COUNCIL OF
THE EUROPEAN UNION

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Council Conclusions on "Towards the Secure Supply of Radioisotopes for Medical Use in the European Union"

3053rd EMPLOYMENT, SOCIAL POLICY HEALTH and CONSUMER AFFAIRS Council meeting
Brussels, 6 December 2010

The Council adopted the following conclusions:

"The Council of the European Union:

RECALLING the outcome of the Informal Meeting of the Health Ministers on 8-9 September 2008 and 6-7 July 2009 and the Council conclusions of December 2009 on the Security of Supply of Radioisotopes for Medical Use (doc. 17034/09),

AGREEING that medical procedures are by far the largest man-made source of radiation exposure of the population. In this development the medical staff bears a great deal of responsibility for ensuring justification of medical exposure and optimized radiation safety of patients as well as radiation safety of their own,

ACKNOWLEDGING that the various reports and assessments that have become available since its December 2009 conclusions confirm the importance of radioisotopes in medical diagnostics and therapy as well as the need for comprehensive and urgent action in order to address possible short term disruption in the supply of radioisotopes for medical use as well as to secure their long term supply,

AGREEING that there is no sufficient incentive for sustainable production of Mo-99 in existing and new facilities within the current economic model underlying the Mo-99/Tc-99m supply chain,

CONSIDERING that production of radioisotopes for medical use in nuclear reactor is a robust and reliable method,

CONSIDERING that the facilities able to produce Mo-99 at the levels required for the medium-term needs of the EU should remain located in the EU, with a view to ensuring self-sufficiency as well as guaranteeing an appropriate price level,

NOTING that continuity of production requires transparent information on the production levels at the different stages throughout the value chain,

NOTING ALSO that various estimates suggest that peak capacity should be at least twice the level of normal production EU-wide in order to ensure continuity of production during scheduled shutdown periods,

URGES the Commission to work further with relevant EU instruments to the appropriate medical applications of ionizing radiation,

ACKNOWLEDGING the relevance of various studies and initiatives when considering the issue of the secure supply of radioisotopes for medical use in Europe[1],

STRESSING the need for continued efforts to actively investigate economically feasible alternatives to the current radioisotope production methods and the isotopes currently used, as well as possible alternative medical approaches that do not require the use of radioactive substances,

CONFIRMING the need to limit the use of radioisotopes in medicine to justified cases, taking into account the most appropriate referral guidance,

REAFFIRMING the paramount importance of nuclear safety and radiation protection of the general population, professionally occupied personnel and patients, including when taking measures to enhance the security of supply of radioisotopes for medical use.

1. TAKES NOTE of the Commission Communication on medical applications of ionizing radiation and security of supply of radioisotopes for nuclear medicine (doc 12848/10),

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[1] - The economic study of the Mo-99/Tc-99m supply chain ("The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain", published on 15 September 2010), prepared by the OECD/NEA High Level Group on the Security of Supply of Medical Radioisotopes, which concludes that the problem is linked to insufficient capital investment and insufficient remuneration in the Mo-99 production and processing sector, and confirms that without changes to address the market, policy and technology failures, a secure supply of Mo-99/Tc-99m will not be achieved,
- The outcome of the meeting on the Security of Supply of Medical Radioisotopes in EU Member States organized by DG ENER (Luxembourg, 4-5 May 2010), especially the position paper by CEA, NRG, SCK-CEN and TUM specifying a Reference Scenario for sustainable Mo-99 production in Europe.
- The outcome of the European Medicines Agency (EMA) Workshop "Current use and future needs of radiopharmaceuticals labelled with radionuclides produced in reactors and possible alternatives" held on 4-5 February 2010, which confirms that for some medical indications there are currently no identified alternatives to the use of Tc-99m diagnostic procedures (Workshop outcome and recommendations, EMA/150127/2010, 20 May 2010)
- The actions prepared by WHO, in particular the launch in 2008 of the WHO Global Initiative on Radiation Safety in Health Care Settings (Global Initiative) to mobilize the health sector in the safe use of radiation in medicine, and the IAEA based on the global concern of the increasing use medical applications of ionizing radiation to limit the increase of the population radiation doses.

