Results of the targeted consultation on European Radioisotope Valley Initiative (ERVI)

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	External			*X*

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Disclaimer

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1. Introduction

Nuclear medicine is an important tool for cancer management, contributing to early cancer diagnoses and prognostic assessments aimed at helping doctors make critical decisions and tailor the treatment to the patient's needs. In the EU alone, more than 1500 nuclear medicine centres deliver about 10 million nuclear medicine procedures to patients each year. Depending on the national practices, up to 65% of these procedures are performed in oncology. Besides cancer, radioisotopes play a vital role in diagnosing cardiac conditions and other diseases.

Europe, with its unique supply network, innovative technology developments and strong clinical research commitment, plays a central role in the nuclear medicine domain. The EU is the leading supplier of medical radioisotopes to the world market, with a market share of more than 60% for some of the most widely used radioisotopes. Significant growth is expected in the coming decade for the use of therapeutic and diagnostic radiopharmaceuticals with significant promises for treating and monitoring more and more types of cancer.

At the same time, the long-term global supply of the necessary radionuclides is not fully secured, with bottlenecks at several steps of the global supply chain. These concerns have increased in the recent years, raising the question of the dependence of Europe on foreign supplies. Radionuclides supply concerns are all the more important now that therapeutic radiopharmaceuticals are directly involved.

In February 2021 the EC adopted the SAMIRA action plan[1], which defines EU actions in priority areas including securing the supply of medical radioisotopes. The actions on supply of medical radioisotopes have as main objective the establishment by 2024 of a European Radioisotope Valley Initiative (ERVI) aiming to maintain a secure, resilient, and sustainable supply of medical radioisotopes to patients across Europe. ERVI would seek:

- To facilitate access to the source materials needed to produce medical radioisotopes through both fission and other production methods, aiming at developing domestic production to reduce the EU reliance on foreign suppliers
- To improve the efficiency and further optimise industrial scale production of radioisotopes aiming at supply security, flexibility, resilience and sustainability
- To develop new production methods through networking actors and promoting advanced research on innovative techniques and technologies of production

[1] COMMISSION STAFF WORKING DOCUMENT on a Strategic Agenda for Medical Ionising Radiation Applications (SAMIRA) SWD(2021) final

2. Consultation on ERVI's objectives and identification of issues/actions within the supply chains of medical radioisotopes

In order to advance with the preparation of the ERVI initiative, the European Commission has decided to launch first a targeted consultation to gather the positions of stakeholders on the ERVI objectives and the specific issues concerning the supply chain of medical radioisotopes. The consultation, held online from the 22nd of August to the 14th of October 2022, is part of an overall process of focused interactions with stakeholders, allowing to efficiently capture relevant views and tapping into a wide range of stakeholders' expertise.

The target groups addressed through this consultation included, as follows:

- Production infrastructures,
- Radionuclides and radiopharmaceuticals industrial players,
- Equipment manufacturers,
- Clinical nuclear medicine,
- Research centres/laboratories,
- Expert groups & Professional associations,
- EU Agencies,
- Patient associations,
- International and third-country organisations.

The link to the questionnaire was transmitted to a list of identified stakeholders and respondents were able to forward the link to their own network within the sector. In addition to that, different professional organisations contributed to this consultation by disseminating the link to their members at national and European level.

3. Content of the present report

This report provides full record of the answers provided by the survey's respondents 'as submitted'.

The survey replies are sorted in the present document following the different categories of respondents from Figure 1, namely:

- professional associations
- clinical nuclear medicine professional
- academic/research institution
- company/business organisation
- individual (EU or non-EU citizen)
- anonymous

Inside each category, the answers are sorted in chronological order (from first to last respondents during the consultation period timeframe).

Regarding privacy's issues, participants were able to indicate whether their personal details (including name or organisation) should be kept confidential or public. To this extent, the answers or the respondents that asked to remain anonymous are included within the present document, but without indicating the personal details of the respondent. They are labelled as "anonymous", though an indication of the respondent's category is provided.

A second report entitled "Results' analysis of the consultation on ERVI's objectives and identification of issues/actions regarding the supply chains of medical radioisotopes" is dedicated to the detailed analysis of the survey's answers.

4. Information on respondents

The present report provides a summary of the different contributions from stakeholders to the ERVI consultation, as well as the series of verbatim of the respondents.

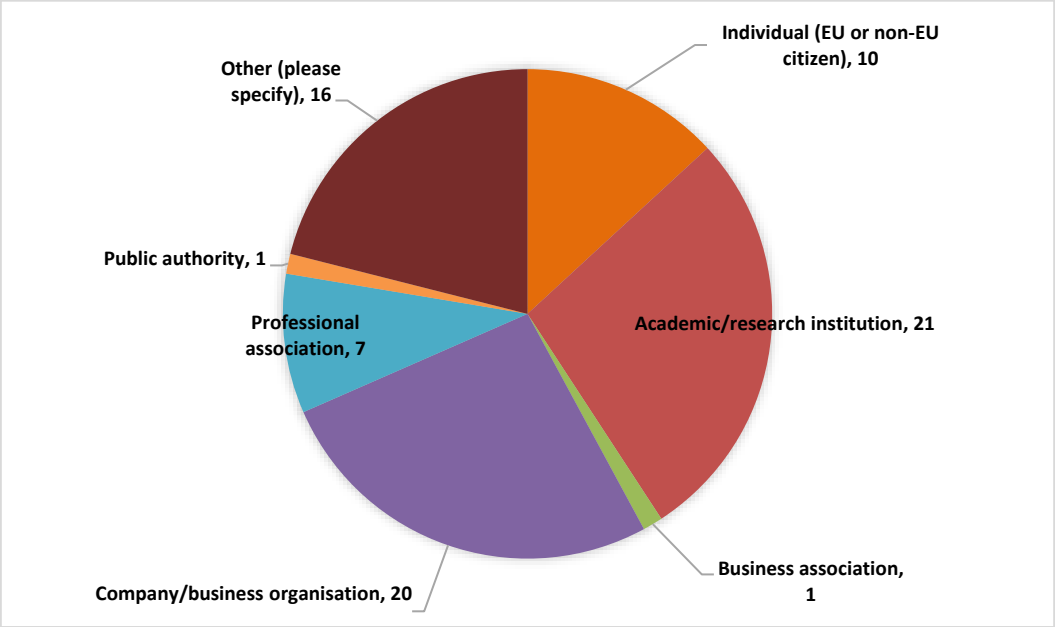

Figure 1: Distribution of the survey respondents by category

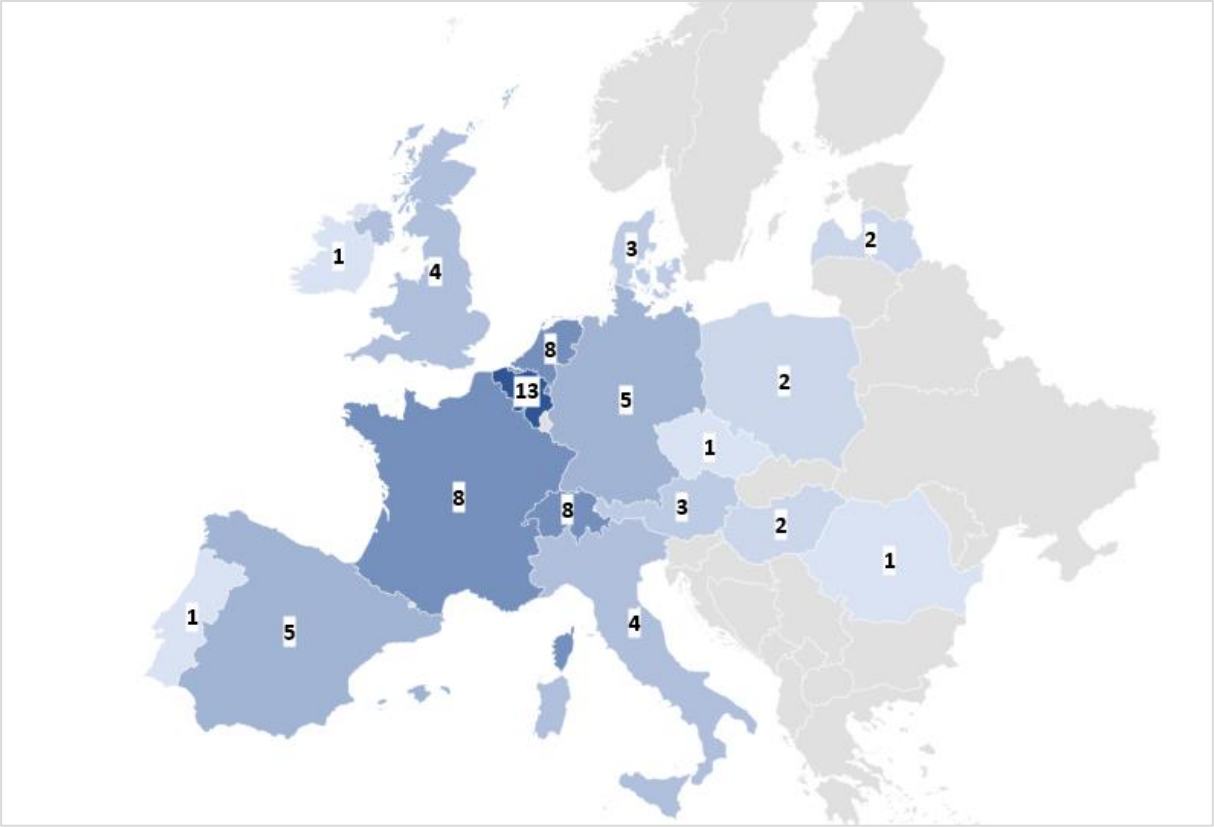

Figure 2: Distribution of the survey respondents by their country of residence

5. ERVI targets: identification of issues

5.1. ERVI's objectives

The SAMIRA Action Plan identifies a series of tentative objectives for ERVI. Do you support the idea that the EU should do more to secure a sustainable supply of radioisotopes in Europe, through the establishment of the ERVI initiative and the 3 following objectives?

5.1.1. To facilitate access to the source materials needed to produce medical radioisotopes, through both fission and other production methods, aiming at developing domestic production to reduce the EU reliance on foreign suppliers.

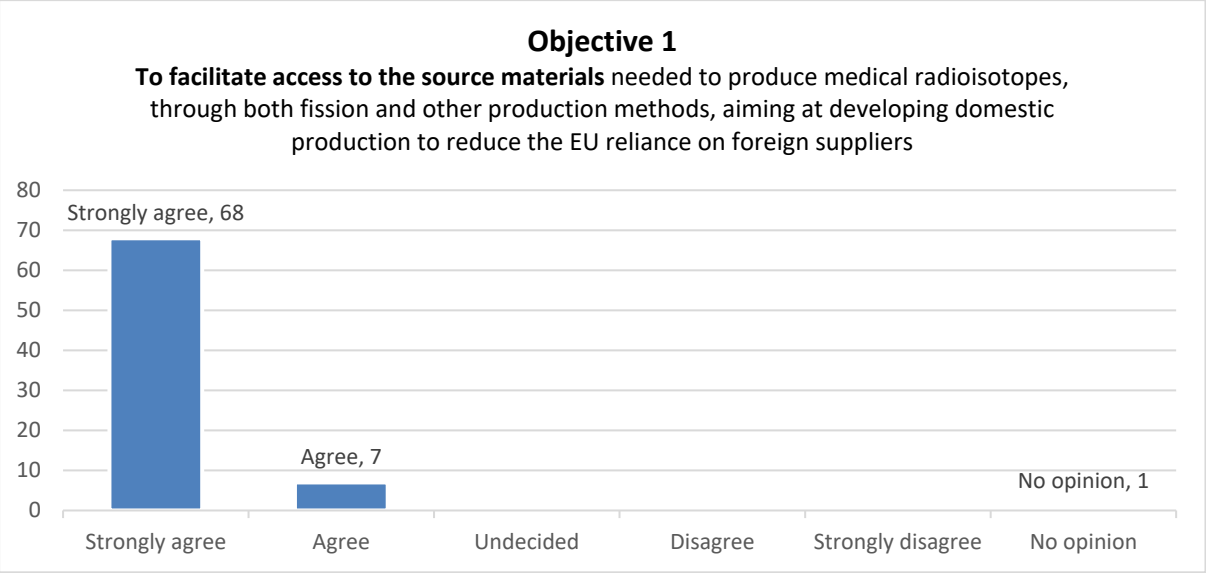

Figure 3: summary of respondents' views on ERVI's objective #1

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Strongly agree
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Strongly agree
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Strongly agree
GEC-ESTRO committee (Professional association)	Strongly agree
French Society of Nuclear Medicine (Professional association)	Strongly agree
BelNuc (Professional association)	Strongly agree
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Strongly agree
Radionuclides for Health UK (Radionuclides for Health UK)	Strongly agree
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Strongly agree
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Strongly agree
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	Strongly agree
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	Strongly agree
SERGAS (Clinical nuclear medicine professional)	Strongly agree
Individual (Clinical nuclear medicine professional)	Agree
Riga Technical University (Academic/research institution)	Strongly agree
Aarhus University Hospital (Academic/research institution)	Strongly agree
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Strongly agree
Lausanne University Hospital (CHUV) (Academic/research institution)	Strongly agree
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	Agree
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Strongly agree
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)	Strongly agree
IN2P3/CNRS (Academic/research institution)	Strongly agree
ENEA (Academic/research institution)	Strongly agree

Respondent	Answer
National Centre for Nuclear Research (Academic/research institution)	Strongly agree
University of Szeged (Academic/research institution)	Strongly agree
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Strongly agree
SHINE EUROPE BV (Company/business organisation)	Strongly agree
Bayer AG (Company/business organisation)	Strongly agree
ORANO (Company/business organisation)	Strongly agree
SWAN Isotopen AG (Company/business organisation)	Strongly agree
Global Morpho Pharma (Company/business organisation)	Strongly agree
Ion beam applications (Company/business organisation)	Strongly agree
SCK CEN (Company/business organisation)	Agree
AlfaRim (Company/business organisation)	Strongly agree
Comecer S.p.A. (Company/business organisation)	Strongly agree
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	Strongly agree
NRG|PALLAS (Company/business organisation)	Strongly agree
STFC (Individual (EU or non-EU citizen))	Strongly agree
Hannover Medical School (Individual (EU or non-EU citizen))	Strongly agree
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))	Strongly agree
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Professional association)	Strongly agree
Anonymous (Business association)	Strongly agree
Anonymous (Scientific association)	Strongly agree
Anonymous (United Nation Organisation)	No opinion
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (nuclear, radiation and accelerator physicist)	Strongly agree
Anonymous (Clinical nuclear medicine professional)	Strongly agree
Anonymous (Clinical nuclear medicine professional)	Strongly agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Agree
Anonymous (Company/business organisation)	Agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Public authority)	Strongly agree

Table 1: respondents' views on ERVI's objective #1

5.1.2. To improve the efficiency and further optimise industrial-scale production of radioisotopes, aiming at supply security, flexibility, resilience and sustainability.

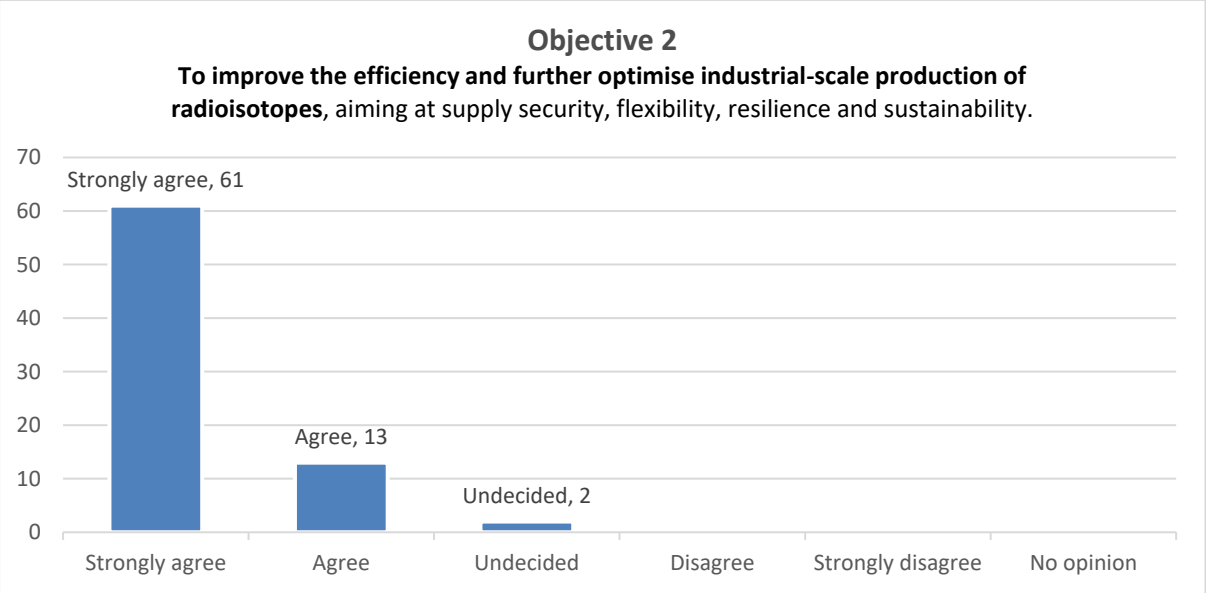

Figure 4: summary of respondents' views on ERVI's objective #2

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Strongly agree
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Strongly agree
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Strongly agree
GEC-ESTRO committee (Professional association)	Strongly agree
French Society of Nuclear Medicine (Professional association)	Strongly agree
BelNuc (Professional association)	Strongly agree
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Strongly agree
Radionuclides for Health UK (Radionuclides for Health UK)	Strongly agree
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Strongly agree
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Strongly agree
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	Strongly agree
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	Strongly agree
SERGAS (Clinical nuclear medicine professional)	Strongly agree
Individual (Clinical nuclear medicine professional)	Strongly agree
Riga Technical University (Academic/research institution)	Strongly agree
Aarhus University Hospital (Academic/research institution)	Strongly agree
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Strongly agree
Lausanne University Hospital (CHUV) (Academic/research institution)	Strongly agree
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	Agree
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Strongly agree
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)	Strongly agree
IN2P3/CNRS (Academic/research institution)	Strongly agree
ENEA (Academic/research institution)	Strongly agree
National Centre for Nuclear Research (Academic/research institution)	Strongly agree
University of Szeged (Academic/research institution)	Strongly agree
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Strongly agree
SHINE EUROPE BV (Company/business organisation)	Strongly agree
Bayer AG (Company/business organisation)	Agree
ORANO (Company/business organisation)	Strongly agree
SWAN Isotopen AG (Company/business organisation)	Strongly agree
Global Morpho Pharma (Company/business organisation)	Agree

Respondent	Answer
Ion beam applications (Company/business organisation)	Strongly agree
SCK CEN (Company/business organisation)	Strongly agree
AlfaRim (Company/business organisation)	Strongly agree
Comecer S.p.A. (Company/business organisation)	Agree
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	Strongly agree
NRG|PALLAS (Company/business organisation)	Agree
STFC (Individual (EU or non-EU citizen))	Strongly agree
Hannover Medical School (Individual (EU or non-EU citizen))	Strongly agree
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))	Strongly agree
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Professional association)	Agree
Anonymous (Business association)	Strongly agree
Anonymous (Scientific association)	Strongly agree
Anonymous (United Nation Organisation)	Agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (nuclear, radiation and accelerator physicist)	Strongly agree
Anonymous (Clinical nuclear medicine professional)	Strongly agree
Anonymous (Clinical nuclear medicine professional)	Strongly agree
Anonymous (Company/business organisation)	Undecided
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Undecided
Anonymous (Company/business organisation)	Agree
Anonymous (Company/business organisation)	Agree
Anonymous (Individual (EU or non-EU citizen))	Agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Public authority)	Strongly agree

Table 2: respondents' views on ERVI's objective #2

5.1.3. To develop new production methods through networking actors and promoting advanced research on innovative techniques and technologies of production.

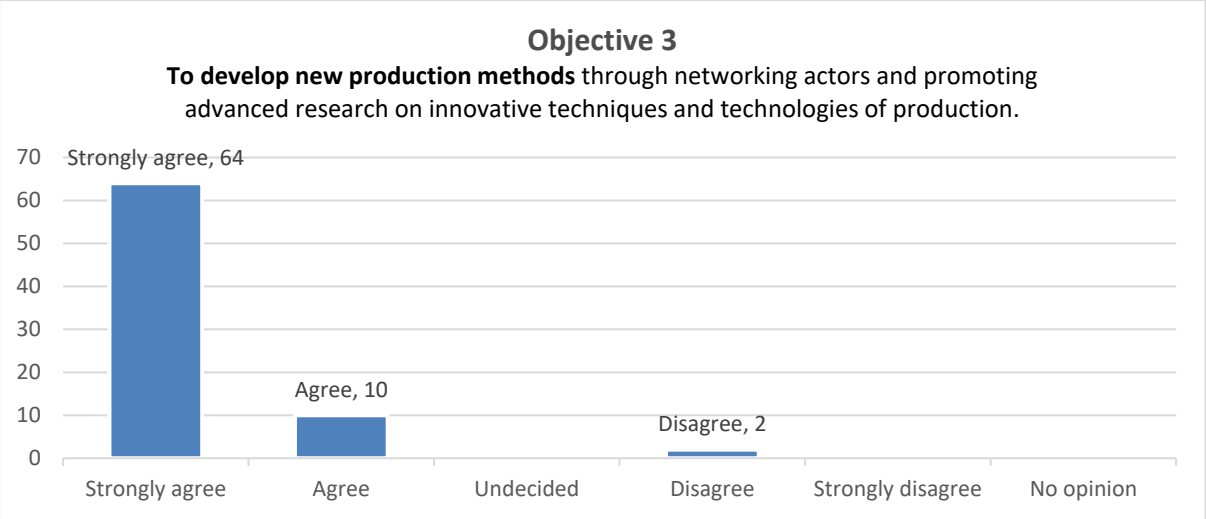

Table 3: summary of respondents' views on ERVI's objective #3

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Strongly agree
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Strongly agree
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Strongly agree
GEC-ESTRO committee (Professional association)	Strongly agree
French Society of Nuclear Medicine (Professional association)	Strongly agree
BelNuc (Professional association)	Strongly agree
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Strongly agree
Radionuclides for Health UK (Radionuclides for Health UK)	Strongly agree
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Strongly agree
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Strongly agree
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	Strongly agree
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	Strongly agree
SERGAS (Clinical nuclear medicine professional)	Strongly agree
Individual (Clinical nuclear medicine professional)	Agree
Riga Technical University (Academic/research institution)	Strongly agree
Aarhus University Hospital (Academic/research institution)	Agree
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Strongly agree
Lausanne University Hospital (CHUV) (Academic/research institution)	Strongly agree
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	Strongly agree
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Strongly agree
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)	Strongly agree
IN2P3/CNRS (Academic/research institution)	Strongly agree
ENEA (Academic/research institution)	Strongly agree
National Centre for Nuclear Research (Academic/research institution)	Strongly agree
University of Szeged (Academic/research institution)	Strongly agree
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Strongly agree
SHINE EUROPE BV (Company/business organisation)	Strongly agree
Bayer AG (Company/business organisation)	Agree
ORANO (Company/business organisation)	Strongly agree
SWAN Isotopen AG (Company/business organisation)	Strongly agree
Global Morpho Pharma (Company/business organisation)	Strongly agree
Ion beam applications (Company/business organisation)	Strongly agree
SCK CEN (Company/business organisation)	Disagree
AlfaRim (Company/business organisation)	Strongly agree

Respondent	Answer
Comecer S.p.A. (Company/business organisation)	Strongly agree
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	Strongly agree
NRG|PALLAS (Company/business organisation)	Strongly agree
STFC (Individual (EU or non-EU citizen))	Strongly agree
Hannover Medical School (Individual (EU or non-EU citizen))	Strongly agree
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))	Strongly agree
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Professional association)	Disagree
Anonymous (Business association)	Strongly agree
Anonymous (Scientific association)	Strongly agree
Anonymous (United Nation Organisation)	Strongly agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Academic/research institution)	Agree
Anonymous (Academic/research institution)	Agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (Academic/research institution)	Strongly agree
Anonymous (nuclear, radiation and accelerator physicist)	Strongly agree
Anonymous (Clinical nuclear medicine professional)	Strongly agree
Anonymous (Clinical nuclear medicine professional)	Strongly agree
Anonymous (Company/business organisation)	Agree
Anonymous (Company/business organisation)	Strongly agree
Anonymous (Company/business organisation)	Agree
Anonymous (Company/business organisation)	Agree
Anonymous (Company/business organisation)	Agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Individual (EU or non-EU citizen))	Strongly agree
Anonymous (Public authority)	Strongly agree

Table 4: respondents' views on ERVI's objective #3

5.1.4. Proposition of additional objectives for ERVI

Aside from these tentative objectives identified within SAMIRA action plan, would you recommend other ones ERVI should address?

