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NOTE

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

Delegations will find attached a revised version of the note on "Security of supply of medical radioisotopes" which was discussed at the meeting of the Working Party on Atomic Questions (WPAQ) on 9 March 2016. Changes compared to doc. 6460/16 are indicated in **bold**; deletions are marked with [].

This revised draft will be presented at the WPAQ on 20 April 2016 and delegations will have the opportunity to make any final comments. The Presidency intends to submit the final version of this note to Coreper and Council for information.

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.

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 notes that the Commission is planning to undertake a comprehensive review in which the long term secure supply of medical radioisotopes will be addressed, which is to be presented in 2018. The Presidency strongly welcomes this review and invites the European Commission to:**

- **Intensify the dialogue** with Member States, 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 in the market of medical isotopes. **Although medical reimbursements are a national competence, a first pragmatic step could be to task the Joint Research Centre, in close collaboration with relevant national authorities and relevant services of the European Commission, with performing a study on national reimbursements of all radioisotopes in Europe to better understand the EU market, stakeholders and present and future patient needs. It should be noted that Belgium performed such an analysis in 2008 and subsequently introduced a system of unbundling prices from the dose of medical radioisotopes and from medical procedures** ;
- Develop, **involving all relevant European Commission services**³ **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:**
 - All medical isotopes for imaging and therapy **should be included;**
 - All production technologies **should be included;**

³ **An EU strategy on the security of supply of medical radioisotopes has to address several policy issues ranging from market failure and competition to national reimbursements. Close coordination between Commission services i.e. DG COMP, DG GROW, DG SANTE, DG ENER, DG RTD and JRC and with Member States is therefore essential.**

- 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;
 - []
 - [] **Equal treatment of EU and non-EU producers operating in the EU market, thus creating a level playing field for EU and non-EU producers;**
 - Emphasis on the economic, safe and secure production of medical radioisotopes in conformity with existing non-proliferation obligations;
 - **Application of a graded approach which is commensurate with the characteristics of the production source and with the magnitude and likelihood of supply risks⁴.**
- 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 alternative production technologies such as cyclotrons and linear accelerators in compliance with EU competition and state aid rules**;
 - Create a favourable research and regulatory environment for the licensing of radiopharmaceutical products with due consideration of their diagnostic and therapeutic potential.

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.**