2. SHARES the Commission's analysis regarding the need to consider measures all along the chain from the production to the end-user stage,

3. TAKES NOTE therefore of the Commission's intention to propose measures for the simplification of administrative procedures for the transport of radioactive material within the EU, as far as nuclear safety is not jeopardized by such measures,

4. While NOTING that the Reference Scenario referred to in the Communication presents a combination of existing facilities that will continue to operate in the medium-term and new reactors which need investments, the Council is aware that investments in maintenance and improvement of existing facilities are also needed,

5. CONSIDERS that further work leading to a sustainable level of production of radioisotopes could be based on a Reference Scenario for the secure supply of radioisotopes for medical use in Europe (hereinafter "the Reference Scenario") that would:
   - Install an appropriate supply of medical radioisotopes in the European Union in the medium and long term, while taking into account international developments in supply of medical radioisotopes
   - Strengthen the European supply network
   - Provide adequate reserve capacity

   duly taking into account the responsibilities of the Community, the Member States and private undertakings,

6. IS OF THE VIEW that the attached Principles for the secure supply of radioisotopes for medical use in Europe should be part of this Reference Scenario and could serve as a basis for an economically viable and transparent model at EU level that could support a sustainable level of production, allowing reactor operators and Mo-99 processors to perform their part in the network of supply as well as to contribute to the reserve capacity deemed appropriate to ensure the EU security of supply,

7. BELIEVES that a mechanism should be established at EU level in order to contribute to:
   - the coordination of reactor operating and maintenance programmes as well as processors' and generators' production schemes and adjustment thereof as called for in the attached principles,
   - the regular assessment and forecast at EU level of the demand for Tc-99m, on the basis of information from national health authorities

8. URGES the Commission to refine further the Reference Scenario in close cooperation with Member States and stakeholders on the supply as well as on the demand side, based on a viable and transparent economic model, duly reflecting all relevant facilities in Europe and taking into account the economic study published by the OECD/NEA,

9. URGES the Commission to define, on the basis of this refined Reference Scenario and after having duly defined the objectives to be satisfied, a European solution, for instance a joint undertaking, for ensuring mid and long term security of supply of radioisotopes within the European Union, without prejudice to Member States' national research budgets,

10. URGES the European Medicines Agency to work further for an efficient use of radiopharmaceuticals derived of Tc-99m, as well as on exploring new and alternative medical approaches.

11. INVITES the Commission to take the necessary measures to develop standardisation in areas such as target design, container design and handling systems and other processes to allow full cross-over use of the total network of supply of medical radioisotopes within the European Union.

12. STRESSES the need to work cooperatively in a joint action together with the radioisotopes processing facilities to enable the future conversion to Low Enriched Uranium targets in an efficient, timely, economically sound and sustainable way, and in this regard INVITES the Commission to consider to include research on this topic in the Euratom Framework Programme.

13. INVITES the Commission to pursue its coordination with other fora (i.e. OECD/NEA High Level Group on the Security of Supply of Medical Radioisotopes, IAEA and WHO) dealing with this issue, to work in close collaboration with the Health Security Committee.

14. INVITES the Commission to report regularly on the progress of the work to the Council and the European Parliament.

Principles for the secure supply of radioisotopes for medical use in Europe

1. Assess the demand of radioisotopes for medical use in Europe.
2. Fully coordinate in a transparent manner operating programmes of supply facilities throughout the whole chain of isotope production in order to ensure continuous full European supply during normal operation.
3. Commitment to adjust operating programmes and to rapidly bring on line reserve capacity when needed due to unplanned events.
4. Commitment from each facility to provide an agreed minimum throughput for the European market and hold open an agreed level of "on-call reserve capacity".
5. Provide "open access" of services to commercial parties within Europe on a "fair trade" basis.
6. Establish a methodology of price calculation that provides for an economically viable price.
7. Support the principle of "fair share" supply in the event of shortages and with regard to the supply of excess capacity to markets outside Europe.
8. Commercial parties to purchase irradiations at a price that reflects the full costs incurred in irradiation services and includes a fair proportion of the investment cost of the reactor and associated infrastructure.
9. The need to maintain adequate reserve reactor capacity must be recognised and the fair costs associated with making available reserve capacity and maintaining it must be recovered in the overall cost/price structure."