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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Security of supply of medical radioisotopes

Following the examination of the draft Presidency note on the "Security of supply of medical radioisotopes" by the Working Party on Atomic Questions on 9 March and 20 April 2016, as well as the careful consideration of the written comments submitted, delegations will find attached the final version of the Presidency note. The Presidency intends to draw the attention of energy ministers to this note under "any other business" at the TTE (Energy) Council on 6 June 2016.

ANNEX

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 year[1].

In the EU, the integrated nuclear infrastructure of research reactors and processing facilities in six Member States and the supply of material for target and fuel fabrication are critical for the European and worldwide supply of medical radioisotopes. In 2008-2010, operational failure of several 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 disruptions 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 radioisotopes[2]. As a result, the European Observatory on the Supply of Medical Radioisotopes was established in 2012, 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.

The EU Observatory established four working groups which address the coordination between reactors, survey the national implementation of Full Cost Recovery methodologies, identified risks of HEU-LEU conversion to the supply chain and analysed infrastructure needs in relation to current and forecast demands. Since its establishment, the EU Observatory effectively ensured the coordination of reactor schedules avoiding Mo-99 shortages and made good progress in fulfilling the tasks of its mandate. The Presidency fully recognises and supports the efforts made by the EU Observatory.

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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.

In the coming years, the planned decommissioning of the Canadian NRU reactor in 2018 and the expected reduction of worldwide production capacity of MO-99 will be offset by the Belgian reactor BR2, which has significantly increased its production capacity since its refurbishment in 2015, and by 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.

However, for the medium and long term the security of supply of medical radioisotopes remains fragile. In 2025-2030 the production capacity of medical radioisotopes will again be significantly reduced due to the planned decommissioning of the Dutch High Flux Reactor in 2024, the Czech LVR-15 reactor in 2028 and the Polish MARIA reactor in 2030. This is why for a secure supply of medical radioisotopes for the medium and long term, further investments in new production facilities within the EU will be 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 revenue of some irradiators and processors is too low to recover production costs and provide conditions for necessary investments.

For the production of medical isotopes, the operational sustainability of an integrated nuclear infrastructure encompassing European manufacturers of research reactor fuel and uranium targets (e.g. CERCA), European research reactors and processing facilities, should be ensured. This integrated nuclear infrastructure is not only necessary for the medium and long term security of supply of medical radioisotopes, but also to keep the EU at the forefront of research and development of new medical radioisotopes and innovative radiotherapies.

To address the aforementioned, additional steps have to be taken at EU level as soon as possible and before 2025 to implement full cost recovery with a view to creating a sustainable and transparent economic structure and improving market conditions for long term investments.

A European strategy on the secure supply of medical radioisotopes

The Presidency believes that further action at EU level is necessary. In this context, the Presidency welcomes and appreciates the Commission's planned comprehensive review of the medical, industrial and research applications of nuclear and radiation technology, which will inter alia address the long term secure supply of medical radioisotopes, to be presented by 2018.

The Presidency invites the European Commission and Member States to:

- Intensify the dialogue between national authorities, industry and healthcare providers to raise awareness and to exchange information 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;

- Increase transparency at every step of the supply chain of medical isotopes. A first pragmatic step could be for the Commission to perform a study of the EU market of medical radioisotopes, including on the relevant parts of the national reimbursement schemes of all radioisotopes to better understand the EU market, stakeholders and present and future patient needs[3]. The Presidency invites relevant national authorities in the Member States to provide all the necessary support for this study, which will also be an important contribution to the work of the EU Observatory;

- Develop, involving all relevant European Commission services and in close cooperation with Member States, an EU strategy 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 following principles:

[3] It should be noted that Belgium performed such an analysis in 2008 and subsequently introduced a system of unbundling payments for isotopes from radiopharmaceuticals, obtaining a full separation of reimbursement rates of isotopes, the cold kit and the medical procedures.

- Functional imaging using medical radioisotopes is an important tool for the diagnosis, treatment, planning and management of patients;
- All medical isotopes for imaging and therapy should be included, applying a graded approach which is commensurate with the characteristics of the production source and with the impact and likelihood of supply risks[4];
- Implementation of a system of full cost recovery, including capital costs for refurbishments, safety and security upgrades, new projects, nuclear waste management and decommissioning costs, as well as outage reserve capacity, is of paramount importance for a sustainable radioisotopes supply[5];
- Equal treatment of EU and non-EU producers operating in the EU market to create a level playing field for EU and non-EU producers;
- Emphasis on the economic, safe and secure production of medical radioisotopes as an important component of public healthcare.

- Assess the possibility of developing a legal framework for the implementation of an EU strategy in compliance with EU competition and state aid rules;

- Facilitate research and development of new medical radioisotopes, innovative radiotherapies and, as far as technically and economically viable, alternative production technologies such as cyclotrons and linear accelerators in compliance with EU competition and state aid rules;

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4 The supply of Mo-99/Tc-99m, which is the most widely used medical isotope, Lu-177, and I-131 faces the most risks since their production is dependent on the ageing nuclear infrastructure in Europe. Not all medical radioisotopes suffer from supply risks; however, an EU strategy should ensure that the long term security of supply of all medical isotopes is ensured.

5 The OECD/NEA (High-level Group on the Security of Supply of Medical Radioisotopes, HLG-MR) developed, in cooperation with the Commission, a full cost recovery methodology in 2012. The full cost recovery methodology described in the NEA Guidance Document identifies the elements that should be included when determining the full cost of irradiation services for radioisotope production, including a reasonable portion of facility common costs, and how these elements should be allocated between various missions in the case of multipurpose facilities. This methodology was later embedded in the HLG-MR six policy principles for the long-term security of supply of medical radioisotopes. (See also http://www.oecd-nea.org/med-radio/security/, http://www.oecd-nea.org/med-radio/guidance/docs/full-cost-recovery-molybdenum-99-irradiation.pdf and http://www.oecd-nea.org/med-radio/statement.html.)

- Create a favourable regulatory environment for the licensing of radiopharmaceutical products with due consideration of their diagnostic and therapeutic potential. As part of this effort, the continuing collaboration with the European Medicines Agency (EMA) should facilitate the resolution of the regulatory issues related to the licencing of radiopharmaceuticals at EU level.