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Prevention of monopoly Potential full control of capacity by the commercial sector which will drive up prices (creating inequalities across EU countries) and will dwarf production of isotopes for innovation (as capacity will be claimed for bulk commercial isotope). Accessibility & Affordability All the above objectives are extremely important to source materials and to ease production, however having radioisotopes available at a huge price only in some regions of Europe should never be an objective. Efforts should be done to ensure that the produced radioisotopes are easily available, at a fair price, anywhere in Europe. In addition to mainly technical challenges, there are as well regulatory hurdles that hamper access to radionuclides for medical use and that should be considered in parallel to ERVI. If ERVI is to be successful, full scope of the supply should be considered. The EANM understands that the ERVI is indented to focus on the initial steps of the supply chain. However, the EANM firmly believes that delivery to patients (including ensuring regulatory hurdles related to marketing authorisations and GMP become more flexible and dealing with constraining local constraints) should be a priority.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	• Distribution of radioisotopes across borders • Promoting continued excellent collaborative working with the UK
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	• Promoting the development of local production of radiopharmaceuticals at the point of use in specialized units compliant with the highest requirements. • Promote the development of generators to allow small scale production of the radiopharmaceutical at the point of use i.e. the labelling step. Even if these would constitute competition with the industry they could be needed to bring the products faster to the patients and even to save some money for the health care system.
Radionuclides for Health UK (Radionuclides for Health UK)	• Development of production of new radioisotopes • Ensuring the security of supply of radioisotopes for health applications, including to countries outside the EU e.g. UK • Education and Training to ensure that the workforce meets the demand for new radionuclides
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	• Maybe also improve the facilities needed for the treatment of the patients, to ensure access of all European patients to radionuclide therapy, to ensure that every country has the facilities needed for that.
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	• Collaboration between all European Institutions
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Closing the gap between industry (providers of equipment, supply of radionuclides, ...) and the (academic/clinical) nuclear medicine 'user' community, especially regarding the preparation of the equipment for its subsequent (pre)clinical use. A lot of time is lost with practical things, like standardization, calibration, ... of equipment, before further steps towards clinical use can be taken. Let alone the administrative, regulatory, and logistic paths that require a lot of time as well. The better these are prepared, and forces are joined, the smoother the journey can be.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	ERVI should help finance the installations aiming at producing radioisotopes in Europe. It should also geographically rebalance the production of radioisotopes in Europe (today most of the production is located in Northern Europe), especially for very short-lived isotopes such as At-211, whose 7-hours period makes it necessary to produce it locally.
IN2P3/CNRS (Academic/research institution)	We recommend a specific action to help for the transport of radionuclides, for air transport in particular. Some agreement with airlines could be established like in the US for the transport of radioactive medical material. A dedicated annotation on the packages could be specified. For this, a collective action of states is strongly needed.
National Centre for Nuclear Research (Academic/research institution)	To support local radionuclide irradiation sites in meeting the production and regulatory requirements
CERN - MEDICIS (acting as PRISMAP coordinator)	Support the proper integration of European large-scale facilities able to provide non-conventional radionuclides and new purity grades, such as high flux neutron reactors and new facilities, hadron and electron beam facilities, radionuclide and stable isotope mass separation facilities, along with their infrastructure developments to include a European medical radionuclide programme.

Respondent	Answer
(Academic/research institution)	
SHINE EUROPE BV (Company/business organisation)	To facilitate a European wide regulatory framework assuring the attractiveness of high-risk private innovation investments in collaboration with the continuation and even improvement of support for public services and infrastructure. The creation of a fair level playing field will allow for a rapid and effective improvement of the overall supply chain for nuclear medicine. Public financial support should never result in the unwanted slowing down or even halting of private investments.
Bayer AG (Company/business organisation)	The initiatives might require change and adjustments of effective legislation in order to allow swift development of the required techniques as well as on frames of working (e.g., adaption and harmonization of handling limits, import and transport requirements).
Ion beam applications (Company/business organisation)	• Development of accelerator-based infrastructure should also be part of the scope. • Focus on ageing accelerator installed based should also be investigated. • Strong involvement of European Commission to support research programs from academic and industry (for instance Isotope Program from the US DOE which supports many academic research programs and scaling up / industrialization for sustainable commercial supply).
SCK CEN (Company/business organisation)	• Reimbursement of medical isotopes needs to be separated from the reimbursement of the treatment, so that cost increases in isotope production, which in many cases are faster than inflation, can be addressed separately in the adaptation of reimbursements. Just by doubling the reimbursement of 99Mo (causing only a few percent increase in the reimbursement of the treatments), commercial production of 99Mo using a nuclear reactor becomes possible and we can stop dependency on taxpayers of one country for the support of research reactors which supply radioisotopes to all of Europe. • Future radioisotopes (177Lu to start with) need to be protected against a similar underpayment resulting in an unsustainable supply chain. The radioisotope cost fraction in the total treatment cost should be at 10-20%, not at 1-2%.
Comecer S.p.A. (Company/business organisation)	We recommend establishing and / or create one stable European suppliers network of isotopes for both medical use and R&D use.
NRG|PALLAS (Company/business organisation)	Promote fair cost-sharing and a level playing field for isotope irradiation facilities.
STFC (Individual (EU or non-EU citizen))	Securing funding to develop research programmes for development of novel radioisotopes. Further, encourage commercialisation of any new technologies that develop out of that initiative ensuring that the supply-chain is well linked into the development process at an early stage. This will ensure distribution channels are in place when new isotopes are developed
Hannover Medical School (Individual (EU or non-EU citizen))	• Reduce legal/regulatory hurdles on the use of radioisotopes as starting material for (complex, not kit-based) radiopharmaceutical productions (i.e. 18F, 64Cu, 177Lu, 225Ac). • Review the limits for release in radioactive waste management in nuclear medicine. Examples of 'troublesome' isotopes are 68Ge, 225Ac, 177mLu, and generally long-lived isotopes from trace impurities.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Improve networking between institutes (both production and research of radionuclides) for facilitated translational research and pre-clinical/clinical studies and staff/expert trainings in specific fields and production method application.
Anonymous (Professional association)	In our country what we observe to be able to access new and current radiopharmaceuticals are two main problems. On the one hand, the high dependence on raw materials from foreign countries and, on the other, the high legislative difference between member countries with different interpretation criteria by regulatory agencies.
Anonymous (United Nation Organisation)	• recommend continuing application of LEU targets for radioisotope production • continue and strengthen the support for production and application of various alpha emitting radioisotopes • some important medical radioisotopes usually produced by medium/high energy cyclotrons (Ge-68, Rb-82, etc.) are still rarely produced in the EU region and this should be more looked into • the potential market of non-EU countries in the region, should be also considered
Anonymous (Company/business organisation)	Nuclear medicine is an international industry and international cooperation needs to be furthere strengthened.
Anonymous (Academic/research institution)	• promote networking among producers in Europe as started by INFRAIA program PRISMAP • promote stable isotope enrichment site in Europe (mandatory to get high purity radionuclides) • support research on mass separation that can be used both for enrichment of stable isotopes and improve purity of radionuclides (as for example those produced using (n,gamma) reaction • ease and uniformize regulatory • support work on nuclear data and metrology
Anonymous (Academic/research institution)	To facilitate research activities towards potential domestic supply of source materials needed to produce medical isotopes (226Ra, 176Yb and others)
Anonymous (Academic/research institution)	The ability to be able to use these new radionuclides by having the licenses/permissions and equipment to do so. Eventually, also develop ways to properly measure these new radionuclides and provide accurate dosimetry [see publication about problems with quantification of Tb-161]. This can be stringent in some countries, which is restrictive to patient treatment.

Respondent	Answer
Anonymous (Academic/research institution)	PRISMAP is already an existing platform where a consortium of 23 partners in industry and academia is working in creating and making novel radioisotopes accessible. This should be the starting block for ERVI.
Anonymous (Academic/research institution)	• We need a European entity responsible for production/procurement, reserve management and distribution of enriched stable isotopes and certain radionuclides, similar to the National Isotope Development Center in the US. • Europe should develop and operate own electromagnetic isotope separators for stable isotope enrichment.
Anonymous (nuclear, radiation and accelerator physicist)	The documents published in the SAMIRA context have strong focus on reactors (or the like) as irradiation facilities and fissile material as the source from which the radioisotopes are produced. There needs to be much more attention for accelerator-based production, in particular for shorter half-life isotopes, and highly enriched isotopes of stable elements needed to produce radioisotopes that cannot be produced through fission. Europe is seriously lacking enrichment capacity to produce these isotopes in the quantities needed to answer the future demand of radioisotopes not originating from fission (177Lu is one example but there are several others such as the chain of Tb isotopes that can be used for diagnostics (PET and SPECT) and therapy (alphas, betas and Auger electrons).
Anonymous (Company/business organisation)	Logistic - transport: to develop fleet and hub for the transport of radiopharmaceuticals in compliance with GMP/GDP.
Anonymous (Company/business organisation)	Logistic for the distribution of large amount of patient doses needs to be developed. The current transport capacity is not able to manage such amount of radioactive package at once.
Anonymous (Individual (EU or non-EU citizen)	Support initiatives towards regulatory changes to enable the use of radioisotopes without marketing authorization for clinical use, especially for clinical development phase

Table 5: respondents' views on additional ERVI's objective

5.1.5. How to improve radioisotopes monitoring?

The European Observatory on the supply of radioisotopes provides, since 2012, a platform for the stakeholders to discuss, monitor and support the EU supply of widely used medical radioisotopes. The observatory focuses on 99Mo/99mTc but also takes into consideration recently widely used diagnostic as well as therapeutic medical radioisotopes (e.g. 131I, 177Lu, etc.).

In your opinion, what could be done to strengthen the existing EU monitoring of radioisotopes?

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	More generally, the problems caused by medicines shortages are serious, threaten the well-being of patients and have far-reaching consequences for European health systems. To minimize patient impact, all supply chain actors, including healthcare professionals, wholesalers, manufacturers and national competent authorities, have the obligation and responsibility to collaborate more closely in terms of resolving the shortage problem. All supply chain actors, especially wholesalers and manufacturers, must communicate more effectively about likely and current shortages. Such communication should be carried out in a timely manner and contain insights on how imminent the issue is, the expected duration of the shortage and whether alternatives are available. Timely notification of shortages is also essential for patients whose treatment is dependent on radionuclides that are not generated widely across Europe and beyond. Thus, EANM calls for improved information exchange between authorities and supply chain actors. For combatting medicine and radionuclide shortages best practice sharing is essential and implementation support for shortage management strategies needs to be provided in the interest of patient safety. Recent initiatives, such as the new European Shortages Monitoring Platform and the planned extension of the mandate of the European Observatory on the Supply of Medical Radioisotopes, should consider the specificities of in-house preparations related to shortages and the technical requirements of radiopharmaceuticals to ensure that all patients across can have timely access to needed medical products. **Coordination with other EU related activities** Coordination with other EU projects related to the supply of radionuclides should be further considered, such as SECURE (developments in the design of irradiation targets, production routes for existing and new isotopes in nuclear therapy and diagnostics), TOURR (optimized use of research reactors in Europe), and PRISMAP (novel radionuclides and novel production technologies). These projects, which are in the core focus of the ERVI questionnaire, are aiming at developing scenarios on the EU supply of radioisotopes and their outcomes should be carefully monitored. Sustainability of these projects beyond their timelines should be supported. Seeking harmonization and coordination between the various EU initiatives related to supply and shortages is of the outmost priority. Potential extension of the mandate of the EU observatory should go hand and hand with the Shortages Monitoring Platform the European Medicines Agency is currently developing. **Potential options for the EU.** The Working Group on European Production of LEU 19.75% has identified 3 potential scenarios/ options for the EU to monitor supply in the coming years. The EANM believes that the option 1, ie. continuing to rely on timely delivery by the US and Russia, would not address the security of supply risks, and would rather increase uncertainty, due to the current geopolitical circumstances and to the growing uncertainties on the US delivery capacities beyond 2030. This is only by developing/ building a European Union production capacity that both objectives of strategic autonomy and security of supply could be achieved. However, it requires a complex setup of actions, commitments and financing from the EU, MS, industries and users. In addition, such a decision and the following implementation would take years. That's why the EANM agrees that in the meantime, as a first step and while discussions are ongoing on the EU production capacity, a rolling reserve should be maintained for the starting materials which could be stockpiled. While this would require flexibility, this also requires further thinking on the relevant instrument and pathway and is not a fully convenient solution on the medium to long term.
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Develop European directives for the transport and delivery of radioisotopes by standardizing at European level criteria for air, rail or road transport, overcoming the current chaotic situation.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Monitoring capacity of suppliers and ability to meet demand to prevent supply disruption and even short notice cancellations of patient appointments for finished products. This includes oversight of maintenance schedules, contingency plans for outages as well as processes for taking orders. For example, DaTSCAN supply can reach capacity and this is not known when orders are taken - this leads to cancellations of orders which have been placed and subsequent cancellation of patient appointments at short notice Gallium-68 generator supply (including lead time for ordering)
French Society of Nuclear Medicine (Professional association)	Monitor 99Mo/99mTc, 131 I, 177 Lu & 68Ge/68Ga

Respondent	Answer
BelNuc (Professional association)	The stimulation of competition on supply. To hold working groups at the EU level for the EU strategy in the coming Decades.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	• Monitoring could be done through the use of the radioisotopes, many countries know through reimbursement how many treatments are done and they know for which diseases (cancers) and the used doses. • Same applies for the use in diagnostic imaging, PET-CT and other.
Radionuclides for Health UK (Radionuclides for Health UK)	• Focus on large volume radioisotopes should remain a priority (99Mo/99mTc). However other isotopes of importance that should be considered include: 111In, 131I, 177Lu, 223Ra, 68Ge for 68Ga • Monitoring of target materials
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Focus on therapeutic medical radioisotopes, since this will demand a large grow, accessibility of all European patients to these new radionuclide therapies, also emphasize the need of new therapeutic medical radioisotopes (Actinium, Terbium etc).
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Know the present and future needs, the rate of growth of implantation of radiopharmaceuticals
Aarhus University Hospital (Academic/research institution)	• Sealed sources relevant for radiation oncology: • After loading brachytherapy relies on availability of 192-Iridium (both 1Ci and 10Ci source strength) • Eye plaque treatment (uveal melanoma) relies on availability 106-Ruthenium plaques • Prostate seed treatment relies on availability of 125-Iodine seeds
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Exchange of knowledge - stimulate the communication between the different stakeholders, especially the multidisciplinary end-users in the clinical fields (physicians, medical physicists, radiopharmacists, technologists) - explore the feedback of all stakeholders that are close to the end of the supply chain. Only an end-to-end analysis will reveal potential problems or suggestions for optimization.
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	Monitoring of radionuclide production facilities across Europe
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	The EU should enlarge the panel of isotopes under monitoring. Broaden the scope to emerging radioisotopes.
IN2P3/CNRS (Academic/research institution)	177Lu and alpha emitters could be considered.
ENEA (Academic/research institution)	a prioritization of radioisotopes to be monitored could be of some help
National Centre for Nuclear Research (Academic/research institution)	Increasing the trust of small radionuclide production sites
University of Szeged (Academic/research institution)	EU monitoring should be expanded from diagnostic radioisotopes to therapeutic applications as well
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Invite PRISMAP-the European medical radionuclides programme in the Observatory to best streamline the needs, the potential of R&D and new radionuclides, and the industrial framework in this respect
SHINE EUROPE BV (Company/business organisation)	I believe that every 'end-user' organisation in the EU (hospitals and other clinical centres, R&D organizations, etc.) should be loading one EU centralized database with vital information. Best is to make this a mandatory requirement. The database should be open source for everyone, but clearly anonymized. The resulting reports should give insight in # and type of procedures per year and also the activity usage per type of isotope per country (all at time of patient administration). The trending and (remarkable) differences per country will not only support the timely elimination of barriers (source materials, irradiations, processing and transport) but will also support the improvement of patient treatment for those EU member states currently underutilizing the full potential of nuclear medicine.

Respondent	Answer
ORANO (Company/business organisation)	Follow-up of the entire supply chain Follow-up of new medicines developed and introduced in the EU market
SWAN Isotopen AG (Company/business organisation)	Currently the European Observatory and the Industry Association NMEu together are assuming the worldwide coordination of the security of Supply of medical isotopes. Strengthening the current activities by giving full recognition and financing of the activities (until today supported by the reactor and generator industry)
Global Morpho Pharma (Company/business organisation)	The observatory should identify and evaluate promising medical radioisotopes that are not yet available or not sufficiently available to be of interest for commercial organizations. Promoting small scale production of promising radioisotopes is important to fuel academic research and early clinical trials and identify the next 'champions' with a 10+ year vision.
Ion beam applications (Company/business organisation)	There is already a strong focus on reactor-based radioisotopes. The monitoring should also be extended to emerging radioisotope in general, which can be issued from accelerators (example: Cu64, Cu67, Zr89, Ac225, In111, At211...).
SCK CEN (Company/business organisation)	Monitoring would be much less necessary if the radioisotope production would be possible on a real commercial basis. There has not been monitoring of F-18 or similar isotopes. The reason why reactor isotopes need to be monitored is the dependency on a too limited number of reactors, mainly because no country is or will be willing to invest in a new reactor only to realise that their taxpayers will be paying for the radioisotopes of other countries. This will only happen if the country has a strategic reason to invest in the reactor, such as nuclear energy development. When Europe invested in HFR, that was their reasoning, but today, notwithstanding the obvious shortage of reactors for medical isotopes, Europe will not invest in a new reactor because the risk is too high.
Comecer S.p.A. (Company/business organisation)	• The market is focusing on 225Ac (radioisotope to be monitored in priority), or in general on alpha isotopes, so the observatory should focus on these ones, as well as the corresponding diagnostic pairs to enable the proper theranostics platform. • Moreover, EU should also focus on the development of a solid and reliable supply chain of the natural and/or enriched materials needed for medical isotopes productions, in order to set up a strong network that can be reached and addressed to, in a European area (nowadays there is no such a supply chain in Europe). It's important to have accessibility in the European area of the starting source materials with highest enrichment (>99,3%). • Finally, we suggest evaluating the need to create a reactor fuel enrichment facility within the EU borders (at the moment there's no such a facility in Europe).
NRG|PALLAS (Company/business organisation)	Better demand forecasting and/or scenario development. There seem to be no real demand volume forecasts based on data.
STFC (Individual (EU or non-EU citizen))	Set up regional observatories so that best practices can be shared and promoted, and these should feed into one central organisation
Hannover Medical School (Individual (EU or non-EU citizen))	The use of therapeutic medical radioisotopes is increasing, especially alpha emitting such as 225Ac, where we are already facing a shortage in supply. The platform is already an important installation to strengthen the EU supply, but in my opinion the visibility of the platform and this initiative needs to be higher. My idea would be an official annual congress/meeting for everybody in the field from academia and industry.
University clinic centre of the Republic of Srpska (Individual (EU or non-EU citizen))	To develop better supply chain for non-EU countries.
CERN, Institute of Chemical Physics - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	• Did not know of such initiative. More publications and newsletters are needed. • Nevertheless, could be useful to emphasize and focus on the end-users, who utilize the radionuclides, to identify upcoming needs and preventatively establish more optimized supply where needed (if possible).
Anonymous (Professional association)	From my point of view, we should try to get all the regulatory agencies of the member countries to establish similar criteria to allow their use.
Anonymous (United Nation Organisation)	• the observatory should look into other emerging radioisotopes supply, deemed to be used further in the future • developing live databases for producers/users
Anonymous (Company/business organisation)	Assess Lu-177 demand/supply situation within a 5-year framework.
Anonymous (Academic/research institution)	Include academic research laboratory such as those in PRISMAP which harmonize schedule among producers of innovative radionuclides including some alpha emitters
Anonymous (Academic/research institution)	In my opinion, it is not the radioisotopes that need close monitoring of the supply, but the source material supply
Anonymous (Academic/research institution)	The options should be published such that the clinical nuclear medicine sector, the authorities and industry (e.g. pharma but also vendors and developers of devices) are aware of the progress of research in the field. Many choose the 'traditional' radionuclides because they are not aware of what else is available. Support the national regulatory processes (for clinical application of novel radionuclides), where possible.
Anonymous (Academic/research institution)	The above-mentioned radioisotopes promote beta emitting radioisotopes that are produced by research reactors and these are aging reactors in Europe and have a limited lifespan. New research reactors need to be investigated in Europe, but this is expensive and against many EU

Respondent	Answer
	countries mandate. Otherwise, sourcing reactor radioisotopes from other sources outside Europe (Australia, South Africa, USA, etc.) needs to be investigated and locked in terms of agreements and back-ups. In addition, other therapeutic radioisotopes alpha and Auger emitting radioisotopes (211At, 225Ac, Tb's, Sc's, Er's, etc need to be investigated and produced at a commercial level to compliment the reactor
Anonymous (Academic/research institution)	The present portfolio has a 'historic' focus that follows the market evolution, but more efforts are needed to anticipate future needs, when novel applications may require other radioisotopes (161Tb, various alpha emitters, 43Sc, 44Sc, 152Tb, etc.) that have different supply constraints to be satisfied.
Anonymous (nuclear, radiation and accelerator physicist)	• There are well over a hundred radioisotopes that may become important for healthcare (and other applications). Whether they will eventually be used is to a large extent a matter of availability for in first instance (pre-)clinical research and later routine clinical use. Ensuring availability of radioisotopes for research is a strong driver for progress in nuclear medicine and molecular imaging. Europe will only be able to remain a leading party in this if it is able to provide those isotopes. • Creating a European equivalent of the US National Isotope Development Center (https://www.isotopes.gov/) that provides radioisotopes and now also enriched stable isotopes for research is a key element in maintaining a leading role in the development of nuclear medicine and molecular imaging.
Anonymous (Company/business organisation)	Include new diagnostic/therapeutic isotopes used: • in radiopharmaceuticals that have granted a marketing authorization (i.e: Ga68) • in research and development of Targeted Alpha Therapy
Anonymous (Company/business organisation)	Address the value chain issue of new emerging isotopes from the beginning of their development.
Anonymous (Individual (EU or non-EU citizen))	Providing a broader view not only involving industrial stakeholders, but also public institutions (e.g. irradiation facilities with larger cyclotrons, linear accelerators and reactors)
Anonymous (Individual (EU or non-EU citizen))	Uniformization of the procedures to follow-up the supply of radioisotopes in the different EU countries.

Table 6: respondents' views on how to strengthen the existing EU monitoring of radioisotopes?

5.1.6. Need for action at radioisotope level

Among the various radiopharmaceuticals in use (or under development) at European level, the study 'Co-ordinated Approach to the Development and Supply of Radionuclides in the EU identified a series of radionuclides of interest for medical applications.

For which step(s) of their respective supply chain do you think that there is a need for actions to maintain (or set) a secured and sustainable supply?

