Annex I to Service Contract n°…….

Procedure nr. JRC/BRU/2017/A.7/0001/OC

"Study on Sustainable and Resilient Supply of Medical Radioisotopes in the EU"

Tender specifications:

Part 2- Technical specifications

Rev. 1 -06/04/2017

DG JRC EURATOM COORDINATION UNIT – JRC.A.7

Revision Description

01 -First issue 06/04/2017

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1. Main purpose and objective

The objective of this study is to provide the European Commission with current information on the diagnostic nuclear medicine market in the EU, focusing on the market of Mo-99/Tc-99m generators. The main purpose is to assess the reimbursement at end-user level and to quantify the financial resources dedicated to the purchase cost of the radionuclide Tc-99m.

The study shall be complementary to the ongoing SAMIRA study commissioned by DG ENER[1]. The necessary coordination and exchange of information can be achieved through the EU Observatory on the Supply of Medical Radioisotopes.[2]

2. General background

The supply of radioisotopes for worldwide medical applications is one of the most important aspects of nuclear science. Every year, around 40 million diagnostic medical procedures are conducted using radiopharmaceuticals.

Emerging approaches and technologies, such as personalised medicine, will create an extra burden in the already fragile supply chain of medical radionuclides. The production of radionuclides for medical applications involves a unique, just in time, chain of supply, in which the half-lives of the radionuclides are extremely limited, and which is strongly relying on the reliable availability of nuclear reactors, until now mainly government-subsidized research facilities. Among other factors, the limitations of the nuclear research reactors, currently the origin of the largest part of Tc-99m eluted from Mo-99/Tc-99m generators and the strategic changes in nuclear policy in the EU member states and worldwide contribute to the critical fragilities in the security of supply of medical radioisotopes, highlighted in the severe shortages of Tc-99m, the most important radioisotope for diagnostic procedures, experienced in 2008-2010.

The concept and implementation of full cost recovery in medical radionuclide production is considered critical for the sustainability of the market of radiopharmaceuticals. Economic studies conducted in the aftermath of the shortages of 2009/2010 have shown that the pricing structure for the reactor production of Mo-99 (the parent radionuclide in Tc-99m generators) was not economically sustainable, as it was heavily subsidized by the states hosting the research reactors. This results in an economic environment which is not prone to investments in relevant infrastructures, maintaining the vicious circle of fragile supply conditions. Furthermore, the hosting states of research reactors involved in the production chain have repeated their intention to put at halt the financial support of the radioisotope production, therefore pricing of the diagnostic procedures must recover the full cost of production to ensure economic sustainability and a long-term secure supply. The EU Council has adopted several conclusions (2009, 2010, 2012 and recently a Dutch Presidency position paper) stressing the importance of medical radionuclides 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.

[1] https://etendering.ted.europa.eu/cft/cft-documents.html?cftId=1888

[2] http://www.aipes-eeig.org/spip.php?article9

3. Scope

In this framework, the European Commission is requesting a contractor to perform a study including a survey on the EU market of medical radionuclides, containing the relevant parts of the national reimbursement schemes for all diagnostic procedures in nuclear medicine to better understand the EU market for medical radionuclides (here focusing on Tc-99m), the role and interests of stakeholders as well as present and future patient needs. This initiative is complementary to an ongoing study for a medium to long term EU strategy on the non-power applications of nuclear science, to develop by 2018 a Strategic Agenda for Medical, Industrial and Research Applications of nuclear and radiation technology (SAMIRA[1]).

The present study shall identify how different public health systems in the EU member states deal with diagnostic procedures based on the use of the radionuclide Tc-99m and how the organisation of health care and the implemented reimbursement schemes affect the efficient and economically sustainable use of Mo-99/Tc-99m generators.

4. Methodology, project team and management

The Contractor shall provide all required personnel (a project team with a minimum of 3 members) for the complete and timely execution, supervision, coordination and implementation of all necessary works for the study.

