

HIGH-LEVEL POSITION PAPER



ON IMPROVING ACCESS TO

RADIOLIGAND CANCER THERAPIES

IN THE CONTEXT OF
EUROPE'S BEATING CANCER PLAN

ACKNOWLEDGEMENTS:

This position paper was drafted with contributions from the SPARC-Europe Steering Committee Members.

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ABOUT SPARC-EUROPE

SPARC-Europe (Stakeholder Political Alliance for Radioligand Cancer Therapies) is a European political initiative aiming to build a comprehensive policy framework for radioligand therapies. The mission of the group is to provide expert knowledge and the necessary guidance for policymakers in the creation of a clear pathway to institutionalise radioligand therapies and other forms of radiotheranostics and increase their accessibility for patients.

The Alliance aims to engage with relevant European policymakers to overcome existing barriers when accessing radioligand therapies.

ABOUT THE HIGH-LEVEL POSITION PAPER

This position paper was drafted by Yordan Aleksandrov and Kinga Wójtowicz, RPP, acting as Policy Secretariat to SPARC-Europe. The Steering Committee had full editorial control over the content of the position. The Committee acts voluntarily as experts in their respective fields of oncology, internal medicine, nuclear medicine, radioligand therapies and patient advocacy.

The goal of this paper is to present the benefits of radioligand therapy treatment and outline policy actions to address challenges to the integration of these novel cancer therapies in European healthcare systems.

The SPARC-Europe project is supported by grants from Advanced Accelerator Applications, a Novartis company, and Isotopen Technologien München AG.

A MESSAGE FROM THE POLITICAL PATRONS OF SPARC-EUROPE

Radioligand cancer therapies are a new paradigm in cancer care. Currently established for neuroendocrine neoplasms (NENs) and metastatic castration-resistant prostate cancer (mCRPC), these therapies have also tremendous potential for breast, kidney, colon and pancreatic cancer patients. Radioligand cancer therapies however face several cross-sectoral barriers to reach patients - including the lack of adequate hospital infrastructure, training programmes, expert care teams etc.

The European Union health policy has a clear added value for its citizens, as it was shown by the COVID-19 pandemic. With long-term European cancer initiatives on-going, the next several years will be crucial in addressing these barriers and in ensuring an effective environment is in place to foster innovation and support cancer patients' access to treatments.

The expert knowledge of SPARC-Europe offers an opportunity to provide us, policy-makers, with a clear understanding of the challenges faced by radioligand cancer therapies and how these can be tackled. Developing and implementing policy actions require the effective collaboration of all relevant stakeholders and in this regard, the EU has a decisive role to play by gathering expert and patient input. In the present political context:

1. Europe's Beating Cancer plan offers the chance to recognise radioligand cancer therapies as a new paradigm in cancer care.
2. The implementation of Europe's Beating Cancer Plan in synergy with other EU healthcare initiatives such as the EU4Health programme, the SAMIRA Action Plan, Horizon Europe and the Pharmaceutical Strategy provides opportunities to address Europe-wide (national and regional) inequalities in terms of access to radioligand cancer therapies.

With cancer being at the forefront of the political agenda, prompt actions are needed to (1) build a comprehensive framework meeting the needs of cancer patients and (2) to make a clear step towards extending treatment options in the field of cancer. As elected representatives of European citizens, we would like to express our commitment to support SPARC-Europe in their continuous political efforts to promote patient access to radioligand cancer therapies.

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EXECUTIVE SUMMARY

Cancer is the second leading cause of mortality in the European Union (EU).¹ It is a major public health and economic challenge. It is estimated that the cancer burden has risen to 2.7 million new cases and 1.3 million deaths in 2020 in the EU², leading to the active European political prioritisation of the topic. The Beating Cancer Plan and other EU initiatives^a undertaken by EU institutions are a positive step towards addressing this burden and ensuring that new paradigms which have the potential to change existing treatment pathways effectively reach patients. Radioligand cancer therapies (RLTs) represent such a paradigm change.

