biotechnology and be eligible for Strategic Project designation. Clear guidance is needed to ensure consistent interpretation across Member States, particularly for innovative theranostic products.
2	**Ensure Strategic Projects Reflect Nuclear Medicine Realities:** The Strategic Projects framework should recognise the nuclear medicine supply chains and radiation protection infrastructure including specialised workforce as strategic biotechnology assets including.
3	**Create an Innovation-Friendly Framework for Data, AI and Emerging Technologies:** The Act should make sure that these points are considered to help unlock innovation while maintaining robust regulatory oversight: • Ensure AI guidance reflects radiopharmaceutical development and dosimetry needs; • Integrate FAIR data principles across relevant frameworks; • Recognise imaging datasets within biotechnology data initiatives; • Embed nuclear medicine expertise in foresight activities, regulatory sandboxes and support networks.
4	**Deliver Risk-Proportionate Clinical Trial Rules:** Many radiopharmaceutical imaging studies are low-risk and conducted by academic institutions and hospitals yet continue to face disproportionate administrative requirements. The final Act should: • clarify the application of low-intervention and minimal-intervention trial categories to radiopharmaceutical studies; • simplify multinational trial procedures; • reduce unnecessary reporting burdens for diagnostic studies; • improve regulatory harmonisation across Member States; and • ensure effective coordination with EURATOM radiation protection requirements.

CONCLUSION

The European Biotech Act can become **a landmark framework for strengthening Europe**'s competitiveness, innovation capacity and patient access to groundbreaking healthcare technologies. By **recognising the specific characteristics of nuclear medicine** and radiopharmaceuticals, policymakers can ensure that one of Europe's most exciting biotechnology sectors is fully equipped to contribute to the Act's objectives.

Beyond the key priorities named above, EANM has also developed a list of **detailed amendment proposals**. They are designed to **support the Act's effectiveness** while ensuring that Europe remains a global leader in radiopharmaceutical innovation. Read them here.

EANM stands ready to support the European Parliament, the Council of the European Union and European Commission throughout the legislative process and to provide technical expertise on the implementation of the Act and its associated measures.

Read our detailed reply here.

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