



Council of the
European Union

Brussels, 2 March 2016
(OR. en)

6460/16

ATO 10
SAN 65

NOTE

From: Presidency
To: Delegations
Subject: Security of supply of medical radioisotopes

Delegations will find attached a note from the Presidency on the security of supply of medical radioisotopes.

The Presidency intends to hold a discussion on this topic at the Working Party on Atomic Questions on 9 March 2016. During the meeting, the Presidency would like to explore delegations' interest in discussing the issue further, and seek delegations' views on the possible form and content of a follow-up document.

Introduction

Radioisotopes play an invaluable role in medical imaging and therapy for a range of conditions including cancer, heart diseases and brain disorders. These procedures have become indispensable for 9 million patients in Europe and 35 million patients worldwide every year¹. In the EU, the integrated nuclear infrastructure of research reactors and processing facilities in six Member States is critical for the European and worldwide supply of medical radioisotopes.

In 2008-2010 operational failure of the ageing nuclear facilities used for the production of medical radioisotopes caused several crises in the supply of Molybdenum-99/Technetium-99m (Mo-99/Tc-99m), leading to cancellations and delays of diagnostic tests and medical treatments. These interruptions constituted a risk to patients and exposed the fragility of the existing production chain.

In response to these crises, the Council adopted Council conclusions in 2009, 2010 and in 2012 stressing the importance of medical radioisotopes and urging Member States and the European Commission to take action and define a European solution to ensure the security of supply of medical radioisotopes².

As a result, the European Observatory on the Supply of Medical Radioisotopes was established, tasked with bringing together all relevant information to the decision makers in the industry, EU institutions and national governments to assist them in defining and implementing strategies to ensure the security of supply of medical radioisotopes. For the short term, cooperation among key stakeholders from government, industry and healthcare has intensified, leading to a better management of unexpected supply interruptions.

¹ For imaging Molybdenum-99 (Mo-99) / Technetium-99m (Tc-99m) is the most widely used radioisotope. In recent years demand for therapeutic radioisotopes, such as Lutetium-177 (Lu-177), Strontium-89 (Sr-89), Iodine-131 (I-131) has significantly increased.

² See docs 17025/09, 16358/10 + COR 1, 17453/12.

However, for the medium and long term the security of supply of medical radioisotopes is still fragile. The planned operation of the Mo-99 irradiation facility at the German FRM-II reactor in 2018 and the French Jules Horowitz reactor in 2021 will add irradiation capacity for the production of medical radioisotopes. However, in 2025-2030 the irradiation capacity for the production of medical radioisotopes will be significantly reduced by the planned decommissioning of the Dutch High Flux Reactor in 2024, the Belgian BR-2 reactor in 2026, the Czech LVR-15 reactor in 2028 and the Polish MARIA reactor in 2030. For a secure supply of medical radioisotopes in the post-2025 period, further investments in new production facilities within the EU are necessary.

Historically the price of medical radioisotopes, and especially the irradiation and processing phases in the production chain, has been established at very low levels, leading to an unsustainable economic structure. Despite the fact that the production of medical radioisotopes is a commercial activity, the industry has not succeeded in implementing a system of full cost recovery. Even today, the revenue of some irradiators and processors is too low to recover production costs and provide conditions for necessary investments.

An integrated nuclear infrastructure is necessary firstly for the medium and long term security of supply of medical radioisotopes and, secondly, to keep the EU at the forefront of research and development of new medical radioisotopes and innovative radiotherapies.

The current mandate of the European Observatory, primarily monitoring, and the work of EU Member States, also in the context of the OECD-NEA, is too limited to create a sustainable economic structure for the production of medical radioisotopes. Additional steps to implement full cost recovery, create a sustainable economic structure and improve market conditions for long term investments have to be taken at the EU level as soon as possible and certainly before 2025.

Objective of the Presidency

The Presidency believes that further action at EU level is necessary and therefore proposes to draw up a document which could, inter alia, invite the European Commission to:

- Engage with Member States, industry and healthcare providers to raise awareness on the unsustainable economic structure of the market of medical radioisotopes and the risk this constitutes to the medium and long term security of supply of medical radioisotopes;
- Facilitate the exchange of information and the exchange of best practices (among national healthcare authorities) to increase transparency in the market of medical isotopes. In this respect, Belgium has introduced a system of unbundling prices of the dose of medical radioisotopes and medical procedures that could provide useful data;
- Develop, in cooperation with Member States, an EU strategy (communication) for the medium and long term security of supply of medical radioisotopes aimed at creating a sustainable economic structure for the production of medical radioisotopes and improving market conditions for long term investments in new production facilities. This strategy should be based on the below principles and include the following aspects:
 - implementation of a system of full cost recovery, including capital costs for refurbishments, upgrades and new projects,
 - implementation of a mechanism of paid outage reserve capacity,
 - creation of a level playing field for EU and non-EU producers of medical isotopes operating in the EU market;
- Assess the possibility of developing a legal framework for the implementation of an EU strategy in compliance with EU competition and state aid law;
- Facilitate research and development of new medical radioisotopes and innovative radiotherapies;
- Create a favourable research and regulatory environment for the licensing of radiopharmaceutical products with due consideration of their diagnostic and therapeutic potential.

Principles for an EU strategy on the security of supply of medical radioisotopes

The Presidency believes that an EU strategy for improving the security of supply of medical radioisotopes should be based on a number of principles. The strategy should:

- Include all medical isotopes for imaging and therapy,
 - Include all production technologies,
 - Apply equally to EU and non-EU producers operating in the EU market,
 - Emphasise the economic, safe and secure production of medical radioisotopes in conformity with existing non-proliferation obligations.
-