	SPECT			PET						Therapy Beta								Therapy alpha					Sealed sources		
	^{99m}Tc	^{123}I	^{155}Tb	^{18}F	^{68}Ga	^{89}Zr	^{64}Cu	^{44}Sc	^{124}I	^{131}I	^{90}Y	^{177}Lu	^{166}Ho	^{67}Cu	^{188}Re	^{47}Sc	^{161}Tb	^{223}Ra	^{225}Ac	^{212}Pb	^{211}At	^{149}Tb	^{60}Co	^{192}Ir	^{125}I
Source material																									
Enrichment																									
Irradiation																									
Processing																									
Transport																									
Nb of resp.	*57*	*36*	*35*	*24*	*49*	*29*	*46*	*36*	*28*	*37*	*24*	*49*	*23*	*33*	*23*	*28*	*33*	*21*	*47*	*20*	*39*	*25*	*13*	*10*	*8*

Table 7: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain

< 25%
[25-50%]
[50-75%]
>75%

Colour code indicates the % of respondents considering that actions would be needed to secure supply chains

In the following tables, the detailed results per radioisotope are given, when a "1" is found in a table, it means that the respondent identified this stage of the supply chain as one needing action(s) to maintain (or set) a secured and sustainable supply chain.

5.1.6.1. $^{99m}Tc/^{99}Mo$ (SPECT radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	1	1	1	1	1	
French Society of Nuclear Medicine (Professional association)	1			1		
BelNuc (Professional association)	1	1	1	1		
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	1					
Radionuclides for Health UK (Radionuclides for Health UK)	1					
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)			1			
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	1				1	
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	1				1	
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1				1	
SERGAS (Clinical nuclear medicine professional)	1					
Individual (Clinical nuclear medicine professional)					1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	1		1	1	1	
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)	1	1		1		
National Centre for Nuclear Research (Academic/research institution)				1	1	
University of Szeged (Academic/research institution)	1	1	1	1	1	
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	1		1			
SHINE EUROPE BV (Company/business organisation)	1	1	1	1		
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)		1				
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)		1	1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)			1	1		
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
NRG|PALLAS (Company/business organisation)	1	1	1	1		
STFC (Individual (EU or non-EU citizen))	1	1				
Hannover Medical School (Individual (EU or non-EU citizen))	1	1				
University clinic centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physics - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))			1	1	1	
Anonymous (Professional association)	1					
Anonymous (Scientific association)	1	1	1	1		
Anonymous (United Nation Organisation)	1	1	1			
Anonymous (Company/business organisation)	1		1			
Anonymous (Company/business organisation)				1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1	1	1	1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)			1		1	
Anonymous (Academic/research institution)			1			
Anonymous (nuclear, radiation and accelerator physicist)			1			
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)	1					
Anonymous (Company/business organisation)			1		1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)			1			
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1		1	
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1		
Anonymous (Individual (EU or non-EU citizen))	1		1	1	1	
Anonymous (Individual (EU or non-EU citizen))	1					
Anonymous (Individual (EU or non-EU citizen))	1				1	
Anonymous (Public authority)						1

Table 8: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for $^{99m}Tc/^{99}Mo$

5.1.6.2. ^{123}I (SPECT radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	1	1	1	1		
French Society of Nuclear Medicine (Professional association)				1		
BelNuc (Professional association)	1	1				
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	1				1	
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	1		1	1	1	
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1				1	1
Individual (Clinical nuclear medicine professional)				1	1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)					1	
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)				1		
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1	1	1	
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1				
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))		1			1	
CERN, Institute of Chemical Physics - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))				1		1
Anonymous (Professional association)	1					
Anonymous (Scientific association)	1	1	1	1		
Anonymous (United Nation Organisation)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1				
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1		1			
Anonymous (Academic/research institution)			1	1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)						1
Anonymous (nuclear, radiation and accelerator physicist)	1		1	1		
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)	1					
Anonymous (Company/business organisation)			1		1	
Anonymous (Company/business organisation)	1	1		1	1	
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1	1		
Anonymous (Individual (EU or non-EU citizen))			1			
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 9: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{123}I

5.1.6.3. ^{155}Tb (SPECT radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)						1
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)						1
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1	1	1	1		
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	1					
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	1					
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)		1			1	
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	1		1			
SHINE EUROPE BV (Company/business organisation)	1	1	1	1		
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)		1	1	1		
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)		1		1		
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))						1
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	1	1	1		1	
Anonymous (Professional association)						1
Anonymous (Scientific association)	1	1	1	1		
Anonymous (United Nation Organisation)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)		1		1		
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)		1				
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)		1		1	1	
Anonymous (Academic/research institution)	1	1				
Anonymous (nuclear, radiation and accelerator physicist)	1		1	1		
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)			1		1	1
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1	1	1	
Anonymous (Individual (EU or non-EU citizen))		1	1			
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1	1	
Anonymous (Individual (EU or non-EU citizen))	1			1		
Anonymous (Individual (EU or non-EU citizen))	1	1		1	1	
Anonymous (Individual (EU or non-EU citizen))				1	1	
Anonymous (Public authority)						1

Table 10: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{155}Tb

5.1.6.4. Details for SPECT radioisotopes

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	• From a user's perspectives I-123 irradiation and processing capacities seem to come to a limitation and should be expanded • Mo-99 irradiation and processing is a constant challenge, in particular securing irradiation capacities will remain a challenge • Tb-155 is a novel radioisotope, currently with very limited availability due to limited irradiation capacities
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	It is very important to guarantee availability and regular delivery
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	• Global capacity for Mo-99/Tc99m production overall, which includes ensuring sufficient reactors long term to provide consistent supply - this will mean addressing all the steps above. • I-123 has experienced problems particularly this year - we are unsure of all the reasons for this, but do not feel transport is the step which causes problems.
BelNuc (Professional association)	Source material and enrichment is a worldwide problem. Shortages are recurring every year.
Radionuclides for Health UK (Radionuclides for Health UK)	Clearly currently there is a strong reliance on research reactors for Mo-99/ Tc-99m production, but security of supply is threatened by an aging fleet, with expected increases in downtime, and the delay of replacement projects in Europe.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Depending on the radioisotopes, each step of the supply chain deserve attention. Two examples: • For fluorine-18 for PET diagnostic imaging, the supply of the isotope is rather secured but there is a need in the development of new radiopharmaceuticals to improve diagnosis. • For copper-64, that is also used for PET imaging, the supply of isotope is insufficient in Europe. Copper-64 has 12.6 hours half-life that would allow creating centralized manufacturing centers of radiopharmaceuticals (cyclotron to produce the isotope + radiolabelled drug manufacturing), from which end users would be supplied. The situation is not homogenous and depends on each isotope.
IN2P3/CNRS (Academic/research institution)	The enrichment of material targets remains a major problem in Europe, since we depend strongly on Russia (e.g. 64Ni). A US initiative already exists, so EU should proceed similarly.
ENEA (Academic/research institution)	Moly-99 can be produced without use of Uranium target by irradiating Moly-98: using natural Moly disks, the process has too low efficiency. The enrichment cost of Moly-98 is very high so is needed a reprocessing of the used generator to recover Moly 98. Investments and research have to be done in those fields.
National Centre for Nuclear Research (Academic/research institution)	Source material and enrichment for radionuclides such as 177Lu and 161Tb
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	• The supply chain for the production of 99mTc/99Mo has undergone important changes with new uranium enrichment grades, photoelectron and cyclotron routes. Notably the new neutron facilities such as JHR in CEA-Cadarache and ESS-Lund should be identified as possible new irradiation sources in Europe. Suitable infrastructures for the irradiation, processing and dispatch of the radionuclides should be foreseen. • The production of 155Tb is now exclusively done with the combination of high energy cyclotrons/proton accelerators and mass separation facilities and rely on the access to enriched targets in enough quantities and purity grades. Timely online operation of the main isotope mass separation facilities (present such as CERN-MEDICIS and future ones, such as, non-exhaustively, ISOL@Myrrha, SPES, and proper share of the facilities for the medical programme should be earn marked.
SHINE EUROPE BV (Company/business organisation)	• Mo-99: the ageing fleet of RR in Europe asks for a smart infrastructure replacement strategy. ERVI should be technology neutral and therefore support new technologies (like SHINE) and RR replacement strategies equally. Especially when these new initiatives have the potential of using much less HALEU, being safer, create less waste and are much more cost effective (under a level playing field between public and private investments). The significant potential of innovative methods should not be underutilized by supporting incumbent technologies more than these innovations. • Tb-155: The source and enrichment material (Gadolinium) is currently Russia origin. I believe ERVI should support EU domestic enrichment infrastructure. Furthermore, post irradiation processing technology requires dedicated separation technology. As all medical Tb isotopes are early R&D support from ERVI might be a condition to explore the full potential of all Tb-isotopes
ORANO (Company/business organisation)	Regarding enrichment, enrichment of U above 10% and stable isotope enrichment (as target materials: Mo, Xe and Gd) need political and financial support to secure the development of new supply chain like, for example, DOE in the US with the Isotope Program, and the HALEU Availability Program. For the moment, the associated supply chain is predominantly dominated by Russia (and very often as a sole provider).

Respondent	Answer
SWAN Isotopen AG (Company/business organisation)	The switch from HEU to LEU is a major cost for the companies, these community costs (weapon free Uranium) should be supported by EU
Ion beam applications (Company/business organisation)	missing: In111 - prohibitive cost because almost not available anymore
SCK CEN (Company/business organisation)	• Production of 99Mo by fission remains the standard today and is expected to remain that for at least another decade or longer. To effectively produce 99Mo, low-enriched uranium is required, both as target material and as fuel for the reactors in which the targets are irradiated. This is even true for homogeneous subcritical reactors such as the SHINE initiative, even if they require less. Europe has no LEU production capability and depends fully on the US and Russia for this supply. The US LEU supply is expected to run out in the late 2030s at the latest. • Irradiation of targets for 99Mo production is typically done in research reactors. The current fleet of reactors performing this task is over 50 years old and there is insufficient spare capacity to accommodate the unavailability of even just one of the larger ones in the fleet. Even if promises are made for alternative production methods, none of these are proven technologies at the scale of the current supply chain and the replacement of the current reactors will take at least 10 years for each reactor. • Scale-up of 123I production is possible as sufficient cyclotrons capable of doing it are available and there is no specific enrichment of the source material (Xe) needed. Alternatively, the use of 123Te is possible, but not required. • 155Tb production is said to require online mass separation from spallation of a tantalum target, but insufficient R&D has been performed to exclude other production methods. These do require access to high isotopic purity 155Gd and/or 156Gd, which is difficult to obtain.
Comecer S.p.A. (Company/business organisation)	• 99mTc/99Mo: processing is very important, due to a very strong customized line. Regarding the irradiation, the likely critical availability of European irradiation providers should be evaluated, due to reactor programs obsolescence, and the EU should react by enabling the construction and the operation of new irradiation centres. • 155Tb: it's important to have a higher enrichment of the source material.
Hannover Medical School (Individual (EU or non-EU citizen))	• 99mTc (99Mo): HEU vs. LEU • 123I: limited production sites and suppliers • 155Tb: limited production sites and generally still only in research and development phase
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	• 99mTc/99Mo - not a lot of suppliers, long waiting times for access. • 123I - do not know much. Difficult to postprocess after irradiation, need specialized equipment, that is not so common. • 155Tb - Need very pure material in order not to produce impurities. Some countries still need to advance in legislation for import/export and use.
Anonymous (Professional association)	From recent experience we have had supply problems for almost all the radioisotopes that we use in clinical practice. Whether due to lack of raw materials (99Mo) or problems with the limited means of production using accelerators (131I, 177Lu,...)
Anonymous (United Nation Organisation)	• in case of Mo-99/99mTc production using other methods (cyclotron, linear accelerators), a stable Mo-100 target availability should be considered • due to aging of existing research reactors with irradiation capacities, new irradiation capability either in new research reactors, or in NPP should be considered
Anonymous (Company/business organisation)	Mo-99 target production is almost sole source, and therefore quite vulnerable
Anonymous (Academic/research institution)	Not a big need from my point of view.
Anonymous (Academic/research institution)	• 123I - strong advice to strengthen the photonuclear production route from 124Xe, where source material supply is an issue. Strengthen developments towards photonuclear production of isotopes as 3rd pillar of radioisotope supply • 155Tb - sufficiently high enrichment of Gd isotopes available, but supply questionable. Similarly, photonuclear production from 156Dy possible, but heavily relying on available source material
Anonymous (Academic/research institution)	• General comment: The international, political situation became more fragile in the recent past. Supply of enriched material to produce medically interesting radionuclide has become an issue. Alternative/complementary routes/production facilities for radionuclides production have to be explored with high priority. • 99mTc/99Mo: there are a lack of research reactors in Europe, and this will endanger the supply. Enriched target material is required for the proton irradiation means to produce the product. • 123I requires medium-energy protons to produce it. There are few such facilities in Europe, however, this also depends on the demand for the radionuclide.

Respondent	Answer
	• 155Tb: Enriched target material is expensive, and one needs highly enriched material to produce 155Tb. To date, these have only been made available via the calutrons in Russia (an issue with many of the target material required for radiometal production). The use and optimization of mass separation (online or offline) via Isotope Separation OnLine facilities (ISOL) is highly desired to ensure radionuclidic pure product.
Anonymous (Academic/research institution)	• Sourcing 99mTc products is easy, but others such as 123I and 155Tb for example can be difficult. • Other SPECT radioisotopes such as 201Tl still popular for heart studies but still difficult at times to obtain.
Anonymous (Academic/research institution)	• The European centrifuge operators (URENCO and ORANO) should diversify their product portfolio to make stable isotopes of more elements available (Ti, Ni, Ru, Pt...). • Dedicated European electromagnetic isotope enrichment capacities are needed for elements that cannot be enriched with centrifuges, in particular for 43,44,46,48Ca, 102,110Pd, all lanthanide elements such as 152Gd, 155Gd, 168Er, 176Yb, etc. and those not yet available from URENCO or ORANO (Ti, Ni, Ru, Pt...).
Anonymous (nuclear, radiation and accelerator physicist)	• 123I and other iodine isotopes can be produced with relatively small accelerators provided highly enriched Te and Xe targets are available. • Similarly various Tb isotopes can be produced using relatively small accelerators using highly enriched Gd targets. • The same applies to the many other isotopes that are potentially relevant for both diagnostics and therapy • For all these isotopes the processing chain of high efficiency extraction of high purity isotopes from the irradiated targets and quantitative recovery of the very expensive target material is essential for making their use economically viable. Developing the required technology will provide Europe with a competitive edge.
Anonymous (Company/business organisation)	For all the isotopes: it's mandatory to maintain sufficient irradiation capacity with backup options and coordination among the irradiators
Anonymous (Company/business organisation)	The main risk about Mo99/Tc99m production is related to the irradiation capacity based nowadays on aging research reactors.
Anonymous (Individual (EU or non-EU citizen))	Ga-67, In-111
Anonymous (Individual (EU or non-EU citizen))	• Availability/shortage of 99Mo • Increasing relevance of Tb radioisotopes for the development of radiopharmaceuticals.

Table 11: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for SPECT radioisotopes

5.1.6.5. ^{18}F (PET radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	1					
French Society of Nuclear Medicine (Professional association)				1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)					1	
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)					1	
Individual (Clinical nuclear medicine professional)					1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	1					
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)						1
University of Szeged (Academic/research institution)	1	1	1	1	1	
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)				1		
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)					1	
SCK CEN (Company/business organisation)						
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1				
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1		1	
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
Anonymous (Academic/research institution)					1	
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (nuclear, radiation and accelerator physicist)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)	1	1	1		1	
Anonymous (Company/business organisation)	1				1	
Anonymous (Company/business organisation)						
Anonymous (Company/business organisation)		1				
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))			1		1	
Anonymous (Public authority)						1

Table 12: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{18}F

5.1.6.6. ^{68}Ga (PET radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	1			1		
French Society of Nuclear Medicine (Professional association)	1					
BelNuc (Professional association)	1					
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)					1	
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	1				1	
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	1				1	
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1				1	
SERGAS (Clinical nuclear medicine professional)	1					
Individual (Clinical nuclear medicine professional)				1	1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)				1		
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)				1		
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1	1	
University of Szeged (Academic/research institution)	1	1	1	1		
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)			1			
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)	1					
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1	1	1	
SCK CEN (Company/business organisation)						
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1				
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))		1				
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	1	1		1	1	
Anonymous (Professional association)	1					
Anonymous (Business association)						
Anonymous (Scientific association)	1		1	1		
Anonymous (United Nation Organisation)			1			
Anonymous (Company/business organisation)		1				
Anonymous (Company/business organisation)	1	1				
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)			1			
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1	1		1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)		1			1	
Anonymous (Academic/research institution)			1			
Anonymous (nuclear, radiation and accelerator physicist)						1
Anonymous (Clinical nuclear medicine professional)						
Anonymous (Clinical nuclear medicine professional)	1	1	1		1	
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)				1	1	
Anonymous (Company/business organisation)	1					
Anonymous (Company/business organisation)			1	1		
Anonymous (Individual (EU or non-EU citizen))			1			
Anonymous (Individual (EU or non-EU citizen))		1				
Anonymous (Individual (EU or non-EU citizen))				1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1				1	
Anonymous (Public authority)						1

Table 13: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{68}Ga

5.1.6.7. ^{89}Zr (PET radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)			1	1		
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1					
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)				1		
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1					
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)				1		
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1					
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)				1		
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)			1			
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1				1	
University of Szeged (Academic/research institution)	1	1	1	1		
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1		1	1	1	
SCK CEN (Company/business organisation)		1				
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1					
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Professional association)	1					
Anonymous (United Nation Organisation)				1		
Anonymous (Company/business organisation)			1			
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)			1	1		
Anonymous (Academic/research institution)						
Anonymous (nuclear, radiation and accelerator physicist)						1
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1	1		
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))				1		
Anonymous (Public authority)						1

Table 14: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{89}Zr

5.1.6.8. ^{64}Cu (PET radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)			1	1		
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1					
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)				1		
French Society of Nuclear Medicine (Professional association)	1					
BelNuc (Professional association)	1			1		
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)			1			
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	1	1	1	1		
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
SERGAS (Clinical nuclear medicine professional)						
Individual (Clinical nuclear medicine professional)			1			
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	1	1		1		
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)		1	1			
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	1		1	1		
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1			
SCK CEN (Company/business organisation)		1	1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1				
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	1		1			
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	1	1				
Anonymous (Scientific association)	1		1	1		
Anonymous (United Nation Organisation)	1				1	
Anonymous (Company/business organisation)			1			
Anonymous (Company/business organisation)	1	1				
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)		1	1			
Anonymous (Academic/research institution)	1	1		1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1		1		
Anonymous (Academic/research institution)		1				
Anonymous (nuclear, radiation and accelerator physicist)						1
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)	1				1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)		1				
Anonymous (Company/business organisation)			1	1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1	1				
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Individual (EU or non-EU citizen))			1		1	
Anonymous (Public authority)						1

Table 15: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{64}Cu

5.1.6.9. ^{44}Sc (PET radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1					
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)				1		
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1		1	1		
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)		1	1			
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	1		1	1		
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)			1			
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1	1	1	
SCK CEN (Company/business organisation)		1				
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1				
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1			
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	1	1	1	1	1	

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Professional association)						1
Anonymous (Scientific association)	1		1	1		
Anonymous (United Nation Organisation)	1	1				
Anonymous (Company/business organisation)	1					
Anonymous (Company/business organisation)	1	1				
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)		1	1	1		
Anonymous (Academic/research institution)	1			1		
Anonymous (Academic/research institution)	1	1	1	1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1			1	
Anonymous (Academic/research institution)		1	1			
Anonymous (nuclear, radiation and accelerator physicist)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)						1
Anonymous (Individual (EU or non-EU citizen))	1	1				
Anonymous (Individual (EU or non-EU citizen))	1	1				
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1			1	1	
Anonymous (Public authority)						1

Table 16: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{44}Sc

5.1.6.10. ^{124}I (PET radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1					
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)				1		
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1		1	1		
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	1					
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1				1	
Individual (Clinical nuclear medicine professional)					1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1	1	1	1	1	
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)				1		
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)			1			
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1	1	1	
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1				
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Professional association)	1					
Anonymous (Scientific association)	1		1	1		
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1				
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)				1		
Anonymous (Academic/research institution)		1				
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)						1
Anonymous (nuclear, radiation and accelerator physicist)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1	1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 17: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{124}I

5.1.6.11. Details on PET radioisotopes

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	• Zr-89: Currently only one main irradiation and processing site with regular commercial supply, demand is expected to rise • Cu-64: Currently only one producer with marketing authorization with limited capacity, demand is expected to rise • Sc-44: Currently not commercially available
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	• F-18: Limited supply options for good quality O-18 water are an issue, as well as potentially issues with purification if not of high enough quality are a concern. There are a limited number of cyclotrons nationally, and as complex pieces of equipment with many different facets to the production process, multiple things may go wrong to impact on F-18 supply from them (e.g. beam not on target, vacuum problems, etc). Capacity to produce different F-18 products, other than FDG, should be looked at. • Ga-68: Production of the Ga-68 generators does not seem problematic at present, although there are concerns about Russia's contribution to target material. The main problem is in capacity to meet demand domestically, whereby facilities and workforce required to produce Gallium-68 radiopharmaceuticals are limited. • All other isotopes: processing can be a significant challenge because of problems making them to GMP standards , partly because of multiple processes which cannot all be automated or done in closed environment.
BelNuc (Professional association)	• No problem for F18. • For Ga68= Ge68 as source material for the generators and Zn68 for the cyclotron Production • In general source material is an issue all around.
Radionuclides for Health UK (Radionuclides for Health UK)	• Germanium-68 production should be considered as well as gallium-68 in order to produce generators. • No longer a European supply of GMP grade Iodine-124 since Perkin Elmer ceased production - this is impacting clinical trials. • The fact that higher energy cyclotrons are needed to produce radioisotopes other than F-18 restricts where they can be produced and therefore access. • 89Zr, 64Cu and 44Sc are currently mainly used for research, and development of GMP protocols are needed to expand their routine use.
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	18F ok, 68Ga availability problems, no experience with the others
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• Fluorine-18: To pay attention to the supply of oxygen-18 water required to produce fluorine-18 to avoid shortage. • Gallium-68 : Generators are easy to use but a larger development of cyclotron solutions would be valuable • Copper-64: Starting material to prepare copper-64 is still very expensive. Solid targets are more difficult to handle than liquid ones. Developing liquid solutions to produce copper-64 would be valuable • Iodine-124: no sure it will be authorized one day for a large clinical use.
IN2P3/CNRS (Academic/research institution)	See previous comments.
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Other prospective radionuclides should be included, notably those combining diagnostics and therapeutic properties. This can be access to other medically relevant R&D radionuclides, mostly in pre-clinical grades : • 149Tb, combining alpha and PET • 152Tb longer-lived PET isotope part of the Terbium quadruplet • 43Sc, an alternative to 44Sc, for which proper purity grade is not yet available • 128Ba/Cs in-vivo PET-Auger generator
ORANO (Company/business organisation)	Regarding enrichment, enrichment of U above 10% and stable isotope enrichment (as target materials: Zn, Ni, Ti, Ca, Te) need political and financial support to secure the development of new supply chain like, for example, DOE in the US with the Isotope Program, and the HALEU Availability Program. For the moment, the associated supply chain is predominantly dominated by Russia (and very often as a sole provider).
Ion beam applications (Company/business organisation)	remaining barriers for sustainable large-scale availability due to • source material / enrichment (sourced from Russia) • irradiation / processing : lack of financial support for research and to enable commercial production • training / expertise lacking in many countries • transport: different regulations from country to country

Respondent	Answer
SCK CEN (Company/business organisation)	Not a PET isotope, but nonetheless a vital isotope for medical R&D with a precarious supply is C-14. Its characteristics make it particularly difficult and expensive to manufacture and the market in the past has offered it way too cheap to be interesting for commercial operations.
Comecer S.p.A. (Company/business organisation)	• 18F: the current absence of 18O enrichment facility within EU is causing a full dependency for both supply and enrichment. • 89Zr: the partial dependency on EU to stable isotopes suppliers from China can generate a shortage of source material in the future. • 68Ga+ 64Cu+44Sc+124I: no need of any action for irradiation, processing and transport, but it's important to have accessibility in the European area of starting source material and enrichment facilities (currently depending on Russia).
Hannover Medical School (Individual (EU or non-EU citizen))	• 18F: although there is a good cyclotron network, still certain in areas are difficult to get 18F for reasonable costs. Long transport routes are expensive and the quality of the 18F is declining by too long transport times (absorption effects in glass vials, activity concentration etc.). • 68Ga: the release limits for 68Ge (radioactive waste management) are too strict, which strongly increases costs in radiopharmaceutical productions • 89Zr, 64Cu and 124I: limited productions sites and only limited suppliers
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	• 18F - no issues • 68Ga - (From cyclotron) need pure Zn solution and with purification takes some time. Ga-67 byproduct. • 89Zr - No knowledge • 64Cu - Promising but needs enriched material. No knowledge of commercial suppliers, only research centres. • 44Sc - Abundance and cost of 44Ca. If other target material is used, then contaminants of long-lived Sc isotopes as well. Target systems for cyclotrons. • 124I- No knowledge. Need specified equipment for post-irradiation processing.
Anonymous (Professional association)	In my opinion, for gallium 68, due to the low activity that is obtained in the generators, it should be easier to obtain in cyclotrons.
Anonymous (United Nation Organisation)	• F-18 has no problem due to availability of medical cyclotrons • Ga-68 generators becoming expensive and direct cyclotron production method should be considered and strengthened • Zr-89, some purification routes should be studied • Cu-64 due availability and price of the Ni-64 should be considered • I-124 not readily used and produced
Anonymous (Company/business organisation)	• F-18 is mature and secure. • Ga-68 has limited sources of Ge-68, including Russian dependencies. • Zr and Cu-64 have immature supply networks.
Anonymous (Academic/research institution)	• 44Sc - apart from production through proton irradiation of 44Ca isotope (reliable supply?), development of 44Ti/44Sc generators is strongly recommended • 124I - supply of neutron deficient source material questionable in future, please monitor developments
Anonymous (Academic/research institution)	• As for 155Tb above, enriched target material is expensive, and one needs highly enriched material to produce the above PET radiometals. To date, these have only been made available via the calutrons in Russia (an issue with many of the target material required for radiometal production). • Some compact cyclotrons also require solid target stations to be used effectively.
Anonymous (Academic/research institution)	Not enough facilities in Europe producing at high commercial level, long waiting periods at times and expensive.
Anonymous (Academic/research institution)	• Secure supply of enriched 64Ni for 64Cu production. • 68Ga and 44Sc can be generator-derived, provided enough activity of the mother isotope is available. This calls for large-scale production of 68Ge and 44Ti respectively. • Alternatively, 44Sc and the very promising alternative 43Sc can be produced directly, which requires however significant quantities of enriched 43Ca, 44Ca or 46Ti respectively. • The promising PET isotope 152Tb requires highly enriched 152Gd as target material.
Anonymous (Company/business organisation)	• Stable isotopes (source material) for many applications are coming from Russia. There availability in the next months might be challenging. • Irradiation - it's mandatory to maintain sufficient irradiation capacity with backup options and coordination among the irradiators. • Logistic - transport: to develop fleet and hub for the transport of radiopharmaceuticals in compliance with GMP/GDP.

