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Opinion of the European Economic and Social Committee
Europe's Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply

(own-initiative opinion)

(C/2024/4661)

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Outcome of vote (for/against/abstentions)	148/3/5

1. Conclusions and recommendations

1.1. Nuclear medicine saves millions of lives and represents a source of great hope for the fight against cancer. A number of preconditions arise from this, and they are the subject of our conclusions and recommendations.

1.2. The European Economic and Social Committee (EESC) highlights the need to address patients' needs in Europe and ensure that all of them have equal access to cancer treatment. Given the increase in cancer diagnoses and the better response made possible by technological advances, Member States must make the right policy and financial choices in the next five years. Their public health policies should make funding for medical radiological and nuclear technologies a priority.

1.3. In Europe, ten million diagnosis and therapy procedures per year are based on radiopharmaceuticals – a number which is set to increase. The EESC calls on the Commission to include modern nuclear medicine in Europe's Beating Cancer Plan more prominently. Priority should be given to radionuclide targeted therapies, which are precise and often less harmful than other treatments.

1.4. Europe is the world leader in the supply of radioisotopes for medicine. It covers 60 % of global demand and is developing new research radioisotopes. At the same time, it has critical dependencies on third countries for key source materials and specific processing operations.

1.5. Member States should provide greater support for the capacities that Europe has lost in recent decades as a result of economic and political choices. The EESC therefore calls for production incentives ensuring better strategic autonomy in the supply of radioisotopes. In this regard, it calls on the Critical Medicines Alliance ([1]) to carefully monitor the supply of radioisotopes in Europe and support bolstering industrial competitiveness in this sector.

1.6. Radioisotopes are perishable and some of them must be used within a few hours or days after being produced. This creates enormous pressure for them to be managed efficiently, in terms of logistics, transport and storage. Therefore, the EESC calls on Member States to cooperate and remove regulatory hurdles that might create bottlenecks along the entire supply chain.

1.7. In the field of transport, container certifications must be mutually and easily recognised by all Member States; recognition of perishable goods status and appropriate customs formalities are required.

1.8. To ensure equal access to care, the EESC calls on the Member States, and in particular on research centres and hospitals, to work together more closely. Access to radiation therapy is not uniform across the Member States, especially in the development and pilot phases. The aim is to have faster access to medicines in the research phase or in compassionate use ([2]), as well as to improve access for small hospitals that may lack expertise and infrastructure. This access can be vital for some patients.

1.9. The EESC calls for increased awareness of nuclear medicine throughout the supply chain, including among medical and healthcare staff and patients. This can avoid bottlenecks and facilitate choice in terms of therapy.

1.10. The EESC stresses the need to prioritise European funding in research, development and innovation in nuclear medicine, particularly in the Horizon and Euratom programmes, while allowing synergies between the two programmes. It suggests financing strategic projects of common interest in this area under the EU's future Multiannual Financial Framework (MFF).

1.11. The ageing fleet of research reactors plays a key role in the production of radioisotopes. The EESC recommends that they be managed effectively in order to exploit their potential in technical terms for as long as possible, and that investments be made in new capacities capable of meeting increased demand, such as accelerators or small modular reactors, while replacing old reactors.

1.12. In this respect, the EESC welcomes the new projects being worked on in the EU. It also recommends examining the interplay with the electricity generation field and ensuring that new production reactors and facilities help to produce medical radioisotopes, for example in combination with accelerators. The aim is to develop a coordinated network for research based on new medical radionuclides.

1.13. The EESC supports the SAMIRA strategy and the European Radioisotopes Valley Initiative (ERVI) in connection with Europe's Beating Cancer Plan, and calls for tangible progress to be made. It hopes that ERVI will help tackle dependencies more effectively and build high-assay low-enriched uranium (HALEU) and stable isotope capacities in Europe.

1.14. The EESC requests that due care to be taken to ensure that staff safety and security measures are respected throughout the supply chain.

1.15. The EESC calls for urgent investment in the planning, education and training of the people needed in this sector and in staff mobility.

([1]) Critical Medicines Alliance.

([2]) Offering a treatment in development once all approved treatments have been exhausted.

1.16. The EESC recommends working with trusted global partners in research, development, innovation and supply, starting with neighbouring countries located in the European geographical area.

2. **Background**

2.1. Every year, up to 10 million European patients ([3]) benefit from nuclear medical imaging to diagnose diseases, such as cancer or heart disease. Radiological and nuclear technologies are essential in the fight against cancer at all stages of care: early detection, diagnosis, treatment and palliative care.

2.2. A political commitment to take action against cancer was made in Europe's Beating Cancer Plan in February 2021. There are many types of cancer treatment available depending on the type of cancer, how advanced it is and the response of the patient. Radiation therapy (radiotherapy) is a treatment that uses high doses of localised radiation to kill cancer cells to reduce and eliminate tumours, while molecular radiotherapy is capable of targeting radiation to disseminated cancers, minimising the side effects observed with other forms of treatments.