1) A project manager/leader with an EQF level 8 qualifications[3] (PhD or similar) in science, engineering or economics;

2) A health economist with an EQF level 7 qualifications[4] (MSc or similar) in health economics or related topic;

3) A pharmaceutical regulatory affairs expert, with an EQF level 7 qualifications[5] (MSc or similar) in pharmacy or other health-related topic;

The project team shall have combined experience covering a minimum of 5 years of professional experience in the area of nuclear medicine and/or medical radiation technology and a minimum 5 years of professional experience in regulatory affairs, including pharmaceutical pricing and reimbursement.

The contractor shall describe the chosen methodology for gathering the required data and the evaluation of the risks and challenges to provide complete and accurate data to answer the questions below, as well as the mitigation actions to ensure completeness, accuracy and consistency. The methodology, evaluation- and risk mitigation actions shall include (but not be limited to) the following components:

- An adequate structure for the (project) management of the work (survey, evaluation of results, production of reports, liaison with stakeholders and working group)
- A list of the main information sources for the Tc-99m market in the EU Member States;
- An adequate procedure for the assessment of relevance and completeness of the information gathered for each Member State;

[3] https://ec.europa.eu/ploteus/en/content/descriptors-page
[4] https://ec.europa.eu/ploteus/en/content/descriptors-page
[5] https://ec.europa.eu/ploteus/en/content/descriptors-page

- The set-up of an independent advisory panel of experts to be consulted on the project methodology, and to participate in cross-checking the data collected;
    - The advisory panel of experts shall have a minimum of 3 members. The advisory panel of experts shall have combined experience covering a minimum of 5 years of professional experience in the area of nuclear medicine and/or medical radiation technology and a minimum 5 years of professional experience in regulatory affairs, including pharmaceutical pricing and reimbursement. The project team members cannot be a part of the advisory panel of experts and vice versa.
- The liaison with the European Association of Nuclear Medicine (EANM) and in particular with the subgroup of Technologists Committee of the EANM which will provide contacts and information on the practice of using Mo-99/Tc-99m generators in different EU member states; the contacts will be provided by the EC. The mechanism of liaison is to be arranged by the contractor and specified in the methodology;
- The presence of a project team member should be ensured to deliver a presentation and report on the progress and preliminary findings of the study during the regular meetings of the EU Observatory on the Supply of Medical Radioisotopes (2 meetings per calendar year, March/April and October/November, taking place in Luxembourg or in another EU Member State). In case of similar or overlap of scope of the work with other ongoing EC studies performed by the contractor, the person to represent the project team for this study cannot be simultaneously reporting on other relevant projects at the EU Observatory meetings.

5. Tasks

The work will include the following two main tasks:

1) Gathering of data to specify the medical indications and to quantify the number and reimbursement of diagnostic procedures using the radionuclide Tc-99m covering at least 90% of the use of Mo-99/Tc-99m generators in a period of the last five years in all member states of the European Union.

2) Evaluation of the data specifying the number and activity of Mo-99/Tc-99m generators and the number of exams performed with them per year, the cost for the supply of the Mo-99/Tc-99m generators and the fraction of the reimbursement amount that is specifically dedicated to the radionuclide supply.

5.1 Task 1

The contractor shall carry out a survey of the application of Tc-99m for diagnostic procedures in the EU member states, in order to collect data to answer the following questions:

1. Which are the main clinical indications for nuclear medicine diagnostic procedures using Tc-99m? The assessment should at least cover 90% of all diagnostic procedures using Tc-99m.

2. How many patients per year and per EU Member State undergo nuclear medicine diagnostic procedures using Tc-99m (data for the last 5 years) for these identified clinical indications?

3. How many Mo-99/Tc-99m generators are required to satisfy the demand specified in question 2 in each of the member states? Required is: the number of generators specifying their initial activity of Mo-99.

4. What is the price paid per generator/activity level? (Data to be retrieved for each Member State)

5. What are the types of reimbursement mechanisms in place in the different Member States regarding nuclear medicine diagnostics procedures using Tc-99m?