Respondent	Answer
Anonymous (Company/business organisation)	• F18: starting material O18 main source is outside EU (mainly Russia). • Ga68: too few suppliers of Ge68 making the supply chain weak • Cu64: starting material comes outside of Eu (mainly Russia)
Anonymous (Individual (EU or non-EU citizen))	• 64Cu is an interesting theranostic radionuclide that still is not easily available in EU countries.

Table 18: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for PET radioisotopes

5.1.6.12. ^{131}I (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)						1
French Society of Nuclear Medicine (Professional association)	1					
BelNuc (Professional association)	1	1	1			
Radionuclides for Health UK (Radionuclides for Health UK)	1	1	1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	1				1	
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	1				1	
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
SERGAS (Clinical nuclear medicine professional)	1				1	
Individual (Clinical nuclear medicine professional)				1	1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)				1		
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	1		1	1	1	
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
SHINE EUROPE BV (Company/business organisation)	1	1	1	1		
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)				1		
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)			1	1	1	
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1			1	1	
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)			1			
STFC (Individual (EU or non-EU citizen))						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Hannover Medical School (Individual (EU or non-EU citizen))	1	1				
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Professional association)	1					
Anonymous (Scientific association)	1	1	1			
Anonymous (Company/business organisation)			1			
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)						1
Anonymous (Clinical nuclear medicine professional)				1	1	
Anonymous (Company/business organisation)			1		1	
Anonymous (Company/business organisation)				1	1	
Anonymous (Company/business organisation)			1			
Anonymous (Company/business organisation)			1	1	1	
Anonymous (Individual (EU or non-EU citizen))				1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 19: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{131}I

5.1.6.13. ^{90}Y (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)	1			1	1	
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
French Society of Nuclear Medicine (Professional association)				1	1	
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)		1				
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1			1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)		1	1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1					
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Professional association)	1					
Anonymous (Scientific association)	1	1	1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Academic/research institution)				1		
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)				1	1	
Anonymous (Company/business organisation)			1			
Anonymous (Company/business organisation)				1	1	
Anonymous (Company/business organisation)			1			
Anonymous (Individual (EU or non-EU citizen))				1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 20: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{90}Y

5.1.6.14. ^{177}Lu (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)		1	1	1		
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
French Society of Nuclear Medicine (Professional association)	1				1	
BelNuc (Professional association)	1		1			
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	1	1	1	1	1	
Radionuclides for Health UK (Radionuclides for Health UK)	1	1	1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	1	1	1			
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
SERGAS (Clinical nuclear medicine professional)	1				1	
Individual (Clinical nuclear medicine professional)			1			
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	1	1	1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)			1	1		
ENEA (Academic/research institution)	1	1		1		
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
SHINE EUROPE BV (Company/business organisation)	1	1	1	1		
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)	1		1			
Global Morpho Pharma (Company/business organisation)		1	1		1	
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)		1	1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1	1			
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)	1	1	1			
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))			1	1	1	
Anonymous (Scientific association)	1	1	1			
Anonymous (United Nation Organisation)	1	1		1		
Anonymous (Company/business organisation)	1		1			
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)			1			
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1				
Anonymous (Academic/research institution)		1	1			
Anonymous (nuclear, radiation and accelerator physicist)	1	1		1		
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)				1	1	
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)				1	1	
Anonymous (Company/business organisation)			1			
Anonymous (Company/business organisation)	1					
Anonymous (Individual (EU or non-EU citizen))	1	1	1			
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1		1	1		
Anonymous (Public authority)						1

Table 21: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{177}Lu

5.1.6.15. ^{166}Ho (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)			1			
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
Individual (Clinical nuclear medicine professional)				1		
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)			1			
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)			1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1					
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)			1	1		
STFC (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Scientific association)	1	1	1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (United Nation Organisation)				1		
Anonymous (Company/business organisation)						1
Anonymous (Academic/research institution)		1				
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)			1			
Anonymous (nuclear, radiation and accelerator physicist)			1	1		
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)			1			
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 22: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{166}Ho

5.1.6.16. ^{67}Cu (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
IN2P3/CNRS (Academic/research institution)		1	1	1		
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)			1			
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1	1	1	
SCK CEN (Company/business organisation)			1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1	1			
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	1	1	1	1		
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))		1		1		
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Scientific association)	1	1	1			
Anonymous (United Nation Organisation)	1	1				
Anonymous (Company/business organisation)			1			
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)		1	1			
Anonymous (Academic/research institution)			1			
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)		1		1	1	
Anonymous (Academic/research institution)			1			
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)	1					
Anonymous (Individual (EU or non-EU citizen))			1			
Anonymous (Individual (EU or non-EU citizen))		1	1	1		
Anonymous (Individual (EU or non-EU citizen))			1		1	
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 23: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{67}Cu

5.1.6.17. ^{188}Re (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)				1	1	
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
Individual (Clinical nuclear medicine professional)					1	
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)			1	1		
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1			
University of Szeged (Academic/research institution)	1	1	1	1	1	
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)		1		1		
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1	1			
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Scientific association)	1	1	1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (United Nation Organisation)	1	1	1	1		
Anonymous (Company/business organisation)			1			
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)			1			
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)				1	1	
Anonymous (Company/business organisation)	1		1			
Anonymous (Individual (EU or non-EU citizen))			1			
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1			1		
Anonymous (Public authority)						1

Table 24: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{188}Re

5.1.6.18. ^{47}Sc (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1	1		1		
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1				1	
Individual (Clinical nuclear medicine professional)				1		
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)		1	1	1		
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1	1	1	1	1	
SCK CEN (Company/business organisation)						1
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1	1			
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	1		1		1	
Anonymous (Scientific association)	1	1	1			
Anonymous (Company/business organisation)						1
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)		1	1			
Anonymous (Academic/research institution)	1	1	1			
Anonymous (Academic/research institution)	1	1	1	1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1				
Anonymous (Academic/research institution)		1	1			
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)						1
Anonymous (Individual (EU or non-EU citizen))			1			1
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))		1	1	1		
Anonymous (Public authority)						1

Table 25: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{47}Sc

5.1.6.19. ^{161}Tb (Therapy beta radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1	1	1	1		
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	1	1				
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Lausanne University Hospital (CHUV) (Academic/research institution)	1					
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)		1	1	1		
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)	1	1	1	1		
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)		1	1		1	
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)		1	1			
AlfaRim (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)	1	1	1	1		
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	1		1	1		
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	1		1		1	
Anonymous (Scientific association)	1	1	1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (United Nation Organisation)	1	1		1		
Anonymous (Company/business organisation)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)		1	1			
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1	1	1		
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1		1		
Anonymous (Academic/research institution)		1	1			
Anonymous (nuclear, radiation and accelerator physicist)	1	1	1	1		
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)						1
Anonymous (Individual (EU or non-EU citizen))	1	1				
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1		
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1	1	
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Public authority)						1

Table 26: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{161}Tb

5.1.6.20. Details on Therapy beta radioisotopes

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	• Lu-177: Important increase of clinical use, with limited number of suppliers, irradiation capacities, enriched starting material limited supplies • Like 90Y, 169Er and 168Re are used for radiosynoviorthesis, which is the most frequently performed nuclear medicine therapy in Germany (appr. 70,000 treatments per year) and in many other European countries. Problems with irradiation and contaminations often hamper the delivery to the medical institutions which causes a lot of needless costs, organizational work as well as annoyance and frustration for both patients and medical staff.
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	131I, 90Y, 177Lu, 188Re are the radioisotopes available on the market and for which there is authorization by regulatory bodies for clinical use.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	There have been significant issues with I-131 supply, but we are not clear what the exact reason is. We cannot comment on the other isotopes.
BelNuc (Professional association)	In general source material is an issue all around.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Lu177 will be used at a much larger scale with the coming marketing authorization of its use in the treatment of prostate cancer (PSMA-Lu177). At all levels there can be improvements, but there is a need for more research and, as the needs may still increase research in local production (cyclotron with Deuterium) is needed and urgent.
Radionuclides for Health UK (Radionuclides for Health UK)	• Iodine-131 has had significant shortages in recent years and this seems to be mainly sourced from South Africa rather than within the EU. • Y-90 is very difficult to get for research use. • The other radionuclides listed are currently in research use. Availability for research use is important but shouldn't be prioritised over those used regularly for patients. Those with clear applications should be developed to GMP standards.
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	Only I-131 is available routinely in Romania
ENEA (Academic/research institution)	Lu177 is relatively new: a great effort in terms of research and development has to be done
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	• The listed 47Sc, 67Cu, 161Tb are presently included in the PRISMAP radionuclides port-folio. • Accelerator production levels are generally speaking lower than reactor produced, when the enriched target is available: beam time and suitable high energy accelerators, including mass separation facilities, should be operational for 47Sc and 67Cu, while appropriate access to enriched 160Gd targets is needed in the medium terms. • On the long terms, both irradiation infrastructures and enriched targets are needed for all these radionuclides. Other therapeutic radionuclides are also included in PRISMAP, such as: • 169Er, 153Sm newly available with high molar activities and now suitable for targeted molecular radiotherapy, already in use in nuclear medicine for other modalities: proper access to mass separation facilities is required. • 111Ag from reactor facilities. • PRISMAP is also offering Auger electron emitters, with different gamma emissions suitable for imaging, notably 103Pd/103mRh in-vivo generator, 165Er, 165Tm for generator of 165Er, 175Yb.
SHINE EUROPE BV (Company/business organisation)	• I-131 (see Mo-99 remarks • Lu-177. The source and enrichment material is Russian origin. Lu-177 is currently the most promising treatment isotope, so a EU based enrichment infrastructure is a must happen. As EU based RR capacity might become a constraint, especially given the age of these RRs a smart RR replacement infrastructure is needed. ERVI needs to continue to support initiatives with a technology neutral approach so that existing solutions (replacing RRs in EU) and new solutions (SHINE D-T vertical port use) are supported equally (including the creation of a fair level playing field). • 161Tb: See the earlier remarks on Tb-155 - counts for all Tb isotopes
ORANO (Company/business organisation)	Regarding enrichment, enrichment of U above 10% and stable isotope enrichment (as target materials: Te, Lu, Yb, Dy, Zn, Ni, W, Ti, Ca, Gd) need political and financial support to secure the development of new supply chain like, for example, DOE in the US with the Isotope Program and the HALEU Availability Program. For the moment, the associated supply chain is predominantly dominated by Russia (and very often as a sole provider).

Respondent	Answer
Global Morpho Pharma (Company/business organisation)	• Enrichment of Yb-176 and Gd-160 relies mostly on Russian enrichment units and the growing demand already exceeds the offer. • Upscaling of both irradiation and processing capacities is key to meet the projected radioisotope needs within the next 5 to 10 years. • Transport of larger quantities of radioisotopes in type B containers remains challenging due to the limited number of authorized containers.
Ion beam applications (Company/business organisation)	• Lots of research should still be performed to fully understand the production process • Today there is no availability blocking the development of these isotopes, resulting to a chicken-and-egg situation. In the US, the DoE is massively supporting research institutes and industry to bridge the early R&D and commercial phases. There are still high barriers in the areas as above: • source material / enrichment (sourced from Russia) • irradiation / processing: lack of financial support for research and to enable commercial production • training / expertise lacking in many countries • transport: different regulations from country to country
SCK CEN (Company/business organisation)	Irradiation concerns for all these isotopes are linked to the limited availability of research reactors described for 99Mo. • 131I suffers from a significantly too low price on the market, not compatible with the cost of production without subsidies. Its production as a by-product of the Mo99 fission production allows supply to be sufficient most of the time, but its use is increasing and 99Mo production by fission may be decreasing. Irradiation of Te in research reactors is an alternative production route for 131I, but the volatility of Te and I compounds causes this to be a risky route to engage in for today's research reactors with limited exhaust margins. • 177Lu production (non-carrier added) requires high isotopic purity 176Yb, which is sourced in Russia. Electromagnetic isotope separation is required to manufacture it and Europe has no capability in that respect. • 166Ho is difficult to produce for reactors due to the extreme sensitivity of the carrier spheres in the radio embolic therapy. Low gamma flux and temperature control are required. The current price for the product is fully incompatible with the production costs. • 90Y for microspheres has no immediate supply issues, but 90Y pricing for other nuclear medicine applications is totally incompatible with production costs. • 188Re suffers from a reputation that it has an uncertain supply, even though high flux research reactors capable of producing it are available (even if they suffer from the ageing described above) and have considerable extra capacity to produce it. That capacity is often used to manufacture Ir192 (similar fluxes), which is not a medical product and can be produced in lower fluxes as well. Processing of the 188Pb into a 188Re generator is known technology, but the dissolution of the targets is not straightforward. • 161Tb production is relying of the same fleet of reactors previously mentioned and requires the same fluxes as 90Y, 177Lu, 99Mo, etc. It is competing for space with these productions. It relies on Gd160, only sourced in Russia at this moment.
Comecer S.p.A. (Company/business organisation)	• There's a likely shortage of the above-mentioned isotopes in the future, due to the fact that most of the European nuclear reactors are ending their programs within the next ten years. In addition to that, most of the source materials and enrichment needed for the production of these isotopes is not EU-based and mainly demanded to Chinese and Russian suppliers. • The entire supply chain of 131I is weak in Europe and it's mainly based on non-EU providers, a focus on these topics should be addressed as a priority. • Regarding 67Cu, the EU should promote the R&D on alternative methodologies that can enable larger availability of this isotope.
NRG|PALLAS (Company/business organisation)	• For I-131, a shortage in irradiation capacity may emerge, especially if Mo-99 will be produced via alternative technologies (and thus no longer producing I-131 as by-product). • For Lu-177 non carrier added, Yb-176 is in short supply (although I believe that this will be resolved by several ongoing initiatives and potential recycling). Still, current capacity of enrichment, as well as irradiation, is not enough to meet future demand. A lot depends on the production capacity of the CANDU reactors in Canada. • For Ho-166, irradiation is a sensitive process and processing needs to happen very quickly after irradiation because of the 26 hour half-life.
Hannover Medical School (Individual (EU or non-EU citizen))	• 131I: HEU vs. LEU similar to the 99Mo supply • 90Y: everything is fine • 177Lu: using (n,y) process gives 177mLu impurity. Limits for release of 177mLu in waste management are strict and hinder use of approved drugs such as Lutathera. • 160Ho: the general interest in 160Ho is limited, the applications are limited, too. • 67Cu: currently the interest is limited. Radionuclide purity is an issue.

Respondent	Answer
	• 188Re: limited interest, applications are lacking. • 47Sc: interesting isotope in combination with 44Sc and 68Ga as diagnostic partners. But, still limited interest and limited production sites. • 161Tb: as all Tb-isotopes, limited production sites, and still only in research and development.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	• 131I - Do not know • 177Lu - High demand and sometimes waiting time • 166 Ho - Don't know • 67Cu - Don't know • 188Re - Don't know • 47Sc - Target material, need >30 MeV cyclotron. Production of long-lived contaminants. • 161Tb - Very few production sites
Anonymous (United Nation Organisation)	• I-131 availability at the moment has no issue considering fission production, however if alternate production method become available, I-131 production may be affected • Y-90 generator is not widely used due to quality control problems and competing Lu-177 in the field • Lu-177 indirect production route highly depends on the availability of Yb-176 • Cu-67 alternate route using linear accelerators seem more reliable • Re-188 irradiation facilities are limited and no balance at production/application market
Anonymous (Company/business organisation)	Reactor capacity/availability for fission produced and activation produced isotopes is questionable in the longer term. Yb-176 is sole source from Russia.
Anonymous (Academic/research institution)	• 177Lu - 176Yb supply in EU needs attention • 67Cu - as above, photonuclear route requires EU support • 47Sc - Ca46 / Ca48 / 48Ti availability and enrichment (radioisotopic purity), EU should envisage independent supply chain. Photonuclear production possible and promising -> see 67Cu • 161Tb - availability of 160Gd questionable
Anonymous (Academic/research institution)	• Enriched target material is expensive, and one needs highly enriched material to produce the above nuclides. To date, these have only been made available via the calutrons in Russia (an issue with many of the target material required for radiometal production). • 47Sc and 161Tb require irradiation by means of research reactors, of which there is a shortage in Europe. • 67Cu production requires the use of higher-energy cyclotrons, of which there are few in Europe some with limited operation throughout the year. The use of eLINACS to produce 67Cu and 47Sc, but this requires investment and development.
Anonymous (Academic/research institution)	Not enough facilities in Europe producing at high commercial level, long waiting periods at times and expensive.
Anonymous (Academic/research institution)	• 'Clean' 47Sc can be obtained from 47Ca/47Sc generators which require however enriched 46Ca or 48Ca as target material. • Production of short-lived 166Ho requires a highly redundant network of irradiation reactors. Irradiation of 164Dy in high-flux reactors could produce 166Dy for 166Dy/166Ho generators, allowing production of n.c.a. 166Ho without 166mHo admixture and easing logistics due to the longer-lived intermediate isotope.
Anonymous (Company/business organisation)	• I131, Y90, Lu177, Ho166, Re188: require reactor irradiation capacity in Europe • Cu67, Re188: starting material are available from a very limited number of partners outside Europe
Anonymous (Individual (EU or non-EU citizen))	• 67Cu and 161Tb are interesting therapeutic radionuclides that still are nor easily available in EU countries.

Table 27: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for therapy (beta) radioisotopes

5.1.6.21. ^{223}Ra (Therapy alpha radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1	1	1	1		
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	1				1	
Radionuclides for Health UK (Radionuclides for Health UK)	1			1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)			1			
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)			1	1		
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)	1		1	1		
Comecer S.p.A. (Company/business organisation)						1
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))		1				
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Business association)						
Anonymous (Scientific association)	1	1	1	1		
Anonymous (Academic/research institution)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1			1		
Anonymous (Academic/research institution)	1		1	1	1	
Anonymous (Academic/research institution)						
Anonymous (Academic/research institution)						1
Anonymous (Company/business organisation)	1		1		1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)	1					
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1			1		
Anonymous (Individual (EU or non-EU citizen))				1		
Anonymous (Public authority)						1

Table 28: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{223}Ra

5.1.6.22. ^{225}Ac (Therapy alpha radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)				1		
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)	1					
BelNuc (Professional association)	1	1	1	1		
Radionuclides for Health UK (Radionuclides for Health UK)	1		1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	1	1	1			
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1			1	1	
Individual (Clinical nuclear medicine professional)		1				
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)	1		1	1		
ENEA (Academic/research institution)	1	1		1		
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)	1	1	1	1	1	
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)			1	1		
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)	1				1	
ORANO (Company/business organisation)						
SWAN Isotopen AG (Company/business organisation)	1		1	1		
Global Morpho Pharma (Company/business organisation)	1					
Ion beam applications (Company/business organisation)	1		1	1	1	
SCK CEN (Company/business organisation)	1		1	1	1	
AlfaRim (Company/business organisation)	1		1	1		
Comecer S.p.A. (Company/business organisation)	1	1	1	1	1	
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	1		1			
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		
University clinic centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physics - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))			1			

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Scientific association)	1	1	1	1		
Anonymous (United Nation Organisation)	1		1	1		
Anonymous (Company/business organisation)			1	1		
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Academic/research institution)	1	1	1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1		1	1		
Anonymous (Academic/research institution)	1		1	1		
Anonymous (Academic/research institution)	1		1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)			1		1	
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)	1		1	1	1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)	1		1	1		
Anonymous (Company/business organisation)	1					
Anonymous (Individual (EU or non-EU citizen))	1		1	1		
Anonymous (Individual (EU or non-EU citizen))	1			1		
Anonymous (Individual (EU or non-EU citizen))	1		1		1	
Anonymous (Public authority)						1

Table 29: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{225}Ac

5.1.6.23. ^{212}Pb (Therapy alpha radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1	1	1	1		
Radionuclides for Health UK (Radionuclides for Health UK)	1			1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)	1				1	1
Individual (Clinical nuclear medicine professional)		1				
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)	1		1	1	1	
SCK CEN (Company/business organisation)	1		1	1		
Comecer S.p.A. (Company/business organisation)	1					
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)	1	1	1	1		
STFC (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Scientific association)	1	1	1	1		
Anonymous (Academic/research institution)		1				
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1			1		

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Academic/research institution)	1		1	1	1	
Anonymous (Academic/research institution)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)				1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))	1			1		
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 30: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{212}Pb

5.1.6.24. ^{211}At (Therapy alpha radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)	1					
BelNuc (Professional association)	1	1	1	1		
Radionuclides for Health UK (Radionuclides for Health UK)			1	1	1	
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
DEPARTEMENT OF NUCLEAR MEDICINE UNIVERSITY CLINICAL COMPLEX OF SANTIAGO DE COMPOSTELA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)		1				
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	1					
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	1	1	1	1	1	
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)			1	1		
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)				1	1	
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)			1	1		
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)					1	
SWAN Isotopen AG (Company/business organisation)			1			
Global Morpho Pharma (Company/business organisation)			1			
Ion beam applications (Company/business organisation)	1		1	1	1	
SCK CEN (Company/business organisation)			1	1		
Comecer S.p.A. (Company/business organisation)			1			
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))			1	1		
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))			1			
Anonymous (Scientific association)	1		1	1		

