Council of the European Union

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RECH 231
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'I/A' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
Subject:	Draft Council conclusions on the security of supply of radioisotopes for medical use - Approval

1. On 28 February 2024, the Presidency hosted a Workshop on Securing Access to Radiopharmaceuticals for all European Patients. Stakeholders were invited to discuss such issues as the role of precision medicine in cancer therapy by using radiopharmaceuticals, the importance of doctor's knowledge to guarantee patients' quality of life from the patients' perspective, the EU regulatory aspects to foster innovation and prevent shortages for medicines and the hurdles of the regulatory framework for radiopharmaceuticals. The role of JRC in enabling radiopharmaceutical research and how to translate it to clinical use were also discussed. Finally, possibilities for securing the radiopharmaceutical supply chain and fostering the EU autonomy were addressed.

2. On 9 April 2024, the Presidency shared with delegations a set of draft Council conclusions on 'The Security of Supply of Radioisotopes for Medical Use'. The draft and its revisions (documents 8497/24, 9284/24 and 9707/24) were discussed at the Atomic Questions Working Party on 10 April, 30 April, and 14 May 2024. Member States were asked to provide written comments. As a result of the discussions the Presidency shared with the Member States the text as set out in the Annex and informed them of its intention to submit it to COREPER and Council as an I/A item.

2. The draft Council conclusions build on earlier conclusions by the Council (2009, 2010, 2012, 2019, 2021) and on the insights of the Commission and the European Observatory on the Supply of Medical Radioisotopes.

3. The draft Council conclusions aim at ensuring the supply of medical radioisotopes and to maintain Europe's autonomy as well as global leadership in this field. Recalling the commitment of the European Union, the Euratom Community, and the Member States to provide citizens with a high level of healthcare, the draft insists on the role of radioisotopes for medical diagnostic and therapy.

4. The draft Council conclusions urge the Commission to act on five key pillars:

- Europe's global leadership role in the supply of medical radioisotopes by making tangible and swift progress on the relevant identified actions;
- Monitoring and forecast of demand and supply for all relevant medical radioisotopes;
- Research and innovation on topics related to medical radioisotopes and other medical radiological technologies;
- Assessment and development of critical skills;
- Assessment of the framework for transporting radioisotopes for medical use in order to contribute to ensure access for patients in all Member States.

5. The Permanent Representatives Committee is invited to suggest to the Council to adopt, under the "A" items of a forthcoming session, the Council conclusions as set out in the Annex.

ANNEX

DRAFT COUNCIL CONCLUSIONS ON THE SECURITY OF SUPPLY OF RADIOISOTOPES FOR MEDICAL USE

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The Council of the European Union,

CONSIDERING THAT

- achieving strategic autonomy while preserving an open economy is a key objective of the Union;
- health has been identified as a sector where the Union's strategic dependencies need to be addressed;
- the European Union, the Euratom Community and their Member States are committed to providing citizens with a high level of health care;
- radioisotopes play an essential role in medical diagnostics and therapy;
- the need for diagnostic and in particular therapeutic radiopharmaceuticals is steadily increasing;
- cross-border transport needs to take into account short half-life of radioisotopes for medical use as patients across the European Union should benefit from the production that is today mainly concentrated in a limited number of Member States;

- it is therefore necessary to secure the future supply of radioisotopes for medical use in the European Union, reflecting the balance between the needs to cover costs and to ensure public access to modern medical services;

- Directive 2013/59/Euratom establishes uniform basic safety standards for the protection of the health of individuals subject to occupational, medical, and public exposures against the dangers arising from ionising radiation.

