



EUROPEAN OBSERVATORY
on the supply of medical radioisotopes



Press Release

The European Commission and the Nuclear Medicine Industry have jointly created a European Observatory on the Supply of Medical Radioisotopes.

Brussels, 29 June 2012

Today the European Commission¹ and the European industrial association of Nuclear Medicine (AIPES²) have jointly set-up a European Observatory on the Supply of Medical Radioisotopes. Medical radioisotopes are routinely used to diagnose, enable and monitor treatments of a large variety of diseases including cancer, heart and degenerative 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. Imaging using radioisotopes is often indispensable 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 isotope. The production of Tc-99m is a complex process which includes irradiation of uranium targets in nuclear research reactors to produce Molybdenum-99 (Mo-99), extraction of Mo-99 from targets in specialised processing facilities, production of Tc-99m generators and shipment to hospitals.

Following the shortages of medical radioisotopes across the globe between 2008 and 2010 due to unplanned reactor shutdowns, the Council of the European Union³ issued on 6 December 2010 Council Conclusions "Towards the Secure Supply of Radioisotopes for Medical Use in the European Union", asking the European Commission to define a European solution for ensuring mid and long term security of supply of radioisotopes within the EU.

The first response to this request is the creation of the European Observatory on the Supply of Medical Radioisotopes, which role is to recommend strategies and policies for a sustainable and secure supply of medical radioisotopes to the decision makers in the EU, national governments, national and international official bodies, the medical community and the European industry, by gathering relevant and comprehensive information.

The European Observatory has the following 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,

¹ <http://ec.europa.eu>

² Association of Imaging Producers & Equipment Suppliers, <http://www.aipes-eeig.org>

³ <http://www.consilium.europa.eu>

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- to encourage the creation of a sustainable economic structure of the Mo-99/Tc-99m supply chain through supporting the implementation of the full-cost recovery methodology developed by OECD/NEA High-level Group on the Security of Supply of Medical Radioisotopes (HLG-MR⁴),
- 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 needs and supply capacities, and to forecast future needs.

The Observatory will function through Working Groups on four issues:

- global reactor scheduling and Mo-99 supply monitoring,
- full-cost recovery mechanisms for the Mo-99 supply in compliance with OECD/NEA HLG-MR policy principles,
- management of conversion from highly enriched uranium (HEU) to low-enriched uranium (LEU) for medical isotope production,
- Mo-99/Tc-99m capacity and infrastructure development.

The Observatory is composed by members coming from the European Commission and various industry stakeholders, who are key players in the Mo-99 production for medical purposes.

"It is a unique mixed panel of experts from the various competent Directorates-General of the European Commission (led by the Directorate-General for Energy⁵), the Euratom Supply Agency⁶, working as one team with the relevant industry experts" explains Augustin Janssens, Chairman of the Observatory's Steering Committee.

"The Observatory is a primeur," highlights Marc Gheeraert, president of AIPES and Co-Chairman of the Steering Committee, "where European industry works hand in hand with the European Commission, the OECD/NEA and the European Association of Nuclear Medicine (EANM)⁷ for the benefit of the health of patients in Europe and across the world."

This European project is unique and has a global reach and responsibility, which will allow faster, more accurate and safer ways to detect, enable treatment of diseases as well as monitor their evolution.

The mission statement of the Observatory is available on the website:

http://ec.europa.eu/energy/nuclear/radiation_protection/medical/doc/observatory_mission.pdf

⁴ <http://www.oecd-nea.org/med-radio>

⁵ <http://ec.europa.eu/energy>

⁶ <http://ec.europa.eu/euratom>

⁷ <http://www.eanm.org>