This document outlines the policy actions which need to be implemented to ensure these treatments reach patients in the most optimal way.

WHAT ARE RADIOLIGAND CANCER THERAPIES?

RLTs represent an innovative approach to cancer treatment in which radiation is delivered to cancer cells in a targeted and precise way. RLTs are composed of a targeting molecule (ligand) attached to a therapeutic radioisotope. Cancer cells have specific molecules on their surface which may not be present on healthy cells. The ligand utilises this difference to deliver radiation directly to cancer cells, regardless of where they are in the body.³

The treatment is currently established for neuroendocrine neoplasms (NENs)^b and metastatic castration-resistant prostate cancer (mCRPC)⁴. Over the past two decades, an increasing uptake of RLT has been observed, including the official integration into care pathways and guidelines - as a second- or third-line treatment option.⁵ RLTs are part of a wider concept known as radiotheranostics, which, alongside radioligand therapies, include radionuclide therapy, radioimmunotherapy and selective internal radiation therapy (SIRT).

IMPROVING TAILORED CANCER CARE AND PATIENTS' QUALITY OF LIFE

RLTs have shown the potential to change cancer patients' outlook on their disease. They can help patients in reducing bone pain, improve progression-free and overall survival, as well as patients' quality of life (QoL).⁶ In the case of advanced prostate cancer, the availability of radioligand therapies offers benefits for many men with these aggressive cancers, with few side effects and significant improvements in QoL.⁷

Better QoL is crucial for patients and therefore, should be incorporated as part of the endpoints of clinical trials as per the ESMO recommendations⁸. The inclusion of QoL would not only set better standards for future research as to prognostic prediction, but would also allow patients to adapt their lives to the impact of cancer on their well-being.

Given that for patients the availability of RLTs can make a significant difference in terms of QoL during treatment, this criterion should be of vital importance when evaluating the overall benefit of new treatments. It is highly relevant given the estimation that in the coming years additional therapeutic radiopharmaceuticals will be introduced for advanced stages of breast, kidney, colon, and pancreatic cancers.⁹ Although this is a positive advancement, strong support would be needed through appropriate policy actions, providing an effective framework to foster innovation and accessibility to patients. These actions should focus on access to treatment, improvement of cancer survival and QoL.

a. SAMIRA Action Plan, Cross-Border Healthcare Directive, Mission Board on Cancer, Pharmaceutical Strategy for Europe, Euratom Research and Training Programme.

b. Neuroendocrine neoplasms constitute a heterogeneous group of diseases with limited treatment options.

EU'S ROLE IN BRINGING NEW CANCER TREATMENT PARADIGMS TO PATIENTS

The European Union has the power to support the efforts of its Member States in utilising these new paradigm-changing treatments. Through the adoption of the Beating Cancer Plan¹⁰, which aims to address all stages of the disease, access to RLTs could be strengthened. The Beating Cancer Plan elaborates specifically on the need to invest in the creation of Comprehensive Cancer Centres, where cancer patients could be treated by relevant and adequate specialists with high-quality equipment.

Given the potential of radioisotope-based cancer therapies, it is also encouraging to note that the Commission is addressing the need to facilitate innovation in the medical application of radioisotopes. The new Action Plan of the Strategic Agenda for Medical, Industrial and Research Applications (SAMIRA)¹¹ contributes to the call for good integration of radioisotopes in the medical practice, therefore supporting the fight against cancer. The Action Plan also recognises the need to reduce cancer inequalities within and between Member States through improved education and training, improved workforce availability as well as equal access to modern medical ionising radiation technology.

WHAT BARRIERS DO RLTs FACE AND WHAT CAN POLICY-MAKERS DO TO IMPROVE PATIENT ACCESS TO THESE THERAPIES?

