



Brussels, 28 July 2017

Mission statement

Background and purpose of the European Observatory

Radioisotopes are used in medicine for the diagnosis and treatment of various diseases, including some of the most important ones, like cancers, cardiovascular and brain diseases. Over 10000 hospitals worldwide use radioisotopes for the in vivo diagnosis or treatment of about 35 million patients every year, of which 9 million in Europe. The majority of the nuclear medicine procedures today are for diagnosis, with about 100 different nuclear medicine imaging procedures available. Imaging using radioisotopes is often indispensable, for instance due to its ability to identify various disease processes early, long before other diagnostic tests. Technetium-99m (Tc-99m) is the most widely used (diagnostic) radioisotope. Europe is the second largest consumer of Tc-99m, accounting for more than 20% of the global market. The production of Tc-99m is a complex process which includes irradiation of uranium targets in nuclear research reactors to produce Mo-99, extraction of Mo-99 from targets in specialised processing facilities, production of Tc-99m generators and shipment to hospitals. Due to their short decay times, Mo-99 and Tc-99m cannot be stockpiled and must be produced continuously and delivered to hospitals weekly. Any supply disruption can lead to a situation where crucial diagnostic imaging tests must be cancelled or postponed. Mo-99/Tc-99m supply crisis, which occurred in 2009-2010 and resulted in many patients having important diagnostic tests cancelled or delayed, exposed the fragility of the production chain, relying on a low number of nuclear research reactors.

Following the Council Conclusions "*Towards the Secure Supply of Radioisotopes for Medical Use in the European Union*" adopted on 6 December 2010, the rationale for the creation of the European Observatory is to establish a body that can help to solve issues concerning the Mo-99/Tc-99m supply chain which directly impacts on healthcare needs.

The role of the European Observatory is to bring together all relevant information to the 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.

In April 2009, OECD/ NEA established the High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR). The HLG-MR examined the major issues that affect the short-, medium- and long-term reliability of Mo-99/Tc-99m supply and then developed a policy approach to give the supply chain a sustainable basis ensuring security of supply.

The European Observatory follows the original OECD/NEA principles established by the HLG-MR, focussing on their European implementation and specificities.

After an initial period of operation of, and following supportive feedback on the activities of, the European Observatory, and subject to agreement by competent European Union institutions and

AIPES members', a formal Joint Undertaking (Article 45 of the Euratom Treaty) could then be considered taking into account the initial experience and the lessons learned.

The purpose of the European Observatory is based on the following four general strategic objectives:

- to support secure Mo-99/Tc-99m supply for the medium and long term, across the EU taking into account the worldwide need and supply,
- to ensure that the Mo-99/Tc-99m supply issue is given high political visibility in international and national institutions, organisations and bodies,
- to encourage creation of a sustainable economic structure of the Mo-99/Tc-99m supply chain through supporting the implementation of full-cost recovery (FCR) methodology developed by OECD/NEA HLG-MR,
- to establish periodic reviews of the Mo-99/Tc-99m supply chain and capacities with all stakeholders across the EU, taking into account the worldwide need and supply, and to forecast future needs.

Membership and working methods

The European Observatory brings together EU Institutions, industry and governmental representatives. Other stakeholders and organisations can join if requested. It meets twice a year. Ad-hoc meetings or working groups can be organised to deal with specific questions, should this be necessary.

Activities

For the purpose of the European Observatory, the following four main themes will be addressed:

- a. Reactor scheduling and Mo-99 supply monitoring globally (EU and abroad) on a short, medium and long term basis,
- b. Cost recovery mechanism for the EU (cost methodology, drug reimbursement process),
- c. Management of conversion from highly enriched uranium (HEU) to low-enriched uranium (LEU) for medical isotope production,
- d. Mo-99/Tc-99m capacity and infrastructure development.

The European Observatory will address the challenges of the four aforementioned main themes across a global landscape where appropriate; other themes may be incorporated at a later date. There may also be a need to verify later whether a specific legal status would need to be attributed to this European Observatory.

Commitments and values

The European Observatory is committed to:

- taking any initiatives within its mandate to secure supply of radioisotopes for patient care in nuclear medicine,
- complying with competition rules. All necessary precautions against potential competition infringements should be taken prior to adoption of relevant measures,
- enabling each designated member of the Observatory to contribute with relevant data and information dealing with its own domain of expertise or responsibility,
- working in partnership with all stakeholders, governments and international organisations to describe comprehensively and to analyse radioisotope supply for health needs,
- utilising experience from across EU to clarify policy issues,
- looking at selected countries outside Europe where comparisons can be made or where expertise can be gathered to support the countries of EU in taking evidence based decisions,

- bringing together a wide range of academics, policy-makers, companies and practitioners to analyse trends in policies and reforms,
- communicating effectively with policy-makers through a range of comprehensive, relevant data and reports,
- taking into account all regulations especially for nuclear safety, waste management, nuclear non-proliferation, decommissioning and security.

The mission statement allows responding flexibly to decision-makers and their policy needs. All that the European Observatory will do will be in line with its mission and driven by the following values:

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.

Excellence - The European Observatory is committed to the pursuit of excellence in healthcare issue, policy advice, and publications.

Integrity - The European Observatory is committed to integrity, honesty and consistently high standards in all dealings with organisations within and outside the Observatory.

Accountability - The European Observatory is accountable for its actions to the general public and to its partner organizations, and the European Observatory is prepared to submit itself to appropriate audit and scrutiny. The Observatory seeks the counsel of external organisations, policy-makers and academics.