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (United Nation Organisation)			1	1	1	
Anonymous (Company/business organisation)			1	1		
Anonymous (Academic/research institution)					1	
Anonymous (Academic/research institution)			1	1		
Anonymous (Academic/research institution)			1			
Anonymous (Academic/research institution)	1		1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)			1		1	
Anonymous (Academic/research institution)			1			
Anonymous (nuclear, radiation and accelerator physicist)			1			
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)					1	
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)				1		
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Individual (EU or non-EU citizen))			1	1		
Anonymous (Individual (EU or non-EU citizen))			1	1	1	
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 31: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{211}At

5.1.6.25. ^{149}Tb (Therapy alpha radioisotope)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	1	1	1			
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)	1	1	1	1		
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)						1
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)		1	1	1		
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1		
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)			1	1		
SHINE EUROPE BV (Company/business organisation)	1					
Bayer AG (Company/business organisation)						1
ORANO (Company/business organisation)		1				
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)	1	1	1			
Comecer S.p.A. (Company/business organisation)						1
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))			1			
Anonymous (Scientific association)	1	1	1	1		
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)	1	1	1	1	1	

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Academic/research institution)		1				
Anonymous (Academic/research institution)	1		1	1	1	
Anonymous (Academic/research institution)	1					
Anonymous (Academic/research institution)	1	1			1	
Anonymous (Academic/research institution)		1	1	1		
Anonymous (nuclear, radiation and accelerator physicist)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)	1	1	1	1	1	
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)	1	1	1	1	1	
Anonymous (Company/business organisation)						1
Anonymous (Individual (EU or non-EU citizen))			1			1
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1	1	
Anonymous (Individual (EU or non-EU citizen))	1	1	1	1	1	
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 32: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{149}Tb

5.1.6.26. Details on Therapy alpha radioisotope

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Ac-225: Important increase of clinical use with limited number of suppliers
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	223Ra is the only available
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	No concerns have been identified with the supply of any of the above radioisotopes.
BelNuc (Professional association)	Everything is a problem with the supply of alpha's except transport
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Radium is used in prostate cancer treatment and availability is depending on the source and all following steps.
Radionuclides for Health UK (Radionuclides for Health UK)	Limited EU sources of all these isotopes apart from Ra-223. GMP production needs to be developed so that further research can be conducted, and regular clinical use established. Those that can be produced from legacy or naturally occurring material will need different focus in their development than those that need to be produced on a research reactor or accelerator.
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	no experience we do not have availability of them
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	None available in Romania
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	In all cases, for different reasons, the supply of all of these isotopes is not secured today • 212-Pb: difficult to know what OranoMed is doing with that isotope. • 211-At: only two facilities (Nantes already, and GANIL soon) are able to produce this isotope. Due to its rather short half-life, it will be difficult. The important thing is that the whole value chain is in place • 225-Ac: Supply limited today.
IN2P3/CNRS (Academic/research institution)	• Industries exclusively focus on 212Pb. • Need of mass separation technology for 149Tb. • For 225Ac, availability of 226Ra is a problem.
ENEA (Academic/research institution)	225 Ac is produced starting from radium: all the steps are to be investigated very carefully
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	• 149Tb, 211At, 223Ra, 225Ac are already included in PRISMAP. • The production and processing of alpha-emitters is challenging and often requires different infrastructures than for the production and processing of other radionuclides. This originates from possibly the generation of long-lived waste, the recoil properties of the decay products, possible very high radiotoxicity of by-products (227Ac for 225Ac production) or production targets (226Ra for cyclotron route). • While the required activities are generally lower for these applications, the specificities of the full supply chain makes this a dedicated category calling for the support of complementary infrastructures and expertises, eg available in a consortium such as PRISMAP with JRC-Karlsruhe, Arronax, CERN-MEDICIS, as well as biomedical institutes skilled in the developments of such radiopharmaceuticals.
SHINE EUROPE BV (Company/business organisation)	See Tb remarks on Tb-155
Bayer AG (Company/business organisation)	Potential lag of European initiatives in producing Ac-225.
ORANO (Company/business organisation)	• Regarding enrichment, enrichment of U above 10% and stable isotope enrichment (as target materials: Eu, Gd) need political and financial support to secure the development of new supply chain like, for example, DOE in the US with the Isotope Program, and the HALEU Availability Program. For the moment, the associated supply chain is predominantly dominated by Russia (and very often as a sole provider). • Another important point is the harmonization of national legislations / regulations on transport to facilitate the distribution of the radiopharmaceutical drugs within the UE.
Global Morpho Pharma (Company/business organisation)	• Ac-225: access to Ra-226 is currently the main roadblock for Ac-225 production project • At-211: widespread use would require coordinating a European network of cyclotrons
Ion beam applications (Company/business organisation)	• As for beta isotopes, lots of research should still be performed to fully understand the production process.

Respondent	Answer
	• Today there is no availability blocking the development of these isotopes, resulting to a chicken-and-egg situation. In the US, the DoE is massively supporting research institutes and industry to bridge the early R&D and commercial phases. There are still high barriers in the areas as above: • source material / enrichment (sourced from Russia) • irradiation / processing: lack of financial support for research and to enable commercial production • training / expertise lacking in many countries • transport: different regulations from country to country
SCK CEN (Company/business organisation)	• 223Ra results from the decay of 227Ac, which is only produced in one location (HFIR). Competition with the use of 226Ra to produce 225Ac will probably become problematic. Processing is difficult and restricted to specialised labs able to handle Rn emissions • 225Ac demand is expected to skyrocket if the clinical trials can continue (supply issues in the 2023-2025 time period to be expected). Proton route production holds risks for contamination with 226Ra, which can trigger issues for all producers. 229Th cows are too limited. Handling of large 226Ra quantities restricted to specialised labs. • 212Pb as by-product of 225Ac production more interesting than from 228Th as by-product of 227Ac production. • 211At suffers from poorly known astatine chemistry and low availability of alpha particle cyclotrons with finely tuned energy (to avoid 210At production). • 149Tb has a very short half-life and (p,4n) reaction requires high energy protons, which are not readily available. The source material 152Gd is also very difficult to obtain. The spallation alternative requires GeV protons.
AlfaRim (Company/business organisation)	Commercial route towards GMP-grade 225Ac starts with sourcing 226Ra. 226Ra is extremely scarce. In addition, handling, irradiating and processing 226Ra is very complicated. Process technology needs complex and expensive facilities. In turn, funding these deeptech propositions on the (capital) market is very challenging and extremely difficult. Level playing field EU-Funding for 225Ac production facilities (such as AlfaRim's production facility) is the first step towards future sustainable supply of 225Ac to European patients.
Comecer S.p.A. (Company/business organisation)	• 225Ac: the market is moving toward the production of this radioisotope starting from 226Ra, which is an isotope of very difficult accessibility. Moreover, handling 226Ra requires a lot of attention during both irradiation phase and processing phase (100% customized radiopharmacy and target). There also should be a focus on the processing enable to the production of this isotope, especially in radioprotection, due to fact ingrowth of high energy daughter isotopes. • 212Pb: the current supply chain is sufficient to cover the demand (only research) in case of approval of radiopharmaceuticals for therapy, there might be problems in raw material supply and processing facilities within EU (currently only one facility in EU - small scale production).
NRG|PALLAS (Company/business organisation)	Production for Ac-225 will probably be sorted out given the many ongoing initiatives. At-211 seems less important and is produced mainly in Japan.
Hannover Medical School (Individual (EU or non-EU citizen))	• 223Ra: supply currently ok, but radionuclidic impurities are critical. In future, we can expect increased interest as novel chelators will offer 223Ra-based conjugates as radiotherpeutics. • 225Ac: most promising alpha-emitter, and therefore we need mor productions sites in EU for 225Ac. In addition, we need to reduce regulatory hurdles in radioactive waste management and radiation safety for medical use of 225Ac. • 212Pb: Very interesting alpha emitter, but currently limited applications. Needs more research for radiopharmaceuticals. • 211At: needs more productions and processing sites! Very promissing isotope! • 149Tb: as all Tb-isotopes, limited production sites, and still only in research and development.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	• 223Ra - No knowledge • 225Ac - High demand, low supply • 212Pb - No knowledge • 211At - No knowledge, but assume production difficulties • 149Tb - Not a lot of sites producing pure radionuclides
Anonymous (United Nation Organisation)	• Availability of Ra-226 source still is a limitation to the production of Ac-225 • At-211 available production facilities in EU is still a problem,
Anonymous (Company/business organisation)	• Ra-223 has adequate supplies and seems likely to decrease in demand. • Ac-225 - many announced projects, lots of questions regarding technical and economic success.

Respondent	Answer
	• Pb-212 seems like commercial efforts will be sufficient.
Anonymous (Academic/research institution)	• 223Ra, 225Ac, 212Pb - availability of 226Ra as source material. step towards SCK CEN as publicly Belgian funded organisation to enable access to historic 226Ra sources. Secure centralized processing capabilities and know-how within EU for alpha emitters • 225Ac - photonuclear, as above • 211At - availability and open user access to 4He cyclotrons for R&D towards production technology • 149Gd - only sufficient 152Gd enrichment and quantity will make this isotope available in clinically relevant quantities
Anonymous (Academic/research institution)	• 212Pb, 223Ra and 225Ac are generally obtained from 'legacy' radioactive stockpiles, thereby, making them difficult to obtain. 225Ac can be produced via irradiation of 226Ra, which is in short supply and has difficult handling features. • 211At is produced by means of alpha irradiation, of which there are few devices in Europe. • 149Tb is generally obtained via the ISOL technique, which is still in its infancy and requires development. • Alpha-decaying radionuclides require dedicated radioprotection measures and infrastructure not easily available.
Anonymous (Academic/research institution)	Not enough facilities in Europe producing at high commercial level, long waiting periods at times and expensive.
Anonymous (Academic/research institution)	• A fleet of 30 MeV alpha beam accelerators is required for sustainable production of 211At. • Production of the very promising alpha emitter 149Tb is hampered by limited availability of high energy (>500 MeV) proton beams combined with radioactive mass separators.
Anonymous (nuclear, radiation and accelerator physicist)	• 149Tb offers together with the other Tb isotope an interesting opportunity to use the same compound labelled with different Tb isotopes for both diagnostics and therapy. The route to produce it in significant quantities with sufficient purity is not fully established yet and the same applies to extraction from the irradiated targets and the recovery of the highly enriched target material that is needed. • Its relatively short half-life implies that regional production is needed for it to be able to play a role in regular healthcare. There is currently no network of accelerators covering the whole of Europe and establishing such a network requires a very substantial investment. • In my opinion it is therefore questionable whether 149Tb can become part of the healthcare system in an economically viable way.
Anonymous (Company/business organisation)	• Ac225 source material (Ra226) availability is rather limited. Access to existing stock should be opened to producers in the interest of patients. • Irradiation - see above • Processing - today there is no industrial facility dedicated to Ra-Ac processing • Transport - see above
Anonymous (Company/business organisation)	• Ac225: starting material not accessible while some institutions have large stock of Ra226 that they should share with industry to ensure enough production for treating the patients • Ac225: irradiation capacity - efforts are dispersed around different technologies - capacity under construction should receive support to quickly develop capacity in Europe • Ac225, Pb212, At211: too few processing capacities are available, some under construction should receive support to quickly develop capacity in Europe
Anonymous (Individual (EU or non-EU citizen))	211At and 149Tb are interesting therapeutic radionuclides that still are nor easily available in EU countries.

Table 33: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for therapy (alpha) radioisotopes

5.1.6.27. ^{60}Co (Sealed source)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
GEC-ESTRO committee (Professional association)	1					
French Society of Nuclear Medicine (Professional association)	1				1	
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1		1	
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)						1
University of Szeged (Academic/research institution)	1	1	1	1	1	
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)			1			
Comecer S.p.A. (Company/business organisation)	1					
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Scientific association)						1
Anonymous (United Nation Organisation)		1	1			
Anonymous (Company/business organisation)			1			
Anonymous (Company/business organisation)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)			1		1	
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1			
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 34: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{60}Co

5.1.6.28. ^{192}Ir (Sealed source)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)						1
GEC-ESTRO committee (Professional association)	1					
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)			1			
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)		1	1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)	1	1	1	1	1	1
University of Szeged (Academic/research institution)						1
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)			1			
Comecer S.p.A. (Company/business organisation)						1
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)			1			
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Scientific association)						1
Anonymous (Company/business organisation)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Company/business organisation)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)			1		1	
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)			1			
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 35: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{192}Ir

5.1.6.29. ^{125}I (Sealed source)

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
European Association of Nuclear Medicine (Professional association)						1
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)						1
GEC-ESTRO committee (Professional association)	1					
French Society of Nuclear Medicine (Professional association)						1
BelNuc (Professional association)						1
Radionuclides for Health UK (Radionuclides for Health UK)						1
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)						1
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)						1
Individual (Clinical nuclear medicine professional)						1
Riga Technical University (Academic/research institution)			1			
Aarhus University Hospital (Academic/research institution)						1
UZ Leuven, dept. nuclear medicine (Academic/research institution)						1
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)						1
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)			1			
Department of Internal Medicine and Oncology, Semmelweis University (Academic/research institution)						1
IN2P3/CNRS (Academic/research institution)						1
ENEA (Academic/research institution)						1
National Centre for Nuclear Research (Academic/research institution)						1
University of Szeged (Academic/research institution)	1	1	1	1	1	
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)						1
SHINE EUROPE BV (Company/business organisation)						1
Bayer AG (Company/business organisation)						1
SWAN Isotopen AG (Company/business organisation)						1
Global Morpho Pharma (Company/business organisation)						1
Ion beam applications (Company/business organisation)						1
SCK CEN (Company/business organisation)						1
Comecer S.p.A. (Company/business organisation)						1
CUP Laboratorien Dr. Freitag GmbH (Company/business organisation)						1
NRG|PALLAS (Company/business organisation)			1			
STFC (Individual (EU or non-EU citizen))						1
Hannover Medical School (Individual (EU or non-EU citizen))						1
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))					1	
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))						1
Anonymous (Scientific association)						1
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)						1

Respondent	Source material	Enrichment	Irradiation	Processing	Transport	Don't know
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Academic/research institution)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Clinical nuclear medicine professional)						1
Anonymous (Company/business organisation)			1		1	
Anonymous (Company/business organisation)						1
Anonymous (Company/business organisation)						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Individual (EU or non-EU citizen))						1
Anonymous (Public authority)						1

Table 36: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for ^{125}I

5.1.6.30. Details for sealed sources

Respondent	Answer
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	no problem with 60Co
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	No concerns identified
GEC-ESTRO committee (Professional association)	Sealed sources are necessary in brachytherapy. A reliable supply chain is needed. Backup concepts for production should be developed in case a reactor is down. Backup concepts must also include accurate calibration of the sources.
Radionuclides for Health UK (Radionuclides for Health UK)	I-125 (as an unsealed source) is important for research use, often being used as a surrogate radionuclide for I-131 in preclinical research
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	no experience we do not have availability of them
INSTITUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	None available
Aarhus University Hospital (Academic/research institution)	Afterloading brachytherapy with sealed 192-Ir sources is currently performed with either pulsed dose rate or high dose rate. The source strength differs between these two modalities: 1Ci for pulsed dose rate and 10Ci for high dose rate. I am concerned about future availability of 192-Ir and in particular about availability of 1Ci pulsed dose rate sources.
UZ Leuven, dept. nuclear medicine (Academic/research institution)	As a medical physicist, I'm not an expert in the supply chain issues.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Se75 could be added to the list
ORANO (Company/business organisation)	• Cobalt 57 is one of the most widely used radionuclide for the manufacturing of medical sources. They are needed for the calibration of key equipment (SPECT / Dose calibrators). Today's production is mainly located in Russia. • As the element s short lived, needs are frequent and the ability to create long-term storage very limited. • Investment in irradiation capacity and radiochemistry facilities are needed to build a European self-reliance on this critical supply. • Action needed for irradiation and processing.
SCK CEN (Company/business organisation)	• 60Co suffers from significantly too low prices on the market... Re-irradiation of old cobalt sources to eliminate them as waste should be considered as attractive ways to reduce waste costs for owners. • 192Ir requires very high flux reactors to achieve highest specific activities and avoid need for enriched starting material.
Comecer S.p.A. (Company/business organisation)	60Co: the source material suppliers are not EU-based.
NRG|PALLAS (Company/business organisation)	• Ir-192: this isotope is produced mainly in HFR and in Russia and is or will be in short supply. • I-125: this isotope is produced by only 2-3 reactors globally and is in short supply.
Hannover Medical School (Individual (EU or non-EU citizen))	• 60Co and 192Ir are use as sources for external radiation therapy. I do not see any supply issues. • 125I: supply is ok and I do not see any issues
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	No knowledge of any
Anonymous (Academic/research institution)	Not a big need from my point of view.
Anonymous (Company/business organisation)	Irradiation capacity from research reactor is mandatory for producing these isotopes. The PWR technology does not allow to irradiate the material in power reactors.

Table 37: respondents' views for the identification of supply chain steps that need actions to maintain (or set) a secured and sustainable supply chain for sealed sources

5.1.7. Identification of specific regulatory challenges

Please provide details on your selection, describing the identified challenges faced by each radioisotope or add other isotopes
Aside from technical challenges at the supply chain level, do you identify any specific regulatory challenges that could hamper access to these radionuclides for medical use?

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Regulatory hurdles at the European level: A large proportion of radiopharmaceutical development is being undertaken by non-commercial entities, like hospitals, research institutions and universities. Since the availability of commercially available radiopharmaceuticals is limited, most applications of radiopharmaceuticals in daily practice are highly dependent on small scale preparations that are compounded in house under the responsibility of the nuclear medicine department or a hospital pharmacy. Distinguishing commercial and non-commercial preparations of medical products Due to the difference between commercial and non-commercial preparations of radiopharmaceuticals, EAHP and EANM are calling for a specific approach to the regulation of small-scale preparation of radiopharmaceuticals. Industrial Good Manufacturing Practice (GMP) principles are not suitable for this type of preparation and the revision of the pharmaceutical legislation should establish clear non-industrial standards for small-scale preparations that take into account on the one hand the scientific and technological advancements related to novel and complex radiopharmaceutical preparations and on the other hand the specificities of preparations in hospital pharmacies or nuclear medicine departments. Disproportional increase of quality assurance processes that are not fit for purpose and measures that impede innovation should be avoided, while at the same time patient safety and high-quality standards for the in-house preparation of radiopharmaceuticals by non-commercial entities should be upheld. Reducing the regulatory burden for small-scale preparations Nuclear medicine services are challenged by overregulation and unnecessary additional administrative burden related to requirement for marketing authorisations of certain starting materials, resulting in a significant increase in need of resources and in a lack of interest from industrial manufacturers to provide some of the starting materials and active ingredients for complex radiopharmaceutical preparations. Radiopharmacists use authorized kits and combine it with authorized radionuclide precursors in order to compound the final radiopharmaceutical ready for application. These kit-based radiopharmaceutical preparations are developed and validated by the marketing authorisation holder of the kit including adequate quality control procedures. Therefore, kit-based preparations of radiopharmaceuticals are treated in a special way by current legislation: the final radiopharmaceutical does not need a separate marketing authorization when prepared in-house and the preparation process is exempted from the scope of GMP annex 3. However, with the development of more complex preparations aside from kit-based reconstitution processes a clear distinction between starting materials, including radionuclides/ radionuclide precursors, for kit-based preparations and complex radiopharmaceutical preparations has to be introduced. Current gaps in legislative guidance in this regard have led to misinterpretations on such requirements, ultimately impacting the supply negatively. The demand for marketing authorisation should be strictly limited to starting materials for reconstitution and kit procedures and not for starting materials including radionuclides and active ingredients used in complex radiopharmaceutical preparations.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Annex 3 of GMP is not sufficiently clear and as a result there are challenges in making radioisotopes to GMP standards. This can pose a significant barrier to introduction of new radiopharmaceuticals to the market, as a result of ambiguity around where GMP starts to apply. For example, cyclotron production is outside of the remit of GMP and chemical synthesis is part of GMP, but the steps in between ('processing') can be less clear. Interpretation of where GMP starts to apply is different in different countries. For example, if GMP grade Copper is needed to make a product in the UK, this can be extremely difficult to source, as GMP is not considered to apply to earlier parts of the production process in other counties. Overall interpretation of GMP standards can be variable in different countries.
GEC-ESTRO committee (Professional association)	Medical device regulation (MDR) must be followed. This could be time consuming and expensive for producing companies.
French Society of Nuclear Medicine (Professional association)	National regulation on radiopharmaceuticals: Lutetium... Availability of radionuclides for clinical research purposes
BelNuc (Professional association)	Waste management differences in EU countries.

Respondent	Answer
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	In the in vivo use of radionuclides there are more than one regulation-legal system in operation, there is the pharmaceutical aspect and there is the radiation protection aspect and these work through their own regulatory system. Perhaps there could be a special regulatory system with combination rules just for these products. Differences could come from the use, in vivo therapeutic or in vivo imaging.
Radionuclides for Health UK (Radionuclides for Health UK)	Lack of monographs for more novel radionuclides Disposal limits through drainage for therapeutic radionuclides. Storage of clinical waste for therapeutic radionuclides, especially if there are long lived impurities (e.g. Ac-227 in accelerator produced Ac-225)
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Reimbursement rules
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	We have administrative difficulties for the availability of new radiopharmaceuticals, very long procedures
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Yes! It is a real challenge to receive a license to even explore the use of a certain radionuclide in a clinical environment (as a physicist for example). That means a lot of work, even before experience can be gathered. The administrative burden should be weighted with the objective or the purpose of the exploration. E.g. if there is no clinical use in the exploratory phase of this endeavour (like e.g. calibration of equipment, determination of sensitivity of measuring, ...) the licensing for 'a technical use' should not dive into pharmaceutical or clinical related regulatory problems (which sometimes are huge and trigger different authorities or bodies). By that, one could gain a lot of time for doing plain and useful research.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Agencies have to homogenize their rules for the transport of radioisotopes and radiopharmaceuticals.
IN2P3/CNRS (Academic/research institution)	Support to further extend the duration of 60Co sources. See above comments regarding air transport. See attached paper: ' How Efficient Are Monte Carlo Calculations Together With the Q-System to Determine Radioactive Transport Limits? Case Study on Medical Radionuclides', by Maddalena Maietta, Ferid Haddad and Sebastien Avila
ENEA (Academic/research institution)	Intellectual property and patents are a strong barrier to the development made by public institution part of the National Healthcare System
National Centre for Nuclear Research (Academic/research institution)	nuclear reactor regulations
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	For PRISMAP radionuclides specifically, while efforts have already started, the clinical translations from pre-clinical supplies, grades and studies are a major required undertaking.
SHINE EUROPE BV (Company/business organisation)	As said SHINE believes that the key to success is a regulatory framework that stimulates private investors to continue to invest in high-risk solutions. A fair level playing field is absolutely needed.
Bayer AG (Company/business organisation)	Waste limits ought to be harmonized and adjusted in order not to hinder broad scope use of certain radionuclides. Import/export regulations should not hinder the use of radionuclides for medical purposes.
ORANO (Company/business organisation)	• Each country has its own agency which delivers drugs approval. Due to the size of the market, they are very few experts in therapeutic use of radioisotopes (usually one person in each agency, who has other topics to cover, including EMA). Mutualizing these competences at a European level in the EMA and designing an European regulatory framework would accelerate the development of these drugs in Europe while relieving national agencies.
SWAN Isotopen AG (Company/business organisation)	Current geopolitical situation with sanctions on Russian isotopes
Global Morpho Pharma (Company/business organisation)	Under EU directive 2001/83, radionuclide precursors need to hold a marketing authorization in Europe. An update to this regulation would be beneficial to the whole ecosystem: development and use of new medical radioisotopes, development of novel radiopharmaceuticals, diversification of the supply chain. Local nuclear safety regulations can also prove challenging, e.g. in France, time to update the authorization of a licenced nuclear facility in order to use a new radionuclide for an R&D project may exceed 6 months. Disparate local nuclear regulations favor activities in countries that are more responsive.
Ion beam applications (Company/business organisation)	Yes, country specific regulations or variability result in high-entry barriers for many companies. A work on legislation homogenization would be beneficial. Versus US: the FDA is the only medicinal agency regulating drug investigation/approval in such a large territory. European regulation on radionuclide for radiopharmaceutical use: clarification of directive 93 for the definition of the radionuclide precursor.