6. Is there a fraction of the reimbursement amount dedicated to the supply of the radionuclide? If so, how much in absolute value and as percentage of the reimbursement is it? If not, which cost position covers the radionuclide supply?

5.2 Task 2

The contractor shall evaluate the collected data in Task 1 and provide answers to the following questions in the Final report:

1. Specify whether all member states of the EU have been covered in the survey and if not, what is the percentage of the EU population covered by the present analysis?
2. To what percentage is the present analyse covering the diagnostic procedures using Tc-99m? To be specified for each country and the EU as a whole.
3. How much money is spent per year and member state on the supply of Mo-99/Tc-99m generators? Are these cost balanced by a reimbursement fraction clearly accounted for radionuclide supply? What is the fraction of Mo-99/Tc-99m generator cost of the total reimbursement? Are there differences in these figures between the EU member states?
4. Comparing the number and activity of the Mo-99/Tc-99m generators with the number of diagnostic procedures carried out in each member states are there differences in the efficient use of the Mo-99/Tc-99m generators among member states? Can these differences be linked to peculiarities of the public health system or the reimbursement scheme?
5. Are there efficiency reserves or gains in a more efficient use of Mo-99/Tc-99m generators that could be realised? What could be appropriate measures to realise these?
6. Has the reimbursement scheme an effect on the number of diagnostic procedures (normalised to the population) performed per year and on the efficient use of the Mo-99/Tc-99m generators?

6. Deliverables and format

- An **interim report** together with a **descriptive listing** compiling all raw data collected during the survey, organised by Member State, shall be submitted to the Commission no later than **6 months** after the date of signature of the contract. The interim report shall be an administrative report showing the main activities carried out to progress with the study and the preliminary results of the survey. The Interim report and the descriptive listing must clearly indicate that the results and the provided documents have been verified by at least 3 members of the advisory panel of experts.

- A **draft report** shall be submitted to the Commission no later than **10 months** after the signature of the contract. The draft report shall include most of the relevant information from the survey (task 1) and the most of the results of the analysis (task 2). The draft report must clearly indicate that the results and the documentation have been verified by at least 3 members of the advisory panel of experts.

- A **final report** shall be submitted to the Commission no later than **12 months** after the signature of the contract. The final report must include all relevant information from the survey, as defined in Task 1 and the complete analyse and answers to the questions defined in Task 2. The final report must clearly indicate that the results and the documentation have been verified by all members of the advisory panel of experts.

  The **final study** report shall include:

  - an abstract of no more than 200 words and an executive summary of maximum 6 pages, both in English and French;
  - the following standard disclaimer:

    "The information and views set out in this report are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."
  - specific identifiers which shall be incorporated on the cover page provided by the Contracting Authority.

Electronic format is to be considered as standard requirement in order to fulfil obligation of studies, the deliverables shall be provided in an editable format and in a PDF version.

For graphic requirements please refer to the templates provided.[6] For further details you may also contact comm-visual-identity@ec.europa.eu.

All the reports (deliverables) of the study shall contain the following standard disclaimer:

"The information and views set out in this [report/study/article/publication…] are those of the author(s) and do not necessarily reflect the official opinion of the Commission. The Commission does not guarantee the accuracy of the data included in this study. Neither the Commission nor any person acting on the Commission's behalf may be held responsible for the use which may be made of the information contained therein."

All deliverables must contain the signature workflow proving that all members of the project team have approved them; failure to include this proof may result in penalties.

[6] https://myintracomm.ec.testa.eu/budgweb/FR/imp/procurement/Documents/studies-template-en.docx

https://myintracomm.ec.testa.eu/budgweb/FR/imp/procurement/_layouts/15/WopiFrame.aspx?sourcedoc=/budgweb/FR/imp/procurement/Documents/studies-template-en.docx&action=default&DefaultItemOpen=1