The Beating Cancer Plan takes a collective effort to address all stages of the cancer care pathway, including access to high-quality treatment. Delivering high-quality cancer treatment, such as RLTs, depends on factors such as qualified workforce embedded in a multidisciplinary team setting and timely access to special cancer services. To ensure eligible patients have access to Comprehensive Cancer Centres, and to reduce inequalities in cancer care, it is imperative to implement the Beating Cancer Plan and establish at least one National Comprehensive Cancer Centre. The Plan also reflects the need to invest in education and training of healthcare professionals, thus strengthening the multidisciplinary cancer workforce, as well as in the equipment and infrastructure of oncology departments.

The targets and objectives mirror the challenges of the integration of RLTs across the EU, which require a trained healthcare community and a healthcare infrastructure ready to recognise their potential and hope for cancer patients.

The recommendations below aim to provide guidance and potential pathways of action for both EU and national institutions when it comes to addressing access barriers for RLTs in Europe.

INFRASTRUCTURE

Need: Improve healthcare infrastructures to accommodate and effectively deliver radioligand cancer therapies



RECOMMENDATIONS

- In the context of the European Commission's Beating Cancer Plan, Member States should reassess the readiness of the existing cancer centres to infrastructurally accommodate RLTs (e.g. in terms of equipment, lead-protected infrastructures, nuclear waste disposal and storage facilities).
- European institutions should consider the need to invest in nuclear medicine equipment when developing the EU Network of National Comprehensive Cancer Centres. The investments should be made based on the defined local infrastructural needs.
- When establishing National Comprehensive Cancer Centres, Member States should follow recommendations to have at least one cancer centre for every 5 million inhabitants in countries with a larger population. Access to the best possible cancer care is crucial for better patient outcomes, including QoL.
- In line with the SAMIRA Action Plan, the Commission should support Member States in paving the way towards ensuring equal access to modern technology needed for the delivery of RLTs, including specialist equipment for administration of RLTs. Requirements for the storage of equipment and waste disposal systems should also be taken into account when developing national specific plans for equipment replacement.

EDUCATION OF HEALTHCARE PROFESSIONALS & PATIENTS

Need: Healthcare professionals' education should reflect the need for cross-disciplinary oncology and specialisation in the field of radioligand therapies



RECOMMENDATIONS

- EU institutions should promote a fully integrated multidisciplinary care approach for patients who are eligible to receive RLTs in Comprehensive Cancer Centres. This can be achieved through the implementation of the Beating Cancer Plan and policies stemming from it. The overall integration of nuclear medicine specialists in multidisciplinary care teams should be improved to ensure relevant expertise is available to manage the ongoing needs of the patient and a holistic support structure.
- Future measures setting definitions for comprehensive and specialist cancer centres need to include indications on how to compose and form cancer-specific multidisciplinary care teams.
- Include nuclear medicine specialty alongside oncology, surgery and radiology in the Inter-Specialty Training Programme.
- Member States should address the need to improve nuclear medicine education and training standards in medical oncology and other disciplines through the implementation of the Beating Cancer Plan and EU4Health Programme.^c EU institutions and Member States should increase stakeholder collaboration, including national patient organisations, to educate patients about the existence of RLTs. Through the evaluation of the Cross-Border Healthcare Directive as well as platforms such as European Reference Networks (ERNs), EU institutions should facilitate sharing of best practices (e.g. from the Netherlands or Germany) on the composition of multidisciplinary care teams, especially in the field of rare cancers, such as Neuroendocrine Neoplasms.

EQUAL ACCESS TO RADIOLIGAND THERAPIES

Need: Improve access to radioligand therapies



RECOMMENDATIONS

- Within the implementation of the Beating Cancer Plan, the European Commission should identify and address the gaps across and within Member States pertaining to the management of RLTs.

^c EU4Health Programme is a dedicated funding programme for 2021-2027 to build resilient European health systems. The programme will support the implementation of the Beating Cancer Plan, with a substantial funding of €1.25 billion.