Respondent	Answer
SCK CEN (Company/business organisation)	Separation of reimbursement of radioisotope from medical products and treatments is vital to create a sustainable supply for reactor-based isotopes! Alternative production methods of 99Mo and eventually 177Lu will eventually lead to the final demise of research reactors and the loss of the ability to produce some other isotopes.
Comecer S.p.A. (Company/business organisation)	There's not a regulatory distinction between diagnostic and therapeutics isotopes, the advice is to evaluate a differentiation as production challenges and logistics are different for the two types (half-life). There's not a common regulatory handling for alpha emitters for therapeutics purposes in the different countries.
NRG|PALLAS (Company/business organisation)	I am no expert, but I hear that lack of harmonization of transport regulations is an issue. On the financing side, there is an opportunity to improve reimbursement for irradiation costs, similar to the way it is organized in Belgium.
Hannover Medical School (Individual (EU or non-EU citizen))	• Regulatory hurdles on the use of radioisotopes as starting material for (complex, not kit-based) radiopharmaceutical productions (i.e. 18F, 64Cu, 177Lu, 225Ac). And, a regulatory harmonisation across EU would help a lot. Some authorities require approved starting materials for radiopharmaceutical productions (i.e. 18F from external suppliers). • Limits for release in radioactive waste management in nuclear medicine for some isotopes and impurities are to strict and increase costs massively. Examples of 'troublesome' isotopes are 68Ge, 225Ac, 177mLu, and generally long-lived isotopes from trace impurities.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Some smaller, less advanced country regulators often do not have established clear directives of use and utilisation and handling of such isotopes in clinical environment. Then they look at precedents in different countries, therefore more open knowledge of application shpuld be circulated upon the comunity, including the risks, issues and solutions.
Anonymous (Professional association)	Yes, I see many differences between member countries when it comes to authorizing the production of a certain radiopharmaceutical. In fact, in some they are not considered medicines as such.
Anonymous (United Nation Organisation)	GMP production of radionuclides to be used for radiopharmaceutical formulation can be a hinderance for wide-spread availability of radiopharmaceuticals
Anonymous (Company/business organisation)	Drug regulatory pathways continue to be slow and cumbersome. Reimbursement remains a critical challenge.
Anonymous (Academic/research institution)	Transportation has 2 major issues: • A1 and A2 values that are not available for many innovative radionuclides. With Monte Carlo simulations these coefficients can be easily determined • Rules for airplane transportation where the pilot can refuse to transport radioactivity-->imposes delay. Many exotic starting materials are coming from Russia, same for enriched materials. Availability is sometime difficult. Regulation between states must be harmonized concerning radiopharmaceutical production and clinical trials.
Anonymous (Academic/research institution)	• Regulatory limits regarding mainly long-lived impurities such as 227Ac, 210Pb, 46Sc etc. • Waste regulations specific to alpha radionuclides
Anonymous (Academic/research institution)	Licensing from different countries differ, where some are very stringent and limits patient treatment. Regulatory challenges also include the means to produce radionuclides, such as alpha emitters. Determination of a regulation/specification of a new radionuclide for radiopharmaceutical use should be harmonized in EU in a pragmatic manner to keep Europe globally competitive.
Anonymous (Academic/research institution)	Definitely this the biggest stumbling block, different European countries have different regulatory requirements, no consistency across Europe. EMA should play a more meaningful role in this regard. Minimum specifications for products for example...
Anonymous (Company/business organisation)	The duration of the procedure for granting marketing authorization is varying from country to country (from 6 months to 36 months).
Anonymous (Company/business organisation)	The complexity of registering radiopharmaceuticals as a drug with lack of knowledge about these specific products in Health agencies (variable from country to country).
Anonymous (Individual (EU or non-EU citizen))	European pharmaceutical regulations foresee marketing authorization for radionuclide precursors (=radionuclides), this reduces availability for processes where radionuclides are used as starting materials, there should be a distinction for this and no requirement for marketing authorization for many processes carried out in healthcare establishments see e.g. EJNMMI Radiopharm Chem. 2019 Aug 20,4(1):22. doi: 10.1186/s41181-019-0074-3.
Anonymous (Individual (EU or non-EU citizen))	Proper assessment of dosimetry issues relevant for radionuclide transport and medical use.

Table 38: respondents' views for the identification of specific regulatory challenges

6. Radioisotopes supply chain steps: suggestion of actions

6.1. Source material

In your opinion, what are the actions needed (if any) to secure source material (for enrichment or direct use as target material) access in Europe for radioisotopes production?

Respondent	Answer
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	First of all, correct information on the potential of production and on the possible clinical use. Need for multi-center trials for unregistered radiopharmaceuticals.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring equitable cost-effective global access to source materials outside the UK and the EU, including Russia, China and the rest of the world.
French Society of Nuclear Medicine (Professional association)	Increase facilities for Molybdenum production (cyclotron/reactor) in European Country
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Europe should think of the supply of source material that can only be produced in large nuclear plants (high flux and others). Can we (EU) ensure the supply in the future taking into consideration the increasing demand (cancer treatment and diagnostic imaging)? Do we need to think of the construction of a medical nuclear plant, optimally designed for this purpose? It would taken more than decade to realize such a project.
Radionuclides for Health UK (Radionuclides for Health UK)	Stockpiling of source material as joint resource for Europe. Ensuring that existing inventories of materials within are kept up to date and stocks are shared when needed
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Need for stockpile, independent of Russia
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Need for a fluid circuit between production centre, supplier and utilization centre
UZ Leuven, dept. nuclear medicine (Academic/research institution)	In an end-to-end analysis, if it would appear that an ongoing clinical diagnostic or treatment program (on which patients are relying) would seize due to supply issues (i.e. source material or production equipment/facility), quick actions would be needed. That means quick communication across the whole (end-to-end) chain of supply, including the involved regulatory bodies or other stakeholders.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• To give visibility to the sector, in order to launch de the necessary investments. • As long as we will need to obtain starting material from countries outside Europe (and particularly Russia), supply is threatened. The termination of relations with Russia deprives us of a single supplier of certain rare isotopes (including 48Ca), which are essential for some of GANIL's scientific programmes, and for other accelerators in Europe. • Supply of radioactive targets to produce isotopes is a difficulty. • Create a new HA-LEU producing factory in Europe to improve our strategic autonomy level. • Improve LEU independence in Europe • Enrichment of stable isotopes (to Europe independence) and global leadership
IN2P3/CNRS (Academic/research institution)	• For 225Ac, availability of 226Ra is a problem. • The enrichment of material targets remains a major problem in Europe, since we depend strongly on Russia (e.g. 64Ni). A US initiative already exists, so EU should proceed similarly. Enrichment capacities could be beneficial to other industrial domains (not only for radio emitters).
National Centre for Nuclear Research (Academic/research institution)	More production sites of enriched target materials within Europe
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	While enriched targets are commercially available from commercial suppliers, some specific targets are not yet available, or some others were available from Russian institutes. While a dedicated European isotope separation facility could be supported, it would seem appropriate to better coordinate and develop the presently operating isotope mass separation facilities (eg in IJCLab, KuLeuven etc) with radioisotope mass separation facilities.

Respondent	Answer
SHINE EUROPE BV (Company/business organisation)	The dependency on foreign enrichment infrastructure (like Russian Calutrons) should be eliminated. The EU should start its own stable isotope (enrichment) program alike the DOE initiatives in the USA. This should start with identifying and calling out for which isotopes self-dependency is a must. For HALEU the advice is to build the infrastructure in Europe, likely to be supported by public investments, but to have the users pay FCR as a minimum for their usage. As this will be a project with a long lead time (20 years, longer?) it is needed to identify HALEU consumer reduction options. A Centralized EU RR R&D program could identify which RRs should get preference over others so that HALEU consumption is minimized. Uranium recycling initiatives (like RECUMO Belgium), but also the production of (certain) radio-isotopes by non HALEU using initiatives (like SMART), low HALEU using initiatives (like SHINE) and higher using HALEU processes (like RR based Uranium fission supply chains) should be take into account into the HALEU usage mix. If we can reduce HALEU utilization by 50% we buy a factor 2 more lead time for the long-term construction of HALEU infrastructure.
Bayer AG (Company/business organisation)	Specific market tensions: availability of rare source material, e.g., radium-226 to be saved and secured in a proper manner.
SWAN Isotopen AG (Company/business organisation)	The path back to source materials is quite difficult for clinical radiopharmacies. Every step in the chain has its own silos. Sourcing problems are not known in clinic, normally.
Global Morpho Pharma (Company/business organisation)	Joint European initiative to identify and constitute stocks of critical source materials with a 10+ year vision. Mechanism to make critical source materials available to European actors in small and large quantities for research and commercial use.
Ion beam applications (Company/business organisation)	we need to develop in Europe our own supply & enrichment infrastructure (if possible).
SCK CEN (Company/business organisation)	Essential source material for which a shortage of pure material is an issue is 226Ra. Sufficient quantities of 226Ra are available in Europe, but they need to be purified.
Comecer S.p.A. (Company/business organisation)	Regarding the source material, since the dependence is strictly geographically linked, the only possible solution is to strengthen the commercial agreements and increase the cooperation between EU and those countries, which the materials are from.
STFC (Individual (EU or non-EU citizen))	In the first instance, action needs to be taken on strategically important source materials to ensure security of supply. The supply chain then needs to manage and optimise to reduce cost.
Hannover Medical School (Individual (EU or non-EU citizen))	EU stockpile or other EU-specific sources for HEU/LEU.
University clinac centre of the Republic of Srpska (Individual (EU or non-EU citizen))	Need for European stockpile and joint buying mechanism
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Stockpile would be nice but would not work. More rapid and eased supply form producers to distributors would help. Mostly problematic is the availability upon need.
Anonymous (Professional association)	There are very few accelerators in Europe for obtaining isotopes that are routinely used in the clinic. In fact the recent unpower problem would have been solved if we had some back up accelerator
Anonymous (Scientific association)	More places of production in Europe and other alternative methods of production
Anonymous (United Nation Organisation)	Availability of specific starting materials for radioisotope production is a main obstacle, installing facilities for production of enriched materials can be considered by EU
Anonymous (Company/business organisation)	Better information regarding demand-supply of key isotopes. Improved pathways for public-private partnerships, with cost-sharing.
Anonymous (Academic/research institution)	we need to develop in Europe enrichment capacity. At the moment product are coming from Russia or the USA. In this latter country, they are restarting enrichment capacity. we also need to develop some chemistry facility able to provide very ure chemicals (Rb metal for example)
Anonymous (Academic/research institution)	strong need in EU stockpiling, additional efforts similar to DOEs program on stable isotope supply Interaction with industry to facilitate developments towards isotope supply within EU
Anonymous (Academic/research institution)	A stockpile of various metals, particularly precious metals, will be necessary to ensure target material for access towards radionuclide production (it is not clear whether this is the case). Support a dedicated enrichment facility in Europe.
Anonymous (Academic/research institution)	Enriched material for targetry for cyclotrons is always a challenge (sourcing and expensive costs). With some of the material coming from Russia, this is now a concern and current bottleneck. This could compromise future productions. Joint buying is encouraged to ensure availability and less costs.

Respondent	Answer
Anonymous (Academic/research institution)	need for European production and stockpiling of thin Ta foils [used as spallation targets for production of various lanthanides].
Anonymous (nuclear, radiation and accelerator physicist)	Europe should secure the supply of raw materials needed to produce the highly enriched stable isotopes of the elements needed to produce relevant radioisotopes (examples: Gd, Lu, Yb, Te, Xe) and develop the capacity to produce significant quantities (order of magnitude up to kg) of highly enriched isotopes of these elements.
Anonymous (Company/business organisation)	Creation of a source material centralized purchase office managed by an independent European agency. When material is available in Europe, it should be purchased from that source exclusively while keeping a strategic stock available at anytime. If material could be sources outside Europe, it should be purchased to maintain a minimal strategic stock in Europe at a market price.
Anonymous (Individual (EU or non-EU citizen))	Concerted action of EU countries to assure the access to source materials, namely by implementing collaborations/agreements with external producing countries whenever possible.
Anonymous (Public authority)	• Identify on which source material the EU needs strategic autonomy, to have minimal reliance outside EU • Identify needed steps on how to get the strategic autonomy needed on these source material • Implement the needed steps

Table 39: respondents' views for the identification of actions needed to secure source material supply

Please identify and describe the actions for which the ERVI could have a substantial added value.

Respondent	Answer
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring action at EU rather than country level would have more clout and impact and be more likely to succeed and to produce reliable, cost-effective supply to all EU countries and the UK.
French Society of Nuclear Medicine (Professional association)	CEA Cadarache (Jules Horowitz reactor)
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	EU can co-decide and co-fund the research and the construction of at least one future medical-nuclear power plant.
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Coordination
Riga Technical University (Academic/research institution)	Educate students
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Connect with the nuclear medicine (EANM) and medical physics (EFOMP) community at the highest level as possible, so quick communication across the field is possible.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	ERVI could help giving a common trajectory. ERVI could also help accelerating decisions, financing and kicking off new facilities projects.
IN2P3/CNRS (Academic/research institution)	Work on stable isotope enrichment to become independent from Russia and US.
National Centre for Nuclear Research (Academic/research institution)	Supporting the initiatives towards better/more efficient use of existing nuclear facilities and source materials (recovery)
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	• Integrate PRISMAP in ERVI roadmap on the long term • Expand PRISMAP services, eg with stable isotope mass separation facilities • Help translating pre-clinical radionuclide grades into clinical practices • Include link between EU observatory and PRISMAP
Bayer AG (Company/business organisation)	Collect information on stocks, make that information available for relevant users.
SWAN Isotopen AG (Company/business organisation)	For the most promising therapy isotopes , e.g like 177 Lu or 225 Ac and eventually others, -SOUCING should be supported by ERVI
Global Morpho Pharma (Company/business organisation)	See above
Ion beam applications (Company/business organisation)	provide infrastructure / programs to support supply of stable isotopes
SCK CEN (Company/business organisation)	Support R&D and deployment of a central Ra purification facility in which EU countries can 'process' their Ra bearing waste and extract purified radium. Given the amounts of radium required to support the 225Ac and 227Ac productions (and indirectly also 212Pb), it is inefficient to rely on each country performing its own purifications.
Hannover Medical School (Individual (EU or non-EU citizen))	HEU/LEU supply/sources
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Maybe circulating the issue upon community continuously would indirectly advertise producers and distributors to take more action on their own. Sometimes the needed material comes from other continents or further countries, imposing risk of supply, scams or quality. Maybe some emphasis on third-party confirmation of the supplier.
Anonymous (Company/business organisation)	Mandate regular demand-supply studies and assign responsibilities for conducting. Establish legal and administrative framework for public-private partnerships.
Anonymous (Academic/research institution)	• Favoured networking among stakeholders • Support upstream research on innovative radionuclides and masse separation • Work on regulation of clinical trial • As radioactive species disappear with time, logistics is of crucial importance • Transportation coefficient needs to be recalculated taking into account latest nuclear data and simulation tools
Anonymous (Academic/research institution)	EU stockpiling and build-up of stable isotope distribution network
Anonymous (Academic/research institution)	See next section.

Respondent	Answer
Anonymous (Academic/research institution)	Can enriched material be sourced from alternative suppliers in USA, etc. Can Europe and USA have a special agreement on this in terms of availability and costs.
Anonymous (nuclear, radiation and accelerator physicist)	In my opinion the issue of supply of highly enriched stable isotopes for isotope production should be taken up by ERVI (or another European public body). We currently see that attempts to create a monopoly for high specific activity 177Lu by buying up stocks of Yb (enriched in 176Yb as well as 'normal' material). This is on the one hand a cost driver for health care and on the other hand compromises research on the development of other 177Lu-based radiopharmaceuticals.
Anonymous (Company/business organisation)	ERVI could be playing the role of creating the agency for the management of source material. The credibility of ERVI would be higher than the credibility of industrials when negotiating access to source material outside Eu.
Anonymous (Individual (EU or non-EU citizen))	Identifying the source materials and producing countries aiming to establishment possible commercial/collaboration agreements.

Table 40: respondents' views for the identification of actions needed to secure source material supply that could be implemented at ERVI's level

6.2. Stable isotopes enrichment

In your opinion, what are the actions needed (if any) to secure enrichment capacity, or enriched material access in Europe for radioisotopes production?

Respondent	Answer
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Support research by coordinate research protocols. Economically support the research.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring there is consistent and reliable access to suitable enriched products across all member countries in the EU and in the UK. . Consideration of development of enrichment facilities in Europe.
Radionuclides for Health UK (Radionuclides for Health UK)	Investment in a calutron for enrichment, especially for Lu-177 target material
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	New enrichment techniques
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	research for more efficient production methods
UZ Leuven, dept. nuclear medicine (Academic/research institution)	As a medical physicist, I cannot provide a good answer for this question, besides the need for a network of centers/operators/facilities/suppliers that can quickly react in case of supply problems.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Create a new factory of HA-LEU in Europe to improve our strategic autonomy level. Create a new enrichment plant for medical radio isotopes.
IN2P3/CNRS (Academic/research institution)	Help academic to develop new methods.
ENEA (Academic/research institution)	Investment in new enrichment installation
National Centre for Nuclear Research (Academic/research institution)	New or additional enrichment installations
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	While a dedicated European isotope separation facility could be supported, it would seem appropriate to better coordinate and develop the presently operating isotope mass separation facilities (eg in IJCLab, KULeuven etc) with radioisotope mass separation facilities.
SHINE EUROPE BV (Company/business organisation)	See above under source material
Bayer AG (Company/business organisation)	Not applicable
ORANO (Company/business organisation)	• Regarding the heavy stable isotopes (~49 elements out of 65 stables elements that can be enriched), ~37 elements are only produced in Russia as sole provider like Yb for example. The development of the existing plant for new elements (~9 new elements like Ni) and the development of new enrichment techniques (~28 new elements like Yb or Gd) in EU is key to secure the supply chain. • Outside EU, these developments benefit from strong political and financial supports. No developments in the EU can be done without theses supports. • Regarding enrichment of U higher than 10% for target and fuel for irradiation reactors, the challenge is similar.
SWAN Isotopen AG (Company/business organisation)	Enrichment installations should be available in the European political area
Global Morpho Pharma (Company/business organisation)	Invest in enrichment installations. Subsidize the development and routine production of enriched material for novel radioisotopes that are not yet commercially viable.
Ion beam applications (Company/business organisation)	Sourcing of strategic stable isotopes should be performed in Europe if possible, via investment in new or additional enrichment installations, development of new enrichment techniques, import considerations
SCK CEN (Company/business organisation)	Setting up of an electromagnetic separation capability in Europe is crucial. At institutes currently applying or researching ISOL techniques, in particular laser excitation based ISOL, such separation facilities should be readily possible. The proliferation risk does not outweigh the risk for medical supply shortages. Also LEU production should be decoupled from the US or Russian capabilities.
Comecer S.p.A. (Company/business organisation)	Regarding the enrichment of the source material, the advice is to favourite the creation of a European network of enrichment facilities and enrichment know-how (at the moment there's a complete lack of these professionals within the EU).

Respondent	Answer
NRG|PALLAS (Company/business organisation)	To support the ESA (European Supply Agency) in its project to set up European production of low enriched uranium as fuel for research reactors and as targets for Mo-99. Although supply of Yb-176 is currently an issue, I don't know what the EU could do to resolve it. Companies such as Urenco and perhaps IBA are the best candidates to resolve it.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Only speculating - research on enrichment methods and more open knowledge transfer.
Anonymous (Professional association)	new or additional enrichment installations
Anonymous (Scientific association)	Yes, there is a strong need for in EU to have its own enrichment possibilities
Anonymous (United Nation Organisation)	Availability of specific starting materials for radioisotope production is a main obstacle, installing facilities for production of enriched materials can be considered by EU
Anonymous (Company/business organisation)	Yb-176 enrichment urgently needed Possible need for Mo-98 and Mo-100 enrichment
Anonymous (Academic/research institution)	invest in new enrichment facility develop new methods as for example mass separation coupled laser ionisation
Anonymous (Academic/research institution)	invest in calutron - or more modern - technology for stable isotope supply
Anonymous (Academic/research institution)	Investment in calutrons in Europe towards target material enrichment.
Anonymous (Academic/research institution)	Enrichment installations and secure import considerations
Anonymous (Academic/research institution)	Investment in additional installations and development of new methods
Anonymous (Academic/research institution)	• Europe has to build up electromagnetic isotope separation capacity. • Europe should further research into atomic vapor laser isotope separation, e.g. for calcium and lanthanide isotopes. • Europe should have an own entity that stockpiles and distributes enriched isotopes. This is also important for elements that can in principle be centrifuge-enriched by URENCO or ORANO, but de facto are not because the needs of individual end users do not pass the minimum order quantity to launch a separation run. • An interesting EU initiative that would go beyond supply security of medical radioisotopes but would also help geopolitical security could be a proposal to run Iranian centrifuges that are presently enriching uranium, rather for enrichment of stable isotopes. ERVI could propose generous take-off agreements and via the regular delivery of stable isotopes de facto supervise that the centrifuges are not operated for uranium enrichment. Maybe a crazy idea, but nothing should be left untried to unlock the apparently deadlocked Vienna negotiations via novel propositions.
Anonymous (nuclear, radiation and accelerator physicist)	• As already mentioned earlier Europe should develop capacity to produce highly enriched isotopes of essentially any element relevant for radioisotope production for research purposes. This encompasses additional enrichment facilities using current technology but also the development of more efficient enrichment technology. • Creating a European equivalent of the US NIDC that provides both radioisotopes and enriched stable isotopes for research would be an excellent step. The current political situation in Europe shows what the consequence of strong dependence on third parties are. Sooner or later such a dependence will be exploited for political purposes. Eliminating these dependencies, also in the field of radioisotopes, will strengthen the position of Europe.
Anonymous (Individual (EU or non-EU citizen))	Development of technology and support to facilities/companies.
Anonymous (Public authority)	Import considerations

Table 41: respondents' views for the identification of actions needed to secure stable isotopes enrichment

Please identify and describe the actions for which the ERVI could have a substantial added value	
Respondent	**Answer**
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring action at EU level would be more likely to succeed and to produce reliable provision of enriched materials, Eu-level oversight and action would be needed to develop facilities within Europe.
Radionuclides for Health UK (Radionuclides for Health UK)	Investment in new infrastructure
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Investment in production centers and methods
Riga Technical University (Academic/research institution)	educate students
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• acceleration of decision • help financing • kicking off new facilities projects
ENEA (Academic/research institution)	Help in obtaining authorization in country that actually have not enrichment facilities
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Different programmes of the European Commission, and ERVI more particularly as already outlined, has the capacity to integrate at the European level large scale facilities which can make available novel medical radionuclides otherwise not available. While already covered in PRISMAP, a possible sustainable linger term integration into ERVI would be much valuable.
SHINE EUROPE BV (Company/business organisation)	See above under source material
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantitiy
Global Morpho Pharma (Company/business organisation)	Subsidize the development and routine production of enriched material for novel radioisotopes that are not yet commercially viable.
Ion beam applications (Company/business organisation)	Support initiatives aiming to enable availability of stable isotope in Europe
SCK CEN (Company/business organisation)	• Enlarge the mission of the EU Observatory to also include stable isotopes as precursors and incentivize funding of electromagnetic separation R&D with the aim to commercialise. • Set up a European enrichment and metallisation facility for the production of LEU metal. Without such an initiative, research reactor operation is not sustainable, which impacts many fields beyond just medical isotopes.
Comecer S.p.A. (Company/business organisation)	What previously stated.
Anonymous (Company/business organisation)	Demand/supply analysis and monitoring
Anonymous (Academic/research institution)	support new methods as for example mass separation coupled laser ionisation
Anonymous (Academic/research institution)	Have EU agreements with countries to secure supply of enriched material.
Anonymous (Academic/research institution)	All of the points mentioned above.
Anonymous (nuclear, radiation and accelerator physicist)	Everything I mentioned in my answers on the previous questions should be taken up by the EU as a whole. The interests are way beyond those of individual member states and more so of industry
Anonymous (Company/business organisation)	Same as source material.
Anonymous (Individual (EU or non-EU citizen))	Identification of target materials requiring proper enrichment and needed technology.