2.3. European researchers and businesses have developed some of the newest innovative radionuclide cancer treatments, such as pharmaceuticals targeting endocrine and prostate cancer based on Lutetium-177 ([4]), which are localised and often less harmful to the body than other treatments. Tens of thousands of cancer patients need targeted radionuclide therapy, which is often the only treatment available. The collaborative effort is ongoing and researchers and businesses are actively developing new treatments, such as targeted alpha therapy exploiting new radionuclides that have more concentrated radiation properties.

2.4. Most radioisotopes are produced in nuclear reactors and accelerators. There are seven research reactors in Europe producing radioisotopes ([5]). The full supply chain for radioisotopes for medical treatment is highly complex. It includes the supply of raw materials and their storage, irradiation, processing, logistics and application. Once the radioisotopes are produced, they must be processed, shipped and used within a relatively short period of time, some on the same day, others within a few days, depending on their half-life ([6]). The supply chain therefore depends on these properties and on the systems of production using reactors or accelerators, as well as on processing and delivery to hospitals.

2.5. Although the EU is the largest supplier of medical radioisotopes to the world market, it depends entirely on the US and Russia for the supply of metallic HALEU (which is used as a fuel in research reactors), and for the supply of some enriched isotopes for radioisotope production targets. However, dependence on Russia is decreasing, as some reactors are shifting to different supplies. The EU nonetheless remains highly dependent for the supply of stable isotope targets, which allow the production of certain radioisotopes used in modern or developing molecular radiotherapies, such as Yterbium-176 used to produce Lutetium-177.

2.6. The EU also faces another type of challenge in terms of supply: the age of the research reactors used to produce radioisotopes and their possible shutdown in the future. It is therefore necessary to set up appropriate investment programmes to manage and extend their lifetime. New initiatives to respond to current projections are ongoing ([7]), in order to maintain Europe's leadership in innovation.

([3]) SAMIRA action plan (European Commission).

([4]) Radionuclides and radioisotopes are atoms of a chemical substance with radioactive properties. The two terms have slightly different meanings.

([5]) Maria (1974) in Poland, HFR (1961) in the Netherlands, BR2 (1961) in Belgium, FRM-II (2004) in Germany, LVR-15 (1957) in Czechia, BRR (1959) in Hungary, RHF-ILL (1971) in France.

([6]) Time needed for their initial activity level to decrease by 50 %.

([7]) New reactors such as PALLAW, FRM-II, RJH, MYRRHA, Arthur. New European infrastructures such as ESS, IFMIF-DONES, considered in a PRISMAP+ programme.

2.7. SAMIRA is the EU's comprehensive action plan to support the safe, high-quality and reliable use of radiological and nuclear technology in the healthcare sector. This plan sets out initiatives in three priority areas: securing the supply of medical radioisotopes, improving radiation quality and safety in medicine, and facilitating innovation and technological development in medical ionising radiation applications.

2.8. The priority given in the SAMIRA plan to security of supply underpins the process aimed at establishing an ERVI to maintain the EU's global leadership in the supply of medical radioisotopes and help accelerate the development and introduction of new radioisotopes and production methods. This priority flows from a number of Council conclusions (such as those of May 2019) calling for reduced dependency on third countries in relation to the medical radioisotopes supply chain. The EU's resilience in isotope supply has increased since Russia launched its war of aggression against Ukraine.

2.9. Five projects are being developed under the ERVI roadmap: enhancing Europe's production capacity for both metallic HALEU and enriched stable isotopes, creating centralised medical radionuclide production, expanding the European medical radionuclide programme (PRISMAP) and developing more reliable monitoring of supply and demand.

2.10. The use of nuclear and radiation technologies not linked to energy production is defined by Euratom legislation and Member States' own laws. The Euratom Supply Agency plays a role in the supply of basic nuclear materials used as fuel in research reactors and as a target for the production of medical radioisotopes, and co-chairs alongside industry stakeholders the European Observatory on the Supply of Medical Radioisotopes, which monitors the production chain for medical radioisotopes. In addition, the use of radioisotopes is an area that must comply with Euratom regulations, including basic safety standards and waste management directives, the transposition of which is covered by the applicable national regulations. National rules sometimes create barriers to the supply or transport of radioisotopes between Member States. In the production of Mo-99, each step has its own transportation security rules ([8]): from reactor target irradiation, with between 3 and 12 hours needed for transport, to the Mo processing facility by road or air transport, then to the Molybdenum generator and finally to hospitals. This means that, between production and use in a hospital, every minute counts.