SYNERGIES BETWEEN EU POLICIES

Need: Create additional opportunities for synergies through the actions supporting the implementation of the Beating Cancer Plan



RECOMMENDATIONS

- RLTs face several cross-sectoral barriers - in the field of healthcare, education, training, infrastructure, and radiation protection and safety. To address these barriers there is a need for coordinated policy action across ongoing and future EU initiatives.

IMPROVE HEALTHCARE INFRASTRUCTURES TO ACCOMMODATE AND EFFECTIVELY DELIVER RLTs



RECOMMENDATIONS:

-  In the context of the European Commission's Beating Cancer Plan, Member States should reassess the readiness of existing cancer centres to infrastructurally accommodate radioligand therapies (e.g. in terms of equipment, lead-protected infrastructures, nuclear waste disposal and storage facilities).
-  European institutions should consider the need to invest in nuclear medicine equipment when developing the EU Network of National Comprehensive Cancer Centres. The investments should be made based on the defined local infrastructural needs.
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-  In line with the SAMIRA Action Plan, the Commission should support Member States in paving the way towards ensuring equal access to modern technology needed for the delivery of radioligand therapies, including specialist equipment for administration of radioligand therapies. Requirements for the storage of equipment and waste disposal systems should also be considered when developing national specific plans for equipment replacement.

Due to the nature of RLTs, particular healthcare settings are fundamental for their adequate delivery. Specialised hospital centres have specific infrastructural needs in terms of nuclear medicine departments to provide RLTs and ensure effective and expert patient follow-up. These hospital wards need to be radio-protected, shielded, and have adequate storage and nuclear waste systems. In this sense, the European Economic and Social Committee also recognised that investments in occupational safety and health are “essential to realise the potential of cancer therapies”.¹²

Due to healthcare systems being managed at national and regional levels, there are significant discrepancies in terms of specialised centres equipped to deliver RLTs. In the European Union for example, few countries have a high volume of experience in RLTs (e.g. the Netherlands, Austria, Germany).¹³

Healthcare infrastructure needs to be built/renewed and maintained in order for patients to have access to dedicated centres with RLT facilities. Certain centres face not only issues related to ageing equipment, but also note the lack of available physical space to accommodate patients. As such, the increase of hospital readiness for the delivery of these therapies is fundamental for scaling-up their full treatment potential. EU health legislation has an immediate impact on citizens and, as such, needs to keep up with innovation and research developments. Europe's Beating Cancer Plan offers significant opportunities for EU institutions to support Member States in assessing the readiness of hospital centres to deliver RLTs. Furthermore, the development of Comprehensive Cancer Centres in each Member State would reduce the current inequalities in terms of access to cancer treatment by European patients. These Comprehensive Cancer Centres should take into account the overarching needs of the expanding field of RLTs.

The Health strand of the European Social Fund Plus, which is part of the EU Multi-Annual Financial Framework, mirrors the need to support investments in healthcare systems. As such, future funding allocations should be channelled towards realising the potential of RLTs by creating and improving hospital capacities.

HEALTHCARE PROFESSIONALS' EDUCATION SHOULD REFLECT THE NEED FOR CROSS-DISCIPLINE ONCOLOGY AND SPECIALISATION IN THE FIELD OF RLTs



RECOMMENDATIONS

1. EU institutions should promote a fully integrated multidisciplinary care approach for patients who are eligible to receive RLTs in Comprehensive Cancer Centres. This can be achieved through the implementation of the Beating Cancer Plan and policies stemming from it. The overall integration of nuclear medicine specialists in multidisciplinary care teams should be improved to ensure relevant expertise is available to manage the ongoing needs of the patient and a holistic support structure.
2. Future measures setting definitions for comprehensive and specialist cancer centres need to include indications on how to compose and form cancer-specific multidisciplinary care teams.
3. Include nuclear medicine specialty alongside oncology, surgery and radiology in the Inter-Specialty Training Programme.
4. Member States should address the need to improve nuclear medicine education and training standards in medical oncology and other disciplines through the implementation of the Beating Cancer Plan and EU4Health Programme.^d EU institutions and Member States should increase stakeholder collaboration, including national patient organisations, to educate patients about the existence of radioligand therapies. Through the evaluation of the Cross-Border Healthcare Directive as well as platforms such as European Reference Networks (ERNs), EU institutions should facilitate sharing of best practices (e.g. from the Netherlands or Germany) on the composition of multidisciplinary care teams, especially in the field of rare cancers, such as Neuroendocrine Neoplasms.