Table 42: respondents' views for the identification of actions needed to secure stable isotopes enrichment that could be implemented at ERVI's level

6.3. Target manufacturing

In your opinion, what are the actions needed (if any) to secure target manufacturing capacity, or targets access in Europe for radioisotopes production?

Respondent	Answer
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Support research by coordinate research protocols. Economically support the research.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring equitable and cost-effective access to target materials for all EU countries and the UK from all possible available sources, including Russia and China, and the rest of the world.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Target manufacturing will go hand in hand with the increased need for medical radionuclides.
Radionuclides for Health UK (Radionuclides for Health UK)	Facilities to produce targets Understanding about nuclear data to facilitate new routes to produce radioisotopes. Source new target materials
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• Need for a long-term vision and give incentives to the industry so that it can anticipate and develop radioisotope production capacities before they are needed. • Coordination on target optimization and homogenization. • Re-use of radioisotopes from recycling.
IN2P3/CNRS (Academic/research institution)	Need for academic support to help develop new technics.
National Centre for Nuclear Research (Academic/research institution)	dissemination of information on new targetry systems and target materials
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Some rare target enrichment or grades would allow to investigate new production routes for promising radionuclides, such as Dy-158(p,alpha)Tb-155 for which Dy-158 targets would be required. This is alike, for eg Ca-46 for the production of Sc-47
SHINE EUROPE BV (Company/business organisation)	none
Bayer AG (Company/business organisation)	Improvements on regulatory framework required.
SWAN Isotopen AG (Company/business organisation)	difficult to answer for clinical radiopharmacy
Ion beam applications (Company/business organisation)	For accelerator-based radioisotope supply, R&D on target manufacturing and target chemistry must still be performed. Programs supporting such R&D effort are missing in EU (vs. US DOE)
SCK CEN (Company/business organisation)	• Targetry systems are well developed and supported by different commercial manufacturers, with a few exceptions. • Radium targetry is complex, but the issue is related to any large-scale radium handling, not just to the typically used electroplating technology. • Mo99 fission target production is monopolised and the reliance on 2 separate target designs for the largest manufacturers is inefficient. However, there are commercial reasons for it. Biggest help for Mo99 market is the reimbursement policy adaptations.
Comecer S.p.A. (Company/business organisation)	There are already many targetry systems in the European market.
NRG|PALLAS (Company/business organisation)	I can't think of any actions - target manufacturing is usually done by the pharma companies, who prepare targets and send them to irradiators. Perhaps standardization of target materials could be interesting, but probably this is too complex and upsetting for existing supply chains.
Hannover Medical School (Individual (EU or non-EU citizen))	No need
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Irradiation target systems for accelerators, that are more robust for various target materials (gas-liquid-solid). Need to be cost-efficient to manufacture the radionuclides.
Anonymous (United Nation Organisation)	• Manufacturing Ra-226 targets for alpha radioisotope production • Need new ra-226 sources

Respondent	Answer
Anonymous (Company/business organisation)	Fission Mo-99 targets sole sourced, need diversity of supply but commercial factors could work against this. Various cyclotron targets probably Ok
Anonymous (Academic/research institution)	actions mainly necessary for radioactive targets such as Ra226
Anonymous (Academic/research institution)	226Ra targetry for alpha nuclides currently most challenging -> bring together EU experts and institutions to define required R&D
Anonymous (Academic/research institution)	Investment in calutrons in Europe, as well as stockpile of metals for the enrichment thereof. There is a shortage of enriched target material worldwide. The development of alternative production routes using e.g. high-energy proton-induced spallation followed by mass separation could provide sufficient radionuclides without target enrichment needs. This implies the support of Isotope Separation OnLine (ISOL) facilities, current and future, as well as offline mass separation facilities (currently implemented in the EU PRISMAP project).
Anonymous (Academic/research institution)	New targetry systems to optimize production and to have target material readily available is critical.
Anonymous (Academic/research institution)	Developments in target design and in upscaling production of targets
Anonymous (Academic/research institution)	For certain rare target materials, the recycling efficiency could be improved by pooling and recycling used targets in a central target lab (JRC?). Such a lab could also cope more easily with residual radionuclidic impurities compared to the network of distributed cyclotron target labs.
Anonymous (nuclear, radiation and accelerator physicist)	Largely outside my scope but new radioisotopes require development of targetry etc.
Anonymous (Company/business organisation)	Harmonization of target is probably a first step to ensure full redundancy among the producers. Then, manufacturing contract should be concluded with target manufacturer with guarantee of a minimal price and volume. Those contracts should be managed by an independent agency.
Anonymous (Individual (EU or non-EU citizen))	Support to research on targetry.

Table 43: respondents' views for the identification of actions needed to secure target manufacturing

Please identify and describe the actions for which the ERVI could have a substantial added value	
Respondent	**Answer**
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	European economic support could favour lines of research capable of combining universities and industry, freeing research from the logic of mere profit.
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring action at EU rather than country level would have more clout and impact and be more likely to succeed and to produce reliable, cost-effective supply to all EU countries and the UK.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	It is logical that such a development should be coordinated at the European level.
National Centre for Nuclear Research (Academic/research institution)	Library of existing and available technologies
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	The integration of existing stable isotope mass separation facilities should be supported. In addition, the support for a stable isotope mass separation facility could be envisaged.
SHINE EUROPE BV (Company/business organisation)	None
Bayer AG (Company/business organisation)	See above.
SWAN Isotopen AG (Company/business organisation)	The whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantity
Ion beam applications (Company/business organisation)	Create supporting program, grants, project calls, networks, ... (cf. Isotope program from DOE)
Anonymous (Company/business organisation)	Identification of possible additional supply options
Anonymous (Academic/research institution)	Have a local European company or two that is available that serves as a contact to supply new targetry material systems and target material
Anonymous (nuclear, radiation and accelerator physicist)	support research on development of new target technology by science and industry
Anonymous (Company/business organisation)	• Initiative for target harmonization. • Conclude manufacturing contract and ensure the setup of an independent agency.
Anonymous (Individual (EU or non-EU citizen))	Identification of target materials requiring further technology development
Anonymous (Public authority)	European collaboration on research for innovative targetry systems or materials

Table 44: respondents' views for the identification of actions needed to secure target manufacturing that could be implemented at ERVI's level

6.4. Irradiation

In your opinion, what are the actions needed (if any) to secure irradiation capacity in Europe for radioisotopes production?

Respondent	Answer
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Encourage the development of production sites with initiatives aimed at promoting local productions, avoiding monopolistic logics
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring new reactor projects reach completion without interruption to domestic supply, and that there is ongoing and future sufficient capacity to meet European and global demand.
GEC-ESTRO committee (Professional association)	A reliable reactor is needed.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Nuclear irradiation capacity should be monitored at a European if not world level. It is essential that at all times sufficient capacity should be available. If down time is not spread, we can have problems with the supply.
Radionuclides for Health UK (Radionuclides for Health UK)	• It is of concern that the ILL is planned to close in either 2030 or 2036 leaving a gap for development on research into high flux research reactor radionuclide production. • It is of concern that the research reactors are reaching the end of their life and replacement projects are delayed, so unplanned shutdowns could cause major issues, particularly for Tc-99m and I-131
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	New and long-term operation or research reactors, new design projects
Aarhus University Hospital (Academic/research institution)	We need to secure irradiation facilities which can provide 192-Ir
UZ Leuven, dept. nuclear medicine (Academic/research institution)	As a medical physicist, I cannot provide a good answer for this question, besides the need for a network of centers/operators/facilities/suppliers that can quickly react in case of supply problems.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• To build reactors and/or irradiation facilities that are often expensive. • New cyclotrons for isotopes that can be produced in cyclotrons. Dedicated reactors or time slots in existing reactors to produce medical radioisotopes. • Research efforts to elaborate new isotopes generators when possible (like 99Re/99mTc or 68Ge/68Ga). • Support innovative ways of production, in particular with particle accelerators or accelerator-based neutron sources.
IN2P3/CNRS (Academic/research institution)	Support academic research platform and irradiation facilities. Adopt a EU strategy on cost of electricity.
ENEA (Academic/research institution)	Assist member states in the process of life-extension of the research reactors
National Centre for Nuclear Research (Academic/research institution)	Improving the efficacy of existing irradiation sites, see also TOURR project
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	A number of next generation facilities has already integrated the needs for novel radionuclide production, both neutron or accelerators. This is the case for JHR reactor in CEA or SPES at INFN. For other ones, this is only seen as an option, such as at ESS. Finally, an intense deuteron accelerator could become available at IFMIF-DONES facility in Spain where a fraction of one of the most intense deuteron beams could be exploited for radionuclides production.
SHINE EUROPE BV (Company/business organisation)	See earlier remarks on a technology neutral approach.
Bayer AG (Company/business organisation)	Political endorsement for maintaining the facilities. Work on public opinion for emerging medical use of (new) radionuclides in both radiotherapy and diagnostics.
ORANO (Company/business organisation)	Political and financial support to develop a HALEU plant to ensure the long-term operation of research reactors
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantity
Ion beam applications (Company/business organisation)	For accelerator-based radioisotope, focus should be provided on different types of accelerators and alternative processes (such as production of Mo99 via photonuclear reaction). Those could represent a great alternative to traditionally reactor produced isotopes

Respondent	Answer
SCK CEN (Company/business organisation)	Securing new build of research reactors is the most urgent matter to sustain reactor-based isotopes. The medical isotope world is currently turning its back on reactor-based isotope production for lack of a sustainable future. This will eventually result in higher costs and price wars, which will not be beneficial for the patients. It is also unacceptable to continue to expect one country's taxpayers to pay for the production of isotopes for all of Europe (and beyond).
AlfaRim (Company/business organisation)	Supply of funding to production facilities.
Comecer S.p.A. (Company/business organisation)	Regarding low energy medical cyclotrons, there are already some of them in the market. Regarding mid and high energy cyclotrons, there's not a large availability in the EU, and it might be increased. Moreover, the number of nuclear reactors in the EU isn't sufficient, and the ones currently working are on their ending period, so it's suggested that the EU should fund and promote the updating of already existing reactors or the construction of new ones.
NRG|PALLAS (Company/business organisation)	Several actions: • to develop an end vision for the desired irradiation infrastructure, based on the recent reports by DG ENER / NucAdvisor, i.e., what reactors do we want to have in 2040? E.g., FRM-II, Jules Horowitz. PALLAS + Arthur? • to define the level of interaction with other regions: imports / exports to North America, Asia, relation with CANDU reactors and other reactors globally (Opal, Safari 2, Kijang, RA10) • to develop a fair cost-sharing and/or financing scheme for existing and new irradiation facilities - e.g., a fixed mark-up / fee / levy per Curie, to cover the cost of irradiation, waste management and decommissioning • perhaps to promote standardization of isotope characteristics (content purity levels, specific activity) so that they become standard ingredients in several medicines and can be produced by multiple reactors - I haven't thought this through though • to promote education and training in nuclear operations, isotope handling, hot cell operations, and so forth (a job for DG ENEN), lack of workforce may be an issue in the future
Hannover Medical School (Individual (EU or non-EU citizen))	225Ac, 211At, 64Cu, 89Zr, 44Sc
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Upgrade of infrastructure and capacity. For already well-established institutes, the beam time is booked.
Anonymous (Scientific association)	alternative projects for new reactors
Anonymous (United Nation Organisation)	Invest in innovative/alternate technologies for radioisotope production, however it's also necessary to guarantee the continued irradiation capacity with research reactors both through long term operation and new builds to replace aging ones.
Anonymous (Company/business organisation)	Analysis and assessment of required irradiation capacity. Establishment of public-private partnerships.
Anonymous (Academic/research institution)	• Support existing research facility that will provide beam time for isotope production. • Support networking among facilities • Work on the possibility to use nuclear power plant to make irradiation for radionuclide production • Support development of dedicated accelerator optimized for isotope production such as for example an alpha machine only at 30 MeV for At211 production
Anonymous (Academic/research institution)	Build research & high flux reactors dedicated to isotope production) as before, support local initiatives to establish photonuclear technology within EU
Anonymous (Academic/research institution)	Invest in new research reactors towards radionuclide production [politically very difficult]. Possible investment in electron linear accelerators and ISOL facilities as well as isotope enrichment facilities.
Anonymous (Academic/research institution)	long term operation of research reactors
Anonymous (Academic/research institution)	Irradiation capacity at the highest possible thermal neutron fluxes (>1E15 cm-2s-1) should be enhanced. For indirect production the need of enriched stable target material is inversely proportional to the neutron flux and for direct production of radionuclides the achievable specific activity rises with neutron flux. European RR that are operating or under construction should investigate backfitting possibilities of irradiation tubes close to the flux maximum. The design of new RR should cover not only the needs for medium flux irradiations of 235U targets but also aim at highest possible flux for irradiation of stable isotope targets.

Respondent	Answer
Anonymous (nuclear, radiation and accelerator physicist)	more focus on the development of irradiation capacity at small and medium size accelerators, in particular for shorter lived isotopes that can be distributed only regionally Reduce dependence on reactors (waste!)
Anonymous (Company/business organisation)	Support to the latest initiatives for building new irradiation capacity (JHR, Pallas)
Anonymous (Individual (EU or non-EU citizen))	Ensure long-term operation of nuclear reactors and implementation of network of cyclotrons to produce emerging radioisotopes.
Anonymous (Public authority)	Using both proven irradiation systems as well as new innovative design projects.

Table 45: respondents' views for the identification of actions needed to secure irradiation

Please identify and describe the actions for which the ERVI could have a substantial added value	
Respondent	Answer
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	ERVI and the EU should be given oversight of the multiple reactor projects, with the power to co-ordinate them, the companies involved should be accountable to the EU for these projects. The EU should liaise with the rest of the world to ensure robust and consistent supply from all current and future reactors globally, with co-ordination of maintenance programmes and contingencies.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Create monitoring and secure collaboration between the institutions that supply. Question will also be as to what level Russia will still cooperate
Riga Technical University (Academic/research institution)	Educate students
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	It is logical that such a development should be coordinated at the European level.
ENEA (Academic/research institution)	Homogenise the authorization procedures and the testing procedures foreseen by the ageing management
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	ERVI should support the integration of moderate additional infrastructures on future large-scale facilities in Europe, as described in the previous list.
SHINE EUROPE BV (Company/business organisation)	See earlier remarks
Bayer AG (Company/business organisation)	Take a proactive role, be connected with the nuclear medicine community.
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantity
Ion beam applications (Company/business organisation)	Create supporting program, grants, project calls, networks, ... (cf. Isotope program from DOE)
SCK CEN (Company/business organisation)	The natural mechanism within Europe is the reimbursement policies. By adjusting the fraction of the radioisotope in the cost of the full treatment to 10-20%, a sustainable market with commercial interest (even for reactor operation) can be created. The risk will still need to be born by a state, but they will eventually also benefit thanks to other use of the research reactor (science, energy R&D, ...) and the reactor will be able to generate a margin which can be used for promoting research.
NRG|PALLAS (Company/business organisation)	• to develop an end vision for the desired irradiation infrastructure, based on the recent reports by DG ENER / NucAdvisor, i.e., what reactors do we want to have in 2040? E.g., FRM-II, Jules Horowitz. PALLAS + Arthur? Note: the end vision should be based on demand and supply scenarios. • to define the level of interaction with other regions: imports / exports to North America, Asia, relation with CANDU reactors and other reactors globally (Opal, Safari 2, Kijang, RA10)
Hannover Medical School (Individual (EU or non-EU citizen))	All, but especially 225Ac has the absolute highest priority.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Networking of small institutes to large irradiation facilities, fostering the access of novel methods and radionuclides.

Respondent	Answer
Anonymous (Academic/research institution)	• Support existing research facility that will provide beam time for isotope production. • Support networking among facilities • Work on the possibility to use nuclear power plant to make irradiation for radionuclide production • Support development of dedicated accelerator optimized for isotope production such as for example an alpha machine only at 30 MeV for At211 production
Anonymous (Academic/research institution)	Support the EU PRISMAP initiative. The political climate will need to embrace and identify the need for research reactor facilities to be constructed, along with isotope enrichment facilities. Pharmaceutical targets will require development to be able to utilize current and new novel radionuclides, which implies that the PRISMAP platform is very important towards this development.
Anonymous (Academic/research institution)	Have agreements in place for sustainability. Making more funding available for development in the field.
Anonymous (nuclear, radiation and accelerator physicist)	Support accelerator development
Anonymous (Company/business organisation)	Strengthen the need for research reactor and stress the need for support to finalize these initiatives before the current research reactors shutdown.
Anonymous (Individual (EU or non-EU citizen))	Identification of the different production facilities available in Europe and their capacity to produce different radioisotopes. Prospect the needs for new facilities to produce less common and innovative radioisotopes.

Table 46: respondents' views for the identification of actions needed to secure irradiation that could be implemented at ERVI's level

6.5. Processing

In your opinion, what are the actions needed (if any) to secure processing capacity in Europe for radioisotopes production?

Respondent	Answer
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	same as previous question
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Ensuring there is sufficient processor capacity to sit alongside the current and new reactor projects , and that there is ongoing and future sufficient capacity to meet European and global demand. There should be sufficient capacity along all areas of the supply chain.
French Society of Nuclear Medicine (Professional association)	increase number of actors / market competition
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	For short lived isotopes processing should be done close to the source.
Radionuclides for Health UK (Radionuclides for Health UK)	Processing is a key skill needed for the radionuclide extraction, and skills and facilities should be shared, to enable secure radionuclide supply across Europe.
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	new installations
UZ Leuven, dept. nuclear medicine (Academic/research institution)	As a medical physicist, I cannot provide a good answer for this question, besides the need for a network of centers/operators/facilities/suppliers that can quickly react in case of supply problems.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• Research efforts are needed to improve radioisotope purification, particularly from solid targets. • Need for new facilities in the Southern part of the Union.
IN2P3/CNRS (Academic/research institution)	Need for EU support to create new infrastructures (heavy and expensive entry cost before any production).
National Centre for Nuclear Research (Academic/research institution)	new installations are needed, the radiochemical processing techniques - including the novel ones are being developed triggered by research community (see also PRISMAP project)
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Radionuclide production requires processing. Training in radiochemistry only attracts few young scientists. Synergies between the nuclear physics and chemistry communities could be additionally strengthened.
SHINE EUROPE BV (Company/business organisation)	none
Bayer AG (Company/business organisation)	Maybe not on everyone's radar: currently we are facing limited quantities for lead, requested to set up new hot cell facilities.
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantitiy
Global Morpho Pharma (Company/business organisation)	Support and facilitate new build of research and production facilities
Ion beam applications (Company/business organisation)	For accelerator-based radioisotope supply, R&D on processing and purification must still be performed. Programs supporting such R&D effort are missing in EU (vs. US DOE)
SCK CEN (Company/business organisation)	The main issue for processing is the lack of radiochemical education. Insufficient dedicated radiochemistry courses are taught and Europe would benefit from a master-after-master program in radiochemistry (and medical radiation technology).
Comecer S.p.A. (Company/business organisation)	Regarding the processing for diagnostic or therapeutic isotopes, in the EU there are already some facilities for it (beta and gamma radioisotopes). It could be useful to improve the number of facilities and radiochemical processing techniques, for alpha isotopes processing (225Ac).
NRG|PALLAS (Company/business organisation)	I am not sure if any action is needed. A lot of companies are developing processing technologies and / or are setting up processing facilities. I don't expect a shortage in this step. Standardization of containers and transport regulations could help to make this step more efficient and resilient.
Hannover Medical School (Individual (EU or non-EU citizen))	We need more suppliers (processing sites) for 131I capsules!

Respondent	Answer
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Training of staff.
Anonymous (Company/business organisation)	Processing likely to be sufficient from commercial entities
Anonymous (Academic/research institution)	support radiochemistry training at universities. For example, in France, there is no more dedicated master on radiochemistry.
Anonymous (Academic/research institution)	Increase the number of facilities to be able to perform the chemical separation and, later, radiopharmaceutical manufacture (GMP). Support reclamation of enriched materials.
Anonymous (Academic/research institution)	new installations
Anonymous (Academic/research institution)	Optimize processing techniques and automation
Anonymous (Academic/research institution)	More radiochemists will be needed that are trained in fields other than fluorine chemistry, i.e. radiochemical separation of different metallic elements, including noble metals that have promising Auger electron emitters.
Anonymous (Company/business organisation)	Most of installation are aging and some of them are not fulfilling the latest standard (seismic). Provide support for building a reasonable number of processing facilities with a focus on specific isotopes.
Anonymous (Individual (EU or non-EU citizen))	Need of new facilities and technology to produce and purify emerging radioisotopes.

Table 47: respondents' views for the identification of actions needed to secure processing

Please identify and describe the actions for which the ERVI could have a substantial added value	
Respondent	Answer
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	ERVI and the EU should be given oversight of any processor projects, with the power to co-ordinate them. The companies involved should be accountable to the EU for these projects.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• Calls to support collaborative research projects. • It is logical that such a development should be coordinated at the European level
IN2P3/CNRS (Academic/research institution)	A possibility could be to reinforce the existing facilities & capacities
National Centre for Nuclear Research (Academic/research institution)	new installations and support to the existing ones
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Support in maintaining adequate hot cell infrastructures in large national facilities, nuclear reactors and accelerators. Support in adequate training.
SHINE EUROPE BV (Company/business organisation)	none
Bayer AG (Company/business organisation)	Multilayer challenge, so no clear proposal on how to address this at this point.
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantitiy
Global Morpho Pharma (Company/business organisation)	See above
Ion beam applications (Company/business organisation)	Create supporting program, grants, project calls, networks, ... (cfr Isotope program from DOE)
SCK CEN (Company/business organisation)	Promote the installation of an international master-after-master program
Comecer S.p.A. (Company/business organisation)	What previously stated.
Hannover Medical School (Individual (EU or non-EU citizen))	131I processing sites
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Networking on institutes, offering the training to new specialists.
Anonymous (Academic/research institution)	support radiochemistry training at universities
Anonymous (Academic/research institution)	Support the EU PRISMAP initiative.
Anonymous (Academic/research institution)	Making more funding available for development in the field.
Anonymous (Academic/research institution)	Support training programs at all levels (BSc, MSc, ESR, ER).
Anonymous (Company/business organisation)	Strengthen the need for state-of-the-art processing facilities and stress the need for support to finalize these initatives in the next 5-10 years.
Anonymous (Individual (EU or non-EU citizen))	Prospect the need for new facilities at EU level.

Table 48: respondents' views for the identification of actions needed to secure processing that could be implemented at ERVI's level

6.6. Transport and delivery

In your opinion, what are the actions needed (if any) to secure radioisotopes transport and delivery to users across Europe and at the international-level?