NOTING THAT

- Member States have consistently supported Union actions to secure the supply of medical radioisotopes in the European Union, notably by issuing Council conclusions in this area in 2009[1], 2010[2] and in 2012[3], and including this topic in the Council conclusions of 2021 on strengthening the European Health Union[4];

- more specifically, in 2019, the Council called upon the Commission to develop an Action Plan on non-power nuclear and radiological technologies[5];

- in 2021, the Commission adopted the Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) as a comprehensive action plan to support a safe, high quality and reliable use of radiological and nuclear technology in healthcare, contributing to Europe's Beating Cancer Plan;

1 17025/09
2 16358/10
3 17453/12
4 14029/21
5 9437/19

- the SAMIRA action plan provides a cross-policy framework for coordinated EU action in order to improve synergies with all relevant stakeholders in the areas of supply of radioisotopes for medical use, quality and safety of medical radiation applications, and innovation and development of medical nuclear and radiation technology;

- the sustainable supply of high-assay low-enriched uranium (HALEU), enriched stable isotopes and other relevant raw materials is of vital importance to increase the resilience of the European supply chain and to reduce the dependence from third countries, which is stated in the SAMIRA action plan;

- since 2012 the European Observatory on the Supply of Medical Radioisotopes is a valuable instrument for supporting secure supply of notably molybdenum-99/technetium-99m across the European Union, taking into account the global situation.

UNDERLINES the important contribution of European nuclear research reactors and other nuclear facilities able to produce medical radioisotopes at the levels required for the long term needs in the Union and the importance that these facilities, as well as the expertise which enable the production of these radioisotopes, remain located in the European Union;

SUPPORTS the continued monitoring of the supply chain of medical radioisotopes through the European Observatory on the Supply of Medical Radioisotopes;

CALLS ON the Commission, the Euratom Supply Agency, and the Member States, as well as industry and relevant stakeholders, to continue efforts to secure a reliable supply of source material for radioisotope production;

RECALLS the efforts and actions of the Euratom Supply Agency together with the Member States, industry, and research reactors operators, to ensure the secure supply of nuclear source materials for research reactor fuel;

TAKES NOTE of the considerations in some Member States, in view of increasing the security of supply, to work on the exploration and processing of indigenous sources of relevant raw materials;

ENCOURAGES the continuation and expansion of projects that support innovation for the development of production technologies across the supply chain[6];

RECALLS that the safe management of radioactive waste from those reactors and facilities is an important responsibility of Member States and license holders;

STRESSES the need for a better interaction between European Union legal frameworks, in particular for pharmaceuticals and radiation protection, with a view to developing diagnostics and therapies without undue delay and making them accessible to patients in an optimised and individualised manner, thereby ensuring a high level of quality and safety and an efficient use of resources;

EMPHASIZES the importance of a skilled labour force required for the production and use of medical radioisotopes in order to ensure better patient access;

UNDERLINES its strong support to research and innovation into health applications of nuclear science and technology, while fostering synergies between the Euratom and the Horizon Europe research programmes[7] as well as with relevant EU health initiatives;

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6 Current examples of relevant activities include the PRISMAP and SECURE projects.

7 This could include areas, such as enabling and accelerating research on radiopharmaceuticals, theranostics and precision nuclear medicine, as well as advancing production technologies across the supply chain, including the supply of stable isotopes and the development of new production pathways and decentralized production networks.

URGES the European Medicines Regulatory Network to review all the radiopharmaceuticals authorised in Europe and assess their criticality, according to existing methodology.

URGES the Commission to:

- seek to maintain Europe's global leadership role in the supply of medical radioisotopes and make tangible and swift progress on developing ambitious 'building blocks' for specific actions when implementing the European Radioisotopes Valley Initiative (ERVI);

- develop a mechanism, based on the experience of the European Observatory on the Supply of Medical Radioisotopes, to monitor and forecast demand and supply for all relevant medical radioisotopes;

- support research and facilitate innovation, together with the Member States and benefiting, where relevant, from the expertise and infrastructures of the Joint Research Centre (JRC), on topics related to medical radioisotopes and other medical radiological technologies as well as to promote the innovation of new technical methods for medical radioisotope production;

- foster joint efforts in the assessment and development of critical skills necessary to enable a safe and secure production and use of medical radioisotopes;

- assess the framework for transporting radioisotopes for medical use in view of the specific needs of the sector and the half-life of different radioisotopes, as well as available production sites and methods.