The four fundamental pillars of the transport of medical radioisotopes are: safety, speed, reliability and efficiency. Any changes to regulations, particularly those impacting the IAEA's Specific Safety Requirements Series No. SSR-6 (Regulations for the Safe Transport of Radioactive Material), could have a major technical impact on the submission of files, including the inability to update and/or submit a certification request. Multilateral/multi-country certifications for a designated container for transport increase the risk of delay for re-certification and generate extra costs. In other words, no certified container means no transport and no radiopharmaceuticals for patients. Therefore, licences should be granted at EU level, not at national level, to make transport more efficient in the interest of patients.

2.11. Diagnostic radioisotopes are used in molecular imaging and are an important diagnosis tool. Among the different diagnosis tools, methods relating to scintigraphy and SPECT-CT and PET-CT imaging techniques remain unmatched and are the preferred choice. Therapeutic radionuclides are used in pharmaceutical products, as pain relief or part of palliative or curative treatment. Recent breakthroughs in the field of radiopharmacy do not yet have equivalent treatments.

3. **General comments**

3.1. Given the potentially growing needs in healthcare for radioisotope-based treatments, the EU must secure supply of medical radioisotopes in the long term in order to maintain access for European patients to vital medical procedures and support the development of new cancer treatments.

([8]) The transport of dangerous goods is regulated by the UN and its agencies (e.g. the IAEA) and by international transport associations rules (IATA for aircrafts).

3.2. The interests of patients must be at the heart of any initiative undertaken by Member States and the EU. According to the EESC, the main goal should be to provide an effective response to European citizens' desire for affordable cancer prevention, early detection and care, as well as improved quality of life for cancer patients. This requires substantial investment in infrastructure, given the massive discrepancies with respect to access to medical technology and diagnostic and therapeutic radionuclides across the EU.

3.3. The challenge to the supply of radioisotopes is thus fourfold – growing demand for radioisotopes from the healthcare sector; high dependencies on third countries for certain key source materials; the ageing research reactor fleet and delays in plans to build research irradiation reactors; and the lack of harmonisation in the implementation of applicable regulations (nuclear, pharmaceutical and transport) across the EU.

3.4. The safe and stable supply of radioisotopes calls for secure access to raw materials, as well as the treatment, processing, transport, distribution and storage of those materials; it also requires facilities and laboratories with appropriate licenses, including for radioisotopes to be administered to patients by medical professionals. The issue therefore involves various sections of civil society such as industry, patients, scientists and researchers, as well as doctors.

3.5. The ageing of the EU's research reactor fleet is worrying and calls for optimised use of such reactors in the Member States, as well as suitable management programmes. In this regard, the EESC supports the SAMIRA strategy and ERVI. The EESC considers patients' access to medical procedures to be vital and supports the development of new treatments to help in the fight against cancer as set out in the SAMIRA strategy.

It calls for radiation protection and safety to be improved for European patients and medical staff and supports the full implementation in the Member States of high standards for the quality and safety of medical radiation applications. It also calls for key projects (such as PRISMAP) to continue after 2025 and to be more integrated.

The Basic Safety Standards Directive ([9]) already provides a clear framework for radiation protection. However, efforts should be made to harmonise the application of this directive and reconcile it with the pharmaceutical legislation currently under revision, as both sets of legislation regulate the use of radiopharmaceuticals for diagnostic and therapeutic purposes.

3.6. As well as working on the optimal use of research reactors, Member States should also cooperate on research and innovation. Some patients are not offered any solution to aggressive or rare forms of cancer. New innovative advances are therefore needed. Emerging innovative treatments are offered in precision medicine, such as radionuclide targeted therapy or immunotherapy.

3.7. The EU4Health programme supports the quality and safety of radiation technology in cancer diagnosis and treatment. The Euratom research and training programme, which promotes radiation protection in medicine, reliable supply of medical radionuclides, research on their safe use in health applications and their conversion into innovative care for patients, could make synergies possible with Horizon Europe's 'Health' cluster in the future, provided that the Commission services work in a truly coordinated manner.

3.8. In order to mitigate dependencies and to strengthen capabilities, more engagement at EU level is needed. The EESC therefore suggests joint initiatives under the next MFF in all of the areas mentioned above to allow eligible patients access to medical radionuclide-based technologies.

3.9. Some nuclear innovations in the health sector have been developed by national, international or academic laboratories as well as research centres, including the European Commission's Joint Research Centre. Examples include PET-CT diagnostic tools and the radionuclide treatments Lu177-DOTATATE and Ac225-PSMA. These innovations were achieved in very different public and private research settings and call for further streamlining and harmonisation. This streamlining should include the further development of harmonised tools and guidance for early phase clinical trials, particularly for diagnosis, theranostics and therapeutic radiopharmaceuticals.

([9]) Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).