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Problems identified by the EANM: transport by car even over long distances due to difficulties to secure flights, considerable paperwork for export and import licenses, delays due to custom authorities not familiar with radiopharmaceuticals. Transportation and customs regulations often contradict the nature of the products that are to be transported/delivered. In many EU member states, customs regulations state that dangerous/hazardous goods have to settle/wait at customs to prove a basic safety for further national delivery. As radioactive material is generally considered to be dangerous, but so often short lived, it might decay before it can be delivered. In this respect, regulatory bodies/customs should be made aware that generally radiopharmaceuticals are crucial for diagnosis and treatment of severely ill patients and must not stay for too long at customs before it could be transported further on, especially not in situations of shortage, where such issues would exacerbate the situation. In addition, transportation of radioactive material above certain (very low) amounts of activity needs to done by licensed companies. In several countries, the procedure to get and keep such licenses is very elaborate and expensive. Potential solutions: Unified custom rules, harmonization of national regulations, secured access to air transport of medically used radionuclides
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Develop European directives in the form of legislation to which member states must adhere
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Smoothing of border control procedures Ensuring line-hauls run efficiently Good transport contingencies in place
French Society of Nuclear Medicine (Professional association)	no problem in France
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	Thinking of the legal issues with transport of radioisotopes, perhaps there is already an exception for medical isotopes.
Radionuclides for Health UK (Radionuclides for Health UK)	As the UK has left the EU we have been affected more acutely than previously by transport and customs delays - it would be good to establish a prioritization for release of radionuclides and radiopharmaceuticals from customs and for transport.
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Same rules throughout Europe
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	Regulation and facilitation of transport, expanding licenses with safe measures
INSTITIUTE OF ONCOLOGY PROF.DR.I.CHIRICUTA CLUJ NAPOCA (Clinical nuclear medicine professional)	harmonization of different regulation in order to facilitate the transport in Eastern European Countries
UZ Leuven, dept. nuclear medicine (Academic/research institution)	As a medical physicist, I cannot provide a good answer for this question, besides the need for a network of centers/operators/facilities/suppliers that can quickly react in case of supply problems.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	• Production of radioisotopes is concentrated in a few places in Europe. • A better repartition of the producing capacities would be a good thing regarding the need for transports, the security of materials and the delivery times. • Homogenize regulations within Europe.
IN2P3/CNRS (Academic/research institution)	Reglementary actions are strongly needed, e.g. see our previous comments on air transport, and A1 and A2 coefficient calculations.

Respondent	Answer
National Centre for Nuclear Research (Academic/research institution)	Within Europe it's mostly the issue of teaching/training for new production sites
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	Particularly for novel radionuclides, activity limits A1 and A2 tare not necessarily already listed in the transport regulation guidelines from IAEA SSR6. Identification of emerging radionuclides and proper tabulation for their transport should be fully integrated.
SHINE EUROPE BV (Company/business organisation)	none
Bayer AG (Company/business organisation)	Efficient and reliable transport routes are key to ensure timely deliveries for short-lived medical radionuclides.
ORANO (Company/business organisation)	• Orano Nuclear Packages and Services (called Orano NPS) provides a full scope of services around the transport of radioactive material including the transport of radioisotopes for medical use. • It includes, but not limited, to the design/licensing of packaging (from excepted package to type B package), manufacturing, technical assistance, maintenance and transport. • Through our actions, we have indeed identified some topics that require coordinated actions to facilitate and strengthen the transport within European countries: • Licensing of the packages: o type B(M) packages currently requires validations in each crossed country. It could be more efficient if a license type B(M) delivered by 1 European country is valid across all the European countries at least for medical use o harmonization of ICAO and IATA divergences between European countries • Verification and consolidation of the transport regulations which are mainly managed at the national level and not at the European level in particular in these fields: o Security/maliciousness (e.g., sources) o Airport related activities (handling, inspections...) o Custom rules: harmonization of the documents (import/export) required by the different national safety authorities
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantitiy
Global Morpho Pharma (Company/business organisation)	Align national transport regulations Support licencing of type B containers
Ion beam applications (Company/business organisation)	Variety of legislation makes it difficult for isotope transportation within european community makes it difficult to radioisotope supplier.
SCK CEN (Company/business organisation)	Transport is always difficult for radioactive materials. I believe others will be better placed for commenting.
Comecer S.p.A. (Company/business organisation)	There should be uniformity of rules for air transport, since today not all companies accept radioactive cargos with the same policy. Moreover, the EU should focus on on-time delivery, as transport companies do not respect delivery times and usually use passenger flights as means of transport (these flights are usually more punctual than cargo flights).
NRG|PALLAS (Company/business organisation)	I am no expert, but my feeling is that standardization of containers and transport regulations could help to make supply chains more efficient, flexible and resilient.
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Harmonized legislation for each new radionuclide of interest, so no differences between start and end country are found.
Anonymous (Scientific association)	Transport is well covered in EU
Anonymous (United Nation Organisation)	• Transport method barriers for sending radioisotopes among EU/European countries is a problem • Lack of airlines keen on transporting radioisotopes is another issue
Anonymous (Company/business organisation)	Cross-border regulatory reform.
Anonymous (Academic/research institution)	Redefinition fo A1 and A2 coefficient to have more appropriate limits for type A packages. airplane pilot can refuse a package. This is a real problem for radioactive material. rules must be changed.
Anonymous (Academic/research institution)	The IATA has a guideline as to what is required for transport purposes, however, logistics between countries remains a problem. This issue is being addressed in PRISMAP.
Anonymous (Academic/research institution)	National transport guidelines, should have one consistent set of rules across Europe
Anonymous (Academic/research institution)	Common transport rules

Respondent	Answer
Anonymous (Academic/research institution)	Too many countries (BE, IT,...) impose the use of 'national' transport companies or require specific registrations for companies performing class 7 transports. Replacing this by a central European registration would help avoiding such additional obstacles. Transport of radionuclides by small airplanes (point-to-point) should be facilitated.
Anonymous (Company/business organisation)	The radioisotopes transport is shifting toward the transport of radiopharmaceuticals. It means that small amounts of radioactivity will need to shipped to many places at the same time. This business model is closer to large distribution than the radioisotopes business (usually, large amounts to a limited number of places).
Anonymous (Individual (EU or non-EU citizen))	Uniformization of the regulations at EU level and implementation of a stable and reliable transport network.

Table 49: respondents' views for the identification of actions needed to secure transport and delivery

Please identify and describe the actions for which the ERVI could have a substantial added value

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	European reliable transport contracts with airlines, with specific provisions for radionuclides European unified custom procedures: clearance should not be country-specific
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Better international agreement for the transportation of these medical isotopes across borders. In additional to domestic monitoring of issues with border controls by individual countries there could be a European observatory into which individual countries could report on this. Ensuring oversight - companies involved should report to Europe and the UK their arrangements for efficient line haul and their transport contingencies
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	agreements with transport companies
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	Supporting competition between transportation companies
IN2P3/CNRS (Academic/research institution)	See above.
National Centre for Nuclear Research (Academic/research institution)	training programs, interaction with regulators
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	While already part of some PRISMAP actions, this should be fully embedded in the longer term, should new radionuclides not yet identified arise.
SHINE EUROPE BV (Company/business organisation)	none
Bayer AG (Company/business organisation)	Regulations related to border-crossing of radioactive sources might be subject to review and adjustments in order to ease supplies going forward.
ORANO (Company/business organisation)	Licensing of the packages: • type B(M) packages currently requires validations in each crossed country. It could be more efficient if a license type B(M) delivered by 1 European country is valid across all the European countries at least for medical use • harmonization of ICAO and IATA divergences between European countries &bull, Verification and consolidation of the transport regulations which are mainly managed at the national level and not at the European level in particular in these fields: - Security/maliciousness (e.g., sources) - Airport related activities (handling, inspections...) &bull, Custom rules: harmonization of the documents (import/export) required by the different national safety authorities
SWAN Isotopen AG (Company/business organisation)	the whole value chain of the most important and clinically applicable radioisotopes should be available in sufficient quantitiy
Global Morpho Pharma (Company/business organisation)	See above
Ion beam applications (Company/business organisation)	Program to homogenize the legislation of radioisotope transportation
Comecer S.p.A. (Company/business organisation)	What previously stated.
NRG|PALLAS (Company/business organisation)	Study the potential of standardization: options, feasibility, benefits, hurdles, ..

Respondent	Answer
Anonymous (Academic/research institution)	redefinition fo A1 and A2 coefficient to have more appropriate limits for type A packages.: launch a global initiative to use latest nuclear data and simulation tools to redetermine A1 and A2 values and include them in the transport regulation airplane pilot can refuse a package. This is a real problem for radioactive material. rules must be changed.
Anonymous (Academic/research institution)	Support the EU PRISMAP initiative
Anonymous (Academic/research institution)	Organize a roll players together in the logistics sphere to come to a common set of requirements for the different type of shipments. This needs to be workshopped with airlines and manufacturing suppliers.
Anonymous (Clinical nuclear medicine professional)	Specific transport for radioactive isotopes
Anonymous (Company/business organisation)	Create specific working group evaluating the specificity of radiopharmaceuticals transport. Study how to implement the appropriate capacity.
Anonymous (Individual (EU or non-EU citizen))	Foster the elaboration of uniform legislation and procedures in the different EU countries.

Table 50: respondents' views for the identification of actions needed to secure transport and delivery that could be implemented at ERVI's level

6.7. Others

In your opinion, what are the other actions that would be needed to improve the efficiency and further optimise industrial-scale production of radioisotopes, aiming at supply security, flexibility, resilience and sustainability in Europe?

Respondent	Answer
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Look at other alternative sources - for example, the efficient use of legacy waste from the Nuclear Industry.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	See above
Dutch Society of Nuclear Medicine (NVNG), University Medical Centre Groningen (Clinical nuclear medicine professional)	Reimbursement rules
UZ Leuven, dept. nuclear medicine (Academic/research institution)	At least participating with, and if possible coordinating, the sustainability of supply from an umbrella point of view. But also facilitate the communication over the different disciplines (medical physics, radiopharmacy, biomedical use ...) so that the revolution in nuclear medicine is not happening in boxes, but embraced by the whole community. United forces and togetherness will be required to move fast along this exciting endeavour. Not one discipline can do this alone!
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	Support to radioisotopes producing capacities across Europe.
IN2P3/CNRS (Academic/research institution)	Provide in priority much more budget support at the EU level through a dedicated strategy, and support projects more easily and with a simplified procedure at the national scale.
ORANO (Company/business organisation)	Eliminate internal market inefficiencies by harmonizing national legislations / regulations
SCK CEN (Company/business organisation)	Licensing of installations for medical isotope production or purification suffers from excessive requirements which hinder the commercial interest and reduce the competitive position of Europe in this domain. Particularly in comparison with the USA, the European governments appear to fight the deployment of new initiatives and make it more difficult to create new installations. In the US, large scale initiatives are funded by the US DoE. Promoting such support also in Europe would be a big step towards improving our competitive position.
Comecer S.p.A. (Company/business organisation)	The ideal solution would be promoting a common action shared by European Government on this subject, because only a few of European nations do care about the problems on this sector.
Anonymous (Academic/research institution)	push to make the theranostic approach the new standard. this a way to optimize the use of radionuclide therapy to patient that will fully benefit from the treatment.
Anonymous (Academic/research institution)	Develop dedicated power delivery programs (strategic) to keep facilities operating at power shortage ...particularly important for delivery of radionuclides in clinical use.
Anonymous (Academic/research institution)	USE PRISMAP as vehicle to promote and fund development and sustainability in the field. The field is very fragmented and PRISMAP has already got all the major roll players in the radioisotope field under one umbrella already.
Anonymous (Academic/research institution)	Also novel radiopharmaceuticals need to cross the 'valley of death' when being translated from research (proof-of-principle) to clinics (human trials). Here the challenge is doubled because production of novel radionuclides may require significant upfront investments that industry may not wish to undertake. In the long run missed opportunities to bring novel radiopharmaceuticals into clinical application might be equally harmful for the improvement of medical treatments in Europe as the supply insecurity of established radionuclides. Hence, the deployment of novel radionuclides should be supported by non-industrial actors, e.g. European labs or European-funded national labs.
Anonymous (Individual (EU or non-EU citizen))	Implementation of a network of producing facilities and better coordination to avoid redundances, in particular in neighbouring countries. More clear and simple legislation, uniform at EU level, for the different steps involved in the production and distribution of radionuclides.

Table 51: respondents' views for the identification of other actions needed

Is there anything else that you would like to add that has not been covered in this consultation?	
Respondent	**Answer**
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	We have answered these questions to the best of our ability, but primarily we are end users, so don't always have insight of the issues that are occurring further up the line.
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	It is important that research should also be done to allow local and small scale production of radio-pharmaceuticals for treatment and imaging. This also required some creative thinking and perhaps legal work to regulate this local (hospital) production. Here there are at least two sets of rules in operation (medical and radio-protection).
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Not as of this moment. I do would like to mention that I appreciate enormously the EU initiatives and consultations in this topic.
IN2P3/CNRS (Academic/research institution)	A link with the medical community is pivotal (medicine, biology).
ORANO (Company/business organisation)	Orano encourages the European Commission to improve cooperation between national regulators for radiation protection and those responsible for radiopharmaceuticals and medical devices in a timely manner. In order to boost innovation in the EU, support from public authorities is crucial for the development of research in the field of targeted radiotherapy by updating the regulatory framework (both for the development of radiopharmaceuticals treatment and their transport within the EU territory), harmonizing national legislations and optimizing the time for approbation of new medication to accelerate the time-to-market and to allow EU pioneering the fight against cancer
Anonymous (Academic/research institution)	Use PRSMAP as the starting block, no need to reinvent the wheel. All the major roll players are their already and can be expanded.

Table 52: respondents' views for additional considerations not covered in previous questions

7. Research and innovation on radioisotopes production

In your opinion, what are the actions needed (if any) to promote advanced research on innovative techniques and technologies of production?

Respondent	Answer
European Association of Nuclear Medicine (Professional association)	Support currently running EU projects on this topic (PRISMAP, SECURE) and ensure sustainability beyond their project timelines
Associazione Italiana di Medicina Nucleare (AIMN) (Professional association)	Support University research and initiatives in favour of start-up
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	Resourcing: Workforce: supply of suitably qualified and experienced personnel is a challenge - this is not something that can be quickly addressed - it needs a medium-term approach to promote this to students and young professionals, to provide mentorship and early research opportunities, and support for a European-wide community. This is particularly important in the post-Brexit era, as UK and EU researchers benefit hugely from close co-operation. Facilities: Identification of suitable locations is challenging: even if money is made available, space for additional facilities in the UK is limited Cyclotron and production capacity: clinical pressures on existing machines mean that capacity for research is extremely limited. Reserach cyclotrons would help with this, but these are often not seen as financially viable. A business case for national research facilities at one or more location in individual countries would help identify viability, demand and funding for these going forward.
French Society of Nuclear Medicine (Professional association)	increase number of production sites simplify French regulation for the development of new radiopharmaceuticals
The European Prostate Cancer Coalition - Europa Uomo (Representative of a patient organization - Expert Patient Advocate)	EU should provide support (financial) to promote this research but also the formation of multidisciplinary and multinational research teams.
Radionuclides for Health UK (Radionuclides for Health UK)	Investment in education and training. Collaboration/personnel exchanges across sites Please see white paper at this email address as the file was too big to upload https://www.bartscancer.london/radionuclides-for-health-uk/
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	collaboration with engineers, physicists... to investigate efficient acquisition and processing methods
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Whether it is a specific, or a public community, it would be important (from a political point of view) to place the use of nuclear material or technology in the (right) context of medical use with some concrete examples (cf. the end-to-end perspective I mentioned before). Research on its own is nice and fine, but when seeing its result (by means of clinical examples, precision medicine, personalized medicine in the case of dosimetry guided radionuclide therapy) can mean more to the public (hence the policy makers) than a lot of reports will ever be able to do in our lifetime.
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	- To reduce the political barriers to R&I in the nuclear-related field. - To open calls to support collaborative research on radioisotopes. - To support R&D on innovative techniques, in particular the ones using accelerators.
IN2P3/CNRS (Academic/research institution)	-Support of innovative radionuclides, in particular alpha and Auger emitters. -Development of high yields mass separation technique to ensure high purity radio isotope production. -Automation. -Lanthanides research.
ENEA (Academic/research institution)	limit the patented molecules: as soon as a new radioisotope arises, some radiopharma company put it's hat on a molecule to which add the radionuclide and no-one can use this isotope without paying rights that make economically disadvantageous to produce the isotope
National Centre for Nuclear Research (Academic/research institution)	more funds and more frequent calls for project oriented at advanced research
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	PRISMAP already integrates exchanges between leading facilities in the production of non conventional radionuclides, through joint research projects. Development of targets, ion sources, chemical separation techniques have been integrated. Some topics can be shared with other nuclear technology and accelerator communities.

Respondent	Answer
SHINE EUROPE BV (Company/business organisation)	Public and private support on the most promising R&D isotopes, especially the Tb-family.
Bayer AG (Company/business organisation)	Endorse academic sites involved with medical radionuclides.
SWAN Isotopen AG (Company/business organisation)	Open Calls from European Commission on innovative techniques and technologies of production Promote the field Educate the EU institutions and the general public
Ion beam applications (Company/business organisation)	Dedicated calls for radioisotope production, target manufacturing, separation and purification process, etc. Those calls should involve public (academic, small SMEs) and industry for the scale-up/sustainable and financially viable availability.
SCK CEN (Company/business organisation)	R&D needs money and an ability to protect the IP it generates. EURATOM initiatives do not allow the latter and are limited in the domain of radioisotopes (improvement is ongoing). Main reason are the blurry lines between healthcare, nuclear energy and nuclear science in this domain. This causes agencies to point at each other when funding is requested.
AlfaRim (Company/business organisation)	
Comecer S.p.A. (Company/business organisation)	The EU should fund and promote the development of academic and research programs, specifically aimed on this topic. In order to improve the radioisotope production, it's important to find an equipment, which is able to produce multiple radioisotopes and reduce at 100% cross-contamination between processes.
STFC (Individual (EU or non-EU citizen))	Horizon 2020 type programmes to encourage European collaboration on the topic. Furthermore, securing access time on relevant scientific facilities to carry out basic level R&D should seen as a priority and work hand-in-hand with the funding programme.
Hannover Medical School (Individual (EU or non-EU citizen))	1) Research funding and supporting research network and joint research across EU. 2) Financial support for i.e. cyclotron upgrades. In medical institutions often only small cyclotrons (only production of diagnostic isotopes i.e. PET-isotopes) are installed due to costs. But, if one could apply for an upgrade via EU funding, more cyclotrons could be installed for production of 225Ac, 64Cu, 211At, 89Zr...
CERN, Institute of Chemical Physiscs - University of Latvia, NUCLEO Ltd. (Latvia) (Individual (EU or non-EU citizen))	Keep the pressure in the community to address issues. Promote of knowledge transfer.
Anonymous (Scientific association)	encourage consortium between nuclear research centers in EU and medical applications Support the exchange of people through grants
Anonymous (United Nation Organisation)	to our knowledge some EU countries are investing in innovative methods of radioisotope production, however this is not yet widespread
Anonymous (Company/business organisation)	Already described - demand/supply studies and analyses would be highly beneficial. Public/private partnerships to improve infrastructure
Anonymous (Academic/research institution)	favoured small to medium research program at EU level with a small number of partners. dedicated Marie Sklodowska-Curie actions on radionuclides and radiopharmaceuticals
Anonymous (Academic/research institution)	EU funded initiatives targeting R&D activities towards photonuclear production technology
Anonymous (Academic/research institution)	The PRISMAP initiative is pursuing these issues but requires long-term support to ensure its success. Other EU initiatives are also being pursued in this regard. Several Swiss institutions have jointly applied to receive government funding for a large facility (IMPACT: www.psi.ch/impact), a production facility based on high-energy-proton induced spallation followed by ISOL techniques to provide a broad portfolio of mass separated radionuclides towards clinical radionuclide development.
Anonymous (Academic/research institution)	Provide funding in the field to fast-track funding.
Anonymous (Academic/research institution)	Alike NIDC in the US, a European entity should collect user needs, then trigger according R&D actions via dedicated calls for proposals or direct negotiation with European or national labs that master the appropriate technologies.
Anonymous (nuclear, radiation and accelerator physicist)	coordinated research effort by academia and industry with strong EU support (financial as well as prioritization)
Anonymous (Company/business organisation)	Provide infrastructures (irradiation, processing...) where research can be done safely.
Anonymous (Individual (EU or non-EU citizen))	Support initiatives to ensure education and training. There is a threat that with aging experts, much know how in radionuclide production is lost
Anonymous (Individual (EU or non-EU citizen))	Leverage of funding (industrial partners, national agencies, EC...). Attract new talents to field.

Table 53: respondents' views for the promotion of advanced research on innovative techniques and technologies of production

Please identify and describe the actions for which the ERVI could have a substantial added value.

Respondent	Answer
British Nuclear Medicine Society and UK Radiopharmacy Group (Professional association)	A coordinated approach to the development of national research centers is vital. Co-ordination of the research community is needed to facilitate this across member EU countries and the UK Assistance in training, including central funding, at a European level would be extremely helpful - in individual countries there may not be sufficient people to run a course, but on a European level, the case is much stronger.
French Society of Nuclear Medicine (Professional association)	simplify European regulation (EMA) for the development of new radiopharmaceuticals increase regulation Improve communication to promote radioisotope medical application
Radionuclides for Health UK (Radionuclides for Health UK)	Please see white paper at this email address as the file was too big to upload https://www.bartscancer.london/radionuclides-for-health-uk/
Hospital Universitario Puerta de Hierro Majadahonda (Clinical nuclear medicine professional)	funding research projects
Riga Technical University (Academic/research institution)	educate students
UZ Leuven, dept. nuclear medicine (Academic/research institution)	Establish communication and implement action plans. A nuclear medicine department is becoming an advanced radionuclide therapy unit, and this is happening ... right now!
Poznan University of Medical Science, Department of Endocrinology (Academic/research institution)	Increasing financial support for scientific research on radioisotope production
Commissariat à l'énergie atomique et aux énergies alternatives (CEA) (Academic/research institution)	ERVI enables a European approach, which is the right level to lift these barriers. Coordinate the various actors in the field to ensure a good sharing of the knowledge and avoid a duplication of efforts.
IN2P3/CNRS (Academic/research institution)	The 4 items above.
ENEA (Academic/research institution)	protect the small potential producers
National Centre for Nuclear Research (Academic/research institution)	ERVI driven calls for new research projects
CERN - MEDICIS (acting as PRISMAP coordinator) (Academic/research institution)	ERVI should reinforce what had already been started in PRISMAP, with the integration of topics of interest with other communities in nuclear and accelerator sciences, be it on target, ion source, isotope physical or chemical separation, purification, standardization, radiobiology or radioprotection aspects.
SHINE EUROPE BV (Company/business organisation)	ERVI could identify the R&D isotopes of interest and provide support for those
Bayer AG (Company/business organisation)	Actively engage in supporting academic sites. Seek partnering of academic sites with others, e.g., radionuclide producers.
ORANO (Company/business organisation)	Need for a state support in order to de-risk projects to ensure that the needed materials are available for R&D experiments
SWAN Isotopen AG (Company/business organisation)	Open Calls from European Commission on innovative techniques and technologies of production Promote the field Educate the EU institutions and the general public
Ion beam applications (Company/business organisation)	creation of new dedicated calls
SCK CEN (Company/business organisation)	Improve possibilities for IP protection in EURATOM funded R&D on medical isotope production
Comecer S.p.A. (Company/business organisation)	What previously stated.
Hannover Medical School (Individual (EU or non-EU citizen))	ERVI should implement funding for upgrades in radionuclide production sites, such as additional funding to install a larger machines and systems for radionuclide productions.
Anonymous (United Nation Organisation)	n.a.
Anonymous (Academic/research institution)	favoured small to medium research program at EU level with a small number of partners. dedicated Marie Sklodowska-Curie actions on radionuclides and radiopharmaceuticals
Anonymous (Academic/research institution)	Long-term plan for PRISMAP. Permanent update plan on availability of facilities, including emerging new facilities. Particular European support for new nuclear reactors (industrial and research), which offer dedicated irradiation possibilities and handling infrastructure for medical radionuclides within PRISMAP as well as commercially.

Respondent	Answer
Anonymous (Academic/research institution)	Use PRISMAP as a vehicle to drive the agenda
Anonymous (nuclear, radiation and accelerator physicist)	coordinated research effort by academia and industry with strong EU support (financial as well as prioritization)
Anonymous (Clinical nuclear medicine professional)	Invest in production not dependent on governments
Anonymous (Company/business organisation)	Give access to existing infrastructure (JRC's) or create a research platform accessible to research teams.
Anonymous (Individual (EU or non-EU citizen))	Support university programs in radionuclide production physics and chemistry
Anonymous (Individual (EU or non-EU citizen))	Foster the release of EC calls related to the field.

Table 54: respondents' views for the promotion of advanced research on innovative techniques and technologies of production for which