MULTIDISCIPLINARY CARE TEAMS: EDUCATION AND COMPOSITION

The delivery of RLTs requires the involvement of an expert team consisting of healthcare professionals from a variety of specialisations, with each specialisation providing a unique set of knowledge and expertise needed in the decision-making process for individual treatment. It is crucial for the expert team, specifically dedicated to the disease, to frequently meet to discuss clinical cases. For NEN/prostate cancer patients, the multidisciplinary team may consist of experts in: radiology, nuclear medicine, pathology, surgery, gastroenterology, oncology, infectious diseases (ID), radiation oncology, nursing, dietetics and endocrinology (for NENs) or urology (for prostate cancer).¹⁴ The benefits of an expert team approach extend to various dimensions of cancer care, including improvements in patients' QoL and access to clinical trials. As such, the added value of the multidisciplinary team is their cost-effectiveness. It is the perfect way to optimise the effectiveness of cancer management and ensure the right therapy is provided to the right patients at the right moment by the right experts.

RLTs have become an important component of nuclear medicine training. In view of the potentially wide-set

d. EU4Health Programme is a dedicated funding programme for 2021-2027 to build resilient European health systems. The programme will support the implementation of the Beating Cancer Plan, with a substantial funding of €1.25 billion.

application of these therapies, it is essential that professionals trained in the field are included in multidisciplinary cancer care teams.¹⁵

Continuous communication between specialists and physicians is important in facilitating the referral pathways into specialised services that offer expertise and access to innovative therapies such as RLTs. This would enhance the knowledge of general practitioners about the most recent cancer treatments and raise awareness amongst patients. In many countries the expert recommendations are discussed with patients, who are involved in the final decision-making process.¹⁶

To better prepare all members of the multidisciplinary teams to treat patients with such therapies, RLTs should be established as part of nuclear radiology, oncology and radio-oncology fellowships.¹⁷

Furthermore, patient follow-up care is of paramount importance, to monitor any potential side effects of the therapies and assess the course of the disease. Depending on the country/region, the follow-up care is carried out by different specialists. Due to the lack of harmonised guidelines on follow-up care, it is recommended to develop guidelines introducing the need for a patient to be followed by specialists with specific training, alongside with a strict training protocol for surveillance that all experts involved in the follow-up should adhere to.¹⁸

MULTIDISCIPLINARY CARE TEAMS: NEED FOR CROSS-BORDER COLLABORATION

As RLTs are one of the several available therapeutic options, each patient case should be discussed within a dedicated multidisciplinary team to define the personalised therapeutic strategy.¹⁹

For a patient to be able to be treated in a timely manner with this form of therapy, a multidisciplinary endeavour is needed, requiring the expertise of healthcare practitioners gathered in physical cancer centres, or through a virtual network of centres. In this sense, the EU can contribute to strengthening the collaboration not only within multidisciplinary teams but also between different teams, due to existing structures for cross-border knowledge sharing. Moreover, the Inter-Specialty Training Programme foreseen by the European Commission should incorporate RLT specialists alongside other disciplines such as oncology and surgery.

The mentioned collaboration can be further strengthened with the full use of platforms such as the European Reference Networks (ERNs), which will be further addressed in the upcoming evaluation of the Cross-Border Healthcare Directive. Reinforcement of both education and training of healthcare professionals to improve access to innovative high-quality cancer care should be addressed through the work of the Mission Board on Cancer and the implementation of the EU4Health programme and other funding instruments such as Horizon Europe or Erasmus+.

The important role of the European medical societies should also not be omitted, considering their authority when developing guidelines.