3.10. The proper shipment, handling and management of waste falls within the purview of different authorities at national, European and sometimes international level. This lack of harmonisation and the difficulty in interpreting this body of law represent obstacles to accessing medical radionuclides for clinical research. The EESC therefore calls for better coordination between the legislative and regulatory frameworks across the different policy areas involved, to enable coordinated European solutions.

3.11. The EESC also recommends looking for ways of recycling materials after irradiation, and investigating alternative solutions such as combining natural target materials and physical separation methods in order to ensure better access to certain enriched isotopes.

3.12. Europe has lost a generation of qualified workers in the nuclear sector and needs to catch up. We need to increase the number of scientists and medical staff with expertise in nuclear science, from both the pharmaceutical and medical sectors. It is crucial to consolidate the skills of professionals at all levels, from nuclear medicine specialists and engineers to technicians in production and logistics.

3.13. The EESC supports coordinated efforts to assess national capacities, taking stock of the methodology applied by the members of the European Human Resources Observatory for the Nuclear Sector (EHRO-N), and to develop a workforce capable of maintaining the EU's leading position in providing medical radioisotopes and promoting innovation.

3.14. The EU must not remain isolated; the EESC therefore reiterates its call for better cooperation with global partners such as the IAEA on research, innovation ([10]) and supply. This could be achieved through various projects, both private and public.

4. **Specific comments**

4.1. In 2018, scientists analysed the relationship between the number of radiotherapy treatment machines and cancer mortality ([11]). An inverse link was found: the more machines there are, the lower the mortality. It is therefore important to invest more in infrastructure and staff.

4.2. The EESC calls for the strict application of safety rules for staff involved in the supply of raw materials, irradiation, processing and packaging, through to delivery to hospitals, as well as patient care and waste management. Healthcare professionals, especially those working in radiology and nuclear medicine, are critical to the safe management and administration of radioisotopes for patient care. Their expertise is paramount for effectively using these vital resources, emphasising the need for continuous training on the latest radioisotope technologies and safety protocols.

4.3. It is crucial to address patients' needs, and hospitals ([12]) have a role to play in ensuring that each patient receives the best possible treatment at the best price and with a full reimbursement policy. Since patients should lie at the heart of public health, their safety is paramount, and the EESC therefore calls for measures to better inform patients about the treatments they receive.

The EESC also recommends that all actors in the supply chain be aware of the importance and specific characteristics of radioisotopes in order to allow a smooth delivery of these life-saving products.

It calls for professionals and social partners to be consulted when healthcare policies are being developed.

Brussels, 31 May 2024.

The President
of the European Economic and Social Committee
Oliver RÖPKE

([10]) Opinion of the European Economic and Social Committee on Communication from the Commission to the European Parliament and the Council -- Europe's Beating Cancer Plan (COM(2021) 44 final) OJ C 341, 24.8.2021, p. 76 .
([11]) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6163015/pdf/clep-10-1249.pdf.
([12]) Clinical research is typically conducted in large university hospitals.

ANNEX

The following amendments, which received at least a quarter of the votes cast, were rejected in the course of the debate (Rule 74(3) of the Rules of Procedure):

AMENDMENT 2

TEN/833 – Europe's Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply

Point 1.11

Amend as follows:

Section opinion	Amendment
The ageing fleet of research reactors plays a key role in the production of radioisotopes. The EESC recommends that they be managed effectively in order to exploit their potential in technical terms for as long as possible, and that investments be made in new capacities capable of meeting increased demand, such as accelerators or small modular reactors, while replacing old reactors.	The ageing fleet of research reactors plays a key role in the production of radioisotopes. The EESC recommends that they be managed effectively in order to exploit their potential in technical terms for as long as possible, and that investments be made in new capacities capable of meeting increased demand, such as accelerators or small modular reactors, while replacing old reactors. ***In this respect, the EESC welcomes the new projects being worked on in the EU. The aim should be to develop a coordinated network for research based on new medical radionuclides.***

Reason

See amendment 3.

AMENDMENT 3

TEN/833 – Europe's Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply

Point 1.12

Delete point:

Section opinion	Amendment
In this respect, the EESC welcomes the new projects being worked on in the EU. It also recommends examining the interplay with the electricity generation field and ensuring that new production reactors and facilities help to produce medical radioisotopes, for example in combination with accelerators. The aim is to develop a coordinated network for research based on new medical radionuclides.	

Reason

The first and last sentences have been added to point 1.11, and the second sentence has been deleted.

Content: there is so far no link between nuclear energy generation and the production of products needed in nuclear medicine. The EESC should therefore be careful about recommending 'ensuring' that new (energy) reactors simultaneously supply medical radioisotopes too.

Form: in the first section of its opinions (the summary), the EESC should only present aspects and requests that are described in more detail in the following sections. However, the aspect described in point 1.12 is not even briefly mentioned in sections 2-4.

Outcome of the vote

In favour:	52
Against:	89
Abstention:	6