EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

08 April 2025
EMA/95894/2025
Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)

Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) to address vulnerabilities in the supply chain of radiopharmaceuticals

1. Introduction

Radiopharmaceuticals play a key role in medical diagnosis and treatment, especially important in the fight against cancer. The use of radiopharmaceuticals is steadily increasing while the manufacturing capacity remains limited.

The vulnerabilities in the supply chain of radiopharmaceuticals are well-known and are mainly due to vulnerabilities in the manufacturing of medical radioisotopes:

- Dependency on third countries for the enrichment of stable isotopes and key source materials for medical radioisotope production. High-assay-low-enriched uranium (HALEU), used as fuel for research reactors, is currently not produced in the EU and can only be imported from the US or Russia
- Limited manufacturing capacity at aging research reactors in the EU

The supply chain of radiopharmaceuticals is complex, an example representing the manufacturing of Tecnetium 99metastable (Tc-99m) to illustrate this complexity can be found below.

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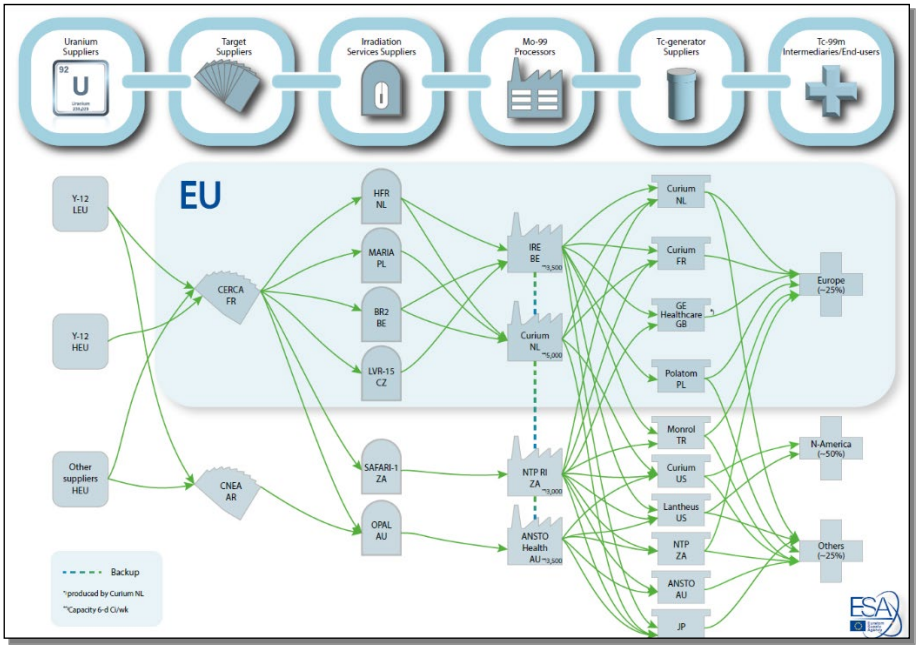

Source: ESA

Ongoing EU policies and initiatives:

- EU Observatory for the Supply of Medicinal Radioisotopes - established in 2012 by the European Commission, aims to assess, monitor and support the supply of medical radioisotopes in the EU with a particular focus on Molybdenum-99/Technetium-99m, a radioisotope used in 80% of nuclear medicine diagnostics.
- Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) action plan - EU initiative under the Europe's Beating Cancer Plan[1]. 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 adopted by the Commission in 2021.
- European Radioisotopes Valley Initiative (ERVI) activities: exploring the possibilities for building European production capacity for metallic HALEU, enhancing Europe's production of enriched stable isotopes, strengthening the medical radionuclide production, expanding the European medical radionuclide programme (PRISMAP), and developing more reliable monitoring of supply and demand.

In 2024, the need to ensure security of supply for radioisotopes for medical use was highlighted in the Council conclusions on the security of supply of radioisotopes for medical use[2] and the European Economic and Social Committee (EESC) "Europe's Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply[3]".

The MSSG, through the Medicine Shortages Single Point Of Contact Working Party (SPOC WP), has being monitoring availability issues of radiopharmaceuticals and providing regulatory support when possible to prevent an/or mitigate the impact of shortages on patients. However, the regulatory tools available are limited to address the vulnerabilities in the supply chain of radiopharmaceuticals which would require long-term industrial policy measures.

[1] Europe's Beating Cancer Plan
[2] Council conclusions on the security of supply of radioisotopes for medical use
[3] Europe's Beating Cancer Plan: Driving forces for the security of medical radioisotopes supply

According to the MSSG recommendations to strengthen supply chains of critical medicinal products4 published in April 2024, the MSSG may propose measures to address vulnerabilities in the supply chain of critical medicines to strengthen their security of supply which will complement the ongoing initiatives mentioned above.

2. Recommendations

2.1. Recommendations to the European Commission

For consideration by relevant Commission Services,

- Consider the MSSG analysis of vulnerabilities in the supply chain of radioisotopes and identify policy measures to support security and continuity of supply of medical radioisotopes in the EU/EEA for the manufacturing of radiopharmaceuticals, including through prioritisation of domestic capabilities to reduce dependency from third countries and address the limited manufacturing capacity in the EU, including
  - consideration of ongoing industrial policy supports and initiatives;
  - developing an EU-based HALEU enrichment and metallisation capacity and
  - optimisation of production installations in the EU.
- Consider the work of the European Observatory on the Supply of Medical Radioisotopes, co-chaired by the Euratom Supply Agency (ESA) and Nuclear Medicine Europe (NMEU) and the work carried out under the Strategic Agenda for Medical Applications of Ionising Radiation (SAMIRA).
- Call upon (ESA) to continue its work to help secure supply of nuclear materials (HEU and HALEU) needed for medical radioisotope production.
- Progress/ Complete the European Radioisotope Valley Initiative (ERVI).
- Consider transport challenges and EU level solutions to address these challenges in cooperation with Member States. This could include harmonisation of certification procedures and mutual recognition of transport containers among Member States, transport logistical challenges or potential challenges and consequences of ban of lead.
- Expand the existing monitoring production chain activities to additional **radioisotopes, beyond Mo-99/Tc-99m**, as a preventative measure for other indications as demand increases.

2.2. Recommendations to Member States

- Map existing supply to national markets (from raw material onwards) and provide relevant feedback through the SPOC WP.
- Provide regulatory support as needed.
- Consider transport challenges at national level and put in place solutions to address those challenges at national level (coordinated with Union level approach, where relevant).
- Consider the inclusion of new radiopharmaceuticals in horizon scanning activities to ensure access to new radiopharmaceuticals.

[4] MSSG recommendations to strengthen supply chains of critical medicinal products

2.3. Recommendations to EMA

- Provide regulatory support as needed.
- To support MS in the horizon scanning activities as appropriate.
- To ensure coordination of relevant activities and avoid duplication of work.

2.4. Recommendations to Companies (MAHs and manufacturers)

- Cooperate and submit information necessary to ensure security of supply to the EU market.