IMPROVING ACCESS TO RLTs



RECOMMENDATIONS:



Within the implementation of the Beating Cancer Plan, the European Commission should identify and address the gaps across and within Member States pertaining to the management of RLTs.

As a consequence of different standards in education and training activities and existing discrepancies in terms of access to specialised cancer centres, the European Union is characterised by uneven access to RLTs. This often results in patients traveling great distances between the Member States to receive treatment.²⁰ This poses additional physical, emotional, and socio-economic burden. Inequalities can also appear within countries. Taking Italy as an example, despite the uneven distribution of 26 centres offering RLT treatment, a number of patients must travel to other regions to seek treatment. Although the situation has recently improved thanks to the enhanced cooperation between hospitals and multidisciplinary teams covering larger territories, other Member States face similar accessibility challenges. This can be solved either by the creation of new centres or through the strengthening of collaboration between the existing cancer centres or hospitals.

The existing geographical and socio-economic variations have a profound impact on cancer survival, the patient's QoL and well-being.²¹ Equality of access is a fundamental right for all patients and the place of living should never define the patients' chances of survival or the QoL. High-quality health care can be attained with a coordinated European approach to robust planning and effective investment. The challenge still remains to map the existing disparities, identify the best practices undertaken to date by different Member States and European medical societies and embed them in policy.

In the area of NENs, cancer patients can access multidisciplinary expertise in one of the 60 Centres of Excellence dedicated for diagnosis and treatment of the disease.²² The existence of such centres, which are certified and monitored by the European Neuroendocrine Tumour Society (ENETS), contribute not only to improved patient follow-up and quality control, but also improved research and the possibility of having more patients included in clinical trials. For a centre to become a CoE, strict criteria²³ must be met, including the annual threshold of 80 new NEN patients, the existence of regular multidisciplinary team meetings, the involvement in research and clinical trials as well as compliance with treatment guidelines.

As such, similar criteria should be defined for the identification of National Comprehensive Cancer Centres where the patients would be given the possibility to be treated with RLTs. Considering the particular needs of RLTs, SPARC-Europe signifies the right stakeholder to guide European transformation towards ensuring equal access to cancer care.

With the use of European funding mechanisms, such as the EU4Health Programme, and in collaboration with the hospital managers, access to RLTs can be improved. By supporting the expansion of hospital capacities and the building of new infrastructures where needed, EU institutions can make the necessary step towards beating cancer.

The European cancer strategies, such as the Beating Cancer Plan, present a further opportunity to build on the existing initiatives, such as the Centres of Excellence Interactive Map of the European Neuroendocrine Tumour Society²⁴. By creating and investing in similar initiatives dedicated to RLTs, the recognition of RLTs can be improved – as well as the collaboration between the centres, multidisciplinary care teams, patient follow-up and cross-centre cooperation.

CREATE ADDITIONAL OPPORTUNITIES FOR SYNERGIES THROUGH THE ACTIONS SUPPORTING THE IMPLEMENTATION OF THE BEATING CANCER PLAN



RECOMMENDATIONS:



Radioligand therapies face a number of cross-sectoral barriers in their delivery - in the field of healthcare, education, training, infrastructure, and radiation protection and safety. To address these barriers there is a need for coordinated policy action across ongoing and future EU initiatives.

RLTs are different from other forms of cancer therapies as they need to follow not only the pharmaceutical legislation but also radioprotection and safety. For this reason, building synergies between Europe's Beating Cancer Plan and other EU policies (ongoing and future) aimed at improving cancer diagnosis and treatment is essential. This alignment is of utmost importance as RLTs face several cross-sectoral barriers - including the need for adequate hospital infrastructure, training programmes, expert care teams, radioprotection. The variety of challenges posed by RLT would not require one solution in one area, but coordinated action across several initiatives. Fortunately, these challenges can be addressed from multiple EU instruments.

Knowledge sharing mechanisms should also be set for the different EU funding mechanisms.



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