



EUROPEAN OBSERVATORY
on the supply of medical radioisotopes



Luxembourg, 30 March 2021

Mission statement

Purpose

The Observatory provides a platform for the stakeholders to discuss, monitor and support the EU supply of widely used medical radioisotopes with the focus on Mo-99/Tc-99m. The Observatory compiles the information provided and brings it further for decision makers in the EU, national governments, national and international official bodies, the medical community and the European industry in order to assist them to define strategies and policies of their implementation.

The role of the European Observatory is not to take decisions.

Background

Following the Council Conclusions "Towards the Secure Supply of Radioisotopes for Medical Use in the European Union" adopted on 6 December 2010, the "European Observatory on the supply of medical radioisotopes" ("Observatory") was jointly proposed in November 2011 and set-up in June 2012 by the European Commission and the industry organisation for Europe, AIPES (now renamed NMEu).

The Observatory supports the security and sustainability of the supply in the EU. It follows the OECD/NEA principles established by the High-Level Group on Medical Radioisotopes (HLG-MR), focusing on their European specificities.

Objectives

The Observatory has the following objectives:

- (1) to support secure and sustainable medical radioisotope supply across the EU taking into account the worldwide need and supply;
- (2) to ensure that the medical radioisotope supply issue is given high political visibility in international and national institutions, organisations and bodies;
- (3) to identify any event or trend likely to impact the medical radioisotope supply, including logistics, and call relevant parties to take appropriate countermeasures;
- (4) to promptly disseminate through agreed communication channels the enquired information regarding any possible supply disruptions or other supply related issues;

- (5) to establish periodic reviews of the medical radioisotope supply chain and capacities with all stakeholders across the EU, taking into account the worldwide need and supply, and to forecast future needs;
- (6) to build a foresight overview of the supply and demand of medical radioisotopes at EU level;
- (7) to acquire the latest information on the development and implementation of new and alternative methods and technologies of medical radioisotope production.

Membership and working methods

The Observatory brings together supply chain stakeholders (industry, research organisations and EU Member States), nuclear medicine organisations, members of NMEu, international organisations concerned as well as relevant Commission services and EU Agencies.

Upon request, the Observatory may accept the membership of other EU-based stakeholders and organisations if approved by the chairs.

Upon request, the Observatory could grant an observer status to other non-EU-based stakeholders and organisations relevant for the mission of the Observatory.

The Observatory, if approved by the chairs, may invite other stakeholders, external organisations, policy-makers and academics to participate in the meetings as and when needed.

A plenary meeting takes place at least once a year, unless otherwise decided. Ad-hoc meetings or working groups can be organised to deal with specific questions, should this be necessary.

Scope

For the purpose of the Observatory, the following core themes will be addressed:

- (1) Reactor scheduling and Mo-99 supply chain monitoring on a short, medium and long term basis;
- (2) Status of research reactors and processors conversion from highly enriched uranium (HEU) to low-enriched uranium (LEU) for medical isotope production;
- (3) Mo-99/Tc-99m capacity and infrastructure development, including transport and regulatory issues to find conditions conducive to the smooth supply of medical radioisotopes;
- (4) Development of alternative Mo-99/Tc-99m production methods;
- (5) The Observatory will review the scope forward looking as needed, taking into consideration recently widely used diagnostic as well as therapeutic medical radioisotopes (e.g. I-131 and Lu-177).

Values and principles

Work for public benefit - The European Observatory is committed to carrying out work, which could lead to evidence-based decision-making. Delivering results will be of the utmost importance. The European Observatory will seek and share information about those results.